Welcome

Please be seated by 9:40 a.m.

The teleconference will go live at 9:45 a.m.

Patient-Centered Outcomes Research Institute

Addressing Disparities Program: Advisory Panel Face-to-Face Meeting

January 13, 2015

9:45 a.m. to 5:00 p.m. ET

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Housekeeping

- Today's webinar is open to the public and is being recorded.

- Anyone may submit a comment through the webinar chat function or by emailing advisorypanels@pcori.org.

- Visit www.pcori.org/events for more information.

- Chair Statement on COI and Confidentiality

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Introductions

- Please quickly state your name, title, and affiliation.

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Meeting Agenda

- **Welcome and Setting the Stage**
- **Updates from Addressing Disparities and Q&A**
  - Obesity Treatment Options Updates
  - General Program Updates
    - Current funding status and newly funded projects
    - Current initiatives (i.e., Hypertension, Perinatal Outcomes, Lower Extremity Amputations, Pragmatic Trials)
    - Program next steps for topics of interest
- **PCORI's Evaluation Framework**
- **Asthma Evidence to Action Network (E2AN) Implementation and Asthma Awardee Presentation**
- **Intersection of Science and Engagement**

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Updates from Addressing Disparities Program

Cathy Gurgol, MS
Program Officer

Romana Hasnain-Wynia, PhD
Program Director

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Obesity Treatment Options Update

Overview

- Background and Significance of Obesity PCORI Funding Announcement (PFA)
- Summary of Obesity Portfolio
- Next Steps for Obesity Awards

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Notable Dates

Activity	Date
Funding Announcement Released	February 2014
Awards Approved	September 2014
Contracts Executed	December 2014
Project Implementation	January 2015 – January 2020

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Background on Obesity PFA

- The Addressing Disparities Program sought to fund projects through the Obesity PFA that:
    - Focus on reducing disparities in obesity outcomes in underserved populations
    - Compare evidence-based comprehensive lifestyle interventions that are set in primary care practices and have strong linkages to community-based partners/practitioners
    - Include clinical and patient-centered outcomes tailored to the needs of individuals and populations

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Background on Obesity PFA (cont.)

PFA	Number of Awards	Project Length	Max. Total Budget per Project	Available Funds
Obesity PFA	2	5 Years	$10M	$20M

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Background on Obesity PFA (cont.)

- The Obesity PFA and portfolio are significant.

    - The Obesity PFA is the program's second targeted funding announcement.

    - Individually and collectively, the funded projects have the ability to improve patient-centered and clinical outcomes for people at risk for experiencing disparities.

    - The funded projects both leverage PCORnet, which can show how developing clinical research infrastructure can aid in conducting trials.

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Summary of Obesity Portfolio

Project Title	Organization	Target Population(s)	Number of Study Participants	Primary Outcome
The Louisiana Trial to Reduce Obesity in Primary Care	Pennington Biomedical Research Center	African Americans; low socio-economic individuals	1,080	Percent change in body weight from baseline
Midwestern Collaborative for Treating Obesity in Rural Primary Care	University of Kansas Medical Center	Rural; low socio-economic individuals	1,400	Weight loss at 24 months

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Next Steps

- Convene awardee in-person meeting to kick off projects and discuss potential cross-study collaboration – January 15, 2015.

- Begin planning for implementation of Obesity Evidence to Action Network (E2AN).

- Continue monitoring project progress.

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Addressing Disparities Program Updates

Addressing Disparities Program
Current Funding Status

Broad PFAs
6 cycles

- **41** projects totaling **$71.3M**

Targeted PFAs

2 cycles

- Treatment Options for Uncontrolled Asthma in African Americans and Hispanics/Latinos: **8** projects totaling **$23.2M**
- Obesity in Underserved Populations: **2** projects totaling **$20M**

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New Projects Awarded through Broad PFA

- **4** new projects awarded in September 2014, totaling $7.4M

Project Title	Organization
Active and Healthy Brotherhood: A Program for Chronic Disease Self-Management for Black Men	Gramercy Research Group
A Comparative Trial of Improving Care for Underserved Asian Americans Infected with HBV	Temple University
Acupuncture Approaches to Decrease Disparities in Outcomes of Pain Treatment - A Two Arm Comparative Effectiveness Trial (AADDOPT-2)	Albert Einstein College of Medicine
Programa Esperanza (Project Hope)	University of Southern California

Hypertension Update
Targeted PCORI/NIH Hypertension Funding Announcement

- Testing of Multi-Level Interventions to Improve Blood Pressure Control in Racial/Ethnic Minority, Low SES, and/or Rural Populations

  - Supported by the Hypertension Disparities Reduction Program Partnership, a research partnership between NHLBI, NINDS, and the Addressing Disparities program at PCORI, with funds provided by PCORI to the NIH

  - **Goal**: To solicit comprehensive comparative effectiveness studies testing multi-component interventions, with strong patient and stakeholder engagement, to reduce hypertension disparities among racial/ethnic minorities, and/or low SES, and/or rural populations

  - **Objective:** To fund up to two multi-component comparative effectiveness trials up to $25M to assess the best strategies to achieve superior blood pressure control levels (>75%) among high-risk patients

  - Important Dates:

    - Applications Due: February 13, 2015

    - Earliest Award Date: September 2015

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Perinatal Outcomes Update

- **Progress to Date**
  - The panel prioritized this topic at the first meeting in April 2013.
  - In partnership with the Improving Healthcare Systems (IHS) program, we held a multi-stakeholder workgroup in October 2013.
  - For the past year, we have worked with our Board and colleagues at NIH to explore evidence gaps and refine topic.
- **Next Steps**
  - We are discussions with potential partners to determine if there is an opportunity for PCORI.

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Lower Extremity Amputations (LEA) Update

- **Progress to Date**
  - The panel prioritized this topic at the first meeting in April 2013.
  - In November 2014, a multi-stakeholder workgroup was convened to identify a patient-centered CER question focusing on clinical interventions that could reduce disparities in LEA among racial and ethnic minorities and low-income populations.
- **Next Steps**
  - Review literature to confirm gaps in research identified by the workgroup.
  - Consult with PCORI's leadership about our potential to have an impact in this area.

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Pragmatic Trials Update

- Three of the PCORI priority topics in the pragmatic trials announcements came from the Addressing Disparities Advisory Panel:

Integration of mental and behavioral health services into the primary care of persons at risk for disparities in health care and outcomes.

Reduction of cardiovascular disease (CVD) risk in underserved populations such as racial and ethnic minorities and those living in rural communities.

Multi-component interventions to reduce initiation of tobacco use and promote cessation of tobacco use among high-risk populations with known disparities.

Pragmatic **PFA**

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Program Next Steps for Topics of Interest

- At the September 2014 webinar, the panel reviewed and discussed four topics.
- **3** topics were of interest to the panel for further exploration:
  - Identification/risk assessment and therapeutic strategies for autism spectrum disorders
  - Treatment strategies for osteoarthritis
  - Pharmacologic and non-pharmacologic treatments for Alzheimer's disease and other dementias
- Based on input from the panel, additional gap analyses are being conducted.
- Addressing Disparities staff will work to determine potential for impact in these areas and how this fits into the larger PCORI strategy for funding CER.

QUESTIONS?

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Our Evaluation Framework

Michele Orza, ScD
Senior Advisor to the Executive Director

Patient-Centered Outcomes Research Institute

Objectives for Today

- Brief overview of PCORI's Evaluation Framework

- Focus on intersections with our Advisory Panels

- Update on Usefulness

- Identify topics for subsequent discussions

- Secure an invitation to come back to you for further assistance and to share more results!

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Evaluation at PCORI

Evaluating Our Work

PCORI takes a unique approach to funding comparative clinical effectiveness research—ensuring that we focus on options and outcomes important to patients, and that patients and others across the healthcare community have a meaningful role in guiding our work.

Patients and other stakeholders help us determine which research topics we should consider for funding, and they help us review proposals. We also require that patients be included as meaningful partners in the research we support, helping to develop and conduct the studies and disseminate the results. We're committed to this approach, which we call "research done differently," to focus the research we fund on producing useful information to answer the questions of greatest importance to patients and those who care for them. But is our approach succeeding? As proponents of evidence-based practice, we're eager to learn what works best to produce useful information that leads to improved health outcomes.

Our Board of Governors oversees our evaluation plans and activities, and our Methodology Committee guides the designs and methods. Each of three Strategy Committees, comprised of Board and Methodology Committee members, focuses on the activities aligned with a specific goal in our strategic plan.

Assisting PCORI with evaluation is the PCORI Evaluation Group, a consultative task force that includes Board and Methodology Committee members, as well as external experts.

PCORI is committed to functioning as a "learning organization," so staff from all departments participate in monitoring our progress toward our goals and in learning how we can improve our work. The Office of the Executive Director coordinates PCORI's extensive evaluation activities. It works in close partnership with our Research Integration and Evaluation program, which implements most of the evaluation activities, and our Engagement program, which ensures the meaningful engagement of patient and other healthcare communities in our evaluation process.

Read our recent blog posts on this work. We welcome your feedback on our evaluation work - Email info@pcori.org with inquiries or comments about our activities and progress.

Posted: November 7, 2014; Updated: December 9, 2014

The Evaluation Overview and Framework (click to view)
[Revised December 9, 2014]

For more detail, please visit our evaluation webpages at

http://www.pcori.org/content/evaluating-our-work

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Our Dashboard

Available on our website and a hard copy is in your folders

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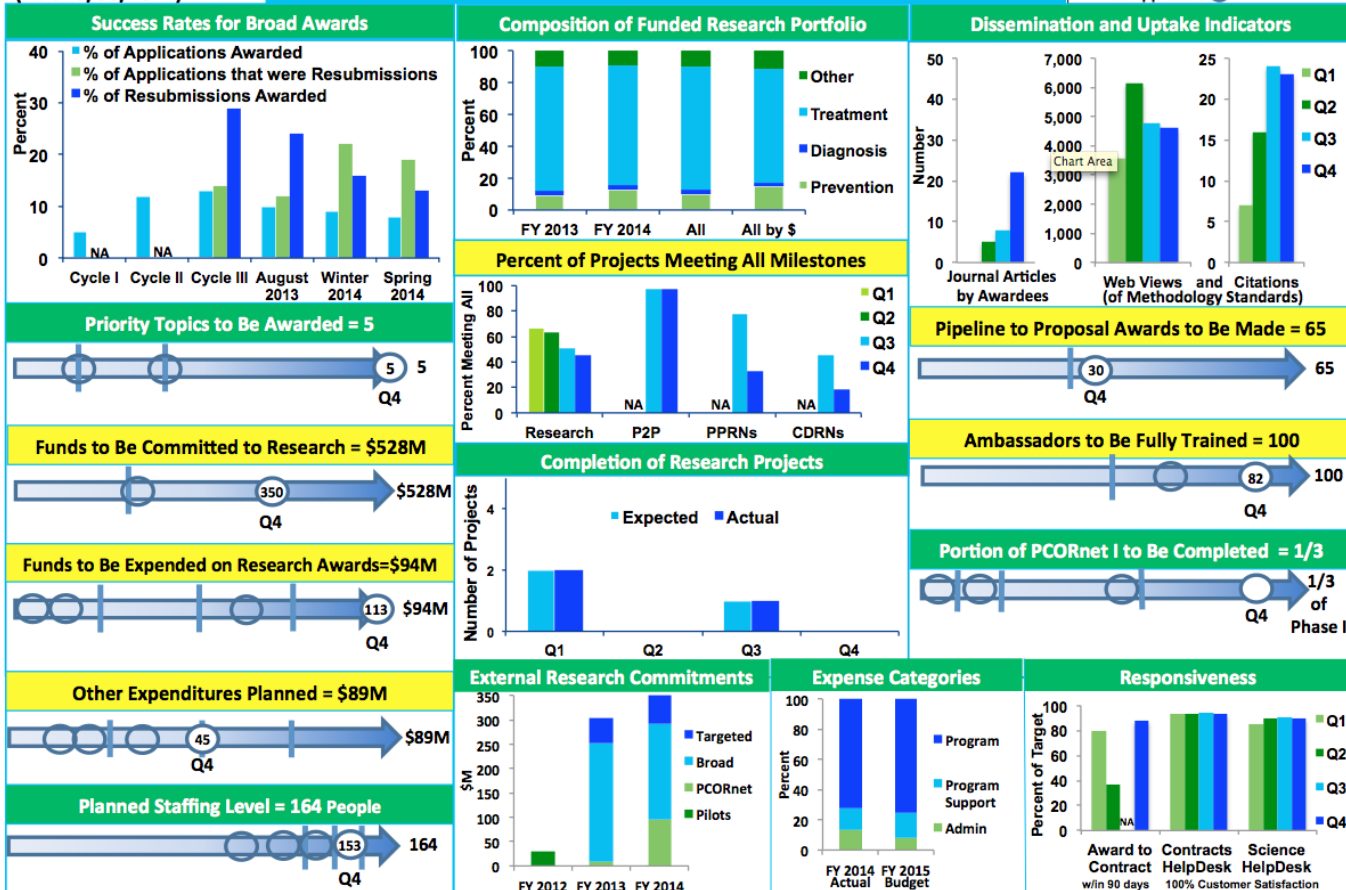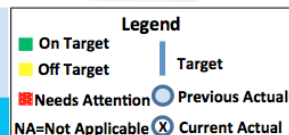
Our Evaluation Framework organizes our questions and outlines how we will answer them
General Questions (Specific versions depending on focus)

Now	Mid Term	Long Term
Are we ***doing*** what we said we would? • What are we doing? • How well are we doing it? • Are we on track?	Are we reaching our ***goals***? • Producing useful information? • Speeding its uptake? • Influencing research?	Are we having an ***impact***? • Better-informed health decisions? • Better health care? • Improved health outcomes?

How do the various components of PCORI's approach contribute to reaching its goals and achieving its mission? ***What difference does "Research Done Differently" make?***

- Patient-Centeredness
- Engagement
- Emphasis in Criteria on Usefulness and Changing Practice
- Methods and Infrastructure Development
- Dissemination and Implementation

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Evaluation Framework:
Model for Evaluating the Overall Impact of PCORI

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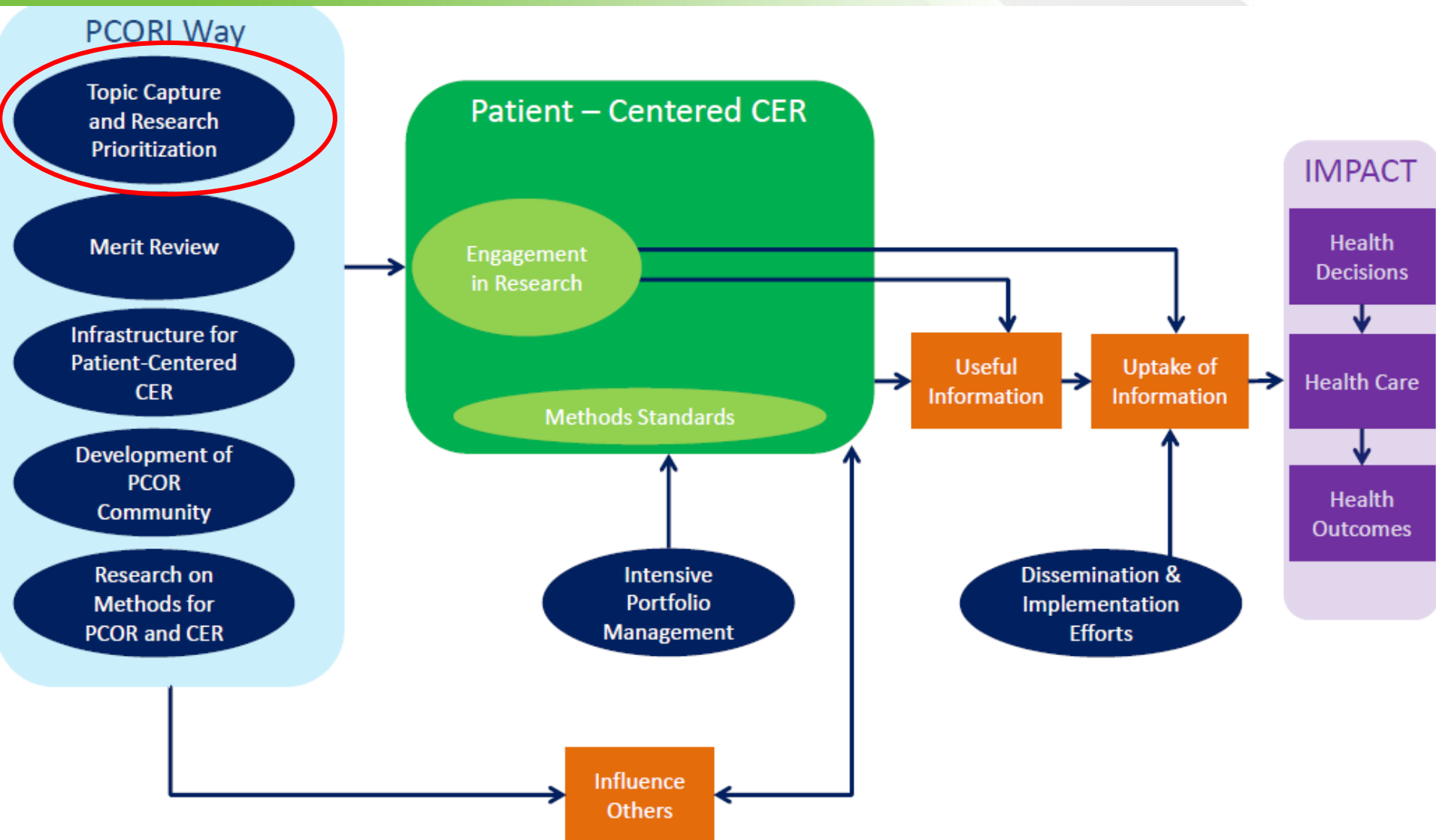
Topic Capture and Research Prioritization Evaluation Questions

1. What is the impact of PCORI's approach to Topic Generation, Prioritization, and Selection (inclusion of patients and other stakeholders, methods for ranking and selection) on:

   - *perspectives incorporated* into topic selection process,
   - the *topics selected* for funding, and
   - new research *gaps identified*?

