



# NIH Collaboratory

Health Care Systems Research Collaboratory

## Stakeholder Advisory Group

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### Meeting Summary

Value Proposition of Learning Health Systems

May 28th, 2014

World Trade Center Baltimore



## Stakeholder Advisory Group Mission

The goal of the Stakeholder Advisory Group (SAG) to the NIH Healthcare Systems Research Collaboratory is to provide the forum within which people from outside the Collaboratory and health care systems research enterprise can bring their different perspectives, expertise, and responsibilities into the work of identifying, defining and overcoming the barriers to the transformation from a delivery system to a learning health care system. SAG membership includes patients, providers, payers, employers, life sciences representatives, policy makers, and other stakeholders from the public and private sector. The SAG convenes to understand agreements and differences of opinion, and channels the information learned back to the Collaboratory and to the constituencies represented by SAG members.

## Background

At the first in-person meeting of the SAG (May 9, 2013), stakeholders cautioned that the notion that learning will lead to better patient care is not in itself sufficient motivation for broad and sustained participation and support from health systems, clinicians and patients. Identifying the barriers to participation and strategies to overcome them, from multiple stakeholder perspectives, is key to achieving the near term goals of the Collaboratory and to ensuring the long-term sustainability of learning initiatives.

Healthcare systems must be convinced that there is a reasonable and sustainable business-case to allocate organizational resources to serve as active partners for Collaboratory researchers and future efforts to integrate learning activities with the delivery of care. Clinicians, including physicians, nurses, and other care providers, must perceive sufficient monetary or nonmonetary benefits to justify adding extra responsibilities to their already substantial clinical workloads. Finally, in order to activate patients as change agents who advocate for learning activities, including more clinical research, patients must first understand the benefits of research and the risks of making decisions with currently available evidence. They must also trust that such research is appropriately regulated, safe, ethical, and beneficial to their own healthcare in addition to society as a whole.

The second in-person SAG meeting (May 28, 2014) was informed by insights drawn from the first SAG meeting and the April 2014 PCORI/IOM Workshop on [Health Systems Leaders Working Toward High-Value Care Through Integration of Care and Research](#). **Our objective was to discuss strategies to promote more active support of learning from three stakeholder communities that are critical to the successful transition to a sustainable learning health system: health system leaders, clinicians, and patients.** The following sections describe the presentation content and multi-stakeholder discussion from May 28<sup>th</sup>. Any phrases that appear in quotation are pulled verbatim from comments made during the meeting.

## Framing the Discussion

Sean Tunis of CMTP, Lead for the Collaboratory Stakeholder Engagement Core, opened the meeting and outlined objectives for the day. To promote the sustainability of infrastructure for research within

health care delivery systems, we need to better understand the value proposition of research to these systems and other key stakeholders (e.g. patients and clinicians). In particular, we hope to better understand the business case for investing in data collection infrastructure to support *hypothesis-driven research* that is integrated with the delivery of care.

The term “hypothesis-driven research” was selected to focus the meeting’s discussion on CER/PCOR that falls on the traditional research side of the quality improvement (QI)-research continuum. Specifically, it refers to 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. Given that the value proposition seems more apparent for learning activities closer to QI/process improvement (PI), identifying the value proposition for learning also requires discussion of activities that have less direct and near term benefit for health systems and patients.

While the group generally agreed that the value case for QI/PI was an easier sell compared to hypothesis-driven research, there was some disagreement over the appropriate definition for the type of research being discussed. Some thought QI and process improvement can also be hypothesis-driven, while other attendees preferred the term “investigator-initiated”. While an alternate term was not selected, there was general agreement that the description of hypothesis-driven research (above) captured the essence of the type of research that creates the most challenges in terms of defining a business case for several key stakeholders. A fundamental differentiator between hypothesis-driven research and data-guided QI is that delivery systems and patients may realize near term benefits from QI activities, while the benefits of hypothesis-driven research are not likely to be experienced in the near term, and those benefits are unlikely to be limited to the institution in which the learning takes place.

Participants also questioned the definition of “sustainability” and how it should influence the day’s discussions. Sustainability could be a) sustaining the willingness of health systems to participate in the research process, where they allow their data to be used and participate as sites in hypothesis-driven research studies funded by outside support such as federal grants, or, b) sustaining a culture of learning for activities that are regarded as so valuable by health systems and healthcare deliverers that they would collectively fund such activities. The group leaned towards a focus on a), sustaining an environment in which health systems participate in work “for the commons” and actively support this types of research, e.g. by providing some level of in-kind support through personnel or infrastructure. The importance of the concept of sustainability is that financial support for research infrastructure is not likely to come from NIH, PCORI or other funding organizations for which a higher priority is to support the studies themselves. The problem to be solved is to determine the conditions under which organizations and individuals that use, manage or provide care will actively and knowingly contribute their time and resources to sustain the learning enterprise.

It will also be important to consider how motivators differ for fee-for-service versus other payment models that reward quality and efficiency, for example, bundled payment models, pay for performance, or risk-adjusted reimbursement. To the extent research assets can help change healthcare delivery to

improve health outcomes, the business case for learning will become an easier sell to organizations operating in the context of financial incentives that reward quality and efficiency.

