



It takes two (adaptation and fidelity) to TANGO!

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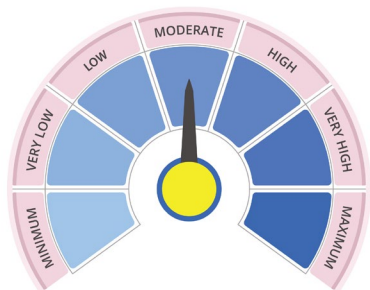
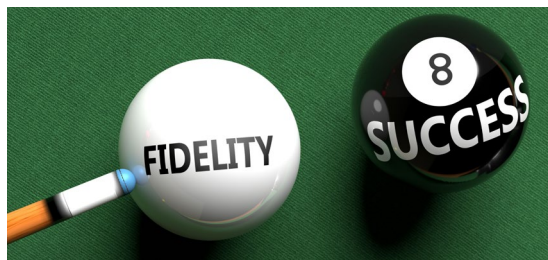


Objectives for today



- Describe the conceptual considerations for fidelity including identifying factors that influence fidelity
- Examine relationships between implementation fidelity and adaptations, implementation strategies, complex interventions, and pragmatic studies
- Explore considerations for fidelity assessment using examples and reflection questions

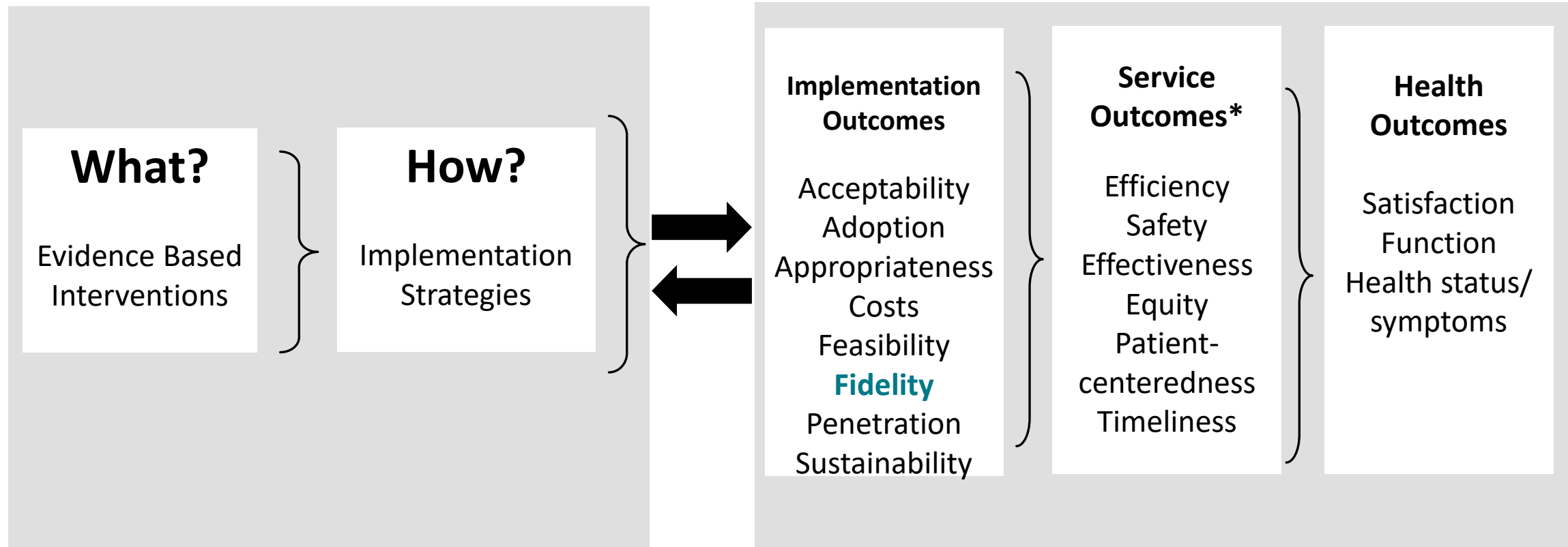
Why pay attention to Fidelity?



- Better fidelity associated with better health outcomes ([Durlak & Dupre 2008](#))
- Ability to identify minimal ‘dose’ of intervention or ‘active ingredients’ required to produce change and impact health outcomes/behaviors of interest
- Possible to detect problems with intervention quality, make corrections, provide encouragement
- Assists with interpretation of results (e.g. is it not effective because EBI not effective or because not fully/properly implemented?)
- Can facilitate replication

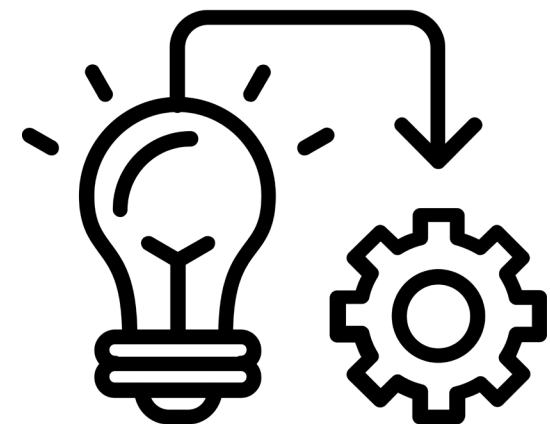
Fidelity is a key implementation indicator

[\(Proctor, et al, 2011\)](#)



***Fidelity** is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers, measured at minimum with (1) adherence to the program protocol, (2) dose or amount of program delivered, and (3) quality of program delivery.*

