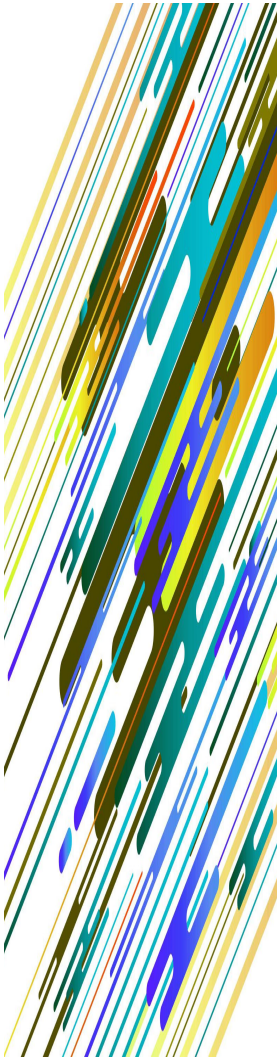
Using FRAME to code equity-oriented adaptations

Shannon Wiltsey Stirman, Ana Baumann, JD Smith

March 2024



Today's goals

- Identify and distinguish adaptations made to promote health equity and to address culture and needs of historically marginalized populations,
- Apply the Framework for Reporting Adaptations and Modifications-Expanded (FRAME) to capture equity-centered adaptations,
- Discuss methodological considerations for evaluating the impact of these adaptations.

We want your input!

- https://padlet.com/abaumannwalker/how-can-we-center-frame-on-equity-i1r70cb3rlvyc8sp

Some assumptions

Assumption 1: You have established (at least in theory, if not empirically) what components that are important for your intervention, and how to track for fidelity.

Assumption 2: Attending to adaptation is important as a complement to the assessment of fidelity, and not necessarily in conflict with fidelity

Assumption 3: Adaptation happens. It may or may not impact different outcomes (we are still learning)

Some assumptions

Assumption 4: If the goal of adaptation is to promote equity, it should happen–and we need to make sure it's effective!

Assumption 5: While we will go over some definitions related to health equity, we start with an assumption that if you are here, you recognize the importance of, and need for adapting interventions to promote health equity

Assumption 6: The field of adaptation science is in progress, and **we are learning together**

Discussions for another day
not today

- How to adapt
- Measurement issues
- Fidelity - How to think about fidelity vs adaptation when you're still developing your intervention, or fidelity to the adaptation or implementation process

There are some adaptation frameworks that specify an adaptation process.
Frame-IS covers adaptations to an implementation process.

Definitions and Distinctions

Modification, Fidelity, Adaptation

Fidelity: the delivery of core intervention components (adherence), with appropriate skill (competence)

