Development of a Maturity Model for Learning Health Systems: A Framework for Self-Assessment and Continuous Improvement

by

Victor Cattani Rentes

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Doctoral Committee:

Assistant Professor Andrew Krumm, Co-Chair
Adjunct Professor Anne Sales, Co-Chair
Assistant Professor Jesse Austin-Breneman
Associate Professor Claire Kalpakjian

Victor C. Rentes

vrentes@umich.edu

ORCID iD: 0000-0001-9214-3815

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Abstract

The concept of a Learning Health System (LHS) was first envisioned as a means to enable value-based health care through the digital transformation of health systems. An LHS aligns people, processes, and technology to support rapid learning cycles of knowledge discovery and implementation. In an LHS, data management and analytics capabilities enable the discovery of scientific evidence from data that are routinely collected from care delivery practices. Concurrently, scientific evidence is integrated into the point of care for practice change and improved patient outcomes. Despite published case studies describing how LHS learning cycles have been enacted in practice, there is limited guidance on how health systems should plan for, measure progress toward, and continuously improve their learning cycle capabilities. To bridge this gap, this dissertation describes the co-development of a maturity model intended to support learning cycle capability development. Maturity models are used to describe and measure components of a system through a series of phases, stages, or levels.

To develop the maturity model and component parts, I engaged in a design-based, action research effort with a clinical department specializing in Physical Medicine and Rehabilitation (PM&R) within an academic health system. To construct the component parts of the maturity model, I incorporated multiple data sources through successive design iterations. Data sources for model design included inputs from clinical and operational stakeholders within PM&R, feedback from an expert panel of LHS researchers from outside PM&R, and a comprehensive literature review. Three design iterations were used to refine the component parts of the maturity model in an integrated manner. Findings from data analyses in each design iteration were used to enhance the component parts progressively until final versions were reached.

The resulting maturity model is comprised of two parts: a process reference model for learning cycles and a self-assessment instrument for learning cycle capability measurement. The process reference model describes activities, outputs, and stakeholder roles required for the execution of learning cycles by clinical teams within health systems. The process reference model utilizes generalizable terminology and provides the basis for capability assessments. It also serves as a standardized reference to streamline project management for capability development across teams. The self-assessment instrument enables measurements of team maturity as a function of its learning cycle capabilities.

The co-developed maturity model is intended to serve as a roadmap for clinical departments and health systems. The maturity model enables objective assessments of the current state of learning cycle capability across individual teams within a health system. Such measures are intended to facilitate continuous improvements and shorten the lead time for capability development across the health system. As envisioned by the LHS principles, improvements to patient outcomes are sought as a direct consequence of the use of the maturity model in practice. The design-based methods used in this dissertation provide an additional contribution to the LHS literature by serving as an example for how to collaboratively create a measurement instrument to support LHS capability development in practice.

Chapter 1 – Introduction

In this introductory chapter, I highlight knowledge gaps and operational challenges that are faced by health system managers and clinician alike during efforts to develop Learning Health System (LHS) capabilities in practice. These gaps animate the collaborative, design-based approach used in this dissertation. To ground the ways in which maturity models can support LHS capability development, I provide a conceptual overview of maturity models and their applicability. Subsequently, I highlight how the practical needs for measurement faced by a clinical department within an academic health system drove the formulation of the specific research questions and aims that are explored in this dissertation. Lastly, in the final section of this introductory chapter, I describe how the subsequent dissertation chapters are structured.

Operational and Research Challenges

Health systems worldwide are facing increasing pressure to move towards value-based health care[1–3]. The Learning Health System (LHS) was first envisioned as a framework to foster value-based health care and improve patient outcomes through the digital transformation of health systems[2,4,5]. An LHS leverages the power of data to promote the integration of clinical research and routine care delivery in order to continuously improve quality of care in real time[2,4–7.]. Thus, the LHS enables scientific knowledge to be discovered from routine care practices and implemented into care delivery in a systematic manner[3,5,8–10]. As defined by the National Academy of Medicine (NAM), an LHS is a health system that is "*designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care"*[10]*.* With available data on factors such as patient outcomes, patient experience, costs of care delivery, and provider work experience, an LHS is able to continuously learn and improve to meet the multiple objectives of value-based health care [1,3,11–14]. To do so, an LHS leverages multiple data sources and analytics capabilities, including computer searchable electronic health records (EHR) databases and software applications to enable clinical studies to be conducted rapidly, using real-world data, and at lower costs[5]*.* This fundamental innovation in the way clinical research is conducted and implemented in the LHS, in turn, contributes to a reduction in the persistent gaps existing between research and practice, ensuring that rapid integration occurs between scientific evidence and routine care delivery for improved quality of care and population health[4,6,15,16].

Efforts to implement LHS principles in practice have been reported in multiple health systems worldwide under different configurations and scales, using different terminology, and focusing on different clinical populations across various clinical specialties[2,3,8,9,15,17–25]. Successful outcomes have been reported in several LHS initiatives[9,17–20,22,26]. However, despite available case studies and multiple conceptual frameworks to support operationalization[2,3,8,9,17,18,21,27–30], LHS efforts continue to face significant organizational challenges. There is uncertainty regarding the delineation of new roles and responsibilities required for developing the capabilities that

enable a health system to systematically learn from its data and drive changes in care delivery at scale for improvements in patient outcomes. Health system managers and clinicians need to coordinate large-scale change management initiatives within complex and varied organizational structures in order to develop the infrastructure that fosters learning and improvements to occur for multiple clinical specialties and care delivery pathways across the health system[19,31]. This invariably involves the engagement of various stakeholders within the health system, with the need for diverse expertise and skillsets. Such stakeholders often operate within siloed departments, which makes cross-functional coordination and engagement towards common LHS goals challenging [2,3,8,9,17–19,27]. Furthermore, the multiple clinical teams engaged in developing LHS capabilities across a health system are often focused on specific patient populations and clinical conditions within narrow sub-specialties, each with their unique needs, values, and clinical approaches. This makes it difficult to standardize the LHS approach across clinical specialties. Academic health systems present added layers of complexity, since these institutions often have teaching and research functions competing for resources, faculty governance, siloed institutes, and group practices that can hinder the alignment of culture, strategy, and processes[19] . Furthermore, efforts to implement evidence-based care models across academic departments and clinics may be hindered by academic individualism and autonomy[19].

The core processes of an LHS are in and of themselves challenging to enact, given that these processes involve not only knowledge generation from routine care delivery through the use of data and technological capabilities, but also knowledge implementation into care through the use of behavior change, implementation science techniques, and standardization of care practices across practitioners and clinics[2,4]. The complementary objectives of these LHS processes require different methodological approaches and expertise, and their integration in practice is not seamless. The methodological approaches and often purely quantitative techniques used for leveraging various datasets and modelling, analyzing, and conducting research with available data to produce clinical or operational insights, often conducted by data scientists, analysts, and/or engineers, are fundamentally different from those used for knowledge implementation into practice. Implementation often requires action-oriented,

mixed-methods research conducted in close collaboration with clinical practitioners for co-design of solutions using implementation research and quality improvement methodologies, with the deployment and evaluation of implementation strategies that drive behavior change and standardization [4,25,32–37] . These methodological differences have not yet been fully integrated into a comprehensive and generalizable framework for LHS research and practice. Doing so requires innovative research methodologies. Furthermore, carrying out the processes of an LHS requires a common vocabulary regarding objectives, mission, vision, values, processes, and capabilities to be developed[18]. This is particularly challenging given the still nascent and varied scientific literature as well as a relative scarcity of successful case reports describing fully developed LHSs as generalizable references.

The competing priorities, resource constrains, and miss-aligned incentives commonly present within health systems pose additional challenges for motivating and engaging teams cohesively towards a common purpose[19,38]. Engaging researchers and clinical practitioners in the pursuit of the dual objectives of knowledge discovery and implementation through novel methodological approaches is challenging. Traditionally, basic sciences have been the focus of most research efforts, while agendas focused on understanding improvement and implementation are less developed as paths to academic advancement[19]. Thus, it is important to create governance models and incentive structures for researchers and clinical practitioners to collaborate within operational and quality improvement frameworks to ensure that research focused on knowledge implementation is not overlooked[19]. Therefore, a structured methodology that accounts for the abovementioned challenges is needed to support development of the necessary LHS capabilities[19].

Developing LHS Capabilities

Developing LHS capabilities requires a gradual change process across the health system, with multiple initiatives happening concurrently [3,18,27,31,39,40]. These may include: i) the strategic alignment of goals and improvement efforts throughout the health system, with continuous support, engagement and championing from senior leadership and stakeholders, including those in health services research and education[19]; ii) redesign of organizational structures and

governance models, delineating new roles, responsibilities, boundaries, and lines of authority needed across the organization for the development of LHS capabilities[8] ; iii) funding for the development of infrastructural capabilities, often in the context of shrinking profit margins, which may require new value-based payment models and arrangements with payer organizations[19]; and iv) a balanced incentive structures to reward high value care and align the business objectives of the health system with research and knowledge implementation objectives[3,19,27,31].

In practice, initiatives to develop LHS capabilities may be comprised of multiple clinical and operational teams within a health system. The multi-stakeholder teams engaged in enacting the LHS principles have been referred to as *learning communities*[2,30,41,42]*.* Each learning community within a health system may be focused on improving care delivery in the clinical pathways for their specific patient populations, using data analysis and implementation science techniques. An LHS program across the health system may be comprised of multiple learning communities operating synchronously. Each learning communities focuses on specific clinical questions and objectives pertaining to the clinical condition of their interest, and are often comprised of clinicians directly involved in care delivery, data scientists, data analysts, data engineers and information technology experts, project and administrate managers, quality and process improvement experts, implementation scientists, policy-makers, among others [2,30,41,42]. The individual learning communities engaged in LHS processes may seek to engage various other stakeholders across the health system and beyond its borders in order to generate knowledge from internally collected data and identify clinical insights pertaining to their patient population that drive change and improvements. The development of data collection and extraction capabilities is an important aspect of this work, and is thus a key element of LHS infrastructure that should be developed progressively over time. The information systems infrastructure supporting the learning communities enables improvements to happen at scale in the long-term. Internal data analysis is often integrated with findings from the available scientific literature regarding best practices for the patient population or clinical condition under analysis. Leadership practices within and across the learning communities should support a

bottom-up, participatory approach so that every member of the team is able and encouraged to contribute according to their expertise and role in the team[2].

Knowledge discovery and knowledge implementation is operationalized in a methodology often referred to as LHS *learning cycles*[2,3]. In a fully developed learning cycle, learning communities are able to improve patient outcomes and value continuously in a cyclical manner. This is done through systematic collection and analysis of data deriving from routine care delivery (e.g., through multiple sources such as medical records and clinical notes within the EHR, patient reported outcomes measures, clinical data registries, etc.), as well as systematic practice change and implementation of the scientific evidence identified as a result of data analysis [25,32,33,43]. Therefore, learning cycles ensure that scientific evidence and best practice are systematically and continuously integrated into routine care delivery for improved outcomes.

Infrastructure, or the enabling socio-technical resources that support the learning communities, can accelerate or hinder the ability to enact synchronous learning cycles for improvements in care delivery. This infrastructure has been variously conceptualized in the LHS literature as “pillars” (i.e., systems, resources, and accelerators) that enable learning and improvements to occur at scale[3,27,44]. LHS infrastructural pillars may include multiple dimensions: scientific, social, technological, policy, legal, ethical[3,27,44]. The LHS infrastructure has also been described as aligning people, processes, and technology to develop the capabilities that enable economies of scale for the various learning communities within the LHS program[2,8] . Additionally, it is important to note that LHSs may vary significantly in their scale: from the micro (e.g., local clinics and hospitals) to meso (e.g., health systems with multiple clinical departments), or macro (e.g., reginal, national, or international networks of health systems)[2,3,8,28]. Figure 1 illustrates a conceptual framework identifying the overarching elements of an LHS.

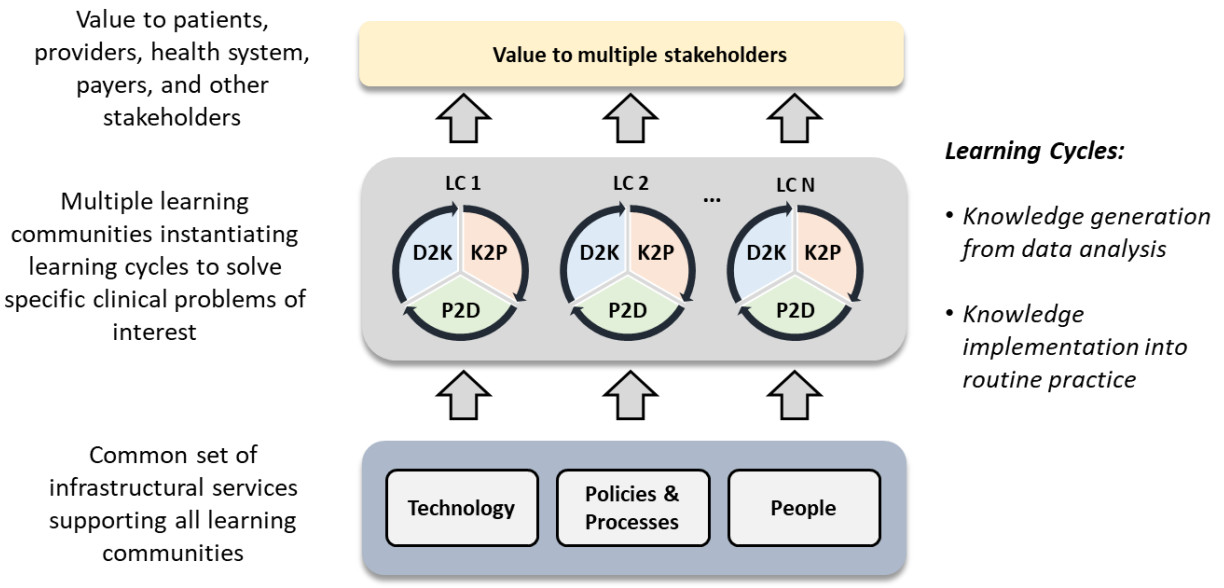


Figure 1 - LHS Conceptual Framework (adapted from Friedman et al, Menear et al)

Scientific research has an important role in the development of LHS infrastructure and capabilities, and requires innovative collaborations across a wide-range of disciplines[7,45–47]. Forrest et identified a set of critical core competencies (i.e., knowledge, expertise) that span across scientific disciplines and methodological approaches to comprise an innovative research agenda for large-scale LHS development in its multiple dimensions and functions. Forrest et al argue that LHS researchers should be a part of the system when conducting research, either as an employee or as an invited partner [45]. An LHS researcher has been defined as "a*n individual who is embedded within a health system and collaborates with its stakeholders to produce novel insights and evidence that can be rapidly implemented to improve the outcomes of individuals and populations and health system performance"*[45,48]*.* This embeddedness contrasts with the traditional approach often employed by health services researchers, who tend to be isolated from the health systems they investigate[45]. LHS researchers, thus, should engage with health system stakeholders in planning, execution, and application of their research studies[45]. This allows for a clear grasp and appreciation for the challenges facing providers and staff in delivering care, and considerations of their perspectives about work practices as important inputs for research and improvements[45]. Action research methodology aligns itself well with this

purpose and allows for a structured approach for the embeddedness of the LHS researcher[49–55]. Through a structured methodology, action-researchers are able to produce meaningful changes in structures and processes across multiple levels of any given systems, while also producing meaningful insights and knowledge about their actions and results [49–55]. In this dissertation, I argue that collaborative research methodologies are needed to solve for practical needs in the operationalization of the LHS concept in practice, and to enable the identification of generalizable insights regarding LHS capability development to contribute to the LHS knowledge base with principles that are applicable to multiple contexts[17]. By driving system change towards the LHS goals and concurrently conducting research about the change process, LHS researchers are in a position to produce meaningful knowledge to support LHS capability development at scale. In supporting this argument, I adopt the role of an embedded LHS researcher within a clinical Physical Medicine and Rehabilitation (PM&R) department working to develop LHS capabilities in support of real-world learning communities. As an embedded researcher, I sought to address practical needs of health system managers leading the LHS capability development effort and to produce generalizable knowledge that is applicable to other settings. Within this research, the concept of *maturity model* was used to organize the various tools and resources that were developed to support the departmental LHS initiative, in alignment with pervious claims made in the available literature for the applicability of the concept in practice[2,4,8,17,18,21,26,30,47]. An overview on maturity models is presented in the next section.

Maturity Models Overview

Maturity models first emerged in the information systems literature, as frameworks for performance evaluation and management of the information systems function[56,57]. Since then, maturity models have been developed and applied in a variety of other settings and contexts. In general, maturity models are used to ascertain and measure dedicated aspects of social and technical systems ‘maturity’. This is done in order to identify gaps between current and desired states which can then be closed by subsequent improvement actions[58,59]. Maturity models have been defined as “conceptual models that outline anticipated, typical, logical, and desired

evolution paths towards maturity" [60]. In turn, maturity may be defined as: "the state of being complete, perfect or ready"[58]. In an organizational context, maturity may be understood as "a measure to evaluate the capabilities of an organization in regard to a certain discipline" [61]. Maturity implies a developmental progress in the demonstration of a specific ability (i.e., competency, capability, level of sophistication or development) or in the ability to accomplish a target, from an initial to a desired or normally occurring end stage [58–60]. The basic argument being that higher maturity is associated with better system performance[56]. Maturity models provide means for maturity measurement, and may be used for systematic planning and improvement [58–60].

A wide range of maturity models have been developed within the scope of both research and practice, and in a variety of industry sectors and business domains, such as software engineering, manufacturing, aerospace technology development, project and program management, IT-business alignment, innovation management, knowledge management, among others[59,60]. The development and use of maturity models may support multiple strategic objectives within organizations, such as: gaining and retaining competitive market advantage, identifying ways to cut costs, developing new technology and products, improving quality of manufacturing or service processes, reducing product time to market, etc.[59,60].

Therefore, maturity models usually assume that predictable patterns exist in system development, which may be conceptualized in terms of evolutionary or maturity stages: these unique stages provide a roadmap for improvement, with each later stage being superior to the previous stage [60]. Maturity may be characterized by different orientations[58]:

- Process maturity: the extent to which a specific process is explicitly defined, managed, measured, controlled, and effective
- Object maturity: the extent to which a particular object like a software product, a machine or similar reaches a predefined level of sophistication
- People capability: the extent to which the workforce can enable knowledge creation and enhance proficiency

In social systems and organizations, maturity is often defined as a multi-dimensional construct composed by people/culture, processes/structures, and objects/technology. Operational definitions for descriptors or benchmark variables that objectively describe each maturity stage are required for measurements of maturity[60]. These descriptors provide the criteria and characteristics that need to be fulfilled in order for a particular maturity level to be reached in the organization, and therefore are the foundation for maturity definitions and assessments[60]. The development of such descriptors involves the representation of system components into constructs to support system evaluation and its ongoing development. A popular approach used to evaluate maturity, and its defining constructs, is a five-point Likert scale with '5' representing the highest level of maturity[59]. Written descriptions of maturity levels across constructs may also be used as well: these are often called 'maturity grids'[58]. Following model design and its use for assessments of the as-is situation of an organization or system, prioritization and implementation of improvement efforts typically occur before another round of assessment is conducted to ascertain whether development has been achieved over time, as planned[60]. Thus, the maturity model provides the basis for an informed approach for continuous improvement.

Maturity models aim to incorporate formality into the improvement initiatives, supporting decision makers in evaluating the current state of their system, determining what actions may be taken for improvements, or ascertaining whether the potential benefits of their actions have been realized or not[58]. A maturity model may be developed and used as a means for self or third-party assessments. The continual use of such models for self-assessment in organizational contexts have been demonstrated to result in growth in the maturity levels of management practices, leading to improved levels of performance[56]. Furthermore, the maturity model approach provides a framework that enables discussions amongst teams involved in the operations under assessment, moderated by facilitation roles when needed. These team discussions driven by maturity assessments have been reported to increase buy-in and ownership of the outcome of the assessment, thus enhancing and facilitating organizational learning. This, in turn, serves to enhance managerial capabilities of the organization and makes teams more critical about their own practices. The safe space for constructive self-criticism

provided by the use of maturity models, if applied as intended, have been shown to reinforce organizational learning and performance improvements[56]. Additionally, the faster production of assessment results enabled by the maturity model approach, when compared to traditional performance reviews, makes it more efficient to revise and foster improvements to organizational practices. This, in turn, encourages the frequency of regular reviews, which further reinforces organizational learning and continuous development of capabilities[56] . Thus, in the context of system performance measurement, the use of maturity models has led to higher levels of effective performance measurement for organizational learning and improvement[56] .

A significant number of models published in the information systems literature are based on the Capability Maturity Model (CMM), and its successor Capability Maturity Model Integration (CMMI) developed by the Software Engineering Institute (SEI) – Carnegie Mellon [59,60]. The CMMI model provides a blueprint, basic terminology, and vocabulary which has been frequently adapted and populated with domain specific content[60]. Maturity models have been developed and applied within healthcare settings, focusing primarily on information technology (IT) and business process management (BPM) capabilities[62–65].

The potential of maturity models in supporting the development of LHSs in practice, specifically, has been highlighted but practical cases are limited[2,8,21,26]. In one study, an LHS maturity grid was developed to assess maturation levels of Learning Networks (LNs).[21] LNs were defined as “network organizational structures comprised of multiple care sites that engages a wide range of stakeholders (patients, families, clinicians, researchers, health systems) to improve health of their patient population”[21]. The maturity grid in the study focuses on LHS process domains for the LNs: 1) systems of leadership, 2) governance and management, 3) quality improvement, 4) community building and engagement, 5) data and analytics, and 6) research [21].

Apart from serving descriptive and prescriptive purposes for the adopting organizations in a practical manner, maturity models have the potential to support reflection and serve as instruments for measurement to produce theoretical insights about the process of maturation in organizations through multiple instantiations and case studies[58,66]. Based on results obtained

in practice, they may provide key contributions to the theoretical frameworks within the specific domains of their focus, with potential to yield insights about the underlying mechanisms driving the maturation process within organizations[60]. Specifically, maturity models are uniquely positioned to test hypothetical propositions and to highlight barriers and facilitators observed in the development from one maturity stage to the next[60]. This is done by providing a realistic, quantitative assessment of an organization's maturation path and exploring questions of why certain paths towards maturity are or are not taken, and why organizations succeed or fail in their efforts to achieve higher maturity stages (and related capabilities associated to each stage)[60]. By tracking specific action-plans and implementation strategies that are deployed over time in a standardized manner, researchers are well positioned to better understand how and why teams and organizations develop capabilities over time through case studies[66,67].

Embedded research regarding LHS development may be enabled by the development and use of maturity model for practical problem solving and generalizable insights. By defining and measuring LHS maturation for individual teams within health systems over time, and understanding the success factors related to i) knowledge generation, ii) knowledge implementation/translation, and iii) value delivery to patients and stakeholders, the following LHS-related research questions may be explored through the use of maturity models: *what does a mature LHS team or health system look like? how can LHS maturity be defined and measured? do mature LHS teams deliver higher value to patients and stakeholders? what are key barriers and facilitators to LHS maturity?* Furthermore, the application of maturity models may support the design of LHS performance measurement system at multiple levels of scale (i.e., LHS infrastructure performance/maturity, LHS team performance/maturity, value outcomes) to enable real-world efforts to enact the LHS principals in practice.

In this dissertation, I use the concept of maturity models to organize the co-development of two deliverables within a clinical PM&R department: a process reference model for learning cycles, and a capability measurement instrument. The two deliverables respectively address maturity questions related to: *what constructs should be measured for maturity assessments? how to measure learning community maturity?* To develop these deliverables, I utilized two methodological approaches commonly used within the information systems research literature

that propose that practice-driven research objectives be formulated as a result of the identification of clear practical needs in real-world settings. The methodological approaches are described in Chapter 3 – Data and Methods. In the next section, I describe the organizational setting in which this research occurred. I also highlight the practical problem that was formulated within this setting, and provide a discussion based on available theory to derive the specific research aims.

Organizational Setting and Problem Formulation

Practical Problem

This project occurred in collaboration with the Physical Medicine and Rehabilitation (PM&R) Department at the University of Michigan Medical School. The PM&R Department established an LHS program in 2016 as part of the department's strategic plans and objectives. The PM&R LHS program aims to enable rapid advancement in the translation of new knowledge to the point of care, enhance quality assurance/quality improvement, improve training, and generate the research needed to advance the field of rehabilitation medicine[2–5,27]. The PM&R LHS program's mission is to "*learn from every patient by aligning clinical care, science, informatics, and culture, enabling continuous improvement and innovation in the practice of medical rehabilitation"*[a]. The specific goals of the PM&R LHS program are stated as follows:

- Provide our patients with the best possible care by putting timely and actionable knowledge, based not just on latest research but on the real-world experiences of patients like them, in the hands of our clinicians
- Empower patients to participate in shared decision-making by collecting and using patient reported outcomes in clinical encounters

[a] For more information regarding the PM&R LHS program, visit < https://medicine.umich.edu/dept/pmr/learning-health-system>

- Implement a continuous improvement loop of information by creating and using high quality data to inform our practice, guide changes, and improve quality and outcomes[2]

The PM&R LHS program aims to achieve these goals by:

- Maximizing the quality and quantity of clinically relevant data available to our clinicians and patients by developing standard clinical documentation and data collection processes in order to efficiently fill gaps in knowledge
- Building a Data Warehouse that provides clinicians with real-time data to inform clinical care.
- Partnering with Michigan Medicine information technology experts to seamlessly integrate changes into clinical workflows.

To achieve the PM&R LHS program mission and objectives, the department established an LHS *operations team*. The LHS operations team established work practices and allocated time and resources to continuously develop the infrastructure in support of the PM&R clinicians, to enable data-driven learning and improvement initiatives to occur. The composition of the LHS operations team and their respective roles are as follows:

- **Faculty Lead:** Directs and executes the vision of the LHS and represents PM&R LHS to the broader Michigan Medicine and UM community. Supervises LHS Project Manager.
- **Project Manager:** Manages each LHS team (i.e., learning community) through the learning cycle, tracking and facilitating team progress. Works closely with analytic team to support infrastructure development.
- **Senior Business Intelligence Anal**yst: Leads the clinical data extraction from EMR based on demands from individual teams (i.e., learning communities); partners with IT builders to ensure documentation creates usable data for analysis and visualization. Responsible for leading the operations team in overall design of the data governance, data management, and data extraction and visualization workflows.

- **Business Intelligence Analyst**: Works closely with the Senior BI Analyst in the preparation of clinical data for use in analysis and visualizations based on the LHS team's (i.e., learning community) needs and specifications.
- **Administrative Manager**: Serves as liaison for clinical operations in the department and Michigan Medicine more broadly; helps ensure alignment of strategies of the overall PM&R LHS and specific teams (i.e., learning communities) with goals and clinical operations. Supervises BI analysts.
- **Clinical Research Project Manager**: Works closely with larger LHS teams (i.e., learning communities) as liaison with LHS operations team to ensure engagement and implementation.

The LHS operations at PM&R team interacts with other departments within the academic health system, such as health information technology services and quality improvement, in order to develop the infrastructural capabilities that enable the learning communities in the department to enact concurrent learning cycles. The learning communities within the department are clinician-led teams focused on specific clinical problems of interest within sub-specialties of PM&R. Each learning community seeks to improve their practice by answering specific clinical questions of interest within sub-specialties of PM&R using data deriving from routine care. Based on the analyses of their internal data, they aim to identify clinical insights about best practices and subsequently foster changes in practice and improvements to patient care based on the clinical insights. At the start of this action research project, the learning communities within the department were focused in the following sub-specialties within PM&R: *interventional spine practice, pediatric neonatal, concussion, orthotics and prosthetics, sport-related concussion, adaptive sports medicine, psychological care for multiple sclerosis, neuropsychological assessment, cancer rehabilitation, pelvic floor disorders, rehabilitation psychology/ therapy, and a post-covid rehabilitation*. The clinicians leading each of the learning communities specialize in the specific patient populations and treatments that the team is focused on.

For example, the PM&R *spine* learning community is centered around the department's interventional spine practice, which treats and manages patients presenting with back and

musculoskeletal pain that results from conditions such as herniated discs, radiculopathy, and stenosis. These patients are managed by the spine providers with a number of non-surgical options including injections, radiofrequency ablations, and nerve blocks. Through the development of LHS capabilities, the spine learning community aims to leverage their data to derive insights that culminate in better care for their patients. Some of the initial clinical questions they are seeking to answer include: *Who are our patients? For example, what are their most important demographic characteristics? What is the distribution of pain chronicity (acute, acute-on-chronic, chronic) among our patients? What are initial pain phenotypes seen in our clinic population? How are these associated with other demographic characteristics? Where should we be focusing our efforts and resources?* By developing robust LHS capabilities, the spine learning community aims to answer these initial questions. With progressive capability developments over time, the implementation of interventions in clinical practice may occur as a result of the insights from data analysis, and new clinical questions and objectives may arise as well. The PM&R LHS program organizational structure is presented in Figure 2.

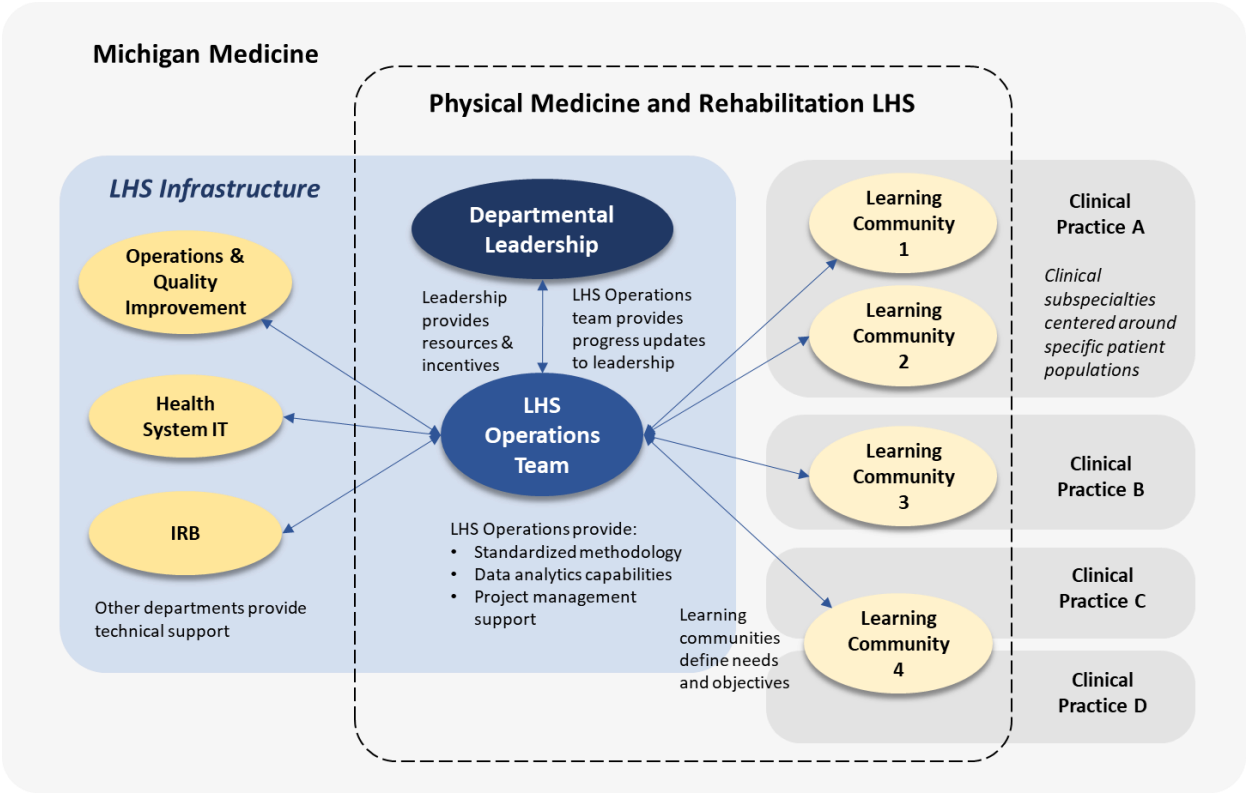


Figure 2 - PM&R LHS Program Organizational Structure

To understand the challenges faced by the LHS operations team, I was embedded into their routine work practices in September 2020. This included my participation in weekly LHS operations team meetings where they discussed progress updates for each individual learning community. The LHS operations team also discussed and planned for their efforts to develop infrastructural capabilities to be shared across learning communities. This includes the development of technical IT-based solutions for data extraction, management, and delivery, as well as a standardized project management approach to be used across learning communities, template documents for the learning communities to use for documentation, work-flow diagrams illustrating their approach for data extraction and management, communication materials to various audiences, etc. In addition to participation in the weekly LHS operations team meetings, I also participated in meetings between the project manager in the LHS operations team and the individual clinician leaders from multiple learning communities in the department. This participation provided me with an understanding and familiarity with the work practices associated in developing the LHS program and the current state of development of the learning communities in the department. The lead faculty member in the LHS operations team and I developed an agreement in which I would be allowed access to the LHS operations team work practices, and, in turn, would explore the applicability of solutions that addressed their needs for infrastructural capability development in the context of an action research project.

Practical problem. The LHS operations team members in PM&R expressed a need to measure progress in developing LHS capabilities across the individual learning communities in the department. A fully developed measurement system would allow them to: i) evaluate how far along each learning community was in their learning cycle processes, ii) communicate progress updates to multiple stakeholders (i.e., health system leadership, clinicians in PM&R, other departments within the health system, outside audience, etc.) regarding the LHS program, and iii) provide the basis for a structured management approach that would enable them to objectively identify key opportunities for improvement and devise action-plans to address bottlenecks for capability development. Thus, the measurement system would serve as a

management tool to facilitate planning and development of the departmental LHS program over time.

In the next section, I discuss connections between the practical problem identified in PM&R and the available theory on the applicability of maturity models for measurement of LHS capabilities. This discussion is followed by the formulation of the specific research aims sought in this dissertation.

Connections Between Practice and Theory

The practical need for system measurement for the LHS has been discussed in the literature. Friedman et al[7] argue that LHSs need to develop the ability to promote system self-improvement, highlighting the necessity for metrics and methods that provide "LHS score-cards" to enable the system to analyze its output and improve on it systematically[7]. Similarly, Forrest et al[48] emphasize the importance of LHS research that demonstrates how the varied components of the health system work together to produce care and outcomes, and identify means for measurement in order to improve performance[45]. Allen et al[29] propose a logic model structure indicating LHS constructs that the authors categorize as system inputs, activities, and outcomes, with examples of measures for their evaluation. Additionally, Lannon et al[21] developed a maturity grid to evaluate what the authors call learning networks (multi-site LHS programs). The maturity grid describes different operational states and levels for a group of constructs that were selected by the authors to support network evaluation. While valuable as references for development, these models do not directly solve for the practical need faced by the PM&R department.

The role of performance measurement methodologies for businesses and organizations across industries has long been regarded as a key driver for competitive advantage and improved results in the business management literature[56,68–73] The balanced-score card (BSC) is an example of a well-known framework used for performance measurement that establishes a means through which an organization may assess how well it is performing, thus learning about itself in order to improve[74]. In the BSC framework, key performance indicators (KPIs) are used to ensure the alignment between strategic and operational objectives within the organization: KPIs

are used to measure the extent to which an organization is meetings its strategic and operational objectives, and to establish causal relationships between them to support planning for improvements. KPIs may be categorized into groups or perspectives: financial, customer, processes culture, etc. [73,74]. In its essence, performance measurement systems translate the organizations' processes and critical success factors into a balanced set of measures that facilitate communication of critical objectives and decision-making, gathering and analyzing critical information about performance and enabling organizational learning[56,73]. The literature on performance measurement focuses on both *structural* and *behavioral* aspects of measuring performance: the first is concerned with defining the metrics used to measure performance and how the metrics relate to one another, while the second is concerned with how measures are used to manage performance in organizations, including managerial routines such as communications, facilitation of informed decision-making across units, establishment of organizational culture, managing change, internal and external communications, etc.[56].

Performance measurement methodologies should be dynamic: metrics and processes for data collection and reporting systems should constantly adapt to changes in strategy, business model, processes, and organizational structure[56,73]. Kraft et al describe the development of a system-wide LHS development program across an academic health system[19], where a centralized performance measurement system was used to define strategic objectives and metrics that cascade down to departments and teams. At the tactical and operational levels, metrics and improvement efforts are prioritized in order to realize specific lower-level objectives that, when aggregated, enable the strategic objectives to be realized at the health system level[19]. In the system described by Kraft et al, report cards were formatted to provide information regarding current performance relative to external benchmarks and internal targets and longitudinal reports demonstrating changes in performance over time[19]. Data collection and reporting was done at all levels of the health system, including physician, unit and clinic, academic and operational departments, and aggregated performance across the whole health system[19]. Information regarding strategic and operational performance improvement programs, directed at key strategic objectives, was provided through reports that were generated and circulated to the relevant stakeholders[19]. Specific initiatives were determined by organizational

leaders after reviewing performance compared with peers, capacity, and readiness to improve at the organization and the potential impact on the health of the populations served by the health system[19]. Workforce capacity adjustments occurred as a result of performance evaluations[19]. This represents an additional valuable contribution to a performance measurement system for LHS development, but the metrics used do not apply directly to the PM&R context and its learning communities given the different scale and purpose for which they were developed.

In the context of PM&R LHS departmental program (considered in this research an instance of a class of departmental LHS programs that may exist in other health systems), I conceptualize a performance measurement system focusing on measuring the multiple components of the LHS program, as highlighted in Figure 3.

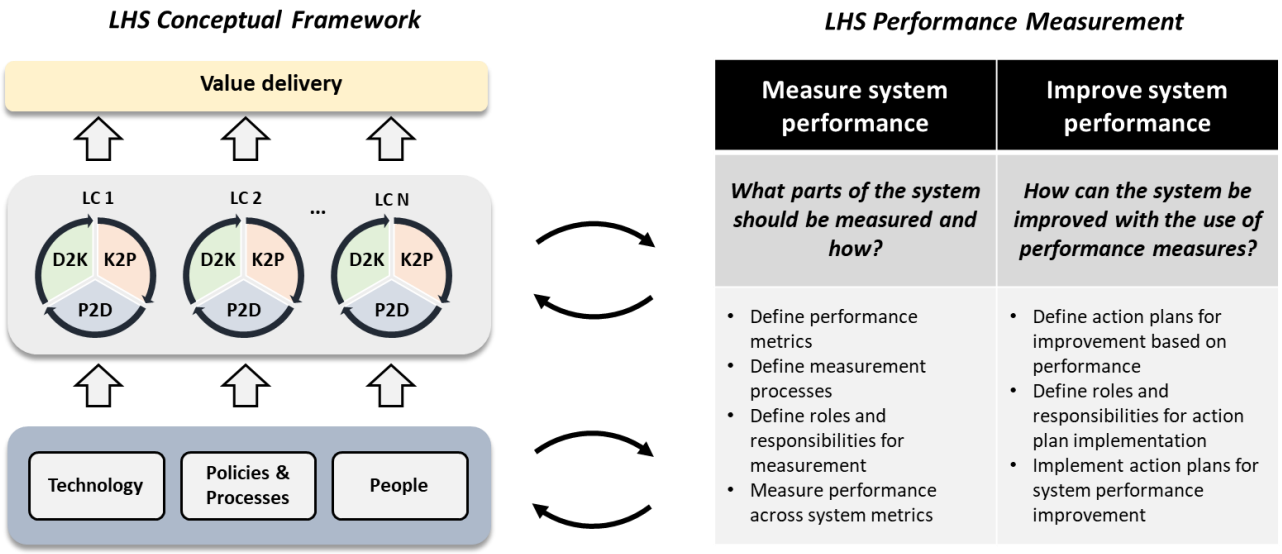


Figure 3 - Performance Measurement for LHS Development

When using systems thinking to represent and characterize any given system, three variables can be used: *structure*, *function*, and *process*[47]. In this form of representation, the system is defined by these variables, along with the environment in which they operate[47] . Defining system structure, function, and processes will, thus, facilitate the development of measures for performance evaluation. *System structure* may be defined as the system

components and their relationships and constraints. *System function* defines the outcomes each component is designed to achieve, which is synonymous with the outputs the components are designed to produce. *System processes* define the sequence of activities required for each component to produce its intended outcomes (i.e., how the function is performed). A core assumption is that the processes for each system component are necessarily iterative in nature, as they may be instantiated multiple times in practice for the outcomes to be produced[47]. In an LHS, one might broadly think of the *infrastructure*, the *multiple learning communities*, and *routine care delivery teams* as key components of the system's structure. Each component has its specific function and processes through which its function is accomplished.

As mentioned previously in the section Developing LHS Capabilities, the function of the LHS infrastructure is to support the LHS learning communities by aligning people, processes, and technology and developing the capabilities to enable learning and improvement to occur at scale. The learning communities, in turn, have the function of generating and implementing scientific evidence in support of changes in care delivery for their specific patient populations. The process for learning communities to achieve their function, thus, involves executing learning cycles that produce knowledge from available data and, subsequently, implement knowledge into care practices for improvements. Finally, the routine care delivery teams seek to treat patients on a routine, ongoing basis according to their medical specialties, and to improve value delivery through the use of scientific evidence produced by the learning cycles. Clinicians directly involved in routine care delivery are often part of the learning communities. This layered representation of the LHS, highlighting the structural components, and their functions and processes, facilitates the conceptualization of a performance measurement methodology by clarifying the parts of the system that may be measured. In addition to this representation, it is important to highlight that in a performance measurement methodology, there are usually *leading* and *lagging* performance indicators. Leading indicators are predictive, usually mediators that can be acted on for change. Productivity indicators are usually leading performance indicators in business settings. They are not, however, the ultimate objectives an organization is aiming to achieve: they are the means to an end. Lagging indicators, on the other hand, are output measurements, and ultimately measuring the objectives the organization aims to

achieve. They cannot be acted on directly, however. Typically, they measure what has happened in the past, and are influenced by the performance of the leading indicators. Profitability indicators are usually lagging indicators in business settings. Therefore, a leading indicator can influence change and a lagging indicator can only record what has happened and represents the ultimate objectives of the organization[56,68,69,74–77].

Sub-dividing the LHS into components that interact and work together to accomplish specific objectives, and identifying the associated leading and lagging performance indicators, may support the development of a performance evaluation system that assesses the extent to which each component is achieving its objectives. As mentioned, the three structural components of an LHS can be measured in ways desired by PM&R: 1) value delivery, 2) the ability to enact learning cycles by individual learning communities' (i.e., knowledge generation and implementation), and 3) infrastructure development to support learning cycles.

Figure 4 illustrates measures to be used in evaluating the current state of the departmental LHS by ascertaining the extent to which the system components are able to meet their objectives. With measures for both leading and lagging indicators as highlighted in Figure 4, health system managers leading LHS initiatives can evaluate their programs and manage change, fostering improvements more effectively. Measuring the leading indicators of the LHS was the primary focus of the PM&R operations team. Their objective is to measure and improve performance to leading indicators that culminate in improvements to the lagging indicators of value delivery. Therefore, measuring the extent to which *value is delivered* to stakeholders in an LHS are lagging performance indicators. There may be multiple learning communities within an LHS program, focused on different patient populations and problems of interest. Indicators for value, thus, should be the focus of each individual learning community, as patient outcomes, patient experience, cost measures, provider experience varies across settings and should be tailored to each individual care delivery team and clinical pathway. Consequently, for the purposes of this research, measuring the extent to which value is delivered to stakeholders was excluded from the scope of development.

To measure the leading indicators associated with the learning communities and supporting infrastructure (and the extent to which their objectives or functions are achieved)

the concept of maturity, as operationalized by maturity models, may be helpful. As argued by Mettler, maturity models have been effectively used to measure social and technical systems in multiple settings[58]. In an organizational context, maturity may be understood as a measure of the extent to which system capabilities have been developed in order to reach the system's objectives[58–60]. Consequently, maturity models leverage this concept in order to identify gaps between current and desired states which can then be closed by subsequent improvement actions[58,59]. Considerations about the notion of maturity include the following:

i) The concept of maturity may vary in nature depending on the focus given and the priorities the maturity model aims to address[58,60,78,79]. When designing the maturity model, therefore, it is important to define what is meant by maturity. The definition of maturity delineates its constructs, or the factors that constitute maturity in the specific context of model development, and measurement approaches [58,60,78,79].
ii) The approach used to measure maturity may also vary. A maturity model may describe specific factors, processes, functions, practices, or capabilities that need to be in place for certain maturity levels to be achieved within the model (e.g., initial, managed, defined, quantitatively managed, optimizing). For measurement, a maturity model may contain survey instruments with Likert-scale questions, or, alternately, a maturity grid with written descriptions for each maturity level across multiple factors or constructs. Additionally, the approach for measurement may be developed in a top-down approach (where levels are defined a priori, followed by measurement) or bottom-up (data are collected a priori from the measured entities, followed by data analysis and categorization of entities into levels). Regardless of the approach chosen, measures for maturity need to be objectively defined in the model [58,60,78,79]
iii) Finally, once measurement takes place, the focus should be the maturation process: a maturity model typically goes beyond measurement and seeks to foster maturity in practice. Factors that inhibit or facilitate maturity should be addressed over time, so that, ideally, subsequent maturity measurements produce higher maturity scores. The identification of these factors is, thus, an important aspect for the maturation process [58,60,78,79].

Therefore, maturity may be conceptualized as a multidimensional construct reflecting the extent to which the system components have developed the capabilities to achieve their specific functions or objectives. By integrating concepts of maturity and maturity measurement with a representation of performance measures for LHS structural components, I was able to identify potential measures for leading performance indicators to be used by PM&R.

In the context of PM&R, measurements of maturity as leading performance indicators may happen at the infrastructure or learning community levels. Measuring the extent to which the *infrastructure* has developed the capabilities to achieve its objectives may prove to be beneficial for developing the LHS program. However, it is a challenging task given that infrastructural support involves multiple stakeholders, both within the clinical department and without it across the health system. Defining constructs and measures for infrastructural capabilities, and identifying factors to be addressed for infrastructural development, thus, were deliberately excluded from scope in this iteration of the maturity model.

PM&R chose to focus on measuring the extent to which the *learning communities* are achieving their objectives. Measuring learning community capabilities can enable an assessment of the current state of each learning community, or their maturity levels. In turn, this allows for communication of progress across stakeholders (e.g., health system leadership, the learning communities in the program, stakeholders in other departments of the health system). Learning community maturity measures can also facilitate planning for learning community development. Learning community leaders and participants may use measures to identify areas that need improvement and prioritize action plans accordingly.

The next section presents the specific research aims associated with the development of a maturity model. The research aims stem from the practical needs observed in PM&R, and seek to measure learning community maturity as leading performance indicators to be used by health system managers in their efforts to evaluate the LHS program and foster continuous improvements. Therefore, the research aims are associated with i) the development of the specific constructs that indicate learning community maturity and ii) the measurement approach and operational instrument that allow for maturity measurements to occur in practice.

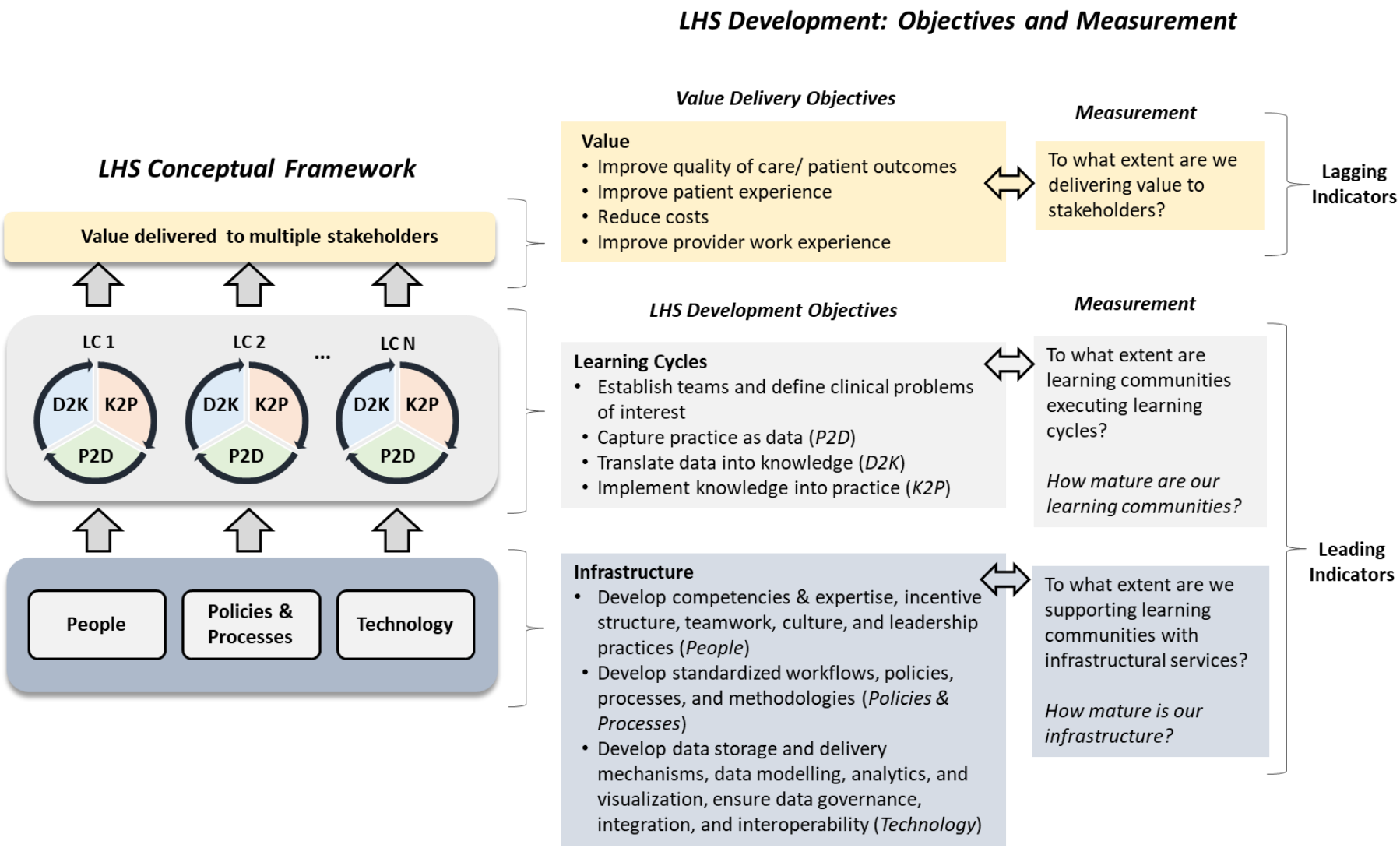


Figure 4 - Measurement Indicators for LHS Development

Research Aims

Research Aim 1

To create a coherent maturity measurement system (i.e., the maturity model), maturity constructs need to be clearly defined. The construct definitions prescribe the definition of the maturity levels, and allow for objective assessments in practice. As postulated by Mettler, the definition of maturity in socio-technical systems may encompass constructs related to people, processes, and/or technology[58].

