Measuring Impact: Patient Engagement in Research Methods Workshop

Workshop Debriefing Summary/Interim Report

November 30, 2016

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Jacquetta Hinton (Patient Partner)

Group Health
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Acknowledgments: The Planning Committee is grateful to the Patient Centered Outcomes Research Institute for project funding; to Lia Hotchkiss, Director, of the Eugene Washington PCORI Engagement Award Program and Lauren Massey, PCORI Contracts Operations, for their guidance and support; to the Daniels Fund in Denver, Colorado for providing a meeting space for the workshop; to Dr. Laura Forsythe of PCORI and Dr. Danielle Lavallee of the University of Washington for their keynote presentations and active participation in our workshop; and to all workshop attendees for their enthusiastic engagement.
Summary

Following 2 ½ months of active planning, a group of more than 30 researchers, patient partners, PCORI representatives, and patient engagement advocates met at the Daniels Fund meeting space in Denver, Colorado on October 26-28, 2016 to begin the process of developing a systematic approach to measuring the impact of patient engagement on the context, conduct, and outcomes of research. Recognizing that approaches to measuring patient engagement vary considerably and that inconsistency in measurement makes comparisons across time and studies difficult, this workshop’s goal was to assemble a community of practice to develop and test a core suite of recommended measures to evaluate the impact of patient engagement in research in a systematic and scalable way.

Our workshop included 5 patient partners, who also served on the planning committee that oversees the project and designed the workshop (and contributed to the generation of this report), as well as more than 2 dozen researchers from academic departments, health care systems, community organizations, and representatives from PCORI. The workshop aimed to embody the principles of engagement. Our patient partners provided strong voices and decades of experiences as patients and community activists. Researchers and patient partners collaboratively set the agenda and tone for the workshop. In addition to targeted discussions, our agenda included a welcome working dinner, and keynote presentations by Laura Forsythe, PhD, MPH, Associate Director, Evaluation and Analysis, PCORI, and Danielle Lavallee, PharmD, PhD, Research Assistant Professor, Division of General Surgery, University of Washington.

Most of the workshop agenda was devoted to small groups and interactive full group facilitated sessions aimed at (1) identifying the desired context, process, and outcomes of research, (2) identifying how patient engagement could influence the research process and its outcomes, (3) a synthesis and distillation of desired outcomes and the impact of patient engagement. In particular, the goal of this three-part process was to engage all workshop participants to build consensus around core components that describe the impact of patient engagement on research.

The workshop members agreed that next steps post-workshop would include: (1) generating written summaries of the workshop and its products to be disseminated to relevant audiences and to support the follow-on activities; (2) measure mapping our core components by identifying or creating measures to capture recordable data on these components; (3) building our community of practice through continued engagement with workshop attendees plus casting our net wider to identify other individuals, instruments, and communities we can leverage as we pursue this work; and, (4) piloting these core measures and obtaining buy-in from others in the community of practice to pilot them in their own work.
Pre-workshop planning

The planning workgroup developed the agenda and assembled materials for background and orientation. Two members of the planning workgroup scanned the literature and held informational interviews with experts in the field. The discovery process identified existing approaches to tracking the extent and impact of engaging patients and other stakeholders in research, including extensive work by PCORI and some of its other awardees. In addition, researchers and community partners had previously created frameworks, surveys and checklists on community-based participatory research and involving the public in research – both are similar to patient-engaged research. However, the planning workgroup found there were limited measures and approaches to evaluate the impact of patient-engagement on the research process and particularly on research results. The planning group chose to focus this project and its workshop on this gap in the science of patient-engaged research.

Prior to the workshop, we emailed the registered attendees a slide set to orient them to the workshop, definitions, expectations and examples from the literature. We also sent them copies of relevant manuscripts and existing summaries that were identified during the literature review. Plus, we created a matrix of existing measures and survey questions to illustrate some of the examples found in the literature (see Appendix 1 for examples). Importantly, a fundamental framework* that can support and organize the current and future discoveries of this project for engagement evaluation is one which recognizes that patient-centered outcomes research can be broadly viewed across a continuum that includes:

- **Foundational Elements** – the environment/context in which engagement happens
- **Actions** – the process by which stakeholders are engaged
- **Outcomes**
  - **Near-term** – e.g., conduct of research is patient-centered
  - **Intermediate** – e.g., products of research are meaningful to stakeholders, utilized
  - **Long Term** – e.g., produces optimal health in target population or community

As mentioned earlier, the state of the science for engagement evaluation leading up to the workshop indicates there has been more accomplished in measurement and standardization on the front end of that continuum, and less work completed on the far end. However, the collective goal is to build from the current state and continue to move our evaluation capacities further along this spectrum.