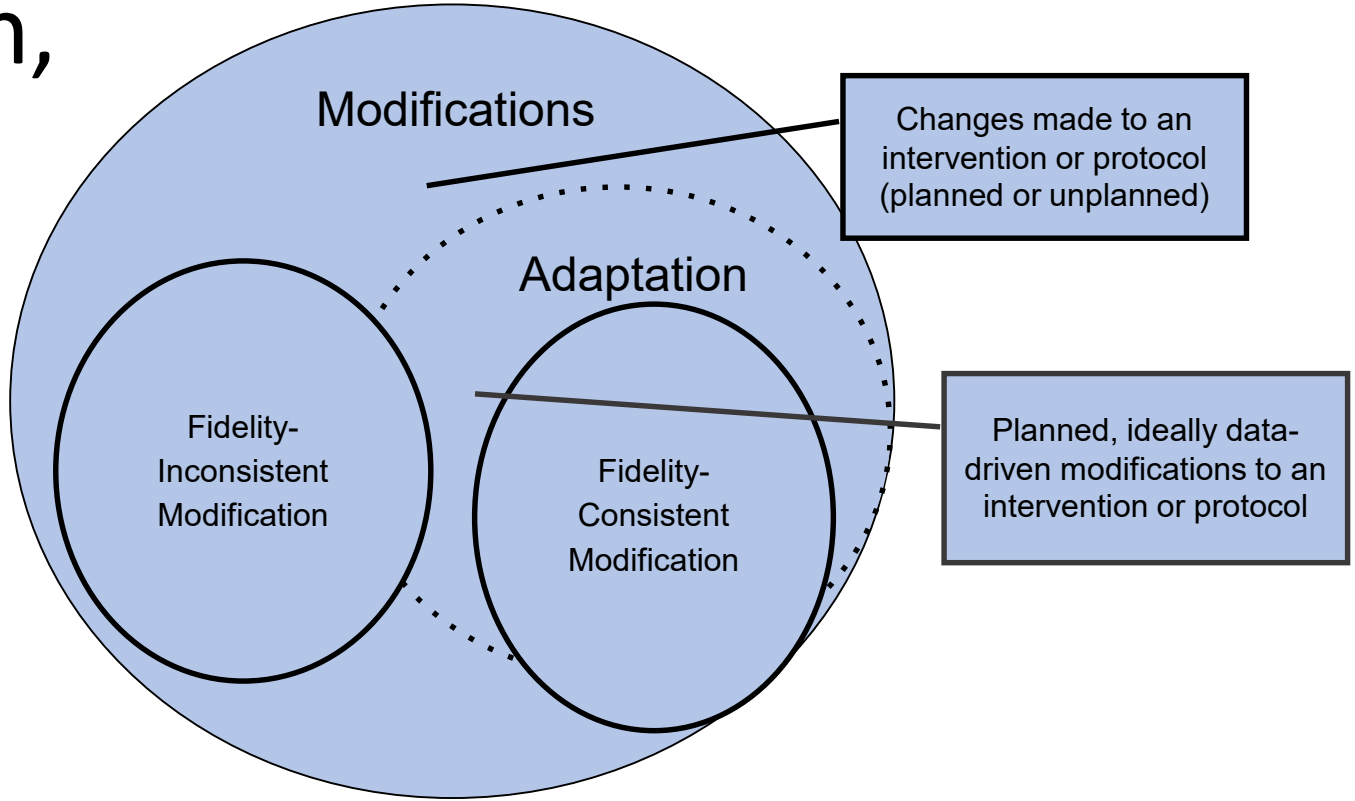
Modification: changes (proactive or reactive) made to the intervention/program

Adaptation: proactive, planned modifications

a *strategy that can address the interplay between the fit of the intervention (the what), the process of implementation (the how), and the context in which the intervention is being implemented (the where).*

Stirman, S. W., Baumann, A. A., & Miller, C. J. (2019). The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*, *14*(1), 1-10.

Modification, Adaptation, Fidelity



Stirman, S. W., Gutner, C. A., Crits-Christoph, P., Edmunds, J., Evans, A. C., & Beidas, R. S. (2015). Relationships between clinician-level attributes and fidelity-consistent and fidelity-inconsistent modifications to an evidence-based psychotherapy. *Implementation Science*, *10*(1), 1-10.

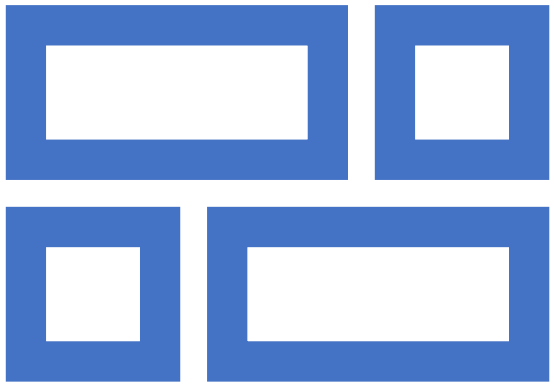
Health Equity and Context

Health equity is a process that requires continuous action to address historical and contemporary injustices and to allocate resources according to need (Jones).

Context is defined by social, organizational, political, and external factors (e.g., organizational culture, finances) that influence the successful delivery and impact of EBIs

We need to ask: how and in what context has this intervention been shown to work, and how can the system or the intervention be adapted to work as well as possible in different contexts?

Braveman P. A new definition of health equity to guide future efforts and measure progress. Health Affairs Blog. 2017;22:1–4.
Jones CP. Systems of power, axes of inequity: parallels, intersections, braiding the strands. Med Care. 2014;52(10 Suppl 3):S71–5. https:// doi. org/ 10. 1097/ mlr. 00000 00000 000216.



