Multi- and mixed-methods approaches for documenting and analyzing adaptations in real-world studies

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- Jodi Summers Holtrop, PhD, MCHES

COPRH Con

Colorado Pragmatic Research in Health Conference

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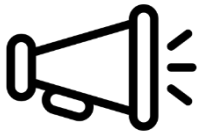
Learning objectives

1. Provide an understanding of key concepts of adaptations as they relate to the documentation and analysis of adaptations
2. Review and compare key strategies for documenting adaptations pre-implementation, during implementation, and during sustainment
3. Identify approaches to analyze adaptations and their impact pre-implementation, during implementation, and after implementation

Poll the Audience



What is your experience with adaptations in your current projects?

A. My project has made **planned adaptations**

B. My project has made **unplanned adaptations**

C. My project has made both **planned and unplanned adaptations**

D. My project did not make any adaptations but they are **happening on the ground**

E. 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).*

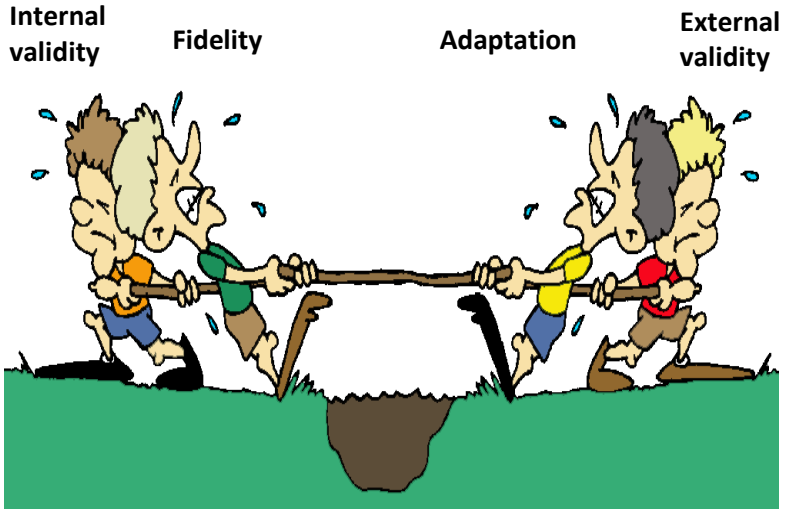
#2: Adaptation often occur **to improve the fit** (or compatibility) of the intervention/implementation strategy to a new context (e.g., population, setting, etc).

#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.

[1] http://www.csun.edu/sites/default/files/FindingBalance1.pdf
[2] Carvalho et al. *J Public Health Manag Pract 2013; 19(4):348-56.*

Historical view of fidelity and 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.

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Adaptation is not good or bad, it just happens…

Adaptation as inherent – perhaps crucial – to the implementation process

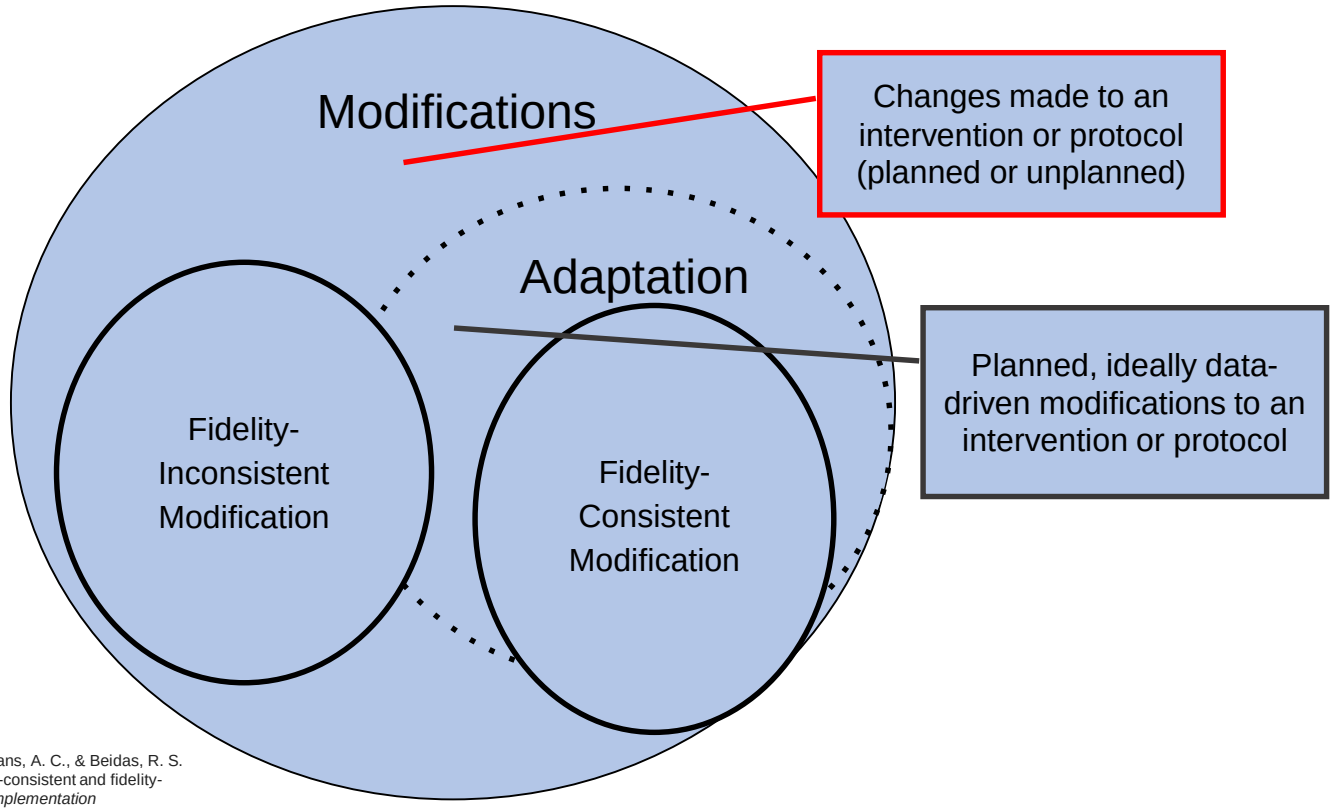
Regarding local adaptations, cultural adaptation, and other efforts to improve fit as flaws in implementation fidelity is ***at best a missed opportunity, and at worst, a recipe for implementation failure***

Baumann, A. A., Cabassa, L. J., & Stirman, S. W. (2017). Adaptation in dissemination and implementation science. *Dissemination and implementation research in health: translating science to practice*, *2*, 286-300.

