

Intervention Delivery Complexity Tool

NIH Pragmatic Trials Collaboratory

Steering Committee Meeting

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Overview

- First half
 - Introduction to the tool (George)
 - Panelists discuss the tool in context of their trial (Volandes and Mor)
 - Questions and discussion
- Second half
 - Next steps for the tool (Ballengee)
 - Panelists comments (Mor and Volandes)
 - Questions and discussion

Why a Tool for Intervention Delivery?

- Intervention complexity has been well described in the literature
 - One example is the Intervention Complexity Assessment Tool (iCAT-SR)
- Lack of attention to intervention **delivery** complexity

Why a Tool for Intervention Delivery?

- This lack of attention may be due to a “blind spot” for explanatory trials
 - Intervention delivery is tasked to research staff
- For embedded pragmatic trials intervention delivery is a highly relevant issue
 - Different parts of the healthcare systems (hospitals, clinics, or primary care practices) will deliver interventions

AIM-Back vs. ADAPTABLE



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AIM-Back vs. ADAPTABLE



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For Pragmatic Trials: Intervention Delivery Varies in Complexity



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For Pragmatic Trials: We Have No Way to Characterize Intervention Delivery Complexity



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Methods

- Gathered several PIs of Collaboratory trials to describe major drivers of complexity
- Performed a literature review
- Development of and iteration on a tool

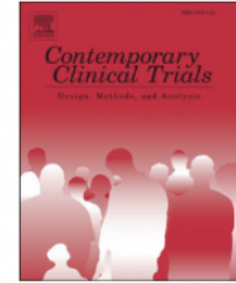


ELSEVIER

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Intervention delivery for embedded pragmatic clinical trials: Development of a tool to measure complexity



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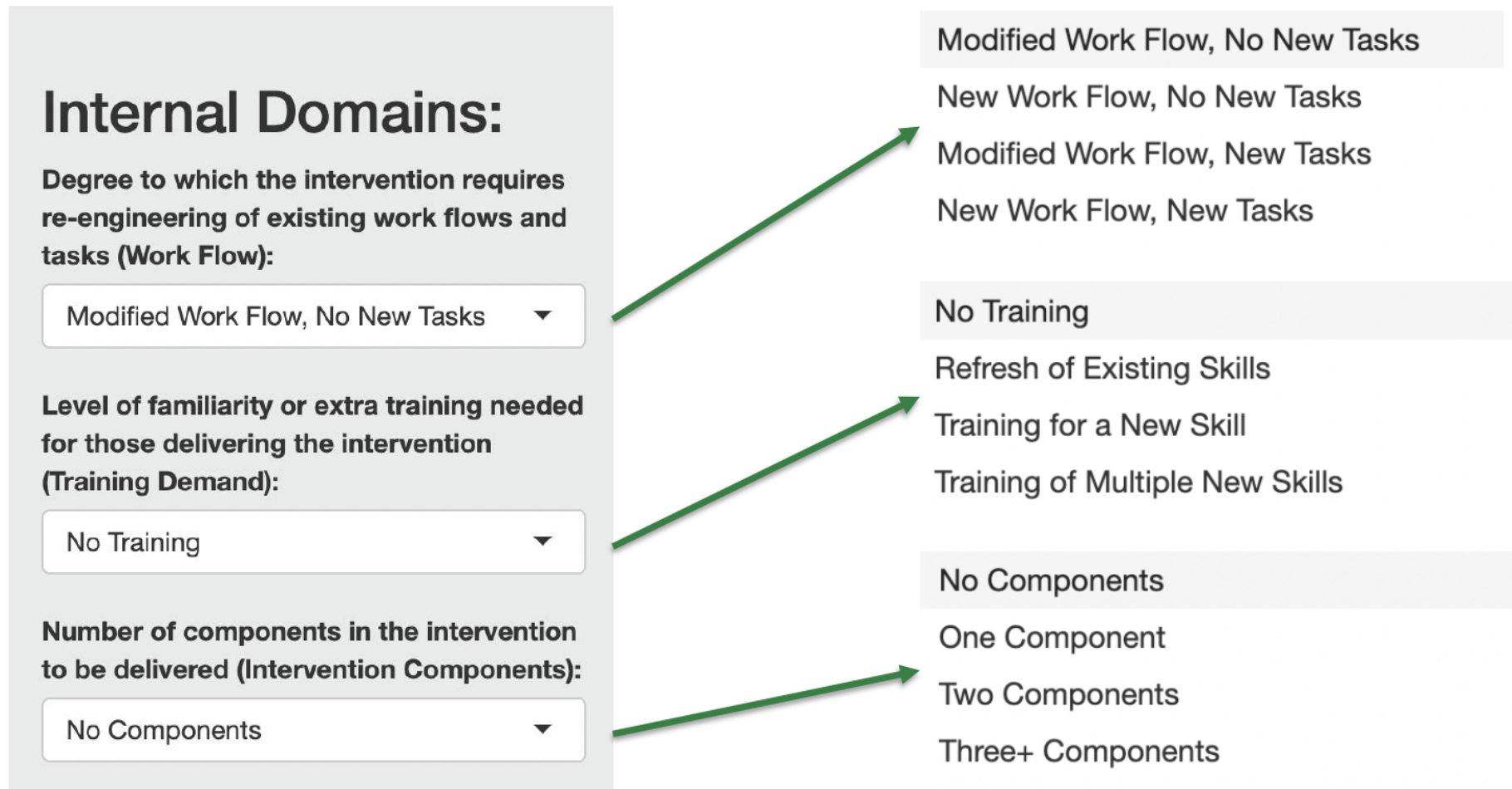


