



Advisory Panel on Improving Healthcare Systems

October 2, 2014

8:30 a.m. – 4:00 p.m. EDT

Patient-Centered Outcomes Research Institute

Welcome & Introductions

*Steven Clauser, PhD, MPA
Director, Improving Healthcare Systems*

Housekeeping

- Today's webinar is open to the public and is being recorded.
- Members of the public are invited to listen to this teleconference and view the webinar.
- Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled.
- Visit www.pcori.org/events for more information.

Panel Leadership

 Doris Lotz, MD, MPH

- IHS Advisory Panel Co-Chair

Unable to Attend

 Trent Haywood, MD, JD

- IHS Advisory Panel Chair

Advisory Panel Members

- **Andrew Adams, BBA**
MBA Candidate, The Wharton School of the University of Pennsylvania
- **Leah Binder, MA, MGA**
President & CEO, The Leapfrog Group
- **Mary Blegen, RN, MA, PhD, FAAN**
Adjunct Professor, College of Nursing, University of Colorado at Denver
- **David Bruhn, PharmD, MBA**
Health Outcomes Liaison, National Accounts, GlaxoSmithKline
- **Daniel C. Cherkin, MS, PhD *(Not Attending)***
*Director, Bastyr University Research Institute
Senior Scientific Investigator, Group Health Research Institute*
- **Alan B. Cohen, MS, ScD**
Professor, Health Policy and Management, Boston University School of Management
- **Elizabeth D. Cox, MD, PhD**
Associate Professor, Departments of Pediatrics and Population Health Sciences, University of Wisconsin-Madison
- **Susan Diaz, MPAS, PA-C**
Physician Assistant, Liver Transplant, Mayo Clinic in Florida
- **Michael R. Dueñas, O.D.**
Chief Public Health Officer, American Optometric Assn.
- **John A. Galdo, PharmD, BCPS**
Clinical Pharmacy Educator, Barney's Pharmacy
- **Eve A. Kerr, MD, MPH**
Director, Ann Arbor Center for Clinical Management Research
- **Joan Leon, BA**
Retired Health Consultant
- **Tiffany Leung, MD, MPH**
Postdoctoral Fellow, Medical Informatics, Center for Innovation to Implementation, VA Palo Alto Health Care System Center for Health Policy/Center for Primary Care & Outcomes Research (CHP/PCOR), Stanford University
- **Annie Lewis-O'Connor, NP-BC, MPH, PhD**
Nursing Scientist Director – Women's C.A.R.E Clinic Brigham and Women's Hospital
- **John Martin, MPH**
Senior Director, Research Operations, Premier Inc.
- **Lisa Rossignol, MA**
Graduate Student, Health Communication, University of New Mexico
- **Anne Sales, RN, PhD *(Not Attending)***
Professor, School of Nursing, University of Michigan
- **Jamie Sullivan, MPH**
Director of Public Policy, COPD Foundation
- **Leonard Weather Jr., MD, RPH**
Director, Omni Fertility and Laser Institute

The Improving Healthcare Systems Program Team



Steven Clauser, PhD, MPA



Lynn D. Disney, PhD,
JD, MPH



Alex Hartzman, MPH,
MPA



Lauren Holuj, MHA



Hannah Kampmeyer



Beth Kosiak, PhD



Penny Mohr, MA

Today's Agenda

Time	Agenda
8:30 a.m.	Welcome / Introductions
8:40 a.m.	Setting the Stage
9:15 a.m.	IHS Portfolio Update
10:00 a.m.	Proposed New Process for Refining CER Questions
10:30 a.m.	Break
10:40 a.m.	IHS Strategic Framework
11:10 a.m.	Topic Presentation "...High Deductible Health Plans"
11:50 a.m.	Topic Presentation "Comparison of ACOs and Traditional Health Systems..."
12:30 p.m.	Lunch
1:30 p.m.	Topic Presentation "Care Management Plans...for Chronic Pain"
2:10 p.m.	Review of All Topics and Other Funding Opportunities
3:00 p.m.	Stakeholder Engagement
3:45 p.m.	Recap of the Day
3:55 p.m.	Next Steps / Closing Remarks
4:00 p.m.	Adjourn

Meeting Objectives

- Review the updated IHS portfolio of projects.
- Review and discuss the IHS strategic framework.
 - Developed in part with a subcommittee of panelists
- Refine our process for identifying high-impact comparative effectiveness research (CER) questions for health systems research.
- Refine three topics previously prioritized.
 - Developed in part with a subcommittee of panelists
- Discuss the importance of engaging key stakeholders as we work to identify high-priority CER topics.



Setting the Stage

*Doris Lotz, MD, MPH
IHS Advisory Panel Co-Chair*

What Makes PCORI Unique

- Produce and promote *Comparative Effectiveness Research*...
 - The direct comparison of existing health care interventions
- ...that focuses on *Patient-Centered Outcomes*...
 - Patients and the public have information they can use to make decisions that reflect their desired health outcomes
- ...which is *guided by patients, caregivers, and the broader healthcare community*.
 - Engagement at every level: on the Board of Governors, on the Advisory Panels, and in the funded studies

What Makes IHS Unique

The IHS Goal Statement:

- To support studies of the *comparative effectiveness of alternate features of healthcare systems* that will *provide information of value to patients, their caregivers, and clinicians, as well as to healthcare leaders*, regarding which features of systems lead to better patient-centered outcomes.

The panel's role in this mission is to advise and provide recommendations to the Board of Governors, Methodology Committee, and staff to help plan, develop, implement, improve and refine efforts toward meaningful patient-centered research.

- Identify and prioritize critical research questions for possible funding initiatives
- Provide ongoing feedback and advice on evaluating and disseminating the research conducted under this program.

Specificity of Prioritized Topics

- Increasing topic focus by time of prioritization will aid staff in funding impactful research.
- Targeted announcements in particular must be very specific to get approval from the Board of Governors.
 - e.g.: Effectiveness of Transitional Care [funding announcement](#)
- Staff and Panel can work together at every part of the prioritization and narrowing processes.
 - Senior Program Officer Penny Mohr will propose a new process later this meeting.

Better Topics Require More Cogent Input

- Co-chair review of public input to topic portal: an “aha moment”
- Panel can help!
 - Solicit topics – and better yet, comparative effectiveness research (CER) questions – from constituency groups.
 - Take up staff offer to help formulate CER questions.
- New process for targeted topics – need Board of Governors approval
 - This will likely entail greater specificity of topics.

Lumping vs. Splitting



Patient-Empowering Care Management

- Panel combined five topics at April 2013 meeting.
- Empowerment is very meaningful & important, but topic itself is extremely nebulous.
- We are co-funding model development project with JA Hartford Foundation.



Insurance Features

- This started off as a very broad topic
- Staff were unable to move forward until Panel Subcommittee formed – split topic into two parts: 1) Accountable Care Organizations and 2) Enrollee Support for High-Deductible Health Plans.
 - The original combined topic was included in the Pragmatic Clinical Studies funding announcement .



Discussion

IHS Portfolio Update

*Steven Clauser, PhD, MPA
Director, Improving Healthcare Systems*

Distinctive Components of IHS Studies

- Adapt patient-centered outcomes research (PCOR) model beyond clinical treatment options to different levels of the healthcare system;
- Require inclusion of well-articulated comparators, for both trials and studies using observational data;
- Focus on outcomes relevant to patients;
- Involve patients and other stakeholders in the entire research process; and
- Conduct research in real-life settings.

Sources of Research Topics and Funding Mechanisms

Topic Sources

- Board of Governors
- Public (Web Portal)
- IHS Advisory Panel
- Constituency groups
- Investigators

Funding Mechanisms

- **Broad Funding**
 - IHS Broad PFA
 - Investigator initiated
- **Targeted Funding**
 - Targeted PFA
 - Partnerships with other organizations
- **Pragmatic Clinical Studies and Large Simple Trials**
 - Specific areas of interest



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Current Foundation: IHS Broad PCORI Funding Announcement (PFA)

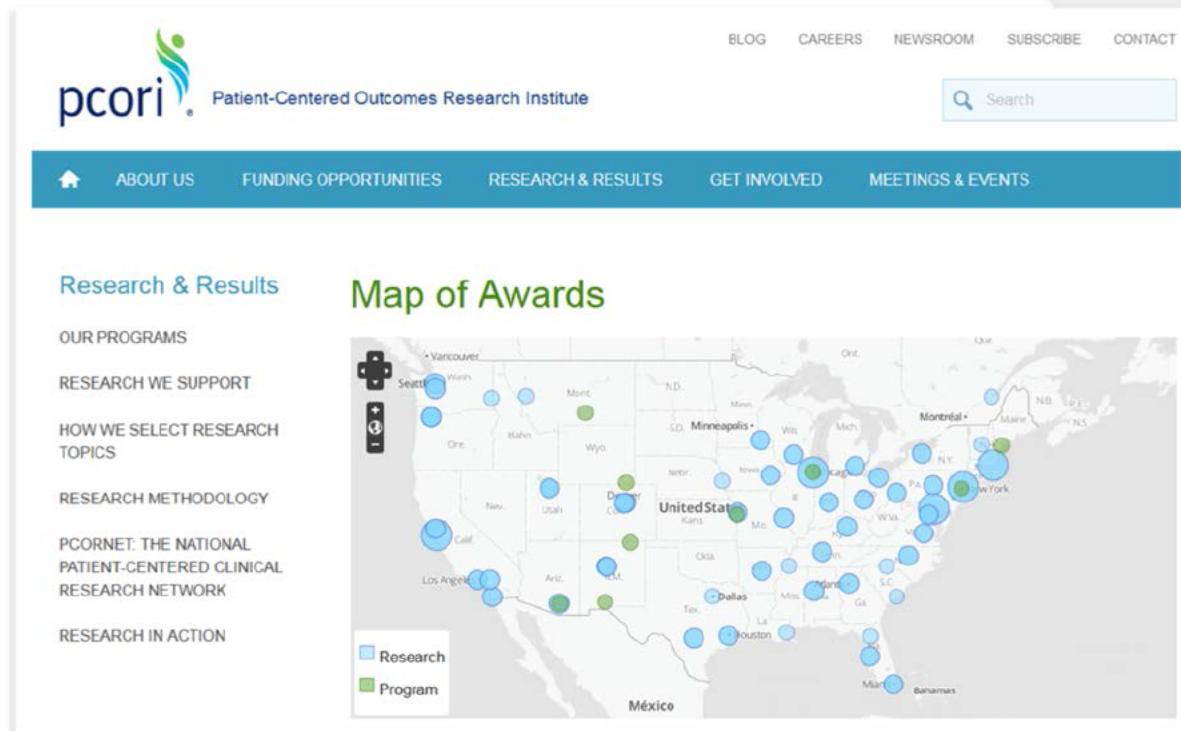
Parameters of the IHS Broad PFA

- Comparative effectiveness of alternate features of healthcare systems
- Priorities reflect investigator interests, merit review assessment, and programmatic balance
- Five funding cycles to date
 - Began funding large studies (up to \$5 million over 5 years) in the Spring 2014 Cycle.
- Funding to date (through Winter 2014 Cycle)
 - 48 investigator-initiated contracts
 - Across 22 states and D.C.
 - \$90.2 million awarded