Workshop format

Prior to the launch of the main workshop program, we held a gathering of attendees the evening of October 26. We used a “conocimiento” exercise, which was successful in helping participants become acquainted with each other and their experiences. During the exercise participants answered three questions: (1) What is your experience with patient engagement? (2) How has engagement changed you? (3) If you were not in your current career what would you be doing?

The official workshop program then began on October 27 and lasted one and a half days (See Appendix 2 for the official workshop agenda). Day 1 included keynote presentations by Laura Forsythe, PhD, MPH, Associate Director, Evaluation and Analysis, PCORI, and Danielle Lavallee, PharmD, PhD, Research Assistant Professor, Division of General Surgery, University of Washington. Day 1 and 2 also included idea generation and clustering exercises, synthesis of what the group identified as “core components” of patient engaged research, synthesis of these core components into the most essential components, or “core core components,” a discussion of how to attach processes to measures, and a group discussion of what our next steps should be (see Appendix 1 for full workshop program). In order to devote sufficient time to these exercises we made a group decision to defer the measure mapping work and the pilot testing planning session to be pursued and completed in the post-workshop funding period by an expanded working group.

Discussion session overviews

1. Desired outcomes of research

Our first goal was to identify common context and process outcomes shared by most studies. To facilitate discussion of desirable outcomes in research, we divided the research process into several research stages (see Table 1). In small groups we brainstormed about outcomes, noted them on sticky notes, and then discussed and edited these outcomes with the participation of the entire group. As an example, the identified outcomes for Stage 4, ‘Conduct Research/Collect Data’ are listed below (see Table 2). Also, several overarching themes across the research stages emerged from the ensuing group discussions: research should be relevant, meaningful, unbiased, feasible, efficient, valid, collaborative, patient-friendly, valuable to relevant communities, ethical, reflect diverse populations, and should adhere to the principle of realistic continuous improvement.

Table 1. Research Stages

<table>
<thead>
<tr>
<th>1. Develop the Question</th>
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<tr>
<td>2. Develop the proposal</td>
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<td>3. Administrative</td>
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<tr>
<td>4. Conduct Research/Data Collection</td>
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<td>5. Recruitment</td>
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<td>6. Data Analysis</td>
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<td>7. Write-Up &amp; Dissemination</td>
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<td>8. Implementation</td>
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Table 2. Example – Desired Outcomes

<table>
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<tr>
<th>Stage 4. Conduct Research/Data Collection</th>
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<tr>
<td>• Appropriate data points selected for collection</td>
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<td>• Validity, internal reliability, monitoring</td>
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<tr>
<td>• Accurate, valid, reliable data</td>
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<td>• Data safety and security</td>
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<tr>
<td>• Generalizable data</td>
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<td>• Managing participant issues</td>
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<td>• Timeline is feasible</td>
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<tr>
<td>• Monitoring timeline</td>
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<td>• Understandable, patient-friendly consent</td>
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2. Potential influence of patient partners on desired research outcomes

As with other sessions of the workshop, this session was facilitated by a researcher-patient partner dyad. Each small table was responsible for brainstorming areas of the potential impact of patient partners on the identified research outcomes. At each table we had at least one patient partner, and worked to answer the question: “How do patient/stakeholder partners change research when they are on research teams?” We used post-it notes to collect these ideas and then had the entire workshop group synthesize items for each of the eight stages of research. See table below for examples of specific impacts for each stage. We also noted recurring themes, including the idea that each step of the process is patient-centered. Examples include: (1) use of patient-centered language (plain language); (2) ensuring research meets patient priorities and that each step of the research is relevant and meaningful; and, (3) better communication both within the research team, and more broadly to affected patient and community groups, and beyond traditional research audiences.

<table>
<thead>
<tr>
<th>Research Stage</th>
<th>Feature/Aspect Changed by Patient Partners</th>
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| Stage 1 Developing the Research Question | • Team members - Specific Patient expertise needed  
  • Question refined (broadened or narrowed)  
  • Language - definitions modified, added  
  • Processes used  
  • Priorities |
| Stage 2 Developing the Proposal | • Collaborations  
  • Target population  
  • Timeline - lengthened or shortened  
  • Language - definitions modified, added  
  • Processes used  
  • Priorities  
  • Assumptions  
  • Funding  
  • Design |
| Stage 3 Administrative | • Privacy process  
  • Safety process  
  • Staffing  
  • Budget |
| Stage 4 Conduct Research/Data Collection | • Data collection process  
  • Patient contact/touch points  
  • Patient communication protocol  
  • Privacy process  
  • Safety process  
  • Language - definitions modified, added |
| Stage 5 Recruitment | • Number of sites change  
  • Target patient profile  
  • Language - definitions modified, added  
  • Privacy process  
  • Conflicts of Interest Addressed  
  • Timeline - lengthened or shortened |
| Stage 6 Data Analysis | • Methodology  
  • Patient Partner Training  
  • Timeline (lengthened or shortened)  
  • Priorities  
  • Assumptions |
| Stage 7 Write-up/Dissemination | • Publication strategy  
  • Methodology  
  • Language - definitions modified, added  
  • Timeline - lengthened or shortened |
3. Determination of meaningful constructs/components

