Engagement across the Phases of Research: PCORI Engagement Rubric

Overview

- Phases of research: planning, conducting, disseminating
- PCORI engagement rubric
- Opportunities for patient/family/care partner involvement
- Challenges to (and potential solutions for) meaningful involvement
Phases of Research

- Planning
- Conducting
- Disseminating
Planning Research

**Planning**
- Identify problem(s)
- Come up with research question(s)
- Pick a research design
  - Chart reviews?
  - Interviews?
  - Clinical trial?
- Develop a plan (**written plan = protocol**)  
  - Where will it be?
  - How will patients be recruited?
  - What data will be collected?
  - How will data be analyzed?
- Find research funding
- Get approval from research oversight group (**Institutional Review Board = IRB**)

**Conducting**

**Disseminating**

Conducting Research

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**Conducting**
- Train study and/or clinic staff on protocol
- Explain study to potential participants and answer questions
- Obtain **informed consent** from patients who want to participate
- Start study
- Analyze study data and interpret findings
- This phase can be short (**days**) or long (**years**)
  - May need to re-train clinic staff
  - May need to update study participants

**Disseminating**
Disseminating Research

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**Disseminating**
- Share results with the community
  - Manuscripts published in journals
  - Presentations at conferences
  - Websites, social media
- Provide follow-up to participants and people who helped with the study
- Identify areas for future research and potential collaborators, funders

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PCORI RUBRIC

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NATIONAL KIDNEY FOUNDATION.
Research Has Many Stakeholders

**STAKEHOLDER: SOMEONE WHO HAS AN INTEREST OR CONCERN IN THE ISSUE**

- Patients, family members, care partners
- Medical providers and personnel
- Researchers
- Hospitals and health systems
- Payers (ex. insurance companies)
- Industry (ex. drug and medical device manufacturers)
- Policy-makers

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PCORI Engagement Rubric *(Statement)*

The PCORI engagement rubric...

- Explains when and how engagement can occur throughout the phases of research
- Defines the PCORI engagement principles
- Includes guidance about potential engagement activities during research and supporting examples

**Planning the Study**

**Conducting the Study**

**Disseminating the Study Results**

Potential Activities

Promising Examples of PCORI-Funded Projects
PCORI Stakeholder Engagement Principles

**Reciprocal Relationships**
- Including patients and other stakeholders as key personnel
- Roles and decision making are defined collaboratively

**Partnerships**
- Fair compensation and reasonable requests for time
- Commitment to diversity and cultural competence

**Co-learning**
- Researchers help patients and other stakeholders understand their process
- Team learning about patient-centeredness

**Transparency – Honesty – Trust**
- Inclusive decision-making
- Information is readily shared

OPPORTUNITIES FOR INVOLVEMENT
Opportunities for Involvement: Planning

**Planning**
- Identify issues that are important to patients
- Come up with research question(s) and relevant outcomes
- Help design the study to reduce disruption and/or hardship on study participants
- Recommend other patients or stakeholders who might be important to involve in the project

**EXAMPLES: PROJECT IDEAS**

**Funding Announcement:**
Small-Scale Pilots to Implement Principles of Patient-Centered Measurement

*American Institutes for Research*
Opportunities for Involvement: Planning

**Examples:** Patient-Prioritized Study Outcomes

**Systematic Review:**
- To identify outcomes that have been reported

**Nominal Group Technique:**
- With patients and caregivers to identify, rank, and describe reasons for outcomes

**Stakeholder Interviews:**
- With patients, caregivers, clinicians, and policy-makers to elicit values and perspective

**Delphi Survey:**
- To distill and generate a list of prioritized core outcomes based on consensus

**Consensus Workshop:**
- To review and endorse the core outcomes and discuss implementation strategies

**Fatigue**
- Cardiovascular Disease
- Vascular Access
- Mortality

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Opportunities for Involvement: Conducting

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**Conducting**
- Draft or revise study materials
- Participate in study recruitment
- Participate in data collection and analysis
- Participate in the evaluation of patient (and other stakeholder) engagement
- Serve as a patient representative on a study monitoring panel (Data Safety Monitoring Board)

**Disseminating**
Opportunities for Involvement: Conducting

**EXAMPLES:** STUDY FLIER + INFORMED CONSENT INFO

Research: Interviews about Goals and Dialysis Care Plans

What is the purpose of this study?
- We are trying to understand how to better reach kidneydialyze.com with your personal goals.
- This is part of a 4-study. This part is only one interview.