Implementation Fidelity



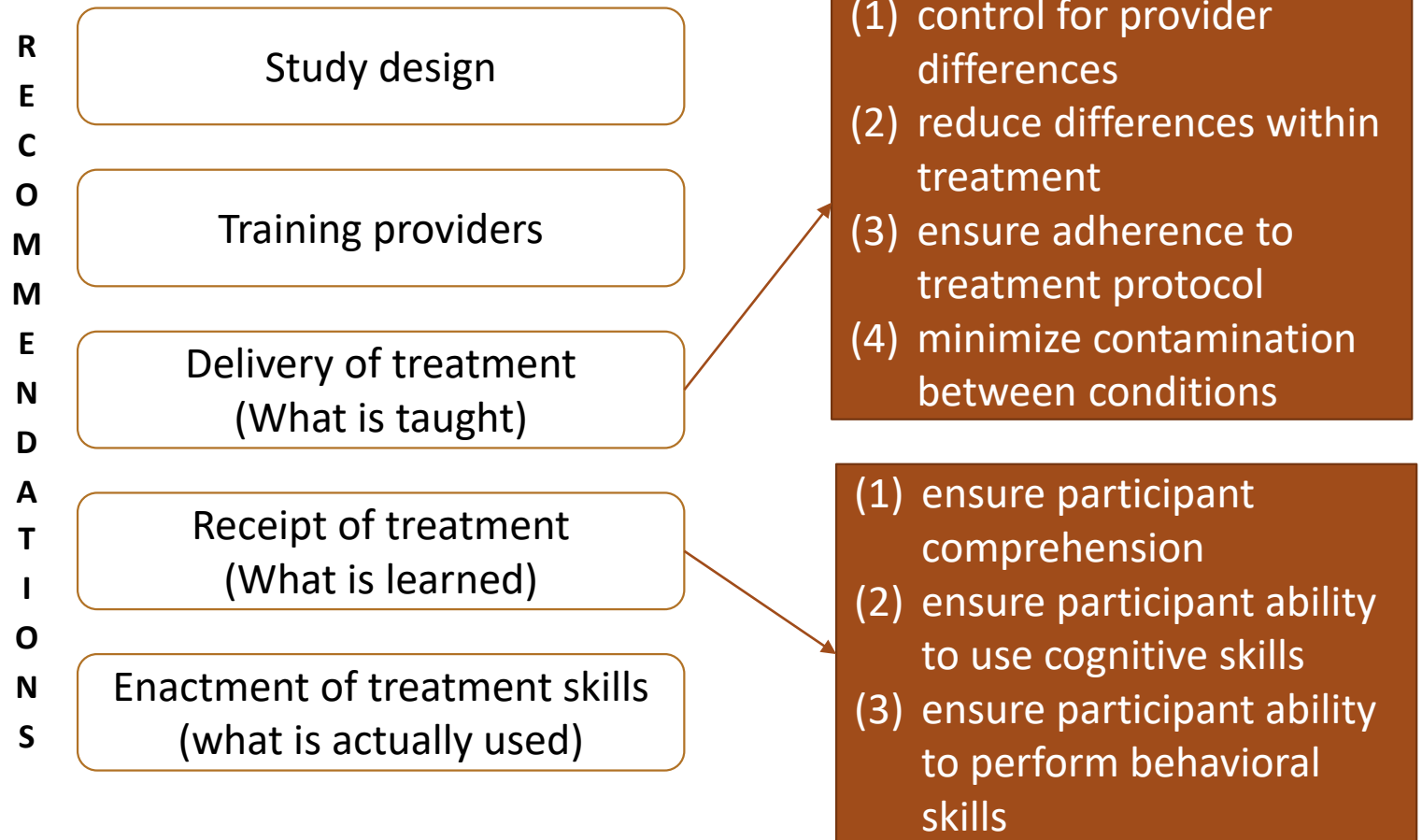
- Refers to the degree to which an intervention or program is **delivered and implemented as intended** by its developers or researchers in a specific context or setting
- Focuses on whether the core components of the intervention are implemented as planned, including the techniques, content, and methods prescribed by the program developers
- Considers how well the intervention is integrated into the target setting, the extent to which staff members are trained and supported in its delivery, and how closely the intervention aligns with the goals and resources of the implementing organization

Conceptual history (1)

Treatment Fidelity Workgroup of the NIH Behavior Change Consortium ([Bellg, et al, 2004](#))

“Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions.”

“Unless treatment fidelity is explicitly maintained, the extent to which the theory-based intervention being tested is the primary mechanism for the observed changes in the dependent variables of interest will remain unclear.”



Letter to the Editor

Changing Behavior: Theoretical Development Needs Protocol Adherence

The Behavior Change Consortium (BCC; Bellg et al., 2004) maintains that rigorous evaluation of behavior change interventions requires strict adherence to protocol-driven study designs, provider training, intervention delivery, understanding of the intervention (receipt), and use of intervention skills (enactment). Leventhal and Friedman (2004) cautioned that this approach may be “a barrier to theoretical and empirical work needed for the development of a science and practice of interventions” (p. 456).

standing, and preparatory behaviors. If people do not respond to the intervention as intended (e.g., poor understanding or adherence to intervention requirements), the nature of the intervention and how it is delivered should be modified. In other words, provider training and intervention delivery are independent variables, and receipt and enactment are dependent variables.

Improving the effectiveness of behavioral interventions requires knowledge of how these inventions work. Leventhal and Friedman (2004) argued that assessing variation in response to interventions across situations, providers, and participants is a necessary part of building a theoretical understanding of the process of change. This is a

theoretical basis of behavior change and the pragmatic difficulties of intervention delivery.

Susan Michie
University College London

References

Bellg, A.J., Borrelli, B., Resnick, B., Hecht, J., Mincucci, D. S., Ory, M., et al. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology*, 23, 443–451.

