Balancing Fidelity and Adaptation

Karen M. Emmons
and
Lawrence Green
Take Home Points

• Fidelity to core elements is a key part of implementation research
• Adaptation does happen, but should follow systematic processes
• Thinking in advance about why adaptation occurs can facilitate better Ix design
FIDELITY

fi·del·i·ty
– /fəˈdelitē/
– Noun
– Faithfulness to a person, cause, or belief, demonstrated by continuing loyalty and support

Extent to which intervention was delivered as planned
Fidelity and Adaptation

- CEASE- Pediatrician-Delivered tobacco treatment (TT) Ix for parents who smoke (Winickoff, et al, 2008)

**CEASE Implementation Guide**

**Three Easy Steps**

<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
<th>Who</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASK about smoking status of family members and household smoking rules. With leadership support, use:</td>
<td>At the front desk During vital signs During the visit Through a mailing</td>
<td>Primary: The receptionist, medical assistant, or nurse: Facilitators:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSIST in quitting smoking and establishing a completely smoke-free home and car. Prescribe or recommend appropriate medication. With leadership support, use:</td>
<td>During the visit</td>
<td>Primary: A physician, nurse, or health educator: Facilitators:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REFER those who use tobacco to the quitline. Make a follow-up plan. With leadership support, use:</td>
<td>During the visit In consultation with a nurse or health educator</td>
<td>Primary: A physician or nurse practitioner: Facilitators:</td>
</tr>
</tbody>
</table>

- Every year, give families a CEASE Action Sheet to ask about household members' smoking status and interest in cessation services.
- Use the CEASE Sticker or Stamp to document family smoking status on the problem list.
- Place the CEASE Action Sheet in the child's medical record.

- In households where tobacco use occurs, address tobacco use and SHS exposure at every visit using the CEASE Action Sheet.
- Use the responses on Step One of the CEASE Action Sheet to guide how you assist with addressing tobacco use.
- Document services delivered on Step Two of the CEASE Action Sheet.

- Using the Quitting Prescription Pad, refer tobacco users to the quitline.
- Arrange follow-up with tobacco users.
What is the cost of ignoring fidelity?

Internal Validity: Don’t know if effects are related to the intervention

External Validity: Limits replicability and generalizability

Effect Size: Implementation variation will reduce statistical power
How “fidel” does fidelity have to be?

• Core elements
  – Essential ingredients
  – Responsible for Ix effects

• Adaptive elements
  – Don’t change internal logic of Ix
  – Not responsible for Ix effect

Key for many implementation efforts: Detect minimum dose needed
5 Elements of Fidelity

- Adherence: To Ix protocol
- Dose: Ix amt, frequency, duration
- Quality of delivery: Content and process
- Participant responsiveness: Audience engagement/satisfaction w/ Ix
- Program differentiation: Core elements

Two Views: Strict adherence vs. Adaptation Happens
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

Allen, Linnan, Emmons, 2012
The ADAPT-ITT Model: Phases and Methodology *(Wingood & DiClemente, 2008)*

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

*Target population, key stakeholders, and agency staff are directly involved in these phases of adaptation.*
Reasons for Adaptation

- Enhance engagement
- Reach specific audiences
- Increase program fit
- Reinforce messages
- Turbulence at site

Carvalho, et al., 2013, J Public Health Management Practice
## Continuum of Fidelity and Adaptation

<table>
<thead>
<tr>
<th>Program implemented with...</th>
<th>Example Adaptations</th>
<th>Degree of Adaptation</th>
</tr>
</thead>
</table>
| High fidelity               | • Added/customized materials  
|                             | • Integrated into infrastructure  
|                             | • Narrowed primary audience  
|                             | • Added activities  
|                             | • Changed order/length of activities  
|                             | • Expanded audience  
|                             | • Shifted focus to other behaviors  
|                             | • Did not complete core elements  | Minor adaptation |
| Low fidelity                 |                      |                      |

Carvahlo, et al., 2013

Needs More Rigorous EVALUATION
Flash Exercise—You Try It!

- Adapt CEASE for the cancer survivorship setting
- What do you need to know? What do you need to change?

<table>
<thead>
<tr>
<th>Step</th>
<th>What</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>ASK</strong> about smoking status of family members and household smoking rules. With leadership support, use:</td>
<td>At the front desk. During initial screening. During the visit. Through the mailing.</td>
</tr>
<tr>
<td></td>
<td>• CEASE Action Sheet, Step One</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td><strong>ASSIST</strong> in quitting smoking and establishing a completely smoke-free home and car. Prescribe or recommend appropriate medication. With leadership support, use:</td>
<td>During the visit. Home and car visit. Doctors' visit. Administrative visit.</td>
</tr>
<tr>
<td></td>
<td>• CEASE Action Sheet, Step Two</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CEASE leaflets</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td><strong>REFER</strong> those who use tobacco to the quitline. Make a follow-up plan. With leadership support, use:</td>
<td>During the visit. In consultation with a nurse or health educator.</td>
</tr>
<tr>
<td></td>
<td>• CEASE Action Sheet, Step Three</td>
<td></td>
</tr>
</tbody>
</table>

- Care delivery process/flow (staffing, visit structure)?
- Content (family)?
- Medication interactions?
- Fidelity to core elements?
- Materials adaptation?
- Ancillary Support?
## CEASE Adaptation - How Did We Do?