2. Compared to broad funding announcements, what is the **effect of targeted funding announcements on the *usefulness, use, cost, and impact of information***?

3. Compared to funding opportunities developed with input from scientists only, what is the **effect of funding opportunities developed with multi-stakeholder input on the *impact of information***?

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Evaluation Framework:
Model for Topic Capture and Research Prioritization
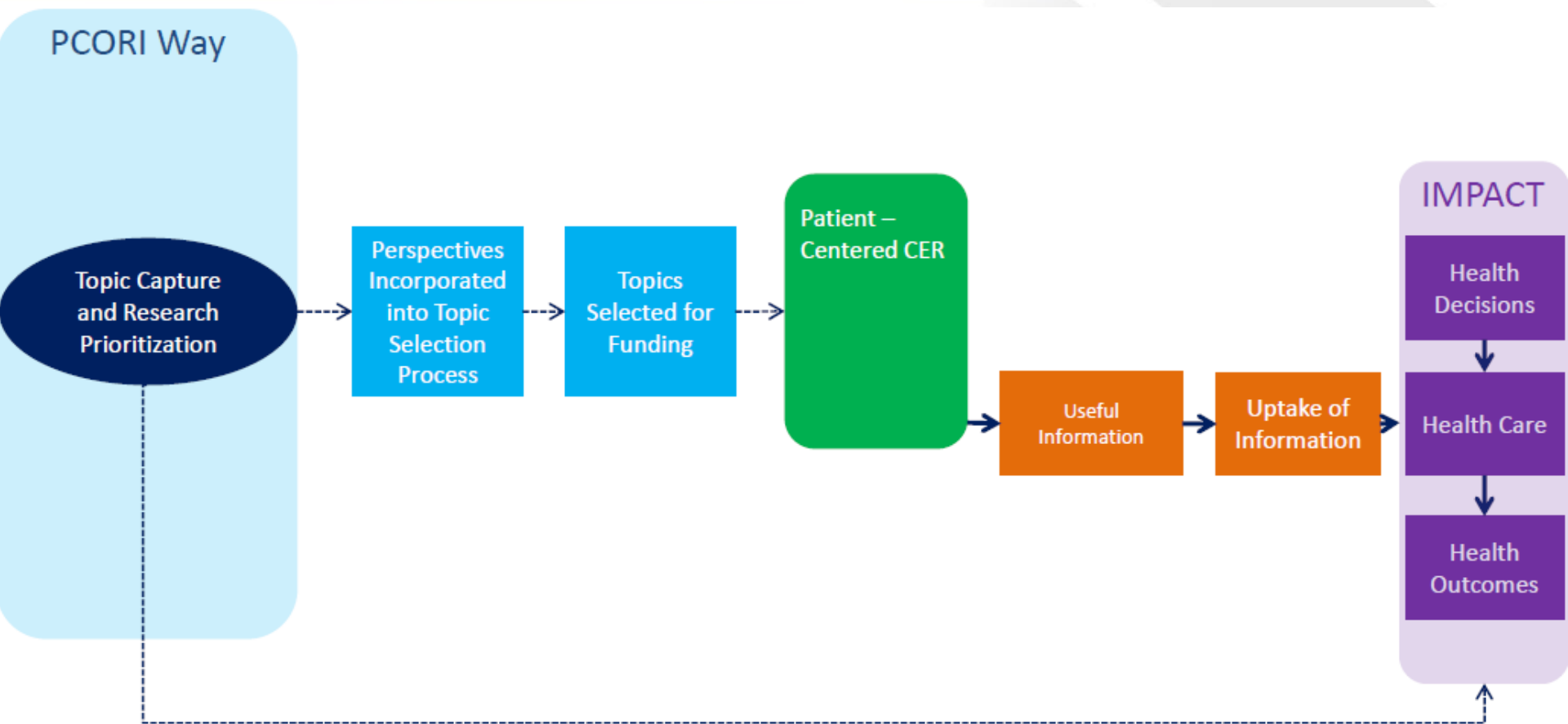
Evaluation Framework:
Topic Capture and Research Prioritization

Table 1. Evaluation Questions for PCORI's Approach to Topic Capture and Research Prioritization (TCRP)

Question	Metrics/indicators	Methods	Sources
1. **What is the impact of PCORI's approach to *Topic Capture, Prioritization, and Selection* (inclusion of patients and other stakeholders, methods for ranking and selection) on:**			
a. *perspectives incorporated into topic selection process,*	• stakeholder perceptions of TCRP process, such as, perceived influence on the content of the topic database • relative contributions of the patients and stakeholders in ranking submitted topics • advisory panelist perceptions of the TGRP process • indicators of dynamics in the panel discussion • number and type of stakeholders submitting topics to PCORI	• focus groups • surveys • database review	• stakeholder communities • PCORI advisory panel survey data • PCORI topic database
b. *the topics selected for funding, and*	• PCORI projects filling identified research gaps, such as IOM and AHRQ identified research gaps	• database review	• PCORI topic database
c. *identifying new research gaps?*	• types of gaps documented as important to patients and other stakeholders that were not previously identified • how many submitted topics score well on the topic selection patient-centeredness criterion	• database review • document review	• PCORI topic database • PCORI administrative data
2. **Compared to broad funding announcements, what is the effect of targeted funding announcements on the:**			
a. *impact of information, and*	• degree of impact on health decisions, quality of health care, and health outcomes	• comparison of PCORI projects funded through broad funding announcements to projects funded through targeted funding announcements	• PCORI Administrative Data

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Evaluation Framework:
Topic Capture and Research Prioritization

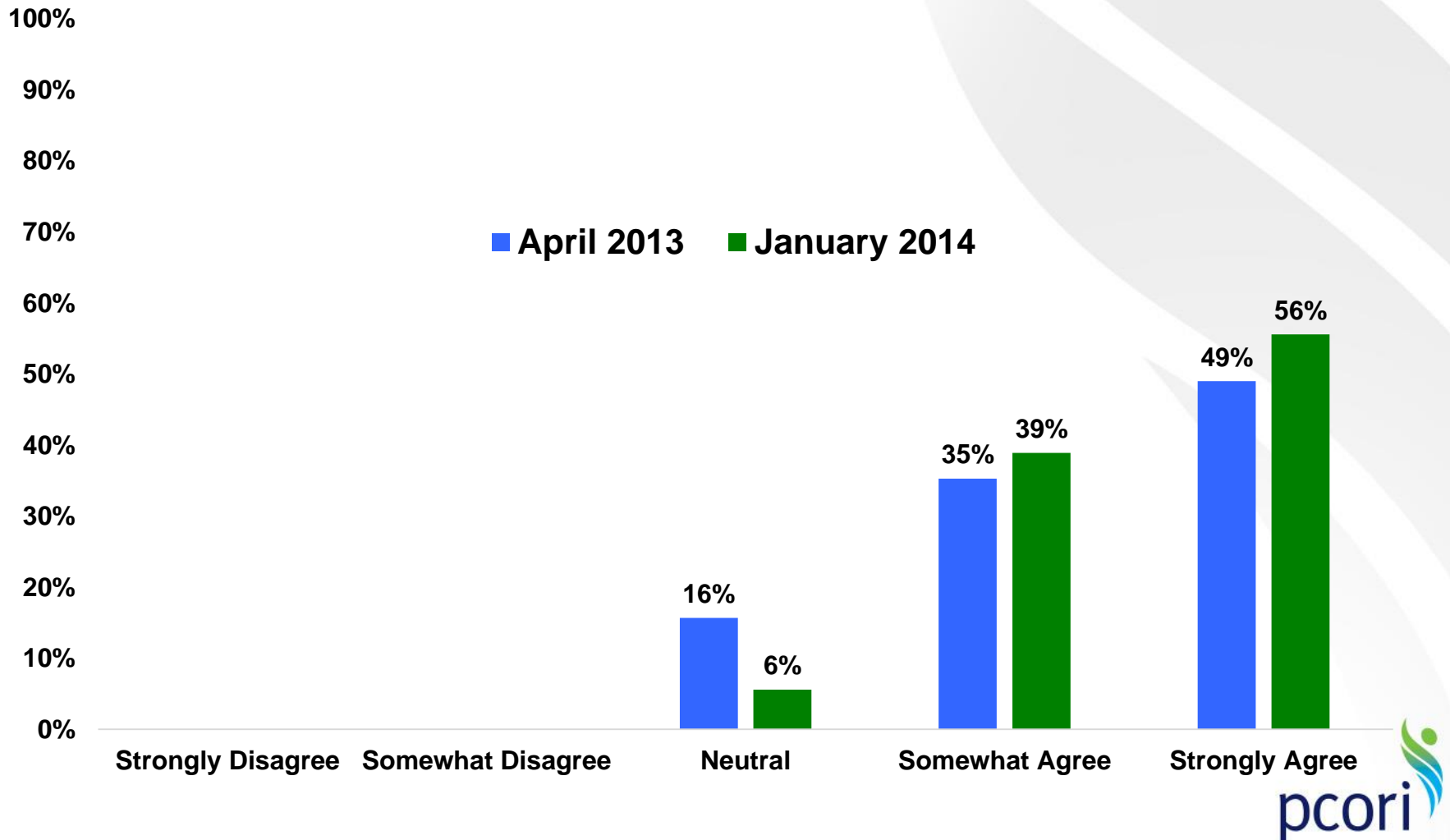| Question	Metrics/indicators	Methods	Sources
b. *core measures: usefulness, use, and cost of information?*	• (core metrics, see 12a,b&c)	• test associations between systematic data for TCRP and usefulness, use, and cost	• (core sources, see 12a,b&c)
3. Compared to funding opportunities developed with input from scientists only, what is the effect of funding opportunities developed based on multi-stakeholder input on the			
a. *impact of information?*	• degree of impact on health decisions, quality of health care, and health outcomes	• comparison of PCORI funding announcements developed with multi-stakeholder input to funding announcements from other organizations that incorporate scientist-input only	• PCORI administrative data • publicly and possibly privately (i.e. pharma funding for CER) available funding information

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What are we learning about Advisory Panels?

- We survey our Advisory Panel members after their meetings

- Two cycles so far have included our Addressing Disparities Panel

- More on this in the general session

Cycle	April 2013	January 2014
Overall Response Rate	81% (51/63)	44% (28/63)

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Survey item:
PCORI's method for research topic prioritization will help PCORI fund research that can inform healthcare decisions by patients

Bar chart comparing April 2013 (blue) and January 2014 (green):

Response	April 2013	January 2014
Strongly Disagree	—	—
Somewhat Disagree	—	—
Neutral	16%	6%
Somewhat Agree	35%	39%
Strongly Agree	49%	56%

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Tracking Progress toward Our Goals

Available on our website and a hard copy is in your folders

Goal 1: Useful Information

Substantially increase the quantity, quality, and timeliness of _useful_, trustworthy information available to support health decisions

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Striving for a Portfolio of Useful Studies: Six Steps

1) Find out what people think makes information useful for their health decisions

2) Develop draft usefulness criteria accordingly

3) Apply to some studies in our portfolio

4) Crosswalk with our other criteria

5) Refine criteria and apply to some more studies

6) Apply what we learn to strengthen our criteria, processes, and guidance for selecting topics and studies to fund

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We were on Step 2 when last we met: Draft Usefulness Criteria

- Rationale/Need for the Research:
  - People who would use the information have been identified
  - Specific uses for the information have been identified
  - People who would use the information are asking the question

Capture *Potential* for Usefulness (apply at funding decision)

- Characteristics of the Research Question:
  - Study compares options that are relevant for the people who would use the information
  - Study assesses the outcome(s) that matter for the people who would use the information

- Real-world Application of the Results:
  - Results could / do provide a clear answer to the question
  - Results could be / are timely and durable
  - Results could be / are tailored to individuals or subgroups
  - Results could be scaled / spread beyond the study setting

Capture *Potential* for Usefulness and *Actual* usefulness (apply at funding decision **and** dissemination decision)

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Issues Raised by You and Others

- *Fair* to apply criteria retroactively?

- *Credible* if PCORI judges its own projects?

- *Feasible* to examine entire funded portfolio, let alone applications?

- *Redundant* given other criteria and reviews?

- *Worthwhile* relative to other efforts?

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Observations from our initial attempts to apply draft criteria (Step 3):

- Applying criteria not as straightforward as we had anticipated
- Needed to have the full application
  - Applying criteria took more than an hour per application on average
  - Much of what we were looking for was in Dissemination section
- Review Summary was helpful
  - We did not feel equipped to second-guess reviewers
- "Not Clear" a frequent choice
  - Often had to "read-into" what was written in the application
- Generally only moderate agreement among reviewers (at least 2 per application)
  - Discussion often necessary to come to agreement
- Many "End-Users" in addition to patients
  - Can make interpretation/application of criteria difficult
  - We did not feel equipped to identify all of the end-users, whether any were "primary", or what their interests might be
- "Usefulness" closely related to but also distinct from "Patient-centeredness" and "Significance" and "Potential to Improve Healthcare and Outcomes"

First round: 12 high-ranking but unfunded applications; Second round: 5 funded applications

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Results of Crosswalk with Other Criteria (Step 4)
PCORI Topic Selection Criteria, Merit Review Criteria, Methodology Standards

Concept	Proposed Usefulness Criterion	Overlap with Other PCORI Criteria
User-Driven	End-Users Identified	◆◆
	Use Identified	◆◆
	End-Users Asking for the Information	◆
	End-Users Committed to Using the Information	◆
User-Focused	Options Compared Relevant for End-Users	◆◆
	Outcomes Assessed Matter to End-Users	◆◆
Real-World Use	Clear, Definitive, Actionable Results	◆◆◆
	Timely and Durable Results	◆◆◆
	Results Tailorable to Individuals and Subgroups	◆◆◆
	Results Can Be Scaled and Spread	◆◆

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After initial attempts to apply draft usefulness criteria (Step 3) and cross-walking them with our other criteria (Step 4), we concluded:

- Much of what end-users are looking for, which we attempted to reflect in our Usefulness Criteria for identifying studies with high potential to yield information inherently useful for decision-makers, is captured partly or wholly in one or more of our

  - Topic Selection Criteria (for example, Timeliness, Durability of Information)
  - Merit Review Criteria (for example, Patient-Centeredness)
  - Methodology Standards (for example, Identify and Assess Subgroups)

- Not as well captured is

  - whether the **demand for the information** is coming from end-users and the degree to which they **have committed to using it** when it becomes available

  - whether the study is focused on end-users' needs **when some of the primary end-users of the information are not patients***

*Regardless of who the primary end-users are, all studies have to be patient-centered, that is, focused on the options and the outcomes that matter to patients

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We thought it boiled down to two concepts that were not addressed directly by our existing criteria

User-Driven

- At a minimum, the application identifies the primary end-users and end-uses of the information that the study will yield

- Optimally, the application demonstrates that the primary end-users are demanding and committed to using the information that the study will yield

User-Focused ("User-Centered")

When primary end-users of the information that the study will yield are not patients, *in addition* to demonstrating the patient-centeredness of the options to be compared and the outcomes to be assessed, the application demonstrates that

- The options compared are those most relevant for the end-users

- The outcomes assessed are those that matter to the end-users

Step 5: Refine Criteria and Apply Again

- Narrowed criteria to "User-Driven" and "User-Focused" and refined them

- Used our Stakeholder Categories as end-user categories and applied the criteria individually to each type of end-user

- Applied them to some funded applications
  - 3rd round: Same 5 funded applications as 2nd round
  - 4th round: 18 additional funded applications

