

Planning an Implementation Research Study

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6/3/2022



Aims of Implementation Science



1. Helps develop **effective strategies for implementing evidence-based practices**, of which improve health-related processes & outcomes.
2. Produces generalizable knowledge regarding selected strategies by **understanding the different processes, barriers, and facilitators that can influence either success or failure.**
3. Aids in the development, testing and refining of relevant theories, conceptual frameworks, as well as measures to advance implementation science.

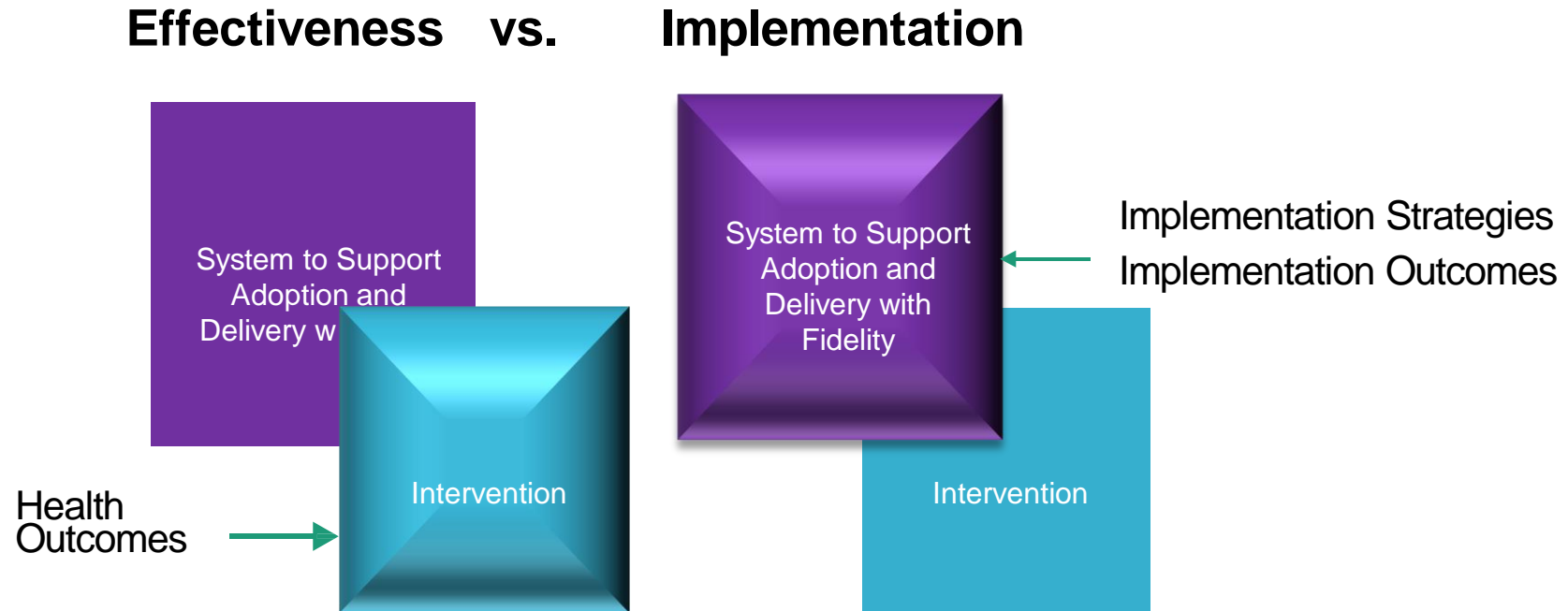
Reference:

Kirchner, J. E., Smith, J. L., Powell, B. J., Waltz, T. J., & Proctor, E. K. (2019). Getting a clinical innovation into practice: An introduction to implementation strategies. *Psychiatry Research*, 112467. doi: 10.1016/j.psychres.2019.06.042

Distinguishing Clinical/Public Health Research from Implementation Research

Study feature	Clinical / Public Health research	Implementation research
Aim: evaluate a / an ...	clinical intervention, health promotion intervention, policy	implementation strategy
Typical intervention	drug, procedure, therapy, prevention program	organizational practice change, training
Typical outcomes	symptoms, health outcomes, patient behavior	adoption, adherence, fidelity, level of implementation
Typical unit of analysis, randomization	Patient, community member	clinic, team, facility, community, school

