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The Foundational Science of Learning Health Systems

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Introduction

The National Academy of Medicine's *Future of Health Services Research* report (1) called for researchers to better address the system-level priorities facing health care organizations, patients, and communities to achieve meaningful impacts in population health outcomes. The report strongly recommended that future research initiatives support close partnerships with health care organization leaders and the end-users they serve (e.g., patients, providers, and communities) to ensure their priorities are addressed. When aligned with health care organization and end-user priorities, health services research has great potential to facilitate translation of research into practice that support population health goals (e.g., access, outcomes, equity, experience, and value) in health care organizations and communities.

Moreover, U.S. health care organizations are increasingly embracing learning health systems (2-4) and the Quintuple Aim framework (improve access, outcomes, equity, experience, and value of care) to better align research with health care organization goals (5-6). The National Academy of Medicine defined learning health systems (LHSs) as when "science, informatics, incentives, and culture are aligned to support continuous improvement, innovation, and seamlessly embed knowledge and best practices into research and care delivery (2)." An LHS is led by a learning community comprised of health care organization leaders, investigators, end-users, and other affected groups who identify shared health priority goals and support continuous, standardized processes that curate multi-level data for ongoing research and quality improvement initiatives that support meeting these goals.

Funding priorities therefore need to be aligned with these NAM recommendations in order to incentivize investigators to conduct partnered LHS research focused on Quintuple Aim goals. Nonetheless, LHSs are impeded by lack of funding sources to enable their development and investigator involvement (7). Differences in research and quality improvement timelines and regulations also impede their ability to sustain research and quality improvement initiatives over time (8). LHSs require upfront administrative and data analytics infrastructure to enable involved

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parties to set priorities, plan and conduct the research and quality improvement initiatives, curate and maintain primary and secondary data over time, and ensure compliance with research and quality improvement regulations (9). While investigators can garner external research funding, this typically supports hypothesis-driven scientific inquiry but not the required infrastructure to enable ongoing administration and data curation to optimize LHS functions. Moreover, research and quality improvement efforts are siloed due to different regulations regarding data curation and intervention monitoring (e.g., research clinical trials require ongoing monitoring and pre-specification of interventions and analyses). Research can take years to achieve results whereas health care organization leaders need answers more quickly, impeding opportunities to directly inform improvements in health system goals (8).

To better align national research funding with population health goals, an updated scientific agenda is needed to support innovations in development and sustainment of LHSs. Foundational research that optimizes the LHS infrastructure and capacity enables health care organizations to better align research with quality improvement goals to improve Quintuple Aim goals. Current LHS-focused funding mechanisms focus on training opportunities in LHS core competencies for early-career investigators (10-12), such as in implementation science, informatics, systems science, and end-user engagement. Yet for health care organizations to fully take advantage of trainees' new knowledge, new funding mechanisms are needed that are grounded in scientific inquiry but also can be directly applied to improve LHS infrastructure, ultimately sustaining a repeatable process of generating new research and quality improvement initiatives to improve population health.

In light of the NAM Future of Health Services Research and Learning Health System reports, we propose an updated scientific agenda for funding agencies to support innovation in development and sustainment of learning health systems, in order to align research with health care organization and Quintuple Aim goals. This scientific agenda encompasses LHS foundational methods derived from the Agency for Healthcare Research and Quality LHS core

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competencies (10, 13) and funding mechanisms and priorities based on the U.S. Department of Veterans Affairs (VA) Office of Research and Development (ORD) Health Systems Research program (14-17). LHS scientific agenda foundational methods include implementation science, data science, engagement science, systems science, and policy analysis. Each method has a research and quality improvement goal, e.g., research validating implementation strategies informs how providers directly implement treatments in routine practice, thus enabling LHS research innovations to be applied directly to quality improvement in health care organizations.