In the context of PM&R, therefore, a question to be answered for maturity model development includes: *what are the constructs that constitute leaning community maturity?* To answer this question, two propositions are made in this research. The first one is that *learning community maturity is an indicator of the extent to which learning communities are able to execute learning cycles.* The second proposition is that *learning cycles are cyclical processes of knowledge discovery and implementation into practice.* Therefore, in this research the definition of learning community is process oriented, pertaining to the extent to which learning communities are able to execute learning cycle processes. Consequently, the first specific research aim is defined as follows: **to define and characterize specific processes involved in executing learning cycles.** Accomplishing this research aim prepares for the definition of the constructs to be measured in order to establish learning community maturity levels.

Frameworks and case studies describing LHS learning cycle processes are available in the literature, but they lack specificity in process characterization[2,3,26,28]. A detailed process reference model for LHS learning cycles could close critical knowledge gaps. Therefore, I sought to define and characterize specific processes for learning cycles based on the empirical experience of PM&R stakeholders and a review of the LHS literature. Defining learning cycle processes was considered the first step in measuring learning community maturity. However, the resulting deliverable from this research aim constitutes a process reference model for learning cycles that serves multiple purposes in addition to providing the basis for maturity measurement. The process reference model for learning cycles provides a comprehensive list of activities to be executed by learning community members, therefore streamlining project

management functions. The process reference model allows for a certain degree of standardization of activities across learning communities in any given health system, thus providing a resource that may be used as a reference or roadmap for multiple teams, thus providing economies of scale for development. The process reference model that resulted from this research aim utilizes clinical-neutral terminology and is generalizable across clinical domains.

Data sources used for this research aim included regular interactions with PM&R operations team members, critical feedback from an expert panel within the University of Michigan, a comprehensive literature review, and critical feedback from learning community members in PM&R who were engaged in specific clinical improvement projects. The primary data used were expert feedback and the literature review. Feedback from subsequent interactions with learning community members for the second aim were integrated into the final process reference model.

Research Aim 2

To use the constructs defined in the previous research aim for measurement purposes, a measurement approach should be defined along with an operational measurement instrument to be used in practice. Therefore, the question that derived is formulated as follows: *How can a learning community effectively and efficiently measure its level of maturity?* Various approaches for maturity measurements exist in the literature. Similarly, multiple constructs have been used in a variety of settings to constitute the notion of maturity [58,59,61,64,65,79,80].

In this research, two propositions were made for the characterization of maturity in relation to the processes defined in the previous research aim. The first proposition is that *measures of learning cycle capabilities may be aggregated to produce a learning community maturity score.* In other words, learning community maturity is defined in this research as a function of learning cycle capability measures. The second proposition is that *measures for learning cycle capabilities may be constructed in relation to learning cycle processes.* Thus, capability measures may derive directly from the processes in the reference model as a result of the previous research aim, and refer to the extent to which learning communities are able to

perform such processes in practice. Thus, the specific research aim is formulated as follows: **to design an instrument to measure learning community maturity as an aggregate indicator of learning cycle capability measures.**

In this specific research aim, I collaboratively designed a learning community maturity measurement instrument alongside stakeholders in PM&R. The instrument is based on the process reference model for learning cycles, and measures capabilities directly involved in process execution. In other words, capability measures were defined for each process in the reference model designed in the previous research aim. The resulting instrument is meant to be used by learning community members and the operations team within PM&R for self-assessments of learning cycle capabilities. Learning community maturity levels may be defined as an aggregate score of capability levels. The measurement instrument provides objective assessments for the learning communities that may be used for evaluation purposes. The maturity scores may constitute a performance measurement system that health system managers and clinicians alike may use to support planning and development of their LHS programs in practice.

Data sources used for this research aim included interactions with PM&R operations team members, feedback from an expert panel, and feedback from members of active learning communities in PM&R. The PM&R operations team members helped in the iterative development of the first version of the measurement instrument based on the process reference model. The expert panel provided valuable input for refinement, and the learning community members then participated in cognitive interviews around the questionnaire items and provided input for further refinements. When reached, the two specific aims in this dissertation lead to the deliverables that constitute the LHS maturity model for learning communities.

Dissertation Structure

The subsequent chapters in this dissertation are structured as follows:

Chapter 2

In chapter 2, I provide further background on the applicability of systems engineering approaches for LHS capability development. As a result of a literature review, process management and existing techniques for maturity measurement are presented, including the use of process reference models for learning communities and the development of process capability measures for maturity assessments. The background provided in this chapter constitutes the theoretical basis upon which the component parts of the maturity model are constructed.

Chapter 3

In chapter 3, I describe the methodological approaches used in this research, as well as the specific data sources and the iterative design methods used to construct the component parts of the maturity model. Design science and action research were used as methodological approaches for the collaborative development of the maturity model and its component parts. The data contemplate both practical and theoretical sources, including inputs from multiple stakeholders within PM&R, feedback from an expert panel of LHS researchers and practitioners outside of PM&R, and a comprehensive literature review. The iterative design methods allowed for successive versions of the model's components to be produced and refined concurrently according to data analysis from the various inputs used. The detailed presentation of the design methods in this research aims to fill a gap in the literature by providing a methodological reference that may be replicated or tailored by others for the design of similar or adjacent instruments within the context of LHS development.

Chapter 4

In chapter 4, I present the results from research aim 1. Thus, the development of the process reference model for learning cycles within the maturity model is described. Firstly, results from the data analyses of each design iteration are presented, describing how the various inputs were used to produce successive versions of the process reference model that were refined over time until the final version was reached. Secondly, the final deliverable of the process reference model is presented. The presentation of the reference model contains detailed descriptions of its purpose and application, the intended users, the configuration and structure used to represent and describe the processes for learning cycles, and a detailed characterization of all processes including activities and tasks, stakeholder roles for process execution, and expected outputs for each process.

Chapter 5

In chapter 5, I present the results from research aim 2 describing the development of the self-assessment instrument for learning cycle capability measurement. As with the previous chapter, I first present results from the data analyses that occurred in the successive design iterations. This includes a description of how the various inputs were used to produce the versions of the instrument that were refined progressively until the final version was reached. Secondly, the final deliverable of the self-assessment instrument is presented, including a description of its purpose and intended users, its configuration and structure, and a detailed presentation of the assessment items in the self-assessment questionnaire.

Chapter 6

In the concluding chapter 6, I discuss the overall design methods used for constructing the two components of the maturity model and derive insights that may be applicable to other contexts. Additionally, I describe the maturity model's intended use in practice beyond the context in which it was developed, and highlight important limitations and implications for future research.

Chapter 2 – Background

The applicability for systems engineering to support the operationalization of the LHS principles in practice has been highlighted in the literature [2,3,7,8,17,18,20,30,44,47,48,81]. This chapter provides further background on process management and maturity measurement approaches, and highlights how such techniques hold promise in supporting health system design, organizational restructuring, and performance measurement to facilitate LHS capability development. I describe how process reference models may utilized as roadmaps for learning communities within LHS programs, streamlining project management for capability development. I also describe how a process-oriented approach may be utilized to construct measures for learning cycle capabilities. These, in turn, form the foundation for a maturity assessment methodology for learning communities in LHS programs. I highlight how the process-oriented approach used in this research bridges an important gap in the LHS literature, and enables pragmatic evaluations of learning cycle capabilities for stakeholders leading LHS development efforts in practice.

Process Management

Process-oriented management has significant promise in supporting the operationalization of the LHS concept in practice. Process management is an alternative to the traditional functional management approach commonly used in the 20th century, where the formation of organizational "islands" was favored, and information tended to be compartmentalized. This previous approach resulted in difficulties in the integration and communication between different departments within the organization, and, ultimately, inefficient management and poor overall performance[82,83].

In a process-oriented management approach, organizations are viewed not in terms of functions, divisions, or products, but as a set of key processes that span across the organizational functions to deliver value to the final customers[84]. Across industries, process management programs aim to restructure how organizations are viewed, managed, and improved, and ensure that systematic performance improvements occur. Through process management, strategic goals are thus achieved over time to enable rapid responses to new technologies, changing market demands, and competition[81,84–86]. To do so, process management initiatives focus on analyzing, designing, implementing, managing, transforming, and establishing governance over processes for high performance, while integrating strategic objectives, organizational structures, roles, policies, culture, methods, and technology. [81,87]

In process management, coordination and management of functional interdependencies are fostered with the implementation of cross-functional solutions and processes[84]. Well known process-oriented approaches include Business Process Management (BPM), Lean Management and Six-Sigma, which are commonly used in operational and quality improvement methodologies in organizations of all sizes and industries, including healthcare[82–84,86–91]. An organizational process may be defined as a set of logically related set of activities that take one or more kinds of input and creates an output that achieves a specific organizational objective and is of value to its customer[84,87,92]. Improvement is achieved, thus, through the analysis and redesign of organizational processes from beginning to end with the use of information technology, or what has been referred to as *process innovation*, with the goal or reducing

process cost or time, quality, flexibility, service levels, or any other business objectives[84]. Information technology (IT) is a key enabler to process management, allowing for process modelling, measurement, analysis, control, coordination, and automation[86,87,92].

The competing demands and pressure to reduce costs, streamline workflows and care pathways, and to improve quality of care for multiple patient groups, thus, make process management a promising approach for health systems worldwide[47]. Health system process bottlenecks such as long wait times, incomplete patient information, poor provider coordination and communication, lack of resources to perform certain tasks and procedures, duplicity of tasks, and discrepancies in roles and responsibilities across care delivery processes often hinder quality and provide important justifications for a shift towards process orientation in healthcare for improved performance, including higher quality of care delivery and lower costs[47,93].

With process management, roles and responsibilities for specific processes are clearly delineated and documented, including those responsible and accountable for process performance. This provides a shared understanding across the multiple departments in the organization for who does what when caring for patients and performing management functions, allowing for better coordination and resource utilization in achieving the strategic and operational objectives. In process management programs, the relationships between processes are established in a structured manner, highlighting how different functions within the organization impact and are impacted by one another through process inputs and outputs[47,81,84,87,92,93].

Additionally, process orientation and process structures allow for performance measurement to occur in a variety of dimensions[47,84,86,87,93]. Processes may be measured in terms of the time and cost associated with their execution for measurements of process efficiency. Process outputs and inputs may be assessed in terms of consistency, variability, freedom from defects, usefulness, and numerous other factors for measurements of process efficacy. These measures define performance indicators that provide the basis for ongoing improvement programs and quantifying the impact of process modifications[47,84,86,87,93].

Numerous process improvement programs in healthcare have significantly impacted parameters such as patient health outcomes, patient wait times, availability of hospital

operating rooms and beds, number or patients treated, etc.[83,92–94]. In BPM initiatives utilizing IT capabilities in healthcare, value-added functionalities such as real-time process control and monitoring using dashboards, clinical information sharing and process automation, and the integration of artificial intelligence algorithms for the development of clinical decision support systems for improved decision making have demonstrated the feasibility and usefulness of IT-based process management programs in healthcare[47,93].

The delineation of clearly specified roles and responsibilities involved in process execution is important in the context of high turnover and rising costs for hiring and training new employees: the documentation of processes facilitates shared knowledge and understanding of activities and tasks to be performed across roles. This decreases the loss of knowledge about best practices for process execution when key team members involved in specific processes leave the organization[81,84,87].

However, despite realized and potential benefits, the healthcare sector has underperformed other industries in process management, and the related information infrastructure development requirements, due to multiple factors [93]. Health system management is often function-oriented, and not process-oriented, due to the high degree of specialization of different activities conducted by functional units with high level of decentralization[93]. Clinical processes involved in delivering care to patients are usually complex and involve a wide variety of actors from different departments[47,93]. Care delivery for each patient is based on individual demands for care, resulting in high process variability. Additionally, variations in patient volume also cause important challenges to process standardization as the number and qualification of staff needed for care delivery vary accordingly[47,93]. Lack of process standardization, thus, results in patients with the same clinical condition or pathology being treated differently and consequent variability in the quality of care provided and observable patient outcomes.

Furthermore, modifications or improvements to processes in healthcare often require the involvement of multiple departments in the health system, which often prolongs and delays efforts for process improvement[47,93]. Willingness and collaboration across actors involved in process execution are key to the success of process improvement and change initiatives. Factors

such as mistrust, disagreements, lack of communication and confidence in delegating tasks at the middle management level, time management and competing incentives faced by providers, coupled with high degree of decentralization of functional units are factors that limit the success of process management initiatives in healthcare[93]. When clinical providers are not involved in improvement efforts from the beginning, and when they do not feel empowered by change or when proposed changes are not perceived to be beneficial as a result of process modifications, resistance to change invariably occurs and leads to failure[47,93].

Those who occupy managerial and leadership positions in healthcare organizations and systems often possess clinical (and not management) training as their primary professional background, which is understandable given the very nature of the service provided by the organization. However, this fact frequently leads to failures in process management and improvement, as leadership may lack adequate expertise and knowledge to conduct process management and improvement initiatives in a structured manner using best available practices and techniques[93].

When planning and developing a process management programs and initiatives within health systems, it is important to establish a structured methodology to target specific organizational processes depending on strategic priorities and goals. The establishment of a high-level process architecture describing the main processes of the organization and how they relate to the strategic objectives and value delivery is often a first step in process management intiatives[82,84,87]. Operational and/or managerial processes are targeted using a common set of steps are undertaken for improvement and control. These steps often include i) planning for change and measurement, ii) analysis, design and modeling, iii) implementation of changes, iv) performance monitoring and control, and v) refinements and sustainability [84,86,87].

It is important to note that there are different types of processes occurring at the operational, tactical, or strategic levels within any give organization. Processes may pertain to operations, management, support functions, new product or service development, strategic planning, etc[81,84,87,92]. In healthcare systems, processes may involve the flow of patients, as well as materials (e.g., medical supplies, medications, devices, etc.), and/or information (e.g., clinical, financial, operational, etc.)[94]. Operational processes in healthcare are those that involve direct

clinical care delivery to patients. These are highly complex processes, performed by specialized clinician providers, in multiple iterative steps involved in diagnosing, treating, and discharging patients. Alternately, managerial or administrative processes within health systems are those performed by management or administrative functions at the strategic and tactical levels in support of the clinical (operational) processes. These may involve functions such as medical supply management, financial planning and control, strategic planning, marketing and sales functions, etc. The key in process management, however, is to view processes as cross-functional (going from end-to-end, considering all inputs and outputs that flow through the organization) and to include all stakeholders and departments involved in the processes to understand the relationships between their functions and highlight the bottlenecks that need to be addressed as a collective team[82,84,87].

Process modelling is one of the main activities carried out in early phases of process management projects and initiatives[84,87,92,93]. Process models are typically created to describe the current (as-is) and future (to-be) states. Process models may contain key activities, roles and functions within the organizational structures involved in performing the activities, along with static and dynamic relationships across multiple views: people, resources, information flows and information systems, interconnections across processes, customers, etc[81,87,92,93].

There are multiple types of process models, modelling techniques, and modelling languages that can be utilized across organizations and industries. Different alternatives should be assessed with respect to the project objectives and constraints, and the organizational aims[84,87,92,94]. Criteria used to evaluate the quality of models may include model correctness, relevance, clarity, comparability, modelling efficiency, and systematic design[92,93,95,96]. There is a close relationship between designing and modelling business or organizational processes. Designing a process involves the multiple steps to create an understanding of the key activities and responsibilities involved in performing a new or improved upon process, while modelling refers to the actual representation of the process using a specific modelling language[84,87,92,93].

Modelling languages and techniques describing generic constructs for modelling human roles, processes, and technologies include the Unified Modeling Language, entity relationship modelling, and event-driven process chains[87,92]. In practice, building process models is

supported by process engineering tools that implement the selected modelling methodology and language. Meta models are used to ensure consistency between the design methodology and the models[81,92,93,97]. Designed process and architectural models are finally implemented as operational and information systems in practice, and this is often referred to as migration or change management plan within the organization[87,92,93,97].

Important challenges to process modelling in healthcare involve operational inconsistencies in the design and use of information systems such as electronic health records (EHRs) resulting in poorly defined and understood processes and data flows, inherent high process variability resulting from individual patient demands for care delivery (with patients within the same patient population group or clinical condition demanding highly individualized treatments and procedures), the diversity and variance of specific clinical terminology and process requirements that invariably call for (busy) clinicians to be involved in process modelling, challenges with project management for process modelling activities given the barriers to time management and competing demands and pressures for immediate care delivery (specially within critical care settings), among other factors[81,92,93].

Success factors for process management and process modelling include the support and commitment from top management, ensuring availability of resources and incentives for the project, along with active participation and acceptance at the operational level, with championing from process owners in the design, modelling, and implementation phases[84,87,92]. Given the high degree of specialization and complexity in healthcare, teams involved in process modelling and improvement should be configured accordingly, including experts with diverse skillsets that collaborate and share knowledge across functions and disciplines[92,93]. Additionally, to support process design and modelling of new and existing processes, the use of process reference models has been highlighted as beneficial. In the next section I describe the applicability for process reference models in the context of using process management for the development of LHS programs.

Process Reference Models

Process reference models (PRMs) may be used as a basis for establishing new processes or refining existing processes within organizations, as well as serve as facilitators for the development of information technology infrastructure. PRMs typically synthesize and build upon existing scientific and empirical findings from practical applications to constitute a structural and conceptual reference framework to be re-utilized in multiple instantiations across similar settings. They aim to support process implementation within specific contexts and organizational settings by providing best practices and recommendations that can be tailored according to context-specific objectives and requirements[98]. PRMs aim to ensure universal applicability: they are not meant to be used for a single organization or application case only, but represent a class of solutions that are applicable to multiple contexts[98]. Thus, PRMs are meant to be reusable, providing common patterns and standards for the development of specific processes and information systems[98]. The International Organization for Standardization (ISO), defines a PRM as a "*model comprising definitions of processes described in terms of process purpose and outcomes, together with an architecture describing the relationships between the processes. Using the PRM in a practical application may require additional elements suited to the environment and circumstances*"[90,91].

As such, PRMs are not intended to be utilized as absolute truth for process execution, but as resources that organizations may tailor according to their specific needs when designing, creating, and modelling their own processes pertaining to their specific businesses, operations, and/or objectives[84,91]. Thus, it is expected that modifications may be needed to meet specific requirements and goals to fit the specific organizational structures and objectives. Nonetheless, PRMs ensure that organizations do not "start from scratch", and re-utilize synthesized knowledge derived elsewhere to streamline their own process management and improvement initiatives [47,84,88,96–101]. PRMs may be developed within the context of academic research and/or business practice, and may involve the integration of multiple subject matter domain concepts and previous PRMs that need to be improved upon and expanded for new applications, for example[89,96,98,100,102]. There are PRM design guidelines and techniques for model construction,

along with methods for model evaluation, that have been discussed in the literature [60,81,83,88,97–99,103].

Standards for the development of PRMS are available to provide uniformity in process description. The International Organization for Standardization (ISO), for example, provides guidance on elements to be used for the characterization of processes in any given domain when constructing a reference model[91]. These include process elements such as title, purpose, outcomes, activities, and tasks, in order to provide specificity and clarity when describing processes in the model[91].

PRMs have been developed for multiple applications across industries to facilitate and accelerate IT-based process management and improvement. Applications for PRMs include the streamlining of functions such as project management, product development, software development, construction management, quality management, maintenance for manufacturing processes, supply chain management, sustainability management, information technology implementation and governance, and numerous others [70,88,89,91,96,98,102–107]. Within healthcare, the implementation science literature presents a series of "implementation process frameworks" to be used as reference models across health systems in their efforts to systematically integrate scientific evidence in the form of evidence-based practices (EBP) into routine care delivery for higher quality of care[32,33,35,36]. These processes serve as a reference for EBP implementations across health systems, with adaptations to the processes as needed in order to meet the specific goals, constraints, and other context-specific characteristics of the health system and clinical pathways in which implementation is to occur.

By documenting specific business processes and compiling best practices that may be re-utilized and tailored to multiple contexts and organizations for specific process instantiations, PRMs have been shown to significantly reduce the cost and risk associated with implementing new business processes[100]. While adhering completely to a PRM may not be suitable, they provide the basis for team discussions and allow for shared understanding across stakeholders in order to facilitate planning for process development and execution[100]. When tailored and implemented in practice, PRMs typically serve the following purposes:

a) Establishes a common, standardized reference to be used for consistent process execution, ensuring quality of outputs across multiple instantiations, and to avoid process variation[45,100]
b) Supports process improvement initiatives, by providing a standard upon which the process improvement team may conduct plan, do, check, act (PDCA) cycles to reach their measurable process performance objectives[84,98,100]
c) Documents the relationship between business processes and the requirements for information system interfaces, in order to support the development of information technology infrastructure within the organization that enables and optimizes end-to-end processes [84,87,97,98,100]
d) Enables a comprehensive understanding of the relationships between processes and functions across the organization to support alignment of governance models, organization-wide performance measurement systems, and incentive structures[84,87,97,98,100]

In the context of using process management to streamline the operationalization of LHS programs in practice, I argue that PRMs hold significant promise. A PRM would support health managers and clinicians alike who are involved in initiatives for LHS capability development, by establishing a common standard that ensures consistent execution and quality of process outputs across learning communities, avoiding unwanted variations. The PRM would need to be tailored according to the specific characteristics of LHS programs and the contexts in which they operate, as well as to the specific needs and objectives of the individual learning communities within the LHS program. The PRM could be utilized to streamline process execution and infrastructure development, and enable multiple learning cycles to occur concurrently and rapidly. By documenting the information technology interface requirements for specific parts of the LHS processes, learning communities could be in a better position to plan for infrastructure development by prioritizing development tasks according to process bottlenecks.

Valuable LHS frameworks to support operationalization exist[2–5,8–10,27,29,30], as well as successful case studies reporting positive improvement outcomes and LHS development methodologies that were deployed in specific contexts[17–19,26]. While they provide important

contributions, the resulting conceptual models from the available literature are too broad, remaining on a relatively high-level of description of LHSs, without the provision of detailed guidance for development in practice not the processes involved in LHS development from initial problem specification to the final realization and application

The LHS learning cycle model by Friedman et al[2,7] is referenced in multiple publications. It provides a robust starting point for the representation of the functions involved in knowledge discovery and knowledge implementation. The learning cycle model contemplates the work of clinical and operational teams focused on solving specific problems of interest and improving care for their patient population based on data analysis from routinely collected data, as well as the implementation of the evidence through practice change techniques. The Friedman et al model presents three overarching categories of learning cycle activities[2]:

- Practice to Data (P2D): activities for routine data collection to quantify aspects of care delivery practices
- Data to Knowledge (D2K): activities for data analysis and translation of data into knowledge to support practice change
- Knowledge to Practice (K2P) Processes: activities for knowledge implementation into practice for improvements to care delivery

While useful as a starting point, serving as the basis for multiple LHS programs currently under development worldwide, the learning cycle model by Friedman et al lacks of specificity when detailing the specific activities involved in a) collecting, storing, managing, and processing data to produce information and, subsequently, knowledge and evidence about best practices for care delivery, b) planning and executing practice change across providers and clinics in the health system to ensure care delivery reflects the identified evidence for optimal patient outcomes. Thus, in a learning cycle, there is a continuous flow and transformation of data into information, information into knowledge, and knowledge into action for system change. The lack of a standard reference model specifying the activities and tasks involved knowledge discovery and implementation, in practice, leads to variation across LHS programs and learning communities, as well as long lead times for development resulting in waste of resources and

frustration by team members as they do not see the benefits of the LHS as expected. A PRM detailing the processes involved in learning cycles, thus, would fill a gap in the literature, and support health system managers and learning communities interested in developing LHS capabilities for data-driven, continuous learning and improvement.

In practice, health system programs aiming to develop LHS capabilities are operationalized as incremental projects, with clear deliverables, available resources for execution, roles and responsibilities, budget, and timeline [2,3,5,7,9,18,20,28,29,45,47]. With a representation of the process involved in executing learning cycles, health system managers and learning communities alike may establish a shared understanding of the activities and tasks to be performed, as well as the infrastructural factors that need to be addressed to shorten lead times for LHS capability development. Thus, in support of capability development, a PRM for learning cycles could:

- Facilitate project management, with clear identification tasks, estimated budget and other required resources (including time), and the roles and responsibilities for task execution.
- Support process optimization over time, concurrently to process optimization efforts targeting the care-delivery processes and clinical pathways that directly impact patients
- Establish process measurements for learning cycle efficiency and effectiveness that would be the basis for process optimization
- Serve as a key pillar of infrastructure development within the health system by highlighting the information technology requirements for learning cycle process execution
- Enable economies of scale and standardization for multiple learning communities (existing and new) across the health system
- Facilitate the identification of roles and responsibilities for process execution, thus enabling cross-functional coordination across the health system and optimization of staff and resource allocation

- Provide the basis for team discussions and the identification of additional barriers or system bottlenecks that hinder the objectives of knowledge discovery and knowledge implementation to be met.

In the next section, I describe existing approaches for measuring maturity in organizational and team contexts. I also highlight gaps in the LHS literature, and discuss the applicability of a process-oriented approach for capability measurement as a means to construct a maturity model for learning communities in the context of an LHS program.

Representing and Measuring System Maturity: Existing Approaches

The importance of developing measures for the LHS and accompanying scorecards that ascertain the extent to which the health system is able to operate under the LHS principles (i.e., data-driven, continuous, and systematic knowledge discovery and knowledge implementation for improved care) has been highlighted in the literature[3,7,8,18,26,29,47]. Evaluating the health system's "journey" in developing the LHS has multiple applications for the stakeholders involved in the effort. Planning for the development of LHS capabilities is facilitated with performance measures that allow for quantitative assessments of the current state, which, in turn, allow for a clear and shared understanding of where the health system is pertaining to its LHS efforts and where it hopes to be in the near- and long-term future. Coordinating and communicating with multiple stakeholders and teams across the health system can be facilitated with such scorecards and measures, leading to improved results in developing the LHS capabilities in the long-term.

The notion of system "maturity" may support the development of LHS measures and allow for quantitative assessments and evaluation of LHS programs in practice. The term maturity first originated in the information systems (IS) literature, and has been incorporated into maturity models developed and applied in a variety of business and organizational settings, and for multiple purposes[58,59,61,79,80,108–111].

Maturity models aim to define a progression of maturity states and their evolutionary structure for the purposes of assisting development of any given entity (i.e., a person, team,

organization, system, technological solution, etc.). Additionally, they also provide methods for maturity assessments to support evaluation, as well as improvement practices to be implemented for maturity to be achieved over time. It is implied that higher levels of performance are achieved with higher levels of maturity. Thus, quantitative assessments of the extent to which the organization has achieved the agreed upon definition of maturity provides the basis for continuous improvement and development[58,108,112–114]. The concept of maturity may be conceptualized in two related aspects. Firstly, maturity may reference something or someone having reached a state of completeness in their development or growth (i.e., the state of being complete, perfect, or ready)[79]. Secondly, maturity may imply the process of bringing something or someone to maturity (i.e., to bring to a fully mature state). In a maturity model, both aspects are considered as the model defines the progressive states of maturity and proposes a method for maturity to be measured and reached[59,79,108,109]. The specific definition of maturity, however, always depends on the context within which it is used and applied[58,79].

When designing a maturity model, it is important to clearly specify what is meant by maturity in order to avoid inconsistent or confusing language. Even within one field of expertise or application area, the concept of maturity may vary depending on the maturity model designers' choices[79,108]. When maturity models are designed to apply to a broad range of organizations or application cases within a domain specific user group, the descriptions and measures of maturity are often defined too broadly and/or abstractly. Consequently, many maturity models are subject to criticism regarding their simplicity and vagueness[59,79,108]. Maier et al reviewed the literature and identified multiple ways in which maturity is described and measured when maturity models are used to foster organizational development and improvement, suggesting that there are likely multiple leverage points for maturity to be achieved[79].

Terms such as organizational maturity, organizational capabilities, process maturity, process capability, and project maturity have been used across settings in the reviewed literature on maturity models[79]. Generally, however, maturity is described as a composite term, with multiple characteristics and indicators used to denote and measure maturity[79]. The concept of capability has been used in the strategic management literature, specifically in the

resource-based view or theory which explains organizational performance as a consequence of capability development[79,81,115,116]. Capabilities may refer to the configuration of skills, competences, and resources needed to reach certain objectives or requirements[116]. The development of multiple capabilities, thus, may lead to an overall state of organizational maturity[79,116]. However, irrespective of the way in which terms are used for construct definitions and measurement in maturity model design, transparency in their definitions and relationships is important for the maturity model to be deployed and useful in practice, with validity, reliability, and generalizability[58,59,79].

Different maturity measurement or assessment strategies have been identified in the maturity model literature, and there is no overall accepted maturity measurement methodology[59,64,79,80,108] Design choices need to be made for the definition of the measurement approach, in alignment with maturity construct definition and the intended use for the model [59,64,79,80,108]. Nevertheless, the measurement methodology is a critical component, as it is responsible for the data collection on which basis maturity levels are determined[59,64,79,80,108]. Once data collection has occurred for maturity measurements, visualization techniques using a ladder representation or radar graphs, for example, can be used to represent the current maturity level of the assessed entity[79].

An important aspect to maturity measurement or assessment pertains to the identification of those involved in measurement. A distinction between three types of assessments may be made regarding the stakeholders involved in maturity assessments through the use of maturity model in practice: i) *Self-assessment:* when data about the organization are gathered through the use of the model by internal members of the organization (e.g., team members within the organization using the maturity models for self-assessments), ii) *Third-party assessments*: when data are gathered by external assessor specialists, in support of the internal staff members (e.g., hired consultants using customized methodologies), and iii) *Certified assessment*: when data are gathered by outsourced certified practitioners exclusively (e.g., for formalized certification purposes)[80,108]. In particular, the use of maturity models through *Self-assessments* may be subject to critique, as the model's application in practice may lead to biased measurements due to the fact that maturity measurements are conducted by

internal staff of the organization under assessment[108]. Nonetheless, agility in measurement is an important benefit of *Self-assessments* as they are often less complex and require less resources during model application in practice (i.e., there is no need for external and certified specialists) [79,108]. Measurement methods may also be categorized into human-machine and/or human/human interactions for measurement[108]. An example of human/human interactions is when available documentation of maturity-related information and documents within the organization are collected by the designated assessors. This may form a preliminary assessment, which may subsequently be enhanced by face-to-face interviews or moderated workshops and focus groups [108]. Alternatively, human/machine interactions may be deployed through questionnaires and online survey tools for measurement[108].

The specific criteria used within the maturity models to establish maturity levels, and the internal structures linking specific maturity measures to maturity levels, may vary significantly, and this affects the chosen maturity measurement procedures. The Capability Maturity Model (CMM) and its updated Capability Maturity Model Integration (CMMI) version are widely used[108,112–114,117]. Originally created by the Carnegie Mellon Software Engineering Institute (SEI) to assess the quality and capability of software engineering processes, the CMMI has expanded beyond software engineering to encompass multiple application areas[79,111–114,117]. In general, the CMMI comprises five stages that organizations go through as they move from an immature to a mature state regarding their business processes. Its key assumption is that more mature organizations perform specific processes more consistently and are thus more successful. The maturity levels include: *Initial, Managed, Defined, Quantitatively Managed,* and *Optimizing.* Maturity levels, in turn, derive as a composite score of process capability level measures that are established based on the extent to which specific practices have been implemented and observed during assessments[79,112–114,117]. The successful impact of the CMMI model led to the development of many *CMMI-like* models in the IS literature[58,59,79,80,108]. While comprehensive and detailed, the CMMI and CMMI-like models have faced criticism regarding the rigidity and complexity of their maturity measurement methods[58,59,79,80,108].

CMMI-like models typically identify a list of specified best practices for explicit processes. Evaluations of maturity, thus, occur as a result of the extent to which these practices

have been implemented and observed in practice. Consequently, maturity measurement procedures often include complex evidence-gathering methods to be performed during assessment "events", which may involve a significant effort from multiple stakeholders in the organization and may require third-party specialists or outside consultants to lead the assessment. The emphasis on formalization of improvement activities accompanied by extensive bureaucracy has been criticized, as it can hinder people from being innovative when evaluating and improving performance[58]. Given the characteristics of maturity measurement procedures of the CMMI approach, alternative strategies have been developed. Maturity grids, and adjacent approaches using Likert-scale questionnaires, are relatively less complex and provide for means of measurement that favors self-assessment and present lower degrees of required effort and resources for measurement. Maturity grids typically represent various degrees of behavioral characteristics at multiple pre-established levels of maturity for different domain areas in a matrix structure. They support measurement by enabling a comparison between observed reality as perceived by the assessors and the representations of the described maturity levels in the grid[68,81]. Similarly, Likert-scale questionnaires are designed to collect data from participants regarding their perceptions of maturity in multiple domains in order to establish an overall maturity level of the organization based on pre-defined criteria[65,115]. These latter approaches favor simplicity and practicality, and do not require the need to ascertain whether objective evidence is observable regarding the implementation of specific practices for multiple processes, as is the case in the CMMI-like models[79,108].

Regardless of the chosen methods for maturity construct representation and measurement procedures, a maturity model should be designed to meet the intended audience's needs[59]. Thus, according to de Bruin et *al "model designers should focus on why the audience wants to apply the model, how it can be applied (given different organizational structures), who will apply the model, and what is the possible outcome of the model application"*[59,108]*.* These considerations are incredibly important for maturity model design, given that a balance between granularity, comprehensiveness, feasibility, and understandability must be achieved in the final instrument[59,108]. A maturity model that is overly simple may exclude important information or aspects of organizational maturity during assessments. A

maturity model that is overly complex may limit its usefulness and applicability, or even produce misleading assessment results that not contribute to organizational development[59,108]. In the next section, I describe two available measurement instruments that have been designed for LHSs in practice, and highlight limitations that must be addressed in meeting the needs of the practical setting of the LHS program within which this research is undertaken. I then describe how these limitations are addressed with the proposal of a novel approach for maturity measurement that guided the development of the measurement instrument in this research.

Measuring Maturity for LHS Development

Few measurement instruments have been proposed in the literature in the context of LHS maturity and performance assessments. Lannon et al designed an assessment tool in order to evaluate learning networks (LNs), which the authors define as networks of care sites engaged in LHS development[21]. The tool is intended to allow for self-assessments and evaluations of the evolution of core network domains. The tool is comprised of a network maturity grid (NMG), which contains six domains for measurement: 1) Systems of leadership, 2) Governance and management, 3) Quality improvement, 4) Community building and engagement, 5) Data and analytics, and 6) Research. Each domain contains a set of components the authors identify as critical for the development of the LNs. Each domain, thus, is subdivided into specific components (ranging from 7 to 10 components per domain), and each component contains a sequence of five cells providing details regarding behaviors for the component at five different levels of maturity. Thus, a 5-point rating scale may be applied to rate each component in the grid. The scale represents a maturity range in the following levels i) not started, ii) beginning, iii) intermediate, iv) mature, and v) idealized state. The authors present the results from yearly assessments conducted by network leaders using the NMG tool[21]. They highlight how the use of the tool is intended to support the identification of areas of agreement and disagreement among network leaders regarding their performance on each of the domains, thus allowing for the development of a common “systems” view within the network organizations under evaluation[21]. The tool may also be used to compare and contrast LNs across the observed variations in assessment results[21]. To develop the tool, the authors relied on literature review,

content analysis from existing networks documentation, and expert feedback to establish and refine the grid's domains and components. Nine LNs participated in the development and application of the NMG[21].

The NMG comprises a valuable tool that LNs engaged in LHS development may use for evaluation, but without tailoring its applicability is limited given its intended use and development methods. Its direct application to single health system engaged in developing an LHS, or any other non-network context, is not feasible without modifications. Another limitation includes the language used to describe the domains and components in the tool. The authors describe the components in the NMG as containing processes for LN development, but do not maintain standardized terminology to describe the processes. There is no process reference model to anchor the domains, which provide vague descriptions for the constructs and no specific processes involved in each domain or component are described. They also do not present an explicit definition for the components within the domains in the NMG, which leads to some degree of imprecision as to what the constructs refer to specifically. Another limitation includes the description of the application of the NMG in practice. The yearly self-assessments procedures are also vaguely described, without an identification of the stakeholders involved in the assessment and the specific methods used to produce the scores using the NMG tool. Finally, there is a lack of detail in the NMG development methods which may lead to a lack of reproducibility (e.g., it is unclear what literature was reviewed and used for model construction, what specific contents and documentation were analyzed within each LNs, and how the expert feedback were collected and used for model refinement). Nonetheless, the tool is a valuable contribution to the LHS literature and may serve as a reference for the development of future research and the next generation of maturity grids, which may differ in depth and scope, per the authors[21].

A second instrument by Allen et al provides a roadmap designed to support the operationalization and evaluation of an LHS[29]. The roadmap is comprised of an LHS logic model designed within the contexts of an LHS program in a large health system[29]. The logic model identifies LHS inputs, LHS activities (or LHS outputs), and LHS outcomes that provide the basis for measurement. LHS inputs are defined as "*essential elements for an organization to*

successfully operate an LHS". The authors argue that measuring extent to which LHS inputs are present may determine readiness to transform the health system into an LHS. The constructs identified as LHS inputs are*: People and Partnerships, Health Information Infrastructure, Prioritization, Funding, Improvement Infrastructure,* and *Ethics and Oversight*. A written description is provided for each construct, without a characterization of the constructs as processes or organizational capabilities. The LHS activities (also referred to as LHS outputs in the model), are defined as "*key organization activities and deliverables that add value to care delivery"*. According to the authors, measurements of LHS outputs consists of "counts of deliverables", as well as assessments of the "quality of these deliverables". The constructs identified as LHS outputs are: *Environmental Scanning, Evidence Synthesis and Translation, Data Analytics, Design, Patient and Family Engagement, Implementation Support, Evaluation, Dissemination,* and *Consultation*. Finally, LHS outcomes are defined as the "outcomes measures worth measuring for the LHS", which include short-term and long-term goals associated with the quadruple aim and value-based healthcare[1,11–13]. These may be measured at the patient, provider, organization, or project level[29]. The constructs identified as LHS outcomes are: *Knowledge-to-Action Latency, Systematic Adoption of EBPs, Systematic Elimination of Wasteful and Ineffective Practices, Population Health, Care Experience, Utilization/Cost of Care, Work Life for Care Teams, Equity,* and *Programmatic Return on Investment*. For all constructs within each of the three levels of the logic model (Inputs, Outputs, and Outcomes), the authors present a set of available measures and potential data sources to be used for measurement. These measures, thus, are intended to support the evaluation of the LHS as a whole. Data sources and measurement methods include *Direct Observation, Checklists, Administrative Data, Qualitative or Semi-Structured Interviews, Surveys,* and *Focus Groups*. Additionally, sample measures are provided for each construct. By enabling measurement, the LHS logic model described by Allen et al is intended to support system wide strategic and operational planning and execution for the development of the LHS. The authors provide examples of improvement efforts within their own health system that align to the specific measures within the LHS logic model[29].

To develop the model, the researchers convened an interdisciplinary working group of LHS researchers with expertise in implementation science, QI, operations, communications, and

translational research to identify core LHS constructs. Subsequently, they used a narrative literature review approach to identify further constructs in the published LHS models or LHS core constructs listed the literature. The authors present the 17 articles that were reviewed for model design, and describe how the constructs were identified in the literature based on: a) strength of conceptual or empirical support for impact on an LHS, b) consistency in definitions, c) alignment with their own experience and d) potential for measurement. After review, consensus was reached on the final list of constructs, and operational definitions and potential measures were subsequently created. The authors highlight the widespread inconsistency in terminology observed in the LHS literature, and the effort to harmonize terms in the final LHS logic model. While valuable as a resource that may be generalizable in practice, with potential measures and data sources to be used for measurement, the resulting model does not provide a practical measurement tool that may be directly used by those involved in developing an LHS for its evaluation (in contrast to the NMG tool developed by Lannon et al[21]). Thus, the direct application of the logic model in practice requires further development in order to embody the list of measures into a practical instrument or tool. Furthermore, the language used to define the constructs by Allen et al is inconsistent with a process-oriented management approach. The terms inputs, outputs, and outcomes are often used in process characterizations, providing specification for inputs and outputs that processes either consume or produce, for example. These process-related terms are defined broadly and vaguely in the logic model by Allen et al[29], without a process reference model to anchor their measures. Furthermore, the measures provided for each construct lack operational definitions. Therefore, it is unclear whether the measures are intended to reflect process efficiency, effectiveness, or capability. Nonetheless, the model is valuable as a resource that may be further refined for its application in practice given that the constructs provided and associated measures are useful as a starting point for the development of an instrument.

As highlighted, an important gap exists in the LHS literature regarding measurement instruments that are explicitly anchored in learning cycles processes. In this research, I sought to describe the processes involved in executing learning cycles and create a reference model containing such processes that may be utilized across learning communities. The process

reference model establishes the foundation for learning cycle capability measurement. In this context, learning cycle capabilities refer to the extent to which learning communities are able to perform the learning cycle processes contained within the developed reference model (i.e., thus, I utilize the notion of process capabilities to construct the maturity model for learning communities). The focus on process capability for measurement provides specificity and consistency in terminology, and produces assessment results that are clear and useful to practitioners involved in implementing and executing the specific processes of knowledge discovery and implementation of the LHS learning cycle. The measurement instrument, therefore, is designed to assess learning community maturity as a function of learning cycle capabilities. As such, the responses to the instrument are intended to produce learning cycle capability scores for each learning community, which, in turn, are aggregated to produce an overall maturity score for each learning community. The instrument is intended to be used for self-assessment by learning community members and health system managers involved in developing LHS capabilities and coordinating with multiple learning communities across the health system.

By providing a means for evaluations of the current state of development (or maturity levels) of the learning communities in the departmental LHS, the resulting instrument is intended to facilitate communication of results to various stakeholders (i.e., health system leadership, clinicians involved in care delivery within the department, other departments within the health system, and outside audience of interest). Furthermore, the instrument is also intended to facilitate efforts to plan for improvements and manage multiple projects associated with developing capabilities for the learning communities in the health system. The quantitative measures provided by the instrument allow for objective assessments and team discussions regarding the learning cycle capabilities to be targeted for improvements.

Chapter 3 – Data and Methods

In this chapter, I describe the methodological approaches used in this research to construct the component parts of the maturity model and to reach the specific research aims as formulated. I describe the multiple data sources used to develop and evaluate the component parts of the maturity model, and the iterative design methods used to produce successive versions that were refined progressively throughout this research based on the obtained feedback. The detailed presentation of the iterative design methods aims to fill a gap in the literature by providing rigor for this design-based research and to serve as a methodological reference that may be replicated or tailored by others for the design of similar or adjacent instruments within the context of LHS development.

Methodological Approach

Sein et al argue that information systems research must respond to a dual mission: to make theoretical contributions and to assist in solving the current and anticipated problems of practitioners and organizations[50]. Information systems research is, thus, considered an "applied" discipline: it applies theory (frequently from other disciplines, such as economics, computer science, and the social sciences) to solve problems at the intersection of information technology and organizations[118]. According to Hevner et al, "*information systems are implemented within an organization for the purpose of improving the effectiveness and efficiency of that organization. Capabilities of the information system and characteristics of the organization, its work systems, its people, and its development and implementation methodologies together determine the extent to which that purpose is achieved*"[119,120]. The design and implementation of information systems, within underlying existing organizational structures, drive the development of organizational infrastructure to support organizational strategy and its objectives[119]. Thus, the LHS maturity model seeks to contribute to infrastructural development for the LHS and support the objectives of continuous, data-driven learning and improvement. This section presents the two key methodological approaches commonly used in information systems research and practice that were used in this research: design science research, and action research.

Design Science Research

The *design science research* approach has had a long tradition in information systems research, particularly in Europe [58]. In design science, researchers seek to build and evaluate 'artificial solutions' to practical problems and, as a consequence, produce knowledge and understanding about the problem domain as a direct result of the application and evaluation of the solutions[58,119,121,122]. In other words, by understanding how the solution affects the organizational setting within which it is designed and used, researchers are able to produce meaningful insights about the subject matter that is the focus of the solution. Consequently,

design science researchers are able to contribute to the subject matter knowledge base through design[58,119].

Thus, design science research differs from the natural sciences: in the latter, researchers seek to explain and predict behavioral aspects of reality (e.g., from an individual, group, organization, and market perspectives) by developing and verifying theories[58,121]. Despite their differences, design and natural science research are complementary for relevant and effective results within information systems research and practice[118,121]. Blessing et al[122] describe design science research methodology as a series of alternating descriptive and prescriptive studies, where assumptions about reality are a) formulated to describe factors of the current and future states of any given problem or context, b) incorporated into design solutions that aim to reach the future state, c) objectively evaluated in practice once the solution is applied to the problem or context, and d) refined iteratively as needed for improvements. The resulting process, therefore, uses cycles of design and objective evaluation to contribute to both theory and practice. Theoretical contributions may constitute insights about the interaction between the solution and its environment, or about the design process itself: both of which may be generalizable to other contexts[122]. Once again, according to Hevner et al[119] *"purposeful artifacts are built to address heretofore unsolved problems. They are evaluated with respect to the utility provided in solving those problems".* Thus, the contributions of the design artefact or instrument are assessed a) as they are applied to the business or practical need in the intended environment and b) as they add to the content of the knowledge base within the field of research[119].

Figure 5 illustrates the design science research approach utilized for the development of the LHS maturity model in this dissertation.

In design science research, artificial solutions, or the "design artefacts", may be broadly defined as *constructs* (i.e., vocabulary and symbols, language used to specify problems and solutions), *models* (i.e., abstractions and representations of the identified problem and future solutions), *methods* (i.e., algorithms and practices, procedures for solving problems and developing future solutions), and *instantiations* (i.e., implemented and prototype systems, the physical conversion as proof-of-concept of the prior artefacts)[58,119,121]. Mettler argue that

maturity models typically combine constructs, models, methods, and instantiations into a single artifact. They define constructs to create a model that represents system maturity progression over time. They also constitute a method for evaluating maturation by providing specific maturity measures associated with the constructs, and provide procedures or improvement strategies to be implemented for maturation[58.]. Instantiations provide the basis for evaluating model feasibility, utility, and purpose: they enable researchers to learn about how the maturity model performs in practice regarding its objectives, how it affects the organizations within which it is applied, and how users of the model appropriate it and use it in practice[58].

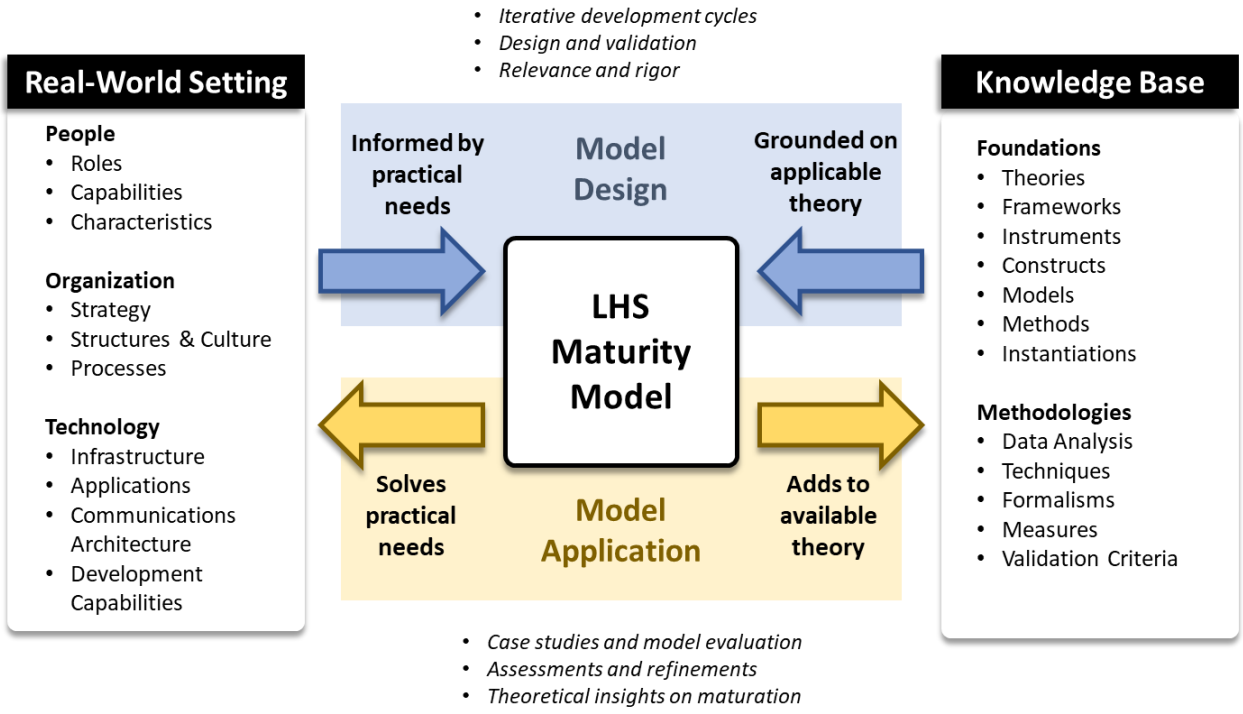


Figure 5 - Design Science Research Approach (adapted from Hevner et al)

When applied in practice, therefore, an LHS maturity model should address practical needs of clinical and operational stakeholders for maturity measurements of their LHS initiatives, and serve as the basis for an information (or performance measurement) system to assist those engaged in evaluating and developing LHS initiatives. In developing an LHS maturity model, this dissertation utilizes multiple data sources to encompass both empirical and

theoretical knowledge to inform model design. It also highlights how model design and evaluation are intended to contribute to both LHS practice and theory. The maturity model was designed in close collaboration with clinical, operational, and data analytics staff within a clinical department, whose job was to implement LHS principles in practice through a structured initiative or program. Action-research methods were also used to guide this work and are presented next.

