

Advisory Panel on Patient Engagement

Spring 2015 Meeting

June 2, 2015

Washington, DC



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agenda for June 2

9:00 – 9:15 a.m. – Recap of Day 1, Overview of Day 2

9:15 – 9:45 a.m. – Dissemination and Implementation Action Plan

9:45 – 10:30 a.m. – Engagement Evaluation (Update)

10:30 – 10:45 a.m. – BREAK

10:45 – 11:45 a.m. – Engagement Awards

11:45 a.m. – 12:30 p.m. Wrap-up, Next Steps, and Reflections

12:30 p.m. – Meeting Adjourned (Boxed Lunch)



Recap of Day 1, Overview of Day 2

Sue Sheridan, MIM, MBA, DHL
Director of Patient Engagement



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PCORI and Dissemination

Jean Slutsky

Chief Engagement and Dissemination Officer and
Program Director, Communication and Dissemination Research

PEAP
2 June 2015

Patient-Centered Outcomes Research Institute



Authorizing Legislation

“The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed ~~through research and evidence synthesis...~~

... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and cost-effectiveness of medical treatments, services...



Dissemination is Complicated

resources

incentives

accessible payers

multidisciplinary

process and outcome measures

underserved groups

strength of the evidence

engagement

needs and priorities

convener

existing priorities

body of evidence

context

audience

actionable

champions

partners

sustainability

buy-in

relevance to audience

challenges

costs

stakeholders

real-world applications

motivations

business case

regulatory and policy levers

trusted sources

unintended consequences

early in the process



Dissemination and Implementation Start Before Findings Are Ready

Effective dissemination and implementation start at the point of research topic selection, as emphasized by stakeholders—long before research is conducted and evidence is ready to be shared. To understand the ***needs of audiences*** who will use evidence to make health and healthcare decisions, research must address ***questions that are relevant*** to those audiences. To that end, those individuals and organizations who may partner with PCORI to disseminate and implement evidence should be engaged as ***partners from the beginning***.



PCORI's Obligation Under its Authorizing Legislation

Conduct Peer Review of Primary Research

- Assess scientific integrity
- Assess adherence to PCORI's Methodology Standards

Release of Research Findings

- No later than 90 days after “conduct or receipt”
- Make available to clinicians, patients, and general public
- **Make comprehensible and useful to patients and providers for healthcare decisions**
- Include considerations specific to certain sub-populations, risk factors, and comorbidities
- Describe process and methods, including conflicts of interest
- Include limitations and further research needed



Important Issues about Research Findings

- The primary questions and challenges to be addressed when assessing evidence include: ***Is the evidence ready for use and adoption now? What stakeholder priorities, needs, and concerns does the evidence address?***
 - Determine how the evidence relates to existing evidence.
 - Determine why the evidence matters to patients, other stakeholders, health policy, and practice.
 - Anticipate barriers to use in decision making.



- When should PCORI results be actively disseminated to decision makers (patients, clinicians, policy/practice leaders) with a recommendation for their implementation, vs. disseminated more passively because implementation is deemed premature? I.e., what are the criteria for determining when research results are suitable for immediate implementation vs. research results requiring validation, replication and/or synthesis with other similar studies to comprise a stable evidence base suitable for decision making and implementation?



Concepts Fundamental to Effective Dissemination and Implementation



Context. D&I efforts are not one size fits all. Evidence, audience, and setting all determine the context for D&I activities. Identifying the relevant aspects of context related to an audience or setting can take time and resources, and requires help from partners and stakeholders.

Engagement. D&I efforts will not succeed without ongoing stakeholder engagement to provide the context needed to tailor D&I activities. Ongoing support for engagement can help activate stakeholders and encourage capacity building among partners.

Evaluation. Understanding how and why certain D&I activities work better than others is vital. Evaluation should be considered as soon as planning for D&I activities begins. Evaluation should focus on measurable processes and short-term outcomes that provide timely information on the effectiveness of D&I activities. Ongoing feedback based on assessment of processes and short-term outcomes can inform future D&I efforts.



Figure 1: Conceptual Framework for PCORI Dissemination Efforts

DRAFT

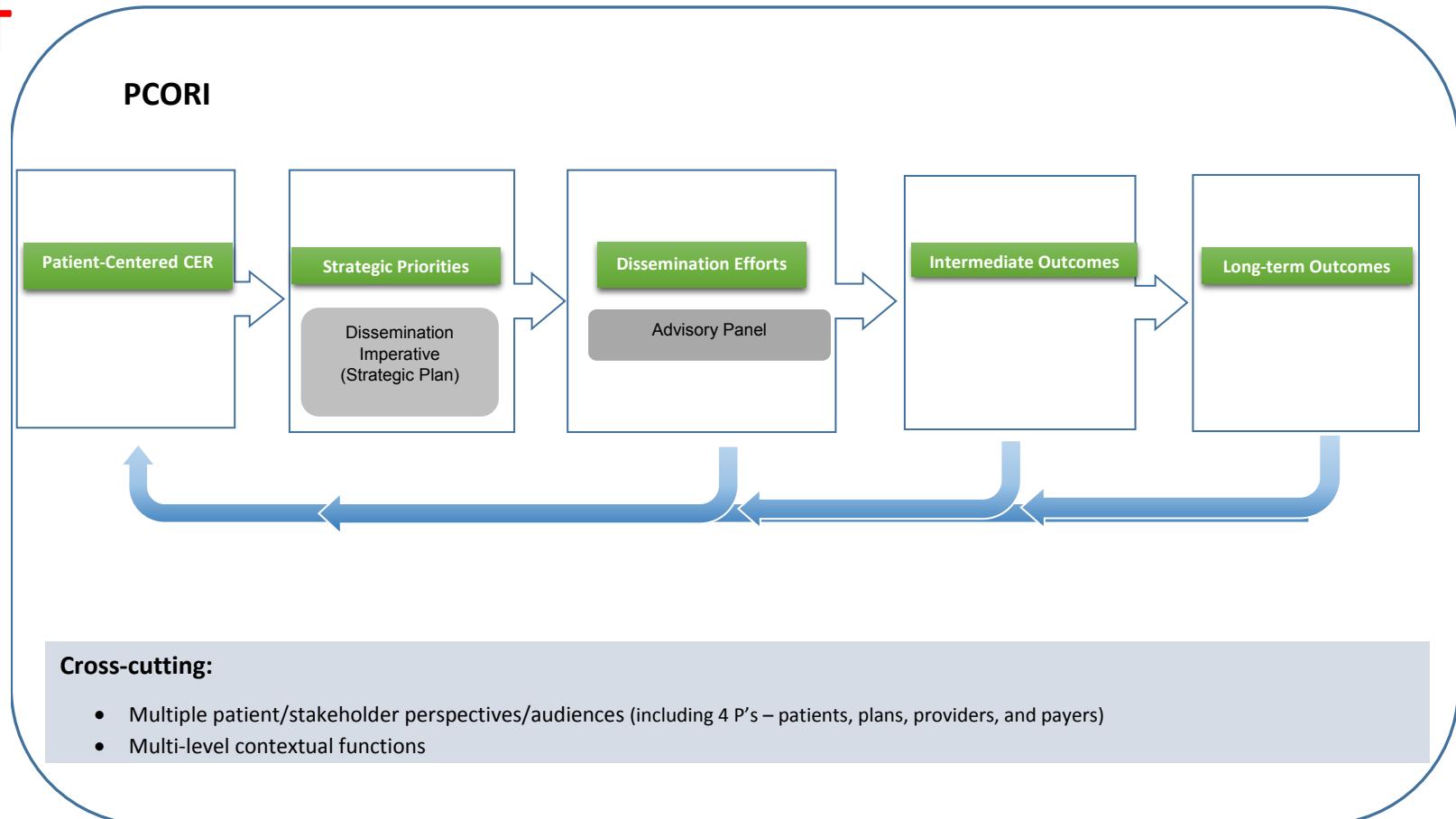
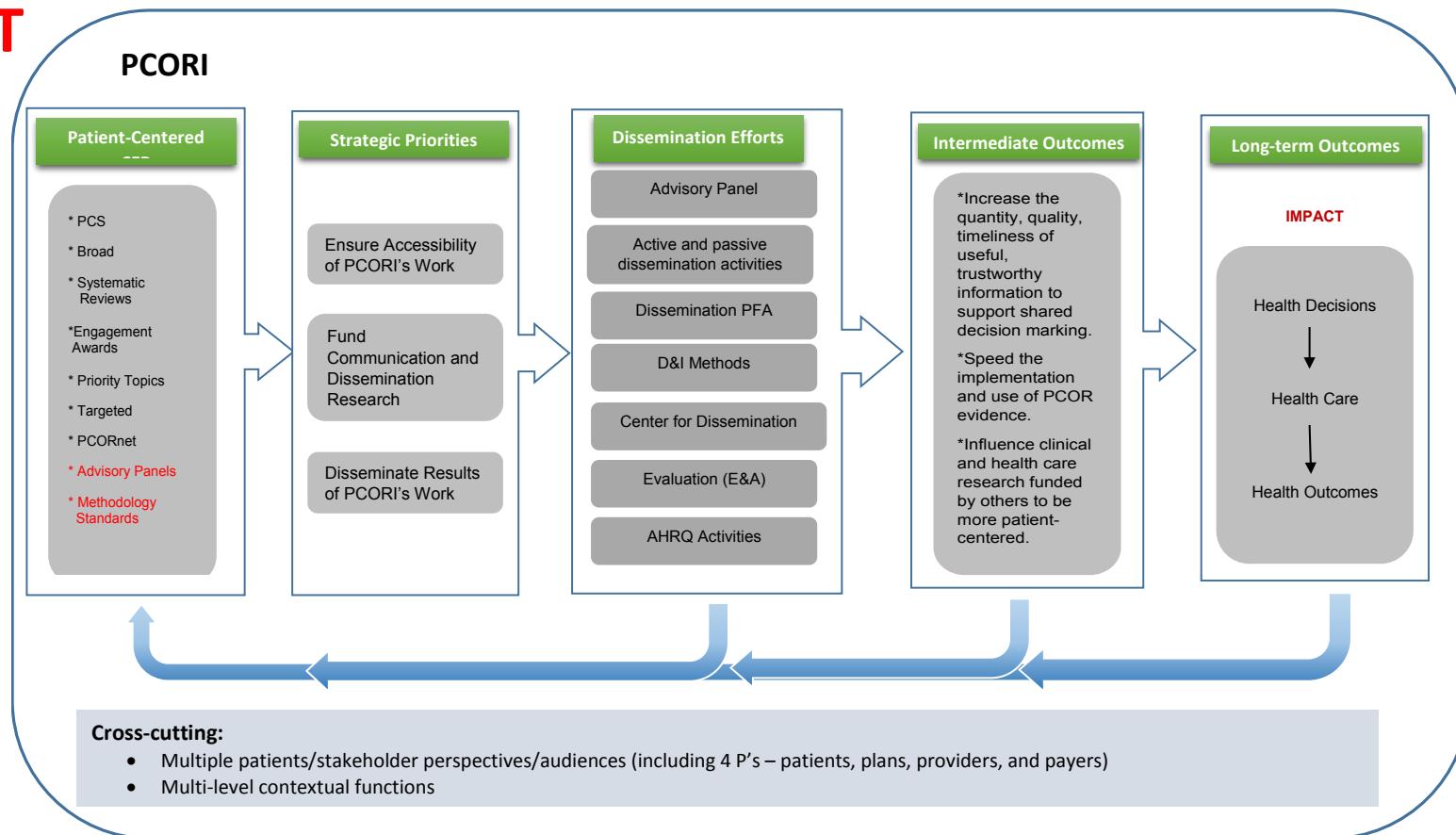
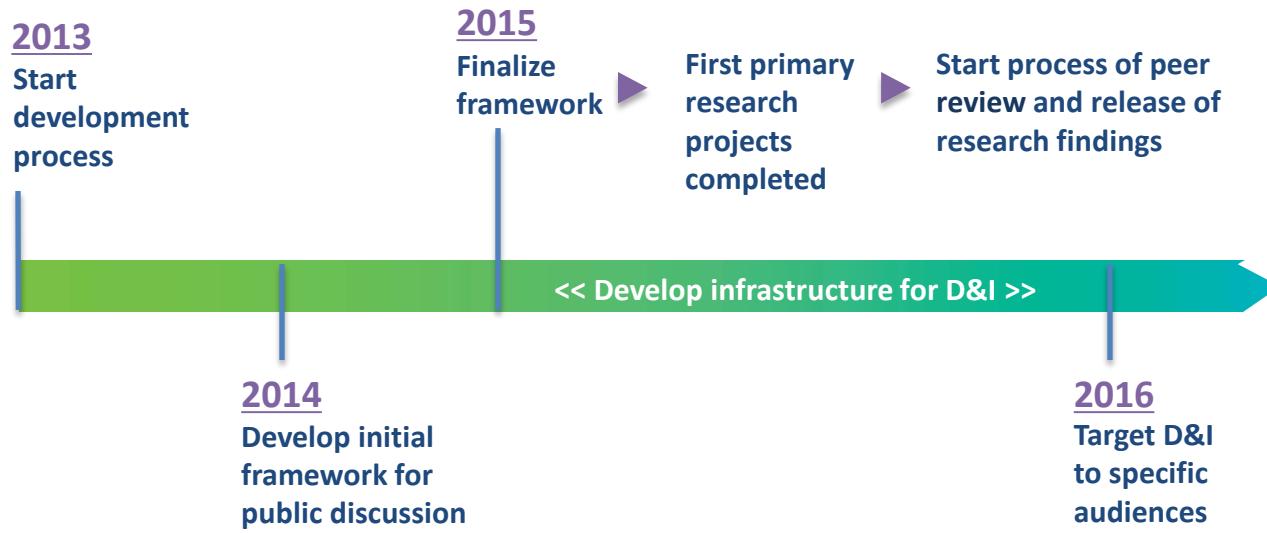