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Internal Domains

Factors pertaining to the intervention



External Domains

Impact intervention delivery

External Domains:

Number of health care systems involved in delivering the intervention (Organization Levels):

1

Number of clinics involved in delivering the intervention (Organization Levels):

1

Number of steps between the intervention and the outcome's intended effect (Number of Steps):

Pathway is short (only one or two steps between intervention and outcomes), direct, and linear

Degree to which delivery of the intervention is dependent on setting in which it is implemented (Dependency on Setting):

Not dependent on setting (could be delivered in any setting)

The calculator multiplies systems x clinics

Pathway is short (only one or two steps between intervention and outcomes), direct, and linear

Longer (three or more steps between intervention and outcomes) but still linear

Non-linear (including the potential of more than one provider)

Variable steps, long pathway, multiple providers

Not dependent on setting (could be delivered in any setting)

Minimally dependent on setting (could easily be delivered in a low resource setting)

Moderately dependent on setting

Largely dependent on setting (could only be delivered in a high resource setting)

Demonstration Project Experiences



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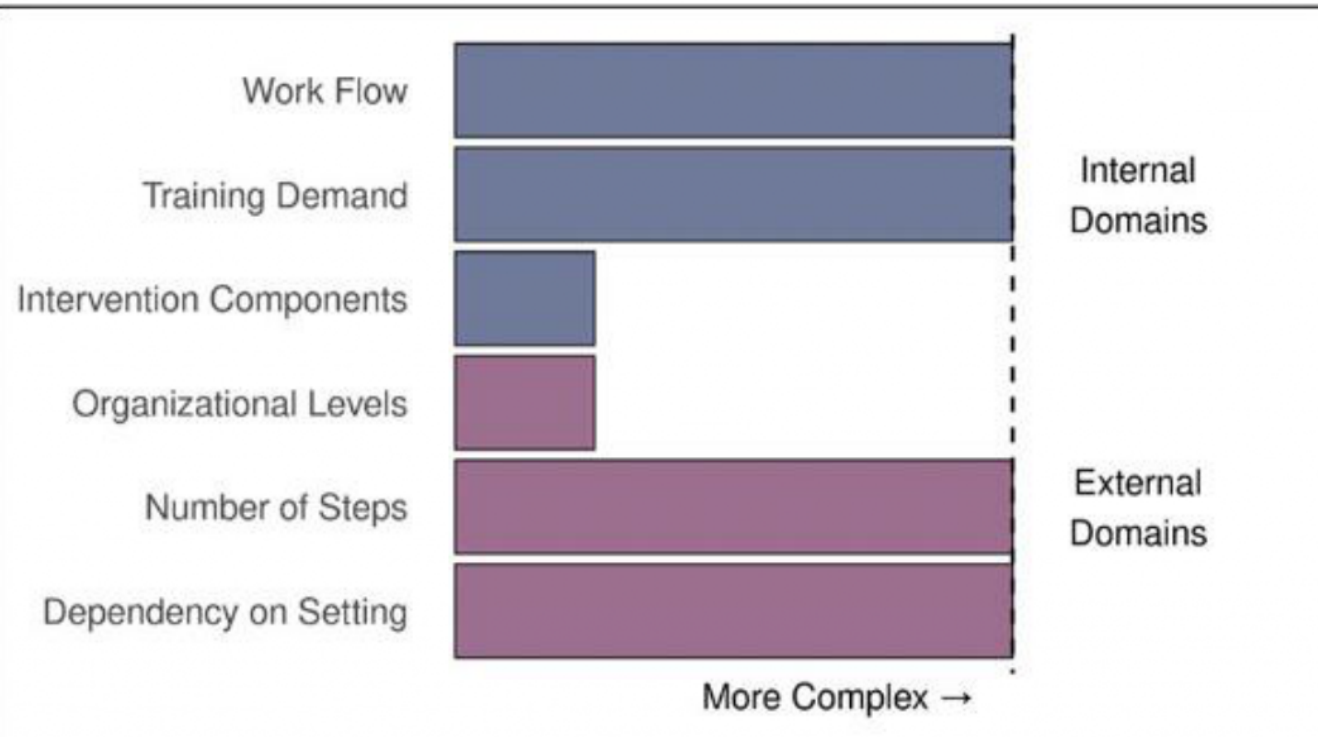
PROVEN [3,26]

Pragmatic Trial of Video Education in Nursing Homes

NCT02612688

Goal: Determine if showing advanced care planning videos in nursing homes affects the rates of hospitalization

Setting: 2 nursing home health systems; 359 nursing homes / Nursing home health systems serving long-stay (>12 months) patients with advanced comorbid conditions (166,196 patients)