Implementation Research Has a Different Emphasis



Smith & Hasan, 2020, *Psychiatry Research*

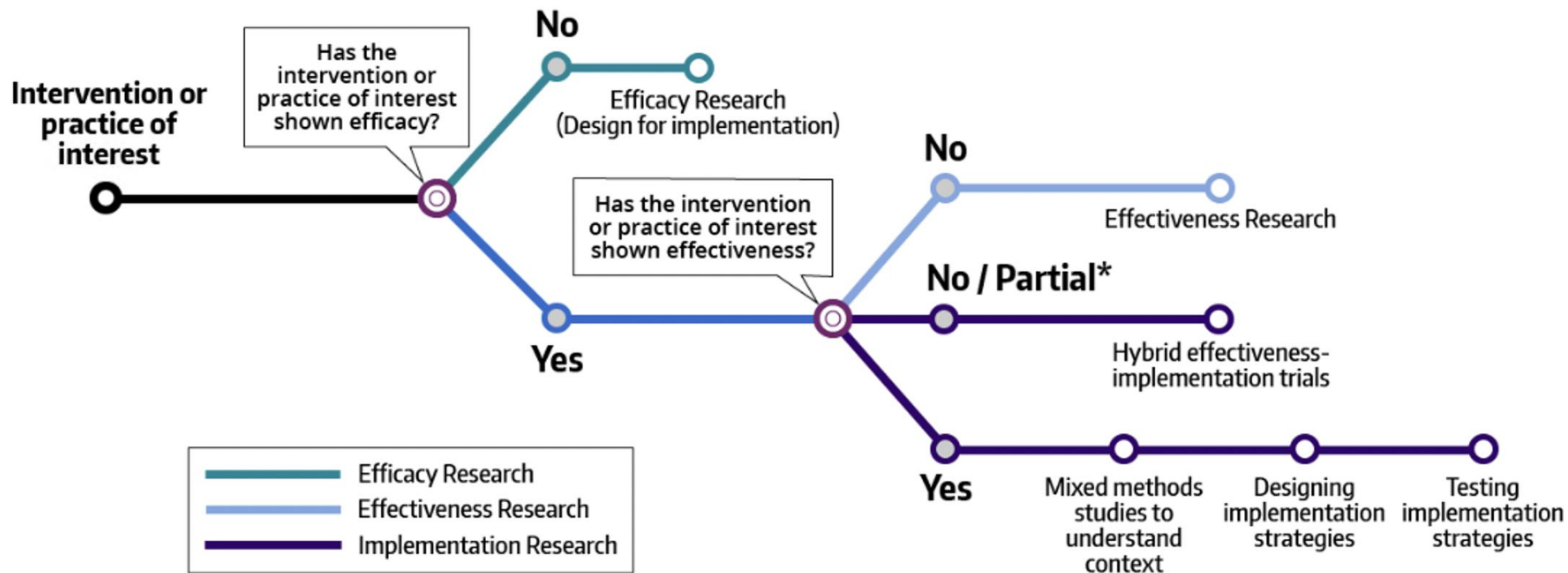
Step by Step Guide

1. Frame/Identify your research question
2. Create an implementation logic model
3. Pick an implementation science theory, model, or framework
4. Identify implementation strategies
5. Select research method
6. Select study design
7. Choose measures and evaluation approach
8. Secure Funding
9. Conduct Study
10. Disseminate Results

Step 1

Frame the Research Question

Locating yourself on the “subway line” of translational research



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>

*In some cases it may be appropriate to move forward with a hybrid Type I trial in the absence of effectiveness evidence (e.g. very strong efficacy, indirect evidence supportive of potential effectiveness in context of interest, and/or strong momentum supporting implementation in a health care context).