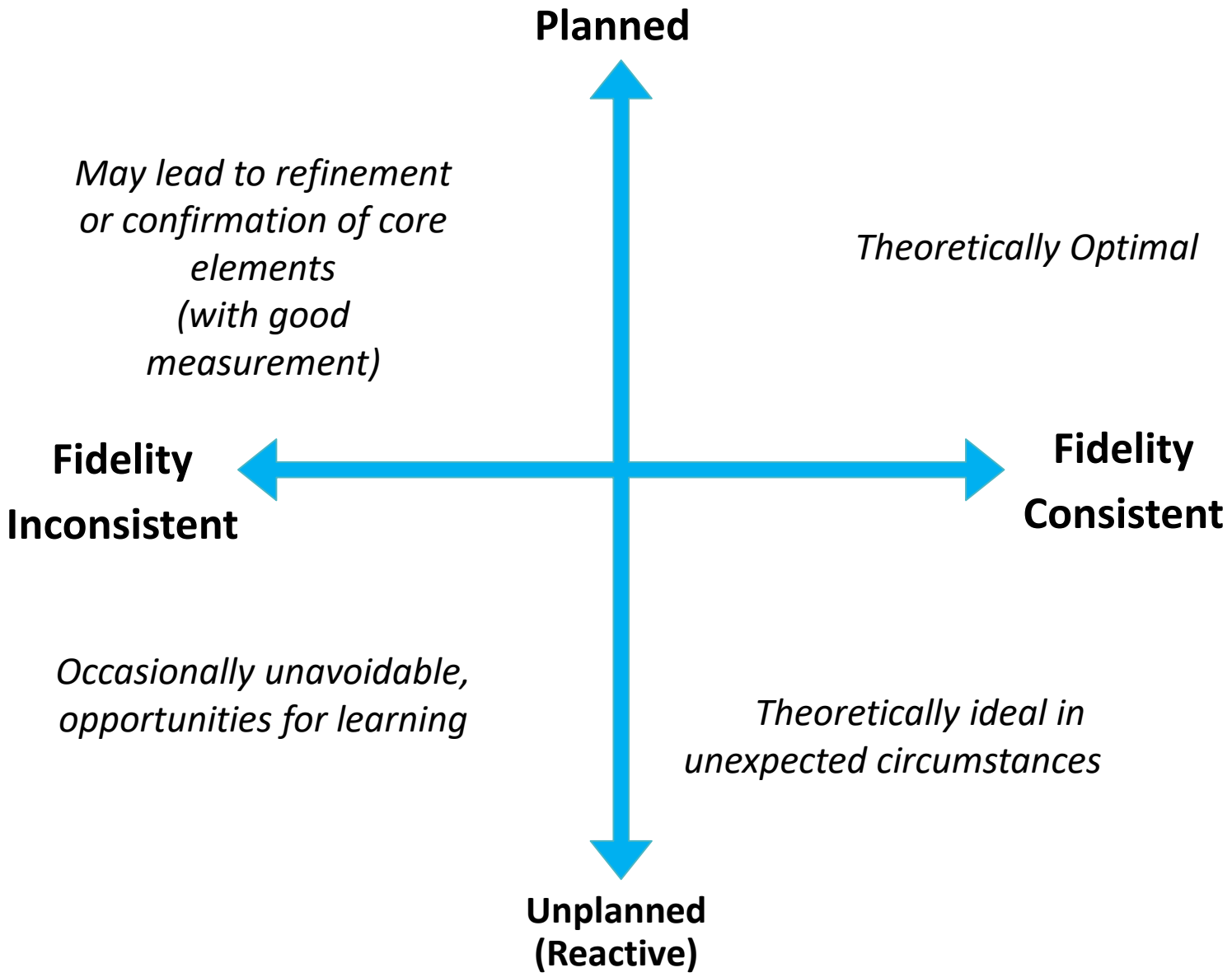
Baumann, A., Mejia, A., Lachman, J., Parra-Cardona, R., Lopez-Zeron, G., Amador Buenabad, N. G., ... & Domenech Rodrigeuz, M. M. (2018). Parenting programs for underserved populations: Issues of scientific integrity and social justice. *Global Social Welfare*.

Parra-Cardona, R., Leijten, P., Lachman, J. M., Mejía, A., Baumann, A. A., Buenabad, N. G. A., ... & Ward, C. L. (2018). Strengthening a culture of prevention in low-and middle-income countries: Balancing scientific expectations and contextual realities. *Prevention Science*, 1-11.