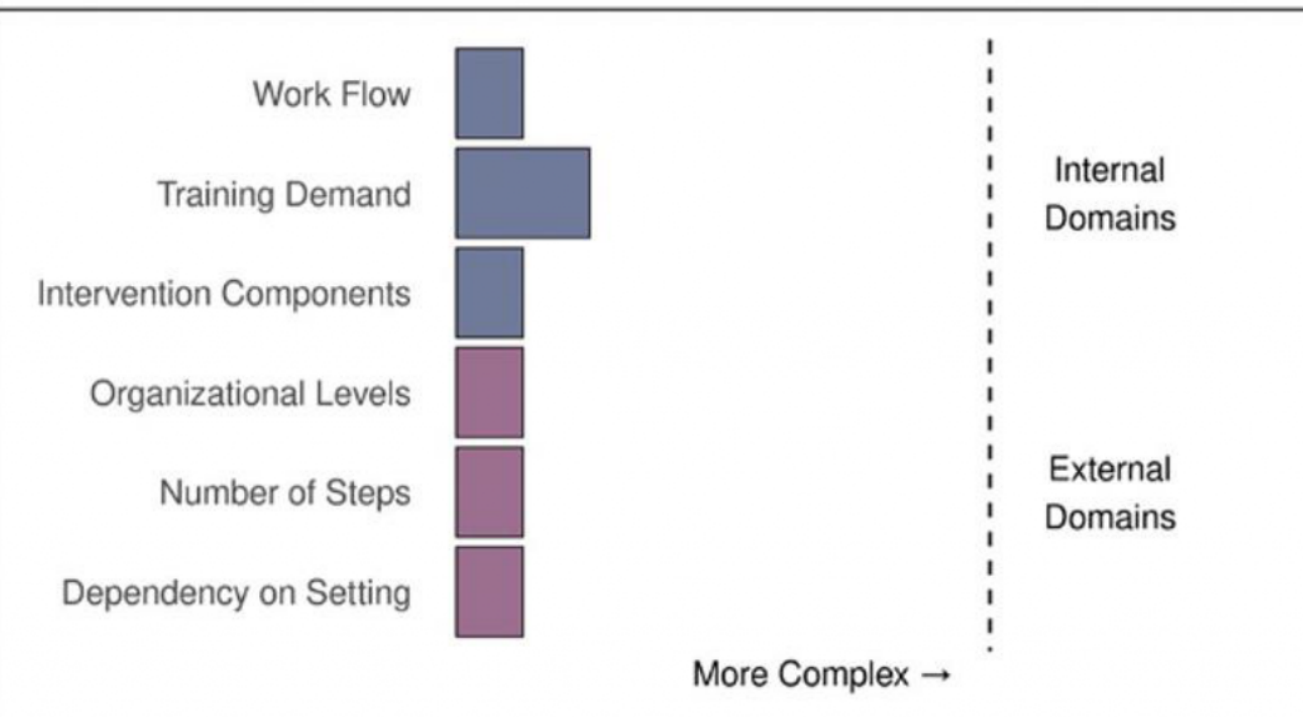
ACP COVID

Advance Care Planning: Communicating with Outpatients for Vital Informed Decisions

NCT04660422

Goal: Test whether clinician communication skills training and patient video decision aids increase completion of advance care planning

Setting: Patients >65 years of age at risk for COVID at Northwell Health



Intervention Complexity Tool

Next Steps



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A bit about me...



