

The Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Christopher Miller, PhD

VA Boston Center for Healthcare Organization and Implementation Research (CHOIR)

Harvard Medical School Department of Psychiatry



Outline

- Acknowledgments and Disclaimers
- Definitions
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- Future Directions
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Acknowledgments and Disclaimers

- Views are our own; no conflicts of interest to declare
- Associated paper now available in *Implementation Science*:
<https://link.springer.com/article/10.1186/s13012-021-01105-3>
- Thanks to a FABULOUS set of co-authors!
- Also thanks to those who weighed in on drafts of the FRAME-IS (details follow)

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The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare



Christopher J. Miller^{1,2*} , Miya L. Barnett³, Ana A. Baumann⁴, Cassidy A. Gutner^{5,6} and Shannon Wiltsey-Stirman^{7,8}

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Definitions

- Evidence-based practice (EBP): a clinical intervention that has been demonstrated to be effective
 - Could be a medication, psychotherapy, new type of surgery, etc.
 - Curran: the EBP/intervention/practice is “THE THING”
- Implementation strategy: a method or technique used to enhance the uptake of an EBP
 - Implementation strategies are the “stuff we do to try to help people/places DO THE THING”

Definitions

- Modification: changes (proactive or reactive) made to an intervention/program
- Adaptation: subset of modifications that are planned/proactive



Setting the Stage: Why Should We Care?


- Clinical trials view of modifications: avoid at all costs (threatens internal validity)



- Realist view: modifications inevitable, so might as well document



Setting the Stage: Why Should We Care?

- Current view: modifications *essential to maximize EBP success and reduce health disparities* 
- Developing science of adaptations seen as one of five key elements to address inequities
 - <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-4975-3>

DEBATE

Reframing implementation science to address inequities in healthcare delivery

Ana A. Baumann[†] and Leopoldo J. Cabassa^{*†} 

Setting the Stage: Why Should We Care?

- Without measurement, there is no study
- Without study, there is no improvement
 - When, where, how, why, and by whom should modifications be made? → *requires documentation*

Am J Prev Med 2016 October ; 51(4 Suppl 2): S124–S131. doi:10.1016/j.amepre.2016.05.011.

The Adaptome:

Advancing the Science of Intervention Adaptation

David A. Chambers, DPhil and Wynne E. Norton, PhD

Setting the Stage: Why Should We Care?

- Thus, Shannon Wiltsey-Stirman developed two frameworks for documenting modifications to EBPs:
 - Original 2013 framework:
<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-65>
 - Expanded version: Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME):
<https://implementationscience.biomedcentral.com/articles/10.1186/s13012-019-0898-y>

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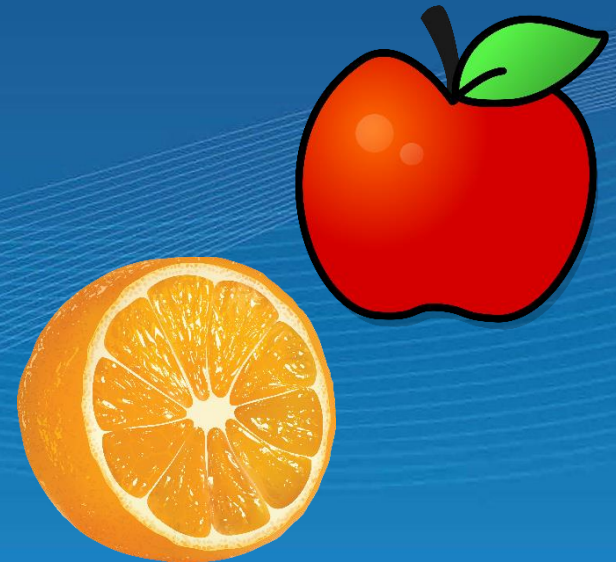
The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions



Shannon Wiltsey Stirman^{1*}, Ana A. Baumann² and Christopher J. Miller^{3,4}

Setting the Stage: Current Gap

- Both frameworks (and other research) oriented around documenting modifications to EBPs.
- BUT... what about the *implementation strategies* used to get those EBPs into practice?
 - Different actors, different mechanisms: FRAME not quite applicable
 - Thus, we set out to develop a version for tracking modifications to implementation strategies specifically: the FRAME-IS!



Development of the FRAME-IS

FRAME-IS development steps

1. Identify goals and scope	<ul style="list-style-type: none">• Goal: to develop a framework for documenting modifications to implementation strategies• Scope: implementation strategies to enhance EBI uptake
2. Identify changes needed from previous framework	CJM reviewed FRAME and changed language (e.g. EBI → implementation strategy; included training of implementers)
3. Development draft of new framework	CJM developed initial version; co-authors weighed in
4. Pilot new framework	Study authors piloted initial version of FRAME-IS in their own ongoing implementation studies and made additional edits.
5. Solicit and integrate stakeholder feedback	<ul style="list-style-type: none">• Sought feedback from several groups (e.g. IRG, WUNDIR)• Conduced one-on-one “think-alouds” with implementation experts (n=6) to provide further refinement; integrated various sources of feedback to develop final FRAME-IS.
6. Apply new framework to additional project(s)	Applied final FRAME-IS to ongoing study of PCIT (credit to co-author Miya Barnett!)

Development of the FRAME-IS

- Stakeholder feedback:
 - Initial version way too long, with too many “not applicable” items
 - Strong desire for modular format, with guidance around core/optional modules



Components of the FRAME-IS: Module 1

Module 1: BRIEFLY DESCRIBE the EBP, implementation strategy, and modification(s)

The EBP being implemented is: _____

The implementation strategy being modified is: _____

The modification(s) being made is/are: _____

The reason(s) for the modification(s) is/are: _____

Components of the FRAME-IS: Module 2

Module 2: WHAT is modified?

Content

Modifications made to content of the implementation strategy itself, or that impact how aspects of the implementation strategy are delivered

Evaluation

Modifications made to the way that the implementation strategy is evaluated

Training

Modifications to the ways that implementers are trained

Context

Modifications made to the way the overall implementation strategy is delivered. For Context modifications, specify which of the following was modified:

- Format** (e.g. group vs. individual format for delivering the implementation strategy)
- Setting** (e.g. delivering the implementation strategy in a new clinical or training setting than was originally planned)
- Personnel** (e.g. having the implementation strategy be delivered by a systems engineer rather than a clinician facilitator)
- Population** (e.g. delivering the implementation strategy to middle managers instead of frontline clinicians)
- Other** context modification: write in here:

Components of the FRAME-IS: Module 3

Module 3: What is the NATURE of the content, evaluation, or training modification?

- Tailoring/tweaking/refining
- Changes in packaging or materials
- Adding elements
- Removing/skipping elements
- Shortening/condensing (pacing/timing)
- Lengthening/ extending (pacing/timing)
- Substituting
- Reordering of implementation modules or segments
- Spreading (breaking up implementation content over multiple sessions)
- Integrating parts of the implementation strategy into another strategy (e.g., selecting elements)
- Integrating another strategy into the implementation strategy in primary use (e.g. adding an audit/feedback component to an implementation facilitation strategy that did not originally include audit/feedback)
- Repeating elements or modules of the implementation strategy
- Loosening structure
- Departing from the implementation strategy (“drift”) followed by a return to strategy within the implementation encounter
- Drift from the implementation strategy without returning (e.g., stopped providing consultation, stopped sending feedback reports)
- Other (write in here):

Optional addendum to Module 3: Relationship to fidelity/core elements?

- Fidelity to core elements/functions preserved
- Fidelity to core elements/functions NOT preserved
- Unknown

Also note this Module only applicable for content, evaluation, or training modifications

Components of the FRAME-IS: Module 4

Module 4, Part 1: What is the GOAL?

