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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 subgroup) or even perceived benefits (e.g., staff like the intervention). Second, effective interventions—even those solicited by the health system and/or designed with significant health system partner buy-in—may not be sustained if they require significant resources. Third, alignment with policy incentives is essential for achieving sustainment and scale-up of effective interventions. Our experiences point to several recommendations to aid in considering post-trial sustainment or de-implementation of interventions tested in 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 policymakers 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. Interventions tested in ePCTs are intentionally designed to align with health system priorities and leverage existing healthcare system infrastructure and resources, with the goals of easing intervention implementation during the trial and increasing the likelihood that effective interventions will be translated into routine practice post-trial.

The NIH Pragmatic Trials Collaboratory,[3] funded by the National Institutes of Health (NIH), supports the conduct of large-scale ePCT Demonstration Projects[4] that address major public health issues within diverse healthcare systems. The Collaboratory has a unique opportunity to draw on the Demonstration Project experiences to generate lessons learned

related to the design and conduct of ePCTs, and the dissemination and implementation of interventions tested in ePCTs. In this article, we draw on case studies from six completed Demonstration Projects to summarize the Collaboratory's experience with post-trial interpretation of results and implications for the sustainment (or de-implementation) of tested interventions.

METHODS

In June 2022, we conducted 1-h individual semi-structured interviews with the leaders of six Collaboratory Demonstration Projects to learn how the project's design, objectives, setting, and results contributed to the level of sustainment or de-implementation (i.e., active removal of a study intervention) of the study intervention. Projects were chosen based on project leader willingness to participate, successful completion of the project study, and publication or presentation of study results (see Table 1 for details regarding Demonstration Projects). Interview questions focused on gathering details about trial results, post-trial sustainment or de-implementation of the study intervention, and factors that led sites or healthcare systems to sustain or de-implement the study intervention. All interviews were conducted by the same two interviewers. Notes from each interviewer were compared and discrepancies were resolved by contacting the Demonstration Project leaders for clarification. The two interviewers worked together using a rapid qualitative analysis and inductive strategy to identify factors that led to sustainment or de-implementation of an intervention.[5,6] Identified factors were grouped into three common overarching themes: benefits outside of the primary outcome, intervention resource intensiveness, and alignment with policy incentives or requirements.

RESULTS

We identified several factors—outside of the primary results of an ePCT—that may influence whether a participating health system implements (or not) the tested intervention. Below, we discuss these factors and present case examples from completed ePCTs conducted within the Collaboratory.

Benefits Outside of the Primary Outcome

Benefits for a Subgroup. Even when an ePCT is null for the primary outcome, a participating health system or systems may sustain, or even expand, the intervention if the intervention has measured or perceived benefits other than the primary outcome. For example, the intervention may benefit an important subgroup of patients.

Demonstration Project Example: ABATE (Active Bathing to Eliminate) Infection Trial. ABATE: Design The ABATE Infection trial was a cluster randomized trial conducted in general medical and surgical units of hospitals in HCA healthcare. The ABATE Infection trial used mupirocin ointment for nasal decolonization of carriers of methicillin-resistant *Staphylococcus aureus* (MRSA) combined with chlorhexidine antiseptic soap for all bathing and shower needs. The trial compared this combination treatment with regular soap alone for all bathing and shower needs.

ABATE: Results The ABATE Infection trial found that the intervention did not significantly reduce multidrug-resistant bacteria or bloodstream infection in the overall non-critical care population. Further post hoc analysis of patients with medical devices (including central venous catheters and accessed ports, midline catheters, and lumbar drains) showed that the intervention was associated with significant reductions in all-cause bloodstream infections and multidrug-resistant organism cultures.