Campbell, M., Fitzpatrick, R., Haines

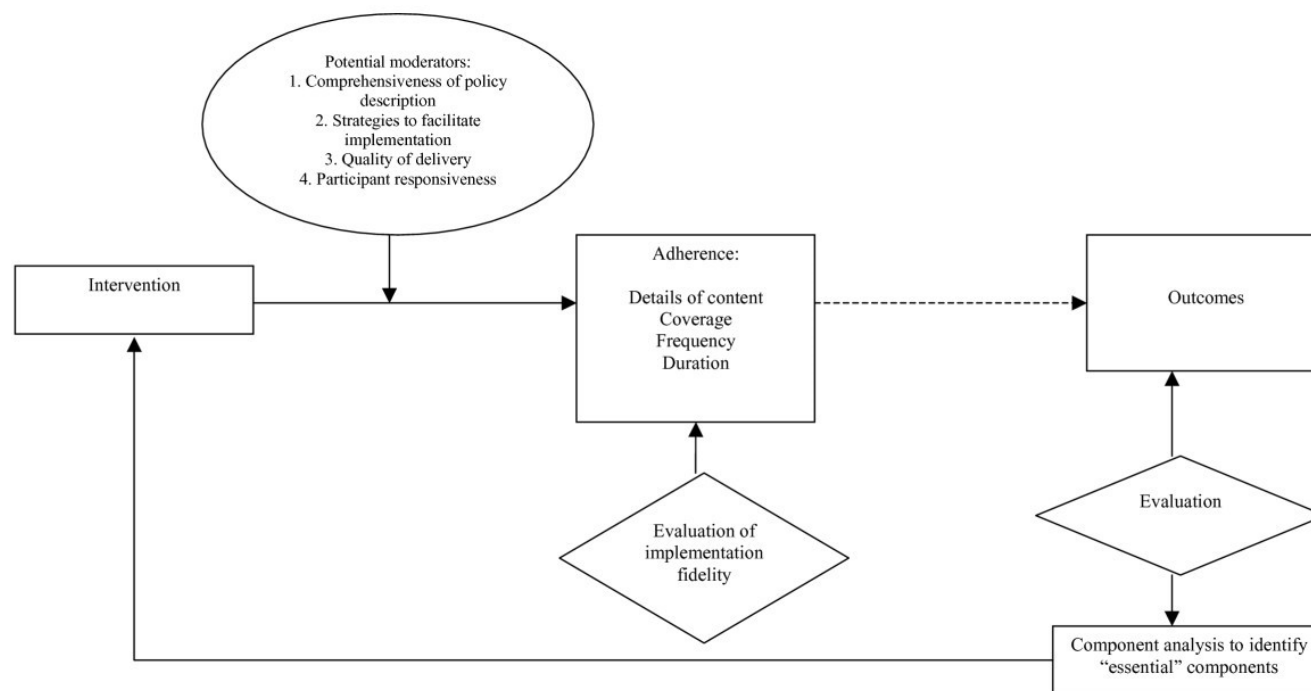
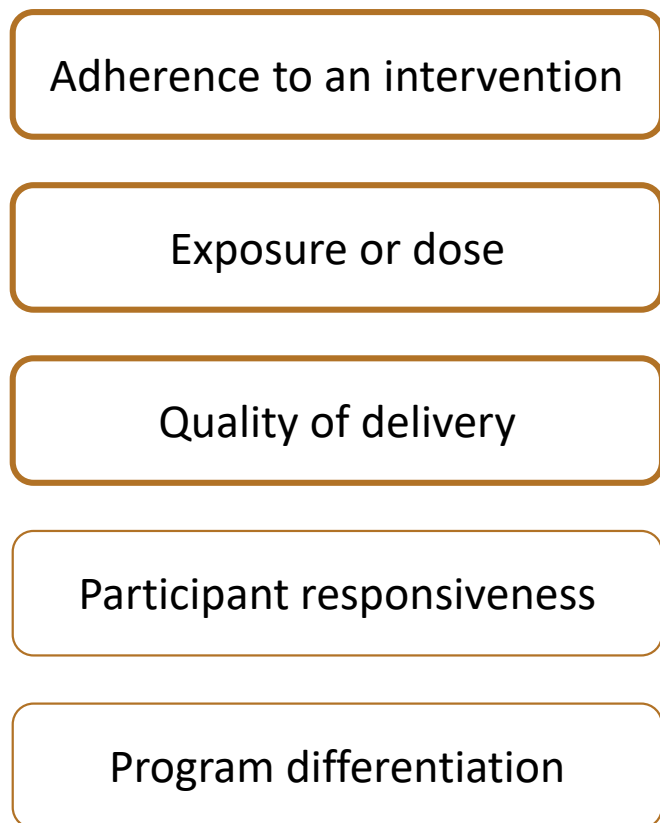
“It does not matter whether the planned intervention is a flexible application of behavioral components or whether it is rigid and manualized: One should be clear about which it is and assess its fidelity accordingly.”

“...data can be collected on which aspects of the manual were adhered to and which intervention components were delivered, and therefore had the potential to change behavior. In this way, two areas that are necessary for intervention development can be advanced: the understanding of the theoretical basis of behavior change and the pragmatic difficulties of intervention delivery.”

Conceptual history (2)

A conceptual framework for implementation fidelity ([Carroll, et al, 2007](#))

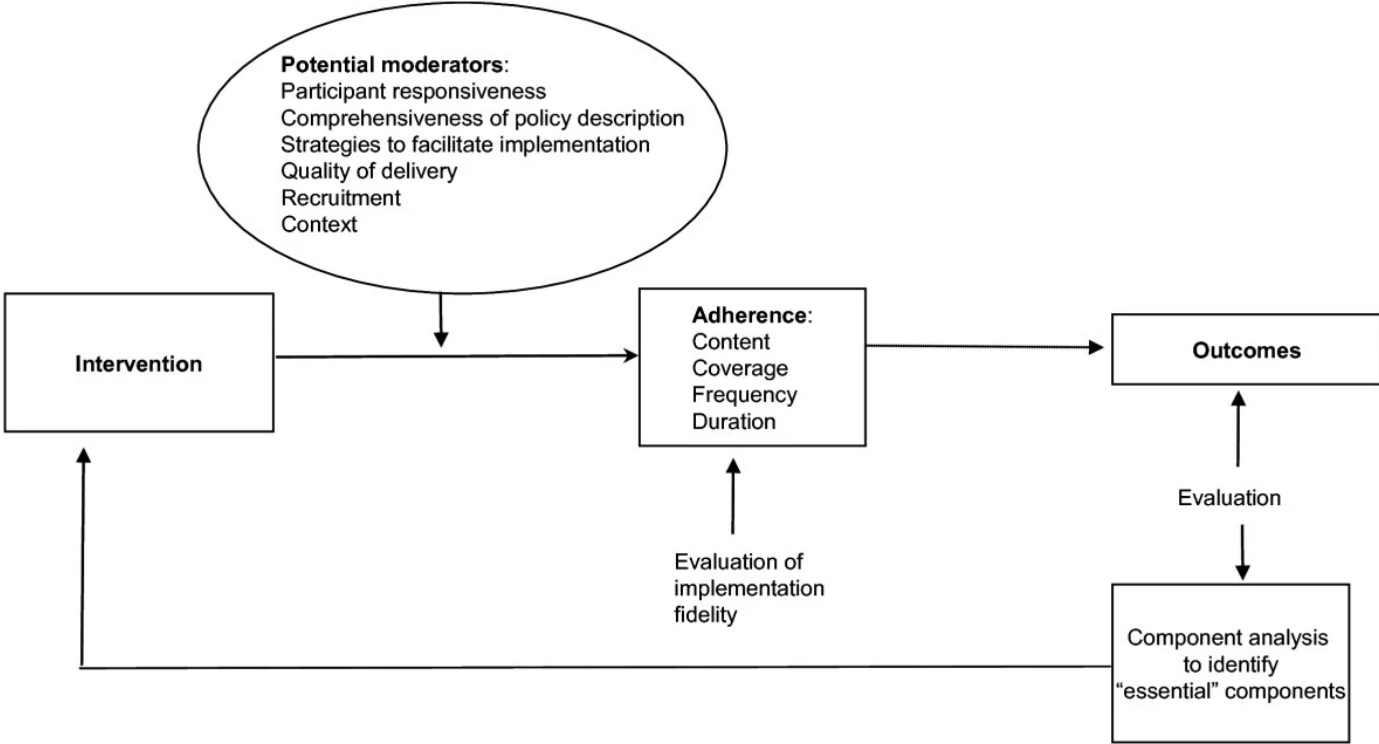
Provided a framework within which to understand and measure the concept and process of implementation fidelity.