Duke University
School of Medicine
Doctor of Physical Therapy



**Department of Population
Health Sciences**

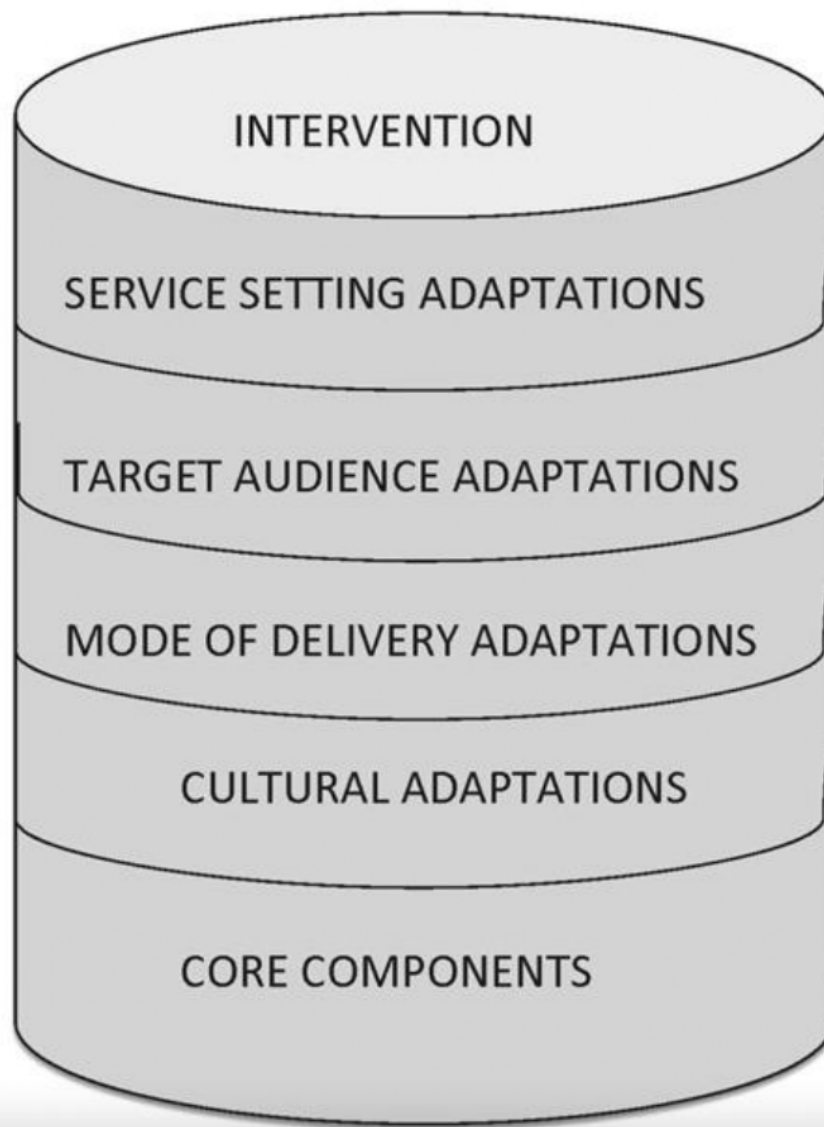
Duke University School of Medicine

AIM

Investigate relationship between intervention complexity and adaptations to explore impact on implementation outcomes.

Hypothesis: More complex interventions require a greater number of adaptations to be implemented.

