

Implementation-Related Data Collection Within the NIH Pragmatic Trials Collaboratory: Current State and Future Opportunities

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Background

- Embedded pragmatic clinical trials (ePCTs) are conducted in routine healthcare settings and with real-world patient populations, providing an ideal opportunity to evaluate interventions' implementation potential.
- The National Institutes of Health (NIH) Pragmatic Trials Collaboratory (Collaboratory) supports large-scale ePCT Demonstration Projects that address major public health issues.
- The Collaboratory has a unique opportunity to draw on Demonstration Project experiences to glean lessons learned with respect to implementation successes and challenges. To that end, it is important to understand the current landscape of implementation-related data collection among Collaboratory Demonstration Projects.

Methods

- We developed and administered an online survey to investigators of the 13 ongoing Collaboratory Demonstration Projects as of June 22, 2023.
- Survey questions focused on project teams' assessment of (and methods for assessing) implementation determinants (i.e., barriers and facilitators) and outcomes.
- Our goal was to identify opportunities to support common approaches to measuring implementation constructs that are not yet consistently assessed across projects.

Results

- Representatives from all 13 Collaboratory Demonstration Projects responded to the survey.

NIH Pragmatic Trials Collaboratory Demonstration Projects	
ACP PEACE	Improving Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly
BackInAction	Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults
BeatPain Utah	Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics
FMTIPS	Fibromyalgia TENS in Physical Therapy Study
GGC4H	Guiding Good Choices for Health: Testing Feasibility and Effectiveness of Universal Parent-Focused Prevention in Three Healthcare Systems
GRACE Trial	Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain
ICD-Pieces	Improving Chronic Disease Management with Pieces
IMPACT-LBP	Implementation of the American College of Physicians Guideline for Low Back Pain
INSPIRE	INtelligent Stewardship Prompts to Improve Real-Time Empiric Antibiotic Selection for Patients
NOHARM	Non-pharmacological Options in postoperative Hospital-based And Rehabilitation pain Management
Nudge	Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications
OPTIMUM	Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting
PRIM-ER	Primary Palliative Care for Emergency Medicine

For additional project information, visit rethinkingclinicaltrials.org.

Fidelity and Adaptations

- **Fidelity:** Respondents for nearly all (12/13) projects reported assessing intervention fidelity. The most common methods for assessing fidelity included direct observation (5/12) and self-report (6/12).
- **Adaptations:** Fewer (10/13) reported assessing the related construct of intervention adaptations, primarily by recording adaptations in a log (6/10).
- Most (8/13) projects measuring fidelity and/or adaptations indicated that they were not using a framework (e.g., Framework for Adaptations and Modifications, Core Forms and Functions) to guide assessment.

Other Implementation Outcomes

- **Reach:** 10/13 projects reported measuring the proportion of eligible patients participating in the intervention, and their representativeness.
- **Adoption:** Fewer (5/13) reported measuring the proportion and representativeness of participating clinicians and health systems.
- **Sustainability:** Only 2/13 projects reported measuring anticipated sustainability, both using interviews with health system partners.
- **Sustainment:** More projects (4/13) reported plans to measure actual sustainment (use after the trial).
- **Costs:** Few projects (3/13) reported measuring intervention costs.

