RISE³ Lab

A RISE³ LAB PRIMER

Getting started with implementation science

What the field is, the concepts you need, and how to plan a first project. A practical primer consolidating ten foundational papers.

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Version 1.0 · November 2026

McGill

Version 1.0 · November 2026

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Suggested citation Fontaine G. Getting started with implementation science: a practical primer. Version 1.0. Montréal: RISE³ Lab, McGill University; 2026.

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About this guide

This primer is for clinicians, managers, trainees and researchers who are meeting implementation science for the first time, or who want a compact map of the field before a first project.

It consolidates ten foundational, open-access papers [1–10] into one document: the reasons the field exists, its vocabulary, the main types of theories, models and frameworks, how to assess context, how to choose and describe implementation strategies, how to measure success, how to design a study, and how equity, adaptation and sustainability fit in. A short list of further reading [11–17] points to the next layer of detail. Where the guide goes beyond the sources, for example in the roadmap at the end, this is marked as the RISE³ Lab's synthesis.

Read it once from start to finish, then use the contents list to return to a section when you need it. Each section ends with a practical note. Numbered citations in square brackets link to the reference list.

THREE IDEAS TO KEEP IN VIEW

- Implementation science studies *how* evidence-based practices get used in routine care, not whether the practices work [1, 2].
- Keep the intervention (the thing being implemented) separate from the implementation strategies used to put it in place, and measure each with its own outcomes [5–7].
- Context shapes everything. Assess it early, choose strategies that address what you find, and plan for adaptation, equity and sustainability from the start [3, 5, 10, 12].

1 Why implementation science exists

Research produces findings that could improve care, but findings cannot change outcomes unless health services and professionals adopt them. Uptake is uneven across settings, specialties and countries [1]. A widely cited estimate, reported in the introductory review by Bauer and colleagues, is that evidence-based practices take on average 17 years to enter routine practice, and that only about half ever reach widespread use [2]. Implementation science grew out of this research-to-practice gap.

Bauer and colleagues describe the research process as a pipeline running from efficacy trials through effectiveness trials to sustained use, with blockages at each stage. Competing demands on frontline providers, gaps in knowledge, skills and resources, and misalignment between research evidence and operational priorities all impede uptake. Effectiveness trials alone offer little guarantee of impact, because the research resources that support them are external, time-limited and gone when the protocol ends [2].

Definitions

> Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services. It includes the study of influences on healthcare professional and organisational behaviour.
>
> Eccles and Mittman, 2006 [1]

This is the founding definition of the journal *Implementation Science* and the one most often reused [2, 4]. Peters and colleagues offer a broader definition for use across research traditions: implementation research is "the scientific inquiry into questions concerning implementation—the act of carrying an intention into effect, which in health research can be policies, programmes, or individual practices (collectively called interventions)" [3]. In this view, implementation research can examine the factors affecting implementation, its processes and its results, including how to introduce solutions into a health system and how to promote their large-scale use and sustainability [3].

Three features follow from these definitions. The field works in real-world conditions rather than controlling them away [3]. It operates at several levels at once: patient, provider, organization and policy, which is why it needs transdisciplinary teams that include health services researchers, economists, social scientists and operational partners such as administrators, clinicians and patients [2]. And it is concerned with the users of research, who should often be involved in identifying, designing and conducting studies rather than being only the targets of dissemination [3].

What implementation science is not

Related activity	How it differs	Source
Quality improvement	Starts with a specific problem in a specific system and designs a fix for that system. Implementation science usually starts with an under-used evidence-based practice and aims at generalizable knowledge. The two share goals, values, a concern for rigour and many methods.	[2]

Related activity	How it differs	Source
Dissemination	The spread of information about an intervention, assisted at most by education. Implementation efforts may include dissemination, but embed it in more comprehensive, targeted and active work.	[2]
Diffusion	The passive, untargeted and unplanned spread of new practices. Dissemination is active and planned; implementation is the process of putting new practices to use within a setting.	[4]
Effectiveness research	Tests the health effects of an intervention. Implementation research studies the rates and quality of its use. When an effort fails, this distinction tells you whether the intervention did not work in the new setting (intervention failure) or a good intervention was deployed poorly (implementation failure).	[2, 6]
Knowledge translation and related terms	Knowledge translation, exchange, transfer, integration and research utilization describe overlapping research on putting knowledge to use. In Canada the terms are often used interchangeably with implementation science.	[4]

IN PRACTICE

When you describe a project, say in one sentence which evidence-based practice is under-used, in which setting, and whether your question is about the practice itself or about how to get it used. That sentence decides whether you are doing effectiveness research, implementation research, or a hybrid of the two (section 7).