Conceptual history (3)

Modified version of conceptual framework for implementation fidelity ([Hasson, 2010](#))

Modified the Carroll, et al, 2007 framework to add two additional moderating factors (context and recruitment), which would help contribute towards the growing literature of complex interventions



Implementation Fidelity vs. Adaptations

Implementation
Fidelity

Adaptation

- Refers to the degree to which an intervention or program is delivered and implemented as intended by its developers or researchers within a specific context or setting
- Involves making deliberate modifications or adjustments to an intervention to better fit the needs, context, and characteristics of the target population or setting
- Acknowledges that interventions often need to be tailored or customized to be more relevant, acceptable, or effective in specific contexts

Implementation Fidelity vs. Adaptations

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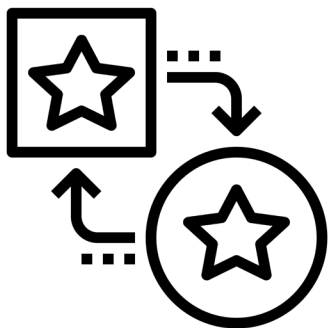
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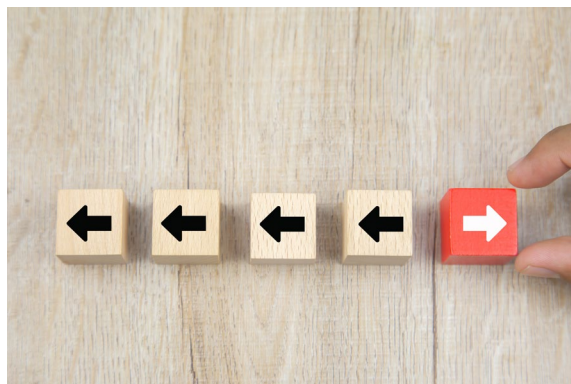
Adaptation

- Involves making deliberate modifications or adjustments to an intervention to better fit the needs, context, and characteristics of the target population or setting
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Relationship with adaptations



- Move away from thinking about either/or fidelity and adaptation; but **understanding and measuring both**
 - e.g. what are the modifications to the intervention that are made and why did they occur? Are there planned modifications we should make?
- Move away from idea that must have strict fidelity at all times, towards understanding that **adaptations happen**, we should proactively plan for and document to understand them
- **Fidelity and adaptation not incompatible** if there is fidelity to core components, and is encouraged if it is aimed to improve intervention outcomes/fit



How do you balance fidelity and adaptation in Implementation Science?



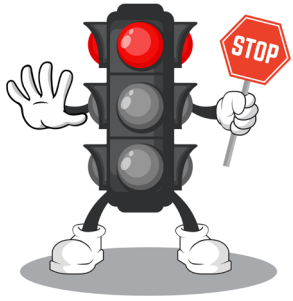
Identify **core components and flexible components** of the intervention
(Fidelity-consistent vs. Fidelity-inconsistent modifications)