Overview of the FRAME

Adaptation: Documenting

Wiltsey Stirman *et al. Implementation Science* (2019) 14:58
https://doi.org/10.1186/s13012-019-0898-y

Implementation Science

DEBATE Open Access

The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions

Shannon Wiltsey Stirman[1*], Ana A. Baumann[2] and Christopher J. Miller[3,4]

Framework for Reporting Adaptations and Modifications-Expanded*

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/purveyor
- Researcher
- Treatment/Intervention team
- Individual Practitioners (those who deliver it)
- **Community members**
- **Recipients**

Optional: Indicate who made the ultimate decision.

PROCESS

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

SEE FRAME-IS for:

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
- Loosening 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

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

REASONS

SOCIOPOLITICAL
- Existing Laws
- Existing Mandates
- Existing Policies
- Existing Regulations
- Political Climate
- Funding Policies
- Historical Context
- Societal/Cultural Norms
- Funding or Resource Allocation/Availability

ORGANIZATION/SETTING
- 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

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

RECIPIENT
- Race; Ethnicity
- Gender identity
- Sexual Orientation
- Age/Developmental phase
- Access to resources
- Cognitive capacity
- Physical capacity
- Literacy and education level
- First/spoken languages
- Motivation and readiness
- Technology (comfort/access)
- Legal status
- Cultural or religious norms
- Comorbidity
- Immigration Status
- Crisis or emergent circumstances

Level of trust in the system

HOW?

Fidelity Consistent/Inconsistent

To use these codes, we assume you are working with an intervention that has been tested, and/or we know what fidelity is (e.g., components or functions have been clearly specified and there is a measure of fidelity)

If you are using the fidelity-consistent/fidelity inconsistent code on the FRAME, note that there is an “unknown” specifier.

Who?

WHO participated in the decision to modify?

- Here, pay attention to:
  - Who makes the final decision, and why
  - How are the decisions being made (diversity <> equity)
  - Attention to power, positionality
  - Who is missing in the room.. And why?

Why?

Goals related to equity

Increase reach or engagement	Could be applied if adaptation is to make intervention more appealing or accessible for a specific group
Increase retention	If adaptation is to reduce dropout among specific demographic groups
Improve feasibility	If it makes it more likely that the intervention can be done in an under-resourced setting
Improve fit with recipients	May or may not relate to culture or equity (could be a preference–people want to do it at home rather than office because they work during office hours)
To address cultural factors	Specify when the goal is to improve fit with a specific culture (e.g., *consider language, culture, and context in such a way that it is compatible with the client's cultural patterns, meanings, and values; Bernal 2009)*
Improve effectiveness/outcomes	If it is to improve outcomes for a historically marginalized population or where a disparity has been identified
Increase satisfaction	To increase satisfaction among a historically marginalized population
To reduce disparities or promote equity	Added to make the intention explicit
Cost	*Be mindful of whether decisions to reduce cost impact equity over the short, medium and long term

Not all adaptations are cultural adaptations

Adaptation	**Cultural**	**Not Cultural**	**Depends**
Tailoring stories or analogies that illustrate concepts (content)	To make examples/stories familiar to individuals from a **different country or of a specific ethnicity**	To make them **developmentally appropriate** for a different age group (e.g., originally for adults now for teens; instead of a work scenario it becomes a school scenario)	
Changing a health promotion intervention from a clinic/hospital to another setting (in-home; library) (Context)	To address a **religious or cultural reason** for not accessing medical care	To increase access due to **geographic distance** from medical facilities	If there is stigma related to cultural or religious beliefs around accessing care or addressing specific health behaviors

Adaptation	**Cultural**	**Not Cultural**	**Depends**
Change reading level or amount of writing expected/required	If in a specific cultural context, there are **cultural norms** about who gets how much education (e.g., girls only attend grade school)	If the intended population has **learning differences or disabilities** that require simplified language or has difficulty writing	Consider whether educational opportunity is due to available resources vs cultural norms (or both)

What?

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

What is the relationship to fidelity*?

-Fidelity Consistent
-Fidelity Inconsistent
-Unknown
**preservation of essential elements*

Context 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
- Repeating elements or modules
- Loosening structure
- Departing from the intervention (“drift”) followed by a return to protocol within the encounter
- Drift from protocol without returning

Reasons?

