Fidelity and Adaptation for Implementation Science: how can we reconcile the tension?

CRISP Seminar Series

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Overview

• Defining fidelity and adaptation

• Addressing the tension between fidelity and adaptation

• Models and instruments to document fidelity and adaptation

• Fidelity and adaptation – future directions
Defining fidelity and adaptation
Fidelity adaptation defined 1

#1: Fidelity describes the **degree of fit** between the developer-defined components of a program and its actual implementation in a given organizational or community setting.¹

#2: **Core elements** are the essential program components that are believed to make an evidence-based program effective and that should be kept intact to maintain intervention effectiveness.²

#3: Programs that are implemented with **high fidelity** are more likely to have outcomes comparable to the original study.²

Fidelity adaptation defined 2

#3: Adaptation can be defined as the *deliberate or accidental modification of the program*, including the following:

a. deletions or additions (enhancements) of program components;

b. modifications in the nature of the components that are included;

c. changes in the manner or intensity of administration of program components called for in the program manual, curriculum, or core components analysis; or

d. cultural and other modifications required by local circumstances.

#4: Adaptation of programs often occur to improve the fit (or compatibility) of a program to a new setting or to increase the cultural appropriateness of a program.

#5: Adaptations to evidence-based interventions are common. Some researchers suggest that adaptation is inevitable to meet the needs of a specific context, while others believe that an adapted program will be less effective than the original program and will compromise the core elements and underlying logic of a program.


Historical view of fidelity and adaptation
‘Tug of war’

- Internal validity
- Fidelity
- External validity
- Adaptation
A mature view of fidelity and adaptation

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 types and examples

<table>
<thead>
<tr>
<th>Types of Adaptation</th>
<th>Example Adaptations</th>
<th>Reasons for Adaptation</th>
<th>No. of Sites (Out of 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes to educational materials</td>
<td>Added supplemental educational materials</td>
<td>Generate/maintain engagement</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Updated content</td>
<td>Strengthen or reinforce message</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customized for local audience</td>
<td>Reach specific audiences—especially hard to reach audiences</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Changed formatting</td>
<td>Need for program materials to address local context</td>
<td></td>
</tr>
<tr>
<td>Changes to intended audience</td>
<td>Expanded audience (beyond primary audience)</td>
<td>Reach specific audiences</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Shifted primary audience (different than original intended audience)</td>
<td>Program sparked desire to reach a broad audience</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Narrowed audience (focus on subset of original audience)</td>
<td>Strengthen or reinforce message</td>
<td></td>
</tr>
<tr>
<td>Changes to program delivery</td>
<td>Modified program provider</td>
<td>Generate/maintain engagement in the program</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Changed order or length of activities</td>
<td>Strengthen or reinforce message</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Used different communication channels</td>
<td>Reach specific audiences Increase fit</td>
<td></td>
</tr>
<tr>
<td>Adding new activities</td>
<td>Added other activities beyond core elements</td>
<td>Generate/maintain engagement in the program</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Added content within core element activities</td>
<td>Strengthen or reinforce message</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Integrated into existing infrastructure/activities</td>
<td>Reach specific audiences Increase fit</td>
<td></td>
</tr>
<tr>
<td>Deleting core elements</td>
<td>Could not complete</td>
<td>Turbulence/Barriers: Schedule/time conflicts</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Decided not to complete</td>
<td>Staff/leadership transitions Slow economy/financial difficulties</td>
<td></td>
</tr>
</tbody>
</table>

Factors that Influence Fidelity

- **Influences on Fidelity**
  - **Implementer Characteristics**
    - Knowledge/Skill/Training
    - Previous experience
    - Beliefs & attitudes about EBIs
    - Resources/support
  - **Intervention**
    - EBI/Components
    - Complexity
    - Trialability
    - Flexibility
  - **Organization/Setting/Community**
    - Support/Champion
    - Trained staff
    - Budget, materials
    - Fit with organizational mission
  - **Population**
    - Demographic characteristics
    - Literacy
    - Health access
    - Socio-cultural norms

- **Fidelity**
  - Adherence to intervention
  - Exposure or dose
  - Quality of delivery
  - Participant responsiveness
  - Program differentiation

- **Adaption**
  - Population
  - Setting
  - Outcome

- **Implementation Effectiveness**

- **Dissemination**

- **Social, Political, and Environmental Influences**

From Presentation by Emmons K and Green L. TIDIRH, 2013.
Scenarios and considerations

#1: Implementation of an evidence-based intervention/program
   • ‘Green-yellow-red light’ model
   • Continuum of fidelity and adaptation

#2: Developing new interventions and programs with fidelity and adaptation in mind
   • Designing for Dissemination and implementation
   • Flexible adaptive program development
   • Empowerment implementation
   • Hybrid programs
Scenario #1:
Implementation of an evidence-based intervention/program
Green, Yellow & Red

Light Adaptations

Provides guidance on whether a particular adaptation is ...

