Understanding Patient and Stakeholder Engagement in Patient Centered Outcomes Research

Darius Tandon, PhD
Associate Professor & Associate Director,
Center for Community Health
Northwestern University Feinberg School of Medicine

Chau Trinh-Shevrin, DrPH
Associate Professor, Population Health
Co-Director, NYU-HHC CTSI Community Engagement & Population Health Research Core
New York University School of Medicine
Objectives of Today’s Workshop

By the end of today’s workshop, participants should be able to:

1. Recognize the potential role of patients and other stakeholders in patient-centered outcomes research
2. Articulate and apply the ‘PCORI Patient and Family Engagement Rubric’ as a guide to engaging stakeholders in the conduct of research
3. Discuss the process involved in obtaining patient and other stakeholder input during the research planning process
What is the Patient Centered Outcomes Research Institute (PCORI)?

• Independent non-profit research organization authorized by Congress as part of 2010 Patient Protection and Affordable Care Act (ACA)

• PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community
What Does PCORI Fund?

• Comparative Effectiveness Research (CER)
• Research that is **Patient Centered** and **Stakeholder Driven**
• Five portfolios/priorities for research:
  – Assessment of Prevention, Diagnosis, & Treatment Options
  – Improving Healthcare Systems
  – Communication and Dissemination Research
  – Addressing Disparities
  – Improving Methods for Conducting Patient-Centered Outcomes Research
• Other funding opportunities outside the five portfolios
What Does PCORI Fund? (cont...)

• Funding for pre-research & non-traditional researchers (e.g. patient groups & community-based organizations seeking partnerships with academic medical centers)
  --Pipeline to Proposal Awards to develop partnerships and patient-centered research proposals

http://www.pcori.org/funding-opportunities/eugene-washington-pcori-engagement.awards/
PCORI Review Criteria

• Five main review criteria
  – Impact of the condition on health of individuals and populations
  – Potential for study to improve health care and outcomes
  – Technical merit
  – Patient-centeredness
  – Patient and stakeholder engagement
PCORI Review Process

• All proposals reviewed by four individuals: two researchers, one patient, one stakeholder

• Patient-centeredness and stakeholder engagement reviewed by all individuals; other aspects of research plan only reviewed by researchers
What is Patient-Centeredness?

As defined by PCORI:

- Proposal demonstrates patient-centeredness at every stage of research. Addresses the following questions:
  - Is the research focused on questions that affect outcomes of specific interest to patients and their caregivers?
  - Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?
  - How credible are claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?
What is Patient & Stakeholder Engagement?

As defined by PCORI:

The proposal integrates patients and stakeholders in the development of the research plan and in key elements of conducting the research. It addresses the following questions:

– Does proposal describe how patients and stakeholders were or will be identified and engaged in the research?

– Are roles of patients and key stakeholders significant in formulating the study’s research questions, hypotheses and design and in the study’s conduct and dissemination of results?

– Are roles proposed for patients and stakeholders in any planned dissemination or implementation plans meaningful and likely to be effective?

– If engagement is not applicable to proposed research, does the application justify why it is not?
What is the Spectrum of Patient & Stakeholder Engagement?

• **Community Engaged Research:**
  
  “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people.”

  (CDC, 2005, Principles of Community Engagement)

• Community engagement is broad and includes full spectrum of approaches that involve community in research
Spectrum of Patient & Stakeholder Engagement

Inform

Consult

Involve

Collaborate

Empower

We will keep you informed

We will consider your input and give feedback about how it informed our decisions

We will ensure that your input is considered among the choices we implement

We will work together and incorporate your views as much as possible (CBPR)

We will implement what you decide (CBPR)
Community Research ≠ Community Engagement

Community Research:
A form of research focused on improving community health and vitality

Community Engagement:
Principles & processes for involving communities (stakeholders) in any form of research
Importance of Patient & Stakeholder Engagement Beyond PCORI

• While PCORI is a prominent new funder, patient and stakeholder engagement is increasingly emphasized in grants funded by:
  – NIH
  – CDC
  – Private foundations
  – Industry/Pharmaceutical

• The framework and strategies for engagement in the subsequent slides, therefore, are useful for proposals beyond PCORI
Who are Stakeholders?

