

PCORI in Practice Webinar Series

Patient and Stakeholder Engagement in Research: Making A Difference in PCORI Projects

September 19, 2017



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Introductions



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Evaluation & Analysis



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Today's Agenda

- Introduction to PCORI
- Key Findings: The Role of Patient and Stakeholder Partners in PCORI Research Projects
- Presentations by PCORI Awardees and Partners
 - ❖ Deborah Quint Shelef and Tiara Cuthbertson
 - ❖ Annette Crisanti and Gina James
- Q&A
- Wrap-up



Learning Objectives

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

- Describe the range of ways patients and other stakeholder partners are involved in research across PCORI's portfolio of funded research projects
- Identify examples of how partners impact the research process and the research team



Housekeeping



Phone lines are muted. You can submit your questions and comments at any time during the webinar via the “question” function on the right side of your screen.



If we are unable to address your question during the webinar, please e-mail us at surveys@pcori.org.



An archive of this webinar will be posted to
<https://www.pcori.org/events/2017/patient-and-stakeholder-engagement-research-making-difference-pcori-projects>
following this event.



Introduction to PCORI



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

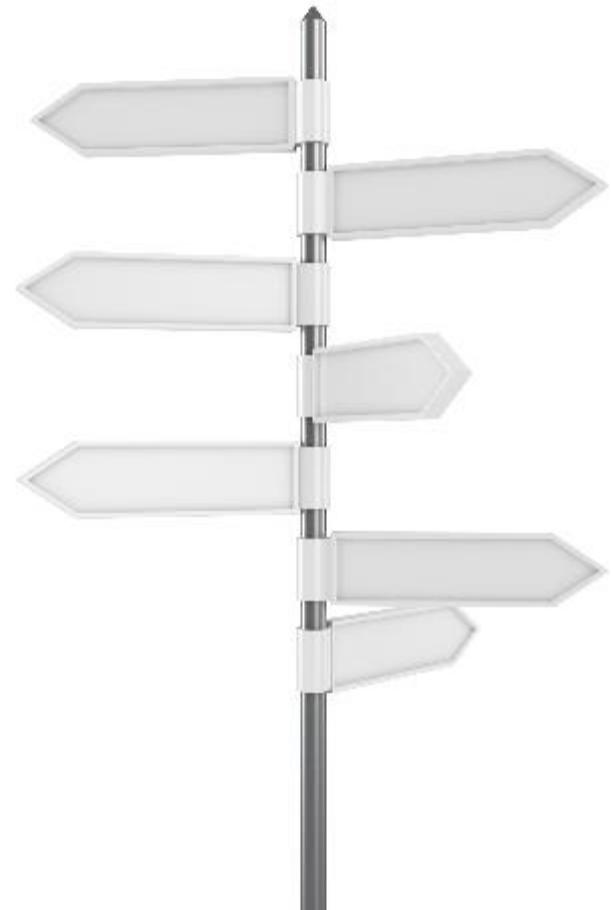
About Us

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns



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

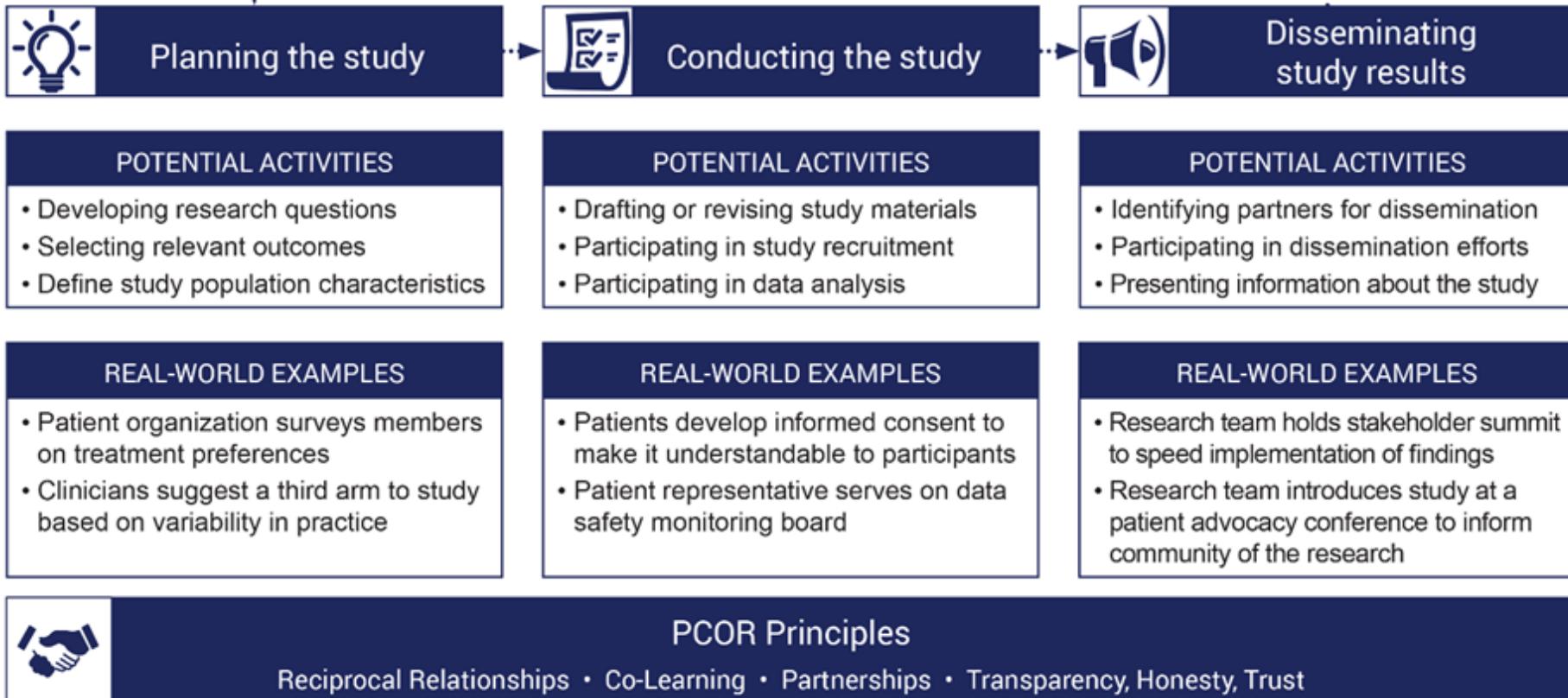


“Patient and stakeholder engagement”

- 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



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: The Role of Patient and Stakeholder Partners in PCORI Research Projects



Information Sources and Methods

Awardee Engagement Report



PCORI Research Awardees

N=305 awardees

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



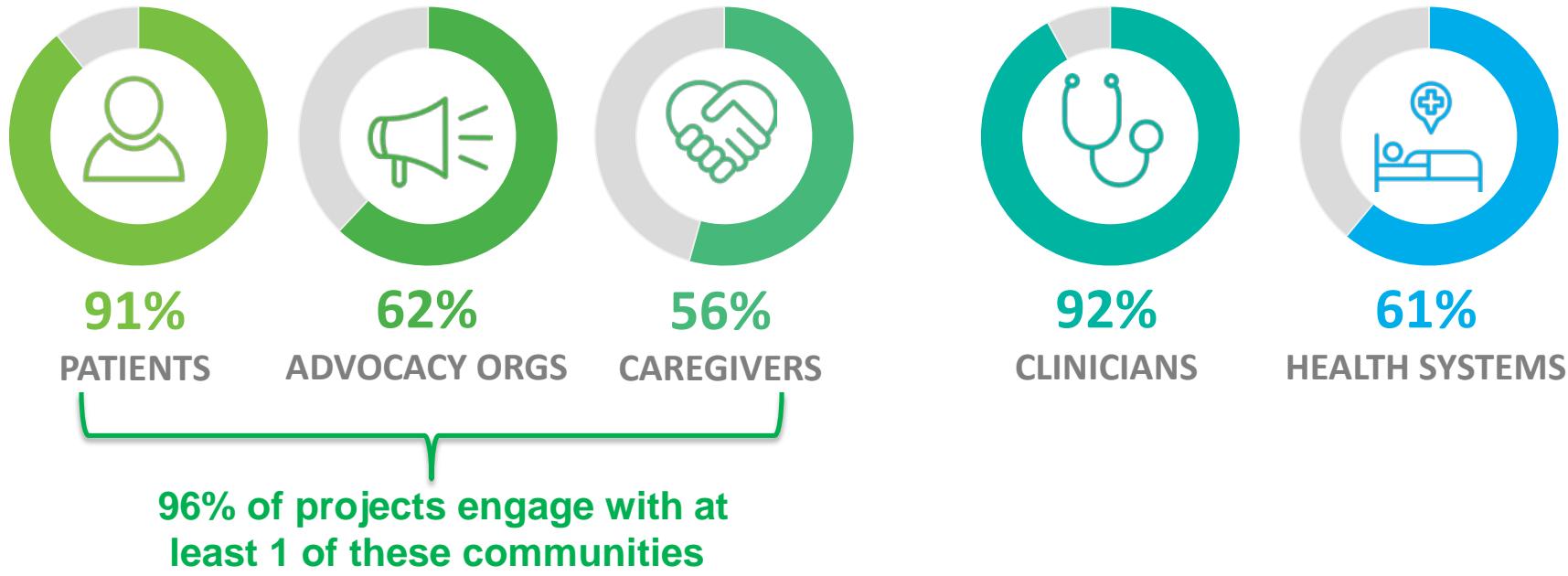
Patient & Stakeholder Partners

N=260 partners



PCORI projects engage with partners from many communities

Communities engaged in PCORI research projects: (by percent of projects)