...safe (green)

...should be made cautiously (yellow)

...should be avoided (red)
Things That **Can Probably** Be Modified

- Names of health care centers or systems
- Pictures of people and places and quotes
- Hard-to-read words that affect reading level
- Wording to be appropriate to audience
- Ways to recruit your audience
- Incentives for participation
- Timeline (based on adaptation guides)
- Cultural preferences based on population

**NOTE:** Some of these adaptations may require formative work.
Things That **Can** Probably Be Modified: Proceed with Caution

- Substituting activities
- Adding activities to address other risk factors or behaviors
- Changing the order of the curriculum or steps (sequence)
Things That Cannot Be Modified

- The health communication model or theory
- The health topic/behavior
- Deleting core elements or whole sections of the program
- Reduction of program
  - Timeline
  - Dosage (e.g., activities, time/session)
- Putting in strategies that detract from the core elements
The continuum of fidelity and adaptation

<table>
<thead>
<tr>
<th>Program Implemented with . . .</th>
<th>Example Adaptations</th>
<th>Degree of Adaptation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Fidelity</td>
<td>• Added/Customized Materials</td>
<td>Minor Adaptation</td>
</tr>
<tr>
<td></td>
<td>• Integrated into infrastructure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Narrowed Primary Audience</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Added Activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Changed order/length of activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Expanded Audience</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Shifted Focus to other behaviors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Did not complete core elements</td>
<td></td>
</tr>
<tr>
<td>Low Fidelity</td>
<td>Needs more rigorous EVALUATION</td>
<td></td>
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</tbody>
</table>

Scenario #2:  
Developing new interventions and programs with fidelity and adaptation in mind
Designing for D&I defined

#1: Designing for Dissemination and Implementation refers to a set of processes that are considered and activities that are undertaken throughout the planning, development, and evaluation of an intervention to increase its dissemination and implementation potential.¹

#2: Designing for diffusion is the taking of strategic steps early in the process of creating and refining an evidence-based intervention to increase its chances of being noticed, positively perceived, accessed, and tried and then adopted, implemented, and sustained in practice.²

¹http://www.makeresearchmatter.org/glossary.aspx
Designing for D&I

(1) an active, systematic, planned and controlled approach
(2) planning for D&I in the early stage of conceptualization and development of the intervention
(3) early involvement of and partnership with target users in the conceptualization and development
(4) close understanding of and building on the characteristics, beliefs, norms, and wants of target adopters
(5) study designs and measures that generate practice-relevant evidence facilitate and inform later-stage D&I efforts

http://www.makeresearchmatter.org/glossary.aspx
Designs that build in fidelity and adaptation

#1: Flexible adaptive program development\(^1\)

#2: Empowerment implementation\(^2\)

#3: Hybrid program development and program adaptation guidelines\(^3\)

\(^2\) Van Daele et al. Health Promotion International
Flexible adaptive development

#1: Implementation fidelity is the extent to which the implemented program reflects theoretical methods, strategies, and determinants; completeness (or dose) is the extent to which all intervention components are delivered; and reach is the extent to which the program has reached the intended target population.

#2: Conceptualizing interventions as a standardized process (adaptive and flexible) rather than standardized set of procedures.

#3: Testing interventions in a real world context

#4: Engaging stakeholders from the start

#5: Monitoring fidelity and completeness throughout the lifecycle of project

Empowerment implementation

#1: Builds on the notion of ‘empowerment evaluation’ – which aims to increase program success by providing program stakeholders with tools for assessing their program. This is closely linked with capacity building.

#2: Empowerment implementation provides the community with concepts, tools, and skills to identify the core components of the intervention, to adapt it to their context and culture, and to assess, monitor, and maintain the implementation quality.

