

## Development of the Learning Health System Researcher Core Competencies

### Abstract

**Objective:** To develop core competencies for learning health system (LHS) researchers to guide the development of training programs.

**Study Design:** The competencies were developed from August to December 2016. Qualitative methods were used to elicit, refine, and prioritize the competencies.

**Data Collection/Extraction Methods:** The process started with a systematic literature review, which formed the basis for the initial draft of a competency domain framework. Key informant semi-structured interviews, a modified Delphi survey, and three expert panel (n=19 members) consensus development meetings were done to produce the final set of competencies.

**Principal Findings:** The iterative development process yielded seven competency domains: (1) Systems Science; (2) Research Questions and Standards of Scientific Evidence; (3) Research Methods; (4) Informatics; (5) Ethics of Research and Implementation in Health Systems; (6) Improvement and Implementation Science; and (7) Engagement, Leadership, and Research Management. A total of 33 core competencies were prioritized across these seven domains.

**Conclusions:** The LHS researcher core competencies can be used to guide the development of learning objectives, evaluation methods, and curricula for training programs.

**Key Words:** learning health system; health services research; stakeholder engagement; graduate education; professional competence

## **Introduction**

The learning health system (LHS) is a novel and rapidly evolving approach for improving the outcomes of individuals, populations, and health care organizations. As defined by a 2012 Institute of Medicine report, the LHS combines research, data science, and quality improvement, yielding knowledge as a by-product of the patient-clinician interaction (Roundtable on Value & Science-Driven Health Care, 2012). An essential and distinguishing attribute of the LHS is the engagement of patients and families in its governance, research studies, and improvement projects.

Several trends have been converging over the past several years to create the context for the LHS emergence. There is widespread recognition that health care suffers from pervasive and persistent gaps between available evidence and its application in clinical practice (Mangione-Smith et al., 2007; McGlynn et al., 2003), which has resulted in significant health system investments in quality assessment and improvement. As a result of a mix of incentives and penalties implemented by the U.S. Department of Health and Human Services' Office of the National Coordinator of Health Information Technology and Centers for Medicare & Medicaid Services, the proportions of office-based physicians and hospitals that use electronic health records (EHRs) reached 88% and over 98%, respectively, as of 2015 (The Office of the National Coordinator for Health Information Technology, 2017). The widespread use of EHRs has digitized health care in ways that allow for repurposing of clinical information to support quality improvement efforts and patient-centered outcomes research (Cimino, 2007). Innovative approaches to improving health care have demonstrated that by engaging patients and physicians in communities organized around a common purpose—such as improving the health of patients with a particular disease—significant advances in outcomes can be achieved (Crandall et al., 2012).

Although there have been calls to create a national-scale LHS (Friedman, Wong, and Blumenthal, 2010), to align academic medical centers around the vision of the LHS (Grumbach, Lucey, and Johnston, 2014), and to develop specialty-specific networks organized to promote the LHS across institutions (Forrest et al., 2014; Kwon et al., 2012), there has been limited attention given to the unique attributes of LHS researchers and the skills and knowledge assets they need to be successful. The aim of this project was to address this need by developing and prioritizing a set of core competencies to guide the design, implementation, and evaluation of training programs for LHS researchers. We adopted a prior definition of competencies as knowledge- or skill-based assets that trainees should acquire during their training (Forrest et al., 2009). Core competencies are those that should be common to all training programs. Each competency will have associated learning objectives, which describe the educational and experiential approaches for achieving it. Although the end-results (i.e., competencies) of training programs should be similar, the approaches used to attain them (i.e., learning objectives and evaluation methods) will differ. This manuscript does not propose specific learning objectives, curricula, or methods that could be used for each competency.

## **Methods**

The development of the LHS researcher competencies occurred in three phases. Most of the work was completed during three consensus development meetings with a 19-member expert panel. The

panelists included experts in patient-centered outcomes research, statistics, epidemiology, health services research, quality improvement and implementation science, and informatics—from both the public and private sectors—as well as practicing clinicians and patients.

We started by developing an LHS researcher definition and a domain framework to organize the competencies. This first phase involved a literature review, semi-structured interviews with key informants, and a consensus development meeting with the expert panel. During the second phase, the panel formed 10 writing teams and drafted specific competencies. These were reviewed and revised during a second consensus development meeting. The final list was winnowed based on a modified Delphi survey of the expert panel and a final consensus development meeting. Each of these activities is described below.

