Patient and clinician support for the learning healthcare system: recommendations for enhancing value

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Rapid progress has been made over the past decade in the shift toward a learning healthcare system (LHS) in the USA. As defined by the Institute of Medicine (IOM), an LHS links data from patients and populations to researchers and practitioners to dramatically increase knowledge and guidance concerning the effectiveness of interventions [1]. The ideal LHS is characterized by the continuous generation of knowledge seamlessly integrated with the provision of care [2]. Major initiatives in the LHS movement include the NIH Health Care Systems Research Collaboratory [3] and the Patient Centered Outcomes Research Institute's (PCORI's) National Patient-Centered Outcomes Research Network (PCORnet) [4]. Both the NIH Collaboratory and PCORnet are developing essential knowledge, infrastructure and tools to accelerate learning as part of the delivery of healthcare. However, the ultimate success of a paradigm shift to an LHS will also depend on the active engagement and support of a broad range of key stakeholder groups within the health system.

For this transformation to be successful and sustained, it will be particularly critical for patients, clinicians and health system leaders to believe there is significant value in this new approach to research and care delivery. Specifically, health system leaders must be convinced that there is a reasonable and sustainable business case to allocate organi-

zational resources to serve as active partners in learning activities. Clinicians, including practicing physicians, nurses and other care providers must perceive sufficient monetary or nonmonetary benefits to justify adding new responsibilities to their already substantial clinical workloads. Finally, patients must understand the benefits of obtaining their care in a learning environment, as well as the risks of making decisions with currently available (and often incomplete) evidence. They must also trust that research is appropriately regulated, safe, ethical and beneficial to society and to their future care.

LHS stakeholders are more likely to perceive value in learning activities that fall closer to the quality and process improvement (QI/PI) end of the learning spectrum because they provide direct, relatively near-term benefit to individual health systems. The immediate value to health system stakeholders is less obvious for activities that are intended to produce generalizable knowledge about the effectiveness of healthcare services, particularly when those questions require higher quality data and more rigorous study designs. However, the capacity to conduct this type of research is also critical to the goals of an LHS. In this commentary, we focus attention on the value proposition for the latter, what we refer to as 'hypothesis-driven research'; in other words, research that is usually investigator-initiated, answers

a question of value to society overall rather than just the immediate needs of a particular system and may require combining data from multiple systems in order to have reliable and unbiased results.

Health system leaders who see value in integrating research and care delivery are likely to create an environment of continuous learning that filters down to clinicians and the patients they care for [5]. These types of leaders are open to engagement; for example, a recent series of IOM workshops brought together researchers and value-seeking health system leaders to explore the business case for integrating research and practice and identify strategies to facilitate continuous learning within healthcare delivery systems [2]. It is no less critical, however, to consider the direct value of research activities to clinicians and patients. Activated clinicians and patients can be essential partners in the research process and serve as agents of change who advocate for learning activities, including more clinical research that will ultimately improve health. In this commentary, we draw from existing knowledge and real world examples, as well as input from the NIH Collaboratory Stakeholder Advisory Group (SAG), to recommend strategies for researchers seeking to increase the value of participation in research activities for clinicians and patients.

Examples

A number of ongoing learning initiatives offer useful insights related to the value proposition for healthcare system stakeholders to partner in hypothesis-driven research. The examples described below represent initiatives from a range of healthcare settings that have garnered the necessary support from health system leaders, clinicians and patients to integrate research and care delivery.

Distributed Ambulatory Research in Therapeutics Network Institute

Distributed Ambulatory Research in Therapeutics Network (DARTNet) is a nonprofit organization that partners with 85 healthcare organizations, including practice-based research networks (PBRNs) and 13 academic medical centers, to support research and collaboration across healthcare providers and organizations. DARTNet depends on active and sustained participation from busy clinicians to function effectively, and therefore provides useful insights concerning factors that motivate clinicians to participate in collaborative learning activities. DARTNet provides the IT infrastructure, administrative support and research training opportunities to enable primary care practices and other member networks and organizations to collaborate on a variety of comparative effectiveness research (CER) and

quality improvement activities [6]. Value to clinicians is enhanced by a Practice Performance Registry endorsed by the American Academy of Family Physicians that makes participating providers eligible for increased revenue. In addition, point-of-care decision supports can be used for both research and clinical care improvement, as well as assisting with patient management decisions. Finally, DARTNet offers Learning Communities that enable clinicians to visit and learn from high-performing sites (based on practice performance reports) and participate in research training opportunities.

