THE LEARNING HEALTH SYSTEM SERIES



ACCELERATING Medical Evidence Generation AND USE

SUMMARY OF A MEETING SERIES

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Joe Selby, Eric Larson, Rainu Kaushal, Maryan Zirkle, Marianne Hamilton Lopez, and Danielle Whicher, *Editors*

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ACRONYMS AND ABBREVIATIONS

| ACA | Patient Protection and Affordable Care Act |
|----------|--|
| ACO | accountable care organization |
| AHRQ | Agency for Healthcare Research and Quality |
| CDRN | Clinical Data Research Network (funded by PCORI) |
| CEO | chief executive officer |
| CHAB | community health advisory board |
| CHOP | Children's Hospital of Philadelphia |
| CLABSI | central line-associated bloodstream infection |
| CMS | Centers for Medicare & Medicaid Services |
| СТ | computed tomography |
| ED | emergency department |
| EHR | electronic health record |
| ELN | NAM Executive Leadership Network |
| FDA | US Food and Drug Administration |
| IHI | Institute for Healthcare Improvement |
| IOM | Institute of Medicine (now National Academy of Medicine) |
| MRI | magnetic resonance imaging |
| MRSA | methicillin-resistant Staphylococcus aureus |
| NAM | National Academy of Medicine |
| NIH | National Institutes of Health |
| NQF | National Quality Forum |
| ONC | Office of the National Coordinator for Health Information Technology |
| PCMH | patient-centered medical home (or primary care medical home) |
| PCORI | Patient-Centered Outcomes Research Institute |
| PCORnet | National Patient-Centered Clinical Research Network |
| PICC | peripherally inserted central catheter |
| PPRN | Patient-Powered Research Network |
| REACHnet | Research Action for Health Network |
| ROI | return on investment |
| TCPI | Transforming Clinical Practice Initiative |

1

INTRODUCTION AND OVERVIEW¹

L earning health systems seek to use administrative and clinical data for continuous improvement in the quality, effectiveness, and efficiency of care. They work to embed knowledge generation and performance transparency as part of their organizational culture, reinforced by a growing demand from external stakeholders to ensure that data be applied to improve the quality and outcomes of care. In developing the National Patient-Centered Clinical Research Network (PCORnet), the Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI) envisioned a large data infrastructure that would enable more rapid, efficient, and economical comparative effectiveness research that could inform practice and advance health system improvement, and thus contribute to a continuously learning health system.

According to Joe Selby, executive director of PCORI, PCORnet was designed to capitalize on the volumes of data being accumulated in electronic health records (EHRs), claims data, and other disparate data sources across the country that are often underutilized or not routinely captured by payers and providers (e.g., social determinants of health, patient-reported outcomes, and genomic data). Structurally, PCORnet is a network of networks that offers a standard way of organizing and aggregating data on large numbers of patients to facilitate multisite research. PCORnet's mission is to harness these data and research findings to facilitate health system improvement and, in the process, transform the culture of clinical research from one directed by researchers to one driven by the needs of patients and those who care for them. More than 130 health systems across the United States are organized

¹ The planning committee's role was limited to planning the meeting. This meeting summary has been prepared by the rapporteurs as a factual summary of what occurred at the meeting. Statements, recommendations, and opinions expressed are those of individual presenters, and not those of the National Academy of Medicine, and should not be construed as reflecting any group consensus.

into PCORI-funded Clinical Data Research Networks (CDRNs) that collect, organize, and aggregate data from EHRs and Patient-Powered Research Networks (PPRNs) that are focused on specific health conditions. Now in the second phase of its development, PCORnet is focusing on expansion and sustainability.

To assist PCORI in engaging researchers and health system executives in the development of PCORnet, two workshops were hosted by the National Academy of Medicine (NAM) Leadership Consortium for a Value & Science-Driven Health System (formerly the Institute of Medicine (IOM) Roundtable on Value & Science-Driven Health Care), in April and June 2014. At these workshops, participants discussed that the ongoing, iterative process of research draws from data on system performance, quality of care, efficiency of care, and patient experience, repeatedly—optimally, continuously—over time. Especially underscored was the importance of partnerships between researchers and health system leadership. These workshops are summarized in the 2015 report *Integrating Research and Practice: Health System Leaders Working Toward High-Value Care* (IOM, 2015a).

In continuing this work, in 2016 the NAM hosted a series of meetings on Accelerating Clinical Knowledge Generation and Use. The series was sponsored by PCORI and held under the auspices of the NAM Executive Leadership Network (ELN) for Continuously Learning Health Care, an executive-level initiative of the Leadership Consortium for a Value & Science-Driven Health System aimed at investing health system executives to advance progress toward a continuous learning health system. The ELN draws on leaders from health care institutions around the nation for synergy in this work.

The motivation for this new meeting series was to consider opportunities to build institutional capacity, cross-institutional synergy, and system-wide learning. More specifically, participants convened to discuss building infrastructure that simultaneously facilitates care delivery, care improvement, and new knowledge; ways to accelerate progress through cooperation and sharing across organizations; and approaches to steward system-wide progress toward continuous and seamless learning and improvement throughout health and health care.

A number of recurring themes emerged across the meeting series, as participants considered the data needs of executive-level decision makers, and the role and potential of PCOR net in facilitating clinical knowledge generation and use. The themes and opportunities highlighted in Box 1-1, drawn by the editors from the individual presentations, breakout sessions, and open discussions, are discussed further in the succeeding chapters.

BOX 1-1

Common Themes and Opportunities For Action

Executive needs

- Data structured for priority action
- · Findings that are context-applicable
- · Workflow-friendly continuous learning and improvement
- Strategies for integrating knowledge generation into the business proposition
- Innovation that enhances efficiency
- · Patient- and provider-resonant research returns

Success factors: the PCORnet Example

- Health system leaders helping to shape research priorities
- Shared leadership accountability
- Engaged clinicians
- Early focus on dissemination and implementation
- Full collaboration between research side and operations/practice side

Capacity requirements

- EHR systems designed for flexible incorporation of emerging core elements
- · Continuous training and peer learning networks
- Visualizations and delivery system toolkits that facilitate translation to decisions
- · Analytic capacity and practice that integrates multiple data sources

Stakeholder action priorities

- Research models and methods proven in real-world settings
- Training and competencies for researchers embedded in delivery systems
- Access to, and integration of, social determinants data from outside health care
- Demonstrated strategies for implementing new practices into health care systems
- Better evidence on the impact of EHR-embedded information on outcomes
- Inventory of research issues most important to address

SOURCE: Summary of closing remarks, speaker presentations, and participant discussions.

SCOPE AND OBJECTIVES OF THE MEETINGS

The two-meeting series summarized in this publication was designed to inform the PCORnet Health Systems Demonstration Project (see Box 1-2), and builds on prior NAM work in partnership with PCORI, including the 2014 workshop series noted earlier (IOM, 2015a). The first meeting was held in January 2016. The chair of the planning committee Eric Larson, vice president for Research and Health Care Innovation at Kaiser Permanente Washington Health Research Institute, outlined the goals of the meeting as follows:

- 1. **Identify compelling care questions**. Propose important questions on system performance, measurement, and operations that might be answered from systematic capture of care delivery data. Explore the views of health system leaders on the highest priority questions to be addressed, including the value of standardized data collection.
- 2. **Explore common priorities**. Identify common priorities to help improve communication, synergy, and progress among health care organizations with related interests.
- 3. **Consider research-ready data systems**. Characterize and consider clinical data system characteristics necessary to generate usable knowledge in real time, including use of PCORI's Common Data Model.
- 4. **Explore strategic options**. Provide input to the PCORI demonstration projects, as well as the expansion of strategic priorities.

As follow-up to the January meeting, a second meeting, convened in September 2016, focused on health executive leadership for development, spread, and scaling of a continuously learning health system. It extended the January discussion to consider three core questions:

- Consider benefits: What specific and identifiable benefits (care, evidence, outcomes, and value) might be expected from the infrastructure envisioned? Are there examples from PCOR net, the National Patient-Centered Clinical Research Network?
- 2. **Explore strategies:** What strategic levers can health care executives use to accelerate progress?
- 3. **Identify priorities:** What key action items and priorities by the NAM and PCORI can accelerate progress?

BOX 1–2 Statement of Task

In collaboration with the PCORnet Health Care System Interaction and Sustainability Task Force, the NAM will draw on its Executive Leadership Network and convene an invited group of senior leaders from health delivery centers and systems for a face-to-face meeting focused on leadership for accelerating clinical knowledge generation and use. Invitees will include the participants from the 2014 Integrating Research and Practice workshop, sponsored by PCORI and convened at the National Academies. The meeting, which will be a component of the PCORnet Health Systems Demonstration Project, will engage stakeholders in assessing the relevance and value of health systems projects within PCORnet; providing input to the Demonstration Project's early pilot projects as well as the strategic priorities for future awards; discussing how improved data might impact systems' performance, measurement, and operations; and exploring the prospects for the use of common data models to get measurement sets to "study, measure, and improve" care locally and nationally. In order to potentially further expand this work, a follow-on meeting with key principals will focus on lessons learned and explore next steps in developing a multiyear meeting series.

ORGANIZATION OF THE MEETING SERIES

In addition to three expert panel sessions, the first meeting was specifically designed to inform the PCOR net Health Systems Demonstration Project by gathering input from CDRN principal investigators, health system senior leaders, and other stakeholders in a moderated breakout session and plenary discussions.² It was also intended to inform similar clinical research networks developing to accelerate findings important to health care improvement. Participants divided into five groups to discuss the data and analytic needs of importance to executive-level decision makers, consider the value of PCOR net and PCOR net studies in improving health care delivery locally and nationally, and contemplate next steps for further development of PCOR net. Group facilitators reported back on the breakout discussions in plenary session and participants considered a set of care

² See Appendix A for the meeting agenda.

system research questions that were developed prior to the workshop, as part of the first phase of the PCOR net Health Systems Demonstration Project. An open discussion followed with participants sharing their thoughts on needs, opportunities, successes, failures, and strategies that could help inform the PCOR net Health Systems Demonstration Project.

As outlined in introductory comments by Michael McGinnis, executive director of the Leadership Consortium for a Value & Science-Driven Health System, the second meeting built upon the recent initiatives that have been undertaken in close partnership with PCORI to facilitate stronger engagement by health executives in knowledge generation and the alignment of research and operations. The meeting convened invited representatives from the NAM's Executive Leadership Network and PCOR net research partners. The meeting included five sessions: vision and progress; NAM Executive Leadership for a Continuously Learning Health System; an overview of the PCOR net Health Systems Demonstration Project awardees; an open discussion of needs, opportunities, and strategies; and an overview of the day's discussion. For each panel, the moderator and speakers provided framing comments and presentations leading to general discussion.

This publication summarizes the presentations and discussions that took place at the meetings. Chapter 2 discusses the data needs of executive-level decision makers in health systems as they put new knowledge into practice with the goal of achieving improved outcomes for patients. Chapter 3 considers the return on investment of evidence generation for health delivery systems. The stakeholder input sessions are summarized in Chapter 4, including the breakout discussions, the discussion of the set of care system research questions, and the general discussion of needs and opportunities. Chapter 5 considers the use of health system data for understanding performance, measuring performance, and creating the next generation of more meaningful performance measures. In the concluding chapter (Chapter 6) the moderators reflect on the progress and advances made since the two 2014 workshops, the recurring themes from the current meeting series, opportunities for stakeholder action, and future directions for PCOR net.

2

EXECUTIVE DECISION NEEDS AND DATA PRIORITIES

To set the stage for the breakout discussions, the first meeting's panel addressed the needs of executive-level decision makers in health systems as they strive to put new knowledge into practice and achieve improved outcomes for patients. Herb Pardes, former CEO and current executive vice chair of New York-Presbyterian Hospital, commented on clinical data as a change tool from the perspective of a health care executive. Nirav Shah, senior vice president and chief operating officer for clinical operations at Kaiser Permanente, introduced the concept of evidence generation from real-time care delivery. As a case example of data transforming practice, Ron Keren, vice president of quality and chief quality officer at the Children's Hospital of Philadelphia (CHOP), discussed the comparative effectiveness of intravenous versus oral antibiotics for the postdischarge treatment of children with acute osteomyelitis. The presentations were followed by a brief open discussion. Highlights and main points of this session are summarized in Box 2-1.

A HEALTH EXECUTIVE'S PERSPECTIVE

In his opening remarks at the first meeting, Pardes emphasized that the health care landscape is experiencing extraordinary change; health system networks are expanding, and physician practices are consolidating. Payment reform is under way and there is a movement from fee-for-service to value-based care, with health systems becoming increasingly responsible for delivering the highest quality of care, as efficiently and effectively as possible. There is also a growing emphasis on population health management. However, he also stated that medicine in health care should always focus on what is unique to the individual patient.

As a former health system CEO, Pardes noted that executive decision makers want as much information about their patients as possible, to be able to make patient care better. Having accessible data is critically important, especially

BOX 2-1

Comments on Decision-Needs and Data Priorities

Timeliness and applicability. Having access to timely, actionable data is critically important for health system executives, especially when deciding what to prioritize and where to invest. While they have access to data from their own systems, they often have difficulty obtaining data from other systems for comparison purposes. [Pardes]

Digital infrastructure limits. The use of electronic data systems in clinical care has helped to decrease the time it takes for evidence-based care to become routine practice; however, the process still needs to be much more efficient. A national clinical data infrastructure could provide actionable data more rapidly to multiple stakeholders, and facilitate more effective and efficient research. PCORnet is a step in this direction. [Pardes]

Social circumstance data. Especially for the basic health needs of complex patients, without data on the social determinants of health, those needs cannot be met. What is needed is real-time flow to the point of care of actionable information on social circumstances. [Shah]

Practice-research bridge. Participants discussed the importance of establishing a partnership between research and clinical practice from the beginning (e.g., involving those that will be implementing the findings in the design of the studies). Those generating evidence must plan for its dissemination, and those implementing the findings in practice must provide data and feedback to foster a learning system of continuous improvement. [open discussion]

Success elements. Elements of success for knowledge generation and translation of comparative effectiveness research include: access to the necessary data; a funding source interested in supporting comparative effectiveness research; engaged clinicians to conduct chart reviews; a dissemination and implementation plan in collaboration with key partners and stakeholders, targeting education where change is most needed; updated and validated administrative codes to facilitate automated reports; and audits and feedback to system medical, quality, and safety officers. [Keren] when making decisions regarding what to prioritize and where to invest. While health system executives have access to data from their own health system, they struggle to obtain actionable data from outside their system, even within the same geographic region. They have even less ability to access data for comparison purposes from other health care systems, including academic medical systems.

There has been an explosion in research findings. A long-standing estimate suggests that is takes about 17 years for evidence-based care to become routine practice, but that time frame is shrinking with the introduction of electronic systems into routine clinical care. Still, the process of moving new knowledge from the bench to the bedside needs to be more efficient. In this regard, according to Pardes, there is a tremendous need to establish a national clinical data infrastructure to provide actionable data more rapidly and to facilitate more effective and efficient research. He cited the National Patient-Centered Clinical Research Network (PCORnet), with its consortium of Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs), as a step in this direction. The PCORnet national infrastructure supports patient-centered clinical research, which is critical because the patient voice has long been overlooked, and aims to improve the delivery of health care.

GENERATING EVIDENCE IN HEALTH SYSTEMS

Much of the information used for the improvement of health care over the past 50 years has been repurposed from regulatory, administrative, or payment data. Although substantial useful information has been gleaned from billing data, these data have a very poor signal-to-noise ratio, according to Shah, and cannot be the basis of improvement for the coming decades. Means or averages do not provide information about individual variation, but data on these variations are needed for improvement over the coming years.