Engage **stakeholders** early and throughout

Make adaptations **intentional** rather than accidental through planning

Assess and document fidelity and **adaptation** throughout the process

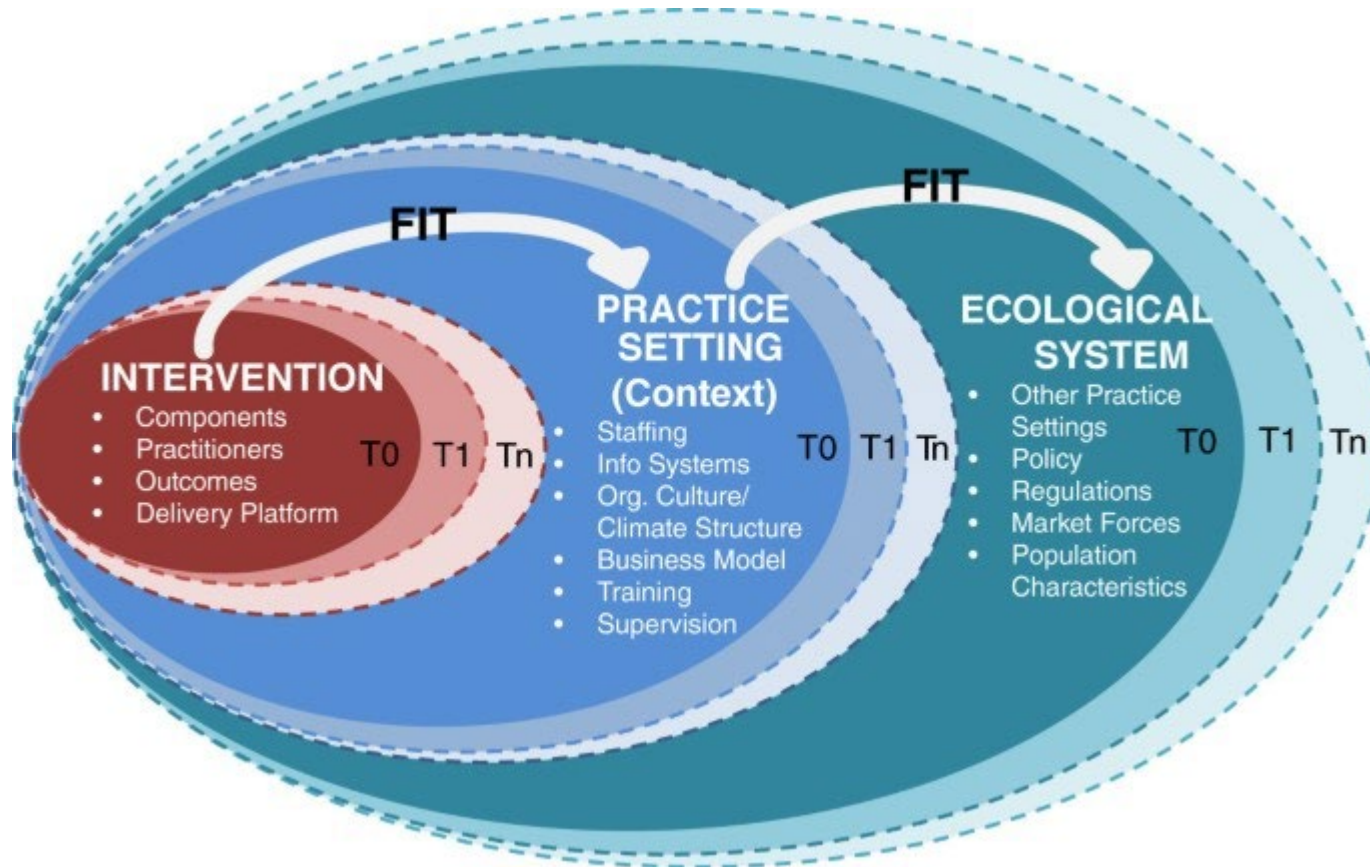
Core vs adaptable elements



- Not enough information on identifying and delineating these elements in the original research
- The logic behind why an element is core is based on theory and not empirical data (ideal would be both)
- Several studies over time are needed in different settings, populations, or both
- Debates on what is a “no go” adaptation

Fidelity and adaptations for sustainability

(Chambers, Glasgow, and Stange, 2013)



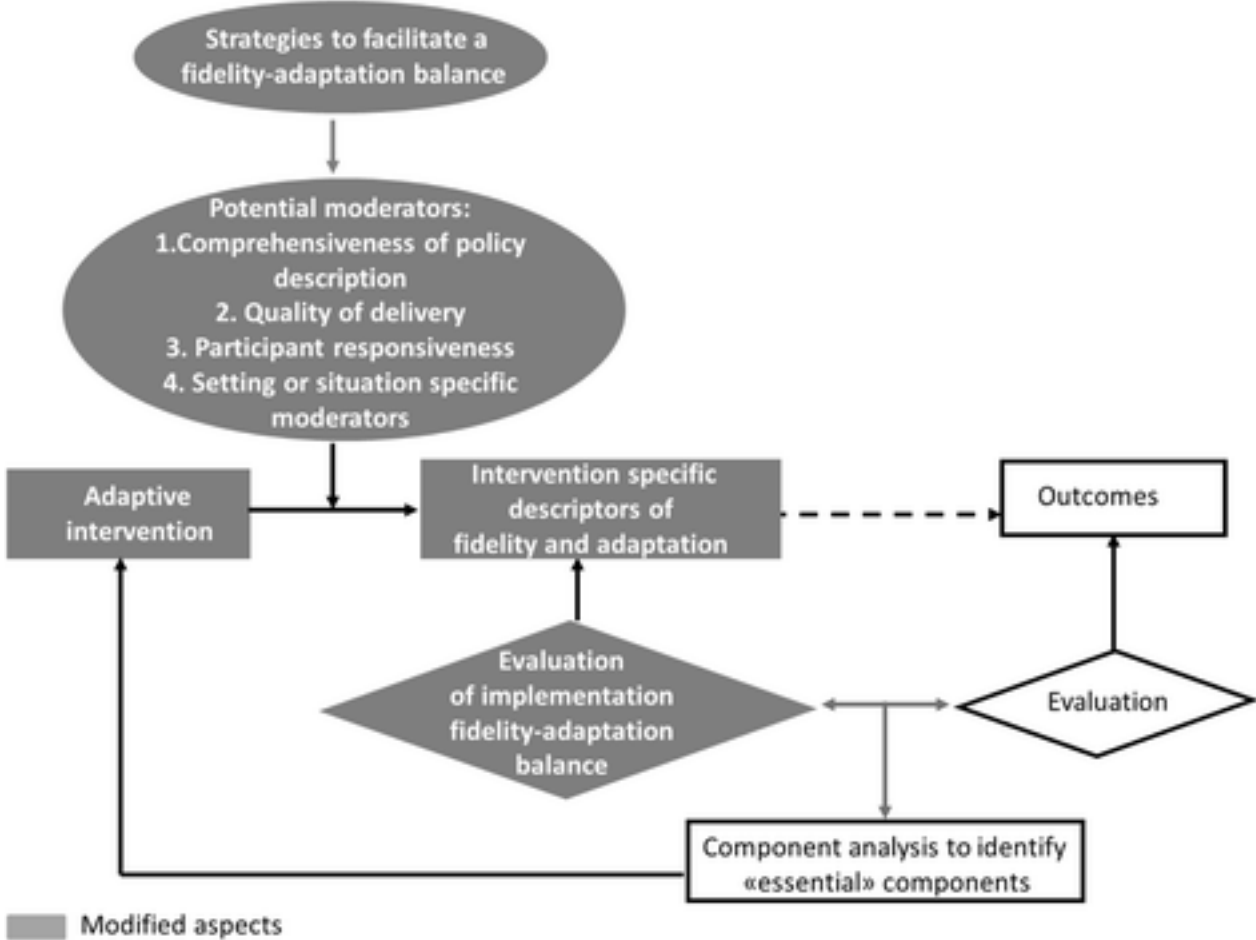
- Change is constant
- Introduced the idea of “program drift” where the expected effect of the intervention is presumed to decrease over time as interventions are adapted and “voltage drop” in which effect of the intervention is presumed to decrease as testing moves from T1-T4 phase
- Although now ten years old, the framework suggests a new paradigm to recognize that continuous exposure of the intervention to new populations, new settings, or both, can result in continued improvement (which should be the goal for sustainability)

