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Research Study Designs: Implementation Science

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Research Training #2
Multidisciplinary Research Council
October 21, 2025

SDSU HealthLINK Center for Transdisciplinary Health Disparities Research
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https://healthlink.sdsu.edu/

Community Engagement Core

Center Partnership with Innercare

https://healthlink.sdsu.edu/community-partner-organizations/

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Funder: National Institute on Minority Health & Health Disparities

Award Numbers: U54MD012397 (Center) & S21MD010690 (Endowment)

Network: One of 20+ Research Centers at Minority Institutions (RCMIs)

Proposed MRC Research Training Topics

Ideas for future trainings welcome

Intro to Different Types of Study Designs (Part I - August 2025)
What can you learn from different types of studies?

Implementation Science
(Part II – October 2025)
How do you close the research to practice gap?

Other topics for future:
Controlling Sources of Bias
What is it and why does it matter?

Interpreting Data
What conclusions can you draw?

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Training # 1 Evaluation – Brief Results

- 10 individuals invited to participate:
  7 completed survey, 2 partial responses
- Mean (SD) years worked at Innercare: 8.8 (7.4)
- 50% (4 of 8) reported a little bit of education and training in research
- 75% (6 of 8) agreed/strongly agreed with the “content of training was relevant to work and/or profession”
- All 7 respondents agreed/strongly agreed the training:

- “will improve my research skills”
- “increased my confidence in my ability to evaluate research proposals”
- “improved my understanding of research methods and study designs”
- “helped me understand my role in the research process”

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Outline

Evidence and the “Know-Do Gap”

Introduction to Implementation Science - What is it and why do we need it?

Implementation Science Research Pathway

3 types of hybrid study designs

Implementation Science Frameworks, Theories, Models

Guidance for when to prioritize a gap in clinical practice?

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Levels of evidence *(from Training #1)*

Type of study	Brief description
Systematic reviews and meta-analysis	Summary of results of several studies
Experimental / Intervention studies (including different types of trials, quasi-experimental; implementation science)	Different study designs to test intervention or implementation effectiveness.
Cohort study *	Follow a group of people (cohort).
Case-control study *	Examines a group of people exposed to an adverse event and a group not exposed.
Cross-sectional survey *	Snapshot of a group of people at one timepoint.
Case series and case reports *	Examine individual/group with a disease.

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* *Non-experimental analytic study designs*

https://bestpractice.bmj.com/info/us/toolkit/ebm-tools/a-glossary-of-ebm-terms/; https://libguides.sdsu.edu/pico; https://guides.dml.georgetown.edu/ebm/ebmclinicalquestions

Evidence-Based Practice (EBP)

- Different study designs yield different levels of evidence.
- Do you have an effective intervention?
- How do you move that evidence-based practice (EBP) to routine clinical use?

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What is the "Know-Do" Gap?

- Often a long delay between the discovery of effective research findings and their consistent use in everyday clinical practice

- **QUESTION:** How many years do you think it usually takes to adopt an Evidence-Based Practice?

  (please unmute and share your guess, or put # in comments)

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What is Implementation Science (IS)?

The scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare practice and policy.

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What is an implementation science question?

Implementation science is centrally focused on the effectiveness of implementation ***strategies***, rather than interventions or evidence-based practices.

Specifically, implementation science attends to the context in which strategies are applied, and how that context shapes effectiveness of implementation strategies.

https://impsciuw.org/implementation-science/research/frame-your-question/

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The Implementation Science Research Pathway

1. Frame Your Question
2. Pick Theories, Models, & Frameworks
3. Select Implementation Strategies
4. Select Research Method
5. Choose Study Design
6. Choose Measures
7. Get Funding
8. Report Results

https://impsciuw.org/implementation-science/research/

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In very non-scientific language…

- The intervention/practice/innovation is THE THING
- Effectiveness research looks at whether THE THING works
- Implementation Science research looks at how best to help people/places DO THE THING
- Implementation strategies = the stuff we do to try to help people/places DO THE THING
- Main implementation outcomes = HOW MUCH and HOW WELL they DO THE THING

Source: Curran, G. M. (2020). "Implementation science made too simple: a teaching tool." *Implementation Science Communications* 1(1): 27.

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“7 Ps”

These interventions should have some evidence supporting them.