Action Research

Action research methodology aligns itself well with design science research and the propositions for LHS researcher embeddedness, as identified by Forrest et al[48]. As the name suggests, action research is an approach to research that seeks to both take action and create knowledge or theory about the actions taken[51,83] . Action research has been used in a variety of organizational and business settings to study aspects of *operations management*. Coughlan et al[51] highlight typical questions that operations management researchers and practitioners are interested in through the use of action-research, such as: *what makes this operation work as it does? could it work better than its current form? what different forms could it take to achieve better results? what internal or external factors affect the working of the operation the most, and with what effect?*[51]. To answer these questions, therefore, action researchers aim to conduct research that can benefit both the organization or setting in which it takes place and the body of knowledge the researchers aim to contribute to pertaining to the factors influencing the operations under investigation[51,55]. Theory and practice are, therefore, linked through iterative testing and refining of hypotheses over repeated cycles of practical exploration[50]. Action researchers should plan and execute their studies in close collaboration with practitioners, thus aiming to solve practical problems within the focal organization participating in the research project, while also seeking to contribute to generalizable knowledge.

This methodological approach is most appropriate when a researcher is embedded in an unfolding series of actions within a group, community, or organization for their investigation. As a member of the group, the action researcher is interested in understanding both how and why

change occurs[51]. The changing conditions under investigation often involve complex and dynamic problems. Thus, the process of learning about such conditions is intricately related to the acts of changing the conditions[55].

A real problem must be present in an action research project, and the problem must be of both practical and research importance. Importantly, planning and use of tools for data collection should be well thought-out with members of the organization and be clearly integrated into the research process. Both qualitative and quantitative tools for data collection are often utilized in action research, and the data collection tools may be themselves considered interventions (e.g., the application of surveys or interviews with members of the organization may interfere with the change process occurring, by generating expectations and feelings such as anxiety, suspicion, or even hostility)[51]. Action researchers, therefore, should attend to this when collecting data, and planning and promoting changes, otherwise they risk ignoring significant factors that are critical to the success of the project[51]

Action research projects must have implications beyond practical problem solving. An important goal is to apply findings to other situations and identify how findings may benefit or inform similar organizations with similar issues[51]. Action research, consequently, demands an explicit concern with producing theory that is formed from the conceptualization of the particular experience in ways that are meaningful to other contexts and settings with similar or equivalent issues[51,53,55]. In moving from the particular to the general, action research builds theory across small cycles of data collection, data analysis, action, and evaluation of results. Evaluation may be of formative and/or summative natures. Thus, action research generates theory from what emerges from practice as well as from the application of pre-existing concepts within a body of knowledge that informs the intervention and research aims[51,53,55].

The development of artifacts as viable solutions for the problems encountered in the organizational context may occur during action research. The design artifact emerges from interactions between researchers and practitioners, even if design is guided by the researchers[50]. The artifact may utilize information technology (IT) applications or platforms to serve any given purpose(s) within the organizational context. It will, thus, be inherently shaped by the organizational context during development and use[50]. Hence, an action research process

may be inseparable from (or inherently interwoven with) a design science research process: research activities may involve collection and analysis of data, designing an artifact, intervening in the organization through implementation of the artifact, and concurrent evaluation of results in a cyclical process that terminates once achieved results have been deemed to be satisfactory for both researchers and practitioners[50]. In action research, however, the basis for the development and application of artifacts must be explicit and shown to incorporate and test available theories, so that findings are generalizable[51,53]. Sein et al propose a combined approach integrating action research and design science research: action-design research (ADR). The authors define ADR as *"a research method for generating prescriptive design knowledge through building and evaluating ensemble IT artifacts in an organizational setting. It deals with two seemingly disparate challenges: (1) addressing a problem situation encountered in a specific organizational setting by intervening and evaluating; and (2) constructing and evaluating an IT artifact that addresses the class of problems typified by the encountered situation. The responses demanded by these two challenges result in a method that focuses on the building, intervention, and evaluation of an artifact that reflects not only the theoretical precursors and intent of the researchers but also the influence of users and ongoing use in context"*[50]. In this methodological approach, multiple data sources and data analysis are utilized to foster cycles of design and formative evaluation to produce a design artifact in collaboration with (and to be utilized by) the practitioners in the participating organization in the research project[50,51,122,123].

According to both design science research[58,118,119,122] and action research[50–52,55], data sources for model design should include both empirical and theoretical knowledge to inform model constructs and configuration. This increases the comprehensiveness of the model, its applicability in practice, and allows for an evaluation (once applied) of both empirical and theoretical assumptions that are built into the model[58,118,119,121,124]. The approach by Sein et al, along with methodological process models by Coughlan et al, Peffers et al, and Mettler provide the basis for the methodological steps used in this dissertation[50,51,58,118]. As highlighted previously, I argue that the steps taken in this dissertation may be replicated or tailored by others, filling am important methodological gap observed in the LHS literature. The data sources used in this research as described next.

Data Sources

The two specific research aims were sought concurrently using the methodological approaches described above through iterative design methods that leveraged multiple data sources to produce successive versions of the components in the model. Thus, the data sources were used as inputs for the design and formative evaluation of the two deliverables, which developed progressively and in an integrated manner through the design iterations.

The input data contemplated both empirical and theoretical sources. For empirical data, I relied on input from stakeholders within PM&R that were used for model design and refinements. Stakeholders included the LHS operations team members and clinician members of the individual learning communities within the department. The LHS operations team members and I co-designed the first version of the deliverables. The clinician members of the learning communities provided feedback for refinements in a later version of the deliverables. This was done in order to incorporate their input to reflect their needs and experience.

For theoretical knowledge, I relied on the LHS published literature and input from an expert panel of LHS researchers not directly involved in PM&R. I reviewed available literature on LHS conceptual frameworks and cases studies, as well as the implementation science literature to extract constructs that informed model design. I also solicited feedback from an expert panel consisting of LHS researchers and practitioners within the University of Michigan Medical School. The expert panel scrutinized earlier versions of the two deliverables and provided quantitative and qualitative feedback that were used for refinements. The specific methods used in the design iterations are presented next.

Design Iterations

The iterative methods used in this dissertation were informed by available research frameworks for conducting design science research, action research, and maturity model development[50,51,58,118]. As such, the research aims derived from a practical problem facing the PM&R department. The identified practical problem was considered an *instance of a class of problems* faced by health systems in general that are developing LHS initiatives [50,58,119,123] .

According to Sein et al, "*the action researcher should generate knowledge that can be applied to the class of problems that the specific problem exemplifies".* Consequently, the co-developed maturity model not only serves the purpose of solving the practical problem observed in the clinical department in focus for this dissertation, but is also intended to be generalizable to other clinical departments.

In alignment with Forrest et al[48] and with action research principles[50,51], I first embedded myself within daily meetings and operations of the clinical department in focus to understand the current work practices, objectives, and culture of the departmental LHS initiative, and to identify the main challenges faced by its stakeholders in order to design an effective solution. During the initial stage of this research, an informal agreement was established between me and health system managers within the department which enabled this research project to occur. After this, problems and needs were identified in collaboration with stakeholders in the clinical department, and contextualized in light of available theory. Subsequently, with contextual theoretical knowledge around the problem formulation, I was able to cast the practical problem as an instance of a broader class of problems of which a maturity model could be a solution. The proposed maturity model solution presents a set of process construct definitions that guide the development of learning communities within an LHS program, and a measurement tool (anchored in the set of processes) which enables maturity assessments over time.

Once the initial problem was clearly identified, and a general solution proposed in the form of a maturity model, I engaged in a collaborative design process alongside practitioners to develop the specific components in the model in detail. A total of 3 design iterations were conducted the data sources described previously, in accordance with design science and action research principles[49–51,55,58,118,119,123,125,126]. Therefore, a total of three respective versions of the model's components were produced throughout development. Each design iteration utilized specific methods for data collection and analysis, using different data sources as inputs. The data collection and analysis methods were used to refine the model progressively: data collection and analysis were conducted to evaluate earlier version of the model for formative evaluation in support of model refinements and the design of the successive model versions.

The three design iterations were conducted sequentially until the final version was reached and considered ready for application. The design iterations, data sources, and activities for data collection analysis are presented in Figure 6. The data sources in the upper part of Figure 6 represent the empirical knowledge from the PM&R LHS program stakeholders that were used for model design, namely the health system managers leading the LHS departmental program and the LHS learning community members. The data sources in the lower part of Figure 6 represent available knowledge base outside of the PM&R LHS program, namely feedback from outside LHS researchers not directly involved with the departmental PM&R LHS program, based on their expertise and experience, as well as the published literature on LHS conceptual frameworks and case studies. The design iterations and their respective data collection and analyses methods are detailed next.

Design Iteration 1

The first versions of the process reference model and the measurement instrument were co-designed alongside the health system managers in the LHS operations team within the PR&R department. This was done in order to i) capture their empirical experience and knowledge regarding the development of the multiple learning communities in the department, ii) incorporate terminology that reflects their experience into the process reference model, and iii) develop meaningful capability measures that would be of value to them in practice. For this, a collaborative design method was used.

Collaborative Design

A weekly meeting series was set up for the collaborative design of the first version of the process reference model and measurement instrument, starting in October 2020. The meeting participants included a) the lead doctoral researcher, b) the faculty lead of the PM&R LHS program, and c) the LHS project manager for the department. Each weekly meeting lasted for ~1 hour. The scope for the two instruments were delineated early in the meeting series. We decided to focus on describing the processes involved in executing learning cycles of data-driven

knowledge discovery and implementation, and defining the capabilities measured related to the learning cycle processes. The capability measures were intended to reflect the extent to which the learning communities within the PM&R department were able to operationalize the learning cycle processes in practice.

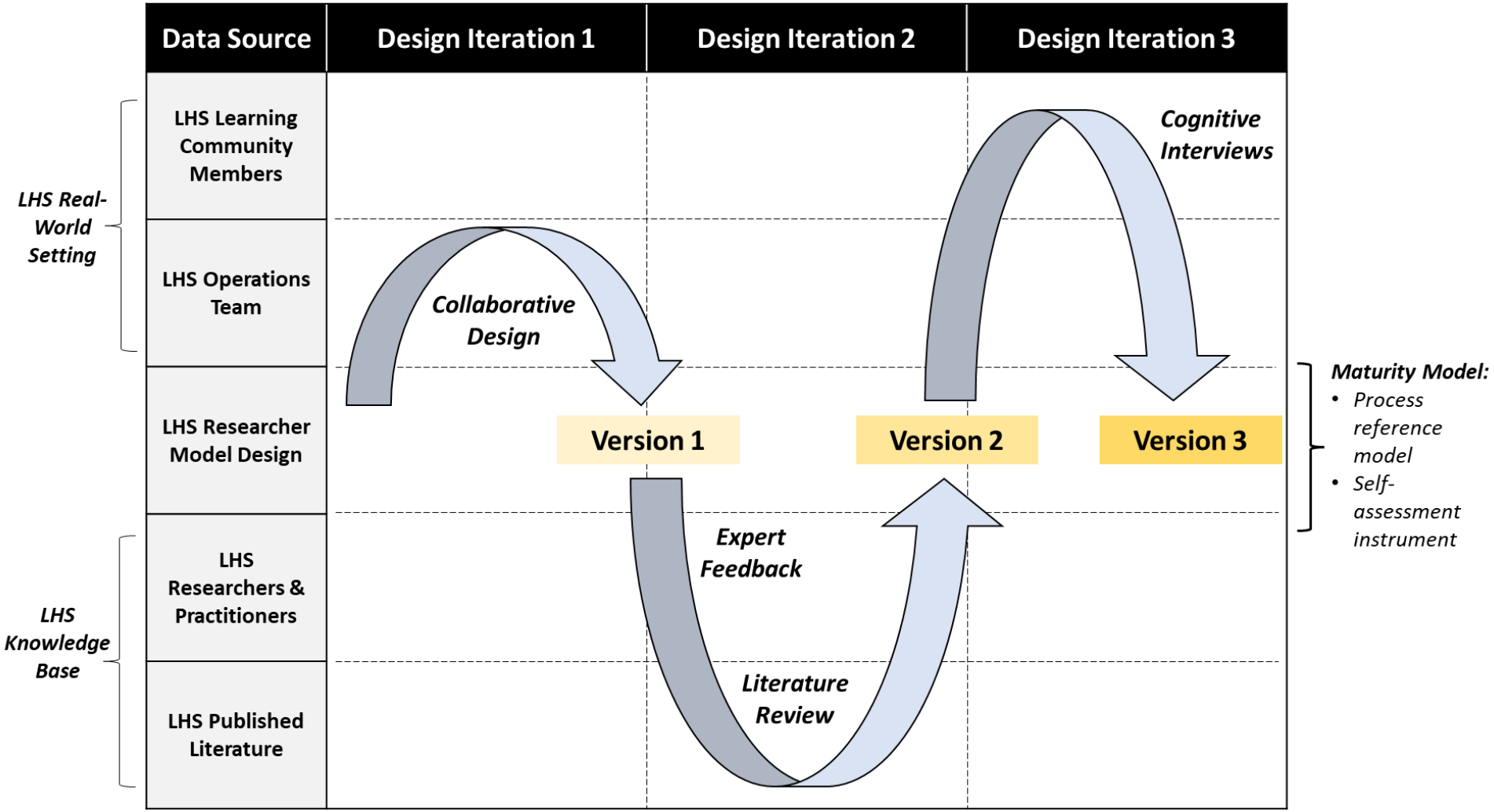


Figure 6 - Design Iterations for Model Development (adapted from Sein et al)

During the meeting series, we operationally defined the processes that characterize a typical learning cycle. These processes expanded upon the model by Friedman at al[2] We relied on the LHS program managers' experience and understanding of the key activities involved in enacting learning cycles for each of the learning communities within the department to provide granularity and specificity to the processes. The model by Friedman et al[2] contains three overarching learning cycle phases or categories of processes: Practice to Data (P2D), Data to Knowledge (D2K), and Knowledge to Practice (K2P). For each learning cycle phase in the model, we identified and described a set of processes that reflected the practical experience of the LHS program managers and provided definitions to support their execution in practice in a pragmatic manner. In order to establish capability measures for the processes, we concurrently developed process capability measures by defining a progression of process capabilities levels for each process. In this first version of the measurement instrument, therefore, we developed short written definitions for a progression of 5 process capability levels for all processes in the reference model. The descriptions were largely provided by the LHS operations team members, with my inputs based on prior experience in other LHS and implementation science projects.

It is important to note that the learning communities within PM&R were at various stages of development at the time of the design of the first version of the process reference model and associated capability measurement instrument. None of the learning communities had matured to the point of achieving practice change and knowledge implementation objectives. Thus, the processes identified in collaboration with the PM&R operations team and the associated measures reflected both their experience to date as well as their envisioned future state of development (or what they perceived to be an ideal state of what learning communities should do in the future in order to perform fully developed learning cycles). The meeting series for this design iteration ended in April 2021 (~7 months duration). We did not consider the resulting first version of the instruments to be complete and ready for use. It merely constituted a starting point that captured potential processes and associated capability measures. After developing this initial version of the instruments, I sought to collect data from an expert panel of reviewers to be used as input for formative evaluation and refinements.

Design Iteration 2

To refine the first version of the instruments in the maturity model, I sought two additional data sources that would provide input to be used for refinements: i) feedback from experienced LHS researchers and practitioners outside of the PM&R LHS program and ii) a literature review on existing LHS frameworks, models, and case studies. These two methods for data collection and analysis for model refinement are presented next.

Expert Feedback

To refine the collaboratively designed process reference model and capability measurement instrument, I sought feedback from LHS researchers and practitioners not directly involved with the PM&R LHS program at the University of Michigan Medical School. The experts were asked to scrutinize the first version and provide assessments regarding the terminology used in process descriptions and the capability measures and evaluate their potential applicability beyond the PM&R LHS program. For this, I identified a list of 21 potential expert reviewers within faculty and staff at the University of Michigan Medical School, in the Department of Learning Health Sciences, whose feedback I considered valuable for model refinement. The list of experts represented a broad range of expertise and backgrounds in LHS research, including qualitative to quantitative researchers focusing on a broad range of focus areas, including informatics, data analytics and artificial intelligence, implementation science, social sciences, project management, and organizational studies for LHS development. The expert panel was selected to review both the process reference model and capability measures. To collect feedback, I designed an expert feedback collection form document to be sent to the identified list of experts. The expert feedback form is structured in three parts, as follows:

1. The first section provides an introduction to the maturity model project and the component parts within the model: the process reference model and capability measurement instrument. This section also describes the context in which the project is occurring and scope within the PM&R LHS program, the purpose and intent of the

maturity model, and its development methods to date (i.e., description of the collaborative design activities used to obtain the first versions in design iteration 1).

2. In the second section of the form, I solicit assessments by the expert reviewers on the collaboratively designed instruments, including specific feedback on all processes and capability measures. For all items in the model, I ask reviewers to provide quantitative evaluations (i.e., using Likert-scale questions) and qualitative evaluations (i.e., by soliciting comments and suggestions for improvement). Process attributes that were assessed using Likert-scale questions include: *i) clarity of process definitions, and ii) alignment between process definitions and the key attributes used to characterize the processes*. For all measure sets, I also asked reviewers to provide quantitative evaluations and qualitative evaluations. The capability measure attributes that were assessed using Likert-scale questions included*: i) logic of the order of progression for the capability level descriptions, ii) distinction between capability level descriptions, and iii) alignment between capability level descriptions and the process definition they pertained to.* The Likert scale response options for all question above were as follows*: i) Not at all, ii) A little, iii), Somewhat, iv) Quite a bit, and v) Very much.* The expert reviewers were asked to use the Likert-scale response sets to evaluate these aspects for all processes and associated capability level progressions in the instruments. Reviewers were also encouraged to suggest changes in the wording used for process descriptions and capability level definitions. and to provide any other comments they found pertinent for improvements, when applicable.
3. In the final section of the form, I solicit an overall assessment of the maturity model as configured. I ask for both quantitative (i.e., using Likert-scales) and qualitative assessments (i.e., by soliciting open-ended comments and suggestions). For overall quantitative evaluation, the following maturity model attributes were assessed via Likert-scales: implementability/feasibility, generalizability across clinical contexts, potential for contribution to practice, potential for contribution to LHS theory, and readiness for use. The Likert scale response options for the question above were defined as follows: *(0) Not at all, to (10) Very much.*

After form development, I obtained IRB approval for review exemption (HUM00204655), and sent the expert feedback form to the 21 identified faculty and staff. Forms were sent in October 2021 and once there were returned back with feedback, I compiled the responses from all expert reviewers into a single Microsoft Excel spreadsheet. The feedback from outside experts provided the basis for a formative evaluation step in which the internally designed instruments were scrutinized. That is, the feedback received by outside experts provided critical assessments on the internally developed instruments that supported refinement and the design of the second version of the maturity model. The expert feedback data analysis was concluded in February 2022 (~4 months duration for analysis). Based on this input, we created multiple successive sub-iterations of the process reference model and capability measurement instrument before reaching the second version, as we explored different configurations through team discussions (i.e., meetings between the doctoral researcher and doctoral dissertation committee members). The second version of the capability measurement instrument utilized a modified approach. This version was comprised of a Likert-scale questionnaire that assessed capability levels for all processes in the learning cycle (as opposed to the capability level progression format used in the first version). This choice was made in order to streamline the instrument and reduce measurement burden on users.

Literature Review

In addition to expert feedback, I also reviewed the published literature on LHS conceptual frameworks and case studies. This was done to complement the expert feedback and provide additional inputs for the design of the second version of the model. I chose to utilize a pragmatic or rapid review approach[127–132] given the broad focus of the review and the need to streamline the review process. In contrast to rapid reviews, systematic reviews are encouraged when the research questions have a narrow focus[127,128]. For example, they may be conducted to confirm or refute whether or not current care practices are based on relevant scientific evidence, to establish the quality of the evidence, and/or to address any variation in care practices that may be taking place[127]. The goal was to extract broad themes and constructs from the literature that would support the refinement of the process descriptions and capability

measures. Additionally, I sought to streamline the literature review process given the time constraints of the project, as well as the iterative nature of the design method and the complementarity of the empirical and theoretical data sources. Thus, a rapid review approach was chosen. The advantage of the rapid review approach included a relatively shorter effort or timeframe for review when compared to a systematic literature review [127–132]. This allowed me to review the literature and utilize the review findings to design the next version of the model in a relatively shorter timeframe than otherwise would have taken had I chosen to conduct a systematic literature review. Limitations of this rapid approach include a potentially limited thematic and content analysis for model design, resulting from unintentionally excluded literature. Nevertheless, I argue that the other data sources for model design compensate for this limitation, and future research and iterations of the model may incorporate an enhanced literature reviews using systematic methods.

The literature review began in October 2020, and it was conducted in parallel to the previous two methods described above (collaborative design and expert feedback). The literature review was concluded in June 2021 (~9 months duration). The model by Friedman et al[2] served as a starting point for the review since it introduces the learning cycle model at a high level and it is the reference used by the PM&R departmental LHS program. From this reference, I sought other publications via snowball sampling. The additional publications chosen presented relevant conceptual models, frameworks, methods, and LHS case studies that were considered valuable for our context and for model design[3,8,9,17,18,20,21,25–27,29,30,32,33,37,40,41,44,133–135]. The reviewed literature is presented in Table 1.

Table 1 - Reviewed Literature for Model Design

Selection Criteria	Citation	Title
Starting point	Friedman et al[2]	Toward an Information Infrastructure for Global Health Improvement
Snowball Sampling 1st Round	Lannon et al[21]	A Maturity Grid Assessment Tool for Learning Networks
	Allen et al[29]	A Roadmap to Operationalize and Evaluate Impact in a Learning Health System
	Menear et al[3]	A Framework for Value-Creating Learning Health Systems
	Platt et al[44]	An Analysis of The Learning Health System in Its First Decade in Practice: Scoping Review
	Lessard et al[27]	Architectural Frameworks: Defining the Structures for Implementing Learning Health Systems
	Adler-Milstein et al.[8]	Preparing Healthcare Delivery Organizations for Managing Computable Knowledge
	Psek et al[18]	Operationalizing the Learning Health Care System in an Integrated Delivery System
	Greene et al[9]	Implementing The Learning Health System: From Concept to Action
	Lindsell et al[17]	Learning From What We Do, And Doing What We Learn: A Learning Health Care System in Action
	Harrison et al[40]	Multi-Level Analysis of The Learning Health System: Integrating Contributions from Research on Organizations and Implementation
Snowball Sampling 2nd Round	Ferguson et al[30]	Operationalizing A Learning Community for A Learning Health System: A Practical Guide
	Forrest et al[133]	PEDSnet: How A Prototype Pediatric Learning Health System Is Being Expanded into A National Network
	Britto et al[20]	Using A Network Organisational Architecture to Support the Development of Learning Healthcare Systems
	Soejima et al[26]	A Functional Learning Health System in Japan: Experience with Processes and Information Infrastructure Toward Continuous Health Improvement
	Kilbourne et al[25]	Quality Enhancement Research Initiative Implementation Roadmap: Toward Sustainability of Evidence-Based Practices in A Learning Health System
	Grol et al[37]	Improving Patient Care: The Implementation of Change in Health Care. Chapter 3 - Effective Implementation of Change in Healthcare: A Systematic Approach
	Fernandez et al[33]	Implementation Mapping: Using Intervention Mapping to Develop Implementation Strategies
	Smith et al[32]	The Implementation Research Logic Model: A Method for Planning, Executing, Reporting, And Synthesizing Implementation Projects
	Grimshaw et al[134]	Knowledge Translation of Research Findings
	Vinson[41]	Culture as Infrastructure in Learning Health Systems
	Kraft et al[19]	Building the Learning Health System: Describing an Organizational Infrastructure to Support Continuous Learning
	McLachlan et al[38]	A Framework for Analysing Learning Health Systems: Are We Removing the Most Impactful Barriers?

I first reviewed the literature broadly, to develop an overview comparative analysis and identify high-level LHS components and elements. This supported the development of the LHS conceptual framework presented in the introduction chapter of this dissertation. I then reviewed the literature above in detail, in order to expand upon and further characterize the specific learning cycles processes to complement the first version that was collaboratively defined alongside the LHS program managers.

I used thematic analysis across the reviewed models in order to analyze content and interpret, describe, and group contextualized themes or pieces of content information into categories using a categorization scheme[136,137].

Table 2 summarizes the categorization scheme for thematic analysis. In the categorization scheme, I defined 3 levels for thematic analysis:

1) *Health system levels:* I categorized specific content in the reviewed literature as it pertained to either: i) the work of learning communities, ii) thew work of LHS operations team and health system managers, or iii) work conducted at the health system leadership or broader institutional level, within which specific LHS departmental programs may operate
2) *Learning cycle phase*: I categorized specific content in the reviewed literature as it pertained to either the P2D, D2K, or K2P phases of the learning cycle from the Friedman et al model [2]. For example, for any given LHS case study or conceptual model I highlighted content in the publication regarding its applicability to expand or refine our understanding of the processes within any of the three cycle phases proposed by Friedman et al[2]
3) *Learning cycle capability factors*: I categorized specific content in the reviewed literature as it pertained to factors describing the development of specific process capabilities for learning cycles, either relating to a) activities and tasks, b) technology, tools, or other resources, c) skills, competencies, and incentives, or d) organizational policy and documentation. This was done to further our understanding of capability factors and refine process construct definitions.

Table 2 - Literature Review - Thematic Analysis Categorization Scheme

LHS Level	Learning Cycle Process Group	Process Capability Factors
• LHS learning communities	• Foundational (core)	• Activities and tasks
• LHS operations team & department	• Practice to data (P2D)	• Technology, tools, resources
• LHS broader infrastructure & health system	• Data to knowledge (D2K)	• Skills, competencies, and incentives
…	• Knowledge to practice (K2P)	• Organizational policies and documentation

The thematic analysis of the reviewed literature informed the design of the second version of the model, complementing the input from the expert feedback. However, the second version was not yet considered ready for use, and another cycle of review and refinement was conducted using cognitive interviews with learning community members at PM&R. In the next section, the methods used in the cognitive interviews are presented.

Design Iteration 3

In order to refine the second version of the two component instruments in the maturity model, I interviewed learning community members of the PM&R LHS program to gather their input and perceptions. As the intended users (along with the LHS program managers), it was important to incorporate their input to ensure that the final products met their needs. Thus, I interviewed learning community members using a cognitive interview format, which allowed me to collect data regarding learning community members' perceptions of the component parts of the model. I then used that data to refine each component of the maturity model and design the third version. This allowed me to improve constructs in the model and complement the input from LHS program managers, outside LHS researchers, the available literature that were used in previous design iterations.

Cognitive Interviews

Cognitive interviewing is a methodological technique used to provide insight into users' perceptions, where individuals are invited to verbalize thoughts and feelings as they examine information and conduct tasks [138]. The insights from the interviews may be used improve the development of materials[138]. The cognitive interview format, thus, allowed me to collect data regarding learning community members' perceptions of the second version of the process reference model and associated measurement instrument.

For the cognitive interviews, I targeted learning community members who were clinician leaders of their respective learning communities within PM&R. However, since learning communities are clinician-led multi-stakeholder teams, it was important to receive feedback not only from clinician leaders but from participants with complimentary roles as well, in order to ensure the understandability and clarity of the model's processes to all team members. Thus, I also interviewed participants who performed the roles of data analysis and project management in the LHS operations team at PM&R. To conduct the cognitive interviews, I first developed a cognitive interview protocol, detailing the methodological steps and procedures, as well as an information sheet and the cognitive interview form that were sent to prospective participants within the PM&R department. For the cognitive interviews, I obtained IRB approval for review exemption (HUM00217331).

The learning community members within PM&R who agreed to participate in the interviews were instructed to respond to the second version of the measurement instrument according to their experience in practice. Consequently, their answers to the measurement instrument reflected their perceptions of the current state of capabilities of their own learning communities. The cognitive interviews were scheduled within 2-3 business days after the conclusion of the questionnaire by participants to ensure that answers were still fresh in their minds for the interviews.

A total of 5 clinicians (from 5 different learning communities), 1 data analyst, and 1 administrative manager (from the PM&R operations team) agreed to participate in the cognitive interviews. A total of 16 interviews were then conducted with the 7 participants (i.e., 2

participants provided 3 interviews each, and the remaining 5 participants provided 2 interviews each). All interviews lasted ~60-90 minutes.

During the interviews, I sought to identify whether the wording used to define the processes in the model and the associated questionnaire items were appropriate and meaningful[138]. I used a *think-aloud* interview method and verbal probing to collect data regarding participants' perspectives on the process constructs and the associated questionnaire. The interviews were semi-structured: I used a list of pre-defined open-ended questions that were asked to all participants regarding their perceptions of the processes and questions in the instrument, with follow-up questions as needed to probe participants' overall impressions and interpretations. For each of the items in the questionnaire, participants were asked the following open-ended reflective questions during the interviews and instructed to answer spontaneously regarding thoughts that went through their minds when they were answering the questionnaire:

- How did you answer [referring to the item on the questionnaire]? How did you arrive at your answer?
- Tell me what you were thinking when you chose an answer to this question. Tell me a little more about … [probe based on the responses.]
- Was this an easy or hard question to answer?
- How did the answer choices work for you? Did they make sense? Were there enough, too few or too many?
- Do you think this is an important question to ask LHS team (i.e., learning community) members about the work of developing an LHS?
- What are some of the challenges associated with developing aspects of this part of the learning cycle covered in [referring to the item on the questionnaire]?

Not all participants were able to provide feedback regarding all items in the questionnaire, as I was not able to cover the entire questionnaire with all participants during the interviews. I ensured, however, feedback from at least 5 participants for all items in the

questionnaire. All cognitive interviews were conducted virtually (i.e., Zoom meeting) and audio-recorded, to supplement notes taken during the interview by the interviewer. Once interviews were completed, the recordings were transcribed and the resulting data were compiled into a single Microsoft Excel spreadsheet. The interview process began in June 2022, when participants were first contacted. Th results from interview transcript analysis were concluded in December 2022. The analysis of cognitive interview data prepared me to refine questions in the instrument and the associated processes. A thematic analysis was conducted with the interview transcripts: themes were identified in order to categorize the feedback received from the cognitive interviews, which were then used for refinements.

Positionality Statement

Before presenting the results from the methods described above, I recognize that my positionality may have in part affected the outputs of this research[139]. I am a 36-year-old mixed-race man with dual citizenship Brazilian-Italian living in the United States. I hold a Bachelor's degree in Industrial Engineering, a Master's Degree in Management Science and I am currently pursuing a PhD in Health Infrastructures and Learning Systems. As an industrial engineer by training with a multicultural background and as an embedded researcher within a clinical department developing an LHS program, I acknowledge that my interpretations and prior professional and cultural experiences may have impacted how data were collected and analyzed to produce findings. As such, I strive to be consciously aware of my own biases and recognize how these may shape my research.

Chapter 4 – Process Reference Model for Learning Cycles

In this chapter, I present the results from the methods described above pertaining to the development of the *process reference model for learning cycles* within the maturity model. Firstly, I present the results from the successive design iterations describing how the data were analyzed to produce successive versions of the process reference model until the final version was reached. Secondly, a present the final deliverable of the process reference model to be used by learning communities in practice within the context of LHS capability development. The presentation of the reference model contains detailed descriptions of its purpose and application, the intended users, the configuration and structure used to represent and describe the processes for learning cycles, and a detailed characterization of all processes including activities and tasks, stakeholder roles for process execution, and expected outputs for each process.

Process Reference Model – Design Iterations

This section presents the results from data analyses for the three successive design iterations of the process reference model.

Design Iteration 1

The collaborative development of the first version of the process reference model was conducted alongside the operations team within PM&R, and it began with the identification of activities to be performed by learning communities at the start of a learning cycle, such as the learning community formation process. Using the model by Friedman et al[2] as a guide, we progressively detailed activities to be performed for all steps in a learning cycle, from data extraction to practice change at the point of care. Therefore, we collaboratively identified the required processes for all phases of the learning cycle model. The resulting first version of the model added specificity to the model by Friedman et al[2], and reflected the empirical experience of the health system managers of PM&R in practice. This first version contained 28 processes across 3 learning cycle phases: P2D, D2K, and K2P. For each process, we provided a written description comprised of a short (1-3 sentences) presenting what that process entails in practice and its purpose. Each process also contained a set of key attributes as indicators or concrete elements intended to support an objective assessment of process capability in practice (i.e., the elements that should be observable in practice to attest that the learning community has executed the process). For example, in the process "Learning Community Formation", the written description provided stated: *"Process of establishing the learning community, identifying the relevant stakeholders. The learning community should define who the people involved are and how they plan to communicate and/or meet. The learning community may consist of clinicians, LHS operational support, scientists, patients, and non-clinical subject matter experts (e.g., IT, administration). The LHS Learning Community will have one or more champions".* The process key attributes for the process were identified as follows: *presence of a learning community champion or leader, ongoing team meeting/communication channel established, development of a communication plan, identifying list of stakeholders, presence of non-clinical*

stakeholders and diverse perspectives. In describing the processes, we used clinical-neutral terminology to ensure the model would describe the work of learning communities in any clinical setting. Therefore, in defining the processes, we did not include any terminology that could be considered specific to physical medicine and rehabilitation. We considered that there could be potential model overfitting for the context in which it was developed. Therefore, we did not consider this first version of the model to be complete and ready for use. It merely constituted a starting point that captured the processes and activities for performing learning cycles as perceived by the LHS program managers in practice, expanding upon the model by Friedman et al[2]. I then sought additional data for model refinement.

Design Iteration 2

I used the data from the expert feedback and the literature review as inputs to refine the first version of the process reference model (PRM), and subsequently designed a second version. I began by analyzing the responses from all expert reviewers within the compiled Microsoft Excel spreadsheet. Quantitatively, I asked expert reviewers to answer Likert-scale questions to provide their assessments regarding the process definitions and process key attributes within the model. Reviewers were asked to rate all process written descriptions for clarity, and to rate the key attributes regarding their alignment with the process written description. Once responses were received from reviewers, I calculated the mean and standard deviation from their answers to produce scores for the two process characterization elements for all processes. This allowed me to identify the constructs that were poorly rated by the reviewers, and therefore needed to be refined. For example, the process entitled "Understanding Gaps Between Current and Future State" within the P2D phase of the learning cycle received low scores by reviewers regarding both the clarity of process description (3.0, 1.2) and the alignment of the key attributes (3.1, 1.2). Thus, I prioritized this and other processes that received low scores and targeted them for improvements in the second version of the model. The results from quantitative feedback received from the expert panel for all processes in the first version of the PRM are presented in Table 3.

Qualitatively, I asked reviewers to provide open comments for editing or re-wording suggestions for all processes in the model. Once compiled, I was able to compare comments from multiple reviewers regarding each process and use that input to re-write or re-design a significant number of processes in the model. Terminology used for process description was clarified based on the expert feedback. For example, when scrutinizing the process "Understanding Target Clinical Population" in the P2D phase of the learning cycle one interviewee stated: *"Language suggestion: consider using "population of interest" and avoid the term "target"".* An alteration was, thus, made accordingly. Additionally, when providing feedback to the process "Data Specification Refinements", in the D2K learning cycle phase, one of the reviewers commented: *"This entire entry is confusing because of loose language (highlighted section: "The data specifications for data extraction must be identified and refined") and a disorganized further description. In particular "data refinements" is not clear operational language. A start might be something like: Specifications for data extraction must list key aspects of the clinical question(s), identify data element/items relevant to those questions, and specify data manipulations (e.g., construction of measures) relevant to answering those questions"*. This comment was utilized to improve the language used for process description. Based on the reviewer's input, the process was sub-divided and resulted in three different processes in the third version of the PROCESS REFERENCE MODEL. Another example includes the process "Preparing for scale-up and update/adapt as needed", in the K2P learning cycle phase. For this process, the following comment was made "*I am not sure that the phrase "scaling up" will be immediately understandable to everyone. It reads better when attached to the word implementation."* Changes in process description, thus, were made accordingly.

A sample of comments provided for each process is presented in Table 4. The overall comments made by the expert panel implied that while the first version that was developed collaboratively with the LHS program managers served as an adequate starting point which incorporated the experience to date at PM&R, it was incomplete, and, therefore, needed expansion and refinements.

Table 3 - Quantitative Evaluations from Expert Feedback

Learning Cycle Phase	Process	Process Description		Key Attributes	
		Mean	SD	Mean	SD
P2D – Practice to Data	1.1. Learning Community Formation	4.4	0.7	4.1	0.7
	1.2. Learning Community Identity and Agency	3.9	1.3	3.9	1.1
	1.3. Understanding Target Clinical Population	4.9	0.3	4.8	0.4
	1.4. Identification and Prioritization of Important Questions Relevant to Clinical Practice	5.0	0.0	4.4	0.7
	2.1. Understanding Current State of Practice	4.0	0.9	3.1	1.0
	2.2. Envisioning Future State of Practice	3.4	0.9	3.3	1.4
	2.3. Understanding Gaps Between Current and Future State	3.0	1.2	3.1	1.2
	2.4. Identification of Potential Data-Capturing Solutions or Informatics-Based Solutions to Address the Gaps	3.9	1.3	4.1	1.1
	2.5. Implementation of Selected Solutions	4.1	0.8	4.1	1.0
	2.6. Compliance with using Solutions	4.0	0.9	4.0	1.2
D2K – Data to Knowledge	3.1. Data Quality Monitoring and Assurance	3.7	1.3	4.1	1.1
	3.2. Data Specification Refinements	3.6	1.0	3.7	1.0
	3.3. Data Extraction, Manipulation, and Transfer	4.4	0.7	4.6	0.5
	4.1. Preparing for Analysis	4.0	1.1	4.1	0.6
	4.2. Executing and Validating Analysis	5.0	0.0	4.6	0.8
	5.1. Interpreting Results	4.0	1.2	4.2	0.7
	5.2. Reviewing External Evidence	3.9	1.1	4.6	0.5
	5.3. Generating, Representing, and Visualizing Knowledge	4.0	1.8	3.7	1.3
K2P – Knowledge to Practice	6.1. Defining Scope for the Evidence-Based Intervention	3.6	1.2	4.4	0.9
	6.2. Defining/updating outcomes to measure intervention success	3.6	1.2	3.9	1.0
	7.1. Generating initial implementation strategies	4.3	0.7	3.9	0.8
	7.2. Defining/updating outcomes to measure implementation success and study design	3.5	1.2	3.8	1.3
	7.3. Pilot testing/initial implementation and reviewing results	4.7	0.5	4.7	0.5
	8.1. Preparing for scale-up and update/adapt as needed.	4.3	0.5	4.4	0.5
	8.2. Widespread adoption	4.4	0.7	4.6	0.5

Learning Cycle Phase	Process	Process Description		Key Attributes	
		Mean	SD	Mean	SD
	8.3. Measuring performance and monitoring progress	4.3	0.7	4.3	0.7
	9.1. Periodic evaluation, sustainment, and maintenance	4.4	0.7	4.3	0.7
	9.2. Communicating/disseminating results	4.7	0.5	4.5	0.5

Table 4 - Qualitative Evaluations from Expert Feedback: Comments for Refinements

Learning Cycle Phase	Process	Sample of Feedback Comments
P2D – Practice to Data	1.1. Learning Community Formation	• *"Should the description say something about the community being centered around a clinical issue or something to that effect? Should it make some mention of purpose or mission?"* • *"Why are non-clinical stakeholders key? Can they be key but not come to all the meetings, as much of the prep work is very clinical?"*
	1.2. Learning Community Identity and Agency	• *"Identity and agency are different. Why combine them into a single capability? Agency is an important concept and should be treated as distinct"* • *"Suggest adding a charter to help define roles, responsibilities, operating procedures, how members will engage with each other, metrics for success, etc."*
	1.3. Understanding Target Clinical Population	• *"I think this is important in PM&R, but would have less importance in other clinical areas, so it may be an instance of overfit. Possibly it wouldn't matter; LCs in other clinical areas might just start at a higher level. I'm not sure why a conceptual framework for patients is important in all instances."* • *"Language suggestion: consider using "population of interest" and avoid the term "target""*
	1.4. Identification and Prioritization	• *"I'm not sure that documenting what information is needed to answer questions fits into this group."*

Learning Cycle Phase	Process	Sample of Feedback Comments
	of Important Questions Relevant to Clinical Practice	• *"A foundational aspect that is relevant to all three segments of the cycle. The Capability Description and the Key Attributes are generally stated. In the levels below, I highlighted some words that are more limiting than the construct definitions"*
	2.1. Understanding Current State of Practice	• *"Consider evaluation on dimensions such as speed in which data can be extracted to make a population health decision (e.g., how long would it take for them to identify all patients with X diagnosis on X treatment that did not have a complete lab test to monitor levels of treatment X)"* • *"Again, "practice" is a technical/jargon term that typically refers to activities of health care professionals. More common wording would be "capturing actions/activities as data.""*
	2.2. Envisioning Future State of Practice	• *"These do not seem to fit in: What do we need to capture? Identify Important Questions, Problems, and Opportunities for Improvement in Clinical Data Collection Practices. I would re-word and clarify it to "Identify critical data to capture""* • *"The focus on data seems out of place in a broad statement about envisioning future state, which is not just about data. If this and the previous one are just about the current and future state of data, then that should be explicit."*
	2.3. Understanding Gaps Between Current and Future State	• *"What are gaps in content? Is this about finding gaps in practice (i.e., areas of improvement? Or gaps in data capacity? These are very different things"*
	2.4. Identification of Potential Data-Capturing Solutions or Informatics-Based Solutions to Address the Gaps	• *"I would cut the word 'informatics-based'. Maybe say technical? "* • *"I guess where I am confused is on this "…team's ability to address their specific problem or question". That makes me think of all kinds of issues related to best practice, practice features, education, etc."*
	2.5. Implementation of Selected Solutions	• *"Are you talking about EMR solutions to fix the clinical problem? Or to get the right data to monitor and define the problem? This is not at all clear."* • *"How is "rolled out" different from "implemented"? Do all data-capturing solutions require technical experts?"*
	2.6. Compliance with using Solutions	• *"Honestly, I think this is more detail than you need. What if a system already had great data collection. (I doubt it, but what if in the future they did?) The big issue is to assess data availability against practice goals. (If they rate low, then they make improvements, but it is not like a required step that they implement a technology solution"*

Learning Cycle Phase	Process	Sample of Feedback Comments
D2K – Data to Knowledge	3.1. Data Quality Monitoring and Assurance	• *"Define integration of data more here; and are you talking about data on provider use of the tool or patient outcomes data, or both?"* • *""Data" is the plural of "datum" (single item of information). Technically verb forms should be plural (data are). While common usage has made singular verbs (data is) acceptable, using plural verbs shows a better understanding of language"*
	3.2. Data Specification Refinements	• *"This entire entry is confusing because of loose language (highlighted section: "The data specifications for data extraction must be identified and refined") and a disorganized further description. In particular "data refinements" is not clear operational language. A start might be something like: Specifications for data extraction must list key aspects of the clinical question(s), identify data element/items relevant to those questions, and specify data manipulations (e.g., construction of measures) relevant to answering those questions. (Then provide elaborations.)"*
	3.3. Data Extraction, Manipulation, and Transfer	• *"Simply standardizing the extraction process seems necessary but not sufficient in this context"* • *"The description to the right seems more like data quality"*
	4.1. Preparing for Analysis	• *"Ability of Learning Community (LC) to work with data analysis to prepare for data analysis that will address clinic's important questions" - Do you mean data "analysts" rather than "analysis"? "LC needs to know how they are going to use the data " - See comments in D2K3.2 about specifying data to be extracted, how it will be manipulated, and how it will be analyzed at that stage. Need to think through how general plans at that stage relate to subsequently carry them out operationally, including here."*
	4.2. Executing and Validating Analysis	• *"The Key attributes of definition and refinement of metrics do not seem to be reflected in the capability description"*
	5.1. Interpreting Results	• *"Specify how data results will be communicated (not just in papers but visual abstracts, briefings, etc.)"* • *""To integrate the knowledge gained from informatics solutions into "- This phrase introduces undefined jargon: "knowledge gained" and "informatics solutions". Where did this jargon come from (not in this document)? Clearer and more appropriate wording is "integrate the results and their interpretations into operational actions"*
	5.2. Reviewing External Evidence	• *"Relates to 1.4, that includes review of current best practices and how the data help understand gaps in best practices and where improvements were made. Separate out best practices from the literature with ones that employees in the organization came up with"*

Learning Cycle Phase	Process	Sample of Feedback Comments
	5.3. Generating, Representing, and Visualizing Knowledge	• *"User centered design on input of data should occur earlier during the time providers are piloting and evaluating tools I think"* • *"Do we expect LCs to design 'knowledge visualization tools?' Aren't there many of these out there? Shouldn't this be about choosing one? I do not understand the middle attribute—how is "stages in the process" a key attribute? Is it describing several stages, and are each of them an attribute?"*
K2P – Knowledge to Practice	6.1. Defining Scope for the Evidence-Based Intervention	• *"Definition is very comprehensive but suggest outlining the questions: level, population of interest, priority groups based on LC input (where we focus our energy on first). Need framework to outline the action steps- have them identify one"*
	6.2. Defining/updating outcomes to measure intervention success	• *"See note above on RE-AIM outcomes at the EHR level. Add in patient and provider outcomes such as quintuple aim (provider experience, patient experience, cost, quality, equity)"*
	7.1. Generating initial implementation strategies	• *"Detail mechanisms of change at provider unit and organization levels, as well as between providers such as team functioning"* • *"Need to better define implementation vis-à-vis being actionable by the key people involved"*
	7.2. Defining/updating outcomes to measure implementation success and study design	• *"See what effectiveness and implementation measures are able to be captured in EHR data. Assess provider participation in implementation strategy (gets as its feasibility and burden). Assess implementation strategy cost (how much time the expert or implementer spends with providers, making tools, etc.)"* • *"Again, define RE-AIM / study design implies research – could it also be program evaluation? E.g., Developmental evaluation may not be viewed in the same way as research / quantitative metrics."*
	7.3. Pilot testing/initial implementation and reviewing results	• *"Consider adding validation of EHR and other data capture of implementation strategy effectiveness such as utilization of the thing"* • *"Perhaps mention some metrics in ascertaining how well the implementation/pilot worked?"*
	8.1. Preparing for scale-up and update/adapt as needed.	• *"I am not sure that the phrase "scaling up" will be immediately understandable to everyone. It reads better when attached to the word implementation."* • *"What is meant by scaling up and where preparation to do so fits in, could all be made clearer."*
	8.2. Widespread adoption	• *"Specify adjustments intervention versus implementation plan"* • *"Need to clarify that this is widespread adoption – may need to define what that means (as opposed to local implementation of an intervention)"*

Learning Cycle Phase	Process	Sample of Feedback Comments
	8.3. Measuring performance and monitoring progress	• *"Specify adherence to intervention and implementation plan (especially if implementation plan is delivered by existing providers such as managers)"*
	9.1. Periodic evaluation, sustainment, and maintenance	• *"Specify that transition of ownership to practice includes a business case or ROI (return on investment) analysis of the implementation plan"*
	9.2. Communicating/disseminating results	• *"Include and specify communication to leaders or personnel with resources and decision-making authority to influence change"* • *"I assumed that "wider audiences" referred to people elsewhere, assuming that internal reports would go to local stakeholders. (The interests of these groups and content of documents for them differs.) I was surprised to see "stakeholders" listed in key attributes when they were not mentioned in the Capability Description. Align content. "*

The literature review also served as input for model refinement. The review categorization scheme enabled me to analyze content used in other LHS models and case studies and incorporate items and terminology into the PRM, and improve the list and definition of processes. For example, the following piece of content from Friedman et al[2]: "*LHSs embrace but also transcend the secondary use of health data: recognition that a much wider array of data sources--including purposefully collected data outside of care experience, such as geospatial data or data addressing the social determinants of health--can be important components of the learning process"* was used to shape our understanding that data collection regarding patient health and patient care may originate from multiple sources for learning, which was not yet operationalized within the PM&R LHS program and therefore not presented in the first version of the model. Another example includes content from Greene et al[9] pertaining to the value of evaluating prototypes and pilot tests before wide-spread implementation of clinical interventions deriving from the scientific-evidence as a result of data analysis *"A rigorous prototype evaluation may be valuable because system-wide implementation may require major investments and widespread redesign".* This complemented the feedback received from the expert panel and supported the re-writing of process description. Multiple examples like these were used throughout the model for process refinement and incorporation of terminology used in the published case studies describing LHS capability development initiatives.