## Early Insights from IOM/PCORI Meeting on High Value Care

Claudia Grossman, Senior Program Officer at the Institute of Medicine (IOM), shared initial thoughts from the Roundtable Meeting, “Health System Leaders Working Toward High Value Care through Integration of Care and Research,” jointly hosted on April 23<sup>rd</sup>-24<sup>th</sup> by PCORI and the IOM. Among the numerous insights from the meeting, a clear take-away was the critical importance to health system leaders that research initiatives align with institutional improvement priorities, because those are the considerations that drive decision-making at the executive level. Other critical factors included the speed of results and potential complications related to governance. Research conducted “at speed” implies that results are quickly captured and reported back to stakeholders, e.g. in a matter of months as opposed to the multi-year timelines typical of clinical trials. Complications related to governance can arise in situations where multiple health systems collaborate on a study, and oversight of research may come from a central or external body which is not aligned with internal oversight mechanisms for care, QI and research. Attendees discussed how integrating research and care delivery necessitates a change in culture on both the research and operations sides, as these activities are guided by different objectives, behavioral norms, regulations, etc. The potential value of such a culture change would be the development of shared and reusable research assets that are useful to both the research community and to the care delivery institutions. One ongoing challenge for researchers is learning how to effectively communicate the value of the work that they do in a language that health system executives can understand and appreciate. Equally challenging is the communication from health system executives to researchers about what learning activities are best aligned with their priorities and responsibilities.

Another issue raised at the IOM/PCORI meeting was that health systems still struggle to implement at scale a wide range of health interventions that are already known to improve care. It is a hard sell to get health system leaders to enthusiastically support the generation of *new* knowledge when they are struggling to support changes to patient care that they already know will improve outcomes for their patients. As a practical matter, focusing resources on increasing uptake of these underused beneficial services, is supported by a more direct business case than deploying those same resources to supporting studies of services for which the benefits and risks are not currently known. The challenge faced by proponents of hypothesis-driven research is thus to create a persuasive argument that the use of limited resources to support hypothesis-driven research is of higher value than the alternative approach of directing those resources toward quality improvement or implementation science. What would such an argument look like? One possibility is to assert that external investments in a multi-use data collection infrastructure that enables hypothesis-driven research could also be leveraged to address inefficiencies and prevent waste, addressing many QI questions and supporting implementation science.

The potential importance of partnerships between health systems, their patients and families was also explored at the IOM/PCORI workshop. The [IOM Workshop in Brief](#) cites Peter Margolis of Cincinnati Children’s Hospital Medical Center, who suggested in his presentation that partnerships with clinicians,

patients, and health system leaders that are based on ethical principles and mutual respect are hallmarks of success for continuously learning health systems. He further proposed that the partnerships created between health systems and their stakeholders will be just as important to the long-term success of PCORNet as the ability to generate the necessary data to inform continuous learning. Other presenters also emphasized the importance of learning health system infrastructure models that include formal pathways for enabling patients and families to play a significant role in designing care and research.

Eric Larson, Executive Director of Group Health Research Institute and a member of the planning committee for the IOM/PCORI workshop, shared his thoughts on the presentation from Dr. Grossman, including key considerations for the SAG discussion. Dr. Larson re-emphasized the importance of alignment between the research community and the delivery system, noting that there is still a large gap in understanding between these stakeholder communities with respect to prioritizing learning activities. Researchers think on a different timescale than those who are responsible for the efficient operations and financial performance of health systems. Learning “at speed” is critical to an organization’s immediate priorities, and organizations have limited energy and capacity, already fully engaged in more immediate and business-critical challenges. Health system leaders do not generally view learning activities as a “burning platform” that requires obligatory focus. Adding tasks to health systems that are already operating “at breaking point,” even to a very limited degree, is not likely to be a viable strategy for long-term sustainability.

Dr. Larson also shared preliminary findings from a recent survey of April workshop attendees. Consistent with the discussions, alignment of learning activities with business mission, strategies and priorities was a key theme. While the majority of respondents saw great value in integrating delivery and research, many also expressed concern about whether integrating the two would help an organization. They were skeptical that researchers would truly be able to think in the same value terms as delivery systems, or would consistently find research topics that were both intellectually engaging and of practical value to the health systems. Furthermore, the health system executives, as well as a range of other workshop attendees, expressed concern about the challenges of overcoming the significant cultural differences between learning and delivery.

## Discussion

Out of these insights from the IOM/PCORI workshop, a question introduced to the SAG for discussion was: In what ways might the increasing efforts of health systems to develop community engagement mechanisms become a mechanism to create patient demand for learning (including QI/PI *and* hypothesis-driven research)?