Source:
https://impsciuw.org/implementation-science/learn/implementation-science-overview/

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Efficacy vs Effectiveness

Efficacy measures if an intervention works under ideal, controlled conditions

Effectiveness measures how well it works in the real world

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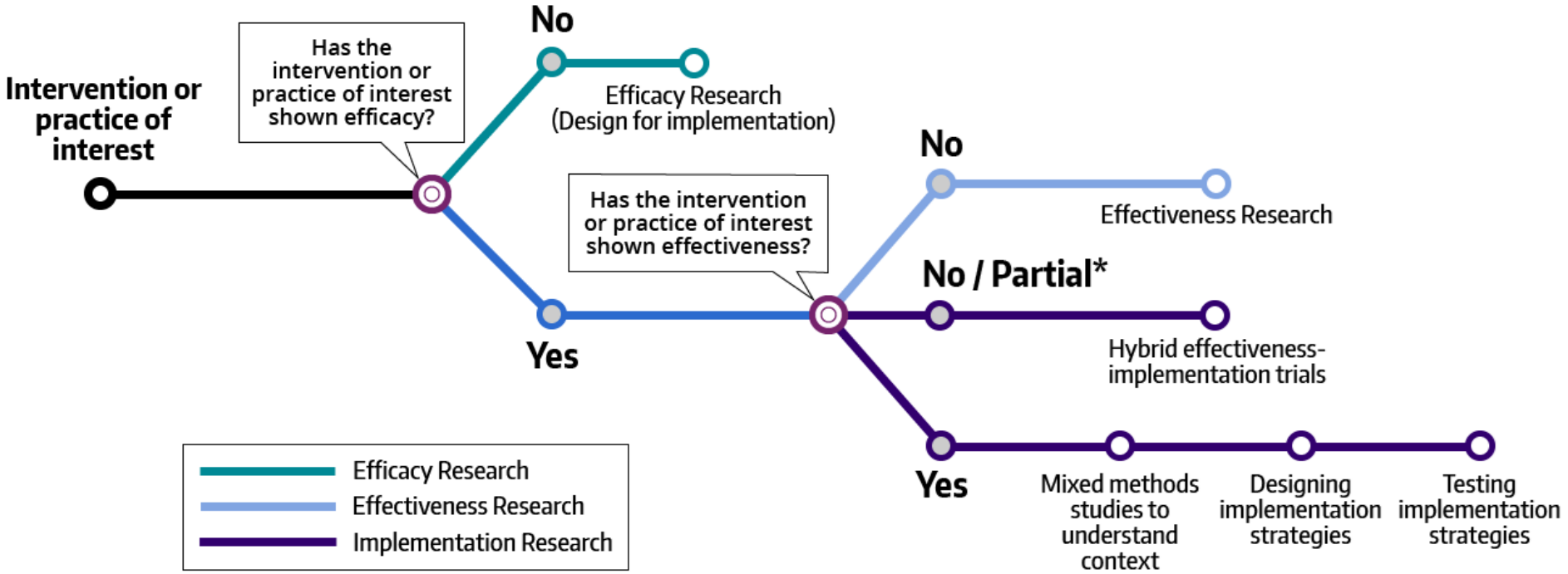
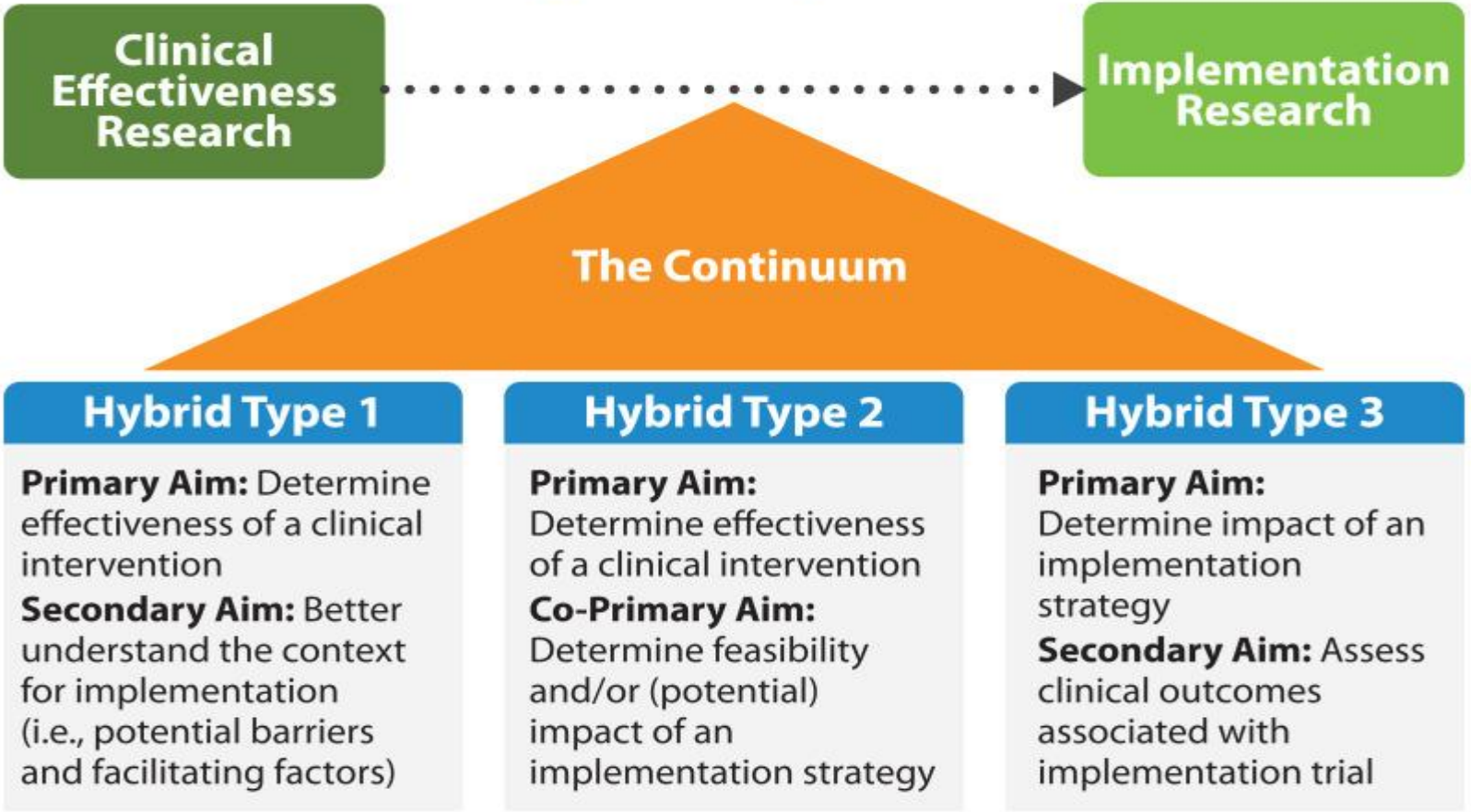
When to do implementation science?