Conceptual history (4)

Modified version of conceptual framework for implementation fidelity ([Perez, 2016](#))

Modified the Carroll, et al, 2007 framework to add a focus on adaptive interventions

- Descriptors of fidelity and adaptation
- Strategies to facilitate fidelity-adaptation balance
- Evaluation of the fidelity-adaptation balance
- Adaptive intervention



Conceptual history (5)

Factors influencing fidelity (Shelton, 2023)

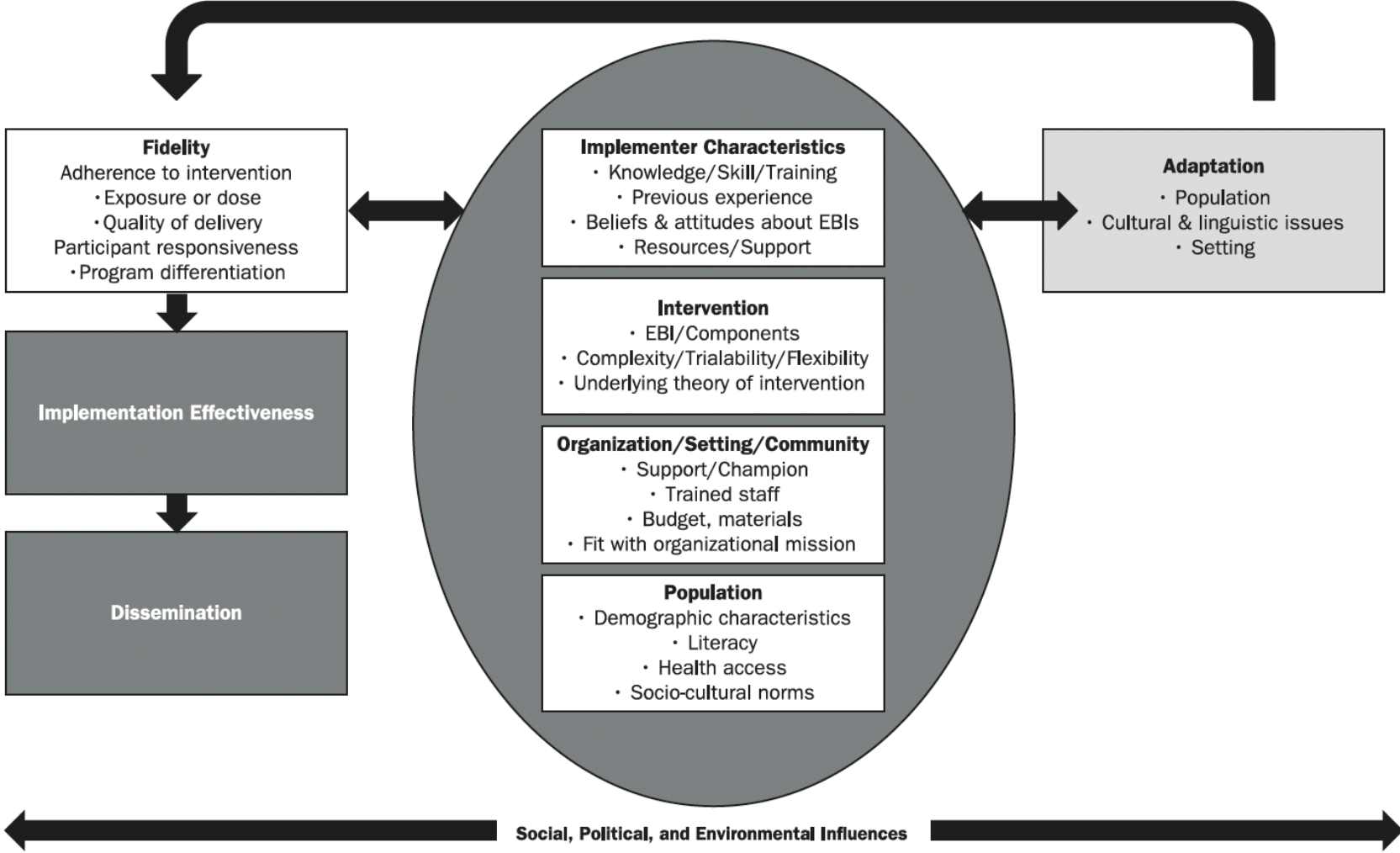


FIGURE 16.1 Factors that influence fidelity.

Factors influencing fidelity

Implementer Characteristics

- E.g., less experienced or untrained implementers may be less able to anticipate implementation challenges and problem solve when issues arise

Intervention Characteristics

- E.g., highly complex, low advantage interventions maybe more difficult to deliver, and or receive

Setting or Organization Characteristics

- E.g., organizational resources, such as fiscal investments, policies, may have a strong impact on implementation of interventions

Population Characteristics

- E.g., differences across and within populations influence the relevance, impact, and appropriateness of core or adaptive elements

Additional recommendations in the field

[Toomey, et al., 2020](#)

- (1) Clarifying **how fidelity is defined and conceptualized**
- (2) Considering fidelity beyond intervention delivery,
- (3) Considering strategies to both enhance and assess fidelity,
- (4) Making use of existing frameworks and guidance,
- (5) Considering the quality and comprehensiveness of fidelity assessment strategies,
- (6) Considering the balance between fidelity and adaptation
- (7) Reporting the use of **fidelity enhancement and assessment strategies** and their results

Focusing on fidelity: narrative review and recommendations for improving intervention fidelity within trials of health behaviour change interventions