As an example, Shah described using practice-based evidence in breast cancer treatment. Because younger women have fewer comorbidities, resulting in cleaner data, the average age of women enrolled in a breast cancer randomized controlled trial is 48 years old. But 48 may be very different from the average age of a particular cohort of women undergoing breast cancer treatment. After analyzing more than 2,000 different protocols for treating cancer patients at Kaiser Permanente, Shah pointed out that the average woman being treated for breast cancer was not 48, but 72 years old. In addition, while the rate of febrile neutropenia in randomized controlled trials was about 2 percent, Kaiser data from treatment protocols indicated that it was closer to 18 percent (i.e., one in five women in treatment was having this unexpected, potentially fatal outcome). As a result of this finding from

practice-based evidence, Kaiser now pretreats all women with breast cancer to avoid febrile neutropenia. To achieve the next level of health care improvement, evidence must be more relevant to real-world circumstances. Leveraging data at scale will be the basis of competitive advantages for health systems.

Top Health System Users

The 40,000 patients in Southern California who constitute the top 1 percent of health system users are seen in a hospital on average by 62 different individuals and cost more than \$60,000 each. This population interacts frequently with the health system, and yet its needs are not being met. In partnership with Health Leads (a national organization that connects low-income patients with the basic resources they need to be healthy), Kaiser reached out to people in this group to ask questions about their health, including not only health care use but also food insecurity, transportation, housing insecurity, and other social determinants of health.

Although these patients often had three or four different social workers and case coordinators calling on them (e.g., one for hypertension, one for diabetes, one for asthma, etc.), many basic elements of health were still being missed. One very simple example was the need for a handrail to be installed in a stairwell for an elderly woman to help prevent falls.

The implication is that economic assessments by health care leaders should more broadly define health care and make the business case for investing in the social determinants of health. There is a return on investment for health systems in addressing social determinants of health and relationships with patients are a tactical advantage. Accountable care organizations (ACOs) are evolving, and, Shah noted, while they have the basic "anatomy of integration" by bringing together hospitals, nursing homes, and other health groups, they do not yet have the "physiology of integration," which is the real-time flow of actionable data to the point of care across teams of providers. He observed that PCOR net embodies the opportunity to "move knowledge, not people."³

DATA TRANSFORMING PRACTICE: CHILDHOOD OSTEOMYELITIS EXAMPLE

To illustrate the challenges of knowledge generation and translation, Keren described the experience in treatment of acute osteomyelitis in children, specifically, the comparative effectiveness of intravenous versus oral antibiotics

³ For more information see the IHI New Rules for Radical Redesign in Health Care at http:// www.ihi.org/Engage/collaboratives/LeadershipAlliance/Documents/IHILeadershipAlliance_ NewRulesRadicalRedesign.pdf (accessed May 31, 2016).

postdischarge. Children who present at a hospital with osteomyelitis are treated with intravenous antibiotics until the fever, swelling, and pain subside, and function returns. Continued antibiotic therapy is needed for several weeks postdischarge which, traditionally, is administered via peripherally inserted central catheter (PICC). There is a trend, however, to continue treatment at home via oral antibiotics.

In 1997, Peltola and colleagues published a study showing that 50 Finnish children with acute staphylococcal osteomyelitis were successfully treated postdischarge with an oral antibiotic (Peltola et al., 1997). Over the years, Ruebner and colleagues observed variation in how osteomyelitis was being treated postdischarge and, in 2004, they undertook a retrospective cohort study of all children admitted to CHOP from 2000 through 2003 with acute hematogenous osteomyelitis (Ruebner et al., 2006). Of the 80 children who met the inclusion criteria, only 5 had been transitioned to oral antibiotics. Of the 75 children who had received at least 2 weeks of antibiotic treatment at home via central venous catheter, 41 percent had a catheter-associated complication (catheter malfunction or displacement, catheter-associated bloodstream infection, fever with negative blood culture, or local skin infection).

Concerned about the high complication rate in children who are treated postdischarge via central venous catheters, Keren and colleagues conducted a retrospective cohort study of prolonged intravenous versus oral antibiotic therapy (Zaoutis et al., 2009). Zaoutis and colleagues searched the Pediatric Health Information System⁴ for children aged 2 months to 17 years who were diagnosed with acute osteomyelitis from 2000 through 2005. At that time there were 29 hospitals submitting data, and 1,969 children were identified who met the inclusion criteria. Approximately half had been treated via central venous catheter (n = 1,021) and half had been treated orally (n = 948). The authors found a wide variation across the 29 hospitals in terms of the percentage of children who were converted to oral therapy, ranging from 10 percent to 97 percent. Propensity score-adjusted rates of treatment failure (rehospitalization within 6 months) were similar (5 percent among children treated via central venous catheter versus 4 percent among those treated with oral therapy). A catheter-associated complication that required hospital admission was identified in 3.4 percent of children who received prolonged intravenous therapy. Keren noted that this number is significantly lower than the

⁴ The Pediatric Health Information System is a database of the Children's Hospital Association. It currently compiles data from 44 children's hospitals and includes 5 million inpatient cases, 30.2 million inpatient days, and 20.2 million emergency department encounters, as well as data from billing systems, patient abstract data, and *International Classification of Diseases, Ninth Revision* (ICD-9) diagnoses and procedures data.

41 percent observed in the CHOP study because it is based on admissions only and does not include other provider visits for complications due to catheters (e.g., visits to the emergency department or a primary care provider).

Despite these findings, Keren's review of data from 2009 through 2011 found that there were still hospitals where fewer than half the children were being transitioned to oral therapy. He sought to understand why his earlier findings had not led to a change in practice. Foremost was that there had been no dissemination and implementation plan for the 2009 findings. In addition, colleagues at hospitals that were still using central venous catheters said they had some concerns about the 2009 study. For example, the use of only administrative data led to concerns about the ascertainment of the diagnosis, exposure, and outcome. There were also concerns about residual confounding and new concerns about the rise of community-acquired methicillin-resistant *Staphylococcus aureus* (MRSA), which was not an issue at the time of the study.

To address this further, Keren and colleagues proposed a clinical effectiveness study to the Patient-Centered Outcomes Research Institute (PCORI) that would include chart reviews to confirm the diagnosis, exposure, and outcomes of the children identified through the Pediatric Health Information System. In addition, more up-to-date methods for dealing with confounding would be included, as would propensity score-based full matching within and across hospitals. Stakeholders would also be engaged to help facilitate dissemination and implementation.

The retrospective cohort study included data from 36 children's hospitals on children hospitalized from 2009 through 2012 (Keren et al., 2015). The primary outcome was treatment failure, defined as a revisit or rehospitalization for a specified indication (change in antibiotic or dosage, prolongation of antibiotic therapy, conversion from oral to PICC route, bone abscess drainage, debridement of necrotic bone, bone biopsy, drainage of an abscess of the skin or muscle, arthrocentesis, and diagnosis of a pathologic fracture). Of 2,060 children with osteomyelitis, about half (n = 1,055) were treated via PICC lines and about half (n = 1,005) were treated with oral antibiotics. The percentage of children who were treated postdischarge via PICC line varied widely across hospitals, ranging from zero to 100 percent. The treatment failure risk was about 4 percent, similar to the 2009 study, and the risk difference was 0.3 percent, which Keren noted was not statistically significant. Fifteen percent of the children with PICC lines had a catheter-associated complication that required an emergency department visit, rehospitalization, or both.

Keren concluded his presentation on the research findings by focusing on the value of the retrospective cohort study design for this particular research question

and population. According to Keren, randomized controlled trials for children with osteomyelitis would not be feasible given the number of children who would need to be enrolled in order to show a small difference in what is already a relatively low complication rate. By using the retrospective cohort design, researchers were able to confirm the results of the prior study that was done using only administrative data. The results are consistent, even with the rise in MRSA prevalence. Keren suggested that the findings from the retrospective cohort design study are likely the strongest evidence available to answer the question of oral versus intravenous postdischarge antibiotic therapy. As a result of this effort, evidence-based knowledge was ultimately applied to impact practice transformation.

Elements of Success

Keren highlighted several elements that helped to enable knowledge generation and translation for the recent clinical effectiveness study. First, it was essential to have a funding source that was interested in supporting comparative effectiveness research, access to the necessary data (in this case, the Pediatric Health Information System), and engaged clinicians to conduct the chart reviews. The Pediatric Research in Inpatient Settings research network helped to identify the site leads at each hospital who could facilitate the chart review.

For dissemination, Keren partnered with PCORI to hold a continuing medical education seminar on the findings, and the publisher of the article, *JAMA Pediatrics*, sponsored a Twitter Journal Club. In addition, the Children's Hospital Association sponsored a webinar, and there was coverage of the findings in dozens of pediatric and lay media. With regard to implementation, Keren is now working with the Children's Hospital Association to produce quarterly reports that will be disseminated to key stakeholders and each of the children's hospitals. Administrative codes have been validated and now have high sensitivity and specificity for case, exposure, and outcome ascertainment so that reports can be produced in an automated fashion. Audits and feedback reports will be shared with chief medical officers, chief quality officers, and chief safety officers. A change package is also being developed that will include education, guidelines, and treatment recommendations for dissemination to sites that are still using PICC lines for postdischarge antibiotic treatment.

In closing, Keren posed three questions for consideration relative to clinical data as a change tool: (1) Why did it take almost 20 years to move from the first treatment innovation in Finland in 1997, to the comparative effectiveness research, to the actual implementation work? (2) How many children were treated unnecessarily with central venous catheters? (3) How can we make better use of data to accelerate knowledge generation and translation?

DISCUSSION

In the open discussion that followed the presentations, participants emphasized the need for better communication and feedback between the research community and the practice community, in order to accelerate the application of findings. Danielle Lloyd of Premier, Inc., highlighted the importance of feedback, connecting back to the research, and applying lessons learned to retesting or the creation of new guidelines. She raised the question of how to get community hospitals more involved with the implementation aspect. Keren agreed that the separation between the academic and operational sides is a problem for a variety of reasons, including the absence of expectation of a dissemination/ implementation plan for research findings. Researchers have historically relied on publication as the primary method of getting the word out. He observed, however, that there is a movement toward engagement and collaboration between the organizations that are generating the evidence and those that are putting it into practice. He reiterated his example of CHOP working with the Children's Hospital Association to translate the results of research findings into practice.

Pardes observed that disparate groups are coming together, and that there is more inclusiveness of different constituents in health care than ever before. PCORI is the essence of this. There are challenges, he acknowledged, but the mood is becoming one of collaboration geared toward restoring the health care system. Participants stressed the importance of establishing a partnership between academia and clinical practice from the beginning and involving those who will be implementing the findings in the design of the studies.

Also referenced as a possibility for slowing progress was the existence of a contradiction in the tenets of medical professionalism. Health professionals are taught to "first, do no harm," which leads to a healthy skepticism and conservatism about new ways of doing things. The other side of professionalism, however, is constant learning and looking at where the evidence points. The evidence may be there (e.g., for the transition to oral antibiotics for osteomyelitis postdischarge), but doubts about administrative data, and reluctance to test further and find a better way, can result in providers taking the fallback position and continuing with the "tried and true ways." Moderator Larson expressed optimism that the medical profession is moving in a direction where people are questioning the standard assumptions.

3

EVIDENCE GENERATION RETURNS-ON-INVESTMENT

A question for health delivery systems is how to justify evidence genera-Ltion from the standpoint of returns on investment (ROI). This question is also relevant to the funding of a national data infrastructure. In this session, Kate Goodrich, director of the Center for Clinical Standards and Quality at the Centers for Medicare & Medicaid Services (CMS), discussed the value of research and data infrastructure to health and health care, describing the CMS Transforming Clinical Practice Initiative (TCPI) as an example of evidencebased quality improvement that rewards value. Peter Pronovost, senior vice president for Patient Safety and Quality at Johns Hopkins Medicine, described the reduction of central line-associated bloodstream infections (CLABSI) as a case example of the spread and scale of knowledge to advance policy and practice and improve outcomes. Thomas Carton, principal investigator at the Research Action for Health Network (REACHnet) and the Louisiana Public Health Institute, described the REACHnet process as an example of one Clinical Data Research Network's (CDRN's) approach to this problem. An open discussion followed the presentations. Highlights and main points of this session are summarized in Box 3-1.

THE VALUE OF THE RESEARCH AND DATA INFRASTRUCTURE

The ROI of evidence generation should be better outcomes at lower cost. CMS has long been involved in the improvement of care. Since the passage of the Patient Protection and Affordable Care Act, CMS has been working to help frontline clinicians improve care and transform the care delivery system to meet the three aims of better care, smarter spending, and healthier people. To meet these aims, CMS is focusing on three key areas: incentives, care delivery, and information. Changing the incentive structure includes promoting

BOX 3-1

Comments on the Returns on Investment in Evidence Generation

Clarify goals. Elements of successful spread and scale of knowledge for improved performance at the health system level include clear definition and communication of goals from system leadership, leadership support of an enabling infrastructure (e.g., project management staff, training/peer learning communities for clinicians, and transparent data reporting), engaged frontline clinicians, and a system of shared leadership accountability. [Pronovost]

Link full spectrum of problem-solving. Improvement science is focused on solving specific problems, starting with the end goal (i.e., improved outcomes) and working backward. It requires partnerships among researchers and providers, transdisciplinary teams from medical and social sciences aligned around the common goal, structures that support peer learning communities and data collection, and reliable and valid mixed-methods approaches to evaluation to facilitate spread and scale of successful solutions. [Pronovost]

Build linkages and synergy. Participants highlighted the need for synergy among different clinical networks and data systems, and discussed the potential of a common, national clinical database. The ROI for PCORnet and other such networks includes the ability to use common clinical data across multiple sites for comparative effectiveness; a community of engaged stakeholders to enable more rapid transformation of evidence into practice; and the ability to readily engage patients in studies both as participants, and as partners in research design. [open discussion]

Drive transformation. The CMS TCPI model aims to build the evidence base for practice transformation, improve health outcomes, reduce unnecessary utilization, scale effective solutions, achieve savings, and reward value fundamental to transforming the care delivery system in improving how information is shared and distributed. This includes transparency of cost and quality information, and bringing electronic health information to the point of care. [Goodrich] value-based payment systems and transforming from fee-for-service to alternative payment models. CMS is doing this through a number of mechanisms, working with both the public and private sectors to test new models and bring proven models to scale. The focus on care delivery involves encouraging the integration and coordination of care and services; improving communication; improving population health; and meaningfully engaging patients, families, and caregivers in their care through shared decision making. Fundamental to transforming the care delivery system is improving how information is shared and distributed. Goodrich noted the need to create transparency on cost and quality information, and to bring electronic health information to the point of care for meaningful use.

In 2015, the US Department of Health and Human Services established specific goals for the Medicare program's move toward value, and invited commercial payers and states to share in these goals (Burwell, 2015). The first goal, set for the end of 2016, was for 30 percent of Medicare payments to be tied to quality and value through alternative payment models where providers are held accountable for patient outcomes and cost of care. By the end of 2018, the goal is for 50 percent of Medicare payments to be through such alternative payment models. The second goal was for 85 percent of Medicare fee-for-service payments to be tied to quality and value by the end of 2016, reaching 90 percent of payments tied to quality and value by the end of 2018.

The CMS Transforming Clinical Practice Initiative (TCPI)

These goals compelled providers to improve outcomes for patients and to lower costs, and CMS recognized the need to provide support and tools for hospitals, doctors, and other frontline clinicians to help them achieve these goals. In 2015, CMS launched TCPI, a quality improvement initiative to help clinicians transform their practice and transition into alternative payment models. Nearly \$700 million has been awarded by TCPI to support transformation.

The seven goals of TCPI, as outlined by Goodrich, are to

- support more than 140,000 clinicians in their practice transformation (Goodrich noted that 140,000 clinicians is the starting point and that there are about 1.3 million frontline clinicians that participate in the Medicare program);
- 2. **improve health outcomes** for millions of Medicare, Medicaid, and Children's Health Insurance Program beneficiaries and other patients;
- 3. reduce unnecessary hospitalizations for five million patients;

- 4. generate \$1 billion to \$4 billion in **savings** to the federal government and commercial payers;
- 5. sustain efficient care delivery by **reducing unnecessary testing** and procedures by focusing on appropriate use of testing and diagnostics;
- 6. transition 75 percent of practices completing the program into **alternative payment models**; and
- 7. **build the evidence base** on practice transformation so that the solutions can be scaled.