Figure 1a: Framework for PCORI Dissemination Efforts

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Dissemination and Implementation Timeline



Going Forward

- Continue Building a network of organizational and community partners.
- Establish a dissemination expert panel made up of patients and other stakeholders who will assist in a process to assess if broad dissemination is appropriate.
- Build on existing efforts to synthesize D&I lessons.
- Test the process.



Current State

- CE/CME capacity Done
- Dissemination Center RFP in process
 - Lay and clinician translation
 - Shared decision making
 - Addressing health literacy
 - Advisory Panel
- Engaging communities and “intermediaries” EA Awards to start
- Limited competition dissemination PFA PFA in process
- Program Director, Dissemination Recruitment in process



Thank You

Jean Slutsky

Chief Engagement and Dissemination Officer
and
Program Director, Communication and
Dissemination Research



Understanding Engagement in Research

Laura Forsythe, PhD

Lori Frank, PhD

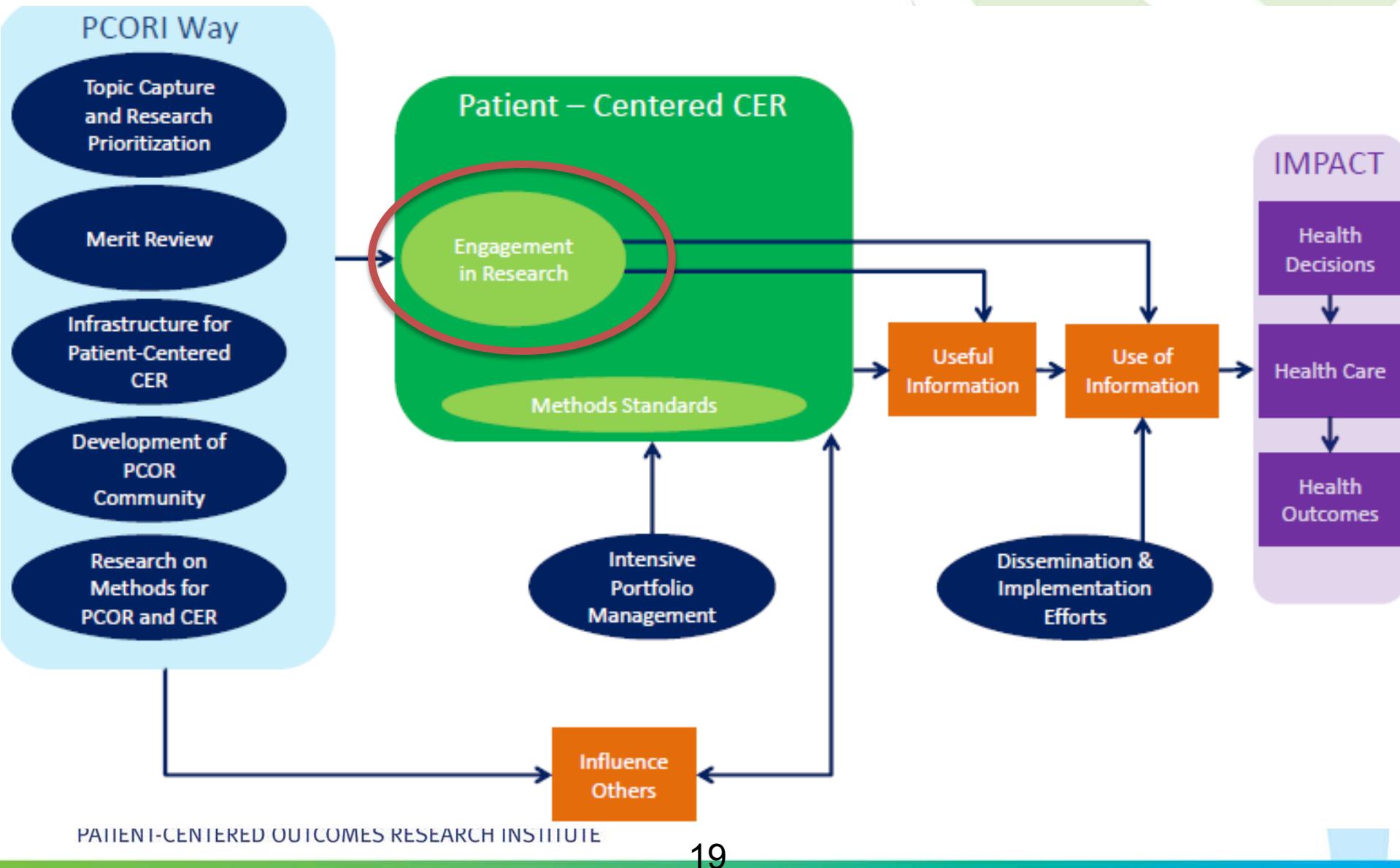
Victoria Szydlowski

Evaluation & Analysis



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PCORI Evaluation Framework



Objectives for Measuring Engagement

- **Describe** engagement in PCORI funded projects
- **Evaluate** impact on PCORI strategic goals
- **Inform** PCORI funding requirements
- **Guide** current awardees, future applicants, and others interested in PCOR
- **Support** project progress based on learnings



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

- Pilot project awardees:
Baseline and Project End
- Subsequent awardees:
Baseline and Year 1
- Awardees nominate research partners to be invited to respond



WE-ENACT Data Collection

	Researchers N (% response rate)	Patient/stakeholder partners N (% response rate)
Baseline	60 (82%)	97 (54%)
Year 1	99 (71%)	177 (56%)
End of project (Pilot projects)	27 (54%)	25 (56%)
TOTAL	186	299



Methods for Qualitative Analysis

(N= 105 researchers, 93 patients and stakeholders)

- Partnership with American Institutes for Research
- Developed & applied codebook based on research questions and review of the open-text responses
- Identified major themes
- Mapped themes to conceptual model of PCOR¹

¹ Frank L, Forsythe L, Ellis L, Schrandt S, Sheridan S, Gerson J, Konopka K, Daugherty S. Conceptual and practical foundations of patient engagement in research at the patient-centered outcomes research institute. Qual Life Res. 2015 Jan 6.