Sources of Intervention Adaptation



Adaptation Examples

Who delivers the intervention; fit with other interventions; financing source

Age-appropriateness; health literacy; responsive to individual needs; comorbid conditions

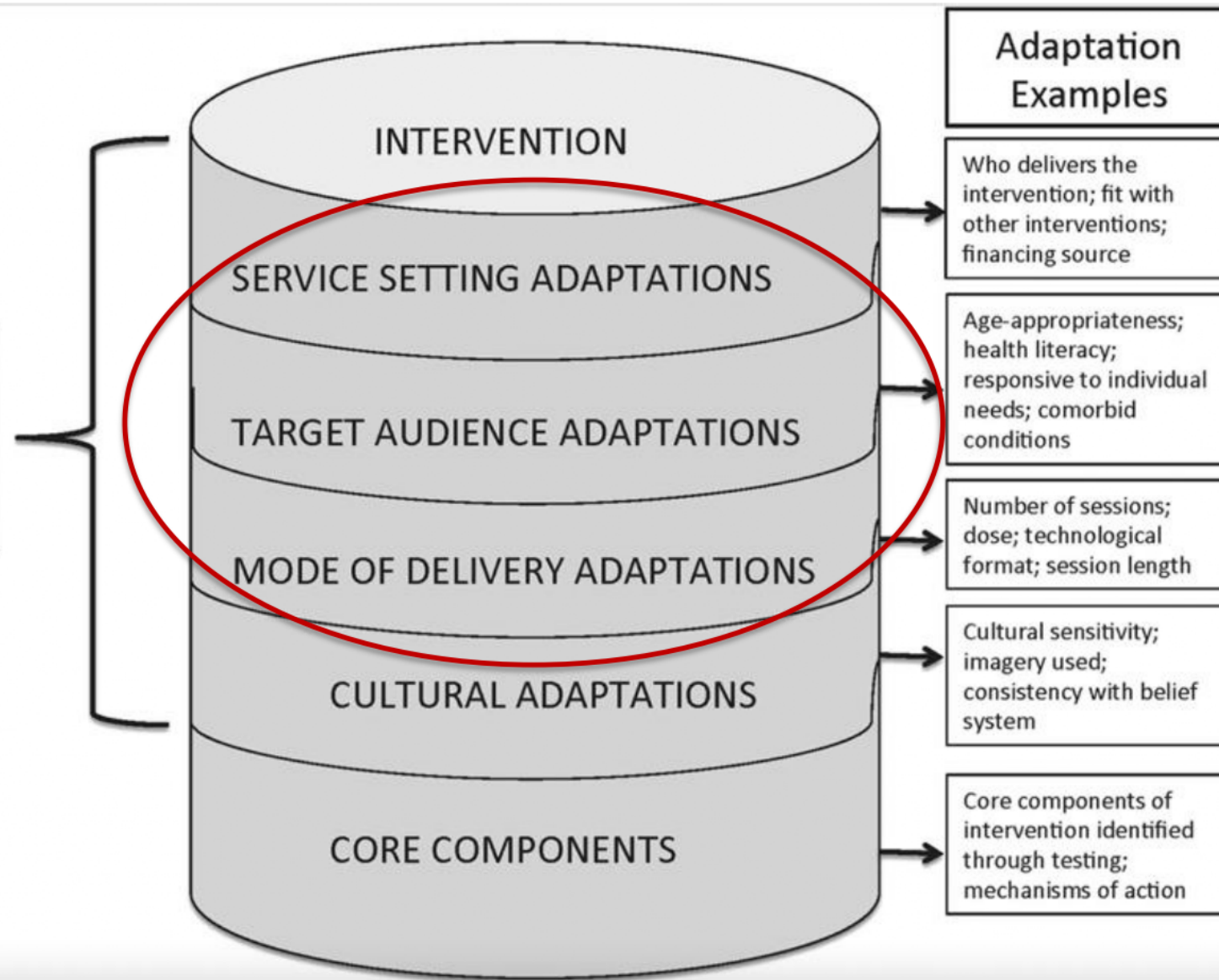
Number of sessions; dose; technological format; session length