► PCORI projects also engage with subject matter experts (56%), community-based organizations (36%), policymakers (19%), payers (17%), training institutions (17%), industry (7%), and purchasers (3%)



PCORI projects engage partners in multiple ways

Approaches used to engage partners: (by percent of projects)

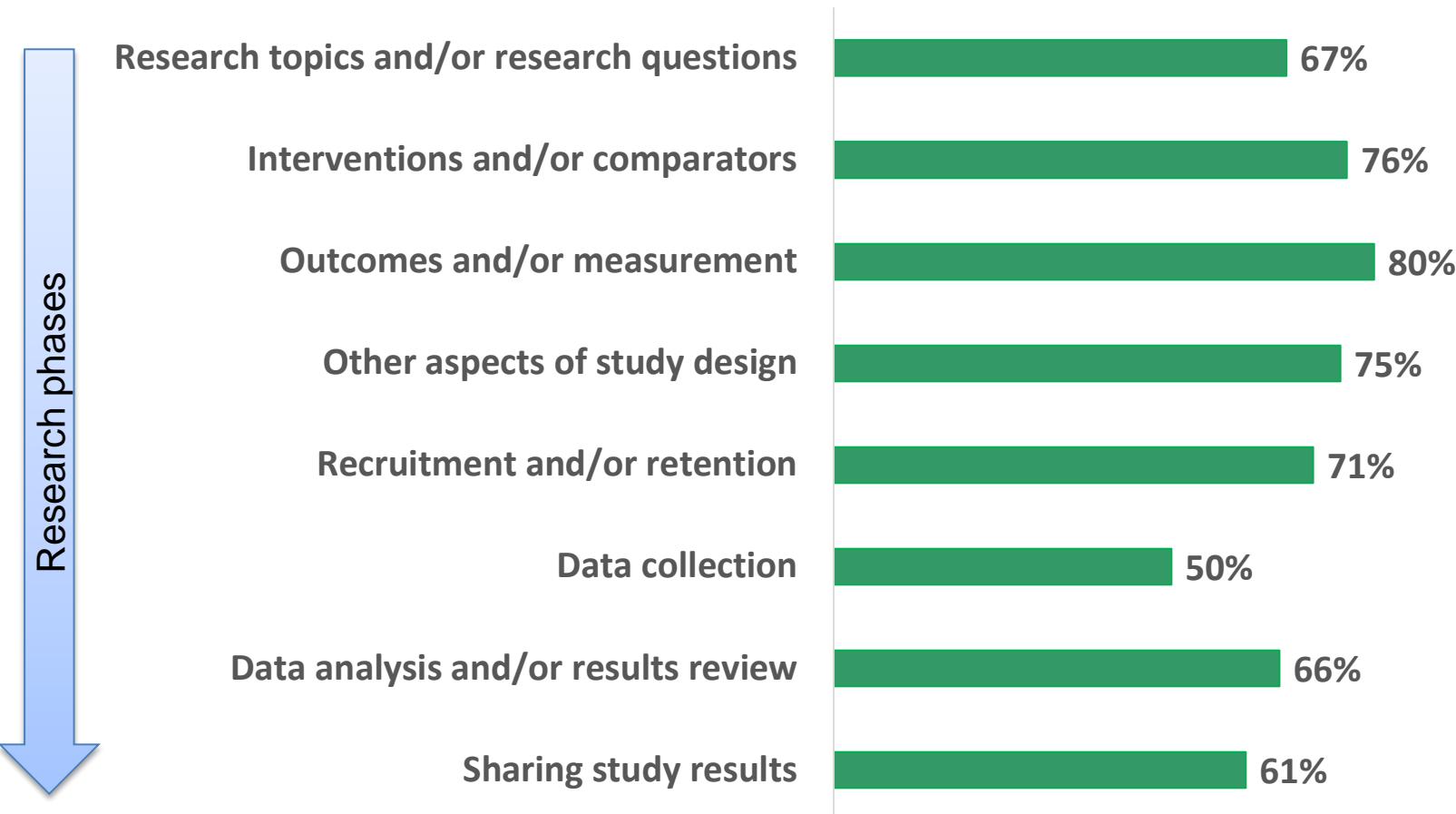


*Note: Data from annual awardee reports collected through 6/30/17;
N=305 awardees: 70 projects at project year 1, 116 projects at project
year 2, 119 projects at project year 3.*

PCORI projects engage partners throughout the research process

Research phases engaging partners:

(by percent of projects)



Note: Data from annual awardee reports collected through 6/30/17; N=305 awardees: 70 projects at project year 1, 116 projects at project year 2, 119 projects at project year 3.



Common engagement activities



Share personal perspectives (e.g., priorities, experiences)



Give guidance and share in decision-making for research project design, processes, and materials (e.g., outcomes studied, recruitment strategies)



Active participation in study conduct (e.g., recruiting participants, collecting data, sharing study information or results)



Engagement makes a difference in PCORI projects



Better understanding of stakeholders' personal perspectives (e.g., priorities, experiences)



Enhanced patient-centeredness of study process and outcomes

- Research questions
- Interventions and/or comparators
- Outcomes and measures
- Data collection
- Recruitment/retention strategies
- Data analysis and/or results review
- Sharing study information or results



Enhanced study design, conduct, or efficiency



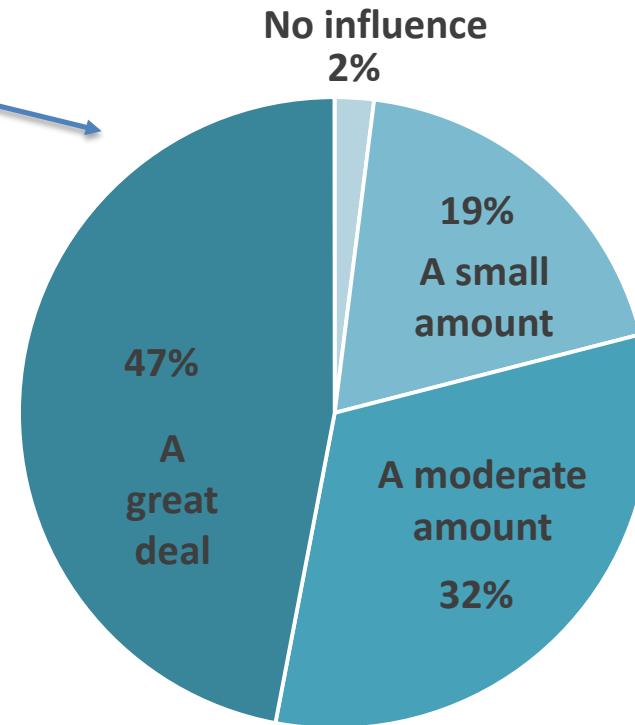
Awardees report partner influence across all phases of research

Awardees report partners' influence on:

- Research topics and/or research questions
- Interventions and/or comparators
- Outcomes and/or measurement
- Other aspects of study design
- Recruitment and/or retention
- Data collection
- Data analysis and/or results review
- Sharing study results

Research phases

Research topics and/or research questions



Note: Data from annual awardee reports collected through 6/30/17; N for chart=205 awardees (out of 305 total) who indicated engaging partners in research topics and/or research questions.