Reasons

- Based on implementation determinants and social determinants of health
- For Organizational and individual levels, the focus is on more proximal, rather than distal determinants.
- Distal determinants might be captured through Socio-Political/Outer context
- E.g., Historically inequitable distribution of resources due to systemic racism
- The proximal determinant would be policy/allocation of resources [outer context] and/or available resources [inner context]
- WHY? Because we need more granularity to understand whether the adapted intervention is effective in addressing the proximal causes and appropriate mechanisms

Reasons

- Intended to be a tool to characterize reasons for making specific adaptations
- If a specific SDOH or Implementation framework is a better fit for reasons for your project, ok to swap our FRAME reasons for a different framework
    - E.g., if there is a more detailed framework of determinants of technology implementation
    - E.g., National Institute on Minority Health and Health Disparities Research Framework
- However, we recommend careful consideration and that you avoid indiscriminately adding without consulting work/frameworks that already exist

National Institute on Minority Health and Health Disparities Research Framework

		Levels of Influence*			
		Individual	**Interpersonal**	**Community**	**Societal**
Domains of Influence *(Over the Lifecourse)*	**Biological**	Biological Vulnerability and Mechanisms	Caregiver–Child Interaction Family Microbiome	Community Illness Exposure Herd Immunity	Sanitation Immunization Pathogen Exposure
	Behavioral	Health Behaviors Coping Strategies	Family Functioning School/Work Functioning	Community Functioning	Policies and Laws
	Physical/Built Environment	Personal Environment	Household Environment School/Work Environment	Community Environment Community Resources	Societal Structure
	Sociocultural Environment	Sociodemographics Limited English Cultural Identity Response to Discrimination	Social Networks Family/Peer Norms Interpersonal Discrimination	Community Norms Local Structural Discrimination	Social Norms Societal Structural Discrimination
	Health Care System	Insurance Coverage Health Literacy Treatment Preferences	Patient–Clinician Relationship Medical Decision-Making	Availability of Services Safety Net Services	Quality of Care Health Care Policies
Health Outcomes		**Individual Health**	**Family/ Organizational Health**	**Community Health**	**Population Health**

National Institute of Minority Health and Health Disparities, 2018

*Health Disparity Populations: Racial and Ethnic Minority Groups (defined by OMB Directive 15), People with Lower Socioeconomic Status, Underserved Rural Communities, Sexual and Gender Minority Groups, People with Disabilities

Other Fundamental Characteristics: Sex and Gender, Disability, Geographic Region

SOCIOPOLITICAL	ORGANIZATION/SETTING	PROVIDER	RECIPIENT	
- 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	- Race - Ethnicity - Sexual/gender identity - First/spoken languages - Previous Training and Skills - Preferences - Clinical Judgement - Cultural norms, competency - Perception of intervention - Comfort with Technology	- Race; Ethnicity - Gender identity - Age/developmental phase - Sexual Orientation - Access to resources - Cognitive capacity - Physical capacity - Literacy and education level - First/spoken languages - Motivation and readiness - Comfort with technology	- Legal status - Cultural or religious norms - Comorbidity - Immigration Status - Crisis or emergent circumstances - Level of trust in the system

Reasons-Individual Level

- Code if the provider is of a different race, ethnicity, sexual orientation, gender identity religion or disability status than the recipient and adaptations are made to facilitate cultural competence and shared understandings, or to acknowledge different experiences that the provider and recipient may have had

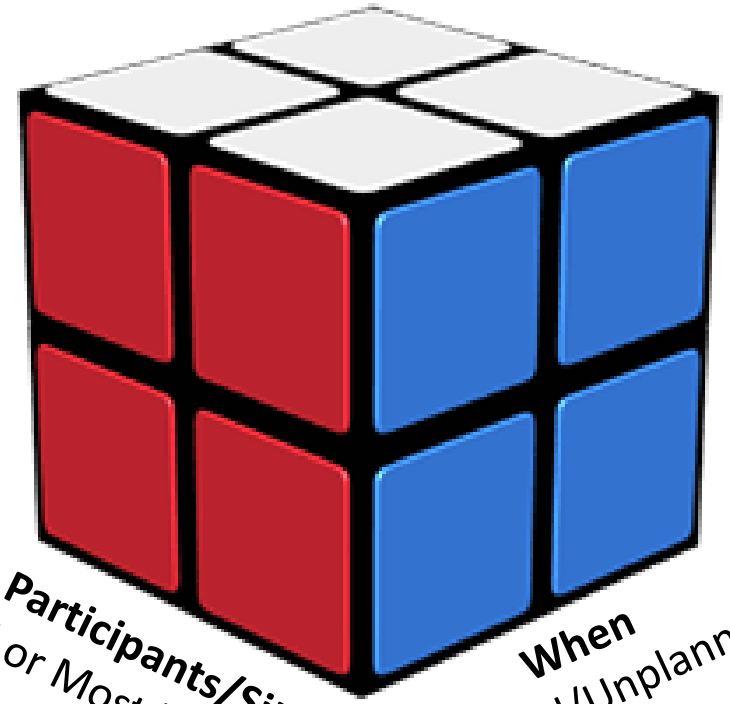
- Decisions on whether to code these factors at the provider, recipient level, or both may depend on who identifies the need, or whether the adaptation applies to a single or few recipients or provider