ABATE: Factors Leading to Sustainment/De-implementation The study team and health system partners concluded that targeting patients with devices may be particularly valuable, as they represented 10% of the non-critical care patient population, yet accounted for 56% of all bloodstream infections and 37% of multidrug-resistant organism cultures.[7]

ABATE: Sustainment/Spread Based on these results, in intervention hospitals, HCA healthcare chose to (1) discontinue (i.e., de-implement) the protocol as a universal practice for all non-critical care patients, (2) sustain the protocol for patients with a medical device in participating hospitals, and (3) implement the protocol for patients with a medical device in all other HCA hospitals. Implementation support included corporate enterprise offerings to hospitals (e.g., trainings, order sets). Outside of HCA healthcare, the ABATE Infection team partnered with AHRQ to develop and disseminate an intervention toolkit and accompanying recommendations specific to patients with medical devices.[8]

Benefits for a Secondary Outcome. An intervention that is null for the primary outcome could demonstrate effectiveness for a secondary outcome or outcomes that are important to the health system.

Demonstration Project Example: LIRE (Lumbar Imaging with Reporting of Epidemiology). LIRE: Design The LIRE trial evaluated the impact of including epidemiological information describing the prevalence of common, possibly incidental, findings in spine imaging reports on subsequent spine-related healthcare utilization using a stepped-wedge design. The intervention was tested in 98 primary care clinics in four large health systems.

Table 1 Summary Details of NIH Pragmatic Trials Collaboratory Demonstration Projects

Project name	Project start/end date	Project focus	Results for primary outcome	Intervention status (sustained, spread, de-implemented)	Factors leading to sustainment or de-implementation
ABATE (Active Bathing to Eliminate Infection)	April 2014/February 2019	Evaluate chlorhexidine bathing plus mupirocin versus regular soap bathing to reduce bloodstream infection in hospitalized patients	Null	*Sustained* for those with medical devices in HCA *Spread* to other systems via partnership with AHRQ	*Benefits outside primary outcome*—Subgroup of patients with medical devices saw reduction of bloodstream infections *Policy*—Study team partners with AHRQ. Policy penalizes infections for urinary catheters and central lines
LIRE (Lumbar Imaging with Reporting of Epidemiology)	October 2013/December 2018	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	*Benefits outside primary outcome*—Secondary analysis showed a reduction in subsequent opioid prescriptions *Resource intensive*—For health systems that sustained the intervention, there were no additional costs required to do so
PPACT (Collaborative Care for Chronic Pain in Primary Care)	April 2014/February 2018	Test the use of CBT interventions in primary care settings to improve chronic pain for patients in long-term opioid therapy	Positive	*Modified sustainment* of less resource-intense versions of the intervention	*Resource intensive*—Heavy staffing costs and system needs led to feasibility concerns. Cost analysis cannot be conducted until all claims are received resulting in a lack of cost-effectiveness data when considering intervention sustainment
PROVEN (Pragmatic Trial of Video Education in Nursing Homes)	March 2016/May 2019	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	*Benefits outside primary outcome*—Clinician satisfaction and reduced hospital transfers at end of life *Low Resource Intensiveness*—Low implementation costs
STOP-CRC (Strategies and Opportunities to Stop Colorectal Cancer in Priority Populations)	January 2013/August 2018	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	*Policy*—Medicaid incentivized CRC screening and commercial insurers eliminated patient co-pays for follow-up procedures
TSOS (Trauma Survivors Outcomes and Support)	October 2015/November 2019	Test the effectiveness of early interventions for traumatically injured patients with PTSD	Positive for main outcome measure at 6 but not 12-month timepoints	*Minimal sustainment* in a small number of trial sites *Spread* to other trauma centers via partnership with ACS/COT	*Policy*—Trial results presented to national policy making group ACS/COT helped inform a requirement for PTSD screening in all level I and II trauma centers nationally

LIRE: Results The LIRE intervention did not result in decreased spine-related healthcare utilization after imaging. However, in prespecified secondary analyses, the intervention slightly reduced subsequent opioid prescriptions.[9]

LIRE: Factors Leading to Sustainment/De-implementation In the context of the opioid and overdose crises, health system leaders perceived decreased opioid prescriptions to be an important benefit of the intervention. Other important

considerations, discussed in more detail below, were that (1) no additional resources were required to sustain the intervention and (2) informal feedback from clinicians indicated there might be other potential benefits of the intervention (e.g., supporting more effective communication with patients).