Learning Health System Scientific Agenda

ORD's Health Systems Research program is applying the LHS scientific agenda (17) to better align the research priorities of investigators with the needs of VA clinical operations partners in order to ensure substantial real-world impacts on Quintuple Aim outcomes for Veterans. As an embedded research program within the VA's national health care system, ORD funds VA-employed investigators to conduct research across the translational spectrum on Veteran-focused health priorities. Specifically, ORD's Health Systems Research program funds investigators to conduct innovative research on the overall organization, financing, and delivery of care in the VA health care system in order to improve Veteran Quintuple Aim goals (access, outcomes-quality/safety, equity, experience, value) using LHS foundational methods (implementation science, data science, engagement science, systems science, policy science) (16-17). Health Systems Research also supports the Quality Enhancement Research Initiative (QUERI), which is funded separately through VA clinical services, enabling VA investigators to conduct quality improvement projects and curate data more quickly in the VA health care system (14-15). Hence, ORD provides a unique opportunity to align separate funding sources to support research and quality improvement efforts to achieve common Quintuple Aim goals using LHS methods.

Table 1 describes the foundational methods that encapsulate the LHS scientific agenda,

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with examples of research and quality improvement initiatives for implementation science (18), data science (19), engagement science (20), systems science (21-23), and policy science (24-25). The examples provided are cross-cutting rather than disease- or condition-specific per recommendations from the NAM Future of Health Services Research report in order to promote scientific advancements that impact the health system as a whole.

Figure 1 describes how these foundational methods support LHS infrastructure and processes needed to achieve health system and Quintuple Aim goals. These methods can inform innovations in infrastructure, and, through repeatable cycles of research and quality improvement initiatives, achieve health impacts for a given priority. The figure is based on ORD's application of the Learning Health System Learning Cycle (4, 9, 15) in research and quality improvement funding mechanisms (14). LHS foundational methods inform the infrastructure through engagement of the learning community to set priorities, guiding the LHS data curation process using data science/informatics innovations, and by studying and applying systems, implementation, and policy strategies that promote the discovery and uptake of evidence-based interventions into practice.

The LHS cycle begins with the formation of a learning community, comprised of health care organization leaders, investigators and end-user representatives (e.g., patients, providers, community members), who agree on a shared priority goal. Examples of priority goals that have been studied in ORD using LHS methods include suicide prevention, opioid use/pain treatment, access to virtual care, and precision oncology (16, 26-27). Initial work starts with the performance to data (P2D) phase where the learning community commissions investigators to work with health care organization leaders and end-users to develop a population-based cohort using existing data to ascertain gaps in Quintuple Aim measures. In the data to knowledge (D2K) phase, investigators identify determinants impacting gaps in Quintuple Aim measures, incorporating external evidence (e.g., systematic reviews) and generating new evidence (e.g., new clinical trials, longitudinal studies, or informatics interventions). This phase involves

collection of new data that are added to the population-based cohort for future research and quality improvement initiatives. In the third phase, knowledge to performance (K2P) involves application of foundational LHS methods such as implementation strategies to scale up and evaluate evidence-based interventions and determine their overall population health impact, often yielding new information on Quintuple Aim gaps for the cycle to be repeated.

Learning cycles can be short-term to achieve a health care organizational goal, or longer-term when there is a need for a more definitive clinical trial. An example of a short-term (6-month) VA-based Learning Cycle (28) included assessment of gaps in vaccination rates, mixed-methods data collection to identify individual perspectives regarding vaccine preferences, and implementation and evaluation of communication strategies to encourage vaccination among VA patients. Another example involved ascertainment of gaps in pediatric surgical outcomes using electronic health record data (performance to data), assessment of effective strategies that reduce complications (e.g., with wound closures), and applying those strategies in routine practice (knowledge to performance) (29). Longer-term cycles typically involve research protocols and include, for example, detection of a health care disparity, understanding the origins of the disparity, and testing an intervention mitigating the disparities in a given practice setting (30). Assessment of outcomes from the intervention study may also discover new observed gaps in quality and equity among subpopulations that in turn inform a repeated cycle of investigation and improvement.