- Examples of our initial results follow. A few caveats:
  - Generous in our application of the criteria
  - Hot off the press
  - Further analysis needed – some puzzling results

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End-Users Identified
N = 18 Studies from Winter and Spring 2014 Cycles
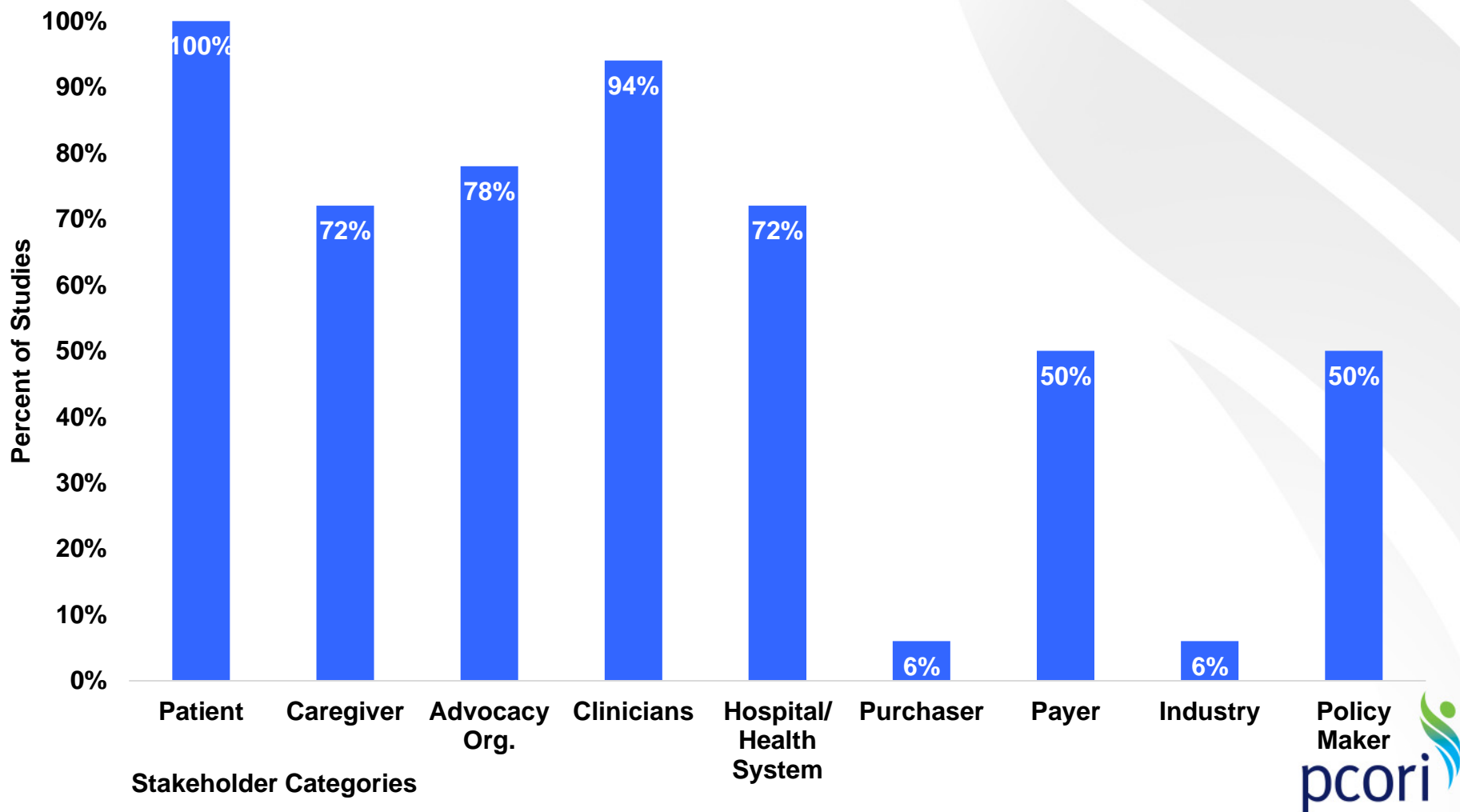
Patients Identified as End-Users
N = 18 Studies from Winter and Spring 2014 Cycles

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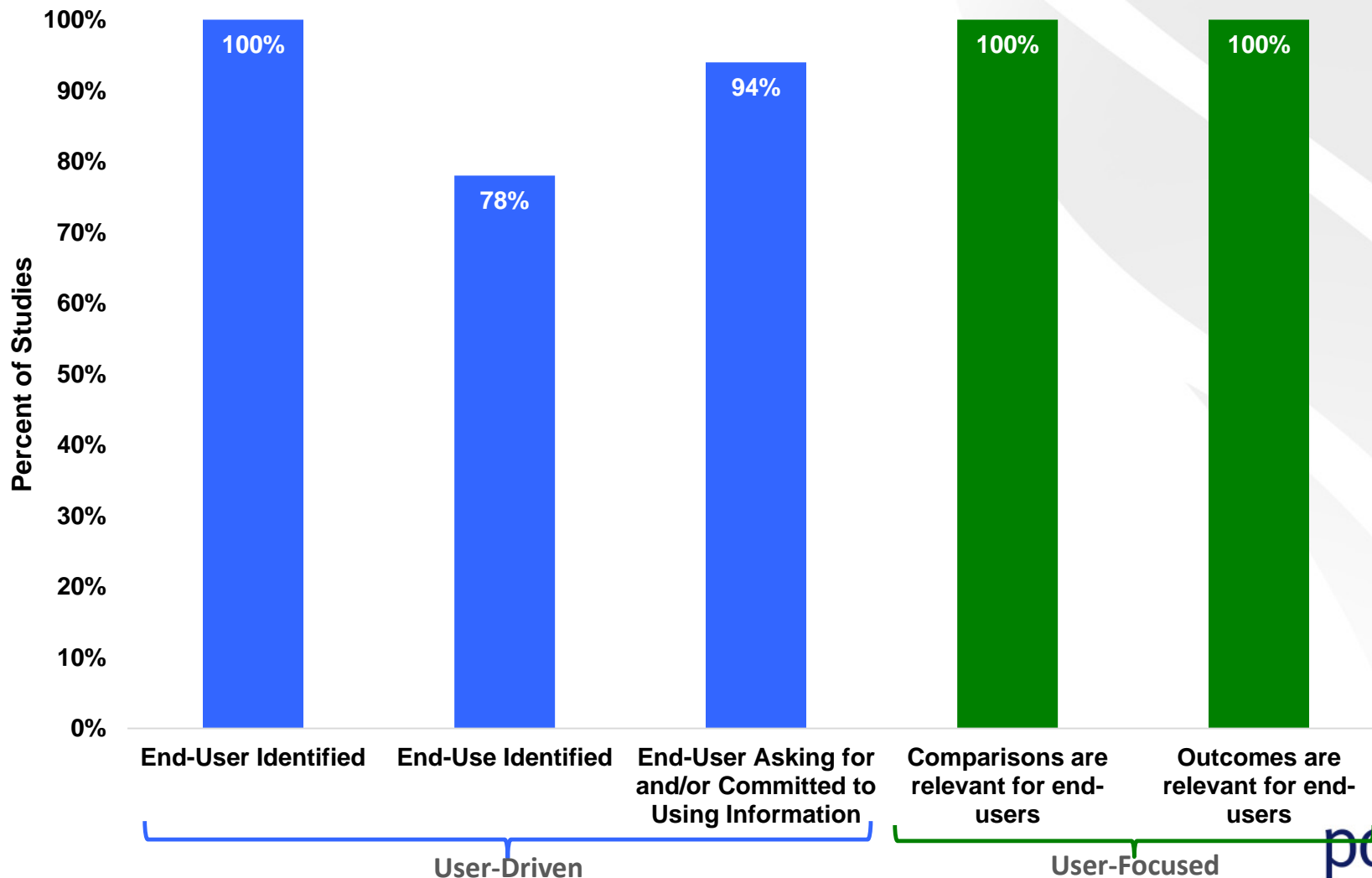
Advocacy Organizations Identified as End-Users

N = 18 Studies from Winter and Spring 2014 Cycles

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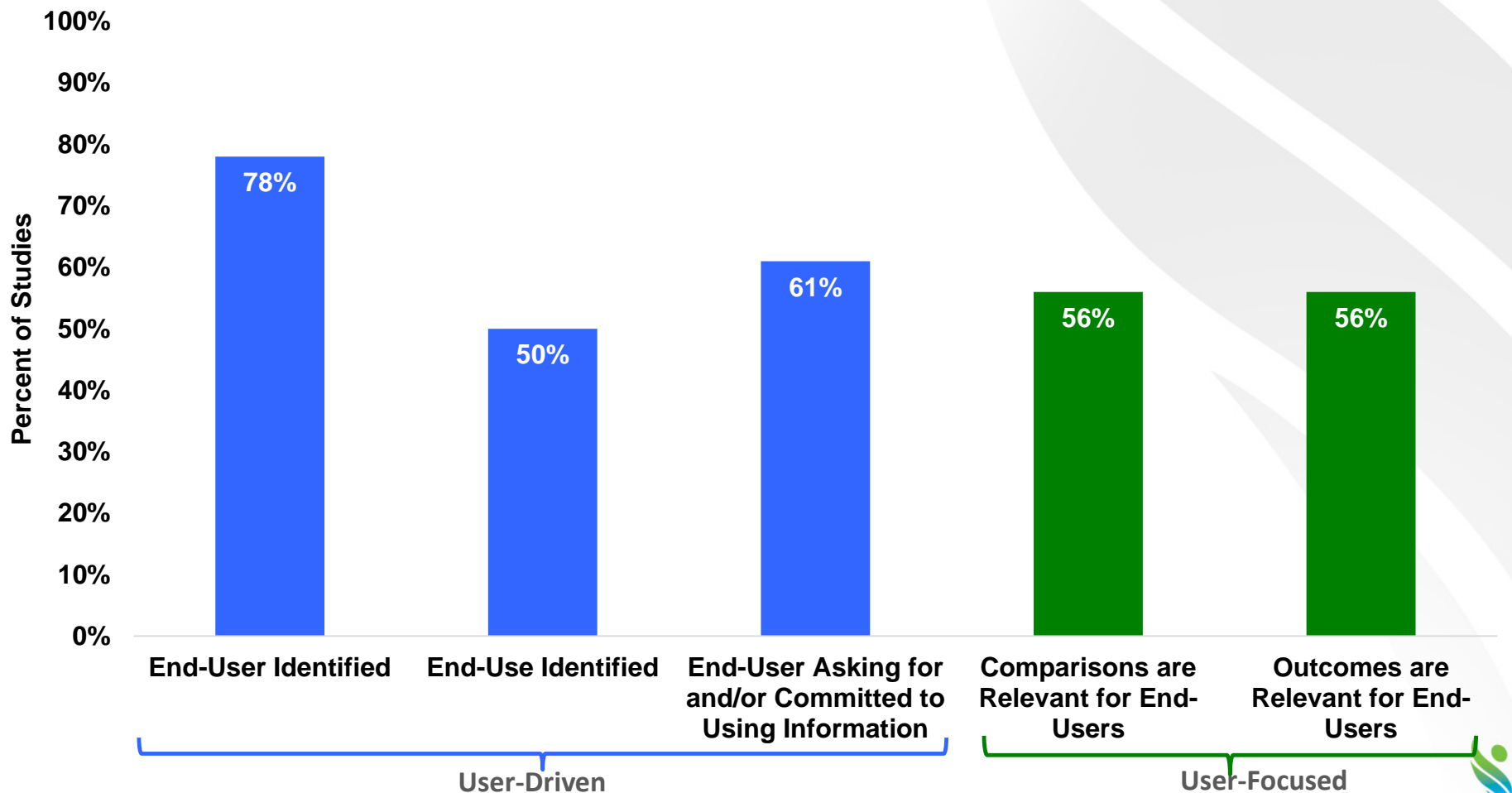
Hospitals/Health Systems Identified as End-Users
N = 18 Studies from Winter and Spring 2014 Cycles

Percent of Studies

Category	Value
End-User Identified	72%
End-Use Identified	44%
End-User Asking for and/or Committed to Using Information	50%
Comparisons are Relevant for End-Users	33%
Outcomes are Relevant for End-Users	39%

User-Driven

User-Focused

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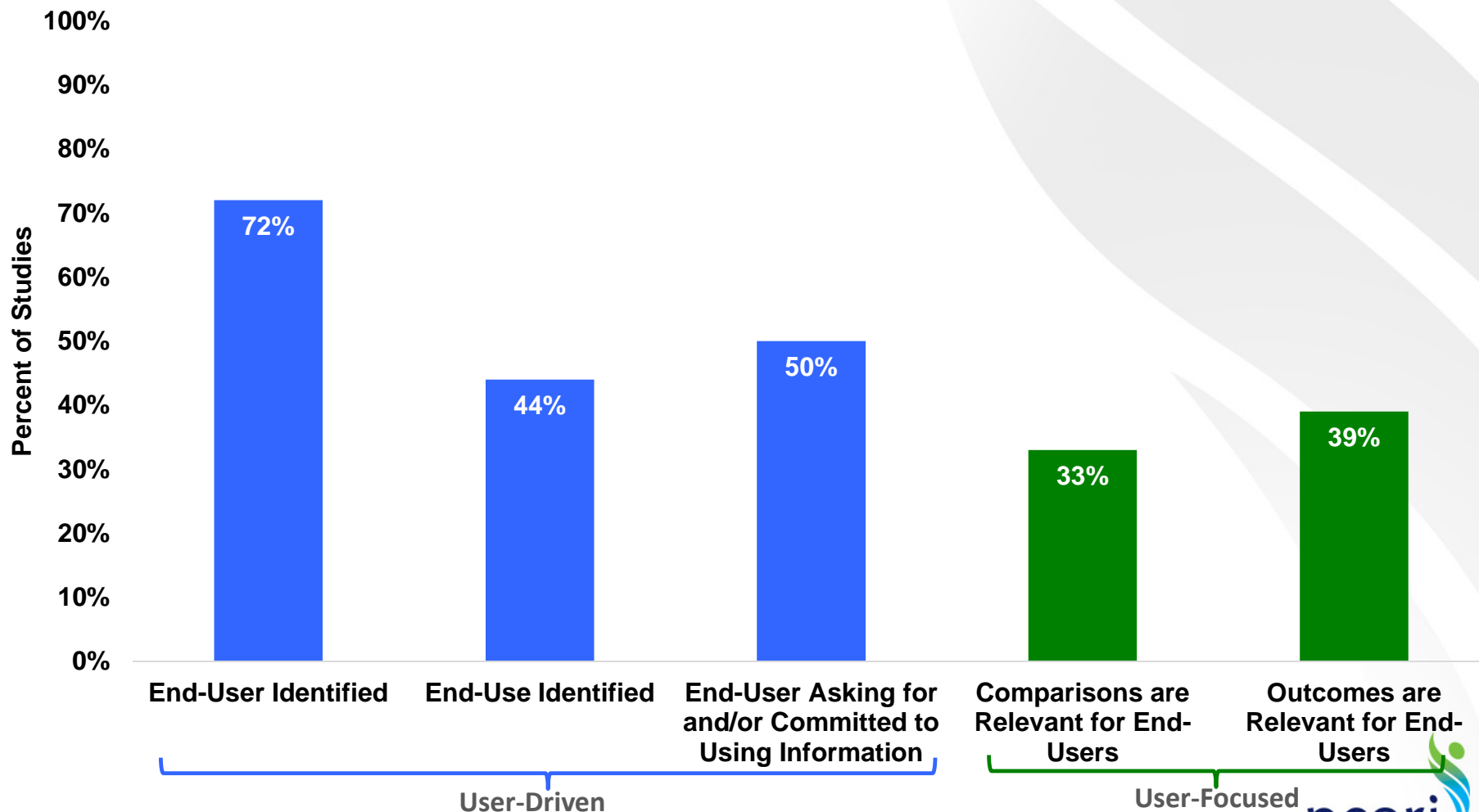
Some Further Observations

Mulling these over to determine how best to proceed with usefulness:

- Appears that sometimes patients are thought of as **beneficiaries** of the information rather than the users of it (the **decision-makers**)

- Depending on specific study and criteria, **stakeholders** may not be the same as **end-users**

- Seems like sometimes focus is on **use of the intervention** under study rather than use of the **information** for decision-making

- Often a **series of decisions/end-users** before it would get to the clinician/patient

- Comparators/outcomes most relevant for **other end-users** could be different from those most relevant for patients/clinicians

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Step 6 – We are thinking that we should:

- Examine our current criteria, standards, and processes for **opportunities to emphasize end-users** (decision-makers) and end-use (decision-making) of information

- Give some more thought to the possible difference between **stakeholders and end-users** and when it might be relevant

- More directly **ask applicants to demonstrate** that their studies are user-driven and user-focused

- Examine whether **engagement of end-users in** the identification of the study question and **development of the application** makes a difference to its focus on end-users*

- Consider the **balance in our portfolio** among studies that address the needs of different kinds of end-users

- Consider the **proportion of our portfolio that could be less user-driven** (less "pull") because we think the topic is nonetheless important and are willing to devote additional resources to "pushing" it

*We already require engagement in the study itself, but not in the development of the letter of intent or funding application

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Original Plan for Assessing Usefulness: Apply Criteria, Ask People, Monitor Use

How do the studies we fund measure on usefulness criteria?