### **Stakeholder Reactions to Insights from IOM/PCORI Workshop**

- The fact that U.S. healthcare has not been able to translate the findings of research into value for patients is “a bit of a scandal” – both for our country to have to wait so long for benefits, and for so many research projects to not produce benefits.
- It may be useful to examine what proportion of process improvements being overseen by health systems actually aim toward improved outcomes for the beneficiary population captured by the health system, as opposed to process improvements that focus just on the process. The assumption is that a direct connection exists between current incentives provided to systems to improve patient outcomes and actual improvements in outcomes.
- It would be helpful to understand where systems succeed at implementing and using the knowledge that is gained through research to inform policy and decisions for coverage.
- If a model similar to industry’s internal research and development (R&D) were proposed for healthcare delivery, concerns would remain over the potential for knowledge hoarding, or the unwillingness of organizations to share findings with other health systems. The hope would be that within the healthcare delivery industry, contributing to the common good would outweigh competitive advantages of hoarding knowledge.
- On the other hand, some health system leaders have expressed frustration at the difficulty of sharing knowledge generated through their quality improvement evaluations, because the less rigorous methods make it hard to publish in some cases. The limited ability to publish results in research journals from existing learning healthcare initiatives creates another potential obstacle to transforming to a system of collaborative research and care.

If research partnerships focus on aligning with health system priorities, do we exclude an important universe of questions which are not health system priorities but are nonetheless critically important? A high level “three-step approach” was proposed to build a value proposition for research that is unlikely to have immediate payoff for the participating health systems:

1. First, figure out how to do the short-term, immediate payoff research much faster, more efficiently, and at lower cost than we do now, drive down those costs by expanding and exploiting an infrastructure that is currently under-developed, informed by the highly functional models that exist in some systems.
2. Once there has been wider progress on the first priority, try to minimize incremental costs for doing hypothesis-driven research, with clear understanding that it is going to cost more than NOT doing the research (to those systems), but that our ultimate goal is to ultimately reduce those research costs by an order of magnitude.
3. Being clear that the incremental costs for HYPOTHESIS-DRIVEN RESEARCH will generally not be absorbed by the health systems – but may be funded by traditional researchers at much lower projects costs than is currently the case in the absence of extensive infrastructure to conduct this research within health systems.

In reaction to this proposed approach, it was noted that the buy-in and resources needed to support immediate payoff versus long-term payoff research activities, including expertise and staff skill sets, are

very different. Although this is true currently, there is reason to anticipate that these two learning disciplines will eventually become familiar to an expanding learning workforce, and we are already seeing a rapid rise in the academic and health system experts with technical capabilities that span a broad range of learning activities. Much hypothesis-driven research can be designed to produce information that is valuable to a variety of users. Even if results are not fully generalizable to other populations, there may be insights that can inform follow-on studies to test external validity. Assuming we ultimately embed both types of learning activities within the same network, a key requirement will be to ensure that there is adequate funding for these activities from *outside* the health system.

## Lessons from Ongoing Learning Initiatives

The following session included multiple presentations on case studies representing successful learning initiatives from different care settings. For each case presentation, the objective was to identify key lessons learned that may be applicable to the broader question of the business case for health systems to partner on hypothesis driven research. Presenters discussed the value of their initiatives, considering why their efforts were working, key ingredients for success, remaining challenges, and what else they still hoped to accomplish.

## Distributed Ambulatory Research in Therapeutics Network (DARTNet)

Wilson Pace, Professor of Family Medicine at University of Colorado Denver and Director of the Distributed Ambulatory Research in Therapeutics Network (DARTNet) Institute, presented insights he had gathered through his DARTNet experience. DARTNet is a 501(c)(3) 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.<sup>1</sup> 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 and quality improvement activities. For example, DARTNet provides decision support tools and the software to extract and de-identify data from multiple partner organizations to enable queries of clinical data across systems. Data on practice performance and clinical measures are shared with members to identify high performers and facilitate sharing of best practices with members. The DARTNet infrastructure provides a standardized dataset for research, but requires separate permissions for each study, thus leaving local practices in full control of the use of their data. The DARTNet platform can also be efficiently leveraged to check the feasibility of implementing proposed external projects. DARTNet uses a portion of the funds from research grants to support the centralized data collection infrastructure, following transparent processes for determining which awards should fall to the individual research partners as primary investigators, and which awards DARTNet should lead (those focused on infrastructure).

DARTNet depends on active and sustained participation from busy practicing clinicians in order to function effectively. Dr. Pace emphasized the importance and value of data extracted locally being used locally. Lessons from DARTNet provide useful insights with respect to the factors that motivate clinicians

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<sup>1</sup> About DARTNet Institute. Available at: <http://dartnet.info/AboutDI.htm>. © 2014 DARTNet Institute.

to participate in collaborative learning activities. These insights may be applicable to understanding how best to engage clinicians (and patients and health systems leaders) in other learning initiatives such as the Collaboratory and PCORNet.