Qualitative Research Questions

- Engagement strategies
- Barriers and facilitators
- Impact of engagement
- Differences by respondent type
- Questionnaire improvements



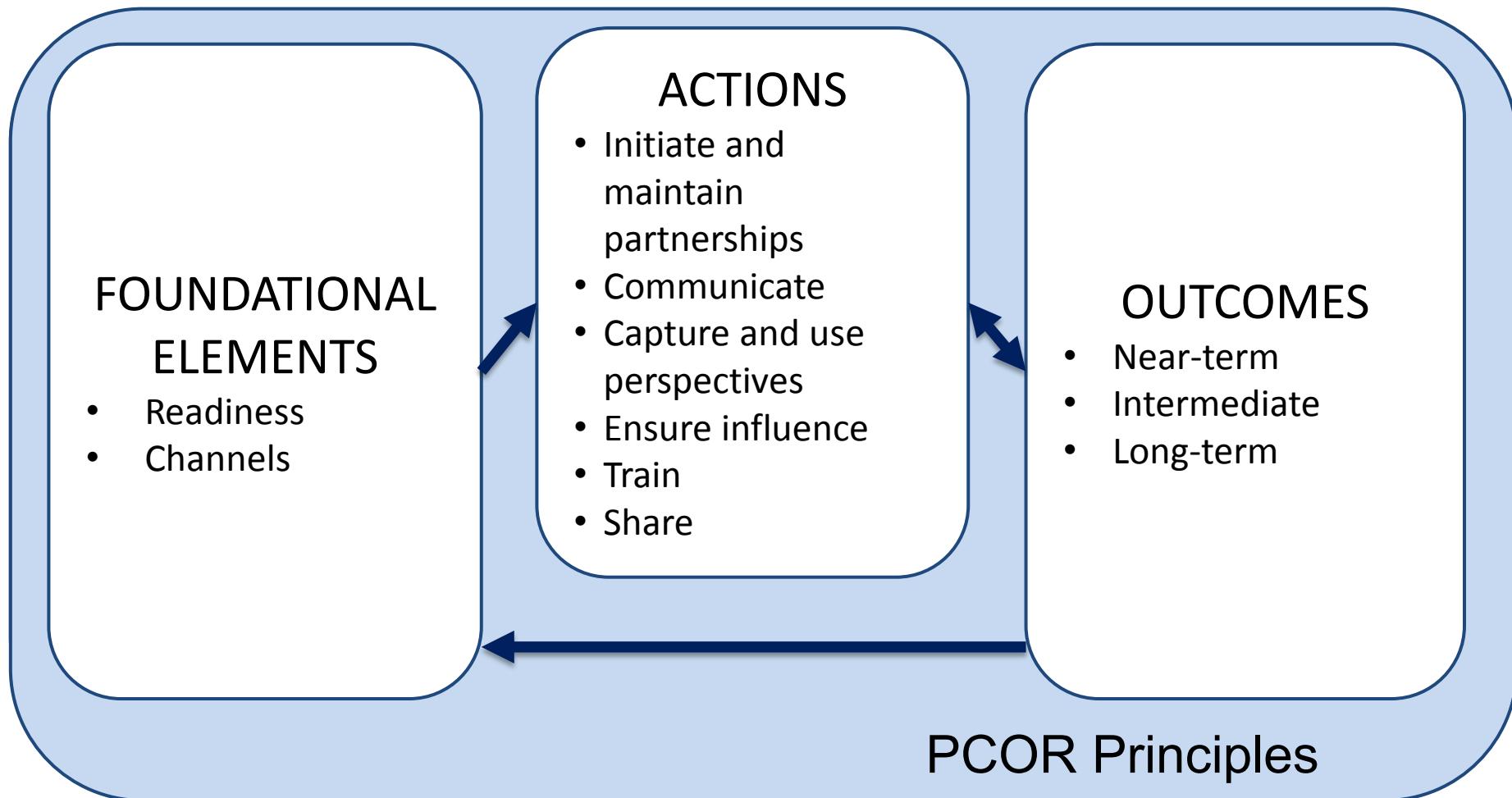
Data analyzed by content codes

Focus on codes with >25 responses

- engagement strategies
- engagement impact
- barriers
- facilitators
- how stakeholders got involved in the project
- relationships
- knowledge/training
- logistical issues
- PCOR principles



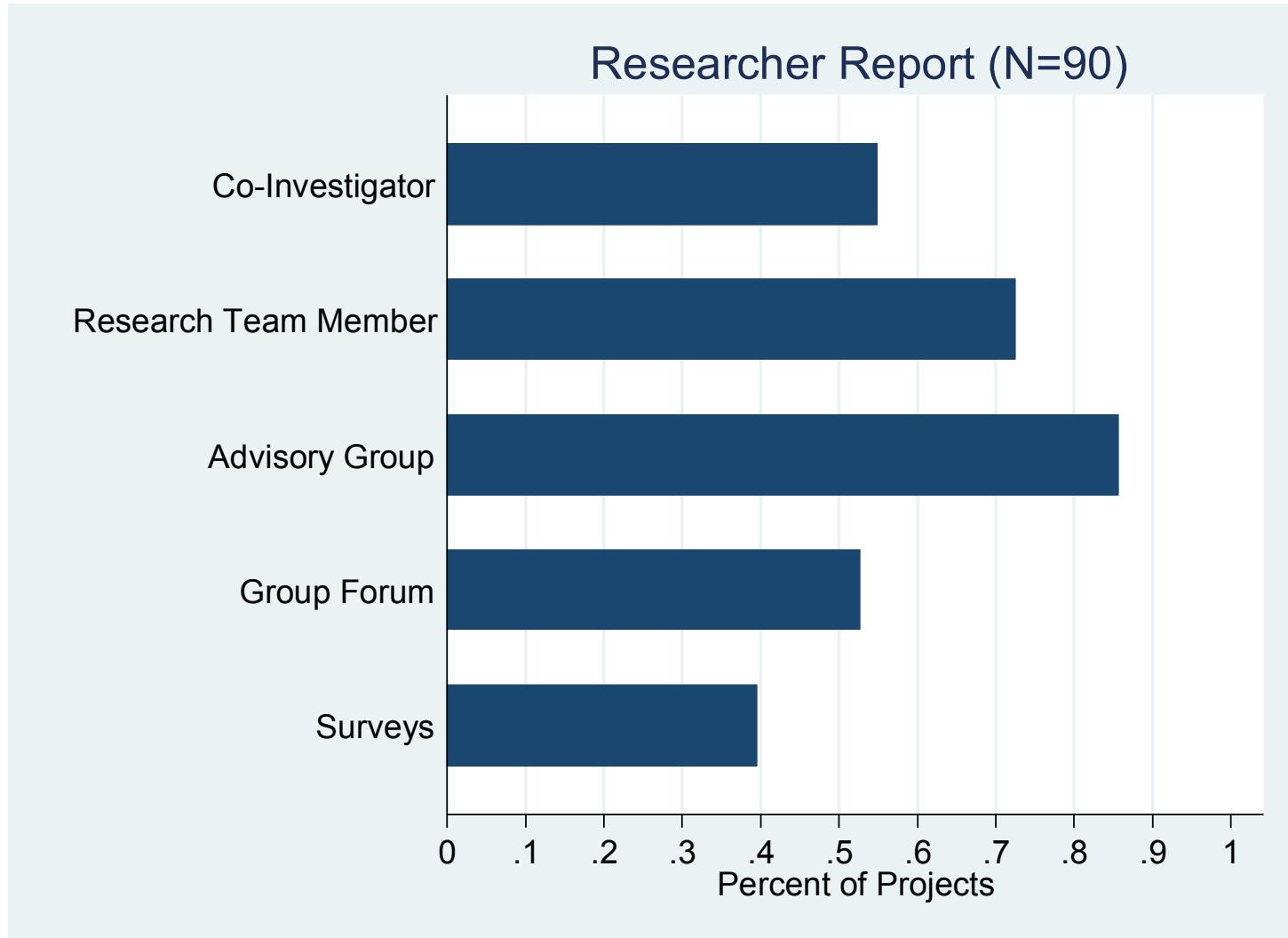
Conceptual Model of PCOR



Frank L, Forsythe L, Ellis L, Schrandt S, Sheridan S, Gerson J, Konopka K, Daugherty S. Conceptual and Practical Foundations of Patient Engagement in Research at the Patient-Centered Outcomes Research Institute Plans. *Quality of Life Research* 2015. 24(5):1033-1041 DOI 10.1007/s11136-014-0893-3