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^aHealth Behaviour Change Research Group, School of Psychology, National University of Ireland Galway, Galway, Ireland; ^bHealth Promotion Research Group, School of Health Sciences, University of East Anglia, Norwich, UK; ^cFaculty of Social Sciences, University of Helsinki, Helsinki, Finland; ^dSchool of Public Health, University College Cork, Cork, Ireland; ^eCentre for Behaviour Change, University College London, London, UK

Fidelity to intervention vs implementation strategies



- Implementation strategies are to be considered as interventions themselves ([Proctor, et al, 2013](#))
- Specific strategies could aid in fidelity, for e.g., audit and feedback, facilitation, among others
- Greater recognition in the field for reporting and specifying implementation strategies, their mechanisms ([Powell, et al 2019](#); [Weiner, et al., 2012](#); [Lewis, et al., 2022](#))
- Fidelity assessments would be important as the field grows, however, are insufficient ([Slaughter, et al., 2015](#))

Implementation Strategy Fidelity Checklist

Built on the review of research on fidelity of implementation ([Dusenbury, 2003](#)) and collated by ([Slaughter, et al., 2015](#))

Table 1. in Slaughter, et al., 2015

| Domain | Dusenbury definition | Adapted operational definition |
|----------------------------|---|---|
| Adherence | The extent to which implementation of particular activities and methods is consistent with the way the program is written | Specifying the implementation strategy(s) <i>and</i> evidence of the extent to which this/these implementation strategy(s) took place |
| Dose | The amount of the program content received by participants | Proportion of intervention providers who received the implementation strategy(s) (i.e., number of people <i>and</i> specific strategy received) |
| Participant Responsiveness | The extent to which participants are engaged by and involved in the activities and content of the program | Extent to which intervention providers are involved in the development of the implementation strategy, evaluation of the implementation strategy or their receptivity to the implementation strategy <i>and</i> extent of involvement |

[Ginsburg, et al, 2021](#)

Six fidelity assessment challenges were identified:


- (1) Need to develop succinct tools to measure fidelity given tools tend to be intervention specific,
- (2) Determining which components of fidelity (delivery, receipt, enactment) to emphasize,
- (3) Unit of analysis considerations in group-level interventions,
- (4) Missing data problems,
- (5) How to respond to and treat fidelity 'failures' and 'deviations' and lack of an overall fidelity assessment scheme, and
- (6) Ensuring fidelity assessment doesn't threaten internal validity.

METHODOLOGY

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Fidelity is not easy! Challenges and guidelines for assessing fidelity in complex interventions



Liane R. Ginsburg^{1*} , Matthias Hoben², Adam Easterbrook², Ruth A. Anderson³, Carole A. Estabrooks² and Peter G. Norton⁴

Relationship with complex interventions

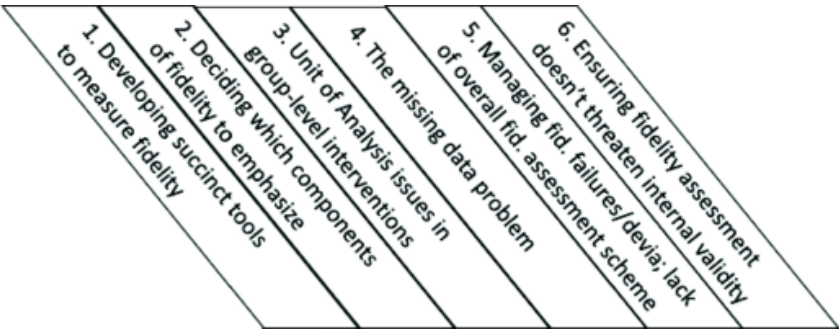
Ginsburg, et al, 2021

METHODOLOGY **Open Access**

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| | | | | | | |
|---|---|---|---|---|---|---|
| <i>Guideline C1: Undertake theoretical & empirical work to inform operationalization of fidelity delivery/receipt/enactment and to inform their combination & link to effectiveness results in trials</i> | ✓ | ✓ | | | ✓ | |
| <i>Guideline M1: Use multiple methods of fidelity assessment and build redundancy into assessment of aspects of fidelity that are under participants' control (receipt and enactment)</i> | ✓ | | | | ✓ | |
| <i>Guideline M2: Devote attention to ensuring fidelity data are complete (i.e. low rates of missing data).</i> | | | | | ✓ | |
| <i>Guideline M3: Measurement - Attend to psychometric properties of fidelity measures and unit of analysis issues</i> | ✓ | | | ✓ | ✓ | |
| <i>Guideline P1: In multi-site interventions delivered by a single, trained resource person, assessment of receipt and enactment requires more attention and resources than assessment of delivery</i> | | | ✓ | | | |
| <i>Guideline P2: Build opportunities for assessment of fidelity receipt and enactment directly into interventions</i> | ✓ | | | | | ✓ |

Measuring fidelity in complex interventions

[Walton, et al., 2019](#)

- Propose five steps that can be systematically used to develop fidelity checklists for researchers, providers, and participants to measure fidelity and engagement:
 1. Reviewing previous measures,
 2. Analyzing intervention components and developing a framework outlining the content of the intervention,
 3. Developing fidelity checklists and coding guidelines,
 4. Obtaining feedback about the content and wording of checklists and guidelines, and
 5. Piloting and refining checklists and coding guidelines to assess and improve reliability

Developing quality fidelity and engagement measures for complex health interventions

Holly Walton^{1*} , Aimee Spector², Morgan Williamson³, Ildiko Tombor⁴ and Susan Michie²

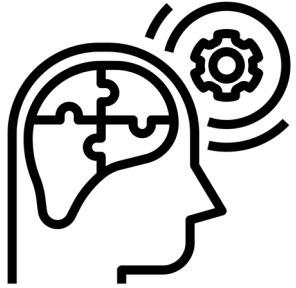
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Relationship with pragmatic studies



- Few pragmatic studies report implementation fidelity ([Stecher, et al, 2023](#))
- Pragmatic studies often permit and promote continuous adaptations, deviating from the original protocol, decreasing fidelity ([Gupta, et al, 2023](#))
- No statistically significant relationships between fidelity and outcomes were found, in a pragmatic study with real-world implementation in seven sites (potentially due low variation in fidelity?) ([Latimer, et al, 2022](#))