Would/Do people find information from PCORI studies useful?

Is the information from PCORI studies being used? By whom? How?

Refine Usefulness Criteria and Incorporate into Funding Decisions

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For Discussion – General

Please tell us *what you would like to know about PCORI's work* so that we can be sure we are answering, or at least thinking about ways to answer, your questions about:

- *How well* we are working

- Whether we are progressing toward *our goals*

- *What difference* our engaged and patient-centered approach is making

- What *impact* we are having

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For Discussion – Specific

- What would you like to ***focus on next***?
  Some possibilities mentioned today:

  - More thinking about how the work of our Advisory Panels fits into our conceptual model

  - How best to evaluate: the work of our Advisory Panels, topic capture efforts, topic prioritization process

  - What we have learned so far from our surveys of Advisory Panelists, study of usefulness, other evaluation work

  - How best to evaluate the influence/impact of our topic prioritization and other methods

- What is ***your preferred process*** for us to seek your assistance and share results with you?

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Lunch

We will resume at 1:00 p.m.

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PCORI Asthma Evidence to Action Network

January 13, 2015

Addressing Disparities Advisory Committee
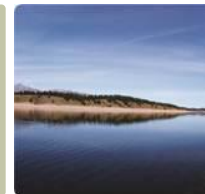
Presentation overview

- Why create a network?

- Goals of the Asthma E2AN

- The Asthma E2AN Team

- The Abt Team approach

  - Conduct a Needs and Strengths Assessment

  - Co-create a Shared Vision

  - Engage Network Participants

  - Build Relationships and Collaboration

  - Engage End Users and Facilitate Dissemination

  - Evaluate and Improve

Why create a network?

"Maybe we need different types of clubs for different types of situations."
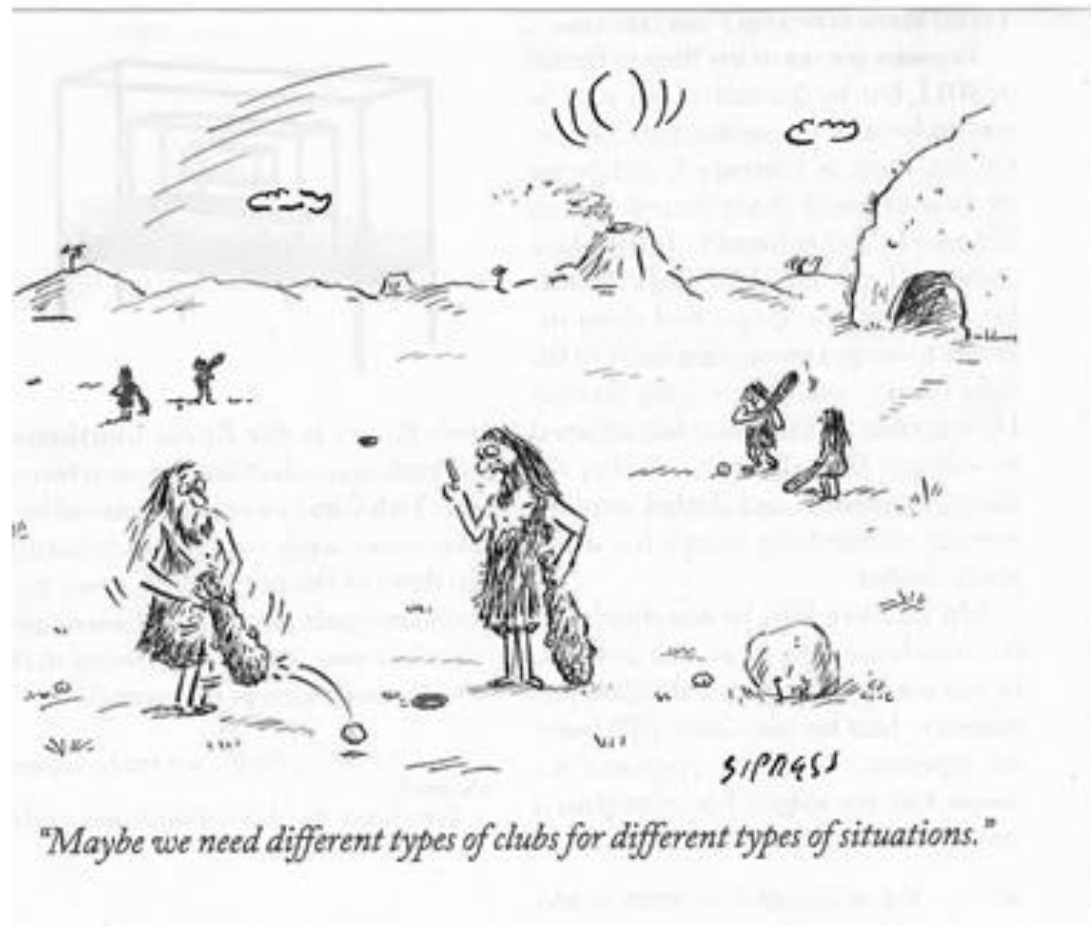
Health care networks

All kinds of networks are being created in health care

- Quality Improvement Learning Collaboratives

- Research Networks

- Learning Communities

- *AND NOW*….PCORI Evidence to Action Networks (E2AN)

Goals of the Asthma E2AN

- Foster cross learning among network participants

  - Share interim findings

  - Uncover shared questions and methods

  - Apply multiple perspectives and disciplines to the research

- Encourage innovative technologies and techniques that further patient and stakeholder engagement

- Disseminate research findings to end users (patients, stakeholders, policy makers, national decision makers)

- Ultimately, improve patient care for asthma

The Asthma E2AN team

- PCORI

- Asthma awardees

- Abt Associates

- MacColl Institute for Health Care Improvement

- gravitytank

- Expert Consultants in Asthma

Seattle - King County Public Health Department

Puget Sound Asthma Coalition

University of Utah

San Diego State University Research Foundation

Nuestra Salud, LLC

The Chicago Community Trust

University of Illinois at Chicago

Washington University, St. Louis

Mount Sinai School of Medicine

University of Pennsylvania

Children's Research Institute, Washington, D.C.

Carolinas Healthcare System

Baylor College of Medicine

Program Area

- Addressing Disparities
- Clinical Data Research Network
- Communication and Dissemination Research
- Improving Healthcare Systems
- Pipeline to Proposal Tier 1

- **Imperial County Asthma CER Project**
  San Diego State University Research Foundation |
  John Elder, MPH, PhD

- **Guidelines to Practice (G2P): Reducing Asthma Health Disparities through Guideline Implementation**
  Seattle - King County Public Health Department |
  James Krieger, MD, MPH

- **The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) for African Americans**
  Baylor College of Medicine | Winifred Hamilton, MS, PhD

- **Preference and effectiveness of symptom based adjustment of inhaled corticosteroid therapy in African American children**
  Washington University, St. Louis | Kaharu Sumino, MD, MPH

- **The Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes (CHICAGO) Trial**
  University of Illinois at Chicago | Jerry Krishnan, MD, PhD

- **Parent-centered innovations to improve adherence in at-risk youth with asthma**
  Children's Research Institute, Washington, D.C. | Stephen Teach, MD, MPH

- **Using IT to Improve Access, Communication and Asthma in African American and Hispanic/Latino Adults**
  University of Pennsylvania | Andrea Apter, MD, MA, MSc

- **Clinic-Based vs. Home-Based support to improve care and outcomes for older asthmatics**
  Mount Sinai School of Medicine | Alex Federman, MD, MPH

- **Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN)**
  The Chicago Community Trust | Terry Mazany, MA, MBA

- **Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention**
  Carolinas Healthcare System | Hazel Tapp, PhD, BSC

- **Redesigning Ambulatory Care Delivery to Enhance Asthma Control in Children**
  University of Utah | Flory Nkoy, MD, MS, MPH

- **Puget Sound Asthma Coalition: A Community, Clinical, and Academic Partnership**
  Puget Sound Asthma Coalition | Julie Postma, PhD

- **The Hispanic Family Asthma Outcomes Research Network**
  Nuestra Salud, LLC | Jorge Otero

Expert consultants

Michael Cabana, MD, MPH
PI, UCSF Pediatric AsthmaNet Research Center

Michael B. Foggs, MD, FACAAI
President (2013-2014), American College of
Allergy, Asthma & Immunology

Michael Rich, MD, MPH
Director, Center on Media and Child Health,
Boston Children's Hospital

The Abt Team approach

- Conduct needs and strengths assessment
- Establish shared vision for network
- Engage awardees, including patients, caregivers and stakeholders
- Build Relationships and collaboration
- Engage end-users; facilitate dissemination
- Evaluate and improve
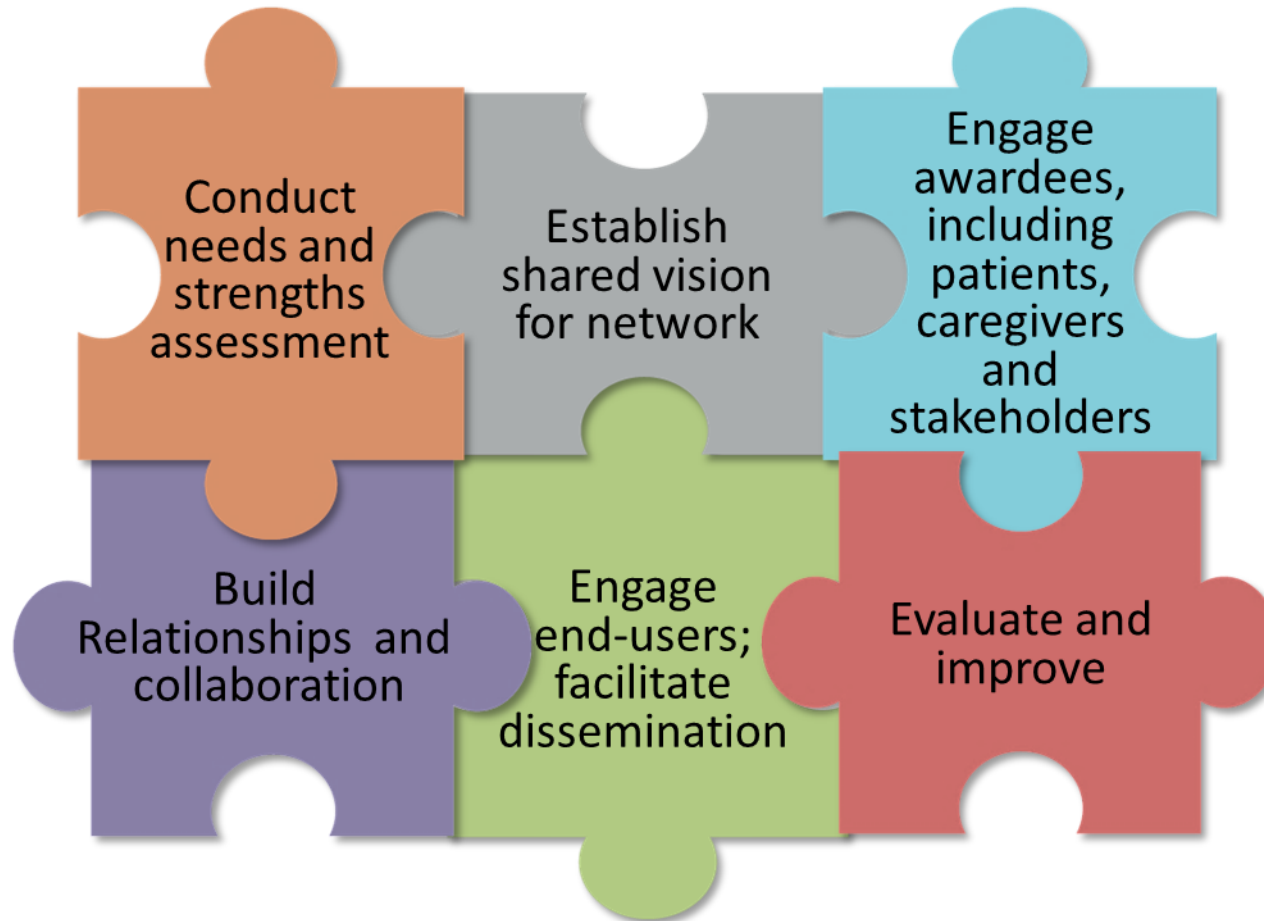
Needs and strengths assessment: Activities

- Introductory telephone calls with 13 research teams

- Web-based survey: 90 respondents of 137 invited (67% response rate)

- Review of administrative database; program materials such as grant proposals, quarterly progress reports, etc.

- *We will repeat the needs assessment annually*

Needs and strengths assessment: What have we learned? (preliminary)

- Teams have faced challenges:

  - Patient and stakeholder engagement, especially maintaining engagement over an extended time period

  - Building relationships with other organizations

  - Hiring for the project and staff turnover

- There is <u>great</u> interest in learning from each other

  - Desire for in-person meeting(s)

  - Desire to learn from <u>other</u> teams

- Desire for improved likelihood of next funding

- Desire to find ways to pool data; streamline measures

Needs and strengths assessment: What have we learned? (preliminary)

- Desire for input into the goals of the network

- Caution regarding time constraints, additional activities (burden)

- Teams mentioned that it may be difficult to find commonalities because their projects are different

- Concerns about sharing intellectual property

Needs and strengths assessment: What have we learned? (preliminary)

Web Survey Respondents by Project Role
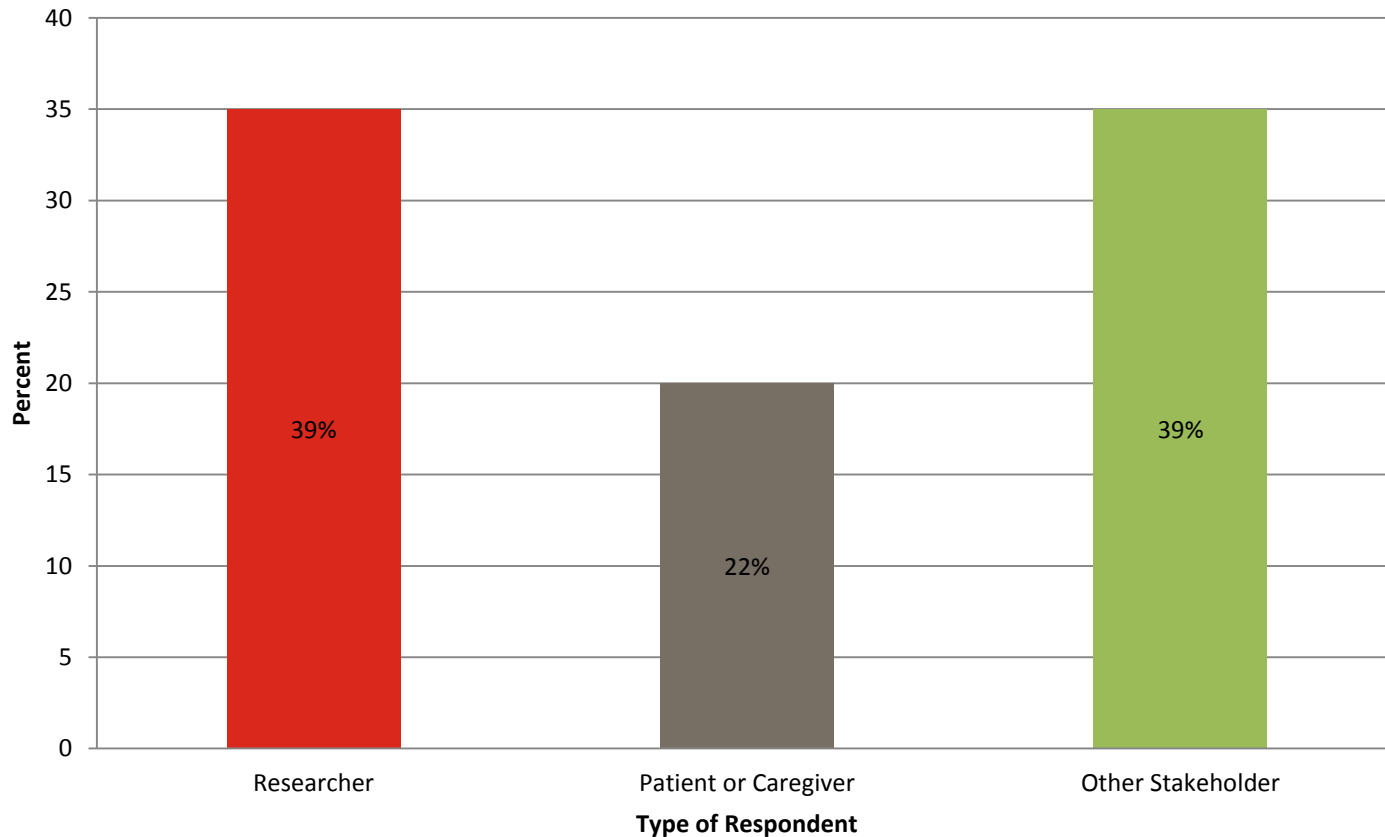
Needs and strengths assessment: What have we learned? (preliminary)

