Iterative pragmatic approaches to guiding and evaluating adaptations in real-world settings with implications to the research within the EHE Initiative

Borsika Rabin, PhD, MPH, PharmD
Russell Glasgow, PhD
Presenters:

**Borsika A. Rabin, PhD, MPH, PharmD**
UC San Diego ACTRI Dissemination and Implementation Science Center/SD CFAR IS Hub
Herbert Wertheim School of Public Health and Human Longevity Science
University of California San Diego
barabin@health.ucsd.edu
@BorsikaRabin
disc.ucsd.edu

**Russell E. Glasgow, PhD**
ACCORDS Dissemination and Implementation Program, School of Medicine
University of Colorado
russell.glasgow@cuanschutz.edu
@RussGlasgow

Acknowledgements:

Collaborators and colleagues:
- Ana, Bauman, Shannon Wiltsey Stirman, Christopher Miller
- Marina McCreight, Michaela McCarthy, Lexus Ujano-DeMotta, Catherine Battaglia, Nicole Stadnick, Clare Viglione, Jessica Montoya, and many others

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Topics for today

• Overview of key concepts of adaptations as they relate to complex, real-world interventions

• Overview of approaches for the planning of adaptations prior to implementation

• Documenting and analyzing adaptations including their impact

• Introduce one pragmatic way to guide adaptations: Iterative RE-AIM

• Reflections on current status and future directions and opportunities
Poll the Audience

1. What is your experience with adaptations in your current projects?
   - My project has made **planned adaptations**
   - My project has made **unplanned adaptations**
   - My project has made both **planned and unplanned adaptations**
   - My project did not make any adaptations but they are **happening on the ground**
   - My project **did not make any adaptations** at all
Adaptation defined

#1: Adaptations are changes or modifications to an intervention, an implementation strategy, or the context.

#2: Changes or modifications can be deliberate or accidental (i.e., drift).

#2: Adaptation often occur to improve the fit (or compatibility) of the intervention/implementation strategy to a new context (e.g., population, setting, etc).

#3: Adaptations are common and (some researchers suggest) inevitable to meet the needs of a specific context.

#4: Adaptations might lessen the effectiveness if they compromise the core elements and underlying logic of the intervention.

Attention to BOTH program fidelity and adaptation during the complex process of program implementation is critical to successful, sustained implementation of evidence-based programs.
Adaptation is not good or bad, it just happens...

Adaptation as inherent – perhaps crucial – to the implementation process

Regarding local adaptations, cultural adaptation, and other efforts to improve fit as flaws in implementation fidelity is *at best a missed opportunity, and at worst, a recipe for implementation failure*


## Adaptations – when and what?

<table>
<thead>
<tr>
<th>Focus of Adaptation</th>
<th>Timing of Adaptation - Point in the Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Planning Pre-implementation</td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
</tr>
<tr>
<td>Strategy</td>
<td></td>
</tr>
<tr>
<td>Context</td>
<td></td>
</tr>
</tbody>
</table>

Balancing fidelity and adaptation

#1: Identify core components/functions and flexible components/forms of the intervention

#2: Make adaptations intentional through planning and based on data

#3: Assess and document adaptations throughout the process
What makes an intervention complex?


Craig et al. Developing and evaluating complex interventions: the new Medical Research Council guidance BMJ 2008;337:a1655

Guise et al AHRQ series on complex intervention systematic reviews/paper 1: an introduction to a series of articles that provide guidance and tools for reviews of complex interventions JCE 2017;90:43-50.

UK Medical Research Council: Developing and Evaluating Complex Interventions

PCORI Methodology Standards:
https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards

Definition of complex interventions

All complex interventions have two common characteristics; they have multiple components (intervention complexity) and complicated/multiple causal pathways, feedback loops, synergies, and/or mediators and moderators of effect (pathway complexity). In addition, they may also have one or more of the following three additional characteristics; target multiple participants, groups, or organizational levels (population complexity); require multifaceted adoption, uptake, or integration strategies (implementation complexity); or work in a dynamic multidimensional environment (contextual complexity)

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviors required by those delivering or receiving the intervention
- Number of groups or organizational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted
It is not easy to untangle....

AND

CORE COMPONENTS

DISCRETIONARY COMPONENTS

Hawe et al. BMJ 2004;328:1561–3
TRANS(ending) the HIV Epidemic –
Drs. Laramie Smith and Jill Blumenthal

Core functions = the key processes/mechanisms of an intervention

Forms = specific activities that may be customized to local contexts that are needed to carry out the core functions

Hawe et al. Complex interventions: how “out of control” can a randomised controlled trial be? BMJ 2004;328:1561–3
Jolles et al. 2019 in Journal of General Internal Medicine “Core functions and forms of complex health interventions: a patient-centered medical home”
<table>
<thead>
<tr>
<th>Motivating need/problem</th>
<th>Core function (standardized)</th>
<th>Form (locally defined)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EBP = PrEP peer navigation program</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-centered care</td>
<td>A. Foster a relationship-based care (vs. impersonal)</td>
<td>I. Peer navigator shares personal experience accessing PrEP with patient, which is then used as a guide to develop the patient’s action plan for addressing barriers to accessing PrEP</td>
</tr>
<tr>
<td>Lack of provider-patient relationship that is based on mutual trust and responsibility</td>
<td>B. Educate and support patients in learning to manage their own care</td>
<td>II. Peer navigator models skills (e.g., role play conversations) for patient</td>
</tr>
</tbody>
</table>