### ***Literature Review***

To start the competency development process, we conducted a literature review (August 2016) to identify LHS conceptual frameworks and definitions and to generate an initial competency domain framework. Starting with seminal articles and reports that describe structures and functions of the LHS (Etheredge, 2007; Forrest et al., 2014; Friedman et al., 2010; Greene, Reid, and Larson, 2012; Roundtable on Value & Science-Driven Health Care, 2012), we identified relevant medical subject heading (MeSH) terms that have been used to index LHS literature in MEDLINE to construct search strategies. The MeSH terms were combined with free-text terms using Boolean operators to search PubMed. Because of the relative novelty of the field of LHS research, no time restrictions were applied to the search results. The search was limited to the English language, humans, and the United States. We supplemented the list of articles retrieved from MEDLINE with additional searches using Google Scholar and a review of reference lists of identified articles. These methods produced 197 articles. The full text of each article was reviewed by two members of the project team; those that provided a conceptual framework or definition of an LHS (n=23) were reviewed more thoroughly. We extracted a list of LHS functions from these articles, produced a preliminary competency domain framework, and drafted an initial definition of an LHS researcher.

### ***Key Informant Interviews***

To ensure the completeness and clarity of the domain framework, we conducted eight semi-structured interviews with key informants with expertise in LHS research or health services research. Additional feedback was obtained from six health services research training directors, each of whom led a training program funded by the Agency for Healthcare Research and Quality. These 14 individuals provided a critical review of the LHS researcher definition, the competency domains, and the specific competencies. Their feedback was reviewed and discussed during the second and third expert panel meetings.

### ***Expert Panel Meetings***

We convened an expert panel (n=19 members) to develop a definition of an LHS researcher, the competency domain framework, and the specific competencies. The panel integrated the information from the literature review and key informant interviews during its deliberations. It met three times—twice for in-person, all-day meetings, and once by teleconference.

During the first meeting, the expert panel agreed to adopt the Institute of Medicine's 2012 definition of an LHS in order to guide further work: [A system in which] “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience” (Roundtable on Value & Science-Driven Health Care, 2012). After examining the literature review, the panel produced an initial competency domain framework and the definition of an LHS researcher.

### ***Development of Individual Competencies***

The expert panel formed writing teams for each of 10 initial domains. The teams were charged with drafting competencies relevant to their domain. A total of 91 competencies were produced at this stage. We then asked the 19 panel members to provide ratings on a 5-point Likert scale from not at all important (1) to extremely important (5) for LHS researchers. These ratings and additional comments from the full panel review of the competencies were used during the second consensus development meeting of the expert panel. During that meeting, the 91 competencies were winnowed to 67.

### ***Modified Delphi***

Between the 2<sup>nd</sup> and 3<sup>rd</sup> expert panel meetings, we conducted a modified Delphi survey in which panel members rated the importance of each of 67 competencies on a scale from 1 (low) to 9 (high). These ratings were used to produce a prioritized list of competencies during a final in-person expert panel meeting. For each competency, the median and the percentage of respondents giving a competency a high rating, defined as between 7 and 9, were computed. Only those competencies with a median of at least 7 and  $\geq 75\%$  of panel members rating it between 7 and 9 were evaluated for retention in the final list.

## **Results**

### ***Definition of an LHS Researcher***

Guided by the 2012 Institute of Medicine's definition of an LHS (Roundtable on Value & Science-Driven Health Care, 2012), our literature review, and expert-panel discussion, we iteratively revised a definition of an LHS researcher, producing the following final version:

*An 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.*

The embedded characteristic of an LHS researcher is a key distinguishing feature. The researcher must be part of the system as an employee or invited partner who leads or assists with the development, conduct, implementation, and dissemination of research designed to address questions of interest to the stakeholders within the health system. This embeddedness allows the LHS researcher to execute research in such a way that does not disrupt day-to-day operations, and it

ensures that the investigator has an appreciation for the perspectives of those operating the system and those receiving its care. Researchers who are not part of the system, but use data collected within health systems, would not be considered LHS researchers because they are not embedded.

The expert panel took a broad view of the concept of a *health system* as one or more organizations that restore or promote individual or population health. These organizations could be primary care centers, academic medical centers, hospitals, retail clinics, or other organizational models that focus on improving health. The term *stakeholder* refers to patients, caregivers, clinicians, system leaders, improvement specialists, and other individuals who interact to carry out the functions of the health system. Finally, the word *rapidly* was used to connote the need in LHS research to ensure prompt and efficient knowledge generation and application to meet the needs of the patients, clinicians, and leaders within health care organizations.

