Integrating Implementation Outcomes into Effectiveness Studies

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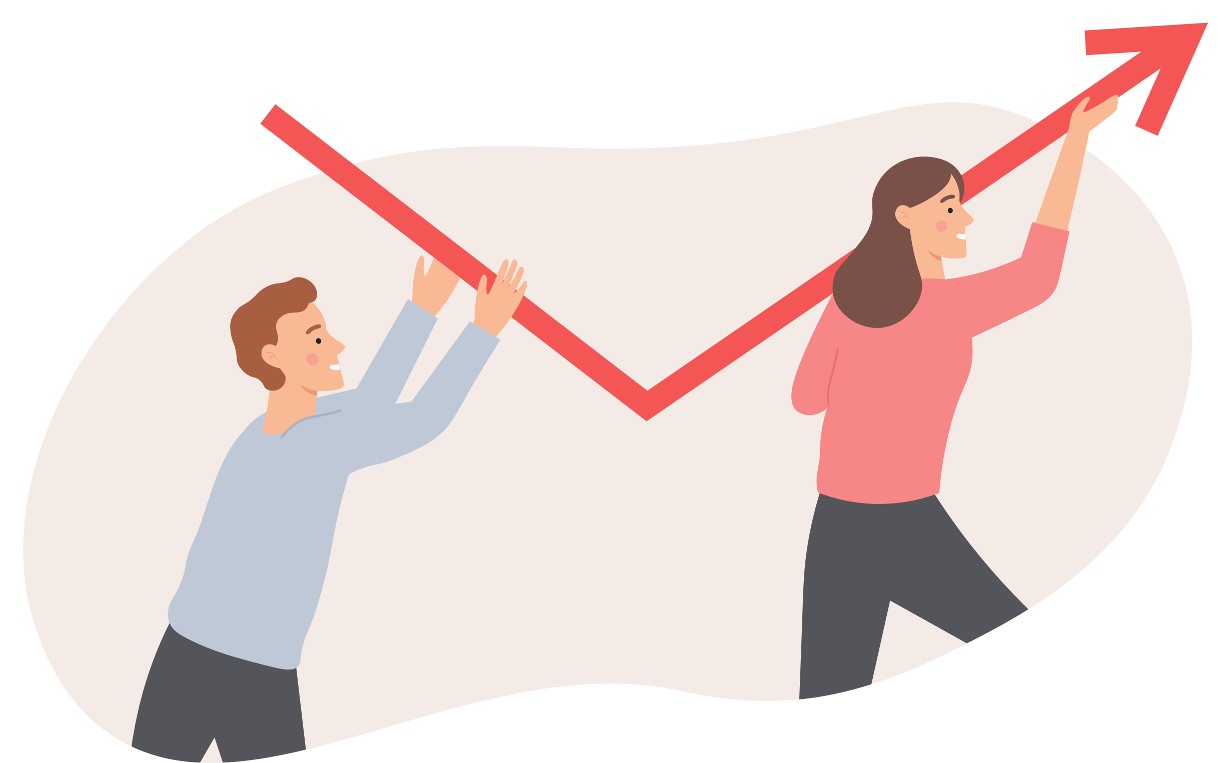
INTRODUCTION

This guide helps users select implementation outcomes for intervention effectiveness studies and understand who the measure can be collected from (leaders, providers, patients), when to field it (baseline, follow-up), and how to measure and interpret results. The guide also includes sample measures and case studies showing how implementation outcome measures have been used in published effectiveness studies.



TERMS

Intervention

The treatment, program, or policy designed to improve the outcome of interest; the "thing" being tested for effectiveness in an effectiveness study.

Implementation Strategies

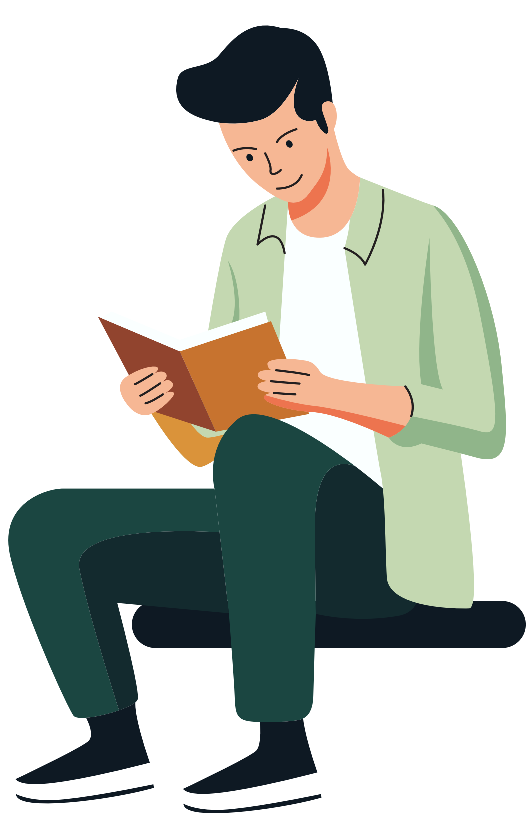
The specific methods or techniques used to get the intervention implemented. Even in effectiveness studies where the study team delivers the intervention, implementation strategies are common. Staff training or performance feedback to study staff delivering the intervention are examples.