Results: Approaches to Engagement

Year 1



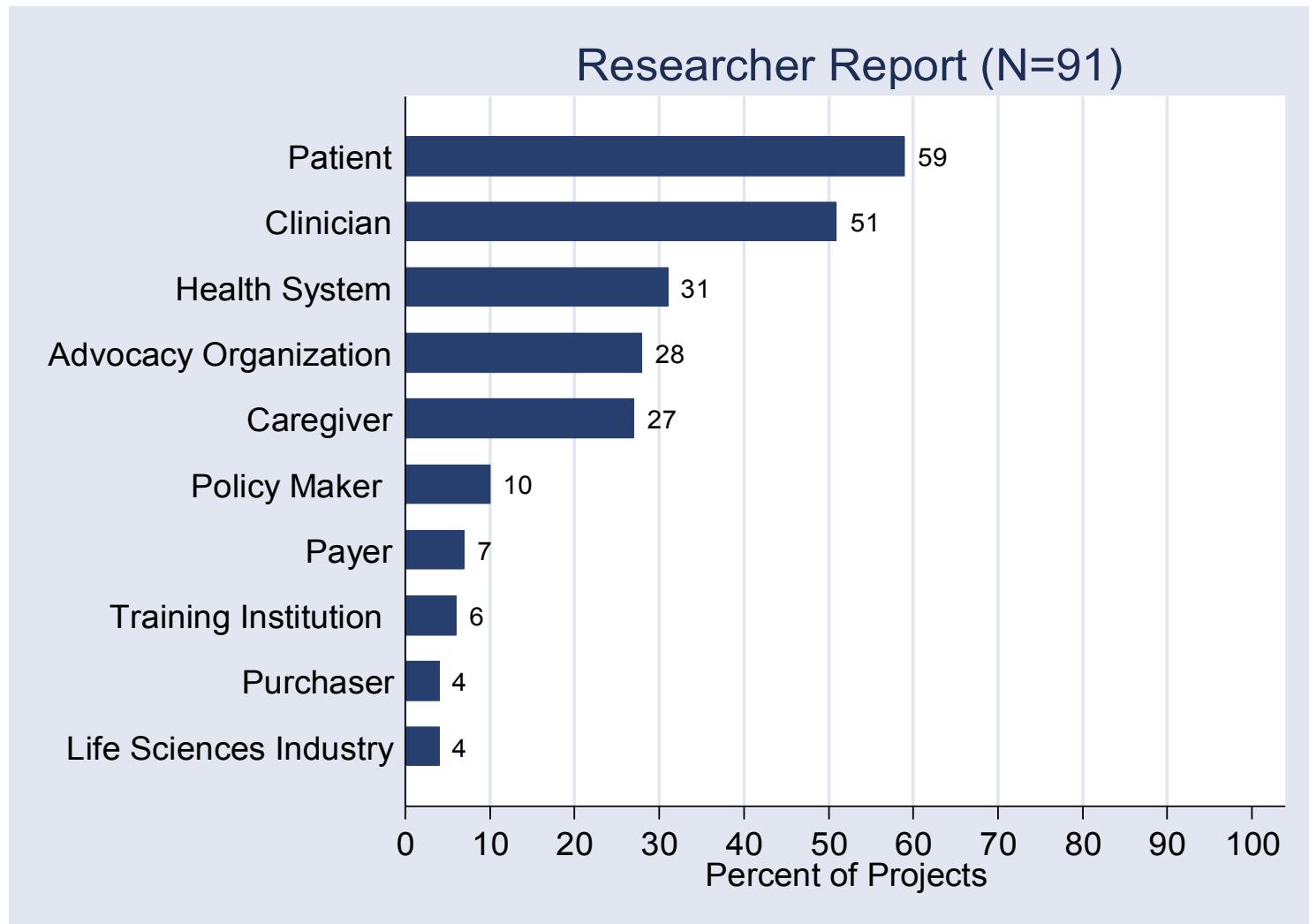
Results: Stages of Engagement

Year 1

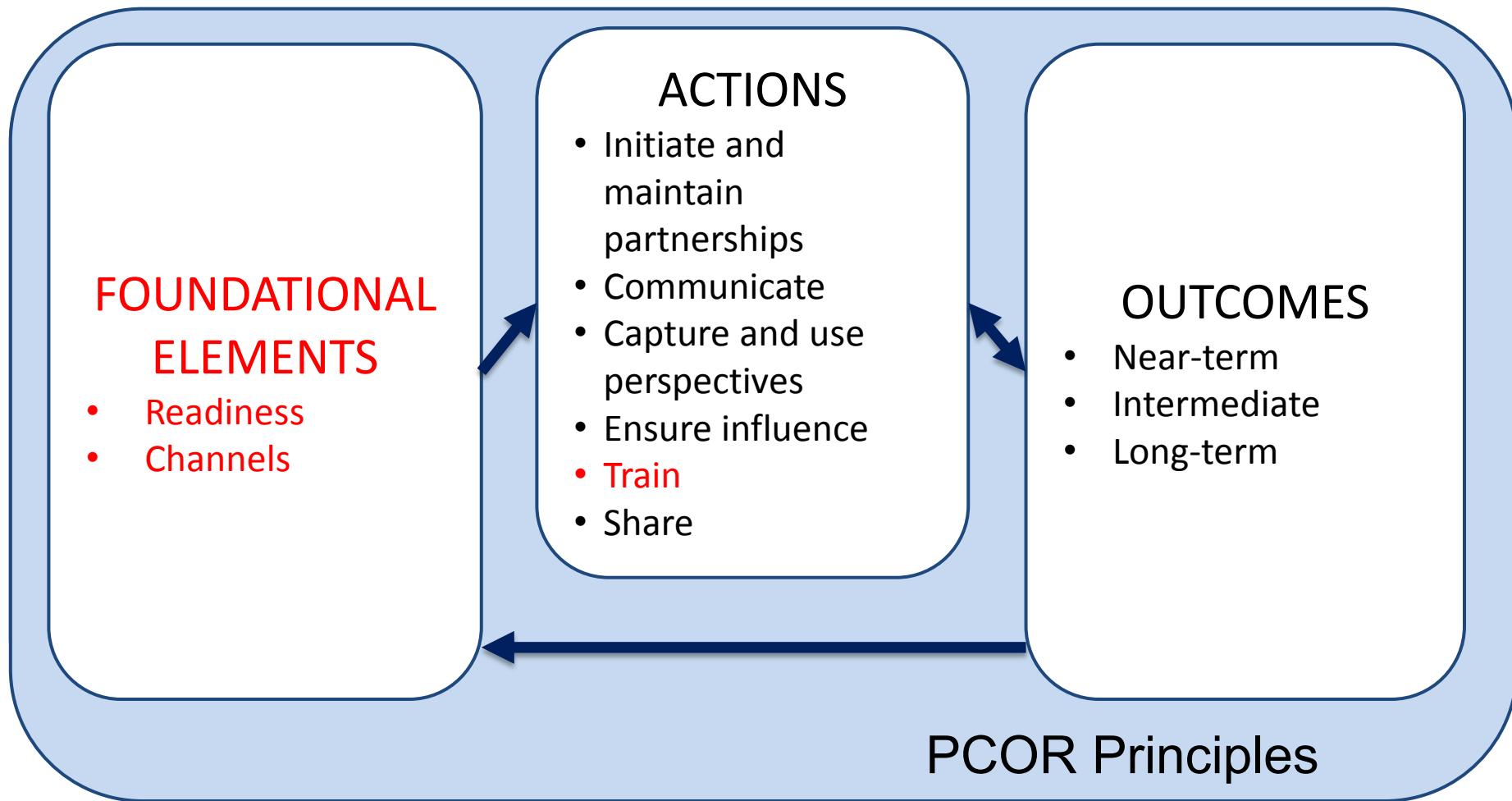


Results: Type of Stakeholders Engaged

Year 1



Conceptual Model of PCOR



Foundational Elements & Training: Institutional Review Board (IRB)

- Researchers noted challenges with IRB communications:
 - Categorizing patient/stakeholder partners
 - Involving protected or special populations as partners
 - Explaining IRB process to patient/stakeholder partners
- Several researchers noted the need for human subjects protections training for patient/stakeholder partners

Stakeholders don't always understand the confines of IRBs, contractual agreements and ethical responsibilities.

Getting projects through the IRB has been even more difficult than anticipated. Stakeholder study team members are not research subjects but are not scientific co-investigators (thus, they shouldn't have to do 6 hour of computer module ethics and study design training to be able to be a "co-investigator" on the project).



Foundational Elements: Compensation

- Many respondents noted the importance of compensating patients and stakeholders for their time
- Some researchers expressed concerns about:
 - balancing appropriate compensation vs. coercion
 - unintended adverse consequences (e.g., eligibility for social programs)
 - discrepancy between physician and patient