Source: https://impsciuw.org/implementation-science/research/frame-your-question/
Adapted from Lane-Fall, M.B., Curran, G.M. & Beidas, R.S. Scoping implementation science for the beginner: Locating yourself on the "subway line" of translational research. *BMC Med Res Methodol* 19, 133 (2019). https://doi.org/10.1186/s12874-019-0783-z

Types of Hybrids



Source: https://www.ncbi.nlm.nih.gov/books/NBK566228/figure/ch8.fig2/
Adapted from: Curran, Bauer, Mittman et al. 2012 Med Care.

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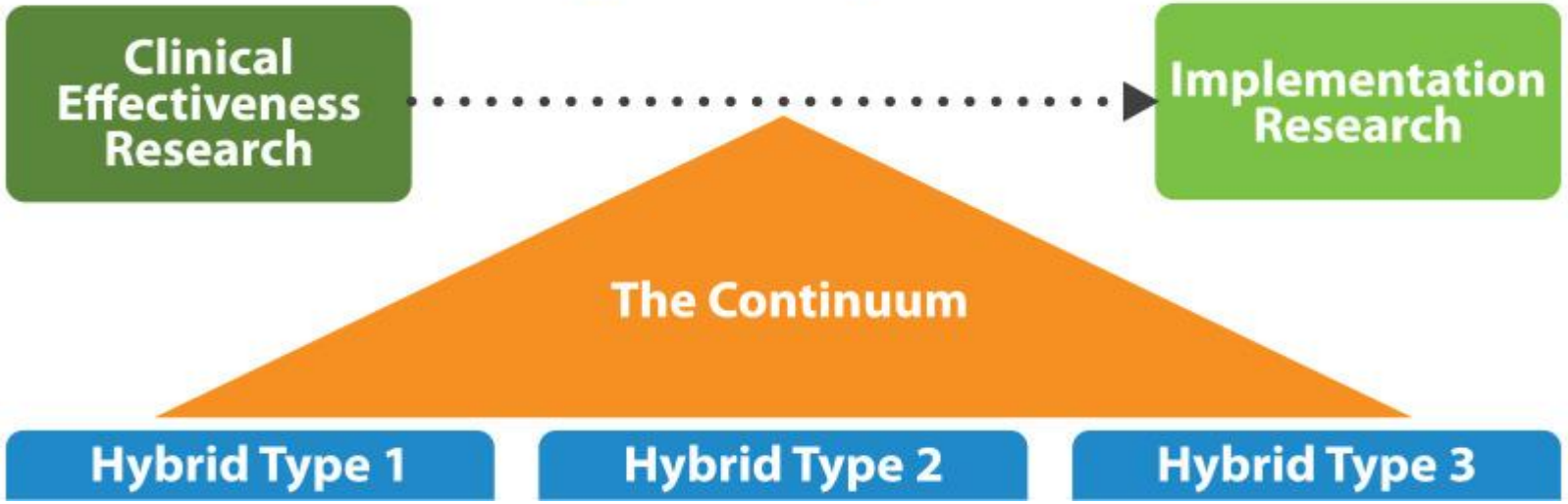
Types of Hybrids



Test THE THING, observe/ gather information on DOING THE THING

Test THE THING, study DOING THE THING

Test DOING THE THING, observe/ gather information on THE THING

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Source: adapted from Geoffrey Curran's overview of hybrid designs slidedeck

Hybrid Type 1 Design

Test clinical intervention and explore implementation-related factors

Description:

- Conventional effectiveness study “plus”: Describe implementation experience (worked/didn’t; barriers/facilitators)
- How might the intervention need to be adapted going forward?
- What is needed to support people/places to do THE THING in the real world?

Considerations:

- Often qualitative or mixed method “implementation-focused” process evaluation
- Sites visits, interviews, surveys (e.g., feasibility, acceptability, appropriateness)
- Focused on locations where the trial took place
- Often see frameworks guide analysis (interview guides, coding)

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Source: adapted from Geoffrey Curran’s overview of hybrid designs slidedeck & Curran et al 2012 *Med Care*

Hybrid Type 2 Design

Test clinical intervention and test/study implementation strategy

Description:

- Dual-focus study - Clinical Effectiveness trial within Implementation trial of 2+ strategies/packages
- Pilot (non-randomized) study of single implementation strategy/package

Considerations:

- Clinical effectiveness data available, though perhaps not for context or population of interest for this trial
- Data on barriers and facilitators to implementation available

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Source: adapted from Geoffrey Curran's overview of hybrid designs slidedeck & Curran et al 2012 *Med Care*

Hybrid Type 3 Design

Test implementation strategy, observe/gather information on clinical intervention and outcomes

Description:

- Largely focused on trial of implementation strategies
- Randomization usually at level of provider, clinic, or system
- Clinical outcomes are “secondary”

Considerations:

- Sometimes proceed with implementation studies without completing a “full portfolio” of effectiveness studies (e.g. mandates)
- Strong momentum in a system (e.g., “We are rolling this out!”)
- Interested in exploring how clinical effectiveness might vary by level/quality of implementation?

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Source: adapted from Geoffrey Curran’s overview of hybrid designs slidedeck & Curran et al 2012 *Med Care*

Implementation Science Frameworks

Pick a guiding Implementation Science framework, model, theory

5 categories (Nilsen, 2015):

1) Process models
2) Determinants frameworks
3) Classic theories
4) Implementation theories
5) Evaluation frameworks