LIRE: Sustainment/Spread Following the trial, two of the four health systems chose to sustain the intervention based in part on its potential to reduce opioid prescriptions.

Benefits for Clinicians. A positive clinician association or experience with an intervention could lead to sustainment of an intervention despite a null primary outcome.

Demonstration Project Example: PROVEN (Pragmatic Trial of Video Education in Nursing Homes). PROVEN: Design PROVEN tested the effect of an advance care planning video program on hospital transfers among long-stay nursing home residents. The trial used a cluster randomized design involving 360 nursing homes in 32 states owned by two for-profit corporations.

PROVEN: Results There was no significant reduction in hospital transfers; secondary outcomes (burdensome treatments, hospice enrollment) also did not differ between intervention and control groups.[10] However, additional post hoc analyses of selected subsets of the study population found that facilities in the intervention group increased their documentation of explicit advance directives in this advanced illness population and reduced burdensome hospital transfers for patients at the end of life.[11,12] Quantitative and qualitative process evaluations of the PROVEN intervention revealed substantial variation in implementation across facilities, with higher implementation rates at facilities where local staff's engagement in the intervention and personal investment in advance care planning were high.[13,14]

PROVEN: Factors Leading to Sustainment/De-implementation Staff at facilities with higher levels of implementation liked the intervention. At those facilities, staff's continued interest in offering the PROVEN intervention—coupled with its low cost of implementation, lack of evidence of any negative consequences, and potential benefits for a subgroup (as with ABATE, described above)—prompted select facilities to consider sustainment.

PROVEN: Sustainment/Spread Following the trial, based on the null results, participating facilities did not require, incentivize, or offer concrete support for intervention sustainment. However, facilities with highly engaged champions and receptive staff members were encouraged by clinic leaders to continue offering the videos. PROVEN appeared to have been adopted into regular practice in about a quarter to a third of experimental facilities. However, without institutional reinforcement, once staff champions left, the program was not sustained.

Intervention Resource Intensiveness

Intervention resource intensiveness (e.g., monetary costs, human resource costs) is also a critical consideration for health systems considering whether to sustain an intervention that achieves its intended effect on the primary outcome. Even interventions that are effective may not be sustained, or fully sustained. This is also true for interventions that are conceptualized/designed with significant buy-in from health system leaders. Conversely, interventions that are not resource intensive may be sustained regardless of their effectiveness.

Demonstration Project Examples: PROVEN and LIRE. As noted in the PROVEN and LIRE case examples, above, when an intervention is null for the primary outcome but has other benefits (e.g., secondary outcomes, clinician experience), it may be especially likely to be sustained if it does not require substantial resources. For example, after the LIRE trial, which determined the impact of informing clinicians of common imaging finding on subsequent spine-related healthcare utilization, one of the two health systems that chose not to sustain the intervention after the trial, would have needed additional resources to do so. The healthcare center implementing LIRE switched EHR systems following the trial. Integrating the intervention into the new EHR system would have been costly. Moreover, as described above, the PROVEN intervention, which evaluated the effect of advance care planning videos shown to nursing home residents, appeared to have been adopted into regular practice in about a quarter to a third of experimental facilities, in part because of its low cost.

Demonstration Project Example: PPACT (Collaborative Care for Chronic Pain in Primary Care). PPACT: Design PPACT was a cluster randomized trial testing the impact of a cognitive behavioral therapy intervention that included pain self-management skills and yoga-based adapted movement among patients on long-term opioid therapy (LTOT) receiving primary care in one of three large health systems. The PPACT intervention consisted of a comprehensive intake evaluation, 12 weekly group sessions, and primary care provider consultation. In addition, the study worked with clinical leadership to embed a four-item validated pain-related assessment (PEGS—pain intensity and interference with enjoyment of life, general activity, and sleep) into the electronic health record for all participating healthcare systems. As such, the PEGS scale was considered standard of care for routine clinician use. Embedding the PEGS scale as part of routine clinical procedure supported the sustainability of this element of the intervention in these settings.