Intervention Outcome(s)

Indicator(s) of how well the intervention worked to improve participant outcomes. For example, if the goal of the intervention is to reduce drug overdose, drug overdose is the intervention outcome.

Implementation Outcome

Indicators of how much and how well the intervention was delivered. For example, fidelity—whether the person(s) delivering the intervention did so as intended—is an implementation outcome.



WHO SHOULD USE THIS GUIDE?

This user guide is designed for researchers conducting effectiveness studies, where the primary goal is to test the effectiveness of an intervention. This includes any kind of effectiveness study, including “hybrid type I” effectiveness-implementation studies, which are primarily focused on testing intervention effectiveness while examining secondary implementation outcomes.(1)

Implementation outcomes are often used as primary outcomes in implementation studies focusing on the adoption and utilization of interventions. There are unique considerations for embedding implementation outcomes within effectiveness studies where they are not the primary outcome. This user guide advises whether, when, and how to incorporate implementation outcomes in effectiveness studies.

This guide, produced through the National Institute on Drug Abuse (NIDA)-funded Center for Dissemination and Implementation at Stanford (C-DIAS) and HEAL Data2Action Program‘s Research Adoption Support Center, uses examples related to interventions to treat addiction and pain and prevent drug overdose. Still, the principles can be applied to any intervention.

WHAT ARE IMPLEMENTATION OUTCOMES?

Implementation outcomes measure how much and how well an intervention was implemented. In this guide, we use a standard set of outcomes described by Proctor and colleagues: acceptability, appropriateness, adoption, feasibility, fidelity, implementation cost, penetration, and sustainability (1). Each of these is defined in the *Definitions of Implementation Outcomes* section below.

DEFINITIONS OF IMPLEMENTATION OUTCOMES

Acceptability

The extent to which the intervention is considered suitable, agreeable, and satisfactory.

Appropriateness

The perceived fit of the intervention for a practice setting, provider, or participant.

Adoption

The decision by an organization or provider to take on or deliver an intervention. Also known as "uptake."

Feasibility

The extent to which the intervention can be successfully used in a given setting considering context, resources, etc.

Fidelity

The degree to which the intervention is implemented as the protocol prescribes.

Implementation Cost

The financial cost of the start-up activities required to begin delivering the intervention and/or the costs of delivering the intervention itself.

Penetration

The degree of use of the intervention within the population of organizations, providers, and clients. Also known as "reach."

Sustainability

The extent to which a newly implemented intervention is maintained with an organization's ongoing operations.(2)

WHY EMBED IMPLEMENTATION OUTCOMES IN EFFECTIVENESS STUDIES?

Measuring implementation outcomes can help to interpret the effectiveness study's primary outcomes.

The degree to which and how well the intervention is implemented may explain overall intervention effects on primary outcomes. In other words, measuring implementation outcomes can answer the question, "Did the intervention fail to produce the hypothesized benefits because it was not effective or because it was not (or was only partially) delivered with fidelity (i.e., as expected or planned)?" If the intervention is delivered with fidelity but is not effective, it needs to be redesigned or replaced. But, suppose a planned, contemporaneous analysis of implementation outcomes reveals the intervention is not being implemented with high fidelity. In that case, it may be possible to adjust the intervention format and/or implementation strategy such that the intervention is implemented with higher fidelity and effectiveness can be reevaluated. An example of adjusting the intervention format is changing 6 60-minute therapy sessions to 12 30-minute sessions. An example of adjusting an implementation strategy is to add ongoing supervision and consultation for staff to increase their ability to deliver the intervention.

Measuring implementation outcomes can help to interpret heterogeneity in the effectiveness study's primary outcomes.

It is not unusual for there to be heterogeneity in primary effectiveness outcomes across study sites and client subgroups. Study sites (e.g., health systems, schools) have different staffing, resources, and cultures that might influence how the intervention is implemented for the subgroups of people receiving services at those sites. For example, a school-based substance use prevention program might show stronger effectiveness in students at schools in high-income neighborhoods compared to low-income neighborhoods. However, this outcome might not be due to differential effectiveness of the intervention, but rather that the intervention was fully implemented at a well-resourced school serving students from a high-income neighborhood, but only partially implemented at a school with fewer resources serving students in a lower-income neighborhood. In-depth implementation outcome measurement during the study can help reveal these factors.

