



Contributions of Patient Engagement In Research: Early Findings From The Patient-Centered Outcomes Research Institute

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Disclosures

- Laura Forsythe and Kristin Carman have nothing to disclose.

Objectives

- At the conclusion of this activity, the participant should be able to:
- Understand the levels and contributions of engagement to PCORI-funded CER
 - Understand the engagement approaches PCORI teams use to achieve these contributions
 - Describe the significance and impact of engagement on PCORI-funded CER
 - Understand implications of findings on practice and research

Project Contributors

Advisory Panel on Patient Engagement

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- Jane Perlmutter
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PCORI Staff Members

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- Lisa Stewart
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PCORI Board of Governors

- Robert Zwolak

PCORI Methodology Committee

- Naomi Aronson

The Key Points

- PCORI teams describe contributions of engagement to all aspects of CER projects
- Significance of engagement contributions are in 4 key areas: acceptability, feasibility, rigor, and relevance
- Impact of engagement was achieved through both traditional and more collaborative approaches to engaging with patients and other stakeholders

Analyzing Articles on PCORI-Funded CER, We Sought to Answer:

- What are the contributions of engagement to PCORI-funded CER?
- What engagement approaches did PCORI teams use to achieve these contributions?

Why this Study?

- Existing literature from PCORI projects provides a rich source of information on engagement
- PCORI's funding, requirements, and evolving guidance provide a shared context for studying the contributions of engagement on a large scale
- Add to the evidence about the contributions of engagement and the significance of those contributions

How Did We Do this Study?

- Guided by PCORI's Advisory Panel on Patient Engagement
- Identified and extracted articles based on guidance for consistency and quality
- Thematic analysis of extracted text
- Included 127 articles that **explicitly** describe contributions of engagement to PCORI-funded **CER**



Contributions of Engagement

Research Focus Research Design Interventions:
Tailoring/ Delivery Recruitment & Retention Data Collection & Measures Data Analysis Dissemination

PCORI teams describe engagement contributions
to **all aspects** of CER projects

Contributions of Engagement - 2

Research Focus

Research Design

Interventions: Tailoring/ Delivery

Recruitment & Retention

Data Collection & Measures

Data Analysis

Dissemination

- Identification of topic or project
- Formulation or expansion of research aims or questions
- Choice of comparator(s)
- **Determination of research outcomes (primary and secondary)**

“We knew regaining functional status was an important component of recovery, but we did not realize how much depression, anxiety, and fatigue weighed on many stroke survivors’ minds. So we revisited our aims, overhauled our data collection plan, and ensured that our goals were not only informed by patients but also aligned with the issues that patients cared about the most.” ¹

Contributions of Engagement - 3

Research Focus

Research Design

Interventions:
Tailoring/
Delivery

Recruitment &
Retention

Data Collection
& Measures

Data Analysis

Dissemination

- Practical guidance on how to carry out the research
- Choice of design (e.g. delayed start, mixed methods)
- Study participant allocation and randomization designs
- **Broader inclusion and less restrictive exclusion criteria**

“This allowed us to reach a real-world sample of children with critical health needs, rather than be constrained by requiring a confirmed clinical diagnosis that many families may not have been able to afford or may not have wanted to pursue.” ²