#3: Steps of empowerment implementation:
   (1) Developing a core component
   (2) Selecting partners
   (3) Assessing the fidelity/adaptation concerns with partners
   (4) Developing an overall implementation plan

1 Van Daele et al. Health Promotion International
Hybrid program development

Program adaptation guidelines emphasizing balancing program fidelity and adaptation (12 step approach):

#1: Define the fidelity/adaptation balance
#2: Assess community concerns
#3: Review targeted program to determine fidelity/adaptation issues
#4: Examine program’s theory of change, logic model, core components
#5: Determine needed resources
#6: Consider available training
#7: Consider how to document adaptation efforts
#8: Consult with the program developers
#9: Involve the community
#10: Integrate all prior steps into a plan
#11: Include fidelity/adaptation issues into the plan
#12: Conduct ongoing analysis of adaptation/fidelity issues

Reconciling the tension between fidelity and adaptation

#1: identifying core components and flexible components of the intervention: theories and frameworks and core component analysis

#2: choosing design approaches that balance internal and external validity

#3: early and ongoing stakeholder engagement

#4: measuring/tracking fidelity and ESPECIALLY adaptation throughout the process

#5: Make adaptations intentional rather than accidental through planning
Conceptualizing and measuring fidelity and adaptation
Methods to document/assess fidelity and 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
Quantifying fidelity and adaptation

<table>
<thead>
<tr>
<th>Measure</th>
<th>Program</th>
<th>Complexity</th>
<th>Domains</th>
<th>Fidelity measurement</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive Therapy for Psychosis Adherence Scale</td>
<td>Cognitive-behavioral therapy for psychosis</td>
<td>Low</td>
<td>Single intervention, single practitioner</td>
<td>Practitioner adherence in dyadic interactions</td>
<td>Direct observation via audiotape</td>
</tr>
<tr>
<td>Strengths Model Fidelity Scale</td>
<td>Strengths model of case management</td>
<td>Moderate</td>
<td>Single practice philosophy; multiple practitioners and program components</td>
<td>Group adherence to intervention philosophy; program structure and quality maintenance mechanisms</td>
<td>Records review; on-site interviews and observation</td>
</tr>
<tr>
<td>Illness Management and Recovery Program Fidelity Scale</td>
<td>Illness management and recovery</td>
<td>Moderate</td>
<td>Multiple interventions, practitioners, and program components</td>
<td>Group adherence to criteria for practice delivery within multi-component program; program structure</td>
<td>Records review; on-site interviews and observation</td>
</tr>
<tr>
<td>Tool for Measurement of ACT</td>
<td>Assertive community treatment</td>
<td>High</td>
<td>Multiple integrated interventions, disciplines, and practitioners; complex multicomponent program model</td>
<td>Program- and practitioner-level adherence to criteria for program structure and multiple team- and discipline-specific practices</td>
<td>Records review; on-site interviews and observation</td>
</tr>
</tbody>
</table>

Footnote: Relative scope of specified program levels and elements

Stirman et al. Implementation Science 2013, 8:65

**BY WHOM are modifications made?**
- Individual practitioner/facilitator
- Team
- Non-program staff
- Administration
- Program developer/purveyor
- Researcher
- Coalition of stakeholders
- Unknown/unspecified

**WHAT is modified?**
Content
(Modifications made to content itself, or that impact how aspects of the treatment are delivered)
Context
(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)

**At what LEVEL OF DELIVERY (for whom/what are modifications made?)**
- Individual patient level
- Group level
- Individual practitioner level
- Clinic/unit level
- Hospital level
- Network level
- System level

**What is the NATURE of the Content modification?**
- Tailoring/tweaking/refining
- Adding elements
- Removing/skipping elements
- Shortening/condensing (pacing/timing)
- Lengthening/extending (pacing/timing)
- Substituting
- Reordering of intervention modules or segments
- Integrating 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
- Loosening structure
- Departing from the intervention (‘drift’)