### **Domain 1: Systems Science**

During the early stages of competency development, the themes of using systems thinking to develop and implement LHS projects; understanding the structures, functions, and outcomes of health systems and how they interrelate; and using systems theories in LHS research were highlighted across multiple competency domains. During the final consensus development meeting, the expert panel concluded that systems science is an essential and distinguishing attribute of LHS research, meriting its own domain (**Table 1**). Knowing how to conduct research and implement its findings in the context of complex systems will benefit from a deep understanding of systems science.

LHS researchers must be able to design and conduct research within the context and complexity of an operational health system. This ability requires an understanding of how health systems are led, how they operate, how health care is delivered, and how the varied components of the health system work together to produce care and outcomes. LHS researchers must also be able to rapidly apply new knowledge generated from research to system stakeholders. In addition, the ability to facilitate rapid implementation of new knowledge generated from research requires an understanding of the complexity of health systems and an ability to demonstrate how research activities will contribute to the quality, equity, and value of the health system.

### **Domain 2: Research Questions and Standards of Scientific Evidence**

This competency domain addresses the need to ask *meaningful* research questions, engaging stakeholders in their elicitation and prioritization, and critically analyzing scientific evidence with special relevance to a health care organization (**Table 2**). LHS researchers should investigate questions that are important not only to scholars and experts in the field, but also to the LHS researcher's health care organization, its patient population, and its clinicians. Research questions should build on prior research, although some questions that confirm prior evidence or provide insights into sub-populations served by the LHS are appropriate. An important feature of the LHS researcher is that research questions must be considered meaningful to patients, families, clinicians, or system leaders. This means that the LHS researcher must understand such features of a health system as its structures and functions, and the financial and non-financial incentives that affect

stakeholder behavior. Although LHS research can and should be rigorous, its focus is the applicability of findings to the care settings and populations of the health system.

### **Domain 3: Research Methods**

This competency domain addresses the use of models and frameworks, selecting and evaluating appropriate study designs, outcome measurement, and data analysis for research done within the context of a health system (**Table 3**). All LHS researchers need to know how to design and analyze intervention studies using experimental (individual- and cluster-level randomization) and quasi-experimental approaches (Stürmer and Brookhart, 2013; Wagenaar and Komro, 2011) that permit the estimation of the effect of treatments or interventions. They must know how to design mixed method studies to understand how, why, for whom, and in what contexts a given intervention works, and how a model can be amended to work in new settings. When the research question involves the translation and spread of innovations, the issues of concern are: How and why does the intervention work? What works for whom and in what contexts? How can a model be amended to work in new settings? Based on the goal of the analysis, researchers should be able to explain the criteria for choosing a statistical model and for selecting the model parameters. They should also be able to interpret and explain the analysis and inferences made within the context of a particular LHS.

LHS researchers need to understand and apply principles of measurement science to the selection and assessment of outcomes as well as to moderators and mediators of these outcomes within an LHS. Although most LHS researchers will not develop new measures or need to be expert in modern psychometric theory, they do need to be able to identify, incorporate, and interpret a range of health outcome measures appropriately and understand the limits of the measures available. In addition to measurement error, reliability, and validity, LHS researchers should be familiar with a variety of psychometric properties including normative reference samples, sensitivity to change, and differential item function.

### **Domain 4: Informatics**

Informatics focuses on the science of information, and the technologies, processes, and personnel involved in the use of information. The LHS is a paradigm for the continuous transformation of data to knowledge to action, and for which informatics is a core capability. Informatics is by nature multidisciplinary, and LHS researchers must possess a broad understanding of informatics and be able to communicate effectively with experts in multiple areas (**Table 4**).

LHS researchers need to be capable of identifying outcomes from EHRs and methods for combining various signals of a specific outcome of interest from disparate data fields using validated algorithms. LHS researchers need to understand the limits of outcome data from the EHR, and the importance of augmenting outcome measurement by incorporating new measures that will increase temporal density for within-subject analyses (e.g., daily blood pressure versus blood pressure at each visit) or that will assess outcomes that are important to patients and other stakeholders (e.g., patient-reported symptoms and care experiences) while minimizing respondent burden. LHS researchers also should be able to identify additional data sets that can be linked to the EHR to expand the measures available (e.g., area-level data on environmental influences of health linked via geocodes).