US FDA Mini-Sentinel & Sentinel

Mini-Sentinel is the US FDA-funded pilot project to create the FDA Sentinel System, an active surveillance system for monitoring the safety of FDA-regulated products. Mini-Sentinel has managed to function over several years with the sustained and active participation of their data partners. As of July 2014, 18 organizations served as partners, providing access to quality-checked data on approximately 178 million health plan members for surveillance and safety studies within the Mini-Sentinel distributed database [7]. Under the Mini-Sentinel's distributed database model, data are housed locally, and data partners have the power to decide whether or not to respond to a query. In addition, health plans are given opportunities to leverage their own data to generate knowledge and value for clinicians and plan members. Mini-Sentinel has fostered a culture of collaboration where participating plans consider themselves to be true partners as opposed to data contributors. Providers and patients are engaged through Brookings Institute convening activities, public meetings and webinars. Finally, partner commitment is sustained by providing some financial support for the time and effort of individuals involved in Mini-Sentinel activities.

Clinical Directors Network

Clinical Directors Network (CDN) is a PBRN that works with federally qualified health centers (FQHCs). The network has utilized a number of successful mechanisms to engage clinicians in the translation of research into practice. CDN aims to retain high-quality clinicians in these practices by creating professionally satisfying work experiences. Membership offers access to a range of academic partners and a network of networks that provides online training. Training resources include CME accredited webcasts, guidance on research methodology, and tools for building research capacity among primary care clinicians in FQHCs who wish to become more actively involved in research [8]. Clinician participation in learning activities provides valuable opportunities for

role diversification, professional development and ultimately, increased job satisfaction. In addition, CDN actively engages clinicians and community members in generating relevant, high-priority research questions.

Alliance of Chicago Community Health Services

The Alliance is a network of community health centers serving primarily low-income and uninsured patients [9]. Its mission is to share resources and integrate services in order to more efficiently and effectively deliver accessible quality healthcare to the communities they serve. The Alliance brings an important patient and community perspective to research by engaging community stakeholders in developing intervention and recruitment activities. For many community health centers, both patients and staff are individuals from the local community, providing increased opportunities for engagement in learning and research.

ImproveCareNow

ImproveCareNow (ICN) represents a ‘peer-production’ LHS model where the means of producing information are broadly distributed, and patients, family members and clinicians are actively engaged in the learning and research process [10]. ICN started as an improvement network with the goal of transforming the healthcare and cost of Crohn’s disease and ulcerative colitis in children and youth, and is now one of 20 PPRNs funded as part of PCORnet. ICN has been associated with major improvements in patient outcomes. Parents and patients make up the majority of the board of directors and are an integral part of the network. Care protocols allow flexibility for patients and their doctors to make individualized decisions at the point of care, and a data-in-once approach (by which data entered at the point of care can be used for individual patient care as well as research) helps to minimize data entry burden.

Insights & recommendations

The examples described above were presented as case studies to the NIH Collaboratory SAG, followed by a discussion of lessons learned regarding clinician and patient engagement that can be applied to Collaboratory projects as well as other LHS initiatives. The SAG provides a forum within which stakeholders from outside the Collaboratory can bring their different perspectives and expertise to the work of identifying, defining and overcoming barriers to the transformation from delivery-only to an LHS. SAG membership includes patients, providers, payers, life sciences representatives, policy makers and other stakeholders from the public and private sector. Discussion with the SAG was instrumental to developing the recommendations that follow.

The value proposition for clinicians

Though clinicians may acknowledge the value of learning in general, as well as specific research activities, there are many competing demands on clinician time. Clinicians consistently identify this time pressure as a major barrier to efforts to build learning into the delivery of care. Other barriers include the demands of an evolving payment landscape [11], and perceived conflict with commitment to the mission of patient care [12].

Despite ongoing efforts to leverage electronic infrastructure and effectively remove clinicians from data collection protocols, not every study can be so streamlined. It is unlikely that in the near term it will be possible to conduct learning activities in healthcare, particularly hypothesis-driven research, without requiring additional effort by clinicians. Clinicians may be asked to enroll patients in studies, explain studies during clinical encounters, collect data beyond that required for strictly clinical purposes and possibly assist with follow-up.

“Time spent on research-related activities in a nonacademic health system means less billable time providing patient care.”

The SAG discussion around the ImproveCareNow network highlighted ways that several barriers can be addressed to increase clinician support for learning. First, a ‘culture of data collection’ is fostered in large part because clinicians know that the data will be used for research, and to improve care, and to help individual patients. In addition, data collected can be leveraged by clinicians to make work easier and more efficient, for example, by generating previsit planning reports, progress notes, letters for referring physicians and other useful real-time reports. Research activities may also present more meaningful value to clinicians through credit for maintenance of board certification, continuing education credits or pay for performance criteria.