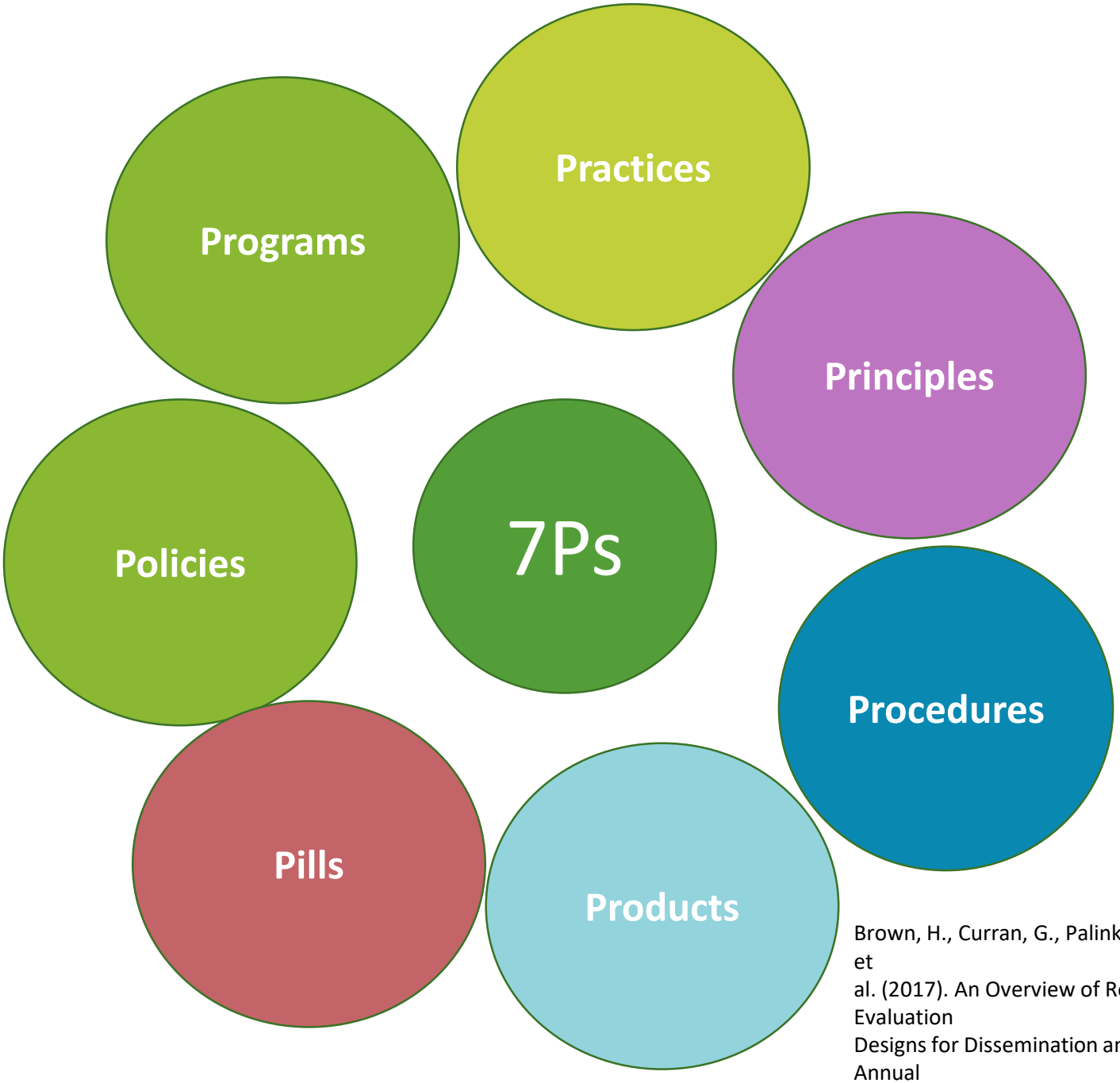
Modification, Adaptation, Fidelity



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.



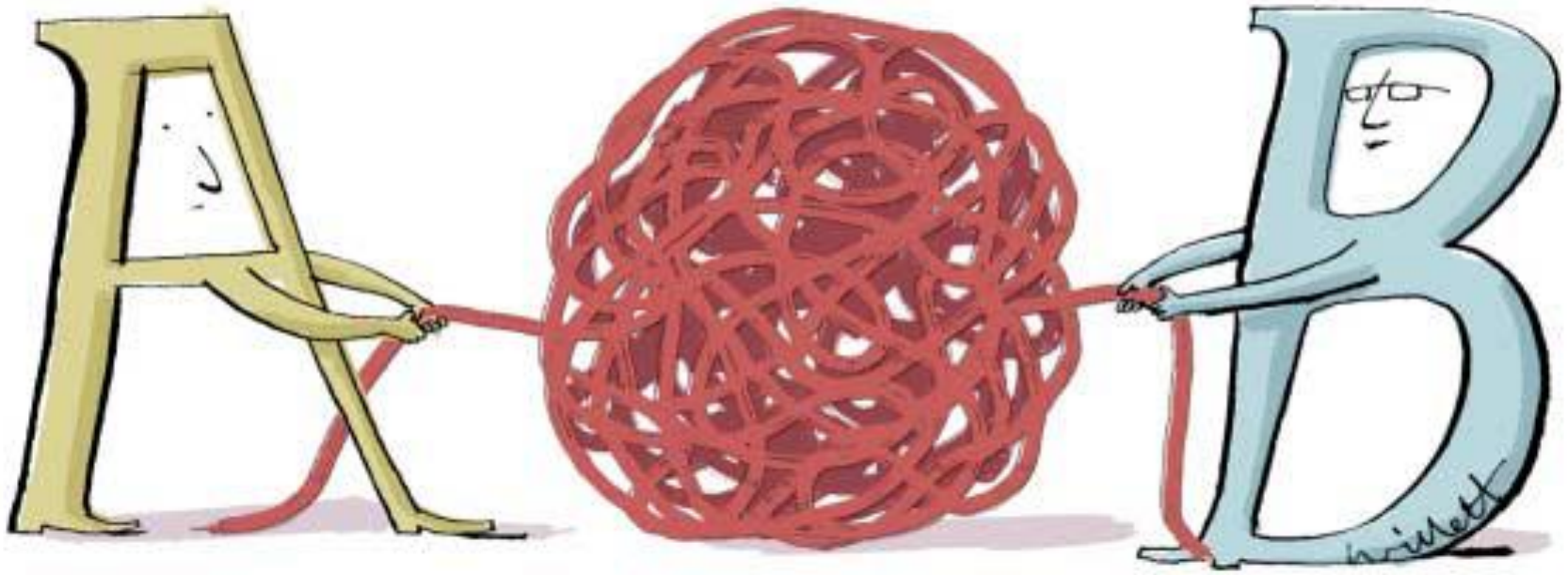
Miller, C. J., Wiltsey-Stirman, S., & Baumann, A. A. (2020). Iterative Decision-making for Evaluation of Adaptations (IDEA): A decision tree for balancing adaptation, fidelity, and intervention impact. *Journal of Community Psychology*, *48*(4), 1163-1177.



Brown, H., Curran, G., Palinkas, L.A., Aarons, G.A. et
al. (2017). An Overview of Research and Evaluation
Designs for Dissemination and Implementation. Annual
Review of Public Health 38;1-22.

It is not easy to untangle….

CORE COMPONENTS **AND** **DISCRETIONARY PERIPHERY**



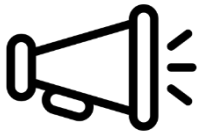
Hawe et al. BMJ 2004;328:1561–3

Adaptations – when and what?

Focus of Adaptation	Timing of Adaptation - Point in the Study Planning Pre-implementation	During Implementation	Following Sustainment
Intervention			
Implementation Strategy			
Context			

Rabin BA, McCreight M, Battaglia C, et al. Systematic, Multimethod Assessment of Adaptations Across Four Diverse Health Systems Interventions. *Front Public Health*. 2018;6:102.