Finally, LHS researchers should be able to identify and incorporate data from the rapidly expanding digital traces that patients provide from personal wearable and home sensors.

### **Domain 5: Ethics of Research and Implementation in Health Systems**

Training for clinical and health services research has long had an ethics component, and specific standards for training in the responsible conduct of research is required of clinical research trainees. Areas of focus of research ethics training typically begin with protection of human subjects. It is critical that researchers understand the underlying principles (and their origins in the Belmont report and subsequent policies and regulation) and how the current regime of institutional review boards, with Federal oversight, operationalizes them. Privacy of health information is covered by specific regulations (e.g., Health Insurance Portability and Accountability Act), but it is important that the ethical principles underlying these are understood. In addition, research ethics training should provide knowledge and skills to understand and manage potential conflicts of interest, and issues of research integrity.

The above ethical principles and concepts generally apply to all clinical and health services research. However, additional ethics training and skills for conducting research and implementation while embedded in LHSs will be needed (**Table 5**). The categories outlined above will largely be the same, but the competencies within each may differ. For example, pragmatic, cluster-randomized trials in which whole clinical units may be assigned to one or another care delivery mode raise new issues regarding appropriate notification and consent (Platt, Kass, and McGraw, 2014).

Ethical issues in engagement of patients, clinicians, and health system leaders in research and implementation activities may also require additional attention in training programs. While privacy issues have always been part of research ethics, new uses of large amounts of LHS data collected in the course of routine care require different training for researchers. Finally, a defining feature of LHSs is the rapid implementation of research evidence and further rapid cycle improvement in systems to reliably implement best practices for patients, tailored to individual circumstances and preferences. Ethics training must, therefore, include attention to activities on the borderline between research and improvement, and the ethical issues related to each (Finkelstein et al., 2015).

### **Domain 6: Improvement and Implementation Science**

LHS researchers need the skills to apply and integrate the knowledge generated from research at the point of care (**Table 6**). Functioning LHSs generate new knowledge as a natural outgrowth of patient care (Roundtable on Value & Science-Driven Health Care 2012). This requires near-real-time data aggregation, analysis, and evaluation to prompt changes that feed back into the system to improve care delivery (Wysham et al., 2016). LHS researchers should understand traditional quality improvement methods and the relationship to research performed in the LHS. They must also be able to apply principles of quality measurement that can be used to assess process improvements. This includes employing systems engineering processes and control tools to study and design interventions that can be utilized to support implementation such as clinical decision support along with teamwork, leadership, engagement, and change management methodologies. It is critical that

researchers in LHSs consider specifically how implementation of innovations or improvements can help to mitigate health and health care disparities to promote health system equity.

### **Domain 7: Engagement, Leadership, and Research Management**

A special skill that LHS researchers must employ is being able to engage diverse health system stakeholders in all aspects of the research process (**Table 7**). Engagement refers to the deliberate practice of identifying and integrating diverse stakeholders as active participants in the planning, execution, and application of research studies and results. The unique perspectives, experiences, and skills of each stakeholder group are recognized as valuable and critical to achieving study goals and improving outcomes. Dissemination involves the distribution of new knowledge and effective communication of the implications of this knowledge across diverse stakeholder groups and to the public at large. Engagement and dissemination within an LHS requires a unique set of skills and knowledge due to the diversity and interactions of the stakeholder groups, the complexity of the health care system, and the desire to improve care in a timely manner.

LHS research is unique in its pragmatic approach. It requires researchers to be keenly aware of clinical and research operations, and organizational governance and culture related to research. Because the results are practical and meaningful to system stakeholders, the LHS researcher may rely on institutional financial support as a major source of sponsorship. Finally, researchers must conduct their work and disseminate their findings on shorter timelines than conventional clinical research.

### **Discussion**

The LHS researcher core competencies described in this report were developed using an iterative, multi-method process to elicit, refine, and prioritize 33 knowledge- and skills-based capacities that all LHS researchers should acquire during their training. The core competencies and domain structure generated from this process are intended to provide a framework for designing training programs that will prepare a cadre of LHS researchers ready to consistently address real-world health care delivery challenges; drive improvements; and promote individual, population, and system outcomes. They should be considered a first attempt to define the scope of training for LHS researchers, and will evolve as the field matures. The individual competencies focus on specific assets needed to generate and apply new knowledge within the context of health systems. This real-world context, the embeddedness of the researcher within the health system, and engagement of stakeholders in all aspects of research and improvement are distinguishing characteristics of LHS research.