2 The vocabulary

The field has been described as a "Tower of Babel" because the same things are given different names and the same names mean different things [7]. The terms below are the ones used in this guide, with the definitions the sources give them.

Evidence-based intervention (or innovation)
The "thing" being implemented: a treatment, program, practice, policy or guideline recommendation. It is what continues once implementation is complete [5]. The updated CFIR uses "innovation" for any idea, practice or object perceived as new, "recipients" for the people meant to benefit, and "deliverers" for the people delivering it [5].

Implementation strategy
"Methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice" [7, 8]. Strategies are the activities that end once implementation is complete [5]. They can be discrete (a single action such as training), multifaceted (training plus supervision plus audit and feedback) or blended into a branded package such as a learning collaborative [7].

Determinants
The barriers and facilitators that influence implementation outcomes. Determinant frameworks organize them into types or domains [4, 5].

Context
The social, cultural, economic, political, legal and physical environment, the institutional setting with its stakeholders and their interactions, and the demographic and epidemiological conditions in which implementation takes place [3]. In implementation science, contextual factors are treated as active and dynamic forces working for and against implementation [5].

Implementation outcomes
"The effects of deliberate and purposive actions to implement new treatments, practices, and services": indicators of implementation success, distinct from service outcomes and from client or patient outcomes [6].

Mechanism
The "process or event through which an implementation strategy operates to affect desired implementation outcomes" [13]. Determinants may explain why a strategy did or did not work; mechanisms explain how it worked [13].

Fidelity and adaptation
Fidelity is the degree to which an intervention is implemented as prescribed in the original protocol or intended by its developers [6]. Adaptation is the degree to which users modify the strategy or the intervention during implementation to suit local needs [11].

Sustainability

The extent to which a newly implemented treatment is maintained or institutionalized within a setting's ongoing, stable operations [6]. A widely used definition is the continued use of program components and activities for the continued achievement of desirable program and population outcomes [12].

Hybrid effectiveness–implementation study

A study that takes a dual focus from the outset on the effectiveness of an intervention and on its implementation [9]. The originators now recommend the term “hybrid study” rather than “hybrid design” [15].

> **IN PRACTICE**
>
> Name each element of your project explicitly: the intervention and its core components, the strategies, the determinants you expect to matter, the outcomes you will measure and at which level. Confusion between the intervention and the strategies is the most common source of unclear implementation studies [5, 7].

3 Theories, models and frameworks

Early implementation research was largely empirical. Nilsen quotes Eccles and colleagues' description of it as “an expensive version of trial-and-error”, and a review by Davies and colleagues that found only 10% of guideline implementation studies gave an explicit rationale for their strategies [4]. Theories, models and frameworks (TMFs) are the field's answer: they make assumptions explicit, help explain how and why implementation succeeds or fails, and allow findings to accumulate across studies [2, 4].

Three words that are not interchangeable

A **theory** is a set of analytical principles that explain and predict: it defines variables, a domain, relationships between the variables and specific predictions. A **model** is a deliberate simplification of a phenomenon; it is descriptive rather than explanatory, and in implementation science models are mostly used to describe or guide the process of getting research into practice. A **framework** is a structure of descriptive categories (concepts, constructs, variables) and the relations between them; frameworks describe, they do not explain [4]. Bauer and colleagues make the same point: frameworks organize constructs without specifying causal relationships, whereas a model depicts a hypothesized pathway of change that can be tested [2].

