Pragmatic Implementation Science Guides and Measures to Enhance the Impact of Your Research

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NIDA 50DA054072, NIDA U2CDA057717
Evaluating the “Implementability” of an Intervention, Program, or Service

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Authors & Acknowledgements

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Intervention researchers want...

• To increase the potential for translation and true public health impact for the interventions, programs or services they are designing, evaluating, or disseminating

• To understand the potential real world “implementability” of their interventions ranging from pharmacological to psychosocial to data dashboards

• To do more than qualitative interviews about barriers and facilitators in their Specific Aim 3

• Pragmatic guidance from the field of implementation science… not theories, models, and frameworks
Pragmatic implementation science to improve the chance for translation: 5 key components

- **Evidence for the Intervention**: Research supporting the intervention’s effectiveness, delivery, and adaptation
- **Partner Engagement**: Collaboration with partners (participants, sites, community) to define the population, problem, intervention, & strategies
- **Contextual Determinants**: Systems, cultural, organizational, and individual factors that affect the reach and adoption of the intervention
- **Implementation & Sustainment Strategies**: Procedures to support end-users to install and sustain the intervention
- **Implementation & Sustainment Outcomes**: Effects of actions to implement the intervention including extent of use by the deliverers (adoption) and receivers (reach)
DIRC-SS: A pragmatic measure of “implementability” considerations in your research

- Five key dimensions
- Concrete, practical value
- Can be used to enhance your project at the proposal stage or to modify or augment your project if underway
What is the DIRC-SS?

- Team-based self-assessment (1 hour)
- No value judgement, consensus based, no implementation science expertise necessary
- 5 dimensions, 3-benchmarks per dimension (15 items total)
- Global ratings on a 5-point scale from
  1- None
  3- Partial/Moderate
  5- Full/Comprehensive/Complete
- Honest ratings are best, using DIRC-SS to get to “5” is transparent
- Sometimes zero, sometimes significant budget impact
DIRC-SS Applied: NIH HEAL Data2Action

• 10 Innovation/Acceleration Research Projects
• 3 Support Centers: DISC, MERC and RASC
• RASC role to support the translation of Project findings
• Method:
  1) DIRC-SS review by Project PI and research team
  2) DIRC-SS review by RASC Expert Dyads
  3) Shared decision-making approach to develop “Implementation Support Plans”
  4) Technical assistance to achieve revised project goals
Baseline ratings across 9 HD2A Innovation and Acceleration Projects

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<thead>
<tr>
<th>Project</th>
<th>Evidence for the Intervention</th>
<th>Partner Engagement</th>
<th>Contextual Determinants</th>
<th>Implementation Strategies</th>
<th>Implementation Outcomes</th>
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Mean Score

- Project Rating
- RASC Rating
DIRC-SS Applied: Key Takeaways

• The DIRC-SS gathered systematic information from an existing or proposed research project

• The DIRC-SS stimulated ideas about potential pragmatic opportunities to enhance the implementation aspects of the project

• Led to fascinating, productive dialogue between HD2A Research Project teams and RASC implementation research experts

• Exposed implementation science as an ironic implementation nightmare of theories, models, and frameworks with a beleaguering and infinite warehouse of options for non-experts
What Implementation Science Appears to Offer
What the Field Needs
Pragmatic Guides and Measures Across 4 D&I Science Domains

Prioritizing rigor and reproducibility in measurement; and usability

C-DIAS/RASC Design & Development Workgroups

• Partner Engagement: Terri Powell & Andrew Subica
• Contextual Determinants: Cece Calhoun & Hélène Chokron Garneau
• Implementation Strategies: Bryan Garner & Heather Gotham
• Implementation Outcomes: William Becker & Beth McGinty
Meaningfully Engaging and Integrating Partners into the Research Process

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Partner Engagement

“A primary goal of D&I research is to achieve broad, sustainable use of an evidence-based program, policy, or practice, which requires inclusivity and shared ownership and buy-in from a range of partners and community members” (Villalobos et al., 2023)
Why is it important?

- Crucial for developing effective and sustainable interventions across diverse groups/contexts.
- Necessary to improve the health and well-being of those affected by substance use disorders and pain.
- Poor partner engagement can negatively impact intervention outcomes and foster distrust among the affected groups.
Partner Engagement Resources

What has been done before?

