

**Where the Rubber Meets the Road: A Learning Health Care System for Australia**  
*A Working Paper Providing a Synthesis of Ideas Drawn from Selected Literature*

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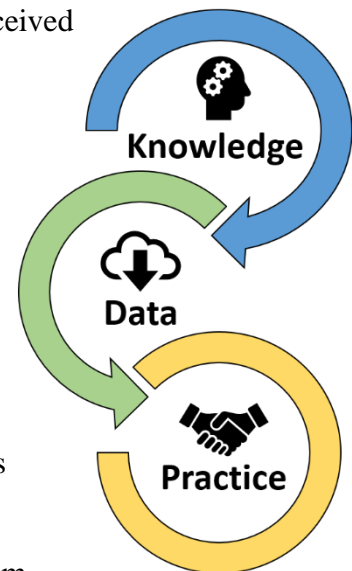
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## Where the Rubber Meets the Road: A Learning Health Care System for Australia

*“If learning is the understanding of how to apply knowledge to patient care, a learning health system distinguishes itself by the capacity to generate new learning, while delivering patient care.”<sup>1</sup>*

### Background

While the idea of organisational learning goes back decades,<sup>2</sup> it received fresh impetus from a roundtable discussion by the Institute of Medicine (IoM) in 2006.<sup>3</sup> The IoM vision of a learning healthcare system (LHCS) has best clinical practice, implementation of research-based knowledge and continual improvement at the core of service delivery.<sup>4</sup> A learning system is at the cross-roads of people and information systems – i.e., it is ‘sociotechnical’ – and is one that enables virtuous learning cycles through an underlying information infrastructure. Through the implementation of virtuous learning cycles, a learning system is informed by evidence and actionable data in ‘real-time’ and creates the foundations of a system capable of meeting systems-wide, clinically-oriented, and patient-relevant delivery targets.<sup>5</sup> In providing context for future models, the Australian Health and Hospitals Association (AHHA) has captured many of the systems-wide factors needed for a LHCS at the national level in a diagram (Appendix 1).

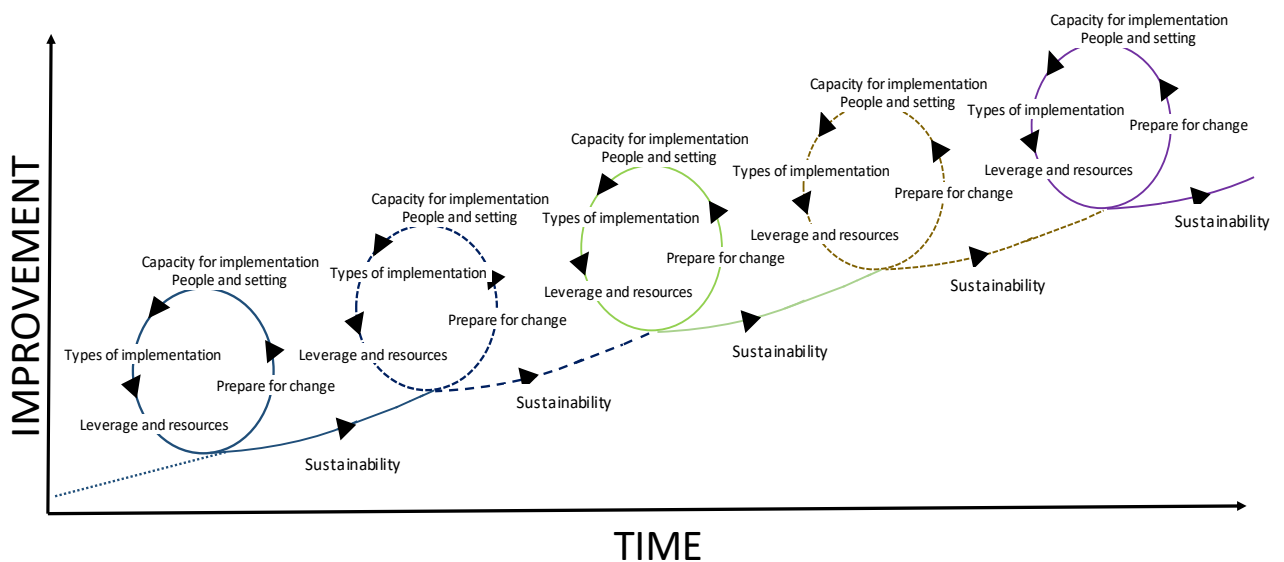


The LHCS is moving closer than ever before, and the next five years will see major developments take place in a series of natural experiments. The LHCS seeks to improve health services and deliver higher value care, through reduction of waste and aligning science, informatics, incentives, and culture to pave the way for continuous improvement.<sup>4</sup> Although previously more theoretical than real, the uptake and incorporation of LHCS models are emerging now. As the LHCS movement gains momentum, the transition allows us a unique opportunity to develop and engineer a health system for the future. The constituent elements of the LHCS infrastructure are being put in place. A starting point is the capacity to harness electronic health record (EHR) data, already in widespread use in general practice, hospitals, and community settings. EHR data can be married with local clinical data, inpatient statistics, financial information, research findings and increasingly available data from wearables and other data sources such as social media, population information on

injuries, accidents, and socio-economic data.<sup>6</sup> In accumulating such information, we can create a data-rich environment and shorten the time it takes to get intelligence into the hands of decision-makers. The goal is to have real-time or close to real-time information available in a useable format to clinicians, patients, managers and policymakers. A well-designed system will speed up the progression of data synthesis to generate knowledge that can be used on the front-lines by healthcare providers, managers and health consumers. It will also interface smoothly with the latest knowledge generated by research, and speed up translation of such knowledge from bench-to-bedside. Incorporating secure and trusted data collection mechanisms that communicate with each other and provide feedback information to a workforce that is skilled in the use of this knowledge are essential to support a LHCS. This, as it is achieved, would be the cornerstone of ongoing healthcare systems reform.<sup>7</sup>

As we engineer the LHCS, getting evidence into practice more rapidly will emerge as a natural by-product of care delivery. All-in-all, the desired infrastructure will ideally collect data which is thoroughly documented and accurate, pooled for continuous analysis and integrated with insights from research and empirical evidence.<sup>8</sup> This data is then fed back into the system to improve the consistency, effectiveness and appropriateness of care. Figure 1 encapsulates core aspects of this improvement model at the systems level.