- **First/spoken languages**—e.g., if training or therapist materials need to include translation of concepts and terminologies; if intervention may need to include use of multiple languages to facilitate understanding

- **Mistrust of system** may lead to adaptations to improve engagement or satisfaction (e.g., lay health workers providing education or intervention)

Methodological and Statistical Considerations for Adaptation

Three Dimensions of Adaptations



Planned Adaptation During a Trial

- Fidelity-Consistent Adaptation of an existing EBI during a trial applied to all study participants
- Why?
  - Compare the effectiveness of the unadapted EBI vs. the EBI adapted for the context and/or population
    - Use an adaptive study design or interrupted time-series
    - Dynamic Adaptation Process (DAP) model (Aarons et al. 2012, *Implement Sci*)
    - (probably) Better to simply do a parallel two- or three-arm trial

Unplanned Adaptation

Whoops! Now what?

Unplanned, Fidelity Consistent Adaptation to All Study Participants

- Minor adaptation
  - might not need to do anything beyond applying FRAME to characterize/describe the adaptation
- Major adaptation
  - Post-hoc pre-post adaptation analysis (within-group)
  - Could be treated as a fixed effect or as a moderating variable depending on the analytic approach (i.e., Does the treatment effect vary as a function of receiving the adapted vs. unadapted version of the EBI)

Unplanned, Fidelity Consistent Adaptation to a Subgroup of the Study Participants

- (major or minor) Adaptation applied to all participants within a subgroup of the study sample
  - Obesity prevention program – families experiencing food insecurity
    - Subgroup analysis (FI vs. FS)
    - Post-hoc within group comparison (FI pre-adaptation vs. FI post-adaptation)
    - 2-way Interaction effect

Unplanned, Fidelity Inconsistent Adaptation by a Site(s)/Implementer(s)

- From the beginning of the study (and not rectified)
  - Major – might need to throw out the data (strict RCT rules)
  - Minor – sensitivity analysis (with and without the data)
- Clear point of departure from the protocol during the study
  - Major – might need to throw out the data after the protocol deviation/violation (strict RCT rules)
  - Minor – sensitivity analysis (with and without the data)

