

## PROGRESS NOTES

# Methodological progress note: Implementation science contributions to healthcare research and practice

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### Funding information

Agency for Healthcare Research and Quality, Grant/Award Number: K08HS026512

## INTRODUCTION

Evidence adoption is painfully slow, and the gap between what we know from research and what clinicians and patients practice is vast and has measurable impacts on health. Implementation science works to close this gap. As defined by the National Institutes of Health, implementation science is the scientific study of the use of strategies to increase the uptake of evidence-based health interventions in clinical settings to improve service delivery and patient outcomes.<sup>1</sup> By itself, informing clinicians and patients of clinical research findings will not improve health. Implementation science is needed to understand how to change health-related practices and improve health. Along the research continuum, efficacy research informs “what” works; effectiveness research identifies “for whom” it works; and implementation science informs “the process” for integrating what works into practice. Understanding the evidence integration process ideally begins early in the research continuum. Therefore, it is of great value for researchers and clinicians to have a fundamental understanding of implementation science.

This methodological progress note, the first in a three-part series, offers a high-level overview of implementation science focusing on healthcare settings (vs. community settings).

### The “what” and “how” of implementation science

Implementation scientists often consider the strategies used to implement evidence-based practices (EBPs) separately from the EBP they are implementing. The EBP is “what” is being implemented, and the implementation strategies are “how” it is implemented (see “Implementation Frameworks and Implementation Strategies” section

below for a discussion of implementation strategies). What defines an EBP? The answer is complex. The *practice* or the *evidence* being implemented can take many forms, including guidelines, medications, or programs that have been shown effective. The evidence may include results from randomized controlled trials, observation studies, or mixed-methods studies. How much and what type of evidence is enough to call something evidence-based and implement is a complex question. While randomized-controlled trials have long been the gold standard of evidence, an EBP shown to be effective in a tightly controlled RCT may prove ineffective in the real world or for some populations. There has been a call for a wider definition of EBP, including the incorporation of practice-based or community-defined evidence.<sup>2</sup> The bar for sufficient evidence for implementation must involve considerations of effectiveness, implementation climate, barriers and facilitators to implementation, partnerships with and the priorities of the settings or populations where implementation is being considered, the cost of implementing versus not, and equity.

## IMPLEMENTATION FRAMEWORKS AND IMPLEMENTATION STRATEGIES

Implementing EBPs begins with understanding context or how settings, people, and system characteristics affect successful implementation. This understanding of context is then used to select, develop, and test implementation strategies and measure outcomes. Implementation science frameworks guide the assessment of context, the selection of implementation strategies to address context, and the choice of appropriate outcome, process, and balancing measures. Numerous frameworks exist and framework selection depends on the specifics of the project. An interactive

webtool available at <https://dissemination-implementation.org/tool/> can be used to select the appropriate framework(s) for a given study. Guided by frameworks, implementation scientists often employ qualitative methods to understand context or the barriers and facilitators to successful and sustained implementation on multiple levels, including, organizational, individual (clinician or patient), system, and community. Implementation strategies are then selected to overcome these multilevel and complex contextual factors. Implementation strategies are plentiful. A compilation of strategies, the expert recommendations for implementing change (ERIC), lists 73.<sup>3</sup> There are no universally effective implementation strategies nor highly reproducible ways to map barriers and facilitators to strategies. Methods including partner engagement, expert consensus methods, and implementation mapping can be used to select and tailor strategies to context. Implementation mapping is an iterative process that includes choosing mechanisms of change, selecting, or designing implementation strategies, producing implementation protocols and materials, and evaluating implementation outcomes.<sup>4</sup> The Consolidated Framework for Implementation Research (CFIR) ERIC Matching Tool available at [www.cfirguide.org](http://www.cfirguide.org) can also be used to select strategies. The ERIC strategies have been mapped to the CFIR. When CFIR is used to guide the understanding of barriers to implementation, the matching tool can be used to select strategies that experts believe will address those barriers. While these methods increase confidence in implementation strategy effectiveness, the field of implementation science remains focused on developing and testing reliable and reproducible methods for strategy selection.