- Increase reach of the EBP (i.e. the number of patients receiving the EBP)
- Increase the clinical effectiveness of the EBP (i.e. the clinical outcomes of the patients or others receiving the EBP)
- Increase adoption of the EBP (i.e. the number of clinicians or teachers using the EBP)
- Increase the acceptability, appropriateness, or feasibility of the implementation effort (i.e. improve the fit between the implementation effort and the needs of those delivering the EBP)
- Decrease costs of the implementation effort
- Improve fidelity to the EBP (i.e. improve the extent to which the EBP is delivered as intended)
- Improve sustainability of the EBP (i.e. increase the chances that the EBP remains in practice after the implementation effort ends)
- Increase health equity or decrease disparities in EBP delivery
- Other (write in here):

Module 4, Part 2: What is the LEVEL of the rationale for modification?

- Sociopolitical level (i.e. existing national mandates)
- Organizational level (i.e. available staffing or materials)
- Implementer level (i.e. those charged with leading the implementation effort)
- Clinician or Teacher level (i.e. those implementing the EBP)
- Patient or Other Recipient level (i.e. those who will ideally benefit from the EBP)
- Other (write in here):

Components of the FRAME-IS: Module 5

Module 5, Part 1: WHEN is the modification initiated?

- Pre-implementation/planning/pilot phase
- Implementation phase
- Scale up (i.e. when the EBP is being spread to additional clinics/settings within your system)
- Maintenance/Sustainment
- Other (write in here):

Module 5, Part 2: Is modification PLANNED?

- Planned/Proactive (proactive adaptation)
- Planned/Reactive (reactive adaptation)
- Unplanned/Reactive (modification)
- Other (write in here):

Components of the FRAME-IS: Module 6

Module 6: WHO participates in the decision to modify?

- Political leader(s)
- Program Leader, Manager, or Administrator
- Funder
- Implementer or implementation strategy expert
- Researcher
- Clinician(s) or teacher(s) who are being asked to use the EBP being implemented
- Community members
- Patients or other recipients who will be the ultimate target of the EBP being implemented
- Other: write in here:

- Optional: Indicate who makes the ultimate decision:**

Components of the FRAME-IS: Module 7

Module 7: How WIDESPREAD is the modification? (i.e. for whom/what is the modification made?)

- Individual patient or other recipient for whom the EBP is being implemented
- Group of patients or other recipients for whom the EBP is being implemented
- Patients or other recipients that share a particular characteristic (e.g. all patients from a specific language background)
- Individual clinician or teacher charged with implementing the EBP
- Clinic/unit
- Organization
- Network system/community
- Specific implementer/facilitator
- Implementation/facilitation team

Example Completion of the FRAME-IS

- Parent Child Interaction Therapy (PCIT) is an evidence-based parenting program for young children with disruptive behavior disorders
- PCIT delivery: task-sharing model
 - Professional clinicians provide PCIT
 - Lay health workers promote treatment adherence to improve skill acquisition for families
- Implementation strategy: training program for lay health workers (Miami → California)

Example Completion of the FRAME-IS: Core Modules

FRAME-IS module or sub-component	Example completion
Module 1	
The EBP being implemented is:	Parent-Child Interaction Therapy (PCIT)
The implementation strategy being modified is:	Training program for lay health workers to enhance parent engagement in PCIT
The modification(s) being made is/are:	<ul style="list-style-type: none"> - Tailoring of training content (e.g., language) to local context to fit population differences - Removal of the behavioral coding component of the training
The reason(s) for the modification(s) is/are:	<ul style="list-style-type: none"> - Improve appropriateness/feasibility
Module 2	
What is modified?	<ul style="list-style-type: none"> - Content (details provided in Module 3) - Context (setting, based on transition from Miami to California)
Module 3	
What is the nature of the content, evaluation, or training modification?	<ul style="list-style-type: none"> - Tailoring (modifying language) - Removing/skipping elements (specifically, removal of behavioral coding training component)
OPTIONAL: what is the relationship to core elements?	<ul style="list-style-type: none"> - Unknown
Module 4	
What is the goal?	<ul style="list-style-type: none"> - Increase the acceptability, appropriateness, and feasibility of the implementation effort
What is the level of the rationale for the modification?	<ul style="list-style-type: none"> - Practitioner and Patient level (address cultural and linguistic differences for a population of predominantly Mexican descent)

Example Completion of the FRAME-IS: Optional Modules

FRAME-IS module or sub-component	Example completion
Module 5	
When is the modification initiated?	- Pre-implementation/planning/pilot phase
Is the modification planned?	- Planned/proactive
Module 6	
Who participates in the decision to modify?	- Researcher, program leader, and clinicians (lay health workers)
OPTIONAL: Who makes the ultimate decision?	- Researchers
Module 7	
How widespread is the modification?	- Network system/community (listed modifications were applied for entire California rollout)

Future Directions

- Questions to be answered:
 - How frequently should FRAME-IS be completed?
 - By whom?
 - How best to limit documentation burden?
 - Is it more useful for certain implementation strategies (e.g. more vs. less complex or flexible)?
 - Most importantly, do patterns in implementation outcomes emerge?
- FRAME-IS currently being piloted in two-country, ten-site implementation study

Wrap-Up

- Broad agreement that modifications (to EBPs and to implementation strategies) are important for healthcare innovations to “stick”
- Need for careful documentation of those modifications
- FRAME-IS can be used to track modifications to implementation strategies
- We hope that its use helps further our understanding of how modifications can be made to maximize health outcomes and address inequities

Discussion

Thank you for your time and attention!

For more details see:

- Linked articles in slideset
- F.A.S.T.Lab - <https://med.stanford.edu/fastlab.html>

Want to use the FRAME-IS for an upcoming project?
Contact us!

- Christopher.Miller8@va.gov, @christojoe1979



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Abstract

Background: Implementation strategies are necessary to ensure that evidence-based practices are successfully incorporated into routine clinical practice. Such strategies, however, are frequently modified to fit local populations, settings, and contexts. While such modifications can be crucial to implementation success, the literature on documenting and evaluating them is virtually nonexistent. In this paper, we therefore describe the development of a new framework for documenting modifications to implementation strategies.

Discussion: We employed a multifaceted approach to developing the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS), incorporating multiple stakeholder perspectives. Development steps included presentations of initial versions of the FRAME-IS to solicit structured feedback from individual implementation scientists (“think-aloud” exercises) and larger, international groups of researchers. The FRAME-IS includes core and supplementary modules to document modifications to implementation strategies: what is modified, the nature of the modification (including the relationship to core elements or functions), the primary goal and rationale for the modification, timing of the modification, participants in the modification decision-making process, and how widespread the modification is. We provide an example of application of the FRAME-IS to an implementation project and provide guidance on how it may be used in future work.

Conclusion: Increasing attention is being given to modifications to evidence-based practices, but little work has investigated modifications to the implementation strategies used to implement such practices. To fill this gap, the FRAME-IS is meant to be a flexible, practical tool for documenting modifications to implementation strategies. Its use may help illuminate the pivotal processes and mechanisms by which implementation strategies exert their effects.

Keywords: Modification, Adaptation, Implementation strategy

* Correspondence: Christopher.Miller8@va.gov

¹VA Boston Healthcare System, Center for Healthcare Organization and Implementation Research (CHOIR), Boston, MA, USA

²Department of Psychiatry, Harvard Medical School, Boston, MA, USA

Full list of author information is available at the end of the article



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Contributions to the literature

- Implementation strategies are typically required to ensure that evidence-based practices (EBPs) are adopted in real-world clinical settings.
- These implementation strategies, like EBPs themselves, are often modified based on the clinical setting or patient population being served.
- To our knowledge, the field lacks a systematic way of documenting and tracking modifications to implementation strategies, complicating efforts to understand the mechanisms by which those implementation strategies exert their effects.
- To fill this gap, in this paper, we describe the development of the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS).
- Systematic use of the FRAME-IS will allow healthcare system leaders, administrators, and implementation scientists to better understand the ways that implementation strategies may be modified to improve health outcomes across settings and populations.