Measuring implementation outcomes can help speed the translation of research into practice.

Many effective interventions for treating substance use disorders and pain and preventing overdoses are never implemented or sustained in routine practice settings. Integrating measurement of implementation outcomes into effectiveness studies can address this implementation gap by helping researchers gauge how the implementation of the effectiveness study would work in real-world settings, allowing a jump start to the dissemination process.

WHAT ELSE SHOULD YOU CONSIDER?

Sample size's influence on measurement choices

When there are small sample sizes of organizations, providers, and/or clients in effectiveness studies, qualitative measures of implementation outcomes may be more informative than quantitative measures. Qualitative measures can provide deep insight into implementation outcomes even with small samples, whereas quantitative measures provide ratings with limited precision due to the small sample.

Example: A quantitative measure of adoption is not informative when three organizations were invited to deliver the intervention and two agreed (adoption = 2/3, 66.6%). But qualitative interviews with leaders at the three organizations could provide useful information about how barriers/facilitators influenced adoption decisions.

Alternative implementation outcomes framework, RE-AIM

The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework can also be used to measure implementation outcomes. Reach, as discussed in this guide, is similar to penetration. Effectiveness is the impact of the intervention on primary outcomes (e.g., client health outcomes) and is thus not an implementation outcome per se. Adoption in the RE-AIM framework is identical to adoption in the Proctor framework used in this guide. In RE-AIM, implementation is comparable to fidelity and maintenance is comparable to sustainability. (3)

Equity

Implementation inequities, or differences in access to evidence-based interventions stemming from unfairness or injustice, contribute to inequitable health outcomes. There is increasing recognition that all implementation outcomes should be measured and interpreted with equity in mind. Researchers should ask questions like, is the intervention acceptable, appropriate, and feasible for priority groups experiencing health inequities? Is the intervention implemented with higher fidelity in high-resource versus low-resource settings? Is the intervention differentially not reaching communities marginalized by structural determinants of health, like racism? Is the cost of implementing the intervention prohibitive for community health centers serving people without insurance? (4)

Cost of adding implementation outcomes to effectiveness studies

Benefits of adding implementation outcomes to effectiveness studies need to be balanced with costs, including participant data collection burden and study staff time spent collecting and analyzing data. Prioritizing key implementation outcomes, rather than including all outcomes, can help balance benefits and costs

Choosing implementation outcomes

A starting point for determining which implementation outcomes are appropriate for your study is answering three fundamental questions:

1. Who is delivering the intervention?
2. Do the organizations, providers, or clients involved in the effectiveness study have a choice to participate in the intervention or not?
3. What is the phase of the effectiveness study?

Some implementation outcomes, like acceptability, are only appropriate when real-world implementers, not study staff, are delivering the intervention. Adoption is only relevant if organizations, providers, and/or clients have a choice to participate in the intervention. Acceptability, appropriateness, and feasibility are often most useful in the pre-intervention phase, as they help gauge the fit of the intervention with the target population and the likelihood of recruitment success. Measurement of adoption, the decision to deliver (organizations, providers) or participate (clients) in an intervention, occurs in the early phase of an effectiveness study, whereas penetration—the degree to which adoption actually happened—occurs later. Results should also be interpreted in the context of the study's consent procedures; for instance, estimates of intervention reach may not be generalizable if study participants are limited to those who have already consented to receive the intervention and participate in research. Sustainability, if measured as institutionalization of an intervention, is measured after the primary effectiveness study is complete.

Measurement Modalities

Implementation outcomes can be measured using a variety of modalities, including self-reported surveys or qualitative interviews (at the client, clinician, or administrator level[s]), querying electronic health records, or examining administrative data (e.g., insurance claims). Some implementation outcomes, like acceptability and feasibility, lend themselves to self-reported surveys or qualitative interviews. Others, including adoption, fidelity, and penetration, can be built into electronic health records or other administrative data systems.

HOW TO SELECT AND USE IMPLEMENTATION OUTCOME MEASURES IN EFFECTIVENESS STUDIES

In measuring implementation outcomes, investigators may choose to measure some, but not all, implementation outcomes for a variety of reasons. Here we provide guidance on how to select and measure implementation outcomes, with a section for each outcome followed by cross-cutting considerations for all implementation outcomes.

1. Acceptability
2. Appropriateness
3. Adoption
4. Feasibility
5. Fidelity
6. Implementation Cost
7. Penetration
8. Sustainability

1 ACCEPTABILITY

The extent to which the intervention is considered suitable, agreeable, and satisfactory.

Why measure it?

Gauge the likelihood of recruitment and retention success. Measuring the acceptability of the intervention can help you understand why organization leaders, providers, or clients are or are not willing to participate in the intervention. Also, client perceptions of acceptability may correlate with the likelihood of retention.