## MEASURES AND EVALUATIONS

A combination of measures, including clinical, system, and implementation outcomes, are employed in implementation studies. Clinical outcomes measure the effectiveness of the EBP in improving health. Implementation outcomes help understand the reasons for and distinguish between successful and unsuccessful implementation. Enola Proctor's implementation outcomes are commonly used to provide a comprehensive and holistic view of the implementation process and its impacts. They include feasibility, acceptability, appropriateness, adoption, fidelity, implementation costs, penetration, and sustainability.<sup>5</sup> Implementation science evaluation frameworks can help guide outcomes measurement. One of the most used evaluation frameworks is RE-AIM which stands for reach, effectiveness, adoption, implementation, and maintenance. RE-AIM guides clinical and implementation outcomes measurement<sup>6</sup> (Figure 1).

## THE YIN AND YANG OF IMPLEMENTATION – FIDELITY AND ADAPTATIONS

Having been proven effective; it stands to reason that EBPs ought to be implemented with fidelity (or as previously studied) to avoid changes that render them less effective. Fidelity is, in fact, one of

Proctor's implementation outcomes. However, both context and systems are dynamic; they are constantly changing. Therefore, while fidelity to EBPs as studied is essential, EBP and implementation strategies must be adapted to different and ever-changing contexts. This is necessary and purposeful adaptation is often guided by frameworks to carefully identify the need for adaptation or contextualization to specific settings or local factors. Implementation scientists recognize the importance of tracking and understanding adaptations and their impact. The FRAME<sup>8</sup> is a research model that helps researchers report when, how, and why adaptations to EBPs are made and the impact.