Within the TCPI, there are five phases of transformation for practices. In the first phase, practices set very specific aims for how they want to improve. Next, practices are taught how to use data to drive improvement at the point of care. In the third and fourth phases, practices achieve progress on the aims they have set and achieve specific benchmarks that CMS sets for each of those aims. In the final phase, the goal is for the practice to thrive as a business through payfor-value approaches.

TCPI has awarded contracts to two different types of networks: Practice Transformation Networks and Support and Alignment Networks. Practice Transformation Networks are organizations that provide "on-the-ground" technical assistance to clinician practices to help them understand where there is existing evidence on how to improve care in a particular area and how to collect data and generate evidence on how to improve care. Support and Alignment Networks help practices to align their multiple programs (e.g., continuing medical education, maintenance of certification, registries, and other requirements) with the aims of TCPI.

Overall, the TCPI model aims to transform practice, improve health outcomes, reduce unnecessary utilization, scale effective solutions, achieve savings, and reward value. Goodrich reemphasized that a major goal of the program is to build the evidence base for practice transformation so that these solutions can be scaled if they are found to be successful. She also emphasized the importance of collaboration and information sharing among all of the quality improvement networks that CMS supports. What works within a hospital may or may not work within an individual practice or a treatment facility.

SCALE AND SPREAD: A NETWORK OF CONTINUOUS LEARNING

Eliminating harm is an iterative process, and there have been many learning cycles over the years. When the landmark Institute of Medicine report *To Err Is*

Human was published (IOM, 2000), central line–associated bloodstream infections (CLABSIs) were so common that they were practically the norm, Pronovost noted. To emphasize the point, he mentioned the case of a young girl who died in his hospital of catheter infection around that time, and the root-cause analysis did not even mention her central line infection. But cases like hers challenged the medical professions and the country to eliminate these infections.

Fifteen years later, rates of CLABSI in intensive care units have been reduced by over 80 percent in all types of hospitals across the United States, in both children and adults (Pronovost et al., 2015). Pronovost and colleagues described this as a remarkable success story, and he reflected on what allowed this to happen, first at a policy level, and then at the local health system level.

Improvement Science

The science of improvement starts with the end goal (i.e., improved outcomes) and works backward (Dixon-Woods et al., 2013; Marshall et al., 2013). Improvement science involves both basic and applied science, but it is focused on solving specific problems. It requires partnerships among researchers and providers and is informed by transdisciplinary teams from medical and social sciences. Improvement science uses multifaceted interventions and employs mixed-methods evaluations to learn not just whether an approach worked, but why and how it worked so that it can be scaled and spread.

Pronovost and colleagues studied the improvement in the rates of CLABSI and identified five elements that contributed to this success at the national policy level (Pronovost et al., 2015). First, efforts at improvement used a reliable and valid measurement system that clinicians believed. He noted that CLABSI is one of the few harms for which there are valid measures. Efforts also relied on decades of National Institutes of Health (NIH) and Centers for Disease Control and Prevention basic and clinical research to identify strategies to reduce infections and develop guidelines and checklists for clinicians. There were investments by the Agency for Healthcare Research and Quality and others in implementation science to understand how to change behavior at the bedside. There were also "cascading structures" that supported peer learning communities and data collection. Finally, stakeholders were aligned and synergized their transdisciplinary efforts around a common goal and measure (the reduction of CLABSI).

To understand improvement at the provider level, Pronovost and colleagues employed an approach called peer-to-peer review, where social scientists and clinicians visited high- and low-performing institutions. While on the surface it might have appeared that the use of an implementation checklist created for clinicians was the solution, the reality was more complex, and they identified a
series of explicit requirements for improved performance. First, it was essential that the board and the CEO declare a goal of zero infections and communicate that broadly across the organization. It was also essential that leadership create an enabling infrastructure, with staff to coordinate project management, data, improvement science, and training to support clinicians. Frontline clinicians were engaged and connected in peer learning communities, and data were transparently reported to create a system of shared leadership accountability. This is accountability "from board to bedside," Pronovost explained, where leaders, before holding clinicians accountable, must first ask themselves if they have provided the clinicians with the elements needed to succeed (e.g., clear goals, skills, time, and data). Finally, a key element of transformation was telling a new story. The old story was that harm was inevitable, and clinicians did not feel empowered to change the outcome. However, when clinicians felt they could succeed, this created intrinsic motivation. Importantly, the clinical community structure supported peer learning, and clinicians had a new story to tell, one that said that CLABSIs are preventable.

Applying Lessons to Broadly Eliminate Harms

How might these lessons from the approach to CLABSI reduction be applied to eliminate all harms across the health system? The first step, Pronovost suggested, is to create a governance and leadership system for quality that functions similarly to that for finance. There is one line of oversight of every dollar spent in a complex organization. Could a similar structure be created for quality of care?

Pronovost described applying the lesson of clinical communities to the health system. Health system clinical communities are clinician led, and their charge is to achieve the purpose of the health system: to help patients thrive; to prevent disease when possible; to cure when you cannot prevent; to care when you cannot cure; and, all along, to respectfully and empathetically partner with patients and their families to end preventable harm, continuously improve patient outcomes and experience, and eliminate waste. The institute serves as the enabling infrastructure to improve quality in the system, and to link operations, research, and training. One of the challenges, he noted, is financing this infrastructure and analytics and demonstrating the ROI.

Pronovost shared an example where building a capacity for improvement saved over \$50 million in supply costs. Supply chain savings rely heavily on what clinicians use. The clinical communities added driving down supply costs to their purpose, under the conditions that physician choice was maintained and that some of the savings went to support comparative effectiveness research, analytics, and implementation. This combining of research and operations has been very successful.

The PCORnet Health Systems Demonstration Project

In preparation for this National Academy of Medicine (NAM) meeting, PCORI provided support to PCOR net CDRNs to engage health system leaders, and to work jointly to identify and prioritize a set of data-driven research activities of high interest to health systems and clinicians. The CDRNs were guided in their research topic selection by five principles: (1) topics should be rated as priorities by CEOs and health system leaders; (2) selection should involve iterative review and discussion between researchers and health system leaders; (3) the research should be of interest and add value to at least two PCOR net health systems; (4) projects should leverage existing data resources (e.g., PCOR net and the Common Data Model) with or without additional health system data; and, finally, (5) projects should be able to be completed in less than 1 year.

Carton described the Research Action for Health Network (REACHnet) CDRN approach to engaging health systems in defining the three research questions that REACHnet would bring to this NAM meeting for discussion. He emphasized that REACHnet is one of 13 CDRNs participating in this PCORI process and that the CDRNs employed a diverse array of methods to achieve the same goal of identifying research questions for discussion and prioritization at the NAM meeting. REACHnet is a network of health systems containing clinical records for more than 3 million patients in Louisiana and Texas. The network is focused on facilitating patient-centered, comparative effectiveness research. Partners include Ochsner Health System, Tulane University Medical Center, Louisiana State University and the Pennington Biomedical Research Center, Baylor Scott & White Health, and the Partnership for Achieving Total Health (a community-based health information exchange of 12 federally qualified health centers in the greater New Orleans area).

REACHnet, and all the CDRNs, seek to transform the culture of research by engaging patients, caregivers, and the broader health community in the research process, from idea generation to translation and dissemination. This is a three-phase approach. The first phase is topic solicitation, prioritization, and framing of the question, and Carton pointed out that this NAM meeting is part of the first phase. Next is selection of comparators and outcomes, conceptual frameworks, analysis plan, and data collection. The last phase is review of data, interpretation of results, translation, and dissemination.

Research question formation is a stakeholder-led approach. REACHnet brings together researchers, health system leaders, patients, clinicians, payer groups, and community health activists and workers, and creates a safe space for discussions, learning together, and collaboration, with the ultimate goal of establishing PCORI research priorities and pursuing funding opportunities.

Identifying Research Needs on the Ground

The REACHnet Health Systems Demonstration Project engaged 38 unique stakeholders, including health system leaders (CEOs, chief medical officers, a chief quality officer, and systems vice presidents), patient representatives, clinicians, researchers, a medical student, payer representatives, and community health advisory board members, coordinated by staff from the REACHnet Coordinating Center.

The process spanned 6 months, from June 2015 until December 2015, and engaged different stakeholders at different events across three phases: generation, prioritization, and refinement (see Figure 3-1). In the generation phase, an administrative board of health systems leaders and payer representatives met to set goals and objectives and brainstormed ideas that would value system collaboration, use data outside of individual systems, and leverage the community that REACHnet brings. Twelve potential topics were selected. A community health advisory board (CHAB), including patients, participated in the prioritization phase and narrowed the dozen ideas down to three. These three ideas were then refined, and the research questions for discussion at this NAM meeting were finalized.



FIGURE 3-1 REACHnet method and timeline for research question formation.

NOTE: HSD = Health System Demonstration SOURCE: Carton presentation, January 21, 2016. A number of tools were leveraged throughout the process. At the generation phase, a topic prioritization matrix was used by the two advisory-group boards to assess the feasibility of each of the 12 topics through various metrics such as congruence with the PCOR net Common Data Model and alignment with patient preferences, payer priorities, and national research priorities.

At the CHAB meeting, patients were oriented to the process, and three patients were selected by their peers to participate in the rest of the process. The patient orientation seminar highlighted the goals and objectives of the prior meetings, familiarized the patients with the process, and empowered them to participate and share their ideas. The prioritization process then employed a topic voting scorecard for those who were present and an online voting tool for those who were not. Finally, during the refinement process, REACHnet Coordinating Center staff presented a discussion guide and a literature review matrix, which allowed stakeholders to develop the topics into clear research questions. The final topics, research questions, and sample populations from the REACHnet process were then ready for discussion at this NAM meeting. (The REACHnet final topics are provided in Table 3-1; a summary of the discussion of all of the CDRN priority topics submitted for this meeting is provided in Chapter 4.)

| TOPIC | QUESTION | SAMPLE |
|--|--|--|
| Effects of end-of-life care on health outcomes and utilization | Examine patterns of health care utilization 1 year prior to mortality to better under- stand comparative effects of advanced illness man- agement/end-of-life care on patient health outcomes and resource utilization. | Patients with advanced illness who have died in the past year; condition- specific subsamples |
| 2. Effects of mental health and weight loss interven- tion strategies on weight management outcomes | Evaluate the effects of multi- ple factors (change in mental health, medication regimen, etc.) on weight-loss mainte- nance after initial weight-loss success (e.g., postbariatric surgery). | Patients who experience a defined magnitude of weight loss during a speci- fied time frame |
| 3. Efficacy of <i>postdischarge</i> <i>follow-up</i> programs, pro- tocols, and/or practices | Compare the influence of postdischarge follow-up and encounter patterns postdis- charge (e.g., time to follow- up and method of follow-up) on patient health outcomes. | All patients; condition- specific subsamples |

TABLE 3-1 | REACHnet Final Topics

24 | Accelerating Medical Evidence Generation and Use

In closing, Carton highlighted several key points about the REACHnet process. The events took place over 6 months, which helped to increase stakeholder buy-in, dedication, and comfort. Multiple types of stakeholders contributed their unique perspectives, both independently (through CHAB and the Administrative Board) and collaboratively in larger groups (such as the dinner meetings). Numerous tools were used to collect and organize the ideas. The process was deemed worthwhile for the stakeholders. For example, the meet-and-greet sessions for networking before the dinners, proper compensation for patient partners, and the dinner meetings helped to create a community that was unified around the goals and objectives of the project. Finally, health system leaders were engaged both directly (through the meetings and discussions) and independently (via health system principal investigators), and they ultimately endorsed both the process and the findings (i.e., the three questions).

DISCUSSION

During the open discussion that followed, participants talked about the need for and benefits of synergy across networks and data systems, and increasing the focus on population health.

Synergy Among Networks and Data Systems

Participants pointed out the synergy between PCORnet CDRNs and CMS TCPI Practice Transformation Networks with regard to learning health systems. They also noted that one ROI for PCORnet is the ability to do research differently, moving away from traditional clinical trials and looking at common clinical data across multiple sites for comparative effectiveness. With PCORnet there is also an engaged community of stakeholders that can enable more rapid transformation of that evidence into practice.

Carton also commented on the design features of PCOR net for learning health systems. He mentioned the Health in Our Hands Patient Network, an initiative of REACHnet designed to engage patients in research. This registry incorporates a consent to contact that allows researchers to contact patients as clinical trials become available without having to go through the individual health systems. Another aspect is the ability for researchers developing a trial to query the database and connect to patients with particular characteristics who have agreed to be contacted. They are not being contacted to be research participants at that time, but to be part of the protocol development and grant writing.

John Gallin of NIH mentioned that the The All of Us Research Program (formerly the President's Precision Medicine Initiative) is seeking to establish a cohort of 1 million patients and noted that one of the challenges is integration with other data systems, perhaps through a common, national, clinical database. In response, Pronovost encouraged participants to think about broadening the lens beyond precision medicine to precision measurement. There will be other nonelectronic health record data of interest in addition to genomics (e.g., proteomics) and what is needed is a policy solution that will reduce the barriers to accessing data interfaces.

Increasing the Focus on Population Health

Gary Rosenthal of the University of Iowa asked about the infrastructure and partnerships that will be needed to drive population health improvements. He observed that prior CMS demonstration projects (e.g., Physician Group Practice Demonstration; Pioneer Accountable Care Organization [ACO] Model) have had relatively modest impact with regard to cost savings, which he said were about 1 percent per year. This is small relative to the potential, he commented. The findings of the Pioneer ACO project, for example, show that the only ACOs that were able to achieve cost savings were those located in high-cost areas of the country. Addressing population health requires a much broader framework and more consideration of the social determinants of health, as highlighted by Shah (see Chapter 2). Goodrich agreed with the need for an increasing focus on population health. She noted that there is a population health group within the CMS Innovation Center that is working on the Accountable Health Communities model and is also thinking more broadly about topics such as additional tests that could be done; how to integrate different partners within a community to improve population health; target metrics; and addressing the social determinants of health. Population health and community health are relatively new territories for CMS, but there is a tremendous amount of interest. There has also been more evidence generated from successes at the local and regional levels, where improvements have resulted, in part, from coordination across sectors. At a conceptual level, Pronovost observed, medical care, public health, personal health behavior, and community support still exist in silos, and clinical providers still see their role as medical care. He called for frameworks that can erase those silos and focus on helping people thrive in those different spaces. Moderator Larson referred participants to a recent NAM report on social and psychological determinants of health (NASEM, 2016) and noted that accountable care groups are beginning to recognize these domains in which they have to work.

4

NEEDS, OPPORTUNITIES, AND STRATEGIES FOR ACCELERATING PROGRESS

number of needs, opportunities, and strategies exist for the National Patient-Centered Clinical Research Network (PCORnet) Health Systems Demonstration Project to accelerate progress. These were discussed in five breakout groups focused on the data and analytic needs of importance to executive-level decision makers; the value of PCORnet and PCORnet studies in improving health care delivery locally and nationally; and possible next steps for further development of PCORnet. Following the breakout session, participants reconvened in a plenary session, where group facilitators reported back on the discussions, and also talked about five themes identified by the Patient-Centered Outcomes Research Institute (PCORI) from the questions submitted by the Clinical Data Research Networks (CDRNs, as discussed by Carton in Chapter 3). Rainu Kaushal, chair of the Department of Healthcare Policy and Research at Weill Cornell Medicine, New York-Presbyterian Hospital, presented an overview of the five themes and key research questions for each and facilitated an open discussion in which participants considered strategic opportunities and the specific steps needed to move priorities forward, both in participant's own institutions and collaboratively. Highlights and main points are summarized in Box 4-1.

PCORNET: HARNESSING THE POWER OF HEALTH CARE DATA

The presentations provided examples of the importance of systems-level data for improving the efficiency and effectiveness of care. The examples also demonstrated the need for systems-level data to be better organized, standardized, and validated, and for better facilitation of collaboration across systems. The need to better engage health system clinicians in these efforts to improve performance was mentioned. Speakers also discussed the need to bring operations and research together. To set the stage for the breakout discussions, Selby provided a brief primer on PCOR net.