https://impsciuw.org/implementation-science/research/frameworks/

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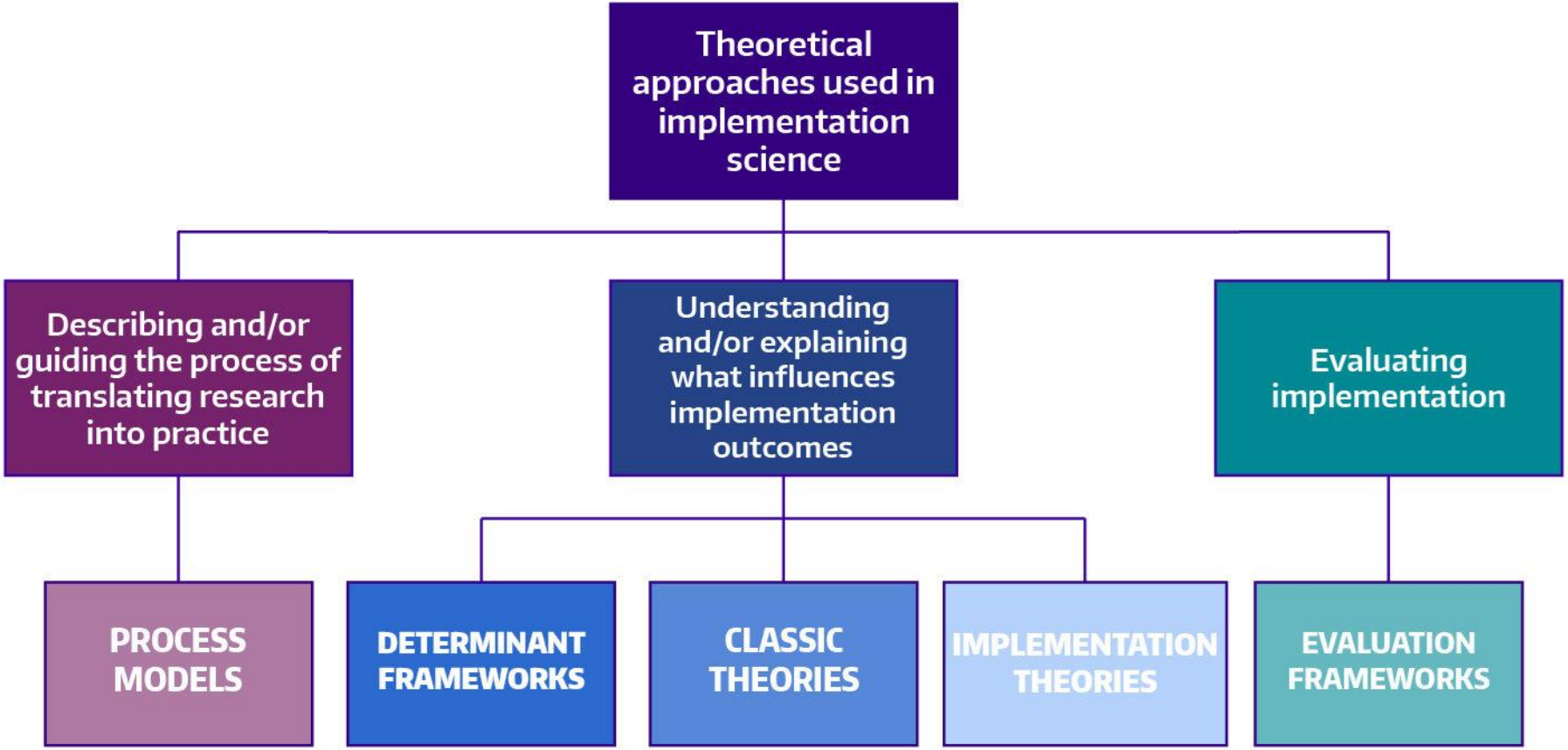

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Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10(1):1-13.

