Advancing the State of Evidence for Decision Makers about Telehealth Meeting Summary

Introduction

On May 24, 2018, the Patient-Centered Outcomes Research Institute (PCORI) held a multi-stakeholder workshop aiming to:

- Identify themes related to the potential impact of PCORI's telehealth portfolio to aid in decision making for various stakeholder groups
- Discuss barriers to the sustainability and replicability of the telehealth interventions being studied, and how they could be addressed before the study findings are released
- Provide information that would be useful to PCORI principal investigators to magnify the utility of the findings from their project for decision makers before the studies are completed

The workshop consisted of 22 participants representing patients, clinicians, health systems, payers, telehealth advocacy organizations, and policy makers, among others.

The day began with two presentations, one providing an overview of PCORI's telehealth portfolio and the other showcasing an evidence map on mHealth to improve the self-management of chronic disease. A few highlights of these presentations are provided below.

- **Overview of PCORI's Telehealth Portfolio and How It Is Addressing Evidence Gaps** Penny Mohr, MA, Senior Advisor, Emerging Technology and Delivery System Innovation Research Initiatives, Healthcare Delivery and Disparities Research, PCORI

  As of March 2018, PCORI had invested more than $200 million to fund 64 studies in telehealth, with a significant proportion providing education or support to patients for self-management of their disease or condition through mobile health technology. PCORI's portfolio has several unique strengths. Studies have been developed with significant end-user (e.g., patient, clinician) input into the design of the interface, potentially addressing common concerns about the lack of user-friendly designs. All studies focus on outcomes of importance to patients. About half of the studies enroll diverse, underrepresented populations. Many use active comparators, and a significant number of studies will enhance the generalizability of findings through large, multisite, cross-state research. Findings from some of the early studies are just now beginning to become available, but most are ongoing. A goal of this workshop is to provide helpful advice to investigators who have studies underway about what information would be most useful to

stakeholders after their study to aid in the uptake of their findings.

Participants commented that few PCORI studies evaluate remote monitoring, and more research is needed to understand the use of telehealth for assisting the elderly.

- **Evidence Map on mHealth for Improving Self-Management of Chronic Disease** James Reston, PhD, MPH, Associate Director, ECRI Institute

  The literature on mHealth is extensive, with many systematic reviews. In the last seven years, more than 100 systematic reviews have been published on mHealth for improving self-management of chronic disease that have assessed the quality of the included studies. Most findings from these reviews were unclear with low-quality studies. PCORI's investment in this area addresses several evidence gaps identified by authors of the reviews, including a lack of studies that focus on patient-reported outcomes, a paucity that target the pediatric population, and a lack of well-designed, randomized controlled studies.

  A participant questioned whether in this field where the pace of change is so rapid, we need more randomized controlled studies, or if what was needed was more real-world studies (implied retrospective, observational studies). Real-world studies may have a place, but they need to be well designed. Another participant emphasized that clinicians, patients, and caregivers need to have assurances that what they are using has efficacy.

The rest of the morning focused on a facilitated discussion with participants that aimed to: obtain feedback on the way PCORI was characterizing the portfolio, including definitions of certain aspects of the technology; identify themes in PCORI's portfolio that resonated with stakeholders; and understand what additional information they would need to judge the relevance of these studies for decision making.

How Does PCORI's Telehealth Portfolio Address Stakeholder Needs?

The first question discussed was: "Is PCORI's framework for illustrating its investment in telehealth research helpful?"

Regarding the overarching category for the studies included in this portfolio, several participants agreed that digital health was more appropriate than telehealth (Box A on following page). The latter is associated with the Medicare definition, which offers a much narrower concept than is commonly accepted for this diverse and dynamic field of using technology to improve health. Participants also

cautioned that the definition should not require interaction with a healthcare provider, but should allow for advances in this field, such as the use of artificial intelligence.

There seemed to be a feeling that identifying telemedicine as a subcategory of digital health was important, but PCORI should allow for a broad definition of clinician (not exclusively physician) to include pharmacists and nurse practitioners, and broaden this to include store and forward technology.

A common theme expressed by participants is that classifying studies by technology (e.g., text or mobile app) is not as important as portraying what service is being provided; health systems must take into consideration patients' needs and resources (e.g., do they have a smart phone, do they have access to broadband internet, do they have a grandson at home to support them?) and then offer the technology that is most appropriate to accomplish their goals.