Five categories, three purposes

Nilsen identified three overarching aims for which TMFs are used in implementation science: describing or guiding the process of translating research into practice; understanding or explaining what influences implementation outcomes; and evaluating implementation. These give five categories [4]:

Category	What it does	Examples named by Nilsen
Process models	Specify the steps or phases of translating research into practice; “action models” give practical guidance for planning and executing implementation.	Knowledge-to-Action Framework, Stetler Model, Iowa Model, Ottawa Model, Quality Implementation Framework
Determinant frameworks	Specify types of determinants (barriers and enablers) that influence implementation outcomes. Some also hypothesize relationships among them.	CFIR, PARIHS, Theoretical Domains Framework, Active Implementation Frameworks, Ecological Framework
Classic theories	Theories from other fields (psychology, sociology, organizational theory) that explain aspects of implementation.	Theory of Diffusion, Theory of Planned Behaviour, Social Cognitive Theory, organizational theories
Implementation theories	Theories developed or adapted by implementation researchers to explain aspects of implementation.	Normalization Process Theory, COM-B, Implementation Climate, Organizational Readiness, Absorptive Capacity
Evaluation frameworks	Specify the aspects of implementation that can be evaluated to determine success.	RE-AIM, PRECEDE-PROCEED, Proctor and colleagues' implementation outcomes

Adapted from Nilsen, 2015 [4].

The categories overlap. A determinant framework can guide implementation practice because it lists what to address, and most TMFs can serve evaluation because their constructs can be measured. What matters is recognizing that TMFs differ in their assumptions and aims, and that a single TMF seldom tells the whole story: combining approaches offers fuller understanding, as long as their contrasting assumptions are acknowledged [4].

Choosing

Recent reviews cited in the SELECT-IT scoping review counted 159 and 143 implementation science TMFs, which makes choice a real problem [16]. That review, led by the RISE³ Lab, identified seven overarching purposes TMFs serve, 24 attributes that describe them and 10 practical considerations for selecting one, and proposes SELECT-IT, a four-step meta-framework for choosing TMFs according to purpose, attributes and fit with the project context. It gives particular weight to attributes that earlier selection tools neglected, such as equity, trust and cultural safety [16]. An earlier tool, the Theory Comparison and Selection Tool (T-CaST), rates TMFs on usability, testability, applicability and familiarity [16].

IN PRACTICE

- Decide what you need the TMF for before you choose it: to plan the process, to assess determinants, to explain change, or to evaluate. Many projects use one TMF for each purpose [4, 16].
- State which TMF you used and how, at every stage from data collection to interpretation, and report what you learned about its usefulness so that it can be improved [2, 5].
- Use theory as a guide, not as blinders. Nilsen's warning is that theory can lead us to ignore problems that do not fit it [4].

4 Understanding context and determinants

Far too many efforts to implement evidence-based innovations fail, even with well-developed plans, because contextual factors that trials control away are active in the real world [5]. Determinant frameworks give a shared set of concepts and definitions for describing these factors and developing measures of context [5]. Their overarching aim is to predict or explain barriers and facilitators to implementation effectiveness, which in turn informs the choice of implementation strategies [4, 5].

The Consolidated Framework for Implementation Research

The CFIR is one of the most cited determinant frameworks. It was updated in 2022 from a literature review and a survey of authors who had used it. The updated CFIR contains 48 constructs and 19 subconstructs across five domains [5]:

1. **Innovation**: the thing being implemented, with constructs such as evidence base, relative advantage, adaptability, trialability, complexity, design and cost.
2. **Outer setting**: the setting in which the inner setting exists (a hospital system, a region, a province), including local attitudes, local conditions, partnerships, policies and laws, financing and external pressures.
3. **Inner setting**: the setting in which the innovation is implemented (a hospital, a clinic, a team), including structural characteristics, relational connections, communications, culture, tension for change, compatibility, relative priority, incentive systems, mission alignment, available resources and access to knowledge.
4. **Individuals**: two subdomains. Roles (high- and mid-level leaders, opinion leaders, implementation facilitators, leads and team members, innovation deliverers and recipients) and characteristics (need, capability, opportunity and motivation, drawn from the COM-B system [14]).
5. **Implementation process**: the degree to which teaming, assessing needs, assessing context, planning, tailoring strategies, engaging, doing, reflecting and evaluating, and adapting take place.