**Figure 1: Phases of Implementation as Formative Evaluation Feedback Loops (FEFLs)**



FEFLs adapted from Braithwaite J, Marks D, Taylor N (2014) *Harnessing implementation science to improve care quality and patient safety: a systematic review of targeted literature.*<sup>9</sup>

## **Literature scoping review**

To better inform the development of an emerging model, a literature scoping review was conducted in PubMed on August 27, 2018. Appendix 2 provides a snapshot of key articles.

The initial search resulted in 2,706 articles and was sorted by 'best match' to ensure the most relevant literature was captured in this early-phase review. Exclusion criteria were: if the full text was unavailable; discussed irrelevant topics; and language other than English. The search strategy used the terms "learning" and "health system\*" or "healthcare system\*" or "health care system\*". The first 50 articles best meeting the criteria were included and summarised.

## **Discussion**

The literature was mostly normative and aspirational, and portrayed the LHCS in a positive light. Almost no author doubted that creating a LHCS was of critical importance, and some reported strategies to assist in moving towards a LHCS, although progress was mostly early and uneven. Authors recognised the opportunities for decreasing health expenditure, reducing waste and improving care in all aspects of service delivery.

Contributions were thus theoretical with a preponderance of commentary and perspective articles, mostly scene-setting, and which provided an overview as to why this new mode of organisation would be beneficial. Confirming this observation, Budrionis and Bellika (2016)<sup>10</sup> conducted a systematic review on the LHCS which highlighted a lack of empirical evidence. They reported that out of 32 included articles in their review, 13 were empirical and only one described estimates of impact, including on the economy.<sup>10</sup>

There are challenges to today's relatively static health systems transitioning to one predicated on rapid-learning and continuous improvement. Widespread concerns in translating research findings into practice have been identified, notably through the documentation of significant barriers to improving healthcare safety and quality globally.<sup>11</sup> Areas needing attention include:

- Building capacity to conduct pragmatic clinical trials
- Enhancing policy capacity
- Bringing data together in useable forms for differing stakeholders to handle information adeptly
- Applying quality improvement methods on-the-ground
- Factoring in patients' perspectives in care decisions

- Focusing on systems-based rather than individual-based practice and the way change is handled

It will be critical to conduct formative evaluation of LHCS models applied in real-world health settings so that feedback informs progress over time. This remains an important piece of work that is yet to be done.

## **Strategies**

### ***Integrated data and Artificial Intelligence***

Integrated data and Artificial Intelligence (AI) are the foundation of a LHCS and sound infrastructure is essential to both its success and implementation progress. Some authors discussed the kinds of data that may be captured, and how it might be synthesised – research findings, for example, need to be married with patient-reported outcomes, clinician ratings, statistics of recovery time, health service utilization journeys and health economic analyses. Two articles discussed the inclusion of genomics data in the infrastructure of a LHCS as a widely untapped and misunderstood area that has significant potential to improve value and patient care.<sup>12,13</sup> The IoM Roundtable on Translating Genomic-Based Research for Health sought to evaluate both the challenges and opportunities for capturing genomic data in a learning system.<sup>12</sup>

Krumholz et al (2014)<sup>14</sup> discussed avenues in which big data can be harnessed to aggregate health information from patients, populations and organisations, using AI to then draw meaning from this data. A more integrated approach to data storage is required to ensure prediction and performance are at a sufficiently advanced stage, and based on reliable data.<sup>14</sup> According to some experts, the lack of integrated data sharing necessary for the infrastructure of a LHCS may be attributed to three false assumptions: 1) the generalisability of evidence across populations; 2) the stability of evidence over time; and 3) the reduction of evidence into specialised sub-systems that communicate effectively with each other.<sup>15</sup>

Although few empirical studies were captured in the scoping review, one article presents an observational analysis of the Comparative Effectiveness Research Translation Network (CERTAIN), a learning system bringing together hospitals and outpatient clinics across Washington State, USA.<sup>16</sup> Key findings in the study concluded that data operational challenges were a key barrier to implementation.<sup>16</sup> Further to this, Marsolo et al (2015) discussed the strategies applied in transitioning an existing health registry to one that is linked

to the electronic health system. This posed multiple operational challenges, in particular that the current process requires groups to work with individual software vendors.<sup>17</sup> The movement of data and the process of integrating systems may present challenges, particularly in the Australian context. This is due in part to Australian health providers' lack of standardised record management software, with the Australia wide EHR interfacing separately with each software vendor. Many practice management systems require lengthy and manual movement of patient record data into the secured national system, My Health Record (<https://www.myhealthrecord.gov.au/>).

### ***Reducing the time from bench-to-bedside***

Keeping up with rapid scientific discovery and accessing the complex mix of data elements needed to make good health-related decisions have represented a continuing challenge for health systems worldwide. The LHCS aims to close the divide between research and clinical practice. Seamless translation of research holds much promise to support an LHCS. However, the transition needs to be made, and translation needs to be implemented effectively. Several articles discussed the concept of a constant input of real-time 'trials'.<sup>18</sup> These trials draw from the comparative effectiveness of care patients receive in various aspects of their treatment (e.g. medications received and the effect on recovery time, and subsequently patient reported quality of life). This information then guides decisions and provides care recommendations which are constantly updating and improving. Lewis (2016)<sup>19</sup> suggested that adaptive clinical trials can be embedded into the settings and practice of everyday care, generating high-quality data to simultaneously improve care to patients in real time. Using simulation studies, this approach has demonstrated that it has the potential to save lives by identifying the best treatment strategies, particularly in critically ill patients.<sup>19</sup> The purpose of the 'pragmatic randomised trial' concept is essentially to harness technology and conduct quality improvement research every day, reducing the evidence translation issue that has existed for decades, with little change.<sup>19</sup> Many commentators have argued that under certain conditions these trials can be conducted ethically within the context of the LHCS without the informed consent of patients for research participation.<sup>20</sup>

Ainsworth et al (2015) discussed the challenge of separate information pipelines in health systems and suggests suboptimal analyses may be performed due to lack of expertise, and that contextual knowledge is essential for accurate analysis and interpretation.<sup>15</sup> Some experts have suggested that healthcare quality improvement activities and quality improvement

research should be one and the same within a LHCS.<sup>21</sup> If health systems are to shift towards reducing the delay in getting evidence into practice, minimal-risk quality improvement projects should require minimal oversight, and unnecessary ethical obstacles need to be removed, including waivers for informed consent for these projects to ensure that pragmatic adaptive trials can be unburdened by unnecessary patient over-protection. Whilst there needs to be reasonable ethical oversight, better collaboration with policy actors is needed to achieve a more appropriate pathway to meet the information and data requirements of a LHCS.<sup>21</sup>