The core competencies are meant to guide the development or expansion of existing training programs. They do not prescribe the pedagogical or experiential methods by which the skills and knowledge are to be acquired and evaluated. Individual training programs will determine their specific learning activities (teaching strategies, curricula, and participation in LHS activities), approaches for assessing competency achievement, and areas of specialized emphasis. For example, one training program may choose to focus more in-depth training in implementation science, while another may focus more on experimental designs for patient-centered outcomes research. It should be noted that LHS research requires multiple disciplines to work together to produce the science and



translate its results; thus, it is not expected that any one individual will be an expert in all competency domains. However, the LHS researcher must be able to assemble and lead multidisciplinary teams of experts who collectively bring expertise in each of the domains outlined in the framework to realize the broader goals of the LHS.

The expert consensus panel identified *foundational* knowledge and skills that LHS researcher trainees should either possess coming into an LHS training program, or acquire in parallel during their participation in a training program. These competencies include existing health services research competencies (Forrest et al., 2009) and basic knowledge in epidemiology, biostatistics, and clinical research. However, the expert panel highlighted the importance of not requiring a set of foundational competencies as prerequisites for entry into an LHS researcher training program. Such a requirement could have the unintended consequence of limiting training programs to post-graduate health services researchers only.

There are several distinct attributes of research in LHSs that have implications for training their researchers. First, LHS research is concerned with the generalizability of results to the context of an individual system (i.e., external validity). For health systems, research evidence may not need to meet the same standards as medical evidence for clinical decisionmaking; often *good enough* evidence is sufficient to make strategic, operational, or financial decisions. Balancing the desire of health systems for rapidly generated, practical evidence with the rigors of peer-review and scientific standards is one of the key challenges for LHS researchers. Second, the timeline for LHS research does not usually fit the classic grant-funded, 5-year research award. LHS research must capitalize on an imminent policy or program phenomenon needing evaluation and study using a rapid cycle approach. It is often an iterative process with continuous cycles of analysis and feedback and output, rather than a one-and-done study. Third, this cycle of LHS research tends to not fit well with conventional grant funding opportunities. LHS researchers may rely on health systems to invest in their research.

The LHS researcher framework, domains, and core competencies serve as a starting point for further work and discussion. The core competencies are meant to evolve together with LHS science and research. Greater understanding of how the competencies are operationalized with regard to curricula and teaching strategies will inform future iterations. We encourage the use and refinement of the competencies among health systems that are dedicated to the LHS approach and that seek to train individuals in the methods for rapidly advancing and applying new knowledge to improve patient and system outcomes.

## References

- Cimino JJ. Collect once, use many. Enabling the reuse of clinical data through controlled terminologies. *J AHIMA*. 2007;78(2):24-9;quiz 31-2.
- Crandall WV, Margolis PA, Kappelman MD, et al. Improved outcomes in a quality improvement collaborative for pediatric inflammatory bowel disease. *Pediatrics*. 2012 129(4):e1030-41.
- Etheredge LM. A rapid-learning health system. *Health Aff*. 2007 26(2):w107-18.
- Finkelstein JA., Brickman AL, Capron A, et al. Oversight on the borderline: Quality improvement and pragmatic research. *Clin Trials*. 2015 12(5):457-66.
- Forrest CB, Margolis PA, Bailey LC, et al. PEDSnet: a National Pediatric Learning Health System. *J Am Med Inform Assoc*. 2014 21(4):602-6.
- Forrest CB, Martin DP, Holve E, and Millman A. Health services research doctoral core competencies. *BMC Health Serv Res*. 2009 9:107.
- Friedman CP, Wong AK, and Blumenthal D. Achieving a nationwide learning health system. *Sci Transl Med*. 2010 2(57):57cm29.
- Greene SM, Reid RJ, and Larson EB. Implementing the learning health system: from concept to action. *Ann Intern Med*. 2012 157(3):207-10.
- Grumbach K, Lucey CR, and Johnston SC. Transforming from centers of learning to learning health systems: the challenge for academic health centers. *JAMA*. 2014 311(11):1109-10.
- Kwon S, Florence M, Grigas P, et al. Creating a learning healthcare system in surgery: Washington State's Surgical Care and Outcomes Assessment Program (SCOAP) at 5 years. *Surgery*. 2012 151(2):146-52.
- Mangione-Smith R, DeCristofaro AH, Setodji CM, et al. The quality of ambulatory care delivered to children in the United States. *New Engl J Med*. 2007 357(15):1515-23.
- McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *New Engl J Med*. 2003 348(26):2635-45.
- Platt R, Kass NE, and McGraw D. Ethics, regulation, and comparative effectiveness research: time for a change. *JAMA*. 2014 311(15):1497-8.
- Roundtable on Value & Science-Driven Health Care. *The Roundtable*. Washington, DC: Institute of Medicine. 2012.