How Helpful Respondents Believe the E2AN May Be

Researcher: 3.8
Other Stakeholder: 4.2
Patient or Caregiver: 4.3

1 — Not at all helpful
5 — Very helpful
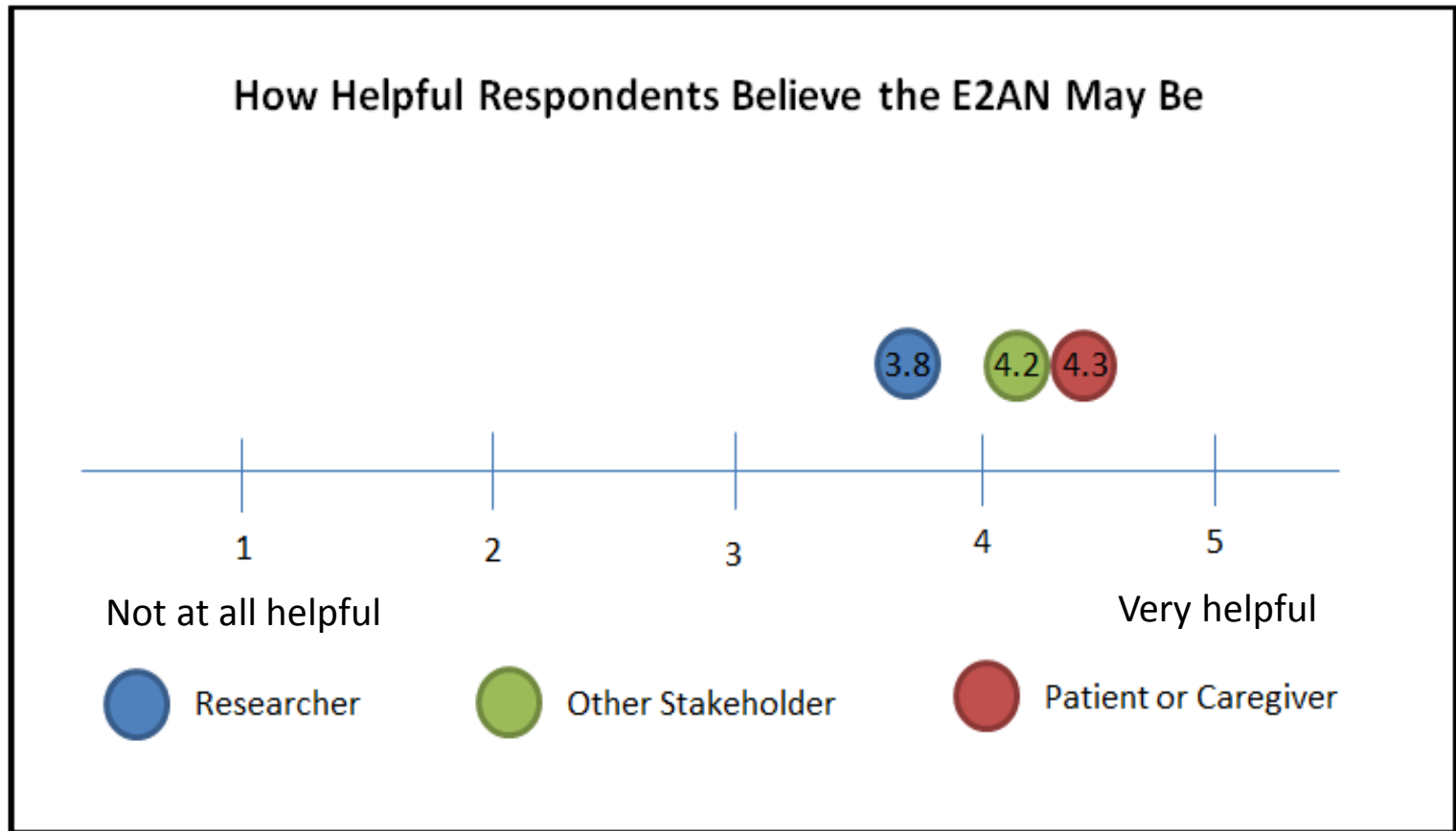
Needs and strengths assessment: What have we learned? (preliminary)

Potential Areas of Collaboration

Legend:
- Researcher (blue)
- Patient or Caregiver (red)
- Other Stakeholder (green)

Categories (top to bottom):
- Patient engagement/recruitment
- Research design/implementation
- Use of EHR for decision support
- Clinical guideline implementation
- Build PCOR infrastructure
- Care coordination
- Medication adherence/mgmt
- Dissemination activities
- Other
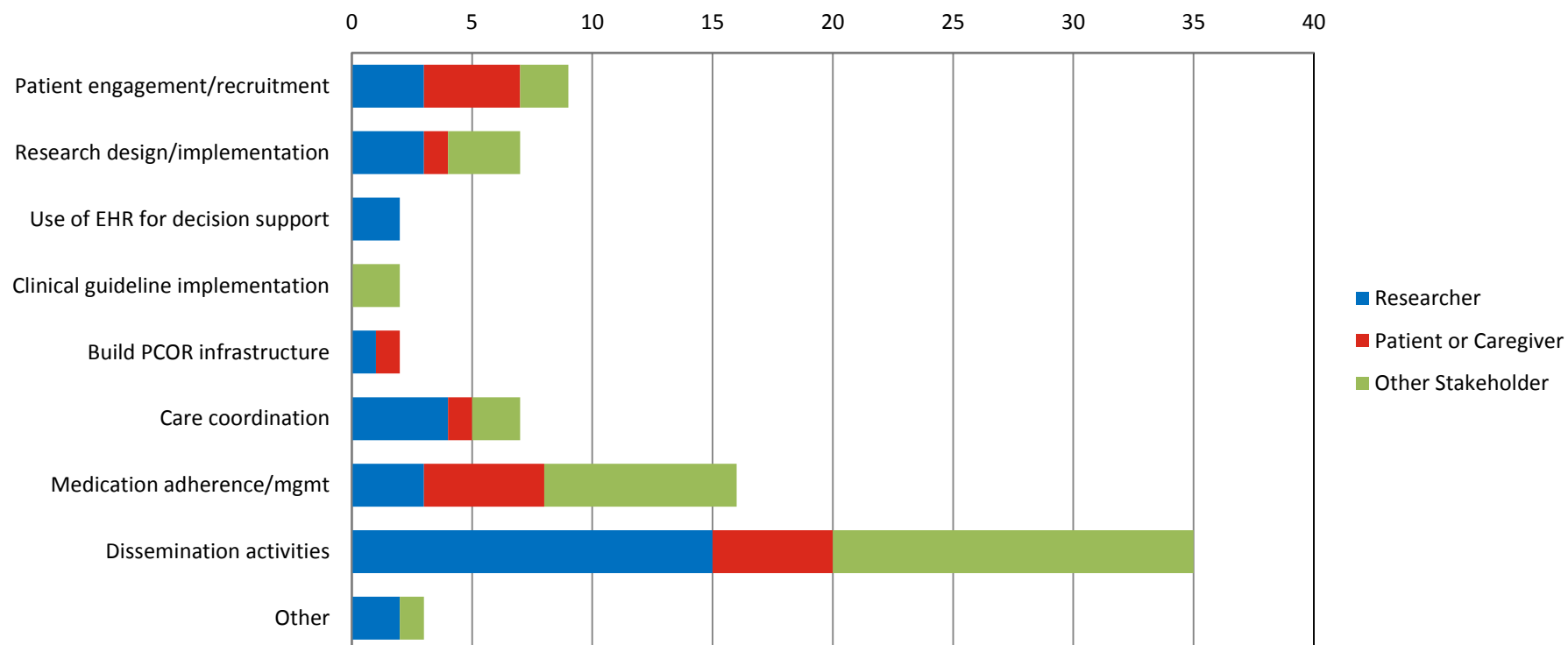
Needs and strengths assessment: What have we learned? (preliminary)

Stakeholders with Whom Network Participants Want to Connect

Legend:
- Researcher (blue)
- Patient or Caregiver (red)
- Other Stakeholder (green)

Categories: Asthma researchers, Prof societies and clinicians, Advocacy grps and policymakers, Payers/Insurers, Training institutions, Hospitals/health systems, Industry, Nat/regional QI initiatives, Other, None of the above
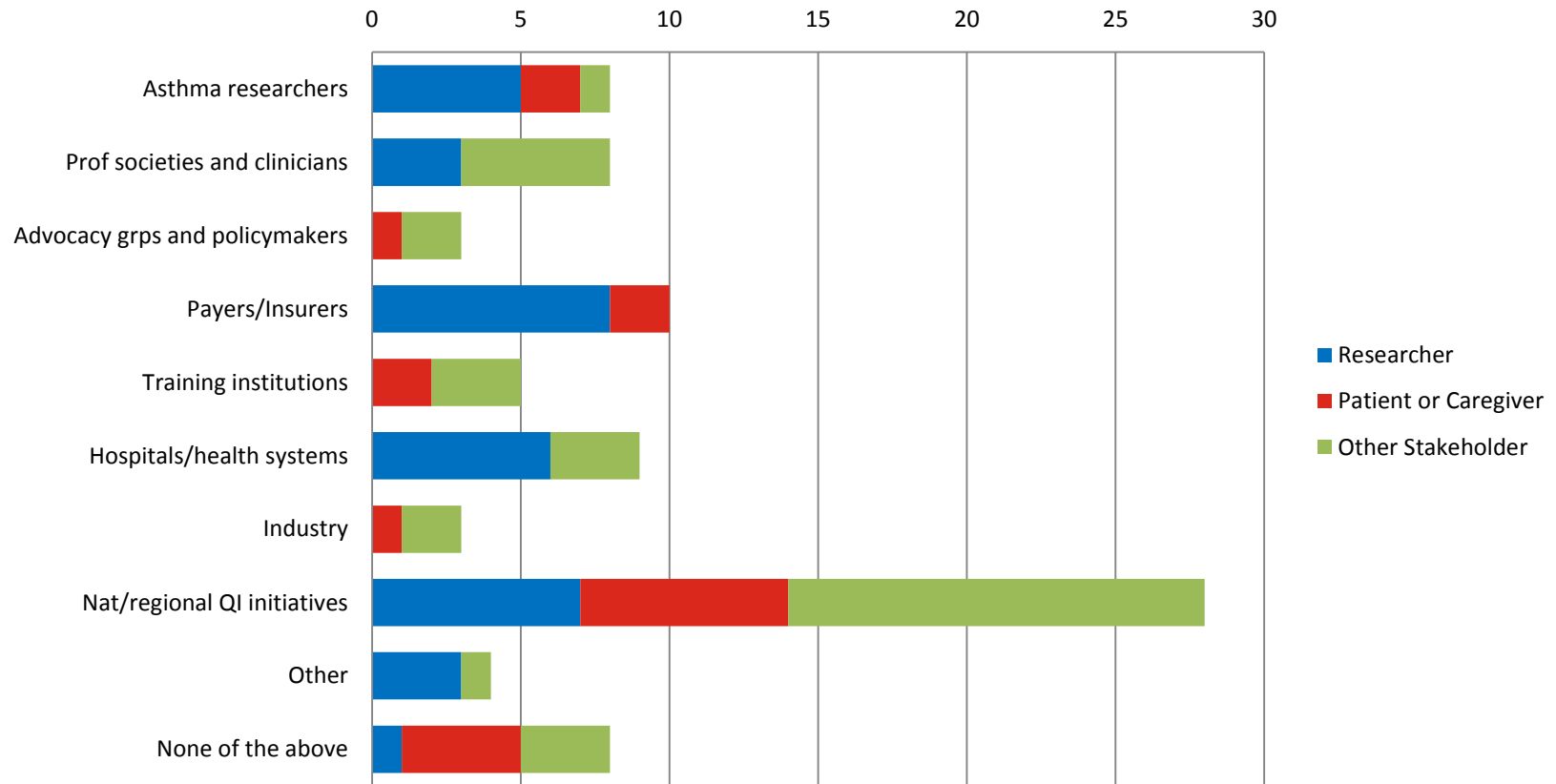
How will we utilize what we learn?

- Understand and tailor the network according to awardees' needs

- Provide technical assistance (methodological, content, engagement, publication support)

- Engage appropriate stakeholders and end users

- Facilitate peer-to-peer learning and collaboration

- Enhance dissemination and outreach, including overarching issues and findings across studies

Establish a shared vision

- PCORI has established Asthma E2AN goals but there are infinite ways those can be shaped

- In collaboration with the awardee teams we will create a logic model or shared goals for the network

- We will then prioritize activities that contribute to the shared vision
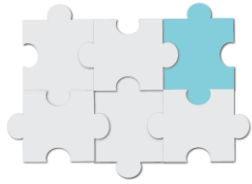
Engage awardees including patients, caregivers, and stakeholders

- Annual in-person meetings

  – Using interactive techniques (world café, fishbowl, panels, roundtables, visioning exercises, TED-like talks, etc.)

- Work groups

- Webinars

- Joint panel presentations at national meetings

- Publications and products

Build and strengthen relationships and collaboration

- Bring people together

- Bring awardee teams together

- Bring research ideas together

- Provide just-in-time technical assistance

Engage end users and facilitate dissemination

- **Identify and talk with end users external to the research teams**

    - **Understand their information needs and communication channels**

    - **Invite their participation in Asthma E2AN meetings and activities**

- **Develop a network project summary for stakeholders**

- **Produce a bimonthly newsletter**

- **Develop a summary of each award (plain language)**

- **Coach TED-like talks; 60 second videos; other innovative dissemination methods**

- **Create profiles of researchers, patients, awardees, stakeholders**

- **Publish achievement briefs (snapshots of collaborative activities)**

- **Develop stakeholder toolkits (for end users)**

- **Create a best practices handbook (key issues of interest to the network, e.g., ways to engage patients and families in asthma research)**
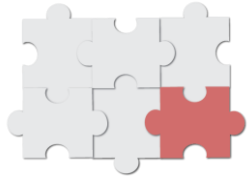
Evaluate and improve

- There are few rigorous evaluations of networks

- We are currently designing the evaluation which will involve multiple levels and activities

- We know what resources we are starting with and the outcomes we hope to achieve…but what lives in the middle is the "BLACK BOX"

Evaluation Domains and Mixed Methods Data Sources

DOMAIN 1
Collaboration and cross-learning among researchers, patients and other stakeholders

DOMAIN 2
Uptake and use of findings by end users external to project teams

DOMAIN 3
Interim resources and activities that enhance collaboration and lay the groundwork for use of study findings

Administrative Data

TA logs and assessments

Web analytics

Ongoing participant observation

Abt self-evaluation

Qualitative interviews

Annual meeting assessment

Annual web survey

Social network data

Mission of the Asthma E2AN:

- Facilitate collaboration and cross learning among awardees
- Link awardees with end-users to facilitate relevance and use of findings

INPUTS	ACTIVITIES	OUTPUTS	COLLABORATIVE PROCESS OUTCOMES	INTERMEDIATE OUTCOMES	LONGTERM OUTCOMES
• Prior collaborative activities • Individual Research Projects • PCORI funding and monitoring of research projects • PCORI funding of Abt E2NA infrastructure	• Annual meeting • Newsletters • Webinars • TA • Round tables • Poster sessions • Other	Engagement in Network - # contacts # participants in activities Analytic metrics Types of Network Participants across Activities – # researchers # patients # other stakeholders # end users Resource Outputs – # new collaborative working groups # new collaborative activities & resources	Value and influence of collaboration with respect to the interests and goals of researchers, patients and other stakeholders. Influence of collaboration on how the research is conducted. Knowledge and skills gained through network participation	End user interest in and intent to use findings Interim dissemination activities and tools used by researchers, patients and other stakeholders. Production of relevant findings for researchers, patients and other stakeholders	Uptake and use of findings among end users who are outside of PCORI-funded project teams

------------------------ **Logic Model for the Evaluation** ------------------------