### ***Policy capacity***

When further assessing the challenges faced in obtaining the data necessary to develop a LHCS, policy barriers have been identified as one of the key areas of resistance. Gardner (2015) proposed that improving policy capacity and expanding capabilities among healthcare policy actors is required to lay the foundations of a well-integrated LHCS.<sup>22</sup>

Much of the literature identified in the scoping review focused primarily on enhancing data capabilities. However, Gardner (2014) recognised that translation of healthcare reform into healthcare change is a crucial aspect of development.<sup>23</sup> In engineering and designing the system infrastructure, embedded policy experts are required to ensure successful translation of policy into practice.<sup>23</sup> Slutsky (2007) advocated major public policy interest in information technology, and in promoting value-based healthcare spending should also be considered in LHCS frameworks for future implementation.<sup>24</sup>

One challenge that may arise when engineering a LHCS is a lack of incentives to incorporate innovation, which was reported as a key barrier in integrating LHCS in some Portuguese health services, for example.<sup>25</sup> Policies to provide financial incentives for innovation and for the shift to a rapid-learning system will be crucial, and may ensure wider cooperation of relevant stakeholders.<sup>25</sup>

## **Recommendations**

### ***Patient-centred care***

Several articles identified patient-centred care as a key attribute to facilitate best-practice care and as a major component of an integrated LHCS. Slutsky (2007) argued that patient engagement is at the heart of a LHCS and will be crucial to ensure the transformation goals of organisations and services are met.<sup>24</sup> The patient-centred approach should be viewed as an essential component that empowers patients to communicate with clinicians and service

providers. This will ensure all measures of data are effectively fed into the EHR and patients are effectively engaging with the technology.

### ***Empirical research***

This review shows that there is a distinct lack of empirical evidence supporting the transition to an LHCS environment.<sup>16</sup> Psek et al (2016) argued that leaders need operational strategies that support organisational learning and proposes that continuous learning will need to be an embedded and multi-disciplinary function of care delivery.<sup>26</sup> Budrionis et al (2016) advised that whilst researchers have shown interest in exploring the workings of the LHCS, there has been minimal focus on measuring impact and presenting real-world evaluation of learning systems in action.<sup>10</sup>

Psek et al (2015) suggested that realistic assessments of culture, resources and capabilities of organisations related to their capacity for learning are critical and remain under investigated, and that a clearly defined scope in which organisations operate needs to be established from the offset.<sup>27</sup> Psek et al (2015) concluded that leadership support is imperative to success and suggests the application of an organisational framework may inform other organisations looking to transition to a LHCS.<sup>27</sup> Similarly, we need to evaluate the possibility of designing and applying the LHCS model in an Australian setting and developing an evidence-based organisational framework to enable the transition. This is where the Zero Childhood Cancer Model of care and the Flagship demonstration models from the Australian Genomic Health Alliance (AGHA) are revolutionising the way clinical decisions are made, by refocusing models of care; working in partnerships to get effective treatments from bench to bedside as quickly as possible; and developing a personalised medicine program for patients.<sup>28</sup>

### **Conclusions**

Overall, there was a lack of information provided in the literature to effectively identify 'how' to implement a LHCS. Only four articles presented empirical results or observations with a real-world application. This suggests a significant gap in the research base requiring attention. Until challenges and barriers that may be faced in the Australian context are assessed, the LHCS will remain a theory rather than an organisational intervention. In the future planning of LHCS in Australian healthcare settings, empirical findings have highlighted incentives, standards, and measurement requirements as key factors in the integration of service delivery systems.<sup>25</sup> Conceptualising population wide LHCS models with in-built capacity for rapid improvement will require us to examine progress, create and



test in the field new models suitable for adoption, and to explore both opportunities and challenges to translate these models widely across Australian healthcare settings.

## Appendix 1: A vision for a healthy Australia

# our vision for a healthy Australia supported by the best possible healthcare system



Source: Australian Healthcare and Hospitals Association, 2017<sup>29</sup>

## Appendix 2: Summary of literature on a LHCS

Citation	Abstract or excerpt
Faden RR, Beauchamp TL, Kass NE. Learning health care systems and justice. <i>Hastings Cent Rep.</i> 2011;41(4):3. <sup>30</sup>	[No abstract]
Abernethy AP. "Learning health care" for patients and populations. <i>Med J Aust.</i> 2011;194(11):564. <sup>31</sup>	A patient-focused learning health system, using integrated data sources, will facilitate optimal care of individuals and result in better care of our populations and society.
Gardner W, Kelleher K. A learning health care system for pediatrics. <i>JAMA Pediatr.</i> 2014;168(4):303-304. <sup>23</sup>	[No abstract]
Cummins MR. Nursing informatics and learning health system. <i>Comput Inform Nurs.</i> 2014;32(10):471-474. <sup>32</sup>	[No abstract]
Seid M, Margolis PA, Opiari-Arrigan L. Engagement, peer production, and the learning healthcare system. <i>JAMA Pediatr.</i> 2014;168(3):201-202. <sup>33</sup>	[No abstract]
Dahabreh IJ, Kent DM. Can the learning health care system be educated with observational data? <i>Jama.</i> 2014;312(2):129-130. <sup>34</sup>	[No abstract]
Greene SM, Reid RJ, Larson EB. Implementing the learning health system: from concept to action. <i>Ann Intern Med.</i> 2012;157(3):207-210. <sup>18</sup>	Clinicians and health systems are facing widespread challenges, including changes in care delivery, escalating health care costs, and the need to keep up with rapid scientific discovery. Reorganizing U.S. health care and changing its practices to render better, more affordable care requires transformation in how health systems generate and apply knowledge. The "rapid-learning health system"-posited as a conceptual strategy to spur such transformation-leverages recent developments in health information technology and a growing health data infrastructure to access and apply evidence in real time, while simultaneously drawing knowledge from real-world care-delivery processes to promote innovation and health system change on the basis of rigorous research. This article describes an evolving learning health system at Group Health Cooperative, the 6 phases characterizing its approach, and examples of organization-wide applications. This practical model promotes bidirectional discovery and an open mind at the system level, resulting in willingness to make changes on the basis of evidence that is both scientifically sound and practice-based. Rapid learning must be valued as a health system property to realize its full potential for knowledge generation and application.
Faden RR, Kass NE, Goodman SN, et al. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. <i>Hastings Cent Rep.</i> 2013;Spec No:S16-27. <sup>35</sup>	Calls are increasing for American health care to be organized as a learning health care system, defined by the Institute of Medicine as a health care system "in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care." We applaud this conception, and in this paper, we put forward a new ethics framework for it. No such framework has previously been