Ultimately, the Learning Cycle enables health care organizations to identify, rigorously study, and apply effective tools or strategies that are derived from LHS foundational methods to improve Quintuple Aim goals. Repeatable cycles of research and quality improvement in turn can also in turn inform innovations in the LHS foundational methods. For example, foundational research in implementation and engagement science informs how health care leaders and investigators can better cultivate and incorporate end-user perspectives into the co-design of interventions and implementation strategies. Investigators who design a new patient

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engagement process for eliciting input on clinical interventions can also apply a similar process to identify new priorities for the next iteration of the Learning Cycle. Data and systems science methods help optimize clinical workflows to enable more efficient study of new interventions or quality improvement practices (e.g., patient-level precision health data to inform clinical trials eligibility, ambient dictation into the electronic health records to mitigate provider workload). Innovations in the data, systems, and implementation sciences can improve automation of quality improvement processes such as audit and feedback or process mapping. Policy science can inform how new health care payment models or regulatory relief can improve quality of care, strengthening health care organization leadership support for ongoing research intervention or quality improvement initiatives.

Examples of Learning Health Systems

The following are two examples of U.S. health care organizations that have implemented LHSs. Both have lessons for building and sustaining LHSs using different funding sources and enterprise-wide infrastructure using LHS foundational methods.

Vanderbilt University Medical Center leveraged funding from its health care organization and the NIH's National Center for Accelerating Translational Science Clinical and Translational Science Award Program to fund the Learning Health Care System (LHS) Platform (31). Using LHS data science methods, the Platform uses electronic health record data to deploy pragmatic trials of new medications and other interventions such as community-based care coordination for opioid use disorder (32), or implementation strategies to improve clinician prescribing (33). The LHS platform also uses engagement and systems science, where end-users select priority topic areas (Performance to Data) and help design the research and ensure outcomes and methods fit with clinical workflows (Data to Knowledge). Investigators and clinical partners also apply point of care randomization in the overall study execution to maximize rigor (Knowledge to Performance).

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In VA, the Women's Health Research Network (WHRN) involves over 75 clinical practice sites that support research and quality improvement to enhance delivery of evidence-based care tailored to women Veterans (34). Using engagement science, WHRN gathers rapid Veteran feedback on gaps in access and quality of care to inform shared research and quality improvement goals among VA leaders and investigators (Performance to Data). WHRN also supports investigators to develop new research interventions (Data to Knowledge) and implementation strategies to disseminate research findings into practice (Knowledge to Performance) (35). While the WHRN supports the infrastructure needed for multi-site research initiatives, investigators also are involved in the QUERI-funded Enhancing Mental and Physical Health of Women through Engagement and Retention (EMPOWER) program, which supports ongoing data curation and quality improvement initiatives addressing WHRN priorities (36).

Conclusions

The LHS scientific agenda articulates the core foundational methods that enable investigators, health system leaders and end-users to work together to study and apply tools that improve population health for a given health care organization priority. These foundational methods along with the Learning Cycle also provide funding agencies with an LHS research roadmap for how discovery simultaneously supports innovation, health system improvements, and Quintuple Aim Goals. By identifying performance gaps in Quintuple Aim goals using existing data, LHSs enable health care organization and investigators to curate more comprehensive data and knowledge (evidence) supporting interventions that address these gaps, and then their scale-up to improve overall performance and population health goals.

Ideally, well-funded LHSs support investigator and clinical operations teams to conduct research and quality improvement projects focused on a shared health priority goal, facilitating extraction and analyses of data from electronic health records and other sources (e.g., health information exchanges, mobile technologies). To this end LHSs leverage both internal health

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care organization and external (e.g., federal, private foundation) sources to support the learning community to gather input and priorities from affected users as well as the personnel to support the infrastructure to manage and sustain the LHS over time (7). Internal funding sources are essential to ensure leadership buy-in, notably through administrative support of learning communities and for seamless data curation for the benefit of health systems operations and research. Joint funding enables adequate support for a stable group of LHS personnel including statisticians, informaticists, clinical trialists, and mixed-methods experts, who generate the data, work with investigators to help design research and quality improvement study protocols, conduct analyses, and work with the learning community to disseminate/publish results. Well-funded LHSs also support system-level studies including pragmatic trials that use outcomes from electronic health record data (31-33), as well as develop and evaluate novel clinical decision support or artificial intelligence tools. With population-based data, LHSs can also measure Quintuple Aim goals efficiently and with sufficient numbers across subpopulations.