• Patient-Centered Outcomes Research Institute (PCORI) Engagement Resources
• Opioid Research Consortium of Central Appalachia (ORCCA) Community-Engaged Research Training
• International Association for the Study of Pain (IASP) Partnering with People with Lived Experience

What are the current gaps?

• Core principles and practices for researchers focused on addiction, pain, dissemination, and implementation
• Accessible and practical resources

Our Partner Engagement Guide

• Provides recommendations on how to identify and meaningfully engage with partners in research
• Helps researchers (1) improve the quality of their research and (2) increase empowerment among communities who partner with them
Methods – National Team of Experts

GROUP MEETINGS

ASYNCHRONOUS WORK

SMALL-GROUP MEETINGS
Introduction to the Guide

Core Principles

The Partnering Process

Case Studies, Worksheets, and Resource List
Seven Core Principles

CO-LEARNING & CO-PRODUCTION
EQUITY
HUMILITY
RELATIONSHIP BUILDING
RESOURCE SHARING
ACTION & CHANGE
SUSTAINMENT
The 7-Step Partnering Process

Step 1: Identify and secure needed support for partner engagement
- Administrative support and time allocation
- Compensation for partners
- Space
- IRB support

Step 2: Develop a partner engagement strategic plan
- Explore the WHY, WHO, WHAT, WHEN, and HOW
The Partnering Process

Step 3: Identify levels of engagement
- Informing
- Consulting
- Collaborating
- Leading/Co-Leading

Step 4: Select methods of engagement
- Steering committee, advisory board, or workgroup
- Open-ended guidance, prescriptive feedback, and/or human-centered design

Step 5: Engage partners in the research process
- Engage partners throughout the research process
- Monitor for engagement and possible conflicts
The Partnering Process

**Step 6:** Evaluate your engagement
- Process evaluation: # and types of activities, # community members reached
- Outcome evaluation: new community resources developed (increases in community partners’ staffing or membership), acceptability and feasibility of interventions, policy changes

**Step 7:** Disseminate information about your engagement strategy and outcomes
- Develop materials with partners
- Appropriately center the expertise and efforts of community partners
Two Case Studies

PEARL-PURPLE

Research Advisory Committee (RAC) at the University of Maryland-College Park Addictions Programs
Advised on programmatic/non-research projects and co-develop research proposals
RAC served as a social support and information-experience exchange platform

HEAL Justice Community Opioid Innovation Network

HEAL Justice Community Opioid Innovation Network (JCOIN) host a Practitioner Board and a Stakeholder Board
Started with goals of 0% tokenism and making engagement meaningful
Host a meeting series and tailor events and materials to different audiences
Supplemental Resources

Scientific Resources and Training for Partnership Engagement

Worksheets
Partner Engagement Strategic Plan Worksheet
Support and Resource Checklist
Impact and Implications

The goal is for researchers to improve the quality of their research by promoting partnered engagement with the affected communities.

Engaging communities—particularly those historically excluded from health research processes and decision-making—is essential for translating substance use and pain interventions and programs for maximal public health impact.

Ending addiction to substances, effectively managing pain, and reducing overdose deaths will require meaningfully engaging and integrating partners to help develop high-quality, equitable, and sustainable solutions.
Understanding the Context in which Interventions Are Implemented

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Contextual Determinants

• Factors that affect the implementation and sustainment of evidence-based practices and innovative solutions
  • May be conceptualized as barriers and facilitators
  • Multi-leveled and dynamic
Why does context matter?

• Context shapes the intervention's implementation, delivery, and sustainment
• Guides selection of implementation strategies to successfully increase the intervention's reach, adoption, maintenance, and sustainability
What has been done before?