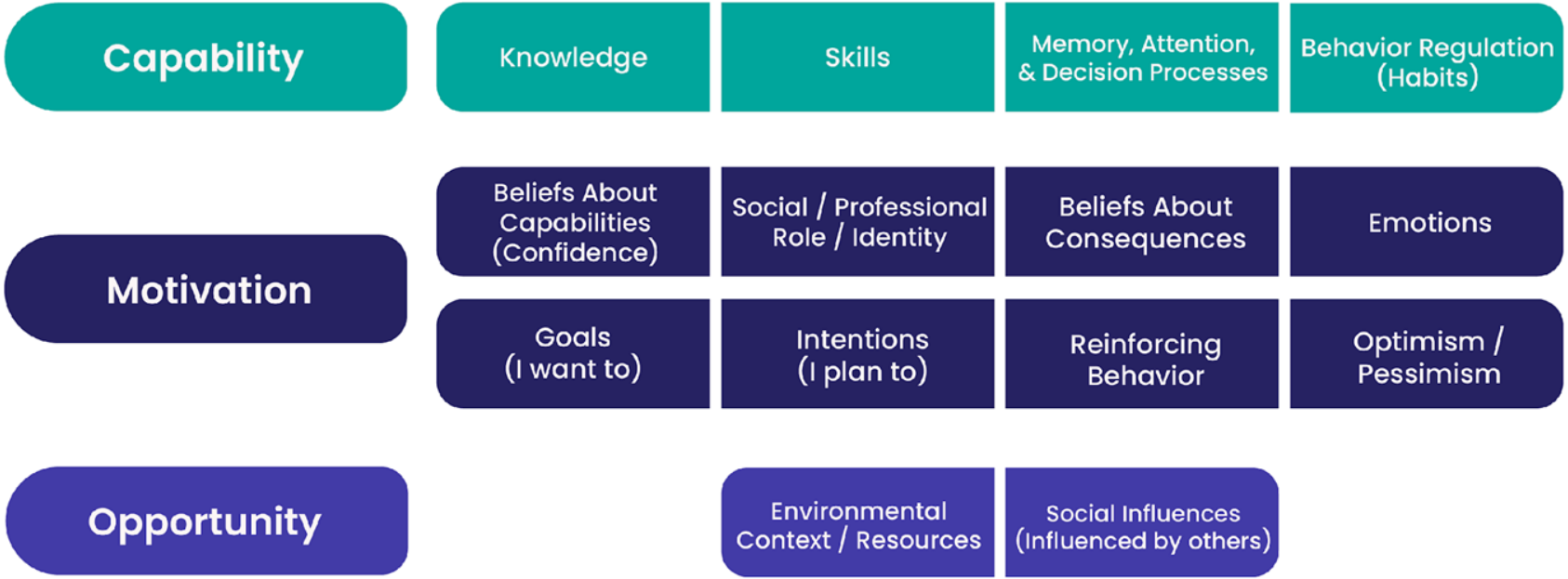
Theoretical Domains Framework (TDF)

Implementing new practices requires changes in the behavior of relevant actors, and this is facilitated by understanding of the determinants of current and desired behaviors

The Theoretical Domains Framework (TDF) was developed by a collaboration of behavioral scientists and implementation researchers who identified theories relevant to implementation and grouped constructs from these theories into domains.

Source: Atkins, L., et al. (2017). "A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems." Implementation Science 12(1): 77.

Capability, Motivation, Opportunity - Behavior & Theoretical Domains Framework



The Center for Implementation

Based on Michie, van Stralen, & West (2011). Image developed by The Center for Implementation,
© 2023 | V2024.01 | For full citation: https://thecenterforimplementation.com/toolbox/com-b-tdf

https://thecenterforimplementation.com/toolbox/com-b-tdf

Framework

What is RE-AIM?

RE-AIM is a framework to guide the planning and evaluation of programs according to the 5 key RE-AIM outcomes

- **R**each the target population
- **E**ffectiveness or efficacy, including unintended consequences and equity of results
- **A**doption by target settings or institutions and delivery agents
- **I**mplementation, consistency, and costs of delivery of intervention
- **M**aintenance of intervention effects in individuals and settings over time