Awardees report partner influence across all phases of research

Awardees report partners' influence on:



- Research topics and/or research questions
- Interventions and/or comparators
- Outcomes and/or measurement
- Other aspects of study design
- Recruitment and/or retention
- Data collection
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- Sharing study results

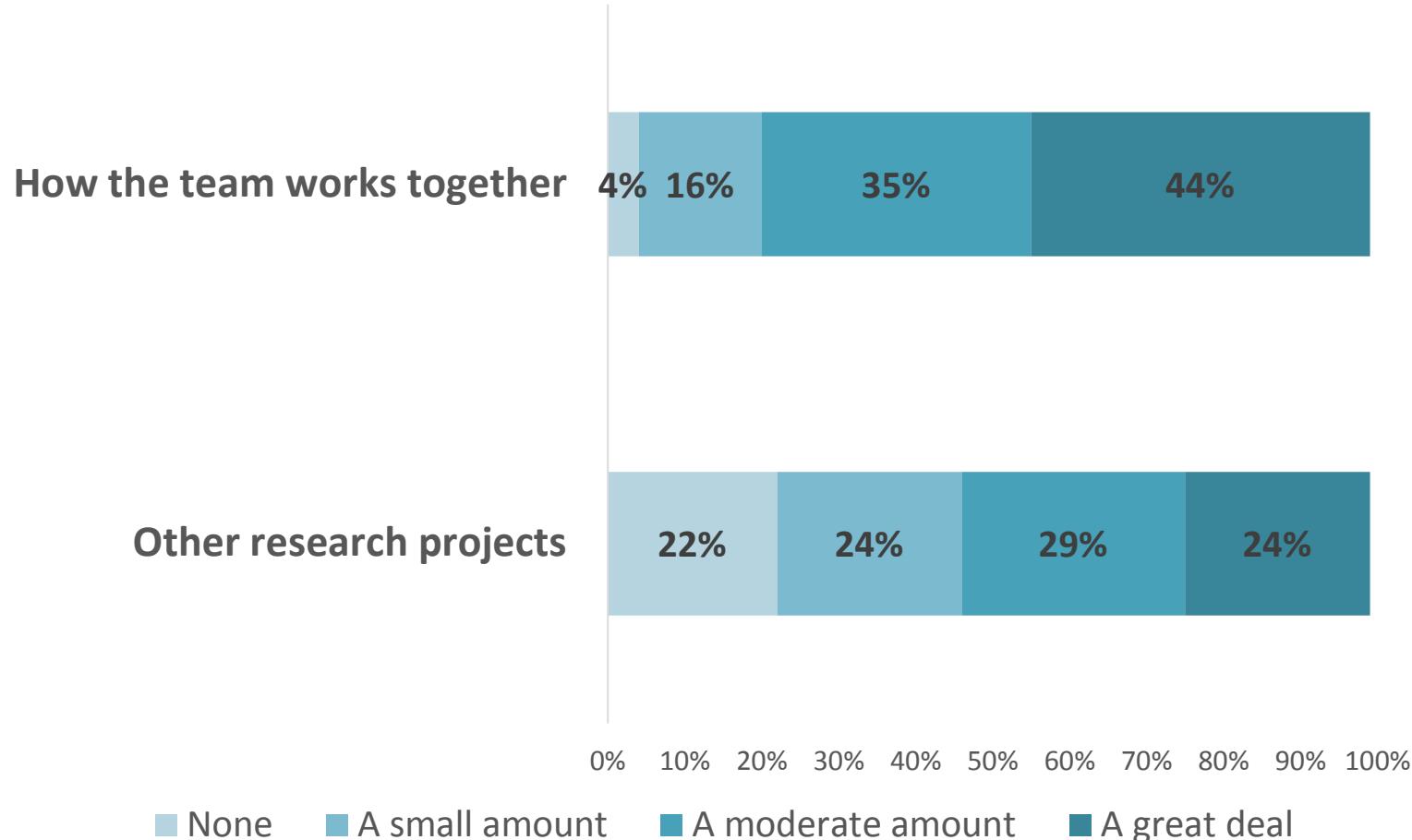


For each phase of research,
>95% of awardees
who engaged with partners
at that phase report partner
influence



Additional examples of partner influence

Awardee report of partners' influence on:



Note: Data from annual awardee reports collected through 6/30/17; N=305 awardees: 70 projects at project year 1, 116 projects at project year 2, 119 projects at project year 3.



Engaging in research impacts partners' personal and professional lives

- Established new relationships
- Improved personal health management
- Made a difference in the lives of others
- Personal growth or self-improvement
- Gained new knowledge and insights about research
- New professional opportunities
- Belief in patient/stakeholder representation in research



Patients I've been working with have taught me to be a better patient, to self advocate. – *Caregiver/Family Member*



Panelist Presentations

Improving Asthma Outcomes through Stress Management

Deborah Quint Shelef, MPH, CCRP, AE-C
Program Director
IMPACT DC
Children's National Health System



Tiara Cuthbertson
Parent Partner
IMPACT DC
Children's National Health System



Improving Pediatric Asthma Outcomes through Stress Management

Deborah Quint Shelef
IMPACT DC, Center for Translational Science

Tiara Cuthbertson
Stakeholder, BEAMS Study
Member, IMPACT DC Parent Advisory Council



IMPACT DC

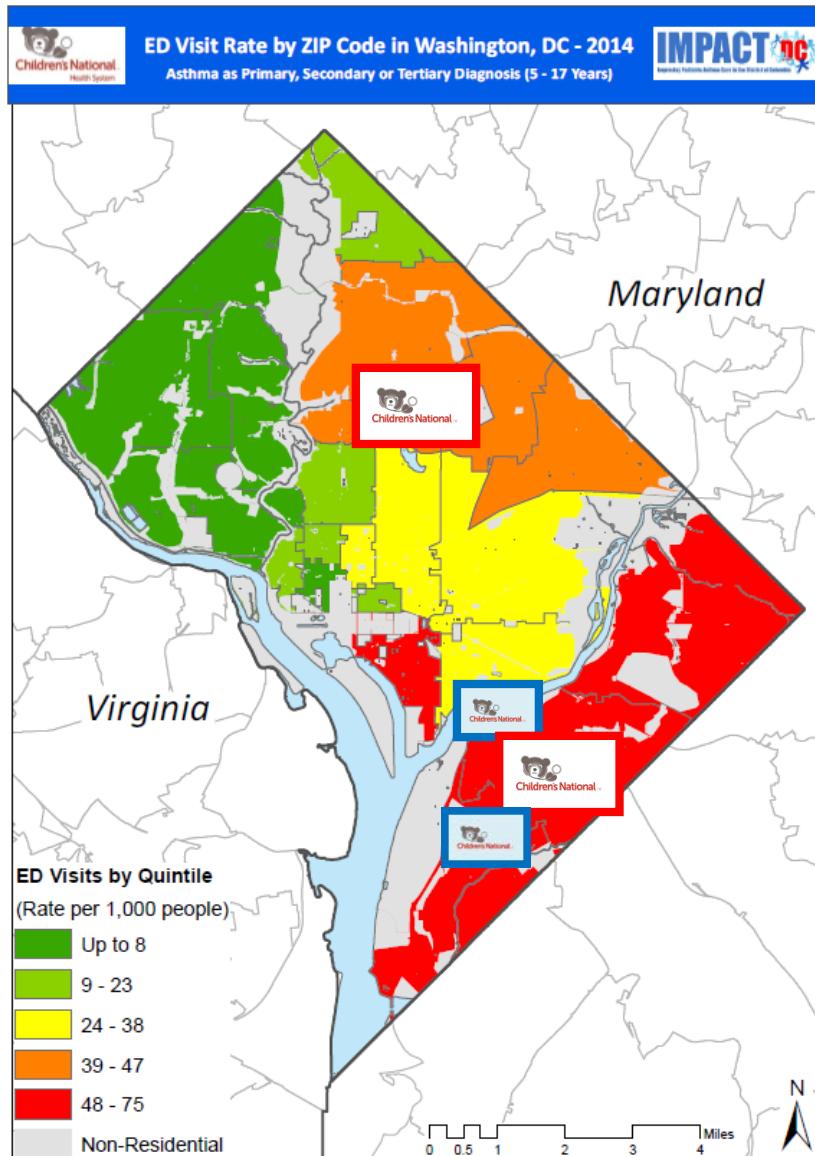
“Improving Pediatric Asthma Care in the District of Columbia”

- Highly collaborative program of care, advocacy, research and education
- Focus on urban children with high ED recidivism
 - *The biggest single predictor of an exacerbation of asthma requiring systemic steroids is having had an exacerbation of asthma (Teach et al, 2016)*
- Conducts patient-centered research, with a specific focus on disparities
- Prior to PCORI award, had not specifically engaged parents and stakeholders in our research process.