Adapted from Jolles et al. 2019 in *Journal of General Internal Medicine*  
“Core functions and forms of complex health interventions: a patient-centered medical home”
A scoping study of frameworks for adapting public health evidence-based interventions

Cam Escoffery,1 Erin Lebow-Skelley,1 Hallie Udelson,1 Elaine A. Böing,1 Richard Wood,2 Maria E. Fernandez,2 Patricia D. Mullen2

Abstract
Evidence-based public health translation of research to practice is essential to improve the public’s health. Dissemination and implementation researchers have explored what happens once practitioners adopt evidence-based interventions (EBIs) and have developed models and frameworks to describe the adaptation process. This scoping study identified and summarized adaptation frameworks in published reports and grey literature. We followed the recommended steps of a scoping study: (a) identifying the research question; (b) identifying relevant studies; (c) selecting studies; (d) charting the data; (e) collating, summarizing, and reporting the results; and (f) consulting with experts. We searched PubMed, PsycINFO, PsycNET, and CINAHL databases for articles referencing adaptation frameworks for public health interventions in the published and gray literature, and from reference lists of framework articles. Two reviewers independently coded the frameworks and their steps and identified common steps. We found 13 adaptation frameworks

Implications
Practice: These frameworks can offer guidance for steps in the adaptation process for evidence-based interventions (EBIs).

Policy: Funders or agencies that recommend the use of EBIs should encourage organizations implementing them to report on any adaptation and the steps taken for the modifications.

Research: Future research should examine the use of these frameworks in adaptations of EBIs in the field and their impacts on health.
<table>
<thead>
<tr>
<th>Step name</th>
<th>Step descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess community</td>
<td>• Identify behavioral determinants and risk behaviors of the new target population using focus groups, interviews, needs assessments, and logic models</td>
</tr>
<tr>
<td></td>
<td>• Assess organizational capacity to implement the program</td>
</tr>
<tr>
<td>2. Understand the intervention</td>
<td>• Identify and review relevant EBPs and their program materials</td>
</tr>
<tr>
<td></td>
<td>• Understand the theory behind the programs and their core elements</td>
</tr>
<tr>
<td>3. Select intervention</td>
<td>• Select the program that best matches the new population and context</td>
</tr>
<tr>
<td>4. Consult with experts</td>
<td>• Consult content experts, including original program developers, as needed</td>
</tr>
<tr>
<td></td>
<td>• Incorporate expert advice into program</td>
</tr>
<tr>
<td>5. Consult with stakeholders</td>
<td>• Seek input from advisory boards and community planning groups where program implementation takes place</td>
</tr>
<tr>
<td></td>
<td>• Identify stakeholder partners who can champion program adoption in new setting and ensure program fidelity</td>
</tr>
<tr>
<td>6. Decide what needs adaptation</td>
<td>• Decide whether to adapt or implement original program</td>
</tr>
<tr>
<td></td>
<td>• Theater test selected EBP using new target population and other stakeholders to generate adaptations</td>
</tr>
<tr>
<td></td>
<td>• Determine how original and new target population/setting differ in terms of risk and protective factors</td>
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<tr>
<td></td>
<td>• Identify areas where EBP needs to be adapted and include possible changes in program structure, content, provider, or delivery methods</td>
</tr>
<tr>
<td></td>
<td>• Retain fidelity to core elements</td>
</tr>
<tr>
<td></td>
<td>• Systematically reduce mismatches between the program and the new context</td>
</tr>
<tr>
<td>7. Adapt the original program</td>
<td>• Develop adaptation plan</td>
</tr>
<tr>
<td></td>
<td>• Adapt the original program contents through collaborative efforts</td>
</tr>
<tr>
<td></td>
<td>• Make cultural adaptations continuously through piloting testing, flexible components responsible for change should not be modified</td>
</tr>
<tr>
<td>8. Train staff</td>
<td>• Select and train staff to ensure quality implementation</td>
</tr>
<tr>
<td>9. Test the adapted materials</td>
<td>• Pretest adapted materials with stakeholder groups</td>
</tr>
<tr>
<td></td>
<td>• Conduct readability tests</td>
</tr>
<tr>
<td></td>
<td>• Pilot test adapted EBP in new target population</td>
</tr>
<tr>
<td></td>
<td>• Modify EBP further if necessary</td>
</tr>
<tr>
<td>10. Implement</td>
<td>• Develop implementation plan based on results generated in previous steps</td>
</tr>
<tr>
<td></td>
<td>• Identify implementers, behaviors, and outcomes</td>
</tr>
<tr>
<td></td>
<td>• Develop scope, sequence, and instructions</td>
</tr>
<tr>
<td></td>
<td>• Execute adapted EBP</td>
</tr>
<tr>
<td>11. Evaluate</td>
<td>• Document the adaptation process and evaluate the process and outcomes of the adapted intervention as implemented</td>
</tr>
<tr>
<td></td>
<td>• Write evaluation questions, choose indicators, measures, and the evaluation design; plan data collection, analysis, and reporting</td>
</tr>
<tr>
<td></td>
<td>• Employ empowerment evaluation approach framework to improve program implementation</td>
</tr>
</tbody>
</table>
The ADAPT-ITT Model
A Novel Method of Adapting Evidence-Based HIV Interventions