Poll the Audience



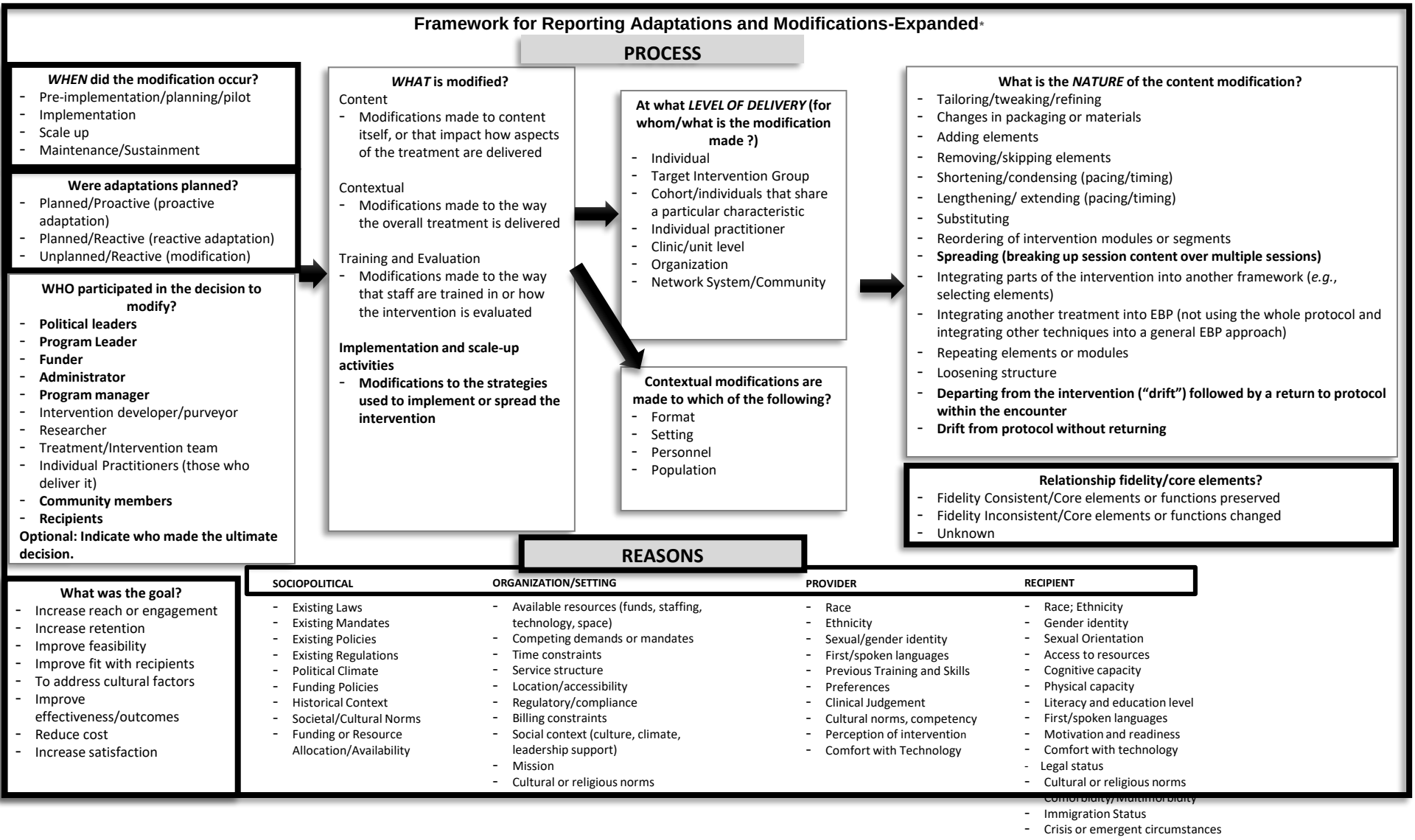
How are you documenting adaptations in your current project(s)?

A. **Not** documenting adaptations
B. **Systematically and comprehensively** documenting adaptations
C. **Pragmatically** documenting adaptations

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**

The FRAME: an expanded framework to report adaptations and modifications



Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implement Sci*. 2019;14(1):58.

When, what, and how document adaptations?

Focus of Adaptation	Timing of Adaptation - Point in the Study: Planning Pre-implementation	During Implementation	Following Sustainment
Intervention			
Implementation Strategy			
Context			

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

Rabin BA, McCreight M, Battaglia C, et al. Systematic, Multimethod Assessment of Adaptations Across Four Diverse Health Systems Interventions. *Front Public Health*. 2018;6:102.

frontiers in Public Health

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

Borsika A. Rabin[1,2,3,4], Marina McCreight[1], Catherine Battaglia[1,5], Roman Ayele[1,5], Robert E. Burke[1,6], Paul L. Hess[1,6], Joseph W. Frank[1,6] and Russell E. Glasgow[1,3,4]*

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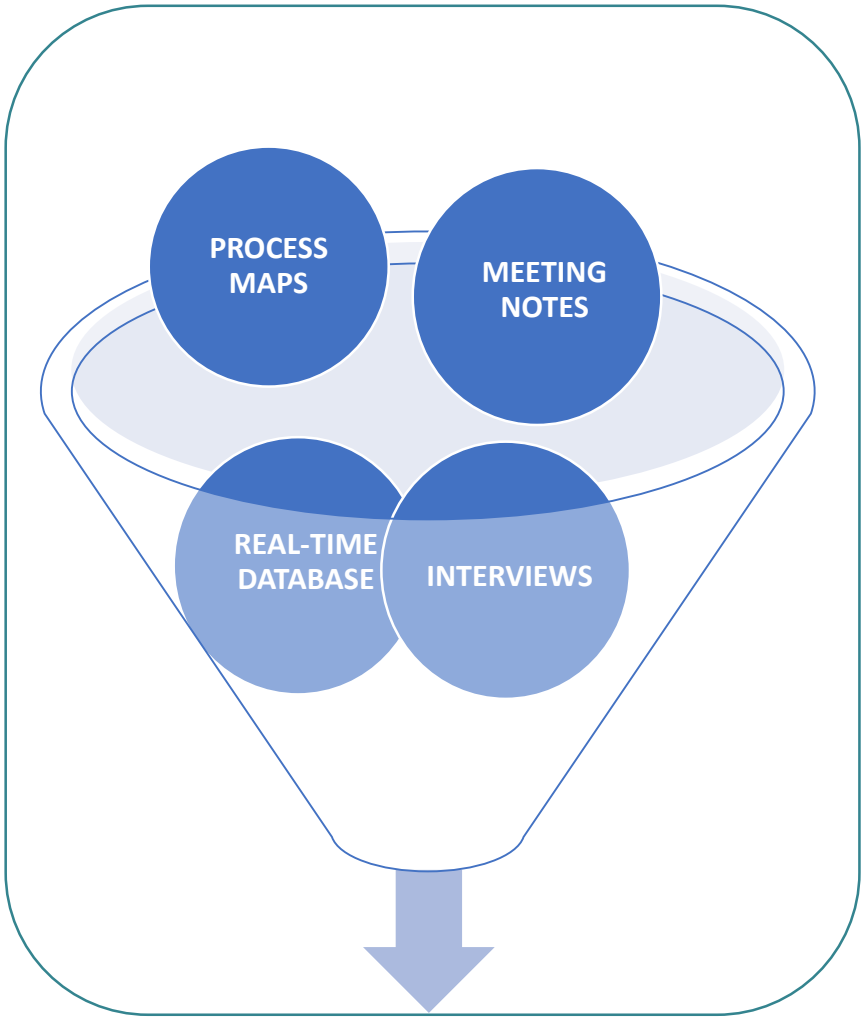
Triangulation of data