IMPACT DC Asthma Clinic

- Validated intervention proven to improve asthma outcomes
- Occurs within 2-4 weeks of hospital visit, *leveraging the teachable moment*
- Patient-centered approach: occurs in the ED
- Education, Environmental Management and Clinical Care
- Short-term intervention: typically 1-2 visits total

IMPACT DC Asthma Clinic



- Provides care to >1300 new patients each year
- Fully integrated in continuum of care at Children's National
- Locations in communities with high asthma morbidity

New Initiative: Psychosocial stress

- Psychosocial stress is well documented as a mediator of poor asthma outcomes
- Growing evidence of a causal relationship between exposure to individual or community stressors and asthma morbidity through various mechanisms:
 - Genetics
 - Epigenetics
 - Altered immune response
 - Decreased response to treatment
 - Behaviors
- High priority research area, with no tested interventions

Pre-Award Engagement

- During proposal development, created new role of “stakeholder liaison”
- Spoke with African American parents of children with asthma to learn about their experiences of stress and stress management
- Spoke with local partners to discuss planned study and ask for participation
- Reviewed prior qualitative research

Funded Proposal

- Funding from PCORI beginning March 2014
- Two stages of funding:
 - Stage I: Planning
 - Stakeholder Engagement
 - Intervention Development/Refinement
 - Protocol Development/Refinement
 - Stage II: Implementation
 - Conduct of RCT
 - Continued Stakeholder Engagement

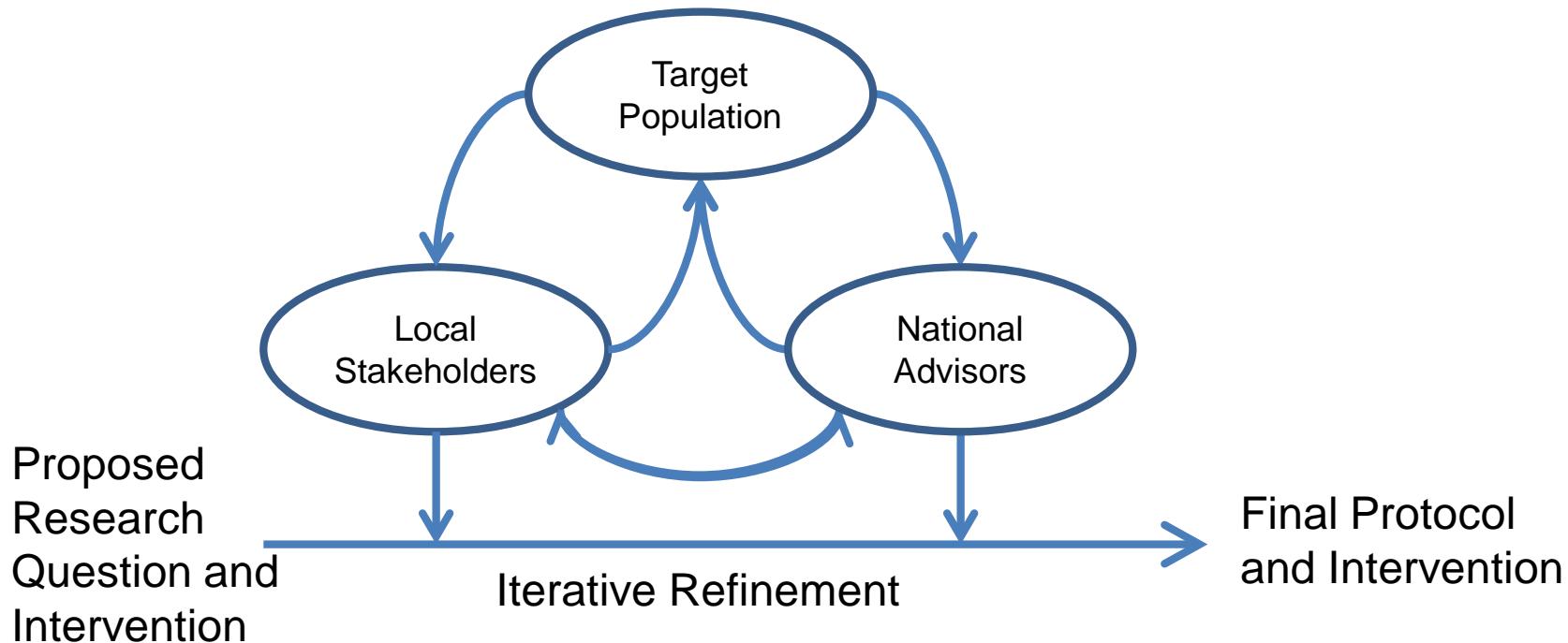
Stage I: Planning

- Stakeholder Engagement Core (SEC)
 - Parents of children with asthma
 - Local providers of social, medical, legal and educational services
- Preparation of participants
 - Orientation to research process
 - Expectations regarding process, including reimbursement
- Key engagement principles: reciprocal relationships, co-learning, partnerships, transparency, honesty and trust.

Stage I: Planning

- National Advisory Core (NAC)
 - Researchers with expertise in asthma trials among at-risk youth, psychosocial stress, and medication adherence
 - Provided input on methodological questions
 - Focused on designing study that was both responsive to local context and feasible, and with the potential to address questions of national relevance
- Qualitative Research
 - Focus groups and one-on-one interviews of parents of children with asthma

Stakeholder Engagement



Adapted from Shelef DQ et al, JACI 2016

Stage I: Iterative Refinement

- SEC and NAC helped us refine questions prior to initiation of focus groups and interviews with target population
- SEC and NAC helped us interpret findings of qualitative research, and better understand how our study may need to be modified to be responsive to the experience and preferences in our community
- Study outcomes
- Study design
- Intervention design and content

Stage I: Specific Changes

- Changed primary outcome:
 - From medication adherence to symptom-free days
- Changed intervention structure:
 - Initially planned to include individual sessions and bidirectional monitoring using mHealth technologies
 - Reduced emphasis on technology, using text messages just for reminders and reinforcement
 - Added in group sessions for peer support
 - Staffed by “community wellness coaches” would be both relatable and experienced in practicing techniques

Stage I: Other contributions

- Parents emphasized the importance of non-judgmental language regarding stress, and provided suggested wording
- Our intervention needed to be responsive to individual circumstances. While some parents identified asthma as a key stressor, while others were only able to focus on asthma when symptoms were serious, due to other more pressing concerns.

Stage I: Final Protocol Developed

- *Breathe with Ease: A Unique Approach to Managing Stress (BEAMS)*
- Prospective single-blind RCT
- African American parent-child dyads
- Children age 4-12y with persistent asthma, Medicaid insurance, and no significant medical comorbidities
- Follow-up conducted at 3m, 6m, and 12m



Stage I: Final Protocol (cont.)

- Intervention:
 - Four 1:1 sessions with community wellness coaches, focused on stress management techniques including breathing, mindfulness, positive thinking, and gratitude
 - Group sessions
 - Text message reminders
- Comparator: the IMPACT DC Asthma Clinic
 - Validated intervention previously shown to improve multiple measures of asthma care and control
 - Targets children with ED recidivism and hospital admissions for asthma

Timeline

- Stage I Planning
 - March 2014 – February 2015
- Stage II Implementation and Analysis
 - Study Enrollment
 - May 2015 – May 2016
 - 6-month follow-up
 - Data collection completed November 2016
 - Analysis completed January 2017.
 - 12-month follow-up
 - Data collection completed May 2017
 - Analysis completed July 2017.

Stakeholder Engagement Core Rubric
Overview - BEAMS/SEC Next Stage Involvement

POORI Engagement Principles:

- Reciprocal relationships/Shared decision-making
- Co-learning (partners learn about research process; researchers learn from stakeholders)
- Fair partnerships
- Trust and transparency

Phase	STUDY PLANNING	IMPLEMENTATION	DISSEMINATION PLANNING	SUSTAINABILITY PLANNING
Cycle	Year 1	Years 2/3	Years 2/3	Year 3
Tasks	<p>Accomplished:</p> <ul style="list-style-type: none"> ✓ Contributed to defining parameters of the study. ✓ Reviewed findings of focus groups and semi-structured interviews. ✓ Changed project emphasis to mindfulness and stress relief practices. ✓ Pilot tested intervention curriculum with Parent members. 	<p>Training and Troubleshooting</p> <p>Peer session support (e.g., logistics, retention)</p> <p>Identify data trends</p>	<p>Identify "lessons learned" to promote widely</p> <p>Identify local and national audiences</p> <p>Develop messaging frames for different audiences</p> <p>Review draft manuscripts</p> <p>Serve as a community spokesperson, training provided</p>	<p>Identify future partnerships</p> <p>Communicate with potential partners</p> <p>Identify funding sources for partnerships</p>
<p>Decisions (6/2/15):</p> <ul style="list-style-type: none"> ▪ SEC will receive monthly status updates, to include dashboard summary of enrollment and participation statistics. ▪ Full group will meet quarterly in years two and three. ▪ Will break into workgroups according to stakeholder interests and needs of each phase. 				