### Value Proposition of DARTNet Institute

According to Dr. Pace, DARTNet offers the following value to clinicians:

- A Practice Performance Registry endorsed by the American Academy of Family Physicians that can generate practice performance reports meeting Stage 2 Meaningful Use Measure 6 requirements. (Providers participating in the registry are then eligible to receive more revenue.)
- Point of care decision support that can be used for both research and clinical care improvement, as well as assisting with patient management decisions.
- Learning Communities: clinicians and practice communities can visit with high performing sites and participate in regularly available training opportunities in methods and research

In addition, DARTNet offers the following value to health systems:

- As a patient safety organization, DARTNet offers partners clearly defined legal protection for sharing aggregate, de-identified data.
- Integration of third party software and population management software into partner EHRs.
- Grant dollars can support the integration of third party software and population management software into partner EHRs - for smaller health system partners, this is often at no additional cost to themselves

### SAG Discussion

It is also important to support patient education and research training as part of these learning activities, for the same reasons that learning health systems need to equip clinicians to become effective partners in learning. Part of patient engagement is helping patients to become familiar with common learning terminology, research concepts, and specific skill sets that are need to be able to participate meaningfully in various aspects of the design and implementation of research studies. Better patient education and research training ought to improve patients' satisfaction with their engagement in the health system, as well as the satisfaction of the researchers and clinicians who interact with them.

### FDA Mini-Sentinel and Sentinel

Gregory Daniel, Managing Director for Evidence Development & Innovation at the Brookings Institution Engelberg Center for Health Care Reform, presented on the FDA Mini-Sentinel<sup>2</sup> and Sentinel Initiative<sup>3</sup>. Mini-Sentinel is the FDA-funded pilot project to create the FDA Sentinel System, an active surveillance system for monitoring the safety of FDA-regulated products. Collaborating institutions of the Mini-Sentinel project, include both data partners and academic partners. Data partners are largely

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<sup>2</sup> Welcome to Mini-Sentinel. Available at: <http://mini-sentinel.org/>. © 2010-2014 Mini-Sentinel Coordinating Center – All Rights Reserved.

<sup>3</sup> FDA's Sentinel Initiative. Available at: <http://www.fda.gov/Safety/FDASentinelinitiative/ucm2007250.htm>. U.S. Department of Health and Human Services.



commercial health plans or their subsidiaries, such as HealthCore, Inc., a subsidiary of Wellpoint Inc. As of July 2014, 18 organizations serve as data 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. A common data model facilitates the work of the Mini-Sentinel operations center, which develops SAS (statistical analysis) programs, modular programs or protocol-based assessments that can be distributed through the secure network to each of the data partners. 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.

While commercial health plans are the backbone of the data used in Mini-Sentinel, no two organizations are alike, cautioned Dr. Daniel. Each has different business needs, organizational structures, and data sharing policies, and each has unique views with respect to the priority of hypothesis-driven research. What is unique about the Sentinel system is that it is a tool to be used by the FDA, for the FDA. To-date, the focus of Mini-Sentinel has remained on safety outcomes. Dr. Daniel cautioned that when approaching data partners about opportunities to use the infrastructure for CER or to look at cost outcomes, there may be some concern about how expanding the use of Mini-Sentinel to CER activities may impact the business models of data partners or their parent health plans. Furthermore, CER researchers may assume that the demands on data partners and their data will only multiply, creating pressure to manage and prioritize new requests with an already constant stream of data extraction requests and reporting requirements.

### Keys to Success of Mini-Sentinel

A number of insights are suggested by the factors that have enabled Mini-Sentinel to function over several years with sustained and active participation of their data partners. Many of these are likely to be applicable to thinking through the value proposition for health systems to partner with researchers and others in collaborative learning activities. According to Dr. Daniel, health plans were originally motivated to join Mini-Sentinel in part because the safety of regulated medical products is important to public health and to their health plan members, thus making partnership in Mini-Sentinel a priority for CEOs. Furthermore, Mini-Sentinel offered health plans the opportunity to leverage their own data and to generate knowledge and value back to the parent company and plan members.

Other potential success factors for the ongoing trust and strong relationships between Mini Sentinel and data partners include the following:

- Culture of collaboration: Mini-Sentinel partners have established professional working relationships and a high level of trust. The positive culture reflected by the fact that plans consider themselves “partners” instead of data “donors” or “contributors”
- Participation in Mini-Sentinel exposed partners to additional opportunities to participate in funded projects with external research partners
- Best practices for data management and analysis in Mini-Sentinel could be adopted by partners and applied to other projects to support the parent organizations
- Partners *remain committed* because they received some financial support for the time and effort of individuals involved in related activities
- Mini-Sentinel Distributed data network minimizes transfer of PHI and proprietary data

- Participation in each activity is voluntary

### Value Proposition of Mini-Sentinel, Sentinel, and Other Learning Health System Activities

The following bullets summarize the proposed value proposition of Mini Sentinel and Sentinel, for A) Patients and Providers, and B) Manufacturers, as presented by Dr. Daniel on May 28<sup>th</sup>.

#### **A. For Patients and Providers:**

- Mini-Sentinel: Engagement and input from patients and providers through Brookings convening activities, public meetings and webinars
- Sentinel: It is increasingly important to go beyond general updates and develop better tools that link Sentinel results to digestible information that providers and patients need to know

Value Proposition of Learning Health System Activities: Generation of tools that provide the necessary feedback loop in the LHS that can help change practice patterns based on new evidence; Help patients and providers realize the value and benefits for participating and contributing their own data

#### **B. For Manufacturers**

- Mini-Sentinel: Engagement and input from manufacturers through Brookings convening activities, public meetings and webinars;
- Sentinel: The Reagan-Udall Foundation's [IMEDs \(Innovation in Medical Evidence Development and Surveillance\) program](#) is a public private partnership that facilitates support and participation by manufacturers and others in:
  - Developing new methods and evaluating existing methods to support Sentinel in using electronic health data for safety surveillance and CER
  - Participation in safety assessments using the Sentinel tools and capabilities in collaboration with data partners

Value Proposition of Learning Health System Activities: Better post-market data infrastructure to support continued evidence generation for new expedited approval pathways, programs like Coverage with Evidence Development (CED), and better evidence of off-label use.