Asthma E2AN: The Journey Begins
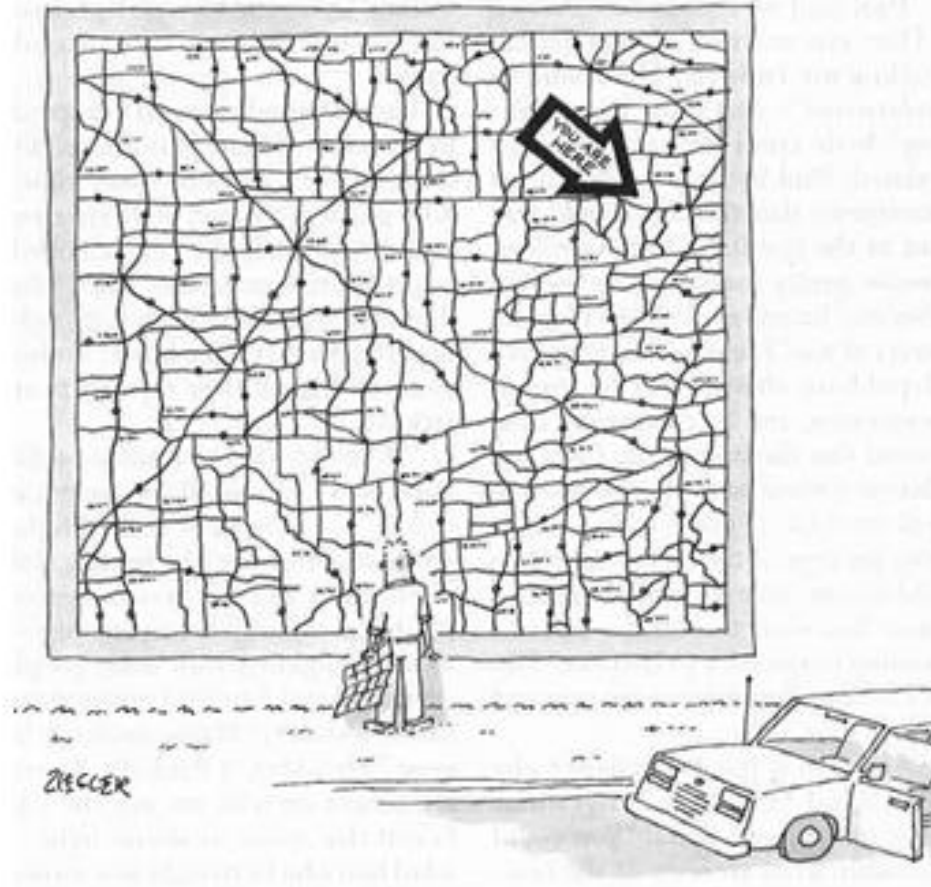
For more information contact:

Ayodola Anise

Program Officer

Addressing Disparities Program and Asthma E2AN

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Lisa LeRoy

Project Director, Asthma E2AN

lisa_leroy@abtassoc.com

(617) 349-2723

Parent-centered Innovations to Improve Outcomes in At-risk African American Youth with Asthma

Stephen J. Teach, MD, MPH
Chair, Department of Pediatrics
Children's National Health System
George Washington University School of Medicine
and Health Sciences

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

IMPACT DC
Improving Pediatric Asthma Care in the District of Columbia

Children's National ™

FINANCIAL DISCLOSURES

Commercial Interest	What was received?	For What Role?
Uptodate	Royalties	Section Editor
Novartis	Grant support paid to Children's National for NIH/NIAID funded PROSE study (NCT01430403)	Site Principal Investigator

Conceptual Model of Asthma

Child With Asthma

Individual & Social Factors
- Genetics
- Physical conditioning
- Socioeconomic status
- Stress
- Hormone levels

Medical Care Factors
- Access to care
- Quality of care
- Medication plan
- Adherence
- Technique
- Immunizations

Environmental Factors
- Allergen sensitization and exposure (dust, mold, roach, mice, pollen…)
- Viral infections
- Weather changes
- Air quality (irritants)

Level of Asthma Control

Low Morbidity
- Few Symptoms
- Few school absences
- **Few ED Visits**

High Morbidity
- Many symptoms
- Many school absences
- **Many ED Visits**

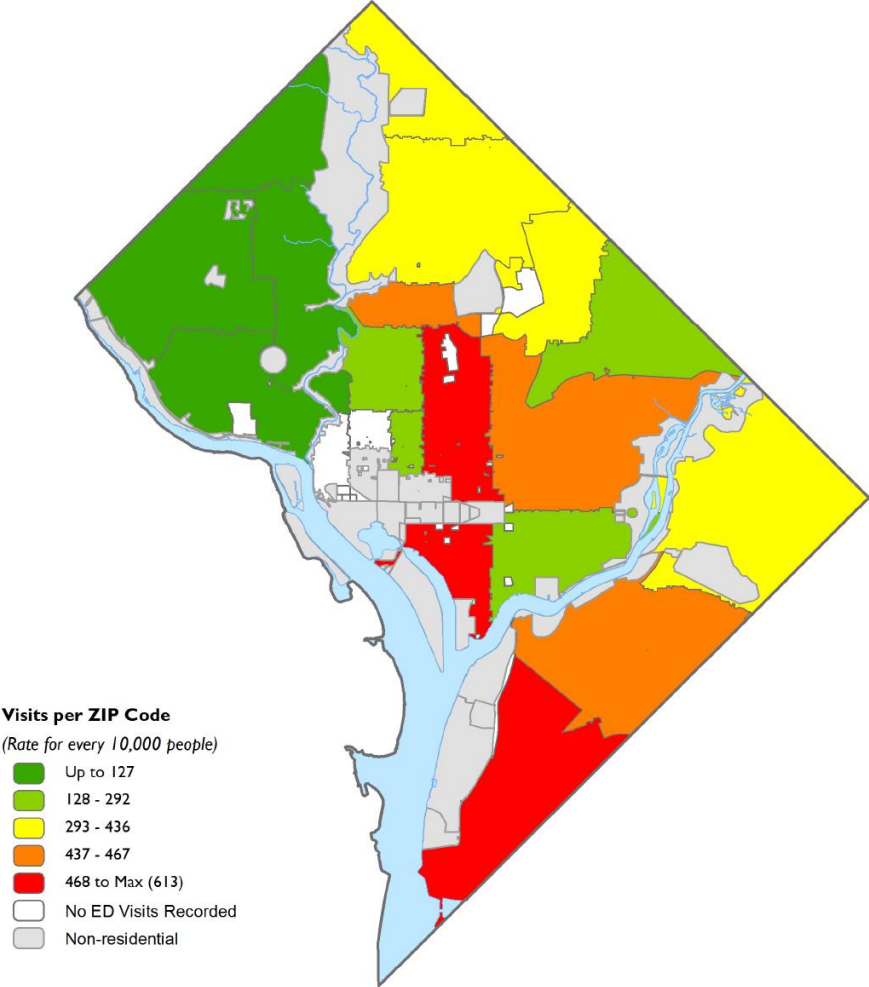EMERGENCY DEPARTMENT VISITS IN WASHINGTON, DC - 2010
Asthma as Primary, Secondary or Tertiary Diagnosis (5 - 14 years)

>10 fold Difference in Rate
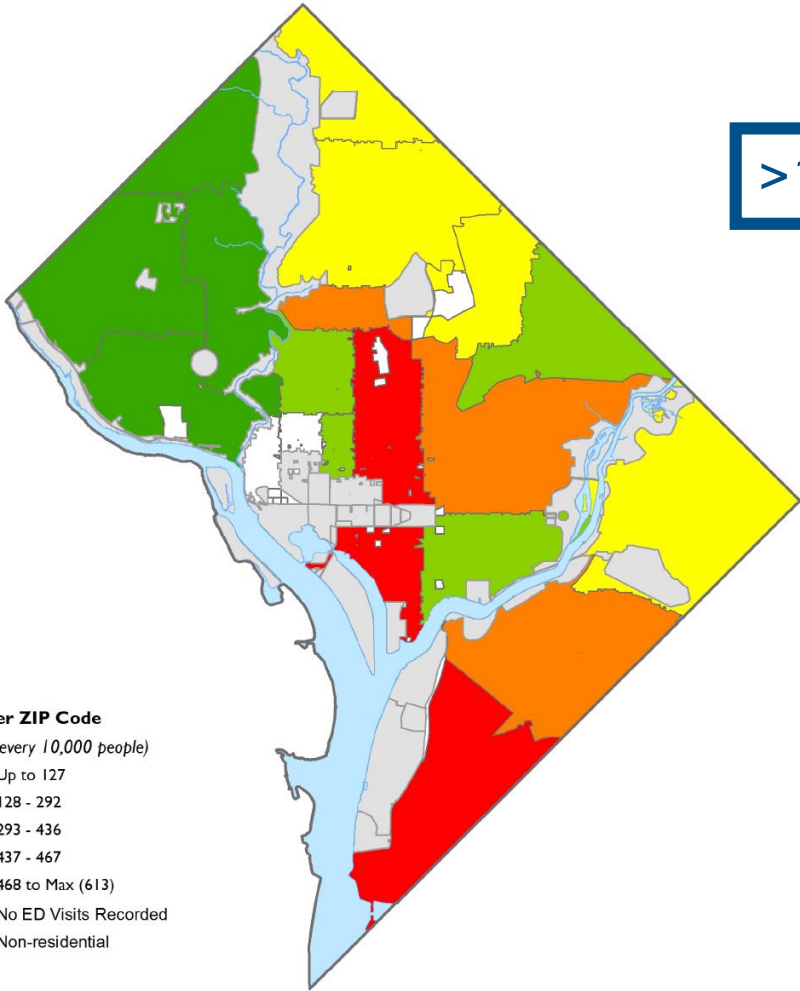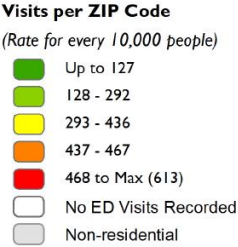
Visits per ZIP Code
(Rate for every 10,000 people)
- Up to 127
- 128 - 292
- 293 - 436
- 437 - 467
- 468 to Max (613)
- No ED Visits Recorded
- Non-residential

EMERGENCY DEPARTMENT VISITS IN WASHINGTON, DC - 2010
Asthma as Primary, Secondary or Tertiary Diagnosis (5 - 14 years)

Poverty in DC, 2000

Visits per ZIP Code

(Rate for every 10,000 people)

- Up to 127
- 128 – 292
- 293 – 436
- 437 – 467
- 468 to Max (613)
- No ED Visits Recorded
- Non-residential

N

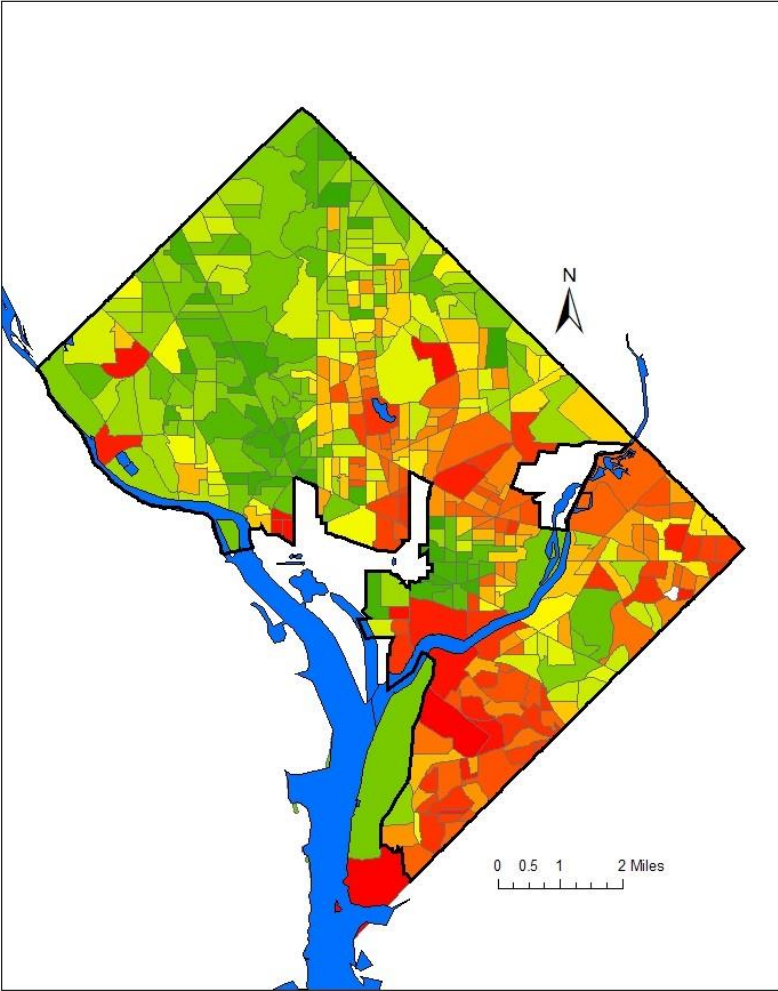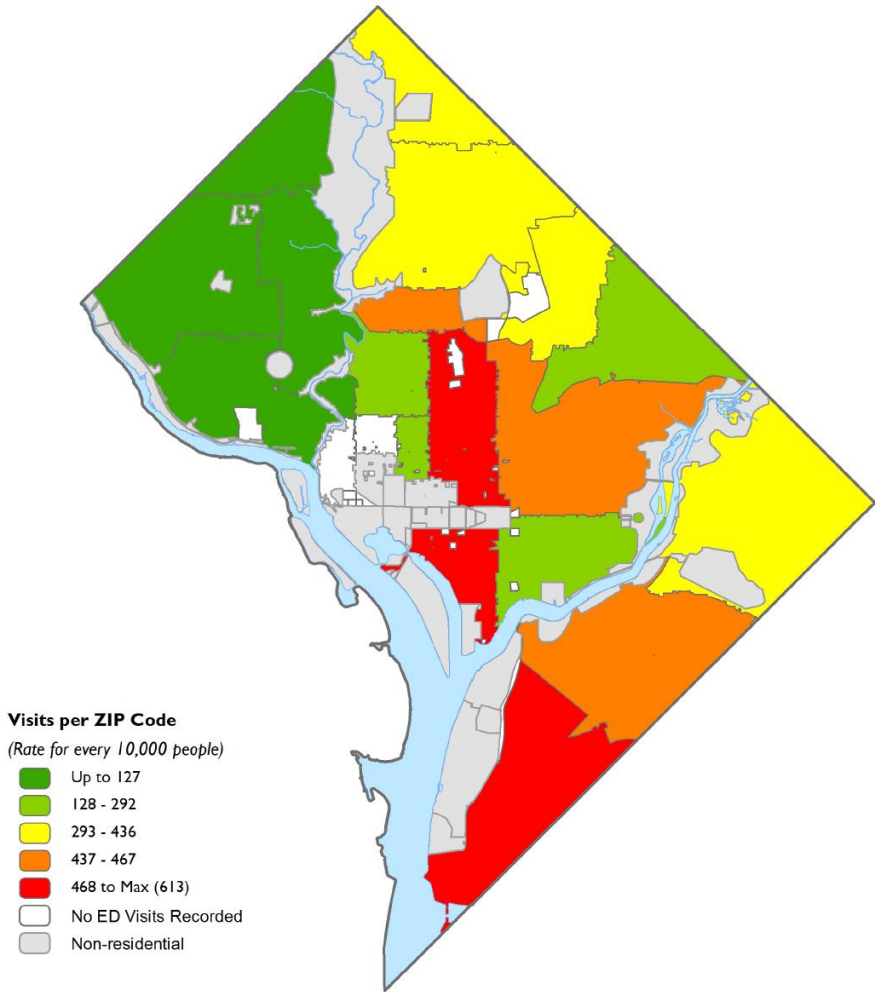0 0.5 1   2 Miles

EMERGENCY DEPARTMENT VISITS IN WASHINGTON, DC - 2010
Asthma as Primary, Secondary or Tertiary Diagnosis (5 - 14 years)

Visits per ZIP Code
(Rate for every 10,000 people)
- Up to 127
- 128 - 292
- 293 - 436
- 437 - 467
- 468 to Max (613)
- No ED Visits Recorded
- Non-residential

Primary Care Access, 2005

Washington, DC

Maryland

N

Providers per 100,000 children <18 yrs
- 0 - 30
- >30 - 50
- >50 - 70
- >70 - 90
- >90

0 1 2   4 Miles

Created by Mark F. Guagliardo, PhD
for the IMPACT DC Project

EMERGENCY DEPARTMENT VISITS IN WASHINGTON, DC - 2010

Asthma as Primary, Secondary or Tertiary Diagnosis (5 - 14 years)