BOX 4-1

Comments on PCORnet Opportunities to Accelerate Progress

Insights from diverse systems. A strength of PCORnet is the ability to conduct studies across diverse health systems for a variety of purposes (e.g., benchmarking, variability in outcomes of procedures, rare diseases, predictive modeling, and evaluation of dissemination/implementation efforts). [McGlynn, Shenkman, open discussion]

Enhanced Common Data Model. There is a need to capture additional data elements in the PCORnet Common Data Model. Suggestions included social determinants of health, markers of behavioral health, patient-reported data, pharmacy data, longitudinal data, data related to costs of care, and other elements not normally captured in electronic health records (EHRs). [McGlynn, Kaushal, Shenkman, Selby, open discussion]

Link clinical and plan data. Linking health care delivery data to health plan data was identified as a need by many participants. The ideal approach would be one of data sharing for collaborative research on common questions that are of mutual value to both providers and payers. [open discussion]

Workforce training. The PCORnet infrastructure could be leveraged to facilitate training and workforce development. [Kaushal, Selby, open discussion]

Multi-stakeholder dissemination. Dissemination and implementation is one of the major challenges for PCORnet and was highlighted as an ongoing need across all research topics. Engagement of clinicians at the start of the research process was encouraged. Patients also play an important role in dissemination. [Roger, Selby, open discussion]

Better decisions. Health system leaders must make decisions every day, whether or not data are available. Timely dissemination of actionable data is needed to help decision makers and frontline providers facilitate improvement of care. [McGlynn, Roger]

PCORnet Mission and Structure

Getting complete data for research purposes is challenging and requires extensive coordination. Patients get care at multiple institutions and sites, and data are stored within multiple, disparate systems that are not generally interoperable. In addition, there are other factors critical to health that are not captured in inpatient or ambulatory EHRs or claims (e.g., social determinants of health, patient-reported outcomes, genomic data, prescriptions paid out of pocket, biospecimens, registry data, and death data). PCOR net is a "behind-the-scenes" infrastructure that offers a standard way of organizing and aggregating data to enable the collection of "complete" data on large numbers of patients to facilitate multisite research. PCOR net's mission is to harness these data and research findings to facilitate health system improvement and, in the process, transform the culture of clinical research from one directed by researchers to one driven by the needs of patients and those who care for them. PCOR net collects, organizes, and aggregates data from EHRs from more than 130 health systems across the country, as well as claims data and other data sources. The network is organized into 13 PCORI-funded CDRNs and 21 Patient-Powered Research Networks (PPRNs; see Box 4–2, Box 4–3, and Figure 4–1).⁵

BOX 4-2

PCORnet CDRNs

- 1. The Chicago Community Trust (CAPriCORN)
- 2. The Children's Hospital of Philadelphia (PEDSnet)
- 3. Harvard University (SCILHS)
- 4. Kaiser Foundation Research Institute (PORTAL)
- 5. Louisiana Public Health Institute (REACHnet)
- 6. Mayo Clinic (LHSNet)
- 7. Oregon Community Health Information Network (ADVANCE)
- 8. University of California, San Diego (pSCANNER)
- 9. University of Florida (OneFLorida)
- 10. University of Kansas Medical Center (GPC)
- 11. University of Pittsburgh (PaTH)
- 12. Vanderbilt University (Mid-South CDRN)
- 13. Weill Medical College of Cornell University (NYC-CDRN)

SOURCE: Selby presentation, January 21, 2016.

Organizationally, PCOR net is led by the PCOR net Council, including representatives from each of the CDRNs and PPRNs, which advises on strategy and operations. An executive committee serves the council and provides oversight of operations. There is also an advisory group that includes all potential funders of

⁵ PPRNs are networks of patient organizations focused on a particular health condition that are interested in sharing health information and engaging in research. See also https://academic.oup. com/jamia/article/21/4/583/2909240/Patient-powered-research-networks-building. (accessed January 3, 2018).

PCOR net (both government and private sector). The council has three critical working committees: (1) the Data Committee, which promotes the acquisition, standardization, and sharing of data; (2) the Engagement Committee, which works on bringing patients, clinicians, systems representatives, and leadership together with researchers; and (3) the Research Committee, which aims to identify and promote the kinds of research at which PCOR net excels. Finally, the Coordinating Center coordinates operational activities, maintains data infrastructure, identifies research opportunities, and coordinates multisite research.

BOX 4-3

PCORnet PPRNs

- 1. ABOUT Patient-Powered Research Network
- 2. Arthritis Partnership with Comparative Effectiveness Researchers
- 3. CCRFA Partners Patient Powered Research Network
- 4. Collaborative Patient-Centered Rare Epilepsy Network
- 5. Community Partnered Participatory Research Network
- 6. Community-Engaged Network for All
- 7. COPD Patient Powered Research Network
- 8. DuchenneConnect Patient-Report Registry Infrastructure Project
- 9. Health eHeart Alliance
- 10. ImproveCareNow: A Learning Health System for Children with Crohn's Disease and Ulcerative Colitis
- 11. Interactive Autism Network
- 12. Mood Patient-Powered Research Network
- 13. Multiple Sclerosis Patient-Powered Research Network
- 14. National Alzheimer's & Dementia Patient & Caregiver-Powered Research Network
- 15. NephCure Kidney Network for Patients with Nephrotic Syndrome
- 16. Patients, Advocates and Rheumatology Teams Network for Research and Service
- 17. Phelan-McDermid Syndrome Data Network
- 18. PI Patient Research Connection
- 19. Population Research in Identity and Disparities for Equality Patient-Powered Research Network
- 20. Sleep Apnea Patient Centered Outcomes Network*
- 21. Vasculitis Patient Powered Research Network

*Affiliate PPRN

SOURCE: http://pcornet.org/participating-networks/



FIGURE 4-1 Coverage of the 13 CDRNs and 21 PPRNs in PCORnet. SOURCE: Selby presentation, January 21, 2016.

The Common Data Model

To organize the disparate data from hospitals and health care delivery systems into a standard structure such that they can be more effectively used for research, PCOR net developed the Common Data Model (see Figure 4-2). Each PCOR net partner network maps data to the same consistent format (e.g., with the same variable name, attributes, and other metadata). Undertaking this step before initiating any PCOR net research studies creates a platform that enables much more rapid responses to research-related questions. The vision is that the Common Data Model will expand to go deeper within each of the current categories but also add new categories over time (e.g., biospecimen and genomic data, patient satisfaction information, and death index data).

Data from more than 70 million people across the 130 health systems participating in PCOR net are currently arrayed in over 60 nodes or "data marts." In essence, Selby explained, there are 60 instances of the Common Data Model.

PCORnet Common Data Model Domains, v3.0 and v3.1

DEMOGRAPHIC V1.0

Demographics record the direct attributes of individual patients.

ENROLLMENT V1.0

Enrollment is a concept that defines a period of time during which a person is expected to have complete data capture. This concept is often insurance-based, but other methods of defining enrollment are possible.

ENCOUNTER V1.0

Encounters are interactions between patients and providers within the context of healthcare delivery.

DIAGNOSIS V1.0

Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery. Data in this table are expected to be from healthcare-mediated processes and reimbursement drivers.

PROCEDURES V1.0

Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures and lab orders, delievered within a healthcare context.

VITAL V1.0

Vital signs (such as height, weight, and blood pressure) directly measure an individual's current state of attributes.

LAB_RESULT_CM V2.0

Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. The common measures are defined in the same way across all PCORnet networks, but this table can also include other types of lab results.

CONDITION V2.0

A condition represents a patient's diagnosed and self-reported health conditions and diseases. The patient's medical history and current state may both be represented.



Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.



Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing may not be directly captured within healthcare systems.



Provider orders for medication dispensing and/or administration. These orders may take place in any setting, including the inpatient or outpatient basis.

PCORNET_TRIAL V3.0

Patients who are enrolled in PCORnet clinical trials.

DEATH V3.0

Reported mortality information for patients.



The individual causes associated with a reported death.

HARVEST V3.0

Attributes associated with the specific PCORnet datamart implementation including data refreshes.

FIGURE 4-2 | PCOR net Common Data Model.

SOURCE: http://www.pcornet.org/wp-content/uploads/2014/07/2015-07-29-PCORnet-Common-Data-Model-v3dot0-RELEASE.pdf.

PCORnet-Sponsored Research

PCOR net demonstration projects enable the network to build out aspects of its function and its infrastructure and demonstrate its capacity to do particular types of research. There are three major PCORI-funded demonstration projects currently under way. Two are observational studies, including a study of the outcomes of the three common types of bariatric surgery for severe obesity, and a study investigating the use of broad-spectrum versus narrow-spectrum antibiotics and the development of childhood obesity. The third is a randomized clinical trial comparing the effectiveness and safety of two different doses of aspirin (81 mg versus 325 mg) in high-risk patients with coronary artery disease. Multiple CDRNs are involved in each of the studies.

PCORnet contributes importantly on multiple levels. It creates the capacity for standardized and more efficient project start-up and provides a reusable infrastructure, which limits project shutdown costs. PCORnet is a learning model, and each new project benefits from prior studies. The scale and diversity of patients and providers in the network are also assets. The ability to study and understand personalized medicine, for example, requires much larger populations than can generally be built in any one system. The network engages patients and clinicians to help develop the research questions, plan and conduct the studies, and disseminate the findings. According to Selby, investigators will find that accessing and using PCOR net resources is easy and cost effective. PCOR net creates a culture of collaboration and a network of relationships among researchers and all players in health care delivery. Finally, there is health system commitment to sustaining PCOR net and building a track record of success.

Selby reiterated the concept of the PCORnet Health Systems Demonstration Project. As discussed, this meeting was designed to be the culmination of the first phase of the project, generating a list of priority topics of interest to health systems leaders and clinicians. Funded projects will bring researchers and health system leaders together to plan research activities that help both to cement the relationship between system leaders and PCORnet and to answer important early questions about the utility of PCORnet data and the capacity of those data to support performance improvement and comparative effectiveness questions. Selby encouraged participants to reflect on the ideas discussed at the workshop and submit proposals.⁶ Following this meeting, PCORI issued a limited funding announcement awarding \$5 million to support five quick-turnaround, research demonstration projects.

BREAKOUT DISCUSSIONS

According to Kaushal, this is a critical point in time because there are now enough data available to start asking and answering the questions that prompted these efforts by PCORI 2 years ago. She described the three key aims of the breakout session:

- Identify key data and analytic needs that CEOs and other executive-level decision makers involved in health care administration perceive as important unmet needs;
- Explore the role of PCOR net, as an exemplar of a clinical-data infrastructure, in improving research and health care delivery locally and nationally; and
- Consider important next steps in building and improving PCOR net.

Participants divided into five preassigned breakout groups of about 10 to 12 people. Groups were provided with a set of more specific questions to help guide

⁶ The application period closed in April 2016. Funding was awarded in June of 2016, and projects began in September. For the full funding announcement see http://www.pcori.org/sites/default/files/PCORI-PFA-2016-Health-Systems.pdf (accessed May 31, 2016).

their discussions (see Box 4–4), which were facilitated by a CDRN principal investigator and one or two CEOs. Upon reconvening in the plenary session, facilitator group reports were provided by Kaushal; Beth McGlynn, director of the Kaiser Permanente Center for Effectiveness and Safety; Veronique Roger, director of the Center for the Science of Health Care Delivery at the Mayo Clinic; Elizabeth Shenkman, director of the Institute for Child Health Policy at the University of Florida College of Medicine; and Kathleen McTigue, associate professor at the University of Pittsburgh School of Medicine.

Each of the facilitators observed that there was much similarity across the five groups' discussions. The outcomes they reported are organized by aim, below (Box 4–4).

BOX 4-4 Breakout Discussion Guide

- 1. **Information needs.** Given your responsibilities and priorities as a health care executive, what information most necessary for your key decisions is not currently available?
- 2. **Questions.** When you think about your priority information needs, what types of questions do you think would be best answered by comparing experiences from different health care organizations around the country? What questions require greater focus on your own institution's experience and context?
- 3. **Design priorities.** Which characteristics (e.g., rapidity of results, crossmarket comparisons, generalizability, diverse patient populations) of PCORnet studies are most critical to you and why?
- PCORI. What do you think would make PCORnet most valuable to you and other health system executives? (This might include analysis, learning collaboratives, opportunities to exchange and test ideas with other systems, and so on.)
- 5. **Infrastructure**. What do you see as the overall value of a national infrastructure, such as PCORnet, in improving health care delivery and research?
- 6. **Next steps.** What are important next steps in building and improving PCORnet?

Pressing Data and Analytic Needs of Executive-Level Decision Makers

A point made by the CEOs, McGlynn reported, was that they must make decisions every day, whether or not data are available, and many decisions are made in an "evidence-free environment." For evidence to be a part of their conversations, time is of the essence, and the process of providing data needs to be much more nimble. Roger added that her group also discussed the need for nimble and timely dissemination of data to help decision makers and frontline providers facilitate improvement of care.

McGlynn's group felt that planning the work that will be done under the health systems demonstration projects should start with clearly defining a set of desired outcomes and then working backward from there. It was suggested that target outcomes would be high level but still focused in a specific area (e.g., no infections in the hospital, or an uncomplicated journey of cancer treatments). Keren's description of the success in eliminating central line infections (see Chapter 2) inspired Kaushal's group to consider some specific topics that might be "low-hanging, high-impact fruit," that is, projects that could readily yield successes. A variety of research topics were suggested in areas such as transitions of care, transitioning to increased antibiotic use, effective sleep apnea screening, choosing appropriate measures and incorporating them more strongly, and trying to move away from iatroepidemics. McTigue's group noted the need to build on the context in which care is delivered. There was discussion, for example, about the variation in public insurance programs at the state level across the country. A question was also raised about how to measure cultures within health systems, which can impact implementation and translation.

PCORnet's Impact on Health Care Delivery Locally and Nationally

McGlynn's group discussed that there is a great opportunity to learn using PCOR net by leveraging the variation that exists across systems in outcomes and in the processes that produce those outcomes. Shenkman reported that there was much discussion about the value of being able to do studies across different health systems for a variety of purposes. Examples of such cross-system studies included benchmarking, trending, and forecasting; variability in outcomes related to new technologies or procedures as well as high-cost, complex procedures; outcomes related to rare diseases or unusual patient populations; and evaluating the success of dissemination efforts. Participants in McTigue's group discussed further the concept of precision measurement raised by Pronovost in his talk (see Chapter 3), and how big data could be leveraged to more effectively define and measure quality.

Participants in Kaushal's group suggested utilizing the PCOR net infrastructure to facilitate training and workforce development on how to use data for health system improvement. It was observed that a new generation of providers needs to be trained in working with this type of big data. Selby concurred with the importance of workforce training and noted the need to train researchers to think as members of systems and to work with system leaders to ask and answer important questions.

Roger's group noted the array of different health systems present at the workshop and emphasized that the value proposition for PCOR net will not be a "one size fits all." For example, the needs of a tertiary coronary referral setting will be different from those of an integrated health system that focuses more on population health. It is important to keep this diversity in mind as the value proposition of PCOR net is refined. Participants in Roger's group also noted that many health systems are already part of data networks, and it will be important for PCOR net to differentiate itself and demonstrate its value relative to those other data networks.

Important Next Steps in Building and Improving PCORnet

Participants identified a variety of ways that PCOR net could be enhanced to assist health system leaders in addressing topics of interest. McGlynn emphasized that there is an increasing focus on social determinants of health by health systems, and her group highlighted the need to capture data on social determinants in the PCOR net Common Data Model. Kaushal reported that her group also suggested the need for additional data sources, including, for example, patientreported data, not only on outcomes but also on education level, social structure, mental health conditions, and the like. Participants raised the question of whether social media or marketing data could be more effectively utilized to round out a patient's profile. Shenkman highlighted several additional types of data that her group suggested would be useful to include, such as pharmacy data, data on postacute care, data on the true cost of care, and data from wearable devices (e.g., physical-activity monitors). Selby agreed that incorporating socioeconomic and demographic influences on health status, for example, could lead the work of PCOR net in expanding and promising directions.