### Implications for sustainability of a learning health system

Dr. Daniel proposed to the group that small incremental changes to the “data model(s)” up-front may make participation and interest in the effort much more vested. In particular:

- Can participation off-set “other” data requirement costs? (e.g., eliminating the need for All-Payer Claims Database participation)
- Can participation add efficiency to things they are already doing? (e.g., using the data to track outcomes and quality for payment reform reporting)

Finally, Mini-Sentinel and Sentinel data partners may be more willing to participate in CER and other learning activities outside of QI and safety surveillance if researchers can demonstrate: a) participation

helps identify waste and inefficiencies in their own programs, and b) participation helps them improve the quality of care that they provide and manage.

### SAG Discussion

- Mini-Sentinel data partners may be willing to consider participating in randomized trials, but their real interests would be those trials that align with their organizations' strategic areas.
- *Health plans* spend money on standardized data extracts for all-payer state databases. Perhaps Mini-Sentinel's common data model can actually be used to help support the state's data needs.
- *Patients and providers* find value from Mini-Sentinel through engagement in Brookings Institution convening activities, public webinars and meetings. Online resources that translate findings into meaningful messages for patients and providers could be very valuable to help improve care and build more support for research in the patient and clinician communities.
- If the value proposition for *industry* can be well described, industry may become a key source of support for health systems research infrastructure. Such an investment would support their efforts to generate real world evidence from EHRs and other sources to evaluate their products.
- For example, *manufacturers* may find value by supporting new public private partnerships such as the IMEDS program. Through collaboration with the FDA and other learning health system stakeholders, manufacturers may benefit from learning the latest and best analytic and methodological techniques to apply to electronic health data moving forward.

Already faced with a large volume of request for data extractions, it is very likely that the demands on data partners will continue to multiply. For learning initiatives that engage health plans as data partners to be sustainable, health plans need to be truly vested in the long-term success of learning activities; this will depend heavily on the degree to which these activities have identifiable benefits to the work of the data partners, their parent organizations, and/or their members. For example, if collaborating on learning activities can reduce the costs of other core activities the data partners already conduct, engagement will prove valuable to plans and delivery systems as care becomes more integrated. Alternately, if some health plans do not receive direct value learning activities, they may still see a business case for engagement if the infrastructure they invest in is useful for other aspects of business.

### Clinical Directors Network

Jonathan Tobin, President and Chief Executive Officer of the Clinical Directors Network (CDN) and Co-Director for Community Engaged Research at Rockefeller University Center for Clinical and Translational Science, presented on his experience with CDN, a Practice-Based Research network (PBRN) that works with federally qualified health centers (FQHCs). Specifically, Dr. Tobin shared thoughts about successful mechanisms to engage practicing clinicians to translate research into practice. CDN provides its members with infrastructure support to facilitate collaborative practice-based research, education and training opportunities. CDN aims to retain high quality clinicians in these practices by creating professionally satisfying work experiences.

CDN membership offers access to a range of academic partners and a network of networks (called N-squared) that provides online training. Training resources include CME accredited webcasts, guidance on research methodology, and tools for building research capacity among practicing primary care

clinicians in FQHCs who wish to become more actively engaged in research. Moving forward, clinician participation in learning activities will provide important opportunities for role diversification, professional development, training and education – all of which increase job satisfaction.

Dr. Tobin shared two examples of research questions generated by CDN practicing clinicians: 1) a randomized trial evaluating a curriculum for care managers designed to improve cancer screening and early detection in primary care practices, and 2) a study of community-acquired methicillin-resistant staphylococcus aureus (MRSA).

1. The first study was a randomized trial that tested the efficacy of a new curriculum for training care managers to use care management strategies to improve early detection of breast, cervical and colorectal cancer in community health centers. Approximately 2,000 patients were randomized to usual care or to a care manager. The study demonstrated that the new curriculum could significantly improve the rates of early cancer detection among women seen in community health centers. After positive findings from the initial trial, researchers used National Cancer Institute pilot funding to work with Chief Medical Officers and Chief Financial Officers to evaluate whether the curriculum could be used to train care managers in Medicaid managed care organizations to provide the same services and generate the same results. Results were positive but showed a smaller effect size, leading to additional questions on how to identify patients where the care management did not increase screening rates, how issues related to social determinants of health competed with the intervention in these community health centers that treated poor, disenfranchised, non-English-speaking patients, and whether partnering with other community organizations might improve screening rates and early detection in these vulnerable populations.
2. The MRSA study examined patterns of hospital acquired MRSA and developed a point-of-care protocol to manage recurrent infections among neighborhood patients receiving their care at community health centers. Researchers engaged clinicians to understand their workflow and community members to understand other settings where community members might receive care. This information was used to develop an observational study design for management of patients with MRSA infections that clinicians themselves could conduct with minimal outside assistance or interference with clinical productivity. When the study expanded to other PBRNs, the protocol could be implemented by other primary care physicians at the point of care. They also engaged clinicians, laboratory investigators and molecular epidemiologists to refine the research questions. Clinicians were treating with systemic antibiotics and seeing recurrent infections, and were frustrated by treatment failures (as were their patients). Laboratory investigators were most interested in the basic science question of whether the recurrent phenotype represented a single or multiple genotypes. Clinical investigators wanted to better understand predictors of recurrence. Through focus groups and town hall meetings, researchers found that patients were most concerned about the recurrence of skin and soft tissue infection and its impact on pain and ability to work. With this input, the study team was able to refine the research question to answer something useful to every stakeholder group: clinical, laboratory, patients and the community.