Gina M. Wingood, ScD, MPH*† and Ralph J. DiClemente, PhD*‡†‡

<table>
<thead>
<tr>
<th>Phase</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assessment</td>
<td>• Conducted focus groups with young adult Zulu-speaking women</td>
</tr>
<tr>
<td></td>
<td>• Conducted focus groups with key stakeholders in a rural primary care clinic in KwaZulu-Natal</td>
</tr>
<tr>
<td></td>
<td>• Conducted elicitation interviews with key stakeholders who were HIV/AIDS prevention scientists</td>
</tr>
<tr>
<td></td>
<td>• Analyzed results of formative evaluations</td>
</tr>
<tr>
<td>2. Decision</td>
<td>• Decided to adapt the SiHLE HIV intervention defined as an EBI by the CDC⁵</td>
</tr>
<tr>
<td>3. Administration</td>
<td>• Administered theater test with Zulu adolescents</td>
</tr>
<tr>
<td></td>
<td>• Analyzed results of the theater test</td>
</tr>
<tr>
<td>4. Production</td>
<td>• Produced draft 1 of the adapted EBI and developed process measures</td>
</tr>
<tr>
<td>5. Topical Experts</td>
<td>• Identified 3 topical experts knowledgeable about HIV prevention and the population of Zulu-speaking adolescents living in KwaZulu-Natal, the target audience for intervention</td>
</tr>
<tr>
<td>6. Integration</td>
<td>• Integrated content from topical experts and created draft 2 of the adapted EBI</td>
</tr>
<tr>
<td></td>
<td>• Integrated scales that measure new intervention content in the study survey</td>
</tr>
<tr>
<td></td>
<td>• Integrated readability testing into draft 2 of the EBI to create draft 3</td>
</tr>
<tr>
<td>7. Training</td>
<td>• Trained recruiters, facilitators, assessors and data management staff to implement draft 3 of the adapted EBI</td>
</tr>
<tr>
<td>8. Testing</td>
<td>• Pilot study is being planned</td>
</tr>
</tbody>
</table>

Step 1: Document Needs & Build Logic Model
- Describe needs and goals
- Describe personal determinants and individuals in the environment
- Create logic model of change

Step 2: Search for EBIs
- Find EBIs
- Review EBIs for basic fit
- Select EBIs for further review

Step 3: Assess Fit & Plan Adaptations
- Describe EBI materials and activities, content, design and delivery
- Compare EBI with logic model
- Make adaptation decisions

Step 4: Make Adaptations
- Link adaptation decisions with specific EBI materials and activities
- Pre-test
- Implementation plan for the adapted EBI
- Scope & Sequence

Step 5: Test Your Progress
- List process evaluation questions
- List outcome evaluation questions

Helps planners:
1. Document their community needs and expected logic of change
2. Search for EBA and determine potential fit
3. Characterize the EBA to identify the core elements and keep them intact during adaptation
4. Base changes on your community assessment results
5. Develop/adapt and implementation and evaluation plan.

imadapt.org
Asystematic review of adaptations of evidence-based public health interventions globally

Cam Escoffery1, E. Lebow-Skelley1, R. Haarderfer1, E. Boing1, H. Udelson1, R. Wood2, M. Hartman2, M. E. Fernandez2 and P. D. Mullen2

Abstract

Background: Adaptations of evidence-based interventions (EBIs) often occur. However, little is known about the reasons for adaptation, the adaptation process, and outcomes of adapted EBIs. To address this gap, we conducted a systematic review to answer the following questions: (1) What are the reasons for and common adaptations being made to EBIs in community settings as reported in the published literature? (2) What steps are taken in the process of adaptation? and (3) What outcomes are assessed in evaluations of adapted EBIs?

Methods: We conducted a systematic review of English-language publications that described adapted EBIs. We searched Ovid PubMed, PsycINFO, PsycNET, and CINAHL and citations of included studies for adapted EBIs. We abstracted characteristics of the original and adapted populations and settings, adaptations, types of modifications, use of an adaptation framework, adaptation steps, and evaluation studies.

Results: Forty-two distinct EBIs were found focusing on HIV/AIDS, mental health, substance abuse, and chronic diseases. More than half (62%) of studies reported on adaptations in the USA. Frequent reasons for adaptation included the need for cultural appropriateness (64.3%), focusing on a new target population (59.5%), and implementing in a new setting (57.1%). Common adaptations were content (100%), context (95.2%), and delivery (61.9%). Most study authors conducted a community assessment, prepared new materials, and implemented the adapted intervention, evaluated or planned to evaluate the intervention, determined needed changes, trained staff members, and consulted experts/stakeholders. Most studies that reported evaluation included behavioral outcomes (71.4%), acceptability (66.7%), fidelity (52.4%), and feasibility (51.2%). Fewer studies measured adoption (47.6%) and changes in practice (21.4%).

Conclusions: These findings advance our understanding of the patterns and effects of modifications of EBIs that are reported in published studies and suggest areas of further research to understand and guide the adaptation process. Furthermore, findings can inform better reporting of adapted EBIs and inform capacity building efforts to assist health professionals in adapting EBIs.

Keywords: Adaptation, Intervention, Modifications, Implementation, Evidence-based
WHY document adaptations?