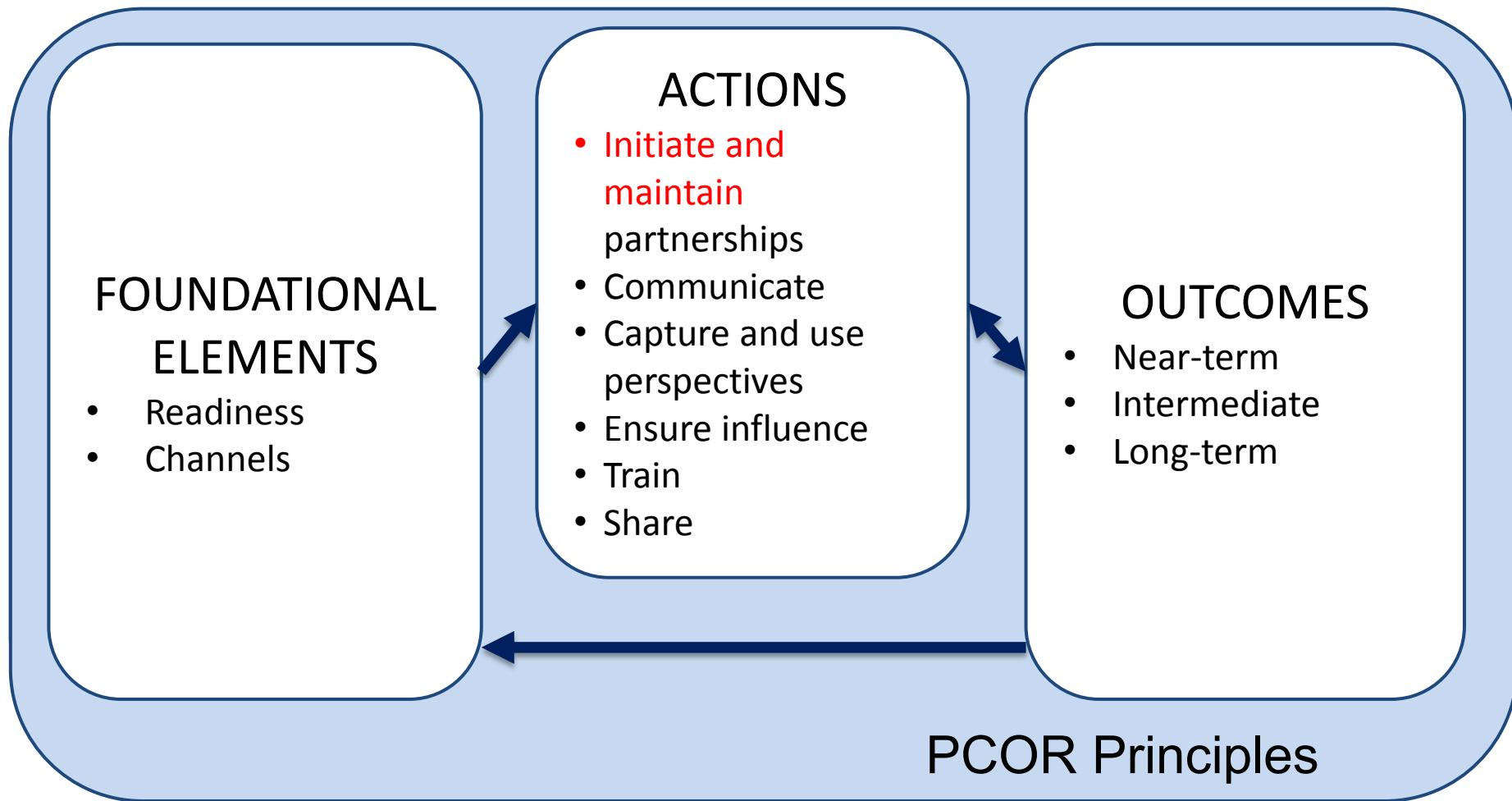
We are concerned about how compensation affects eligibility for public benefits, including Medicaid, welfare, and food stamps.

In all honesty, the amount I am being paid (\$100/hour) really helps me engage because it makes me so willing to help in any way possible, as well as offer ideas on how I can help.

...At what level do you compensate patients without it seeming like they are being co-opted?



Conceptual Model of PCOR



Results: Initiate and Maintain Partnerships

- Patients and stakeholders noted the usefulness of being involved early or experienced a desire to be involved earlier
- Researchers noted several challenges: keeping patients engaged throughout the project, setting expectations for project funding, and lacking funds for early involvement

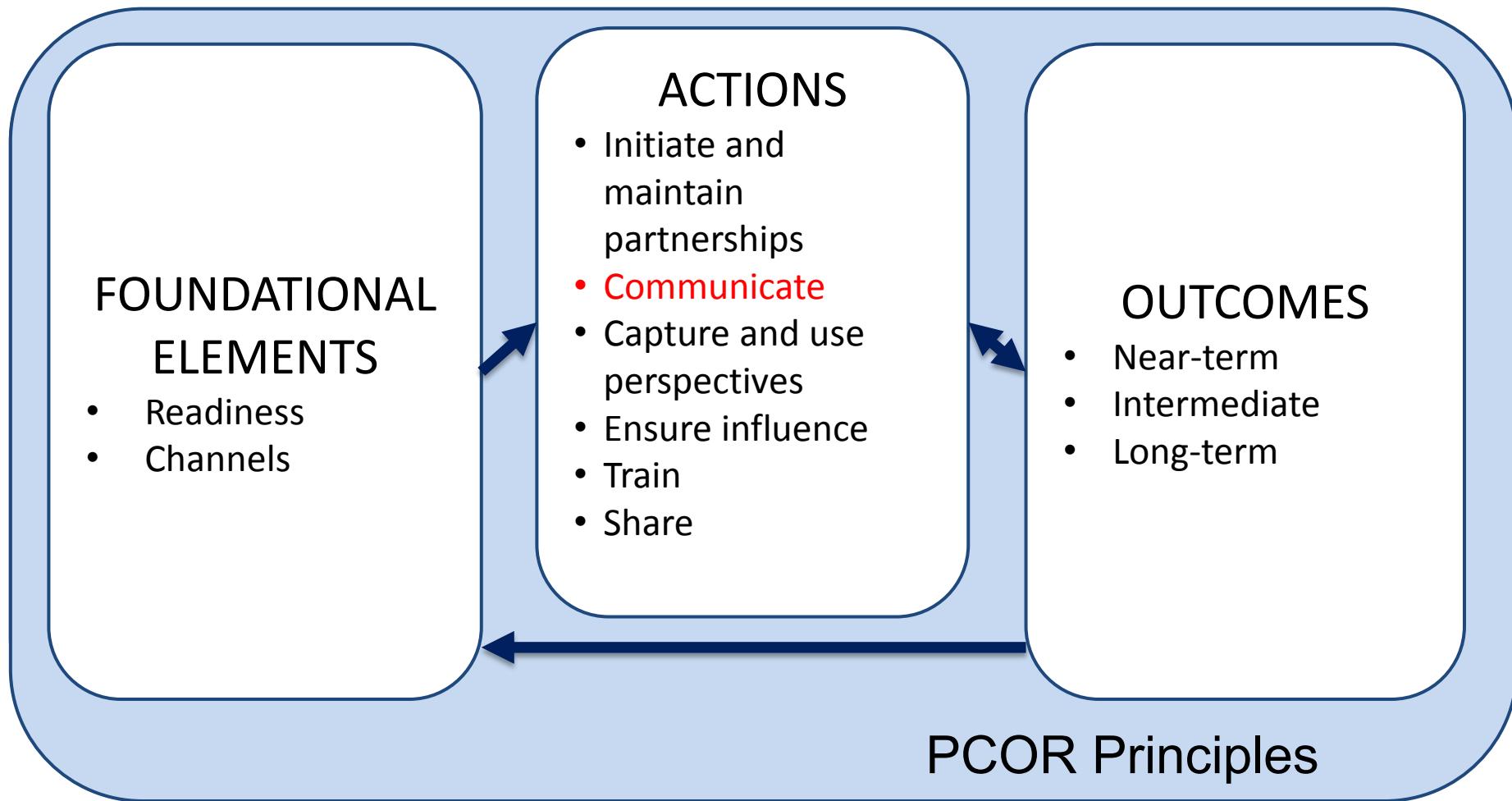
“I wish they would have contacted us earlier in the grant process so we may have been able to work in more areas of the state vs. a small section.”

“We did not have money to reimburse patients/stakeholders as we prepared the grant.”

“It is always hard to go back to stakeholders...when a project has not been funded. This, in my opinion, is one of the greatest challenges to engaging with patients in the conceptualization and planning phases.”



Conceptual Model of PCOR



Results: Communication

- Managing power differentials
- Managing diverse groups
- Using plain language

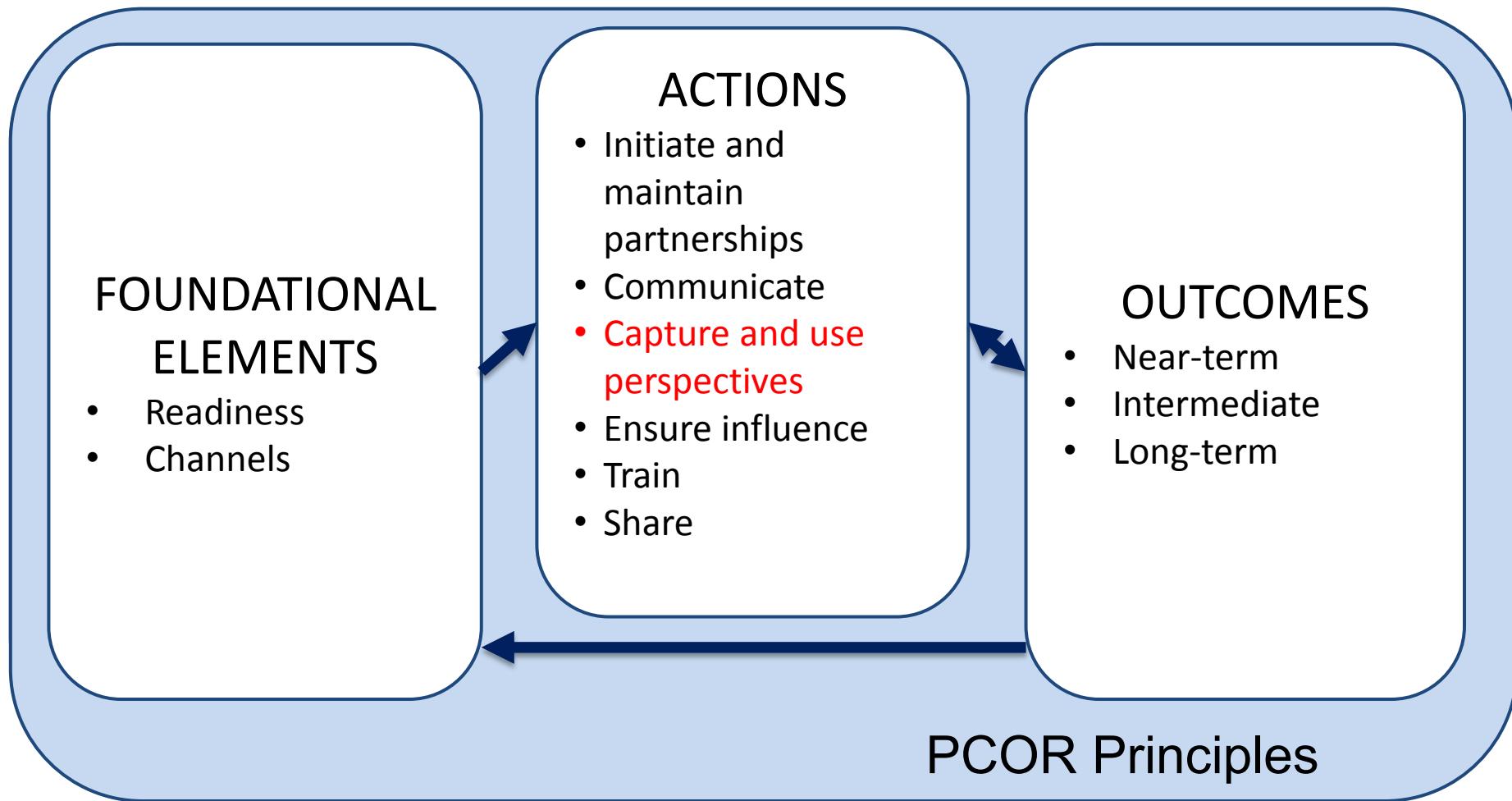
“How does one facilitate conversations across different stakeholder groups when there are strong feelings that can conflict?”