Broadly defined as: “Individuals who have an interest in a particular study”
When Should Stakeholders Be Involved?

• Planning the Study
• Implementing the Study
• Disseminating Study Findings & Planning for Sustainability

— These stages are consistent with PCORI’s Patient & Family Engagement Rubric

Planning the Study
Planning the Study: Selecting Key Stakeholders

Considerations in selecting stakeholders:

– Funder requirements (e.g., PCORI, NIH)
– Objectives of project
– Type of input needed
– Importance of obtaining broad spectrum of perspectives
– What type of input is needed pre-award, during project, and post-award
Planning the Study: Selecting Key Stakeholders (cont...)

• What can maximize likelihood that stakeholders will collaborate?
  – Clearly defining roles and responsibilities of patients/stakeholders
  – Clearly articulating what they will gain- “what’s in it for me?”
  – Developing sound bites/materials that can be used to recruit
    • Linked to project goals, roles/responsibilities, and what members will gain
Planning the Study:
Selecting Key Stakeholders (cont...)

• How do I approach patients/stakeholders?
  – Build on Existing Relationships
  – Referrals/recommendations from colleagues
  – Shared Interest/Common Goals
  – Commitment and Willingness
  – Equal Standing
  – Shared Decision-Making
Questions that Stakeholders May Ask Researchers

– Who are you?
– Why are you here?
– What’s your experience/relationship with us and how a disease/condition impacts us? What’s your experience with engagement?
– Are you committed to a long-term relationship after the research?
– What is the research topic/project?
– What’s in it for us/our community? Is the research of interest to us? How will we benefit from the research project/findings?
– What are my roles and responsibilities?
– How do we equally engage/participate?
– What does our relationship look like?
Planning the Study: Research Questions & Study Design

• Stakeholders can be involved in:
  – Identifying topic for investigation
  – Developing research question(s)
  – Defining key characteristics of study participants
  – Identifying comparators (key for CER studies)
  – Identifying outcomes (key re: patient-centeredness)
  – Developing research design
  – Selecting appropriate methods and data collection strategies
Planning the Study: Important Considerations

- Engagement with multiple stakeholders in a meaningful way takes time—i.e., don’t expect to engage stakeholders a couple weeks before submitting your proposal.
- Do you need to spend time developing and nurturing relationships before submitting for a larger grant?
NYU Case Study

Planning the Study
Background

Bangladeshi Community of NYC: ≈ 64,000*

- 54% LEP
- 31% live in poverty
- 74% foreign-born

*US Census, 2010
Background

- Although there is growing evidence that diabetes is a major issue in the general South Asian and Asian Indian community in the U.S., there are few studies documenting rates of diabetes in the US Bangladeshi community.

- Community-based studies in the U.S. demonstrate diabetes prevalence rates between 20-25% among Bangladeshi immigrants.
Who should be “at the table”?
Key Stakeholder Engagement

- Academic Researchers & Project Staff
- Representatives from CBOs and target community
- Primary Care Providers
- Community Health Workers
- Health Educators

DREAM Project Coalition
“At the Table” vs “In the Room”

- Ethnic Media
- Faith-Based Organizations
- Community Leaders and Representatives of Target Community
Focus groups illuminated importance of ethnic media as purveyors of health-related information.

Developed partnerships with ethnic media to help promote project name as well as create a greater awareness of the issue of diabetes within community.