The list of processes expanded from the initial set identified collaboratively with the LHS operations team members at PM&R. Based on the literature review and the expert feedback, I added content that was not initially incorporated into the first version of the model, likely due to the limited development experience to date at the PM&R department. For example, the importance of operationally defined outcomes measures as a direct result from the clinical questions the learning communities should define in early stages of development was emphasized in the literature. Regarding this, Britto et al[20] state: "*A focus on improving the outcomes that matter most to patients, families and clinicians results in shared purpose. The relentless focus on outcomes leads to a sense of shared accountability for results".* Lindsell et al[17] add to this point by suggesting the learning communities ask the following questions: "*Are the*

outcome measures of interest sufficiently reliable, valid, and mechanistically linked to the intervention to draw inferences about cause and effect?". Given these recommendations from the literature, a specific learning cycle process pertaining to the definition of outcomes of interest ("Identify, prioritize, and document the clinical outcomes measures of interest") was added in the second version of the PRM.

Based on expert feedback comments, I also decided to add an extra learning cycle phase to the model, in order to include processes pertaining to team formation, clinical problem of interest definition, and work planning for the learning cycle that preclude the original three phases of the model by Friedman et al [2]. The following comment was made by an expert reviewer regarding the "Identification and Prioritization of Important Questions Relevant to Clinical Practice" process in the P2D learning cycle phase: *"A foundational aspect that is relevant to all three segments of the cycle".* As a general comment on the first version of the PRM as a whole, the same reviewer added: "*An additional thought: To the set of capabilities that define/characterize a learning community (currently starting as P2D-1.1, which I suggested be foundational for all activities rather than P2D), consider adding two additional necessary characteristics of any functioning group/organization/community: 1) Infrastructure for leadership and coordination. Necessary to identify and carry out mission/goals/strategy/activities. (This is different than identifying community.), and 2) Availability of adequate stable resources to carry out activities (e.g., funding, equipment). Includes components of amount (adequate) and consistency (stable) to carry out mission/goals/strategy/activities".* The addition of an extra learning cycle phase was the result of direct expert feedback, but also based on the understanding of the LHS literature pertaining to the development of learning cycles. The inclusion of the Foundational learning cycle phase, thus, resulted in a change in the order in which some of the processes are presented in the model. For example, the learning cycle process pertaining to reviewing the available scientific literature to support the learning community in identifying knowledge or evidence-based practices was moved to the Foundational phase in the second version of the PRM, due to input from interviewees.

Finally, important process characterization elements were altered and added in the second version of the PRM. When naming the processes, the naming convention for business process modeling was implemented, as a result of the literature review analysis[84,91]. Process names were altered to include a verb-noun combination, beginning with a verb. For example, the process "Learning Community Formation" was altered to "Form the learning community". Another example includes the process "Data Quality Monitoring and Assurance", which was sub-divided into two new processes in the second version of the PRM: "Develop and implement a quality control process for data extraction" and "Ensure data quality and refine data extraction practices as needed". To clarify process descriptions for the intended users of the model, I also decided to include a list of questions that support process execution in practice as an additional characterization element for all processes in the model. These questions are not intended for measurement, but to support team discussions for the development and execution of specific processes. For example, the following guiding questions were identified to support the execution of the newly created process "Clinical Problems of Interest Definition" in the second version of the PRM: *What is our clinical population of interest? Are there sub-groups within the clinical population we need to identify and characterize? What are the criteria that define our clinical population and its sub-groups? What are the clinical questions we need answers to? What are the clinical outcomes that matter most to our patients and their care?* These types of guiding questions were included in the second version of the PRM for all processes, resulting from expert feedback and the need for clarity regarding process descriptions as identified in the analysis of the obtained comments.

With the consolidation of the expert feedback and the literature review, input from experienced LHS researchers outside of the PM&R LHS program were incorporated and integrated with content from the available body of knowledge within the LHS literature to produce an improved, second version of the model. The second version of the PRM contained an expanded list of processes, totaling 53 processes across the 4 learning cycle phases, using refined terminology and descriptions according to findings from data analysis. However, the resulting second version was not considered to be complete yet, and further inputs from learning community members at PM&R were sought through the cognitive interviews. The data

analysis from the third design iteration that were used to create the final version of the PRM are presented in the next section.

Design Iteration 3

During cognitive the interviews, open-ended questions were asked encouraging participants to talk freely about the list of processes in the PRM and their practical experience executing such processes. With this, I sought to understand how interviewees perceived the processes described in the PRM as they applied to their experience in practice at PM&R. The interview transcripts for all interviews were compiled in a single Microsoft Spreadsheet, which allowed me to compare input from the different interviewees side-by-side for all processes individually. The data analysis from the interview transcripts revealed that terminology used in the second version of the PRM had to be further refined to ensure understandability by the learning community members. For example, I was able to identify that several interviewees expressed uncertainty about the definition of the term "learning community" when presented with the first processes in the model pertaining to learning community formation. The leader of the PM&R learning community focused on interventional spine treatment expressed this with the following: "*By learning community, do you mean our entire Spine program or do you mean the 4 or 5 of us that meet together on a regular basis?".* Another interviewee adds: *"The term learning community is fine, but for someone who is less informed or familiar with the LHS, I wonder whether they would know what that means....".* Therefore, it became clear that I had wrongly assumed the term *"*learning community", which is often used in the LHS literature [2,3,9,30,41], was sufficiently well understood in the context of the PM&R LHS program. Thus, when designing the third version of the PRM, I accounted for this and provided a clear definition for the term.

The need to clarify several other process descriptions were identified during the interviews. For example, in the process "Ensure stakeholder buy-in and motivation" in the Foundational phase of the learning cycle, the following comment was made regarding terms used in the process's description: *"I don't necessarily know that people will know what equitable participation means".* Therefore, the description for the newly entitled process "Develop

participatory leadership" in the third version of the PRM included the following descriptive activity: "Enable participation of all members according to their roles, expertise, and individual preferences and expectations".

Another example of terminology refinement based on comments made during the cognitive interviews includes changes made to account for interviewees uncertainty around the language used to describe clinical knowledge deriving from data analysis in the LHS (which is then meant to be integrated into practice for improvements in care delivery to patients). I explored different terms for this process, including *clinical knowledge, clinical insights*, or *meaningful insights.* According to one interviewee, the terms have different connotations: *"Meaningful insights imply to me insights whether the LHS is working... as in insights about things we can do with the data... and the LHS. Knowledge implies knowledge about this condition, what we have been learning about this condition... so are we talking about clinical information or insights into how the LHS is functioning – those are two different things. Maybe use word clinical knowledge. Insights about how the LHS is functioning – as in: "oh look what the LHS is able to do!""*. Consequently, the process "Identify knowledge for dissemination and implementation" included the following descriptive activity: "Identify knowledge, clinical insights, or scientific evidence deriving from data analysis to be implemented routinely in practice for improvements in care delivery".

Additional issues were identified with language used to describe the data analysis processes within the learning cycle. When talking about the terminology used for the process "Define a data analysis plan", one interviewee stated: "*I have a problem with this question: I think that for the non-research aspect of an LHS, I might not need a statistical data plan- we do need a general analytics approach though, of what analytics we want to use... and that may be enough. But I'm not sure we need a statistical data analysis plan. Are we doing research and are we looking at this purely from a research perspective? Then maybe we need that plan. Otherwise, not so much. The term data analytics plan is better than statistical data analysis plan".* Thus, the newly named "Develop data analytics and visualization" process, the descriptive activities: "Develop a data analytics and visualization plan (including the analytics approach, analytic models, and/or data visualization techniques to enable interpretation)" were used.

Some concerns with terminology were a direct result of the specific expertise of the interviewees and their roles in the learning community. LHS learning communities are formed by multiple stakeholders with complementary skillsets that are required to foster learning and improvement from data. Therefore, the different technical backgrounds of learning community members lead to challenges in establishing a common set of terms that is understood by all when describing and evaluating learning cycle processes. In the context of representing and describing the learning cycle processes within a reference model to be used by an LHS learning community, a common terminology must be understandable to all members. Similarly, when evaluating the extent to which learning cycle process capabilities have been developed, learning community members should have enough expertise in the domain area to be able to provide adequate assessments. For example, when commenting on processes related to data storage and management, one clinician stated: *"It could be useful to explain what data storage and management system mean, but you'd imagine anyone would think a data storage and management system would include hardware and software, and things like that....data dictionaries - depends on how detailed you want to get when evaluating maturity. But in my role, I think other people in my team would be able to answer this better. Data people in the team have more expertise in this area. I'm comfortable answering all questions up until we start talking about data quality and data storage, then it gets beyond my area of expertise... and I would like someone else on the team to take over that work. Similarly, when talking about the clinical questions and clinical population, the data people might not know what those mean exactly.... I know enough in this data part to answer, I can't select "don't know" but still. It's possible that I skew the data by giving the wrong answer... I think the answers you get from me on the data questions won't be quite as good as what you get from data people, and vice-versa with the clinical questions early in the questionnaire".* With this type of feedback, I was able to identify the processes in the model that were problematic during the cognitive interviews, pertaining to the interpretability of the terms vis-à-vis the interviewee's expertise and role in the learning community. With that information, I was able to provide additional content in describing those processes in the next version of the model, thus seeking to minimize interpretability issues.

Additionally, I was also able to use data from the cognitive interviews to identify the need for further changes in the order in which processes were presented in the model. For example, when discussing the need to conduct a literature review of the available scientific evidence to identify the state-of-the art best practices within the team' clinical area of focus, one interviewee stated: *"This item should be placed after the clinical problem definition, because that comes first- you define the clinical questions, then you look at the literature."* As a consequence, the process "Review and synthesize available literature" was placed after processes pertaining to the definition of the clinical population of interest and clinical questions.

With this type of feedback for all processes, I was able to refine terminology in the language used to describe the learning cycle processes, and modify the order in which processes were presented to account for users' perceptions and interpretations. Table 5 presents an additional sample of comments made during the cognitive interviews that were used for model refinement.

Table 5 - Sample Comments from Cognitive Interviews

Domain	Processes	Sample of Interviewees' Comments
1. Learning Community Stakeholder Configuration	1.1. Identify, engage with appropriate/interested stakeholders 1.2. Form the learning community 1.3. Update learning community member list (recruit new members when needed)	• *"The term learning community is fine, but for someone who is less informed or familiar with the LHS, I wonder whether they would know what that means...."* • *"There is a need to clarify smaller groups vs larger group (Spine program), I'm having a difficult time bouncing back and forth between the two: a smaller, multidisciplinary group that meets regularly and the larger Spine physicians"*
2. Leadership, Identity and Values	2.1. Define Learning Community champion 2.2. Ensure stakeholder buy-in and motivation 2.3. Develop a sense of team identity and culture 2.4. Ensure team members are familiarized with the LHS approach to problem solving 2.5. Develop and maintain key documents such as Team Charter, Team Roster, Mission, Vision, and Value statements	• *"I don't necessarily know that people will know what equitable participation means"* • *"Learning community leadership.... I can't tell if this is leadership in the department or just our small group leadership trying to develop this. Leadership varies across levels (university, Michigan medicine, PM&R, spine program, small LHS group) – all of these are different and unique"*
3. Communication	3.1. Develop and sustain communication tools (i.e., document repository, collaboration space, a "commons") and meeting channels 3.2. Establish appropriate meeting frequency to share and discuss work deliverables 3.3. Monitor and ensure team participation in meetings 3.4. Ensure documents are accessible to all relevant stakeholders	• *"I have an issue with the word tools for document sharing, to me it's more like a system for document sharing… as opposed tool ...we have access to all of these systems. We didn't develop the tool, Dropbox, SharePoint ...we are just using them and we have a system that takes advantage of them. So, I wouldn't have worded it that way although I think I interpreted it the way you guys meant it to be interpreted"* • *"Maybe instead of asking about the overall communication you could ask if there are any problems of communication or any portion of the team you are not able to communicate with as much... or just more specifically asking are there any issues as opposed to just the overall quality"*

Domain	Processes	Sample of Interviewees' Comments
4. Literature Review	4.1. Scan available literature on published studies in the clinical domain and clinical problems of interest the team is focusing on 4.2. Synthesize available literature and update findings 4.3. Disseminate findings from literature review and synthesis to all relevant stakeholders in the team	• *"I don't think all members need to review all of the literature. Some of the things are more relevant to the IT, some are more relevant to clinical, so IT people don't need to be in the weeds of clinical measures and things like that"* • *"I felt that the order feels out of place though for this question, maybe it has more to do with data to knowledge where you are identifying published studies... and looking at the data and you want to know what else is out there so you can compare it with the data you are getting. It felt too early in the process"*
5. Clinical Problems of Interest Definition	5.1. Define and document the clinical problems of interest: clinical population, clinical questions, and clinical outcome measures 5.2. Identify and characterize clinical population of interest 5.3. Identify, prioritize, and document the clinical questions 5.4. Identify, prioritize, and document the clinical outcomes measures of interest 5.5. Ensure input and consensus around the problems of interest from all relevant stakeholders	• *"Maybe slide this question up in the order and ask if all stakeholders were involved in defining the clinical questions of interest to the learning community... and then ask if the learning community defined the clinical outcomes that would address the clinical question"* • *"All I said applies from last question. Previous question focuses on the research question, and this focuses on the tool used to answer the question – how we are going to measure the answer to the clinical question. That's how I interpreted this. So yes, makes sense to have two different items in the questionnaire for these"*
6. Goals Definition	6.1. Define improvement objectives associated with the clinical problems of interest 6.2. Ensure input and engagement from all relevant stakeholders in defining the improvement objectives	• *"This is getting at "what is the clinical problem you are interested in thinking about? how would you measure it? and if we could measure that, how would we like to see things different in the future and can we make that a smart, tangible goal in the future so that we can measure how we are doing along the way? those are three different aspects... I think that "clinical goals" would be a more straightforward way of asking this. "Has the learning community clearly defined its clinical goals?" or something to that effect."*
7. Scope Definition and Work Planning	7.1. Define project plan with key activities, timeline, required resources, and responsibilities & roles	• *"I would call this a project plan, not work plan. But I'm not sure whether clinicians would prefer the term work plan instead. this is my thinking as an analyst though"*

Domain	Processes	Sample of Interviewees' Comments
	7.2. Ensure all relevant team members participate in defining the project plan 7.3. Update plan and needed and monitor progress	
8. Funding and Partnerships	8.1. Ensure availability of resources (e.g., funding, staff, capacity) and sustainability of LHS program over time 8.2. Develop and manage internal and external partnerships	• *"The wording is not clear, what does that mean exactly what are we talking about it. What do partnerships mean exactly? Does it mean partnering with (the LHS operations team faculty lead) to get the resources I need, does it mean... what exactly are we talking about here?"*
9. Documentation Practices for Data Extraction	9.1. Identify required data to answer the clinical questions and measure the clinical outcomes of interest 9.2. Define a data analysis plan 9.3. Develop and implement data collection/extraction systems and/or practices 9.4. Improve and refine data collection/extraction systems and/or practices as needed 9.5. Extract data and measure outcomes 9.6. Demonstrate changes in performance over time (i.e., before and after interventions have been implemented)	• *"I struggled a little bit with the wording, but can't come up with a better suggestion..."* • *"A little confusing to me, not sure what you mean by data sources? If you are considering the EMR to be the main data source, by definition if they have done the previous question then that means yes, they have already secured access to this... but other teams may consider data sources outside the EMR, maybe like benchmark data or national data that's available, so just make sure if that is what you are trying to get at. For concussion, they could say: "we don't need any outside data sources, so that does not apply to us" right?"*
10. Data Quality	10.1. Develop and implement a quality control process for data extraction 10.2. Ensure data quality and refine data extraction practices as needed	• *"If we have done the work up to that point, we have probably worked out many of the kinks/ challenges by default, shown that the data is reliable and consistent. embedded within the process. The team has been thoughtful and everything done has been agreed upon, this is what we are going to do right? So, you are going to have high quality data. Would probably make more sense to ask: Have they ensured data quality? Have a plan for how to do the quality cycle with the data? like a plan for depending on what's coming out, how are we going to address this and refine*
11. Data Management	11.1. Develop and maintain a data management system, including: data access and governance policies, data	• *"I think the term data management system is fairly clear... in our case the data would be stored on the Tableau server, which you don't really*

Domain	Processes	Sample of Interviewees' Comments
	dictionaries, hardware and software applications for data storage, analysis, and delivery/visualization	*think of o as data management system but I can't think of better word. I don't think of Redcap as a data management system either so... but I think that is the right word to use with most people. I wonder if data delivery mechanism could be better way to phrase that - and those are standard terms*
12. Regulatory Compliance	12.1. Ensure compliance with IRB and regulatory requirements	• *"Maybe you should specify that the LC needs to meet any necessary regulatory requirements. You might say: "has the LC assessed whether or not you need an IRB for this type of work?" I think this might not be necessary for an LHS though. This might be applicable to the K2P section though, as the team learns new stuff and might want to start some formal research project"*
13. Data Analysis	13.1. Analyze data and interpret findings 13.2. Integrate findings from data analysis with findings from published clinical literature 13.3. Specify and document the evidence-bed practices that have been shown to improve patient outcomes and need to be implemented in practice	• *"Appropriate terminology, but a little blurry line between 13.1`and 13.2. If you are interpreting findings, you are generating knowledge... maybe take away "interpret findings" from question, then not redundant with next question."* • *"Poorly defined (terms), that could mean so many things."* • *"I'm not sure what advanced analytics mean. What if I'm not going to do that (AI/ML)? There was no answer for: we have no plans to do that*
14. Data Visualization	14.1. Develop data visualizations and data delivery to frontline providers at the point of care 14.2. Update and refine data visualization as needed	• *"Something like: "Do you have a process for continuously updating data visualization? Since we are talking about continuous learning and the continuity of a learning cycle, I would ask about that process for continuous data flow, updates, and visualization. I don't like the terms figures and tables – those terms are very research/manuscript oriented. Include: dashboards containing trending graphs, tables*
15. Preparing for Practice Change	15.1. Identify barriers and facilitators to implementation with frontline providers 15.2. Prioritize barriers and facilitators to implementation in collaboration with frontline providers 15.3. Identify opportunities for improvement and design implementation strategies	• *"Unclear whether "in collaboration with" means the whole group has identified barriers and facilitators or whether it means barriers to the participation itself, as in barriers to collaboration"* • *"Perhaps you meant "all relevant stakeholders, including frontline providers". That would have made more sense to me. I think this is a great question though. Like the word collaboration"*

Domain	Processes	Sample of Interviewees' Comments
	15.4. Design implementation study (i.e., evaluation of strategy effectiveness)	
16. Promoting Practice Change	16.1. Promote practice change using implementation strategies 16.2. Evaluate implementation effectiveness 16.3. Monitor and ensure implementation fidelity 16.4. Ensure and document implementation adaptations as needed 16.5. Monitor and ensure implementation sustainability	• *"I think that "insights" maybe better word here too, rather than knowledge though"* • *"Terminology: a little jargony, it's what we want to do in an LHS but could simplified to clinicians who are not as familiar with this.... "Has the team been able to change practice according to the clinical insights gained from data analysis? "I like the term clinical insights… in 15.3. you asked whether you were able to design implementation strategies.... so, 16.1. sounds like you are asking whether I implemented those strategies..."*
17. Knowledge Dissemination	17.1. Identify appropriate dissemination channels (i.e., journals for publication, conferences) and target audience 17.2. Disseminate on findings from learning cycle to wider audience	• *"Maybe reword to include a plan for disseminating information. A better question would be: has the learning community established a plan to target audience? As in yeah, clinicians and patients... those are the people we are trying to help but do we have plan on how to broadcast this information… maybe rewording that."*

Finally, I was able to assess the overall applicability of the PRM from the perspective of the PM&R learning community members. Some of the comments provided reflect a positive perception regarding the model and its intended use, demonstrating its validity. One interviewee commented: *"As an early-stage team, I like that this prompts us to think ahead".* Another interviewee adds: *"I like how the questions prompted us to think, a lot of thoughtfulness around designing an LHS in the first place…"*. These comments suggest the processes in the PRM were perceived to be comprehensive and useful for learning communities in practice. As stated by another interviewee: "*I will say that this questionnaire could be fantastic - once it is refined to your liking – it could be used at the outset of any kind of LHS team convening... or development process. Because this helped me understand that there is a lot of things that I didn't even know were things I should be thinking about. You don't know what you don't know... I didn't even know to ask about many of this stuff. So, I appreciate that some of this was in there."* This indicates the utility of the PRM in identifying processes that could be otherwise overlooked. One other interviewee complements with the following statement: *"There is a lot of clear objectives identified in the questions, that I kind of see as a checklist to do this work. Making sure you are identifying a clear timeline, roles and responsibilities, resources, and that everyone is on the same page regarding the plan. Which is sort of the purpose of the questionnaire in my opinion, not just to have a checklist but making sure everyone is doing these things right? Putting together their LHS program, the clearer those steps are the more likely people are to do it".* This statement suggests the PRM may be useful as a tool to ensure team members are aware of the steps to be taken for the development of the LHS program and to increase the likelihood that such steps are taken in practice for optimal development.

Therefore, the participants' answers helped me identify important opportunities for improvement in the way processes were described and represented in the model, and validated its applicability and usefulness in practice. After concluding the data analysis deriving from the cognitive interviews with the learning community members of the PM&R LHS program, I completed the refinement of the processes in the model and achieved the third and final version of the PRM. The resulting deliverable from the successive design iterations is presented in the next section.

Process Reference Model – Final Deliverable

In this section, the final version of the PRM is presented as follows: firstly, the PRM's purpose and its intended users in practice are identified, including the learning community roles involved in performing the specific learning cycle processes. Secondly, the PRM's configuration is presented, describing how the processes in the model are organized in a hierarchical and layered structure. Thirdly, the learning cycle phases are presented in detail, expanding from the model by Friedman et al[2]. Finally, the detailed list of processes for the learning cycle phases is presented, as well as the process characterization elements that provide specificity and support for all processes' execution in practice.

Purpose and Intended Users

To support the operationalization of the LHS learning cycles in practice, the PRM achieves the following specific purposes:

- Provides a comprehensive and detailed roadmap for learning community development by characterizing specific processes and activities involved in executing LHS learning cycles and their expected outputs.
- Facilitates staff allocation and cross-functional coordination across the health system by specifying the roles involved in executing specific learning cycle processes
- Streamlines project management activities and enables economies of scale by providing a standard that is applicable to multiple learning communities across the health system
- Uses clinical-neutral terminology that may be tailored across clinical specialties to honor the diversity of practice and the specific objectives of new and existing learning communities across the health system
- Promotes higher quality in process execution and output, by incorporating available best practices from the LHS body of knowledge

- Enables quality improvements and shorter lead times for LHS capability development by facilitating process execution and process optimization over time, with a shared understanding of learning cycle processes across team members
- Provides the basis for process measurement and evaluation of the LHS program by enabling the development of quantitative performance indicators for the specific processes involved in knowledge discovery and implementation

The PRM is intended to be used by multiple stakeholders in any given departmental or health system LHS capability development program. In an LHS, multi-stakeholder teams should be configured to improve quality of care by solving specific problems of interest to their patient population using the power of data. Learning communities work together to develop the capabilities that enable them to generate knowledge from practice and implement knowledge into care for improved outcomes. These teams are often clinician-led. However, the development of data extraction and analysis capabilities along with knowledge implementation and evaluation processes require a broader skillset from the team. Thus, in order to reach its objectives, a learning community is often composed by multiple stakeholders with diverse expertise. In an LHS program, a learning community may be configured by stakeholders with expertise in: a) the clinical domain area, b) information technology and data analytics, c) strategic and operations management, d) research, and e) patient representatives with lived experience[2–4,8,10,25]. Table 6. presents the learning community roles required for executing learning cycle processes. Each stakeholder type in the learning community plays different but complementary roles in executing the specific learning cycle processes. To ensure their objectives are met, learning communities should foster a working environment that is all-inclusive, collaborative, creative and practical in approaching the health problem of interest. The learning community should achieve shared values and a common purpose as a team. The learning community may also seek to form partnerships within and without the health system to facilitate and enable the team in its objectives as supporting stakeholders.

Table 6 - Learning Community Roles

Learning Community Roles				
Clinical	**Analytics**	**Operations**	**Research**	**Patients**
Interprofessional clinicians and care providers directly involved in caring for the patient population	Team members with expertise in information technology (IT) (e.g., IT builders), information systems, and data science (e.g., data modelling, data analytics, data visualization, statistical analysis)	Team members with expertise in project management, operations and quality improvement, research coordinators, and/or health system leadership	Investigators focused on generating scientific evidence from and within the LHS (e.g., multiple research fields applicable to advancing the LHS through either quantitative or qualitative research methodologies)	Patients, family members, and community representatives with lived experience pertaining to the clinical condition under focus (e.g., able to provide valuable knowledge regarding prevention, diagnostics, or treatment)
• Physicians • Nurses • Therapists • Pharmacists • Clinical assistants • Others	• Data scientists • Data analysts • Data engineers • Information technology (IT) experts/builders • Statisticians • Others	• Project manager/research coordinator • Process/quality improvement specialist • Health system leadership • Administrative staff • Others	• Clinical domain investigators • Information systems researchers • Implementation science researchers • Quality improvement/operations researchers • Social sciences researchers • Psychometrics/measurement researchers • Others	• Patient representatives • Family representatives • Community members or groups with lived experience • Others

Model Configuration: Hierarchical Structure

The processes within the PRM are structured in 4 hierarchical levels. In this structure, process description specificity increases from Level I (high-level) to Level IV (operational and detailed). Level I contains the learning cycle phases, expanded from the model by Friedman et al. The learning cycle phases in the PRM are: *Foundational, Practice-to-Data (P2D), Data-do-Knowledge (D2K), and Knowledge-to-Practice (K2P).* Each learning cycle phase contains a set of process domains, at Level II. Process domains add specificity to the learning cycle phases by describing specific aspects of each phase. In turn, each process domain contains a set of process domain areas, at Level III. Process domain areas add specificity by further detailing aspects of the process domains. Finally, each process domain area contains a set of detailed processes for learning cycles, at Level IV. The processes specify the activities, expected outcomes, and the learning community roles involved in process execution. Figure 7 illustrates the relationship between the 4 levels in the PRM. The PRM is, thus, structured as follows:

- *Level I: 4 Learning Cycle Phases*
- *Level II: 9 Process Domains*
- *Level III: 18 Process Areas*
- *Level IV: 34 Processes*

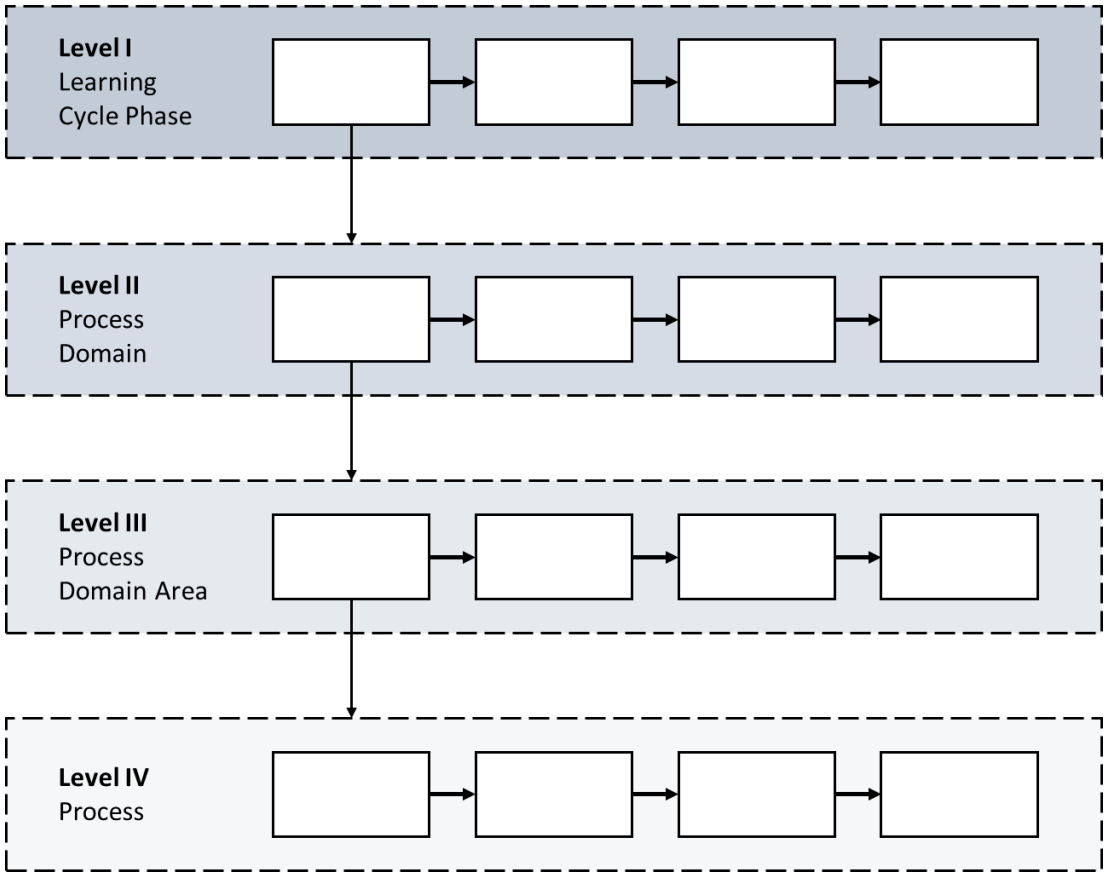


Figure 7 - PRM - Process Levels Structure

In the next section, the Level I learning cycle phases are described in detail.

Learning Cycle Phases

The term *learning cycle* refers to the systematic effort to generate knowledge from care (i.e., to learn from care delivery through data analysis) and implement knowledge into care (i.e., to improve care delivery through practice change)[2,8,9,20,30,133]. Learning cycles, thus, allow for the continuous integration of research and clinical practice, and are designed to empower clinicians at the point of care to make higher quality clinical decisions informed by the scientific evidence generated from real-time data routinely collected from practice. The ability to execute all of these processes concurrently to routine care delivery on an ongoing, systematic basis, is what drives continuous improvements to quality of care and patient outcomes in the LHS model. The

learning communities within the LHS should aim to implement, sustain, and refine the processes within the PRM for higher-value to all stakeholders in the long-term. This requires continuous infrastructure development, sustained commitment from health system leadership, and changes in organizational structures and policies to enable effective cross-functional coordination.

The continuous nature of the processes in the PRM is the reason why they are characterized as cyclical: once knowledge discovery from data analysis occurs, interventions in care delivery processes are deployed for practice change, and subsequent data collection occurs for evaluation of changes made. Evaluations will, in turn, produce new knowledge about the effects of the interventions, and so forth continuously. Therefore, the processes in the PRM are meant to represent and enable a cyclical methodology for learning and improvement that happens concurrently to care delivery. The learning cycle phases and the specific processes involved in each phase are the described in the PRM to support their implementation and execution in practice. The four learning cycle phases, and their respective process domains are illustrated in Figure 8. Each learning cycle phase is presented next.

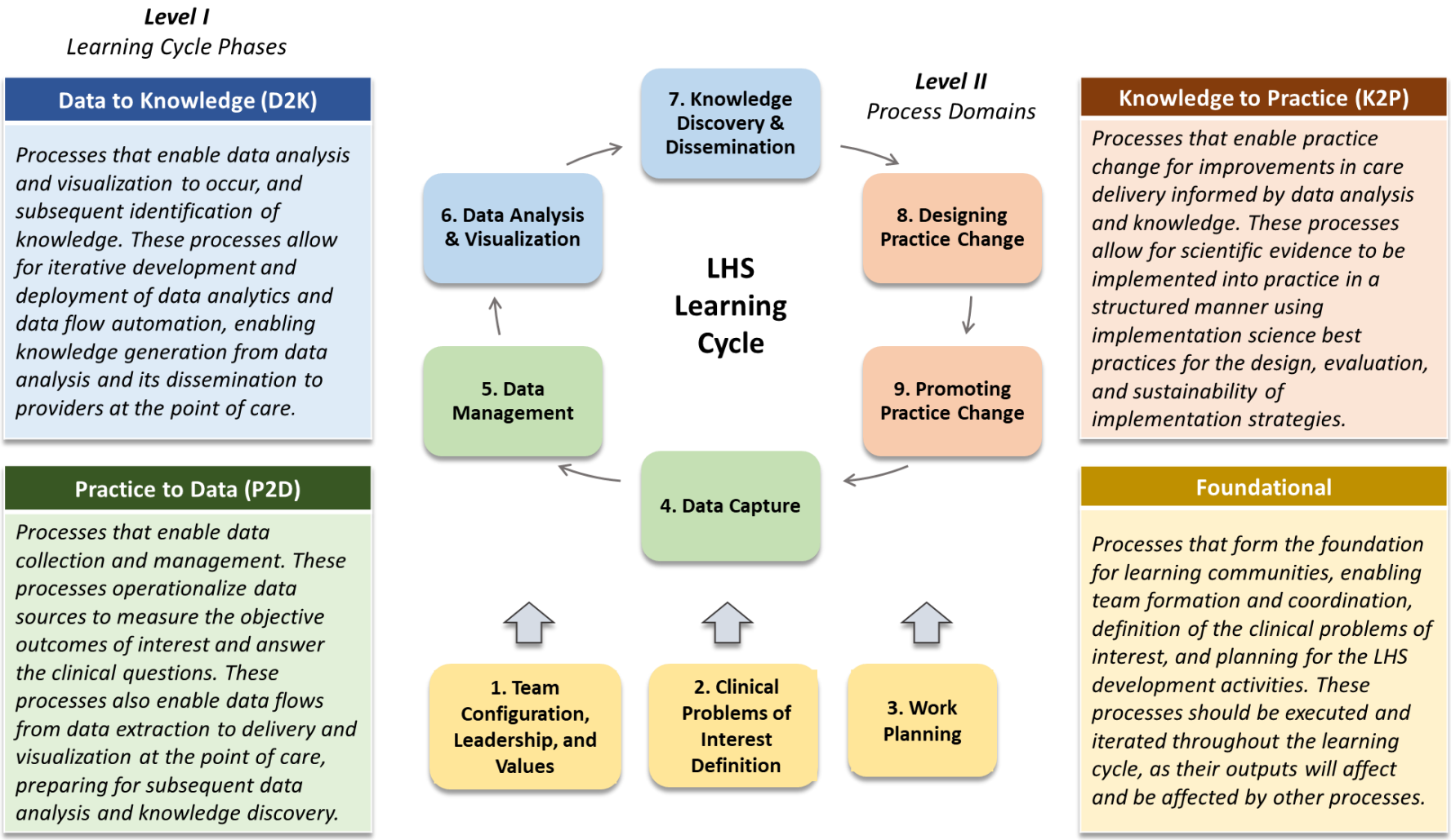


Figure 8 - PRM - Learning Cycle Phases and Process Domains

Foundational

The Foundational phase of the learning cycle encompasses the processes required to form and manage the team, as well as those involved in defining and updating the clinical questions and outcomes of interest. Additionally, planning for the development effort of the subsequent learning cycle phases is also contemplated within the Foundational phase. This phase describes the processes to be executed in early stages of an LHS development project, but will also happen and be iterated on an ongoing basis as the learning community improves over time.

When forming the learning community to develop the LHS capabilities, it is important to include the appropriate stakeholders within the health system that possess the right expertise for the different tasks involved in the learning cycle. It is also important to form additional partnerships and establish coordination with those who are well-positioned within the organizational structure to enable LHS capability development and process execution to occur. Effective leadership practices and communication systems are also a requirement when managing the team. Over time, the learning community develops and integrates LHS values that drive their continuous search for learning and improvement. The LHS principles should, thus, become the new norm for care provision within the team and throughout the health system in the long term. The processes required to achieve these learning community objectives are contemplated in the Foundational phase of the PRM for learning cycles.

Defining the clinical problems of interest that the team aims to focus on and the specific outcomes measures that dictate data collection for the LHS is also an important domain of the Foundational phase of the learning cycle. Teams should be specific about what they seek to learn through data collection and analysis, and this involves clearly describing their learning objectives and/or clinical questions. Formulating these with specificity facilitates the efforts to define appropriate data sources and collection or extraction methods. Managing collected data for optimal delivery and visualization at the point of care is also contemplated in this phase. Additionally. reviewing the available scientific literature to support an understanding of the current evidence and best practices is important for clear problem formulation. The external

evidence from published studies is eventually integrated with the internal data analysis to constitute the scientific evidence the team implements in practice. Furthermore, with clear definitions for operational clinical questions, learning objectives, and outcomes measures, as well as an understanding of the available scientific evidence, the team may articulate their clinical or quality improvement goals in practice and set benchmarks for their practice change efforts. The processes involved in formulating these objectives are also encompassed in the Foundational phase of the learning cycle and should be defined upfront and refined over time as the team develops.

Finally, the Foundational phase also includes processes involved in developing a project plan for LHS capability development. The project plan specifies items such as activities and tasks, timeline, budget, additional resources required, and roles and responsibilities for project execution. Additionally, a communication system must also be developed so the team is able to effectively and efficiently coordinate activities and deliverables across stakeholders, and share results frequently. Acquiring or developing all of the resources needed for LHS capability development (i.e., time, money, staff allocation, office space, etc.) is also an important objective that must be met in the Foundational phase of the learning cycle.

Practice to Data (P2D)

The Practice to Data (P2D) phase of the learning cycle encompasses the processes required for data collection, data extraction, data management and governance, and subsequent data delivery to the point of care to enable clinicians to make evidence-based decisions when delivering care to patients. Thus, the P2D processes ensure that data streams are established to effectively capture data points from relevant aspects of care delivery practices to form the basis for learning to occur. The P2D phase initiates once the team has been able to minimally execute Foundational processes as a requirement (Foundational processes are further instantiated and improved upon over time as the team initiates the subsequent learning cycle phases). The operational outcomes measures defined in the Foundational phase that deriving from the clinical questions and learning objectives, for

example, dictate the definition of data sources, data points, and data extraction methods to be developed in the P2D phase of the learning cycle.

Whether data collection occurs using patient reported outcomes measures (PROMs), medical records and clinical documentation notes within electronic health records (EHRs), or any other data source the team deems appropriate to answer their clinical questions, the P2D processes for data extraction need to be defined and executed continuously, systemically, and concurrently to the care delivery processes. Establishing and delineating roles and responsibilities for these processes, thus, is essential for continuous learning from practice to occur. Continuous improvement and optimization of data collection and extraction methods over time should seek to minimize burdens placed on clinicians and patients alike for improved results when collecting and using data from care delivery. Ensuring data quality through validation checks and standardization of data collection practices is also key. The processes required for data quality are contemplated within the P2D learning cycle phase. These processes may also be refined over time, as the team develops new and improved ways of ensuring data quality in feasible and practical manners. The team also needs to develop a data delivery, management, and governance systems. Data delivery refers to the tools or systems used for visualizing data at the point of care to enable providers to make evidence-based decisions at the point of care (e.g., Tableau, REDcap, etc.). Data management includes mechanisms and tools for data storage and data delivery to the point of care, and data governance includes policies delineating roles and responsibilities for data access and data manipulations, as well as any meta-data documentation such as data dictionaries to facilitate access to data. These are also developed and refined over time, as the data management and governance processes improve progressively from an initial starting point. Therefore, the P2D processes in this learning cycle phase prepare for data analytics and knowledge discovery to occur, which is the focus of the next phase.

Data to Knowledge (D2K)

The Data to Knowledge (D2K) phase of the learning cycle encompasses the processes for developing and deploying data analytics for knowledge discovery, as well as establishing data

flow automation using the data delivery mechanisms to ensure real-time data visualizations at the point of care for providers. Data analysis and visualizations support evidence-based clinical decision making for improved patient outcomes. Therefore, this learning cycle phase involves the identification of insights deriving from data analysis, including any evidence-based practices that have shown to be effective in improving quality of care. It also involves the dissemination of insights to clinical care providers across the health system, in preparation for efforts to change practice for the implementation of the scientific evidence into routine care.

It is important for the team to ensure all regulatory and ethical requirements for data manipulations and analysis are met for the LHS, ensuing data privacy and security compliance. The team develops a data analytics plan or approach that meets their needs, and deploy analytics to answer the clinical questions and reach the learning objectives in practice. The specific analytics approach used may vary across teams, with either advanced or simpler techniques depending on the available data and specific learning objectives. The analytics approach may be refined over time, so the team may wish to begin with a simpler approach (e.g., graphics, pivot tables, dashboards) for rapid results, and develop more complex approaches (e.g., machine learning, artificial intelligence, predictive modelling) as the team matures over time. The D2K phase also encompasses a process for establishing data flow automation, so providers may access the results from data analysis and visualizations at the point of care seamlessly. Data flow automation allows for quick manipulations and updates to data analysis as new data are collected over time. Similarly, this process also ensures that data flow automation may be developed incrementally: the team may begin by providing clinicians with on-demand data files, reports, or spreadsheets, and ultimately advance and mature towards full integration of analytics into the information systems and visualization tools used by providers during patient encounters. Once providers and other team members have access to results from data analytics, interpretations and identification of knowledge (i.e., learning) may occur. At this point, the team is able to identify the care practices that are shown to be the most effective and, thus, define the interventions to be implemented and standardized in routine care across providers. Knowledge dissemination to all relevant stakeholders then occurs, to ensure awareness in preparation for practice change. Therefore, the D2K phase also

encompasses the process of planning for and executing knowledge dissemination activities across the health system.

Knowledge to Practice (K2P)

The Knowledge to Practice (K2P) phase of the learning cycle encompasses the processes required for designing efforts to change practice according to the insights from data analysis, and deploying the strategies that are used to change and standardize behavior across providers in order to implement clinical evidence into routine practice. Therefore, once data analysis has occurred and the team has been able to identify clinical insights about best practices that should be implemented in practice, implementation planning may begin. The team should use implementation science methodologies to plan for implementation strategy design according to the barriers and facilitators observed in practice. The K2P phase also encompasses the deployment and evaluation of implementation strategies in practice, and, ultimately, the sustainability of improvements in the long-term.

Implementation planning aims to establish a shared understanding across learning community members regarding the methods to be used for practice change and the desired outcomes. Once plans have been defined, it is time for the execution of the practice change initiative. The team should use implementation science resources to design new implementation strategies or select from exiting compilations of strategies that have been developed elsewhere and deploy them in practice in close collaboration with front line providers. Subsequently, practice changes resulting from implementation strategy deployment are evaluated to ascertain whether change has impacted care delivery as intended. Implementation outcomes and patient outcomes are measured, and an assessment is made regarding the efficacy of the intervention. If successful, practice change should be sustained overtime according to sustainability plans. This should include the transition of ownership of the evidence-based care delivery from those involved in designing and implementing change to frontline providers responsible for routine care delivery. If practice change has undesired outcomes, the identification of root-cases for failure occurs and appropriate adjustments are made.

Once the K2P phase is concluded, the team has established the process capabilities to continuously improve care delivery based on the learning cycle approach. Once the learning cycle is executed once in its entirety, the processes may be refined and improved upon over time as the team matures. With the execution of multiple learning cycles, improvements to the capabilities for learning and improvement occurs. Consequently, patient outcomes also improve over time. In the long-term, therefore, value is continuously improved through the systematic execution and improvement of the learning cycle processes. In the next section, the elements used to further characterize each process in the learning cycle are presented in detail, in support of their execution in practice.

Process Characterization

Each of the 4 learning cycle phases in the PRM contains a set of process domains. The process domains add specificity in describing specific functions for each learning cycle phase. There are 9 process domains in total across the learning cycle phases. Process domains are subdivided into process domain areas, which provide further specificity in describing the process domains. There are 18 process domain areas across the process domains. Finally, process domain areas are subdivided into processes, providing even further specificity. There are a total of 34 processes in the PRM. Table 7 presents the process hierarchy across all levels of the PRM.

All 34 processes in the model are, in turn, further specified through characterization elements used to describe the processes in detail. There are 4 characterization elements that provide detailed information for all processes: i) activities, ii) outputs, iii) guiding questions for process execution, and iv) stakeholder involvement. A definition for each process characterization element is provided in Table 8. The characterization of all 34 process in the PRM may be see in the Appendix.

Table 7 - Learning Cycle Process Hierarchy

Cycle Phase	Process Domain	Process Domain Area	Process
Foundational	1. Team Configuration, Leadership, and Values	1.1. Stakeholder configuration and partnerships	1.1.1. Form the learning community
			1.1.2. Develop and manage partnerships
		1.2. Leadership and team values	1.2.1. Develop participatory leadership
			1.2.2. Develop team identity and values
	2. Clinical Problems of Interest Definition	2.1. Defining clinical problems of interest	2.1.1. Define patient population
			2.1.2. Define clinical questions
			2.1.3. Define outcomes of interest
			2.1.4. Define improvement goals
		2.2. Literature review and synthesis	2.2.1. Review and synthesize available literature
	3. Work Planning	3.1. Project management	3.1.1. Develop and implement a project plan
			3.1.2. Develop team communication and coordination systems
		3.2. Resources	3.2.1. Acquire and manage necessary resources
Practice to Data (P2D)	4. Data Capture	4.1. Data extraction and integration	4.1.1. Develop, implement and optimize data sources and extraction methods
			4.1.2. Integrate data sources and measure outcomes of interest
		4.2. Data quality and refinements	4.2.1. Ensure standardization of data entry practices
			4.2.2. Develop and implement a data validation plan
	5. Data Management	5.1. Data delivery	5.1.1. Develop and maintain a data delivery system
		5.2. Data governance	5.2.1. Develop and maintain meta-data documentation
Data to Knowledge (D2K)	6. Data Analysis and Visualization	6.1. Data analytics & visualizations	6.1.1. Ensure regulatory compliance
			6.1.2. Develop data analytics and visualization
			6.1.3. Deploy data analytics and visualization
		6.2. Data flow automation	6.2.1. Establish data flow automation
	7. Knowledge Discovery and Dissemination	7.1. Knowledge discovery	7.1.1. Identify knowledge for dissemination and implementation
		7.2. Knowledge dissemination	7.2.1. Disseminate knowledge from data analysis

Cycle Phase	Process Domain	Process Domain Area	Process
Knowledge to Practice (K2P)	**8. Designing Practice Change**	**8.1. Implementation planning and coordination**	8.1.1. Plan for implementation strategy design
			8.1.2. Plan for implementation strategy deployment and evaluation
			8.1.3. Plan for sustainment of improvements
		8.2. Implementation strategy design	8.2.1. Identify and prioritize determinants to implementation
			8.2.2. Design implementation strategies
			8.2.3. Pilot test and refine implementation strategies
	9. Promoting Practice Change	**9.1. Implementation strategy deployment & evaluation**	9.1.1. Deploy implementation strategies
			9.1.2. Ensure fidelity and adaptations
			9.1.3. Evaluate implementation outcomes
		9.2. Sustainment of improvements	9.2.1. Ensure sustainability of improvements
4 Phases	***9 Process Domains***	***18 Process Domain Areas***	***34 Processes***

Table 8 - Process Characterization Elements – Definitions

Elements	Description
Activities	List of activities to be undertaken for process execution. Activities may group together related tasks to be performed for process execution
Outputs	Observable results obtained from successful process execution
Guiding Questions for Process Execution	Guiding questions to support and facilitate process execution. These may be used by the team for planning and execution purposes, as they identify the questions need to be answered for process execution. Some questions refer to the expected barriers that need to be overcome for effective process execution in practice.
Stakeholder Roles	The degree of involvement across stakeholder roles within the learning community (i.e., clinical, analytics, operations, research, patients) varies across processes in the learning cycle. This characterization element describes the learning community's stakeholders and roles involved in process execution and their degree of involvement.

Intended Application

When applied in practice, the PRM may be used as a framework to standardize the learning cycle for multiple learning communities in the health system concurrently, with the aim to streamline efforts for capability development by shortening lead-time to development and reduce wasted resources. Its use in practice, therefore, is intended to provide economies of scale and facilitate the realization of the health benefits envisioned by the LHS. By detailing the activities and roles involved in executing learning cycles, the PRM enables shared understanding across learning community members and facilitates cross-functional coordination across the health system. The PRM, thus, allows for process management to occur in support of LHS capability development initiatives. It aims to break down siloes in the organization through a comprehensive end-to-end reference model describing all activities required for knowledge discovery and knowledge implementation to occur to improvement in patient care.

Consequently, the use of the PRM is intended to be accompanied by progressive organizational changes. New governance models, with novel roles and responsibilities across the health system, may be needed for its implementation in practice. If a centralized unit or operational team within the health system or department is created to coordinate efforts to develop LHS capabilities across multiple learning communities, the PRM facilitates planning for staff and resource allocation. Process owners for knowledge discovery and implementation for specific clinical pathways may be identified in the organization. These stakeholders may be responsible and accountable for process performance and resource utilization (i.e., time, money, people, space, etc.), thus creating an incentive system that fosters data-driven learning and improvements to care delivery. Therefore, model establishes a basis for measurement of the extent to which LHS objectives are met. With measures of LHS process lead time across teams, for example (i.e., how long it takes for teams to enable data capture, data analysis and visualization, and, ultimately practice change and improved outcomes), managers involved in the development of LHS capabilities may establish a clear understanding of their performance and initiate efforts to optimize learning cycle processes. In the context of this dissertation, the PRM forms the foundation for efforts to develop an LHS maturity model, by describing the processes that are measured (in terms of the observed capability for their execution in practice) as indicators of maturity. In Chapter 3, I describe the development of measures for learning cycle capabilities that are anchored in the PRM. The capability measures be used to constitute measures for learning community maturity, as performance indicators to be used for LHS evaluation.