- Create an **organized list of adaptations** that future implementers can consider for success
- Provide **contextual process data** to interpret outcomes (i.e., how adaptations contribute to outcomes)
- Consider **refinements** to the recommended intervention & implementation strategies based on observed changes
- Propose **refinements** to existing frameworks and measurement approaches and develop a replicable, easy-to-use documentation method for adaptations/modifications
- Anticipate and **describe the impact of adaptations**
- **Challenges:** conceptual/historical and methodological
Don't Let 'Perfect' Be the Enemy of 'Done'
The FRAME: an expanded framework to report adaptations and modifications

WHEN did the modification occur?
- Pre-implementation/planning/pilot
- Implementation
- Scale up
- Maintenance/Sustainment

Were adaptations planned?
- Planned/Proactive (proactive adaptation)
- Planned/Reactive (reactive adaptation)
- Unplanned/Reactive (modification)

WHO participated in the decision to modify?
- Political leaders
- Program Leader
- Funder
- Administrator
- Program manager
- Intervention developer/ployer
- Researcher
- Treatment/Intervention team
- Individual Practitioners (those who deliver it)
- Community members
- Recipients

Optional: Indicate who made the ultimate decision.

WHAT is modified?
Content
- Modifications made to content itself, or that impact how aspects of the treatment are delivered
Contextual
- Modifications made to the way the overall treatment is delivered

Training and Evaluation
- Modifications made to the way that staff are trained in or how the intervention is evaluated

Implementation and scale-up activities
- Modifications to the strategies used to implement or spread the intervention

At what LEVEL OF DELIVERY (for whom/what is the modification made ?)
- Individual
- Target Intervention Group
- Cohort/individuals that share a particular characteristic
- Individual practitioner
- Clinic/unit level
- Organization
- Network
- System/Community

Contextual modifications are made to which of the following?
- Format
- Setting
- Personnel
- Population

What is the NATURE of the content 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 intervention modules or segments
- Spreading (breaking up session content over multiple sessions)
- Integrating parts of the intervention into another framework (e.g., selecting elements)
- Integrating another treatment into EBP (not using the whole protocol and integrating other techniques into a general EBP approach)
- Repeating elements or modules
- Looseing structure
- Departing from the intervention (“drift”) followed by a return to protocol within the encounter
- Drift from protocol without returning

Relationship fidelity/core elements?
- Fidelity Consistent/Core elements or functions preserved
- Fidelity Inconsistent/Core elements or functions changed
- Unknown

When did the modification occur?
- Pre-implementation/planning/pilot
- Implementation
- Scale up
- Maintenance/Sustainment

Was the modification planned?
- Planned/Proactive (proactive adaptation)
- Planned/Reactive (reactive adaptation)
- Unplanned/Reactive (modification)

Who participated in the decision to modify?
- Political leaders
- Program Leader
- Funder
- Administrator
- Program manager
- Intervention developer/ployer
- Researcher
- Treatment/Intervention team
- Individual Practitioners (those who deliver it)
- Community members
- Recipients

Optional: Indicate who made the ultimate decision.

What was the goal?
- Increase reach or engagement
- Increase retention
- Improve feasibility
- Improve fit with recipients
- To address cultural factors
- Improve effectiveness/outcomes
- Reduce cost
- Increase satisfaction

SOCIOPOLITICAL
- Existing Laws
- Existing Mandates
- Existing Policies
- Existing Regulations
- Political Climate
- Funding Policies
- Historical Context
- Societal/Cultural Norms
- Funding or Resource Allocation/Availability
- Available resources (funds, staffing, technology, space)
- Competing demands or mandates
- Time constraints
- Service structure
- Location/accessibility
- Regulatory/compliance
- Billing constraints
- Social context (culture, climate, leadership support)
- Mission
- Cultural or religious norms

ORGANIZATION/SETTING
- Race
- Ethnicity
- Sexual/gender identity
- First/spoken languages
- Previous Training and Skills
- Preferences
- Clinical Judgement
- Cultural norms, competency
- Perception of intervention
- Comfort with Technology

REASONS
- Race
- Ethnicity
- Gender identity
- Sexual Orientation
- Access to resources
- Cognitive capacity
- Physical capacity
- Literacy and education level
- First/spoken languages
- Motivation and readiness
- Comfort with technology

When, what, and how document adaptations?

<table>
<thead>
<tr>
<th>Focus of Adaptation</th>
<th>Planning Pre-implementation</th>
<th>During Implementation</th>
<th>Following Sustainment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strategy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Context</td>
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<td></td>
</tr>
</tbody>
</table>

**Methods to Assess Adaptation**

1. Observational techniques
2. Focused interviews
3. Questionnaires, checklists, and logs
4. Content analysis of key documents and curricula
5. Study databases and clinical databases

Systematic, Multimethod Assessment of Adaptations Across Four Diverse Health Systems Interventions

Borsika A. Rabin1,2,3,4*, Marina McCreight1, Catherine Battaglia1,5, Roman Ayele1,5, Robert E. Burke1,6, Paul L. Hess1,6, Joseph W. Frank1,6 and Russell E. Glasgow1,3,4

1 Denver-Seattle Center of Innovation for Veteran-Centered and Value-Driven Care (COIN), Denver VHA Medical Center, Denver, CO, United States, 2 Department of Family Medicine and Public Health, School of Medicine, University of California San Diego, La Jolla, CA, United States, 3 Adult and Child Consortium for Health Outcomes Research and Delivery Science, School of Medicine, University of Colorado, Aurora, CO, United States, 4 Department of Family Medicine, School of Medicine, University of Colorado, Aurora, CO, United States, 5 Department of Health System Management and Policy, Colorado School of Public Health, University of Colorado, Aurora, CO, United States, 6 Department of Medicine, School of Medicine, University of Colorado, Aurora, CO, United States
Triangulation of data