Stage II: Implementation

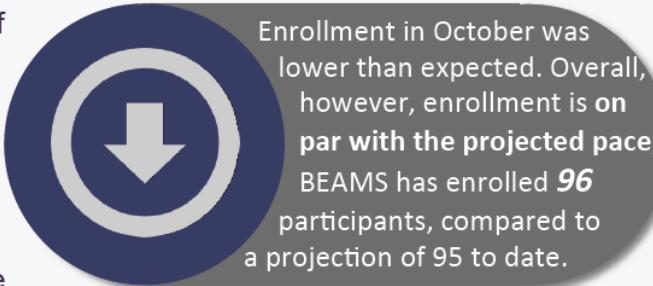
- Training and orientation of new study staff
- Monitoring study progress and identifying trends
- Troubleshooting processes

Recruitment Summary

96



October saw an uncharacteristically low number of patients coming to the IMPACT DC clinic. Thus, recruitment into the BEAMS study was lower than expected. Overall, however, recruitment continues to go well and we are **still on pace** with our expected number of participants. As of the end of October, we have enrolled **96 participants**—46% of our total study sample. We expect to cross the halfway mark early in November.



Request for Help

We need your ideas! As noted above, attendance at the group sessions has been lower than expected. The BEAMS Study team is wondering if you might be able to help us answer the following questions:



1. **What might be contributing to the low attendance rate at the group sessions?**
2. **How can we improve attendance at the group sessions?**

Phase II: Dissemination and Sustainability Planning

- Identify lessons learned
- Identify local and national audiences
- Develop message frames for different audiences
- Review and interpret data summaries
- Serve as spokespeople
- Identify future partnerships
- Identify funding opportunities for potential partnerships

Thank you!

- Principal Investigator: Stephen Teach, MD, MPH
- Co-Investigators: Randi Streisand, Kabir Yadav, Ivor Horn, Cynthia Rand
- Research Team: Naja Fousheeé, Erin Collins, Ashley Seymour, Nadirah Waites
- Wellness Coaches: Tilli Williams, LaShone Wilson
- Stakeholder Liaisons: Lisa Stewart and Damian Waters
- Stakeholders and Advisors
- Parents and children from the BEAMS study

Patient-Centered Trauma Treatment for PTSD and Substance Abuse: Is It an Effective Treatment Option?

Annette S. Crisanti, PhD

Associate Professor & Research Director
Division of Community Behavioral Health
Department of Psychiatry & Behavioral Sciences
School of Medicine
University of New Mexico



Gina James, CPSW

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School of Medicine
University of New Mexico



The Impact of Partnering with Patients and Other Stakeholders: A RCT in Rural New Mexico

Annette S. Crisanti, Ph.D.,
and Gina James, CPSW

Department of Psychiatry
and Behavioral Sciences,
University of New Mexico

September 19th, 2017



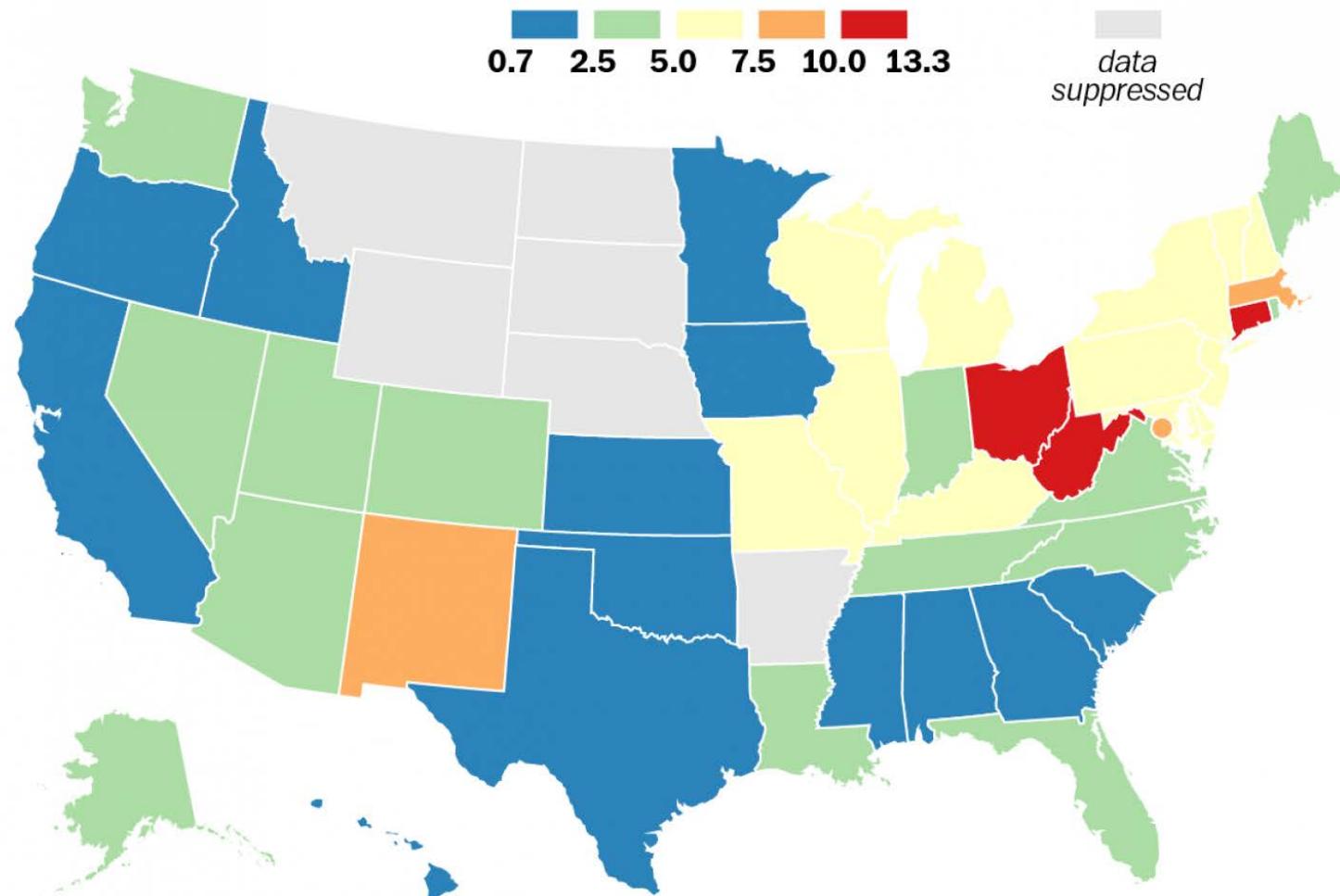
- Funded - Patient-Centered Outcomes Research Institute (PCORI) Award (CE-12-11-4484).
- The statements presented in this presentation are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee

Presentation Goals

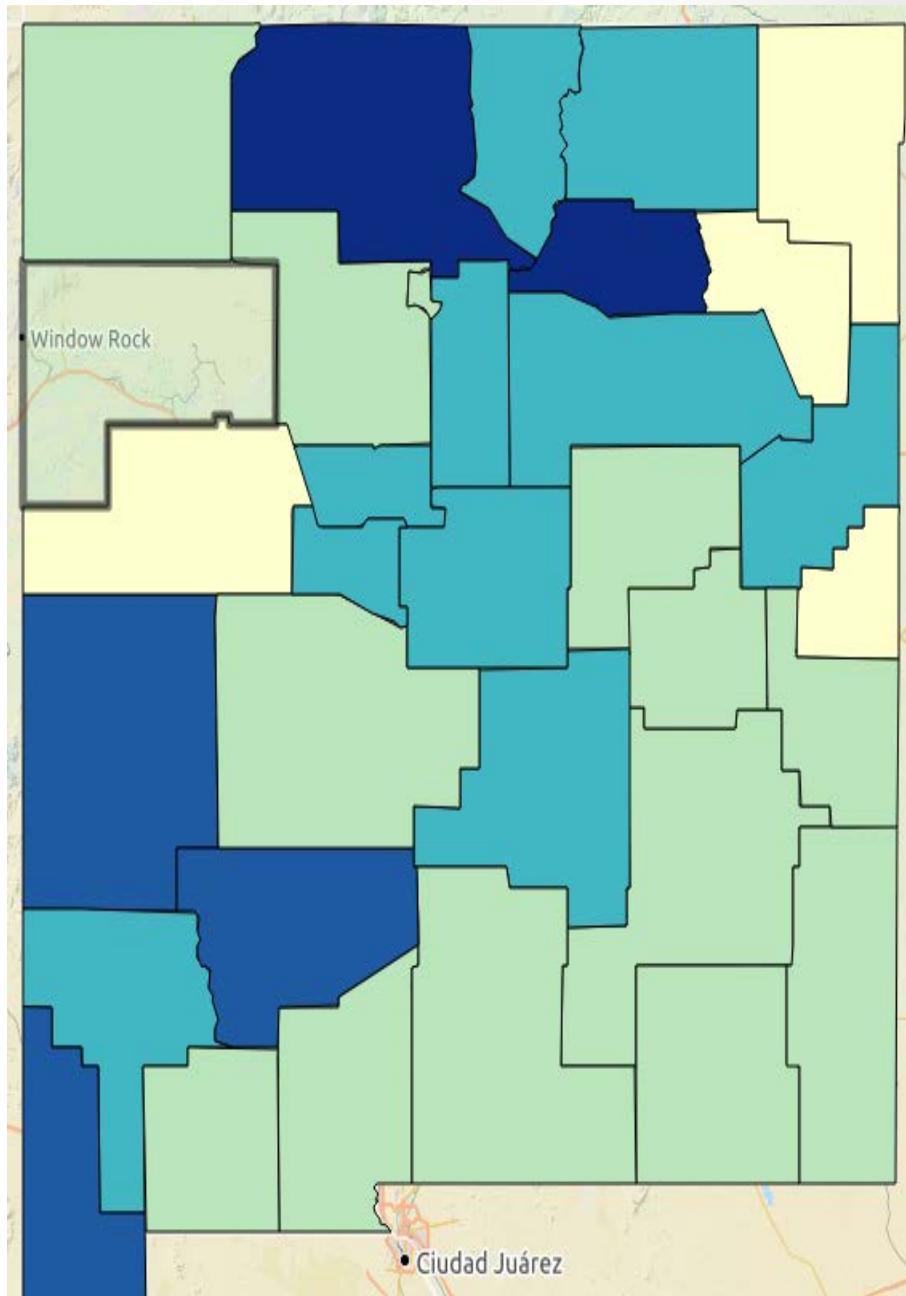
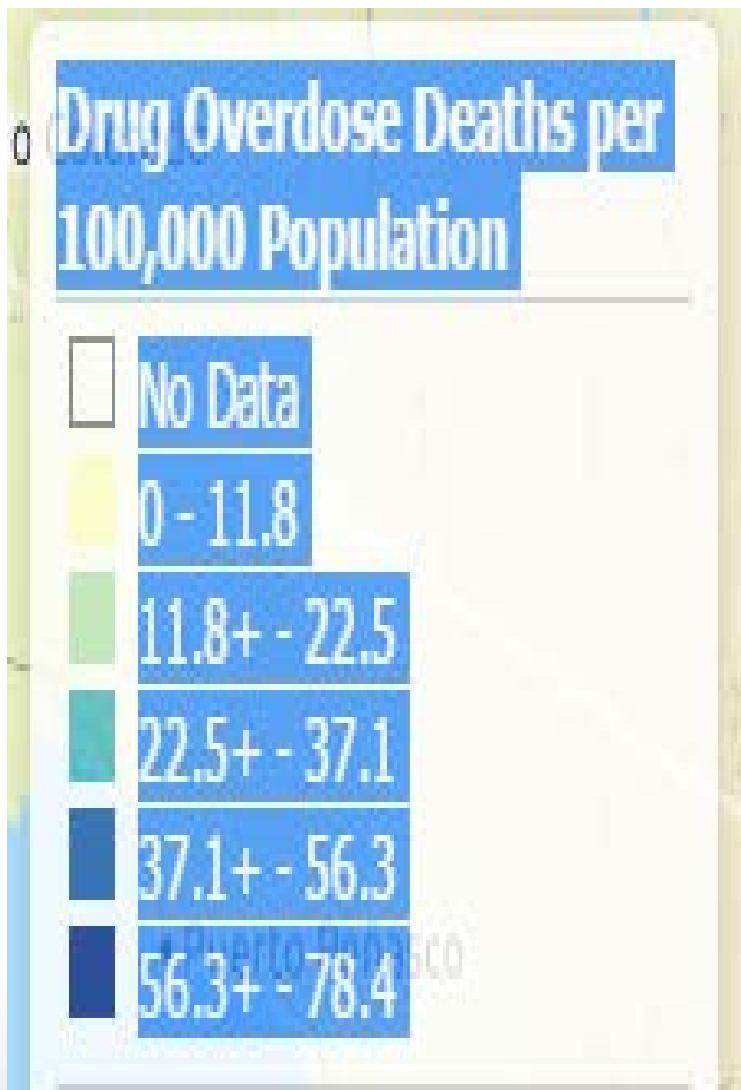
- Background Information -PCORI Funded Study
- Patients and stakeholders as partners – “walking the talk” (examples)
- How we achieved our partnership and Impact on Patients

Heroin deaths in 2015

Age-adjusted heroin overdose death rate (per 100,000)



NEW MEXICO 2010-2014

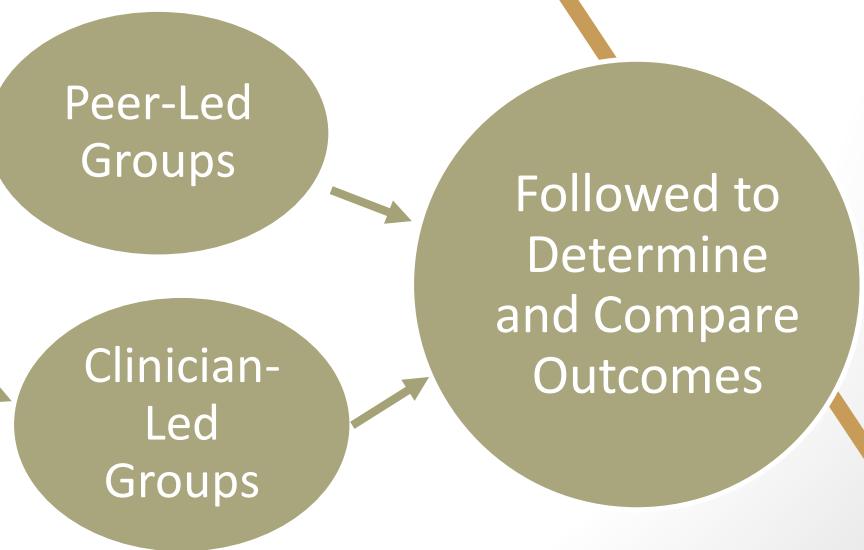


Undertaking & Managing the Research

- Patients and Other Stakeholders were in multiple influential, paid positions, including:
 - Project Director
 - Group facilitators
 - Group support coordinator
 - Researchers (data collection)
 - Steering committee members

Patient-Centered Trauma Treatment for PTSD and Substance Abuse: Is it an Effective Treatment Option?