PPACT: Results The primary trial outcome was self-reported pain on the PEGS scale. Secondary outcomes included pain-related disability, satisfaction with care, and opioid and benzodiazepine use as reflected in electronic health record data. Cost-effectiveness analyses were also conducted. The intervention was positive for the primary outcome, and compared with usual care, resulted in modest but sustained reductions in measures of pain, pain-related disability, and use of benzodiazepines.[15] Notably, while there was a significant reduction in LTOT among all participants and health systems, the PPACT trial did not specifically target, nor demonstrate a reduction in opioid prescribing/use associated with the intervention. In addition, the PPACT intervention was found to reduce healthcare costs overall (including the cost of the intervention and its delivery), reduce costs per quality-adjusted life years (QALY; a measure of quality of life over the length of life), and reduce costs per responder (a patient who experiences ≥ 30% improvement on the PEGS scale).[16]

PPACT: Factors Leading to Sustainment/De-implementation Upfront staffing costs and feasibility were a concern for participating systems. Leading up to, and at the outset of the trial, PPACT had the significant health system leadership support necessary to overcome these concerns about costs and resource intensiveness; however, over the course of the trial, health system leadership and, correspondingly, priorities, shifted. Further, delay in cost effectiveness analyses outcomes precluded the positive findings of such to be considered at the time clinical decisions about sustainability were under consideration.

PPACT: Sustainment/Spread Despite positive results and overall cost effectiveness,[16] post-trial intervention uptake was variable. All participating systems adopted the PEGS pain measure used in the trial for routine assessment among patients with chronic pain on LTOT. One system discontinued the intervention entirely. The two remaining systems have attempted to sustain versions of the intervention (e.g., less intensive, or more psychoeducational vs. skills-based programs), although sustainment waned after monthly support calls from PPACT ended and behavioral health staffing challenges arose. Further, as delivered, it was difficult to preserve the *core functions* of the intervention.

Alignment with Policy Incentives or Requirements

In recognition of the evolving nature of health system priorities and resources, several project teams shared that the most effective way to facilitate sustainment and scaling of effective interventions after ePCTs is to focus on relevant policy. Project teams sought to align their study objectives with current policies that would aid the sustainment and spread of effective interventions. Project teams also leveraged their research results to influence the creation of new policy and prompt updates to existing policy.

Demonstration Project Example: STOP CRC (Strategies and Opportunities to Stop Colorectal Cancer). STOP CRC: Design The objective of the STOP CRC trial was to determine the effectiveness of an EHR-embedded outreach program implemented in health centers as part of standard care to improve colorectal cancer (CRC) screening rates. STOP CRC was a cluster randomized trial in 26 federally qualified health center clinics in eight health centers in Oregon and California. The intervention involved embedding a tool in the EHR to identify patients who were overdue for colorectal cancer screening, mailing a fecal immunochemical test (FIT) kit and reminder letter to eligible patients, and implementing a practice improvement process at participating clinics.

STOP CRC: Results Compared with clinics that practiced usual care, intervention clinics had a significantly higher proportion of participants who completed a FIT (3.4 percentage points) and any colorectal cancer screening (3.8 percentage points).[17] During the trial, implementation of the intervention was highly variable across clinics, and higher levels of implementation were associated with higher rates of FIT completion.[18]

STOP CRC: Factors Leading to Sustainment/De-implementation STOP CRC trial results did not necessarily drive implementation. Study leaders advocated for the inclusion of CRC as an incentivized metric at the beginning of the trial, and worked closely with a legislative member of the study's advisory board to eliminate an identified barrier (co-pays for follow-up colonoscopy) to promoting stool-based testing in health centers. As a result, the study team credits two relevant policy changes—both influenced by their prior/related research. First, Oregon's Medicaid program adopted CRC screening as an incentivized quality metric,[19] prompting interest in the STOP CRC program among health systems serving a large proportion of Medicaid-insured patients. Monetary incentives were given to Medicaid health plans for reaching established performance or improvement targets in CRC screening rates. This policy change spurred interest in sustaining the program among health plans, with health plans assisting clinics with the resources required for and the costs associated with program implementation. Second, commercial insurers in the state began fully covering (with no patient out-of-pocket costs) recommended follow-up procedures after positive FIT (already covered by Medicaid).[19] Commercial insurers' coverage reduced structural barriers to screening and supported the continued use of FIT as an initial screening option.