SURVEYS

OBSERVATION

INFORMAL CHECK-IN WITH TEAMS

PERIODIC REFLECTIONS



ELECTRONIC RECORDS

CHECKLISTS & LOGS

Full Picture of Adaptations

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

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

	A	B	C	D	E	F	G	H	I
1	**Analyst**	**Site**	**Interview Date**	**Type of exit interview**	**Source**	**Adaptation Description**	**Role**	**1. What was changed - elements?**	**2. What was changed - type of change**
2	**tials of analyst ducting the analysis**	Site code (Enter N/A for all)	Date when interview was conducted or adaptation identified (N/A for pre-implementation adaptations)	Simple Detailed adaptation (Enter N/A for all)	**Types:** Baseline interviews Pre open trial ART Meetings Pre open trial clinician interviews Post open trial Veteran interviews Post open trial clinician interviews Post open trial ART Meetings Post RCT C1 Veteran interviews Post RCT C1 clinician interviews Post RCT C1 ART Meetings Post RCT C2 Veteran interviews Post RCT C2 clinician interviews Post RCT C2 ART Meetings Post RCT C3 Veteran interviews Post RCT C3 clinician interviews Post RCT C3 ART Meetings Final ART interviews Clinician supervision Periodic reflections- research staff Periodic reflections- clinicians Periodic reflections- admin	**Brief description of the adaptation that was made** (Try to keep it to 1-2 sentences but provide enough context that it stands alone. *For example: Recruitment criteria was changed to include all patients with XX code as well.)*	**Role of interviewee on project**, e.g.: Research staff ART Veteran- non CDST participant ART Veteran- CDST participant ART Clinician CDST provider	**Which of the following elements was primarily changed as part of the adaptation?** The setting The format Personnel involved Condensing a component The target population How the intervention is presented Other	**Which of the following was the primary type of change involved?** Tailoring to individuals Adding a component Removing a component Condensing a component Extending a component Substituting for a component Changing the order of components Integrating with other programs we are doing Repeating a component Loosening the structure or protocol Otherwise changing the intervention
3	**tabase field**						Nurse, Champion, ??	What_Description	What_Description

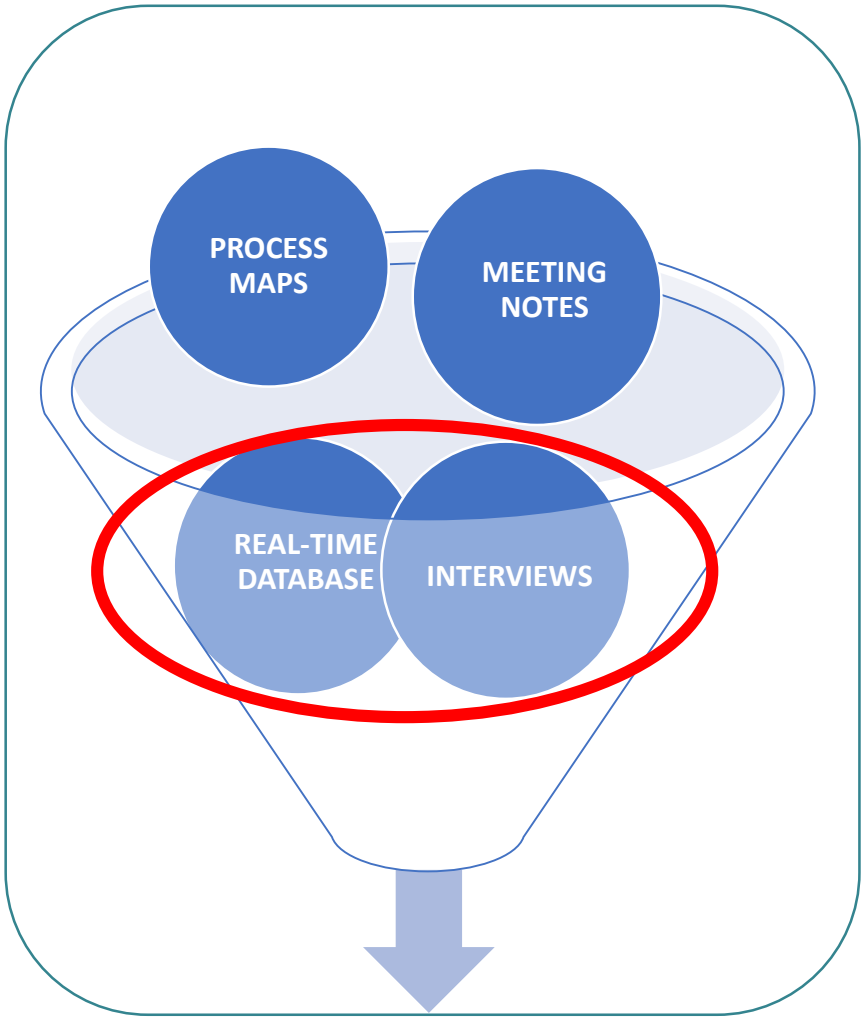
Study 1: TNP - Triangulation of data

SURVEYS

OBSERVATION

INFORMAL CHECK-IN WITH TEAMS

PERIODIC REFLECTIONS



ELECTRONIC RECORDS

CHECKLISTS & LOGS

Full Picture of Adaptations

Key findings from analysis Study 1: TNP

Table 1: Distribution of unique adaptations across sites and time points

Timing of Adaptations Across Sites and Timepoints					
Phase	Pre-I	Early-I	Imp	Late-I	Sustainment
Site 1	0	0	5	3	0
Site 2	0	2	4	0	0
Site 3	0	0	7	1	0
Site 4	0	1	8	0	0
Site 5	1	3	6	0	0
Total	**1**	**6**	**30**	**4**	**0**
Pre-I = pre-implementation, Early-I = early implementation, Imp = implementation, Late-I = late implementation					

McCarthy M, Ujano de Motta L, Nunnery M, Gilmartin H, Leonard C, …, Rabin B. Adaptations during the implementation of the Transition Nurse Program. *In press in Implementation Science*

Adaptation constructs	Pre-Implementation	Early-Implementation	Mid-Implementation	Late-Implementation	Sustainment		Total
Elements							
Format	0	0	2	1	0		3
Personnel Involved	1	0	7	1	0		9
Target Population	0	4	16	2	0		22
Intervention Presentation	0	2	4	0	0		6
Other	0	0	1	0	0		1
What was changed							
Tailoring to individuals	0	0	3	2	0		5
Adding a component	0	0	0	0	0		0
Removing a component	0	0	0	0	0		0
Condensing a component	0	0	0	0	0		0
Extending a component	0	0	1	0	0		1
Substituting for a component	0	0	1	0	0		1
Changing the order of components	0	0	0	0	0		0
Integrating with other programs	0	3	1	0	0		4
Repeating a component	0	0	0	0	0		0
Loosening the structure or protocol	0	0	0	0	0		0
Otherwise changing the intervention	1	3	24	2	0		30
Who was responsible for this change							
Entire or Most of Team	0	3	9	0	0		12
Provider (TN/SC)	1	3	16	0	0		20
Administrator	0	0	3	1	0		4
Researcher	0	0	0	3	0		3
Developer	0	0	0	0	0		0
Stakeholder	0	0	1	0	0		1

McCarthy M, Ujano de Motta L, Nunnery M, Gilmartin H, Leonard C, …, Rabin B. Adaptations during the implementation of the Transition Nurse Program. *In press in Implementation Science*

Key findings from analysis Study 1: TNP

- Longitudinal and multi-stakeholder database entries and interviews were used to assess adaptations across five sites over three years.
- Collecting data at different time points from different stakeholders allowed us to triangulate the data for a richer understanding.
- Member checking with the main implementation team provided rich contextual details that were not reflected in the database and interviews.
- We observed a change in the type and the intention of adaptations depending on when these adaptations happened.
- Adaptations are heavily influenced by personnel and context, often in interplay with each other. Few adaptations that were identified occurred in isolation.
- 73% of adaptations were coded as planned (proactive) and 27% as unplanned (reactive).
- Systematically documenting the impact (positive or negative) of adaptations on process and effectiveness outcomes as well as sustainment proved challenging.
- Some methodological challenges in using the adaptation documentation process.