Strategies for increasing the value of LHSs from the clinician perspective

- Provide learning opportunities for clinicians on pragmatic trials and other topics related to research conducted in partnership with delivery systems;
- Engage clinicians in identifying, prioritizing and refining research questions that are most important to them and the patients they care for;
- Provide point-of-care data collection that can be used for research, clinical care improvement and patient management decisions;

- Create ways to leverage data collected to make clinical work easier and more efficient;
- Link participation in learning activities to opportunities for role diversification and professional development;
- Explore new ways to measure and compensate clinicians for time participating in research and learning activities;
- Explore new ways to measure performance based on participation in learning activities.

Discussion

A major policy barrier stems from the reality that where physicians practice directly impacts how their time is valued. For example, a fee-for-service environment encourages higher utilization of healthcare services and therefore higher costs to the system, while clinicians practicing within a capitated system are incentivized to contain costs within a fixed budget [13]. Time spent on research-related activities in a nonacademic health system means less billable time providing patient care. In other words, clinicians face the real possibility of less compensation by spending time on research-related activities.

“At minimum, support for increased learning in healthcare requires acceptance of the notion that many treatment decisions are based on limited evidence about which option is best for which patient.”

Embi and Tsevat have proposed a research-specific calculation parallel to the relative value unit (RVU) used to measure the value of physician services for reimbursement. This would enable non-researcher clinicians to be compensated for the time they spend participating in research-related initiatives at non-academic medical centers [11]. A relative research unit (RRU), they propose, would be similar to the way in which teaching is factored into an RVU for lecturers.

However, the bigger challenge remains identifying the source of funding for such reimbursement. A national stakeholder dialogue that includes US policy makers, payers, health system leaders, clinical leaders and professional societies, and practicing clinicians could facilitate a common understanding. Consensus-driven conversations will be necessary to address the largely unanswered question of how to transform care delivery in a way that facilitates learning and justly compensates clinicians for their time.

The value proposition for patients

The transition to an LHS obviously cannot succeed without the support and participation of its fundamental element: patients receiving care. Although efforts such as the NIH Collaboratory and PCORnet are just beginning to tap into the perspectives of patients and the public at large regarding the concept of an LHS, a number of likely barriers to patient participation can be identified, as well as potential approaches to overcoming these barriers. Ethical and regulatory issues related to research and care delivery in LHS settings currently receive considerable attention [14] and are not the focus of this paper. Rather, we explore other obstacles to and strategies for building patient and public support for LHSs.

At minimum, support for increased learning in healthcare requires acceptance of the notion that many treatment decisions are based on limited evidence about which option is best for which patient. Although one national survey reported that 50% of the public believe half or less of the care they receive is evidence-based [15], this does not necessarily translate into support for increased evidence generation to inform clinical decision-making. Patients and consumers tend to believe that physicians, particularly their own, know what is best for patients and will always act in the patient's best interest [16,17]. To the extent that Americans perceive a problem with the health system, they do not blame doctors for the state of affairs. Moreover, they are apt to react negatively to efforts they perceive as interfering with patient-physician relationships or decision-making autonomy [15].

One challenge to increasing support for research within the context of care delivery, therefore, is motivating patient demand for better evidence without appearing to undermine the centrality of the patient and physician in care decisions. A communication strategy that emphasizes the potential to ‘help your physician help you’ might be more effective than focusing solely on limitations of the current body of clinical evidence. Such a strategy would also emphasize that the goal of increasing the quantity and quality of evidence is to provide patients and clinicians with information and tools to enhance shared decision-making, not replace it.

Strategies for increasing the value of LHSs from the patient perspective

- Emphasize opportunity to help physicians provide the best possible care by participating in learning activities;
- Create environment where patients and family members trust that their opinions are valued

and that expressing a negative opinion would not adversely affect care;

- Engage community members and patients in governance, priority setting, data privacy policies and other aspects of design and use of learning infrastructure;
- Support patient education and research training as part of learning activities;
- Develop mechanisms for feedback of information to patients, and opportunities to submit requests for data queries that are of personal interest;
- Provide resources that translate findings into meaningful messages;
- Establish forums for social networking, peer learning and collaboration.

Discussion

The insights we share in this paper add to the literature on methods for incorporating patient, family and consumer perspectives in the design and implementation of research. PCORI has developed guidance for patient engagement across the continuum of CER and PCOR [18], and meaningful patient engagement is a key focus for the 13 Clinical Data Research Networks (CDRNs) and 20 PPRNs that comprise PCORnet. Challenges to engagement during the infrastructure development of PCORnet have included engaging patients in network governance, reaching underrepresented patient populations and establishing value for patients to participate in research activities. As the PPRNs and CDRNs progress, they will undoubtedly produce valuable information regarding effective strategies for engaging patients in research. Lessons learned from the CDRNs, which are characterized by diverse healthcare systems partnering to conduct PCOR within collaborative data networks, will be particularly informative for patient engagement in the LHS.