STOP CRC: Sustainment/Spread After the trial, the study team saw widespread sustainment of their intervention across 22 of the original 26 participating health systems in

Oregon and California, and new uptake by an additional 19 sites within these health systems.[20] Ultimately, state health department contracts with the CDC supported the spread of the STOP CRC intervention into numerous health centers, including 68 clinics in Oregon, 81 in Washington, and five in California. Funding from the CDC supported a critical adaptation to the program that facilitated its dissemination through Medicaid health plans, involving two health plans and over 500 clinics in Washington and Oregon.[21] Now, the health centers that have implemented the intervention span multiple states.[22] So, while the study may have started in Oregon and California, it has spread to other states through the health centers' networks. Project leaders have described STOP CRC as a "catalytic project" and emphasized that this was the intent. Project leaders worked with the CDC to update an implementation guide[23] and provider training modules for national dissemination efforts.

Anticipating the important role of policy in influencing sustainment and scaling of effective interventions from ePCTs, several other Demonstration Project teams proactively established partnerships with government or non-government organizations in a position to facilitate practice change and implementation efforts.[24]

Demonstration Project Example: ABATE. ABATE: Policy Factors Leading to Sustainment/De-implementation As mentioned earlier, the Agency for Healthcare Research and Quality (AHRQ) partnered with ABATE Infection investigators, who compared chlorhexidine antiseptic soap and mupirocin ointment with regular soap bathing in medical units, to publish and promote a Toolkit for Decolonization of Non-ICU Patients With Devices.[8] AHRQ is an agency of the US Department of Health and Human Services that works to make healthcare safer, higher quality, and evidence-based. Healthcare providers and policy-makers rely on AHRQ data and tools to improve healthcare. The toolkit contains instructional handouts and video training materials to assist healthcare providers in implementing the ABATE Infection decolonization program. By working with best practice building organizations like AHRQ, the ABATE Infection team was able to facilitate implementation of their intervention beyond their original study sites. In addition, hospital adoption of the ABATE Infection intervention in the subset of patients with devices may have been spurred by federal penalty programs. These penalty programs withhold part of hospital reimbursements from the Centers for Medicare & Medicaid Services for poor performance on quality measures including high rates of central-line–associated bloodstream infections and urinary catheter infections. In this way, external hospital financial penalties and evidence for marked benefit in critical care patients who commonly have devices may have incentivized uptake of the ABATE intervention in the subset of non-critical care patients with devices based upon an important post hoc analysis.

Demonstration Project Example: TSOS (a Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support)). TSOS: Design TSOS was a stepped wedge cluster randomized pragmatic clinical trial studying the effect of PTSD screening and implementation of screening procedures in healthcare systems. The trial involved 635 patients from 25 US trauma centers and followed patients for 12 months. TSOS project leaders leveraged a decades-long relationship with the American College of Surgeons Committee on Trauma Regulation (ACS/COT), which develops national policy requirements and clinical best practice guidelines for US trauma centers and affiliated trauma care systems, to proactively request a policy summit at the trial's end.[25] Post-trial sustainment of the intervention in participating centers was not a main focus for TSOS. The primary goal of the TSOS project was to bring evidence-based recommendations to ACS/COT to facilitate guidance development and policy change.

TSOS: Results The TSOS intervention was positive for the primary outcome, with a significant reduction in PTSD symptoms at 6 months, but not at 12 months. Secondary outcomes of depressive symptoms, alcohol use, and physical function were not statistically significant. TSOS also found that patients with higher baseline PTSD risk had greater treatment effects.

TSOS: Factors Leading to Sustainment/De-implementation At the trial end summit, TSOS presented key partner first-hand accounts as well as study results to ACS/COT. TSOS project leaders believe that health system change is best effected when policy makers are engaged and policy change is planned for before a trial begins. Trials that aim to change policy may not be widely implemented upon trial completion, but they may lead to a cascade of requirements that allow change to be widespread and sustained.