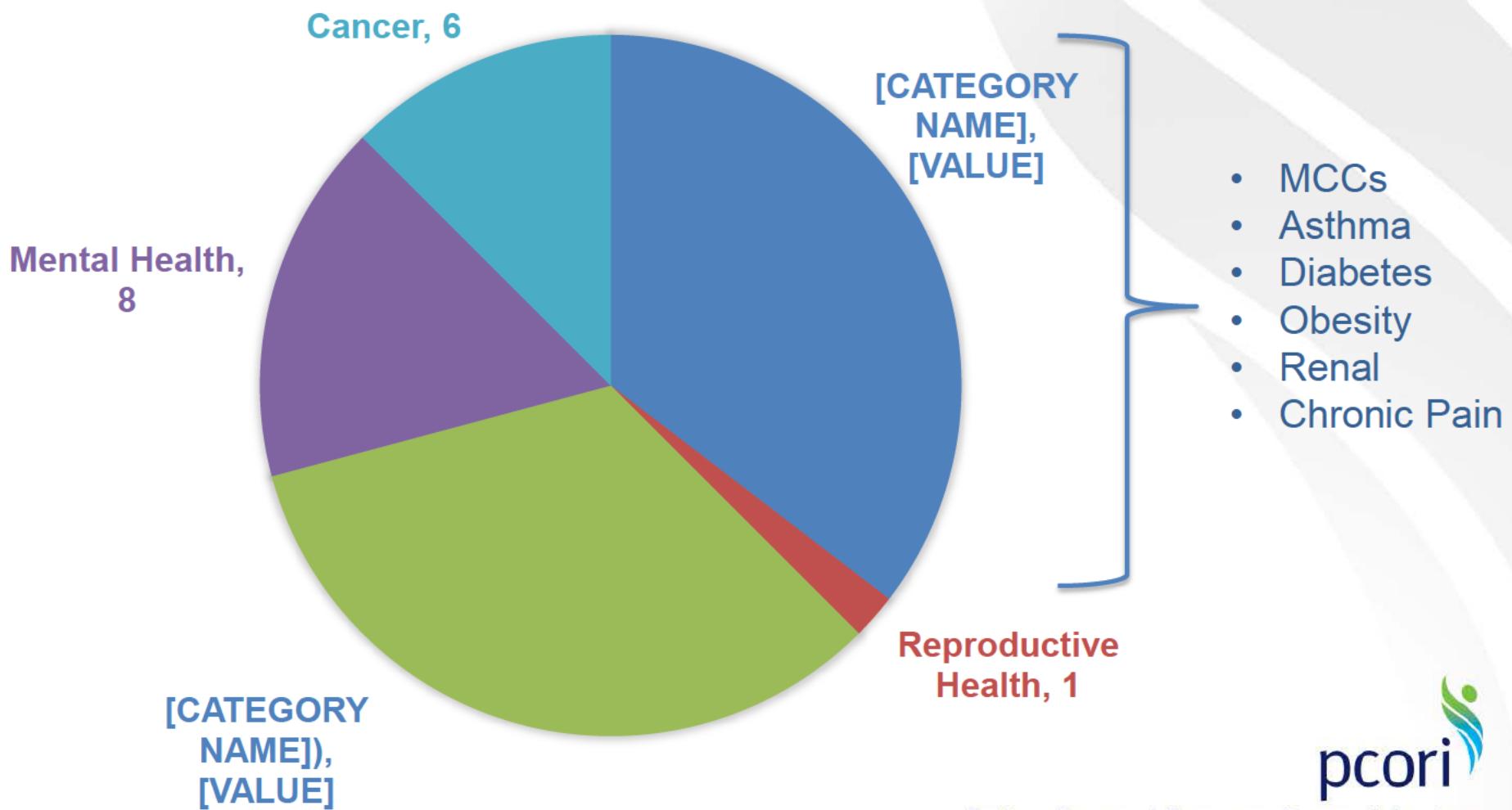


Funded Projects – A Full List Is Available on the PCORI Website

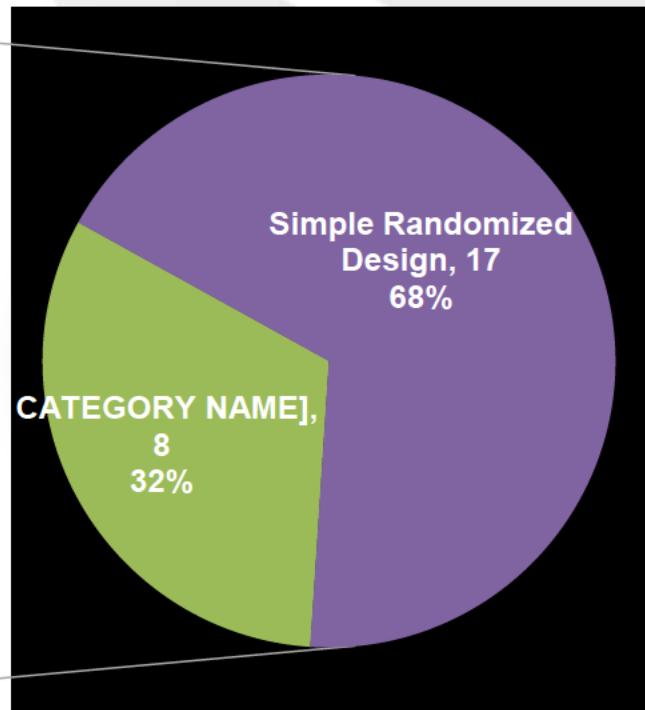
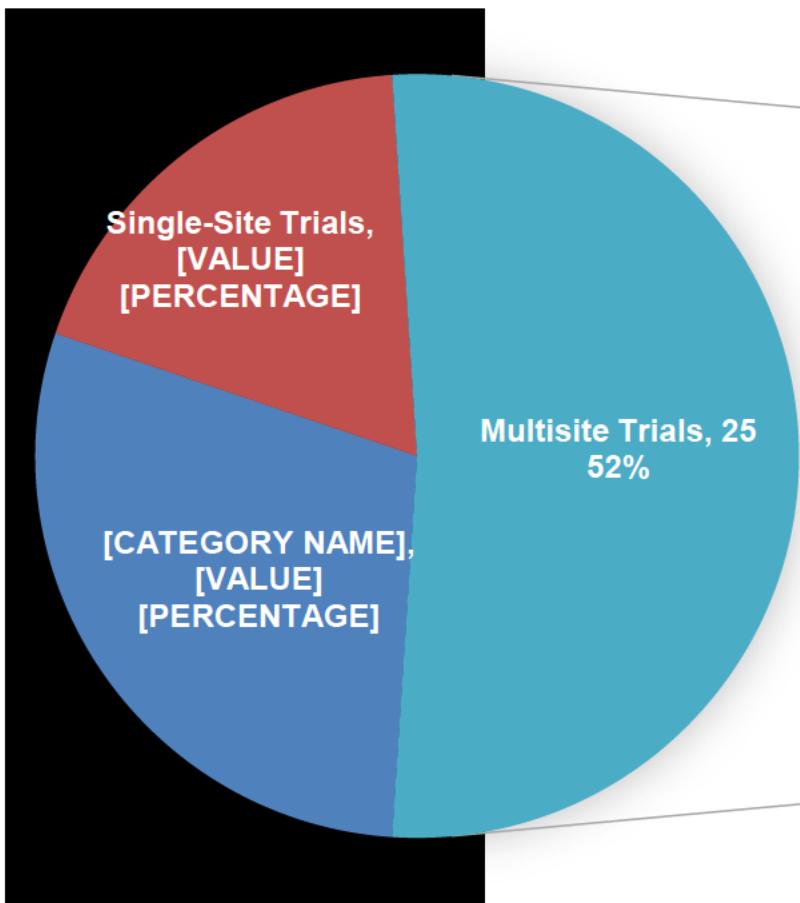
- Follow this [link](#) to view funded projects online
 - Your handout was obtained from this site



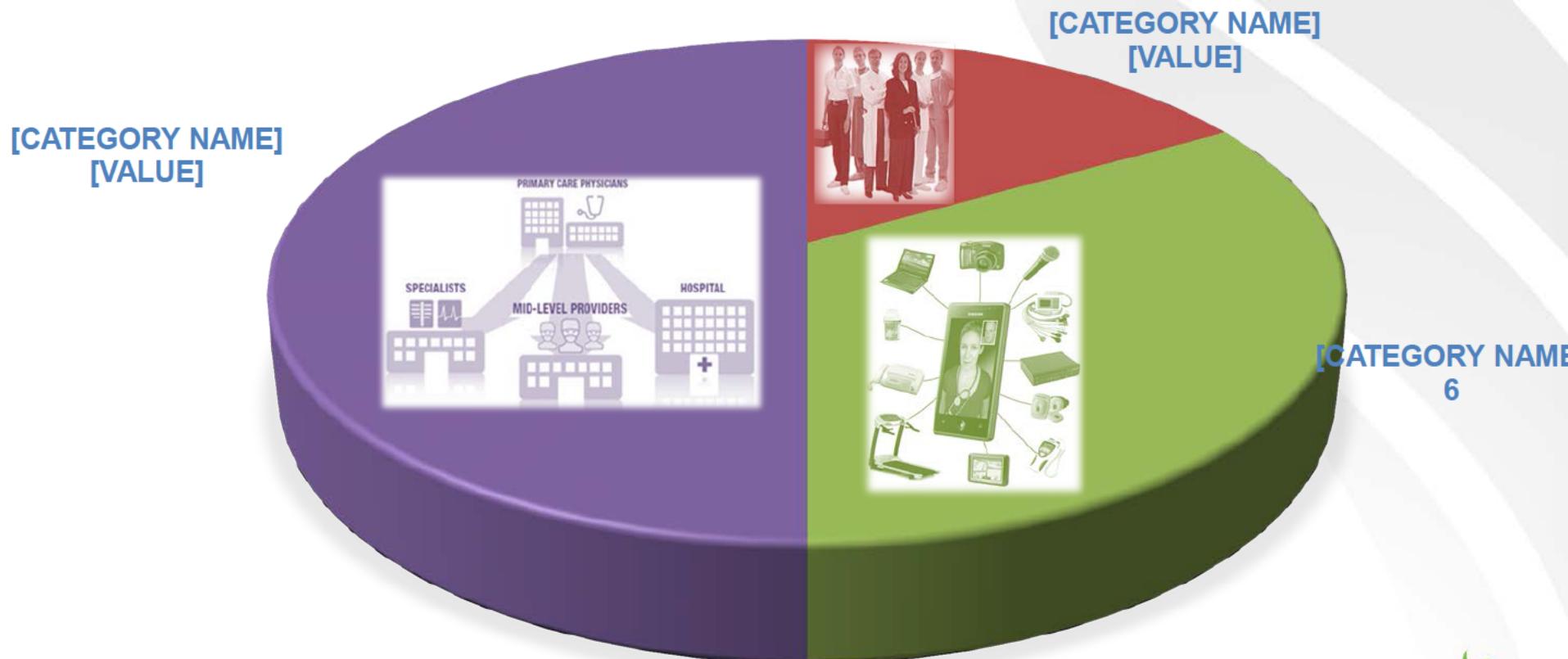
Conditions (n = 48)



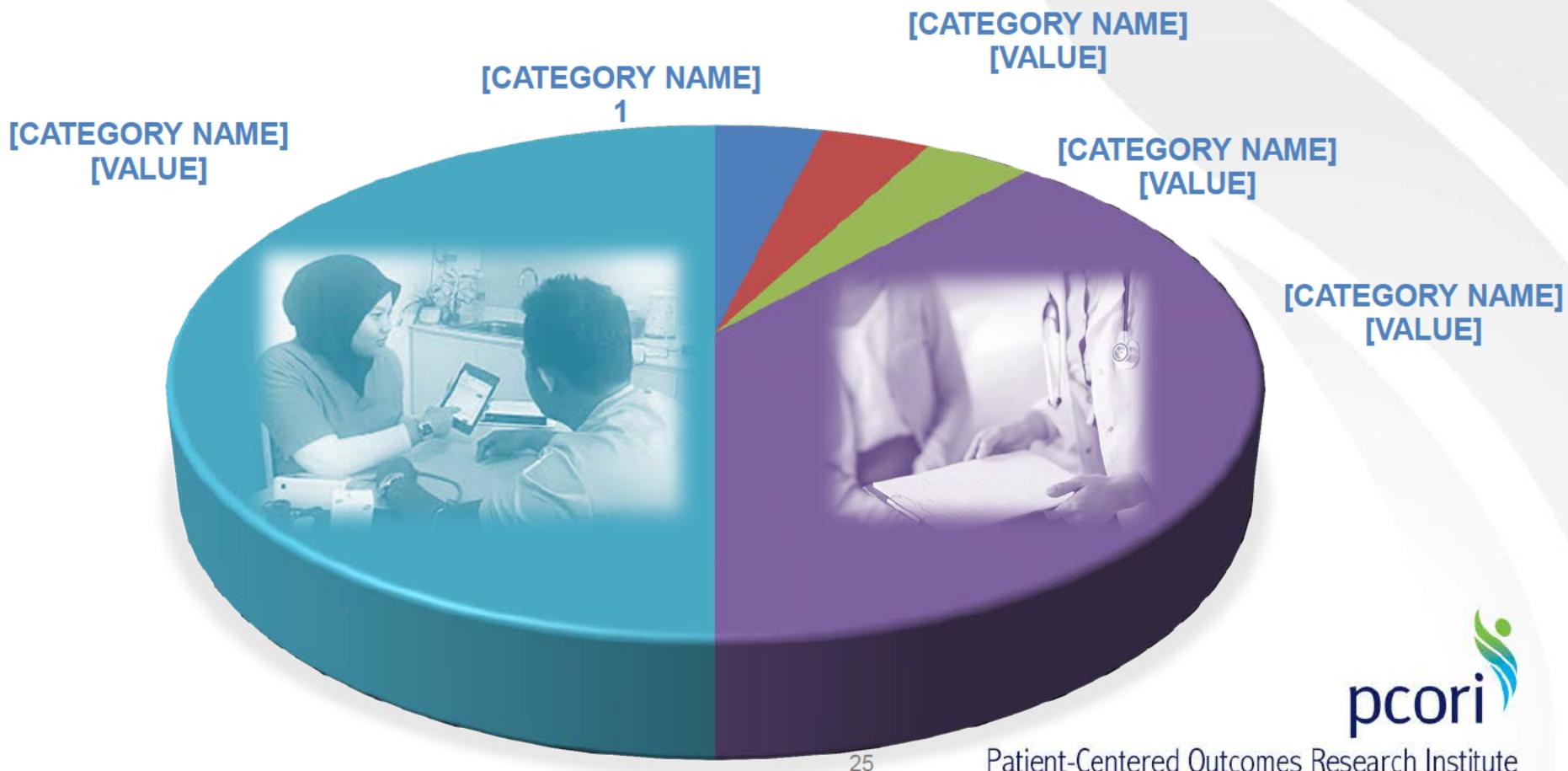
Study Designs (n = 48)



Projects with Single-System Interventions (n = 22 out of 48)



Projects with Multicomponent Interventions (n = 26 out of 48)



IHS Targeted Funding Portfolio: Stakeholder-Initiated Priorities

STRIDE (STrategies to Reduce Injuries and Develop confidence in Elders)

- PCORI-National Institute of Aging research partnership
 - \$30 million / 5-year award made June 1, 2014
 - 3 Co-PIs:
 - Shalender Bhagat, MD, Harvard Medical School
 - David Reuben, MD, David Geffen School of Medicine at UCLA
 - Thomas Gill, MD, Yale School of Medicine
- Multisite cluster randomized clinical trial
 - 6,000 participants
 - 10 sites / 80 local practices
- Intervention: Falls Care Manager using evidence-based, multifactorial individually-tailored services to reduce the risk of serious fall injuries among older persons (age 75+)
- Comparator: Primary care with falls risk assessment and patient educational materials

Upcoming Targeted Initiative

- Effectiveness of Transitional Care (\$15 million)
 - Compare which transitional care service clusters (e.g., pre-discharge planning, medication reconciliation) are most effective in improving patient-centered outcomes
 - Intervention: Hospitals or communities that implemented defined clusters of transitional care components
 - Comparator: Hospitals or communities that rely on traditional discharge and referral programs

This is the first topic prioritized by a PCORI Advisory Panel to complete the entire targeted PFA process.