We spent the latter half of the workshop reviewing and discussing the identified constructs/components within each step of the research process, particularly to identify those that we thought were most important when assessing the impact of patient-engaged research. (See Appendix 3 for image of the discussion summary for Research Stage 5 – Recruitment). At the start, we were as comprehensive as possible and then narrowed down the list to the most essential or core components we thought were important to measure. During this process, we observed that group discussion tended to blend both how patient-engagement could impact the engagement process along with how it could impact the research process and its outcomes, which we plan to separate and supplement as needed using the PCORI continuum framework, as our work continues through the remainder of the funding period.

Below are examples of core components that we identified.

- **Team collaboration**: (some called it “teamness”) having an appropriate, collaborative team that includes a variety of researcher and patient expertise and experiences.
- **Patient/Patient Partner centered**: optimal for patient participation, outcomes, comparators, content Research that anticipates participant issues, respects and reflects the patient experience and validates the patient partner input/contributions, including materials. Study activities are feasible for the participant and other stakeholders and respects diversity. Engage patient in a respectful, culturally and condition/disease sensitive manner.
- **Common language**: use engaging common language that includes specific and measurable questions.
- **Meaningful/valuable**: research and methods are reflective of, relevant and meaningful to the community and impactful (as perceived by community and all stakeholders).
- **Scientific rigor**: generalizable, reliable and validated by the patient partners and reflects the diverse participants in an ethical, unbiased and timely fashion. Honest/accurate results.
- **Integrity/adaptable**: research that maintains balance between process improvement and study goals. Willingness to change study design through “realistic continuous improvement.”
- **Legitimacy**: contribute to legitimacy of findings, increases likelihood that results will be translated/adopted (trust & buy-in).
- **Feasible**: identify and address assumptions to make goals realistic.
- **Fair/ethical/transparency**: ensure transparency in a format that is clear and engaging to foster truly informed consent.
- **Timeliness**: analysis and reporting (deadlines/timelines); iteratively share data with patient partners.
- **Sustainable**: long-term value of research and findings to scientific/healthcare/patient community. Maintaining relationships over time with patients and patient partners.

PCORI’s PCOR principles (trust, respect, honesty, co-learning, reciprocal relationship, education) also resonated with the group, although we recognize these might pertain more to impact on engagement/interactions between patient partners and researchers than on the research process.
Next Steps

Through closing discussions, the workshop members agreed that next steps following the workshop in this funding period would include:

(1) Generating a debriefing summary of the workshop (this document) to be distributed to PCORI and further detail its products for dissemination to relevant audiences to support follow-on work

(2) Mapping our core components to reportable measures by identifying or creating useful metrics to capture data on these components, placing these measures along the framework of the PCORI continuum, and identifying and filling gaps as needed.

(3) Building a community of practice among interested workshop participants, and casting a wider net to find other individuals, instruments, and communities we can leverage as we pursue this work

(4) Piloting these measures and obtaining buy-in from others to pilot them in their own work.

In addition, we intend to summarize the process, content, and products of the full 8-month project, including the workshop advance materials, attendees and bios, structured presentation slides, and discussion summaries, and the achievements of the follow-up period, for a final report to PCORI by March 31, 2017. We also expect to produce a corresponding manuscript for the peer-review literature. Patient partner discussions during the workshop suggested a second manuscript may be developed on patient partner perspectives on measuring impact.
Appendix

1. Example of background materials – pulled from literature-based matrix of existing impacts and measures (full set to be included in final report)

Potential impacts and outcomes

✓ Patient-centered topics for research agenda and research questions, prioritized topics
✓ Sensitivity to patient community (ensure questions/intervention/consent/methods are acceptable)
✓ Increased training/workload/costs/budget
✓ Faster recruitment through greater access and effective/acceptable recruitment approaches
✓ Improved timing of interventions
✓ Personal rapport built/empathic insights
✓ Divergence from scientific methods to meet partner feedback
✓ Community concerns conflict with research methods
✓ Time needed for planning for and collaborating/developing relationships

Potential measures

EACH RESEARCH STUDY STEP: 1) How much influence did you (patient partner) have on each part of the project? 2) How much extra time did you spend planning for, collaborating with and training partners (logistics, de-briefs, etc)? Costs of this extra time?