TSOS: Sustainment/Spread The TSOS intervention was sustained in a small number of trial sites post trial; however, TSOS study leaders were more focused on effecting health system change through policy. The results of the TSOS study were one element among multiple factors that catalyzed the ACS/COT to require protocols at all level I and II trauma centers nationally to screen, identify, and refer patients at high risk for PTSD after injury.[26,27]

DISCUSSION

The idea that trials proceed in a straightforward fashion to implementation within participating healthcare systems ignores the multiple factors that must be considered post trial. Also, assuming that a trial null for the primary outcome should always be discontinued may ignore other valid reasons for sustaining a trial intervention. The experiences of 6

diverse NIH Pragmatic Trials Collaboratory Demonstration Projects reveal a nuanced set of factors influencing sustainment or de-implementation of interventions following the completion of ePCTs.

In the ABATE Infection and LIRE studies, we found examples of trials that were null for the primary outcome but were at least partially sustained in participating healthcare systems due to benefits for a subgroup of patients or secondary outcome. These experiences underscore the importance of ePCT teams working with health system partners to identify salient secondary outcome measures and subgroup analyses. Relatedly, teams should consider collecting data on clinician and staff satisfaction with the intervention, either as a secondary outcome or as part of a process evaluation.

Based on the experiences of the LIRE and PROVEN trials, and consistent with established implementation determinant frameworks (e.g., Consolidated Framework for Implementation Research (CFIR)),[28] clinicians' experiences with or beliefs about the intervention may be relevant to post-trial sustainment decisions. Information about clinician satisfaction may be particularly valuable (although potentially challenging to collect) in clinical contexts with high rates of burnout.[28]

When describing their trial results, several interviewees mentioned substantial facility-level variation in implementation of a complex intervention during the trial. The project leaders did not explicitly describe implementation variation as a factor influencing eventual sustainment. However, their comments raise important questions about how facility-level variation in intervention implementation during a trial may affect later considerations around intervention sustainment.

With PPACT, we show an example of a study that was positive for the primary outcome and cost effective, yet saw limited or declining post-trial sustainment due to the staffing required to sustain it. As described by the PPACT and several other project teams, the more resource (including staffing) intensive the intervention, the higher the threshold for implementation, and the more important for the intervention be considered high priority by health system leadership. Intervention cost and complexity are established determinants of successful implementation,[28] as is the degree to which an intervention fits with the infrastructure and resources of its target setting. Expensive interventions that have heavy or particular staffing needs, especially those targeting a clinically challenging yet smaller subgroup of patients, require significant and ongoing buy-in from health system leadership. Yet, support can be difficult to sustain in the context of frequent leadership turnover and constantly evolving priorities and pressures.

Notably, the PPACT intervention was found to be cost-effective. Yet, as is often the case given the need for full post-trial health services data, the cost-effectiveness analysis for PPACT was completed after the "pivot point" for sustainment had passed. This experience highlights misalignment between the usual timing of intervention cost-effectiveness analyses and the timeline on which decisions about whether to sustain or dismantle resource and staffing intensive interventions are made.

Based on the Collaboratory's experience so far, and consistent with established implementation determinant frameworks,[28] a key driver of post-trial implementation is healthcare policy. TSOS and STOP CRC are interesting examples of study interventions that were effective for their primary outcomes, but sustained (and ultimately scaled) mainly because of policy changes that occurred external to participating health systems. The TSOS experience, together with the ABATE Infection and STOP CRC trials, highlights a key opportunity for ePCT teams to proactively identify and partner not only with leadership within the health systems in which they plan to test their interventions but also with decision-makers positioned to incentivize or require change at the state or national levels.

Recommendations

To aid studies with post-trial interpretation and sustainment/de-implementation considerations, we have synthesized our observations into four recommendations: (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.

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Declarations:

Conflict of Interest: *Terren Green has nothing to declare.*
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