The 2022 update also added determinants related to equity, such as subconstructs of culture (human equality-centeredness, recipient-centeredness, deliverer-centeredness, learning-centeredness) and the outer-setting constructs of local attitudes and local conditions, and it asks users to define the boundary between the innovation and the strategies used to implement it [5].

What determinant frameworks have in common, and what they leave out

Comparing eight widely cited determinant frameworks, Nilsen found that they account for the same five types of determinants: characteristics of the implementation object, of the users or adopters, of the end users (such as patients), of the context, and of the strategy or other means of facilitating implementation [4]. A later scoping review of 17 determinant frameworks found considerable variation in how context itself is defined and in which contextual determinants are included [17]. Determinant frameworks do not address how change takes place or any causal mechanism, so they are not theories, and the determinants they list can interact in ways that are difficult to predict [4]. Surveying a fixed list of barriers can miss factors that matter, and perceived barriers may not match actual ones [4].

EXAMPLE: USING A FRAMEWORK TO EXPLAIN VARIATION

A US Veterans Affairs evaluation found wide variation in the implementation of a weight management program 18 months after its dissemination. Interviews guided by the CFIR, with quantitative ratings applied to the coded data, identified ten constructs that distinguished sites with better and worse implementation outcomes. Sites with the poorest outcomes, for example, rated low on "goals and feedback" because staff lacked the time or skills to set goals and monitor progress. That finding pointed to discrete strategies such as audit and feedback and identifying champions [2].

IN PRACTICE

- Operationalize the framework for your project: define the inner and outer settings, replace generic construct language with project-specific language, add constructs for themes the framework misses, and select a subset of constructs to assess rather than all of them [5].
- Collect data from the people who have power or influence over implementation outcomes, and keep open-ended questions so that themes outside the framework can surface [5].
- Use mixed methods: semi-structured interviews, focus groups, direct observation and document review alongside surveys and administrative data [2, 3].

5 Choosing and specifying implementation strategies

Implementation strategies are the "how to" component of changing healthcare practice [7]. They range from provider training and decision support, toolkits, checklists and protocols, through learning collaboratives and organizational interventions such as plan-do-study-act cycles, to economic, fiscal and regulatory strategies [7]. The evidence for particular strategies is growing, but strategies are often inconsistently labelled, poorly described, rarely justified theoretically and bundled into packages whose components are unclear, which prevents replication and meta-analysis [7].

A shared menu: the ERIC compilation

The Expert Recommendations for Implementing Change (ERIC) project engaged a panel of 71 implementation and clinical experts in a three-round modified Delphi process to refine an earlier compilation of 68 strategies. The panel reached consensus on 73 discrete implementation strategies, each with a name and a definition [8]. The authors are explicit that the compilation is not a checklist: no effort could use every strategy. It is a list from which to select discrete strategies as building blocks for a tailored, multicomponent strategy, and the contexts in which each strategy works remain to be established [8]. The earlier compilation grouped strategies by six processes: planning, educating, financing, restructuring, managing quality and attending to the policy context [7].

Specifying a strategy: name it, define it, operationalize it

Proctor, Powell and McMillen argue that strategies are a type of intervention and must be specified with the same care as clinical interventions. They recommend three steps. **Name it**, preferably with a term already used in the literature. **Define it** conceptually, distinguishing the components of a multifaceted strategy. **Specify it** on seven dimensions [7]:

Dimension	Question it answers
Actor	Who delivers the strategy? (payers, administrators, external facilitators, clinicians, patients, community members)
Action	What specific actions, steps or processes are enacted, stated with active verbs?
Action target	Toward what or whom, and at which level, is the action directed? Use a conceptual model or framework to name the target.
Temporality	When, or at what phase of implementation, is the strategy used? Strategies for planning differ from strategies for sustaining.
Dose	At what frequency and intensity?
Implementation outcome affected	Which implementation outcome is the strategy expected to change? Training typically targets fidelity; financial and policy strategies target feasibility and acceptability.
Justification	On what theoretical, empirical or pragmatic grounds was the strategy chosen, given the determinants identified?

The seven dimensions proposed by Proctor, Powell and McMillen, 2013 [7].