What would I do in this study?
If you choose to participate, you would take part in a 40-50 minute interview.

What would I talk about in the interview?
- We will talk about your personal goals and your experience with dialysis care plans.
- We also want to hear your thoughts on how to personalize your dialysis treatment plan.

What are some possible benefits to being in this study?
- Enhancing your dialysis experience in a supportive environment.
- Helping future dialysis patients.

Would I receive anything for participating?
You will receive $50 for interview participation.

When would I know the results of the study?
- We will go over updates on what we are learning in about 2 months.
- We expect all 4 parts of the study to be done by the end of 2021.
- We will share the final results with you if you are interested.

What will study staff do with the information I share?
- Our conversation is private. Your answers will help our team figure out how to better match patient goals with dialysis treatment plans.

What if I have more questions in the future?
Contact Andrew Oinnugh, Study Coordinator
Email: donagh@kidney.com; Phone: (916) 681-2206

Opportunities for Involvement: Conducting

**EXAMPLES:** CLINICAL TRIAL - SOCIAL MEDIA POST

For questions about the study or to learn about enrollment, email contact-US@sanoff.com.

Do you have Alport Syndrome?
See if you qualify for this clinical trial.

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For more information or to get involved, visit www.kidneyfoundation.org.
Opportunities for Involvement: Disseminating

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**Disseminating**
- Identify partner organizations to help share the information
- Participate in dissemination efforts (manuscripts, presentations)
- Share on social media
- Help reach patients who might not use the internet much
- Identify areas for future research

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Opportunities for Involvement: Disseminating

**Examples:** PATIENT VOICE - SOCIAL MEDIA POST

- National Kidney Foundation (@KidneyNews) on Twitter: "Patient voice is so critical, especially when it comes to topics as important as this one. NKF advocate and patient Monica Fox (@MonicaFox59) talks about "Barriers to Kidney Transplantation in Racial/Ethnic Minorities."" Read more.

- Patient Voice - ASN CJASN

- DIALYSIS RESEARCH

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Online Toolkit

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## Challenges

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<tr>
<th>Challenges</th>
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<tbody>
<tr>
<td>Mistrust</td>
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<td>Insufficient research understanding</td>
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<td>Perceived “tokenism”</td>
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Challenges: In Their Own Words

- Do I want to go out of my way to help [the researchers]? Have they made a connection with me, so that I want to help them? **Trust**

- Communication is the biggest word in dialysis. That’s with the research assistants. That’s with your techs. That’s with your doctors. That’s with your nurses. Communicate. Get on the person’s education level. Just communicate. **Communication/Follow-up**

- Don’t use those big words ... break it down to a human level. Come down to a level that I understand. **Plain Language**

- I mean, it’s a no-brainer, you would try to do [research] while we’re in the center. **Convenience**

- Are you doing [research] for yourself or are you doing it for humanity? **Plain Language**

Potential Solutions

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Potential Solution</th>
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<tbody>
<tr>
<td>Mistrust</td>
<td>• Build trust through transparency</td>
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<td>• Engage trusted intermediaries</td>
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<tr>
<td>Insufficient research understanding</td>
<td>• Provide appropriate education</td>
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<td>• Frequent check-ins to verify understanding</td>
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<td>Perceived “tokenism”</td>
<td>• Respect individual stakeholder expertise</td>
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<td>• Incorporate input throughout research process – including the very start</td>
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<td>Inconvenience/Poor accessibility</td>
<td>• “Bring it to them” – reduce burden of involvement</td>
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<td>• Offer different ways to get involved</td>
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<td>Insufficient communication</td>
<td>• Establish and adhere to a co-developed communication plan</td>
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<td>• Follow-up, check understanding, follow-up...</td>
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Summary

• The three phases of research are planning, conducting, and disseminating.

• There are many opportunities to engage patients/family members/care partners in each of these phases.

• Effective patient engagement rests on commitment to shared values and objectives, trust, transparency, respect for individual perspectives, among other factors.

  • *Engagement of patients/family members/care partners is possible and makes research more meaningful and impactful.*