Straight From the Source: Clinicians’ Views on Participating in CER/PCOR

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Rationale

• Engagement of front-line clinicians has been cited as a key challenge to conducting successful Pragmatic Clinical Trials (PCTs)

• Qualitative, empirical evidence pertaining to clinician participation in PCTs and CER/PCOR more broadly is very limited
Clinician Participation in PCOR: Defining a Framework for More Effective Engagement (September 2016)

• Overarching objective: Develop guidance regarding effective strategies for partnering with clinicians to conduct CER/PCOR in the context of healthcare delivery
PCORI Engagement Award

Phase 1
- Review of literature to identify factors that might influence clinician engagement in research activities

Phase 2
- Focus groups with clinicians to understand opinions regarding clinician engagement in CER/PCOR and solicit feedback on facilitators of engagement

Phase 3
- Key informant interviews with investigators and clinicians involved in the ADAPTABLE trial (+1 other PCT) to assess approaches to clinician engagement in the context of real-life PCTs
Literature Review Categories

- Clinician Attitudes
  - Motivations
  - Barriers

- Case Studies
  - Clinician participation in research

- Professional Motivations
  - Physicians
  - Nurses

- Quality Improvement
  - Frameworks
  - Case studies

- Commentaries
  - Improving clinician engagement
<table>
<thead>
<tr>
<th>Motivations for Research Participation</th>
<th>Citation Frequency</th>
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<tbody>
<tr>
<td>Knowledge to Improve Patient Care</td>
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<tr>
<td>Contribution to Clinical Knowledge</td>
<td>4</td>
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<tr>
<td>Professional Development</td>
<td>3</td>
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<td>Financial Benefit</td>
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<td>Intellectual Stimulation</td>
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<tr>
<td>Interaction with Colleagues</td>
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<tr>
<td>Shape Research Questions</td>
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<tr>
<td>Recognition from Colleagues</td>
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<td>Continuing Education</td>
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<tr>
<td>Patient Access to Trials</td>
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<tr>
<td>Ability to Attract Clinicians</td>
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<td>Reputation of Organization</td>
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Citation Frequency range: 0 to 6
Barriers to Research Participation

- Lack of time
- Lack of organizational support
- Inadequate space
- Inadequate staffing
- Administrative tasks
- Lack of experience
- Not valued by colleagues
- Insufficient compensation
- Patients not interested
- Lack of eligible patients
- Knowledge of topic
- Workflow disruption
- Potential loss of patients
- Lack of researcher support
- Difficult to implement
- Concern about intervention
- Topic not relevant
- Lack of information about studies
- Contributions not recognized
- Productivity demands

Citation Frequency
Case Studies

Pre-Engagement

- Identify topics of mutual interest
- Understand organizational landscape and culture
- Foster awareness and enthusiasm prior to outreach

Preparing for Study Implementation

Maintaining Engagement
Case Studies

Pre-Engagement

• Identify topics of mutual interest
• Understand organizational landscape and culture
• Foster awareness and enthusiasm prior to outreach

Preparing for Study Implementation

“\textit{The assertive diplomacy and relationship-building skills of our project manager and principal investigator were instrumental in gaining the trust and engaging the program directors and providers}” *

Maintaining Engagement

Case Studies

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Preparing for Study Implementation

- Adapt protocol to practice environment
- Provide comprehensive training
- Develop tools such as flowcharts and scripts

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Maintaining Engagement
- Provide ongoing or “booster” training
- Use multiple strategies to maintain awareness, interest, and commitment
- Recognize effort
Quality and Process Improvement

• Begin with **why** rather than **how**

• Find **effective** champions
  • Someone who has:
    
    “...both the courage to speak up when the project is about to be paralyzed ...and the social skills to be able to use one’s voice effectively.”