> A chosen implementation strategy that cannot be justified theoretically, empirically, and/or pragmatically should be carefully reconsidered.
>
> Proctor, Powell and McMillen, 2013 [7]

From determinants to mechanisms

Lewis and colleagues note that about two-thirds of implementation efforts fail to achieve the intended change, and that two systematic reviews of implementation mechanisms found only 31 studies and no mechanism established empirically [13]. They propose building causal pathway models that link a specified strategy to the mechanism through which it is expected to work, to the proximal outcome that would show the mechanism is active, to distal outcomes, and to the moderators and preconditions that shape the effect [13]. The behaviour change wheel offers a systematic method for the same purpose at the level of individual behaviour: it starts from the COM-B model (capability, opportunity, motivation) and links the analysis of a target behaviour to intervention functions and policy categories [14].

EXAMPLE: MATCHING STRATEGIES TO DETERMINANTS

In a Veterans Affairs study to increase pharmacotherapy for alcohol use disorder in primary care, earlier interviews had identified three main barriers: providers' lack of confidence in the medications, lack of skills and knowledge about using them, and perceived low patient demand. Guided by the Theory of Planned Behaviour, the team chose provider strategies (social marketing, peer expert consultants, feedback on prescribing rates, education and decision-support tools) and a patient strategy (direct-to-consumer mailings), and refined them through formative evaluation as implementation unfolded [2].

IN PRACTICE

- Choose strategies after assessing determinants, not before, and write down the link between each determinant and the strategy meant to address it [5, 7].
- Draw names and definitions from the ERIC compilation so that others can recognize what you did [8].
- Write out the seven dimensions for each strategy in a table in your protocol, and record what was actually delivered (the dose) so that fidelity to the strategy can be assessed [7].
- State the mechanism you expect each strategy to activate and the proximal outcome that would show it [13].

6 Measuring success: implementation outcomes

Studies of implementation have measured success in widely varying ways, some by inferring it from clinical outcomes, others by measuring provider behaviours [6]. Proctor and colleagues advanced a conceptual framework that distinguishes three interrelated types of outcome [6]:

- **Implementation outcomes**: the effects of deliberate actions to implement a practice. They indicate implementation success, are proximal indicators of implementation processes, and are necessary preconditions for the other two types, since an intervention cannot be effective if it is not implemented well.
- **Service outcomes**: drawn from the six quality aims of the Institute of Medicine: safe, effective, patient-centred, timely, efficient and equitable care.
- **Client outcomes**: satisfaction, function and symptoms at the individual level.

Eight implementation outcomes

Outcome	Working definition	Typical level and timing
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory.	Individual provider or consumer; early, ongoing and late.
Adoption	The intention, initial decision or action to try or employ an innovation or evidence-based practice (also called uptake).	Provider or organization; early to mid.
Appropriateness	The perceived fit, relevance or compatibility of the innovation for a setting, provider or consumer, or for a particular problem.	Provider, consumer or organization; early, before adoption.
Feasibility	The extent to which a new treatment or innovation can be successfully used or carried out within a given agency or setting.	Provider or organization; early, during adoption.
Fidelity	The degree to which an intervention was implemented as prescribed in the original protocol or as intended by its developers (adherence, dose, quality of delivery).	Individual provider; early to mid.
Implementation cost	The cost impact of an implementation effort, which varies with the intervention, the strategy and the setting.	Provider or institution; across stages.
Penetration	The integration of a practice within a service setting and its subsystems; for example, eligible people who receive a service divided by all eligible people. Peters and colleagues use the term coverage [3].	Organization; mid to late.
Sustainability	The extent to which a newly implemented treatment is maintained or institutionalized within a setting's ongoing, stable operations.	Organization; late.

Adapted from Proctor and colleagues, 2011 [6].

Three of these outcomes, acceptability, appropriateness and feasibility, are often used interchangeably in the literature. Proctor and colleagues keep them distinct: a treatment can be a good fit for a problem

(appropriate) yet unacceptable to providers because of a rigid protocol, or appropriate for a setting's mission yet not feasible because of resource or training requirements [6]. They also warn that most measurement has been home-grown with little attention to psychometrics, and that measures used in efficacy research will often be too cumbersome for real-world implementation studies [6].