Award announced September 30, 2014 at the PCORI Board of Governors meeting. Meeting information is available at: www.pcori.org/events/2014/board-governors-meeting-10



Pragmatic Clinical Studies PFA

Improving Healthcare Systems Priority Topics

- April 2013  ■ Integration of Mental Health and Primary Care
- April 2013  ■ Health Insurance Features
- May 2014  ■ Involvement by Patients and Caregivers in Management of Chronic Mental Illness
- Jan. 2014  ■ Innovative Strategies for Medication Adherence

Other IHS-relevant research topics included in IOM's Top 100 Topics for CER or AHRQ's Future Research Needs



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Status of Other Prioritized Topics

April 2013 Meeting

- Perinatal Care
 - Continue to work with the Addressing Disparities program and the Science Oversight Committee of the PCORI Board
- Patient-Empowering Care Management
 - Working with the John A. Hartford Foundation on a jointly funded project to develop the CaRe-Align model of empowering care for older adults with multiple chronic conditions

May 2014 Meeting

- Patient Engagement in Quality Improvement Projects
 - Subcommittee met to refine this topic.
- Multidisciplinary Treatment Approaches to Chronic Pain
 - Refined topic will be discussed later today.
- Linkages Between Providers and Community.



Conclusions and Future Directions

Goals for the Next 12 Months

- Evaluate new initiatives to improve Broad PFA applications and programmatic fit.
 - Competitive screening of Letters of Intent
 - Allow larger project applications (up to \$5 million / 5 years)
 - Area of emphasis for funding opportunities
- Work with Advisory Panel to identify refined high-impact health systems CER topics.
 - Engage with key stakeholders
- Develop new initiatives with other PCORI Programs.
 - Communications and Dissemination – Choosing Wisely®
 - Methods and Infrastructure PCORnet – Rapid-Cycle Research



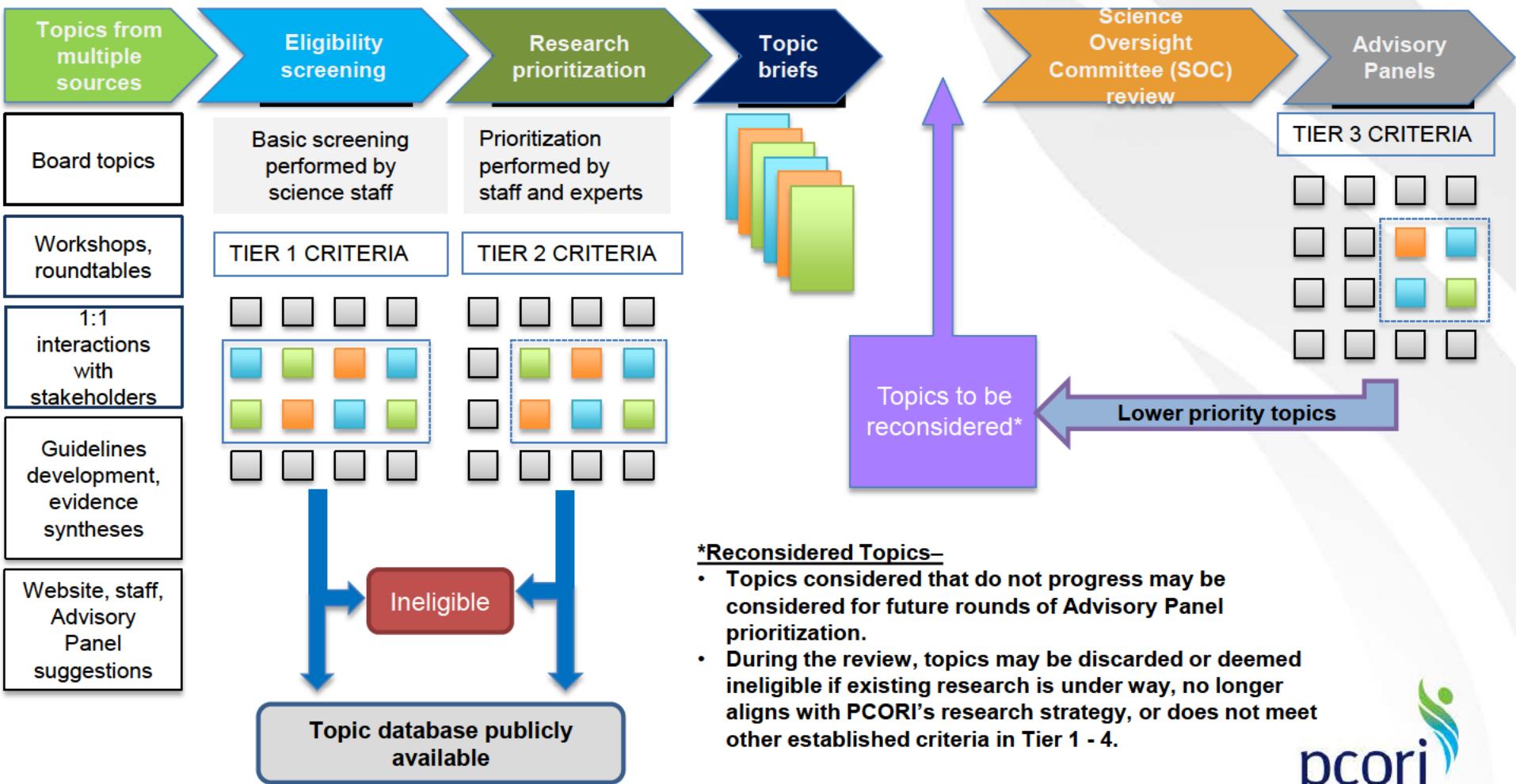
Questions / Discussion

Refining Our Process for Identifying and Selecting Priority Topics

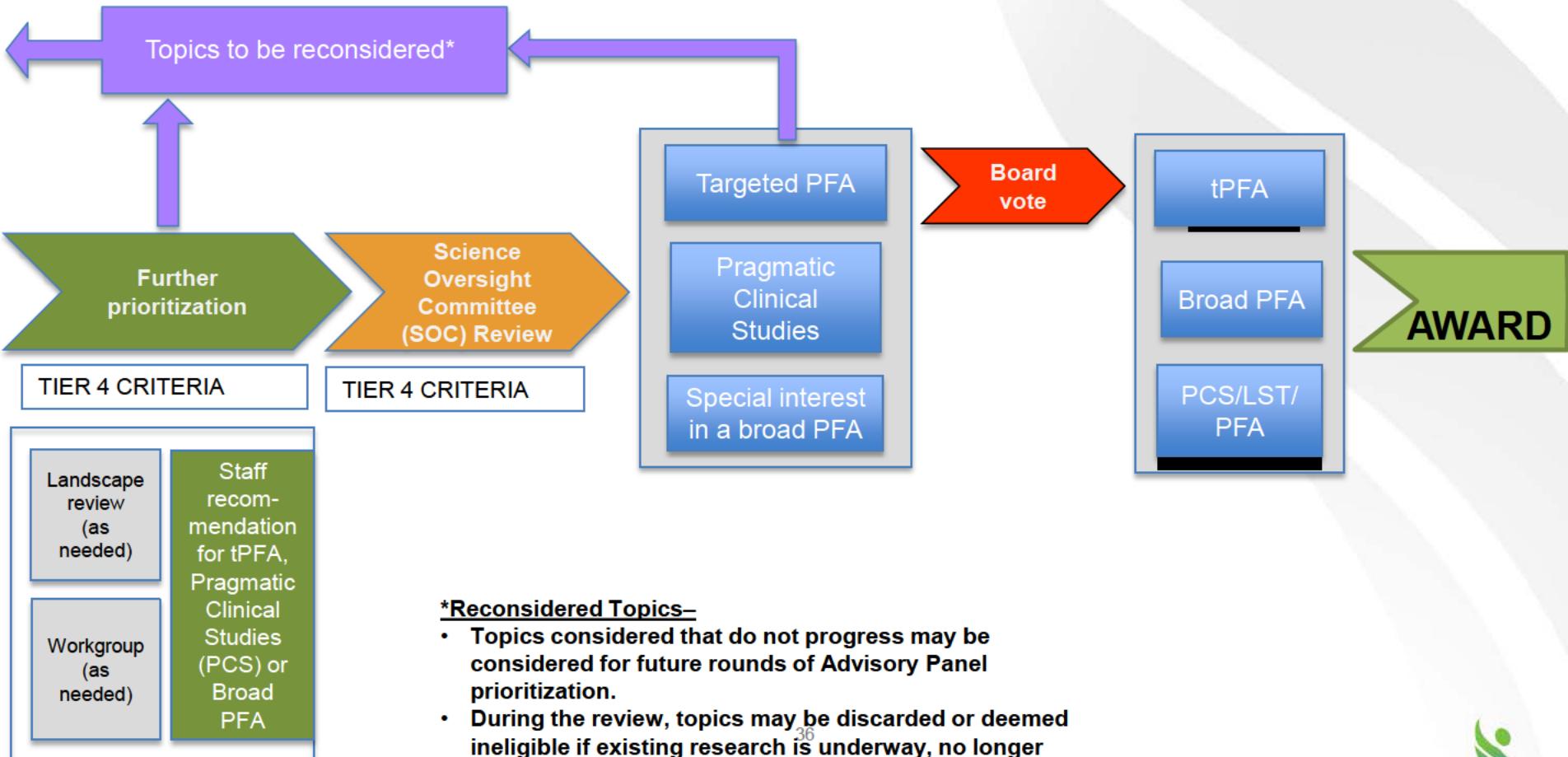
Penny Mohr, MA

Senior Program Officer, Improving Healthcare Systems

PCORI Pathway for Topic Generation and Research Prioritization



PCORI Pathway for Topic Generation and Research Prioritization



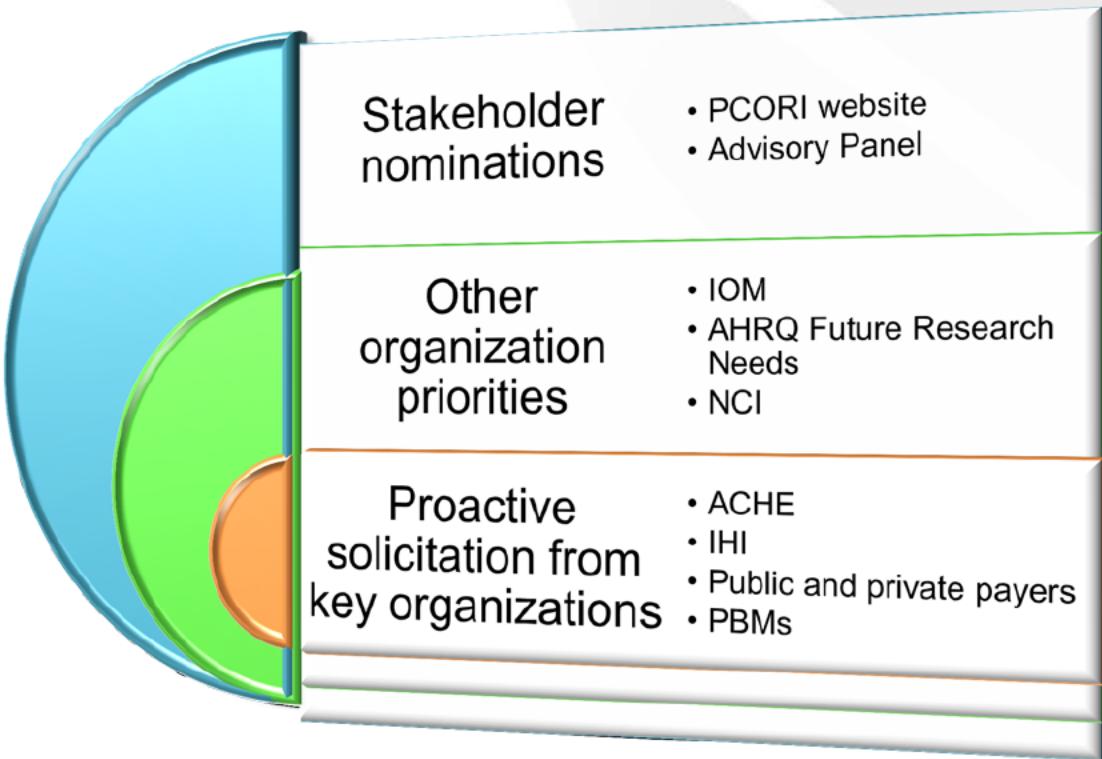
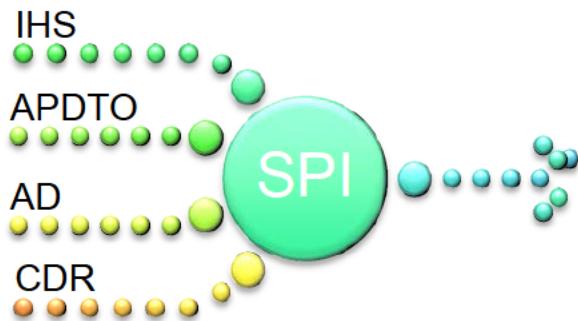
Why Change?

