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**Note:** Today’s presentation is being recorded and will be posted on PCORI’s website.
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An archive of this webinar will be posted to http://www.pcori.org/events/2017/patient-and-stakeholder-engagement-research-strategies-initiating-research-partnerships following this event.
Introductions

Rachel Hemphill, PhD  
Program Officer  
Evaluation & Analysis

Chinenye Anyanwu, PharmD, MPH  
Engagement Officer  
Public & Patient Engagement

Sunbo Igho-Osagie, MHSA, PMP, CSSGB  
Program Associate  
Public & Patient Engagement
Agenda

• Introduction to PCORI

• Key Findings: Initiating Research Partnerships

• Presentations by PCORI Awardees and Community Partners
  ❖ Karen Wernli and Dianne Johnson
  ❖ Giana Davidson and Nathan Shapiro

• Q&A

• Wrap-up
Learning Objectives

At the conclusion of this webinar, participants will be able to:

• Describe strategies for finding potential patient and stakeholder partners and initiating partnerships for research projects

• Identify challenges that may arise when establishing partnerships between researchers, patients, and stakeholders

• Understand the value patient and stakeholder partners bring to research projects
Introduction to PCORI
Our Mission and Strategic Goals

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.

Our Strategic Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence research funded by others to be more patient-centered
How Is Our Work Different?

• We fund research on which care options work, for whom, under which circumstances.
• We focus on answering questions most important to patients and those who care for them.
• We aim to produce evidence that can be easily applied in real-world settings.
• We engage patients, caregivers, clinicians, insurers, employers, and other stakeholders throughout the research process.
• This makes it more likely we’ll get the research questions right and the study results will be useful and taken up in practice.
PCORI’s Approach to Research

“Patient-centeredness”

• The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
• Research questions and outcomes should reflect what is important to patients and caregivers

“Patient and stakeholder engagement”

• Patients are partners in research, not just “subjects”
• Active and meaningful engagement between scientists, patients, and other stakeholders
• Community, patient, and caregiver involvement already in existence or a well-thought-out plan
PCORI's Approach to Engagement - Our Engagement Rubric

<table>
<thead>
<tr>
<th>Planning the study</th>
<th>Conducting the study</th>
<th>Disseminating study results</th>
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<tbody>
<tr>
<td>POTENTIAL ACTIVITIES</td>
<td>POTENTIAL ACTIVITIES</td>
<td>POTENTIAL ACTIVITIES</td>
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<tr>
<td>- Developing research questions</td>
<td>- Drafting or revising study materials</td>
<td>- Identifying partners for dissemination</td>
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<td>- Selecting relevant outcomes</td>
<td>- Participating in study recruitment</td>
<td>- Participating in dissemination efforts</td>
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<tr>
<td>- Define study population characteristics</td>
<td>- Participating in data analysis</td>
<td>- Presenting information about the study</td>
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<tr>
<th>REAL-WORLD EXAMPLES</th>
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<tr>
<td>- Patient organization surveys members on treatment preferences</td>
<td>- Patients develop informed consent to make it understandable to participants</td>
<td>- Research team holds stakeholder summit to speed implementation of findings</td>
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<td>- Clinicians suggest a third arm to study based on variability in practice</td>
<td>- Patient representative serves on data safety monitoring board</td>
<td>- Research team introduces study at a patient advocacy conference to inform community of the research</td>
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**PCOR Principles**

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

Reciprocal Relationships: Demonstrated when roles and decision-making authority of all research partners are defined collaboratively and clearly stated.

Co-Learning: Researchers help patient partners better understand the research process, and researchers will learn about patient-centeredness and patient/stakeholder engagement.

Partnerships: The time and contribution of patient and other stakeholder partnership is valued and demonstrated through compensation, cultural competency, and appropriate accommodations.

Transparency, Honesty, Trust: Major decisions are made inclusively and information is shared readily among all research partners.
Key Findings: Initiating Research Partnerships
Information Sources and Methods

Ways of Engaging-ENgagement ACtivity Tool (WE-ENACT)

PCORI Research Awardees

Patient & Stakeholder Partners

Applicant Survey

N=179 awardees from PCORI’s early funding cycles

N=246 partners from PCORI’s early funding cycles

N=893 applicants across 9 funding cycles
Who engages as partners in PCORI research projects?