BOX A: DEFINITIONS USED BY PCORI

TELEHEALTH: The use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status.

TELEMEDICINE: Telemedicine seeks to improve a patient's health by permitting two-way, real-time interactive communication between the patient and the physician or practitioner at the distant site. This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and video equipment.

MHEALTH: The use of mobile and wireless devices to improve health outcomes, healthcare services, and health research.

BOX B. PURPOSE

EDUCATION

PROMOTE SELF-MANAGEMENT

IMPROVE ACCESS TO PRIMARY AND SPECIALTY CARE

REMOTE MONITORING

PCORI classifies telehealth studies according to their purpose (Box B). Participants suggested adding addressing disparities to these categories as this aspect of PCORI's portfolio is an important strength to emphasize. The stakeholders added that it may be better to use the concept of care coordination rather than singling out improving access to primary or specialty care. Other suggestions included using the term communication rather than education, and remote management rather than remote monitoring.

Regarding outcome targets (Box C), participants underscored the need to understand patient experience. They pointed out that patient satisfaction is integrally linked to clinical outcomes and quality of care. If patients are not satisfied, they will not use the technology. The second question discussed was: "What additional information do you need to assess the usefulness of these studies for decision making?"

BOX C. OUTCOME TARGETS

- Quality
- Access
- Economics and Resource Use
- Clinical
- Health Status and Well-Being

User experience, again, was an important theme raised by participants, but this time in a more qualitative sense. As several people noted, telehealth services are underutilized. PCORI studies offer an opportunity to understand what is needed to get patients to use the services that are already reimbursed. There is a need to better understand what it takes for them to work in specific subpopulations, such as vulnerable populations who have been underrepresented in prior studies, where social determinants of health need to be considered.

As one participant suggested, "It is not just software and hardware, but human-ware." Representatives from health systems noted there is often not a lot of training or infrastructure support, which is a deterrent to adoption. Health system adopters need to know what kind of support is needed to help patients use this. Similarly, what needs to be done to train providers? As there are difficulties in sustaining long-term interest, by both patients and clinicians, it would be helpful to know what happens beyond the study period. Is the service sustainable? If so, what is needed to make it successful?

The final discussion questions for the morning were: "Do the main messages presented about the strengths of our telehealth portfolio resonate with you? What additional points should PCORI be emphasizing?"

Based on a premeeting survey that was completed by 66 percent of participants, nearly all said they placed high or very high importance on the fact that PCORI's studies are measuring outcomes of importance to patients, such as clinical outcomes, functioning, and quality of life. Similarly, nearly all expressed a strong interest in the fact that PCORI's telehealth studies target vulnerable populations and address cultural tailoring. For a health system, understanding what it takes for it to work in specific subpopulations is important.

Other strengths of the portfolio that were mentioned were that these studies often look at long-term outcomes and are conducted across multiple systems and states, to enhance the generalizability of findings. These features are important to insurers.

Addressing Barriers to the Sustainability and Replicability of Telehealth

After lunch, Penny Mohr presented on addressing sustainability and replicability of telehealth. During this presentation, Mohr provided an overview of barriers to the adoption of findings for telehealth studies. These barriers were identified through key informant interviews with PCORI-funded principal investigators with telehealth studies. The barriers identified included challenges with reimbursement, clinician acceptance, system requirements (i.e., device interoperability, privacy/security), the engagement of patients, and the pace of innovation. Mohr then provided some examples of how selected projects in the PCORI portfolio have addressed those barriers.

Following the presentation, a participant brought up cost as another barrier that was not addressed. This participant expressed that patients are concerned about the cost of telehealth and the effects it has on them. Another participant added to the discussion on licensure barriers. This participant shared that there has been a tremendous amount of progress to remove barriers related to licensure. The American Medical Association, for one, has developed toolkits to help people navigate licensure issues. According to her, reimbursement, billing, and payment are the largest barriers, not licensure.

Breakout Session and Report Back

Participants were organized by their interests and expertise into three breakout groups discussing different case studies that were drawn from existing studies in PCORI's portfolio: the use of mHealth to improve diabetes self-management; the use of telepsychiatry for patients with severe mental illness (SMI) in FQHCs; and the use of pharmacist-supported remote monitoring of blood pressure for people with uncontrolled hypertension. The breakout groups were given the following questions to discuss and report back:

- What do you perceive are the major barriers to sustainability and replicability of this intervention, and why?
- How do these barriers differ by the different stakeholder perceptions in your group?
- What recommendations would you provide to PCORI investigators for enhancing the likelihood of adoption into practice?
- What can be done to enhance the likely sustainability of this intervention?