RECRUITMENT: 1) Percent of population consented and enrolled; 2) Time to desired enrollment numbers/ recruitment; 3) Recruitment rates and retention of hard-to-reach populations

METHODS: 1) For researchers: did your project partners suggest research methods that could compromise the rigor of the study? 2) For researchers/patients: did the research methods raise concerns by partners or the target communities? How resolved?

DATA: 1) Number and type of patient-reported outcomes (PROs) and patient-generated information (PGI) used; 2) proportion of PROs and PGI that were new or modified after patient involvement.
Appendix

2. Workshop Agenda

**Measuring Impact: Patient Engagement in Research Methods Workshop**

Presented by the Patient Engagement in Research Scientific Interest Group (PER SIG) of the Health Care Systems Research Network (HCSRN)

October 26 – 28, 2016, Denver, CO

**OVERALL OBJECTIVES:**

1) Understand the effects of patient engagement on a) the research process, and b) research findings/results

2) Identify and agree on the core components of engaged research and their related outcomes and desired impacts

3) Mine existing identified outcomes, measures, and frameworks that assess the impact of patient/public/community/stakeholder involvement in research.

4) Select or develop measures to assess the impact of engagement on research and the processes for using them in research

5) Create a suite of recommended outcomes, impacts and measures, and agree to pilot the use of a suite in the patient-engaged research that workshop participants are involved in

**AGENDA**

**Wednesday, October 26th – Inn at Cherry Creek (233 Clayton St., Denver, CO 80206 - Garden Room and Terrace, 2nd floor)**

6:30 – 8:30 Welcome dinner

**Thursday, October 27th - Daniels Fund (101 Monroe St., Denver, CO 80206; use Guest Parking as needed)**

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<tr>
<th>Time</th>
<th>Session</th>
<th>Facilitators</th>
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<tbody>
<tr>
<td>8:00 – 8:30</td>
<td>Welcome</td>
<td>Bob Greenlee and Sarah Madrid</td>
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<tr>
<td>8:30 – 9:15</td>
<td>Keynote #1: Laura Forsythe, PhD MPH; Associate Director, Evaluation and Analysis, PCORI</td>
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<tr>
<td>9:15 – 10:15</td>
<td>Idea Clustering #1: Desired outcomes of patient engagement in research</td>
<td>Heather Olden and Jacquetta Hinton</td>
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<td>10:15 – 10:30</td>
<td>Break (coffee and snacks)</td>
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<tr>
<td>10:30 – 11:30</td>
<td>Idea Clustering #2: How do patient/stakeholder partners change research when they are on research teams?</td>
<td>Leah Tuzzio and Neely Williams</td>
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<tr>
<td>11:30 – 12:00</td>
<td>Synthesis of Idea Clustering Activities</td>
<td>Ellis Dillon and Mary Schramke</td>
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<td>12:00 – 1:00</td>
<td>Lunch; Keynote #2: Danielle Lavallee, PhD, PharmD; Research Assistant Professor, Department of Surgery, University of Washington</td>
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<tr>
<td>1:00 – 1:30</td>
<td>Sunshine Break</td>
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<td>1:30 – 2:15</td>
<td>Measure Mapping activity</td>
<td>Heather Tabano and Gina</td>
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<td>Time</td>
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<tr>
<td>2:15 – 3:15</td>
<td>Measure Mapping synthesis</td>
<td>Napolitano</td>
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<td>3:15 – 3:30</td>
<td>Break</td>
<td>Sarah Madrid and Ursula Salas</td>
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<td>3:15 – 4:15</td>
<td>Pilot Test</td>
<td>Leah Tuzzio and Danielle Lavallee</td>
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<tr>
<td>4:15 – 4:30</td>
<td>Wrap up and dinner assignment</td>
<td>Bob Greenlee and Sarah Madrid</td>
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**Friday, October 28th - Daniels Fund**

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<tr>
<th>Time</th>
<th>Session</th>
<th>Facilitators</th>
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<tr>
<td>8:30 – 9:00</td>
<td>Dinner group report outs</td>
<td>Neely Williams and Mary Schramke</td>
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<td>9:00 – 10:15</td>
<td>Attach processes to measures</td>
<td>Ellis Dillon and Ursula Salas</td>
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<td>10:15 – 10:30</td>
<td>Break</td>
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<tr>
<td>10:30 – 11:30</td>
<td>Have we moved the needle?</td>
<td>Bob Greenlee and Heather Olden</td>
</tr>
<tr>
<td>11:30 – 12:30</td>
<td>Next steps</td>
<td>Leah Tuzzio and Sarah Madrid</td>
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<tr>
<td>12:30</td>
<td>Adjourn – to-go lunches provided</td>
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Appendix

3. Example of discussion products – ‘Desirable Outcomes and Core Components’ (full set to be included in final report)