- To be more proactive in seeking input from a broad constituency focused on improving healthcare systems
- To include IHS-specific criteria that would improve the chances that our research findings are adopted and influence systems change
- To bring greater clarity and precision to the topic briefs
- To enable more discussion and consensus building among Advisory Panel members by using a formal modified-Delphi process



Horizon Scanning

PCORI Programs



Acronym Legend:

SPI: Strategic Portfolio Initiative

IOM: Institute of Medicine

AHRQ: Agency for Healthcare Research and Quality

NCI: National Cancer Institute

ACHE: American College of Healthcare Executives

IHI: Institute for Healthcare Improvement

PBM: Pharmacy Benefit Management

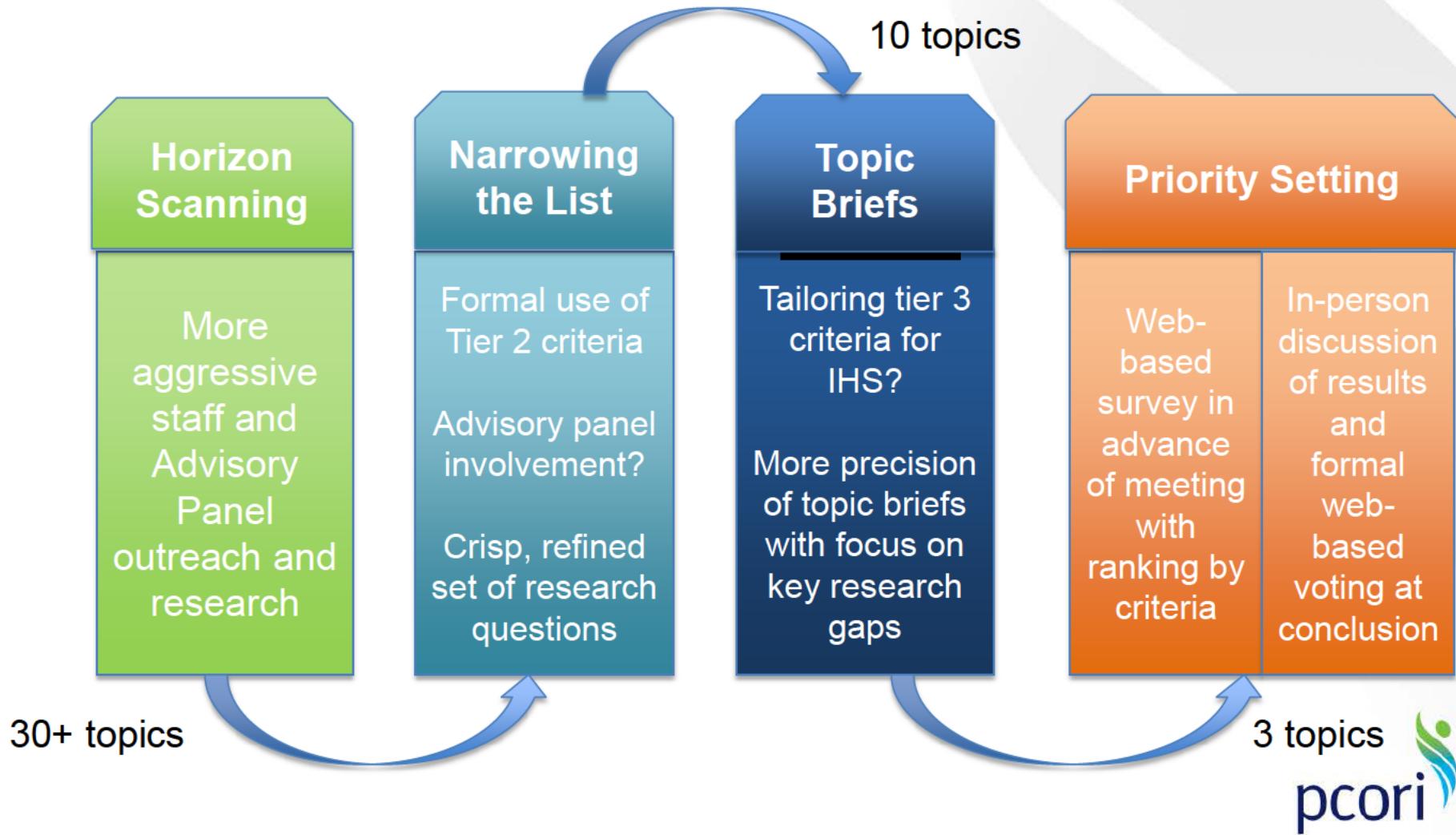


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Tier 3 Advisory Panel Criteria

- **Patient-Centeredness:** Is the comparison relevant to patients, their caregivers, clinicians, or other key stakeholders, and are the outcomes relevant to patients?
- **Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity, or individual suffering?
- **Assessment of Current Options:** Does the topic reflect an important evidence gap related to current options that is not being addressed by ongoing research?
- **Likelihood of Implementation in Practice:** Would new information generated by research be likely to have an impact in practice? (e.g., Do one or more major stakeholder groups endorse the question?)
- **Durability of Information:** Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?

Formalizing the Process



BREAK

10:30 – 10:40 a.m. EDT

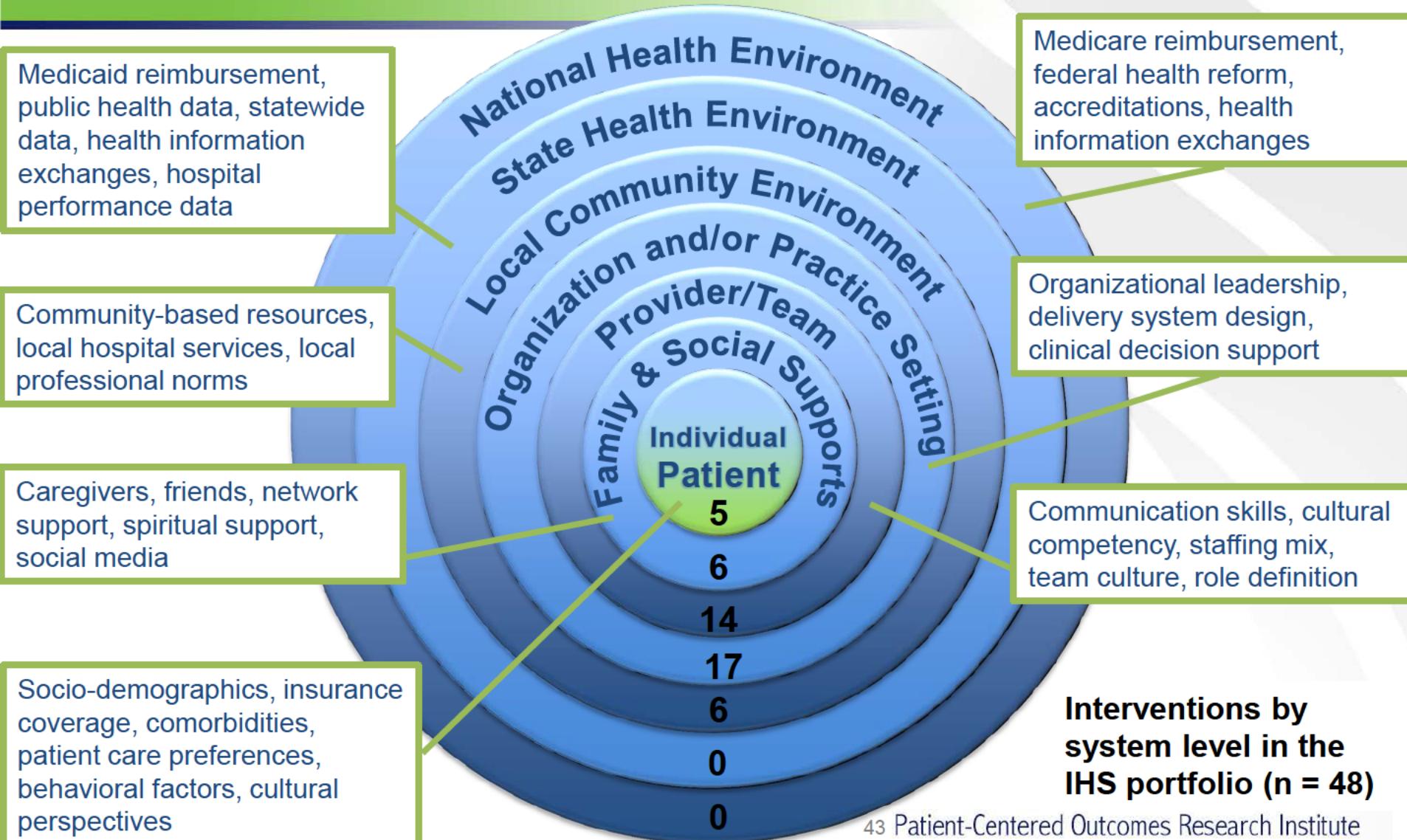
IHS Strategic Framework

Doris Lotz, MD, MPH

Steve Clauser, PhD, MPA

The Healthcare System

Figure adapted from: Taplin, S. H., Clauser, S., et al. (2012). Introduction: Understanding and Influencing Multilevel Factors across the Cancer Care Continuum. *Journal of the National Cancer Institute*, 44, 2-10.