Introduction

Implementation science aims to maximize the adoption, use, and sustainability of evidence-based practices (EBPs) in real-world healthcare settings. These EBPs can include specific medications, treatment algorithms, manualized therapies, and ways of structuring care. Adaptation of an EBP has been defined as the deliberate alteration of its design or delivery to improve its fit in a given context [1, 2]. For example, an evidence-based psychotherapy that is traditionally completed in 12 sessions could be shortened for use in a new clinical setting if 12 sessions is shown to be burdensome, too costly, or unnecessary for that patient population. Modifications to EBPs may be made in either an ad hoc or planful manner; the latter category of planned modifications may be labeled as adaptations [3, 4]. Despite the importance of modifications for improving EBP effectiveness [5] and decreasing healthcare disparities [6], they remain understudied in implementation science. Recent work has aimed to fill this gap by fleshing out ways to design, document, and evaluate modifications to EBPs (e.g., [7–10]).

It is increasingly evident that similar processes of tailoring and modification occur for implementation strategies as they are used to support implementation of EBPs in different contexts. Implementation strategies are methods or techniques used to adopt, implement, and sustain EBPs in routine practice [11]. Implementation strategies range from relatively “light touches” (e.g., audit

and feedback [12]) to more intensive strategies that include multiple components and may act on more than one level of a health system (e.g., implementation facilitation [13]). Recent work suggests little consensus in the field regarding the selection of specific implementation strategies for a given implementation project, or the mechanisms of action for those strategies [14]. As such, scholars have suggested that implementation strategies should be theoretically or empirically driven, and their components (e.g., actions, actors, goals) described so as to promote replicability and testing of their mechanisms of action [15–17].

Concurrently, scholars acknowledge the importance of modifying implementation strategies to fit with the unique characteristics of the EBP, setting, and stakeholders involved in an implementation effort [18]. For example, consider provider training as an implementation strategy. A traditional training may involve in-person workshops, but due to the COVID-19 pandemic, many trainings have been adapted to be conducted online. In addition to tracking the specific implementation strategies being used in a given project [19, 20], we advocate for the need to document and evaluate *modifications* to implementation strategies that have been well-defined and characterized. Although implementation strategies should always be operationalized to fit each context, documentation and reporting of these adaptations has to date not been consistently undertaken. It is crucially important to develop a more nuanced understanding of modifications to implementation strategies because of the inherent dynamism and complexity of implementation itself [5]. Without such an understanding, it is difficult to determine the processes or mechanisms by which implementation strategies exert their effects on implementation outcomes. Furthermore, because many implementation strategies may consist of several components delivered in dynamic contexts (e.g., [19]), changes are typically required to one or more of those components to improve fit or address constraints. Indeed, the modification of implementation strategies fits within co-creation models, in which researchers and stakeholders collaborate to exchange, generate, and utilize knowledge [21–23]. Local modifications are key to co-creation models [24], which provide opportunities to generate collaborative knowledge about how modifications to implementation strategies impact clinical and implementation outcomes.

A first step for understanding modifications to implementation strategies is to develop a framework for characterizing those modifications across studies and settings. This can allow implementation scientists, healthcare leaders, and quality improvement specialists to track when, why, and how implementation strategies have been modified. Akin to developing a database of

modifications to EBPs [25], we propose that systematic documentation is needed to determine what modifications to implementation strategies are associated with successful versus unsuccessful implementation.

Based on our previous work on developing a framework for tracking adaptations of EBPs, we have used the Framework for Reporting Adaptations and Modifications – Expanded (FRAME) [10] as a foundation from which to build a new framework, focusing on modifications that may be made to implementation strategies rather than EBPs. As described in more detail below, we found that a new framework was necessary because our pilot work highlighted key differences in tracking modifications to implementation strategies versus EBPs. Thus, the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) aims to meet the need in the implementation science field for a tool to document modifications to implementation strategies. Below, we describe the development of the FRAME-IS and include an example of its application to a recent implementation trial.

Development of the FRAME-IS

The FRAME-IS is based on the FRAME, the development of which is described in detail elsewhere [10, 26]. Briefly, the FRAME is a framework for tracking modifications to EBPs focused on *what* to adapt, alongside a related adaptation framework blending the *content* and *processes* of adaptation [27, 28]. The FRAME was developed based on earlier research [26], combined with results from a literature review, focus groups, and coding process rooted in grounded theory [29, 30].

Our process for in turn developing the FRAME-IS can be found in Table 1. We began with the FRAME [10] and used it to develop a first draft of the FRAME-IS by

changing the wording to refer to modifications to implementation strategies instead of EBPs. We also changed the language regarding the personnel involved in the modification (e.g., emphasizing the role of implementers themselves in the modification process). The authors then used the preliminary version of the FRAME-IS to describe modifications to implementation strategies in their own ongoing and completed projects, which informed further refinement (e.g., [31]). While the FRAME-IS is meant to be applicable to implementation efforts in traditional healthcare settings, it also includes language related to educational settings where some healthcare interventions may be implemented.

We then presented the FRAME-IS to several groups of stakeholders, including implementation experts from our networks, as well as international groups of implementation scientists and practitioners. These groups included the Washington University Network for Dissemination and Implementation Researchers (WUNDIR [32]); and the VA Quality Enhancement Research Initiative Implementation Research Group (QUERI IRG [33]). During these presentations, stakeholders (total $n > 50$) noted the importance of streamlining the FRAME-IS (e.g., eliminating some options, emphasizing a modular approach). We also used those presentations to identify volunteers to complete one-on-one “think-aloud” sessions [34]. Thinking aloud requires stakeholders to talk aloud while performing a task, allowing developers to understand their experiences and perspectives to shape the product to better meet their needs and constraints. This method has been applied in research on cognitive processes and in human-centered design approaches to product development. In our case, think-aloud participants ($n = 6$) were asked to review the FRAME-IS, apply it to implementation strategies while verbalizing their thought

Table 1 FRAME-IS development process

Steps	Process/operationalization
1. Identify goal and scope	- Goal: to develop a framework for documenting modifications to implementation strategies that includes the rationale for those modifications as well as the personnel involved in the modification decision. - Scope: implementation strategies meant to enhance the uptake of evidence-based practices in healthcare and educational settings.
2. Identify changes needed from previous framework	The first author (CJM) reviewed the FRAME and identified areas where language would need to be changed to refer to modifications to implementation strategies rather than modifications to evidence-based practices.
3. Develop draft of new framework	The first author (CJM) developed the initial version of FRAME-IS; this version was reviewed and edited by all co-authors.
4. Pilot new framework	Study authors piloted the initial version of FRAME-IS in their own ongoing implementation studies and made additional edits.
5. Solicit and Integrate stakeholder feedback	- Presented draft FRAME-IS to several groups of stakeholders, including international groups of implementation scientists and practitioners. Sought broad feedback on content, format, and structure of the draft FRAME-IS. - Conducted one-on-one “think-alouds” with implementation experts ($n = 6$) to provide further refinement; integrated various sources of feedback to develop final FRAME-IS.
6. Apply new framework to additional project(s)	Applied the final FRAME-IS to an ongoing study by one study author (MB; see text and Table 2 for details).

process as they did so, and provide general feedback afterward. The authors facilitated this process and took notes, which were reviewed by the full author team and used to refine the FRAME-IS. These sessions took about 30 min to complete and focused on a variety of implementation strategies including implementation facilitation, provider training, and audit/feedback. Aggregate results suggested the need for additional streamlining and clarification of the answer options to be included in the FRAME-IS. Stakeholders also suggested that the module documenting the rationale for the modification (Module 4 below) should be tied more closely to existing theories and frameworks (e.g., [16, 35]). Incorporating these suggested revisions led to the final version, which consists of a series of modules meant to capture different aspects of the modification process. The resulting FRAME-IS is multifaceted and is intended to be applicable to a variety of implementation strategies and contexts. Below, we describe each component of the FRAME-IS, as well as literature relevant to its conceptualization and challenges that may emerge in its use.