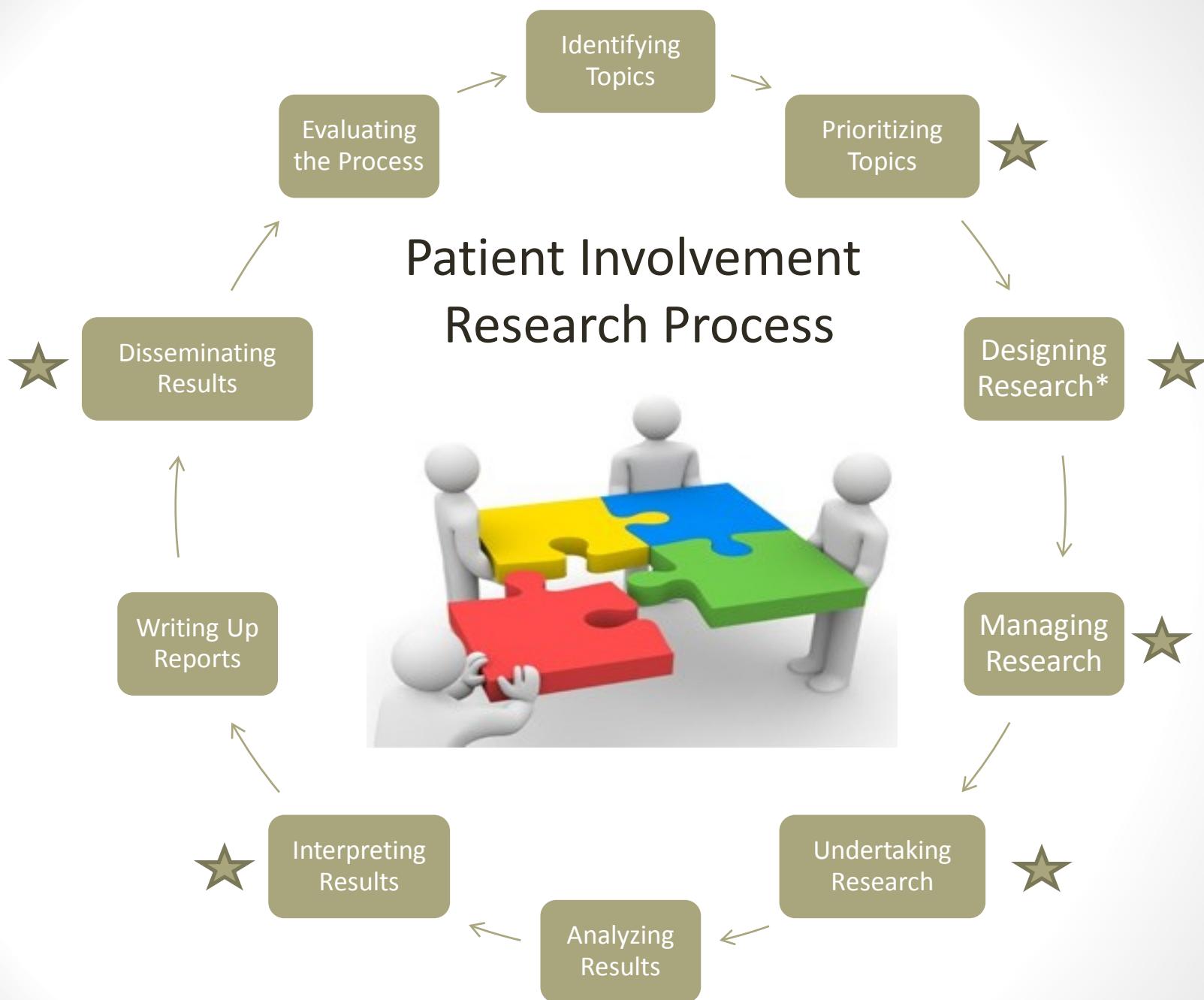
Participants Randomized to Seeking Safety Treatment



Project Period:
August 2013
July 2016

Target Pop:
-Adults 18+
-PTSD &/or Sub Abuse

Patient Involvement Research Process

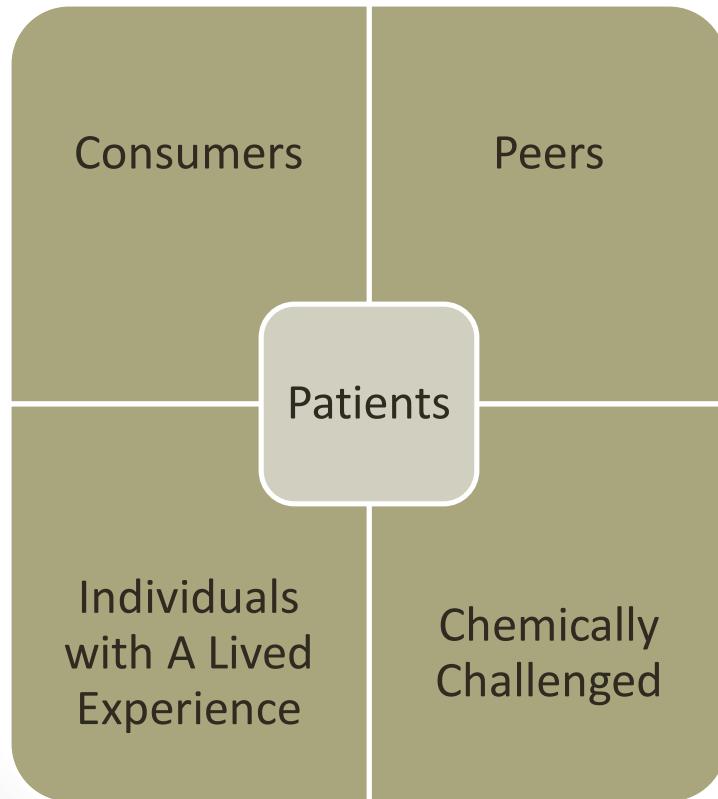


Stakeholders and Their Role

- **The University of New Mexico, Department of Psychiatry and Behavioral Sciences**
- **Inside Out Recovery Center:** A consumer-run non-profit organization dedicated to supporting communities in northern NM - focus on opiate addiction and recovery
- **The Life Link:** Provides outpatient emergency assistance, housing, employment services, and other supportive programs including advanced addiction and mental health treatment services to residents in northern NM.
- **Recovery Based Solutions:** Dedicated to supporting past and current recipients of behavioral health services in NM
- **National Alliance of Mental Illness (NAMI) New Mexico**
- **Hoy Recovery Program:** A residential substance abuse treatment program

The Most Important First Step...

Establishing Trust And Respect

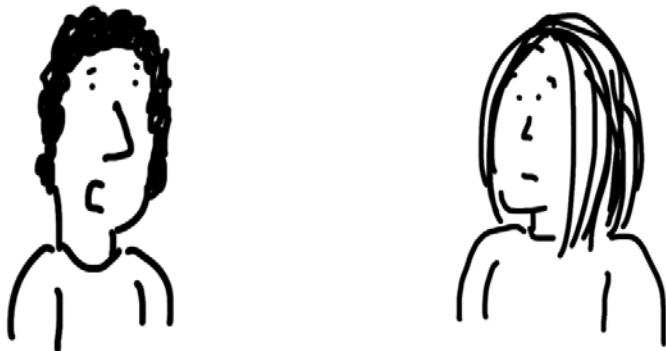


Identification of the Problem and Solution

- Patient partner was the impetus for grant application.
 - Concern about the substance abuse problem and lack of services in area
 - Reached out to researcher
- Patient partner identified treatment appropriate for target population

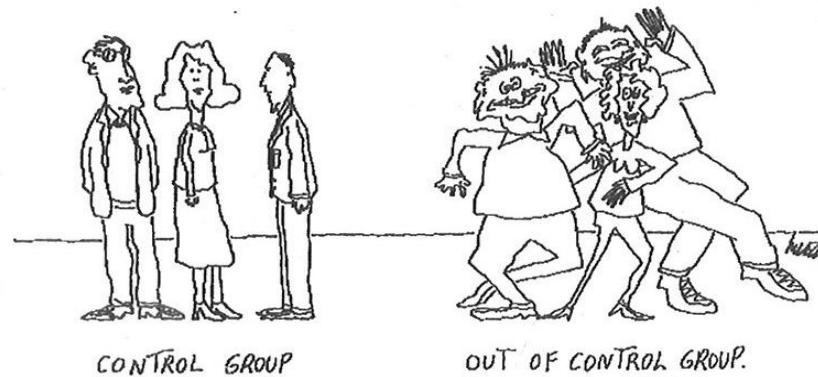
Awareness of Different Areas of Expertise and Language

Do you know about any RCTs that provide evidence that we should use RCTs?