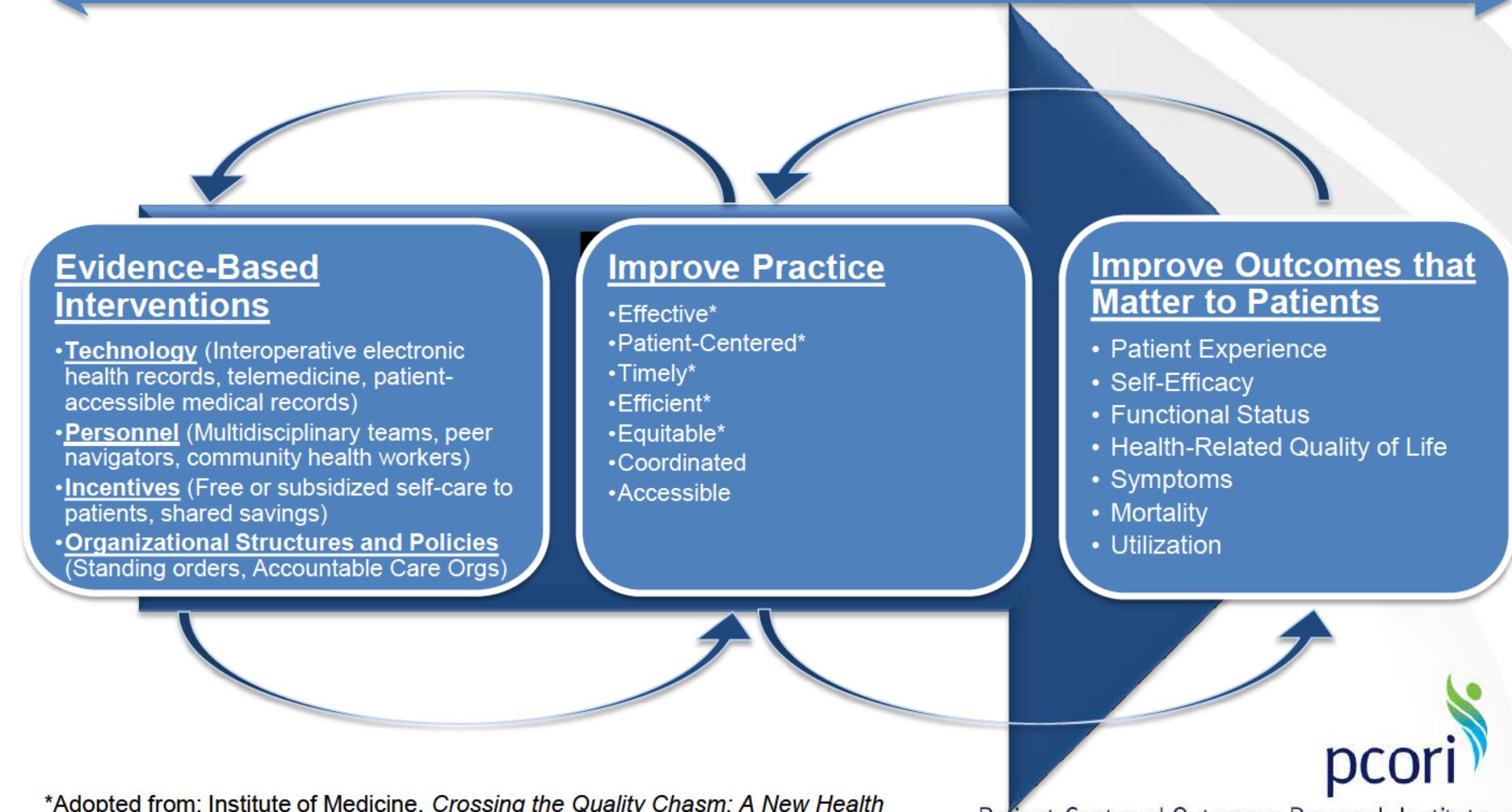


Studies Comparing Interventions by System Level

System Level	# of Studies in the IHS Portfolio	Examples of Comparisons in the IHS Portfolio
Individual Patient	5	Compares the use of an electronic asthma medication tracker to standard primary care (no tracker) for children with asthma and their parents and caregivers
Family and Social Supports	6	Compares the use of advance planning tools for access to community-based and in-home services for the frail elderly and their caregivers to an electronic educational intervention of available services and programs
Provider/Team	14	Compares nursing home staff team-based training and palliative care delivery using an adapted National Quality Forum protocol to a standard nursing home palliative care protocol
Organization and/or Practice Setting	17	Compares elements of Patient-Centered Medical Home (e.g., addition of a primary care physician in the context of regularly scheduled dialysis sessions and health promoters to help support patients and their caregivers) to traditional team-based specialty care for end-stage renal disease patients
Local Community Environment	6	Compares an emergency department to home community health worker that links patients with community-based social-support (e.g., home-delivered meals) and medical follow-up, to care transition programs using written and verbal discharge instructions alone.

IHS Strategic Framework

Patient and Stakeholder Engagement Throughout



*Adopted from: Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: The National Academies Press, 2001.

Discussion

- Comments from subcommittee members
- Questions and comments from the panel
- Keep this information in mind as we move through the next few agenda items
- We will revisit this information at the end of the day to circle back and think about:
 - Where are there opportunities in the IHS portfolio?
 - How can the Advisory Panel apply this framework to prioritization exercises and in engagement activities?
 - How does this shape our future work?



Topic Presentations and Discussions

Patient-Centered Outcomes Research Institute

Overview



3 topics:

- Enrollee Support for Patients in High-Deductible Health Plans
- Comparison of Accountable Care Organizations (ACOs) and Traditional Health Systems for Improving Patient-Centered Care
- Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain



For each topic:

- Two panelists will present the topic brief from their perspectives, including relevant PCORI funding or noted research gap.
- The panel will discuss these topics and potential opportunities for funding.



Topic: Enrollee Support for Patients in High Deductible Health Plans

Leah Binder, MA, MGA
President & CEO, The Leapfrog Group

Susan Diaz, MPAS, PA-C
Physician Assistant, Liver Transplant, Mayo Clinic in Florida

Patient-Centered Outcomes Research Institute

Enrollee Support for Patients in High Deductible Health Plans

Presented by Leah Binder, The Leapfrog Group

Overview of topic

- One in 5 workers in a high-deductible plan with HRA/HAS
- Average deductible over \$2300/single & over \$4,300/family
- Different from other plans: employees typically pay every dollar (excluding some preventive care) underneath the deductible.
- Creates a new kind of patient, suddenly price-conscious
- 50% escalation in overall deductibles for all types of health coverage (ie PPOs, managed care, etc) since 2009



Relevant PCORI-Funded Studies

- No studies relating directly to effects of HDHPs on health for varying populations, or HDHP-specific decision support
- PCORI funds many studies relating to informational support

Enrollee Support for Patients in High Deductible Health Plans

Presented by Leah Binder, The Leapfrog Group

Significance

- Rapid escalation in HDHPs creates major shifts in nation's \$2.7 trillion health care system--driven in large part by patient decisions
- Public and private sectors are grappling with ideas to help consumers navigate, and need evidence on effectiveness of options that lead to best health outcomes



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Enrollee Support for Patients in High Deductible Health Plans

Presented by Leah Binder, The Leapfrog Group

What CER questions need to be answered?

- Compare communication strategies for informing and engaging patients who have high deductible health plans about the price and quality of care, such that they achieve desired outcomes.
- Studies could focus on certain subsets of patients, ie diabetic patients, patients with emergency conditions, maternity patients, etc.
- Studies could compare communication and education strategies, such as health plan materials, web-based materials, direct education, physician-based communication, and specific designs of materials so patients get what they need to make decisions that lead to best health outcomes.



Enrollee Support for Patients in High Deductible Health Plans

Presented by Leah Binder, The Leapfrog Group

Timeliness – why should PCORI take this up now?

- CMS actuaries named HDHPs as one of 2 reasons (along with the economy) for the stable growth in national health spending in 2011 and 2012
- Very significant shift in our healthcare system, patient-driven, virtually zero evidence around it.

Enrollee Support for Patients in High Deductible Health Plans

Presented by Susan Diaz MPAS, PA-C

● Overview of topic

Enrollees do not know or understand HDHPs and avoid preventive and necessary care due to this lack of knowledge. Studies that looked at employers that had one HDHP still found that enrollees did not understand their deductibles or what services are covered without additional cost. This shows that the information available now is not sufficiently understood to support enrollees. The fact that ACA requires health plans to explain benefits in a way that enrollees can understand demonstrate the need for improvement.

● Significance (from my perspective)

- Regardless of social and economic background, enrollees avoid care which shows that there is tremendous difficulty understanding the information currently available. This makes the problem worse since the literature already shows health literacy plays role.
- 80-90% of enrollees avoid preventive care due to lack of understanding about deductibles. This means basic medical care is not done which leads to chronic disease or more severe health consequences.



Enrollee Support for Patients in High Deductible Health Plans

Presented by Susan Diaz MPAS, PA-C

- What CER questions need to be answered?
 - How do focus groups and decision making tools compare to current decision making tools in choosing HDHPS?
 - Does use of focus groups and decision making tools/literature at 3- grade reading level lead to improve understanding of HDHPs compare to current summary of HDHP benefits?
- Timeliness – why should PCORI take this up now?
 - There has not been any meaningful improvement over the last 5 years to help consumers understand HDHPs.
 - The implementation of ACA means more enrollees will have to make decisions about their health plans by themselves. If the current state is not adequate, the ability to chose through the health exchange will be even more difficult for anyone.
 - Technology continues to grow and expand, the addition of a resource for enrollees to use electronically can be achieved.





Topic: Comparison of ACOs and Traditional Health Systems for Improving Patient-Centered Care

Andrew Adams, BBA

MBA Candidate, The Wharton School of the University of Pennsylvania

David Bruhn, PharmD, MBA

Health Outcomes Liaison, National Accounts, GlaxoSmithKline

Patient-Centered Outcomes Research Institute

Relevant PCORI-Funded Studies

IHS projects:

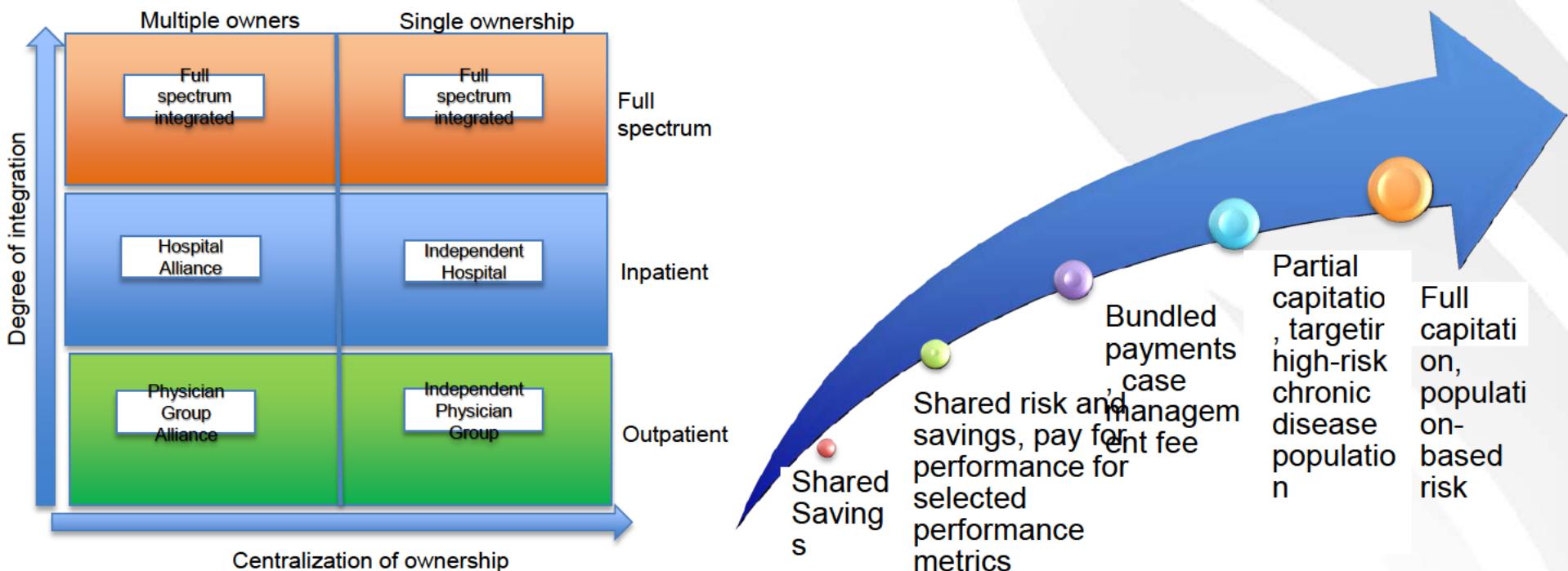
- Relative Patient Benefits of a Hospital-PCMH Collaboration within an ACO to Improve Care Transitions (Cycle 1)
- Improving Care Coordination for Children with Disabilities Through an Accountable Care Organization (W14)
- The Comparative Impact of Patient Activation and Engagement on Improving Patient-Centered Outcomes of Care in Accountable Care Organizations (W14)

Pipeline to Proposal:

- Connecting Research and Real Life: Building a Network in the Columbia River Gorge

Taxonomy and Risk Sharing Models of ACOs

Presented by David Bruhn



- Adapted from Muhlstein et al. A Taxonomy of ACOs. Leavitt and Partners. June 2014.
- Adapted from Delbanco et al. Promising Payment Reform: Risk Sharing with ACOs. The Commonwealth Fund. 2011

Comparison of ACOs and Traditional Health Systems for Improving Patient-Centered Care

Presented by David Bruhn

● Overview of topic

- ACOs included in PPACA in 2010 as a new payment and care coordination model with the goal of improving health outcomes and controlling costs by allowing providers to share in the financial responsibility for patient care
- More than 600 ACOs in 2014 (23 CMS Pioneer, 338 Medicare Shared Savings Program, 287 commercial, 10+ state Medicaid), up from 41 in 2010. ACO market is evolving rapidly.

● Significance

- The number of ACOs and patient population in ACOs is growing rapidly
- Yet, surprisingly few studies in progress on ACOs (e.g., only 5 on ClinicalTrials.gov), with very few on patient-centered outcomes. No systematic reviews comparing ACOs to traditional models for improving patient-centered care exist.
- Mixed results from previous studies, yet ACOs have potential to significantly change the way care is delivered and paid for in the U.S.
- ACOs still in early stages of evolution and robust health IT infrastructure highly variable.



Comparison of ACOs and Traditional Health Systems for Improving Patient-Centered Care

Presented by Andrew Adams

What CER questions need to be answered?