Stürmer T and Brookhart MA. 2013. Study Design Considerations. In *Developing a protocol for observational comparative effectiveness research: a user's guide*, edited by Velentgas P, Dreyer NA, Nourjah P, et al. Rockville, MD: Agency for Healthcare Research and Quality.

The Office of the National Coordinator for Health Information Technology. 2017. Quick Stats <https://dashboard.healthit.gov/quickstats/quickstats.php>.

Wagenaar AC and Komro KA. Natural experiments: design elements for optimal causal inference. Philadelphia, PA: Public Health Law Research. 2011.

Wysham NG, Howie L, Patel K, et al. Development and Refinement of a Learning Health Systems Training Program. EGEMS (Wash DC). 2016 4(1):1236.

<b>Table 1: Systems Science Competency Domain</b>
<p><b>Domain Definition</b> To understand how health systems operate and how to apply systems theory to research and implementation.</p> <p><b>Competencies</b></p> <p>1.1: Demonstrate knowledge of how systems theories can be used to understand how the interactions of the parts of health systems operate to produce value for stakeholders.</p> <p>1.2: Demonstrate systems thinking in the design and conduct of research and implementation of its findings within the context of complex health systems.</p> <p>1.3: Demonstrate knowledge of the financing, organization, delivery, and outcomes of health care services and their interrelationships.</p> <p>1.4: Demonstrate the ability to assess the extent to which research activities will likely contribute to the quality, equity, or value of health systems.</p>

<b>Table 2: Research Questions and Standards of Scientific Evidence Competency Domain</b>
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<b>Domain Definition</b>
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To ask meaningful questions and evaluate the usefulness of scientific evidence and insights.
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<b>Competencies</b>
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2.1: Demonstrate the ability to compose feasible and timely research questions and hypotheses, incorporating stakeholder priorities, to generate evidence that informs meaningful clinical and policy decisions.
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2.2: Demonstrate the ability to engage with all relevant stakeholders (patients, families, clinicians, and system leaders) in the elicitation and prioritization of research questions that address current and future stakeholder needs.
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2.3: Demonstrate the ability to critically analyze and assess available scientific evidence from peer-reviewed articles, systematic reviews, meta-analyses, and gray literature to identify novel LHS questions and to judge the applicability of the evidence to a local care setting.
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**Table 3: Research Methods Competency Domain**

**Domain Definition**

To conduct research within the context of complex health systems using appropriate study designs and analytic methods to assess outcomes of interest to health systems stakeholders.

**Competencies**

3.1: Demonstrate the ability to use theory and conceptual models in the design and interpretation of LHS research.

3.2: Demonstrate the ability to develop an appropriate observational, quasi-experimental, or experimental study design while mitigating threats to internal and external validity for research that is minimally disruptive to operations in real world health systems and practices.

3.3: Demonstrate knowledge of mixed methods and how they can be used to improve LHS research studies.

3.4: Demonstrate knowledge of how to assess multilevel determinants of health and health care disparities when designing studies.

3.5: Demonstrate the ability to select and interpret appropriate clinical, financial, and patient-centered outcomes of interest based on the concepts they measure and their measurement properties.

3.6: Demonstrate the ability to apply the principles of hypothesis testing and statistical inference to data collected routinely through the course of care as well as supplemental data from patients, providers, and health systems.

