Patient Engagement in Research and Infrastructure Development

Grand Rounds March 7, 2014

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Patient Representative,
Executive Leadership Committee
PCORnet Coordinating Center

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The National Patient-Centered Clinical Research Network
Meaningful Patient Engagement in: Clinical Research (PCOR) and Infrastructure Development

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Director of Patient Engagement

The National Patient-Centered Clinical Research Network
Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.
Patient Engagement Priorities and Long Term Goals

- Develop PCOR Community...
  to successfully establish an infrastructure for patients, caregivers, and other stakeholders to increase CER information and engage them in research, dissemination and evaluation.

- Engage Community in Research Process...
  to influence research and establish trust and legitimacy for successful uptake of research findings.

- Promote Dissemination and Implementation...
  so that patients, caregivers and other stakeholders have CER information they can use to make decisions that reflect their desired health outcomes and to speed implementation of our findings.
Why Engage Patients in Research or Infrastructure Development?

- Lived experience of condition or disease
- Research questions that are important to patients
- Outcomes important to patients such as quality of life and PROs
- Power of data (new currency)
- Focus on patient-centeredness, ethics and safety
- Sense of urgency
- Greater likelihood of trust and patient participation in research networks when patients are involved in infrastructure development
- Greater likelihood of uptake of research findings when patients are involved as partners in the design and conduct of the research
What does patient engagement look like in the conduct of research?
Rubric: Patient and Family Engagement in Patient-Centered Outcomes Research (PCOR)

- Planning the Study
- Conducting the Study
- Disseminating the Study Results
- PCOR Engagement Principles
What does patient engagement look like in Infrastructure Development?
Rubric: Patient and Family Engagement in Infrastructure Development - PCORnet

- Governance
- Network Recruitment
- Data Collection and Access
- PCOR Engagement Principles
Patient and Family Engagement in Infrastructure Development

Development of research network structure, policies, procedures and bylaws

Patient partners participate in:

- Governance of network development
- Developing policies for data sharing and implementing data sharing and data linkage agreements
- Plans for cross-network collaboration and influencing patient engagement across a large national distributed research network

Examples:

- A patient governance committee posts all draft policies for the broader patient community to comment on before they are adopted.
- The organization has developed a successful conference model that brings patients together in innovative ways. The conference features convenient bio specimen collection on site under “sunny conditions” where patients educate professionals about gaps in information services, gaps in treatment, and personal experiences.
- Crowdsourcing of our membership and post-test evaluation to determine optimal language for consent language.
- Consent language for PPRN participation: crowdsourcing of our membership and post-test evaluation to determine optimal language for consent language.
- How can you demonstrate this in your proposal?
  - Provide examples of decisions made by the governing body that reflect patient input
  - Describe plans to reinforce policies that demonstrate transparency in data sharing, patient access to data and research results
  - Describe how patients involvement in developing consent process and processes for various levels of data sharing and contribution
### Patient and Family Engagement in Infrastructure Development

#### Network Recruitment

**Patients participate in:**

Developing plans for increasing the size, diversity, and representativeness of the network

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<thead>
<tr>
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<td>The patient-governed membership committee and the Enrollment and outreach diversity plan was developed based on analysis of patient population and in the general US population. Outreach strategies include Spanish language translation of the Registry Profile Survey, homepage, consent and log-in pages.</td>
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#### Data Collection and Access

**Patients participate in:**

The development of data collection tools, strategies to minimize missing data from patient reported data, and the establishment of patient-centered elements

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<td>Researchers and clinicians will be surveyed to determine the essential elements of the clinical research database including the best standardized methods for diagnosis, symptoms, functioning, quality of life, and wellness. Determine the best methods to use mobile or web-based platforms to monitor longitudinal course in close collaboration with the patient advocacy groups.</td>
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#### Patients participate in:

- The development of plans and budgets to support patients in obtaining their data through standards-based approaches to download and view data, or in using blue button applications
- Patients will receive USB keys and education on access to health data to help facilitate the collection of electronic health records

**How can you demonstrate this in your proposal?**

- Describe role of patients in outreach activities
- Clearly define how patients from underrepresented populations will participate in the network
- Describe approaches for efficient data collection by leveraging patients input and/or ability to access their own data
- Clearly define the role of patients in establishing what patient reported data will be collected, the best technology to enable data collection and access
- Describe what patients identified as specific challenge in obtaining data from clinicians and hospitals
- How you will ensure that all patients have equal access to the network

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**Network Participation:**

Patients will participate in the network by:

- Developing plans for increasing the size, diversity, and representativeness of the network
- Contributing to the development of data collection tools and strategies to minimize missing data
- Providing input on the establishment of patient-centered elements
- Participating in the development of plans and budgets to support access to their data
- Receiving education and support in using blue button applications for accessing their health records

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**Network Recruitment Strategies:**

- Spanish language translation of the Registry Profile Survey, homepage, consent and log-in pages
- Collaboration with patient advocacy groups to determine essential elements of the clinical research database
- Use of mobile or web-based platforms to monitor longitudinal course
- Development of plans and budgets to support patient data access

**Data Collection Tools:**

- Standardized methods for diagnosis, symptoms, functioning, quality of life, and wellness
- Mobile or web-based platforms for data monitoring

**Data Access Options:**

- Personalized health records for patients
- USB keys for accessing health data
- Blue button applications for data collection

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**Patient Engagement in Network Development:**

- Patients are involved in plans for increasing size, diversity, and representativeness of the network
- They contribute to the development of data collection tools and strategies to minimize missing data
- Provide input on the establishment of patient-centered elements
- Participate in the development of plans and budgets to support access to their data
- Receive education and support in using blue button applications for accessing their health records
## Data Collection and Access

**Patients participate in:**
The development of data collection tools, strategies to minimize missing data from patient reported data, and the establishment of patient-centered elements.
## Patient and Family Engagement in Infrastructure Development

### Develop Research Network Infrastructure

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Reciprocal Relationships

The roles and decision-making authority of all research partners, including patient partners, are clearly stated.

Examples:

• Many applications state that patient partners are co-investigators, and that decisions about the study are made by consensus among all the research project partners.

• Many applications describe patient partners as key personnel, and their biosketches illustrate how the skills and experiences of the patient partners prepare them to function effectively in this role.
PCOR Engagement Principles

Trust, Transparency, Honesty

- Major decisions are made inclusively and information is shared readily with all research partners
- Patient partners and research partners express commitment to open and honest communication with one another
- The study team commits to communicate the study’s findings back to the study community in a meaningful and usable way

Example:
Commitments to trust, transparency, and honesty are stated in many applications – and supported by descriptions of how the research team will communicate with each other frequently, and make decisions about the study by consensus.
The project includes plans to ensure that the patient partners will understand the research process and the researchers will understand patient centeredness and patient engagement.
PCOR Engagement Principles

Partnership

- Time and contributions of patient partners are valued and demonstrated in fair financial compensation, as well as reasonable and thoughtful time commitment requests.

- When the patient partners represent unique populations, the research team proposes to accommodate their cultural diversity and/or disability.
Have Questions?

We welcome your questions and comments at getinvolved@pcori.org
Matching Engagement Methods to Different PCOR Activities

Sean R. Tunis MD, MSc
Co-lead, PCORnet Patient Engagement Task Force
March 7, 2014
PCOR/CER Activities

- Establish / manage research Infrastructure
- Topic Identification
- Priority Setting
- Framing Study Questions
- Protocol Development
- Study Implementation
- Review and Interpret Results
- Dissemination
- Implementation
Models / Methods of PCE