Visits per ZIP Code
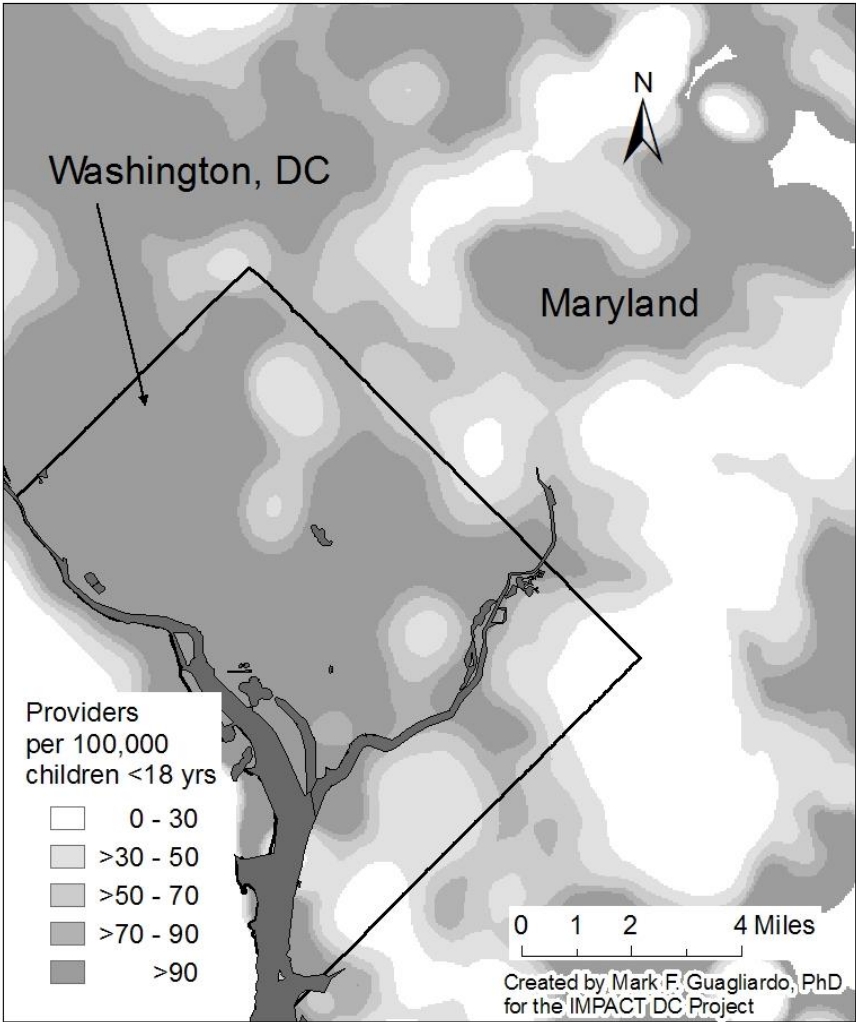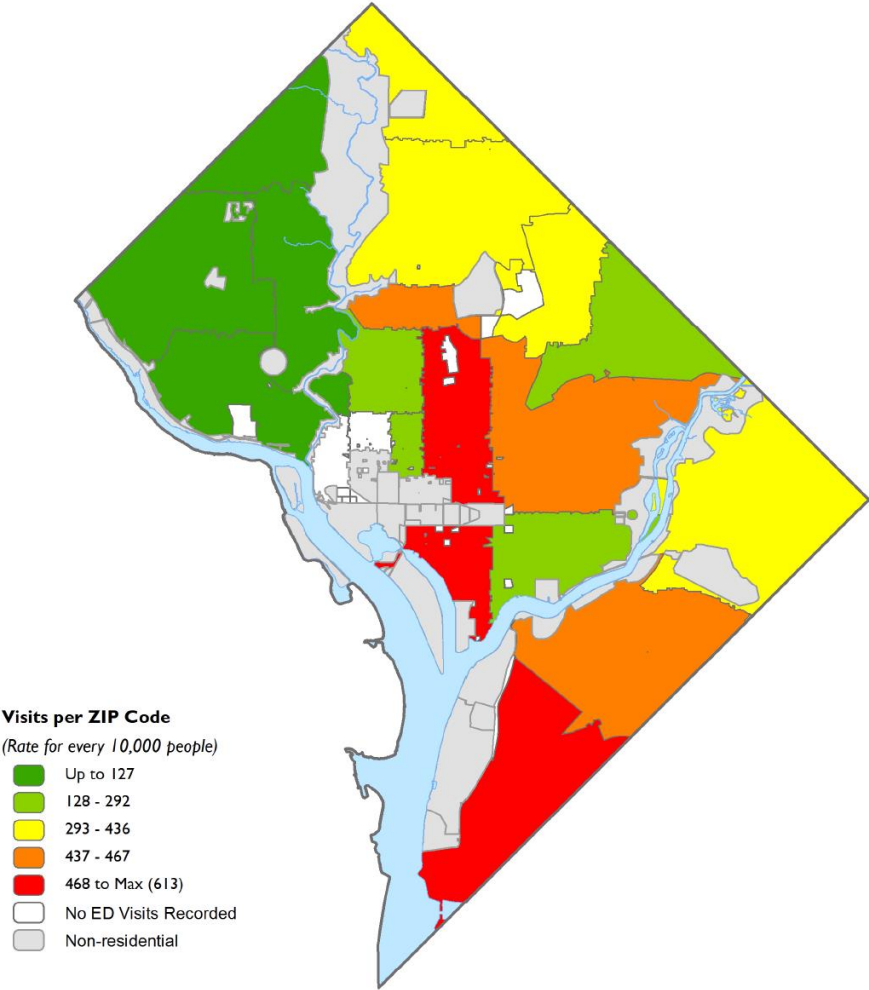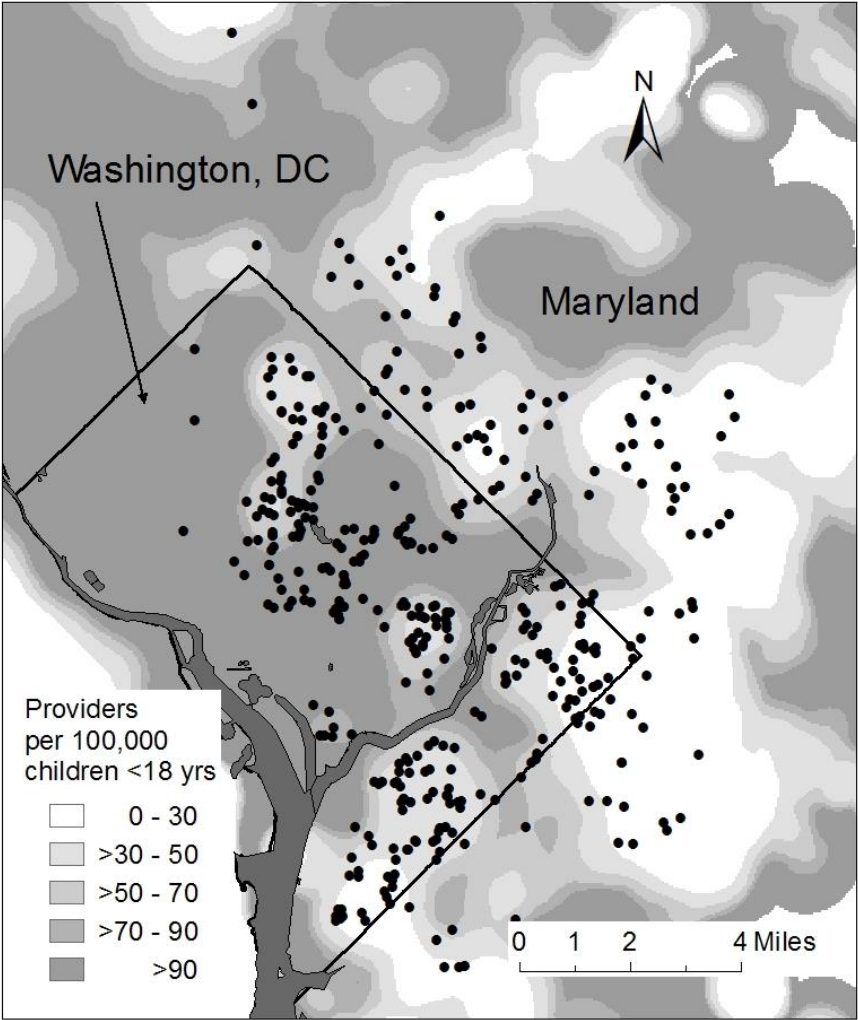*(Rate for every 10,000 people)*

- Up to 127
- 128 - 292
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Primary Care Access, 2005

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- 0 - 30
- >30 - 50
- >50 - 70
- >70 - 90
- >90

0 1 2 4 Miles

National Institutes of Health
Guidelines for Asthma Care
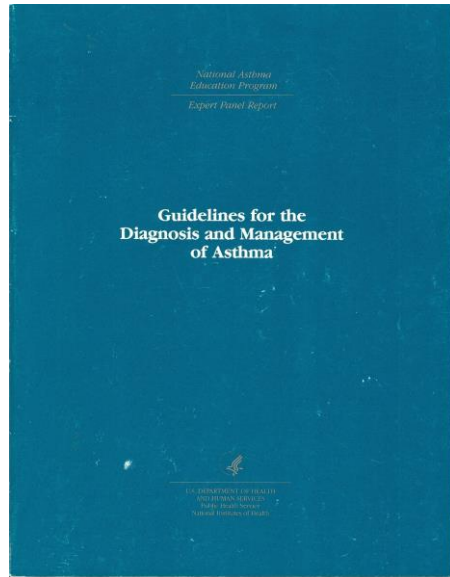
1991
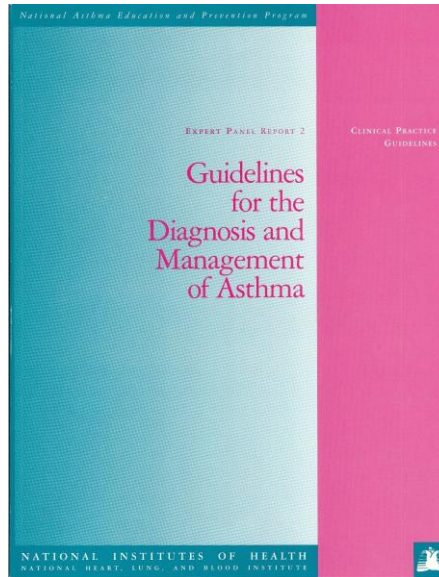
1997
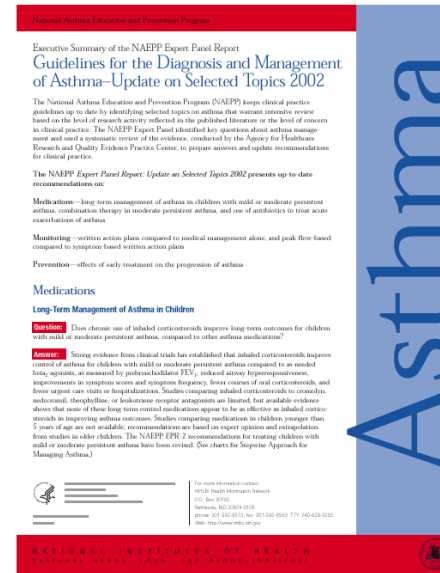
2002

2007

IMPACT DC Asthma Clinic

| Component	Education Provided
Asthma Education: Environmental Triggers and their Control	- Basic pathophysiology/emphasis on its chronic nature - Role of environmental triggers (i.e. tobacco smoke, mold, pests)
Medical Care	- Symptom recognition - Disease control with controller medications - Management of exacerbations with relievers - Proper device use (i.e. spacer, diskus, nebulizer)
Care Coordination	- The role and importance of longitudinal asthma care with a primary care provider - Counseling on communication strategies with PCP about asthma - Ensure school-based care through school nurses and coordinate with managed care organizations - Provision of booster calls to address barriers to care

IMPACT DC *ASTHMA CLINIC*

Improving Pediatric Asthma Care in the District of Columbia
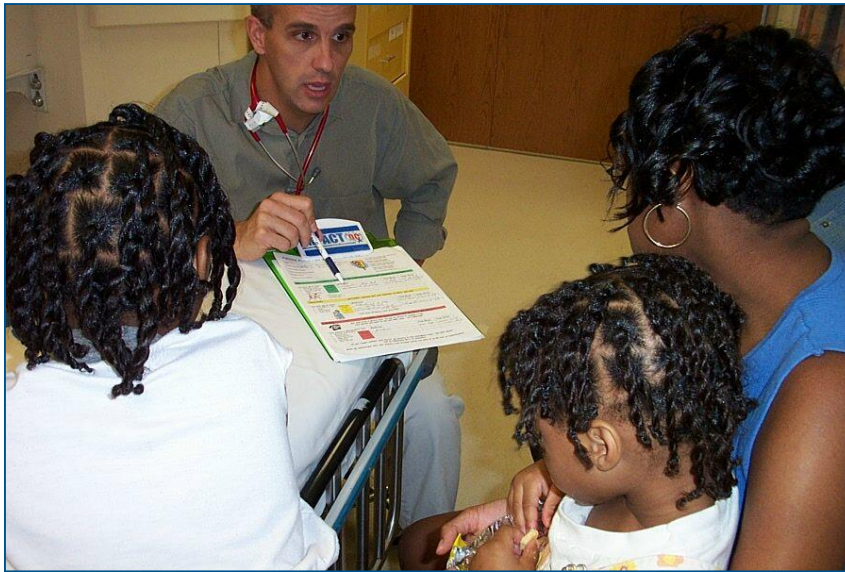
Rate of ED Visits for Asthma per 1000 At-risk DC Residents Aged 1-17y
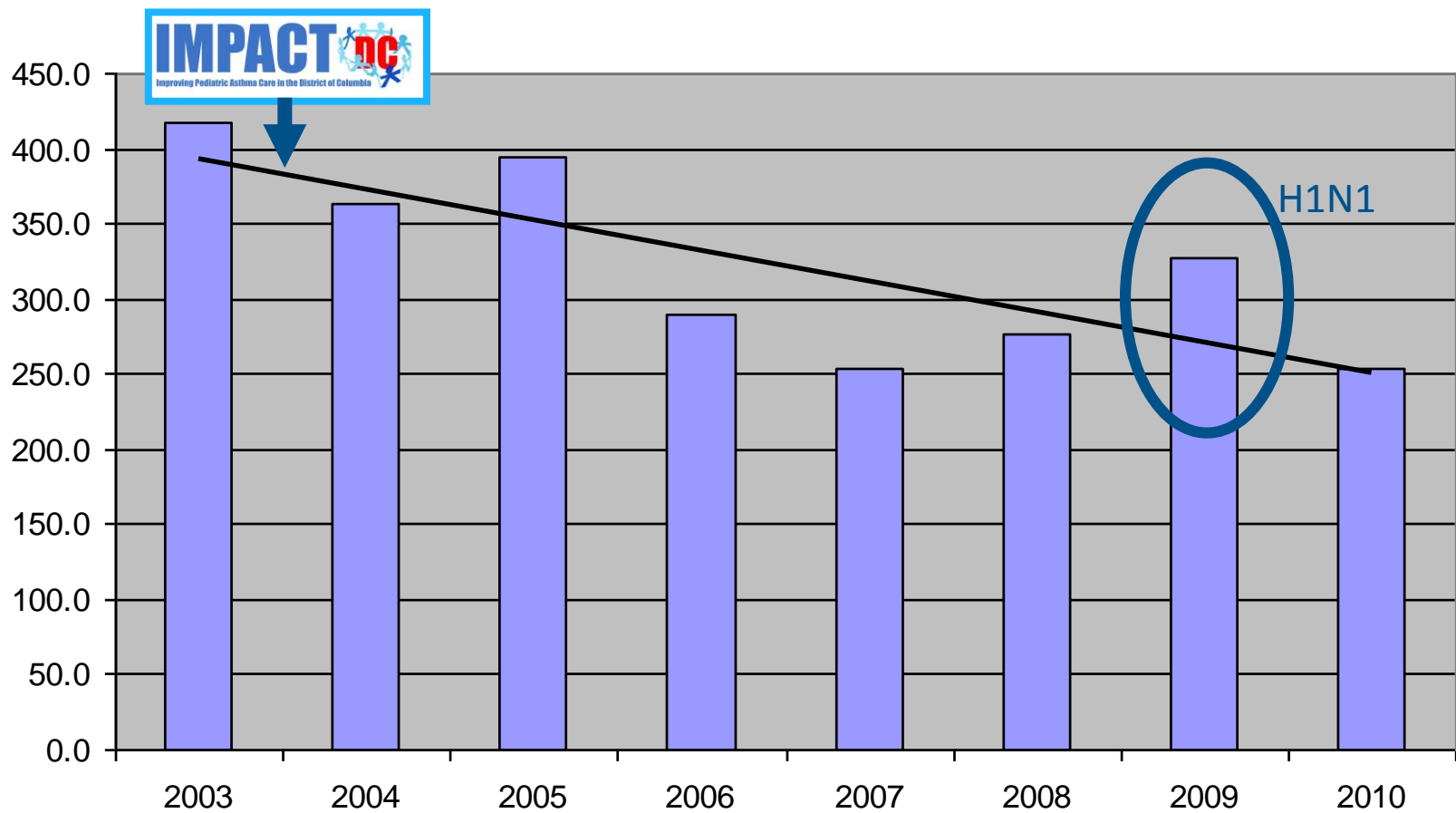
Rate of ED Visits for All Reasons DC Residents Aged 1-17y

Conceptual Model of Asthma

Child With Asthma

Individual & Social Factors
• Genetics
• Physical conditioning
• Socioeconomic status
• Stress
• Hormone levels

Medical Care Factors
• Access to care
• Quality of care
• Medication plan
• Adherence
• Technique
• Immunizations

Environmental Factors
• Allergen sensitization and exposure
  (dust, mold, roach, mice, pollen…)
• Viral infections
• Weather changes
• Air quality (irritants)

Level of Asthma Control

Low Morbidity
• Few Symptoms
• Few school absences
• **Few ED Visits**

High Morbidity
• Many symptoms
• Many school absences
• **Many ED Visits**

Project Description & Outcomes

- Develop, implement and evaluate a multi-dimensional, culturally appropriate and community-based stress management intervention for parents of urban, African-American youth with asthma.