Many frameworks exist

- Consolidated Framework for Implementation Research (CFIR)
- Promoting Action on Research Implementation in Health Services (PARIHS)
- Theoretical Domains Framework (TDF)
- Practical, Robust Implementation and Sustainability Model (PRISM)

Gaps

- These frameworks and tools are complex to use for non researchers
- Data is difficult to harmonize limiting cross-study comparability, reproducibility, and pooled findings
To develop a **pragmatic, user-friendly** guide which identifies the contextual determinants that influence the implementation of a chosen intervention.
Methods

- Identified a team of experts
- Co-chair leadership
- Group meetings
- Asynchronous work
- Iterative design
Priorities of the workgroup

- Fluid & non-prescriptive
- Pragmatic & user friendly
- Four audiences: Intervention developers; Intermediary/purveyor organization; Public and private health or social service systems; Implementation Researchers
- Captures context at multiple levels
- Considers equity
- Captures how contextual factors may influence each other
Product

Contextual Determinants Affecting Implementation
Qualitative Interview Guide

• Semi-structured
• Self-administered or used as a guide for qualitative interviews
• Probes organized around common domains of major frameworks
• Equity-focused lens
Contextual Determinants Affecting Implementation

1. Can you think of any challenges or barriers to:
   a. Getting (NAME OF INTERVENTION) implemented?
   b. Getting (NAME OF INTERVENTION) delivered as intended? And
   c. Slowing down, interfering, or halting the process?

2. Can you think of anything that will (or did) help to:
   a. Get (NAME OF INTERVENTION) implemented?
   b. Get (NAME OF INTERVENTION) delivered as intended?
   c. Reinforce or accelerate the process?

3. Can you think of ways that these barriers and facilitators are connected to one another (i.e., how they may work together)?

4. How would you define implementing this intervention in an equitable fashion, in your context, for the population that you work with? What may get in the way of making this happen?

5. What kinds of disparities exist among [recipients]?
   a. How might implementing [service] help close those gaps?
   b. How might [service] implementation make those gaps worse?
   c. What should we avoid so we don't make things worse?
Impact and Implications

This guide will allow for:

- Easy and wholistic assessment of determinants and their interconnectedness
- Focus on equity
- Guide the selection of implementation strategies

Use the information gathered to develop an implementation roadmap based on which contextual determinants are most readily addressable.
Documenting Strategies that Support Implementation of Effective Interventions

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Implementation Strategies

• “the stuff we do to help people DO THE THING (i.e., intervention)” (Curran, 2020)

• “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” (Proctor et al., 2013)

• There are several existing lists of implementation strategies
  • Powell et al.’s (2015) Expert Recommendations for Implementing Change (ERIC)
Why Track Implementation Strategies?

• Allow other researchers to replicate the results of a study
  • What happened to get the intervention used in study sites?

• Translate interventions into practice
  • What steps are needed to embed an effective intervention into a real-world setting?

• Analyze intervention effects
  • Did differences in implementation strategies affect differences in intervention outcomes across sites or samples?
Why is This Tool Needed?

• Researchers have strategy tracking methods
  • Bunger et al. (2017) - Tracking Implementation Strategies
  • Boyd et al. (2018) - A Method for Tracking Implementation Strategies
  • Walsh-Bailey et al. (2021) - A pilot study comparing tools for tracking implementation strategies
  • Smith et al. (2023) - Longitudinal Implementation Strategy Tracking System (LISTS)

• However, there is a need for a more simple, pragmatic tool
  • Doesn’t rely on D&I experts
  • Flexible and modifiable based on level of specificity needed
  • Easy for research staff to use
Methods

- Identified a team of experts
- Regular team meetings
- Facilitator meetings
- Sought feedback from research collaborators
- [TBC] Piloting with research collaborators
Strategies Timeline, Activities, & Resources (STAR) Log

• Provides a simplified, centralized method for research teams to track implementation strategies
• Can be used at any time in your project (e.g., planning, execution)
• Can be completed and/or updated on a cadence that makes sense for your project (e.g., monthly, quarterly)
# Strategies Timeline, Activities, & Resources (STAR) Log

## STAR Log Template

<table>
<thead>
<tr>
<th>Strategy Start Date</th>
<th>Strategy End Date</th>
<th>Strategy Group</th>
<th>Strategy Name</th>
<th>What did you do?</th>
<th>Why did you do it?</th>
<th>Who delivered the strategy?</th>
<th>How many people delivered the strategy?</th>
<th>On average, how long did it take to prepare and deliver the strategy?</th>
</tr>
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- Select One
- Plan
- Educate
- Finance
- Restructure
- Quality Management
- Attend to Policy Context

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**Center for Disastous Infrastructure Security and Sustainability**