Interpret study results. Providers are more likely to implement the intervention, and clients are more likely to engage in the intervention, when they find it acceptable. High/low acceptability can help interpret effectiveness study results. For example, low acceptability might help explain results showing that the intervention did not have the intended effects on client outcomes.

Potential for adoption in routine settings. High acceptability of the intervention makes it more likely to be adopted later on in routine practice settings.

From whom?

Leaders of organizations delivering the intervention? **Yes**

Providers delivering the intervention?

- **No**, if study staff deliver the intervention
- **Yes**, if real-world providers deliver the intervention in their routine practice setting

Clients participating in the intervention? **Yes**

When?

Pre-intervention rollout: If the effectiveness study involves recruiting organizations, providers, and/or clients, measuring acceptability before recruitment can help gauge the likelihood of recruitment success.

End of study: Understanding organization leaders', providers', and/or clients' perceptions of acceptability at the end of the effectiveness study can help explain study findings. If they found it unacceptable, the intervention may have lacked the buy-in needed for success.

How?

Qualitative or survey measures.

- Qualitative interview item example: Would you recommend this intervention to your family or friends? Why or why not?
- Survey examples: See the Implementation Outcome Repository for publicly available survey instruments

Acceptability: Key Considerations

1. **Consider measuring the acceptability of implementation strategies and the acceptability of the intervention**. For example, if study team facilitators met at regular intervals with clinicians delivering the intervention to troubleshoot challenges, consider measuring the acceptability of that facilitation. These measures will help inform the design of implementation strategies for future scaling of the intervention to additional practice settings.
2. **Low acceptability increases the likelihood of ad-lib intervention modification.** Intervention modifications may necessitate subsequent study protocol modifications. For example, modifying the mode of intervention delivery (e.g., from in-person to virtual visits) or components of the intervention may require subsequent protocol modifications. This points to the need to measure intervention fidelity.
3. **Acceptability is measured by self-report.** If your study is using data from an electronic health records or other data system, you will need to collect additional data directly from participants.

Acceptability Examples

Project Khanya: a randomized, hybrid effectiveness-implementation trial of a peer-delivered behavioral intervention for ART adherence and substance use in Cape Town, South Africa (5)

Acceptability was measured using a 15-item subscale administered to intervention participants and included items such as, “Did you feel satisfied with the program’s services?” and “Did you enjoy learning skills from the program?”

The Transitions Clinic Network: Post Incarceration Addiction Treatment, Healthcare, and Social Support (TCN-PATHS): A hybrid type-1 effectiveness trial of enhanced primary care to improve opioid use disorder treatment outcomes following release from jail (6)

The study team created a data collection smartphone application that pushes questions to participants at pre-programmed times. Acceptability was measured when participants received questions such as, “Have you been contacted by your community health worker today? Is the way they contacted you your preferred method?”

2 APPROPRIATENESS

The perceived fit of the intervention for a practice setting, provider, or participant.

Why measure it?

Gauge the likelihood of recruitment and retention success. Measuring appropriateness can help you understand if the intervention is a good match across organizations, providers, and/or client populations in an effectiveness study (i.e., why organization leaders, providers, or clients are or are not willing to participate). For example, leaders and providers may perceive an intervention as inappropriate if the intervention's components are at odds with organizational culture. Client perceptions of appropriateness may correlate with the likelihood of retention. For example, if clients do not perceive the intervention as concordant with their values or resources (e.g., time to participate), retention may be low.

Interpret effectiveness study results. Providers are more likely to fully implement the intervention, and clients are more likely to fully engage in the intervention, when they find it appropriate. High/low appropriateness can help interpret effectiveness study results: for example, low appropriateness might help explain results showing that the intervention did not have the intended effects on client outcomes.

Potential for adoption in routine settings. High appropriateness of the intervention makes it more likely to be adopted later on in routine practice settings.

From whom?

Leaders of organizations delivering the intervention? Yes

Providers delivering the intervention?

- **No,** if study staff deliver the intervention
- **Yes,** if real-world providers deliver the intervention in their routine practice setting.

Clients participating in the intervention? Yes

When?

Pre-intervention rollout: If the effectiveness study involves recruiting organizations, providers, and/or clients, measuring appropriateness before recruitment can help gauge the likelihood of recruitment success.

End of study: Understanding organization leaders', providers', and/or clients' perceptions of appropriateness at the end of the effectiveness study can help explain study findings. If they found it to be a poor match, the intervention may have lacked the buy-in needed for success.

How?

Qualitative or survey measures.

- Qualitative interview item example: How did the intervention fit in your organization [leaders]/for your clients [providers]/in your life [clients]?