- Compare ACOs to traditional health systems in the following areas
 - Patient satisfaction
 - Out-of-pocket costs to patients
 - Health outcomes
 - Vulnerable populations
- Comparison of different ACOs on the metrics above, patient-centered outcomes
 - How does the difference in ownership and difference in features of the ACO models affect patient-centered outcomes within ACOs? (e.g., physician-led, versus hospital-led, versus fully integrated models)

Timeliness – why should PCORI take this up now?

- ACOs now encompass an est. 14% of U.S. (Kaiser), growing rapidly
- Limited research on the effects of ACOs on patient-centered outcomes
- Early stages of ACOs, findings of studies can be used to improve development and execution of ACOs (e.g., best practices)
- ACOs are positioned to evaluate and measure outcomes for comparison and assessment



Lunch break

12:30 – 1:30 p.m. (EDT)

Patient-Centered Outcomes Research Institute



Topic: Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

Annie Lewis-O'Connor, NP-BC, MPH, PhD

Nursing Scientist Director – Women's C.A.R.E Clinic Brigham and Women's Hospital

John Martin, MPH

Senior Director, Research Operations, Premier Inc

Patient-Centered Outcomes Research Institute

Relevant PCORI-Funded Studies

- IHS pain management studies:
 - Computerized PAINRelievelt Protocol for Cancer Pain Control in Hospice (Cycle 3)
 - Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis (Cycle 3)
 - Optimizing Patient Engagement in a Novel Pain Management Initiative (August 2013)
 - Evaluation of a Health Plan Initiative to Mitigate Chronic Opioid Therapy Risks (August 2013)
 - Specialized Community Disease Management to Reduce Substance Abuse and Hospital Readmissions (August 2013)
 - Prescription Opioid Management in Chronic Pain Patients: A Patient-Centered Activation Intervention (Winter 2014)

Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

Presented by Annie Lewis-O'Connor and John Martin

● Overview of topic:

- Keys words used: adults, chronic pain, alternative medicine, pain management with/without pharmaceuticals. 5 years or less.
- Impressive amount of evidence
- Better understanding of how the sensation of pain occurs has led to many new treatments.

● Significance (from your perspective)

- Multimodal pain management is the state of the science as it approaches pain from a bio-psychosocial and holistic integrative platform.
- Physical pain and psychosocial distress are integral to each other.
- **Non-opioid interventions** aimed at reducing the burden of pain associated distress allows for better pain management and quality of life as measured by mood and ability to participate in desired activities
- Chronic pain management is still very individualized, and it would be difficult to study standardized approaches in this population without a randomized, controlled study.



Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

Presented by Annie Lewis-O'Connor and John Martin

- Advance Include: new pharmacological approaches, use of medical devices, surgical and Complimentary and Alternative Medicine (CAM)
- CAM thought to be effective for chronic pain: physical activity, physical therapy, mind-body therapies (relaxation techniques, meditation, guided imagery, biofeedback, hypnosis), acupuncture, chiropractic treatment, massage
 - Limited evidence of effectiveness of CAM approaches and their side effects when used on their own (unimodal)
 - Most CAM is paid for out of pocket, but accounts for 30% of costs in chronic low back pain
 - CAM is increasingly being sought by patients, but there is still a hesitance to use it in the traditional medical community
- Chronic pain treatment is typically very individualized and requires a lot of trial and error before finding the correct combination of treatments
- Other important considerations:
 - Patients are not always aware there are pain management physicians, and often only see them in advanced stages of pain, when more difficult to reduce or prevent chronic pain.
 - AHRQ currently funding systematic review of non-invasive treatment for back pain – to be completed mid-2015

Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

Presented by Annie Lewis-O'Connor and John Martin

- Patients with chronic pain experience feelings of isolation- these feelings of pain are often magnified when management is solely based on a medical model.
- One JAMA article suggested:
 - Treatment planning for persistent pain in later life requires a clear understanding of the patient's treatment goals and expectations, co-morbidities, and cognitive and functional status, as well as coordinating community resources and family support.
 - A combination of pharmacologic and non-pharmacologic as well as rehabilitative approaches in addition to a strong therapeutic alliance between the patient and physician is essential in setting, adjusting, and achieving realistic goals of therapy.
- The conventional "here, take this pill" and come back in two weeks approach is quite lonely when compared to those who are being seen by physical therapists, use integrative modalities such as light, guided imagery, meditation, on top of a medication regimen that is focused on treating the cause of the pain as opposed to relieving it with medication.
- Support groups have been found to reduce the feeling of isolation especially for people suffering from chronic pain related to sensitive illnesses.
- A meta-analysis shows significant improvement using meditation for psychological stress (JAMA, 2014)
- Summary: bi modal therapy, relationship and coordination key, pain psychology, physical therapy realistic goals of patient,

Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

Presented by Annie Lewis-O'Connor and John Martin

- What CER questions need to be answered?
 - Seems much is being done in regards to treatment. Wonder if to advance the field more focus needs to occur on education of patients and providers.
 - What are the adverse effects of non-medical/non-pharmaceutical therapy for chronic pain management?
 - What are the long term effects of non-medical/non-pharmaceutical therapy for patient outcomes and potential side effects of long term care?
 - What impact can primary care providers with education of non-medication/non-pharmaceutical therapy have on patient outcomes ?
- Timeliness – why should PCORI take this up now?
 - It appears a number of studies are in progress related to pain. We wonder whether the results of those studies should be reviewed prior to starting another.
 - Important topic and could help a significant number of patients if non-medical/non-pharmaceutical treatments are effective, but may want to wait on solid efficacy of treatments in smaller populations prior to attempting to implement an effectiveness study.
 - May want to wait for AHRQ systematic review in 2015 to formulate appropriate CER questions.

Review of All Topics and Other Funding Opportunities

Doris Lotz, MD, MPH

Steve Clauser, PhD, MPA

Focus and Refinement

- Do we have a clear set of refined CER questions and next steps?
- Where should we focus our time first?

● **Funding Mechanisms**

- **Broad Funding**
 - IHS Broad PFA
 - Investigator initiated
- **Targeted Funding**
 - Targeted PFA
 - MOU with other organizations
- **Pragmatic Clinical Studies and Large Simple Trials**
 - Specific areas of interest



Other Funding Opportunities to Consider

Choosing Wisely®

- Collaborate with PCORI Communication and Dissemination Research Program
- Comments from Eve Kerr?

PCORnet – Rapid-Cycle Research

- Collaborate with PCORI Methods and Infrastructure Program

Telemedicine

- Veterans Affairs and Department of Defense

Open Discussion of Opportunities

Overview of Stakeholder Engagement

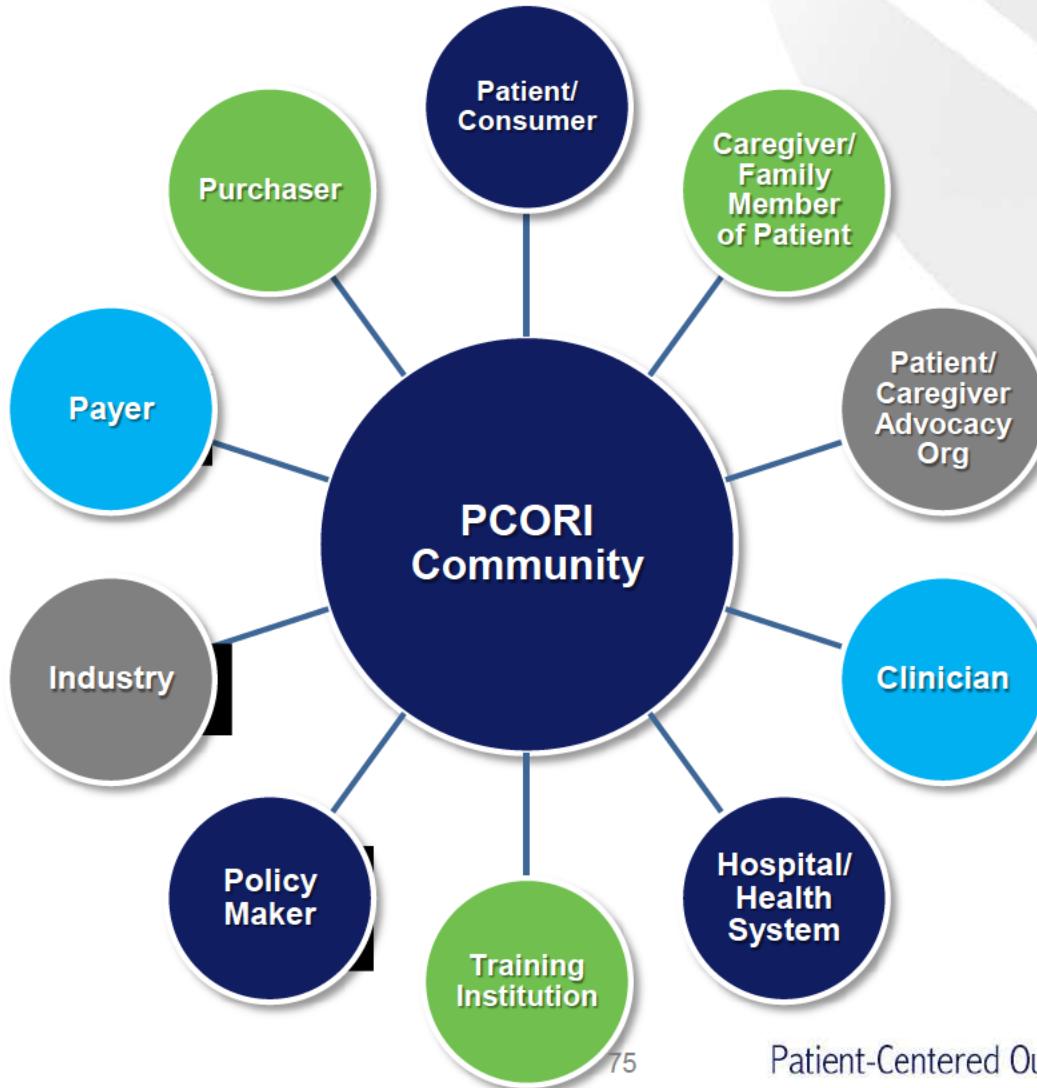
Susan Hildebrandt, Director, Stakeholder Engagement

Greg Martin, Deputy Director, Stakeholder Engagement

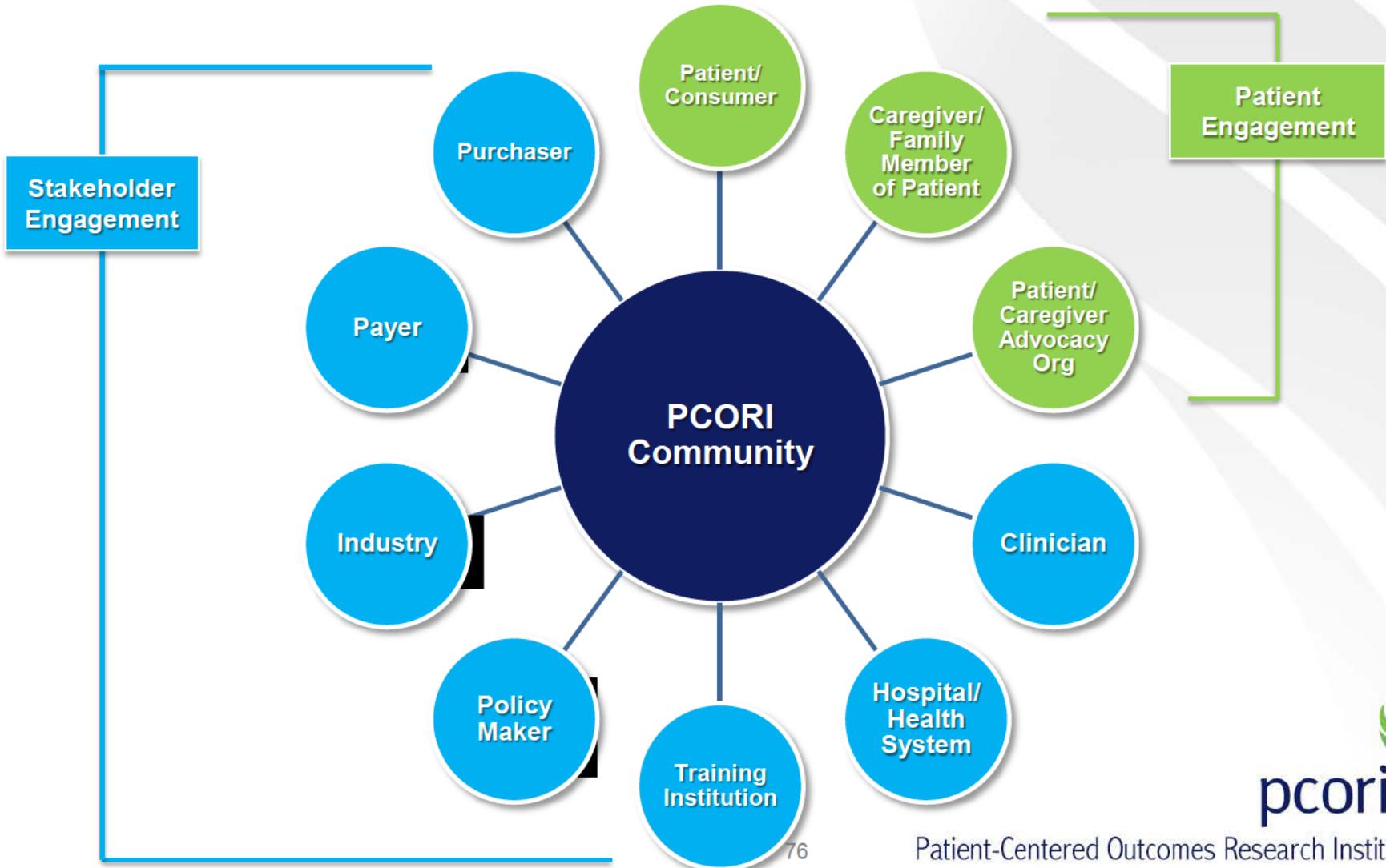
What We Will Cover

- Definition of stakeholder communities
- Involvement of stakeholders in PCORI activities
- Discussion of stakeholders of interest to the IHS Advisory Panel

Who Are Our Stakeholders?