Example: Ethnic Media
Implementing the Study
Types of Engagement During Project

• Input on:
  – Intervention protocols
    • When should intervention be conducted?
    • Where should it be conducted?
    • Who should deliver the intervention?
    • What are possible barriers to implementation?
  – Recruitment & retention strategies
  – Preparation of intervention materials (e.g., manuals, visual aids)
  – Preparation of consent forms
Types of Engagement During Project

- Can stakeholders be hired and trained to assist with participant recruitment and/or data collection?
  - Is there a need to develop capacity among stakeholders to engage in these activities?
Types of Engagement During Project

- Ongoing evaluation/assessment of partnership functioning
  - Do stakeholders feel they are being equitably and meaningfully involved?
  - Are there suggestions for improvement?
  - Are certain stakeholder group wield more influence?
Mechanisms for Facilitating Engagement During Project

• Develop a Memorandum of Understanding or Letter of Agreement to document agreements concerning roles/responsibilities, etc.

• Establish mechanisms for communication among researchers/partners during project

• Form an advisory or steering committee to provide feedback/input throughout project
  – Is this committee representative of key stakeholders?
NYU Case Study

Implementing the Study
DREAM Project Coalition

- Academic Researchers & Project Staff
- Representatives from CBOs and target communities
- Health Educators
- Primary Care Providers
- Community Health Workers

Institutions and Organizations:
- HHC
- Community Healthcare Network
- NYU School of Medicine
- NYU Center for the Study of Asian American Health
- Johns Hopkins University
- Andolan
- Adhunika
- Morris Heights Health Center
Partnership Development Process

1. Contacting stakeholders/partners and convening initial meeting(s)

2. Developing an understanding of how partnership will benefit both parties

3. Developing a Memorandum of Understanding (MOU), in some cases, to formally outline expected roles, responsibilities, and activities for both community and academic partner

4. Holding an initial group meeting and determine appropriate meeting schedule/location

5. Facilitate the process of communication, consensus building, & communication between and among stakeholders

6. Demonstrate support of community partners outside of Coalition (e.g. attendance at community events, providing letters of support for funding, serve as advisory board member, engage in 1v1 meetings, etc)

7. Evaluate !!!
Coalition provided … :

- key input related to curricula selection and tailoring for use in the Bangladeshi community with specific feedback from those living with or caring for someone with diabetes
- key input on study outcomes and strategies for outreach, recruitment, retention, and continual community engagement
- regular evaluation and feedback to ensure continued cultural and linguistic relevancy
- key input related to selection and training of project Community Health Workers (CHWs)
Co-Learning

Opportunities:
- Learning Exchanges
- Trainings
- Community Forums
Disseminating Study Findings
Data Analysis & Interpretation

• Stakeholders should be involved in data analysis and interpretation even if not actually analyzing data
  – Do stakeholders have same interpretation of study findings as researchers?
  – Are there findings that would benefit from stakeholder explanation/contextualization?
Dissemination of Findings

• Stakeholders should be involved in preparation of scientific articles and conference presentations

• Dissemination should go beyond “academic” channels
  – What are effective ways of communicating findings to key stakeholders in a way they can understand AND use the findings?
Dissemination & Sustainability

• Developing sustainability plan for program/service/intervention

• Assisting in dissemination of study findings to key stakeholders (e.g., patients, patient advocacy organizations, policy-makers)
  – Dissemination plan a requirement of PCORI applications
NYU Case Study

Disseminating the Study
Dissemination & Sustainability

Coalition provides … :

- promotion and dissemination re: project-related events and communication of information through their respective networks/channels

- key input related to data analysis & interpretation

- feedback on potential grant submissions to help sustain project
Dissemination & Sustainability

Reporting of results to all audiences

Academics & Clinicians

Community & Patient

Stakeholders
Questions.....
• This presentation was supported in part by the NYU-HHC Clinical and Translational Science Institute (grant #UL1TR000038) from the NIH National Center for Advancing Translational Sciences and by the NYU Center for the Study of Asian American Health (grant # P60MD000538) of the NIH National Institute for Minority Health & Health Disparities.