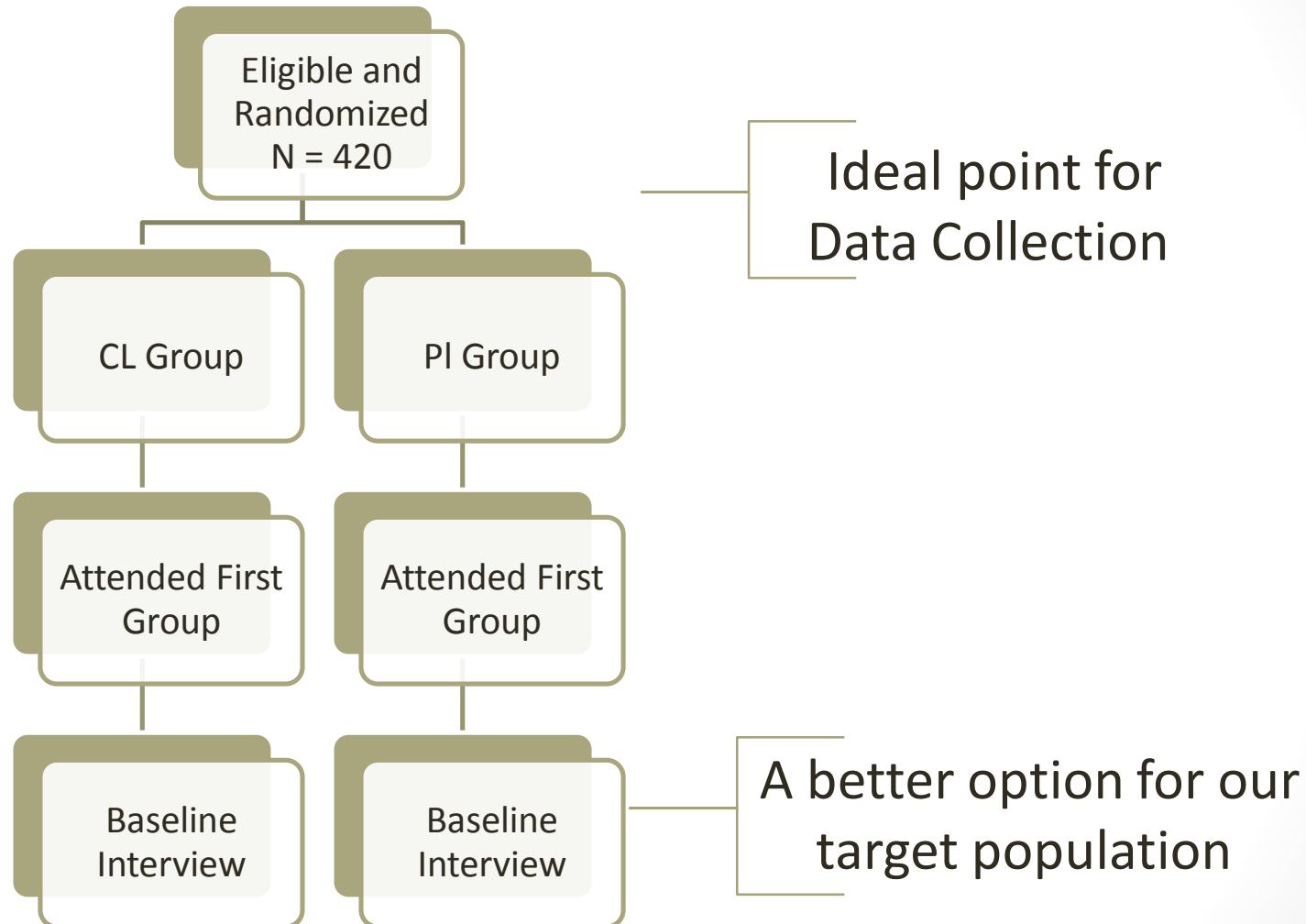


Tweaking
Shot down or
Riding the Wave
Sandwich

Randomization
Blinding
Control Group
Treatment Arms



Influence on Research Design



Influence on Engagement & Retention

Based on insight and familiarity with target population:

- Open group format compared to closed
- Time of groups
- Development of recruitment flyers using target population specific language
- Determination of type of incentives
- Expansion to second site to achieve proposed sample size

Another Benefit of Insight and Lived Experience

- Identification of challenges associated with the implementation of the evidence-based practice that might be impacting engagement & retention
 - Need for alignment with literacy level and culture of target population

*“Not to laugh,
not to lament,
not to judge but to understand”.*
(17th century Dutch philosopher Baruch Spinoza)

Influence on the Interpretation of Results

Addiction Severity Index-Lite (ASI)

- How many days in the past 30 have you experienced Alcohol problems? _____
- How troubled or bothered have you been in the past 30 days by Alcohol problems? _____
- How important to you *now* is treatment for Alcohol problems? _____

RESEARCHER – PATIENT PARTNERSHIP



- Encourage a safe environment for all individuals to be able to speak freely and openly, recognizing the benefit of healthy conflict over group-think.
- Continuously improve the quality of the implementation of the study with respect to feelings of mutual respect, and empowerment among ALL those involved.

Impact on Patients Involved

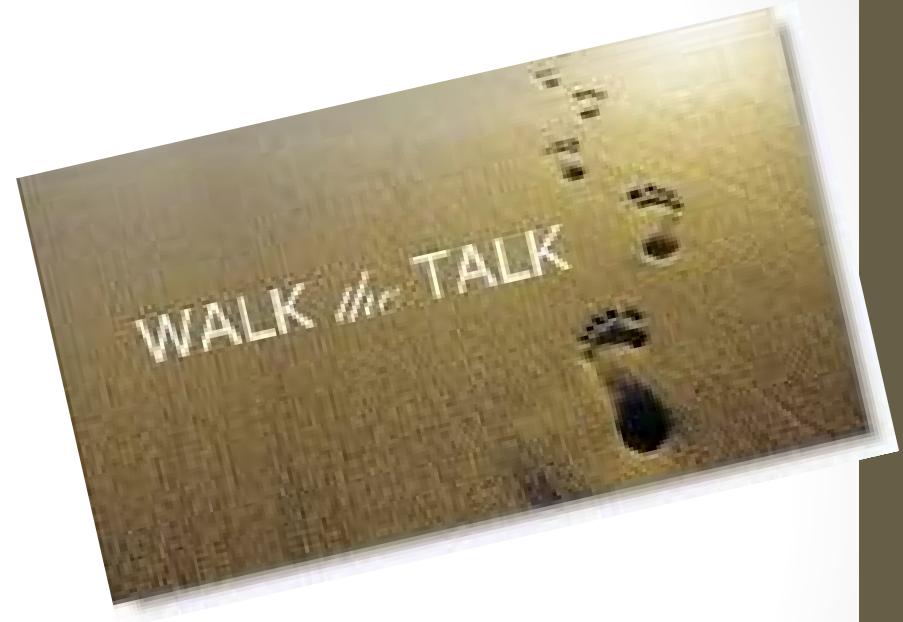
- Background
- Personal Impact
- Professional Opportunities
- Others Impacted
- Appreciation



Impact!

“Revolutions begin
when people who
are *defined as*
problems achieve
the power to
redefine the
problem”

John McKnight



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Q&A



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Resources



Journal of Allergy and Clinical Immunology

Volume 138, Issue 6, December 2016, Pages 1512-1517



Reviews and feature article

Using stakeholder engagement to develop a patient-centered pediatric asthma intervention

Deborah Q. Shelef MPH ^a , Cynthia Rand PhD ^b, Randi Streisand PhD ^a, Ivor B. Horn MD, MPH ^c, Kabir Yadav MDCM, MS, MSHS ^d, Lisa Stewart MA ^e, Naja Foushee MS ^a, Damian Waters PhD ^a, Stephen J. Teach MD, MPH ^f

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<https://doi.org/10.1016/j.jaci.2016.10.001>

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CLINICAL PSYCHOLOGY & NEUROPSYCHOLOGY | RESEARCH ARTICLE

Evaluation of an evidence-based practice training for peer support workers in behavioral health care

A.S. Crisanti^{1*}, C. Murray-Krezan², L.S. Karlin³, K. Sutherland-Bruaw⁴ and L.M. Najavits⁵



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Resources (cont.)

Qual Life Res
DOI 10.1007/s11136-017-1581-x



SPECIAL SECTION: MEASURING WHAT MATTERS (BY INVITATION ONLY)

Methods and impact of engagement in research, from theory to practice and back again: early findings from the Patient-Centered Outcomes Research Institute

Laura Forsythe¹ · Andrea Heckert¹ · Mary Kay Margolis¹ · Suzanne Schrandt² ·
Lori Frank¹ 

Annals of Family Medicine.

Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA; Advisory Panel on Patient Engagement (2013 inaugural panel). [The PCORI Engagement Rubric: Promising Practices for Partnering in Research](#). Ann Fam Med. 2017 Mar;15(2):165-170. doi: 10.1370/afm.2042. PubMed PMID: 28289118.



Thank you!

- Acknowledgements
 - Webinar panelists
 - Awardees and partners
- Slides, a recording, and additional materials for this webinar will be posted to <https://www.pcori.org/events/2017/patient-and-stakeholder-engagement-research-making-difference-pcori-projects> following this event.
- Send any questions or comments about today's webinar to surveys@pcori.org
- Stay tuned for our next engagement webinar!
 - Topic: Challenges & Facilitators of Research Engagement – Fall 2017



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