Components of the FRAME-IS

Based on stakeholder feedback, the FRAME-IS is modular and includes both core (i.e., required) and optional modules to maximize its practicality across implementation projects with a variety of goals, priorities, and available resources. Core modules can be found in Fig. 1, and

optional modules can be found in Fig. 2. The decision regarding which modules to designate as core versus optional was made by the authors based on consensus discussions, incorporating stakeholder feedback. Additional descriptive text can be found in the supplement. Completing core modules requires specifying: a brief description of the EBP, implementation strategy, and modifications (Module 1); what is modified (Module 2); the nature of the modification (content, evaluation, or training modifications only; Module 3); and the rationale for the modification (Module 4). Optional modules, which can be completed at the discretion of the study investigators or project team, involve specifying when the modification occurred, and whether it was planned (Module 5); who participated in the decision to modify (Module 6); and how widespread the modification is (Module 7). Module 3, while itself considered a core module, includes the option of documenting the extent to which the modification was considered fidelity-consistent with the original implementation strategy.

Module 1: Brief description of the EBP, implementation strategy, and modification(s)

To facilitate tracking modifications and to complete the remainder of the FRAME-IS, we recommend briefly describing the EBP in question, and the initially defined implementation strategy. The Expert Recommendations for Implementing Change (ERIC) compilation [11] may be useful in describing the

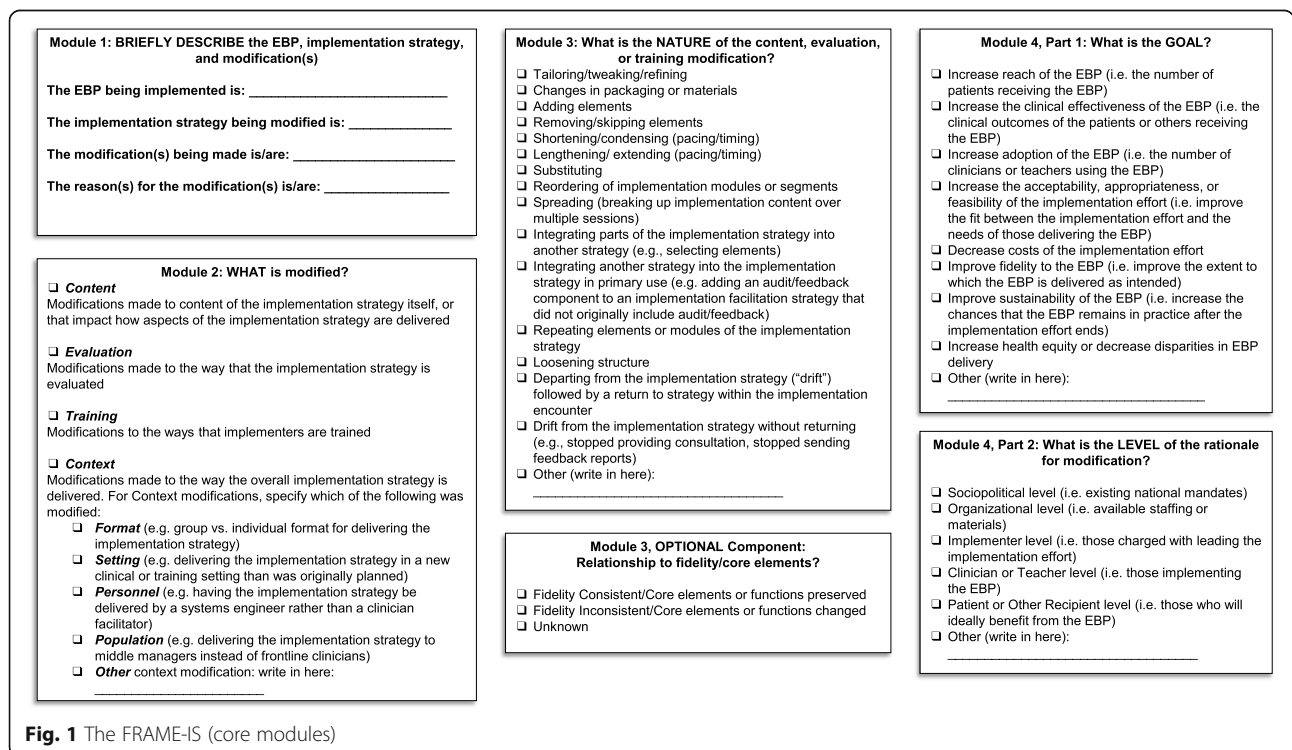


Fig. 1 The FRAME-IS (core modules)

<p>Module 5, Part 1: WHEN is the modification initiated?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pre-implementation/planning/pilot phase <input type="checkbox"/> Implementation phase <input type="checkbox"/> Scale up (i.e. when the EBP is being spread to additional clinics/settings within your system) <input type="checkbox"/> Maintenance/Sustainment <input type="checkbox"/> Other (write in here): _____ 	<p>Module 6: WHO participates in the decision to modify?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Political leader(s) <input type="checkbox"/> Program Leader, Manager, or Administrator <input type="checkbox"/> Funder <input type="checkbox"/> Implementer or implementation strategy expert <input type="checkbox"/> Researcher <input type="checkbox"/> Clinician(s) or teacher(s) who are being asked to use the EBP being implemented <input type="checkbox"/> Community members <input type="checkbox"/> Patients or other recipients who will be the ultimate target of the EBP being implemented <input type="checkbox"/> Other: write in here: _____ <p>Optional: Indicate who makes the ultimate decision: _____</p>	<p>Module 7: How WIDESPREAD is the modification? (i.e. for whom/what is the modification made?)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Individual patient or other recipient for whom the EBP is being implemented <input type="checkbox"/> Group of patients or other recipients for whom the EBP is being implemented <input type="checkbox"/> Patients or other recipients that share a particular characteristic (e.g. all patients from a specific language background) <input type="checkbox"/> Individual clinician or teacher charged with implementing the EBP <input type="checkbox"/> Clinic/unit <input type="checkbox"/> Organization <input type="checkbox"/> Network system/community <input type="checkbox"/> Specific implementer/facilitator <input type="checkbox"/> Implementation/facilitation team
<p>Module 5, Part 2: Is modification PLANNED?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Planned/Proactive (proactive adaptation) <input type="checkbox"/> Planned/Reactive (reactive adaptation) <input type="checkbox"/> Unplanned/Reactive (modification) <input type="checkbox"/> Other (write in here): _____ 		

Fig. 2 The FRAME-IS (optional modules)

implementation strategy. If it is feasible, more comprehensive guidance [16] may be used to describe the implementation strategy in more detail to delineate the core elements, processes, or functions of the strategy. We also suggest identifying potential initial modifications to the strategy. We note that many modifications may be “bundled”—i.e., may involve changes to multiple aspects of the implementation strategy. For example, the content and the length of a provider training may be modified simultaneously. In those cases, the research or implementation team can determine whether to complete the FRAME-IS separately for each modification or to document all of the separate modifications at once. Completing it separately for each individual modification may allow for finer-grained analysis of what was most helpful—but may also represent an undue documentation burden in cases where separate components of a modification cannot be disentangled. Similarly, depending on the goal of the project, users should determine whether it is best to use the FRAME-IS separately for each component of a multifaceted implementation strategy or to define the entire strategy and modification in Module 1. For example, Leadership and Organizational Change for Implementation (LOCI [36]) is a multi-component implementation strategy that includes coaching calls. If the modification in question involved changing the frequency of LOCI coaching calls, the research team would need to decide whether the change in coaching call frequency should be

documented alongside modifications that may be made simultaneously to other LOCI components.

Module 2: What is modified?