### Implications for sustainability of a learning health system

Both of these examples offer useful case studies in the level of effort required to identify learning priorities that are shared by researchers as well as a range of key stakeholders within the health care system. It suggests a model for the approach that will likely be necessary to better align the learning priorities of health systems and researchers. It also demonstrates that researchers will need to develop new perspectives and skills that would enable them to engage in focus groups and other mechanisms of interacting with clinicians, patients, health system leaders and other stakeholders (such as community leaders) in order to identify common interests. The additional time and resources required for these activities, which have not been a major focus in past research, may be challenging for researchers for whom time and resource pressures, in addition to requirements for academic advancement, may create barriers to investing the necessary time and effort to this preparatory work.

For clinicians, time devoted to learning activities will have to be streamlined to minimize the stress and burnout that clinicians often experience. According to Dr. Tobin, key challenges include 1) the ongoing issue of unprotected time for clinicians in community care settings that are focused on care delivery, and 2) ways for addressing social justice through generalizability of findings also have to be built into the cost of protocols in a meaningful and respectful way; for example, refining interventions so as to be feasibly implemented in non-academic settings, or creating follow-up opportunities to evaluate the interventions in other care settings, such as the cancer screening example.

### SAG Discussion

The group considered the unique structure of FHQCs, which have community members on their boards, and whether some of the successes of FQHC governance models and engaging community members might offer insights for leadership and governance models of a sustainable learning health system. However, there is little or no direct evidence to-date on the role and impact of FQHC governance models. In the context of the initial phases of building the infrastructure to support PCORNet, substantial emphasis has been placed on having active engagement of patients, clinicians and the general public in research network governance, research priority setting, data privacy policies, and all other aspects of the design and use of the learning infrastructure. While there is not yet a significant body of empirical evidence on how best to achieve effective and sustained engagement, there are strong conceptual arguments for taking this path, in addition to growing anecdotal experience and evaluation results.

In addition:

- Researchers will need to hone skills for engaging in focus groups and other techniques for interacting with clinicians, patients, health system leaders and other stakeholders in order to identify common interests
- Patient education and research training will be just as important for learning activities as clinician education and research training

## Alliance of Chicago Community Health Services

Fred Rachman, attending physician at Children’s Memorial and Northwestern Memorial hospitals and Chief Executive Officer of the Alliance of Chicago Community Health Services, shared some of his perspective from the community health center safety net domain. Dr. Rachman reminded the group that although the discussion focuses on “hypothesis-driven research,” learning activities still exist along a continuum. There are rapid turn-around and long-term studies, large scale and small scale studies, studies designed to be carried out in academic settings, and studies designed to be carried out in community settings. He argued that viewing these activities as clearly different categories with emphasis on their differences may result in lost opportunities for collaboration. The majority of learning activities are not purely targeted to near term systems improvement or only long term generalizable knowledge.

Many community health centers originated as community development initiatives, thus many patients of these centers are individuals from the local community, as are the staff, nurses, medical assistants, and etc. To the extent that community stakeholders are involved in developing intervention and recruitment activities, there are more opportunities to bring a patient or community lens to research. However, community health settings must also deal with the negative experiences of minority groups and communities with research. These experiences and perceptions can influence study participation, the success or failure of interventions, and the way results are disseminated.

Dr. Rachman noted that the average patient spends less than 0.5% of his or her life in a doctor’s office. Therefore, if patients and communities are going to be meaningfully engaged in a sustainable learning health system, researchers may need to consider new approaches that involve gathering information beyond that available in institutional records. As data become more interoperable and more consumers collect and transmit their own information through mobile applications and home-based devices, it is important to consider new data infrastructure models that reflect these developments.

## SAG Discussion

The group discussed the need to expand the scope of learning activities to include the time horizon and life course of patients: when and how do healthy babies become unhealthy patients? Such questions are beyond a health institution’s priorities and capacity to support, and may be better suited for a long-term public health surveillance model. These research questions also present unique practical challenges that make it readily understandable why they have not been a major focus of the research community to date. For example, payers have no way to predict whether an insured child will remain in the same covered population later in life or even a few years later. Thus, collecting and linking data from a wide range of payers and providers may be the only way to do this type of research. Another challenge to answering these long-term research questions is the federal focus on the short-term clinical and economic impacts of clinical and organizational interventions (e.g., one participant noted that the [U.S. Congressional Budget Office](#) scores interventions at a max of a ten-year intervals).