**Research and Support Center**

**Prepare Implement Sustain**
<table>
<thead>
<tr>
<th>Who received the strategy?</th>
<th>How many people received the strategy?</th>
<th>On average, at what frequency did this strategy occur?</th>
<th>On average, how long was each occurrence?</th>
<th>What resources or materials were used to deliver the strategy?</th>
<th>Was the strategy planned or unplanned?</th>
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Impact and Implications

• How can the STAR Log be used?
  • Outline resources and costs needed while planning a study
  • Replicate interventions in research studies or real-world settings
  • Track adaptations in implementation strategies used
  • Facilitate cost-effectiveness analyses to share with policymakers and government officials
  • Harmonize information across studies in meta-analyses or other reviews
Integrating Implementation Outcomes into Effectiveness Studies

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Implementation Outcomes

• **Implementation outcomes** measure how much and how well an intervention was implemented

• Popular frameworks for measuring implementation outcomes include
  
  • Proctor et al. (2011): acceptability, appropriateness, adoption, feasibility, fidelity, implementation cost, penetration, and sustainability
  
  • RE-AIM: reach, effectiveness, adoption, implementation, and maintenance (Glasgow 1999).
Implementation Outcomes (Proctor et al., 2011)

- **Acceptability**: Extent to which the intervention is considered suitable, agreeable, and satisfactory
- **Appropriateness**: Perceived fit of the intervention for a practice setting, provider, or participant
- **Adoption**: Decision by an organization or provider to take on or deliver an intervention. Also known as “uptake”
- **Feasibility**: Extent to which the intervention can be successfully used in a given setting considering context, resources, etc.
- **Fidelity**: Degree to which the intervention is implemented as the protocol prescribes
- **Implementation cost**: Financial cost of delivering the intervention
- **Penetration**: Degree of use of the intervention within the population of organizations, providers, and clients - also known as “reach”
- **Sustainability**: Extent to which a newly implemented intervention is maintained with an organization’s ongoing operations
Why Embed Implementation Outcome Measures in Effectiveness Studies?

• Clarify reasons for the intervention's success or failure
• Address variability across contexts - unique sites and diverse patient groups
• Accelerate research-to-practice translation
• Inform how to tailor implementation strategies
• Assist in long-term planning
• Aid in understanding impact in real-world settings
Why is This Specific Guide Needed?

• Several lists or repositories of outcome measures, but no guide to why, when, or how to use them
• Our guide uniquely includes case studies that demonstrate practical applications
What Our Guide Provides

- Define outcomes
- Supply tools for selection
- Provide case studies
- Bridge the gap between research and routine practice
Methods

**Interdisciplinary Collaboration**
- Formed workgroup including experts in dissemination and implementation (D&I) science, opioid use disorder, and pain management

**Defined Implementation Outcomes using Proctor et al.**
- Adopted the Proctor et al. (2011) framework to define the implementation outcomes

**Selection Criteria**
- Came to consensus on criteria for selecting implementation outcomes based on study context and targeted population
- Iterated on decision criteria for each outcome

**Inclusion of Real-World Examples**
- Incorporated case studies from published studies to demonstrate the application of these methods
Integrating Implementation Outcomes into Effectiveness Studies

Integrating Implementation Outcomes into Effectiveness Studies

Strategies and the collaborators met at unknown location. These are for future section. No point study. Intervention delivery section may require measure intervention. Report and data from an collect additional.

To intervention the program's section. Healthcare, all of enhanced. Children release to

Risks

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? In the way they contacted you your preferred method?”
Integrating Implementation Outcomes into Effectiveness Studies

Example: Acceptability

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.
Integrating Implementation Outcomes into Effectiveness Studies

Example: Acceptability

**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.
Integrating Implementation Outcomes into Effectiveness Studies

Example: Acceptability

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](#)
Integrating Implementation Outcomes into Effectiveness Studies

Example: Acceptability

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.

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 Employment (5).

C-DIAS, RASC
Impact and Implications

• Improves Implementation Quality
  • Identify and address factors that influence intervention delivery

• Encourages Sustainable Practices
  • Plan for long-term sustainability of interventions

• Reduces Research-to-Practice Gap
  • Aims to shorten the time between discovery and practical application, leading to faster improvements
Available Now!

Download here:
www.c-dias.org/implementation-guides-and-measures
References


- ORCCA. Retrieved January 12, 2024, from https://the-orcca.com/training