Overall, there is an urgent need for funding agencies to invest in research that enhances discovery and innovation in these foundational methods so that LHSs can be more effective and efficient in improving Quintuple Aim goals and overall population health. Both research funders (e.g., VA, AHRQ, NIH) and health care organizations need to co-invest in the infrastructure and processes that enable LHS functioning in order to ensure innovation and discovery of new tools, methods, and processes so that patients can benefit from the most up-to-date treatments, technologies, and information in a continuous, equitable fashion (37). More stable sources of funding for LHS foundational methods also can incentivize investigators to partner with health care organization leaders to achieve population health impacts on shared priority goals, thereby addressing the persistent barriers to translation to practice. Health care organizations in turn benefit from the application of well-established LHS methods to ultimately improve Quintuple Aim goals for those they serve.

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Table 1: Scientific Agenda for Learning Health System Foundational Methods

Foundational Method	Description	Benefit to End-users (e.g., Patients, Providers)	Examples of research topics linked to Quintuple Aim goals	Application to quality improvement
Implementation Science	Scientific study of strategies used to promote the uptake of effective interventions or treatments real-world settings, especially when faced with organizational constraints (also referred to as knowledge translation)	Ensures "what we know is what we do" on a routine basis and that effective innovations get to patients and communities more quickly	Rigorous assessment of value (e.g., cost-effectiveness) of the effectiveness of specific implementation strategies to improve effective practice uptake and enable end-users to "own" implementation process (sustainment)	Application of artificial intelligence in deployment of implementation strategies to enhance equity, end-user experience and outcomes Deployment of dissemination of implementation playbook for health system leaders that outlines strategies to support ongoing maintenance of effective practices
Data Science	Use of computable biomedical and social knowledge in practice, incorporating inter-disciplinary fields, e.g., statistics, scientific computing, informatics, artificial intelligence, measurement, anthropology, and knowledge management	Clinical, patient-centered outcomes, and social determinants data can be leveraged to help improve patient care, outcomes, and experience in a way that ensures privacy and equity	Effectiveness of machine learning, predictive models to improve treatment decision-making Validation of data captured beyond health care (e.g., social media, conversational analysis) in predicting health outcomes Ethics of using data science tools and applications including potential for algorithmic bias	Application of artificial intelligence (e.g., natural language processing and deep learning) to improve provider efficiency and patient care experience Monitoring ethical uses of data at the patient and provider levels including privacy mechanisms
Engagement Science	Systematic incorporation of input from affected groups to inform all stages of the scientific process, from identification of the scientific question to dissemination and sustainment of health care interventions, findings, and products	Involving patients, providers, and other interested groups ensures treatments, programs, and policies work for end-users, and that lived experiences are considered	Develop and test novel strategies to optimize input and involvement of patients, caregivers/families, providers, communities Engagement strategies that leverage existing networks of end-users to promote sustained involvement to ensure care equity, access, and experience	Application of user-centered design or co-design of effective interventions and implementation strategies to improve practice uptake Social network analysis to optimize communication and impact of community partner input and experience on health care improvement