The ability to capture longitudinal data was highlighted as a need by McGlynn's group so that questions could be asked not just about episodes of care, but about the care trajectory that people experience over a longer period of time. Roger agreed and noted that her group discussed the fragmentation of care, and how the ability to reconstitute the timeline for a patient's course of care would be important in terms of developing knowledge.

McGlynn's group noted that even though PCORI is prohibited from funding cost-effectiveness or cost-comparison studies, there does need to be some way in PCORnet to capture costs of care. It may be that this will need to be done through funding from sources other than PCORI, and this could be possible as PCOR net evolves as an independent entity.

McGlynn's group suggested that the ability to characterize diverse systems would be helpful; that is, some sort of systems-level variable would help researchers understand something about the systems that are producing the outcomes that are being demonstrated. The group also suggested that PCOR net could be more powerful if there were systems to help translate national-level findings into local action and change. McTigue reported that her group raised the issue of data quality and interpretation. Even with the Common Data Model, it was noted that there could still be variations in what the data mean. The group also discussed the importance of the development of standardized common definitions in PCOR net, which impact studies related to triggering events, super utilizers, and risks for poor outcomes, for example.

HEALTH CARE SYSTEM RESEARCH QUESTIONS

For the first phase of the PCOR net Health Systems Demonstration Project (July 2015 to January 2016), each of the CDRNs was charged with developing and submitting three research questions to PCORI that would be feasible to accomplish within 12 months (utilizing data that were likely to be available by the July 2016 start date); leverage PCOR net and the Common Data Model; be relevant to the delivery of health care and the health of large populations; and be of potential impact and importance.7 PCORI then collated and organized the submitted questions according to five major themes: high health care utilizers, specific populations, new models of health care delivery, novel analytic tools and models, and assessment of value. Two to three priority research topics per theme were then selected for further discussion and prioritization at this meeting. Kaushal provided an overview of the major themes, and key research questions for each, adding that they were chosen to be illustrative and to prompt a discussion and are not in any way a final product (topics are summarized in Box 4-5). She also noted that many CDRNs submitted similar questions, and that many of the questions cut across themes.

⁷ Discussed by Carton in Chapter 3. See also https://www.pcori.org/sites/default/files/PCORI-PFA-2016-Health-Systems.pdf (accessed May 31, 2016).

BOX 4-5

Summary of Health System Research Themes and Questions for Discussion

Identifying and Managing High Health Care Utilizers

- Methods for classifying high utilizers
 - How to implement these methods
 - Epidemiology across health systems
 - · Determining and addressing modifiable factors of high utilization
 - Successful examples of utilization management
- Readmissions
 - Epidemiology of readmissions
 - · Effectiveness/accessibility of available data sources
 - Predictors of readmissions
 - Utility of clinical data

Specific Populations

- · Co-occurring behavioral and physical health conditions
 - Utilization patterns and outcomes
 - Specific combinations
 - Determining successful interventions
 - · Context of population health
- Social/nonmedical needs
 - Most effective programs in which settings

New Health Care Delivery Models

- Palliative care consults
 - Epidemiology
 - Unmet needs
 - Effect on outcomes and utilization
- ACO and PCMH
 - Outcomes (admissions, readmissions, ED utilization)
 - Specific subsets of patients (e.g., COPD, heart failure, AMI)

Novel Analytic Tools and Methods

- Risk-adjustment model for high utilizers
 - · Using claims, clinical, and socioeconomic data
 - Routinized use in delivery setting
- · Patient and system predictors of future utilization
 - ED visits for patients with ambulatory-sensitive conditions
 - Inpatient admits from the ED for patients with ambulatory-sensitive conditions
 - Similar questions for patients with specific diagnoses (e.g., heart failure, DVT)

Assessment of Value

- Prescribing and using new, expensive drugs for high-morbidity conditions (e.g., hepatitis C, multiple sclerosis, and rheumatoid arthritis)
 - Considering mortality/morbidity and effective use of resources
- Variability in high-cost imaging (CT and MRI)
 - For patients with head trauma in the ED
 - · For patients with headache in ambulatory settings
- · Efficiently identifying or predicting overuse of testing and treatment

NOTE: ACO = accountable care organization; AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disease; CT = computed tomography; DVT = deep vein thrombosis; ED = emergency department; MRI = magnetic resonance imaging; PCMH = patient-centered medical home.

SOURCE: Kaushal presentation, January 21, 2016.

Identifying and Managing High Health Care Utilizers

Classifying High Health Care Utilizers

The first set of questions in this theme revolves around the most useful methods for classifying patients, and subsets of patients, who utilize the most health care services. Could socioeconomic status, claims data, and clinical data be used to enhance classification? How might methods of classification be routinized and incorporated into care delivery? Is it possible to determine epidemiology across health systems, and start to understand which health systems have the highest utilizers or subsets of utilizers? Is it possible to determine and address modifiable factors of high utilization? Are there successful examples of utilization management that could be more rapidly and effectively shared?

Readmissions

The second set of questions related to high health care utilizers focuses on readmissions. Kaushal noted that her breakout group discussed readmissions as a marker of quality. When patients are readmitted, what hospitals are they readmitted to, what are their predictors, and how well do available data sources capture those readmission patterns or predict readmission? Can data available through EHRs improve the characterization of patterns of readmission or the predictive validity of existing models? A combination of claims and clinical data could allow for much more effective research on the epidemiology of readmissions than has been done thus far using solely claims data. It was also noted in a breakout session that there is often a time lag in the ability to access Medicare data. How might the accessibility of data sources through PCOR net change this?

Specific Populations

The second major theme was identifying and managing the needs of specific populations by diagnoses (e.g., behavioral or physical health) or patient characteristics (e.g., socioeconomic status).

Co-occurring Behavioral and Physical Health Conditions

What are the utilization patterns and outcomes of patients who have cooccurring behavioral and physical health conditions? Are certain combinations of behavioral and physical health conditions associated with higher utilization and/or poorer outcomes? What interventions are most successful for patients with co-occurring conditions (e.g., focusing on the behavioral health condition or co-locating behavioral and physical health treatment), particularly in the context of population health programs?

Social and Nonmedical Needs

What specific programs are most effective in meeting the social/nonmedical needs of patients (e.g., food insecurity, transportation, and housing)? Which programs should be adopted by the health system?

New Health Care Delivery Models

Palliative Care Consults

How commonly are palliative care consults recorded, and for which patients? Is there an identifiable subset of patients who could have benefited from palliative care but who were not offered the option? What is the effect of palliative care on health outcomes and utilization? Kaushal noted the intentional use of the word "utilization" to conform with the PCORI process, but the real question is what are the effects on cost.

Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes

How do individuals enrolled in ACOs or patient-centered medical homes (PCMHs)⁸ compare with those not enrolled in an ACO/PCMH in rates of admission, 30-day readmission, and emergency department (ED) utilization,

⁸ Also referred to as primary care medical homes.

with a focus on subsets of individuals with pneumonia, chronic obstructive pulmonary disease, heart failure, acute myocardial infarction, total hip arthroplasty, total knee arthroplasty, and coronary artery bypass graft? Kaushal added that questions about bundled payments also fit into this category.

Novel Analytic Tools and Methods

Risk-Adjustment Model for High Utilizers

A topic raised in many of the CDRN interviews and in the breakout group discussions was risk-adjustment models for high utilizers, making use of the novel data sources available through PCORnet. Can a risk-adjustment model that incorporates claims, clinical, and socioeconomic data more accurately predict high utilization than existing claims-based risk-adjustment models? If so, how could these prediction models be incorporated into care delivery settings?

Patient and System Predictors of Future Utilization

Also under the theme of analytic tools and methods were questions about patient and system predictors of future utilization, especially given the potential availability of new data sources. What characteristics of the patient and the system predict visits to the ED for ambulatory-sensitive conditions, or predict admission from the ED to inpatient care for ambulatory-sensitive conditions or among patients with particular conditions of interest (e.g., heart failure, deep vein thrombosis, and dehydration)?

Assessment of Value

The assessment of value in health care includes cost, quality, safety, access, and patient experience.

Prescribing and Using New, Expensive Drugs for High-Morbidity Conditions

The first questions related to value centered around the effective prescribing and use of new, expensive drugs for high-morbidity conditions such as hepatitis C, multiple sclerosis, rheumatoid arthritis, and cancer. What is the epidemiology across different health systems, and how can recommendations take into account morbidity, mortality, and the effective use of limited resources?

Variability and High-Cost Imaging

What is the variability (risk adjusted) in high-cost imaging such as computed tomography and magnetic resonance imaging for patients with head trauma seen in the ED and patients with headache seen in outpatient settings (primary and specialty care)?

Overuse of Testing and Treatment

How can overuse of testing and treatment be efficiently identified and/or predicted?

Prioritization of Themes and Questions

Following the overview of the five major themes and corresponding research questions as submitted by the CDRNs, Kaushal called on participants to consider additional themes to be included (or themes to remove), additional pressing research questions, and prioritization of topics. One suggestion was the challenge of prioritizing the specific disease conditions, or clusters of disease conditions, mentioned in the major theme areas. Kaushal reiterated that the questions were organized into themes to help facilitate the meeting discussion and that some questions could easily be categorized under more than one major theme area. Participants made comments relevant to the five major themes and raised additional topics, including implementation science/iterative learning and the sustainability of PCOR net.

It was observed that answering some of the questions will require specific data elements such as social determinants and markers of behavioral health, and it was suggested that the demonstration projects might incorporate the ability to test different approaches for gathering this type of information that is not typically part of the health system. According to Kaushal, adding additional time to the patient–physician interaction for data gathering is infeasible. She highlighted the need for other, more tenable methods to increase collection of data from patients. One suggestion was that the Office of the National Coordinator for Health Information Technology (ONC) develop a star-based rating system for EHR technologies to guide health care organizations in selecting a system and that ONC collaborate with those organizations on research about the different characteristics of available EHR systems.

The importance of planning for dissemination and implementation across all of the research topics was also emphasized.

Identifying and Managing High Health Care Utilizers

David Blumenthal of The Commonwealth Fund pointed out that high health care utilizers are not a homogeneous group. The Commonwealth Fund is investing in trying to understand and segment the population of high health care utilizers and develop care delivery models that are adapted to the different segments. However, the data opportunities for studying the heterogeneity of the high health care utilizer population are currently limited to modest-sized national samples (e.g., the Medicare Current Beneficiary Survey and the Medical Expenditure Panel Survey) and claims data. According to Blumenthal, the information available through PCOR net would be a substantial addition to defining the needs and requirements of caring for those populations. Blumenthal suggested that the topic of frail elders, discussed below in the context of special populations, also fits within the major theme of high health care utilizers. In addition to the need to address the health and well-being of the frail elderly, there is increasing public policy interest in their use of health care resources and the associated costs.

During the open discussion that followed, participants concurred that most studies are looking at all high utilizers together, and relayed an interest in looking at specific populations to try to identify which patients could become high utilizers and potentially intervene. High utilization is a problem that bridges both inpatient and outpatient services, and that it has a strong behavioral and mental health element.

Concern was expressed about the likelihood that year-long, observational studies done with PCOR net data could determine which programs work with regard to high utilizers. This is a complex problem that researchers have been working on for quite some time. Some institutions, for example, have developed disease-specific programs, often organized around Centers for Medicare & Medicaid Services (CMS) penalties, which work in the short run and prevent penalties but are costly in the long run and probably not sustainable. In contrast, characterizing the nature of the populations of high utilizers in health systems (similarities, differences, and how different programs and populations overlap) may be more practical and useful in the short run than trying to understand whether programs work. Such characterization could provide critical evidence for preparing to answer longer-term comparative effectiveness questions. Kaushal observed that this also ties in to the major theme of novel tools and methods and the topics of risk-adjustment models for high utilizers and predictors of future utilization.

Specific Populations

Several suggestions related to specific populations were raised during the course of the discussion. One suggestion was to link records from mothers and babies and study how resource utilization patterns for pregnant women are connected to outcomes for babies. Another suggestion was to look at early childhood behavioral health issues and outcomes for children. Other participants mentioned current examples of where this is being done, such as a study looking at early childhood exposure to antibiotics and subsequent development of obesity. One of the aims of that study is mother–baby linkages to understand prenatal exposures.

Palliative and supportive care for the frail elderly was raised as a topic needing attention, as was the extent of care, services, and community-based supports

required in the last decade of life. Participants also discussed long-term care; avoidable admissions and readmissions of the elderly; and the sharing of data and records among nursing homes, health systems, and primary care and other care facilities.

New Health Care Delivery Models

With regard to health care delivery models, participants suggested that a more precise distinction is needed in the proposed questions between those enrolled in an ACO or a PCMH versus those who are not. It was also pointed out that much of the discussion had been centered on hospitals and hospital systems, but that health care is most often delivered by providers who are not necessarily integrated in a hospital system; it is important to make PCOR net relevant to those providers as well. To accomplish this, it is necessary to consider what themes and questions will resonate with them as they seek to influence outcomes.

Palliative care for frail elders, discussed above as an issue of a special population, could also fit within the major theme of new health care delivery models. The issues surrounding death (at any age) were also raised as an area in need of research attention.

Novel Analytic Tools and Methods

According to Lloyd, a particular interest to Premier is risk adjustment and predictive modeling across a broad group, with the ability to overlap with the identification of subgroups of high-risk patients. Katherine Newton of Kaiser Permanente Washington Health Research Institute noted that a consistent theme among the breakout groups was having the ability to compare data across sites. It would be helpful if, for example, PCOR net could interact with the health systems to incorporate Medicare claims data and census tract data globally (rather than each health system having to do the work itself). Kaushal agreed and noted that this concept is embedded in the methodological issues but may need to be made more explicit. For example, for reliable comparisons, do at least two CDRNs have to be involved?

Assessment of Value

Also highlighted was the need for the development of measures that can be used to assess what combinations of value-based payments, team-based care, and other structural elements are most effective for patients, providers, and payers.

In considering other questions for demonstration projects, participants discussed developing a portfolio of strategies to bring down costs (e.g., in areas such as high-cost imaging, specialty drugs, oncology drugs, and high utilizers). However, the challenges of obtaining cost data were noted. Another idea was using the Common Data Model to study various aspects that could be proxies for cost (e.g., readmissions) that might occur in association with a new care event (e.g., the availability of a new oncology service).

Implementation Science and Iterative Learning

Another point discussed is that care delivery is iterative. As such, the discussion should address not only whether these are the right themes and questions, but how the answers to the questions are best obtained. How can the dynamic, iterative nature of health care practice be taken into account in seeking answers to the questions or in defining new directions to investigate? For example, there are multiple approaches to predicting high utilizers; different researchers looking at different cuts of data will use those data in different systematic approaches to study utilization. It was suggested that, in some ways, a learning organization is an experimental model in and of itself. A learning organization incorporates new findings, learns from them, modifies the approach, and then learns and modifies again and again. Kaushal summarized that she heard calls for an increased emphasis on the implementation science aspect of the research questions, and a focus on both the process of learning as well as the outcome of a specific study.

Sustainability of PCORnet

Kaushal raised the issue of sustainability and the need for ongoing commitments to support the CDRNs and fund studies utilizing the CDRNs. There are grants and other funding opportunities, as well as support from health systems and medical schools and nontraditional sources of funding. A participant recommended thinking both locally and nationally and starting the dialogue with potential funders now to demonstrate the value of working together and the strength in numbers that comes with PCORnet. Kaushal agreed and referred back to Selby's overview of PCORnet and the organizational structure for the demonstration projects that emphasizes the importance of bringing together multiple partners for the projects.

Participants discussed the concept of funding five short-term, specific demonstration projects versus demonstrating the value of the process by showing how the entire network could be engaged to address one or two broad questions. It was suggested that the opportunity for learning is greater with five projects than a single project, and there were concerns about the risk and implications of failure of a single project. Participants suggested that having more projects is a better approach, but cautioned against spreading projects over too many disease populations, noting that there is a lot of alignment or overlap among the questions in the five theme areas and that spreading across too many disease areas could reduce the opportunity to demonstrate that alignment. Instead, straightforward, short-term demonstration projects addressing questions that are highly relevant to a large patient population, and that could provide actionable results, would be of value.