Special Considerations for Stepped Wedge/Roll-Out Trial Designs

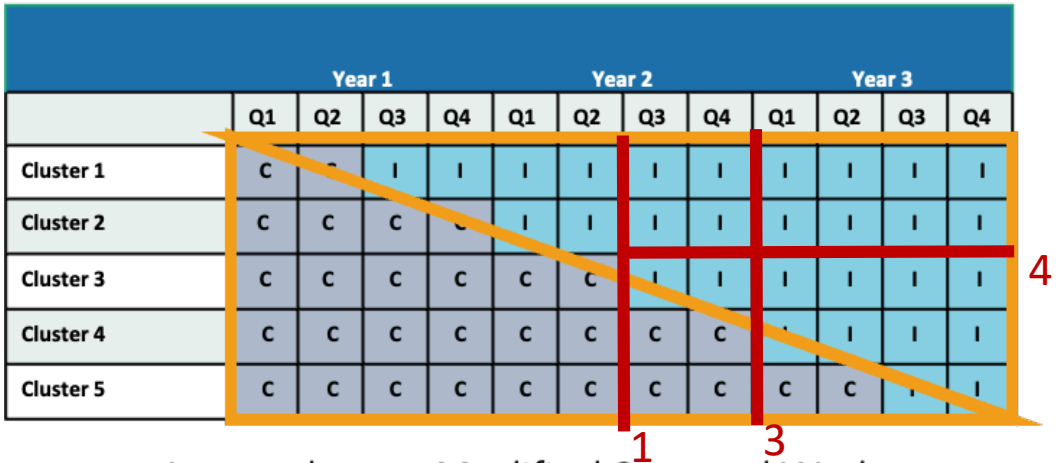
Stepped Wedge

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cluster 1	C	C	I	I	I	I	I	I	I	I	I	I
Cluster 2	C	C	C	C	I	I	I	I	I	I	I	I
Cluster 3	C	C	C	C	C	C	I	I	I	I	I	I
Cluster 4	C	C	C	C	C	C	C	C	I	I	I	I
Cluster 5	C	C	C	C	C	C	C	C	C	C	I	I

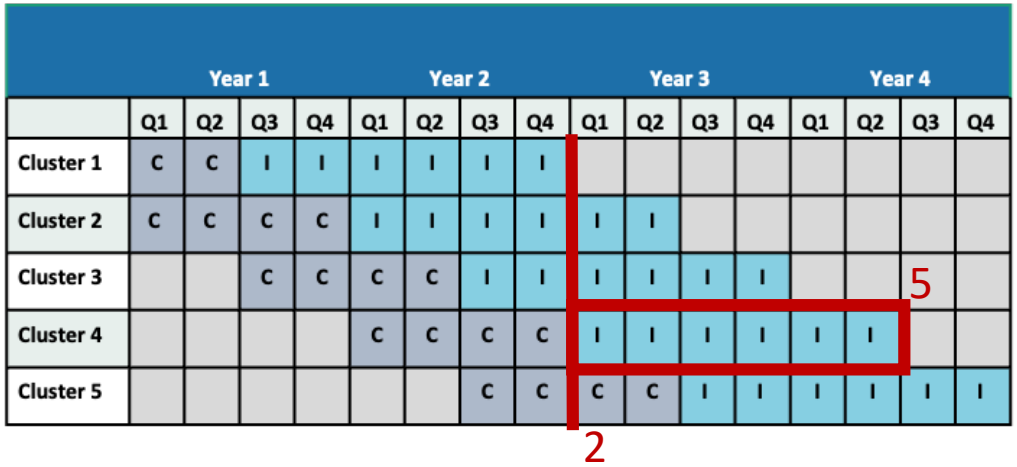
Incomplete or Modified Stepped Wedge

	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cluster 1	C	C	I	I	I	I	I	I								
Cluster 2	C	C	C	C	I	I	I	I	I	I						
Cluster 3			C	C	C	C	I	I	I	I	I	I				
Cluster 4					C	C	C	C	I	I	I	I	I	I		
Cluster 5							C	C	C	C	I	I	I	I	I	I

Stepped Wedge



Incomplete or Modified Stepped Wedge



1. enough C and I data to test before-after adaptation
2. a. C1 is done so that data might need to be thrown out depending on nature of the adaptation (how different is it?)
   b. otherwise can test for before-after adaptation
3. Not enough control data for comparison (except for C5), but can compare within I condition
4. Sufficient data to examine before-after adaptation effects
5. Might have to toss the data from this cluster OR conduct sensitivity analysis

Learning Health Systems
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RESEARCH REPORT | Open Access

Analysis of *FRAME* data (A-FRAME): An analytic approach to assess the impact of adaptations on health services interventions and evaluations

Heather Z. Mui, Cati G. Brown-Johnson, Erika A. Saliba-Gustafsson, Anna Sophia Lessios, Mae Verano, Rachel Siden, Laura M. Holdsworth

First published: 15 March 2023 | https://doi.org/10.1002/lrh2.10364

A-FRAME Method

Three-step analysis plan:

1. calculated the frequency of adaptations by FRAME categories across projects;
2. qualitatively assessed the impact of adaptations on project goals; and
3. qualitatively assessed relationships between adaptations within projects to thematically consolidate adaptations to generate more explanatory value on how adaptations influenced intervention progress and outcomes.

Best suited for interpretation of results/process, not quantitative analyses

Final Questions or Comments?

Resources

- Adaptation Resources | The F.A.S.T. Lab | Stanford Medicine: https://med.stanford.edu/fastlab/research/adaptation.html
- Codebooks, talks on FRAME and FRAME-IS, updated FRAME figure, sample coding forms, etc are here.