McCarthy M, Ujano de Motta L, Nunnery M, Gilmartin H, Leonard C, …, Rabin B. Adaptations during the implementation of the Transition Nurse Program. *In press in Implementation Science*

Adaptations Matrix

CO-CREATE

Record ID

_____

Who is Creating this Adaptation?

Analyst/Reporter

- ☐ UCSD CRC(s)
- ☐ UCSD Investigator(s)
- ☐ CSAB
- ☐ SYH Research Staff
- ☐ SYH Investigator(s)
- ☐ SYH Provider(s)
- ☐ SYH CRC(s)
- ☐ Other

(who is reporting adaptation in REDCap)

Please specify OTHER Analyst/Reporter

_____

Identifier

- ☐ UCSD CRC(s)
- ☐ UCSD Investigator(s)
- ☐ CSAB
- ☐ SYH Research Staff
- ☐ SYH Investigator(s)
- ☐ SYH Provider(s)
- ☐ SYH CRC(s)
- ☐ Other

(who identified adaptation, may be same as Analyst/Reporter)

Please specify other identifier

_____

Site Code

- ☐ MCHC
- ☐ Community Sites
- ☐ Across Project
- ☐ CSAB
- ☐ Other

Please specify OTHER site:

_____

Date Recorded

_____

(date when record was made)

Date of Change (MM/YYYY)

_____

(when change was implemented)

Adaptation Information

Adaptation Title

_____

(ex: change in recruitment)

Adaptation Brief Summary

Brief description of the adaptation that was made (Try to keep it to 1-2 sentences but provide enough context that it stands alone. For example: Recruitment criteria was changed to include all patients with XX code as well.)

_____

(summary of what was changed)

Was it planned or unplanned?

- ◯ Planned
- ◯ Unplanned

Planned - discussed with team & made decision based on data/experience

Unplanned - change was made without shared discussion and agreement and possibly without looking at data

Details About Adaptation

What element was changed?
(Select all that apply)

- ☐ The setting
- ☐ The format (ex: in-person changed to tele)
- ☐ Personnel involved
- ☐ The target population
- ☐ How the intervention/program is presented/delivered - how core components are operationalized
- ☐ Other

Please specify OTHER type of element changed

_____

What was the type of change?
(Select all that apply)

- ☐ Tailoring to individuals
- ☐ Adding a component
- ☐ Removing a component
- ☐ Condensing a component
- ☐ Extending a component
- ☐ Substituting for a component
- ☐ Changing the order of components
- ☐ Repeating a component
- ☐ Integrating with other programs we are doing
- ☐ Loosening the structure or protocol
- ☐ Otherwise changing the intervention
- ☐ Other

Please specify OTHER type of change

_____

Mixed versus Multi Methods

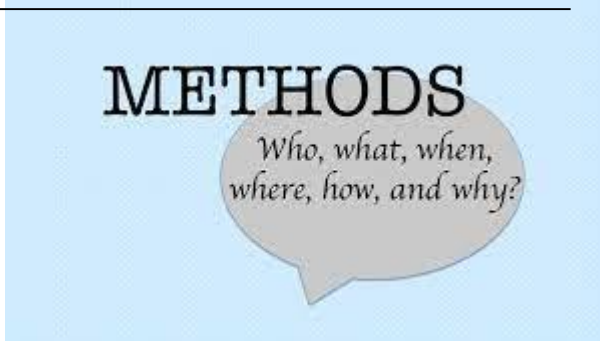
Multi Methods

- Uses more than one method
- Can be two qualitative or two quantitative or some quantitative and some qualitative

Mixed Methods

- Uses both qualitative and quantitative
- Involves mixing and integration of the data so that one type of data informs another

Analytic Methods



Qualitative

- Traditional qualitative analysis (grounded theory, thematic, content analysis, etc.)

Quantitative

- Basic descriptive statistics (frequencies, cross tabs/co-occurrence)
- Cluster analysis (statistics)

Mixed Methods

- Joint display analysis
- Configurational comparative methods (QCA, CNA)

