

Posttrial Sustainment or Deimplementation of Study Interventions

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**NIH PRAGMATIC TRIALS
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Learning goals

- Identify factors influencing sustainment and deimplementation of study interventions
- Discuss strategies to assist investigators and research partners with posttrial interpretation and sustainment/deimplementation considerations



Sustainment factors for pragmatic trial interventions

Factors Affecting Post-trial Sustainment or De-implementation of Study Interventions: A Narrative Review



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ABSTRACT

In contrast to traditional randomized controlled trials, embedded pragmatic clinical trials (ePCTs) are conducted within healthcare settings with real-world patient populations. ePCTs are intentionally designed to align with health system priorities leveraging existing healthcare system infrastructure and resources to ease intervention implementation and increase the likelihood that effective interventions translate into routine practice following the trial. The NIH Pragmatic Trials Collaboratory, funded by the National Institutes of Health (NIH), supports the conduct of large-scale ePCT Demonstration Projects that address major public health issues within healthcare systems. The Collaboratory has a unique opportunity to draw on the Demonstration Project experiences to generate lessons learned related to ePCTs and the dissemination and implementation of interventions tested in ePCTs. In this article, we use case studies from six completed Demonstration Projects to summarize the Collaboratory's experience with post-trial interpretation of results, and implications for sustainment (or de-implementation) of tested interventions. We highlight three key lessons learned. First, ineffective interventions (i.e., ePCT is null for the primary outcome) may be sustained if they have other measured benefits (e.g., secondary outcome or

ePCTs: (1) include secondary outcome measures that are salient to health system partners; (2) collect all appropriate data to allow for post hoc analysis of subgroups; (3) collect experience data from clinicians and staff; (4) engage policy-makers before starting the trial.

KEY WORDS: embedded pragmatic clinical trials; de-implementation; implementation; post-trial decisions

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INTRODUCTION

Traditional randomized controlled trials (RCTs) are conducted outside of standard patient care. This separation of research from clinical practice slows the translation of effective research-tested interventions into real-world practice settings.¹ The time lag between RCT completion and implementation of an effective intervention averages 17 years.²

In contrast to traditional or explanatory RCTs, embedded pragmatic clinical trials (ePCTs) are conducted with real-world patient populations and within healthcare settings.

Evaluated experiences in 6 diverse NIH Collaboratory Trials

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Trials overview

Trial name	Focus	Results	Intervention status posttrial
ABATE Infection	Evaluate chlorhexidine bathing + mupirocin vs regular soap to reduce bloodstream infection in hospitalized patients	Null	Sustained for those with medical devices in HCA Spread to other systems via partnership with AHRQ
LIRE	Evaluate impact of including standard epidemiologic information in lumbar spine imaging reports to reduce spine-related healthcare utilization after imaging	Null	Sustained in 2 of 4 health systems
PPACT	Test the use of CBT interventions in primary care settings to improve chronic pain for patients on long-term opioid therapy	Positive	Modified sustainment of less resource-intense versions of the intervention
PROVEN	Test the effectiveness of an advanced care planning video program to reduce hospital transfers and increase hospice enrollment in nursing home residents	Null	Sustained in a quarter to a third of facilities with engaged champions and staff members
STOP CRC	Evaluate an EHR-embedded outreach program to improve colorectal cancer screening rates	Positive	Sustained in 22 of 26 health systems Spread throughout multiple states and hundreds of clinics
TSOS	Test the effectiveness of early interventions for traumatically injured patients with PTSD	Positive at 6 but not 12 mos	Minimal sustainment in small number of sites Spread to other trauma centers via partnership with ACS Committee on Truam

Sustainment factors in NIH Collaboratory Trials

- Benefits outside of the primary outcome
 - Benefit for a subgroup
 - Benefit for a secondary outcome
 - Benefits for clinicians
- Intervention resource-intensiveness
- Alignment with policy incentives or requirements

Benefit for a subgroup: ABATE Infection



- Intervention did not significantly reduce multidrug-resistant bacteria or bloodstream infection in overall study population
- In post hoc subgroup analysis of patients with medical devices, intervention was associated with significant reductions in multidrug-resistant bacteria cultures and bloodstream infections
- **Sustainment factor:** Subgroup represented 10% of study population but accounted for 56% of all bloodstream infections and 37% of multidrug-resistant bacteria cultures
- **Sustainment/spread:** Health system (1) deimplemented protocol as universal practice; (2) sustained protocol for patients with devices in participating hospitals; (3) implemented protocol for patients with devices in all other health system hospitals