> The science of implementation cannot be advanced without attention to implementation outcomes. All studies of implementation should explicate and measure implementation outcomes.
>
> Proctor and colleagues, 2011 [6]

IN PRACTICE

- For each outcome, state the referent (one treatment, the strategy, or a broad effort), the level of analysis (provider, team, organization) and the time point. Few studies do, and this limits comparison [6].
- Think in terms of leading and lagging indicators. Acceptability may rise before penetration does; sustainability may only be observable well after implementation ends [6].
- Choose pragmatic measures and, where possible, triangulate self-report with administrative data or observation [6].

7 Designing an implementation study

Implementation studies differ from clinical trials in their hypothesis and in their approach to validity. In the hypothetical example used by Bauer and colleagues, an efficacy or effectiveness trial asks whether motivational interviewing beats a control condition; an implementation trial asks whether motivational interviewing will be adopted and sustained. The unit of observation may be patients, providers or clinics; outcome measures emphasize adoption; the clinicians are the setting's own; research support is limited; and the protocol may be optimized in real time through formative evaluation while adaptations are documented [2].

Three kinds of evaluation

Bauer and colleagues distinguish **process evaluation**, which describes how a practice is used without feeding results back; **formative evaluation**, which uses the same methods but feeds data back to the implementation team during the study, by design, to improve the implementation as it proceeds; and **summative evaluation**, which compiles the impact of the strategy at the end, typically on processes of care and often with a business impact analysis of costs [2].

The research question comes first

Peters and colleagues take a pragmatic approach: the research question, or implementation problem, is the starting point and dictates the methods. They classify questions by objective (to explore, describe, influence, explain or predict) and match each to suitable qualitative, quantitative or mixed methods [3]. Because implementation often takes place in complex adaptive systems where what is implemented changes over time, designs that require a single fixed intervention, such as a conventional randomized trial, may be inappropriate, and studies often need several methods, several sources of information and observations at several points in time [3].

Design options

- **Parallel group designs**, randomized at the level of the patient, provider, clinic, facility or system depending on the strategy and outcome, including **stepped wedge** designs in which all sites receive implementation support in a staggered order [2].
- **Interrupted time series**, when randomization is not feasible for pragmatic, political or ethical reasons; most feasible when the strategy is a discrete event such as a policy change [2].
- **Sequential multiple assignment randomized trials (SMART)** and adaptive designs, which bring rigour to within-study formative evaluation [2].
- **Pragmatic trials**, which test effectiveness in normal practice with the full range of participants [3].
- **Quality improvement studies** built on plan-do-study-act cycles, **participatory action research**, in which power over the process rests with participants, and **mixed methods**, which Peters and colleagues describe as particularly suitable because they capture multiple perspectives, causal pathways and types of outcome [3].

Hybrid effectiveness–implementation studies

Curran and colleagues proposed blending effectiveness and implementation research in a single study to speed translation and produce more useful information for decision makers. A hybrid design "takes a dual focus a priori in assessing clinical effectiveness and implementation" [9]:

Type	Primary aim	Secondary aim	Conditions suggested by the authors
Type 1	Test the effectiveness of a clinical intervention	Observe and gather information on implementation (barriers, facilitators, promising strategies), usually through a process evaluation with stakeholders	Strong face validity and at least indirect evidence for the intervention; minimal risk
Type 2	Test the clinical intervention and the implementation strategy simultaneously	Each test needs at least one outcome and one hypothesis; randomization and power can differ between the two	The conditions for type 1, plus "implementation momentum" in the system and a strategy that is supportable in the context
Type 3	Test an implementation strategy	Observe and gather information on the clinical intervention and its outcomes	Strong momentum or mandates to implement, and evidence that the strategy is feasible in the context

Adapted from Curran and colleagues, 2012 [9].

Reflecting on ten years of use, the originators now recommend the term "hybrid study" rather than "hybrid design", because hybrid types describe the relative emphasis on effectiveness and implementation aims, not the research design. A study should be labelled with both, for example "a parallel cluster randomized hybrid type 3 effectiveness-implementation study", and the choice of type should be justified against alternatives, considering the level of evidence for the intervention, how much it is expected to be adapted, how much is known about implementation determinants, and how ready the implementation strategies are for evaluation [15]. Hybrid studies can also use non-trial designs [15].