	articulated. The goals of our framework are twofold: to support the transformation to a learning health care system and to help ensure that learning activities carried out within such a system are conducted in an ethically acceptable fashion.
Krumholz HM. Big data and new knowledge in medicine: the thinking, training, and tools needed for a learning health system. <i>Health Aff (Millwood)</i> . 2014;33(7):1163-1170. <sup>36</sup>	Big data in medicine--massive quantities of health care data accumulating from patients and populations and the advanced analytics that can give those data meaning--hold the prospect of becoming an engine for the knowledge generation that is necessary to address the extensive unmet information needs of patients, clinicians, administrators, researchers, and health policy makers. This article explores the ways in which big data can be harnessed to advance prediction, performance, discovery, and comparative effectiveness research to address the complexity of patients, populations, and organizations. Incorporating big data and next-generation analytics into clinical and population health research and practice will require not only new data sources but also new thinking, training, and tools. Adequately utilized, these reservoirs of data can be a practically inexhaustible source of knowledge to fuel a learning health care system.
Burns J. Are we on the way to a real 'learning health care system'? <i>Manag Care</i> . 2013;22(2):12-16. <sup>37</sup>	[No abstract]
Yu PP, Hoffman MA, Hayes DF. Biomarkers and oncology: the path forward to a learning health system. <i>Arch Pathol Lab Med</i> . 2015;139(4):451-456. <sup>1</sup>	<p>[No abstract] Understanding what we mean by <i>learning</i> and how to accelerate learning is among the great challenges facing oncology. We are tasked to develop more sophisticated models of tumor biology and to learn how to apply tumor and host molecular profiles to direct treatment of patients with cancer. To accomplish that, we need to consider the clinical needs of the individual patient, as well as the opportunities to learn across populations of patients with cancer even as we subdivide anatomically defined cancers into multiple subpopulations categorized by tumor biology models driven by molecular test data. Biomarkers are the critical data elements that underlie how we understand cancer, develop new diagnostics and therapeutics, and improve patient lives. However, there are fundamental differences in the role biomarkers have depending on whether they are used to direct individual patient therapy or to create new learning. If learning is the understanding of how to apply knowledge to patient care, a learning health system distinguishes itself by the capacity to generate new learning, while delivering patient care.</p> <p>In its broadest sense, the term <i>biomarker</i> implies a measurement of a biological process whether as an assessment of health or disease.<sup>1</sup> Although measurement may include various health data such as blood pressure or medical imaging results, in oncology the term is typically used for laboratory-based tests of abnormal germline or cancer cell genetics, gene and protein expression or modifications, and metabolites. Traditionally, clinicians have used singly measured abnormalities in a</p>

	<p>specific process to guide therapies (eg, overexpression of estrogen receptor protein to select endocrine therapy in breast cancer). More recently, the ability to perform deep whole-genome sequencing and analysis of DNA and RNA quickly and inexpensively has led to the ability to identify less common but potentially clinically important single abnormalities that may be used to determine future outcomes or serve as targets for novel therapies. Furthermore, advances in technology during the past decade have permitted interrogation of large numbers of abnormalities that can be combined into multiparameter signatures (genomics, transcriptomics, proteomics, and metabolomics), which lead to greater insights into the heterogeneous behavior of cancers and might provide guidance for clinical decision making in individual patients and a new classification of cancers based on laboratory pathology. These areas of science have been collectively referred to as omics.</p>
<p>Grady C, Wendler D. Making the transition to a learning health care system. Commentary. <i>Hastings Cent Rep.</i> 2013;Spec No:S32-33.<sup>38</sup></p>	<p>The authors of the two main articles in this supplement recognize the enormous potential of learning health care systems. Their first article argues that the development of these systems calls into question existing guidelines and practices that treat clinical care and clinical research as distinct activities. Their second article proposes to replace this traditional approach with a new framework, one intended to promote two important goals: support the transformation to a learning health care system and help to ensure the ethical appropriateness of the activities carried out within such a system. To promote these goals, the authors propose a framework consisting of seven obligations. The authors are aware that their framework does not provide much guidance for promoting their second goal. At first glance, the seven obligations also might appear to offer little in the way of promoting the first goal. In what way, then, is the proposed framework novel and transformative, as the authors claim? The answer appears to lie largely in how the authors interpret the sixth obligation in the framework—the obligation to conduct learning activities.</p>
<p>Sledge GW, Hudis CA, Swain SM, et al. ASCO's approach to a learning health care system in oncology. <i>J Oncol Pract.</i> 2013;9(3):145-148.<sup>39</sup></p>	<p>The promise of emerging science and the challenges confronting today's health care system can both be addressed by fully embracing the IoM's vision of a learning health care system. ASCO's initial foray into realizing this vision for oncology shows great promise.</p>
<p>Chambers DA, Feero WG, Khoury MJ. Convergence of Implementation Science, Precision Medicine, and the Learning Health Care System: A New Model for Biomedical Research. <i>JAMA.</i> 2016;315(18):1941-1942.<sup>40</sup></p>	<p>[No abstract]</p>
<p>Krumholz HM, Terry SF, Waldstreicher J. Data Acquisition, Curation, and Use for a Continuously Learning Health System. <i>JAMA.</i> 2016;316(16):1669-1670.<sup>14</sup></p>	<p>[No abstract]</p>
<p>Harrington RA. Appropriate Use Criteria for Coronary Revascularization and the Learning Health System: A Good Start. <i>JAMA.</i> 2015;314(19):2029-2031.<sup>41</sup></p>	<p>[No abstract]</p>