Survey examples: See the Implementation Outcome Repository for publicly available survey instruments

Appropriateness: Key Considerations

1. Consider measuring appropriateness of implementation strategies and the appropriateness of the intervention. For example, if study team facilitators met at regular intervals with clinicians delivering the intervention to troubleshoot challenges, consider measuring the appropriateness of that facilitation. These measures will help inform the design of implementation strategies for future scaling of the intervention to additional practice settings.
2. Low appropriateness increases the likelihood of ad-lib intervention modification. Mid-course intervention modifications may necessitate subsequent study protocol modifications. For example, the mode of intervention delivery or components of the intervention might need to be modified.
3. Appropriateness is measured by self-report. If your study is using data from an electronic medical record (EMR) or other data system, you will need to collect additional data directly from participants.

Appropriateness Examples

The Transitions Clinic Network: Post Incarceration Addiction Treatment, Healthcare, and Social Support (TCN-PATHS): A hybrid type-1 effectiveness trial of enhanced primary care to improve opioid use disorder treatment outcomes following release from jail (6)

The study team created a data collection smartphone application that pushed questions to participants at pre-programmed times. Appropriateness was measured when participants received questions such as, "Does speaking to your community health worker help you deal with the issues you may be facing today?"

The EMBER trial for weight management engagement: A hybrid type 1 randomized controlled trial protocol (7)

Appropriateness was measured by participant report of the Intervention Appropriateness Measure (IAM) at two-month follow-up. Items included, "EMBER seems fitting," "EMBER seems suitable," "EMBER seems applicable," and "EMBER seems like a good match." Respondents answered using a five-point Likert scale ranging from "Completely disagree" to "Completely agree."

3 ADOPTION

The decision to deliver (organizations, providers) or participate (clients) in an intervention.

Why measure it?

Potential for adoption in routine settings. High adoption of the intervention in the effectiveness study suggests good potential for wider adoption in routine practice settings later. Poor adoption suggests that the intervention may need to be adapted to be taken up in routine practice.

From whom?

Did organizations, providers, or clients involved in the effectiveness study have a choice to deliver (organizations, providers) or participate in the intervention?

- **No,** adoption is not an appropriate measure for your study.
- **Yes,** consider measuring adoption. It can be measured among organizations, providers, or clients if they chose to delver/participate in the intervention.

Examples of having a choice:

- Multiple organizations and/or providers were invited to deliver the intervention. Some agreed, and some declined.
- Clients were offered the opportunity to participate in the intervention and had the choice to opt in or opt out.

Examples of not having a choice:

- The principal investigator conducted the effectiveness study testing the intervention in their clinic; no other clinics were invited to participate. Study staff were required to deliver the intervention to all clients meeting eligibility criteria.
- An organization made a top-down decision to deliver the intervention, and all providers and clients participated.

When?

When you know which organizations, providers, or clients adopted the intervention among the larger pool of those eligible. This might be at the beginning of the effectiveness study if organizations, providers, and/or clients agree to participate before the intervention is implemented. It might be in the middle or end of the study if participation choices are ongoing, as with rolling client recruitment.

How?

- **Intervention adoption by organizations or providers** is defined as the proportion of organizations/providers eligible to deliver the intervention who agreed to deliver it.
- **Intervention adoption by clients** is defined as the proportion of clients eligible to participate in the intervention who agreed to participate. This may already be tracked for a CONSORT (Consolidated Standards of Reporting Trials) diagram.

Adoption: Key Considerations

1. Disentangling intervention adoption and research study participation. Was the choice to participate in the intervention synonymous with the choice to participate in the research study?

No. A top-down decision was made to adopt the intervention, and when organizations, providers, and/or clients decided to participate, they did not know it was a research study. For example, a system leader agreed to participate in the effectiveness study testing the intervention. Clinics, providers, and/or clients were then randomized to receive the intervention without knowing they were participating in a study (this is most common for quality improvement interventions that do not require client consent).

- In this case, adoption measures reflect a willingness to adopt the intervention.

Yes. Organizations, providers, and/or clients were recruited for the study and chose whether to participate. For example, study staff recruited community clinics to participate in the effectiveness study testing the intervention. Within clinics that agreed, study staff recruited providers to deliver the intervention and clients to participate in the intervention.

- In this case, adoption measures reflect a willingness to adopt the intervention **and** participate in a research study. This adoption measure will be biased, because research participation requires commitments that go beyond clinical care (e.g., data usage, additional time commitments). Qualitative or survey research is needed to ask organization leaders/providers/clients why they chose to participate/not participate to understand if their decision was related to the intervention or the research study. If this type of supplemental research is not feasible in the effectiveness study, measuring adoption may not make sense.

Adoption Examples

Self-administered acupressure for veterans with chronic back pain: Study design and methodology of a type 1 hybrid effectiveness implementation randomized controlled trial. Contemp Clin Trials (8)

Adoption was evaluated by the number of participating providers who referred veteran patients to the Whole Health Classes.