<b>Table 4: Informatics Competency Domain</b>
<p><b>Domain Definition</b></p> <p>To know how to use information systems to conduct LHS research and improve patient and health system outcomes.</p> <p><b>Competencies</b></p> <p>4.1: Demonstrate the ability to use data derived from electronic health records and other clinical information sources for research and quality improvement.</p> <p>4.2: Demonstrate knowledge about additional data sources that can be linked to health system clinical data in order to augment exposure and outcome ascertainment.</p> <p>4.3: Demonstrate the ability to assess data quality and apply data quality assurance processes, including error prevention, data cleaning, data monitoring, documentation, and relevant data standards.</p> <p>4.4: Demonstrate knowledge of population health informatics, including disease surveillance, monitoring of community health, assessment of social and behavioral determinants of health, and geographic information systems.</p> <p>4.5: Demonstrate knowledge of clinical information systems, including electronic health records, clinical documentation, computerized physician order entry, clinical decision support systems, electronic prescribing, medical imaging, and clinical/population dashboards.</p>

<b>Table 5: Ethics of Research and Implementation in Health Systems Competency Domain</b>
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<b>Domain Definition</b>
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To ensure that research and quality improvement done in health care settings adheres to the highest ethical standards.
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<b>Competencies</b>
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5.1: Demonstrate the ability to apply ethical principles in the engagement of health systems, including issues of business ethics and the importance of publishing both positive and negative findings in the public domain.
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5.2: Demonstrate knowledge of what activities constitute research as opposed to quality improvement activities and seek appropriate oversight for each.
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5.3: Demonstrate knowledge of specific Health Insurance Portability and Accountability Act requirements associated with varied data sources used in health systems research activities, and seek appropriate approvals.
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5.4: Demonstrate the ability to identify and minimize potential conflicts of interest in the design, conduct, and reporting of research conducted in health systems.
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5.5: Demonstrate knowledge of ethical and legal considerations when engaging in multi-system studies for compliant collaboration and study conduct.
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<b>Table 6: Improvement and Implementation Science Competency Domain</b>
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<b>Domain Definition</b>
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To reduce avoidable variation in process and outcomes and ensure the systematic uptake of research findings in a health system.
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<b>Competencies</b>
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6.1: Demonstrate the ability to employ specific quality improvement methods to reduce avoidable variation in clinical processes and outcomes in routine practice.
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6.2: Demonstrate the ability to employ specific implementation science or quality improvement methods to study and promote systematic uptake of research findings and other effective clinical interventions into routine practice.
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6.3: Demonstrate knowledge regarding when to mount larger efforts to scale up, spread, and sustain successful interventions based on strength of clinical evidence and organizational and provider readiness to change and adopt interventions.
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**Table 7: Engagement, Leadership, and Research Management Competency Domain**

**Domain Definition**

To engage stakeholders in all aspects of the research process and effectively lead and manage LHS research teams and projects.

**Competencies**

7.1: Demonstrate the ability to build and lead research teams with diverse health system stakeholder representation.

7.2: Demonstrate knowledge of the values and communication mechanisms used by stakeholder groups involved in research in health systems.

7.3: Demonstrate the ability to translate, disseminate, and communicate the value proposition and business case for research to diverse health system stakeholders.

7.4: Demonstrate the ability to conduct effective team-based project management, employing skills in leadership, communication, negotiation, consensus building, and problem solving.

7.5: Demonstrate the ability to develop protocols consistent with health systems needs and timelines, employing patient and clinician engagement, and using a mix of conventional and alternative funding sources.

7.6: Demonstrate the ability to implement protocols aligned with health systems operations and integrated into clinical settings, including engaging clinicians in the research process.

7.7: Demonstrate knowledge of participatory research approaches that foster participation and engagement of vulnerable populations.

# LHS Competency Project – Contributors

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# LHS Researcher Competency Framework and Key Definitions

## Learning Health System

A system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience.

**Source:** Roundtable on Value & Science-Driven Health Care. *Best care at lower cost: The path to continuously learning health care in America.* (2012) Washington, DC: The National Academies Press. Washington, DC: Institute of Medicine.

## Learning Health System Researcher Definition

An 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.

- By ***embedded*** we mean that the researcher is part of the system when conducting the research, either as an employee or as an invited guest who assists with the development, conduct, implementation, and dissemination of research.
- ***Health systems*** refer to one or more organizations and individuals that interact to restore or promote individual and population health.
- ***Stakeholders*** are patients, caregivers, clinicians, system leaders, improvement specialists, and other individuals who interact to carry out the functions of the health system.
- The word "***rapidly***" is used to connote the need in LHS research to ensure prompt and efficient knowledge generation and application.
- ***Outcomes*** include health, well-being, care experiences, quality, and costs of care.