<p>Tyson J, Pedroza C, Wootton SH. Analyses of Large Data Bases and Pragmatic Clinical Trials: Advancing Comparative Effectiveness Research in a Learning Health Care System. <i>Am J Perinatol.</i> 2015;32(12):1095-1097.<sup>42</sup></p>	<p>[No abstract]</p>
<p>Williams JK, Cashion AK, Shekar S, Ginsburg GS. Genomics, clinical research, and learning health care systems: Strategies to improve patient care. <i>Nurs Outlook.</i> 2016;64(3):225-228.</p>	<p>[No abstract]</p>
<p>Roundtable on Translating Genomic-Based Research for H, Board on Health Sciences P, Institute of M. The National Academies Collection: Reports funded by National Institutes of Health. In: <i>Genomics-Enabled Learning Health Care Systems: Gathering and Using Genomic Information to Improve Patient Care and Research: Workshop Summary.</i> Washington (DC): National Academies Press (US) Copyright 2015 by the National Academy of Sciences. All rights reserved.; 2015.<sup>12</sup></p>	<p>The inclusion of genomic data in a knowledge-generating health care system infrastructure is one promising way to harness the full potential of that information to provide better patient care. In such a system, clinical practice and research influence each other with the goal of improving the efficiency and effectiveness of disease prevention, diagnosis, and treatment. To examine pragmatic approaches to incorporating genomics in learning health care systems, the Institute of Medicine Roundtable on Translating Genomic-Based Research for Health hosted a workshop which convened a variety of stakeholder groups, including commercial developers, health information technology professionals, clinical providers, academic researchers, patient groups, and government and health system representatives, to present their perspectives and participate in discussions on maximizing the value that can be obtained from genomic information. The workshop examined how a variety of systems are capturing and making use of genomic data to generate knowledge for advancing health care in the 21st century. It also sought to evaluate the challenges, opportunities, and best practices for capturing or using genomic information in knowledge-generating health care systems. <i>Genomics-Enabled Learning Health Care Systems</i> summarizes the presentations and discussion of the workshop.</p>
<p>Sacristan JA, Dilla T. No big data without small data: learning health care systems begin and end with the individual patient. <i>J Eval Clin Pract.</i> 2015;21(6):1014-1017.<sup>43</sup></p>	<p>[No abstract]</p>
<p>Gardner W. Policy Capacity in the Learning Healthcare System Comment on "Health Reform Requires Policy Capacity". <i>Int J Health Policy Manag.</i> 2015;4(12):841-843.<sup>22</sup></p>	<p>Pierre-Gerlier Forest and his colleagues make a strong argument for the need to expand policy capacity among healthcare actors. In this commentary, I develop an additional argument in support of Forest et al view. Forest et al rightly point to the need to have embedded policy experts to successfully translate healthcare reform policy into healthcare change. Translation of externally generated innovation policy into local solutions is only one source of healthcare system change. We also need to build learning healthcare systems that can discover new health solutions at the frontline of care. Enhanced policy capacity staffing in those organizations will be key to building continuously learninghealth systems.</p>

<p>Flum DR, Alfonso-Cristancho R, Devine EB, et al. Implementation of a "real-world" learning health care system: Washington State's Comparative Effectiveness Research Translation Network (CERTAIN). <i>Surgery</i>. 2014;155(5):860-866.<sup>16</sup></p>	<p><b>BACKGROUND:</b> Learning health care systems apply the experiences of prior patients to inform care and help to guide decision making for current patients. These systems should help to deliver more effective, efficient, and appropriate care. Most examples of learning systems derive from integrated care delivery systems and examples of such systems in the community at large have been lacking.</p> <p><b>METHODS:</b> The comparative effectiveness research translation network (CERTAIN) is a learning system bringing together hospitals and outpatient clinics across Washington State. CERTAIN leverages existing medical record-based data collection taking place at nearly all statewide hospitals and links this data collection with patient-reported information about function and quality of life.</p> <p><b>RESULTS:</b> We have described the components of the CERTAIN infrastructure, the elements of a pilot project evaluating treatments of claudication, and the opportunities and challenges of developing and implementing a "real world" learning system. Examples in the areas of vascular disease, spine care, gastrointestinal disease, and urology.</p> <p><b>CONCLUSION:</b> Learning health care systems face many operational challenges but hold great promise for discovery and implementation of more effective clinical practices.</p>
<p>Psek W, Davis FD, Gerrity G, et al. Leadership Perspectives on Operationalizing the Learning Health Care System in an Integrated Delivery System. <i>EGEMS (Wash DC)</i>. 2016;4(3):1233.<sup>26</sup></p>	<p><b>INTRODUCTION:</b> Healthcare leaders need operational strategies that support organizational learning for continued improvement and value generation. The learning health system (LHS) model may provide leaders with such strategies; however, little is known about leaders' perspectives on the value and application of system-wide operationalization of the LHS model. The objective of this project was to solicit and analyze senior health system leaders' perspectives on the LHS and learning activities in an integrated delivery system.</p> <p><b>METHODS:</b> A series of interviews were conducted with 41 system leaders from a broad range of clinical and administrative areas across an integrated delivery system. Leaders' responses were categorized into themes.</p> <p><b>FINDINGS:</b></p>

	<p>Ten major themes emerged from our conversations with leaders. While leaders generally expressed support for the concept of the LHS and enhanced system-wide learning, their concerns and suggestions for operationalization were strongly aligned with their functional area and strategic goals.</p> <p><b>DISCUSSION:</b> Our findings suggests that leaders tend to adopt a very pragmatic approach to learning. Leaders expressed a dichotomy between the operational imperative to execute operational objectives efficiently and the need for rigorous evaluation. Alignment of learning activities with system-wide strategic and operational priorities is important to gain leadership support and resources. Practical approaches to addressing opportunities and challenges identified in the themes are discussed.</p> <p><b>CONCLUSION:</b> Continuous learning is an ongoing, multi-disciplinary function of a health care delivery system. Findings from this and other research may be used to inform and prioritize system-wide learning objectives and strategies which support reliable, high value care delivery.</p>
<p>Budrionis A, Bellika JG. The Learning Healthcare System: Where are we now? A systematic review. <i>J Biomed Inform.</i> 2016;64:87-92.<sup>10</sup></p>	<p><b>BACKGROUND AND OBJECTIVE:</b> The Learning Healthcare System paradigm has attracted the attention of researchers worldwide. The great potential originating from high-scale health data reuse and the inclusion of patient perspectives into care models promises personalized care, lower costs of health services and minimized consumption of resources. The aim of this review is to summarize the attempts to adopt the novel paradigm, putting emphasis on implementations and evaluating the impact on current medical practices.</p> <p><b>METHOD:</b> PRISMA methodology was followed for structuring the review process. Three major research databases (PubMed, IEEE Xplore and ACM DL) were queried with the predefined search terms "learning healthcare" and "learning health". Publications containing specific theoretical or empirical results were considered.</p> <p><b>RESULTS:</b> Three hundred and fifty-eight publications were identified; however, only 32 met the inclusion criteria. Nineteen papers were characterized as theoretical contributions, while the rest presented empirical achievements. Only one paper described the initial estimates of impact and economy.</p> <p><b>DISCUSSION:</b></p>