The "mHealth for Diabetes Self-Management" breakout group identified barriers to sustainability and replicability within this intervention including: regulatory issues, reaching people on government-sponsored programs, cybersecurity, clinician engagement and buy-in, and scalability. Some patient concerns identified included cost, time, training, and tech support. Payer concerns that were identified were: cost, return on investment, and receiving consent. Policy makers expressed concerns with cost and data security. Recommendations to PCORI principal investigators included measuring the provider experience, identifying and tracking unanticipated outcomes, and using patient engagement to design

the research study and to better understand the patient experience. To enhance the likelihood of sustainability, this group recommended that researchers design their study with the end in mind, consider developing tailored messaging to key stakeholders, track outcomes long-term, get endorsement from national groups in the beginning of the study, and develop a toolkit and mechanism to train other organizations on how to implement the findings. The group recommended that PCORI implement a mentorship program for successful investigators to mentor new investigators.

The "Telepsychiatry for SMI in FQHCs" breakout group focused their discussion on sustainability and replicability barriers that may be unique to their study. It was discussed that barriers to sustainability tend to have less to do with the technology, but more to do with receiving buy-in from overburdened primary care physicians and psychologists. In addition, many challenges presented were unique to FQHCs, as many FQHCs are under-resourced facilities (including lack of IT support) with high clinician turnover. Due to these challenges, the group recognized that it may be difficult to have champion physicians and/or FQHC leadership to lead the implementation of a telehealth program over time. Some recommendations for principal investigators included evaluating utilization outcomes and patient characteristics. It was also recommended that PCORI evaluate the telehealth portfolio, reviewing what context and models worked and did not work when implementing telehealth, and then create a guide for those who could benefit from it.

The "Pharmacist-Supported Remote Monitoring of Blood Pressure" breakout group discussed barriers to sustainability and replicability of this study, which included: coverage and reimbursement, costs of equipment, data flow, data sharing, relevance to other settings, sustained patient engagement, liability exposure, patient and clinician trust, and culture changes. These barriers were then broken down by different stakeholder perspectives. Recommendations to PCORI investigators included providing detailed protocols to describe how the larger healthcare team is involved in the telehealth intervention, describing who the intervention is best suited for (population and setting), and demonstrating how these interventions can be scaled. To enhance the sustainability of this intervention, the group stated that it must be paid for, have support from various stakeholders, demonstrate value, impact patient quality of life, and reduce time spent.

During the report-back session, recommendations to PCORI investigators largely fell into the following categories:

- Communicate the context of the intervention that contributed to the telehealth intervention's success or challenges
- Measure outcomes beyond the study period (to assess continued adherence and sustainability)
- Focus on the methods of implementation as much as the technology
    - *"The studies are about methods as much as they are about technology. If you have a method of implementation to engage stakeholders which works with*

outcomes, it doesn't matter what the technology is, as you can still apply it to other interventions."

- Capture engagement of patients and other stakeholders
    - *"The opportunity to look at stakeholder groups' involvement is necessary and doing a social network analysis would be beneficial. There are so many resources involved that could be tapped into. How does this engagement happen, who can we share this information with for future interventions?"*

Next Steps

To conclude the day, the stakeholders provided their key takeaways from the meeting. Penny Mohr began with sharing that one lesson learned was that context is a vital component when communicating the telehealth portfolio and the studies within them. Although findings and publications are important, it was evident that PCORI must pay attention to the clinician and patient experience as well as where the interventions worked best and where they did not. This information is necessary to address scalability once the studies are completed. Some other key takeaways included:

- Methodology, or the "how," is more important than the technology being used, particularly because technology is constantly changing.
- Having the right stakeholders involved in a study from the beginning is important to support dissemination and scalability once a study is completed.
- Studies utilizing telehealth interventions must ensure that they are user-friendly and simple for patients, caregivers, and healthcare teams.

For next steps, PCORI will be providing participant feedback that came out of this meeting to PCORI-funded telehealth investigators, with the goal of enhancing the relevance of their findings to key stakeholders. It is anticipated, as well, that there will be more opportunities in the future to bring stakeholders back to discuss findings and a strategy for dissemination as the studies mature.