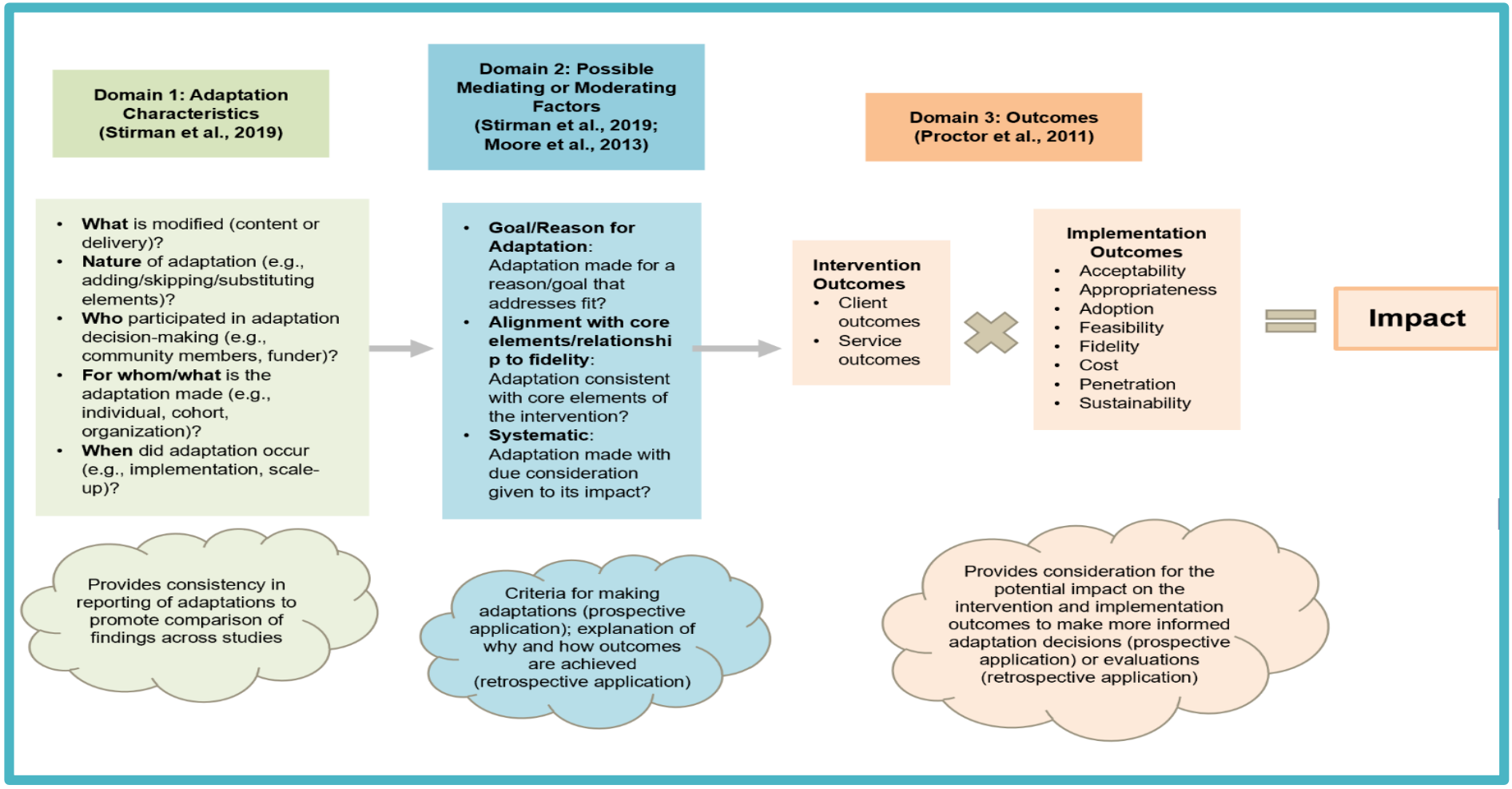
Joint Display Analysis

Qualitative Theme	Quantitative Result	Concordance/ Discordance
Adaptations occurred in both implementation (process) and delivery of sessions (content)	Adaptation Types Process: 123/202 (61%) Content: 79/202 (39%)	Agreement, although slightly more process adaptations

Data Collection Method	Adaptations Identified	Summary
Interview	164	Best at explaining what happened in detail and why/desired result
Observation	85	Best at identifying changes during the sessions such as length of time and content covered
Field Notes	74	Best source of process information given that challenges were discussed with coaches
Total (all methods)	202	
Overlap (at least 2 methods)	75%	

Model for Adaptation Design and Impact (MADI)

MADIguide.org



Kirk, M.A., Moore, J.E., Wiltsey Stirman, S. *et al.* Towards a comprehensive model for understanding adaptations' impact: the model for adaptation design and impact (MADI). *Implementation Sci* **15,** 56 (2020).

Configurational Comparative Methods: Form of Mixed Methods (Quantitizing)

- CCM is a family of methods that allows considering program features and contextual conditions to examine relationships in groups or sets with outcomes – ideal for adaptations
- Two main methods: Qualitative Comparative Analysis (QCA), Coincidence Analysis (CNA)
- Use to identify necessary and sufficient conditions and conditions in configurations with an outcome
- Math, but not statistics

Finley et al. BMC Medical Research Methodology (2018) 18:153
https://doi.org/10.1186/s12874-018-0610-y

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Periodic reflections: a method of guided discussions for documenting implementation phenomena

Erin P. Finley[1,2,3*], Alexis K. Huynh[3,4], Melissa M. Farmer[3,4], Bevanne Bean-Mayberry[3,4,5], Tannaz Moin[3,4,5], Sabine M. Oishi[3,4], Jessica L. Moreau[3,4], Karen E. Dyer[3,4], Holly Jordan Lanham[1,2], Luci Leykum[1,2] and Alison B. Hamilton[3,4,5]

TBM

ORIGINAL RESEARCH

A case study of a theory-based method for identifying and reporting core functions and forms of evidence-based interventions

M. Alexis Kirk,[1] Emily R. Haines,[2] Franziska S. Rokoske,[3] Byron J. Powell,[4] Morris Weinberger,[2] Laura C. Hanson,[5] Sarah A. Birken[2]

Kirk et al. Implementation Science (2020) 15:56
https://doi.org/10.1186/s13012-020-01021-y

Implementation Science

Miller et al. Implementation Science (2021) 16:36
https://doi.org/10.1186/s13012-021-01105-3

Implementation Science

DEBATE Open Access

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

M. Alexis Kirk[1*], Julia E. Moore[2], Shannon Wiltsey Stirman[3] and Sarah A. Birken[4]

DEBATE Open Access

The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare

Christopher J. Miller[1,2*], Miya L. Barnett[3], Ana A. Baumann[4], Cassidy A. Gutner[5,6] and Shannon Wiltsey-Stirman[7,8]

Coronado et al. Implementation Science (2020) 15:77
https://doi.org/10.1186/s13012-020-01037-4

Implementation Science

RESEARCH Open Access

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

Gloria D. Coronado[1*], Jennifer L. Schneider[1], Beverly B. Green[2], Jennifer K. Coury[3], Malaika R. Schwartz[4], Yogini Kulkarni-Sharma[5] and Laura Mae Baldwin[4]

Coury et al. Implementation Science Communications (2021) 2:5
https://doi.org/10.1186/s43058-020-00104-7

Implementation Science Communications

RESEARCH Open Access

What's the "secret sauce"? How implementation variation affects the success of colorectal cancer screening outreach

Jennifer Coury[1*], Edward J. Miech[2], Patricia Styer[3], Amanda F. Petrik[4], Kelly E. Coates[5], Beverly B. Green[6], Laura-Mae Baldwin[7], Jean A. Shapiro[8] and Gloria D. Coronado[4]

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) of what works when, with whom, and how

- Many methods can be used to identify what adaptations occur and their effect on outcomes