Additionally, by providing a representation of the learning cycle processes, the PRM facilitates teams' efforts to identify process bottlenecks and barriers to their execution. In practice such bottlenecks may be associated with socio-technical infrastructural factors within the health system, such as lack of expertise or available staff in areas such as data analytics and information technology to support multiple learning communities, or technological constraints such as limitations within the information systems and analytics capabilities that hinder the effective use of data for learning. For example, if multiple learning communities are seeking support from available analysts and information

technology staff in the health system for data extraction and analysis, delays may occur if resources aren't matched to the demand (i.e., the accumulation of tasks and time constraints faced by the supporting information technology staff lead to delays). Bottlenecks associated with the information system and requirements for process execution may indicate the need for further improvements that drive infrastructure development over time. With an explicit identification of such constraints and their root-cases, through team discussions around the PRM as a reference, interventions may be explicitly identified for improvements. The optimization of resource allocation and/or prioritization criteria may be implemented for information technology staff to streamline workflows and allow for higher LHS process performance, for example. Figure 9 illustrates how a PRM for LHS learning cycle processes may sever as the basis for process management in support of LHS operationalization efforts in practice.

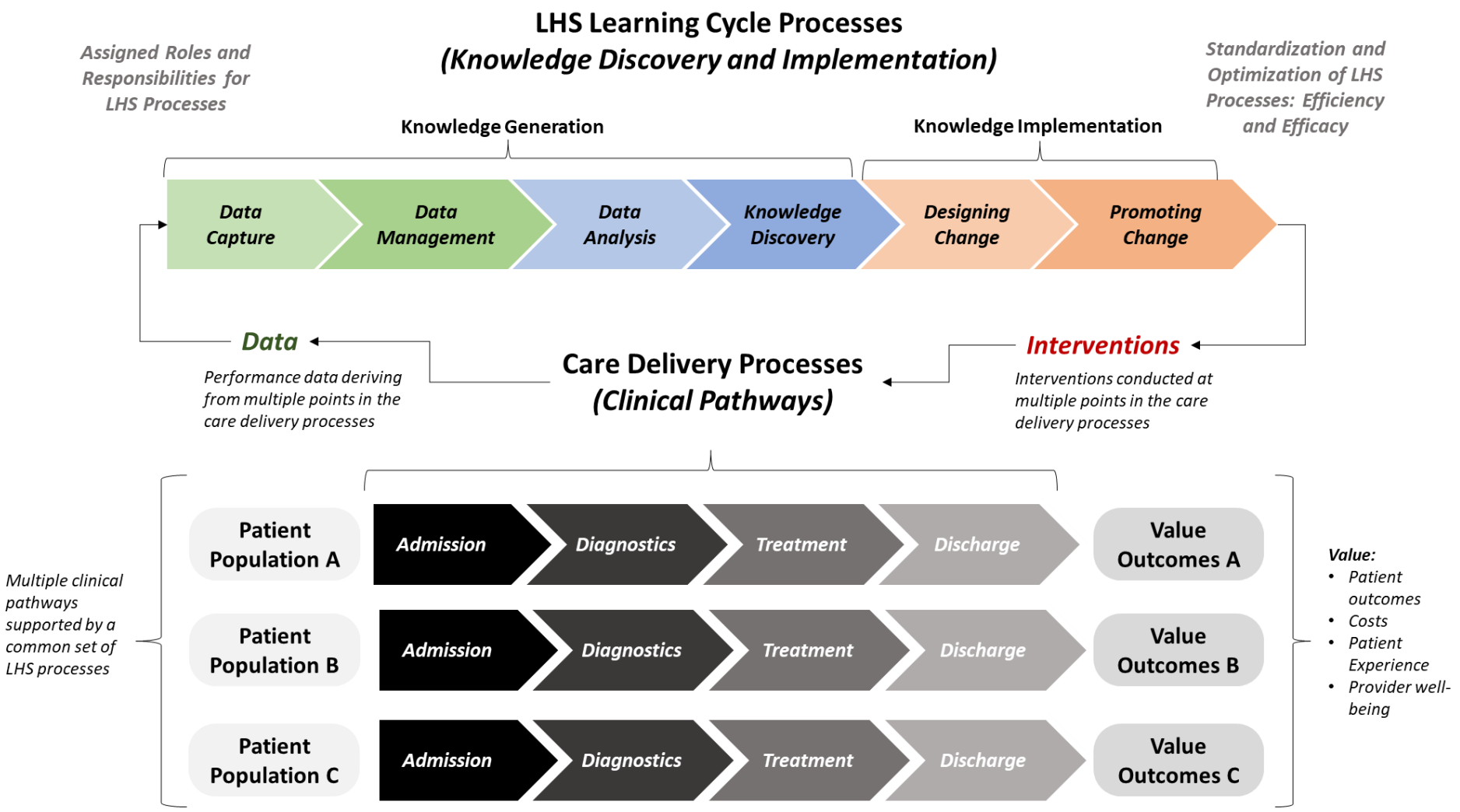


Figure 9 - Streamlining LHS Processes for Knowledge Discovery and Implementation

As configured, the PRM for learning cycles suggests a sequence of processes to be performed in practice by various stakeholder within an LHS once the model is applied in practice. While the sequence indicates an overall progression of learning cycle phases that cascade down from the Foundational phase to the K2P phase, the development and execution of the specific processes may occur at different orders, concurrently, or iteratively. For example, when defining clinical questions and outcomes of interest in early stages of development, in the Foundational phase, the team may not yet have access to data, as they may have not yet established any data collection, extraction, and/or analysis processes. Once these are implemented and executed, the newly available data may either restrict the team's ability to answer its clinical questions given feasibly issues and/or challenges for appropriate data collection, for example. In this case, the team may need to go back to the previous process and revise its clinical questions according to the data that are feasibly collected. Alternately, newly collected data may instead allow the team to expand its clinical questions: the data may highlight insights the team had not considered when formulating its initial questions and learning objectives for the LHS. Thus, an iterative process execution approach is appropriate. Similarly, when implementing the evidence into care in the K2P phase, the team may encounter practical issues that inhibit them to implement knowledge as originally planned. Feasibility challenges related to implementing an evidence-based practice may be related to multiple factors, such as clinician resistance, barriers with the information systems, organizational barriers, policy constraints, etc. This may force the team to go back to data analysis and identify other evidence-based practices for implementation, for a more feasible implementation process. Thus, the iterative nature of the learning cycle in practice dictates that the PRM should not be seen as a list of processes to be implemented and executed invariably in a sequential manner. Rather, concurrent and iterative application is recommended.

In practice, the development of learning cycles often occurs through projects. A timeline and budget may be allocated for specific teams, as well as roles and responsibilities for the implementation and execution of specific processes in the learning cycle. This is done so the LHS objectives are achieved within resource constraints that are imposed by the organizational context. The PRM is intended to facilitate project management with the list of processes to be

implemented and executed in practice. One of its purposes is to provide a standard that may apply to multiple learning communities concurrently and facilitate the work of project managers. The list of processes serves as a reference for the activities that need to be performed for development. A Gantt-chart may be developed with the list of processes in the PRM, for example. This is intended to reduce lead time for project management and execution by providing a roadmap for agility. Project management best practices, including agile project management approaches, may be facilitated with the use of the PRM. It is important to note that not all processes as described in the model may apply to all learning communities and to all LHS programs. Therefore, processes may be edited, removed, or added as needed according to context.

Finally, those involved in developing LHS capabilities in practice using the PRM should establish a framework for continuous improvement and refinements of the LHS processes represented in the model. With each instantiation of a learning cycle, the objectives should be two-fold: a) to achieve the specific learning and improvement goals for each learning community (i.e., to foster data-driven knowledge discovery and knowledge implementation for higher quality of care), and b) to promote refinements to the PRM used by clinical and operational teams within the health system. Therefore, the processes in the PRM may need to be updated and refined with the model's application in practice, with new processes added or improved terminology refinements to reflect the work of different learning communities over time. For this, a system should be established for periodic reviews of the model as a knowledge asset and for stakeholders to promote edits and document any lessons learned that need to be incorporated into the reference model itself, for continuous improvement of the LHS methodology in the health system.

Chapter 5 – Self-Assessment Instrument for Learning Cycle Capabilities

As with the previous, this chapter firstly presents the data analyses from the three successive design iterations that resulted in the *self-assessment instrument* within the maturity model. The findings from data analysis in each design iteration were used to produce the successive versions of the measurement instrument, which were progressively refined until the final version was reached. Subsequently, the final deliverable of the self-assessment instrument is presented, including a description of its purpose and intended users, its configuration and structure, and a detailed presentation of the assessment items in the self-assessment questionnaire.

Self-Assessment Instrument – Design Iterations

This section presents the results from data analyses for the three successive design iterations of the self-assessment instrument.

Design Iteration 1

In the first design iteration, the process capability measures were developed in collaboration with the operations team in PM&R and concurrently with the development of the process descriptions in the reference model. We began by developing process descriptions and associated capability measures for the first processes in the learning cycle model by Friedman et al[2], and continued sequentially down the list until we had written descriptions and capability level definitions for all processes in the model. The resulting instrument contained a total of 28 processes, with each process containing 5 capability levels describing a developmental progression. Therefore, a total of 140 capability level descriptions were defined in the first version of the instrument. The capability levels for each process were defined as follows: *Level 0 - No capability, Level 1 - Low capability, Level 2 - Intermediate capability, Level 3 - High capability, Level 4 - Optimal capability.* For example, the process "Data Extraction, Manipulation, and Transfer" had the following process description: "At this stage, the data extractor performs data extraction of the data previously identified by the Learning Community team. The data extraction process should be set up so that it can be replicated over time. Extracted data may require additional processing (such as data cleaning, pivoting, etc.) before data analysis can be conducted." For this process, the 5 capability level descriptions were defined as follows:

- **Level 0 - No capability**: "No current data extraction of the LC data is possible or has been conducted. Ad hoc extraction, if at all"
- **Level 1 - Low capability**: "Discussions have begun to understand data extraction processes and possible pathways, including assessments of feasibility and effectiveness of each option. Extraction may have not been implemented yet. There is limited capacity available for data extraction. If current data extraction occurs, it may be in a

non-standardized way or ad hoc. There may not be consistent processes for necessary data processing"

- **Level 2 - Intermediate capability**: "Data extraction and manipulation processes exist but are still under development. Some of the elements are not consistent yet. The LC is working with technical experts to build consensus on what is needed before data analysis can begin"
- **Level 3 - High capability**: "Pathways for data elements and data processing have been implemented. Some refinements may still be needed at times. LC members and IT support staff are working in coordination to refine pathways"
- **Level 4 - Optimal capability**: "Pathways for data elements are known and automated when possible. Clear where everything is located and the process to extract data is well-defined and efficient, quickest way to get the data. Data processing is consistent, documented, and conducted before data analysis. The team is utilizing the most efficient and complete tools to implement this process. Data can be handed off to data analysis with high confidence"

The written descriptions for all capability levels reflected the experience to date of the departmental LHS program managers in the operations team, as well as their vision for the future regarding the progression of learning cycle capabilities that the learning communities in the department *should* develop for each process in the model. In describing the capability levels for all processes in the instrument, we used clinical-neutral terminology to ensure applicability across clinical settings. However, we considered that there could be potential overfitting for the PM&R context in which the instrument was developed, since the main source of data was comprised of the LHS program managers' limited experience to date at PM&R. Therefore, we did not consider this first version to be complete and ready for use in practice. It merely constituted a starting point that captured potential capability measures for learning cycles processes as perceived by the LHS program managers. Therefore, I then sought additional data for instrument refinement.

Design Iteration 2

The input received from the expert panel that reviewed the first version of the instrument was used for its improvement and the design of a second version. A total of 11 experts (52% response rate) agreed to participate and completed the form, providing their feedback on the first version of the instrument. All responses from the experts, both quantitative and qualitative, were compiled into a single Microsoft Spreadsheet. This allowed me to compare expert's feedback for the capability level progressions constituting the measure sets in the instrument. I began by analyzing the responses to the Likert-scale questions regarding each capability level progression. First, I calculated a mean and a standard deviation score for each capability measure set. The attributes assessed by the experts for each capability measure progression included: i) logic of the order of progression for the capability level descriptions, ii) distinction between capability level descriptions, and iii) alignment between capability level descriptions and the process definition they pertained to. The quantitative assessment results from the expert panel for all capability measure sets in the instrument are shown in Table 9.

The quantitative analysis allowed me to visualize the overall assessments for all process capability level progressions, and prioritize those that were rated poorly per the responses to the Likert-scale questions. For example, the capability level progression for the process "Understanding Gaps Between Current and Future State" was rated relatively poorly by reviewers on all three attributes as assessed by the Likert-scale questions: *capability level order* (4.3, 1.0), *capability level distinction* (3.5, 1.6), and *capability level alignment* (3.8, 1.0). Given the quantitative assessments for this capability measure, along with qualitative comments from the expert panel, this process and the associated capability measures were significantly altered in the next version of the instrument. Other capability measure sets with low scores were prioritized for improvements as well. Alternately, the capability measures that were rated with high scores received low priority for refinements. For example, the process "Executing and Validating Analysis" received high scores for all attributes: *capability level order* (4.8, 0.4), *capability level distinction* (4.5, 0.8), and *capability level alignment* (4.5, 0.8). These and other

process capability measures that received high scores were not a priority for change, but were still refined based on subsequent data collection.

For each capability level progression, I also obtained qualitative feedback from the expert panel that were used for refinements in terminology and description for the constructs in the instrument. I compiled the qualitative comments for each capability measure set in the form of open comments, questions that reviewers posed regarding the descriptions, as well as editing suggestions for wording improvements. The experts' qualitative feedback was thus consolidated across all capability measure sets, and used as inputs for designing the subsequent version of the instrument. For example, for the capability measures for process "Identification and Prioritization of Important Questions Relevant to Clinical Practice" one reviewer stated: *"Under (capability) level 3 and 4 add review of evidence-best practices addressing clinical problem, and under level 4, whether there is evaluation of current best practices in the organization addressing the problem, to inform what is needed".* This statement suggests that a comprehensive understanding of available scientific evidence regarding the best practices for the clinical questions the team is addressing, as well as a review of organizational policies and already existing best practices in the health system to be indicative of intermediate and high capabilities, as perceived by the reviewer. This notion was incorporated in the next version of the instrument, in newly defined processes and capability measures. Regarding the same process and capability measures, another reviewer added: *"Everything is very clear and well explained. However, I wonder if the tight framing of everything as a clinical question might overlook learning communities' abilities to address systemic problems. Systemic problems impact outcomes that are relevant to clinical practice, but this seems to be not possible to fit into this capability"*. This indicates that there is potential overfitting of this process and capability measures to the PM&R context. The learning communities in involved in this research, and upon which the instrument was developed, tend to focus on clinical questions pertaining to their patient populations. Restricting the process description to the clinical questions and outcomes, excluding "systemic problems" as suggested by the expert reviewer, was a design choice that reflected the experience to date at PM&R. This comment also served as valuable input for description refinement in the next version of the instrument.

Some processes and capability measures received significantly more attention than others. For example, the process "Compliance with Using Solutions" and the associated capability measures, in the P2D phase of the learning cycle, received comments such as "*Add in (capability) level 3 whether there is a process to incorporate improvements to the tool based on provider feedback",* "*Need to make language consistent",* and "*Again, the levels don't seem clearly distinct to me"* These statements indicate that the set of constructs represented in the process description and capability measures needed significant revisions. This contrasts with the process "Widespread Adoption" and its capability measures, in the K2P phase of the learning cycle. No comments were provided for this set of capability measures and associated process description. This difference is congruent with the respective quantitative evaluations for both processes, as shown in Table 9. The differing levels of scrutiny provided by the expert panel suggests that some parts of the instrument were closer to reaching a satisfactory level of description and, therefore, applicability in practice, than others in the first design iteration.

As I compiled and compared comments and suggestions from the expert panel, both the capability level descriptions as well as the process definitions were refined concurrently. Therefore, the inputs provided a valuable source for refinements to the measurement instrument as well as to the associated process reference model described in Chapter 2. A sample of feedback comments and suggestions from the expert panel is presented in Table 10. The feedback comments are presented across all processes and capability measures in the first version of the instrument, and constitute the inputs that were used for refinements.

Table 9 - Quantitative Evaluations for Capability Measures

Learning Cycle Phase	Process	Cap Level Order		Cap Level Distinct		Cap Level Align	
		Mean	SD	Mean	SD	Mean	SD
P2D Practice to Data	1.1. Learning Community Formation	4.9	0.3	4.5	0.7	4.4	1.0
	1.2. Learning Community Identity and Agency	4.5	1.0	4.3	0.8	3.9	1.4
	1.3. Understanding Target Clinical Population	4.8	0.7	4.8	0.4	4.5	0.7
	1.4. Identification and Prioritization of Important Questions Relevant to Clinical Practice	4.6	1.0	4.4	0.5	4.3	0.8
	2.1. Understanding Current State of Practice	4.4	0.9	4.3	0.8	3.9	1.3
	2.2. Envisioning Future State of Practice	5.0	0.0	4.9	0.3	4.0	1.3
	2.3. Understanding Gaps Between Current and Future State	4.3	1.0	3.5	1.6	3.8	1.0
	2.4. Identification of Potential Data-Capturing Solutions or Informatics-Based Solutions to Address the Gaps	4.6	0.7	4.0	1.3	4.3	1.0
	2.5. Implementation of Selected Solutions	4.9	0.3	4.4	0.9	4.4	0.7
	2.6. Compliance with using Solutions	4.6	0.7	4.0	0.9	3.6	1.1
D2K Data to Knowledge	3.1. Data Quality Monitoring and Assurance	5.0	0.0	4.0	0.8	3.9	1.2
	3.2. Data Specification Refinements	4.8	0.4	4.5	0.8	4.5	0.8
	3.3. Data Extraction, Manipulation, and Transfer	4.9	0.3	4.6	0.7	4.3	0.7
	4.1. Preparing for Analysis	4.9	0.3	4.4	0.7	4.3	0.7
	4.2. Executing and Validating Analysis	4.8	0.4	4.5	0.8	4.5	0.8
	5.1. Interpreting Results	4.6	0.5	4.4	0.7	3.7	1.2
	5.2. Reviewing External Evidence	4.9	0.3	4.6	0.7	4.4	0.5
	5.3. Generating, Representing, and Visualizing Knowledge	4.7	0.5	4.6	0.8	4.8	0.4
K2P Knowledge to Practice	6.1. Defining Scope for the Evidence-Based Intervention	4.6	0.7	4.6	0.7	4.3	0.8
	6.2. Defining/updating outcomes to measure intervention success	4.8	0.4	4.6	0.7	4.3	0.8
	7.1. Generating initial implementation strategies	4.5	0.7	4.4	0.9	4.3	0.7
	7.2. Defining/updating outcomes to measure implementation success and study design	4.4	1.0	4.3	1.2	4.0	1.2

Learning Cycle Phase	Process	Cap Level Order		Cap Level Distinct		Cap Level Align	
		Mean	SD	Mean	SD	Mean	SD
	7.3. Pilot testing/initial implementation and reviewing results	4.8	0.7	4.4	0.9	4.3	0.7
	8.1. Preparing for scale-up and update/adapt as needed.	4.8	0.7	4.5	0.9	4.4	0.7
	8.2. Widespread adoption	4.8	0.4	4.4	0.9	4.5	0.5
	8.3. Measuring performance and monitoring progress	4.9	0.3	4.4	0.7	4.3	0.7
	9.1. Periodic evaluation, sustainment, and maintenance	4.6	0.7	4.4	0.9	4.4	0.7
	9.2. Communicating/disseminating results	4.9	0.3	4.5	0.5	4.8	0.4

Table 10 - Qualitative Evaluations for Capability Measures: Comments and Suggestions

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
P2D – Practice to Data	1.1. Learning Community Formation	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Level 3 and 4 are not different enough. The levels discuss engagement but do not incorporate the key attributes. The final level should be all team members engaged, communication plan and meeting scheduled completed. Level 3 should have engagement but other aspects not accomplished—that sort of thing—to reflect attributes.* • *The distinction between high and optimal is vague; opportunities for continuous improvement (learning how to learn better) even when optimal need to be made clear.*
	1.2. Learning Community Identity and Agency	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *For level 4 add in whether the team understands who the levers are in the organization to influence change through policies, as well as resources (e.g., IT changes, staffing responsibilities, etc.)* • *Level 3: I suggest not confusing "thinking scientifically" (systematic, structured investigation" with being "a scientist." That label has connotations that can be confusing because being a scientist can be a separate profession. Perhaps "identities in both providing and improving care is solidifying."* • *Difficult to distinguish low and intermediate; distinction seems ambiguous and subject to judgment.*
	1.3. Understanding Target Clinical Population	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *I think this is important in PM&R, but would have less importance in other clinical areas, so it may be an instance of overfit. Possibly it wouldn't matter; LCs in other clinical areas might just start at a higher level. I'm not sure why a conceptual framework for patients is important in all instances.* • *Consider adding in level 3 the team's capacity to develop vignettes of "typical" users from the population to inform diversity of patient groups in which to elicit more input (in level 4)*
	1.4. Identification and	*0 - No capability* *1 - Low capability*	• *I think Level 0 is more "LC has not identified clinical questions". I think identification must come before prioritization; prioritization without a fairly*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
	Prioritization of Important Questions Relevant to Clinical Practice	*2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	*complete set of questions seems premature. Why is importance essential immediately?* • *For Level 4, the requirement to have a plan to answer questions seems like a different capability*
	2.1. Understanding Current State of Practice	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *This seems muddled and the levels don't appear to align well with the Capacity Description—but that's partly that the CD is not very clear, and seems a bit muddled. Also, this is supposed to be about the current state of practice, but it seems all about data—that seems to be a mis-match.* • *Level 3 is the problem. You went from high level to good level. Then level 3 did very little to distinguish from level 2. It could be that just the mapping out, with some detail about understanding classification measures, documentation of interventions, and outcome measures would fit here.*
	2.2. Envisioning Future State of Practice	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *See my notes above. The metric definitions don't mention data, but the Capability Description seems to center on data. This seems like a mis-match.* • *Word "vision" is used repeatedly in capability level definitions, but is not part of capability description.* • *I am unclear about the determination of what data is going to be collected, see my comment in 1.4. Data element definition is mentioned here in the capability description, but it is not in the attributes or levels. When in this model do we define the data collected?* • *Should these metrics be about the future state of practice r/t capture practice as data?*
	2.3. Understanding Gaps Between Current and Future State	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability*	• *See notes above and prior two capabilities.* • *"Making good progress" (level 3), perhaps trade for a different/more specific adjective, such as "steady"*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
		4 - Optimal capability	• *See comments above. I wonder if you could just fold this capability into the previous one, expanding that capability and giving clearer definition to the five steps.* • *Again, five levels seems like a stretch for this particular capability*
	2.4. Identification of Potential Data-Capturing Solutions or Informatics-Based Solutions to Address the Gaps	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Distinction between levels 2 and 3 is not very clear. See note above.* • *Levels 2 and 3 seem difficult to distinguish in real life*
	2.5. Implementation of Selected Solutions	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *This capability seems to overlap and also be dependent on the previous one. I suspect it may represent higher levels of the prior capability in many ways rather than a different capability.* • *Not sure that Levels 3 and 4 are very distinct from each other.* • *Add in leadership support/buy in and "definition of done" (when is the completion of the work?)*
	2.6. Compliance with using Solutions	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *As in my comment on the last one, this seems like possibly a higher-level capability of P2D-2.3 and 2.4 rather than being entirely distinct. There is a natural hierarchy of decide-create-adhere that I think is being invoked here but separated out somewhat artificially. Within this capability, however, I think that things are a bit muddled in terms of levels.* • *Should level 3 include something about "majority of stakeholders are using tool."?*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
			• *In high and optimal, need to better consider how incentives and culture make this happen; beyond just actively checking in*
D2K – Data to Knowledge	3.1. Data Quality Monitoring and Assurance	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *See above comment on the types of data this includes* • *A lot has to happen in level 2—I wonder if some of this could also be happening in Level 1, especially since there is some overlap between "There may be some initial monitoring, but it is not consistent" and "Some monitoring has occurred."* • *For the last item, if the Capability Descriptions are not clear, the answer has to be low.* • *High is a bit unclear; simply having a plan and starting to implement it seems insufficient and a bit ambiguous.*
	3.2. Data Specification Refinements	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *I am having trouble understanding why the specifications for which data should be extracted is being decided at this point and not earlier. I understand the need to clarify the protocol for extracting data. Is the team collecting data that is not necessary for the addressing the question? Was this not clarified earlier in the process? I am missing something*
	3.3. Data Extraction, Manipulation, and Transfer	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Automation is discussed as a goal in capability levels, but is not mentioned in capability description* • *Level 1 should reflect some level of discussion between IT and clinicians, even at a low level.* • *High should require something beyond pathways described.*
	4.1. Preparing for Analysis	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability*	• *Use of "integration" in levels 0-2 is not intuitive for a non-specialist—perhaps "relationship"?* • *There is a problem with the this and other capabilities where there is an assumption that the tech team, extraction team, and data analysts are all*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
		4 - Optimal capability	*separate from the learning community, and that the data analysis is not done by the clinicians. The tech team etc. could be part of the LC"*
	4.2. Executing and Validating Analysis	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Should level 4 reflect the attribute that calls for documentation of the completed analysis?* • *Need more consideration of metrics even at low and intermediate levels.* • *2 and 3 are very similar*
	5.1. Interpreting Results	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *See above comments about alignment between capability description and key attributes. I find similar alignment issues here. See above note about problem with Capability Description* • *What happens if the answer to the question is: This area of practice is great, no need to improve care? I will admit that this would be so rare it can be ignored—the team can certainly find areas that they know will produce potential for improvement.*
	5.2. Reviewing External Evidence	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Add in criteria for evaluating quality of systematic review e.g.- PROSPERO* • *Not sure how possible level 4 is—perhaps instead of "complete" knowledge of the literature available, the LC should strive for "comprehensive" knowledge of the literature available* • *What if there are no relevant external resources?*
	5.3. Generating, Representing, and Visualizing Knowledge	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *"Level 3 – revise for clarity* • *Seems like a big jump between levels 3 and 4* • *I do not see the role of documentation fleshed out in the capability levels"* • *The levels are ordered and align, and are distinct, but I still have the question about developing a knowledge visualization tool. I think you can change this to talk about choosing one—unless I am missing what this means.*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
K2P – Knowledge to Practice	6.1. Defining Scope for the Evidence-Based Intervention	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *An ambiguity is that if the learning community consists of member groups, the identification of interventions may need to be locally customized or even appreciably different. How will you handle assessments of maturity of a larger community with individual member groups are at different stages?* • *The levels are fine, I think that there should be some wording in the capability and the levels about using the analysis of the data to make these decisions*
	6.2. Defining/updating outcomes to measure intervention success	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Level 4 should note that different dimensions of outcomes are captured (e.g., quintuple aim)* • *Capability levels align well with key attributes but not as well with capability description*
	7.1. Generating initial implementation strategies	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Assuming this step is about how to implement the intervention, that would apply there is no performance data, so there would be no reason to speak about improving performance.* • *The phrase "determinants of practice" is unfamiliar to me – could require explanation*
	7.2. Defining/updating outcomes to measure implementation success and study design	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Alignment is better with the key attributes than with the capability description itself* • *"These definitions address three independent factors as though they are linked: Measure of outcome success, Study design and appropriateness for purpose, Plans for reporting findings… These factors have no functional relationship and cannot be assumed to go together in defining capability levels"* • *How does this one differ from 6.2?*
	7.3. Pilot testing/initial implementatio	*0 - No capability* *1 - Low capability*	• *Level 4 should have LC offer input on adapting imp strategies*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
	n and reviewing results	*2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Some overlap between 3 and 4 in terms of when testing occurs/is completed. Could have greater alignment between level 4 and capability description in terms of defining what resources are needed to move forward to widespread adoption/implementation in scale.* • *See edit in level 0. Should level 1 include 'plan developed?'*
	8.1. Preparing for scale-up and update/adapt as needed.	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *"Add consideration and buy-in of study design evaluating the scale-up* • *Add in economic evaluation of implementation strategies"* • *It seems like levels 0 and 1 overlap with 7.3 in ways that might need to be clarified* • *The scope of preparations needs to be made clearer.*
	8.2. Widespread adoption	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *NA*
	8.3. Measuring per formance and monitoring progress	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *For high, it is difficult to understand what some communication means in this context; also, actionability of communication is important to incorporate.*
	9.1. Periodic evaluation, sustainment, and maintenance	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability*	• *The sustainment plan itself needs to better incentivize and engender a culture of continuously learning how to learn better, grounded in some sense of urgency or learning imperative.*

Learning Cycle Phase	Process	Process Capability Level Descriptions	Feedback Comments - Examples
		4 - Optimal capability	
	9.2. Communicating/disseminating results	*0 - No capability* *1 - Low capability* *2 - Intermediate capability* *3 - High capability* *4 - Optimal capability*	• *Include and specify communication to leaders or personnel with resources and decision-making authority to influence change* • *Level 3 needs some work—what is the definition of "expanded?"*

Feedback regarding the overall instrument's applicability in practice was also obtained from the expert panel and used for validity demonstration and further refinements. Instrument attributes assessed via Likert-scales include: implementability/feasibility, generalizability across clinical contexts, potential for contribution to practice, potential for contribution to LHS theory, and readiness for use. The results from reviewers' answers for the Likert-scale questions assessing the overall instrument were compiled and are presented in Figure 10. As illustrated, the model was considered to be generalizable across settings. It was also considered to make significant contributions to both LHS theory and practice. However, the model did not perform as well regarding its implementability/feasibility and readiness for use. This indicated that further refinements were needed.

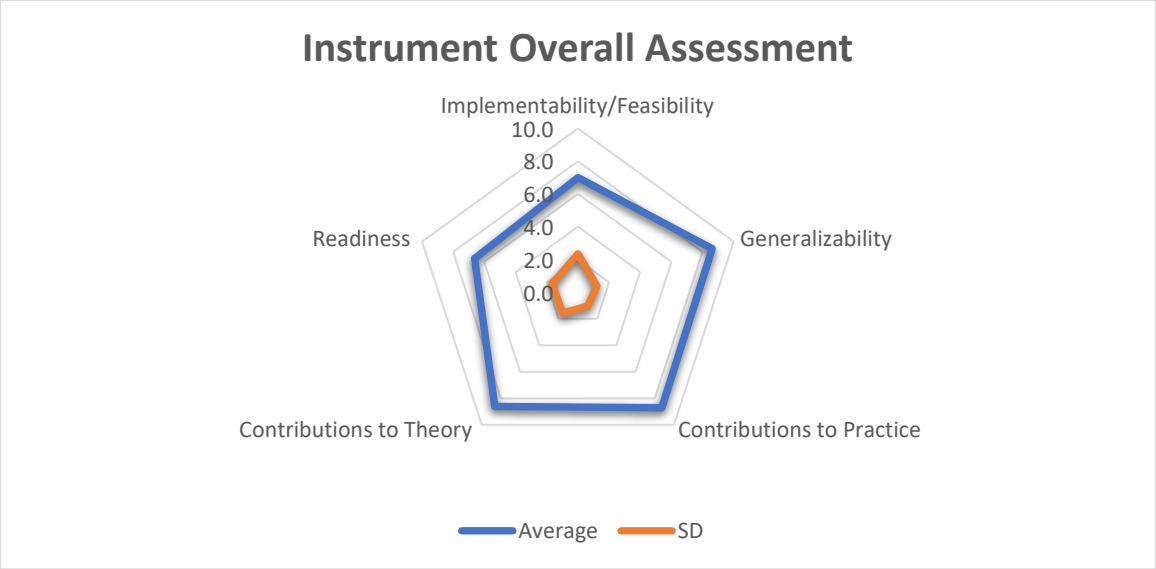


Figure 10 - Overall Quantitative Instrument Assessment by Expert Reviewers

Qualitative comments were also obtained demonstrating validity evidence for the instrument as a whole. Some of the experts in the review panel provided valuable inputs regarding the instrument's applicability in practice and suggested meaningful changes for improvement. These inputs are useful in corroborating the assertion that the measurement instrument has the potential to support LHS evaluation and capability development in practice,

even if modifications were still considered necessary before its use. For example, one reviewer commented: *"The tool is well thought out and detailed. It maps to and navigates the learning cycle(s) beautifully. But in places it feels overly complex and theoretical, and too challenging to make concrete and implementable. It represents a step in very important directions, and hence merits significant commendation. Seeking feedback from practitioners will help in making it actionable and usable; it has significant potential to move the dialogue forward and to grow into a practical tool to advance Learning Health Systems."* This statement suggests that while the instrument holds promise as a useful tool to support the development of LHS capabilities in practice, improvements in the terminology are still needed to streamline language used to describe processes and capability levels. Reducing complexity and including the use of terms that reflect those used in practice as opposed to theoretical terms often encountered in the LHS literature were important recommendations. Additional statements from the expert panel's feedback regarding the instrument's applicability are presented in Table 11.

. The statements provide insight into the overall structure, purpose, and applicability of the instrument in measuring learning community maturity within an LHS. The feedback received indicates that while the instrument was considered comprehensive, there may be a need for shortening it for its application in practice given the effort required for its completion as an assessment tool. Additionally, the visualization of capability assessment results (once the instrument is applied for the evaluation of learning communities in practice) was highlighted as a potentially effective means of communicating progress to stakeholders. Furthermore, the expansion of the instrument to include public health and prevention focused learning communities was also highlighted, indicating the need for tailoring to different contexts other than PM&R. Finally, suggestions were made regarding the development of instructional materials to facilitate the understanding of the instrument's purpose and intended use in practice to those less familiar with the LHS principles, such as an online tutorial video for example.

Table 11 - Expert Feedback Statements - Overall Instrument Evaluation

Expert Feedback – Evaluation Statements	
Expert Reviewer A	*"Overall, a very comprehensive tool! The only worry I have is the length given that I am unsure who would complete this and whether they would receive training in how to use the tool. But given how complex LHS investments are it is well worth the length and will really serve to help advance the field. I especially like how each part of the cycle was given equal attention. Now the fun part is to come up with a visual to describe the maturity of the LHS (I am thinking of a spider web or something like PRECIS-2 uses to assess degree of pragmatic trials). Great job!"*
Expert Reviewer B	*"This is an extraordinary tool, and I cannot wait to be able to use it in practice!"*
Expert Reviewer C	*"This work is so impressive and I can't imagine how much time and research this has taken?!"*
Expert Reviewer D	*"Could expand to include more public health and prevention, beyond clinical medicine. Also, this is an overwhelming looking document – may need to present it in a way that would not intimidate learning community organizers who wouldn't be steeped in LHS theory necessarily. Perhaps that could be aided by graphic design and an online video tutorial / intro. Overall this is really interesting! I wish we'd have had this when starting the OHCA Learning Community. Would love to stay informed of your progress"*
Expert Reviewer E	*"I am very enthusiastic about this tool and I think it will be valuable for assessing the status of an LC, and of an overall LHS. I would be more than happy to discuss any of my comments, and I also understand completely that I may have missed something, made a worthless comment, or that you and others just plain disagree. That is fine."*

By incorporating the expert reviewers' comments and suggestions regarding the capability level progressions for each process, I was able to refine terminology and make significant modifications to the first version of the instrument. Some of the expert review feedback reflected a need for change approach used to measure capabilities, however. For example, one reviewer stated: *"I understand the advantage of having a uniform structure (5 capability levels) but there isn't anything to guarantee that that number of divisions or distinctions are really meaningful or discriminable. Some Capabilities may only be a simple dichotomy (yes-no)".* This comment suggests that the definition of 5 capability levels for all processes in the instrument may be problematic, as some processes may not require a

progression description. Furthermore, while the comprehensiveness of the measurement instrument was considered a desirable attribute by experts, some of the feedback indicated the need to streamline it for agility and practicality during its use in practice. As highlighted, the intended users of the instrument are clinicians and other stakeholders involved in delivering routine clinical care to patients. Their competing priorities and time constraints within health care systems restrict their availability for developing learning cycle capabilities, and require a low measurement burden when using the instrument for evaluation purposes. As demonstrated by the following statement from one of the reviewers: "*My main comment is that I think some of these (capability level descriptions) could be collapsed, and for a number of reasons, I think they should be. First, I think this needs to be shorter for everyone's sake; yours and the PM&R team; reviewers; and most especially the users of the future. I think the cognitive burden is very great, and that's for someone like me who has been involved in this process off and on for some time. For someone coming in fresh, this will not only seem overwhelming, the detail of trying to figure out what's needed in each area will be overwhelming".* For the reasons highlighted above, and after deliberation and team discussions about alternative versions for the instrument, I opted to change the approach used for capability measurement.

In the second version of the instrument, a significant amount of content was incorporated in the descriptions for the learning cycle processes to account for the feedback received. The list of process for learning cycles, therefore, expanded. Thus, after deliberation, we opted to utilize a Likert-scale questionnaire format for the measurement of capabilities in the second version of the instrument (if we were to keep the capability level progression structure for measurement, we considered that the resulting instrument would have been too extensive and not feasible when applied in practice). The alternative questionnaire format for capability measurement is meant to provide a quicker assessment, as users are asked to read questions regarding each process and respond using Likert-scales to indicate their perceived capability level. Therefore, our reasoning was that by responding to Likert-scale questions, the intended users of the instrument would provide information regarding process capability levels without having to read multiple capability level descriptions and decide which most resembled their current state of development. Thus, the questionnaire format was considered to

streamline the self-assessment without losing descriptive detail. The resulting second version of the instrument contained 50 Likert-scale questions across 53 processes in the learning cycle: intended users are asked about the extent to which their teams have been able to operationalize processes in practice, on a scale from 1-5, and the responses to the questions produce process capability levels.

While significant modifications and improvements were made from the first version, we did not yet consider the second version to be finalized and ready for use in practice. An additional design iteration for instrument refinements was needed. A series of cognitive interviews were conducted with learning community members at PM&R to collect further inputs for analysis and improvements.

Design Iteration 3

During the cognitive interviews, I asked open-ended questions to participants meant to encourage them to talk freely about their experience filling out the questionnaire (i.e., the second version of the measurement instrument). With this, I was able to collect valuable inputs that were used to validate and/or refine the questions in the questionnaire. Once transcripts were compiled with feedback from all participants, I was able to compare participants' feedback for all questions in the instrument. A comparative analysis of the obtained feedback allowed me to validate questions as well as identify themes that led to important insights for questionnaire improvements.

Interview participants provided valuable feedback that demonstrated construct validity for multiple questions throughout the instrument. Examples of positive feedback regarding questions in the instrument are provided in Table 12. These statements provide evidence that multiple questions captured what respondents perceived to be relevant capabilities for learning cycles. However, further comments also indicate the need for refinements throughout the questionnaire. Several themes were highlighted upon the analysis of interview transcripts that led to changes in the next version of the instrument.

The first theme that emerged was the *need for terminology changes*. For multiple questions in the instrument, participants indicated the need for changes in the terminology for

several reasons. For example, for the question *“Has the Learning Community developed tools for document sharing? (i.e., document repository and/or online collaboration space or a “commons”)?”* within the Foundational phase of the learning cycle, one interviewee stated: *“So this one is a close ended question…. So, it requires a binary response, I think. If you wanted to know "to what extent did this get developed" then a Likert response would be appropriate”.* This comment highlighted that the Likert-scale response options provided for all questions required changes in terminology in the way questions were phrased throughout the instrument. For the same question, another interviewee stated: *“I think I'm interpreting this in the way you guys intended it to be, but I have an issue with the word tools for document sharing, to me it's more like a system for document sharing… as opposed tool ...we have access to all of these systems. We didn’t develop the tool, Dropbox, SharePoint ...we are just using them and we have a system that takes advantage of them. So, I wouldn't have worded it that way although I think I interpreted it the way you guys meant it to be interpreted. We have access to all these systems, and my issue is that we don't have just one system we all use - but it's not like we developed that tool. We just started using that tool”.* This statement allowed me to identify further need for terminology changes. The perception that document sharing tools are adopted rather than developed by the learning communities was incorporated into the new version of the question. Thus, to reflect the interviewees’ comments, modifications were made as follows*: To what extent has the learning community developed an effective communication system (including document sharing platforms, meeting channels, and established meeting frequency) that meets the needs of the team?* Terminology changes were promoted throughout the questionnaire, for questions in all phases of the learning cycle.

Table 12 - Cognitive Interview Feedback - Evidence of Construct Validity

Cycle Phase	Question	Construct Validity – Sample Feedback
Foundational	2.4. Does the learning community leadership facilitate co-development of activities across roles? (i.e., fostering "bottom-up" leadership, instead of "top-down")?	• *"I felt the anchoring words "bottom-up" or "top-down" helpful in understanding at you are asking and making the question clear"*
	5.3. Has the Learning Community clearly defined the clinical outcomes it is interested in measuring?	• *"This is an important question, and fairly clear."*
	7.1 Does the Learning Community have a work plan describing the key activities within their LHS program, including a clear timeline, responsibilities/roles for each activity, and identification of resources needed?	• *"Clear question though. I think the work plan is well defined by the descriptors in the question, the items in the question help understand what a work plan is..."*
Practice to Data (P2D)	9.2. Has the learning community defined methods and data extraction strategies for documentation?	• *"We are going to be working within the frameworks of the cerebral palsy research network, so some of those methods for data extraction or data collection are defined within that network infrastructure.... I don't think the question is redundant with the previous one. 9.1. is paper work, "what data do we need to collect?" and 9.2. is hard IT stuff... Yes, question is clearly worded – makes sense to me"*
	9.3. Has the learning community defined and secured access to the appropriate data sources?	• *"I think this is a well worded question" what access do we need and have we got it""*
	9.5. Has the learning community been able to extract data as planned?	• *"I think it is a good question, valuable and easy for me to answer and probably for champions too"*
	9.6 Has the application of the learning cycle changed patient outcomes?	• *"Clear question. Seems like this is asked in the right order"*
	10.1. Does the Learning Community have a process to ensure data quality and to develop refinements as needed?	• *"Clear and well phrased."*
	11.1. Has the Learning Community developed a data storage and management system?	• *"The questions are very readable, I think you have a balance and found terminology that is understandable across specialties, without going to deep in any domain (clinical, data, analytics). The questions make sense"*

	12.1. Is the Learning Community fully compliant with all regulatory (e.g., IRB) requirements?	• *"Probably less importance to ask but still need to ask because you're dealing with health care data. Not so much an LHS maturity thing, but definitely needs to be asked as we are dealing with health data from patients."*
Data to Knowledge (D2K)	13.1. Has the Learning Community been able to analyze extracted data and interpret findings?	• *"Clear question, it was fine"*
	13.3. Has the Learning Community been able to deploy advanced analytics methods/techniques (e.g., AI)?	• *"I think it's a good maturity question, you are not going to get to this until you are more mature"*
	14.2. Have data products (e.g., figures and tables) presented to clinicians been refined and updated as needed based on ongoing data analysis?	• *"I really like the question, because it's either you get it down but never did anything with it (the data) … might be a yes/no question though. I like data visualization instead of data products to be consistent. Really good question though, I think it indicates maturity."*
	14.3. Does knowledge visualization meet the needs of frontline providers within the Learning Community?	• *"Good question, wording clear. I don't think this is redundant with last questions, it is a logical sequence: you got the data, you pulled it out, you're making charts and graphs, you are updating them… do you feel like that meets your needs? I feel like it is a logical sequence."*
Knowledge to Practice (K2P)	15.1. Does the Learning Community have a clear understanding of barriers and facilitators affecting implementation of knowledge into care?	• *"Great question, clear terminology"* • *"I think this is a pretty straight forward question"* • *"Clear terminology in the question"*
	15.3. Has the Learning Community been able to design implementation strategies?	• *"I interpreted it as: "did you take the knowledge and figure out what you are going to do next?" I like this question a lot"* • *"Terminology clear"*
	16.1. Has the Learning Community been able to implement knowledge into practice?	• *"Good question"*
	16.2. Has the Learning Community been able to refine or adjust its implementation strategies as needed?	• *"Question clear, this flows from 15.3 and 15.4., so that's why I think 16.1. could be adjusted to reflect same terminology as well. Wording is clear. Makes sense, did I design, did I put into practice, did I adjust and regime… flows nicely"*
	17.2. Has the Learning Community disseminated findings from its learning cycle to a wider audience?	• *"Not as important as the actual implementing of the change but still important"*

In the P2D phase, for example, the question *Has the learning community defined and secured access to the appropriate data sources?* was identified as problematic by the following statement: *"A little confusing to me, not sure what you mean by data sources? If you are considering the EMR to be the main data source, by definition if they have done the previous question then that means yes, they have already secured access to this... but other teams may consider data sources outside the EMR, maybe like benchmark data or national data that's available, so just make sure if that is what you are trying to get at. For concussion, they could say: "we don't need any outside data sources, so that does not apply to us" right?".* Based on this and other feedback, the question was modified as follows: *To what extent has the learning community been able to secure access to its data sources and implement the data collection and extraction methods? (For example, extraction of clinician documentation notes, other medical records in the electronic health record system, development and implementation of patient reported outcomes measures, access to data registries if applicable, etc.).* This modification was intended to clarity meaning for participants according to the feedback received in the cognitive interviews.

The second theme that emerged in transcripts analysis constituted *suggestions for eliminating or merging questions.* For example, there were two questions in the second version of the instrument pertaining to the definition of improvement goals for the outcomes measures the learning community is focused on. The first question stated: *Has the Learning Community clearly defined its improvement objectives related to the outcomes of interest?* The importance of this question, with the need for modifications, was highlighted by the following statement: *"This is getting at "what is the clinical problem you are interested in thinking about? how would you measure it? and if we could measure that, how would we like to see things different in the future and can we make that a smart, tangible goal in the future so that we can measure how we are doing along the way? those are three different aspects... I think that "clinical goals" would be a more straightforward way of asking this. "Has the learning community clearly defined its clinical goals?" or something to that effect.".* The second question pertaining to the definition of improvement objectives was defined as follows: *Have all relevant Learning Community members participated in defining the improvement objectives?* For this question,

several interviews provided valuable comments. One interviewee stated: *"I don't know, some of this is repetitive – asking whether people are participating on all these different levels. An overall question about equal participation on all activities might suffice and could eliminate some of these questions".* A second interviewee commented: *"Same problem with question 5.4. – the word "all" is not great. "Have stakeholders had the opportunity to participate" could be a better way to phrase. When we talk about things like the learning community defining the clinical problems of interest, I think that participation from all stakeholders may not be needed in all these activities. 5.4., or 6.2. – may easier to group questions about opportunity to participate into one question as well.".* A third interviewee provided the following statement: *"Similar comment to 5.4., it is important to have input from everybody, the whole bottom-up approach is important but there are lots of questions that ask something about whether all the team members or community contributing and so...maybe redundant with other questions".* Therefore, questions about team participation in specific processes in the learning cycle were grouped into a single question in the Foundational phase pertaining to collaborative leadership for the learning community. The second question, as presented above regarding participation of team members in defining improvement goals, was, therefore, eliminated. The first question presented above pertinent to the definition of improvement goals was modified as follows: *To what extent have improvement goals been clearly defined regarding the quantitative outcomes measures?* This represents an example of questions that were either eliminated or merged into other questions in the instrument according to the feedback received.

The third theme that emerged includes *suggestions for changes in the order of questions within the questionnaire.* For example, for the question: *Has the Learning Community reviewed the published literature focused on their clinical problems of interest and potential solutions?* I collected the following statement: *"This question should be placed after the clinical problem definition, because that comes first- you define the clinical questions, then you look at the literature.".* Another interviewee adds: *"I felt that the order feels out of place though for this question, maybe it has more to do with data to knowledge where you are identifying published studies... and looking at the data and you want to know what else is out there so you can compare it with the data you are getting... It felt too early in the process".* These statements

suggest that participants perceived the question pertaining to the literature review was asked earlier in the questionnaire than they would have expected. Based on this feedback, the order of question was changed (along with the associated process in the reference model). The question was modified as follows *"To what extent has the learning community reviewed and synthesized the published scientific literature pertaining to its clinical population, clinical questions, and/or clinical interventions?"* The question, and the associated process "Review and synthesize available literature" in the reference model, were both changed in the order in which they are presented in the instrument to reflect the interviewees' comments.

The fourth theme that emerged includes the *identification of new questions (and associated processes in the reference model.* For example, for the question: *Have data products (e.g., figures and tables) presented to clinicians been refined and updated as needed based on ongoing data analysis?* The following statement was provided by an interviewee: *"Look at maturity model resource for terminology improvement. Something like: "Do you have a process for continuously updating data visualization? Since we are talking about continuous learning and the continuity of a learning cycle, I would ask about that process for continuous data flow, updates, and visualization. I don't like the terms figures and tables – those terms are very research/manuscript oriented. Include: dashboards containing trending graphs, tables.".* This statement allowed me to identify the need to address data flow automation as an important capability for the learning cycle. Thus, the newly created process "Establish data flow automation" was incorporated into the new version of the questionnaire and process reference mode. For this new process, the following capability measurement question was formulated: *To what extent has the learning community established automated data flows that enable ongoing, continuous, and repeatable data analytics and visualizations for clinicians at the point of care in real time?* This addition was meant to address the need for measuring data flow automation capability for learning cycles.

The fifth theme constitutes *considerations about the Likert-scale response set options.* Validating comments regarding the appropriateness of the response options were made throughout the interviews. When commenting on the terminology used to describe the Likert-scale options for the questions, one interviewee stated: *"It's a Likert scale so we are primed to*

be anchored by the numbers... my thinking is: we are not a 5 in any of these, so regardless of what the words are…". This comment suggests that the numbers in the Likert-scale response options are likely more important than the words used to describe the options, as perceived by the interviewee. This information, along with confirmations from multiple interviewees that the response options provided were reflective of the questions asked, led to me keep the terminology used for response options in the next version of the questionnaire: *1) Not at All, 2) Very Little, 3) Some-what, 4) Quit a Bit, and 5) A Great Deal.* When asked about whether or not all questions should have the same Likert-scale response options, one interviewee stated: *"If you want people to respond quickly, a standard response for all questions may be useful"*. Based on this, response options for all questions in the next version of the questionnaire were standardized.

