Learning Health Systems: Connecting Research to Practice Worldwide

Opening guest commentary:

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The practice of medicine and clinician learning have seen constant change over the past century. This change has been driven not only through new scientific discoveries leading to new treatment options for patients, but also through new technologies and the exponential increase in digital data.

In A Family of Doctors, Dr. David Hellerstein describes his great-grandfather’s efforts to track his personal success as an obstetrician with notebooks full of handwritten data about successful deliveries and unfortunate deaths (maternal and fetal), from which he himself learned. Presumably, he passed this learning on to his students, but they were not shared broadly. Dr. Atul Gawande, in Complications, describes how doctors in the 1980s were revered, trusted and not questioned with respect to their knowledge or decisions. Yet, in the 1990s, research was done to assess whether computers or doctors were better at reading EKGs. Dr. Gawande himself made attempts to create decision trees with options and possible outcomes, but he was frustrated with the lack of information on probabilities associated with one treatment path vs. another. “In the absence of algorithms and evidence about what to do, you learn in medicine to make decisions by feel. You count on experience and judgment. And it is hard not to be troubled by this.”

An important part of a learning health cycle is devoted to research, which is based upon healthcare information and provides results to inform medical decisions. Research has been defined as “studies inquiry or examination especially investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws.” Clearly, the ability to generate research facts or results relies on data to build evidence.

Data has been called the world’s most valuable resource. Physician educators are encouraging medical students to include data and data management as educational priorities, and new roles and positions are being created such as data scientists, data curators, and data standards experts. The generation of data continues to increase faster than we seem to be able to comprehend or assimilate. Data is the currency of research, and the quality of research is dependent upon the quality and quantity of that data. Also becoming increasingly important is metadata (data about data), which is critical to being able to meaningfully interpret and use the data. A long-term tension has existed between big data and precious data, the latter generally being “cleaner” and more thoroughly curated. Both serve important roles in research, but it is critical to understand the utility and limitations of each. For example, safety surveillance relies on big data and being able to find signals or “needles in haystacks.” Rare disease research relies on small amounts of data from few patients with such diseases, making the data precious.

As data from paper medical records and research case report forms becomes digitized, it is considered to be more accessible. Yet, along with this new world of digital health, a new set of issues has emerged. These issues affect the sharing of healthcare data for research purposes. They include concerns about patient privacy, system security, responsible use of data, data curation, standardization, harmonization, management and mapping, data analysis and interpretation, and other such issues. If these issues can be resolved, there is then the question of how to get the research results back to practicing clinicians such that they can be applied appropriately in practice. Surrounding these data-related issues are others that include technology and regulations, and the latter are often country-specific. All the while, it is increasingly important to put the patient first and consider what patients want. There is added complexity in that different patients have varying experiences with certain procedures, drugs, or therapies.

The theme of this Special Issue is Learning Health Systems: Connecting Research to Practice Worldwide. The articles explore the
issues and the potential solutions for accelerating learning health cycles through more rapid access to research data and more timely provision of the resulting knowledge to clinicians. The article, "The Global Academic Research Organization Network: Data Sharing to Cure Diseases and Enable Learning Health Systems", is an experience report from a Global Academic Research Organization (ARO) Network Workshop held in November 2017. Initiated in Japan, the ARO Council has now expanded into other countries in Asia (Taiwan, Singapore, and Korea) and has also been working with the European Clinical Research Infrastructure Network (ECRIN). The workshop described in this report included representatives from ten AROs or research organizations in the United States, in addition to those from Europe and Asia. There is an introduction to the ARO Council and ECRIN, along with comments from Dr. Chris Austin of NIH/NCATS and a representative of Japan’s "NIH", the Agency for Medical Research and Development (AMED). Common themes emerged across AROs globally, yielding a list of best practices and exemplifying the goals and value of a Global ARO Network.

“The Use of EHR Data for Clinical Research: Historical Progress and Current Applications” explores the challenge of acquiring data from electronic health records to populate clinical research databases. An experience report, it is based upon a panel discussion held at the Bridging Clinical Research and Healthcare Collaborative in April 2018. Panelists with differing perspectives provided their opinions around the incentives and impediments to leveraging EHRs for research. Two examples are provided: 1) an evaluation of the Return On Investment of implementing the integration profile, Retrieve Form for Data Capture (RFD), to populate case report form fields directly with data from EHRs and 2) a description of the method for obtaining research data from EHRs by mapping data using the API-based FHIR standard from HL7 to provide data for research in a format used for global clinical research based on CDISC metadata standards.

A case study in the area of diabetes from Hamamatsu Hospital in Japan, “Development of a New Seamless Data Stream from EMR to EDC System Using SS-MIX2 Standards Applied for Observational Research in Diabetes Mellitus,” describes how RFD is used to populate research case report form fields with EHR data using the EHR Storage Standard Medical Information Exchange (SS-MIX). The electronic case report forms leverage the CDISC data acquisition standard (CDASH), including the therapeutic area standard for diabetes data. SS-MIX is widely used by EHRs in Japan to store EHR data in a standard format for secondary use.

A description of how a hospital in Taiwan has taken significant steps toward realizing a learning health system, leveraging a standards-based clinical information management system (CIMS) that was developed at the U.S. National Institutes of Health, is provided in the article, “Integrative LHS for Precision Medicine Research: A Shared NIH and Taiwan CIMS Experience.” This is a fine example of a collaborative international project to enable a learning health system in one country. Importantly, it could be recreated elsewhere to share knowledge more broadly, aligned with the Global ARO Network goals.

Regulations related to healthcare systems and clinical research, including the need for more alignment across these arenas, is the topic of the article, “Tangential Headwinds When Integrating Industry Funded Clinical Trials Into a U.S. Healthcare Delivery System.” Considerations are given to certain of the aforementioned patient privacy issues in addition to business decisions for healthcare providers considering doing regulated research. This article focuses on rules, guidance, and regulations generated by different departments of the U.S. Health and Human Services.

The progress presented in this Special Issue of Learning Health Systems is tangible and reflects the global interest in connecting research and healthcare to enable learning health systems. Clearly, ongoing robust discussions are required to continue to solve the challenges that remain in connecting practice with research worldwide.

REFERENCES
1. Hellerstein, David, A Family of Doctors, published by Farrar, Straus & Giroux (1994)
2. Gawande, Atul, Complications, published by Atul Gawande (2002)
3. Merriam Webster Dictionary
4. The Data Economy, 9039 London, 6-12 May 2017, The Economist, Vol 423

How to cite this article: Kush RD. Learning Health Systems: Connecting Research to Practice Worldwide. Learn Health Sys. 2019;3:e10078. https://doi.org/10.1002/lrh2.10078