https://re-aim.org/
https://re-aim.org/standard-survey-items-for-re-aim/

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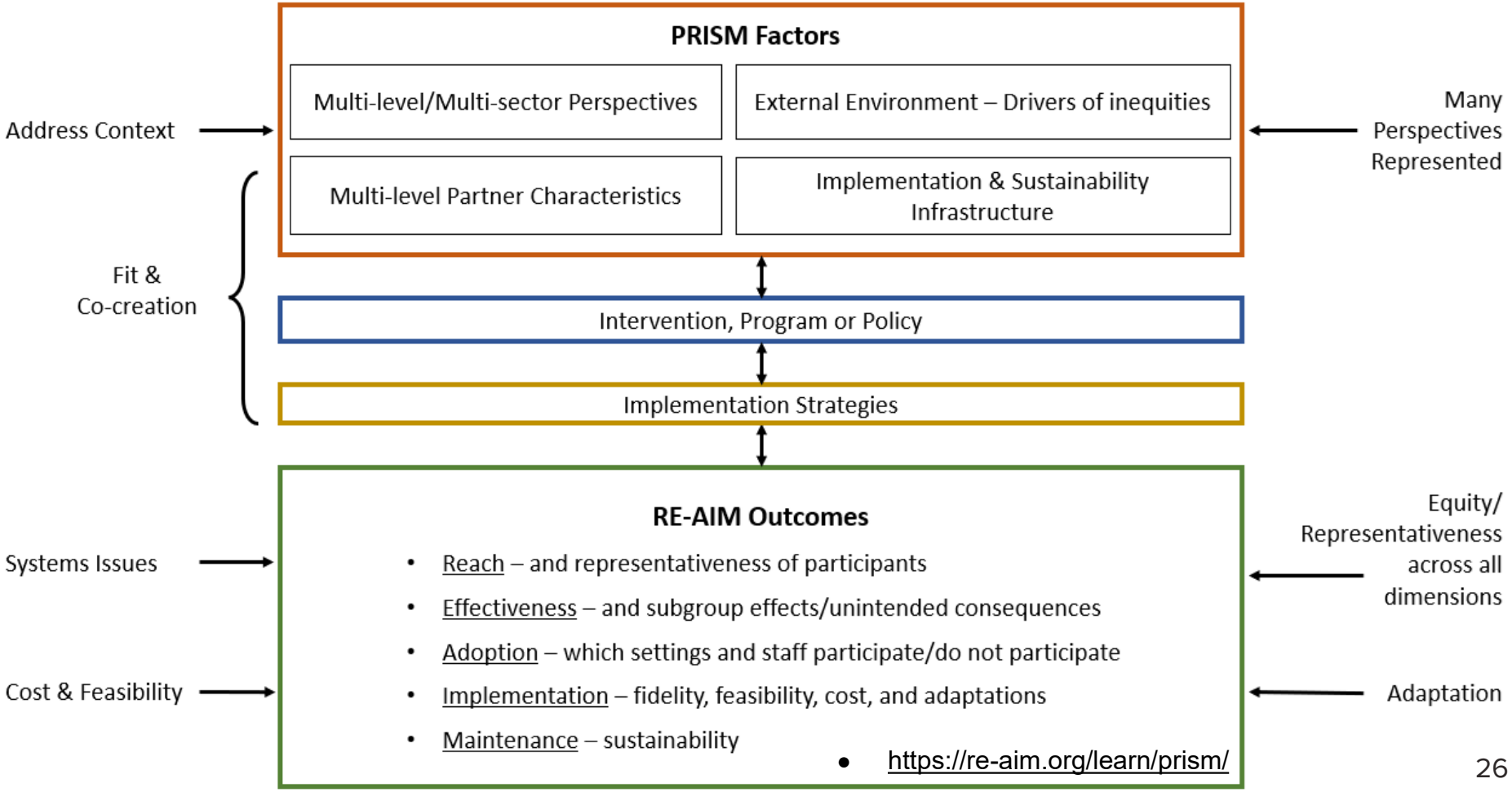
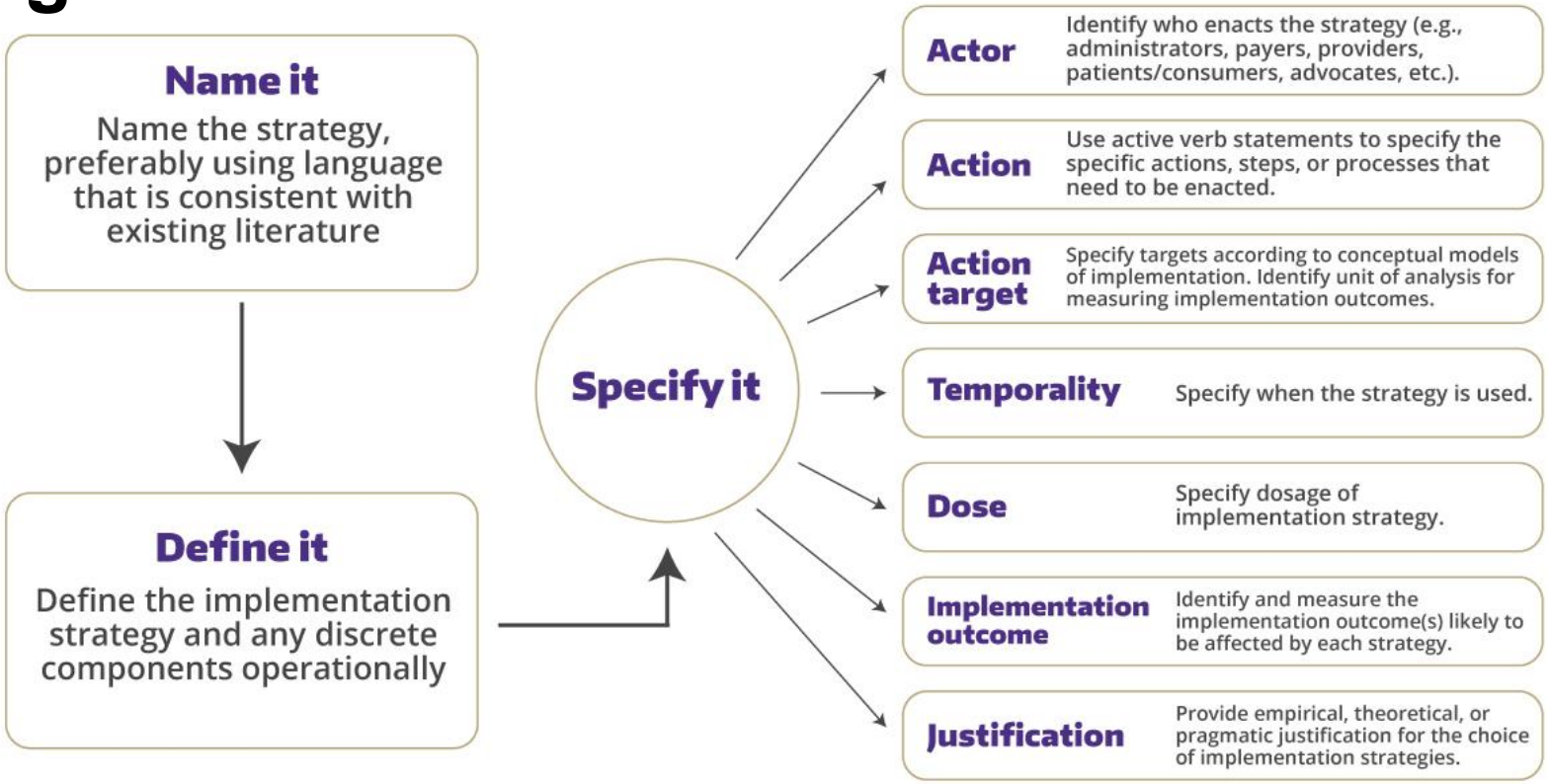
How PRISM (and RE-AIM Outcomes) Address Equity Issues