## Implications for sustainability of a learning health system

A sustainable learning health system will eventually need to be capable of gathering, accessing and interpreting the long-term information that captures patients’ lives beyond the 0.5% spent in doctors’

offices. This information will be of considerable value to accountable care organizations, integrated health systems and payers in particular, as they take on more financial risk for patients and the decisions they make in their daily lives that may affect their health outcomes. The payoff is hard to define from a payer perspective given the challenge of “patient churn” – payers can’t predict if a member will stay with them long-term. The solution may need to include an all-payer/all-systems initiative of some type. Conceivably, such data could eventually be leveraged by payers and systems to create evidence-informed behavioral interventions, policies that influence or encourage healthy behavior, or clinical interventions targeting age- and risk-specific cohorts.

## ImproveCareNow

Richard Colletti, ImproveCareNow Network Director and Physician Leader at Vermont Children’s Hospital, Fletcher Allen Health Care, co-presented with Beth Nash, parent and patient advocate, on lessons from the ImproveCareNow Network. ImproveCareNow 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 18 Patient-Powered Research Networks (PPRNs) funded as part of PCORI’s national patient-centered clinical research network (PCORNet).

ImproveCareNow has been associated with major improvements in the outcomes of these patients with the remission rate of network patients increasing from 55% to 77%. The majority of the board of directors of ImproveCareNow are parents and patients and are an integral part of the network. Care protocols still allow flexibility for patients and their doctors to make individualized decisions at the point of care, and a data-in-once approach helps to minimize data entry burden.

Beth Nash, a physician by training but also a parent and patient advocate for ImproveCareNow, described the multiple ways that patients and parents are involved in the network. For example, the patient advisory council is a group of 20-30 patients in their teens and young 20s, who help advise the network on a variety of issues.

Dr. Colletti and Dr. Nash described the benefits of ImproveCareNow to patients, families, physician researchers, payers, pharmacy and industry providers, and how that value can contribute to the sustainability of a network and system that can support learning, including hypothesis driven research.

## Value Proposition of ImproveCareNow

*Value for Clinicians:* Data collected can be leveraged by clinicians to make work easier and more efficient, for example, by generating progress notes, letters for referring physicians, and other useful reports such as pre-visit planning reports in real time. Furthermore, 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. “The value proposition for clinicians is very high: I am willing to enter data because I know I am getting something back.” Other value to clinicians include credit for maintenance of board certification, continuing education credits, US News and World Report credit, QI criteria for JACHO, and pay for performance criteria (results in clinicians getting a 2% higher payment for their visits).

### *Value for Patients and Families*

Patients and parents of ImproveCareNow post resources online for others to share, comment on the tools others post, and offer in-depth advice about research studies and other concerns. For example, a 9-year-old patient and his father posted an instructional YouTube video of the patient dropping his own nasogastric (NG) tube. Another patient developed a binder for newly diagnosed patients with everything they might need to know because “if you are newly diagnosed you really don’t know where to turn. You are very anxious.”

*Value for Researchers:* Dr. Colletti demonstrated how the ImproveCareNow network offered value to researchers by describing a study that used the ImproveCareNow database to replicate a costly trial previously conducted (and reported) on the effectiveness of a drug for children with Crohn’s disease. Identifying patients who would have been eligible for the original study, researchers were able to replicate findings for just thousands of dollars. In addition they were able to identify a control group from their database, which was missing from the original trial (placebo groups in pediatric trials are considered unethical when an effective therapy exists).

*Value for manufacturers:* ImproveCareNow also offers potential value to the pharmaceutical industry, for example, by building the capacity to do CER and facilitating drug research and implementation. It can also be leveraged to teach clinicians and patients how to optimize their medication use, engage patients and clinicians to prioritize and design studies, identify research subjects, conduct prospective drug efficacy studies, and do post-marketing surveillance.

*Value to payers:* ImproveCareNow is beginning to look at ways to lower the cost of care using the same methods that improved patient outcomes. It costs approximately \$28,000 per year per patient who has Crohn’s disease and it costs centers \$350 per year per patient to participate (just over 1% of the cost of care). If the network can demonstrate that membership can lower costs by more than 1% then it can show it is a good investment for payers to have their patients in the network.

### **Implications for sustainability of a learning health system**

*Insights for health system leaders:* Involvement may not help the bottom line for early adopters who may chose to participate for other reasons. Consequently, sustainability is uncertain and they are now engaging industry, payers, CEOs and other stakeholders. ImproveCareNow is not set up to answer every question but it builds a culture of collecting data for every patient visit so that if you want to do research, you don’t have to start from scratch. You don’t have to ask practices to go from 0 to 100% because they already have momentum.

*Patients and families are natural researchers: they just need a platform to share what they learn.* When parents involved in ImproveCareNow were asked what they were most interested in, it was research. Dr. Nash referred to parents as “natural researchers,” encouraging other systems to tap into their expertise. Once the structure of the parent committee was established and communicated, parents became much



more engaged: they worked on identifying goals and structures for accountability, they regularly identify 90-day goals, post to their website, and provide updates to the network with results.