Cultural sensitivity; imagery used; consistency with belief system

Core components of intervention identified through testing; mechanisms of action

Chambers, David A., and Wynne E. Norton. "The adaptome: advancing the science of intervention adaptation." *AJPM*, 51.4 (2016): S124-S131

Sources of Intervention Adaptation



Chambers, David A., and Wynne E. Norton. "The adaptome: advancing the science of intervention adaptation." *AJPM*, 51.4 (2016): S124-S131

FRAME and FRAME-IS

Module 5, Part 1: WHEN is the modification initiated?

- Pre-implementation/planning/pilot phase
- Implementation phase
- Scale up (i.e. when the EBP is being spread to additional clinics/settings within your system)
- Maintenance/Sustainment
- Other (write in here):

Module 5, Part 2: Is modification PLANNED?

- Planned/Proactive (proactive adaptation)
- Planned/Reactive (reactive adaptation)
- Unplanned/Reactive (modification)
- Other (write in here):

Module 6: WHO participates in the decision to modify?

- Political leader(s)
- Program Leader, Manager, or Administrator
- Funder
- Implementer or implementation strategy expert
- Researcher
- Clinician(s) or teacher(s) who are being asked to use the EBP being implemented
- Community members
- Patients or other recipients who will be the ultimate target of the EBP being implemented
- Other: write in here:

Optional: Indicate who makes the ultimate decision:

Module 7: How WIDESPREAD is the modification? (i.e. for whom/what is the modification made?)

- Individual patient or other recipient for whom the EBP is being implemented
- Group of patients or other recipients for whom the EBP is being implemented
- Patients or other recipients that share a particular characteristic (e.g. all patients from a specific language background)
- Individual clinician or teacher charged with implementing the EBP
- Clinic/unit
- Organization
- Network system/community
- Specific implementer/facilitator
- Implementation/facilitation team

Sample Survey Questions

- Based on the components of your intervention, please describe the adaptations that took place within your trial.
- Was intervention content modified? Yes/no. If yes, please answer the following questions.
- WHEN did the modification occur? Check all that apply.
 - Pre-implementation/planning/pilot phase
 - During implementation of the trial
 - During the scale-up phase
 - During maintenance/sustainment phase

Sample Survey Questions

- WHAT was modified? Check all that apply.
 - Content (e.g., modified the content of the intervention itself or how it is being delivered)
 - Context (e.g., modified the way the overall treatment is delivered)
 - Format
 - Setting
 - Personnel
 - Population
 - Training/evaluation (e.g., modified the way staff are trained or how the intervention is evaluated)
 - Implementation and scale-up activities (e.g., modified the strategies used to implement or spread the intervention)

Panelist Comments

1. Experiences from the NIA IMPACT Collaboratory (Mor)
2. When does adaptation become a different intervention?
(Volandes)



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Questions and Discussion