When asked the question: *To what extent do you perceive that the Learning Community has a shared set of values and sense of identity as a team?* the data analyst, member of the operations team in the department, used the response option *"Don't know"* with the following justification about one of the learning communities: "*I have never met with the team as a whole outside the champion. I think it's a good, clear question though. The words in the question make sense to me. It would be easier to ensure co-development of activities across team members when there is a shared set of values and identity. As opposed to when you don't have that and everyone wants to go in their own direction. My sense of the spine team, based on what I know of the team members, is that they are somewhat divergent and go in different directions - which is odd because they went to med school together. That's why I would say Somewhat, if I were to answer this based on the team members I have interacted with. But I'm going to stick with Don't Know as my answer because I don't know whether the team is split in those two directions for these team members or if they go mostly in one or the other direction. So, I just don't know. I suppose that when you ask the team champions, they will have a much clearer answer".* This statement suggests that the "Don't know" response option in the Likert-scale may be useful to learning community members who are not involved directly in developing the specific capabilities for processes in the learning cycle. Identifying aspects of the learning cycle that are unknown to certain learning community members may be valuable. These aspects may be

discussed during team meetings, and this may provide meaningful opportunities for the learning community to establish a shared understanding of its capabilities and bottlenecks. When discussing questionnaire assessment results regarding team identity and values, per the question above, the learning community may foster a productive conversation that may lead to actionable findings, such as the development and documentation of formalized value statements. Another example of the utility of the response option "Don't Know" is illustrated by the following: when asked the question: *Has the Learning Community reviewed the published literature focused on their clinical problems of interest and potential solutions?,* one interviewee chose the same response option, and commented*: "The team seams strong with literature review and are strong on research, but I (part of the operations team) am not involved in the literature review process... Hard to answer because I was not sure what they did, or how much they have done."*. These two examples provided evidence for the utility of the response option "Don't Know", which was kept in the next version of the instrument.

The sixth theme that emerged, as an extension of the previous theme, involved issues pertaining to the *applicability of questions across roles within any given learning community.* Diverging interpretations of the questions and different comfort levels answering them are to be expected if the questionnaire is to be completed by multiple learning community members with different roles and expertise within the team. For example, when commenting on the question *Does the data storage and management system meet the needs of the Learning Community?* one interviewee stated: "*Hard to answer, because data storage and management system are unclear terms for me (as a clinician), I didn't understand it in the last question so didn't get it for this one either".* Alternatively, when asked the question *Has the learning community defined the data it will need to address its problem of interest and improvement objectives?* the data analyst who was interviewed commented: *"I like the terms "methods and data extraction strategies for documentation", but I'm the person doing it so I don't know what the clinicians think about these."* These two statements imply that the different expertise and roles across the multiple learning community members may lead to diverging interpretations and, consequently, variability in answers. Additionally, some of the questions pertaining to leadership practices within the learning community proved to be challenging when answered by learning community

leaders, per the following statement: *“Hard to answer, because I am the leader – as the leader it is difficult to answer about my own leadership. You are asking me if I am a good guy? (laughter)”.* These statements indicate that, when the questionnaire is applied in practice, variability in answers likely needs to be accounted for due to the different expertise of the learning community members. When discussing this expected variability, one interviewee stated: *“So, I think variations in responses between leadership and foot soldiers, responses may be different, some potential for seeing variations and knowledge about those different perspectives. But also, some pitfalls because you want the scores to indicate where the team is and when someone doesn't know what's going on they might indicate a lower than actual score and bring the average down....so it's not a true response about the team. So, importance to highlight in the instructions, if you don’t know, mark don’t know to ensure people who don’t know don’t answer …to prevent people from thinking: "I don't know about this item, so I think we must not have it or haven’t done anything about it and choose not at all'".... So the best use of the tool might be to send it out to team members/individuals and have everyone answer and have the team meet to review the scores, it would be a great idea to plan ahead for the year... so someone may say we have no idea or plan for how to do data quality, so I'll score low... and the leader and tech people will see that and may say" well interesting that our score is low, because we have the world's best processes!" and the others will say" well I didn't know that!" So, if there is a way available to do the model and adjust the scores based on the team meeting, they have afterwards, you would get much better data once the team has discussed scores. Would be useful to know how many team members gave the extreme scores (especially low extreme), or the spread... calculating spreads and any question withe spread above X should have a little red arrow and discussed by the team- we better talk about this as a team. Goes to prioritization of items that the team will focus on”.* This statement suggests that participants should be instructed to answer accordingly if they do not know the answer to certain questions. Importantly, it was suggested that the learning community meet after questionnaire completion by team members to discuss results. Questions with the greater variability may indicate diverging opinions and a lack of shared understanding of the current state of learning cycle capabilities. These may represent an important point of discussion for the learning community.

The seventh theme that emerged was the *need for branching logic when presenting questions.* Some of the interviewees expressed concern with the extensiveness of the instrument, and suggested that questions be presented to participants for completion according to the development stage of the learning community under assessment. According to one participant *"There is a lot of questions and this could ultimately be streamlined, if you were to ask a team "where are they in the process as far as a) we are just brainstorming, or b) we have had a few meetings and made a few implementations, or c) we are actively in the process… so rating their progress as far as low, medium, or high... and then curtailing the questions around that or filtering through some of the questions... because I feel with a lot of the questions... we are not in the beginning, we are not actively recording data, so some of these are not applicable and you could reduce the redundancies or the inappropriate questions. They are appropriate because you could select "not at all", but if you could curtail the questions, you could probably knock down the number of questions for each group. I would rate our group as intermediate right now, and there are a lot of things that we can get value to and other ones "not at all" or "don't know" so... just a thought".* This evidence helped to support my understanding that learning communities can be more or less mature based on how capable they are across multiple learning cycle processes. Further evidence is shown through the following statement: *"Needs to be thought about as branch logic, because the reason I chose not at all is because it doesn't exist- not because it is not meeting the needs".* Another interviewee adds: *"Teams at the beginning of the program don't need to answer this, so branching logic would be helpful so establishing where the team is in the process and not have a question beyond that process".* To complement, one other interviewee states: *"Again, branch logic is needed, I think this gets to three levels considering the previous questions: data analysis, visualization, refinements.... So there needs to be some branch logic between these questions cascading down to the more specific... Wording is fine though".* This evidence indicates that not all questions may apply to all learning communities, depending on their development. For example, early-stage teams may not want to respond to questions about changing practice, as they may have not reached that learning cycle phase. Thus, in the next version of the instrument, I introduced a branching logic function that asks respondents to assess their learning community according to different levels

in a maturity progression. This initial assessment indicates which parts of the questionnaire they should focus on (and which parts they may chose to ignore).

Finally, the cognitive interviews with learning community members yielded inputs regarding the instrument's applicability that indicate evidence for its overall validity. According to one interviewee in a position of leadership in the department: "*I have teams doing learning health systems work, I do see this as maturity model work. Very important for someone like me to be able to review the projects in my department. If I had graphical presentation based on the data the instrument will be able to collect, the data could be easily graphed and I could take a quick look at where the teams are... and get a feeling for where people are and what they are focusing on. I could see things like spider graphs could be useful to see where people have made progress and areas where they have not progressed yet… I also see usefulness of regular flow graph. And so, you could tell me where teams are on the continuum towards maturity and compare teams "what's going on with this team?"* This statement indicates that health system managers involved in coordinating multiple LHS capability development initiatives may find the instrument valuable as it provides quantitative assessments for multiple learning communities that may be used to track progress and support plans for development. The interviewee further stated: *"For the teams, a way to keep track of progress for teams, like once a year the team will fill this out and assess where they are and next year do this again to compare and see how much progress they have made... so tremendous tool for teams to self-assess.... So, I am doing a lot of team work in the department right now, and had a meeting today to talk about the rehab pediatric physician and we identified our goals and came up with a matrix.... not quite like this or a maturity model, but if we had something like this to use in the meeting to assess our progress and see where we are... Teams often don't know what they have accomplished and this maturity model will be a good way to show what the teams have done, and take a look at their work and failings and what they need work on but also their accomplished and "wow, we worked a lot!"".* This evidence suggests the usefulness of the instrument in demonstrating progress as learning communities develop capabilities over time. Another interviewee commented on the usefulness of the tool not only for assessment purposes but to support planning for development: "*I think that it's the most clear manifestation that I have seen of a*

very detailed components and parts of what needs to go into making an LHS work effectively, being very planful from the beginning to set yourself up for success... so it goes through all the nuts and bolts that need to be put in place. So, I have been thinking about LHS for years and looking at this I was like "oh yeah I didn't think about that nut or bolt..." So, I think from that perspective it just reminds the leaders within the LHS of what precisely they need to be doing and it is very thoughtful, and this being a self-assessment for teams on whether they are doing all of these things it will be incredibly useful as it prompts discussions within groups and see what that brings up. Your scores will depend on what your goals are for assessment; so, for me using assessment tools to guide awareness of process, needs and goals and gaps is incredibly helpful.... I see this helpful as in you give this to your team, everyone answers and you get together and you share responses and talk about the areas where you have discrepancy and share the different perspectives, and you identify your action steps for closing those gaps... so I see this tool useful not only as an assessment tool for the teams, not only as an assessment tool but also for the purpose of communicating about how do we move collaboratively to the next steps. When we actually have a team moving forward with these goals, I'm hoping that we can have this tool as a very useful way and I'd be happy to answer and give you perspective into how useful this is... because it's one thing to look at this as one person, but a very different thing of using these items as discussion prompts within groups and seeing what that brings up". This evidence suggests the need for evaluating the instrument once it is applied, to ensure that it achieves the goals it aims to achieve in practice. One other interviewee commented on the potential usefulness of the instrument in establishing benchmarks and identifying lessons learned that may be shared across learning communities *"When the questionnaire is applied, in broader scope it would be interesting to see where other teams are and their scores, but in a smaller scope it wouldn't make a difference to me to see how other teams are doing. I'm concerned about my team, not other teams. However, if I was just getting started and wanted to know what the maturity level in another domain is and I'd want to know from groups that have high level of maturity in that domain, that may be a good resource to reach out them and see what they did to be successful. So that would be the only reason I'd be interested in other groups, to try to identify how it would be helpful for my own work - sharing lessons learned. I*

think all of this is about moving the process forward, and getting an idea of what the next level would look like, what a more mature version looks like... what are the habits and activities and boxes that have been checked by a more mature team. It would be interesting to know that, I don't really care about the past or less mature teams... you can always learn new things from other people, but when you look at what does that next level, or path forward look like in terms of maturity... I think this could be helpful". Additional statements from cognitive interviews providing an evaluation of the overall instrument's potential and applicability are presented in Table 13.

Table 13 - Cognitive Interview Statements - Instrument Evaluation

Instrument Evaluation – Sample Statements	
Interviewee A	*"I will say that this questionnaire could be fantastic - once it is refined to your liking - be used at the outset of any kind of LHS team convening... or development process. Because this helped me understand that there is a lot of things that I didn't even know where things I should be thinking about. You don't know what you don't know... I didn't even know to ask about many of this stuff. So, I appreciate that some of this was in there."*
Interviewee B	*"I like how the questions prompted us to think, a lot of thoughtfulness around designing an LHS in the first place…"*
Interviewee C	*"My thinking was: "Wow we have got a lot of work to do. As an early-stage team, I like that this prompts us to think ahead"*
Interviewee C	*"There is a lot of work you can do to refine the questionnaire, especially if this was done through a questionnaire software… if there is a lot of (answers indicating) "no" it could streamline the questions for the users"*
Interviewee D	*"Some of these questions do get at the infrastructure aspect of this, scope of the operations team… but some of the answers will reflect the team's perception of the operations team and what needs to be done"*
Interviewee E	*"There is a lot of clear objectives identified in the questions, that I kind of see as a checklist to do this work. Making sure you are identifying a clear timeline, roles and responsibilities, resources, and that everyone is on the same page regarding the plan. Which is sort of the purpose of the questionnaire in my opinion, not just to have a checklist but making sure everyone is doing these things right? Putting together their LHS program, the clearer those steps are the more likely people are to do it..."*

The insights from the cognitive interviews indicate that, with appropriate modifications to address the interviewees' comments, the developed instrument measures that which it is intended to measure (i.e., learning cycle capabilities) and is understandable to users. Important changes were made to the questionnaire to account for interviewee's comments. All question had terminology alterations for improvements in understandability and alignment with Likert-scale response options. A total of 3 questions were eliminated, 6 questions were merged into other questions, and 9 new questions were added in the final version of the instrument. Furthermore, a total of 6 questions were changed in order across the questionnaire. In the next section, we present the resulting self-assessment instrument.

Self-Assessment Instrument – Final Deliverable

This section presents the final version of the self-assessment instrument. The section is structured as follows: firstly, the instrument purpose and its intended users are presented. Secondly, the instrument structure is presented, including a description of the sections within the questionnaire, following the learning cycle phases in the process reference model (PRM). Thirdly, a learning community maturity progression is presented as a branching logic mechanism to streamline the application of the questionnaire in practice. This reflects the reality that learning communities are often at different stages of development or maturity levels, and, thus, not all questions may apply to every learning community. Finally, the questions for each section of the questionnaire are presented, following the structure in the PRM for learning cycles.

Purpose and Intended Users

The instrument allows for learning community members and health system managers alike to conduct self-assessments regarding their learning cycle capabilities. As mentioned, learning cycles enable a) knowledge discovery from routinely collected data, and b) knowledge implementation into practice for improvements of clinical care. Learning communities should develop and incorporate learning cycle capabilities within their practice for continuous

improvements to care delivery leveraged by data analysis. The constructs measured through the instrument, therefore, are the capabilities associated with enacting learning cycle processes of data-driven knowledge discovery and implementation, as characterized by the PRM. When using the self-assessment instrument, learning community member should answer to a series of Likert-scale questions that ascertain participants' perceptions of the current state of their capabilities. The answers from all learning community team members participating in the self-assessment should be computed, and these provide capability scores to foster team discussions and enable a shared understanding of the current state of their learning cycle capability development initiative. Therefore, once team members have answered the questionnaire, they should meet to discuss their collective answers. This prompts them to reflect and plan for improvements towards becoming a mature learning community. Learning community maturity is, thus, defined in this research as a function or aggregate score of learning cycle capabilities: by developing learning cycle capabilities, learning communities become more mature. As mentioned, the questionnaire is anchored in the PRM which contains clinical-neutral terminology when describing leaning cycle processes to ensure its generalizability across clinical domains. This allows for its application across settings for a standardized measurement approach to be conducted across multiple learning communities and clinical domains.

Expertise varies across learning community members (i.e., some team members possess clinical domain knowledge, others have expertise in IT, data science, quality improvement, project management, implementation science, etc.). This may lead to variation in scores, as some team members may be more knowledgeable than others in certain aspects of the learning cycle, and, thus, may be more comfortable answering specific questions in the questionnaire (e.g., questions that focus on clinical domain knowledge aspects of the LHS may not be as obvious or easy to answer to IT experts or data scientists, for example). This variation, however, provides valuable inputs for discussions once the team meets to discuss their answers. Learning community discussions about their capability scores, produced by the self-assessment exercise, provide a valuable opportunity for the development of a shared understanding of their current state or maturity level. During these discussions, learning community members should prioritize capabilities for development and plan for their improvements. To facilitate discussions,

participants may write down notes and open-ended comments as they answer the questions prior to the team meeting. Insights from completing the questionnaire may be useful during team discussions.

The capability (and maturity) measures from multiple learning communities within the health system may be used for aggregate planning and infrastructure development. Aggregate scores for the multiple learning communities in the health system may provide the basis for a performance measurement system for managers leading the LHS initiative, by providing objective assessments of the current state of the LHS program as a whole and facilitating communication across stakeholders for development. Figure 11 illustrates the intended application of the measurement instrument.

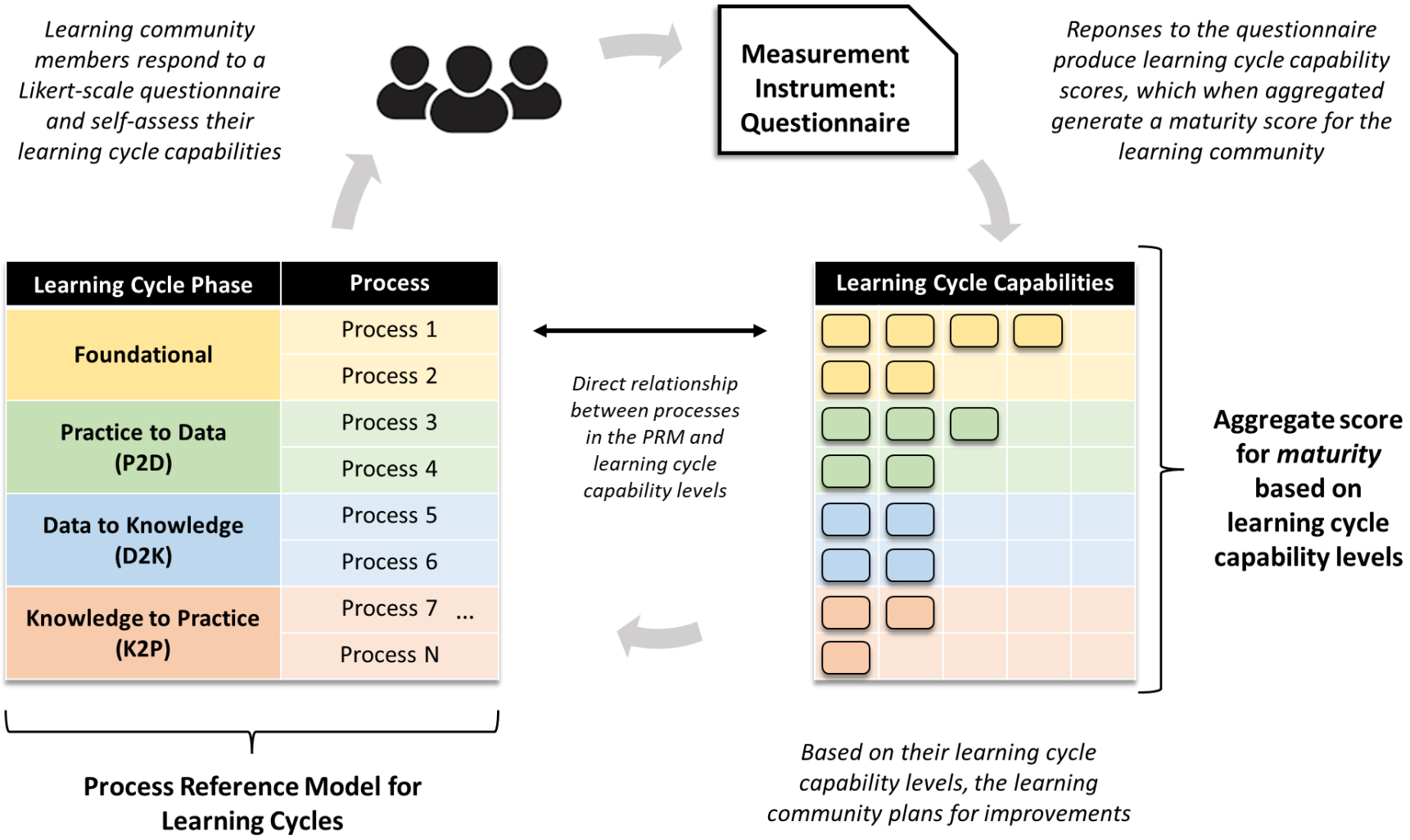


Figure 11 - Learning Cycle Capability Measurement Instrument - Intended Application

Questionnaire Structure

The questionnaire measures learning cycle capabilities across the learning cycle phases in the PRM. Table 14 presents the questionnaire sections per learning cycle phase, the associated capabilities, and number of questions per section. The capabilities in the instrument translate directly from the process domains in the PRM. The aggregate scores from questions within any process domain, thus, result in the individual capability scores for the learning community. The aggregate capability scores, consequently, result in an overall maturity score for the learning community.

Table 14 - Questionnaire Sections - Learning Cycle Phases

Section	Capabilities	Number of Questions
Foundational	• Team configuration, leadership and values • Clinical problems of interest definition • Work planning for the LHS	**19**
Practice to Data (P2D)	• Data capture • Data management	**8**
Data to Knowledge (D2K)	• Data analysis and visualizations • Knowledge discovery and dissemination	**11**
Knowledge to Practice (K2P)	• Designing practice change • Promoting practice change	**12**
Total		***50***

Maturity Progression

Learning communities within an LHS program may be in various stages of development or maturity levels. Early-stage teams may be brainstorming ideas for their LHS, discussing potential clinical questions and data they would like to explore. But they might not be conducting data analysis and practice change yet. Other teams may be further along in the learning cycles processes: implementing knowledge into practice, for example. A potential

maturity progression for learning communities based on the extent to which they have matured in implementing and executing specific learning cycle processes is illustrated in Figure 12. In responding to the questionnaire, team members should first identify where they lie in the progression, and respond to the corresponding sections of the instrument. To optimize for time spent answering the questionnaire, respondents should focus on sections that correspond stage of development of their learning communities. For example, early-stage teams (maturity level 1 and 2) should focus on the Foundational and P2D sections, and may choose to respond to the D2K and K2P sections at a later time once they are more mature. The questions for each section of the questionnaire (i.e., the learning cycle phases) are presented in the next sections.

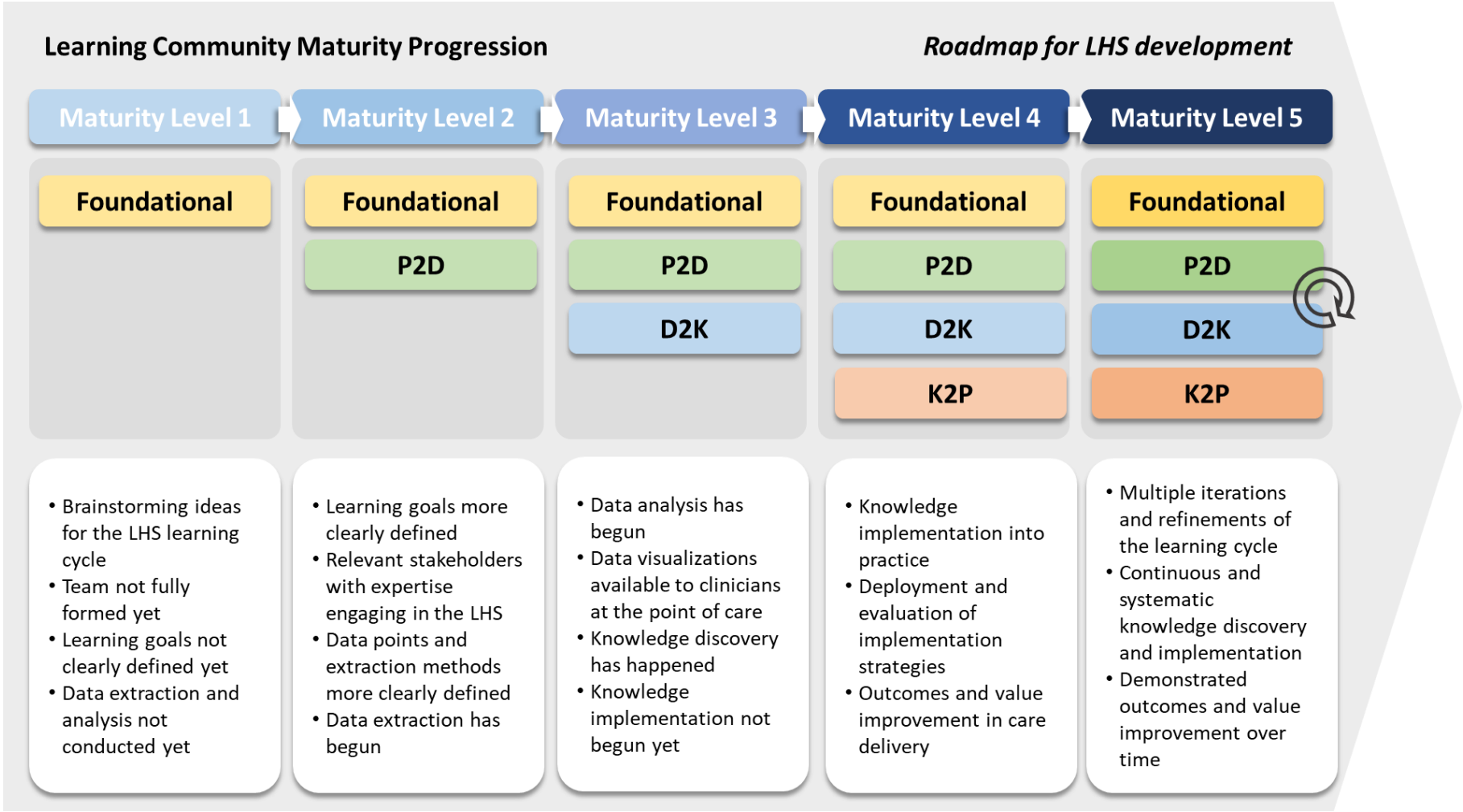


Figure 12 - LHS Learning Community Maturity Progression

Foundational

Table 15 - Foundational Phase - Self-Assessment Questions

Domain Area	Process	Questions	Likert Scales					
1.1. Stakeholder configuration	**1.1.1. Form the learning community**	a) To what extent has a learning community team been formed with individuals that possess the appropriate expertise and experience (e.g., clinical domain knowledge, information technology, data analytics, project management, administrative roles, operations and quality improvement, research, patient representatives, or others) to develop the LHS?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent have roles and responsibilities across team members been clearly delineated?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	1.1.2. Develop and manage partnerships	a) To what extent have patient representatives with lived experience been engaged as active stakeholders in the LHS development process? (For example, patients' inputs may be valuable in early stages such as when the team is defining the clinical questions, or at later stages when the team is designing practice change interventions)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community established the necessary working partnerships within and/or without the health system that the team has identified as important to reach its objectives? (e.g., partnerships with IT or other departments, health system leadership, clinical specialists, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
1.2. Leadership	**1.2.1. Develop**	a) To what extent do you perceive that the team champion or leader has taken an active role in leading the work of the learning community in a collaborative manner: encouraging and enabling participation and co-development of activities	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal

Domain Area	Process	Questions	Likert Scales					
and team values	**participatory leadership**	across team members according to their expertise, roles, and preferences?						
		b) To what extent do you perceive that the learning community team members are participating as expected, according to their expertise, roles, and preferences?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		c) To what extent to do you perceive that the learning community receives the support it needs from leadership at the department and/or health system/institution level?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	1.2.2. Develop team identity and values	To what extent do you perceive that the team has developed a cohesive identity and shared set of values in support of its objectives?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
2.1. Defining clinical problems of interest	**2.1.1. Define patient population**	To what extent has the learning community reached consensus in clearly defining its clinical patient population of interest (and subgroups, if applicable)?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	2.1.2. Define clinical questions	To what extent has the learning community reached consensus in defining the specific clinical questions it aims to answer regarding its patient population?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	2.1.3. Define outcomes of interest	To what extent has the learning community objectively defined quantitative outcomes measures?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	2.1.4. Define improvement goals	To what extent have improvement goals been clearly defined regarding the quantitative outcomes measures?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
2.2. Literature review and synthesis	**2.2.1. Review and synthesize**	To what extent has the learning community reviewed and synthesized the published scientific literature pertaining to its clinical population, clinical questions, and/or clinical interventions?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal

Domain Area	Process	Questions	Likert Scales					
	available literature							
3.1. Project management	**3.1.1. Develop and implement a project plan**	a) To what extent has the learning community defined a project plan for the remaining phases of the learning cycle (i.e., detailing activities, timeline, budget, and responsibilities for developing the LHS)?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community executed the project plan as expected (e.g., within the planned timeline, or budget)?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		c) To what extent has the role of the project manager been delineated, assigned, and performed according to expectations?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	3.1.2. Develop team communication and coordination systems	a) To what extent has the learning community developed an effective communication system (including document sharing platforms, meeting channels, and established meeting frequency) that meets the needs of the team?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent do you perceive that communication between learning community members is carried out effectively and efficiently?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
3.2. Resources	**3.2.1. Acquire and manage necessary resources**	To what extent has the learning community secured the necessary resources it needs to reach its objectives? (Including time availability for its members, funding, personnel availability, technological, logistical, or other)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
6 Domain Areas	***12 Processes***	***19 Questions***	***Likert Scales***					

Practice to Data (P2D)

Table 16 - P2D Phase - Self-Assessment Questions

Domain Area	Process	Questions	Likert Scales					
4.1. Data extraction and integration	**4.1.1. Develop, implement, and optimize data sources and extraction methods**	a) To what extent has the learning community clearly specified data sources, metrics, and data collection and extraction methods to measure its outcomes of interest?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
		b) To what extent has the learning community been able to secure access to its data sources and implement the data collection and extraction methods? (For example, extraction of clinician documentation notes, other medical records in the electronic health record system, development and implementation of patient reported outcomes measures, access to data registries if applicable, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
		c) To what extent has the learning community been able to optimize its data collection and extraction methods as needed? (For example, optimization of clinician documentation practices, optimization of patient reported outcomes questionnaires, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
	4.1.2. Integrate data sources and measure outcomes of interest	To what extent has the learning community been able to extract data from routine practice on a consistent and ongoing basis, integrating data sources into operational measures for the outcomes of interest?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal

Domain Area	Process	Questions	Likert Scales					
4.2. Data quality	**4.2.1. Ensure standardization of data entry practices**	To extent has the learning community developed and implemented a plan to ensure standardization of data collection or data entry practices across providers and other end-users? (e.g., standardization and verification of clinician documentation practices, verification of patient reported outcomes questionnaire responses, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
	4.2.2. Develop and implement a data validation plan	To what extent has the learning community developed and implemented a plan to validate extracted data with end-users (clinicians, patients, others), ensuring that the extracted data are meaningful and usable?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
5.1. Data delivery	**5.1.1. Develop and maintain a data delivery system**	To what extent has the learning community established a data delivery system allowing for data extraction, storage, manipulation, analysis, and/or visualization for clinicians and other end-users to support clinical decision making? (e.g., Tableau, REDCap, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
5.2. Data governance	**5.2.1. Develop and maintain meta-data documentation**	To what extent has the learning community developed and implemented meta-data documentation? (This may include: i) data governance policies defining who has access to what type of data, under what circumstances, and when, ii) a data dictionary defining various data elements, iii) data flow or pathway diagrams illustrating processes and data sources, manipulation tasks, destination, end-users, delivery methods, among other elements)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quite a Bit	5) A Great Deal
4 Domain Areas	***6 Processes***	***8 Questions***	***Likert Scales***					

Data to Knowledge (D2K)

Table 17 - D2K Phase - Self-Assessment Questions

Domain Area	Process	Questions	Likert Scales					
6.1. Data analytics and visualization	**6.1.1. Ensure regulatory compliance**	To what extent has the learning community completed the entire process of: i) identifying, ii) planning for, iii) fulfilling, and iv) ensuring ongoing compliance with all regulatory requirements for its LHS? (i.e., HIPPA requirements, protection of PHI requirements, IRB requirements, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	6.1.2. Develop data analytics and visualization	a) To what extent has the learning community developed a plan or analytical approach for data analysis and visualization to answer the clinical questions of interest?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community assessed the applicability, feasibility, and effectiveness of analytics methods such as machine learning (ML), artificial intelligence (AI), and predictive analytics for its data analysis? (e.g., the team may have explored the possibility but chosen not to use such methods, for example)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		c) To what extent does the infrastructural support and technical capabilities available to the learning community enable the data analysis and visualization to be deployed as planned?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	6.1.3. Deploy data analytics and visualization	a) To what extent has the learning community deployed its analytical plan or approach for data analysis and visualization to provide valid answers to their clinical questions?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community verified with clinicians that data analysis and visualizations are easily interpretable, accessible, and useful to support clinical decision making in routine practice at the point of care?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal

Domain Area	Process	Questions	Likert Scales					
6.2. Data flow automation	**6.2.1. Establish data flow automation**	a) To what extent has the learning community established automated data flows that enable ongoing, continuous, and repeatable data analytics and visualizations for clinicians at the point of care in real time?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community been able to ensure quick manipulations, updates, and adjustments in data analytics and visualizations on an ongoing basis at the point of care as needed?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
7.1. Knowledge discovery	**7.1.1. Identify knowledge for dissemination and implementation**	To what extent have the clinician members of the learning community reached consensus on knowledge or insights deriving from data analyses to be implemented in practice for improved patient outcomes? (e.g., knowledge or insights may be interventions that have shown to improve quality of care, evidence-based practices (EBPs), or any lessons learned from data analysis that could be used to improve routine care when implemented)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
7.2. Knowledge dissemination	**7.2.1. Disseminate knowledge from data analysis**	a) To what extent has the learning community i) identified internal stakeholders involved in care delivery and audiences of interest within the health system and ii) promoted knowledge dissemination efforts targeting them? (e.g., training materials, presentations, reports, policies and procedures)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community i) identified external stakeholders and audiences of interest and ii) promoted knowledge dissemination efforts targeting them? (e.g., submission of manuscripts for publication, conference presentations, reports for research associations, etc.)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
4 Domain Areas	***6 Processes***	***11 Questions***	***Likert Scales***					

Knowledge to Practice (K2P)

Table 18 - K2P Phase - Self-Assessment Questions

Domain Area	Process	Questions	Likert Scales`					
8.1. Implementation planning and coordination	**8.1.1. Plan for implementation strategy design**	To what extent has the learning community developed a plan for designing practice change and knowledge implementation, including i) methods to identify the determinants (barriers or facilitators) to be addressed in practice, and ii) methods implementation strategy design in order to address determinants?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	8.1.2. Plan for implementation strategy deployment and evaluation	a) To what extent has the learning community developed a plan to evaluate the effectiveness of implementation strategies, including a definition of implementation outcomes?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent has the learning community developed a plan to i) evaluate implementation fidelity, and ii) ensure that adaptations to the interventions are conducted and documented as needed?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	8.1.3. Plan for sustainment of improvements	To what extent has the learning community developed a plan to ensure and evaluate implementation sustainability over time?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
8.2. Implementation strategy design	**8.2.1. Identity and prioritize determinants to implementation**	To what extent has the learning community engaged with frontline providers and staff involved in care delivery to establish a clear understanding and prioritization of the main determinants (either barriers or facilitators) that need to be addressed for knowledge implementation to occur in practice?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	8.2.2. Design implementation strategies	To what extent has the learning community designed implementation strategies in a collaborative manner with frontline clinicians and staff directly involved in care delivery in order to address determinants of practice?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal

Domain Area	Process	Questions	Likert Scales`					
	8.2.3. Pilot test and refine implementation strategies	To what extent has the learning community been able to pilot test, refine, and ensure that implementation strategies are ready for wide-scale deployment and evaluation in practice?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
9.1. Implementation strategy deployment & evaluation	**9.1.1. Deploy implementation strategies**	To what extent has the learning community been able to deploy the implementation strategies at scale with clinical providers and staff and promote practice change?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	9.1.2. Ensure fidelity and adaptations	To what extent has the learning community i) evaluated and ensured standardization and fidelity vis-à-vis their intended format of the implementation strategies and clinical interventions across clinical providers ii) identified the need for, promoted, and documented adaptations to implementation strategies and/or clinical interventions when applicable?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
	9.1.3. Evaluate implementation outcomes	a) To what extent has the learning community been able to evaluate the impact the implementation strategies had on the clinical outcomes of interest? (e.g., through an implementation study, for example, and using the specified implementation outcomes measures)	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
		b) To what extent were implementation strategies effective in improving care delivery and clinical outcomes of interest?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
9.2. Sustainment of improvements	**9.2.1. Ensure sustainability of improvements**	To what extent has the learning community been able to ensure and evaluate implementation sustainability over time?	0) Don't Know	1) Not at All	2) Very Little	3) Some-what	4) Quit a Bit	5) A Great Deal
4 Domain Areas	***8 Processes***	***12 Questions***	***Likert scales***					

Intended Application and Simulation

The self-assessment instrument is a pragmatic instrument that learning community members and health system managers alike may use to evaluate the current state of their LHS capability development initiatives in practice. Measurements allow for a shared understanding of the current state across team members, facilitating communication and the development of plans for improvements. The instrument may be used by learning community team members in planning meetings, as well as by health system managers coordinating the development of multiple learning communities across the health system. The instrument enables the creation of a dashboard for performance measures, aggregating scores for each learning community, which managers may then use to better plan for LHS infrastructure development across the health system. With capability measures as indicators, health system managers are better positioned to identify infrastructural bottlenecks that need to be addressed for process execution and improvement. The instrument is anchored in the processes within the PRM developed in Chapter 2, and therefore allow for an assessment of the extent to which the processes are carried out effectively.

To illustrate the intended application of the instrument, I created a simulated assessment with 3 different hypothetical learning communities. For each learning community in the simulation, 3 different team members respond to the questionnaire by providing answers regarding their perceptions regarding their own learning communities (therefore, a total of 9 simulated respondents participate in the assessment). The mean and standard deviation are calculated for each question using team members' responses for each learning community. Thus, capability scores are then produced. Following the PRM construct structure, capabilities may be aggregated at the process domain level. There are 9 process domain levels across the 4 learning cycle phases. Therefore 9 learning cycle capabilities, which may be aggregated at the learning cycle phase level. Capability assessment results may be visualized in radar-graphs for practicality. In the simulated assessment with the 3 learning communities, results are presented for the capabilities deriving from questionnaire completion. These are shown in Figure 13. As illustrated, the learning communities under assessment are at different stages of development

or maturity levels. Visualizing assessment results in the form of radar graphs may support learning community discussions and the development of plans for improvements. The health system managers responsible for developing the LHS infrastructure may also use the radar graphs to measure progress and plan accordingly. Consecutive measurements over time (e.g., every 6 months or every year) may produce valuable insights regarding team progress and indicate whether learning communities are advancing as planned or if key infrastructural bottlenecks or other factors are inhibiting development. Thus, the radar graphs may constitute a dashboard for performance measurement that health system managers coordinating the development of multiple learning communities may use. By analyzing results as performance measures for learning communities and the LHS as a whole, action-plans may be implemented to develop the required LHS infrastructure over time.

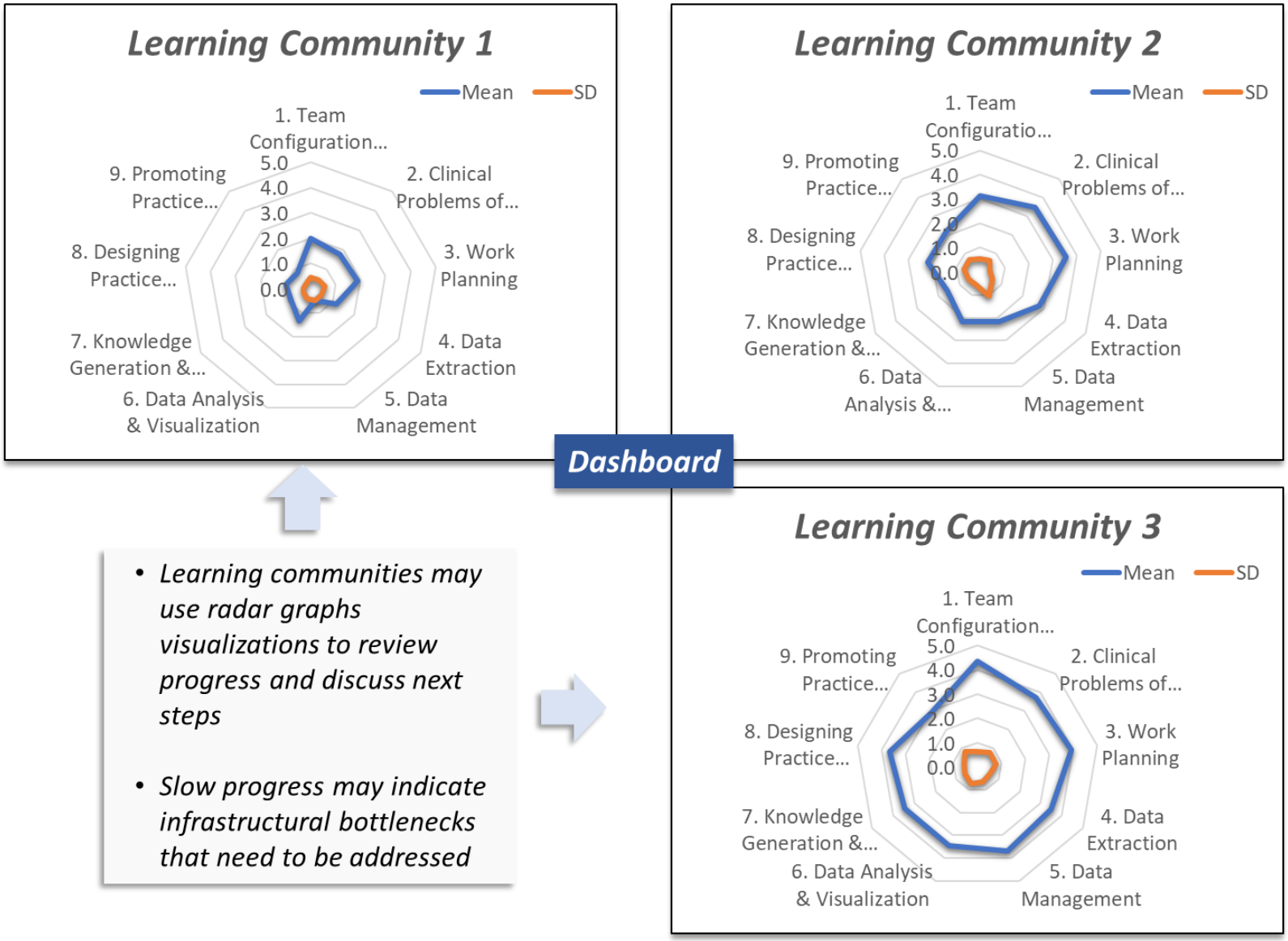


Figure 13 - Simulated Assessment

Given that learning communities are multi-stakeholder teams with various roles and expertise areas (i.e., clinical domain knowledge, IT, data analysis and statistics, quality and process improvement, implementation science, etc.), it is expected that answers to the questionnaire differ across team members depending on their role in the learning community. In other words, for a single learning community under assessment, team members of the learning community may provide different scores for the same questions. This variation may be useful as learning community meet to discuss assessment results after questionnaire completion and identify the reasons for variation. For example, a clinician may not be as well informed regarding the data analytics processes for the learning cycle, and provide lower scores when compared to the IT and data science experts within the team that are directly involved in development. Discussing the differences in scores may provide a valuable opportunity for learning community members to develop a shared understanding of their current state. Once an assessment is conducted through the questionnaire, the learning community should prioritize capabilities for development and devise actionable plans accordingly. The learning community may use the self-assessment instrument as a means to track progress over time, with periodic assessments that indicate whether development is occurring as planned.

Chapter 6 – Conclusions

The two previous chapters in this dissertation present the component parts that constitute the maturity model and the respective methods used for their development. In this concluding chapter, final considerations are made. Firstly, I discuss the overall methodology and data sources used to concurrently design the two components of the maturity model. The methodological steps described represent a contribution to the literature as an approach that could be replicated by others in the development of similar instruments in an iterative and collaborative manner. Secondly, the model's intended use in practice is discussed. This includes a discussion of the model's overall structure, the functionalities of the two components (i.e., the process reference model and measurement instrument), as well as the overall model's intended application in practice to support continuous LHS capability development. Finally, implications for future research are discussed. These include opportunities for summative evaluations of the model's application in practice aiming to ascertain its value to users and the identification of opportunities for further refinements. A discussion of the model's contribution to the theoretical body of knowledge with LHS research is also presented.

Design Methods

In this dissertation, the methodological steps for co-development of the maturity model for Learning Health Systems (LHS) and its individual component parts were described in detail. The resulting maturity model provides a means for teams to self-assess learning cycle capabilities in support of continuous improvement efforts for the LHS program. The model was co-developed within the Physical Medicine and Rehabilitation (PM&R) Department at the University of Michigan Medical School and incorporated multiple data sources that were used through design iterations.

The methods used for designing the component parts of the maturity model were informed by available frameworks within design science research, action research, and maturity model development literatures [50,51,58,1180]. As such, I sought to address practical concerns faced by health system managers in a real-world LHS program by co-creating an instrument that provides a means for capability assessment. The methods relied on multiple data sources and design iterations that were conducted in close collaboration with practitioners in the LHS program. I used approaches from industrial engineering research, such as process and performance management, as well as those from information systems research, such as design science and the concept of maturity models. This research constitutes a multidisciplinary initiative to support the development of infrastructural LHS capabilities in practice, which produced artifacts that may be utilized in other settings[46].

In alignment with Forrest et al[48] and with action research principles[50,51] , I embedded myself within daily meetings and operations of the PM&R department at the University of Michigan Medical School. This allowed for my understanding of the objectives, culture, work practices, and main challenges faced by health system managers in PM&R in their efforts to develop LHS capabilities in support of the learning communities in the department. With this understanding, we collaboratively identified the need for system measurement and chose to explore the applicability of the concept of a maturity model in support of the LHS program. Thus, the research aims in this dissertation derived directly from the formulation of the practical problems faced by PM&R. Namely, the health system managers coordinating the LHS initiative

needed a method to ascertain the extent to which the required capabilities had been developed, and whether the LHS objectives of knowledge discovery and implementation had been met in practice. Such a method would allow them to communicate progress updates to stakeholders, including departmental leadership, as well as support developmental planning in a structured manner. The identified practical problem was described as an *instance of a class of problems* that are faced by health systems in multiple contexts, as postulated by action research and design science principles and exemplified in the LHS literature[2,3,8,9,17–19,29,50,58,119]. According to Sein et al, "*the action researcher should generate knowledge that can be applied to the class of problems that the specific problem exemplifies".* Consequently, the developed solution (i.e., the maturity model and its component parts) aimed to not only solve the practical need observed in the PM&R context, but to also be a generalizable solution that could apply to clinical settings and health systems seeking to develop LHS capabilities in general. As such, the maturity model comprises an artifact that may be used for infrastructure development across settings, in support of LHS capability improvements at scale for systematic enhancements to patient outcomes and value. Consequently, the model is subject to tailoring, evaluation, and refinements when applied to different contexts in future research.

In the beginning of the project, an informal agreement was established between myself and PM&R. In this agreement, my responsibility was to lead the development of the maturity model within the context of the departmental LHS development initiative and in the scope of this doctoral dissertation. The health system managers at PM&R, in turn, agreed to facilitate the work and collaborate in activities to co-design and evaluate the model's components through the design iterations. Within this agreement, there was a progressive development of mutual trust between researcher and practitioners around a common goal that enabled the research objectives to be met through collaboration. Information was freely shared and full access to the department's resources, activities, and meetings were granted to the researcher, which allowed for close partnership and the design of a model addressing the concrete needs of practitioners as observed in practice. Throughout the research, valuable input deriving directly from stakeholders involved in the LHS initiative within PM&R were incorporated and translated into constructs and measures within the maturity model. The resulting instruments were, therefore,

mutually beneficial to the parties involved and a direct result of interdisciplinary collaboration between researcher and practitioners.

From the general research aim of designing a maturity model, we delineated scope in order to better address the complex initiative of developing a departmental LHS, with its multiple concurrent components and challenges. We restricted the breadth and level of analysis for model development to allow for a comprehensive solution to a targeted, smaller component of the larger system. This was also done in congruence with the time and resource constraints of the project, given that a maturity model covering all aspects of the LHS program could not be feasibly developed within the timeframe allocated for this research. Together with the health system managers, we selected the learning communities within the department as the focus of measurement. Consequently, we excluded measurements of infrastructural maturity for the LHS. Nonetheless, future iterations of the model may expand on the delineated scope though refinements and further practical applications of the model in the same or other contexts and expand scope to create constructs and measures for LHS infrastructural maturity.

After defining scope for the maturity model, we collaboratively conceptualized what was meant by learning community maturity. As postulated by Mettler [58], the concept of maturity may be framed in multiple dimensions. In complex organizational systems, maturity may be construed as socio-technical constructs that may be oriented towards people (e.g., expertise, organizational culture, leadership practices, teamwork, values, incentive structure, etc.), processes (e.g., methodologies, procedures, practices, tasks, standardization, efficiency, etc.), or technology (e.g., technological innovations and devices, data analytics capabilities, data management, data visualizations and automation, etc.). From the scope definition (i.e., focus on learning communities), we provided a conceptualization of maturity around the processes required for enacting learning cycles of knowledge discovery and implementation into practice. By measuring the extent to which learning communities are able to perform learning cycle processes, the model is able to indicate capability levels that encompass both social and technical factors that are required for learning cycles to occur in practice. Thus, the process orientation to maturity led to the development of the specific research aims. Each aim sought to

answer pragmatic questions related to learning community maturity and the ability to enact learning cycle processes.

To reach the first research aim, I co-developed a process reference model for learning cycles that delineated the processes needed to foster knowledge discovery and implementation into practice for data-driven improvements in quality of care. By doing so, I collectively defined the constructs to be measured for learning community maturity alongside stakeholders in PM&R. In addition to providing the basis for measurement, the process reference model can help in streamlining project management, standardizing the learning cycle approach across learning communities within the health system, and facilitating cross-functional coordination across departments for the multiple tasks involved in developing capabilities for knowledge discovery and implementation. The co-developed reference model is applicable for both researchers and practitioners. It unites diverging terminology and vocabulary used to describe the multiple objectives and methodological approaches that can enable data-driven learning and practice change to occur.

To address the second research aim, I collaboratively designed a measurement instrument based on the process reference model. The instrument was designed congruently with the reference model and constitutes a self-assessment questionnaire that produces learning cycle capability scores based on the processes for learning cycles in the reference model. The instrument, therefore, stipulates the process capability measures that constitute learning community maturity. The resulting questionnaire may be used by learning community members and those involved in coordinating multiple learning communities concurrently for maturity assessments. Figure 14 illustrates the maturity model's components and their intended application in practice.