Who Are Our Stakeholders?



Engagement Goals

Build a Patient-Centered Outcomes Research Community



Engage the PCOR Community in Research



Promote
Dissemination and Implementation

Engagement as a Path to Useful, High-Quality Research

Topic Selection
and Research
Prioritization

Evaluation

Review, Design, and
Conduct of Research

Dissemination and
Implementation of
Results





Stakeholder Mapping

- Capturing engagement with each of our stakeholder communities
 - Classify past interactions
 - Identify gaps
 - Determine future activities to continue meaningful engagement of stakeholders



Community Building Activities

Activities

- Roundtables
 - Targeted engagement with specific communities
- Webinars
 - Targeted education opportunities with specific communities or on specific topics
- Regional Workshops
 - Broad, multi-stakeholder events to provide interaction among PCORI, patients, and stakeholders

Goals

- Promote interest/understanding of PCORI's mission and activities
- Gain insight into the research priorities of patients and stakeholders
- Highlight opportunities for engagement in PCOR/PCORI
- Inform potential applicants of funding opportunities and how to apply
- Develop and foster ways to disseminate and implement PCORI findings



Engagement in Research Prioritization

Advisory Panels

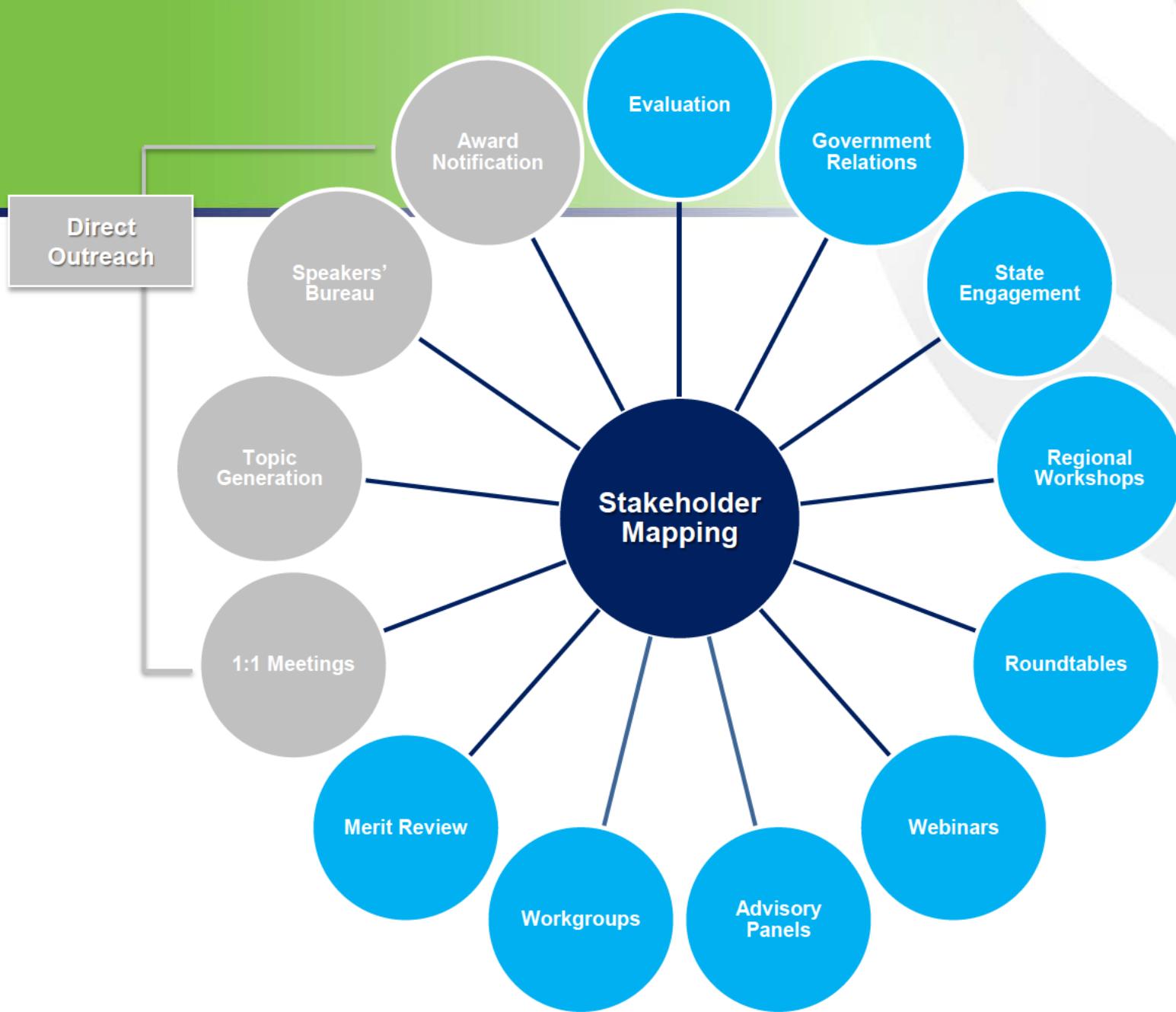
- Developed and led inaugural advisory panel process
- Solicit applications and nominations, review applications and provide strategic advice on final nomination slate

Workgroups

- Identify and recruit key participants from multiple stakeholder constituencies to participate in target refinement activities
 - Stakeholders report workgroups as highly valuable ways to be involved substantively with PCORI

Merit Review

- Manage Patient and Stakeholder (P/S) Reviewer Program
 - Invite stakeholders to join the PCORI P/S Reviewer pool
 - Vet applications
 - Evaluate P/S Reviewers
 - Recruit, train, and manage Mentor Reviewers
- Collaborate with Science and Contracts Management
 - Training
 - Communications
 - Ensure appropriate, balanced P/S representation on panels



Direct Outreach

1:1 Meetings

- Meet proactively with stakeholder organizations to educate them about PCORI
- Facilitate requests to meet with PCORI staff

Topic Generation

- Collect priority topics of key stakeholder organizations
- Analyze topics against present PCORI portfolio
- Create targeted activities for stakeholders to continue to provide advice and input to PCORI around priority topics

Direct Outreach

Notification of PCORI Activities and Awards

- Stakeholder Organizations
 - Targeted notification of PCORI funding opportunities
 - Targeted notification of new PCORI awardees
- US Congress
 - Notify Senators and Representative each time constituent receives PCORI award

Speakers' Bureau

- Prioritize and reach out to stakeholder organizations about PCORI presentations and workshops
- Review incoming requests for PCORI speakers and assess participation, in collaboration with Science and Communications



pcori



Government Relations

Congress

- Have regular communication with staff of four authorizing committees to educate them on PCORI activities and respond to requests for information
- Update PCORI leadership on congressional affairs and conduct regular and ad hoc prep sessions for PCORI leadership
- Develop talking points for PCORI leadership to use in communications about PCORI

Federal Agencies

- Coordinate PCORI activities with federal agencies

State Engagement

Medicaid Medical Directors Network (MMDN)

- Developing closer ties with the MMDN
 - Now under the National Association of Medicaid Directors
- Request for funding from the MMDN is in negotiation

State Engagement Plan

- Updating and refining plan submitted in 2013

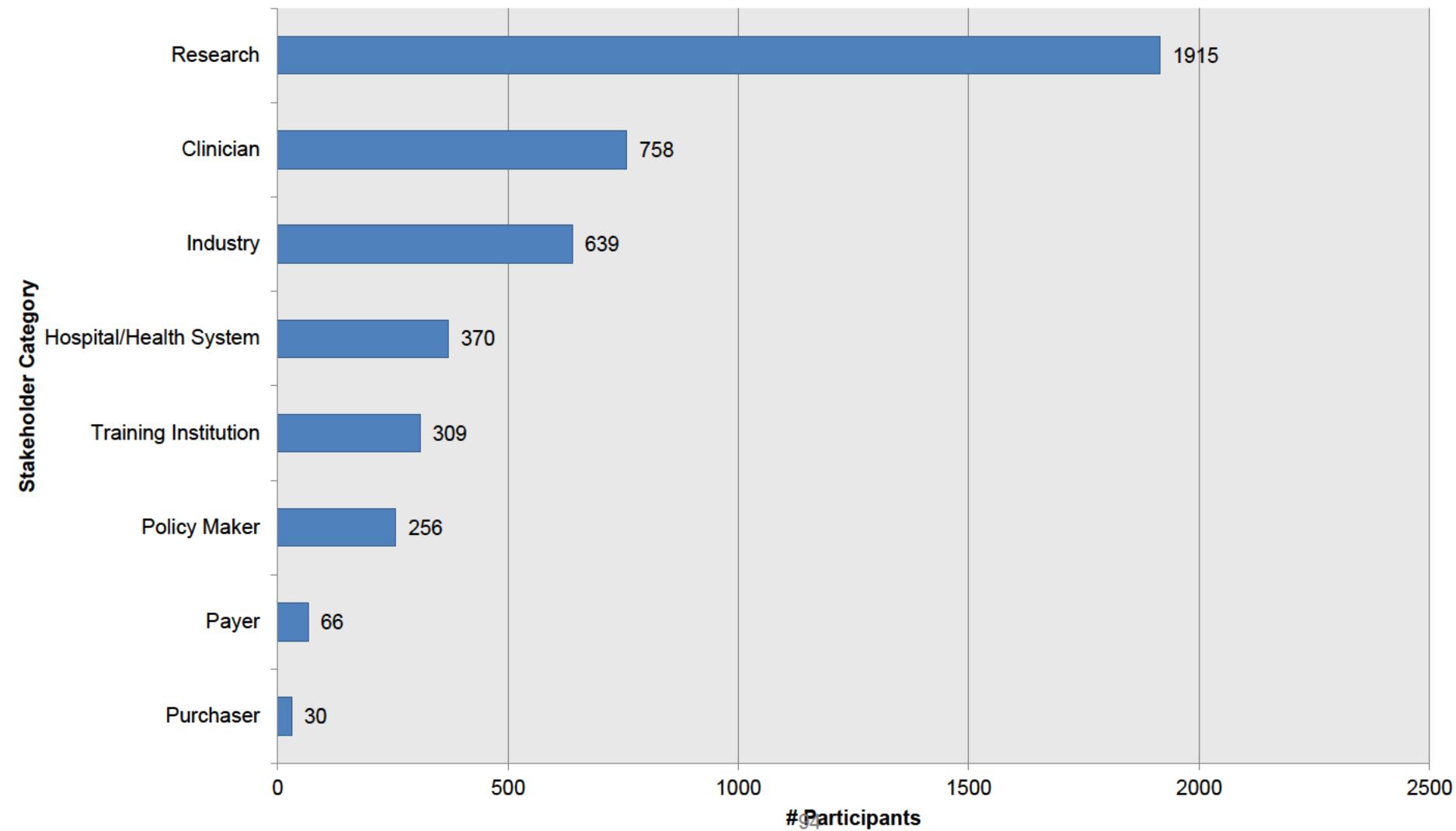
Evaluation

- Work closely with PCORI Evaluation Group to evaluate Engagement programs and projects, along with PCORI activities
 - Evaluate all Engagement activities
 - Align all Engagement-led data collection tools and domains with organizational standards
 - Feed appropriate metrics into institute-wide evaluation
 - Use program and project evaluations to inform future decision making