“Researchers need to understand patients and how to communicate with them, especially if they are not in the same age group or cultural background.”

“It is sometimes difficult to "speak the same language" at group meetings. In other words, the language style tends to be dominated by researchers or clinicians.”



Conceptual Model of PCOR



Capturing the Patient Perspective: Study Design

- Help choose research methods: measures, interventions, comparators, and outcomes
- Decide on data collection methods
- Review and revise study plans and materials

“Helped the investigators decide what cohort of patients to include.”

“Gave clinical input into choice of screening measures.”

“We presented aspects of study design to the group and solicited their input. I.e. - what should the "control group" be for the RCT - is it 'standard practice' ... or should it be a currently existing but potentially ineffective intervention.”



Capturing the Patient Perspective: Recruitment & Retention

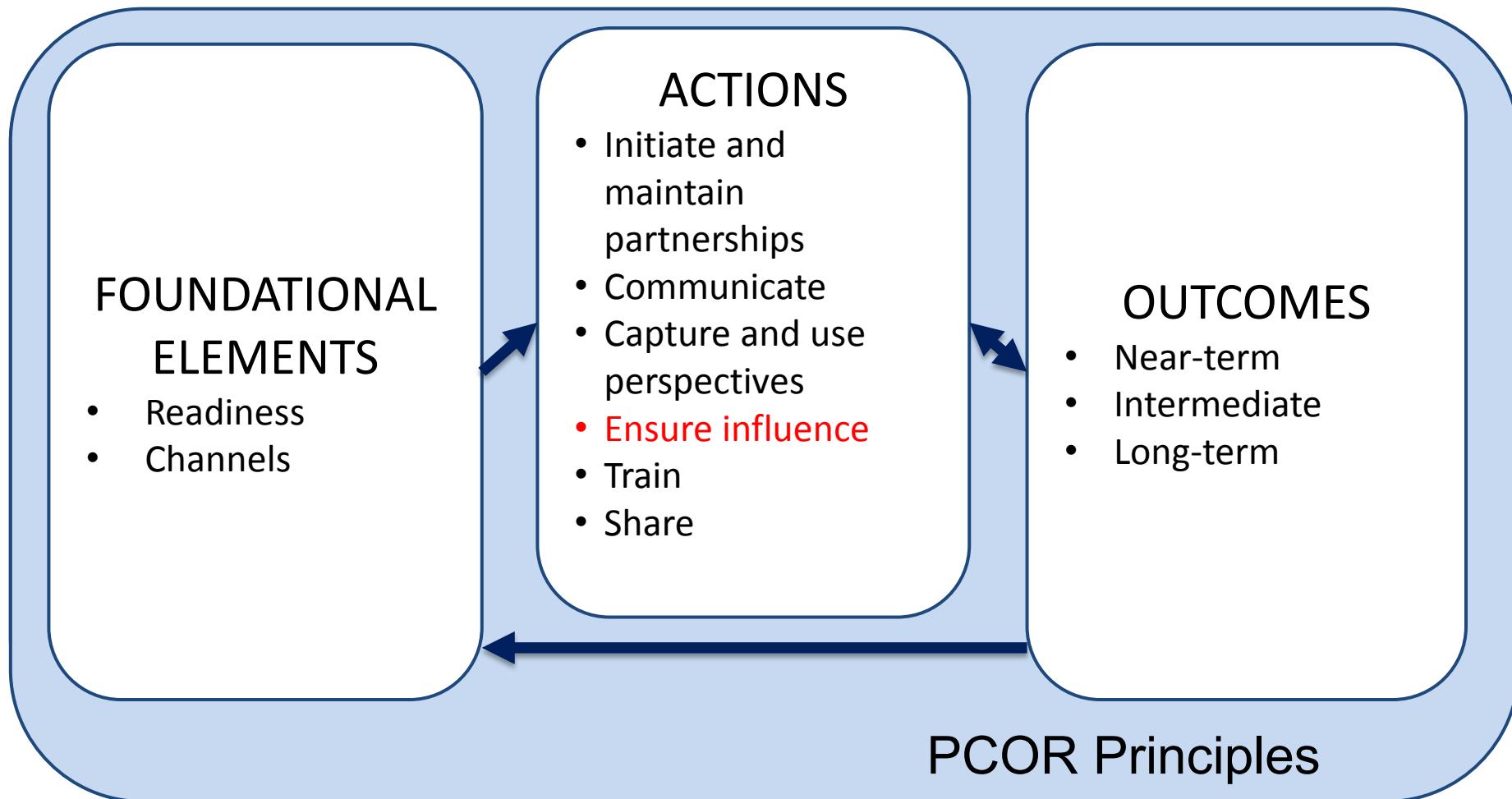
- Strategize for recruitment and retention
- Serve as liaison between research team and groups to be recruited
- On-the-ground recruiting of study participants, practices, and partner organizations

“We helped the researchers to understand potential barriers to enrollment, particularly for minority candidates, and identified responses to these barriers.”

“The stakeholder Co-I's relationship with individuals similar to those recruited for this study allowed her to provide insights to this population that is often difficult to recruit and maintain over the course of the study.”



Conceptual Model of PCOR



Ensure Influence: Study Design

- Changes to study design to make it more responsive to patient needs, feasible in clinical setting
- Range of impact reported, from minimal to major

“High impact - changed design, outcomes, flow of study.”

“Contributed to the approach taken and to creating conditions that would allow maximum participation on the part of both patients and providers.”

“This led us to modify our original 2-group research design and include a 3rd group; community based group exercise.”



Ensure Influence: Recruitment & Retention

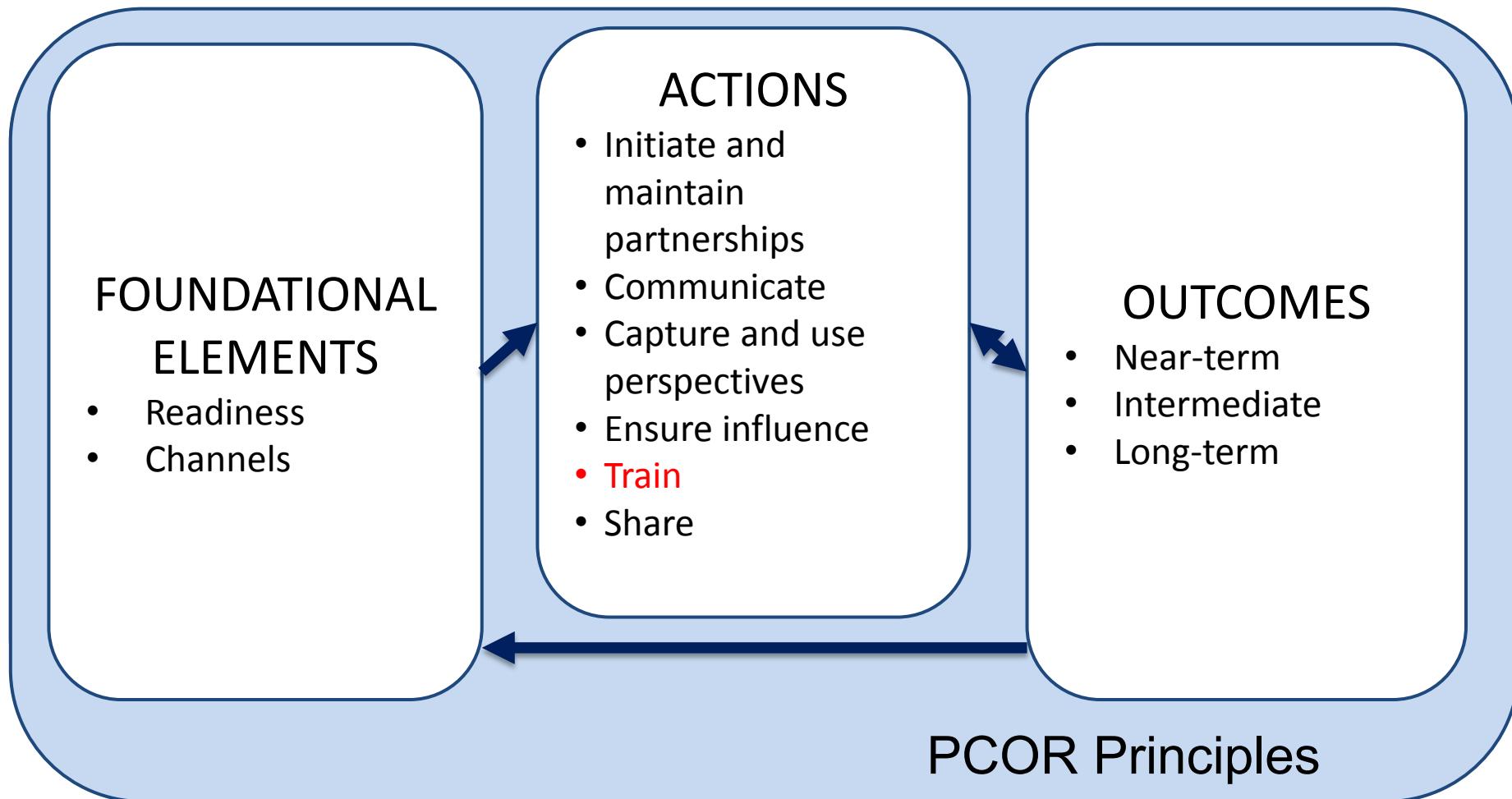
- Recruitment procedures more responsive to patient needs
- Making more potential participants aware of the study
- Improvements in recruiting and retaining difficult-to-reach populations