Full Picture of Adaptations

- SURVEYS
- OBSERVATION
- INFORMAL CHECK-IN WITH TEAMS
- PERIODIC REFLECTIONS
- REAL-TIME DATABASE
- INTERVIEWS
- PROCESS MAPS
- MEETING NOTES
- ELECTRONIC RECORDS
- CHECKLISTS &LOGS
Sample Interview Questions

WHAT component or part of the intervention was changed in this adaptation; in other words, what was the nature of the change? (For instance, was it a change to program content, format, delivery mode, staff delivering it, patients eligible, where, when or how it was delivered, or what?)

WHO was responsible for first suggesting or initiating this change? (Was this the person or persons the ones who implemented the change? (If not, who implemented the adaptation?))

WHEN during the ___ program was this adaptation first made?

WHY was this adaptation made? (For example, to get more people to participate, to make the program attractive to more settings, to increase its effectiveness, to make it easier to deliver, to make it easier to maintain or reduce costs, etc.?)
## Example Tracking form

<table>
<thead>
<tr>
<th>Date of the modification</th>
<th>4/15/2016</th>
<th>6/2/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of the modification</td>
<td>ISurvey questions reordered - moved the Rose Dyspnea questionnaire to the end.</td>
<td>Revised patient letter to include information about automated pre-procedural phone calls.</td>
</tr>
<tr>
<td>Reason for the modification</td>
<td>To improve fluidity of the survey and enhance data capture</td>
<td>To prepare patients for data collection</td>
</tr>
<tr>
<td>BY WHOM are modifications made?</td>
<td>Researcher</td>
<td>Researcher</td>
</tr>
<tr>
<td>WHAT is modified?</td>
<td>Order of data collection</td>
<td>Content of the intervention</td>
</tr>
<tr>
<td>At what LEVEL OF DELIVERY?</td>
<td>Individual patient level</td>
<td>Individual patient level</td>
</tr>
<tr>
<td>CONTEXT modifications are made to…</td>
<td>Intervention format</td>
<td>Intervention format</td>
</tr>
<tr>
<td>What is the NATURE of the Content modification?</td>
<td>Tailoring/tweaking/refining</td>
<td>Tailoring/tweaking/refining</td>
</tr>
</tbody>
</table>

### Notes
- Date of the modification: 4/15/2016, 6/2/2016
- Description of the modification:
  - 4/15/2016: ISurvey questions reordered - moved the Rose Dyspnea questionnaire to the end.
  - 6/2/2016: Revised patient letter to include information about automated pre-procedural phone calls.
- Reason for the modification:
  - 4/15/2016: To improve fluidity of the survey and enhance data capture.
  - 6/2/2016: To prepare patients for data collection.
- BY WHOM are modifications made?:
  - Researcher
- WHAT is modified?:
  - Order of data collection
  - Content of the intervention
- At what LEVEL OF DELIVERY?:
  - Individual patient level
- CONTEXT modifications are made to…: Intervention format
- What is the NATURE of the Content modification?:
  - Tailoring/tweaking/refining
Periodic reflections: a method of guided discussions for documenting implementation phenomena

Erin P. Finley1,2,3, Alexis K. Huynh3,4, Melissa M. Farmer24, Bevanne Bean-Mayber2,4,5, Tannaz Moin3,4,5, Sabine M. Oishi3,4, Jessica L. Moreau2,4, Karen E. Dyer24, Holly Jordan Lanham1,2, Luci Leykum1,2 and Alison B. Hamilton3,4,5

Towards a comprehensive model for understanding adaptations’ impact: the model for adaptation design and impact (MADI)

M. Alexis Kirk1, Julia E. Moore2, Shannon Wiltsey Stirman3 and Sarah A. Birken4

Health plan adaptations to a mailed outreach program for colorectal cancer screening among Medicaid and Medicare enrollees: the BeneFIT study

Gloria D. Coronado1, Jennifer L. Schneider1, Beverly B. Green2, Jennifer K. Couy3, Malaika R. Schwartz4, Yogini Kulkarni-Sharma5 and Laura Mae Baldwin1
Poll the Audience

How familiar are you with the RE-AIM framework?

- I have **read about it** in publications
- I have **used it** in my own research for planning, implementation, or evaluation
- I am **not familiar** with the RE-AIM framework
Making Implementation Science More Rapid: Use of the RE-AIM Framework for Mid-Course Adaptations Across Five Health Services Research Projects in the Veterans Health Administration

Russell E. Glasgow¹,²*, Catherine Battaglia³,⁴,⁵, Marina McCreight⁶, Roman Aydiko Ayele⁷ and Borsika Adrienn Rabin⁸,⁹,¹⁰
# Pragmatic Use of RE-AIM