Benefit for a secondary outcome: LIRE

- Intervention did not reduce spine-related healthcare utilization
- In prespecified secondary analysis, intervention slightly reduced subsequent opioid prescriptions
- **Sustainment factors:**
 - Benefit of reduced opioid prescriptions
 - No additional resources required to sustain intervention
 - Clinician feedback suggested other potential benefits (eg, better communication with patients)
- **Sustainment/spread:** After the trial, 2 of the 4 health systems sustained the intervention based in part on its potential to reduce opioid prescriptions



Benefits for clinicians: PROVEN



- Intervention did not significantly reduce hospital transfers from nursing homes or secondary outcomes
- In post hoc analyses, intervention facilities increased documentation of advance directives and reduced burdensome hospital transfers for patients at end of life
- Process evaluations found higher implementation rates at facilities with good staff engagement and personal investment in advance care planning
- **Sustainment factors:** Staff interest, low cost, potential subgroup benefits
- **Sustainment/spread:** Facilities with engaged champions and receptive staff were encouraged by clinic leaders to continue offering intervention videos, leading to adoption into regular practice in one-quarter to one-third of intervention facilities

Resource-intensiveness: PPACT



- Intervention modestly reduced pain, pain-related disability, and use of benzodiazepines; and reduced healthcare costs overall, cost per QALY, and cost per responder
- **Sustainment factors:** Upfront staffing costs and feasibility; shift in health system priorities; delay in cost-effectiveness analysis outcomes, precluding their consideration at time of sustainment decisions
- **Sustainment/spread:**
 - All health systems adopted pain measure for routine assessment of patients with chronic pain on long-term oxygen therapy
 - One system discontinued intervention entirely
 - Two systems attempted to sustain less intensive versions of intervention; sustainment waned after monthly support calls from study team ended and behavioral health staffing challenges arose

Alignment with policy incentives: STOP CRC



- Intervention clinics had higher proportion of participants who completed fecal immunochemical test (FIT) and any colorectal cancer (CRC) screening
- Higher rates of clinic-level implementation were associated with higher rates of FIT completion
- **Sustainment factors:**
 - Oregon Medicaid adopted CRC screening as incentivized quality metric
 - Commercial insurers began covering recommended follow-up after positive FIT, reducing structural barriers to screening and supporting continued use of FIT as initial screening option
- **Sustainment/spread:**
 - Sustainment in 22 of 26 participating health systems; new uptake by 19 additional sites in these systems
 - State health department contracts with CDC supported spread to 154 clinics in Oregon, Washington, and California
 - CDC funding facilitated dissemination through 2 Medicaid health plans to >500 clinics in Washington and Oregon
 - Intervention has spread to other states through health centers' networks

Alignment with policy incentives: TSOS



- Intervention significantly reduced in PTSD symptoms among trauma patients at 6 months but not 12 months, with greater treatment effects among patients with higher baseline PTSD risk
- **Sustainment factors:** Primary goal of trial was to bring evidence-based recommendations to ACS Committee on Trauma to facilitate guidance development and policy change; investigators presented key partner first-hand accounts and study results to the committee
- **Sustainment/spread:** TSOS results were one element among multiple factors catalyzing the ACS Committee on Trauma to require protocols at all level I and II trauma centers to screen, identify, and refer patients at high risk for PTSD after injury

Nuanced factors in sustainment



Clinician's Role

Clinicians' experiences and beliefs impact sustainment decisions

Valuable insights, especially in contexts with high burnout



Facility-Level Variation

Variation in implementation during trials raises questions about sustainment (complexity a factor)

Degree to which intervention fits with the infrastructure of its target setting



Resource-Intensive

Staffing requirements can limit sustainment

Cost-effectiveness analysis often completed after sustainment decisions = misalignment



Healthcare Policy

Policy changes external to health systems drove sustainment for some trials

Importance of engaging policymakers



Secondary Analyses

Benefits for subgroup of patients or secondary outcomes led to partial sustainment

Important things to do

- Include secondary outcome measures that are salient to health system partners
- Collect all appropriate data to allow for post hoc analysis of subgroups
- Collect experience data from clinicians and staff
- Engage policy-makers before starting the trial



Q&A



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