“Since discussing our challenges with recruiting and retaining study participants, we have had only one participant decline to participate.”

“Outreach materials, recruitment procedures were modified significantly.”



Conceptual Model of PCOR



Results: Training for Partnership

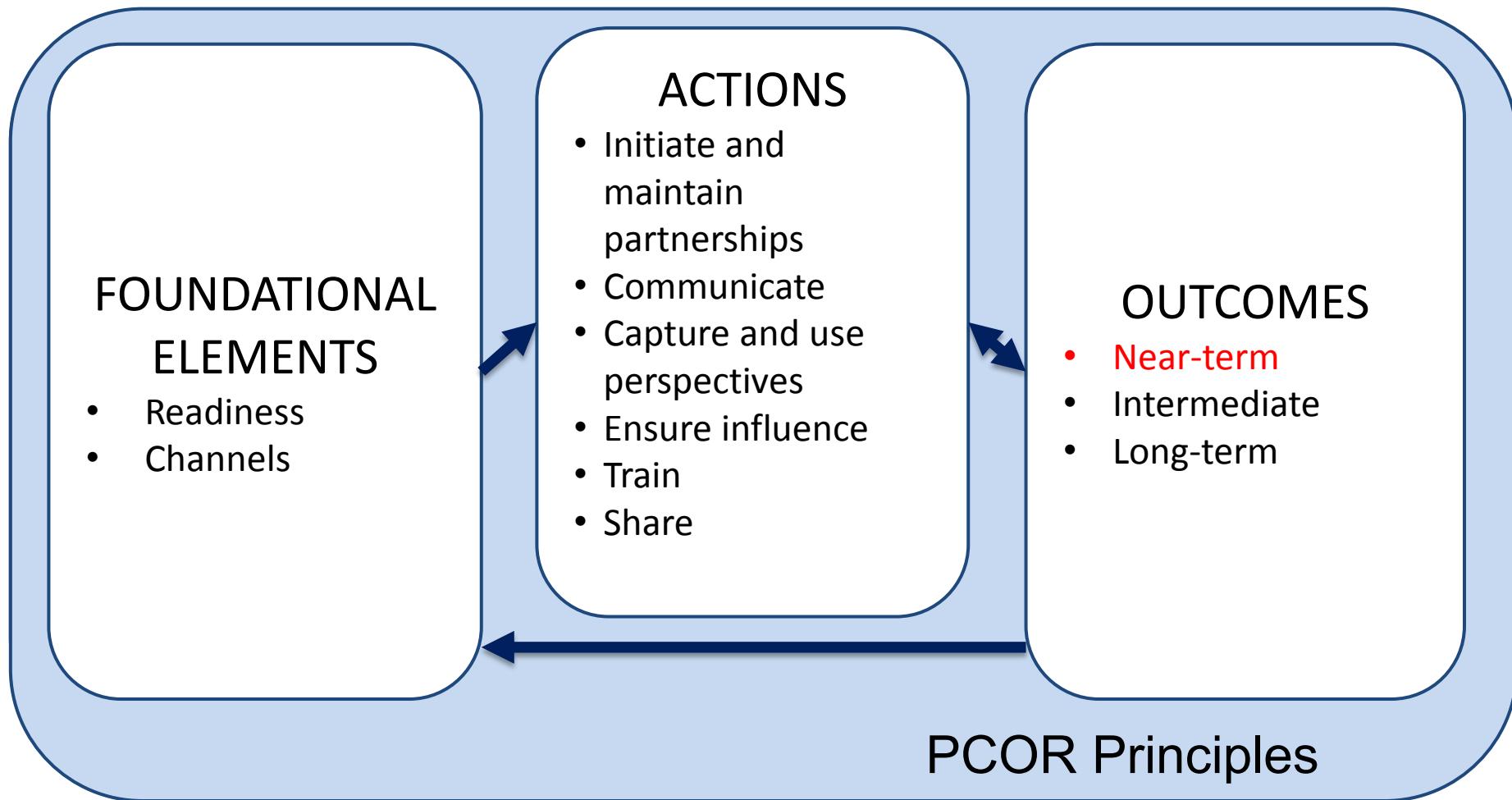
- Training needs
 - Topic background
 - Research methods
 - How to provide input effectively
 - How to communicate about research
 - Training for researchers on how to engage partners

“I have searched for training webinars and other tools to help...my staff to better understand our role.”

“There is a steep learning curve to understanding research and how to conduct research.”



Conceptual Model of PCOR



Early Impacts Beyond the Project - 1

- Increased knowledge and skills about research
- Increased knowledge about or engagement in health

“I have watched my staff improve in their professional skills as well through this project... We have learned skills and developed tools that will enhance our success in the future.”

“The work on this project did inform me of the importance of patient/ family engagement in health care decision-making and has prompted me to adopt some of these approaches in my personal life.”



Early Impacts Beyond the Project - 2

- Increased interest in patient/ stakeholder engagement
- Feeling like participation had impact beyond project

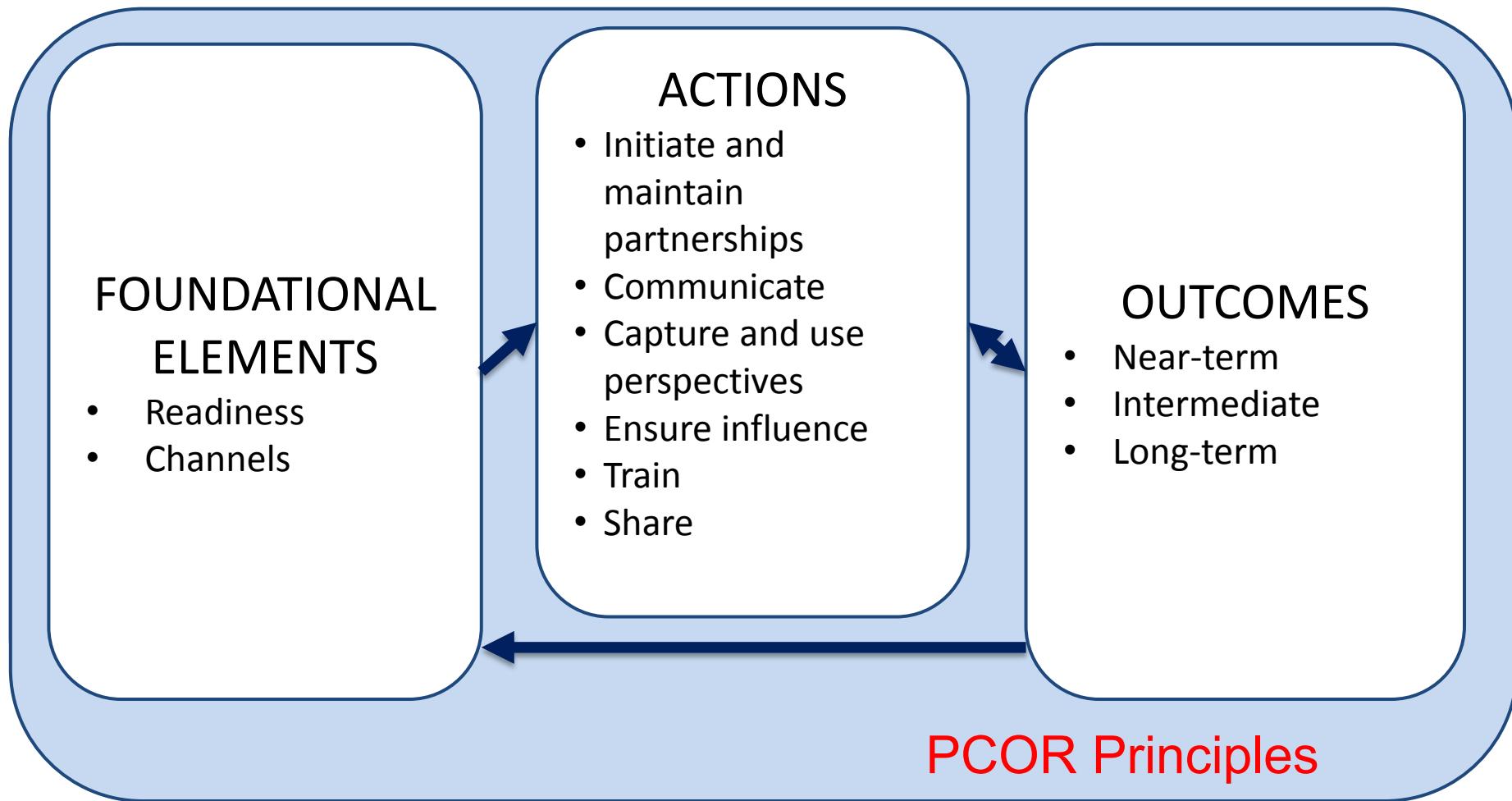
“I am more comfortable suggesting inclusion of patients on research projects.”