EIGHT QUESTIONS TO ASSESS AN IMPLEMENTATION STUDY

Peters and colleagues propose a set of questions that apply across methods [3]: Does the research clearly aim to answer a question about implementation? Does it identify its primary audiences and how they would use it? Is what is being implemented clearly described? If there is an implementation strategy, is it described and examined in full? Is the study conducted in a real-world setting, with the context and sample described in detail? Does it consider implementation outcome variables? Does it consider context and other factors that influence implementation? Does it consider changes over time, the complexity of the system and unintended consequences?

IN PRACTICE

- Write the research question before choosing a design, and let the question decide the methods [3].
- If both effectiveness and implementation questions are open, consider a hybrid study and name its type and design explicitly [9, 15].
- Plan the process or formative evaluation alongside the main design; it is where the knowledge about implementation comes from [2, 9].

8 Equity, adaptation and sustainability

Equity

Inequities in healthcare delivery are unjust differences between populations in the access, use, quality and outcomes of care. Baumann and Cabassa argue that implementation science and healthcare inequities research share goals but remain poorly integrated: populations that experience inequities are underrepresented in the trials that produce evidence-based interventions, implementation efforts often overlook the economic, social, historical and political forces that perpetuate inequities, and scale-up to low-resource settings often lacks the resources it needs [10]. Using Proctor and colleagues' framework, they propose five ways to reframe implementation science [10]:

1. **Focus on reach from the very beginning**: who is invited, who participates and who is missing; broaden the settings in which studies are done, including non-traditional settings.
2. **Design and select interventions with implementation in mind**: place implementation outcomes at the forefront of development and use user-centred and participatory approaches, with, for and in the community.
3. **Implement what works and develop strategies that can reduce inequities**: strategies for underserved communities may need additional components, such as building trust, enhancing cultural competence, raising critical consciousness, supporting advocacy and reducing language barriers.
4. **Develop the science of adaptation**: adapt systematically, consider adaptations to the intervention, the strategies and the context, and track them on a common platform.
5. **Use an equity lens for implementation outcomes**: study whether feasibility, fidelity, penetration, acceptability, sustainability and cost differ between organizations serving different populations, and develop strategies that produce equitable implementation outcomes.

The authors of the updated CFIR reach a similar conclusion from a different direction: they urge users to collaborate with equity experts, to combine the CFIR with an equity-focused framework and a broader theoretical lens, to include recipients and community members in choosing and adapting the innovation and the strategies, and to ask who is represented in the study and how the work could cause harm [5]. Equity and sociocultural responsiveness are also among the attributes SELECT-IT asks users to weigh when choosing a TMF [16].

Adaptation

Interventions almost never fit perfectly the organization in which they are embedded, so some mutual adaptation of the intervention or the context is part of implementation [10]. The tension between fidelity and adaptation is a central concern of the field. StaRI suggests resolving it by defining the core components of an intervention, ideally tied to its logic pathway, to which fidelity is expected, and the aspects that local sites may adapt [11]. Adaptations should follow established practices to avoid drift, involve stakeholders and be documented: what was adapted, by whom, how, when and why [10].

Sustainability

Sustainability has been called one of the most significant translational research problems. In a systematic review of 125 studies cited by Shelton and colleagues, partial sustainability was much more common than continuation of the whole intervention, fewer than half of the programs continued at high fidelity, and 65% of the studies did not define sustainability [12]. The empirical literature points to categories of influence that interact: the outer context (sociopolitical context, funding environment), the inner or organizational context (resources, leadership, champions, staff stability, policy alignment), processes (training, planning, stakeholder engagement, partnerships, evaluation), intervention characteristics (adaptability, fit, benefit) and implementer characteristics [12]. Conceptualizations have shifted from static routinization toward dynamic frameworks that treat ongoing, data-driven adaptation as part of sustainability rather than a threat to it [12].

IN PRACTICE

- Attend to reach and representation from the design stage, and ask who is missing from your sites and samples [10].
- Define the core components of the intervention and the adaptable periphery before implementation starts, and keep an adaptation log [10, 11].
- Plan for sustainability early, and follow up for at least a year after implementation, ideally two or more, with several indicators measured at several time points [12].