	<p>Individualistic communication of studies ignoring popular frameworks for assessing and reporting research achievements prevents the systematic generation of knowledge. Evaluating the impact of the Learning Healthcare System instances where it is implemented could work as a catalyst in reaching higher acceptance and adoption of the proposed ideas by healthcare worldwide; however, it mostly remains described in theory.</p> <p><b>CONCLUSIONS:</b> The review demonstrated the interest of researchers in exploring the Learning Healthcare System ideas. However, it also revealed minimal focus on evaluating the impact of the novel paradigm on both healthcare service delivery and patient outcome.</p>
<p>Lewis RJ. The pragmatic clinical trial in a learning health care system. <i>Clin Trials</i>. 2016;13(5):484-492.<sup>19</sup></p>	<p><b>BACKGROUND/AIMS:</b> A learning health care system ideally incorporates the ability to adapt to the pace of change, the incorporation of new clinical research paradigms, and leverages electronic health record systems and clinical decision support systems to narrow the divide between research and clinical practice.</p> <p><b>METHODS:</b> An adaptive clinical trial can be embedded into the sites and practice of clinical care in a highly pragmatic way to simultaneously generate high-quality data on treatment efficacy and improve the care of patients. This approach can be expanded into a pragmatic platform trial, meaning a trial that is intended to evaluate multiple treatments for a disease or diseases, possibly in combination, and with the available treatments potentially changing over time. This strategy is illustrated using a trial currently being implemented in Europe and funded by the European Union, evaluating three different "domains" of treatments for patients with severe community-acquired pneumonia requiring intensive care.</p> <p><b>RESULTS:</b> Simulation studies demonstrate that this approach has the potential to save lives while identifying the best treatment strategies for this critically ill population.</p> <p><b>CONCLUSION:</b> Patients are likely to benefit if we can merge clinical trials and decision support into a single continuous learning process.</p>
<p>Psek WA, Stametz RA, Bailey-Davis LD, et al. Operationalizing the learning health care system in an integrated delivery system. <i>EGEMS (Wash DC)</i>. 2015;3(1):1122.<sup>27</sup></p>	<p><b>INTRODUCTION:</b> The Learning Health Care System (LHCS) model seeks to utilize sophisticated technologies and competencies to integrate clinical operations, research and patient</p>

	<p>participation in order to continuously generate knowledge, improve care, and deliver value. Transitioning from concept to practical application of an LHCS presents many challenges but can yield opportunities for continuous improvement. There is limited literature and practical experience available in operationalizing the LHCS in the context of an integrated health system. At Geisinger Health System (GHS) a multi-stakeholder group is undertaking to enhance organizational learning and develop a plan for operationalizing the LHCS system-wide. We present a framework for operationalizing continuous learning across an integrated delivery system and lessons learned through the ongoing planning process.</p> <p><b>FRAMEWORK:</b> The framework focuses attention on nine key LHCS operational components: Data and Analytics; People and Partnerships; Patient and Family Engagement; Ethics and Oversight; Evaluation and Methodology; Funding; Organization; Prioritization; and Deliverables. Definitions, key elements and examples for each are presented. The framework is purposefully broad for application across different organizational contexts.</p> <p><b>CONCLUSION:</b> A realistic assessment of the culture, resources and capabilities of the organization related to learning is critical to defining the scope of operationalization. Engaging patients in clinical care and discovery, including quality improvement and comparative effectiveness research, requires a defensible ethical framework that undergirds a system of strong but flexible oversight. Leadership support is imperative for advancement of the LHCS model. Findings from our ongoing work within the proposed framework may inform other organizations considering a transition to an LHCS.</p>
<p>Slutsky JR. Moving closer to a rapid-learning health care system. <i>Health Aff (Millwood)</i>. 2007;26(2):w122-124.<sup>24</sup></p>	<p>This Perspective discusses activities that are necessary for developing a rapid-learning health system. Recognition of the central role that patients play in the successful evolution of such a system will help ensure that the goals of the transformation are met. Understanding the trade-offs of using a less controlled form of research to inform health care decision making and making necessary investments in methodology and translation will help secure the success of continuous-learning research. Major public policy interest in promoting health information technology and in getting more value for health care spending creates a framework for moving ahead.</p>
<p>Liu VX, Morehouse JW, Baker JM, et al. Data that drive: Closing the loop in the learning hospital system. <i>J Hosp Med</i>. 2016;11 Suppl 1:S11-s17.<sup>44</sup></p>	<p>The learning healthcare system describes a vision of US healthcare that capitalizes on science, information technology, incentives, and care culture to drive improvements in the quality of health care. The inpatient setting, one of the most</p>

	costly and impactful domains of healthcare, is an ideal setting in which to use data and information technology to foster continuous learning and quality improvement. The rapid digitization of inpatient medicine offers incredible new opportunities to use data from routine care to generate new discovery and thus close the virtuous cycle of learning. We use an object lesson-sepsis care within the 21 hospitals of the Kaiser Permanente Northern California integrated healthcare delivery system-to offer insight into the critical elements necessary for developing a learning hospital system. We then describe how a hospital-wide data-driven approach to inpatient care can facilitate improvements in the quality of hospital care. <i>Journal of Hospital Medicine</i> 2016;11:S11-S17.
Park K, Park MD, Longhurst CA. Patient and Family Access to Electronic Health Records: A Key Ingredient for a Pediatric Learning Health System. <i>J Particip Med.</i> 2015;7. <sup>45</sup>	[No abstract]
Wicks P, Heywood JA. Data donation could power the learning health care system, including special access programs. <i>Am J Bioeth.</i> 2014;14(11):27-29. <sup>46</sup>	[No abstract]
Starren JB, Winter AQ, Lloyd-Jones DM. Enabling a Learning Health System through a Unified Enterprise Data Warehouse: The Experience of the Northwestern University Clinical and Translational Sciences (NUCATS) Institute. <i>Clin Transl Sci.</i> 2015;8(4):269-271. <sup>47</sup>	[No abstract]
Tepas JJ, 3rd. Injury prevention in a self-learning health system. <i>J Trauma Acute Care Surg.</i> 2015;79(3 Suppl 1):S1. <sup>48</sup>	[No abstract]
Mason AR, Barton AJ. The emergence of a learning healthcare system. <i>Clin Nurse Spec.</i> 2013;27(1):7-9. <sup>49</sup>	A learning healthcare system has emerged as a means of addressing the need to move evidence to the bedside in a manner that is meaningful and efficacious. The advent of electronic healthcare records has translated to massive quantities of clinical data; a learninghealthcare system coupled with locally derived clinical rules will push practice-based evidence to the point of care where its application will mean improved quality and patient outcomes.
Buetow KH, Niederhuber J. Infrastructure for a learning health care system: CaBIG. <i>Health Aff (Millwood).</i> 2009;28(3):923-924; author reply 924-925. <sup>50</sup>	[No abstract]
Marsolo K, Margolis PA, Forrest CB, Colletti RB, Hutton JJ. A Digital Architecture for a Network-Based Learning Health System: Integrating Chronic Care Management, Quality Improvement, and Research. <i>EGEMS (Wash DC).</i> 2015;3(1):1168. <sup>17</sup>	INTRODUCTION: We collaborated with the ImproveCareNow Network to create a proof-of-concept architecture for a network-based Learning Health System. This collaboration involved transitioning an existing registry to one that is linked to the electronic health record (EHR), enabling a "data in once" strategy. We sought to automate a series of reports that support care improvement while also demonstrating the use of observational registry data for comparative effectiveness research.  DESCRIPTION OF ARCHITECTURE:

	<p>We worked with three leading EHR vendors to create EHR-based data collection forms. We automated many of ImproveCareNow's analytic reports and developed an application for storing protected health information and tracking patient consent. Finally, we deployed a cohort identification tool to support feasibility studies and hypothesis generation. There is ongoing uptake of the system. To date, 31 centers have adopted the EHR-based forms and 21 centers are uploading data to the registry. Usage of the automated reports remains high and investigators have used the cohort identification tools to respond to several clinical trial requests.</p> <p>SUGGESTIONS FOR FUTURE USE: The current process for creating EHR-based data collection forms requires groups to work individually with each vendor. A vendor-agnostic model would allow for more rapid uptake. We believe that interfacing network-based registries with the EHR would allow them to serve as a source of decision support. Additional standards are needed in order for this vision to be achieved, however.</p> <p>CONCLUSIONS: We have successfully implemented a proof-of-concept Learning Health System while providing a foundation on which others can build. We have also highlighted opportunities where sponsors could help accelerate progress.</p>
Fagnan LJ, Dolor RJ. PBRNS discuss utilizing big data for research and within a learning health system. <i>Ann Fam Med.</i> 2015;13(2):185. <sup>51</sup>	[No abstract]
Newhouse RP, Melnyk M. Nursing's role in engineering a learning healthcare system. <i>J Nurs Adm.</i> 2009;39(6):260-262. <sup>52</sup>	[No abstract]
Kelley M, James C, Alessi Kraft S, et al. The Role of Patient Perspectives in Clinical Research Ethics and Policy: Response to Open Peer Commentaries on "Patient Perspectives on the Learning Health System". <i>Am J Bioeth.</i> 2016;16(2):W7-9. <sup>53</sup>	[No abstract]
Jackson T. Building the 'continuous learning' healthcare system. <i>Health Inf Manag.</i> 2014;43(1):4-5. <sup>54</sup>	Hospitals are data-rich but information-poor. To develop a 'continuous-learning health care system' we need to harness our myriad information sources so that every patient encounter becomes the basis for new evidence of what works.
Anderson GM. Moving from a Learning-Disabled to a Rapid-Learning Healthcare System: Good Governance for Innovation. <i>Healthc Pap.</i> 2016;15(3):4-7. <sup>55</sup>	[No abstract]
Nahm ES. Mental Health Nurses: Are We Ready for a "Learning Health System"? <i>J Am Psychiatr Nurses Assoc.</i> 2015;21(4):284-286. <sup>56</sup>	[No abstract]
Ainsworth J, Buchan I. Combining Health Data Uses to Ignite Health System Learning. <i>Methods Inf Med.</i> 2015;54(6):479-487. <sup>15</sup>	<p>OBJECTIVES: In this paper we aim to characterise the critical mass of linked data, methods and expertise required for health systems to adapt to the needs of the populations they</p>

	<p>serve - more recently known as learning health systems. The objectives are to: 1) identify opportunities to combine separate uses of common data sources in order to reduce duplication of data processing and improve information quality; 2) identify challenges in scaling-up the reuse of health data sufficiently to support health system learning.</p> <p><b>METHODS:</b> The challenges and opportunities were identified through a series of e-health stakeholder consultations and workshops in Northern England from 2011 to 2014. From 2013 the concepts presented here have been refined through feedback to collaborators, including patient/citizen representatives, in a regional health informatics research network (<a href="http://www.herc.ac.uk">www.herc.ac.uk</a>).</p> <p><b>RESULTS:</b> Health systems typically have separate information pipelines for: 1) commissioning services; 2) auditing service performance; 3) managing finances; 4) monitoring public health; and 5) research. These pipelines share common data sources but usually duplicate data extraction, aggregation, cleaning/preparation and analytics. Suboptimal analyses may be performed due to a lack of expertise, which may exist elsewhere in the health system but is fully committed to a different pipeline. Contextual knowledge that is essential for proper data analysis and interpretation may be needed in one pipeline but accessible only in another. The lack of capable health and care intelligence systems for populations can be attributed to a legacy of three flawed assumptions: 1) universality: the generalizability of evidence across populations; 2) time-invariance: the stability of evidence over time; and 3) reducibility: the reduction of evidence into specialised sub-systems that may be recombined.</p> <p><b>CONCLUSIONS:</b> We conceptualize a population health and care intelligence system capable of supporting health system learning and we put forward a set of maturity tests of progress toward such a system. A factor common to each test is data-action latency; a mature system spawns timely actions proportionate to the information that can be derived from the data, and in doing so creates meaningful measurement about system learning. We illustrate, using future scenarios, some major opportunities to improve health systems by exchanging conventional intelligence pipelines for networked critical masses of data, methods and expertise that minimise data-action latency and ignite system-learning.</p>
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<p>Miller FG, Kim SY. Personal Care in Learning Health Care Systems. <i>Kennedy Inst Ethics J.</i> 2015;25(4):419-435.<sup>20</sup></p>	<p>The idea of a "learning health care system"--one that systematically integrates clinical research with medical care--has received considerable attention recently. Some commentators argue that under certain conditions pragmatic comparative effectiveness randomized trials can be conducted ethically within the context of a learning health care system without the informed consent of patients for research participation. In this article, we challenge this perspective and contend that conducting randomized trials of individual treatment options without consent is neither necessary nor desirable to promote and sustain learning health care systems. Our argument draws on the normative conception of personal care developed by Charles Fried in a landmark 1974 book on the ethics of randomized controlled trials.</p>
<p>Dias C, Escoval A. Hospitals as learning organizations: fostering innovation through interactive learning. <i>Qual Manag Health Care.</i> 2015;24(1):52-59.<sup>25</sup></p>	<p>The article aims to provide an analytical understanding of hospitals as "learning organizations." It further analyzes the development of learning organizations as a way to enhance innovation and performance in the hospital sector. The article pulls together primary data on organizational flexibility, innovation, and performance from 95 administrators from hospital boards in Portugal, collected through a survey, interviews with hospital's boards, and a nominal group technique with a panel of experts on health systems. Results show that a combination of several organizational traits of the learning organization enhances its capacity for innovation development. The logistic model presented reveals that hospitals classified as "advanced learning organizations" have 5 times more chance of developing innovation than "basic learning organizations." Empirical findings further pointed out incentives, standards, and measurement requirements as key elements for integration of service delivery systems and expansion of the current capacity for structured and real-time learning in the hospital sector. The major implication arising from this study is that policy needs to combine instruments that promote innovation opportunities and incentives, with instruments stimulating the further development of the core components of learning organizations. Such a combination of policy instruments has the potential to ensure a wide external cooperation through a learning infrastructure.</p>
<p>Yoder-Wise PS. The Continuously Learning Health System: Recommendations From the Josiah Macy Jr. Foundation. <i>J Contin Educ Nurs.</i> 2015;46(9):379-380.<sup>57</sup></p>	<p>[No abstract]</p>
<p>Abernethy AP. Demonstrating the learning health system through practical use cases. <i>Pediatrics.</i> 2014;134(1):171-172.<sup>58</sup></p>	<p>[No abstract]</p>
<p>Maddox TM, Ferguson TB, Jr. The Potential of Learning Health Care Systems: The SWEDEHEART Example. <i>J Am Coll Cardiol.</i> 2015;66(5):544-546.<sup>59</sup></p>	<p>[No abstract]</p>
<p>Friedman CP, Wong AK, Blumenthal D. Achieving a nationwide learning health system. <i>Sci Transl Med.</i> 2010;2(57):57cm29.<sup>7</sup></p>	<p>We outline the fundamental properties of a highly participatory rapid learning system that can be developed in part from meaningful use of</p>