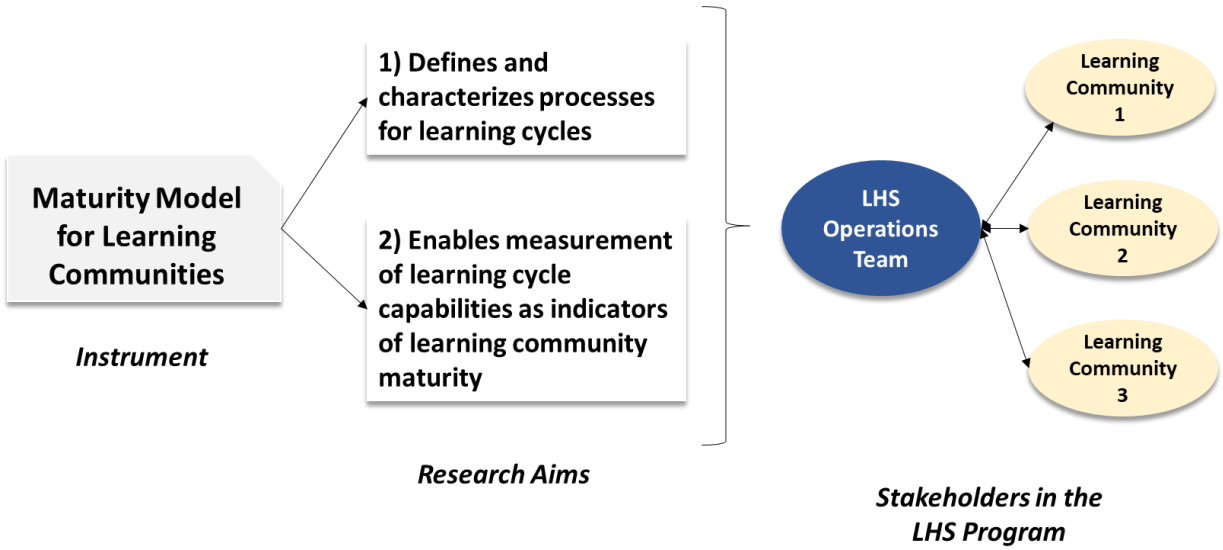


Figure 14 - Maturity Model Function and Structure

An integrated approach was used to explore the two specific research aims simultaneously. This led to the concurrent development of the model's components. The design methodology relied on multiple data sources that were used for the design and iterative refinements of both components in the maturity model. In congruence with design science research methodology, both theorical and empirical sources of knowledge were incorporated into the model[119]. Thus, the multiple data sources ensured that the resulting model and its component parts reflected both theory and practice[50,51]. The iterative approach that was utilized for the design of the maturity model's components allowed for the multiple data sources to be progressively incorporated into versions that were refined according to the feedback obtained. The individual components in the maturity model and their construct definitions were, therefore, validated through the three rounds of data collection and analysis that were the result of my engagement as a researcher alongside practitioners in the PM&R department. The data collection and analysis steps regarding the preliminary versions of the components in the model constituted formative evaluations that allowed for progressive refinements based on the feedback obtained from practitioners and the literature review. These formative evaluation steps contributed to model validity throughout its development[50]. The

collaboration between researcher and practitioners throughout model development was an important attribute of the design methodology that contributed to construct validity[51]. In co-developing the model as an embedded researcher using an iterative methodology, the model structure, its construct definitions, and the model's intended use were explored concurrently and progressively during development. The applicability of the model and its generalizability to other contexts are functions of the concrete data that emerged and were analyzed in close collaboration with stakeholders from a real-world LHS capability development initiative. The methodology used for designing the maturity model in this dissertation contributes to the LHS literature by presenting a research framework that may be used (or tailored) to other research initiatives aiming to develop similar instruments.

One of the key challenges in LHS research involves the integration of varied terminology used to describe the multiple aspects of fostering data-driven learning and improvements. In design iteration 1, the LHS operations team members and I co-designed the first version of the two instruments. By collaboratively designing the first version of the process reference model and capability measures with the operations team within PM&R, we were able to capture constructs that expanded upon the learning cycle model by Friedman et al[2] and reflected the practical work under development in the department. Therefore, terminology used to describe processes and measures reflected the language used in practice at PM&R, which contained similarities and differences when compared with the terminology used in the literature and published case studies.

Further inputs were collected from an expert panel of LHS researchers and practitioners from outside of the PM&R context. The expert panel scrutinized the model's components and provided valuable feedback that were used for refinements. This was done in order to ensure the applicability of the model's components to contexts outside of PM&R. The incorporation of feedback from the expert panel in design iteration 2 aimed to mitigate potential overfitting of terminology used in the instruments to the PM&R context and enhance construct validity and generalizability. I also relied on the body of knowledge to inform model development and foster refinements to terminology. The need for system measurement was emphasized in the available literature, and complemented the practical need identified in PM&R. An effort to standardize

diverging terminology encountered in the literature was made in order to design a model that reflected the specific needs and practices of PM&R and ensured its generalizability to other settings. Diverging terminology in the LHS literature is likely due to the emerging nature of this multidisciplinary field of research, as well as the complexity of developing data-driven learning and improvement capabilities in practice and at scale.

Further feedback from users were sought in design iteration 3. When the instruments were presented to clinicians leading the learning communities within PM&R, it became clear that terminology needed to be refined once again. Clinicians are one of the main end-users of the maturity model, alongside the LHS operations team members and health system managers alike. As end users, clinicians have a very pragmatic view of the LHS and are mostly interested in how the LHS capabilities are going to benefit their clinical practice and patients, and the terminology they use to describe LHS processes and capabilities reflects that. Therefore, it was logical to gather their input in the last design iteration, to ensure that the final instruments met their needs and experience with LHS principles. Additionally, through model design, my own views of the LHS concepts changed and refined, as I learned from those leading the effort in practice and contrasted their approach with the published LHS literature and theoretical constructs. As the LHS field advances and consolidates, it is likely that terminology will converge with more case-studies and real-world applications. This research aims to contribute to that by presenting an instrument that is co-designed by LHS practitioners leading development efforts in practice, while incorporating theory through multiple design iterations for a final instrument that is applicable and generalizable across clinical settings.

In addition to these formal methods of data collection for design and refinements purposes, I was also able to utilize insights from my active involvement in weekly meetings and observation of management processes to guide model development. These insights corroborated the need for the measurement instrument and its applicability in supporting those involved in coordinating multiple learning communities and communicating progress updates to leadership regarding the current state of development of the LHS program.

The concurrent development of the two deliverables in the maturity model allowed me to iteratively refine both the constructs being measured (i.e., learning cycle processes and

associated capabilities) and the measurement method and specific measures (i.e., the Likert-scale questionnaire and capability levels). This approach was advantageous since it allowed me to progressively and concurrently refine my understanding of *what needs to be measured in an LHS* and *how to measure them*. In other words, the research activities involved in defining the constructs in the process reference model impacted the definition of the measurement method and the specific measures for constructs, and vice-versa.

In the designing the component parts of the maturity model, I sought to balance a trade-off between comprehensiveness and practicality. One the one hand, I wanted to create instruments that described and measured every important aspect of performing learning cycles in practice, with detailed process descriptions that incorporated as many potential applications as possible. On the other hand, the resulting instruments needed to be practical and feasible to clinicians involved in providing care for patients, with time constraints and multiple competing priorities within the health system. The iterative nature of the design methods allowed for conclusions to arise regarding instrument format and content that reflected the priorities identified in the data analysis pertaining to the feedback received from multiple stakeholders. I prioritized aspects of the learning cycle progressively, as I interpreted the feedback received from the various stakeholders involved in designing the instrument. The choice of format for the self-assessment instrument (i.e., the Likert scale questionnaire) reflected the need for practicality and simplicity of the measurement instrument. Thus, in design iteration 2, the research team and I decided that the Likert-scale questionnaire format for measurement enabled a quicker assessment when compared to the capability grid structure used in design iteration 1. The capability grid was considered problematic for two key reasons. First designing the grid implied that the instrument designers were responsible for determining a priori what the capability level descriptions and progressions should be. In practice, capability development for the various learning communities is not likely to match a pre-determined progression with precision. This means that the design choices in determining the capability level progressions are arbitrary or hypothetical without prior data for their corroboration. Secondly, using the resulting capability grid for measurement requires that users read every capability level description and choose that which most reflects their current state. This was considered to be

more time consuming than answering Likert-scale questions. For these reasons, the Likert-scale questionnaire format was chosen. Once instrument reliability and validity are further demonstrated in practice, the data collection from the questionnaire should enable the determination of capability and maturity levels from real-world assessments.

Intended Use in Practice

The resulting maturity model, and its component parts, allow for measurements of learning community maturity on the basis of learning cycle capabilities. When used in practice, the model produces measures for learning community maturity that may be used for multiple purposes. Learning community team members may objectively evaluate the current state of their learning cycle capabilities and plan for improvements accordingly. Capability measures may also be used to track progress over time, in order to highlight the team's progress. Learning community maturity measures may also be used by health system managers coordinating the development of capabilities for multiple learning communities. The measures may indicate infrastructural bottlenecks that impede learning communities from maturing in their learning cycle capabilities. As learning communities mature over time, patient outcomes and value delivery improve accordingly as teams enhance their capabilities for knowledge discovery and implementation into routine practice. Figure 15 illustrates the applicability of learning community maturity measures in the context of an LHS program.

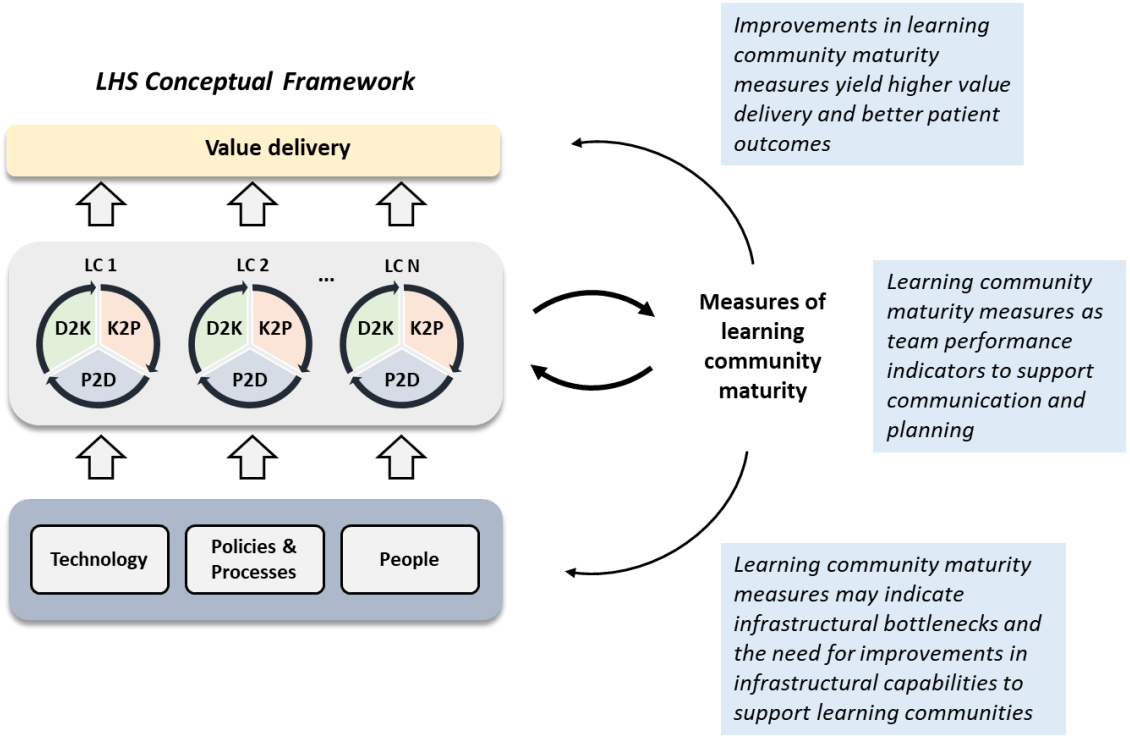


Figure 15 - Applicability of Learning Community Maturity Measures

The use of the maturity model in practice contemplates a cyclical methodology comprised of capability assessments and improvements, which enables maturation to occur. The maturity model, therefore, allows for a double learning loop to occur in the LHS departmental program[140,141]. In the first loop, learning communities are collecting data about patients from routine care practices and discovering knowledge that is, subsequently, applied in care delivery for improved quality of care (i.e., the LHS learning cycle depicted in the process reference model). In second loop, data regarding learning cycle capability measures are collected by team members through the self-assessment questionnaire in the maturity model. These measures provide an assessment of the current state of capability development and are then acted upon for improvements. As learning communities mature, their ability to enact learning cycles (i.e., the first loop) enhances.

Individually, the process reference model for learning cycles provides important contributions. It contains a comprehensive and detailed list of activities, expected outputs, and

specified roles and responsibilities involved in process execution. When used in practice, the process reference model is intended to serve as a roadmap to facilitate planning and streamline project management activities across teams, optimizing resource allocation for development. The process reference model is intended to accelerate development and enable the rapid achievement of the expected benefits of i) improving patient outcomes, ii) patient experience, iii) financial returns for the health system, and iv) provider well-being. By serving as a roadmap for standardization using available best practices, the model aims to reduce the lead time and resource utilization for LHS capability development, thus reducing stakeholder frustration with delays and mitigating organizational resistance to change [84]. The resulting reference model from this research is intended to evolve over time. A structured methodology for continuous process improvement and innovation based on the process reference model for LHS learning cycles, thus, should seek to update the processes in the model with each practical application. In doing so, stakeholders will be well positioned to operationalize the LHS principles in practice and continuously streamline the work of health system managers and clinicians alike.

When using the associated self-assessment instrument in practice, learning community members respond to the Likert-scale questionnaire to ascertain team members' perception of the current state of their learning cycle capabilities vis-à-vis the process reference model. The answers from learning community team members are compiled, and the assessment results aim to foster team discussions and enable a shared understanding of their current state. This prompts team members to plan for improvements in their development efforts towards becoming a mature learning community. Expertise varies across team members (i.e., clinical domain knowledge, IT, data science, quality improvement, etc.) which may lead to variation in scores: some team members will be more comfortable than others in answering specific questions in the questionnaire (e.g., questions that focus on clinical domain knowledge aspects of the LHS may not be as obvious or easy to answer to IT experts, for example). Therefore, variations in answers are to be expected. However, this provides valuable discussions as the team meets to discuss answers and develops a shared understanding of their current state. The capability measures from multiple learning communities within the LHS program may also be shared with the health system managers to provide a broader understanding of the current

state of the LHS program as a whole, and support managers in their communication with stakeholders and plans for infrastructural development over time. Once capability measures are complied, improvement plans are devised and executed for capability development. Figure 16 illustrates the intended application of the self-assessment instrument for learning communities. The methodology for capability measurement and continuous development enabled by the maturity model may be standardized across learning communities in the health system and provide for continuous improvements to occur systematically. Individual learning communities seeking to develop learning cycle capabilities may use this methodology to build from their strengths and identify specific areas that need improvement. The selection of specific interventions and development varies according to clinical context and priorities[19]. However, by continuously assessing and improving their learning cycle capabilities, learning communities in general will be in a better position to improve patient care as envisioned by the LHS principles.

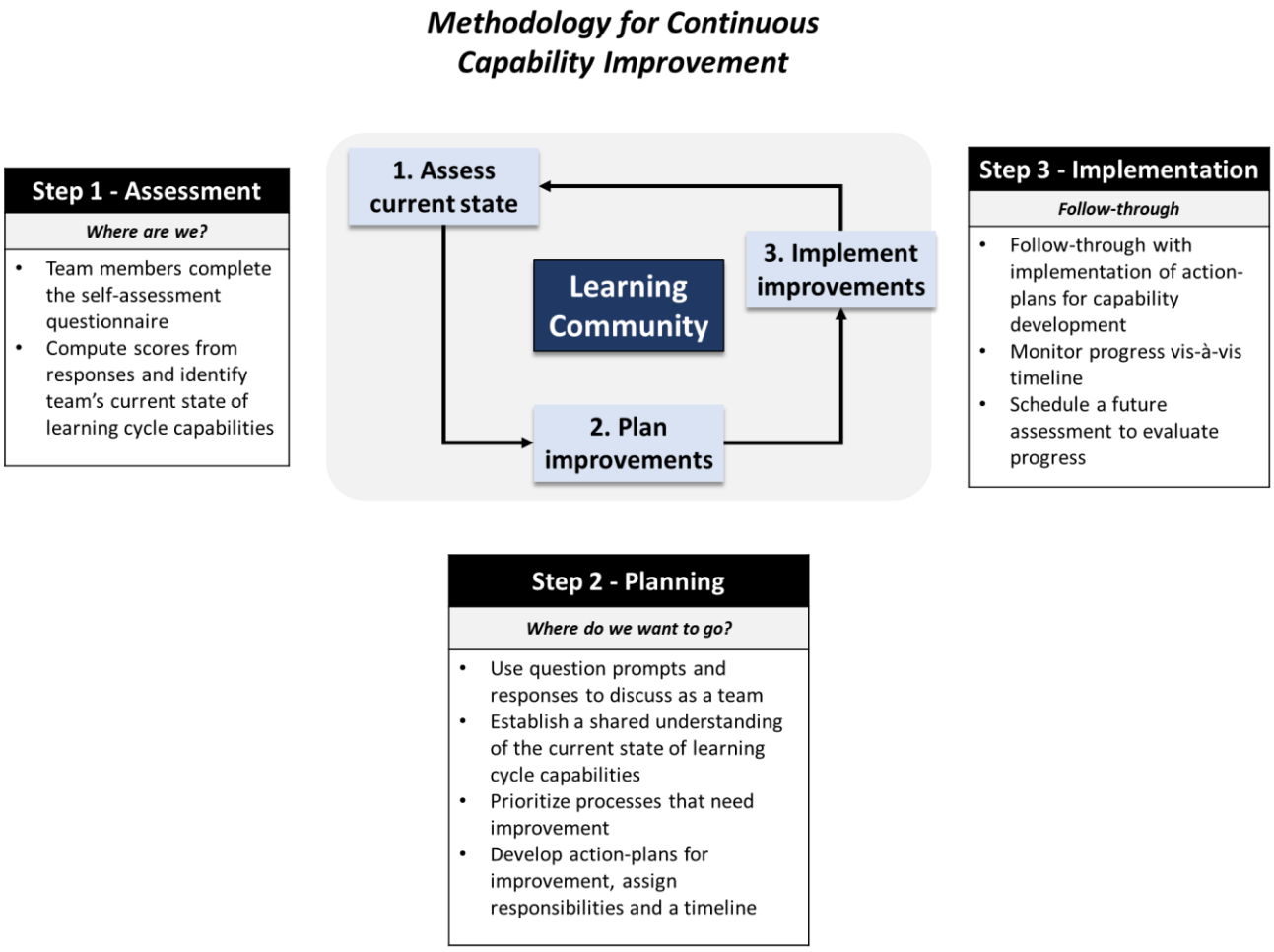


Figure 16 - Methodology for Continuous Capability Improvement

Limitations and Implications for Future Research

While perceived as useful in practice by participants in this research, the process reference model and capability measures may be subject to continuous reviews and modifications through instantiations in other contexts. For optimal results in practice, the process descriptions need to reflect the practical needs and objectives of particular contexts. Despite multiple data sources being incorporated into model design in this research, there is a chance for overfitting of process definitions for the specific setting in which the model was

designed. Thus, regardless of the level of detail captured through the design iterations and the intended universality of the final deliverables in this research, some process definitions may need to change in future research driven by local requirements and particular preferences and approaches of other LHS programs[100].

It is important to note that the early stage of development of the PM&R LHS program in which the model was constructed influenced its final design and may restrict its applicability to other contexts. For example, while some of the learning communities within the PM&R LHS program had established ongoing data extraction methods for data analysis and knowledge discovery in their learning cycles, others were still at very early stage and still discussing learning objectives and clinical questions in the Foundational phase of the model, without any data collection. Some of the discussions for these early-stage teams revolved around defining and reaching consensus on the purpose of their LHS program and the clinical outcomes of interest to their patient populations. Furthermore, none of the learning communities in PM&R had reached the K2P phase of the learning cycle, and no practice change has yet occurred as a result of the LHS at PM&R. Therefore, defining process descriptions for the later phases of the learning cycle relied on the LHS program stakeholders' vision for the future, the feedback from the expert panel according to their experiences with LHS programs in other contexts, and the literature review. New applications of the model in more advanced LHS contexts may provide useful improvements to the process reference model.

Thus, future research may expand the process reference model by applying it in other settings beyond the PM&R context and incorporating lessons learned empirically. Improvements to the model that may occur through further instantiations include: new terminology for process description to be incorporated in order to reflect different stages of LHS development; process additions, merging, or elimination according to newly identified needs and applications in other contexts; and modifications to the hierarchical levels described in the model (i.e., changes regarding granularity or relationships between the cascading levels: *learning cycle phase, process domain, process domain area*, and *process).* If the current configuration is found problematic and the need for change is identified when applied in other contexts the reference model should be modified accordingly.

Apart from the need for instantiations in practice to demonstrate the model applicability in other contexts, there are opportunities for expansion of the processes and capability measures based on further literature review. Subsequent versions of the model may benefit from additional literature reviews covering specific aspects of the learning cycle and its phases. In the rapid literature review approach used in this research, a limited set of LHS focused publications were targeted for review, with a single reviewer analyzing themes and content to incorporate into the process reference model. Future literature reviews using multiple reviewers to cross-examine the literature and an expanded search strategy would hold promise as additional inputs for model refinements and the design of subsequent versions of the process reference model. Topic areas to be covered in future reviews include: data management and data governance models and best practices, data analytics and data modelling best practices, including the artificial intelligence (AI) and predictive modelling literature, as well as a deeper dive into the literature covering team dynamics and implementation science methodologies to further expand process descriptions in the reference model.

When incorporated into routine operations within any given departmental or health system LHS program, a governance system for maintaining and refining the process reference model and capability measures should be established. The components within the maturity model are intended to serve as living documents within LHS programs, and reflect changes in processes and infrastructural developments over time. Therefore, users may develop a system to continuously update and refine the model over time to meet changing needs and circumstances [58]. Multiple components of the maturity model may change over time, including the scope of measures (e.g., future versions of the model may expand scope to measure infrastructural capabilities in addition to learning community capability measures), learning cycle processes descriptions and Likert-scale questions (i.e., new processes and questionnaire items may be added), or even the measurement approach and application methodology (e.g., a capability grid describing process capability levels may substitute the Likert-scale questionnaire if users find it favorable, for example)[58].

Users may define roles and responsibilities for proposing model change (i.e., who will propose changes to the model and how) and the frequency and timeframe for model change

proposals (i.e., changes may be proposed on a continuous basis with model use, or, alternatively, at pre-established timeframes as the team meets to update the model collectively). Therefore, designated meetings may occur to discuss and foster changes to the maturity model with its use in practice[58]. With an operational refinement plan, the maturity model can be updated and improved upon over time according to lessons learned from its use in the organization[58]. Consequently, future research should explore the use of the model in the organizational context and its changes over time, the consequences from its application and modifications, and practical actions for capability development resulting from assessments[50,51,58,118].

Important limitations with the questionnaire may be identified once the self-assessment instrument is applied in practice and at scale with multiple learning communities in different clinical settings. As with the process reference model, refinements or tailoring of the capability measurement instrument may be warranted as it is applied in practice in other settings. Internal validity regarding the instrument structure and questions should be evaluated. For example, the intended users of the instrument are the learning community team members, and these have different roles to play in developing capabilities for learning cycles, given their different expertise and technical background (i.e., clinical domain knowledge, IT, data science and analytics, quality improvement, implementation science). Therefore, user experience with the questionnaire as configured may vary according to their role in the team. Because of the varying degrees of specialization and the different roles that team members play in the learning community, variations in the responses regarding any give learning community are to be expected. Furthermore, it is unknown whether every question should be asked to all team members (e.g., should clinicians be asked about data management capabilities? should data scientists be asked whether a complete literature review has been conducted to better understand the clinical questions, potential treatment options, and evidence-based practices for the patient population?). Future research should explore different options for instrument application in practice considering this factor.

The questionnaire may migrate to a survey software platform (e.g., Qualtrics) in the future, and this may facilitate the exploration of different configurations for instrument

application. For example, once the questionnaire has migrated to a survey platform, participants may be asked about their technical role in the learning community and subsequently be directed towards the questions that pertain to their areas of expertise. Potential problems with specific items in the questionnaire or response sets may also be addressed during the application of the instrument in practice. For example, the response option “0) Don’t know” in the Likert-scales was introduced for all questions to enable the indication of team members’ “blind spots” regarding the learning community’s efforts to enact learning cycles. When reviewing answers as a team during post-assessment meetings once the questionnaire has been applied and answers have been compiled, for example, the team may use the “0) Don’t know” responses to identify processes or activities that need to be discussed so that everyone is informed of the learning community’s progress to date. However, this proposition needs to be tested in practice in future research.

Furthermore, I argued for the maturity level of any given learning community to be computed as an aggregate score of its capabilities. In the instrument, capabilities related to 9 process domains in the process refence model are measured by a set of Likert-scale questions. Answers to the questions regarding each process may be averaged to produce capability scores at the process domain level, assuming that all questions and processes carry the same weight or importance. Consequently, maturity levels may be defined as a function of the capability scores for each learning community. However, without data collection in practice from real-world learning communities, the quantitative definitions for maturity levels as a function of the capability scores may only be defined arbitrarily and a priori. Nevertheless, transparent quantitative definitions for maturity levels conducted in this manner may provide a valuable starting point for the conceptualization of a maturity continuum. A hypothetical quantitative maturity continuum is presented in Table 19, containing the quantitative definitions for 5 maturity levels. This complements the progression shown in Figure 12 by providing quantitative capability measures to construct objectives definitions for each maturity level. In this continuum example, a learning community is considered at maturity level 1 if the average responses for the questions pertaining to the first 3 process domains in the Foundational phase of the learning cycle are ≥2. Thus, with clear quantitative definitions for the maturity levels as a function of the

responses to the questionnaire, learning communities may be objectively categorized across the maturity level continuum based on the results from the self-assessment instrument. This would allow for objective assessments and facilitate the communication of assessment results using the maturity level continuum as a reference for comparison across learning communities, for example. In this system, thus, the goal of health system managers responsible for developing the LHS program is to advance the multiple learning communities across the maturity levels in the shortest amount of time or with least amount of resource expenditure.

Table 19 - Potential Quantitative Definitions for Maturity Levels

		Maturity Level 1	Maturity Level 2	Maturity Level 3	Maturity Level 4	Maturity Level 5
Found.	1. Team configuration, leadership and values	≥2	≥3	≥4	≥4	≥4
	2. Clinical problems of interest definition	≥2	≥3	≥4	≥4	≥4
	3. Work planning for the LHS	≥2	≥3	≥4	≥4	≥4
P2D	4. Data capture	*NA*	≥2	≥3	≥4	≥4
	5. Data management	*NA*	≥2	≥3	≥4	≥4
D2K	6. Data analysis and visualizations	*NA*	*NA*	≥2	≥3	≥4
	7. Knowledge discovery and dissemination	*NA*	*NA*	≥2	≥3	≥4
K2P	8. Designing practice change	*NA*	*NA*	*NA*	≥2	≥4
	9. Promoting practice change	*NA*	*NA*	*NA*	≥2	≥4

One of the underlying hypotheses in this research is that mature learning communities deliver higher quality of care and improved outcomes to patients, since they are better able to learn from their data and drive changes in care delivery to implement evidence-based practices

through developed capabilities. This hypothesis needs to be tested in practice, however. Once reliability and validity are further demonstrated in future research, and assuming that value delivered to stakeholders in its multiple dimensions (i.e., patient outcomes, patient experience, costs, provider well-being) can be measured for specific learning communities, the instrument may support studies to test the abovementioned hypothesis.

With an appropriate sample of learning communities, the instrument may be useful in answering questions such as: *what does a mature learning community team look like? do mature leaning communities deliver higher value to patients?* If the instrument is expanded in future research to measure infrastructure maturity (or the extent to which the surrounding infrastructure is able to support the learning communities), it could be useful in answering questions such as *what does a mature infrastructure look like? does infrastructural maturity lead to learning community maturity?* Therefore, the instrument would support identification of any correlations between measures of value outcomes and measures of learning community maturity, as well as correlations between measures of learning community maturity and infrastructure maturity over time.

Hevner et al argue that formal summative evaluation is a crucial component of design science research[119]. The organizational environment in which the model is designed establishes the requirements that drive both model design and evaluation. Thus, evaluation includes the integration of the model within the organizational environment and assessments of the extent to which it solves the needs for which it was designed[119]. As previously mentioned, future evaluation studies should gather and analyze data for demonstrations of attributes such as model utility, completeness, accuracy, usability, feasibility of application use, fit with the organization, value to the organization, and/or other quality attributes[56,119]. Therefore, formal summative evaluation of the model's use in practice assessing the extent to which the model's objectives are met according to stakeholder's expectations represents an important opportunity for future research. Due to time constraints, the model's application in practice was excluded from the scope of this dissertation. Friedman et al proposed a set of study types for the evaluation for biomedical informatics resources, which may be used to guide future research[124]. Studies aiming to validate the structure and constructs of the maturity model, as well as its

intended functionalities in practice may be conducted through usability tests and field function studies with users across clinical settings[124]. Questions that may be explored in future research include: *is the maturity model appropriately designed to function as intended? can intended users navigate the maturity model so it carries out its intended functions? does the maturity model have the potential to be beneficial in the real world? is the maturity model likely to change user behavior as expected?* Specifically, to ascertain whether the instrument is able to produce capability and maturity measures that are useful in practice for the evaluation of the LHS, future research should also investigate questions such as: *is the instrument helpful in evaluating the LHS? are the capability scores produced by the instrument meaningful to the learning communities and operations team? are the scores helpful for communication and planning purposes? are they actionable? do they drive change and improvements?* Data collection with the use of the questionnaire may be time intensive for participants, so an examination of the benefits provided by the instrument vs. the burden created in achieving those benefits is also warranted[47]. Thus, additional explorations on the usefulness of the questionnaire in practice should inquire about participants' time and effort vis-à-vis the value of responses. Once tested in practice, certain questions may prove to be more useful than others, and for optimization purposes those questions that do not prove to provide as much value should be eliminated.

Through the application and use of the maturity model in practice, further refinements to constructs may be implemented, as previously mentioned. The measurement instrument's reliability and construct validity may be further assessed, and psychometric research for the capability measures in the questionnaire is warranted. Additionally, future research may identify the need for the inclusion of measures of team diversity as further indicators of maturity. For example, future research may test new questionnaire items in order to measure a) the extent to which patient populations addressed by learning communities in the LHS program are representative of minority groups and traditionally underrepresented patients, and b) the extent to which teams are formed by a diverse group of people (i.e., ethnically, socio-economically, religiously, etc.). The underlying assumption is mature learning communities should be composed of a diverse team, and care for a diverse patient population. Identifying

both intended and unintended outcomes of the model's application in practice should also be explored in future research through case-studies[51].

The contributions of the maturity model to the LHS theoretical body of knowledge include its development methodology and the generalizability of the final instruments in supporting capability development across clinical settings. From its use in practice, future research may identify generalizable insights and theoretical contributions about learning community maturation. Novel theories about capability development and learning community maturation may be derived and/or tested in practice with the support of the maturity model. Thus, further research should expand on the notions of *what constitutes LHS maturity.* With the further demonstrations of the model's reliability and validity through applications in practice, learning community maturation may be demonstrated over time and lessons learned about the success factors that led to maturation and capability development should be identified, documented, and shared across teams to support development at scale across health systems. The analyses of individual learning communities may be conducted as case studies independently (i.e., within-case analysis). Alternatively, cross-case analyses of multiple learning communities using the standard capability measures set in the model may be performed. The resulting generalizable insights regarding learning community maturation should provide valuable contributions to LHS theory across disciplines and help to improve patient outcomes at scale.

Appendix

This appendix presents the characterization elements for all processes in the reference model. Firstly, activities and outputs are presented for all 34 processes across the 4 learning cycle phases. Secondly, guiding questions are presented to support process execution in practice. These questions indicate topics that learning community members should explore and discuss when developing capabilities for learning cycles. Thirdly, the different stakeholders' roles within the learning community are presented for each process in the reference model. The analyses of the individual team member's roles are presented to support staff allocation and process execution in practice. Finally, the applicability of the process reference model for streamlining project management is discussed.

Learning Cycle Activities and Outputs

In this section, activities and outputs are presented for all 34 processes.

Foundational

A summary of foundational processes is presented in Table 20.

Table 20 - Foundational Processes

Foundational Processes		
Processes that set the foundation for learning communities, enabling team formation and coordination, definition and of the clinical problems of interest, and planning the LHS development effort. These processes should be executed and iterated throughout the learning cycle, as their outputs affect and are affected by other processes		
1. Team Configuration, Leadership, and Values 1.1. Stakeholder configuration and partnerships 1.1.1. Form the learning community 1.1.2. Develop and manage partnerships 1.2. Leadership and team values 1.2.1. Develop participatory leadership 1.2.2. Develop team identify and culture	**2. Clinical Problems of Interest Definition** 2.1. Clinical problems of interest definition 2.1.1. Define patient population 2.1.2. Define clinical questions 2.1.3. Define outcomes of interest 2.1.4. Define improvement goals 2.2. Literature review and synthesis 2.2.1. Review and synthesize available literature	**3. Work Planning** 3.1. Project management 3.1.1. Develop and implement a project plan 3.1.2. Develop team communication and coordination systems 3.2. Resources 3.2.1. Acquire and manage necessary resources

Table 21 - Activities and Outputs for Foundational Processes

Domain Area	Process	Activities	Outputs
1.1. Stakeholder configuration and partnerships	**1.1.1. Form the learning community**	• Identify and engage with stakeholders with appropriate expertise and experience for the development of the LHS • Delineate roles and responsibilities within the learning community, including a clearly defined clinical champion or leader • Update list of members over time (i.e., recruit and exclude members as needed) • Develop and maintain key documents such as Team Charter and/or Team Roster	• Formation of the learning community as a multi-stakeholder team with diverse expertise • Clearly defined team champion or leader • Team Charter and/or Team Roster documents, containing: i) clearly delineated roles and responsibilities of team members, ii) team members contact information
	1.1.2. Develop and manage partnerships	• Identify, develop, and manage partnerships with departments and functions within (or without) the health system that leverage the work of the learning community on an ongoing basis • Identify, develop, and manage ongoing working relationships with patient representatives with lived experience for their input/perspectives for the LHS • Document list of all partnership stakeholders: roles and departments in the health system, patient representative categories and individuals, contact information, meeting agendas, meeting frequency, communication channels, among others • Define ongoing process for patient engagement, delineating patient recruitment criteria, team members and patients' responsibilities in patient coordination, timelines, frequency and location of meetings, meeting agendas, focus group structure and objectives, among others	• Documentation of list of working partnerships within and without the health system and their contact information • Established communication channels, roles and responsibilities within the learning community for engagement and coordination with partners • Defined engagement process with patients, with specified patient inclusion criteria, as well as activities and responsibilities involved in patient recruitment, patient education about the LHS, focus-groups, data collection and analysis, and reports about patient perspectives and findings that inform the work of the learning community

Domain Area	Process	Activities	Outputs
1.2. Leadership and team values	**1.2.1. Develop participatory leadership**	• Enable co-participation of all team members (i.e., bottom-up leadership) according to their roles, expertise, and individual preferences and expectations • Monitor and assess participation of stakeholders according to preferences, expectations and roles	• Periodic assessments of and discussions about leadership practices • Periodic assessments of and discussions about team members' participation according to their preferences, roles, and expectations
	1.2.2. Develop team identity and values	• Ensure team members are familiarized with the LHS approach to problem solving (i.e., continuous learning from every patient, integration of research and practice, focus on both knowledge discovery from data and implementation into practice) • Develop a sense of team cohesiveness and values in alignment with the LHS approach to problem solving • Develop and maintain key documents such as Team Mission, Vision, and Value statements	• Documentation of Team Mission, Vision, and Value statements • Periodic assessments of and discussions about team mission, vision, values, identity, and culture
2.1. Defining clinical problems of interest	**2.1.1. Define patient population**	• Identify criteria defining the patient population • Identify criteria defining sub-groups within the patient population, if applicable • Reach team consensus and document patient population criteria • Update and refine patient population criteria as needed	• Team consensus around the patient population of interest and its sub-groups, if applicable • Documented criteria defining the patient population of interest and its sub-groups, if applicable • Updates and refinements to patient population definitions as needed
	2.1.2. Define clinical questions	• Define clinical questions regarding the patient population of interest and its sub-groups, if applicable (i.e., learning objectives) • Reach consensus and document the clinical questions • Update and refine clinical questions as needed	• Team consensus around the clinical questions or learning objectives • Documented list of clinical questions • Updates to clinical questions as needed

Domain Area	Process	Activities	Outputs
	2.1.3. Define outcomes of interest	• Define outcomes measures of interest (i.e., what will be measured) for the clinical questions • Reach consensus and document the outcomes measures • Update and refine outcomes measures as needed	• Team consensus around outcomes measures (clinical, operational, provider-related, system-related, cost, or other) • Documented list of outcomes measures • Updates to clinical outcomes measures as needed
	2.1.4. Define improvement goals	• Define improvement goals for each outcome measure (i.e., levels of performance the team aims to reach for specific outcomes measures) • Reach consensus and document improvement goals • Update and refine improvement goals as needed	• Team consensus around the improvement goals • Documented list of improvement goals related to the outcomes measures • Updates to improvement goals as needed
2.2. Literature review and synthesis	**2.2.1. Review and synthesize available literature**	• Identify relevant journals and publications about the clinical population of interest, clinical questions, and available evidence • Based on the clinical population and clinical questions, conduct literature review, synthesize and share findings across team members • Refine and update literature review synthesis documents as needed (i.e., documents containing the results from the literature review and synthesis) • Foster ongoing team discussions (e.g., a journal club) based on reviewed literature	• Synthesis of literature review findings: this may include outcomes measures developed elsewhere, evidence-based practices that have shown improvements to patient outcomes, interventions or implementation strategies that have shown improvements in care delivery, among others • Journal club schedule, agenda, participants, and updated discussion notes documents

Domain Area	Process	Activities	Outputs
3.1. Project management	**3.1.1. Develop and implement a project plan**	• Ensure the role of the project manager has been described, assigned, and is being performed according to expectations • Define a project plan for the LHS program, including: key activities, timeline, responsibilities, budget, and any other resources needed • Reach consensus and share the project plan across team members in the learning community • Monitor progress according to project plan, and share progress updates with team members	• Delineated and assigned role of project manager • Project plan, including list of activities, estimated timeline, roles and responsibilities, and project budget • Progress monitoring and updates reports to team members
	3.1.2. Develop team communication and coordination systems	• Acquire or develop communication system (i.e., document repository, collaboration space, an online "commons") • Ensure organization of documents and accessibility of files to all team members • Define meeting channels and establish meeting frequency to share and discuss work deliverables • Monitor and ensure team participation in meetings and effectiveness of communication practices	• Access to and maintenance of communication and document sharing system/software platform • Ongoing management, organization, and accessibility of documents within the platform • Meeting channels, frequency, agendas, and attendance • Team discussions regarding communication practices
3.2. Resources	**3.2.1. Acquire and manage necessary resources**	• Identify, prioritize, and secure additional resources needed to develop the LHS program over time (i.e., financial, technological, time availability, personnel, office space, materials, access to data sources, logistical access to facilities, etc.) • Identify and coordinate with relevant stakeholders to ensure resources are secured	• Documented list of identified and prioritized resources needed • Documented list of stakeholders across the health system to enable resource acquisition • Coordination with stakeholders and secured resources for the LHS

Practice to Data (P2D)

A summary of P2D processes is presented in Table 22.

Table 22 - Practice to Data (P2D) Processes

Practice to Data (P2D) Processes	
Processes that enable data extraction and management. These processes operationalize data sources in order to answer the clinical questions and measure the outcomes of interest. Operationally defined metrics drive data collection and extraction. The processes also enable data flows from data extraction to delivery and visualization at the point of care, preparing for subsequent data analysis and knowledge discovery.	
4. Data Capture 4.1. Data extraction and integration 4.1.1. Develop, implement, and optimize data sources and extraction methods 4.1.2. Integrate data sources and measure outcomes of interest 4.2. Data quality and refinements 4.2.1. Ensure standardization of data entry practices 4.2.2. Develop and implement a data validation plan	**5. Data Management** 5.1. Data delivery 5.1.1. Develop and maintain a data delivery system 5.2. Data governance 5.2.1. Develop and maintain meta-data documentation

Table 23 - Activities and Outputs for P2D Processes

Domain Area	Process	Activities	Outputs
4.1. Data extraction and integration	**4.1.1. Develop, implement, and optimize data sources and extraction methods**	• Define data sources and data points to measure the outcomes of interest • Define data collection and data extraction methods (i.e., data from medical records, clinical practice documentation notes, within the electronic health records (EHR), patient reported outcomes questionnaires, data from wearable devices, among others) • Ensure access to data for extraction and manipulation from available data sources • Implement and optimize data collection methods (e.g., clinician documentation practices for data extraction, patient reported outcomes instruments/questionnaires, etc.)	• Definition of data sources and data points • Definition and implementation of data extraction methods • Ensured access to data and data extraction and manipulation within the EHR • Optimization of data collection and extraction (e.g., clinician documentation practices, patient questionnaires, etc.)
	4.1.2. Integrate data sources and measure outcomes of interest	• Integrate data sources and data points into operational measures for the outcomes of interest • Share operationalized measures for the outcomes of interest across team members	• Operationalized measures for the outcomes of interest • Baseline performance for the outcomes measures
4.2. Data quality and refinements	**4.2.1. Ensure standardization of data entry practices**	• Develop plan to ensure standardization of data entry practices • Verify compliance and standardization of data entry practices across team members on an ongoing basis • Update and improve data entry practices as needed	• Plan for standardization of data entry practices • Periodic or ongoing verification of compliance and standardization of data entry practices according to plans • Improvements and refinements to entry practices when applicable

Domain Area	Process	Activities	Outputs
	4.2.2. Develop and implement a data validation plan	• Develop a data validation plan to be implemented with clinical team members • Validate data and visualizations with clinical team members on an ongoing basis, according to plan • Refine data extraction and visualizations as needed, according to data validation findings • Ensure quality of extracted data on an ongoing basis	• Data validation plan, detailing: what data need to be validated, how, with whom, and at what time periods or frequency • Periodic or ongoing validation of extracted data and visualizations with clinicians • Ensured data quality for analysis
5.1. Data delivery	**5.1.1. Develop and maintain a data delivery system**	• Select and implement data storage and delivery system from existing options (e.g., Tableau, REDcap, etc.) • Test and verify that data delivery system meets the needs of clinicians in terms of accessibility and usability of data visualizations in practice • Develop, maintain, update, and ensure availably of data files and data visualizations to users • Update and refine data delivery system as needed on an ongoing basis	• Implemented data storage and delivery system • Evaluation of data storage and delivery system with users • Availability of data files to clinicians and researchers, if applicable • Updates and refinements to data delivery system as needed
5.2. Data governance	**5.2.1. Develop and maintain meta-data documentation**	• Develop, maintain, and update a data governance policy (defining rules and permissions for interacting with the data) • Develop, maintain, and update meta-data documentation: data flow diagrams, data dictionary, interoperability standards documents, etc.	• Development and sharing of a data governance policy across team members • Data flow diagrams (indicating the data sources, data storage systems or warehouses, and data delivery mechanisms to clinicians) • Data dictionaries and standards (clarifying meaning for data points to users)

Data to Knowledge (D2K)

A summary of D2K processes is presented in Table 24.

Table 24 - Data to Knowledge (D2K) Processes

Data to Knowledge (D2K) Processes	
Processes that enable data analysis and visualization to occur, and subsequent identification of knowledge. These processes allow for iterative development and deployment of data analytics and data flow automation, enabling knowledge discovery from data analysis and its dissemination to providers at the point of care in real time.	
6. Data Analysis and Visualization 6.1. Data analytics & visualizations 6.1.1. Ensure regulatory compliance 6.1.2. Develop data analytics and visualization 6.1.3. Deploy data analytics and visualization 6.2. Data flow automation 6.2.1. Establish data flow automation	**7. Knowledge Discovery and Dissemination** 7.1. Knowledge discovery 7.1.1. Identify knowledge for dissemination and implementation 7.2. Knowledge dissemination 7.2.1. Disseminate knowledge from data analysis

Table 25 - Activities and Outputs for D2K Processes

Domain Area	Process	Activities	Outputs
6.1. Data analytics & visualizations	**6.1.1. Ensure regulatory compliance**	• Identify ethical and regulatory requirements for research purposes (e.g., HIPPA, IRB, requirements for protection of PHI, etc.) • Plan for and ensure ongoing compliance to all regulatory requirements throughout the LHS initiative	• List of identified regulatory compliance requirements for the LHS • Fulfillment and monitoring of ongoing compliance with all requirements
	6.1.2. Develop data analytics and visualization	• Develop a data analytics and visualization plan (including the analytics approach, analytic models, and/or data visualization techniques to enable interpretation at the point of care) • Update and refine data analytics and visualization plan as needed	• Documented data analytics and visualization plan, including the analytic approach and/or built analytic models to be used, as well as data visualization techniques • Updates and refinements to data analytics and visualization plans as needed
	6.1.3. Deploy data analytics and visualization	• Deploy the data analytics and visualization plan in practice, including any analytic models to be used and data visualizations to clinicians • Verify that data analytics and visualization are interpretable, accessible, and useful in answering the clinical questions • Update and refine data analytics and visualization deployment as needed	• Data analysis and visualization deployment at the point of care to clinicians • Verification of interpretability, accessibility, and usefulness of data analysis and visualization outputs • Ongoing updates and refinements to analytics and visualization as needed
6.2. Data flow automation	**6.2.1. Establish data flow automation**	• Establish a continuous, automated data flow through the data delivery system to the point of care, allowing for quick, repeatable and adjustable data manipulations and visualizations • Update and refine data flow automation processes and mechanisms as needed	• Capability to perform quick, repeatable, and adjustable data manipulations and visualizations at the point of care based on ongoing data streams, as needed (e.g., adjustable dashboards with trending graphs and tables) • Updates and refinements to data flow mechanisms, as needed

Domain Area	Process	Activities	Outputs
7.1. Knowledge discovery	**7.1.1. Identify knowledge for dissemination and implementation**	• Identify knowledge, clinical insights, or scientific evidence deriving from data analysis to be implemented routinely in practice for improvements in care delivery • Reach consensus across team members and document knowledge to be implemented routinely in practice	• Interpretation of data analysis and identification of knowledge to be implemented in care delivery for improved outcomes • Team consensus on knowledge to be implemented in practice • Documentation and clear description of knowledge to be implemented in practice
7.2. Knowledge dissemination	**7.1.2. Disseminate knowledge from data analysis**	• Identify audience and stakeholders for knowledge dissemination: internal (clinical providers and staff involved in care delivery) and external (journals, conferences, research groups, etc.) • Prepare knowledge dissemination content and materials for internal audience • Prepare knowledge dissemination content and materials for external audience • Disseminate knowledge to internal and external audiences and stakeholders according to plans	• List of stakeholders to be targeted for knowledge dissemination within the health system (clinical providers and staff involved in care deliver who should be aware of data analysis findings) • List of external groups to be targeted for knowledge dissemination (journals, conferences, research groups and networks) • Documentation targeted for internal audience: presentations, reports, policies, diagrams, meeting materials, training programs, etc. • Documentation targeted for external audience: manuscripts, presentations, reports, etc.

Knowledge to Practice (K2P)

A summary of K2P processes is presented in Table 26.

Table 26 - Knowledge to Practice (K2P) Processes

Knowledge to Practice (K2P) Processes	
Processes that enable practice change for improvements in care delivery informed by data analysis and knowledge. These processes allow for scientific evidence to be implemented into practice in a structured manner using implementation science best practices for the design, evaluation, and sustainability of implementation strategies.	
8. Designing Practice Change 8.1. Implementation planning and coordination 8.1.1. Plan for implementation strategy design 8.1.2. Plan for implementation strategy deployment and evaluation 8.1.3. Plan for sustainment of improvements 8.2. Implementation strategy design 8.2.1. Identify and prioritize determinants to implementation 8.2.2. Design implementation strategies 8.2.3. Pilot test and refine implementation strategies	**9. Promoting Practice Change** 9.1. Implementation strategy deployment & evaluation 9.1.1. Deploy implementation strategies 9.1.2. Ensure fidelity and adaptations 9.1.3. Evaluate implementation outcomes 9.2. Sustainment of improvements 9.2.1. Ensure sustainability of improvements

Table 27 - Activities and Outputs for K2P Processes

Domain Area	Process	Activities	Outputs
8.1. Implementation planning and coordination	**8.1.1. Plan for implementation strategy design**	• Identify and engage with stakeholders involved in practice change • Co-develop an implementation strategy design plan, detailing approaches and methods to be used with stakeholders • Reach consensus on implementation plan • Disseminate plans for implementation strategy design across stakeholders involved in practice change	• *Implementation strategy design plan*, including: i. Approach or method for identification of determinants to implementation (i.e., understand what needs to change): methods may include semi-structured interviews with providers and staff, field notes from direct observation of care practices, process maps, thematic analysis of interview transcripts. ii. Approach or method used for implementation strategy design (i.e., how to change practice): methods may include use of implementation mapping process, user-centered design, utilization of compilations of available implementation strategies, including audit and feedback systems, training, facilitation, clinical-decision support, among others)
	8.1.2. Plan for implementation strategy deployment and evaluation	• Develop a plan for implementation deployment and evaluation in practice, detailing approaches and methods • Reach consensus on implementation deployment and evaluation plan • Disseminate implementation deployment and evaluation plan across stakeholders involved in practice change	• *Implementation deployment and evaluation plan*, including: i. Deployment plan: assigned roles and responsibilities for implementation strategies roll-out ii. Implementation evaluation outcomes measures: methods and outcomes (e.g., implementation reach, effectiveness, adoption, implementation, maintenance) iii. Implementation evaluation study design (e.g., before-after study, stepped wedge cluster, etc.)