<table>
<thead>
<tr>
<th>RE-AIM Dimension</th>
<th>Key Pragmatic Priorities to Consider and Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>WHO is (was) intended to benefit and who actually participates or is exposed to the intervention?</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>WHAT is (was) the most important benefits you are trying to achieve and what is (was) the likelihood of negative outcomes?</td>
</tr>
<tr>
<td>Adoption</td>
<td>WHERE is (was) the program or policy applied and WHO applied it?</td>
</tr>
<tr>
<td>Implementation</td>
<td>HOW consistently is (was) the program or policy delivered, HOW will (was) it be adapted, HOW much will (did) it cost, and WHY will (did) the results come about?</td>
</tr>
<tr>
<td>Maintenance</td>
<td>WHEN will (was) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)?</td>
</tr>
</tbody>
</table>

Glasgow RE and Estabrooks P. Pragmatic application of RE-AIM. *Preventing Chronic Disease*, 2018; 15:E02
Rationale for Iterative RE-AIM: More Rapid

• D&I Frameworks are often cited, but frequently not used throughout a proposal or project

• If frameworks are used, it is almost always for either planning or evaluation (RE-AIM has been used most for evaluation, but also successfully for planning)

• Neither RE-AIM nor most other D&I models have been used iteratively to guide adaptations at key points

• A major limitation to D&I models and methods is that they are much slower than needed by stakeholders

Glasgow, RE .... & Rabin B. Making implementation science more rapid. (2020) Frontiers Public Health. 8: 194
Study Purpose

• To develop a pragmatic, replicable iterative RE-AIM implementation strategy bundle to inform mid-course corrections

• To use this audit and feedback implementation strategy bundle based on RE-AIM to help stakeholder implementation teams guide adaptations

• To provide a conceptual and data-based process to help stakeholders reflect upon progress, set priorities, and develop action plans

• To test this process across 5 different VA health services research projects (on pain, care transitions, cardiac care, rural health)

Steps in Iterative RE-AIM Process

- **Step 1:** Project team reviewed the specification of RE-AIM dimensions developed at the beginning of the project, and discussed the Iterative RE-AIM process.

- **Step 2:** Team members completed independent ratings on each RE-AIM dimension in terms of a) its importance at the present stage of the project and b) progress to date on that dimension.

- **Step 3:** A second team meeting reviewed summarized ratings from the individual rating sheets. A group engagement, reflection and discussion process was used to identify one to two key RE-AIM dimensions on which to focus and develop SMART goals and action plans.

- **Step 4:** A follow-up interview with the PI and project manager for each project regarding their progress on the implementation of the action plans, as well as collect data on the feasibility and usefulness of the iterative RE-AIM process.

RE-AIM Assessment Rating Form

Please rate each question below regarding the importance of and the need to enhance each RE-AIM dimension in your project. Use your best estimate to provide a 1-5 rating for each item even if you are not sure or do not feel you have quite enough information. Please refer to the documents provided to you through the preliminary meeting (RE-AIM measure table and RE-AIM handouts). Use the comment section to explain your ratings and make initial suggestions on how to enhance the given RE-AIM dimension.

• REACH (to eligible Veterans)

<table>
<thead>
<tr>
<th>How important is Reach to this project, at this time?</th>
<th>How satisfied are you with progress to date on Reach?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = not important</td>
<td>1 = not satisfied</td>
</tr>
<tr>
<td>2 = somewhat important</td>
<td>2 = somewhat satisfied</td>
</tr>
<tr>
<td>3 = important</td>
<td>3 = satisfied</td>
</tr>
<tr>
<td>4 = moderately important</td>
<td>4 = moderately satisfied</td>
</tr>
<tr>
<td>5 = extremely important</td>
<td>5 = extremely satisfied</td>
</tr>
</tbody>
</table>

Comments:
Sample “Gap” Report

Patient Reported Health Status Assessment

<table>
<thead>
<tr>
<th>Importance</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance: 4.50</td>
<td>Progress: 2.50</td>
</tr>
<tr>
<td>Importance: 3.83</td>
<td>Progress: 2.67</td>
</tr>
<tr>
<td>Importance: 4.50</td>
<td>Progress: 3.17</td>
</tr>
<tr>
<td>Importance: 3.20</td>
<td>Progress: 3.40</td>
</tr>
<tr>
<td>Importance: 3.33</td>
<td>Progress: 2.83</td>
</tr>
</tbody>
</table>

REACH | EFFECTIVENESS | ADOPTION | IMPLEMENTATION | MAINTENANCE
Results

• A median of seven team members participated in the two meetings. Qualitative and descriptive data revealed that the process was feasible, and understandable to teams in adjusting their interventions and implementation strategies.

• The RE-AIM dimensions identified as most important were adoption and effectiveness, and the dimension that had the largest gap between importance and rated progress to that point was reach.

• The dimensions most frequently selected for improvement were reach and adoption.