Strategies



Adapted from Proctor EK, Powell BJ, McMillen JC. Implementation strategies: Recommendations for specifying and reporting. *Implement Sci.* 2013;8(139).

https://impsciuw.org/implementation-science/research/implementation-strategies/

Key Implementation Science Questions

- How do contextual factors influence implementation success or failure? How can they be modified to increase chances of success?
- What are the most effective techniques to incorporate new discoveries and evidence-based practices into care delivery?
- What are the most effective techniques to improve the distribution and receipt of evidence in the real world?
- What are the most effective techniques to de-implement practices that are no longer effective or were never effective?

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Should we prioritize this gap in clincial practice?

Questions to Consider:

1. Is the area/problem of clinical concern to patients and/or their families?
2. Is the area/problem of concern to healthcare providers and other stakeholders?
3. Do clinical practice guidelines/evidence exist that you could use to identify best practices to address this area/problem?
4. Are there baseline data available to demonstrate what the practice currently is?
5. Is there sufficient interest from your stakeholders to work on this area/problem?
6. Is there sufficient interest from the frontline/end-users impacted by this area/problem for this implementation work?
7. Is there a local champion that can work on this area/problem?
8. Is there support from management for this area/problem?
9. Does this initiative align with other organizational, regional or national initiatives?
10. Would doing something about this area/problem be:
    a. Feasible?
    b. Practical?
    c. Desirable?
    d. Impactful?

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Sources: Exhibit 2.2, Fahim & Straus, CH 2: Assessing the Practice (Know-Do) Gap. Practical Implementation Science; Straus, Tetroe, Graham (2013) *Knowledge translation in health care: Moving from evidence to practice*. Wiley and Sons; Kitson, & Straus (2010) The knowledge to action cycle: Identifying the gaps. *Canadian Med Assoc J, 182*(2), E73–77.

Next month

ICCRN Project: Factors Influencing Implementation of Continuous Glucose Monitoring for Primary Care Patients with Type 2 Diabetes at a Federally-Qualified Health Center

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Thank you! Questions?

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