- Social media, crowdsourcing
- Mailed or online surveys
- Telephone interviews
- Advisory boards / steering committee / task forces
- Focus Groups
- Multi-stakeholder meetings
- Formal group techniques
  - e.g. modified Delphi, nominal group techniques
Sub-types of Patients and Consumers

- People with specific acute/chronic conditions
- Members of general public
- Reps from patient advocacy organizations
  - With wide range of agendas
- Individuals with deep knowledge of disease, methods, other technical training, policy experience
- Family members and caregivers
Patient Engagement Task Force Charter

To ensure active and effective engagement of patients and consumers in the design and implementation of all components of PCORnet by serving as a technical resource for innovative problem solving, cross-project communication, and application of cutting edge methods.
Primary Task Force Activities

1. Agree on the overall philosophy behind Patient & Consumer Engagement (PCE) and develop a guiding conceptual framework and language for PCE in PCORnet

2. Identify, refine, and/or create practical, implementable strategies to ensure effective patient engagement and patient leadership

3. Provide a forum for collective problem solving, obtaining feedback on specific challenges encountered

4. Serve as a resource to support the Coordinating Center and other PCORnet task forces with regard to patient engagement and leadership issues

5. Emphasis on developing strategies for engaging minority, vulnerable, and under-represented populations

6. Serve as an internal patient engagement advocate and “conscience” within PCORnet
More Reasons to Engage Patients/Consumers

- Patients and other stakeholders bring unique perspective, insights, experience and expertise
- Building trust - easy to underestimate patient/public fears that research results will be used to limit care
- Sustainable infrastructure depends on compelling value-proposition from patient/public perspective
- Not a bad idea to err on the side of over rather than under-inclusion
Conceptual model for stakeholder engagement in comparative effectiveness research

Source: Deverka, Lavallee, Desai et al., JCER 2012

**Stakeholder:** Individuals, organizations or communities that have a direct interest in the process and outcomes of a project, policy or research endeavor – including patients and consumers, healthcare providers, payers and purchasers, policy-makers and regulators, industry representatives, researchers and research funders.

**Stakeholder engagement:** An iterative process of actively soliciting knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue for the dual purposes of creating a shared understanding and making relevant, transparent and effective decisions.

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**Types of evidence**

- Values
- Research
- Professional experience
- Patient and consumer knowledge and experience

**Methods of combining evidence**

**Quantitative**
- Questionnaires
- Delphi method
- Multi-criteria mapping
- Value of information modeling

**Qualitative**
- Nominal group technique
- Facilitated workshops/meetings
- Stakeholder decision analysis

**Decisions**

- Topic generation
- Research priorities
- Study designs
- Evidentary thresholds for clinical and health policy decision-making
- Implementation strategies

**Outputs**

**Process**
- Meta-criteria: trust, respect, accountability, legitimacy, fairness, competence
- Change in knowledge/attitudes
- Change in CER project decisions (e.g., choice of interventions, study design, funding priorities)

**CER**
- More useful evidence for clinical and health policy decision-making
- More efficient use of healthcare resources
- Improved health outcomes

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pcornet
Laying Down Track while Moving at Full Speed

Ref: Wallace and Gromit: “The Wrong Trousers”
Patient Perspective on Patient Engagement in Infrastructure Development

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Patient Representative, Executive Leadership Committee
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## Patient Stakeholder Roles & Associated Verbs

- **Co-Investigators**
- **Advisory Board Members**
- **Focus Group Members**
- **Research Participant**
- **Designers**
- **Influencers**
- **Testers**
- **Experiencers**
Desirable Qualifications of Patient Partners for Research Infrastructure Development

- Previous experience representing patient constituencies at a national level in multi-stakeholder groups
- Understanding of PCOR research and informed consent
- Well-positioned within the patient community both to gather input for research initiatives and to communicate progress to stakeholders
- Ability to represent the patient perspective, but also collaborate and compromise to reach solutions that can be embraced by many
- Ability to act in an unbiased manner for the greater good of all patients and not just one disease
Thank You!