• Follow-up meetings indicated that teams found the process very helpful and were able to implement the action plans they set.
## RE-AIM Dimensions and key phrase from action plans

<table>
<thead>
<tr>
<th>Project Name</th>
<th>RE-AIM Dimension Focus</th>
<th>SMART Goals and Action Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-Reported Health Status Assessment</td>
<td>REACH</td>
<td>1. Conduct workflow assessments to learn where it would fit and how&lt;br&gt;2. Perform chart review to learn about actions taken after decline status note in the EMR</td>
</tr>
<tr>
<td></td>
<td>ADOPTION</td>
<td></td>
</tr>
<tr>
<td>Multimodal Pain</td>
<td>EFFECTIVENESS</td>
<td>1. Effectiveness: summarize feedback from semi-structured interviews with providers and review for opportunities to improve program sessions; share the feedback with operational partners&lt;br&gt;2. Adoption: inform providers of the upcoming sessions;&lt;br&gt;3. Engage/re-engage with program stakeholders for assistance and guidance</td>
</tr>
<tr>
<td></td>
<td>ADOPTION</td>
<td></td>
</tr>
<tr>
<td>Community Transitions</td>
<td>REACH</td>
<td>1. Conduct in-services with community hospital to educate about the program enrollment criteria&lt;br&gt;2. Interview other investigators about how they approach REACH in their projects&lt;br&gt;3. Consider giving out Veterans program cards pro-actively&lt;br&gt;4. Review and revise program exclusion criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced Care Coordination</td>
<td>REACH</td>
<td>1. Schedule and conduct educational in-services in participating community hospitals.&lt;br&gt;2. Program social worker to identify best practices of approach at each participating community hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural Transitions</td>
<td>REACH</td>
<td>1. Review existing literature and plan to collect and analyze real-time return on investment-type data&lt;br&gt;2. Access operational data and performance measures to compare with program outcomes&lt;br&gt;3. Discuss with site champions about what leadership and stakeholders need to sustain the program</td>
</tr>
<tr>
<td></td>
<td>MAINTENANCE</td>
<td></td>
</tr>
</tbody>
</table>
Optimizing the efficiency and implementation of cash transfers to improve adherence to antiretroviral therapy: study protocol for a cluster randomized controlled trial

Laura Packel¹*, Prosper Njau², Carolyn Fahey¹, Angela Ramadhani³, William H. Dow⁴, Nicholas P. Jewell⁵,⁶ and Sandra McCoy⁷

HHS Public Access
Author manuscript
J Acquir Immune Defic Syndr. Author manuscript; available in PMC 2020 December 01.

Published in final edited form as:

Implementation Science using Proctor’s Framework and an adaptation of the Multiphase Optimization Strategy (MOST): Optimizing a Financial Incentive Intervention for HIV Treatment Adherence in Tanzania

Laura Packel¹, Carolyn Fahey¹, Prosper Njau²,³, Sandra I. McCoy¹
¹University of California, Berkeley, School of Public Health
²Health for a Prosperous Nation, Dar es Salaam, Tanzania
³MOHCGEC
Application of Iterative RE-AIM to ART Adherence Program (a hypothetical example)

Steps involved:

1. Team identifies RE-AIM goals (e.g., reach: 60%; adherence level (effectiveness): 75%; staff implementation: 80% fidelity)
2. Assess these 3 outcomes approximately every 4 months
3. Based on decision by full team of stakeholders, select 1-2 RE-AIM target areas on which to adapt the implementation approach
4. Repeat as needed for at least for 3 cycles
Application of Iterative RE-AIM to ART Adherence Program (a hypothetical example)

• Assume the **first iterative assessment** finds reach of 35% (goal of 60%) and inequitable participation); 80% adherence among participants; and 65% (goal = 80%) of staff delivering incentives as in protocol

• Potential decision- work on reach by changing who approaches potential participants, how this is framed and the locations in which recruitment takes place

• Assume **second iterative assessment** finds increased reach (now 55% and more equitable) but now adherence has dropped to 60%

• Potential decision: increase cash incentive amount from $10 to $25
Limitations

• Small number of teams and sample size; and that all were VA projects.
• At least some members of each team had used RE-AIM before.
• Although explicitly involved all implementation team members, it did not include Veteran patients or organizational decision makers.
• Did not experimentally compare this process to other approaches or use of other implementation science frameworks.

Future directions

• Replication in non-VA settings and projects that did not use RE-AIM in their initial proposal.
• More formal evaluation of the long-term impact.
• Assess different timing and intensities and cost-effectiveness of iterative assessments
Conclusions

• Iterative RE-AIM, while still in need of refinement and replication, was helpful across five diverse health services projects, implementation teams, different project phases and content areas.

• This novel application of an implementation science framework driven improvement process appears feasible.

• The rapid, mid-course evaluation process enhanced the practitioner relevance of implementation science approaches and facilitated teams reflecting on their project.

• Adaptations will happen; the Iterative RE-AIM process provides a conceptual and data-driven approach to guide such adaptations.
Summary

- Complex interventions usually can be, will be, and should be adapted

- Adaptation should be:
  - embraced, studied, and guided rather than
  - ignored, and/or
  - Suppressed

- Adaptations are best made based on data/evidence (broadly speaking)

Presentation by Brian Mittman
PCORI Methodology Standards:
https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards
Adapt study – DECIPHer

https://decipher.uk.net/portfolio/the-adapt-study

The development of guidance was underpinned by three key work packages:

- A systematic review of existing guidance and a scoping review of practice in adaptation of interventions for new contexts;

- Qualitative interviews with researchers, funder, journal editors and policy and practice stakeholders about current practice and future directions;

- An expert consensus process, including a 3 round e-DELPHI and a series of online meetings of international experts to discuss a draft of the guidance.
Adaptation, Fidelity, and Tailoring group

• The group **began in January 2016** as part of the IRG

• We currently have **over a 100 members**

• Representation from **many QUERIs**, including: TRIPLE AIM, CIVIC, PROVE, CARRIAGE, EMPOWER, IMPROVE, Bridge, PRISM, and Optimizing Function and Independence