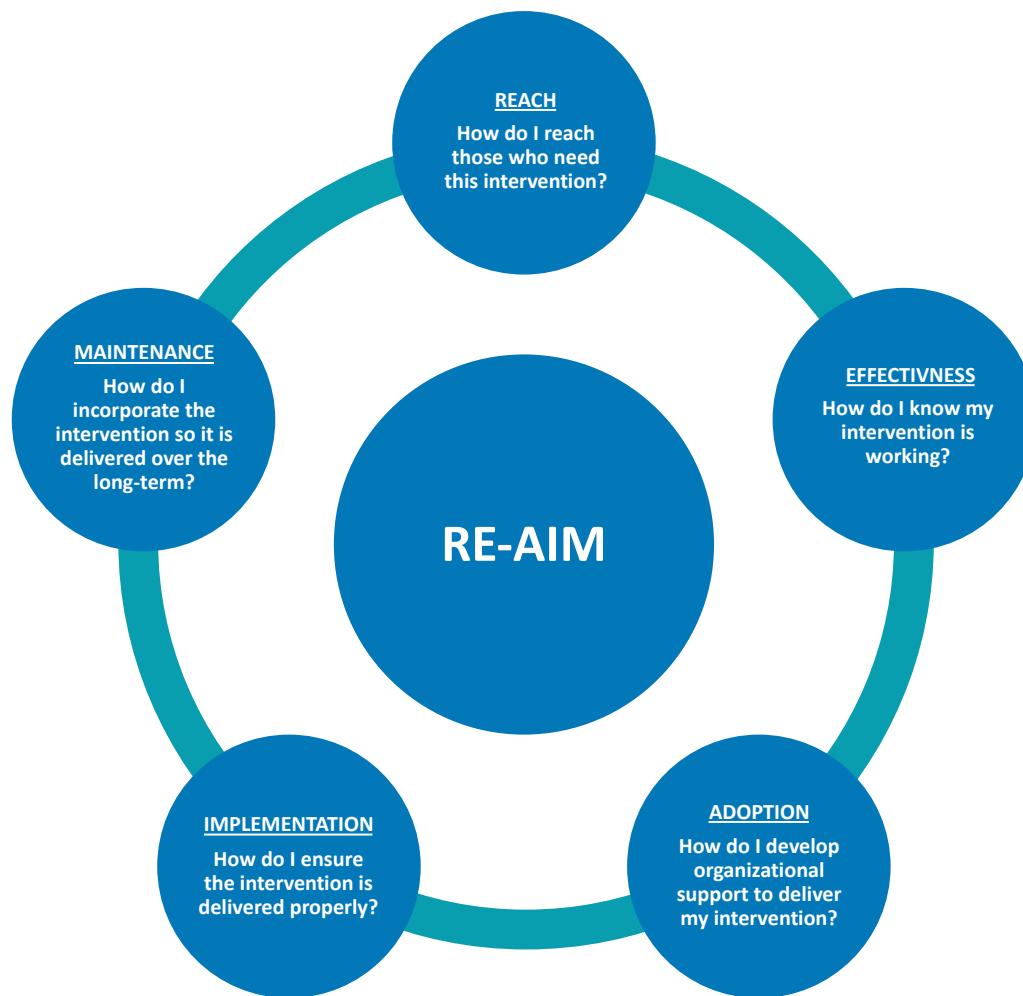
## STUDY DESIGNS

To understand and assess the effectiveness of implementation, implementation scientists use various study designs, including experimental and qualitative. While experimental or randomized study designs are employed, the field recognizes that a high level of control over the study environment may not represent real-world implementation success; therefore, pragmatic study designs are employed to access outcomes in routine clinical practice. Similarly, participatory research involving active collaboration and partnership between researchers and the community or population where implementation is being studied is common. Qualitative methods are often used to develop a more comprehensive understanding of the processes and contextual factors that influence implementation. Researchers use interviews and focus groups to explore the subjective experiences and perspectives of those involved in the implementation process and to understand the complex social, cultural, and contextual factors that may influence implementation. Hybrid study designs are used in implementation science to simultaneously study both implementation outcomes and the clinical effectiveness of interventions using a combination of quantitative and qualitative data. There are three types of hybrid trial designs that vary in their focus on either clinical effectiveness or implementation including type 1 (effectiveness > implementation), type 2 (effectiveness = implementation), and type 3 (effectiveness < implementation).<sup>9</sup>

## AREAS OF INTEREST FOR IMPLEMENTATION SCIENCE

### Engaging clinicians and quality improvement teams

There is both considerable overlap and important differences between quality improvement and implementation science. Both aim to improve healthcare and outcomes but diverge in their methods and stated goals. Quality improvement uses methods to identify *what* works to address a problem in a local context, and implementation science focuses on *how* and *why* implementation succeeds.<sup>10</sup> In healthcare settings, implementation scientists often work with clinicians and quality improvement teams to understand



**FIGURE 1** RE-AIM elements. RE-AIM and other Implementation Science Evaluation Frameworks guide the comprehensive evaluation of the implementation process and the impact of evidence-based practices on health outcomes in real-world settings. *Source:* Ory et al.<sup>7</sup>

the context and overcome barriers to implementation. Likewise, quality improvement teams may engage implementation scientists to spread an intervention. Experts in both fields agree there is an opportunity for greater collaboration through shared tools and methods. Quality improvers may be able to improve the equity, reach, and sustainment of quality improvement efforts by using implementation science frameworks and implementation outcomes; implementation scientists may be able to improve the buy-in for and speed of implementation by using tools familiar to quality improvement teams and clinicians and adopting an iterative approach to change.

## Deimplementation

There is a need to deimplement or reduce unnecessary, outdated, or harmful medical practices. The need for deimplementation rivals that for implementation. Outdated medical practices cost the US economy \$760 billion annually, representing about 25% of total

healthcare spending.<sup>11</sup> This overuse has negative financial, health, and psychological impacts on patients. Deimplementation is distinct from implementation and involves unique contextual barriers such as inertia around established practices, resistance to or discomfort with change, psychological reactance or a perceived threat to autonomy, and concern for omission (or missing a diagnosis) over commission (overdiagnosis). Of particular importance in deimplementation is deciding what practices to deimplement, which must involve considerations of equity, clinical effectiveness, cost-effectiveness, and patient preferences. More studies are needed to understand methods for identifying deimplementation targets and to identify the most effective deimplementation strategies.<sup>12</sup>

## Health equity and engagement

Inequitable implementation can perpetuate or exacerbate existing health disparities and inequities. Implementation science emphasizes understanding local contexts' needs, values, and resources to inform