OPEN DISCUSSION OF NEEDS, OPPORTUNITIES, AND STRATEGIES

Selby invited participants to reflect on the discussions of the day as well as their previous interactions with PCORnet. PCORnet is a learning collaborative across the networks, and he urged participants to share their thoughts on needs, opportunities, successes, failures, and strategies that could help inform the PCORnet demonstration projects. Participants expanded their discussions on the topics of dissemination and implementation, cost/value, and sustainability, and also raised the issues of connecting health system data to payer data and training and workforce development.

Linking Care Delivery Data to Health Plan Data

Russell Rothman of Vanderbilt Health System observed a strong interest during his group discussion in expanding health system connectivity to payer data, and CMS data in particular. This could allow health systems to have a better understanding of predictors of care over time and could also expand the ability to incorporate data on social and behavioral determinants into the Common Data Model for potential use as predictors of care. Selby agreed that care delivery system data without linked health plan data hinders the ability to do certain types of research, in particular, longitudinal follow-up for outcomes. He noted that PCORnet is investing in bringing payer plans into the network. He observed that many health care systems still view health plans only as business partners, rather than also as research partners on issues of mutual interest (e.g., high utilization). PCORnet will be looking to fund projects where there is mutual interest in the questions and the outcomes and will be particularly looking to those stakeholders that can provide data.

Participants emphasized the critical importance of collaboration between and among health plans and researchers, but cautioned against a data mining approach in which researchers simply ask health plans to hand over the data. Selby agreed, and noted that the current PCOR net strategy is one of data sharing and individual-level patient linkage of data around a common question of interest to both payers and delivery systems.

TRAINING AND WORKFORCE DEVELOPMENT

Training and workforce development was discussed, and it was pointed out that training is an aspect of dissemination and engagement. A participant suggested that training and workforce development also sharpens research questions and brings diverse constituencies together in new ways. Selby agreed, and reminded participants that under the Patient Protection and Affordable Care Act (ACA), the Agency for Healthcare Research and Quality (AHRQ) was charged with building capacity for patient-centered outcomes research through workforce training programs and grants. He added that AHRQ is also interested in system-based research, training people to work with delivery system data and in partnership with delivery system leaders, and an advisory committee is exploring how to ensure that those with training and capabilities in these areas are part of the delivery system team. Another participant emphasized the value of other mechanisms for training and workforce development (beyond formal training grants) that are more modular and more accessible for a broader group of individuals.

Dissemination and Implementation

Steve Weinberger of the American College of Physicians highlighted dissemination and implementation as one of the major challenges for PCORnet. There need to be systematic ways to educate the physician community—including providers beyond the organizations that are part of PCORnet—about the results of studies coming from PCORnet. Selby responded that studies funded by PCORnet generally engage national specialty organizations or national provider payer organizations; however, he emphasized that PCORnet would look for additional ways to link to physician groups.

The goal of dissemination and implementation is for information to be used, yet much information is disseminated and goes nowhere. Participants emphasized the need for engagement of clinicians up front regarding what questions are of most interest. In order for clinicians to start putting the information into practice, they need to be assured that the data are reliable and apply across a broad population as well as to their own patients.

Veronique Roger highlighted the power of patient engagement in dissemination. She shared that, when asked what part of research they would most like to be engaged in, patients in her network overwhelmingly responded that they were keen to be involved in the dissemination of research findings. She observed that pharmaceutical companies leverage this interest very effectively with direct-to-consumer advertising that tells patients to "ask your doctor" about whatever product is being promoted. She suggested that PCORI explore engaging patients in dissemination to help fill the gap. Selby responded that PCORI began its process with patient engagement first to ensure that it was asking the "right" questions, and then to ensure that the results would be analyzed meaningfully so that there would be buy-in among the various stakeholders. Over time, it became clear that patient engagement was also important for facilitating dissemination.

Also discussed was that health care is evolving in a digital age, and studies of systems-level interventions need to clearly define "usual care" so that future readers of the studies will understand the comparators and whether those comparators are still relevant.

High-Value Care: Prices, Costs, Access, Incentives, and Outcomes

Issues surrounding price were raised, especially price transparency from the patient's perspective. In other words, what will health care really cost the patient in light of increased copayments and other factors? Selby noted that although PCORI cannot fund studies that directly compare costs of care, it does have an interest in out-of-pocket cost to the extent that increased cost for patients influences the ability to access care or to adhere to care, and influences the intended outcome.

The topic of cost is prominent in the news, especially with regard to drug prices. Selby observed that there are a lot of privately directed efforts to measure value and to use that value to justify price (e.g., given the effectiveness of this agent, and the availability or nonavailability of alternatives, and the development cost, what should the price of this product be?). From the PCORI perspective, Selby asserted, value needs to be measured after consideration of the full range of outcomes. PCORI promotes a broader range of outcomes assessments so that the different potential benefits and harms are understood. Value is also driven by relative worth to the patient. If, for example, a drug is given to a subset of the population that does not stand to benefit, it has no value. If it is given to people who have been shown to truly benefit, it has a much better chance of having value. According to Selby, PCORI does assess value, but it assesses the clinical aspects of value, while others consider the direct costs.

Participants also discussed the concept of price and costs as incentives or disincentives for care. It was noted that, at one time, it was thought that having a copayment engaged the patient further in terms of compliance with behavioral therapy goals. It was suggested that in developing consumer-directed health care plans, it is helpful to consider when a copayment is appropriate or not, relative to its effect on achievement of the therapeutic goal. There is much to be learned regarding the use of incentives to reduce wasteful care and promote high-value care. What are the incentives or structures, including copayments, that promote the value of care and patient-centered outcomes (e.g., drive patients to make the choice to maintain a therapy)?

Sustainability

Participants noted that sustainability comes from partnerships among the health systems and highlighted the importance of buy-in and support from partner health systems. This comes in the form of, for example, information technology support (e.g., to meet data sharing security requirements) and time from executives and people in high-level research positions within the health systems. Steve Safyer of Albert Einstein College of Medicine commented on sustainability based on his experiences with the Weill Medical College of Cornell University NY-CDRN. The CDRN has been a very successful collaboration across five large institutions and others (e.g., community-based organizations and medical schools). He attributed this success to leadership and to an understanding that this is a time of change and, to make that change, questions need to be addressed with funding of research and implementation of findings. Regardless of how many PCORnet demonstration projects are implemented, sustainability is the biggest task because the potential for a high yield in the long-term is substantial.

Sustainability of PCOR net was a key focus during the second meeting of the series. Throughout the meeting, it was emphasized that the contributions from this community of health executives and researchers had helped PCORI develop the PCOR net Health Demonstration Project (a key emphasis of the meeting in January 2016). In his presentation, Selby reflected that, in 2014, the National Academy of Medicine and PCORI first partnered to explore the alignment of research with the pace and priorities of health-delivery centers and systems. Now, PCORI has the engagement of two major health plans as partners in PCORnet and PCORI is hopeful that both plans and systems will find opportunities to work together on issues related to performance, efficiency, and clinical effectiveness research, precisely by agreeing to share data for these purposes and participating together in identifying the questions and helping to design the research. He reflected on the importance of researcher-health executive collaboration and emphasized that PCORI has, and continues to make, an investment in PCORnet in order to create infrastructure in the form of data, people (relationships), tools, and policies to enable more rapid clinical research. However, he also emphasized that PCORI is not planning to support PCOR net alone. PCORnet is a way of doing research and he hopes that more systems and researchers join the network and that sponsors see its value.

5

HARMONIZED PERFORMANCE MEASUREMENT FOR CONTINUOUS LEARNING

Performance measurement is a topic of great concern to health system leaders. In this session, panelists discussed uses of data for understanding performance, measuring performance, and creating the next generation of more meaningful performance measures. David Blumenthal, president and CEO of The Commonwealth Fund, discussed the design of infrastructures for data collection that are also useful for research. Christine Cassel, president and CEO of the National Quality Forum (NQF), described the potential of data infrastructures to serve as the measurement framework for accountability at the national level. Benjamin Chu, group president for Kaiser Permanente's Southern California and Georgia regions, discussed his experiences putting data into action to achieve better outcomes through a systems-based approach. Highlights and main points are summarized in Box 5-1.

INFRASTRUCTURES FOR DATA COLLECTION

A challenge for health organizations is to create data infrastructures that are useful for measurement both at the national level and for the purposes of their own improvement. According to Blumenthal, the way to create such an infrastructure is to design it for research purposes. He acknowledged, however, that the available electronic systems are not designed for research purposes.

He noted that efforts to design EHR technology to meet Centers for Medicare & Medicaid Services (CMS) Meaningful Use requirements have considered what basic clinical elements might be important in laying the foundation for a National Patient-Centered Clinical Research Network (PCOR net)-style research infrastructure. As such, current certified information systems do have a core data component that supports clinical research and the comparison of data across institutions. The quality metrics that are specified under the Meaningful Use rule fit that criterion, for example. There are still many aspects of currently available EHR systems that do not support research, and elements need to be added after the fact. One example is the need for open application programming interfaces that would allow researchers to develop software that could interface with multiple EHR data repositories.

Even if research is considered at the outset, he continued, it is impossible to design a system that anticipates the many evolving research needs of a country,

BOX 5-1

Comments on Harmonized Measurement For Continuous Learning

Leadership. Transparency and aligned leadership are key elements of a datadriven, systems-based approach to improving care and outcomes. Leadership also needs to galvanize the frontline staff who bear the burden of collecting the data and implementing the change. [Chu]

Efficient data purposing. Using the same data for quality and accountability metrics, and for system improvement, could reduce collection burdens and improve clinical relevance. In the future, PCORnet might also be used for developing meaningful quality measures. [Cassel]

Continuous improvement. Feedback is an essential element of an iterative approach to improving care and outcomes. Real-time feedback is also needed on the impact of the metrics in quality and accountability programs, for improving the quality of the metrics, and for ensuring the metrics are meaningful to both consumers and providers. [Cassel, Chu]

Clinical and payer data alignment. Payer and care data complement each other and provide a richer data source, as each alone is a limited data set. [Cassel, Chu, open discussion]

Research-ready data. To be useful for performance measurement and health system improvement, a data infrastructure needs to be designed for research purposes, including core data components that support clinical research and the comparison of data across institutions. Electronic health record (EHR) systems must be adaptable and reconfigurable to be able to meet future data needs. [Blumenthal]

Change management. There are many challenges to implementing change. Change management was suggested as additional clinician competency that could be taught in medical schools, and attention to the foundations of quality, system science, and safety science could be increased. [open discussion] region, or individual system. Because it is not possible to predict the data that will be required to answer as yet unknown questions, EHR systems must be adaptable and reconfigurable to make them useful. Blumenthal suggested that the ability to redesign electronic information systems should be a core competency of health organizations, as essential as the ability to dispense medicines appropriately or ensure a hygienic environment. The capability for adaptation will not be evenly distributed across organizations. For an institution to be an active research participant using EHR data for measurement purposes, having developers capable of system redesign will be a requirement.

Another requirement is the ability to manage the burden of data entry. Entering standardized data in standardized fields enables the extraction of the data and comparison to data from other records and systems. The process of entering data in that way, however, is not intuitive or comfortable. Instead of jotting down shorthand notes and abbreviations on paper, frontline clinicians are now key participants in building a research infrastructure that does not benefit them or their patients in the near term, although it has significant potential societal benefits. A future challenge for the kind of work that PCOR net aspires to is how to build in that reward, whether intrinsic or extrinsic, for those who bear the often frustrating burden of data entry.

TAPPING NEW DATA SOURCES TO IMPROVE HEALTH QUALITY

Cassel discussed the potential of data infrastructures to serve as measurement frameworks, not only for research but for accountability at the national level. She reminded participants that the NQF was created 15 years ago to be the one organization where public and private stakeholders from every part of health care would come together to decide what is meaningful information, and how to conduct rigorous and accurate measurement using that information. The NQF was focused on getting information to the public with the idea that comparisons between providers would facilitate consumer-driven reductions in cost and increases in quality. However, the health care marketplace is not quite that simple and over the past decade there has been increasing focus on linking metrics to payment. It is not just the payers who are demanding these measures, she added, but also consumers who want to know, for example, which doctor or hospital is best.

The current measurement system does not serve any of its constituencies sufficiently. Cassel commented that there are too many measures, and it is too confusing, and there is now a push for developing a set of core measures. Several sets of core measures have been proposed, including those described in the Institute of Medicine (IOM) report titled *Vital Signs: Core Metrics for Health and Health Care Progress* (IOM, 2015b). According to Cassel, while core measures as indicators of progress are essential, they will not necessarily meet the needs of consumers, who want disease- or provider-specific information, not public health measures. There is extensive information available to consumers on the Internet, with wide-ranging accuracy and value. There are also measures for value-based purchasing, which are systems-level measures (system-level accountability and system-level payment) rather than individual clinician measures. The NQF can help to meet the needs of payers, providers, and consumers, she suggested, if better measures can be agreed to.

There is also tension between the requirements by payers to ensure that their money is spent on value (i.e., accountability) and the burden of collecting the data for the many other reasons discussed, including improvement. Cassel relayed the case of a major health care organization that has 100 staff members dedicated solely to collecting the data that must be reported to Medicare. This is waste to the system as those measures are not clinically relevant, do not help the providers improve care, and are not meaningful to consumers because they are not made in real time and do not come out of the real experience of the data systems. Ideally, using the same data for quality and accountability metrics, and for system improvement, could reduce collection burdens and improve clinical relevance. Another need is real-time feedback to better understand the impact of the metrics that are part of accountability programs (e.g., more rapid information about impact on care, and unintended consequences).

This will be essential for improving the quality of the metrics and ensuring that the metrics are meaningful to both consumers and providers. Cassel noted that the NQF has been engaging specialty societies, including the American College of Physicians and the American College of Cardiology, on using their members as a means to obtain real-time feedback about their experience with NQF metrics.

In closing, Cassel described the NQF project called the Measure Incubator,⁹ aimed at addressing the fact that there is a market failure in developing good measures. While many organizations are developing measures, they are not brought through the national process to determine whether they could be used at a national level. There are also areas where there are few reliable measures (e.g., behavioral health, and care coordination for multiple chronic conditions) and

⁹ For more information see http://www.qualityforum.org/NQF_Measure_Incubator.aspx (accessed May 31, 2016).

cases where the development of measures has been inefficient (time consuming and costly). The Measure Incubator brings measure developers together with technical experts, funders, and data sources (e.g., large delivery systems, big data sources, crowdsourced data, and patient-reported outcomes). She suggested that as PCORnet moves forward, the network might also be used for developing meaningful quality measures.

ACCELERATING MEDICAL EVIDENCE GENERATION AND USE

A key concern for a CEO running a health system is how to operationalize knowledge to achieve better outcomes and ultimately improve population health. Benjamin Chu shared some of the lessons from Kaiser's experience in putting data into action to improve outcomes over the past decade. According to the IOM report titled *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* (2013), one of the characteristics of a continuously learning health system is real-time access to knowledge. To achieve this, Chu explained that data need to be translated with intentionality into a systems-based approach. The process begins with defining a desired outcome, determining how to best obtain the real-time actionable data necessary to drive that outcome, and then developing the measures to obtain feedback and maintain an iterative approach to improvement. Transparency is a key element of the process. Aligned leadership direction is also essential, and leadership needs to galvanize the frontline staff, as they are the people collecting the data and implementing the change.