Domain Area	Process	Activities	Outputs
	8.1.3. Plan for sustainment of improvements	• Develop a plan for implementation sustainability, detailing approaches and methods • Reach consensus on implementation sustainability plan • Disseminate implementation sustainability plan across stakeholders involved in practice change	• *Implementation sustainability plan*: i. Approach or method used to evaluate and ensure implementation sustainability over time: roles and responsibilities for transition of intervention into routine care delivery, sustainability measures and measurement procedures, and action-plans to ensure sustainability over time
8.2. Implementation strategy design	**8.2.1. Identify and prioritize determinants to implementation**	• Enact *implementation strategy design plan*: • Engage with frontline providers and staff who are involved in the implementation effort to understand perceptions of determinants (i.e., barriers and facilitators) that need to be addressed • Collect and analyze data regarding determinants (e.g., semi-structured interviews, direct observations of care practices, process mapping, thematic analysis of interview transcripts) • Document and prioritize list of determinants to be addressed during implementation	• Data collection and analysis regarding determinants to implementation (e.g., thematic analysis from interview transcripts, field notes, focus groups) • Documentation and prioritization of determinants to be addressed (i.e., definition of barriers and facilitators that need to be addressed during practice change)

Domain Area	Process	Activities	Outputs
	8.2.2. Design implementation strategies	• Enact *implementation strategy design plan*: • Co-design implementation strategies with frontline providers and staff involved in care delivery • Prioritize and document implementation strategies for testing and deployment • Disseminate implementation strategy description and objectives with stakeholders involved in care delivery	• Description of implementation strategies to be deployed and tested in practice • Team consensus around implementation strategies to be deployed and tested in practice • Dissemination of implementation strategy description and objectives with stakeholders involved in care delivery
	8.2.3. Pilot test and refine implementation strategies	• Enact *implementation deployment and evaluation plan*: • Pilot-test interventions and implementation strategies in small scale, with sub-set of clinicians and staff involved in care delivery • Collect feedback on strategy performance and refine strategies iteratively based on feedback	• Pilot-test results from small scale implementation • Refined implementation strategies informed by pilot-test results
9.1. Implementation strategy deployment and evaluation	**9.1.1. Deploy implementation strategies**	• Enact *implementation deployment and evaluation plan*: • Deploy implementation strategies at scale according to plan with providers and staff involved in care delivery	• Implementation strategy deployment with providers and staff involved in care delivery

Domain Area	Process	Activities	Outputs
	9.1.2. Ensure fidelity and adaptations	• Enact *implementation deployment and evaluation plan*: • Measure implementation fidelity • Ensure implementation fidelity through action-plans designed to intervene when fidelity is not observed • Identify whether adaptations to clinical interventions and/or implementation strategies are needed to fit context • Promote and document adaptations to clinical interventions and/or implementation strategies, if applicable	• Implementation fidelity measurements • Actions taken to ensure implementation fidelity when fidelity not observed • Description of adaptations made to clinical intervention and/or implementation strategies, if applicable
	9.1.3. Evaluate implementation outcomes	• Enact *implementation deployment and evaluation plan*: • Measure implementation outcomes according to pre-defined measures defined in the implementation plan • Share findings with stakeholders	• Measure results from implementation outcomes (e.g., reach, effectiveness, adoption, implementation, maintenance) • Shared findings from implementation outcomes across stakeholders
9.2. Sustainment of improvements	**9.2.1. Ensure sustainability of improvements**	• Enact *implementation sustainability plan*: • Measure implementation sustainability • Ensure implementation sustainability by transitioning ownership of practice changes to frontline clinicians/providers • Promote corrective action plans to implementation efforts when needed to ensure sustainability	• Measure results for implementation sustainability • Ownership transition from implementation team to frontline providers • Corrective action plans deployed when sustainability is not observed

Guiding Questions for Process Execution

In this section, guiding questions for process execution are presented for all 34 processes.

Foundational

Table 28 - Guiding Questions - Foundational Process Domain Areas 1.1. and 1.2.

Guiding Questions			
1.1. Stakeholder configuration and partnerships		**1.2. Leadership and team values**	
1.1.1. Form the learning community	**1.1.2. Develop and manage partnerships**	**1.2.1. Develop participatory leadership**	**1.2.2. Develop team identity and values**
• What stakeholders and expertise do we need in our "learning community"? • Are any specific stakeholders currently missing in our team as configured? • What is each team member responsible for? Have we delineated roles and responsibilities? • Do we have a Team Roster or Team Charter that clearly identifies all team members, their roles and responsibilities in the team, and their contact information?	• What partnerships do we need to develop within and without the health system? • How do we engage, coordinate, and ensure buy-in from these partners? • Should we engage with patients for their insights regarding our objectives and potential solutions? • If so, how should we plan to engage and coordinate with patients? • What information do we want to collect from patients? • Should we carry out focus groups with patients?	• Are we engaging team members and generating buy-in and motivation? • Are we working well together as a cohesive team? • Do all team members feel like they have had the opportunity to participate according to their preferences and expertise? • Are team members participating as expected according to their respective roles? • Do we have a clear clinical champion leading our work? Who are they? • Does leadership reflect the expectations of the team in terms of participation, collaboration,	• What values should we aspire to develop as a team? • What are our current team values? • Do we agree on what our values are (or should be) as a team? • Are our current values in alignment with our LHS objectives? • Are all team members familiar with our LHS objectives? • What challenges do we face in developing a sense of identity as a team and shared set of values? • What challenges do we face in disseminating the LHS objectives and LHS approach to the team? • Does the language we use as a team reflect our LHS objectives and values?

• Are these documents shared and accessible to all team members?	• How many patients should or could we feasibly engage with throughout the learning cycle? • How often should we engage with patients?	motivation, engagement, and planning? • What can we do to address concerns regarding leadership and participation?	• How do we develop individual and collective agency to achieve our objectives?

Table 29 - Guiding Questions - Foundational Process Domain Area 2.1.

Guiding Questions			
2.1. Defining clinical problems of interest			
2.1.1. Define patient population	**2.1.2. Define clinical questions**	**2.1.3. Define outcomes of interest**	**2.1.4. Define improvement goals**
• What is our clinical population of interest? What clinical conditions do we want to focus on? • Are there sub-groups within the clinical population we need to identify and characterize? • Have we reached consensus around the clinical population and its sub-groups? • What objective criteria should we use to define our clinical population and its sub-groups? • Have we included all relevant team members and partners in defining our clinical patient population? • Have all members of the learning community had the opportunity to participate in discussions relating to defining the clinical patient population? • How is our patient population represented in available datasets? (e.g., ICD codes, codes within the electronic health record-EHR, claims data, etc.)?	• What are we trying to learn about (or from) our patient population? • What are some of the clinical questions we want to answer? What are our learning goals with the LHS? • Have all team members had the opportunity to participate in defining the clinical questions? • Have we documented our clinical questions and learning goals? • Have we reached consensus around clinical questions or learning goals?	• Which types of outcomes are we interested in: patient/clinical care, provider, system or process, cost, or other? • What are the outcomes that matter most to our patients and their care? • What are the objective outcomes measures we are interested in? • Are we currently able to measure the clinical outcomes we interested in? • Are we evaluating the effectiveness of any evidence-base practices or clinical interventions? • Are we evaluating the effectiveness of implementation strategies for adherence to any clinical interventions? (i.e., is this an implementation study?) • Have we included all relevant team members in defining our outcomes of interest? • Are there available resources we may use to develop a set of outcomes measures? (e.g., published standard sets for clinical outcomes / clinical patient population) • Do we have access to these resources?	• What improvement goals are we trying to achieve for each of the outcomes' measures? • What does optimal care look like? What future state do we want to achieve? • Are we able to demonstrate changes of performance over time (i.e., before and after interventions) in the outcomes of interest? • Have team members had the opportunity to participate in defining the improvement goals?

Table 30 - Guiding Questions - Foundational Process Domain Areas 2.2., 3.1. and 3.2.

Guiding Questions			
2.2. Literature review and synthesis	**3.1. Project management**		**3.2. Resources**
2.2.1. Review and synthesize available literature	**3.1.1. Develop and implement a project plan**	**3.1.2. Develop team communication and coordination systems**	**3.2.1. Acquire and manage necessary resources**
• What are some of relevant published studies and/or clinical trials pertaining to our clinical questions? • What are the amin findings from available publications? How credible are the findings? • What does state-of-the-art look like in our field? • What are some of the evidence-based practices identified in published studies? • Who are the main investigators in our field? Do we want to establish partnerships with them? • Are there published sets outcomes measures for our patient population/clinical questions? (e.g., validated patient reported outcomes measures) • Are there significant gaps in the available literature? Can we fill them with our study? • How does our data analysis and conclusions compare with published studies?	• Do we have a project plan to develop our learning cycle? • What are the key activities or phases in the project? What is the timeline? • Have roles and responsibilities been attributed to the activities? • Has the role of project manager been assigned to any individual(s) in the team? • Are there any gaps in expertise for the project manager role? • What project management methodology, tools, and software applications should we use? • Are we on track with our timeline? • What are the key bottlenecks and delays we are facing?	• Do we have communication channels in place for our team? • How often should we meet as a team? • Are we meeting frequently enough to reach our objectives? Are we meeting too much? Are our meetings well attended? • Do we have access to appropriate systems for document sharing? (i.e., document repository and/or online collaboration space or a “commons”)? • Are we sharing deliverables and work products during and in between meetings? • Are we communicating effectively and clearly enough to move the work forward? Are we being concise and efficient in our communication? • What barriers do we face in communicating as a team? Are any individuals failing to meet expectations regarding communication?	• What resources do we need to secure in order to execute our project? • Do we need funding? What are the funding sources available to us? • What are some of the challenges in securing funding and how do we overcome these? • Do we have the appropriate number of people and capacity? Do we need more people? • Do people in our team have enough time to spend in the LHS effort? Do we need extended time availability for our team members? • Do we need access to technical systems or solutions? Do we need offices, spaces, or supplies?

Practice to Data (P2D)

Table 31 - Guiding Questions - P2D Process Domain Areas 4.1. and 4.2.

Guiding Questions			
4.1. Data extraction and integration		**4.2. Data quality and refinements**	
4.1.1. Develop and implement data sources and extraction methods	**4.1.2. Integrate data sources and measure outcomes of interest**	**4.2.1. Ensure standardization of data entry practices**	**4.2.2. Develop and implement a data validation plan**
• What data points do we need to collect in order to measure the outcomes of interest and answer the clinical questions? • Can we access the data we need? • Do we have the expertise and skills required to extract the data we need? • Do we need to develop new technical solutions to be able to collect/extract the data we need? • Have we established and optimized technical solutions for clinician documentation that allows for meaningful data extraction? • Do we need to develop, acquire, and/or implement patient reported outcomes measures?	• Are we integrating multiple data sources into our outcomes' measures? (e.g., data from clinician documentation notes, other sources within EHR, patient reported outcomes, or others) • Have we been able to integrate the data sources into operational measures for the outcomes of interest? • What skills and expertise do we need to integrate our data sources and operationalize outcomes measures?	• Do we have checks in place to ensure data entry/collection/extraction are occurring as planned? • How do we verify that data is being entered as planned? • Are patients responding to patient reported outcomes instruments/questionnaires as planned? • How do we evaluate and ensure patients respond to questionnaires as planned? • Are clinicians documenting care consistently and in a standardized way that produces meaningful data within the EHR? • How do we evaluate and ensure that clinicians are documenting care in a standardized manner?	• How do we verity that extracted data is meaningful? • Do we have a plan to validate and ensure data being extracted is of high quality? • Have we validated extracted data? Do extracted data make sense to clinicians? • Does data visualization meet the needs of the learning community for analysis? • What needs to improve in the data as extracted and visualized? • Are we able to refine data specifications and extraction as needed?

Table 32 - Guiding Questions - P2D Process Domain Areas 5.1. and 5.2.

Guiding Questions	
5.1. Data delivery	**5.2. Data governance**
5.1.1. Develop and maintain a data delivery system	**5.2.1. Develop and maintain meta-data documentation**
• How are we going to deliver data to clinicians? • Where are we going to store data? • Do we have the technical expertise to develop a data delivery system? • Do we have access to technical solutions and applications to enable data delivery? (e.g., access to - and expertise in the use of -platforms such as Tableau or REDCap) • Are data well organized and presented in a clear manner to our team members?	• Do we have a data governance policy? (i.e., detailing who has access to what type of data, and under what circumstances) • What do each of the data elements mean? Do we have a data dictionary to help with interpretation of extracted data? • Do we have a diagram or process map illustrating data flows from data sources to delivery at the point of care? • Have we established responsibilities for each step of the different data flows?

Data to Knowledge (D2K)

Table 33 - Guiding Questions - D2K Process Domain Area 6.1.

Guiding Questions		
6.1. Data analytics & visualizations		
6.1.1. Ensure regulatory compliance	**6.1.2. Develop data analytics and visualization**	**6.1.3. Deploy data analytics and visualization**
• What regulatory compliance requirements to we need to meet? (e.g., IRB, HIPPA, PHI) • Do we know what all the requirements are? • Are we complaint with all regulatory requirements? • Do we need support to ensure compliance?	• How are we going to analyze our data? What type of data analysis best fits out needs? • How should we present findings to front line providers visually? • Do we have or need a statistical data analysis plan? • What statistical analysis techniques should we employ? • Do we want to develop predictive analytics models using machine learning/ artificial intelligence (ML/AI)? • Do we have the expertise and skills to develop a data analysis plan? • Does our data delivery system support our data analytics plan?	• How do we deploy our analytics plan in practice? • Do the data visualizations meet the need of providers at the point of care in terms of understandability, usability, accessibility? • What are the providers' preferences for data visualization? How do clinicians prefer to "see the data"? • What issues are we encountering when deploying our analytics plan? • What technical capabilities do we need? • Do we have the technical capabilities we need? • Do we have people in our team with expertise and skills to deploy our data analysis plan?

Table 34 - Guiding Questions - D2K Process Domain Areas 6.2., 7.1. and 7.2.

Guiding Questions		
6.2. Data flow automation	**7.1. Knowledge discovery**	**7.2. Knowledge dissemination**
6.2.1. Establish data flow automation	**7.1.1. Identify knowledge for dissemination and implementation**	**7.1.2. Disseminate knowledge from data analysis**
• How do we develop a continuous data flow that is automated and updates analysis and visualizations informed by ongoing data extraction? • How do we make knowledge accessible at the point of care to support decision-making? • Do our current data analysis visualization techniques/systems/applications enable quick manipulations and adjustments when needed? • Are we able to delivery data analysis and visualizations to providers on a continuous, automated manner? • Can we rapidly update our findings and data visualization based on ongoing data analysis? • Are the results from data analysis and visualization updated continuously on an ongoing basis?	• Have we analyzed our data and made inferences about the clinical questions? • What have we found out through our data? What were the key findings? • What knowledge has been generated? • What conclusions may be drawn based on the data we have? • Was this new knowledge? How does it compare with findings from published studies? • What are some of the challenges in interpreting findings from data analysis to produce meaningful knowledge? • What practice improvement opportunities might there be based on data analysis? • Do we need any additional data for this analysis?	• Are team members and providers aware of the insights we have generated from data analysis? • How do we disseminate results to frontline providers? • What are the key findings from our learning cycle? • Have we produced generalizable knowledge from which others outside our learning community may benefit? • What is the target audience for our findings? • What are the most appropriate dissemination channels? • What resources do we need to disseminate our findings? (i.e., time, labor for writing manuscripts, development of presentations)

Knowledge to Performance (K2P)

Table 35 - Guiding Questions - K2P Process Domain Area 8.1.

Guiding Questions		
8.1. Implementation planning		
8.1.1. Plan for implementation strategy design	**8.1.2. Plan for implementation strategy deployment and evaluation**	**8.1.3. Plan for sustainment of improvements**
• What stakeholders involved in care delivery should we collaborate with to design and foster change? • How should we improve practice based on the insights we have gained? Do we have a plan for implementation? • How should we plan to identify such challenges? How can we map the opportunities for improvement informed by provider's empirical knowledge and perceptions? • Do we want to interview clinicians to identify barriers and facilitators? • How are we going to analyze interview transcripts? • Are there implementation frameworks we could use? Which ones? • How are we going to promote practice change? How are we going to design implementation strategies? • Are there techniques and resources in the implementation science literature we should use?	• How are we going to pilot test and collect feedback before scale-up implementation? • How are we going to deploy our implementation strategies to change practice? • Who is going to do what and in which timeframe? • How are we going to evaluate whether change was effective and successful? • Should we design an implementation study? If so, what study design should we use? • What implementation outcomes should we plan to measure to evaluate success? • What are the available implementation frameworks we can draw on for this?	• How are we going to evaluate whether improvements are sustained over time? How should we measure implementation sustainability? • How can we ensure implementation sustainability over time after deployment? • How are we going to identify and address challenges to sustainability once we have implemented change with providers? • Who is going to be responsible for ensuring sustainability? • Is our implementation plan aligned with our learning cycle improvement objectives?

Table 36 - Guiding Questions - K2P Process Domain Area 8.2

Guiding Questions		
8.2. Implementation strategy design		
8.2.1. Identify and prioritize determinants to implementation	**8.2.2. Design implementation strategies**	**8.2.3. Pilot test and refine implementation strategies**
• What are the challenges and opportunities for improvements in our current care practices as seen by frontline providers? • Have we identified and documented such opportunities and suggestions for improvement from frontline providers? • What are the key barriers and facilitators that affect the ability of frontline providers in providing high quality care and evidence-based practices? • Have we engaged the appropriate stakeholders for implementation? • How are we going to prioritize barriers that need to be addressed? • Are we facing any challenges in identifying barriers and facilitators in collaboration with frontline providers?	• What strategies should we use to change behavior and implement knowledge into care? • How are we going to standardize care practices according to lessons learned from our data analysis to improve care? • Have we developed and disseminated an "implementation toolkit" to providers (i.e., documents explaining what we are trying to achieve including the strategies and interventions we plan to deploy)? • Are we facing any challenges in engaging with team members to design implementation strategies?	• Who should be involved in the pilot test? • What kind of feedback are we collecting through the pilot test? • Have we pilot tested our interventions and implementation strategies before deploying them at scale? • If so, what were some of the findings from the pilot studies? • Does our pilot test provide encouraging feedback and results? • What needs to change based on the pilot test results? How can we refine our implementation strategy design? • Are we convinced our implementation strategies will work if we scale them?

Table 37 - Guiding Questions - K2P Process Domain Areas 9.1. and 9.2.

Guiding Questions			
9.1. Implementation strategy deployment and evaluation			**9.2. Sustainment of improvements**
9.1.1. Deploy implementation strategies	**9.1.2. Ensure fidelity and adaptations**	**9.1.3. Evaluate implementation outcomes**	**9.2.1. Ensure sustainability of improvements**
• What have been some of the challenges in deploying implementation strategies in practice? • Have we experienced any gaps in expertise, technology, and/or methods during deployment? • What worked well? What didn't?	• Are we facing any resistance to change? • Are people adhering to change? • How are we planning to measure fidelity and ensure implementation is happening as planned? • Have there been challenges in measuring and ensuring fidelity? • Have we identified the need for adaptations? • Are we documenting the adaptations we have promoted? • Have we been facing significant challenges in refining and/or adjusting implementation strategies as needed?	• How are we planning to evaluate effectiveness of the implementation strategies? • Have we defined implementation outcomes we want to evaluate? • Have we been able to demonstrate objectively that the implementation strategies have been successful in improving outcomes? • What are the implementation outcomes of our change effort?	• Are we sustaining improvements? • Have we been able to demonstrate objectively that improvements have been sustained over time? • What have been key challenges in ensuring implementation sustainability over time? • Are there gaps in expertise, technology, and/or methods that need to be addressed to ensure sustainability?

Stakeholder Roles

The degree of involvement of different stakeholders in the learning community varies across learning cycle processes in the PRM according to their roles within the team and specific expertise to be leveraged accordingly. In this section, an analysis of the involvement of the different stakeholder roles across the learning cycle is presented. Firstly, we present a descriptive analysis of stakeholder roles for all processes domain areas throughout the learning cycle model. This provides a description of the role each stakeholder type within the learning community performs in the process according to the process expected output and activities. Secondly, we also present a quantitative analysis with varying degrees of involvement per stakeholder role for each process in the PRM. This provides a score indicating the expected level of involvement for each stakeholder role in the learning community. Table 38 presents the 5-point scale used to represent the varying degrees to stakeholder involvement for each process.

Table 38 - Stakeholder Degrees of Involvement Scale

Degrees of Involvement	
5	Extremely Involved
4	Very Involved
3	Moderately Involved
2	Slightly Involved
1	Not at all Involved

Foundational

Table 39 - Stakeholder Involvement - Foundational Processes

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
1.1. Stakeholder configuration and partnerships	Learning communities are typically formed and led by clinicians focused on a specific clinical condition or patient population. They are typically the ones driving team formation and establishing relationships within and without the health system, including patients.	Data analysts and information system experts provide an integral contribution to the team, and are very involved in forming the team and establishing relationships within and without the health system especially if stakeholders such as the IT department need be involved	Team members involved in operations may be responsible for identifying and engaging with key stakeholders, maintaining documents such as team charter, mission and vision statements, etc. Also, they may be responsible for executing processes related to patient engagement, such as recruiting and organizing and performing focus groups, interviews, etc.	Researchers may be an integral part of the team and should be involved in team formation and establishing relationships that will benefit the work of the team, especially if the team aims to target research audiences	Patient representatives may or may not be involved from the start. When possible, they should be involved in team formation. Their contributions may be key, however, in providing insights regarding their lived experience with the clinical condition under investigation, so their partnerships may be valuable to the team
1.2. Leadership and team values	Leadership practices and team values are driven by clinicians leading the effort. They should foster a sense of collaboration and encourage team members to participate throughout the project according to their roles and preferences.	Data analysts and information system experts may or may not play a key role in developing team values and leadership practices. Analysts may place emphasis on the importance of informatics and data visualizations, and may shape team values.	Operations may or may not play a key role in developing team values and leadership practices. Operations may place emphasis on quality improvement and efficiency of resource utilization, and may shape team values.	Researchers may or may not play a key role in developing team values and leadership practices. Researchers may place emphasis on the importance of scientific discovery throughout learning cycles, and may shape team values	Patient representatives may or may not play a key role in developing team values and leadership practices. They may provide valuable insights about the clinical condition that will shape team values.
2.1. Defining clinical problems of interest	Clinicians will drive decision making when defining the clinical problems of interest that the team will focus on since they hold expertise in the clinical population or clinical condition. Clinicians will be responsible for	Analysts and information systems specialists may provide valuable insights into what data are available and extractable from available systems, which may inform decision making when defining the clinical questions	Operations may play a key role in documenting the definitions or criteria for the patient population, clinical questions, clinical outcomes, and improvement goals. But their role is secondary, as they do	If they hold expertise in the clinical domain, researchers may play a key role in shaping the clinical questions with meaningful insights so the team is able to produce scientific	Patient representatives with lived experience may provide valuable insights regarding the clinical condition, clinical questions that may be explored, as well as potential solutions and interventions. Thus, their involvement in

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
	defining the clinical questions, clinical outcomes of interest, as well as clinical improvement goals.	and clinical outcomes the team will focus on: feasibility of data extraction will impact definition of clinical outcomes measures. But their role is secondary, as they do not hold clinical domain expertise.	not hold clinical domain expertise.	evidence from their learning cycles	defining the clinical problems of interest may be highly beneficial.
2.2. Literature review and synthesis	Clinicians will drive the literature review and synthesis, since they hold expertise in the clinical conditions under investigation and potential solutions.	Analysts may or may not be involved in reviewing and synthesize available literature. They may lack expertise in the clinical condition to provide meaningful insights.	Operations may play a secondary role in reviewing and synthesizing the literature. They may be responsible for documentation and updates.	Researchers may play an important role in reviewing and synthesizing available literature if they hold expertise in the clinical domain.	Patient representatives may not play a role in reviewing scientific literature
3.1. Project management	Clinicians may not play a central role in project management and establishing a team communication system, but their involvement in defining timelines, responsibilities, and tracking progress will be very important. They will be key in defining and updating the project plan. As important users, they will provide feedback on the communication systems the team develops.	Analysts may play an important role in defining activities and timeline regarding parts of the project related to informatics and data analysis design solutions. Analysts may not play a central role in managing the project.	Operations plays a central role in managing the project. The project manager in the team should lead the definition and execution of the project plan, engaging with team members throughout the project according to their roles. Operations will also play a central role in establishing a team communication system, including defining the platform the team will use to share documents and establishing meeting agendas and frequency.	Researchers may not play a central role in project management and establishing a team communication system, but their involvement in defining timelines, responsibilities, and tracking progress will be important. They will be valuable in defining and updating the project plan. As important users, they will provide feedback on the communication systems the team develops.	Patient representatives may not plat a key role in project management. They should be consulted for availability and communication preferences.

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
3.2. Resources	Clinicians should be involved in identifying needed resources and may play a role in obtaining resources within and without the health system	Analysts should be involved in identifying needed resources and may play a role in obtaining resources within and without the health system	Operations are responsible for identifying needed resources by consulting all team members, documenting needed resources and, finally, ensuring that needed resources are available for the learning cycle	Researchers should be involved in identifying needed resources and may play a role in obtaining resources within and without the health system	Patient representatives may or may not be involved in identifying resources the team will need

Table 40 - Stakeholder Involvement Quantitative Analysis - Foundational Processes

		Learning Community Stakeholders				
Process		**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
1. Team Configuration, Leadership, and Values	1.1.1. Form the learning community	5	4	5	4	2
	1.1.2. Develop and manage partnerships	5	4	4	4	4
	1.2.1. Develop participatory leadership	5	3	3	2	1
	1.2.2. Develop team identity and values	5	3	3	3	1
2. Clinical Problems of Interest Definition	2.1.1. Define patient population	5	2	3	3	4
	2.1.2. Define clinical questions	5	3	3	4	4
	2.1.3. Define outcomes of interest	5	4	3	4	3
	2.1.4. Define improvement goals	5	2	3	3	2
	2.2.1. Review and synthesize available literature	5	1	3	4	1
3. Work Planning	3.1.1. Develop and implement a project plan	3	1	5	2	1
	3.1.2. Develop team communication and coordination systems	2	2	5	2	1
	3.2.1. Acquire and manage necessary resources	3	2	5	2	1

Practice to Data (P2D)

Table 41 - Stakeholder Involvement - P2D Processes

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
4.1. Data extraction and integration	Clinicians will be involved in defining the data the team will need to measure the outcomes of interest. They will work closely for information technology experts in the team to develop data extraction methods and data sources within the health system	Analysts will play a key role in developing, implementing, and optimizing data extraction methods. They will work with clinicians to understand and meet their needs, and are responsible for data integration.	Operations will play a supportive role in developing, implementing, and optimizing data extraction methods. They may facilitate the work, document work products, and manage project activities with stakeholders	Researchers may play a role in data extraction and integration, if they are involved in shaping the research questions and data analysis approach	Patient representatives will not be involved in data extraction and integration
4.2. Data quality and refinements	Clinicians will play a role in developing and implementing data quality and refinements. They may provide input in planning for how the team will establish checks to data entry and data analysis are happening as planned. They may also play a key role in executing data entry as planned (i.e., via clinical notes documentation, for example), and may be responsible for validating data extraction and analysis as conducted by analysts.	Analysts will play a central role in developing and implementing data quality and refinements. They will consult with clinicians in planning for data quality. They will be involved in ensuring data entry happens as planned, and will be responsible for validating data extraction and analysis with clinician end users	Operations may play an important role in developing and documenting data quality and refinements plans, and in ensuring plans are executed as expected. They may be involved in implementing data quality checks for data entry and data validation with clinician end-users.	Researchers may play a role in developing and implementing data quality and refinement plans. They may be interested in investigating data quality concerns through experimental research methods and in using best practices that may be available in the scientific literature.	Patient representatives not be involved in data quality and refinements

5.1. Data delivery	Clinicians may play a role in planning for, implementing, and validating the data delivery system. As end users, they will provide valuable input regarding usability, accessibility, and usefulness of data delivery systems at the point of care	Analysts play a central role in developing, maintaining, and updating the data delivery system as needed. They are responsible for understanding clinician end-users' needs and ensuring data delivery is usable, accessible, and useful.	Operations may play an important role in developing and maintaining a data delivery system. They may document requirements and potential solutions, and facilitate project management activities with stakeholders.	Researchers may be involved in developing data delivery systems if they are investigating methods and exploring the scientific evidence regarding data delivery	Patient representatives may be involved in data delivery if they are an end user to data visualizations. If so, they will provide input and feedback on data delivery to ensure delivery systems meet their needs
5.2. Data governance	Clinicians may be involved in data governance, by providing valuable input to develop a data-dictionary, data flow diagrams, and governance policies.	Analysts will play a key role in developing and maintaining data governance policies, data dictionaries, and data flow diagrams, as they hold expertise in data management	Operations may play an important role in facilitating development and documenting data governance policies, as well as data dictionaries and data flow diagrams	Researcher may be involved if they are investigating methods and exploring the scientific evidence regarding data governance	Patient representatives may not be involved in data governance

Table 42 - Stakeholder Involvement Quantitative Analysis - P2D Processes

		Learning Community Stakeholders				
Process		Clinical	Analytics	Operations	Research	Patients
4. Data Extraction	4.1.1. Develop, implement and optimize data sources and extraction methods	4	5	3	3	1
	4.1.2. Integrate data sources and measure outcomes of interest	2	5	4	3	1
	4.2.1. Ensure standardization of data entry practices	4	5	4	2	1
	4.2.2. Develop and implement a data validation plan	4	5	4	2	1
5. Data Management	5.1.1. Develop and maintain a data delivery system	2	5	4	2	1
	5.2.1. Develop and maintain meta-data documentation	3	5	5	2	1

Data to Knowledge (D2K)

Table 43 - Stakeholder Involvement - D2K Processes

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
6.1. Data analytics & visualizations	Clinicians will be involved in developing the data analytics plan, as they define the clinical questions and outcomes of interest for the team. They may provide support with ensuring the team is compliant with all regulatory requirements for data use	Analysts will play the key role in developing and deploying data analytics plan. They are responsible for development and deployment activities, and obtaining validation from clinicians and/or researchers	Operations may plan an important role in ensuring the team is compliant with all regulatory requirements by identifying what those are and managing activities with stakeholders. They may plan an important role in facilitating development and deployment of analytics plan	Researchers may plan important role in defining the data analytics plan and deploying models, especially if the team is exploring advanced predictive analytics such as machine learning/artificial intelligence.	Patient representatives will not be involved in data analytics and visualizations
6.2. Data flow automation	Clinicians may play a secondary role in establishing data flow automation. They may provide input and validate final solutions, but may not responsible for execution	Analysts will be responsible for developing the systems that allow for data flow automation, repeatability, updates, and manipulations of data analysis and visualization	Operations may plan an important role in establishing data flow automation, by facilitating and managing project activities with stakeholders	Researchers may play an important role in establishing data flow automation if they are investigating scientific evidence regarding information systems	Patient representatives will not be involved in establishing data flow automation
7.1. Knowledge discovery	Clinicians will play a key role in interpreting data analysis results and identifying knowledge to be implemented in practice from the scientific evidence	Analysts will play an important bit supportive role in interpreting data analysis results. Statisticians may be important to clarify the data and enable interpretations by clinicians.	Operations may play a supportive role in documenting findings and managing project activities with stakeholders to facilitate the identification of scientific evidence from data analysis	Researchers may play an important role in interpreting findings from data analysis and identifying knowledge to be implemented in practice from the scientific evidence, if they hold expertise in the clinical domain	Patient representatives may play a minor role in providing input regarding their lived experience to support identification of knowledge from

					data analysis interpretation
7.2. Knowledge dissemination	Clinicians may play an important role engaging stakeholders within and without the health system for knowledge dissemination. Within the health system, they will be responsible for identifying and ensuring buy-in from providers and staff involved in care delivery to prepare for practice change. Without the health system, they may identify communication channels and engage with the proper audiences for knowledge dissemination	Analysts may play a role in disseminating knowledge by providing support for data analysis interpretations and synthesis. They may participate in documenting the resulting analysis that will be used in knowledge dissemination	Operations may play an important role in facilitating knowledge dissemination within and without the health system. They may provide support in documenting, identifying target audiences and communication channels, and manage project activities with stakeholders	Researchers may play a key role in knowledge dissemination. They may be involved in manuscript writing and submissions for journals and conferences. If researchers are involved in knowledge implementation activities, they may play a key role in disseminating findings to an internal audience within the health system to prepare for implementation	Patient representatives may play a role in knowledge dissemination if the team decides to target the broad public for knowledge dissemination purposes. Patient representatives may also provide input regarding knowledge dissemination to fit the wider public audience

Table 44 - Stakeholder Involvement Quantitative Analysis - D2K Processes

		Learning Community Stakeholders				
Process		Clinical	Analytics	Operations	Research	Patients
6. Data Analysis and Visualization	6.1.1. Ensure regulatory compliance	3	2	5	4	1
	6.1.2. Develop data analytics and visualization	5	5	4	4	1
	6.1.3. Deploy data analytics and visualization	4	5	4	4	1
	6.2.1. Establish data flow automation	2	5	4	2	1
7. Knowledge Generation and Dissemination	7.1.1. Identify knowledge for dissemination and implementation	5	3	3	4	1
	7.2.1. Disseminate knowledge from data analysis	5	3	4	3	1

Knowledge to Performance (K2P)

Table 45 - Stakeholder Involvement - K2P Processes

	Stakeholder Roles				
Domain Area	**Clinical**	**Analytics**	**Operations**	**Research**	**Patients**
8.1. Implementation planning and coordination	Clinicians will play a key role in implementation planning as they are directly involved in care delivery and will provide valuable input to prepare for practice change. They may be involved in all steps of planning, including strategy design, evaluation, and sustainment.	Analysts may provide valuable input in developing the implementation evaluation plan. If the team pursues to develop an implementation study, analysts may contribute with study design and implementation outcomes measurement	Operations will play an important role in planning and coordinating for implementation. They may manage project activities related to planning for implementation, including strategy design, evaluation, and sustainment. Operations specialists with expertise in quality and process improvement will provide valuable feedback	Researchers will play a key role in implementation planning and coordination if they hold expertise in implementation science and knowledge translation. They may provide valuable input to shape plans for implementation strategy design, evaluation, and sustainment with available implementation science tools and frameworks	Patients may play a role in implementation planning if their involvement is valuable in collecting input regarding practice change
8.2. Implementation strategy design	Clinicians will play a key role implementation strategy design. They will provide valuable input regarding barriers and facilitators they face in practice, as they are directly involved in care delivery. They will also provide valuable input regarding potential strategies to be used	Analysts may play an important role in implementation strategy design if this includes digital strategies such as alerts or clinical decision support. Analysts and information technology and science professionals will provide value expertise for digital strategies	Operations may play an important role in implementation strategy design, managing project activities with stakeholders and documenting work products. Operations specialists with expertise in quality and process improvement will provide valuable input for strategy design	Researchers with expertise in implementation science will provide valuable input for strategy design, including available techniques and frameworks used in determinants identification implementation strategy design	Patients may provide valuate input regarding barriers and facilitators to care, if they are to be addressed with implementation strategies for practice change

9.1. Implementation strategy deployment and evaluation	Clinicians will play a central role in deploying implementation strategies, as they are directly involved in care delivery.	Analysts may play an important role in implementation evaluation, if implementation studies are conducted.	Operations will play a key role in coordinating and managing project activities with stakeholders. The may also document work products and ensure study designs are conducted as planned.	Researchers will play a key role in implementation evaluation, if they hold expertise in implementation science methodology and techniques.	Patients may play a role in deployment if they have in role in practice change
9.2. Sustainment of improvements	Clinicians will play a central role in sustaining improvements, as they are directly involved in care delivery and will be responsible for ensuring processes and workflow changes are maintained	Analysts may play an important role in evaluating implementation sustainability over time, by establishing data collection and analysis mechanisms for sustainability measurement	Operations will play a key role in managing project activities with stakeholders and ensuring sustainability of improvements according to plan	Researchers will play a key role in ensuring implementation sustainability, if they hold expertise in implementation science methodology and techniques.	Patients may play a role in sustaining improvements if they have a role in practice change

Table 46 - Stakeholder Involvement Quantitative Analysis - K2P Processes

Process		Learning Community Stakeholders				
		Clinical	Analytics	Operations	Research	Patients
8. Designing Practice Change	8.1.1. Plan for implementation strategy design	5	1	5	5	1
	8.1.2. Plan for implementation strategy deployment and evaluation	4	2	4	4	1
	8.1.3. Plan for sustainment of improvements	4	2	5	4	1
	8.2.1. Identify and prioritize determinants to implementation	5	1	4	4	3
	8.2.2. Design implementation strategies	5	1	4	5	3
	8.2.3. Pilot test and refine implementation strategies	5	2	4	4	2
9. Promoting Practice Change	9.1.1. Deploy implementation strategies	5	1	4	3	2
	9.1.2. Ensure fidelity and adaptations	4	1	5	4	1
	9.1.3. Evaluate implementation outcomes	5	4	4	5	1
	9.2.1. Ensure sustainability of improvements	5	4	4	4	1

Project Management

As configured, the process reference model (PRM) suggests a sequence of processes to be performed in practice by various stakeholder within an LHS. Apart from serving as a reference for capability measurement, the PRM also supports project management activities for capability development. While the sequence of processes indicates an overall progression of learning cycle phases that cascade down from the Foundational phase to the K2P phase, the development and execution of the specific processes within phases may occur concurrently or iteratively at times. For example, when defining clinical questions and outcomes of interest, in the Foundational phase, the team may not yet have access to data, as they may have not yet established any data collection, extraction, and/or analysis processes. Once these data collection practices are implemented and executed, the newly available data may either restrict the team's ability to answer the original clinical questions given data feasibly issues and/or challenges collecting the appropriate data sources, for example. In this case, the team may need to go back and revise its clinical questions according to the data that are feasibly collected. Alternately, newly collected data may instead allow for an expansion of the clinical questions: the data may highlight insights the team had not been considered when formulating its initial objectives for the LHS. Thus, the iterative nature of the learning cycle in practice indicates that the PRM should not be seen as a list of processes to be implemented and executed invariably in a sequential manner during a project. Rather, concurrent and iterative applications of the processes are recommended.

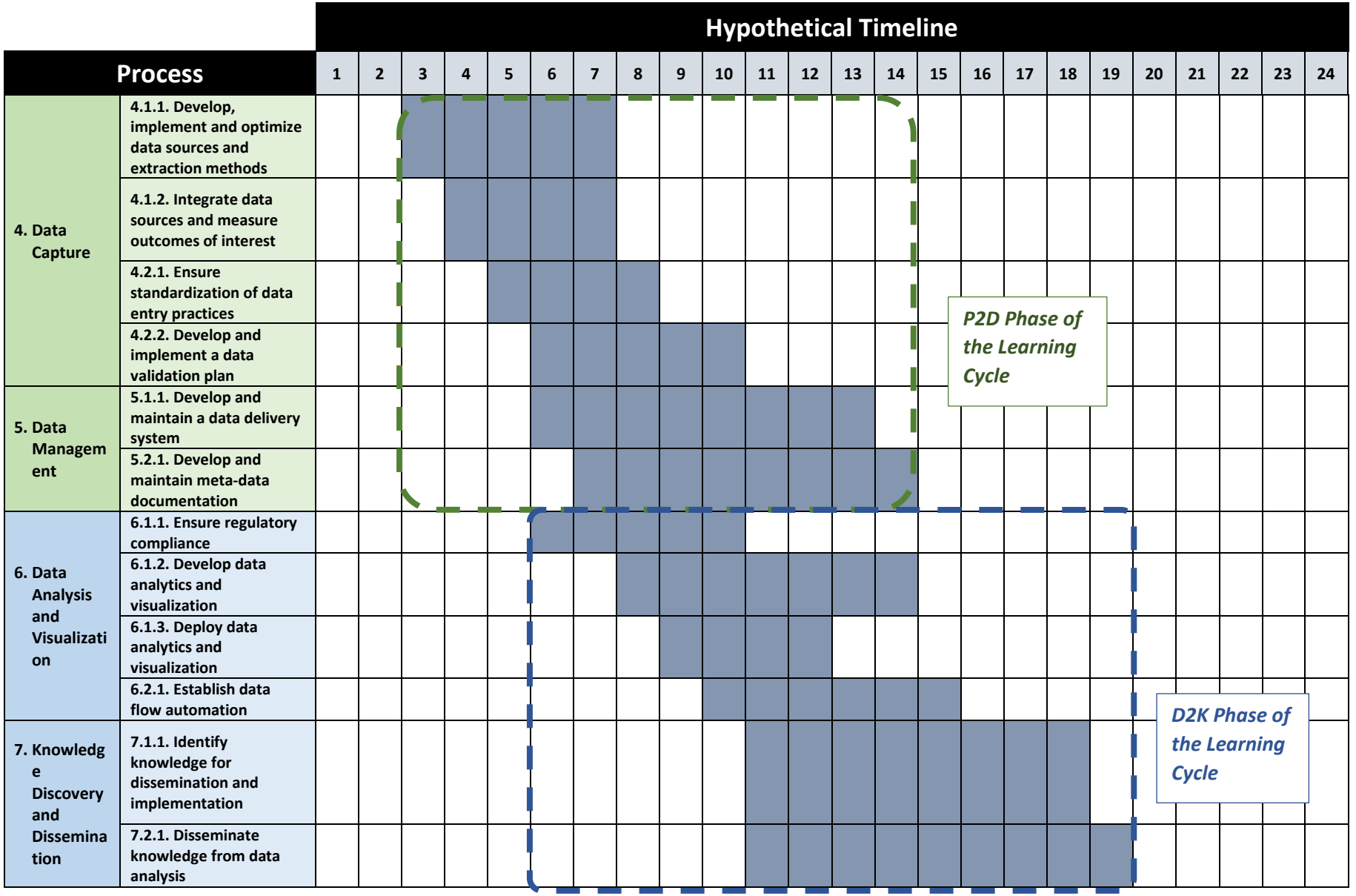
In practice, the development of learning cycle capabilities often occurs through projects. A timeline and budget may be allocated for specific teams, as well as roles and responsibilities for the implementation and execution of specific processes in the learning cycle. This is done so the LHS objectives are achieved within resource constraints that are imposed by the organizational context. The PRM is intended to facilitate project management by providing a list of processes to be implemented and executed in practice and serving as a reference to foster team discussions. Table 47 illustrates a hypothetical

Gantt-chart for an LHS development project, including the list of processes in the PRM to be executed within a given timeline. As portrayed, the learning cycle phases and processes are presented sequentially in the chart, but may be implemented concurrently and iteratively according to the practical needs of the team. Measurements for time and other resources required for the completion of learning cycle phases may provide the basis for an evaluation of LHS development, and prepare for optimization efforts seeking to identify and address the relevant infrastructural factors to shorten lead times. Thus, the PRM provides a standard that may apply to multiple learning communities concurrently in the health system and facilitate the work of project managers and staff allocation. This is intended to reduce lead time by providing a roadmap through which learning cycles may be developed with more agility. Project management best practices, including agile project management approaches, may be facilitated with the use of the PRM. It is important to note that not all processes as described in the model may apply to all learning communities and to all LHS programs. Therefore, processes should be edited, removed, or added as needed according to context-specific characteristics.

Table 47 - Process Reference Model - Support for Project Management

Process		Hypothetical Timeline																							
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1. Team Configuration, Leadership, and Values	1.1.1. Form the learning community																								
	1.1.2. Develop and manage partnerships																								
	1.2.1. Develop participatory leadership																								
	1.2.2. Develop team identity and values																								
2. Clinical Problems of Interest Definition	2.1.1. Define patient population																								
	2.1.2. Define clinical questions																								
	2.1.3. Define outcomes of interest																								
	2.1.4. Define improvement goals																								
	2.2.1. Review and synthesize available literature																								
3. Work Planning	3.1.1. Develop and implement a project plan																								
	3.1.2. Develop team communication and coordination systems																								
	3.2.1. Acquire and manage necessary resources																								

Foundational Phase of the Learning Cycle


Hypothetical Timeline
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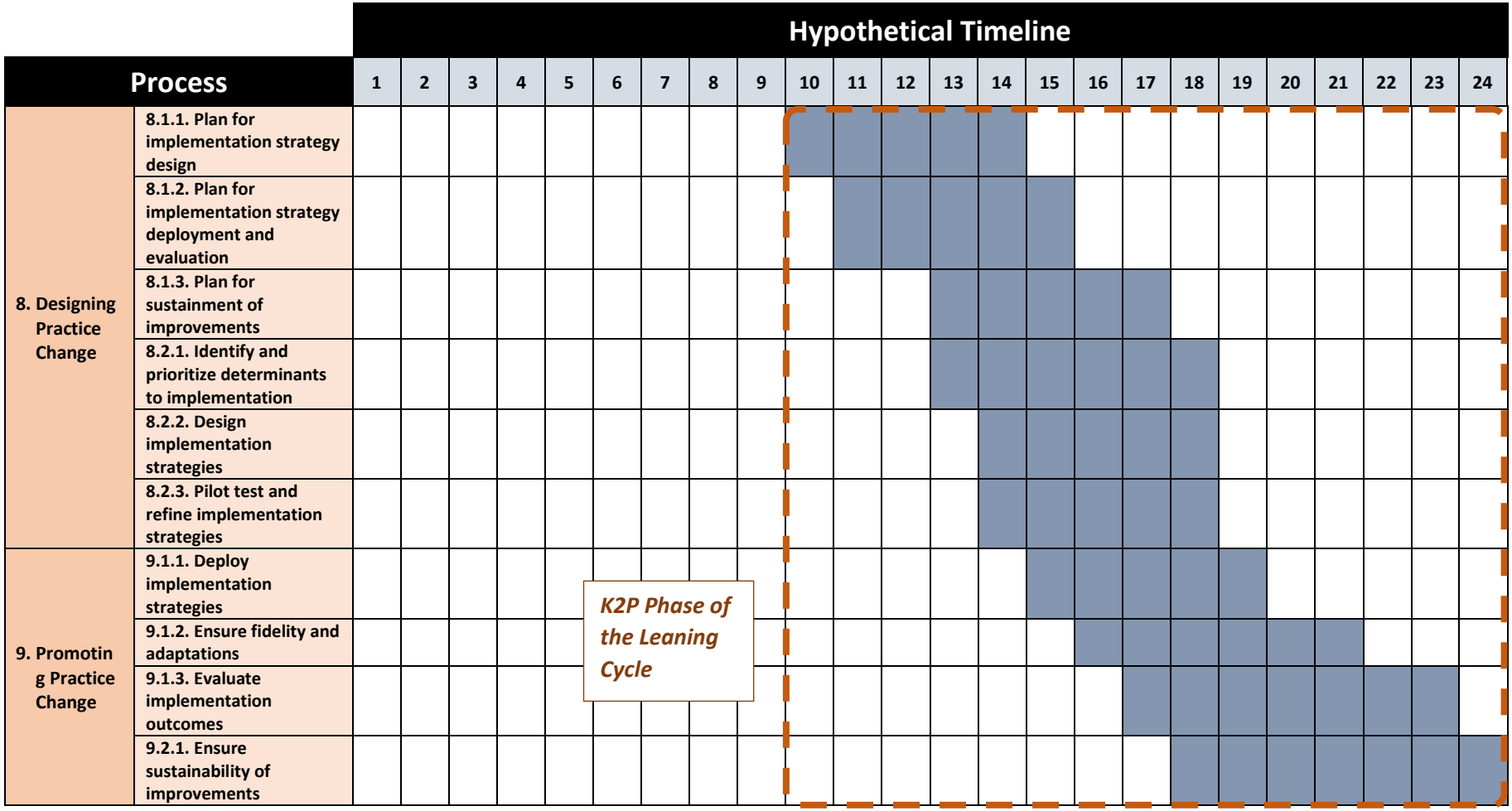
4. Data Capture
4.1.1. Develop, implement and optimize data sources and extraction methods
4.1.2. Integrate data sources and measure outcomes of interest
4.2.1. Ensure standardization of data entry practices
4.2.2. Develop and implement a data validation plan
5. Data Management
5.1.1. Develop and maintain a data delivery system
5.2.1. Develop and maintain meta-data documentation
6. Data Analysis and Visualization
6.1.1. Ensure regulatory compliance
6.1.2. Develop data analytics and visualization
6.1.3. Deploy data analytics and visualization
6.2.1. Establish data flow automation
7. Knowledge Discovery and Dissemination
7.1.1. Identify knowledge for dissemination and implementation
7.2.1. Disseminate knowledge from data analysis
P2D Phase of the Learning Cycle
D2K Phase of the Learning Cycle


Hypothetical Timeline
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8. Designing Practice Change
8.1.1. Plan for implementation strategy design
8.1.2. Plan for implementation strategy deployment and evaluation
8.1.3. Plan for sustainment of improvements
8.2.1. Identify and prioritize determinants to implementation
8.2.2. Design implementation strategies
8.2.3. Pilot test and refine implementation strategies
9. Promoting Practice Change
9.1.1. Deploy implementation strategies
9.1.2. Ensure fidelity and adaptations
9.1.3. Evaluate implementation outcomes
9.2.1. Ensure sustainability of improvements
K2P Phase of the Leaning Cycle

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