The cirrhosis care Alberta (CCAB) protocol: implementing an evidence-based best practice order set for the management of liver cirrhosis - a hybrid type I effectiveness-implementation trial (9)

Adoption was measured by the number of hospital sites enrolled in the study and the number of hospital sites that used the electronic order set to deliver evidence-based best practices for cirrhosis.

4 FEASIBILITY

The extent to which the intervention can be successfully used in a given setting.

Why measure it?

Gauge the likelihood of effectiveness study recruitment success. Measuring the feasibility of the intervention can help you understand why organization leaders and/or providers are or are not willing to participate in the intervention.
Interpret effectiveness study results. Providers are more likely to fully implement the intervention when they find it feasible.
Potential for adoption in routine settings. High intervention feasibility makes it more likely to be adopted later in routine practice settings.

From whom?

Among leaders of organizations delivering the intervention? Yes
Among providers delivering the intervention?

- **No,** if the study staff delivers the intervention
- **Yes,** if real-world providers deliver the intervention in their routine practice setting

Among clients participating in the intervention. No. Implementation feasibility is measured among intervention implementers rather than among intervention participants. Feasibility of the intervention itself can be measured among clients (e.g., how feasible is it for you to participate in this intervention).

When?

Pre-intervention implementation: If the effectiveness study involves recruiting organizations or providers, measuring feasibility prior to recruitment can help gauge the likelihood of recruitment success.
End of study: Understanding organization leaders' and providers' perceptions of feasibility at the end of the effectiveness study can help explain study findings. If they found the intervention not feasible, then it may not have been fully implemented as intended.

How?

Qualitative or survey measures.

- **Qualitative interview item example:** How easy or hard will it be/was it to implement the intervention in your setting?
- **Survey examples:** See the Implementation Outcome Repository for publicly available survey instruments https://implementationoutcomerepository.org/

Feasibility: Key Considerations

1. Consider measuring the feasibility of implementation strategies in addition to the feasibility of the intervention. For example, if study team facilitators met at regular intervals with clinicians responsible for delivering the intervention in their clinical settings to troubleshoot challenges, consider measuring the feasibility of that facilitation. These measures will help inform the design of implementation strategies for future scaling of the intervention to additional routine practice settings.

Low feasibility increases the likelihood of ad-lib intervention modification. These intervention modifications by individuals who deviate from the protocol may necessitate subsequent study protocol modifications. For example, modifying the mode of intervention delivery (e.g., from in-person delivery to virtual visits) or intervention components may require subsequent protocol modifications. This points to the need to measure intervention fidelity (see below).

2. Feasibility is measured by self-report. If your study uses data from an electronic health record or other data system, you must collect additional data directly from leaders or providers.

Feasibility Examples

Adherence intervention for HIV-infected persons who use drugs: adaptation, open trial, and pilot randomized hybrid type 1 trial protocol (10)

Feasibility was assessed qualitatively during exit interviews with clinicians who delivered the intervention and evaluated the intervention length, intensity, frequency, and mode of delivery.

Study protocol for a hybrid type 1 effectiveness-implementation trial testing virtual tobacco treatment in oncology practices [Smokefree Support Study 2.0] (11)

Participating clinicians and staff completed the Feasibility Intervention Measure (FIM) at baseline and again at 12-15 months and 24-36 months post-baseline survey. Assessment items include “Smokefree Support Study 2.0 seems implementable”; “Smokefree Support Study 2.0 seems possible; “Smokefree Support Study 2.0 seems doable”; and ”Smokefree Support Study 2.0 seems easy to use.” Respondents answered using a 5-point Likert scale ranging from “Completely disagree” to “Completely agree.”

5 FIDELITY

The degree to which the intervention was implemented as the protocol prescribes.

Why measure it?

Interpret effectiveness study results. Whether or not the intervention was implemented as intended drives the effectiveness of the study results.
Potential for adoption in routine settings. Low fidelity in the effectiveness study suggests that the intervention may be overly complex or challenging to deliver with fidelity in routine practice settings.

When?

Study start: Measuring fidelity early in the study can determine whether the study staff or real-world providers delivering the intervention have developed the needed skills/competencies.
Ongoing during the intervention: Monitoring fidelity throughout the intervention can support course correction as needed, e.g., by having a study team member provide feedback and coaching to the staff or real-world providers delivering the intervention.

How?

Fidelity instruments focus on specific interventions and have limited generalizability to other interventions. Fidelity is often measured by logging the completion of intervention activities or a sample of observations of the intervention being delivered. See this tip sheet from the Office of Population Affairs:
https://opa.hhs.gov/sites/default/files/2021-03/fidelity-monitoring-tip-sheet-2020.pdf

Fidelity: Key Considerations

1. Consider measuring fidelity to implementation strategies. In addition to measuring fidelity to the intervention, consider measuring fidelity to the implementation strategies like training and performance feedback for the study staff or real-world implementers delivering the intervention.