PCORI projects engage with partners from many communities.

- **89%** PATIENTS
- **89%** CLINICIANS
- **59%** HEALTH SYSTEMS
- **58%** ADVOCACY ORGS
- **53%** CAREGIVERS

PCORI projects also engage with community-based organizations (24%), payers (15%), policymakers (14%), training institutions (14%), industry (6%), and purchasers (2%).

Note: awardee reports of communities engaged in the prior year (N=351); 112 responses about project year 1, 168 responses about project year 2; 71 responses about project year 3.
When do research partnerships begin?

Most applicants for a PCORI research award form partnerships before submitting their applications.

“Did you establish a patient/stakeholder research partnership prior to applying for PCORI funding?”

- Yes: 92%
- No: 8%

“How long before submitting your application did you establish a partnership?”

- Less than 6 months: 32%
- Between 7 months and 1 year: 26%
- Between 1 and 5 years: 24%
- More than 5 years: 9%

Note: data collected via voluntary survey of applicants to PCORI research awards; N=893 applicants across 9 funding cycles; survey response rate=84% across cycles
How do PCORI applicants and awardees connect with potential partners?

<table>
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<th>Organizations</th>
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<tr>
<td>• Patient/family support groups or advocacy organizations</td>
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<tr>
<td>• Community organizations (e.g., senior centers, cultural centers, churches), community leaders, and events</td>
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<tr>
<td>• Existing institutional advisory councils (e.g., hospital’s patient and family advisory council)</td>
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<th>Individuals</th>
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<tr>
<td>• Patients receiving clinical care and their families</td>
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<tr>
<td>• Participants and partners from previous research studies</td>
</tr>
<tr>
<td>• Patients and stakeholder recommended by colleagues or existing partners</td>
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Note: data from open-ended responses collected via voluntary surveys of PCORI research awardees (N=179), PCORI patient/stakeholder research partners (N=246), and applicants to PCORI research awards (N=454).
Some lessons learned from PCORI awardees and partners

Engage early.

• Engage patient and stakeholder partners early in the process, preferably while developing your research proposal.

• Use a variety of methods to connect with patients and other stakeholders.

Plan ahead.

• Keep in mind that it takes time and effort to establish partnerships and build trust.

• Plan ahead to manage proposal deadlines and funding for engagement activities when engaging partners during proposal development.

Note: data from open-ended responses collected via voluntary surveys of PCORI research awardees (N=179) and PCORI patient/stakeholder research partners (N=246).
Some lessons learned from PCORI awardees and partners

Foster positive relationships.

• Ensure that the work is a good fit with partners’ interests and abilities.

• Create a welcoming environment for partners by encouraging, listening to, and valuing their input.

• Be open with partners about the research process and the likelihood of funding.

“Trusting your researchers is hugely important...Transparency and explaining “why” often goes a long way in developing this trust.” – Patient/Stakeholder Partner

Note: data from open-ended responses collected via voluntary surveys of PCORI research awardees (N=179) and PCORI patient/stakeholder research partners (N=246).
Panelist Presentations
Comparative Effectiveness of Surveillance Imaging Modalities in Breast Cancer Survivors (SIMBA Study)

Karen Wernli, PhD
Associate Investigator
Kaiser Permanente Washington Health Research Institute

Dianne Johnson
Patient Partner
Kaiser Permanente Washington Health Research Institute
Solutions and Challenges in Patient Engagement
Lessons from SIMBA

Karen J. Wernli, PhD – Principal Investigator
Dianne Johnson – Patient Partner

July 19, 2017
Our SIMBA goal

Fill the **clinical gap in knowledge** about how well breast MRI in adjunct to mammography works compared to mammography alone in women after treatment for breast cancer

Provide **evidence needed** to assist patients and providers with clinical decision-making