**Context modifications are made to which of the following?**
- Format
- Setting
- Personnel
- Population
Figure 1 Assessing implementation challenges and developing solution strategies. Detailed flow diagram to guide systematic assessment of challenges and development of solutions.
<table>
<thead>
<tr>
<th>Phase (Answers the Following Question)</th>
<th>Methodology</th>
<th>EBI Draft</th>
</tr>
</thead>
</table>
| 1. Assessment* (Who is the new target population and why is it at risk of HIV?) | • Conduct focus groups/needs assessment with the new target population  
• Conduct focus group/elicitation interviews with the key stakeholders  
• Analyze results of formative evaluations | N/A |
| 2. Decision (What EBI is going to be selected and is it going to be adopted or adapted?) | • Review HIV interventions defined as EBI’s  
• Decide on the EBI to be selected  
• Decide on whether to adopt or adapt the EBI | Original |
| 3. Administration* (What in the original EBI needs to be adapted, and how should it be adapted?) | • Administer theater test with members of the new target population  
• Involve key stakeholders as observers of the theater test  
• Administer a brief survey with open-ended and close-ended items to elicit participants’ and stakeholders’ reactions to the theater test  
• Analyze results of the theater test | Original |
| 4. Production (How do you produce draft 1 and document adaptations to the EBI?) | • Produce draft 1 of the adapted EBI  
• Balance priorities while maintaining fidelity to the core elements and underlying theoretic framework of the original EBI  
• Develop an adaptation plan  
• Develop quality assurance and process measures | Draft 1 |
| 5. Topical experts (Who can help to adapt the EBI?) | • Identify topical experts  
• Actively involve topical experts in adapting the EBI | Draft 1 |
| 6. Integration (What is going to be included in the adapted EBI that is to be piloted?) | • Integrate content from topical experts based on the capacity of the agency, and create draft 2 of the adapted EBI  
• Integrate scales that assess new intervention content in study survey  
• Integrate readability testing of draft 2 of the EBI to create draft 3 | Draft 2  
Draft 3 |
| 7. Training (Who needs to be trained?) | • Train staff to implement draft #3 of the adapted EBI, including recruiters, facilitators, and assessment and data management staff | Draft #3 |
| 8. Testing* (Was the adaptation successful, and did it enhance short-term outcomes?) | • Test draft 3 of the adapted EBI as part of a pilot study  
• Analyze results of the pilot study and use results in phase 2 study  
• Analyze results of the phase 2b study to determine efficacy | Final |

*Target population, key stakeholders, and agency staff are directly involved in these phases of adaptation.
Implementation toolkits

#1: Use implementation toolkits to implement evidence-based programs

#2: Develop implementation toolkits for new interventions

#3: Provide technical assistance and/or training to implementers
RESEARCH METHODS & REPORTING

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide
Item 8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose

Examples:
- 8a. . . a loading dose of 1 g of tranexamic acid infused over 10 min, followed by an intravenous infusion of 1 g over 8 h
- 8b. They received five text messages a day for the first five weeks and then three a week for the next 26 weeks

Item 9. Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how

Examples:
- 9a. Those allocated to the intervention arm followed an intensive stepped programme of management, with mandatory visits to their doctor at weeks 6, 10, 14, and 18 after randomisation to review their blood pressure and to adjust their treatment if needed according to prespecified algorithms [provided in supplementary appendix]

Item 10. Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)

Examples:
- 10a. A mixture of general practitioners and practice care nurses delivered 95% of screening and brief intervention activity in this trial. . . Owing to this slow recruitment, research staff who had delivered training in study procedures supported screening and brief intervention delivery in 10 practices and recruited 152 patients, which was 5% of the total number of trial participants

Item 11. How well (planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them

Examples:
- 11a. Pathologists were trained to identify lateral spread of tumour according to the protocol [reference]. The results of histopathological examination of the specimens were reviewed by a panel of supervising pathologists and a quality manager

Item 12: How well (actual): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

Examples:
- 12a. The mean (SD) number of physiotherapy sessions attended was 7.5 (1.9). Seven patients (9%) completed less than four physiotherapy sessions; the reasons included non-attendance, moving interstate, or recovery from pain. Of patients in the physiotherapy groups, 70% were compliant with their home exercise program during at least five of seven weeks
Fidelity and adaptation – future directions
Ongoing opportunities

#1: VA QUERI Programs and Fidelity, Adaptation, and Tailoring Workgroup

#2: PCORI: Overarching focus on stakeholder engagement, real-world relevance and feasibility

#3: NIH D&I RFA: *Studies on the fidelity/adaptation of implementation efforts, including the identification of components of implementation that will enable fidelity to be assessed meaningfully*
Questions for future work

#1: Inventory or systematic review of existing instruments/models for fidelity and adaptation

#2: Understanding patterns of adaptations across settings/program types through routine documentation/reporting of fidelity and adaptations

#3: Characterizing the appropriate balance in fidelity and adaptation for various scenarios

What are your questions in this area?
Recommended readings


(4) Van Daele T et al. Empowerment implementation: enhancing fidelity and adaptation in a psycho-educational intervention. *Health Promotion International*


“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
WHAT DO YOU THINK?

GET IN TOUCH:

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