2. Fidelity has multiple dimensions. Fidelity includes adherence to the intervention protocol, the dose or amount of the program delivered, and the quality of program delivery.

Fidelity Examples

Surmounting Withdrawal to Initiate Fast Treatment with Naltrexone (SWIFT): A stepped wedge hybrid type 1 effectiveness-implementation study (12)

Fidelity was measured using the number of clinicians and non clinical administrative leaders on the site-level implementation team (obtained from the pre-implementation checklist), the number and percentage of staff in attendance at the rapid procedure intervention training (obtained from the pre-implementation checklist), hours of clinical consultation received per site (obtained from meeting time logs), and average rate of adherence to core components of the rapid procedure intervention (obtained from the study Critical Action Checklist).

BeatPain Utah: study protocol for a pragmatic randomised trial examining telehealth strategies to provide non-pharmacologic pain care for persons with chronic low back pain receiving care in federally qualified health centers (13)

Fidelity was measured by the percent of core treatment components provided during intervention sessions (self-reported by the physical therapist using checklists in the project's REDCap platform).

Study protocol for a factorial-randomized controlled trial evaluating the implementation, costs, effectiveness, and sustainment of digital therapeutics for substance use disorder in primary care (DIGITS Trial) (14)

Fidelity was measured entirely with secondary data, operationalized as the number of weeks in which a patient completed four digital therapeutic modules per week while concurrently seeing a clinician for substance use disorder, consistent with recommendations of the smartphone app-based digital therapeutic's vendor and the clinical leaders in the health system.

6 IMPLEMENTATION COST

The cost of delivering the intervention.

Why measure it?

Potential for adoption in routine settings. Cost is a key consideration for real-world adoption.
Supports cost-effectiveness evaluation. Collecting cost data can support subsequent cost-effectiveness evaluation. Demonstrating cost-effectiveness can help convince insurers to cover the intervention and system and organization leaders to adopt the intervention.

When?

Throughout the study: Concluding the end of the study when it is possible to capture the entirety of costs associated with intervention delivery.

How?

Costing templates that track (a) implementation costs, such as costs to support implementation strategies like coaching, training, and facilitation, and (b) intervention costs, like costs of intervention materials and equipment and staff time spent delivering the intervention. An example is the Cost of Implementing New Strategies (COINS) method (reference below). See the article below for additional details on approaches to costing.

- Cost data in implementation science: categories and approaches to costing (15)
- The cost of implementing new strategies (COINS): A method for mapping implementation resources using the stages of implementation completion (16)

Implementation Cost: Key Considerations

1. Consider measuring the cost of the intervention and the implementation strategies. In addition to measuring the cost of delivering the intervention, consider assessing the cost of the implementation strategies involved, like training or coaching for the people delivering the intervention. Financing for both the intervention and the implementation strategies is necessary to scale the intervention to routine practice settings. Implementation costs are sometimes hidden from organizations considering adopting an intervention.

2. Consider what type of cost data is most important for the setting. The type of cost data most salient to decision-makers may vary by setting. For example, the major costs of a clinical decision support intervention might include health IT and staffing. A setting with an already robust health IT system may care more about staffing costs than IT costs. A setting with limited health IT may care about both.

Implementation Examples

Testing a tailored weight management program for veterans with PTSD: The MOVE! + UP randomized controlled trial (17)

Implementation costs were evaluated using a budget analysis, which included intervention costs of care associated with weight management using data from the Veterans Association (VA) Managerial Cost Accounting System (an activity-based cost allocation system that generates cost estimates for health care encounters), cost of intervention space and materials, staff time, and PI training. The study team monetized staff time using an opportunity cost approach, which multiplies hours devoted to implementation by hourly wage rates (as recorded in the VA payroll records).

A cluster randomized clinical trial to evaluate the effectiveness of the Implementation of Infant Pain Practice Change (ImPaC) Resource to improve pain practices in hospitalized infants: a study protocol (18)

Implementation costs were assessed using data on human resources (i.e., time spent on intervention orientation session, navigation through the intervention resources, team meetings, intervention implementation), space for meetings and education sessions, and equipment and materials.

7 PENETRATION

Degree of use of the intervention within the population of organizations, providers, and clients.

Why measure it?

Assessing reach to priority populations. Measuring penetration can help in understanding the proportion of eligible individuals, including those from priority populations (e.g., low income or high-acuity individuals) who receive the intervention.
Understanding the generalizability of effectiveness study results. Suppose organizations, providers, or clients can choose to participate in the intervention. In that case, understanding the characteristics of those who chose to participate can help researchers understand how generalizable study findings are to other organizations, providers, or clients. For example, if the study sample includes mostly high-resource organizations, the intervention may have different effects in low-resource settings.