	<p>electronic health records (EHRs). Future widespread adoption of EHRs will make increasing amounts of medical information available in computable form. Secured and trusted use of these data, beyond their original purpose of supporting the health care of individual patients, can speed the progression of knowledge from the laboratory bench to the patient's bedside and provide a cornerstone for health care reform.</p>
<p>McGinnis JM. Evidence-based medicine - engineering the Learning Healthcare System. <i>Stud Health Technol Inform.</i> 2010;153:145-157.<sup>8</sup></p>	<p>Whether for the generation or application of evidence to guide healthcare decisions, the success of evidence-based medicine is grounded in principles common to engineering. In the Learning Healthcare System envisioned by the Institute of Medicine's (IOM) Roundtable on Evidence-Based Medicine, evidence emerges as a natural by-product of care delivery, which is thoroughly documented, pooled for continuous monitoring and analysis, integrated with insights from related studies, and fed back seamlessly to improve the consistency and appropriateness of care decisions by clinicians and their patients. Drawing from lessons shared at the IOM/NAE symposium, Engineering a Learning Healthcare System, this paper provides an overview of the state-of-play in health care today, some of its key challenges, the vision and features of a learning healthcare system, applicable commonalities and principles from engineering, and potential collaborative opportunities moving forward to the benefit of both fields.</p>
<p>Fiscella K, Tobin JN, Carroll JK, He H, Ogedegbe G. Ethical oversight in quality improvement and quality improvement research: new approaches to promote a learning health care system. <i>BMC Med Ethics.</i> 2015;16(1):63.<sup>21</sup></p>	<p><b>BACKGROUND:</b>  Institutional review boards (IRBs) distinguish health care quality improvement (QI) and health care quality improvement research (QIR) based primarily on the rigor of the methods used and the purported generalizability of the knowledge gained. Neither of these criteria holds up upon scrutiny. Rather, this apparently false dichotomy may foster under-protection of participants in QI projects and over-protection of participants within QIR.</p> <p><b>DISCUSSION:</b>  Minimal risk projects should entail minimal oversight including waivers for informed consent for both QI and QIR projects. Minimizing the burdens of conducting QIR, while ensuring minimal safeguards for QI projects, is needed to restore this imbalance in oversight. Potentially, such ethical oversight could be provided by the integration of Institutional Review Boards and Clinical Ethical Committees, using a more integrated and streamlined approach such as a two-step process involving a screening review, followed by a review by committee trained in QIR. Standards for such ethical review and training in these standards, coupled with rapid review cycles, could facilitate an appropriate level of oversight within the context of creating and sustaining learning health care systems. We argue that QI and QIR are not reliably distinguishable. We advocate for approaches that improve</p>

	<p>protections for QI participants while minimizing over-protection for participants in QIR through reasonable ethical oversight that aligns risk to participants in both QI and QIR with the needs of a learning health care system.</p>
<p>Wysham NG, Howie L, Patel K, et al. Development and Refinement of a Learning Health Systems Training Program. <i>EGEMS (Wash DC)</i>. 2016;4(1):1236.<sup>60</sup></p>	<p><b>CONTEXT:</b>  In the emerging Learning Health System (LHS), the application and generation of medical knowledge are a natural outgrowth of patient care. Achieving this ideal requires a physician workforce adept in information systems, quality improvement methods, and systems-based practice to be able to use existing data to inform future care. These skills are not currently taught in medical school or graduate medical education.</p> <p><b>CASE DESCRIPTION:</b>  We initiated a first-ever Learning Health Systems Training Program (LHSTP) for resident physicians. The curriculum builds analytical, informatics and systems engineering skills through an active-learning project utilizing health system data that culminates in a final presentation to health system leadership.</p> <p><b>FINDINGS:</b>  LHSTP has been in place for two years, with 14 participants from multiple medical disciplines. Challenges included scheduling, mentoring, data standardization, and iterative optimization of the curriculum for real-time instruction. Satisfaction surveys and feedback were solicited mid-year in year 2. Most respondents were satisfied with the program, and several participants wished to continue in the program in various capacities after their official completion.</p> <p><b>MAJOR THEMES:</b>  We adapted our curriculum to successes and challenges encountered in the first two years. Modifications include a revised approach to teaching statistics, smaller cohorts, and more intensive mentorship. We continue to explore ways for our graduates to remain involved in the LHSTP and to disseminate this program to other institutions.</p> <p><b>CONCLUSION:</b>  The LHSTP is a novel curriculum that trains physicians to lead towards the LHS. Successful methods have included diverse multidisciplinary educators, just in time instruction, tailored content, and mentored projects with local health system impact.</p>



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