The FRAME-IS includes four broad categories of modifications to implementation strategies: Content, Context, Evaluation, and Training. These four categories mirror those included in the FRAME, but with some key distinctions. A Context modification refers to changes to the setting or the way the implementation strategy is delivered. For example, if the implementation strategy being modified was implementation facilitation, the context could change if facilitation was provided virtually as opposed to in person. We note that there are some distinctions in Content and Training modifications to implementation strategies. For example, if the implementation strategy in question is a *clinician* training workshop, then modifications to the content of the workshop itself would qualify as a Content modification (because it is part of the package of implementation strategies). In contrast, changes to how *implementers* are trained—e.g., by modifying the ways that external facilitators are trained in the context of implementation facilitation—would qualify as a Training modification. Modifications to evaluation refer to changes in the way that an implementation strategy is evaluated. For example, recent work has aimed to uncover the “core activities” of implementation facilitation [37]; ongoing studies are incorporating assessments of these core

activities into their implementation evaluation plans (e.g., [38]).

Module 3: What is the nature of the content, evaluation, or training modification?

For Content, Evaluation, and Training modifications, it is important to track the nature of the modification itself. These modifications can range from relatively small tweaks or more sweeping changes to the implementation strategy—or even abandonment of an implementation strategy or component altogether. The elements of the FRAME-IS in this domain closely mirror those of the FRAME, but with language specifying modifications made to an implementation strategy rather than an EBP. Adding or removing/skipping elements refer to specific aspects of a discrete implementation strategy (e.g., removing role plays from a training workshop) or package of strategies (e.g., removing feedback, adding incentives in a leadership program). Pacing may refer to pacing of training or frequency of feedback. Integration refers to incorporation of other implementation strategies or approaches (e.g., adding feedback or incentives to training and supervision when the first round of implementation suggests that results are not as robust as desired). Loosening structure might include coaching “on the fly” or immediately after a clinical interaction rather than at scheduled times. Substituting may include adaptations such as changing fidelity assessment from observer-rated to self-report.

As an optional portion of this module, practitioners or researchers may also be interested in documenting the extent to which the modification was conducted with fidelity [39]. In this context, fidelity may be defined as “the adherence to the intervention components, competence with which the intervention is delivered, and differentiation from other treatments” [1]. Fidelity-consistent modifications may be expected to have better outcomes than fidelity-inconsistent ones, which may represent “drift” as they remove core elements of the strategy. Core elements or functions, in this context, refer to components or topics considered essential to that implementation strategy [39]. For example, removing the feedback component from an audit and feedback implementation strategy would likely be fidelity-inconsistent. We acknowledge, though, that the relationships among fidelity, adaptation, and outcomes are complex and not fully understood [40]. Fundamental questions regarding balancing adaptation and fidelity have yet to be answered—especially for the substantial proportion of implementation strategies that are meant to be inherently adaptable, flexible, or modular (e.g., [13]). Thus, completion of this portion of the module may not be warranted in all cases.

Module 4: What is the rationale for the modification?

The goal of this module is to document why a given modification was made to a given implementation strategy. This may allow interested parties to determine what rationales are associated with more or less successful modifications. We break the rationale into two components. First, regarding the goal of the modification, we have derived answer options in part from the Reach – Effectiveness – Adoption – Implementation – Maintenance ((RE-AIM) Framework [35] and Proctor’s implementation outcomes [15], plus one option related to health equity. We note that some goals may be related to the implementation effort itself, while others may be more directly related to the EBP being implemented. We also note that many modifications may aim to achieve multiple goals. For example, shortening an EBP training may simultaneously reduce costs, increase adoption, and increase reach. In completing this Module, we recommend selecting the box corresponding to the primary goal of the modification or selecting multiple boxes in the context of several co-equal goals.

Second, we recommend documenting the level of the organization that most directly informed the modification. For example, modifications made to accommodate available staffing at a clinic would qualify as the organizational level, while modifications made to fit with the professional or cultural values of frontline staff delivering the EBP would qualify as the practitioner level.

Module 5: When the modification is initiated, and whether it is planned

The timing of modifications is crucial in implementation science, with the pre-implementation, implementation, and sustainment phases featuring distinct pressures, challenges, and goals [37, 41, 42]. Modifications made early in the implementation process may leave more time for implementers and practitioners to adjust to the change. Modifications made later (during the implementation or sustainment phases) may nonetheless be required to accommodate shifting priorities or resources (e.g., shifting initial training to a web-based format based on travel restrictions). Documenting the timing of modifications to implementation strategies will allow the field to develop a better understanding of how such timing affects implementation processes and outcomes.

Note that for our purposes here the primary goal is to document when a modification is *initiated*, rather than when it *occurs*, as many modifications to implementation strategies may happen over large portions of the implementation period. For example, consider an implementation strategy of provider training to increase uptake of an evidence-based psychotherapy. If the timing of those trainings is modified, the important question for this section is *when the decision was made to change the*

timing rather than when the (modified) trainings were offered. Documenting when decisions regarding modifications are made may ultimately help shed light on whether modifications made early versus late in the implementation period are differentially successful.

Regardless of the phase in which modifications to implementation strategies are made, there is a conceptual distinction between those that are made in a planful versus reactive manner [43, 44]. For example, consider a hypothetical implementation project featuring a learning collaborative that was originally designed to meet face-to-face four times during the implementation year. Let us further imagine that, due to budget constraints, only two learning collaborative meetings could be funded. If the budget constraints were known early in the implementation year, then the implementer and/or content experts would likely be able to modify the curriculum or format to ensure that all core content of the learning collaborative is covered (i.e., an adaptation or planned modification). Such proactive changes could include, for example, establishing or expanding a virtual component for the learning collaborative, or lengthening the two face-to-face sessions that could be funded. In contrast, having two face-to-face learning collaborative meetings abruptly canceled *midway through* the implementation year (i.e., a reactive modification) might necessitate more substantial changes to the curriculum that leaves some core content unaddressed. Differentiating unplanned, reactive modifications from proactive and planful adaptations will allow implementation scientists to better understand the circumstances under which impromptu modifications to implementation strategies may be more or less helpful.

Module 6: Who participates in the decision to modify?

In some cases, modifications to implementation strategies may be made in a collaborative manner, with multiple stakeholders or “actors” (e.g., administrators, frontline clinicians, implementation specialists) agreeing that a given modification is needed in a given setting [16]. In other cases, the decision to modify an implementation strategy may be unilateral (as when a health system leader requires that a given implementation strategy be scaled back based on personnel changes or competing priorities). Documenting this distinction can inform future decisions regarding when broader consensus on certain types of modifications to implementation strategies is required for implementation success, consistent with the principles of stakeholder engagement [45]. As researchers start to grapple with the intersection of implementation science and health equity [46], carefully identifying who is suggesting the modifications may be an important aspect of tracking the co-creation of implementation strategies [21–24]. Identifying sources of

power in the implementation process [47], and incorporating the voices of those in the community, will be important for the field as we move toward equitable practice in our science.

Module 7: How widespread is the modification?

For modifications documented in Module 2 as Content, Training, and Evaluation modifications, it may be important to document the breadth or scope of the modification to the implementation strategy. This can range from relatively narrow modifications (e.g., in the context of an individual consultation call for a clinician who missed a day of group consultation) to broad-based ones (e.g., modifications made by an entire health system that is using an implementation strategy to roll out an EBP).

Note that some of the answer options refer to the individuals receiving the EBP, while others refer to the practitioners delivering the EBP, and yet others refer to those tasked with supporting the use of the EBP. It is possible that boxes within all three of these categories could be checked. If a single implementation facilitator adds an audit and feedback component to an implementation facilitation strategy within one clinic (and no other facilitators are using the unmodified strategy within the clinics they oversee), then that would qualify as a modification at one clinic/unit and one specific implementer/facilitator.