When?

Throughout the study: At the end of the study, you will know how many organizations, providers, and/or clients participated in the intervention among those who were eligible to do so.

How?

Penetration is defined as the proportion of organizations, providers, or clients eligible to participate in the intervention who participated.

Penetration: Key Considerations

1. Consider the related concept of "reach." Reach, a concept from the RE-AIM framework (reach, effectiveness, adoption, implementation, maintenance), is similar to penetration. Reach is the absolute number, proportion, and representativeness of individuals participating in the intervention and reasons why or why not. While penetration focuses on identifying the proportion of organizations, providers, or clients who use an intervention among those eligible, reach can also be measured as the absolute number of organizations, providers, or clients participating in the intervention. Reach also explicitly considers the representativeness of the study population. In the research literature, "reach" and "penetration" are often used interchangeably.

Penetration Examples

Protocol for the implementation of a statewide mobile addiction program (19)

Penetration (described as "reach") was assessed by the number of program encounters (determined by monthly report submissions from programs), the number of patient encounters (determined by monthly report submissions from programs and aggregate naloxone data from the MA Dept of Public Health),the number of buprenorphine patients (determined by monthly report submissions from programs),and the number of naloxone kits distributed (determined by patient data from the MA Dept of Public Health).

Study protocol for a factorial-randomized controlled trial evaluating the implementation, costs, effectiveness, and sustainment of digital therapeutics for substance use disorder in primary care (DIGITS Trial) (14)

In this hybrid effectiveness-implementation trial, reach was measured as the proportion of patients who were prescribed and then activated a prescription digital therapeutic for substance use disorder among those eligible.

8 SUSTAINABILIY

The extent to which a newly implemented treatment has the potential to be/is maintained with an organization's ongoing operations.

Why measure it?

Gauge the likelihood of organization recruitment success. If the effectiveness study involves recruiting organizations, organizations may be more likely to participate if they have confidence in their ability to sustain the intervention after completing the research study.

Potential for adoption in routine settings. If organizations cannot sustain the intervention after the study ends and they lose research team support, widespread adoption, and sustained implementation of the intervention in routine practice settings may be unrealistic.

From whom?

Among leaders of organizations delivering the intervention? Yes.

Among providers delivering the intervention?

- **No,** if the study staff delivers the intervention
- **Yes,** if real-world providers deliver the intervention in their routine practice setting

When?

Pre-intervention implementation: Measuring perceived sustainability prior to intervention implementation can support the identification of challenges to sustainability and support early planning for sustainment.

End of study: Understanding perceptions of sustainability informs the likelihood that the intervention will be continued at the organization/by the providers participating in the effectiveness study. Perceptions of sustainability also inform the likelihood of wider-spread intervention adoption and sustained implementation in routine practice settings.

After study completion: Whether and the degree to which organizations and providers continued the intervention can be measured at time points following study completion.

How?

- **Qualitative or survey measures**
  - Qualitative interview item example: Could your organization implement this intervention long-term? Why or why not?
  - Survey examples: See the Implementation Outcome Repository for publicly available survey instruments https://implementationoutcomerepository.org/
- **Indicators of continued intervention delivery over time,** e.g., the proportion of organizations or providers delivering all intervention components one year after study completion

Sustainability: Key Considerations

1. Measuring perceived sustainability early on and planning for sustainability can support organization leaders' and providers' buy-in. Organizations and providers may be more willing to participate in the effectiveness study if they are confident the intervention can be sustained after it ends.

2. Leaders and providers may have difficulty gauging sustainability before the intervention implementation. On the one hand, measuring perceived sustainability early on may prompt helpful planning for sustainment, as mentioned above. On the other hand, without direct experience with the intervention, organization leaders and providers may have difficulty accurately gauging the likelihood of barriers and facilitators to sustainment.

3. Post-intervention sustainment often falls outside of grant timelines. Grant funding may not be available to support the data collection needed to measure the continued delivery of the intervention after the study ends.

Sustainability Examples

Adherence intervention for HIV-infected persons who use drugs: adaptation, open trial, and pilot randomized hybrid type 1 trial protocol (10)

Providers who delivered the intervention completed the Organizational Readiness for Implementing Change (ORIC) Scale to examine organizational strengths/weaknesses that support the sustainability of the intervention. ORIC items include rating statements like, "We are committed to implementing this change," "We feel this change is compatible with our values," "We have the resources we need to implement this change," and "We believe this change is cost effective."

A cluster randomized clinical trial to evaluate the effectiveness of the Implementation of Infant Pain Practice Change (ImPaC) Resource to improve pain practices in hospitalized infants: a study protocol (18)

Sustainability was assessed by the duration in months that the participating NICUs continued to use the intervention resources with fidelity, which is captured by the intervention website.

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