Disseminate results effectively for **implementation** in practice
Timeline

- Hosted patient focus groups
- Submitted application in July 2012
- Reconnected with community members
- Reconvened patient advisory board
- Resubmitted application in April 2013
- Application awarded Sept 2013
- Selected patient partners and formed patient advisory board
Hosted patient focus groups

Primary purpose: to identify 2 patient partners
Goal was to find women with general experience of breast cancer outside of my institution and to represent varying perspectives in breast cancer care.
Recruited from:

workplace intranet
young survivor listserv
flyers distributed at Race for the Cure
Invited patient partners and advisory board members

Criteria of selection: different ages and cancer stage and willingness to be open to study results

Sent an email request with a copy of the abstract to patient partner for invitation.

All women not invited to be patient partners were asked to be members of patient advisory board and provided letters of support.
Preparing to partner

- Listen to others and bring more than your story to the research
- Be open to learning
- Be bold and speak up
- Be patient, everyone is learning a new way of conducting research
Reconvened patient advisory board

• Several comments in critiques about the role of the patients in the research
• We used a reconvened patient advisory board meeting to discuss the questions and comments.
• Helped with a compelling argument
• All women provided a letter of support again
How to get involved

• Connect with organizations that support your area of interest
• Participate in focus groups
• Visit web sites that provide resources for your area of interest
• Consider Twitter
Reconnected with community members when funded

• Our focus group participants reflect the community we live: fairly educated Caucasian women
• With funding, we had more time to involve women of color and other diverse backgrounds in our patient advisory board by:
  ▪ Sending Patient advisory board recruitment materials to
    ▪ African American women support group
    ▪ Listservs distinct to particular racial/ethnic backgrounds
    ▪ Posting within cancer support groups, ie Cancer Lifeline
    ▪ Attended play focused on breast cancer in African American women
    ▪ All new members were met in person by PI and project manager
Tips for starting off

• This is cross cultural work – to be successful people need to be flexible and willing to change

• Be prepared – partners and research staff might not agree on what is of value from the study

• Engage all parties and listen carefully before crafting processes or conclusions.
Considerations and Challenges

• Working together is like working with any colleague—Or picking your college roommate!
• Pace of research compared to the real world
• Research culture and communication
Thank You

Karen Wernli: 206-287-2934

wernli.k@ghc.org

@WernliKarenJ
@diannej84
Comparing Outcomes of Drugs and Appendectomy (CODA Study)

Giana Hystad Davidson, MD, MPH, FACS
University of Washington
Assistant Professor, Division of General Surgery
Medical Director, Post-Acute Care UW Medicine

Nathan Shapiro, MD, MPH
Vice Chair of Emergency Medicine Research
Associate Professor of Emergency Medicine
Beth Israel Deaconess Medical Center & Harvard Medical School
Stakeholder Engagement in Protocol Development & Implementation: Building a Village

Giana Davidson, MD MPH
Nathan Shapiro, MD MPH

Patient and Stakeholder Engagement in Research: Strategies for Initiating Research Partnerships

July 19, 2017
Appendicitis: Significance and Background

- Lifetime risk is 7-12%
- Appendectomy is most common urgent general surgical procedure
  - Performed in nearly 300,000 Americans each year (97.5% of appendicitis patients)
Why Appendectomy?

- Perceived safety
- Payment
- Antibiotic resistance
- Variability in outcomes
- Research focus in U.S. on technique
Stakeholder Perspective: Why Rock the Boat?

- Patients
- Hospital
- Surgeon
- Payer
Risk/Benefit of Appendectomy vs. Antibiotics: Multiple Perspectives

• **Emergency Medicine:**
  – Throughput in the ED
  – Repeated imaging
  – Who can I send home vs who needs to be admitted?