**TABLE 1** Overview of contributions from the field of implementation science to healthcare research.

Implementation research area	Contribution to healthcare research	Citation for example research
1. Implementation frameworks	<ul style="list-style-type: none"> <li>To better understand implementation determinants and their link to health outcomes</li> </ul>	<p>Coxe-Hyzak KA, Bunger AC, Bogner J, et al. Implementing traumatic brain injury screening in behavioral healthcare: protocol for a prospective mixed methods study. <i>Implement Sci Commun.</i> 2022;3:17.</p> <p>Srigley JA, Corace K, Hargadon DP, et al. Applying psychological frameworks of behaviour change to improve healthcare worker hand hygiene: a systematic review. <i>J Hosp Infect.</i> 2015;91(3):202-210.</p>
2. Implementation strategies	<ul style="list-style-type: none"> <li>To increase the uptake of clinical interventions in real-life settings</li> </ul>	<p>Deatrack JA, Kazak AE, Madden RE, et al. Using qualitative and participatory methods to refine implementation strategies: universal family psychosocial screening in pediatric cancer. <i>Implement Sci Commun.</i> 2021;2:62. doi:10.1186/s43058-021-00163-4</p> <p>Gabrielian S, Finley EP, Ganz DA, et al. Comparing two implementation strategies for implementing and sustaining a case management practice serving homeless-experienced veterans: a protocol for a type 3 hybrid cluster-randomized trial. <i>Implement Sci.</i> 2022;17:67. doi:10.1186/s13012-022-01236-1</p>
3. Measures/Evaluation	<ul style="list-style-type: none"> <li>To validate measures assessing key areas such as the implementation, implementation costs, and sustainment of EBPs in healthcare</li> </ul>	<p>Malone S, Prewitt K, Hackett R, et al. The Clinical Sustainability Assessment Tool: measuring organizational capacity to promote sustainability in healthcare. <i>Implement Sci Commun.</i> 2021;2:77. doi:10.1186/s43058-021-00181-2</p> <p>Donovan T, Abell B, Fernando M, et al. Implementation costs of hospital-based computerised decision support systems: a systematic review. <i>Implementation Sci.</i> 2023;18:7. doi:10.1186/s13012-023-01261-8</p>
4. Study design	<ul style="list-style-type: none"> <li>To offer hybrid effectiveness-implementation approaches to research as a way to speed translation of evidence into practice</li> </ul>	<p>Orth LE, Feudtner C, Kempe A, et al. A coordinated approach for managing polypharmacy among children with medical complexity: rationale and design of the Pediatric Medication Therapy Management (pMTM) randomized controlled trial. <i>BMC Health Serv Res.</i> 2023;23:414. doi:10.1186/s12913-023-09439-y</p> <p>Wolfensberger A, Clack L, von Felten S, et al. Implementation and evaluation of a care bundle for prevention of non-ventilator-associated hospital-acquired pneumonia (nvHAP)—a mixed-methods study protocol for a hybrid type 2 effectiveness-implementation trial. <i>BMC Infect Dis.</i> 2020;20:603. doi:10.1186/s12879-020-05271-5</p>
5. Areas of interest	<ul style="list-style-type: none"> <li>Engaging clinicians and quality improvement teams</li> <li>Adaptation of quality improvement interventions to local contexts</li> </ul>	<p>Pittman JOE, Rabin B, Almklov E, et al. Adaptation of a quality improvement approach to implement Screening in VHA healthcare settings: innovative use of the Lean Six Sigma Rapid Process Improvement Workshop. <i>Implement Sci Commun.</i> 2021;2:37. doi:10.1186/s43058-021-00132-x</p> <p>Kaplan HC and Walsh KE. Context in implementation science. <i>Pediatrics.</i> 2022;149 (Supplement</p>

(Continued)

TABLE 1 (Continued)