Case example: Application of FRAME-IS in a recent implementation trial

Here, and in Table 2, we illustrate application of the FRAME-IS in an ongoing trial that seeks to train lay health workers to task-share with mental health professionals to improve engagement for Spanish-speaking Latinx families receiving Parent-Child Interaction Therapy (PCIT [48]); PCIT is an evidence-based parenting program for young children with disruptive behavior disorders [49]. In this task-sharing model, professional clinicians provide PCIT and lay health workers conduct outreach and promote treatment adherence to improve access, adherence, and skill acquisition for families [31]. Lay health workers have been identified as an important workforce to decrease disparities in access to care for marginalized communities [50]. However, limited research has identified what implementation supports lay health workers need to successfully engage in EBPs.

Module 1: Description of the implementation strategy

In this case example, we will apply the FRAME-IS to the training model for lay health workers that was developed to support parental engagement in PCIT within a university-based clinic in Miami, Florida. Initial training aimed to prepare lay health workers to identify and refer appropriate cases to PCIT, teach them the parenting

Table 2 Example completion of the FRAME-IS

FRAME-IS module or sub-component	Example completion
Module 1	
The EBP being implemented is:	Parent-Child Interaction Therapy (PCIT)
The implementation strategy being modified is:	Training program for lay health workers to enhance parent engagement in PCIT
The modification(s) being made is/are:	- Tailoring of training content (e.g., language) to local context to fit population differences - Removal of the behavioral coding component of the training
The reason(s) for the modification(s) is/are:	- Improve appropriateness/feasibility
Module 2	
What is modified?	- Content (details provided in Module 3) - Context (setting, based on transition from Miami to California)
Module 3	
What is the nature of the content, evaluation, or training modification?	- Tailoring (modifying language) - Removing/skipping elements (specifically, removal of behavioral coding training component)
OPTIONAL: what is the relationship to core elements?	- Unknown
Module 4	
What is the goal?	- Increase the acceptability, appropriateness, and feasibility of the implementation effort
What is the level of the rationale for the modification?	- Practitioner and Patient level (address cultural and linguistic differences for a population of predominantly Mexican descent)
Module 5	
When is the modification initiated?	- Pre-implementation/planning/pilot phase
Is the modification planned?	- Planned/proactive
Module 6	
Who participates in the decision to modify?	- Researcher, program leader, and clinicians (lay health workers)
OPTIONAL: Who makes the ultimate decision?	- Researchers
Module 7	
How widespread is the modification?	- Network system/community (listed modifications were applied for entire California rollout)

skills targeted in the program (e.g., giving specific praises of positive behaviors), and prepare them to promote adherence to home practice of these skills. Lay health workers were taught how to use a behavioral coding system in PCIT; they were also taught to provide feedback on how to improve weaker skills and reinforce skills that parents were using well. Each lay health worker was provided with an e-book with videos and scripts to help them describe PCIT and the parenting skills to caregivers. Lay health workers in the initial training demonstrated improved knowledge of PCIT over the course of training. They also increased their ability to model the parenting skills taught in PCIT, in order to help parents use them in the home. However, it was challenging for lay health workers to conduct behavioral observations of parent's skill use and provide accurate feedback on which skills to improve [48].

Module 2: What was modified?

The original training model was adapted for community-based mental health settings within California (context), with changes to the training

program content to meet this context and address challenges identified in the initial training program evaluation.

Module 3: The nature of the content modification

The majority of modifications involved *tailoring* (i.e., making minor changes to) the training materials to fit with the local context. Furthermore, the focus on training the lay health workers to conduct behavioral coding was *removed* from the training, as this was not considered a feasible or necessary skill. Instead, lay health workers were taught how to provide general feedback regarding parenting skills.

Module 4: The rationale for the modification

The goal of the adaptations made was to increase the acceptability, appropriateness, and feasibility of the training to fit with cultural differences for providers and clients across the two contexts. Trainings in Miami and California were conducted in Spanish; however, regional language differences needed to be addressed. The Latinx population served in Miami was predominantly from the

Caribbean (e.g., Cuba), South America (e.g., Colombia), and Central America (e.g., Honduras), whereas the population served in California was predominantly from Mexico. Therefore, certain vocabulary and idioms were tailored in training materials. New videos were created for the e-book, featuring children and parents of Mexican descent, to increase cultural and linguistic similarities with the families being served. Behavioral coding was removed from the training to increase the feasibility of training and to ensure adequate fidelity (skill at providing accurate feedback to the parents).

Module 5: When the modification was initiated and planned

Modifications of the training protocol occurred during the pre-implementation/planning phase of the current trial and were planned as part of a research-community partnership (i.e., were proactively made prior to beginning training).

Module 6: Who participated in decisions to modify?

Researchers, who developed and evaluated the initial training in Miami, led decisions surrounding the modifications to the training program based on data from the Miami project. They incorporated feedback from local program leaders and lay health workers, who participated in qualitative interviews and a community-advisory board. Ultimately, this feedback led to modifications that the research team finalized.

Module 7: How widespread is the modification?

Modifications were made for the entire network system/community, specifically for lay health workers living in California and working within community-mental health settings.

Discussion

Recent implementation science work has emphasized the importance of documenting modifications to EBPs [8, 10]. Implementation strategies are used to support the implementation of EBPs, and scholars have recommended specifying components of implementation strategies [16] to support their reproducibility and further elucidate mechanisms of change. As implementation strategies are deployed, however, they can be modified. Comprehensively documenting modifications to implementation strategies will allow the field to study the relationship between those modifications and implementation outcomes across settings. While previous frameworks (e.g., [10]) are meant to track modifications to EBPs, the FRAME-IS is to our knowledge the first tracking tool developed specifically for modifications to implementation strategies, incorporating modular coding and a novel focus on those implementing the

EBP in question (see [Supplemental File](#)). Systematic application of the FRAME-IS to implementation projects—alongside careful assessment of implementation outcomes using RE-AIM [35] or similar evaluation-oriented implementation frameworks—will ideally help to answer fundamental questions about whether, when, how, and why an implementation strategy has been effective in a given setting. This will allow for a co-creation of collaborative knowledge between implementation researchers and stakeholders [21–24], as the FRAME-IS may guide systematic adaptations to implementation strategies when planning a project, and a way to track ad hoc modifications made throughout the project. The FRAME-IS may also be useful to test hypotheses related to core components or functions of implementation strategies: if a component of an implementation strategy is modified in some way, and that modified implementation strategy's effectiveness rivals or surpasses that of its unmodified version, then it raises the possibility that the modified component (in its original form) was not in fact central to the implementation strategy's success and that there are alternative, adaptive forms of the component that can be deployed successfully.

The FRAME-IS is not without limitations, of course. First, completing the FRAME-IS may be difficult in the context of subtle modifications that emerge longitudinally as implementation progresses (e.g., ongoing tailoring of written training materials), depending on who completes the reporting and how frequently it occurs. It may also be difficult to apply the FRAME-IS to multi-component implementation strategies (e.g., implementation facilitation [13]) that are inherently adaptable or intended to be tailored without guidance from the developers of the implementation strategy. In these circumstances, it may still represent a useful tool for tracking the specific ways that the implementation strategy was applied—albeit one that may require time-intensive multi-method assessment to achieve acceptable validity. It is also unclear whether local implementers are able to accurately report on modifications to implementation strategies as they occur in real time, or whether supplemental personnel are required. Local implementer reports may be necessary when expert observation is not feasible or scalable; in those situations, adequate training in the use of the FRAME-IS will be pivotal. One thing that remains to be determined is how frequently reporting should occur to capture the full extent of modifications. We also note that the FRAME-IS is meant to capture modifications to one *a priori* identified implementation strategy. Clear operationalization of what the original strategy entails is essential to accurately track adaptations. For projects featuring multiple implementation strategies rolled out over time (e.g., [51]), additional tracking (e.g., informed by the ERIC compilation [11])

and with well-specified descriptions of the strategies as originally designed) may also be required to ensure a robust understanding not just of the modification process, but of how implementation proceeded more broadly.