9 Reporting

Implementation studies have often been poorly reported, with absent conceptual frameworks, inadequate description of context and incomplete information about how the intervention was promoted and implemented, which makes the evidence hard to find, reproduce and synthesize [11]. The Standards for Reporting Implementation Studies (StaRI) checklist, developed through an e-Delphi exercise and an international consensus meeting, contains 27 items. Its defining concept is two strands: the implementation strategy on one side and the intervention being implemented on the other, with ten items asking authors to address both [11]. StaRI expects an explicit logic pathway spanning how the strategy is expected to work and how the intervention is expected to improve care, a rich description of context, and attention to the balance between fidelity and adaptation [11].

Two further reporting habits come from the sources above. Name, define and specify every implementation strategy on the seven dimensions, and provide manuals or protocols as supplements [7]. For every implementation outcome, report the referent, the level of analysis and the time point [6].

> **FROM THE RISE³ LAB**
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> A secondary analysis of 204 implementation trials led by the lab examined how well implementation strategies are reported and what this means for specifying them. It is listed on the lab's Resources page.

10 A roadmap for a first project

The steps below are the RISE³ Lab's synthesis of the sources in this guide. They are not a prescribed sequence: implementation is iterative, and several steps run in parallel.

01 Start from a gap in practice

Name the evidence-based intervention, the setting and the gap in its use. Check that the evidence base justifies implementation, and that the intervention carries minimal risk in the new setting [2, 9].

02 Define the thing and its core components

Describe the intervention using a reporting guideline, separate it from the strategies you will use, and decide which components must be delivered with fidelity and which can be adapted [5, 11].

03 Engage the people with influence and the people affected

Involve decision makers, deliverers and recipients in identifying, designing and conducting the work. Ask who is missing [3, 5, 10].

04 Choose theories, models and frameworks for each purpose

Decide what you need: a process model to plan, a determinant framework to assess context, a theory to explain change, an evaluation framework to measure. Use a structured selection approach such as SELECT-IT [4, 16].

05 Assess context and determinants

Operationalize your determinant framework, collect mixed-methods data from people with influence over implementation, and identify the determinants that matter in your setting [2, 5].

06 Select and specify implementation strategies

Match strategies to determinants, draw names and definitions from the ERIC compilation, specify the seven dimensions, justify each choice and state the mechanism you expect [7, 8, 13].

07 Choose outcomes and a design

Select implementation outcomes with their referent, level and timing; add service and client outcomes if you have effectiveness questions; consider a hybrid study; plan the process or formative evaluation [2, 6, 9, 15].

08 Plan for equity, adaptation and sustainability

Set reach targets, keep an adaptation log, and plan follow-up of at least a year with several sustainability indicators [10–12].

09 Report fully and feed back

Use StaRI, specify strategies, report outcomes precisely, and say what you learned about the frameworks you used [2, 7, 11].

COMMON PITFALLS

- Confusing the intervention with the strategies used to implement it [5, 7].
- Measuring only clinical outcomes and assuming implementation succeeded [6].
- Treating a determinant framework as a checklist, or assessing every construct instead of the ones that matter [5].
- Choosing strategies before assessing determinants, or without a justification [7].
- Ignoring reach and equity until the analysis stage [10].
- Having no plan for what happens when research support ends [2, 12].

11 Learn more with the RISE³ Lab

The RISE³ Lab (Research in Implementation Science for Healthcare Engagement, Effectiveness and Equity) at McGill University develops methods for implementation science and applies them with health services and community organizations.

- **Fundamentals of Implementation Science**, a four-day course at the McGill Summer Institutes directed by Dr. Guillaume Fontaine: core concepts, practical tools and methods. See the lab's Training page.
- **Global Leaders in Implementation Science**, a free, recorded seminar series with leading implementation scientists. See the Seminars page.
- **Open-access methods papers and protocols**, including the SELECT-IT meta-framework for choosing theories, models and frameworks [16]. See the Resources page.
- **Workshops and implementation support** for healthcare teams, in English and French. See the Training and consulting page.

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