While the knowledge base pertaining to patient engagement methods has grown, understanding of best practices for clinician engagement remains limited. Literature related to PBRNs provide some helpful insights related to concerning the business case for providers to participate in research [19]. The experiences of the Collaboratory pragmatic trials and the PCORnet CDRNs will continue to contribute to this body of evidence as they develop strategies for partnering with clinicians.

Conclusion

The current landscape of US healthcare and the evolving focus on CER and PCOR offer researchers and LHS proponents unique opportunities to involve clinicians and their patients in learning activities. Engaging these groups as energetic partners in hypothesis-driven research will require continued exploration of motivators and barriers in order to develop an empirical evidence base of effective strategies. Understanding the contexts and specific requirements of different research activities is paramount to identifying the most appropriate approach to stakeholder engagement.

We have shared insights and recommendations for researchers working in partnership with healthcare delivery systems who are faced with eliciting the support of practicing clinicians and the patients they care for. While the examples described above offer a range of potential strategies, it is critical that researchers continue to engage with key stakeholders to identify feasible strategies for building and sustaining a learning infrastructure that generates value for health systems, clinicians and the patients they serve.

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Disclaimer

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References

- 1 IOM (Institute of Medicine). *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. The National Academies Press, Washington DC, USA (2013).
- 2 IOM (Institute of Medicine). *Integrating Research and Practice: Health System Leaders Working Toward High-Value Care: Workshop Summary*. The National Academies Press, Washington DC, USA (2014).
- 3 National Institutes of Health. NIH Health Systems Research Collaboratory. www.nihcollaboratory.org
- 4 The National Patient-Centered Clinical Research Network. www.PCORnet.org/
- 5 Johnson K, Grossmann C, Anau J *et al.* *Integrating Research into Health Systems: Executives' Views. Discussion Paper*. Institute of Medicine, Washington DC, USA (2014). www.iom.edu/integratingresearch
- 6 DARTNet Institute. www.dartnet.info/default.htm
- 7 US Food and Drug Administration. FDA's Sentinel Initiative. www.fda.gov
- 8 Clinical Directors Network. www.cdnetwork.org/about-us
- 9 Alliance of Chicago. www.alliancechicago.org
- 10 Seid M, Margolis PA, Opiari-Arrigan L. Engagement, peer production, and the learning healthcare system. *JAMA Pediatr.* 168(3), 201–202 (2014).
- 11 Embi PJ, Tsevat J. The relative research unit: providing incentives for clinician participation in research activities. *Acad. Med.* 87(1), 11–14 (2012).
- 12 Cole AM, Chen FM, Ford PA, Phillips WR, Stevens NG. Rewards and challenges of community health center practice. *J. Prim. Care Community Health* 5(2), 148–151 (2014).
- 13 Kass NE, Faden RR, Goodman SN, Pronovost P, Tunis S, Beauchamp TL. The research-treatment distinction: a problematic approach for determining which activities should have ethical oversight. *Hastings Cent. Rep.* Spec No:S4–S15 (2013).
- 14 Gerber AS, Patashnik EM, Doherty D, Dowling C. The public wants information, not board mandates, from comparative effectiveness research. *Health Aff.* 29(10), 1872–1881 (2010).
- 15 Carman KL, Maurer M, Yegian JM *et al.* Evidence that consumer are skeptical about evidence-based health care. *Health Aff.* 29(7), 1400–1406 (2010).
- 16 Gerber AS, Patashnik EM, Doherty D, Dowling CM. Doctor knows best: physician endorsements, public opinion, and the politics of comparative effectiveness research. *J. Health Polit. Policy Law* 39(1), 171–208 (2014).
- 17 Frank L, Forsythe L, Ellis L *et al.* Conceptual and practical foundations of patient engagement in research at the patient-centered outcomes research institute. *Qual. Life Res.* 24, 1033–1041 (2015).
- 18 Song PH, Reiter KL, Weiner BJ, Minasian L, McAlearney AS. The business case for provider participation in clinical trials research: an application to the National Cancer Institute's community clinical oncology program. *Health Care Manage Rev.* 38(4), 284–294 (2013).
- 19 Froimson MI, Rana A, White RE Jr *et al.* Bundled payments for care improvement initiative: the next evolution of payment formulations: AAHKS Bundled Payment Task Force. *J. Arthroplasty* 28(Suppl. 8), 157–165 (2013).