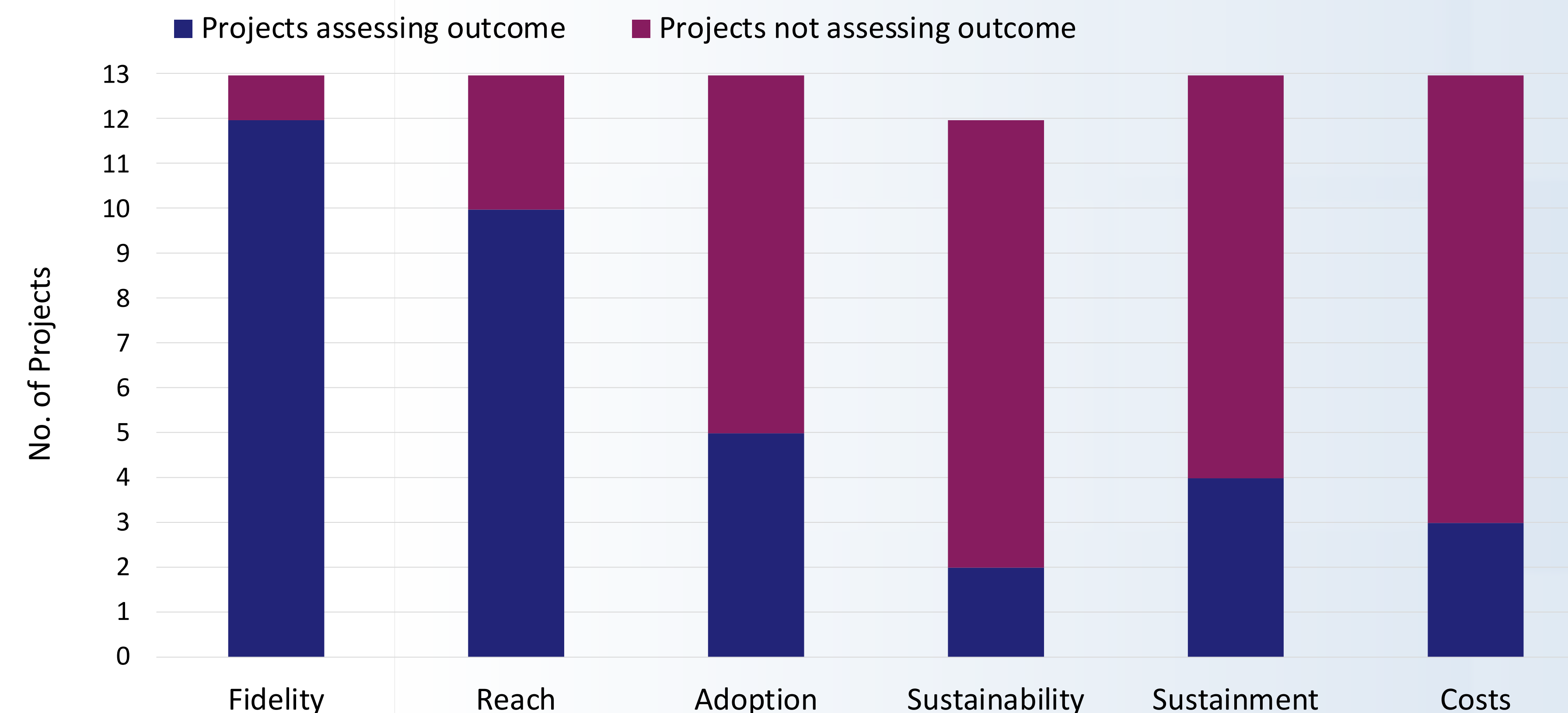
Implementation Determinants

- Nearly all projects (12/13) reported assessing barriers to and facilitators of intervention implementation, primarily using qualitative methods (11/12).
- The RE-AIM framework was the most commonly selected framework for assessing implementation determinants (6/12).

Implications for D&I Research

- ePCTs are intentionally designed to be embedded into health systems' existing infrastructure, with the goal of increasing the likelihood that effective interventions will be sustained post-trial.
- To assess progress towards that goal, it will be important to expand assessment of sustainability and sustainment in ePCTs.
- Survey results also highlight a related opportunity to assess intervention costs, an important factor in health systems' decisions to sustain interventions.
- Finally, it will be critical to promote systematic assessment of the representativeness of people (reach, adoption) and places (adoption) participating in ePCTs, to inform results interpretation and opportunities to promote equity in ePCTs.

Figure. Number of Demonstration Projects Assessing Each Implementation Outcome



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Disclosures

The authors have no relevant conflicts of interest to disclose.

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