Institute for Healthcare Improvement White Paper, 2007
National Health Care Ecosystem -> Payment Reform, Reporting Requirements, Medical Education

**Partnership Formation**

Clinician Motivations
- Excellence in Patient Care
- Autonomy
- Professional Development

Study Characteristics
- Compelling Rationale
- Adaptable Protocol
- Adequate Resources

Researcher Characteristics
- Receptive
- Flexible
- Trustworthy

**Early Engagement**

- Build relationships
- Identify champions
- Adapt protocol
- Motivate
- Prepare

**Ongoing Engagement**

- Training
- Support
- Reminders
- Recognition
- Give-backs

Organizational Environment -> Research Culture, Productivity Pressure, Infrastructure
Clinician Engagement

PCORI Engagement Principles

- Honesty
- Trust
- Co-Learning
- Partnerships
- Reciprocal Relationships
- Transparency

PCOR Guiding Principles
PCORI Engagement Award

Phase 1
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Clinician Focus Groups

Overarching questions:

• What if any role should clinicians have in research conducted in healthcare delivery settings?

• How can researchers do a better job engaging with clinicians to achieve the mutual goal of improving patient outcomes?
Clinician Focus Groups

• To what extent do you feel that research participation is part of your role as a clinician?

“I think just historically doctors have been like physician researchers…that part is just inherent in most clinician’s DNA. I think that has been stamped out by the business of medicine.”

“To me it seems like the culture around research is very rigid and regimented and competitive…And somebody on the frontline saying something just seems like it has no part of that whatsoever. They’re going to think about funding and publishing and all that kind of stuff.”
PCT Phases

Before
- Topic ID
- Study Design

During
- Recruitment
- Enrollment
- Implementation
- Data Collection

After
- Data analysis
- Dissemination
PCT Phases: Before

“What are you trying to solve? Where can that be synergistic so that maybe it’s worth a little bit of hardship because… patients are going to benefit from this project and it’s really a problem we were trying to solve all along.”

“I feel like a lot of researchers are not really aware of the populations that we're dealing with… by the time they come to me, they have their survey already IRB approved, and they're not going to change it or modify it so our patients will understand the questions.”

“Every clinic in an organization is different, and departments in a clinic in an organization are different. … The workflow is the key thing which drives any kind of care, research, or programs, so that is the most critical thing… a lot of people come to us, they don’t really understand our workflow.”
Objective: Compare the benefits and risks of two commonly used aspirin doses (85 mg vs. 325 mg) in preventing heart attacks and strokes in people with heart disease.
PCT Case Study: Aspirin Dosing

Initial Reactions

• Appreciate that burden to clinicians is low

• Concerned about:
  o Use of technology
    ▪ Generational, cultural, and literacy limits
  o Hands-off approach
    ▪ “Dehumanizing”
    ▪ Adherence
    ▪ Data quality
PCT Case Study: Aspirin Dosing

• Concerns related to clinician-patient relationship
  o Clinicians are protective of patients; want to make sure not used as “guinea pigs”
  o Building trust is difficult; don’t want to do anything that might interfere with patients’ trust in their clinicians
  o Think patients would want the opportunity to discuss study participation with their providers before making a decision
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Recruitment Methods*  
(Multi-Modal Multi-Touch Strategy)

- EHR Best Practice Alerts (BPAs)
- E-mails/MyChart
- Letters

- Clinician & Patient Discussion
- In-Clinic Tablets & Study Materials
- Phone Calls

* Slide courtesy of Holly Robertson, PCORnet
Best Practice Sharing Session: Lessons Learned in Adaptable, 3/7/18
ADAPTABLE Key Informant Interviews

• Semi-structured phone interviews with site investigators and clinicians

• Open-ended questions regarding trial experience, challenges, and strategies,

and

• Directed questions regarding the role of clinicians in the trial and specific challenges related to clinician engagement

...Additional Sites TBD
Key Takeaways

• Clinicians want to contribute to research

• Basic engagement principles still apply

• Early involvement improves study design and builds support