Conclusions

Implementation strategies often undergo modification to improve their fit with the EBPs, target populations, and clinical contexts in which they are applied. Without systematically tracking such modifications, it will be difficult for the implementation science field to determine how best to maximize their effectiveness or fully address health disparities [52]. To meet this need, the FRAME-IS is meant to be a first step toward better assessing the ways that implementation strategies may be modified as EBPs are put into practice. Fundamental questions, such as what role the FRAME-IS could play in designing, analyzing, and publishing implementation trials, will need to be explored in future work. Currently, the FRAME-IS is being piloted in a multinational ten-site implementation study; this and other applications of the FRAME-IS may help answer such questions regarding best practices for formatting, administering, and tracking its completion. It is our hope that application of the FRAME-IS more broadly may shed light on the processes and mechanisms by which implementation strategies exert their effects, ultimately improving the uptake of EBPs across settings.

Abbreviations

EBP: Evidence-Based Practice; FRAME: Framework for Reporting Adaptations and Modifications – Expanded; FRAME-IS: Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies; IRG: Implementation Research Group; PCIT: Parent-Child Interaction Therapy; RE-AIM: Reach – Effectiveness – Adoption – Implementation – Maintenance; WUNDIR: Washington University Network for Dissemination and Implementation Researchers

Supplementary Information

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Additional file 1. This .ppt file contains supplemental descriptive text on the core and optional modules of the FRAME-IS.

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Authors' contributions

CJM developed the initial version of the FRAME-IS, and wrote the initial version of the manuscript. MLB applied the FRAME-IS to the example project included in the text. All authors (CJM, MLB, AAB, CAG, and SWS) contributed in the following ways: (a) provided substantive refinement of the FRAME-IS, (b) got feedback on initial versions of the FRAME-IS from other stakeholders, and (c) read, edited, and approved the final manuscript.

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Author details

¹VA Boston Healthcare System, Center for Healthcare Organization and Implementation Research (CHOIR), Boston, MA, USA. ²Department of Psychiatry, Harvard Medical School, Boston, MA, USA. ³Department of Counseling, Clinical, & School Psychology, University of California, Santa Barbara, Santa Barbara, CA, USA. ⁴Washington University at St. Louis, St. Louis, MO, USA. ⁵ViV Healthcare, Innovation & Implementation Science, Research Triangle, NC, USA. ⁶Department of Psychiatry, Boston University School of Medicine, Boston, MA, USA. ⁷National Center for PTSD Dissemination and Training Division, Palo Alto, CA, USA. ⁸Department of Psychiatry and Behavioral Sciences, Stanford University, Stanford, CA, USA.

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Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Contents and Roadmap

Background: The FRAME-IS is intended to help implementation scientists and practitioners track modifications to implementation strategies. It is modular, and includes the following options, described in more detail on the following slides. Completing the FRAME-IS assumes that you already have an evidence-based practice (EBP) that is being implemented, and a specific implementation strategy that is being modified. To complete the FRAME-IS, you will need to have a reasonable knowledge of what that implementation strategy looks like in the “base case” (i.e. you will need to be able to describe the unmodified implementation strategy in enough detail to document modifications).

As indicated by the asterisks below, streamlined completion of the FRAME-IS would at a minimum include completion of Modules 1, 2, and 4 along with Module 3 for Content modifications. To capture additional detail on modifications, consider completing the other Modules as well.

MODULES (* Asterisks indicate Core Modules we highly recommend *)

- Module 1: Brief description of the EBP, implementation strategy, and modification(s) *
- Module 2: WHAT is modified? *
- Module 3: What is the NATURE of the content modification? (* for content modifications only)
 - Includes optional module: Does modification retain FIDELITY to core elements/functions?
- Module 4: What is the RATIONALE for the modification? *
- Module 5: WHEN is the modification initiated, and is it PLANNED?
- Module 6: WHO participates in the decision to modify?
- Module 7: How WIDESPREAD is the modification?

Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Module 1: Brief description of the EBP, implementation strategy, and modification(s)

Background: to make it easier to track modifications and to complete the remainder of the FRAME-IS, we recommend briefly describing the EBP in question, the initially defined implementation strategy being modified, and the modification(s) themselves.

We note that the ERIC compilation (Powell et al., 2015, Imp. Sci. vol. 10 p. 21) may be useful for describing the implementation strategy being used. We also note that many modifications may actually be “bundled” – i.e. may involve changes to multiple aspects of the implementation strategy. For example, the content and the length of a provider training may be modified simultaneously. In those cases, it is up to you whether you want to complete the FRAME-IS separately for each modification, or to complete it once (documenting all of the separate modifications at once).

Example:

The EBP being implemented is:

- *Blood serum monitoring for patients being prescribed lithium*

The implementation strategy being modified is:

- *Audit and feedback*

The modification(s) being made is/are:

- *Feedback to providers on their adherence to lithium serum monitoring is being provided less frequently than originally planned*

The reason(s) for the modification(s) is/are:

- *Clinicians reported feeling overwhelmed by original timing of feedback*

BRIEFLY DESCRIBE the EBP, implementation strategy, and modification(s)

The EBP being implemented is:

The implementation strategy being modified is:

The modification(s) being made is/are:

The reason(s) for the modification(s) is/are:

Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Module 2: WHAT is modified?

Background: We note four types of modifications to implementation strategies: Content, Evaluation, Training, and Context.

We note that the distinction between Content and Training may be particularly difficult to disentangle for modifications to implementation strategies. For example, if the implementation strategy in question is a clinician training workshop, then modifications to the content of the workshop itself would qualify as a **Content** modification. In contrast, changes to how *implementers* are trained—e.g. by modifying the ways that external facilitators are trained in the context of implementation facilitation—would qualify as a **Training** modification.

Also note that completing this Core Module presents our first decision point:

- If modifications are made to **Content, Evaluation, or Training**, then proceed to Module 3.
- If modifications are made to **Context**, then complete the sub-checkboxes and skip to Module 4.

WHAT is modified?

Content

Modifications made to content of the implementation strategy itself, or that impact how aspects of the implementation strategy are delivered

Evaluation

Modifications made to the way that the implementation strategy is evaluated

Training

Modifications to the ways that implementers are trained

Context

Modifications made to the way the overall implementation strategy is delivered. For Context modifications, specify which of the following was modified:

- Format** (e.g. group vs. individual format for delivering the implementation strategy)
- Setting** (e.g. delivering the implementation strategy in a new clinical or training setting than was originally planned)
- Personnel** (e.g. having the implementation strategy be delivered by a systems engineer rather than a clinician facilitator)
- Population** (e.g. delivering the implementation strategy to middle managers instead of frontline clinicians)
- Other** context modification: write in here: _____

Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Module 3: What is the NATURE of the content, evaluation, or training modification?

Background: For **Content, Evaluation, and Training** modifications, it is important to track the nature of the modification itself. These modifications can range from relatively small tweaks or more sweeping changes to the implementation strategy.

OPTIONAL: Does modification retain FIDELITY to core elements/functions?

As an optional module, practitioners or implementation scientists may also be interested in documenting the extent to which the modification is consistent with the core elements or functions of the implementation strategy. Fidelity-consistent modifications may be expected to have better outcomes than fidelity-inconsistent ones.

Core elements or functions, in this context, refer to components or topics considered essential to that implementation strategy. For example, removing the feedback component from an audit and feedback implementation strategy would likely represent a fidelity-inconsistent modification. We acknowledge, though, that core elements or functions of many implementation strategies may be poorly understood, and so completion of this module may not be straightforward in all cases. If theory suggests it is essential to producing change, an element or function would be considered to be core or essential to fidelity.

What is the NATURE of the content, evaluation, or training modification?