<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></td>
<td>Major adaptation or reinvention</td>
</tr>
</tbody>
</table>

Carvahlo, et al., 2013
ADAPTATION: COMPENSATING FOR LIMITED EXTERNAL VALIDITY OF MOST EVIDENCE
Take Home Points

• “Participatory approach at the front-end of the research pipeline is the best assurance of relevance and utilization of the research at the other end of the pipeline.”

• “If we want more evidence-based practice…
• …we need more practice-based evidence”*

* AJPH, 2006
Definition of External Validity

• External validity can be defined as the degree to which evidence can be generalized to other settings, times, and conditions than the ones in which the study or studies were done.

• External validity depends on internal validity and on the representativeness of the studies in which the evidence was generated.

• Design of studies unavoidably involves some trade-off decisions between internal and external validity, between efficacy evidence and effectiveness evidence, between certainty of attribution and certainty of applicability elsewhere.
The Challenges & Opportunities
(from yesterday’s session on evidence)

• The two biggest challenges:
  – To close the gap between the evidence for implementation that policy makers, program planners, practitioners and communities need & what they are getting from our research
  – Reform some peer review & editorial tendencies

• The two biggest opportunities
  – Extend participatory research principles to work with policy makers, program planners & practitioners in use of natural experiments—e.g., surveillance, evaluation and continuous quality improvement methods
  – Combine PR with multi-site RCT methods to expand the external validity of the results
The #1 complaint from practitioners about evidence, and the opportunity

- “Lack of consideration of external validity is the most frequent criticism by clinicians of RCTs, systematic reviews, and guidelines.”

- The *opportunities* of more practice-based and participatory approaches for adaptation to the limits of evidence for their setting, population and circumstances.
Number of Publications on CBPR
Based on Scopus Search*

*Based on unpublished Scopus review by Doug Brugge, Tufts U., 2011.
The Lenses of Scientists, Health Professionals and Lay People*

Closing the Gaps Among Perceptions of Needs*

“Actual needs”

People’s perceived needs, priorities

Resources, feasibilities, policy

Reconciling Perceived Needs, "Actual Needs," & Resources*

People’s perceived needs, priorities

“Actual needs”

Resources, feasibilities, policy

Action

Health education

Participatory research

Advocacy for regulation & organizational development

Policy Research & Surveillance

New (neglected) Evidence Forms

• Participatory research evidence to close gaps among perceptions of need
  – Community-Based Participatory Research
  – Practice-based or action research
• Surveillance evidence
• Population diagnostic evidence
• Program evaluation evidence
  – Multi-component evaluations
  – Continuous quality improvement
  – How context effects (moderates) outcomes
Uses of Evidence & Theory in Population-Based, Diagnostic, Planning & Evaluation Models*

1. Assess Needs & Capacities of Population

2. Assess Causes (X) & Resources

3. Design & Implement Program

4. Evaluate Program

Evidence from community or population

Evidence from Etiologic Research

Evidence from Efficacy Studies, and Use of Theory to Fill Gaps

Program Evidence & Effectiveness Studies, and use of Theory

Reconsider X

*Green & Kreuter, Health Program Planning. 4th ed. NY: McGraw-Hill, 2005, Fig. 5-1.
Reasons for Surveillance as a Challenge and an Opportunity

• For CBPR
  – Communities need/want more *particular*, local data
  – CBPR projects usually can’t afford to do population surveys, much less time-series surveys

• For community research in general
  – Provides the most powerful alternative to RCTs for population-level change & community interventions
  – Provides the most credible source of evidence for external validity and dissemination of practice-based evidence
Mediating and Moderating Variables*

Aligning Evidence* with (& deriving it from) Practice: Matching, Mapping, Pooling & Patching

- **Matching** ecological levels of a system or community with RCT evidence of **efficacy** for interventions at those levels
- **Mapping** theory to the causal chain to fill gaps in the evidence for **effectiveness** of interventions
- **Pooling** experience to blend interventions to fill gaps in evidence for the effectiveness of programs in similar situations
- **Patching** pooled interventions with indigenous wisdom and professional judgment about plausible causes & interventions to fill gaps in the **program** for the specific population

Take Home Points

- Fidelity to core elements is a key part of implementation research
- Adaptation does happen, but should follow systematic processes
- Thinking in advance about why adaptation occurs can facilitate better Ix design
Take Home Points

• “Participatory approach at the front-end of the research pipeline is the best assurance of relevance and utilization of the research at the other end of the pipeline.”

• “If we want more evidence-based practice…

• …we need more practice-based evidence”*

* AJPH, 2006