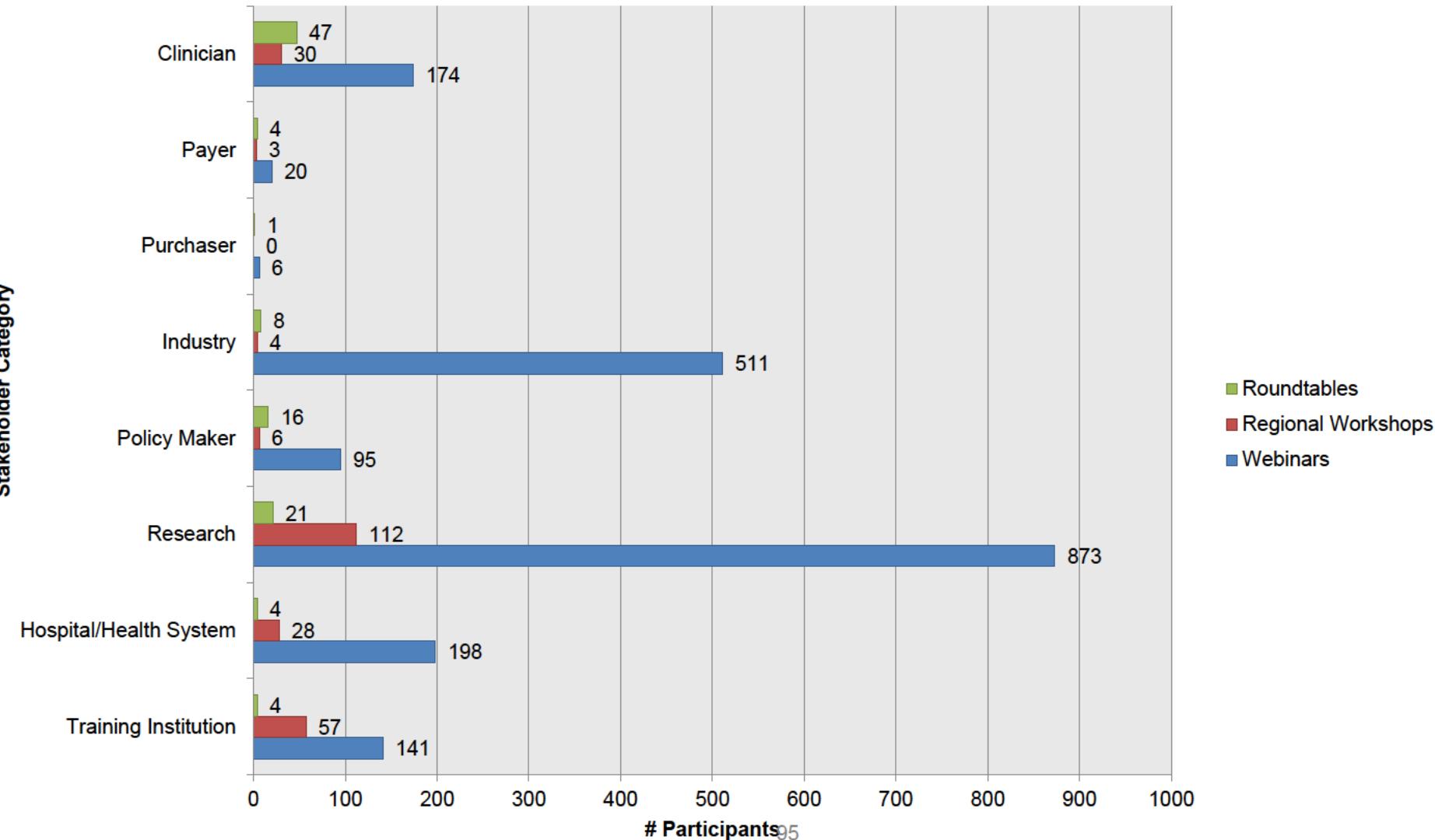
Total Stakeholder Participation (May 2014)

(N = 4,343)



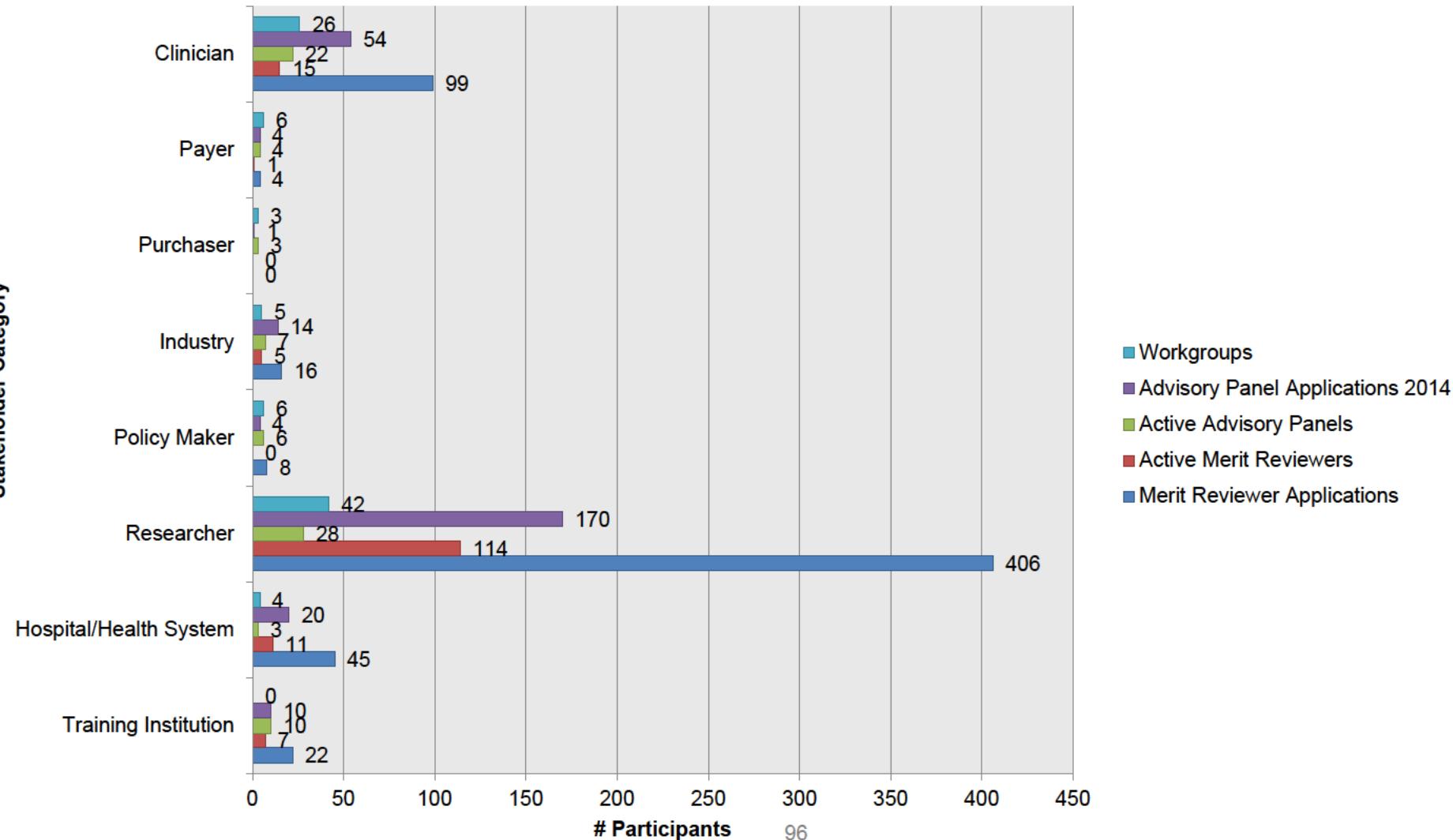
Community Building (May 2014)

By Stakeholder Category (N = 2,363)



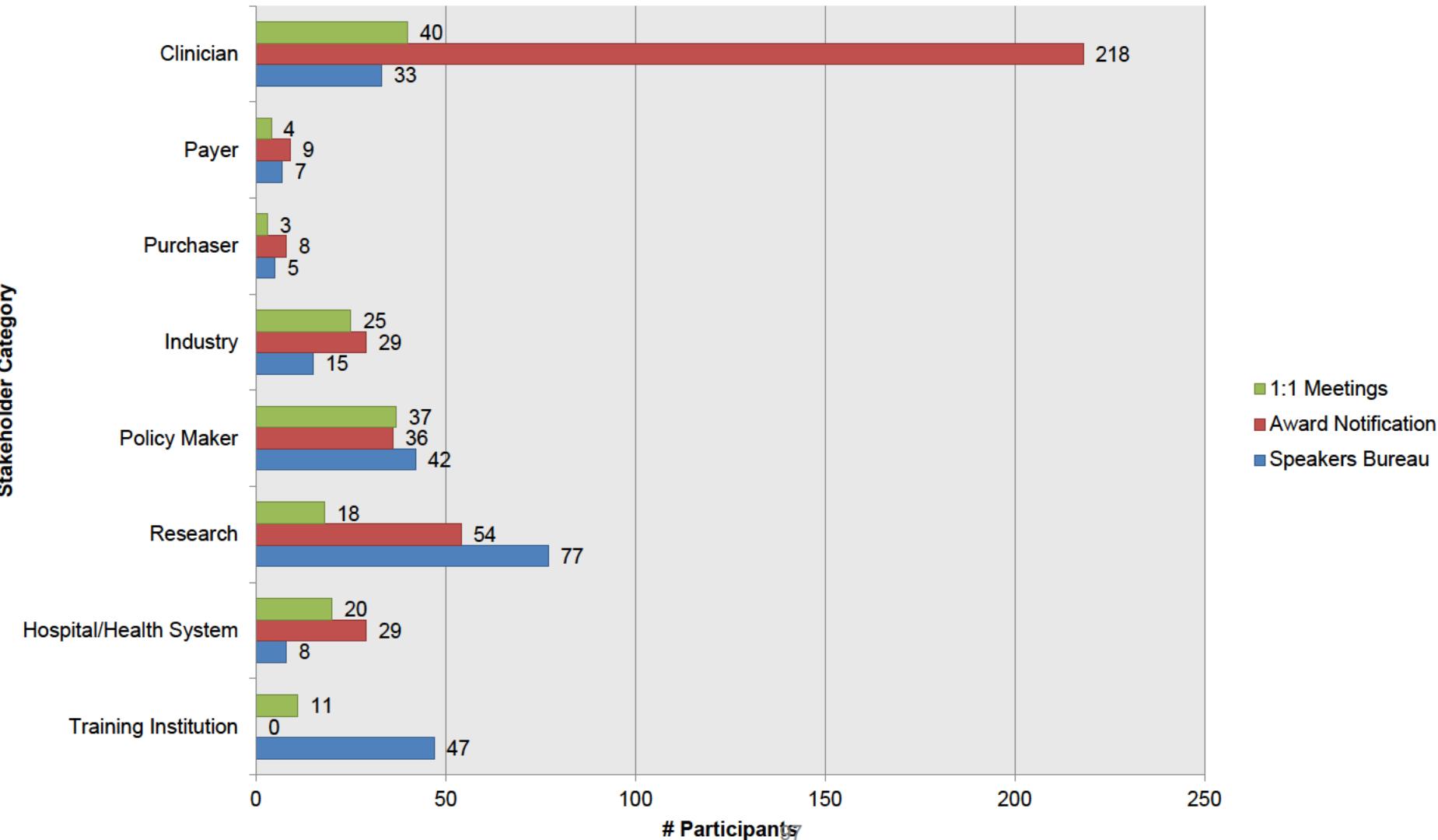
Research Prioritization (May 2014)

By Stakeholder Category (N = 1,205)



Direct Outreach (May 2014)

By Stakeholder Category (N = 775)



Questions?

Recap of the Day

Doris Lotz, MD, MPH

Importance of Incorporating Constituency Perspectives

- Now that we've heard from PCORI Stakeholder Engagement staff, think about how Advisory Panelists can also engage with key constituency groups to strengthen the prioritization process and the IHS research agenda.
 - PCORI staff is available as a resource

The Strategic Framework Discussion

- Now that we've had a full discussion today, continue to think about and apply the IHS strategic framework to your recommendations:
 - Where are there opportunities in the IHS portfolio?
 - How can the Advisory Panel apply this framework to prioritization exercises and in engagement activities?
 - How does this shape our future work?

Opportunities to Submit Questions

- Through PCORI's Website

<http://www.pcori.org/content/suggest-patient-centered-research-question>

- Expedited email to IHS Staff

ihsadvisorypanel@pcori.org

All topics should be submitted in the form of a comparative effectiveness research question. For example:

Do alternate types of care for chronic obstructive pulmonary disease, such as respiratory care at home versus acute hospitalizations, improve patient and caregiver outcomes?

Next Steps and Closing Remarks

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Next Steps

- Next Advisory Panel Meeting January 14 – 15, 2015
 - Details to come
 - Submit suggestions to IHS staff ihsadvisorypanel@pcori.org or to the co-chairs
- Continue to spread the word about PCORI, talk with key stakeholders, and submit CER questions with high potential for impact.
- Staff will continue to develop previously prioritized topics.

Adjourn

Thank you for your participation!

Find PCORI Online



www.pcori.org