Implementation research area	Contribution to healthcare research	Citation for example research
Deimplementation	<ul style="list-style-type: none"> <li>To generate knowledge about why certain practices persist despite evidence of ineffectiveness and develop and test deimplementation strategies</li> </ul>	<p>3):e2020045948C. doi:10.1542/peds.2020-045948C</p> <p>Fenton JJ, Kravitz RL, Jerant A, et al. Promoting patient-centered counseling to reduce use of low-value diagnostic tests: a randomized clinical trial. <i>JAMA Intern Med</i> (published online December 7, 2015). doi:10.1001/jamainternmed.2015.6840.</p> <p>Roczniewska M, von Thiele Schwarz U, Augustsson H, et al. How do healthcare professionals make decisions concerning low-value care practices? Study protocol of a factorial survey experiment on de-implementation. <i>Implement Sci Commun</i>. 2021;2:50. doi:10.1186/s43058-021-00153-6</p>
Health equity and engagement	<ul style="list-style-type: none"> <li>To offer practical guide to incorporating health equity into implementation research</li> <li>To use participatory engagement to inform the planning, design, implementation, and evaluation of interventions</li> </ul>	<p>Woodward EN, Singh RS, Ndebele-Ngwenya P, et al. A more practical guide to incorporating health equity domains in implementation determinant frameworks. <i>Implement Sci Commun</i>. 2021;2:61. doi:10.1186/s43058-021-00146-5</p> <p>Ramanadhan S, Davis MM, Armstrong R, et al. Participatory implementation science to increase the impact of evidence-based cancer prevention and control. <i>Cancer Causes Control</i>. 2018;29(3):363-369. doi:10.1007/s10552-018-1008-1</p>
Sustainment	<ul style="list-style-type: none"> <li>To understand and evaluate multilevel factors contributing to the sustainment of EBPs in local contexts/systems</li> </ul>	<p>Cowie J, Nicoll A, Dimova ED, et al. The barriers and facilitators influencing the sustainability of hospital-based interventions: a systematic review. <i>BMC Health Serv Res</i>. 2020;20:588. doi:10.1186/s12913-020-05434-9</p> <p>Hoben M, Ginsburg LR, Norton PG, et al. Sustained effects of the INFORM cluster randomized trial: an observational post-intervention study. <i>Implement Sci</i>. 2021;16:83. doi:10.1186/s13012-021-01151-x</p>

the design and implementation of health interventions. Implementation science must consider the unique needs and challenges of different groups and take steps to ensure that interventions are implemented or deimplemented in a way that is culturally and contextually appropriate, and that addresses potential barriers to access. This may involve adapting interventions to fit the needs and context of specific populations, providing additional resources and support to ensure that interventions are accessible and effective for all people, and addressing power imbalances and other social and structural determinants of health. Implementation science frameworks may help researchers anticipate and address contextual barriers to equitable implementation,<sup>13</sup> measure inequities that may arise during or after implementation,<sup>14</sup> and focus or adapt implementation to reduce disparities. Participatory engagement approaches such as implementation mapping<sup>4</sup> and cocreation<sup>15</sup> during the planning, design, implementation, and dissemination of interventions help ensure equitable implementation by considering the specific needs, challenges, and strengths of the population or setting.

## Sustainment

Sustainability is an important concept in implementation science, as it refers to the ability of an intervention to be maintained over time and to become an integral part of the routine practice in a setting. Sustainability is a complex and multifaceted concept influenced by various organizational, resource, and implementation-related factors.<sup>16</sup> Understanding these factors can help researchers, practitioners, and policymakers identify strategies for improving the sustainability of interventions. Sustainment necessitates attention to and adaptation to the ever-changing delivery system, evidence, and context. The Dynamic Sustainability Framework has been proposed to address the paradox of sustainment amid ongoing change. The framework can be used to guide iterative changes or adaptations to sustain implementation.<sup>17</sup>

See Table 1 for an overview of how key areas in the field of implementation science have informed healthcare studies.

## CONCLUSION

Implementation science is a growing and promising field of research that aims to translate evidence into practice, with a focus on equity and participatory engagement. This field is essential to ensure that EBPs are integrated into routine healthcare to increase the efficiency and effectiveness of healthcare systems, improve patient outcomes, and reduce healthcare costs. Understanding implementation science will ensure healthcare researchers' work is relevant and useful to practitioners and increase the likelihood that research findings will be used to inform clinical care.

## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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**How to cite this article:** Tyler A, Pérez Jolles M. Methodological progress note: Implementation science contributions to healthcare research and practice. *J Hosp Med.* 2023;18:920-925. doi:10.1002/jhm.13147