- Tailoring/tweaking/refining
- Changes in packaging or materials
- Adding elements
- Removing/skipping elements
- Shortening/condensing (pacing/timing)
- Lengthening/ extending (pacing/timing)
- Substituting
- Reordering of implementation modules or segments
- Spreading (breaking up implementation content over multiple sessions)
- Integrating parts of the implementation strategy into another strategy (e.g., selecting elements)
- Integrating another strategy into the implementation strategy in primary use (e.g. adding an audit/feedback component to an implementation facilitation strategy that did not originally include audit/feedback)
- Repeating elements or modules of the implementation strategy
- Loosening structure
- Departing from the implementation strategy (“drift”) followed by a return to strategy within the implementation encounter
- Drift from the implementation strategy without returning (e.g., stopped providing consultation, stopped sending feedback reports)
- Other (write in here): _____

OPTIONAL: Relationship to fidelity/core elements?

- Fidelity Consistent/Core elements or functions preserved
- Fidelity Inconsistent/Core elements or functions changed
- Unknown

Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)

Module 4: What is the RATIONALE for the modification?

Background: In some situations it may be useful to know WHY a given modification was made to a given implementation strategy. This may allow interested parties to determine what rationales are associated with more or less successful modifications.

We break the rationale into two components. First, what is the **GOAL** of the modification? We have derived these in part from the RE-AIM Framework (Glasgow et al., 1999, AJPB vol. 89 pages 1322-1327) and Proctor's implementation outcomes (Proctor et al., 2011, APMH vol. 38 pages 65-76). We note that some goals may be related to the implementation effort itself, while others may be more directly related to the EBP being implemented. We also note that many modifications may aim to achieve multiple goals. For example, shortening an EBP training may simultaneously reduce costs, increase adoption, and increase reach. In completing this Module, however, we recommend selecting the box corresponding to the *primary* goal of the modification.

Second, from what **LEVEL** of the organization does the rationale stem? For example, modifications made to accommodate available staffing at a clinic would qualify as the *Organizational* level, while modifications made to fit with the professional or cultural values of frontline staff delivering the EBP would qualify as the *Practitioner* level.

What is the GOAL?

- Increase reach of the EBP (i.e. the number of patients receiving the EBP)
- Increase the clinical effectiveness of the EBP (i.e. the clinical outcomes of the patients or others receiving the EBP)
- Increase adoption of the EBP (i.e. the number of clinicians or teachers using the EBP)
- Increase the acceptability, appropriateness, or feasibility of the implementation effort (i.e. improve the fit between the implementation effort and the needs of those delivering the EBP)
- Decrease costs of the implementation effort
- Improve fidelity to the EBP (i.e. improve the extent to which the EBP is delivered as intended)
- Improve sustainability of the EBP (i.e. increase the chances that the EBP remains in practice after the implementation effort ends)
- Increase health equity or decrease disparities in EBP delivery
- Other (write in here): _____

What is the LEVEL of the rationale for modification?

- Sociopolitical level (i.e. existing national mandates)
- Organizational level (i.e. available staffing or materials)
- Implementer level (i.e. those charged with leading the implementation effort)
- Practitioner level (i.e. those implementing the EBP)
- Patient or Other Recipient level (i.e. those who will ideally benefit from the EBP)
- Other (write in here): _____

Module 5: WHEN is the modification initiated, and is it PLANNED?

Background: It is likely that the timing of a modification may affect its ultimate success. Modifications made early in the implementation process, for example, may leave more time for implementers and clinicians to adjust to the change. Thus, we recommend documenting WHEN the modification occurred, if known.

Similarly, it is likely that modifications made in a planful manner (i.e. adaptations) may be more successful in some circumstances than those made “on the fly” (i.e. unplanned modifications).

Note that the “WHEN” box is referring to when a modification is *initiated*, rather than when it *occurs*. For example, consider an implementation strategy of provider training to increase uptake of an evidence-based psychotherapy. If the timing of those trainings is modified, the important question for this section is *when the decision was made to change the timing* rather than when the (modified) trainings were offered.

WHEN is the modification initiated?

- Pre-implementation/planning/pilot phase
- Implementation phase
- Scale up (i.e. when the EBP is being spread to additional clinics/settings within your system)
- Maintenance/Sustainment
- Other (write in here): _____

Is modification PLANNED?

- Planned/Proactive (proactive adaptation)
- Planned/Reactive (reactive adaptation)
- Unplanned/Reactive (modification)
- Other (write in here): _____

Module 6: WHO participates in the decision to modify?

Background: Modifications that are made with broad stakeholder input and buy-in may be more successful than those that are made unilaterally by just one or two stakeholders. We therefore recommend documenting who participated in the decision to modify a given implementation strategy, along with documenting the decision-maker who had the “final say” if one can be identified.

We emphasize here that it is important to delineate the “recipients” of an EBP for the FRAME-IS (who may also participate in the decision to modify the implementation strategy). Specifically, *implementers* here refers to staff tasked with getting an EBP implemented (e.g. internal or external facilitators, program managers, EBP champions, and the like). *Practitioners* (e.g. clinicians, teachers) may be asked to use the EBP in the course of their teaching or clinical work, and are typically provided with instruction, guidance, or feedback from implementers.

Having said that, there may be overlap between these two categories, as when an EBP Champion is also a frontline clinician using that EBP. If such a person participated in the decision to modify the implementation strategy, we recommend checking both applicable boxes in the FRAME-IS. Other changes to implementation strategies may be made to accommodate the needs of the *patient or other recipient* population ultimately hoping to benefit from the EBP being implemented. For example, direct-to-consumer outreach may be used as an implementation strategy to increase adherence to an effective medication. In that context, soliciting patient feedback to modify the direct-to-consumer outreach would qualify as patients participating in the decision to modify the implementation strategy.

WHO participates in the decision to modify?

- Political leader(s)
- Program Leader, Manager, or Administrator
- Funder
- Implementer or implementation strategy expert
- Researcher
- Practitioners (e.g. clinicians, teachers) who are being asked to use the EBP being implemented
- Community members
- Patients or other recipients who will be the ultimate target of the EBP being implemented
- Other: write in here:

Optional: Indicate who makes the ultimate decision:

Module 7: How WIDESPREAD is the modification?

Background: For **Content, Training, and Evaluation** modifications, it may be important to document the breadth or scope of the modification to the implementation strategy. Specifically, we conceptualize this as how *widespread* the modification is, ranging from relatively narrow modifications (e.g. in the context of an individual consultation call for a clinician who missed a day of group consultation) to broad-based ones (e.g. modifications made by an entire health system that is using an implementation strategy to roll out an EBP).

Note that some of the answer options refer to the patients or others receiving the EBP; while others refer to the clinicians, clinics, or teachers using the EBP; and yet others refer to the implementers tasked with implementing the EBP. It is possible that boxes within all three of these categories could be checked. For example, if a single implementation facilitator adds an audit and feedback component to an implementation facilitation strategy within one clinic (and no other facilitators are using the unadapted strategy within the clinics **they oversee**), then that would qualify as a modification occurring for both of the following:

- Clinic/unit
- Specific implementer/facilitator

If they added the component to all 6 clinics they oversaw, and no other facilitators did, it would qualify for “facilitator” but not “clinic/unit” modification, because the facilitator is the common element across the different clinics. Finally, if all of the clinics that the facilitator oversaw were within a single network, and no other clinics within the network were overseen by a different facilitator who did not add the component, it would qualify as a “facilitator” and “network” modification.

How WIDESPREAD is the modification? (i.e. for whom/what is the modification made?)

- Individual patient or other recipient for whom the EBP is being implemented
- Group of patients or other recipients for whom the EBP is being implemented
- Patients or other recipients that share a particular characteristic (e.g. all patients from a specific language background)
- Individual practitioner (e.g. clinician or teacher) charged with implementing the EBP
- Clinic/unit
- Organization
- Network system/community
- Specific implementer/facilitator
- Implementation/facilitation team