Significance of Engagement Contributions

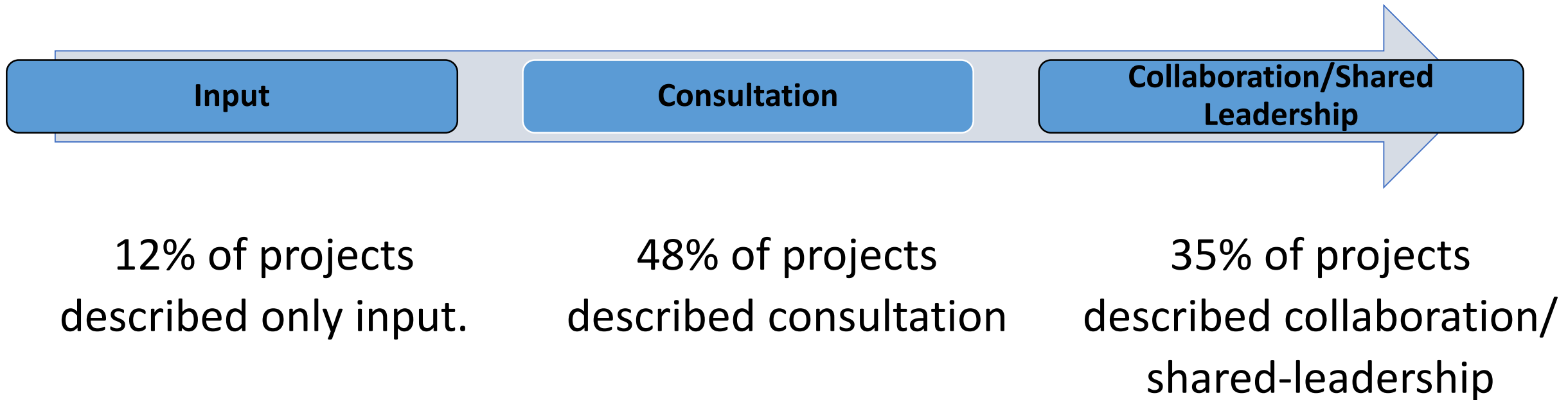
- Acceptability
- Feasibility
- Rigor
- Relevance



All Types of Contributions Can Have an Impact

| | Example |
|---|---|
| Some contributions influence the entire course of the research | Partner input drives primary outcomes or comparators ¹ |
| More narrowly focused contributions can substantially impact research | Changing an enrollment script increased enrollment by 30 percent ³ |
| Not all stakeholder recommendations can be implemented | Study duration (3 years) too short to measure stakeholder preferred outcome 'maintaining independence' ⁴ |
| Some recommendations introduce trade-offs | Using an unvalidated measure to assess outcome prioritized by stakeholders ⁵ |

Engagement Approaches on a Continuum



Putting this Study in Context

Limitations

- Analysis represents these authors' perceptions of engagement
- Variable levels of detail
- Likely under reporting projects with truly integrated partners
- Based on PCORI's earliest studies

Strengths

- Near real-time look at real-world experiences in likely the largest US sample
- Experiences authors' compelled to write about despite article word limits
- Focus on PCORI articles increases confidence that we found and all relevant published information on engagement

Impact of Engaging Stakeholders

- PCORI funding is driving change in research
- Engagement
 - can influence research value, relevance, and utility
 - cannot address all challenges facing the conduct of CER, but it can improve core aspects
 - has value far beyond input and validation of existing research ideas
- Engagement can help balance the inherent tradeoffs affecting research conduct while also responding to end-user needs

Implications for Practice and Research

- Increased emphasis and resources devoted to engagement will likely accelerate adoption and value of engagement
- Potential to catalyze a stronger shift to the culture of engagement and generate more useful findings
- Prioritizing inclusion of information on engagement in peer review articles is critical
- Investment in additional research and translation of findings into guidance is needed

Next Steps

- More rigorous understanding of:
 - how engagement influences research conduct as well as influence on uptake and use in decision-making
 - what are the critical elements of optimal (and sub-optimal) engagement practices and circumstances
 - what are the key characteristics of engaged partners beyond the type of stakeholder group they represent
- Developing of an expanded and robust return on investment on engagement

Where are We Heading?

- Make engagement easier, routine and efficient with evidence-based guidance
- Make the benefits of engagement clear and aligned with stakeholder and PI needs
- Explore the use of alternative approaches that draw on broader reach for input

PCORI Engagement Resources

- [Ambassadors Program](#)
- [Budgeting for Engagement Activities](#)
- [Compensation Framework for Engaged Research Partners](#)
- [Engagement Rubric](#)
- [Eugene Washington PCORI Engagement Awards](#)
- [Methodology Report](#)
- [PCORI in Practice Webinar Series](#)
- [Sample Engagement Plans](#)

COMING SOON:
Guidebook on Engaging
with Research Partners
about Data and Analysis



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Thank You!

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