• **Surgeons:**
  – Do patients that “fail” antibiotics have more complex surgery
  – Who is more likely to be successful in each treatment arm?
  – Missed appendiceal neoplasms

• **Primary Care Providers:**
  – Burden of long-term pain, antibiotic resistance

• **Patients:**
  – I have finals/single parent/income relies on tips…
  – How can I go back to work quicker?
  – How long until this pain goes away?
CODA Research Proposal Development

- Engaged patients, clinicians (ED, surgery, primary care), healthcare administrators, funders and researchers across WA state
- Used multi-modal approach to engagement
- Planning took place over 9 months
- Non-funded work
- 6:30 a.m. Friday morning conference calls
Clinical Stakeholder Engagement

- Identified **Clinician Partners** from 10 hospitals in WA
  - Weekly meeting on proposal development
  - Advise on study protocol and patient-facing materials
  - Serve as study champions at their hospitals

- Clinicians from Europe (ASGBI) surveyed in how they use antibiotics in practice.
1. Are antibiotics as effective as appendectomy for uncomplicated appendicitis?

2. Which patients are most likely to have a successful outcome with antibiotics-first?
What Matters to Patients

Are the benefits of avoiding surgery outweighed by the potential burdens?

• Recurrence of appendicitis and eventual surgical intervention
• Lingering symptoms
• Anxiety and uncertainty impacting quality of life and return to work/school
• Long-term antibiotics
CODA Study Design

- Randomized controlled trial
  - Large-scale (n=1,552)
  - Non-inferiority based
    - Antibiotics “just as good as” appendectomy
  - Pragmatic
    - Routine clinical practice settings, heterogeneous population

- Parallel observational cohort (n=500)
Collaborative Implementation

There is a critical need for collaboration at design and implementation

• Run-in period
• Messaging to Primary Care Providers
• Consistent messaging to patients
• Improves communication to patients
  – Clear message regarding treatment
• Need to normalize options
• Improve patient expectations
• Decrease operating on the antibiotic arm
Standardizing Patient Information

- **Challenge**: Deliver standardized patient information across all sites
- **Solution**: 6-minute video given to all patients diagnosed with appendicitis

- English and Spanish
- Collaborative development: surgeons, ED docs, media team, patient advisors
In This Issue:

- Recruitment Summary
- Appendectomy Treatment Outcomes in Older Adults
- Stakeholder Engagement Twitter Chat Transcript Now Available
- Intern Presents CODA Poster at Research Symposium
- Appendicitis in the News
- Save the Date: 2017 PCORI Annual Meeting
- CODETTA Ancillary Trial: Thank You for Your Support!
Clinical Team Coordination with Research Team

Your CT scan confirms you’ve got appendicitis. We are participating in an important research project that is trying to figure out the best treatment for appendicitis.

I think you’re a great candidate for this national appendicitis study we’re participating in.

Can I invite a research coordinator in to show you a video and talk to you about this ground breaking study?
Real Time Feedback:
Research Coordinator -- Clinical Leadership

- Site:
- Research Coordinator:
- What went well/success stories:
- What challenges did you have/lessons learned:
- Who was most helpful to you during this experience:
- How much total time did you spend recruiting and enrolling this participant? (identification-->enrollment via portal + baseline survey completed)?
- How long did the baseline survey take?
- Reason(s) for declining randomization OR factors that facilitated randomization:
- Times of page, screening call-back, arrival to ED, in-person eligibility confirmation, approach:
Collaboration across research specialties

Basic Science : Health Services Research
Acknowledgments

- CODA is led by investigators at the Comparative Effectiveness Research Translation Network (CERTAIN) in collaboration with surgeon and EM researchers from across 12 hospitals
- ClinicalTrials.gov Identifier: NCT02800785
- Funding
  - Research reported in this presentation was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (1409-24099)
Questions and Information

Hi, my name is Appendix, and sometimes I get so angry I could burst!

You have a purpose! Maybe.

Non-essential organ support group

codastudy.org
Q&A
Reference Articles

Research Involvement and Engagement.


JAMA Surgery.

http://www.pcori.org/research-results/2015/comparing-outcomes-drugs-and-appendectomy-coda
Thank you!

• Acknowledgements:
  o Survey respondents
  o Webinar panelists

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• Send any questions or comments to surveys@pcori.org

• Upcoming Engagement webinars:
  o September 2017 - Topic: Engagement Activities and Impacts
  o September 2017 - Topic: Challenges and Facilitators of Engagement