Chu briefly mentioned several specific examples of different approaches to achieving better outcomes (see Hudson et al., 2015; Kanter et al., 2010, 2013; Sim et al., 2014). One example included the creation of registries, but Chu cautioned that establishing a registry alone is not sufficient; there must be a system around the information in the registry that can drive better performance. Similarly, simply providing information about gaps in care to primary care doctors is not effective; there needs to be an intentional, systems-oriented approach that puts improvement strategies in place. A structural model is not going to drive improved care. Rather, it is the use of the information, and the feedback to push the systems. Diagnostic errors, or "diagnoses of omission," are also a concern. Chu shared that health systems are receiving lawsuits from patients who were tested but for whom there was no timely follow-up on the test, and who 2 or 3 years later developed high-grade prostate cancer or colon cancer. In an integrated system, providers should be responsive;
however, patients are still falling through the cracks. To address this, Kaiser designed an electronic safety net system that uses an "if, then" hypothesis. If there was an abnormal result, then did a follow-up happen? Another example considered the use of high-cost imaging, including computed tomography and magnetic resonance imaging. Looking at comparative rates of diagnosis of diabetic retinopathy, Kaiser found wide variation in diagnosis via retinal screening across medical centers and discovered that interophthalmologist reliability was very poor. To address this, Kaiser implemented a teleophthalmology approach where trained technicians conduct centralized review of retinal screening images. As a result, diagnostic accuracy has increased and variability across centers has decreased.

DISCUSSION

During the open discussion that followed the presentations, participants discussed the burdens of data collection as well as the potential of having access to claims data and to bundling core measures data. Participants also discussed how to more effectively engage providers in implementation and the need to define measures for specific concerns, including measures of inequity within the system and measures of relative improvement.

Data Collection: Maximizing the Uses of Clinical and Claims Data

The challenges and burdens of data collection facing clinicians were discussed further. Cassel suggested that there is a significant burden on care systems to collect data that are used solely for payment purposes and that are not relevant to internal improvement and quality metrics. Many participants agreed. She added that payer and provider data complement each other and are a powerful combination. Chu suggested that an added value of having access to claims data in addition to clinical data is that care providers often cannot get the full picture of their patient's care; they see only the hospital component, or the specialty care, or the emergency department visit. He proposed that PCOR net could look at all of the data sources and think about how to pool a population-level view for individuals in the population. This would be helpful to most health systems.

Bundling Core Measures

Participants raised the ideas of bundling core measures for the series of care events that a patient needs and integrating measurements across patients with multiple chronic conditions. The CMS Million Hearts Initiative was cited as an example of integrating data from EHRs with vital sign data and laboratory data to estimate the risk of cardiovascular events and death across the management of hypertension, diabetes, and smoking. It will be important to develop measures that integrate the totality of care that patients are receiving and summarize their health in a meaningful way, including describing their risk for an event and the ability of a care system to influence that risk independent of what happens to the patient. Also mentioned was the potential of bundling for looking at the elements of care that cluster together from a payment perspective. As mentioned above, payer and care data together provide a richer data source, as each alone is a limited data set.

Engaging Providers in Implementing Change

It was mentioned earlier that one way to advance progress is to bring research much closer to clinical operations, embedded in the clinical delivery system. Implementation will be more timely and successful if clinical staff can be involved in the design and the interpretation of the interventions. In response to a question about dissemination and implementation, Chu stated that Kaiser faces challenges similar to those encountered by other systems. Practitioners want to verify that the strategy is right. One of the ways to get buy-in is to show providers the actual information and to have one of their colleagues present that information. For example, the implementation of centralized review of retinal screening images was guided by an ophthalmologist, and providers were shown the data on screening by each practice versus centralized screening.

Participants agreed with the need for transparency and noted that while comparative performance data may make providers feel uncomfortable initially, professionals care about patients and improving care and want to know how others have achieved better performance. Greater transparency could also lead to a learning network.

Another point was that during medical school and residency, not as much attention is given to the foundations of quality, system science, and safety science as is given to life sciences and social sciences. Participants suggested the need to define such additional competencies at the premedical and medical school levels and, because changing habits is difficult, incorporate change management courses in medical school as well.

Defining Specific Measures

Participants also suggested that measures not be thought of as discrete entities, but as more dynamic. For example, there is a need for a national conversation on a standardized way that systems should be measuring inequity. Cassel pointed out that the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 legislation includes a provision that rewards improvement (in addition to rewarding the attainment of certain levels of performance). There are ongoing internal discussions at CMS about what kind of improvement that would be, and how it would be measured. It is all specialty based, she added, and suggested it would make sense to think about it relative to clinical units or team-based models.

6

FOLLOW-ON, THEMES, AND STRATEGIC EXPANSION

In a relatively short time, important progress and advances have been made since L the two 2014 Institute of Medicine (IOM) workshops on health system leaders working toward high-value care, Larson noted. The Clinical Data Research Networks (CDRNs) have been hard at work, and have made significant progress in creating the basis for a national data infrastructure that will help to improve quality and outcomes in a patient-centered way. Larson observed that the 2014 IOM workshop report was titled Integrating Research and Practice, and attendees included CDRN leaders and staff, people from their delivery systems, and a few experts (IOM, 2015a). It was meant to be a dialogue session but it was more presentations than interaction. In contrast, the present meeting is focused on accelerating clinical knowledge generation and the use of clinical knowledge in the context of PCOR net. Larson lauded the quality of interactive dialogue at the workshops and felt that it is evidence that advances are being made in the area of accelerating knowledge into practice. Finally, Larson highlighted the value of the National Academy of Medicine (NAM) as a convening body for this effort. The NAM can bring together system leaders, the CDRNs, and other experts, as well as new partners, and keep this dialogue going into the future.

Selby concurred, and added that the past 18 months have seen a growth in appreciation of the potential and the importance of linking research with performance and system improvement on a rapid-cycle, quick-turnaround, performance-driven basis. He emphasized that there will be upcoming opportunities for continued dialogue and interaction. There is work to be done in the short term on preparing and funding the demonstration projects, and the health systems research group within PCOR net will continue its work. Additionally, Selby observed that there was clear and broad interest in linking delivery system and health plan data to better facilitate research. The importance of sociodemographic and socioeconomic determinants of health was also emphasized, and PCOR net would keep that in mind in building out the Common Data Model. The importance of patient-reported outcomes was also discussed, and Selby noted the need to ensure that delivery systems and patients are not overly burdened with collecting patient-reported outcomes that are intended only for research and that do not support clinical care or health status improvement.

STRATEGIC EXPANSION

In order to build upon the momentum of the first meeting, the second meeting of the series was an opportunity to explore how the Patient-Centered Outcomes Research Institute (PCORI) had incorporated the feedback gathered at the January meeting to develop the PCOR net Health Demonstration Project, a funding opportunity for researchers and health systems. In the time between the two meetings, PCORI developed a request for proposals, solicited applications, and awarded four PCOR net Health Demonstration Project awardees. In the second meeting of the series, participants heard reports on the progress of the demonstrations projects, with particular attention to the impact and lessons learned from conducting these projects in health systems, with the involvement of clinicians, systems leaders, and patients.

Awardees of the PCOR net Health Demonstration Project discussed their research priorities, research and executive collaborations, and projects plans. Kaushal described her project, Identifying and Predicting Patients with Preventable High Utilization, a collaboration of three CDRNs. As she put it, "what we are trying to do is to integrate and quality assure multiple data sets and then characterize and prevent high utilizers." The project was developed in response to—and in partnership with—health executives.

Kathleen Walsh of Cincinnati Children's Hospital Medical Center provided an overview of her project, Automating Quality and Safety Benchmarking for Children: Meeting the Needs of Health Systems and Patients. The project, which will incorporate leadership from both patients and families and health executives, is focused on implementing and evaluating electronic measures of pediatric safety and quality for three high-priority conditions (transcranial Doppler for children with sickle cell disease, appropriate antibiotics for ear infections, and metabolic screening for antipsychotics) and ultimately determining the value of electronic measurement benchmarking to health system leaders.

Maureen Smith of the University of Wisconsin-Madison next presented on the Variation in Case Management Programs and Their Effectiveness in Managing High-Risk Patients for Medicare ACOs project, a partnership of two CDRNs to characterize case management programs across the country. Through a series of interviews with patients, case managers, and chief executive officers, the programs aim to understand how various stakeholders conceptualize the key elements of case management programs, collect concrete program elements, develop a scheme across programs, and examine three case management programs in depth for effectiveness.

Finally, Jennifer DeVoe of Oregon Health & Science University began her presentation by recounting her own experience in practice with dashboards, benchmarking, and the impact of social determinants on patients' health. She next described a project called The Impact of Patient Complexity on Healthcare Performance, which, through the work of two CDRNs, will integrate multiple social determinant data, such as transportation and environmental hazards, along with clinical and claims data to explore their impact on health care service utilization and health. Through the course of the project, the team will also address a multitude of issues associated with data integration, such as privacy and security concerns.

When asked what being part of PCOR net brings to their individual projects, presenters underscored that the PCOR net data, as well as the Common Data Model, allowed them the opportunity to pull data from multiple sites; that PCOR net provides an opportunity to engage collaboratively with many researchers and move across key networks. During the general discussion, a number of the health executives raised the point that the topics of these projects (e.g., benchmarking, defining metrics, and understanding case management and high utilizers) resonated with their systems' priorities and could potentially provide valuable insights for the larger health community.

In addition to hearing about the progress of the PCOR net Health Demonstration Project, the meeting series also provided participants an opportunity to look ahead at the continued engagement and active involvement of health executives in evidence generation. To sustain the partnerships that first began with the initial meetings in 2014, the NAM has developed the Executive Leadership Network (ELN) for a Continuously Learning Health System. The ELN operates under the auspices of the NAM Leadership Consortium for Value & Science-Driven Health Care to support ongoing communication, collaboration, and synergy among executive-level stakeholders with a common interest in developing the capacity, infrastructure, and culture necessary to drive continuous learning and improvement within and across health care delivery systems. The ELN is a virtual network, and ELN participants serve as a standing group of ad hoc advisors to the NAM on the issues, strategies, and returns from continuous learning capacities that simultaneously support operational decision making, performance improvement efforts, and the generation of better evidence. In addition to the set of activities with PCORI, ELN members are involved in a number of NAM projects including the development of a

discussion paper on the measurement burden that provided the perspectives of large health systems related to the burden of measurement and reporting programs, its consequences, and actions being taken to increase the benefits of metric reporting while minimizing the burden to systems and providers; and NAM's initiative to explore a series of strategic activities designed to improve synergy among health systems as they engage their common interests in broad interoperability of health data.

McGinnis next asked the meeting's participants, "as you look at the sets of challenges related to the evidence generation enterprise, what would you like to see to make your lives easier?" Key comments are highlighted below:

- Amy Abernethy of Flatiron identified the importance of focusing on getting the data "right" and addressing the difficult questions related to data quality.
- A number of meeting participants answered that we need to take into account social determinants and championed stronger connections with social and environmental organizations (a key theme from the first meeting of the series). To this point John Kastanis of University Hospital mentioned that "it would be helpful for you to have better information on the linkages within other agencies, payment models that incorporate social factors, [and] common data sets that made available standardized information for health."
- John Warner of the University of Texas, Southwestern University Hospitals, reflected on the need for the development of a business case for investment in evidence generation and increased synergy between efforts around science and business.
- Steve Allen of Nationwide Children's Hospital stated that our problems are not due to a lack of data but the difficulty in turning that data "into action." And a number of meeting participants also highlighted the need for implementation science—guidance on how to implement new learning activities while addressing work flow and staff satisfaction issues.
- Meeting participants also called for a unification of ongoing regulatory and measurement efforts so that the work of PCOR net might inform the scanning and pilots to test alternative payment models under the Centers for Medicare & Medicaid Services' Center for Medicare & Medicaid Innovation and vice versa. Collaboration among the various large initiatives could lead to less fragmentation.
- Rachael Fleurence of PCORI noted that her vision is that the work of PCORnet will simplify the administrative process and streamline contracting and Institutional Review Board approval, noting that contracts can take over 6 months to get executed while patients are waiting for answers.

OPEN DISCUSSION OF NEEDS, OPPORTUNITIES, AND STRATEGIES

Participants considered next steps for executive and research collaboration in continuously learning health systems. Key foci included the scale and spread of partnership strategies, sustainability objectives and strategies for PCORnet, how health executives seek to further engage in evidence-generation initiatives, and action items for efforts by the NAM and PCORI to address outstanding barriers facing health delivery systems while enhancing and spreading best practices and promising strategies.

Newton framed the discussion by reflecting on the first meeting of health executives and researchers and how perceptions have evolved, as demonstrated by the increased degree of engagement by those in leadership positions. She also noted that this group of meeting participants has become "the choir" and challenged the participants to think about how to engage health executives that have yet to interact with PCOR net or other research networks.

Participants discussed the current health ecosystem in which health systems are taking on increasing risk and how it is important for the work of PCORnet to align with that transformation. In order to increase partnerships between researchers and health executives, there is a role for PCORI and PCORnet to impact the data needs, to continue to focus on key topics of interest to delivery systems such as the metric burden, to streamline key data elements, to begin to address data quality issues, to develop learning across the PCORnet system that has broader implications across health systems, to explore granularity in data that are currently missing, to contribute toward the streamlining of benchmarking metrics, and to move forward the capability of capturing social determinant data.

One issue that was reiterated by the meeting discussants was the importance of articulating the value proposition and business case of research networks. As stated by Smith, when speaking of her own experience of sharing information about this work: "when we have gone out and talked about this project—there's a lot of interest but there is concern about costs to become involved and the burden on staff already changing the wings while flying. The more we could articulate the costs and how PCOR net could reduce the costs of new projects, the better." Amy Abernethy also added that the value of PCOR net could best be offered through the presentation of use cases that demonstrate the success, processes, and costs of these projects within their organizations. Others agreed and also discussed the important role of using visualization of the data to engage stakeholders, such as health executives and clinicians. Finally, the meeting closed with a conversation on training programs for house staff that incorporate the competencies (e.g. clinical informatics, quality improvement) of knowledge generation activities and would help clinical staff have the infrastructure, tools, and support they need to engage in a learning health system.

SUMMARY AND NEXT STEPS

The meeting series themes and opportunities for action, in Box 6–1,¹⁰ were drawn from the individual presentations, breakout sessions, and open discussions and highlight areas for future efforts by the NAM and PCORI to accelerate progress.

One of the key elements of the meeting series' discussion was that even with access to multiple data, delivery systems face the challenges of making the data actionable; implementing findings into their specific institution with their distinctive populations; encouraging learning environments while also addressing workforce burnout; balancing investments in science with necessary investments in business; seeking innovation to make care more affordable and efficient; and demonstrating returns of research findings to patients and to the care providers. To demonstrate better implementation strategies, the participants articulated that delivery systems need toolkits and guidance documents that provide use cases and implementation strategies. In addition, they need data presented in formats (e.g. visualizations) that facilitate decision-making by health executives and clinicians and information on how other organizations are addressing the barriers described above. Participants also articulated that PCOR net could have an important role in meeting these needs. There are some findings that will be translational across all institutions, regardless of populations (e.g. the training strategies for house staff focused on the importance of evidence generation, which incorporates clinical informatics, clinical effectiveness research, and quality improvement).

Other projects, such as the FDA Evidence Generation Initiative, and corresponding paper titled Transforming Evidence Generation to Support Health and Health Care Decisions (Califf, 2016) are focusing on the potential of developing high-quality evidence through the integration of health care and research data systems and its implications for health and health care decision making. Likewise, on the topic of data and analytics, the Accelerating Clinical Knowledge Generation and Use meeting series participants noted that, in an ideal scenario, there would not be parallel universes where care is delivered and where the delivery of care is studied. Strategies for bridging these activities include expanding a common

¹⁰ This section is the rapporteur's summary of main topics and recurring themes from the presentations, discussions, and summary remarks by the breakout session facilitators. Items on this list should not be construed as reflecting any consensus of the meetings' participants or any endorsement by the NAM or the consortium.