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**

"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

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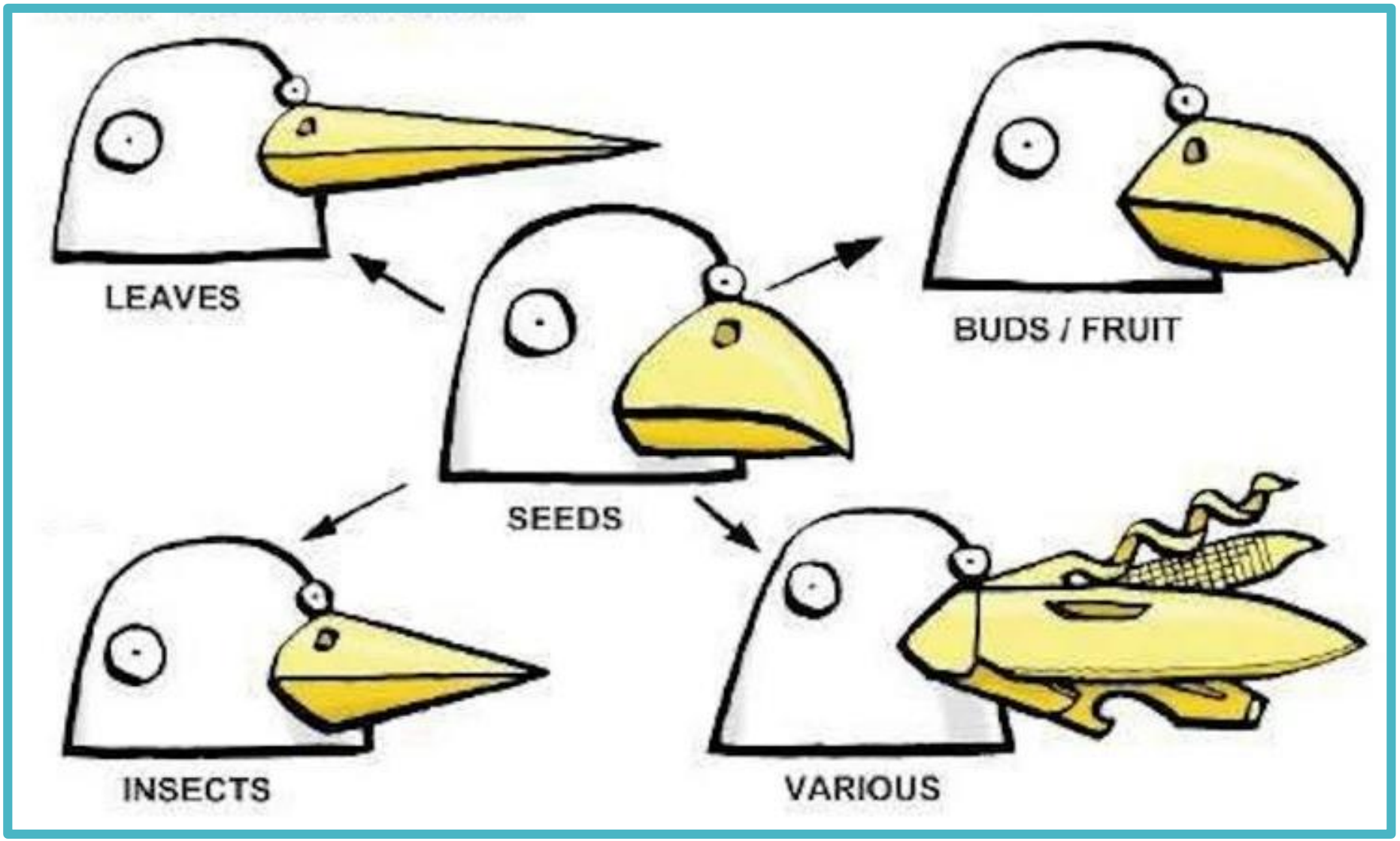
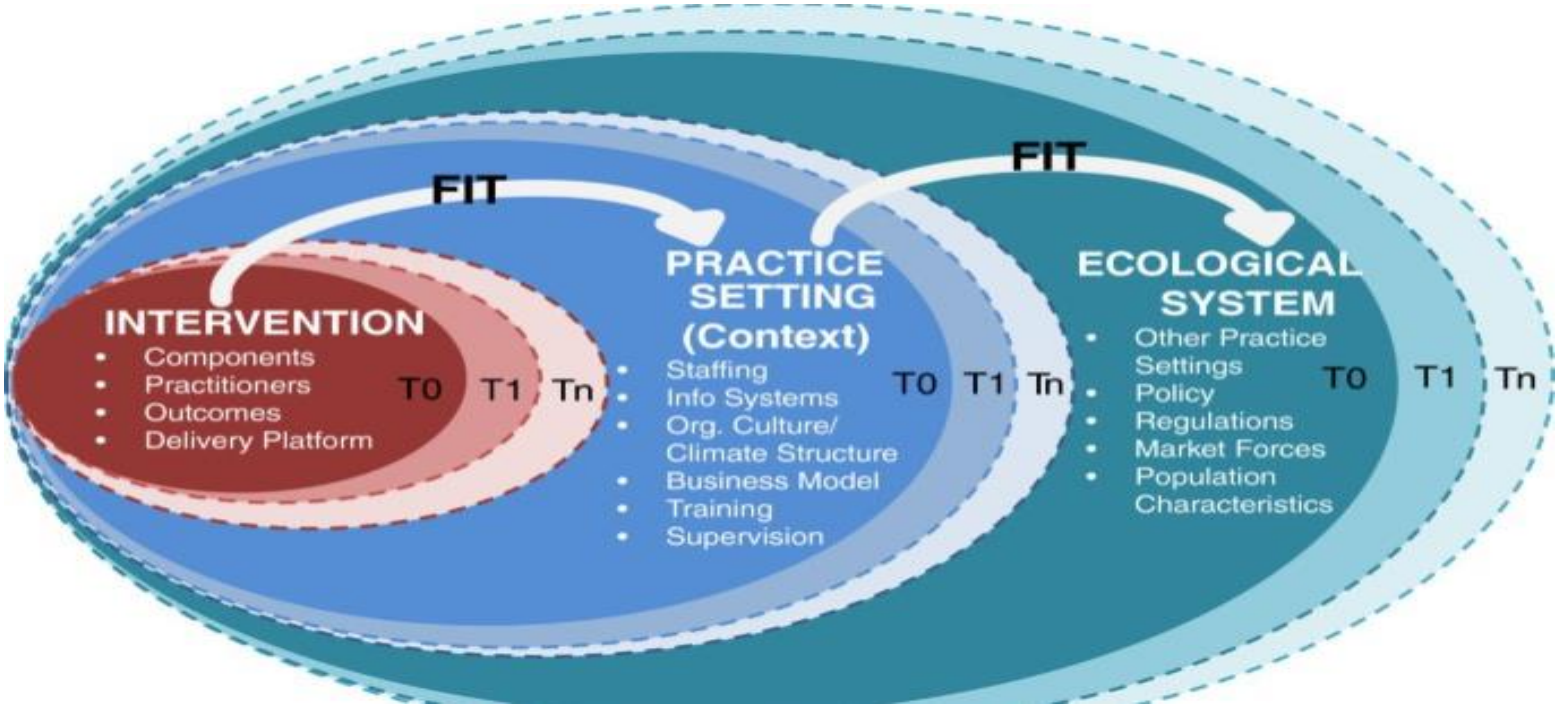
DO YOU HAVE ANY QUESTIONS?



The Dynamic Sustainability Framework



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