“It allowed me to feel like a more rounded physician because I am doing research to help the general community. It expands my influence on the community in which I live.”

“Expanded our interest and relationships with other researchers in our community... We also brought together several of the researchers in our community to discuss who we are and what we do as to try and coordinate projects geared towards senior adults.”



Conceptual Model of PCOR



Conclusions

- Challenges during application phase include uncertainty about viability of partnership
- Impacts on study design ranged from none to major
- Recruitment methods an important area of engagement impact
- Training needs identified by most respondents
- Early evidence for the impact of engagement across stages of the research
- Report on challenges at all stages and ways awardees addressed challenges are being incorporated in ongoing guidance



Turning information into action

- Application phase: expectations about application success, compensation
- Research relationships: in-person meetings, technology supports, protected time
- Opportunity for expanding stakeholder relationships
- Training: inclusiveness, managing groups, communicating expectations, incorporating input
- Facilitating sharing of learnings across awardees



Sharing Findings



Early Learnings about Engagement from PCORI Awardees and Research Partners

CER Methods Program Evidence to Action Network
March 11, 2015

Patient-Centered Outcomes Research Institute

March 2015 webinar with awardees



Inventory of Engagement Activities

Planning the study

- Identifying research topics
- Developing research questions
- Proposal development
- Developing the budget
- Expanding the research team
- Study design

Conducting the study

- Recruiting & retaining participants
- Data collection
- Data analysis
- Results review, interpretation & translation

Dissemination

- Dissemination/ sharing research findings



Questions and Discussion



15 Minute Break

Exploring the Eugene Washington PCORI Engagement Award Program

Lia Hotchkiss, MPH
Director, Engagement Award Program



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PCORI Engagement Goals

Build a patient-centered outcomes research (PCOR) community



Engage the PCOR community in research

Promote dissemination and implementation of PCOR research findings



Eugene Washington PCORI Engagement Award Program

- Launched in February 2014
- Provides support for projects that lead to better integration of patients and other stakeholders in the healthcare research process
- A programmatic funding opportunity—*not* research awards
- Program budget \$15.5 million (FY 2015)
- Awards up to 2 years in duration; \$250,000 total costs
- Fund awards through contracts rather than grants; PCORI programmatic involvement with awardees expected throughout the post-award process



Engagement Awards Intended to Support

- Engagement projects:

Knowledge Awards

- **Increase knowledge** about how consumers of healthcare information view, receive, and make use of PCOR and CER

Training & Development Awards

- **Build capacity** for participating in PCOR and CER and create ways to connect patients, caregivers, and other stakeholders with the research community

Dissemination Awards

- **Develop and strengthen channels** for disseminating and implementing PCOR and CER findings

 Meetings and conferences that align with PCORI's Mission and Strategic Plan* and facilitate expansion of PCOR/CER

*available at <http://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Strategic-Plan-111813.pdf>



Our Growing Engagement Award Portfolio

- Projects focus on a variety of PCORI stakeholder groups: patients, caregivers, advocacy organizations, clinicians, hospitals and health systems, researchers, policy makers, payers
- Will produce deliverables that are useful to awardees, PCORI, and the broader PCOR community for increasing patient and stakeholder engagement in PCOR and CER
- We are committed to sharing and using this information
- Project abstracts available at
<http://www.pcori.org/research-results>



Anticipated Project Deliverables



Network of individuals living with sickle cell disease who are prepared to take part in PCOR



- Educational program on PCOR specifically for staff, patients, and caregivers of rare disease organizations



- Training for community partners to engage in projects to address issues faced by ethnically diverse and under-resourced seniors as they try to age in place



- Meeting with researchers and patients to develop a vision, mission, and research priorities for the nontuberculous mycobacterium research consortium



Anticipated Project Deliverables

-  Landscape review of programs used by policy makers to leverage PCOR and CER, and a roadmap to guide them in the use of PCOR and CER
-  Enhanced year-long training curriculum designed to educate and engage health center teams—including patients and clinical and administrative staff—in PCOR
-  Openly accessible, web-based portal with resources about engagement for both patients and researchers
-  Model for effective engagement of patients and community members in construction of Community Hospital Needs Assessments and effective review and integration of PCOR



Anticipated Project Deliverables



- Conference to explore opportunities and strategies for overcoming obstacles in dissemination and implementation research and a summary of the proceedings



- Sustainable method for conducting research prioritization with bladder cancer patients on an iterative and ongoing basis



- Network to connect parents of children with medical complexity to each other and to their key healthcare providers to identify the most common challenges they face in the healthcare continuum



- Conference summary that defines the academic approaches to PCOR and CER training



Engagement Awards Not Intended to Support

- Research projects
- Planning/pilot studies
- Demonstration projects
- Evaluations of programs or interventions
- Validation of tools or instruments
- Delivery of health care
- Development of registries
- Recruitment of study subjects or activities to increase participation in registries
- Development of decision aids or clinical practice guidelines
- Career development awards
- Meetings that are business as usual, without focus on PCOR or CER



Our Application Process



Who Can Apply

Private Sector

- Nonprofit and for-profit research **organizations**

Public Sector

- Universities and colleges; hospitals and healthcare systems; laboratories and manufacturers; units of state, local, or federal government.

U.S. Organizations

- Must be recognized by the Internal Revenue Service

Foreign Organizations and Nondomestic Components of U.S. Organizations

- May apply if there is demonstrable benefit to the U.S. healthcare system; U.S. efforts in the area of patient-centered research can be clearly shown

Individuals

- Not permitted to apply

How to Submit

<http://www.pcori.org/funding/opportunities>

 Engagement Award (EAIN): Research Meeting and Conference Support

Key Deadlines	Type	Funds Available	Total Costs
LOI: Not required Application: July 1, 2015	Program Award		One-time award total costs must not exceed \$50,000 and multi-year award total costs may not exceed \$250,000.

 Engagement Award: Knowledge, Training and Development, and Dissemination Awards

Key Deadlines	Type	Funds Available	Total Costs
LOI: July 1, 2015 Application: Full proposals are due 40 days after review and approval of the LOI.	Program Award		Award total costs may not exceed \$250,000

What to Submit

Letter of Inquiry	
Organization and Project Lead Information	
Project Information (Project Summary)	
Application	
Organization and Project Lead Information	
Project Information	
Key Personnel	
Collaboration and Partnerships	
Board of Directors List	Upload
Project <u>Workplan</u> and Timeline	Upload
Budget Summary	Upload
Budget Justification	Upload
Professional Profile/<u>Biosketch</u>	Upload
Letters of Support	Upload Optional
Recent Articles/Evaluations	Upload Optional

Engagement Award applicant resources including **online application system user manuals for submitting LOIs and full proposals available on PCORI website**

Review Process



- If applying for meeting/conference support, you do not need to submit an LOI. Applicants proceed directly to submitting a full proposal.
- In FY2015, LOIs and proposals for meeting/conference support accepted on an ongoing basis, but reviewed quarterly beginning on October 1, January 2, April 1, and **July 1**.
- Applications are reviewed by at least 3 members of PCORI's Engagement Team, Contracts Management and Administration, and other internal staff, as needed.



Merit Review Criteria

- Program Fit
- Project Plan and Timeline
- Qualifications of the Project Lead, Personnel, and Organization
- Patient and Stakeholder Engagement Plan and Collaborations
- Past Performance
- Budget/Cost Proposal



Is there adequate engagement of patients and other stakeholders in the design and conduct of the proposed project?

Are collaborations meaningful and appropriate based on aligning the interest, expertise and scope of work of each member of the team and the collaborators involved?



Allowable vs. Unallowable Costs



ALLOWABLE COSTS

UNALLOWABLE COSTS

🚫 ADVERTISING	🚫 DONATIONS	🚫 INTEREST OF BAD DEBTS
🚫 EXCESSIVE AIRFARE	🚫 FUNDRAISING	🚫 ENTERTAINMENT
🚫 ALCOHOLIC BEVERAGES	🚫 PERSONAL EXPENSES	🚫 LOSSES ON OTHER GRANTS
🚫 ALUMNI ACTIVITIES	🚫 STUDENT HOUSING	🚫 MEMBERSHIP
🚫 BAD DEBTS/LOSSES	🚫 IDLE FACILITIES	🚫 LOBBYING

For More Information

Quick Links for Applicants

[Key Terms Glossary](#)

[Frequently Asked Questions \(FAQs\)](#)

[PCORI Online User Manual: Start a LOI](#)

[PCORI Online User Manual: Submitting an Application](#)

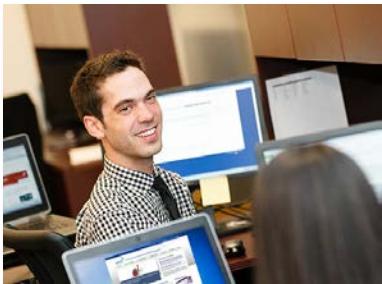
[PCORI Funded Projects: Sample Engagement Plans](#)

Visit

pcori.org/eugene-washington-awards

Contact us at

- **ea@pcori.org**
- **202-370-9312**



Thank You



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Wrap-up, Next steps, and Reflections



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Meeting Adjourned
Thank You!