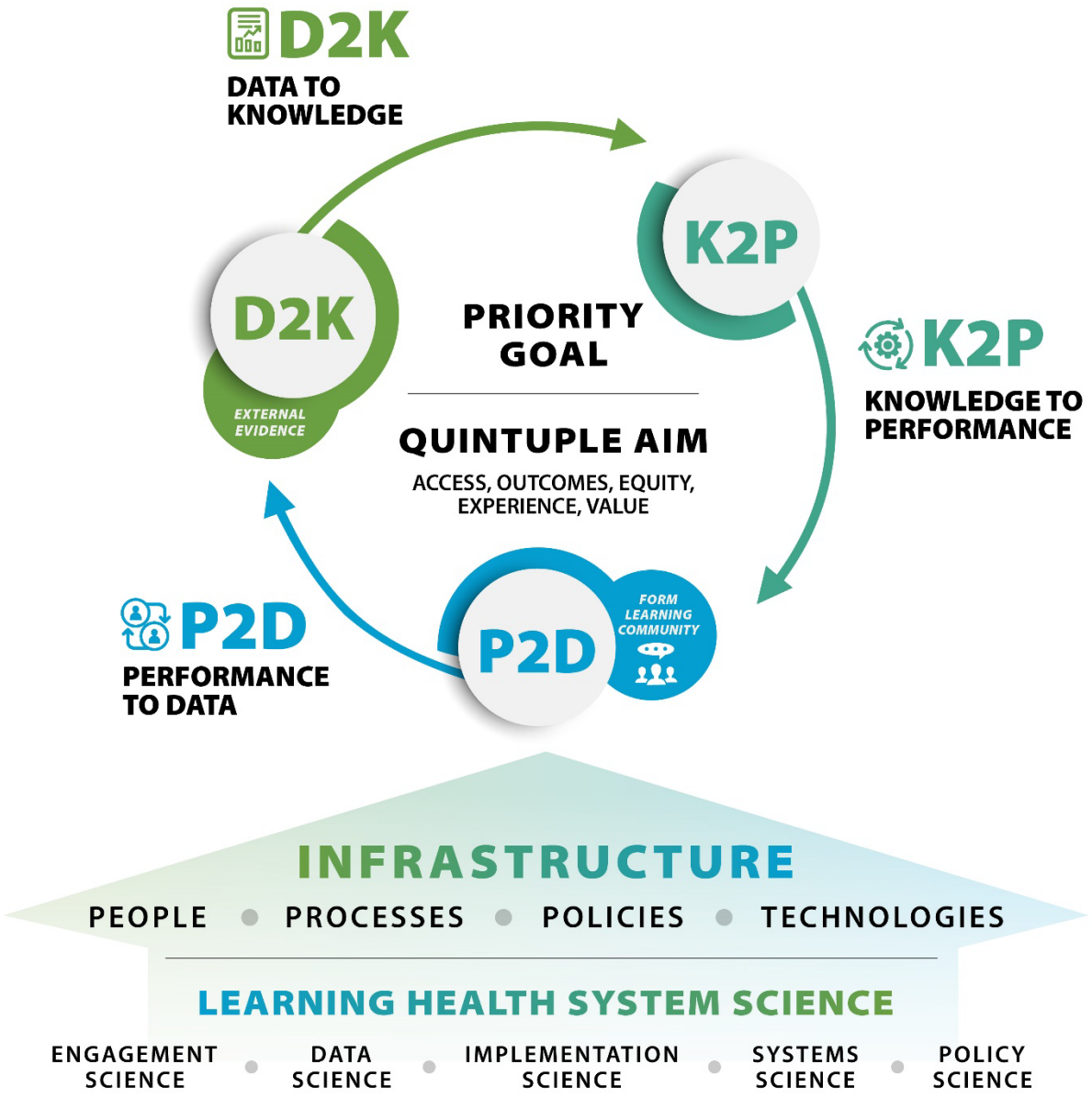
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Systems Science	Process of understanding how health care is delivered in an organization and identifying how this complex adaptive system of people, processes, and resources can improve services and outcomes for patients (also includes health systems engineering, complexity or organizational science)	Health care and health go beyond condition and disease labels; it takes a wider lens to understand the moving parts of the enterprise to improve them and to ensure safe and effective care	Develop and validate systems science or engineering models including high-reliability and mechanistic models to enhance the effectiveness, quality, safety, and efficiency of health care, and whether processes can be replicated/adapted to other settings	Ethnography and process mapping of clinic workflows to improve efficiency of different care models Embedding new tools or models of care in clinical settings (e.g., virtual reality, collaborative care) to improve care experience, outcomes
Policy Science	Process of using scientific methods to determine if, how, and in what capacity programs, policies, or interventions work at the population level, and using the findings to inform improvements to the way programs and policies are delivered (e.g., evidence-based policymaking)	Many health problems have determinants outside the clinic walls, and need to improve alignment and effectiveness of programs, benefits, and policies to ensure optimal patient outcomes	Develop and evaluate programs or policies addressing social determinants of health, e.g., benefits (e.g., housing), legislative mandates, national clinical standards of care, justice programs on health equity and outcomes; Assess impacts of health care workforce recruitment and retention initiatives, policies on access to care (e.g., nursing)	Evaluation of value-based payment models and other payment policies, treatment formularies, clinical reminders, or performance incentives

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Figure 1: How Learning Health System Foundational Methods

Support Quintuple Aim Goals



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