One ongoing challenge to engaging families is helping parents trust that their opinions are valued and that expressing a negative opinion won't adversely affect their child's care. Other challenges include convincing centers that are already struggling to get up to speed with quality improvement to bring parents into the fold, and dealing with concerns about how parents would react when they saw what went on behind the scenes of the health care centers. Parents also raised concerns about access to data: "how come my kid's data is being collected, I am giving permission for all this data and I can't get access to that data? I am in the middle of making a clinical decision and would like to know how other people in the network are doing and how they fared." In reaction, the network is now putting in place a process to make requests to the research teams to be able to query the database on behalf of patients. They are working to identify priority questions and also search the literature and create brief lay person summary reports.

According to Dr. Colletti, "while intrinsic motivation is an important factor, the bottom line for each stakeholder is a very important factor too." ImproveCareNow tries to anticipate and to ensure that all the small, intrinsic motivations are there in addition to bottom line considerations. As the margin of added value for participation in learning activities grows (e.g. 2% to 5% to 10% return), there will be more significant implications for the bottom line.

### SAG Discussion

- There needs to be both short- and long-term value for all stakeholders. For example, as ImproveCareNow expands, the competitive edge of being an early member will diminish. In the long run however, with a continued shift toward accountable care and value-based reimbursement, that will be a sustaining factor for members.
- Some interesting work might be doing a case study on the initial startup of ImproveCareNow, interviewing the different groups and their triggers/motivators for joining.
- There is a lot of quality improvement work being done at the primary care level, but very little being done in specialty care, including identifying outcomes to measure, metrics for measuring performance, etc. Perhaps lessons from ImproveCareNow could offer a potential model to start from in other specialties or disease states.
- Many health plans don't know or understand their own data and come to researchers for help answering questions because they don't have the capacity to do so themselves. This is another potential value add to keep in mind.
- Proponents of learning health systems cannot approach patient communication and patient education in the typical medical way researchers have always done:
  - "We have to explain to people that docs actually don't have a freaking clue as to which of those is better." Reflection on the U.S. health system's collective naiveté can create negative effects, and not all questions are intuitive to patients (e.g. comparing 3 hours versus 4 hours of dialysis).
  - The U.S. healthcare field has led the public to believe that medicine knows everything and a visit to the doctor will make you better. This idea is inaccurate but nonetheless difficult for

the U.S. public to relinquish. It will be better to frame communications to the public in a positive message that emphasizes partnership: you can help your doctor help you. Examples of successful campaigns include the Women's Health Initiative: the U.S. shifted from a large percent of women taking postmenopausal estrogen, to nearly overnight acceptance that this treatment was not the right choice.

- Most intellectually curious people love data once you start showing them data about themselves and what they are doing and what their practices are. This could be a critical selling point for asking people to participate in CDRN and PPRN networks. Perhaps PCORNet could support some work to define a set of "want to haves" from the data: what information would be most important or interesting to network members to feed back to them.
- What is the added value for the health system to get involved? The idea of a learning health system is aligned with the mission of wanting to provide a social good. Furthermore, if a research learning collaborative could build a mechanism to connect patients with each other, it may turn out that patients select participating systems based on the value of the social aspect. However, in the context of an organization that is just starting out, and needing to get their operations in place, there is only a finite amount of energy. A motivated CEO can create some solvency within an organization, but competing demands on organizational energy remain a challenge.

## Conclusions

A fundamental challenge facing researchers today is that health system priorities often will not align with priorities for hypothesis-driven research. Much hypothesis-driven research is more rigorous than health systems generally need, and often requires greater financial support. Any discussion about the future sustainability of hypothesis-driven research will benefit by starting with a discussion between research and health system stakeholders of *when* it is preferable to conduct rigorous studies, without seriously interfering with health system operational priorities. The question remains whether a business case for health systems will ever be sufficiently strong without a clear mechanism through which it becomes a key business imperative for health system leaders to demonstrate that their systems are actively engaged in the full range of learning at local, regional and national levels.

### ***Thoughts on the Path Forward:***

An important intermediate step to finding a solution may be to explore the feasibility of health systems supporting a balanced portfolio of learning activities that adequately contribute to the quality improvement and transformational needs of health systems, while in some cases allowing studies that don't directly contribute to near term operational health system needs. For example, there may be some room for NCQA recognition programs, health plan requirements for providers to be part of preferred networks, and other "market mechanisms" that provide business advantages to fully functional learning health systems."

In conclusion, dialogue between research and health system stakeholders will have to be open and honest, fully acknowledging the likelihood that not all activities will satisfy the goals of each partner. Through ongoing dialogue, stakeholders may more clearly outline the complete picture of benefits and

“harms” to each stakeholder, including clinicians and patients, in order to demonstrate a mutually beneficial relationship. By systematically capturing the pros and cons of different types of learning for each key stakeholder, it may be possible to describe a partnership framework that offers net benefits to each partner, and by extension, to other stakeholder groups such as research funders, life sciences companies and payers.

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### **Additional Information**

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