- Outcomes to be assessed include:
  - Proximal outcomes related to psychosocial stress and depression
  - Distal outcomes related to asthma
    - *Primary outcome: symptom-free days*
  - Uptake of and satisfaction with intervention components

Study Design, Intervention & Methodology

- Single blind, prospective RCT of up to 200 dyads comparing
  - the IMPACT DC intervention ("usual care") to
  - "usual care" *plus* parental stress management

- Intervention designed to be responsive to parent and other stakeholder preferences, including:
  - one-on-one stress management sessions
  - facilitated peer support groups

Patient & Stakeholder Engagement

- **Stakeholder Engagement Core**
  - Parents of children with asthma and professional community members
  - Led by parent of child with asthma with extensive experience in parent empowerment and community engagement.
  - Activities:
    - Refined study questions
    - Reviewed findings of focus groups/interviews
    - Provided feedback on intervention design and components.
    - Will assist in troubleshooting issues during implementation, interpretation of findings, and dissemination.

Patient & Stakeholder Engagement

- **National Advisory Core**
  - National experts in asthma trials in at-risk population, adherence to medications, and psychosocial stress.
  - Provides guidance regarding key decisions for both research methodology and intervention development.

Patient & Stakeholder Engagement

- **Patient Engagement**
  - Conducted focus groups and one-on-one interviews of parents of children with asthma
  - Collected data on key stressors, intervention content, preferred intervention modalities, and incorporation of mHealth technology

Patient & Stakeholder Engagement

- **Engagement has driven key changes:**
  - Change from focus on medication adherence to focus on symptom-free days
  - Emphasis on peer support, including in one-on-one relationships and group setting
  - Decreased emphasis on technology
  - New staffing model for intervention

Asthma Evidence to Action Network

- Exciting opportunity for collaboration with other PCORI grantees
- Sharing of best-practices
- Troubleshooting challenges during all phases of research
- Discussing how best to continue stakeholder engagement during implementation and dissemination

Intersection of Science and Engagement

Romana Hasnain-Wynia, PhD
Program Director, Addressing Disparities

Ayodola Anise, MHS
Program Officer, Addressing Disparities

Sue Sheridan, MBA, MIM
Director, Patient Engagement

Kimberly Bailey, MS
Engagement Officer

Patient-Centered Outcomes Research Institute

Background on Intersection of Science and Engagement

- PCORI's vision for engagement in research:

  - To integrate science and engagement to achieve the gold standard of both meritorious research and research that engages patients and other stakeholders at every step in the process

  - To operationalize the integration of science and engagement in a meaningful way

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Background on Intersection of Science and Engagement (cont.)

- PCORI engagement staff are helping awardee teams to become "PCOR ready."
- PCORI has developed a number of strategies to facilitate PCOR readiness:
  - Engagement officer role to support awardee teams
  - Engagement rubric
  - Pipeline to Proposal program
  - Engagement Awards

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Overview

- Engagement at PCORI
- Awardee Challenges around Engagement
- How PCORI Can Address Engagement Challenges
- Our "Ask" of the AD Advisory Panel

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We Engage Patients and Other Stakeholders at Every Step
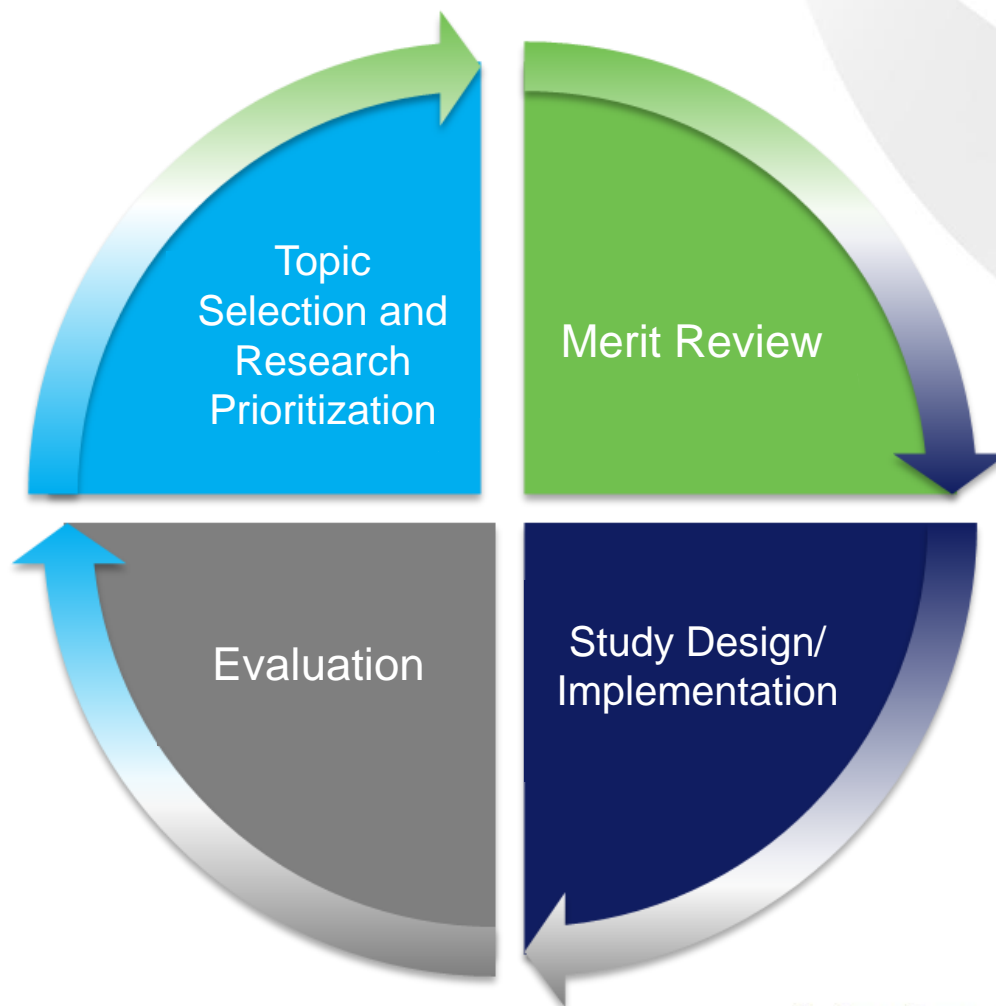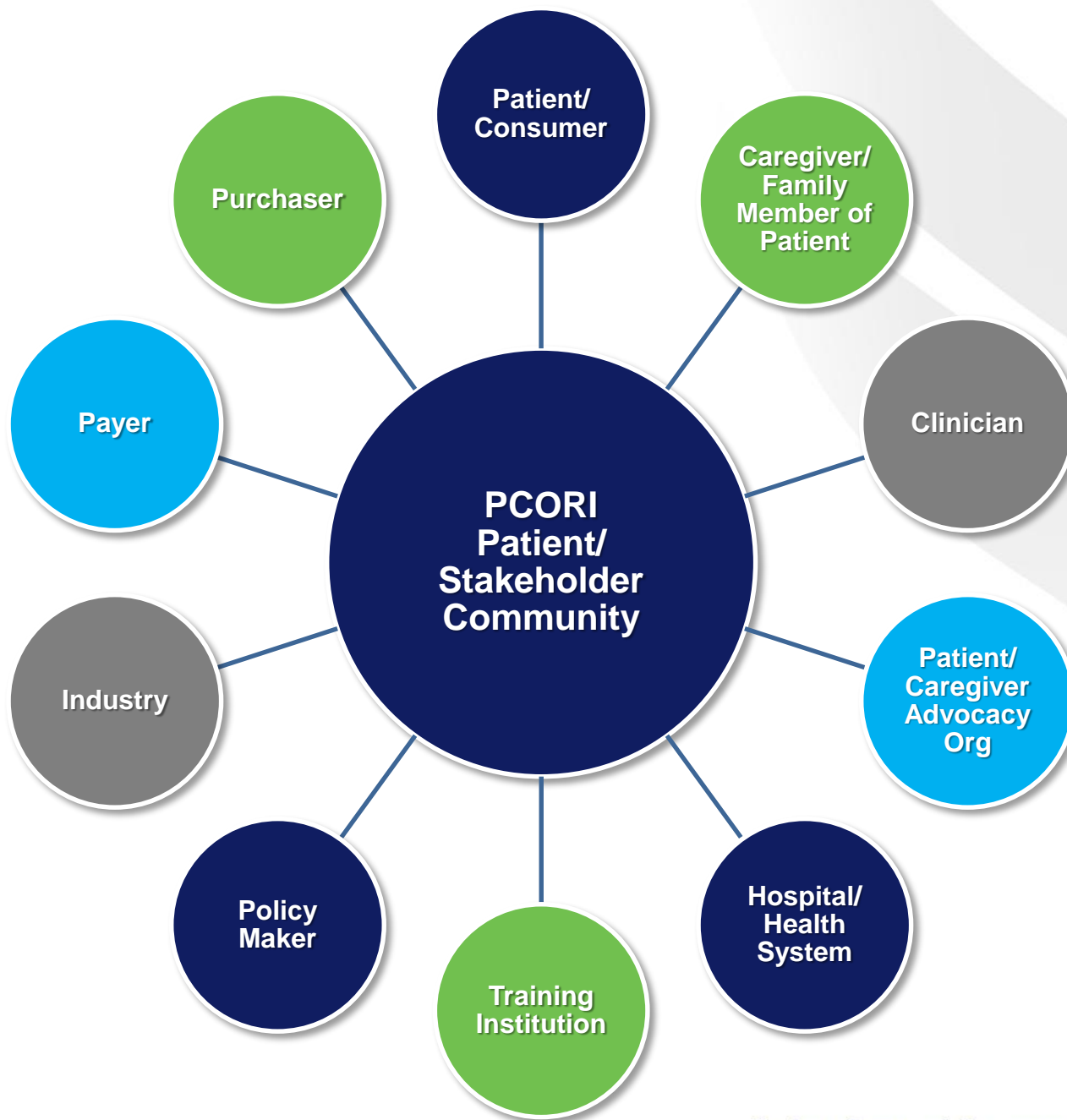
Engagement in Research

- PCORI encourages awardees to engage patients and other stakeholders at every stage of their project
  - Planning the study
  - Conducting the study
  - Disseminating study results
- PCORI encourages creativity and innovation in engagement.
- Spectrum of engagement: from subject to co-PI.
- Engagement should fit the project aims and objectives.

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The Engagement Rubric

The rubric is intended to provide guidance to applicants, merit reviewers, awardees, and engagement/program officers (for creating milestones and monitoring projects) regarding engagement in the conduct of research. *It is divided into four segments:*

Planning the Study

Conducting the Study

Disseminating the Study Results

PCOR Engagement Principles

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Snapshot of the Rubric

<u>1. PLANNING THE STUDY:</u> Describe how patient and stakeholder partners will participate in study planning and design.

Potential activities include:

- Identifying the topic and developing the research question to be studied
- Creating the intervention
- Identifying the comparators
- Defining the characteristics of study participants

Examples of how to demonstrate this in your proposal:

- Provide Letters of Support from patient and stakeholder partners that clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, and goals/outcomes, etc.
- Describe meetings, focus groups, and other events convened to engage patient and stakeholder partners in the planning of your study, and include key guidance on study design offered by your patient and stakeholder partners.
- Discuss how the engagement of patients and other stakeholders helped to refine your study's research question, outcomes, and comparators.

Real-World Examples:

- *Epilepsy study: The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally, while still preventing seizures adequately?*
- *Diabetes study: Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.*

Overarching Challenges Regarding Engagement Identified by Asthma Awardees

- Research teams balance many pros and cons, mediators and moderators, and perceived or real barriers to engagement.
- The 5 Ws & H of engagement:
  - Why engage?
  - Who to engage?
  - What to engage around?
  - When to engage?
  - Where to find patients and stakeholders to engage?
  - How to engage?

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Overarching Challenges Regarding Engagement Identified by Asthma Awardees (cont.)

- Patient and stakeholder engagement in the conduct of research
  - Design of CER question, study, and intervention
  - Implementation, data collection and analysis
  - Dissemination
  - Decision making roles (institutional review boards [IRBs], data and safety monitoring boards [DSMBs], co-principal investigators [co-PIs], advisory boards, and committees)

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PCORI's Role in Addressing Challenges

- Across PCORI some research teams are successful in engagement throughout the research process.
- We want to do the following:
  - Leverage what we know from our funded projects about successful engagement (i.e., best and promising practices).
  - Identify new strategies and ways of engagement that we have not seen.
- This information can be:
  - Shared with PCORI-funded awardees to enhance their engagement efforts
  - Used to support PCORI staff efforts in project monitoring

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PCORI's "Ask" of the AD Advisory Panel

- PCORI's AD and Engagement staff have developed draft documents of best/promising/new practices to address engagement challenges in these areas:
    - Patient and stakeholder engagement in study design and protocol development
    - Patient and stakeholder engagement in recruitment and retention efforts
    - Patient and stakeholder engagement in data collection and analysis
    - Patient and stakeholder engagement in DSMBs and other monitoring committees
- We want your input on these draft documents.

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PCORI's "Ask" of the AD Advisory Panel (cont.)

- Break into 4 groups (slide with preassigned groups to follow).
- Designate a scribe and a reporter in each group.
- Key questions to address:
  - What best/promising/new practices are missing?
  - How do we provide examples such as these to research teams without stifling innovation?
  - How do we make this information accessible to teams? What is the best format for sharing (e.g., 2-page document, slides with graphics, podcast, creative storytelling)?
  - Where else should we look for guidance on how to engage patients and stakeholders? Who else should we speak to?
  - What are the moderators and mediators/barriers and facilitators that awardees should consider with these engagement strategies?
  - What can PCORI do to help overcome potential challenges to successful engagement?

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PCORI's "Ask" of the AD Advisory Panel (cont.)

- Spend from 3:15-4:05 p.m. (50 minutes) in your group addressing the key questions.
- Be prepared to report overarching comments back to the whole panel from 4:10-4:45 p.m.
  - 3-5 minutes for report back from each group
  - 3-5 minutes for Q&A and other suggestions

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PCORI's "Ask" of the AD Advisory Panel (cont.)

Breakout Groups

Study Design	Recruitment and Retention	Data Collection and Analysis	Data Monitoring Boards
Liz Jacobs	Alfiee Breland-Noble	Martin Gould	Kevin Fiscella
Deborah Stewart	Martina Gallagher	Patrick Kitzman	Eschezona Ezeanolue
Chien-Chi Huang	Carmen Reyes	Doriane Miller	Mary Sander
Alan Morse	Monique Carter	Venus Gines	Grant Jones
	Alyna Chien	Russell Rothman	

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Break

3:00–3:15 p.m. ET

Patient-Centered Outcomes Research Institute

Intersection of Science and Engagement (cont.)

The panel is currently in breakout sessions. Audio will resume at 4:10 p.m. ET.

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Intersection of Science and Engagement (cont.)

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Discussion

- Patient and stakeholder engagement in study design and protocol development
- Q&A

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Discussion (cont.)

- Patient and stakeholder engagement in recruitment and retention efforts
- Q&A

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Discussion (cont.)

- Patient and stakeholder engagement in data collection and analysis
- Q&A

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Discussion (cont.)

- Patient and stakeholder engagement in DSMBs and other monitoring committees
- Q&A

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Next Steps

- The next in-person meeting will tentatively take place in Washington, D.C. in late May 2015.

- We will reach out to you as soon as the date has been finalized.

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Special Thanks

- We would like to give a special thanks to those members whose terms end this year:
  - Tammy Burns
  - Jacqueline Grant
  - Monique Carter
  - Venus Gines
  - Alyna Chien
  - Kevin Fiscella
- We truly appreciate your contributions!

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Thank you!

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