Example 1

[Powers, et al, 2022](#)

Powers et al. *Pilot and Feasibility Studies* (2022) 8:234
<https://doi.org/10.1186/s40814-022-01194-x>


Pilot and Feasibility Studies

METHODOLOGY

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Developing an implementation fidelity checklist for a vocational rehabilitation intervention



Katie Powers^{1*} , Sara Clarke¹, Julie Phillips¹, Jain A. Holmes¹, Rachel Cripps², Kristelle Craven¹, Amanda Farrin³, Roshan das Nair^{4,5} and Kathryn A. Radford¹

Key Highlights

- Describes the development and testing of an intervention fidelity checklist for a complex intervention, with several core components that is delivered in four stages (Builds on [Walton, et al., 2019](#) recommendations)
- Five versions, iteratively developed by piloting and with input from an expert panel
- Great interrater reliability (0.69 to 1) because of copious guidance; but took 30-100 mins to complete
- Demonstrated the “feasibility of using a retrospective review of intervention records to assess fidelity, which may facilitate robust longitudinal fidelity assessment procedures in future complex intervention studies”

Example 2

[Gupta, et al, 2023](#)

Gupta et al. *BMC Public Health* (2023) 23:575
<https://doi.org/10.1186/s12889-023-15477-2>

BMC Public Health

RESEARCH

Open Access

Implementation fidelity to a behavioral diabetes prevention intervention in two New York City safety net primary care practices



Avni Gupta^{1*}, Jiyuan Hu², Shengnan Huang³, Laura Diaz⁴, Radhika Gore⁵, Natalie Levy⁶, Michael Bergman^{3,7,8}, Michael Tanner⁹, Scott E. Sherman^{10,11}, Nadia Islam¹⁰ and Mark D. Schwartz^{12,13}

Key findings:

- Demonstrated moderate to high (depending on intervention component) rates of implementation fidelity of CHORD, and moderation by implementation site
 - High variability of fidelity among components: For example, coverage and content adherence were moderate to high, there was high variability in the dosage
 - Showed that fidelity is also related to the “relative advantage of the intervention” For example, the benefits of an prevention intervention are more intangible and could have reduced patients motivation to participate fully in the interventions (compared to a pain intervention)
- use of quantitative methods for fidelity assessment will allow us to use these measures in outcome data analyses to determine the role of fidelity in observed outcomes

Example 2

Gupta, et al, 2023

| Framework construct | Reported measure from the CHORD trial | Corresponding CHORD intervention core component if applicable | Data Source |
|----------------------------|--|---|--|
| Fidelity | | | |
| Coverage | Percent of outreached patients who were enrolled | N/A | Outreach form |
| | Percent of enrolled patients who completed intake | N/A | Intake form |
| | Percent of intake patients who completed the first core component of establishing at least one goal or a Health Action Plan ^a | 1 | Goal Setting Form |
| Content adherence | Percent of intake patients who established at least one goal or a Health Action Plan ^a | 1 | Goal Setting Form |
| | Percent of intake patients who received coaching on at least one education topic | 2 | Encounter Form |
| | Percent of intake patients who received coaching on all education modules | 2 | Encounter Form |
| | Percent of intake patients who had at least 1 PC visit | 3 | Electronic Health Record |
| | Percent of intake patients who received at least one referral | 4 | Encounter and Referral Forms |
| | Percent of intake patients who received at least one successful encounter | N/A | Encounter Form |
| | Percent of intake patients who received all four core components in some capacity | 1–4 | Goal Setting, Encounter and Referral Forms |
| Dose- frequency | Median number of goals established | 1 | Goal Setting Form |
| | Median number of goals completed | 1 | Goal Setting Form |
| | Median number of education sessions delivered | 2 | Encounter Form |
| | Median number of education modules discussed | 2 | Encounter Form |
| | Median number of PC visits | 3 | Electronic Health Record |
| | Median number of referrals | 4 | Encounter and Referral Forms |
| | Median number of successful encounters | N/A | Encounter Form |
| Dose- duration | Median duration (days) of follow-up time ^b | N/A | Encounter Form |
| Moderating factors | | | |
| Participant responsiveness | Baseline Patient Activation Measure Score (< median vs. ≥ median) | N/A | Intake Form |
| Context | Clinical site (VA vs. BH) | N/A | Study Form |

^aPercent of intake patients who established at least one goal or completed establishing a Health Action Plan was operationalized as a measure of two fidelity constructs – content adherence and coverage – because this component was the first component that patients were required to complete in order to proceed with other components of the intervention

^bDuration of follow-up is the time from beginning of outreaching till the last successful encounter

Example 3


[Ginsburg, et al, 2020](#)

RESEARCH

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Examining fidelity in the INFORM trial: a complex team-based behavioral intervention



Liane R. Ginsburg^{1*} , Matthias Hoben², Adam Easterbrook², Elizabeth Andersen³, Ruth A. Anderson⁴, Lisa Cranley⁵, Holly J. Lanham⁶, Peter G. Norton⁷, Lori E. Weeks⁸ and Carole A. Estabrooks²

Key findings:

- Teams with the highest perceived relevance ratings had higher formal team communications scores at follow-up, which lead to high fidelity enactment (i.e., extensive supporting activities undertaken to include the model in care)
- “Best outcomes may come from scaling back the intensity of delivering complex behavioral interventions, instead using scarce resources to support fidelity enactment (i.e., helping teams to successfully implement an intervention). Ways to strengthen enactment may also achieve longer-term sustainment of practice changes in an intervention.”

Reflection questions



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- Given the huge focus of our scientific enterprise on innovation, is it surprising that methodological and conceptual clarity around fidelity remains low, since reproducibility is rarely a goal?
- Would challenges to maintaining fidelity be lower if the interventions or strategies were designed using a co-creation and participatory engagement approaches? (Further reading: [Napoles, et al., 2018](#))
- How do you balance fidelity, when adaptations are needed in settings serving/ communities experiencing disparities? (Further reading: [Alvidrez, et al., 2019](#))



Let's connect!

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