• Members from and outside of the VA nationally and internationally

• Co-chaired by **Borsika Rabin** and **Russell Glasgow** and facilitated by **Christine P. Kowalski**

• We meet **monthly to discuss topics related to adaptation, tailoring and fidelity** with attention to clinical application

• Discussions include how to **define interventions** and **implementation strategies** as well as how to **describe and document adaptations**
# Context and Adaptation in Dissemination & Implementation Research (CLSC 7663)

<table>
<thead>
<tr>
<th>Overview</th>
<th>This course covers concepts, frameworks, and methods for understanding and assessing the context and guiding adaptations as relevant to dissemination and implementation (D&amp;I) health research and practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructor</td>
<td>Christina Studts, PhD, MSPH, LCSW, and Borsika Rabin, PhD, MPH, PharmD</td>
</tr>
<tr>
<td>Meeting Time</td>
<td>Fridays, 11:00am-12:30pm Mountain Time</td>
</tr>
<tr>
<td>Semester</td>
<td>Spring 2021 (February 4 – April 22)</td>
</tr>
<tr>
<td>Format</td>
<td>Fully online, using a combination of real-time video conferences and self-guided study</td>
</tr>
<tr>
<td>Capacity</td>
<td>15 students</td>
</tr>
<tr>
<td>Semester Hours</td>
<td>2</td>
</tr>
<tr>
<td>Key Topics</td>
<td>Topics include the importance of context and key multilevel contextual factors such as policy, history, and organizational climate; types of adaptations (cultural, local); how to conceptualize and assess both context and adaptations; selected tools for D&amp;I research and practice; and emerging and future issues related to context and adaptation.</td>
</tr>
</tbody>
</table>
DO YOU HAVE ANY QUESTIONS?

- Leaves
- Seeds
- Insects
- Buds/Fruit
- Various
“Implementing a program is like constructing a building. An architect draws upon general engineering principles (theory) to design a building that will serve the purposes for which it is designed. However, the specific building that results is strongly influenced by parameters of the building site, such as the lot size, the nature of the site’s geological features, the composition of the soil, the incline of the surface, the stability and extremes of climate, zoning regulations, and cost of labor and materials.

The architect must combine architectural principles with site parameters to design a specific building for a specific purpose on a specific site....This dynamic is mirrored in the rough-and-tumble world of the human services. Despite excellent plans and experience, ongoing redesign and adjustment may be necessary.”

-- Bauman at al. 1991
Select resources


Stirman lab on FRAME and related resources: http://med.stanford.edu/fastlab/research/adaptation.html


Evidence-Based...on what?
Key Equity Related Criteria on which to evaluate program progress- seldom used

- Participant **Representativeness and Equity**
- **Setting** Representativeness and Diversity
- **Context, Setting and Generalizability**
- **Feasibility and Fidelity**
- Community/Setting Engagement
- **Sustainability- and equity of settings and individuals** sustaining programs and improvements
- **Costs/Feasibility**
PRISM CONTEXTUAL FACTORS

EXTERNAL CONTEXT
- EXTERNAL ENVIRONMENT
  - POLICY
  - RESOURCES
  - GUIDELINES
  - INCENTIVES

INTERNAL CONTEXT
- MULTI-LEVEL ORGANIZATIONAL & PATIENT CHARACTERISTICS
- MULTI-LEVEL ORGANIZATIONAL & PATIENT PERSPECTIVES (VALUES)
- IMPLEMENTATION & SUSTAINABILITY INFRASTRUCTURE

FIT AMONG AND INTERACTIONS AMONG ALL OF:
- INTERVENTION COMPONENTS
- IMPLEMENTATION STRATEGIES
- INNER & OUTER CONTEXT
- RE-AIM DIMENSIONS

EVIDENCE-BASED INTERVENTION (COMPONENTS)

IMPLEMENTATION STRATEGIES

MAINTENANCE
- REACH
- EFFECTIVENESS
- ADOPTION

OVERARCHING ISSUES
- PROPORTION / PENETRATION
- REPRESENTATIVENESS
- REASONS: HOW & WHY
- ADAPTATIONS
- COSTS, BENEFITS & VALUE

PRISM = Pragmatic Robust Implementation and Sustainability Model.

FIGURE 1 | Revised, enhanced RE-AIM/PRISM 2019 model.
Conventional thinking about preventive interventions focuses over simplistically on the “package” of activities and/or their educational messages. An alternative is to focus on the dynamic properties of the context into which the intervention is introduced. Schools, communities and worksites can be thought of as complex ecological systems. They can be theorized on three dimensions: (1) their constituent activity settings (e.g., clubs, festivals, assemblies, classrooms); (2) the social networks that connect the people and the settings; and (3) time. An intervention may then be seen as a critical event in the history of a system, leading to the evolution of new structures of interaction and new shared meanings. Interventions impact on evolving networks of person-time-place interaction, changing relationships, displacing existing activities and redistributing and transforming resources. This alternative view has significant implications for how interventions should be evaluated and how they could be made more effective.
“Complexity is defined as “a scientific theory which asserts that some systems display behavioral phenomena that are completely inexplicable by any conventional analysis of the systems' constituent parts.” Reducing a complex system to its component parts amounts to “irretrievable loss of what makes it a system.”

Hawe et al. BMJ 2004;328:1561–3
MADI

Twitter handles: @BorsikaRabin @BaumannAna @christojoe1979 @sws_fastlab