BOX 6-1

Common Themes and Opportunities for Action

Executive needs

- Data structured for priority action
- · Findings that are context-applicable
- · Workflow-friendly continuous learning and improvement
- Strategies for integrating knowledge generation into the business proposition
- Innovation that enhances efficiency
- · Patient- and provider-resonant research returns

Success factors: the PCORnet Example

- Health system leaders helping to shape research priorities
- Shared leadership accountability
- Engaged clinicians
- Early focus on dissemination and implementation
- Full collaboration between research side and operations/practice side

Capacity requirements

- EHR systems designed for flexible incorporation of emerging core elements
- · Continuous training and peer learning networks
- Visualizations and delivery system toolkits that facilitate translation to decisions
- · Analytic capacity and practice that integrate multiple data sources

Stakeholder action priorities

- · Research models and methods proven in real-world settings
- · Training and competencies for researchers embedded in delivery systems
- Access to, and integration of, social determinants data from outside health care
- Demonstrated strategies for implementing new practices into health care systems
- Better evidence on impact of EHR-embedded information on outcomes
- · Inventory of research issues most important to address

SOURCE: Summary of closing remarks, speaker presentations, and participant discussions.

data model to serve multiple stakeholders and encouraging more opportunities for embedded research. They also articulated that to effectively use data for decision making, knowledge generation, and improved care within delivery systems, there is need for analytics layered on top of multiple data; the use of the same data for clinical care, measurement, and reporting (e.g., duplication of data merging as opposed to a comprehensive strategy); the use of data for benchmarking so that systems can understand how they compare; the return of research results back to the delivery systems; access to data from multiple sites/sources that provides a more comprehensive view of their patients' care (outside of their particular institutions); and a focus on data quality.

Additionally, one of the most highlighted discussion points throughout the day was that patient complexity impacts health care delivery and performance and it is therefore necessary for electronic health records to record core social determinants and key behavior patterns. Because social determinants are being addressed by institutions outside of health care, participants considered how delivery systems could better connect with other agencies, obtain better information about how other agencies collect and analyze data, and consider whether there are common data models across different sectors.

The meeting participants emphasized the need for networked evidence systems, such as PCORnet, and pointed to the increasing number of health executives who find value in such evidence systems. According to Kaushal, within the Weill Medical College of Cornell University NY-CDRN, there is a sense of ownership from the health executives involved in the CDRN, and several additional hospitals have asked to join. Drawing from the benefits of the PCOR net experience offering unparalleled research readiness for health executives, as well as access to new partners (i.e., PCOR net's new involvement of health plans), the importance of expanding the opportunities for research partnerships, access to data, tools for collaboration, and continuous learning to other executives and systems across the country is clear.

REFERENCES

- Burwell, S. M. 2015. Setting value-based payment goals—HHS efforts to improve U.S. health care. *N Engl J Med* 372(10):897–899.
- Califf, R. M., M. A. Robb, A. B. Bindman, J. P. Briggs, F. S. Collins, P. H. Conway, T. S. Coster, F. E. Cunningham, N. De Lew, K. B. DeSalvo, C. Dymek, V. J. Dzau, R. L. Fleurence, R. G. Frank, J. M. Gaziano, P. Kaufmann, M. Lauer, P. W. Marks, J. M. McGinnis, C. Richards, J. V. Selby, D. J. Shulkin, J. White, J. Woodcock, J. Woodson, and R. E. Sherman. 2016. Transforming evidence generation to support health and health care decisions. N Engl J Med 375:2395–2400.
- Carton, T. W. 2016. *Identifying research needs on the ground*. Slides presented at the January 21, 2016 Accelerating Clinical Knowledge Generation and Use Meeting, Washington, DC. Available online. http://nam.edu/wp-content/uploads/2016/02/Identifying-Research-Needs-on-the-Ground-Canton.pdf (accessed December 13, 2017).
- Dixon-Woods, M., P. Pronovost, and M. Marshall. 2013. *What is the science of improvement?* The Health Foundations. Available online. http://patientsafety.health.org.uk/sites/default/ files/resources/ what_is_the_science_of_improvement.pdf (accessed May 31, 2016).
- Hudson, S. M., R. Contreras, M. H. Kanter, S. J. Munz, and D. S. Fong. 2015. Centralized reading center improves quality in a real-world setting. *Ophthalmic Surg Lasers Imaging Retina* 46(6):624–629.
- IOM (Institute of Medicine). 2000. To err is human: Building a safer health system. Washington, DC: National Academy Press.
- IOM. 2013. Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press.
- IOM. 2015a. Integrating research and practice: Health system leaders working toward high-value health care. Washington, DC: The National Academies Press.
- IOM. 2015b. *Vital signs: Core metrics for health and health care progress.* Washington, DC: The National Academies Press.
- Kanter, M., O. Martinez, G. Lindsay, K. Andrews, and C. Denver. 2010. Proactive office encounter: A systematic approach to preventive and chronic care at every patient encounter. *Perm J* 14(3):38–43.
- Kanter, M. H., G. Lindsay, J. Bellow, and A. Chase. 2013. Complete care at Kaiser Permanente: Transforming chronic and preventive care. *Jt Comm J Qual Patient Saf* 39(11):484–494.
- Kaushal, R. 2016. PCORnet health systems demonstration project: Key questions by theme. Slides presented at the January 21, 2016 Accelerating Clinical Knowledge Generation and Use Meeting, Washington, DC. Available online. http://nam.edu/wp-content/ uploads/2016/02/Report-Back-and-Review-of-Research-Questions-Rainu-Kaushal. pdf (accessed December 13, 2017).

- Keren, R., S. S. Shah, R. Srivastava, S. Rangel, M. Bendel-Stenzel, N. Harik, J. Hartley, M. Lopez, L. Seguias, J. Tieder, M. Bryan, W. Gong, M. Hall, R. Localio, X. Luan, R. deBerardinis, A. Parker, and the Pediatric Research in Inpatient Settings Network. 2015. Comparative effectiveness of intravenous vs. oral antibiotics for postdischarge treatment of acute osteomyelitis in children. JAMA Pediatr 169(2):120–128.
- Marshall, M., P. Pronovost, and M. Dixon-Woods. 2013. Promotion of improvement as a science. *Lancet* 381(9864):419-421.
- NASEM (National Academies of Sciences, Engineering, and Medicine). 2016. A framework for educating health professionals to address the social determinants of health. Washington, DC: The National Academies Press.
- Peltola, H., L. Unkila-Kallio, and M. J. Kallio. 1997. Simplified treatment of acute staphylococcal osteomyelitis of childhood. The Finnish Study Group. *Pediatrics* 99(6):846-850.
- PCORnet (The National Patient-Centered Clinical Research Network). 2017. Partner Networks. http://pcornet.org/participating-networks (accessed December 14, 2017).
- Pronovost, P. J., J. I. Cleeman, D. Wright, and A. Srinivasan. 2015. Fifteen years after To Err Is Human: A success story to learn from. BMJ Qual Saf 25:396–399.
- Ruebner, R., R. Keren, S. Coffin, J. Chu, D. Horn, and T. E. Zaoutis. 2006. Complications of central venous catheters used for the treatment of acute hematogenous osteomyelitis. *Pediatrics* 117(4):1210–1215.
- Selby, J. 2016. Harnessing the power of healthcare data across the USA. Slides presented at the January 21, 2016 Accelerating Clinical Knowledge Generation and Use Meeting, Washington, DC. Available online. http://nam.edu/wp-content/uploads/2016/02/ Opening-Remarks-and-PCORI-Introduction.pdf (accessed December 13, 2017).
- Sim, J. J., J. Handler, S. J. Jacobsen, and M. H. Kanter. 2014. Systemic implementation strategies to improve hypertension: The Kaiser Permanente Southern California experience. *Can J Cardiol* 30(5):544–552.
- Zaoutis, T., A. R. Localio, K. Leckerman, S. Saddlemire, D. Bertoch, and R. Keren. 2009. Prolonged intravenous therapy versus early transition to oral antimicrobial therapy for acute osteomyelitis in children. *Pediatrics* 123(2):636–642.

APPENDIX A: JANUARY MEETING AGENDA

Leadership Consortium for a Value & Science-Driven Health System

ACCELERATING CLINICAL KNOWLEDGE GENERATION AND USE

*

A meeting of the Executive Leadership Network for Continuously Learning Health Care NAM Leadership Consortium for Value & Science-Driven Health Care

*

- Sponsored by the Patient-Centered Outcomes Research Institute -

*

January 21, 2016

National Academy of Sciences Building, Lecture Room 2101 Constitution Ave NW Washington, DC 20418

MEETING GOALS

Comments on Harmonized Measurement for Continuous Learning

- 1. **Compelling care questions.** Propose important questions on system performance, measurement, and operations that might be answered from systematic capture of care delivery data. Explore the views of health system leaders on the highest priority questions to be addressed, including the value of standardized data collection.
- 2. **Common priorities.** Identify common priorities to help improve communication, synergy, and progress among health care organizations with related interests.
- 3. **Research-ready data systems.** Characterize and consider clinical data system characteristics necessary to generate usable knowledge in real-time, including use of PCORI's common data model (CDM).
- 4. **Strategic options.** Provide input to the PCORI Demonstration Projects as well as the expansion of strategic priorities.

8:00 a.m. Coffee and light breakfast available

8:30 a.m. Welcome, Introductions, and Overview

Welcome from the NAM

Michael McGinnis, MD, MPP, National Academy of Medicine

Opening remarks and meeting overview

Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute

Eric Larson, MD, MPH, MACP, Planning Committee Chair, Kaiser Permanente Washington Health Research Institute

9:00 a.m. Clinical data as a change tool

This session will introduce the concepts and framework for evidence generation from real-time care delivery, highlight an example of data transforming practice, and provide a health executive perspective.

Generating evidence in health systems

Nirav R. Shah, MD, MPH, Kaiser Permanente

Oral antibiotics vs. intravenous (PICC line)

Ron Keren, MD, MPH, Children's Hospital of Philadelphia

A perspective from the field

Herbert Pardes, MD, former CEO and current Executive Vice Chairman of New York–Presbyterian Hospital

9:30 a.m. Exploring the ROI of evidence generation for health delivery systems

Value of research and data infrastructure to health and health care Kate Goodrich, MD, MHS, Centers for Medicare & Medicaid Services, moderator

Scale and spread across institutions: a network of continuous learning Peter J. Pronovost, MD, PhD, FCCM, Johns Hopkins Medicine

Identifying research needs on the ground

Thomas W. Carton, PhD, MS, Louisiana Public Health Institute and the Research Action for Health Network (REACHnet)

Open Discussion

10:20 a.m. Breakout session introduction and instructions

Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute and Rainu Kaushal, MD, MPH, Weill Cornell Medicine, New York-Presbyterian Hospital will provide an overview of PCOR net and describe the focus of the breakout session. Participants will then proceed to assigned breakout rooms.

10:30 a.m. Break

10:40 a.m. Breakout Sessions (breakout rooms: 114, 118, 250, 280, Members Room)

In moderated breakout groups, participants will discuss the data and analytical needs of particular importance to executive-level decision-makers and explore the value of PCOR net and PCOR net studies, to improve health care delivery locally and nationally.

12:30 p.m. Working Lunch: report back and review of research questions

Moderators: Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute and Rainu Kaushal, MD, MPH, Weill Cornell Medicine, New York-Presbyterian Hospital

This session will include 1) a report back and open discussion among meeting participants about the breakout sessions; and 2) a review of a set of care system research questions, developed prior to the meeting.

1:30 p.m. Open discussion of needs, opportunities, and strategies

Moderator: Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute

This session will include a discussion to identify strategic opportunities and commitments from participants to move priorities forward in their own institutions and collaboratively.

2:50 p.m. Relationship between performance and knowledge generation

Christine Cassel, MD, MACP, National Quality Forum will open the session by discussing how systems can use research and data infrastructure for performance measurement. Reactors will explore the various opportunities for standardized data collection to enable continuous, system-wide improvement and learning.

Panel

David Blumenthal, MD, MPP, The Commonwealth Fund Benjamin K. Chu, MD, MPH, MACP, Kaiser Permanente

Q&A and Open Discussion

3:45 p.m. Wrap-up and next steps

Parting comments from the Sponsor and Chair

Eric B. Larson, MD, MPH, MACP, Kaiser Permanente Washington Health Research Institute

Joe V. Selby, MD, MPH, Patient-Centered Outcomes Research Institute

4:00 p.m. Adjourn

APPENDIX B: SEPTEMBER MEETING AGENDA

Leadership Consortium for a Value & Science-Driven Health System

ACCELERATING CLINICAL KNOWLEDGE GENERATION AND USE

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September 8, 2016 Keck Center of the National Academies Room 100 500 5th Street, NW Washington, DC 20001

MEETING FOCUS

Health Executive Leadership For Development, Spread, and Scaling of a Continuously Learning Health System

Core questions addressed:

- 1. **Benefits:** What are the specific and identifiable benefits (care, evidence, outcomes, and value) to be gained from the infrastructure envisioned? Examples from PCORnet, the National Patient-Centered Clinical Research Network?
- 2. **Strategies:** What strategic levers can health care executives use to accelerate progress?
- 3. **Priorities:** What are key action items and priorities for efforts by the NAM and PCORI to accelerate progress?

Anticipated outcome: Action agenda for tools and strategies that will aid executive leaders.

8:30 a.m. Coffee and light breakfast available

9:00 a.m. Welcome, introductions, and meeting overview

Welcome from the NAM

Michael McGinnis, MD, MPP, National Academy of Medicine

Opening remarks and meeting overview

Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute Eric Larson, MD, MPH, MACP, Planning Committee Chair, Kaiser Permanente Washington Health Research Institute

9:30 a.m. Vision and Progress

In 2014, the NAM and PCORI partnered to explore the alignment of research with the pace and priorities of health-delivery centers and systems. During this session, Dr. Selby will discuss the vision for future engagement with health executives and set the stage for exploring the next priorities for action.

Joe Selby, MD, MPH, Patient-Centered Outcomes Research Institute

10:00 a.m. Break

10:15 a.m. NAM Executive Leadership Network for a Continuously Learning Health System

Participants will consider ways to leverage the NAM's Executive Leadership Network to advance the development of executive/research collaboration and sustainability of collaborative research networks, such as PCORnet. Foci include:

- What are additional venues, opportunities, and strategies to engage health system leaders in continuously learning health care?
- What are additional areas to explore for future NAM meetings and papers?
- How would the results of these meetings be most effectively disseminated to health system leaders?

Facilitator: Michael McGinnis, MD, MPP, National Academy of Medicine

11:45 a.m. Lunch: Overview of the PCORnet Health Demonstration awardees

Awardees of the PCORnet Health Demonstration Project will discuss their research priorities, research and executive collaborations, and projects plans.

- Identifying and Predicting Patients with Preventable High Utilization: *Rainu Kaushal*, MD, MPH
- Automating Quality and Safety Benchmarking for Children: Meeting the Needs of Health Systems and Patients: *Kathleen Walsh*, MD
- Variation in Case Management Programs and Their Effectiveness in Managing High-Risk Patients for Medicare ACOs: *Maureen A. Smith*, PhD, MD, MPH
- The Impact of Patient Complexity on Health Care Performance: *Jennifer DeVoe*, MD, DPhil

1:00 p.m. Open discussion of needs, opportunities, and strategies

Participants will consider next steps for executive/research collaboration in continuously learning health systems. Key foci include:

- the scale and spread of partnership strategies;
- sustainability objectives and strategies for PCORnet;
- · how health executives seek to further engage in evidence-generation initiatives; and
- action items for efforts by the NAM and PCORI to address outstanding barriers facing health delivery systems while enhancing and spreading best practices and promising strategies.

Facilitator: Eric Larson, MD, MPH, MACP, Planning Committee Chair, Kaiser Permanente Washington Health Research Institute

2:30 p.m. Summary and next steps

Comments and thanks from the Planning Committee

Eric Larson, MD, MPH, MACP, Planning Committee Chair, Kaiser Permanente Washington Health Research Institute

Comments and thanks from the NAM

Michael McGinnis, National Academy of Medicine

3:00 p.m. Adjourn

APPENDIX C: MEETING SERIES PARTICIPANTS¹¹

- Erika Abramson, MD, MSc*, Assistant Professor, Healthcare Policy & Research, Weill Cornell Medicine
- Steve Allen, MD, Chief Executive Officer, Nationwide Children's Hospital
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- David Blumenthal, MD, MPP, President, The Commonwealth Fund

David Brenner, MD*, Dean, University of California, San Diego, School of Medicine

- Thomas W. Carton, PhD, MS*, Principal Investigator, REACHnet, Louisiana Public Health Institute
- Christine K. Cassel, MD, President & Chief Executive Officer, National Quality Forum
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