Identifying the Problem

- Thorough understanding of the context
- Identify stakeholders
 - ▣ Implementers, clinicians, researchers, community workers, NGOs, health ministry
- Identify the evidence-based intervention*
- Conduct a focused literature review
- Formulate the research question and research objectives

*Brownson, R.C., Shelton, R.C., Geng, E.H. et al. Revisiting concepts of evidence in implementation science. *Implementation Sci* 17, 26 (2022). <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-022-01201-y>

Frame your question

Questions relating to the objective of:

Exploring

Describing

Influencing

Explaining

Predicting

Questions relating to the challenge of:

Scaling up

Sustainability

Replication

Program Integration

Equitability

Real-world effectiveness

Characteristics of a “good” implementation research question

- Relevant
- Appropriate
- Problem-driven
- Actionable
- Specific
- Innovative
- Generalizable

Characteristics of a “good’ implementation research question

Example: What are the most effective strategies to improve the use of evidence-based smoking cessation counseling services among patients at risk for heart disease?

- **Relevant** – to individuals, health systems, and policy makers
- **Appropriate** – answerable with a thoughtfully planned approach
- **Problem-driven** – addresses a known gap or challenge
- **Actionable** – identifying effective strategies can help implement them
- **Specific** – precise focus in a well-defined population
- **Innovative** – should add information and improve knowledge
- **Generalizable** – strive for application of findings across contexts

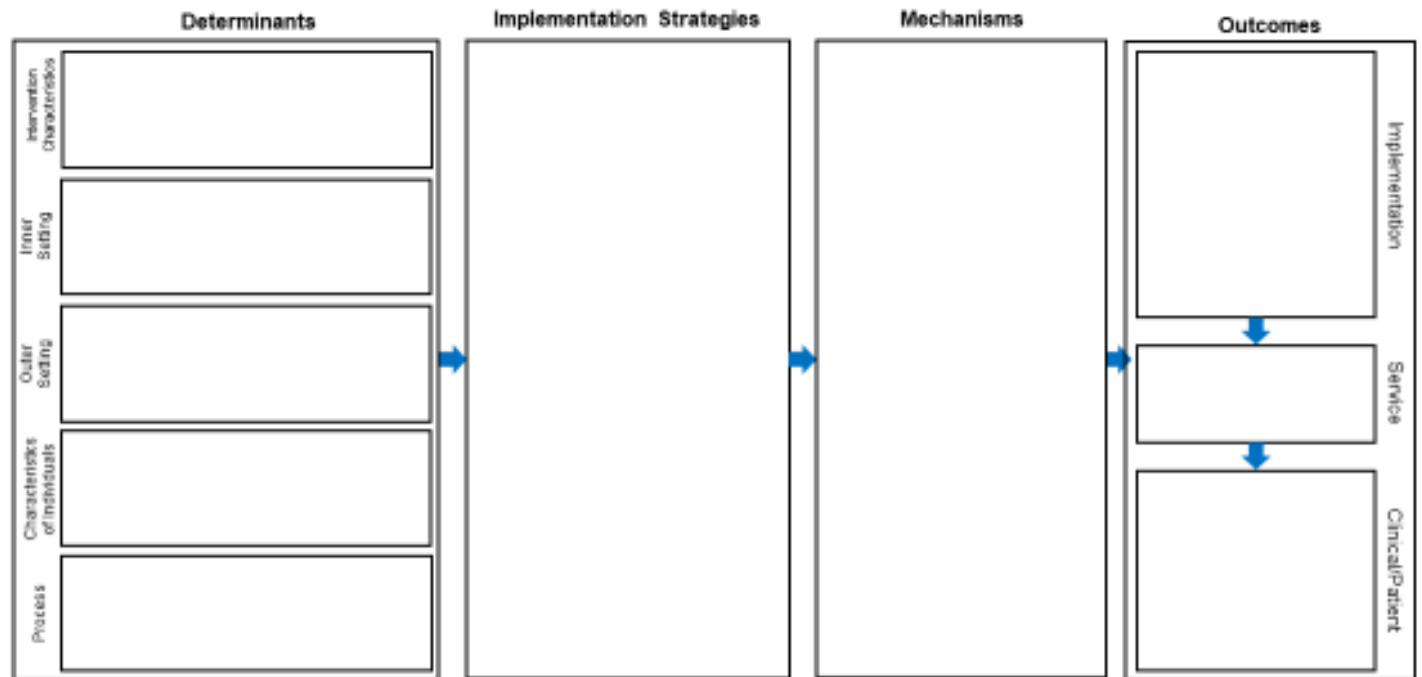
Step 2

Create an Implementation Logic Model

Implementation Research Logic Model

Planning
Executing
Reporting
Synthesizing

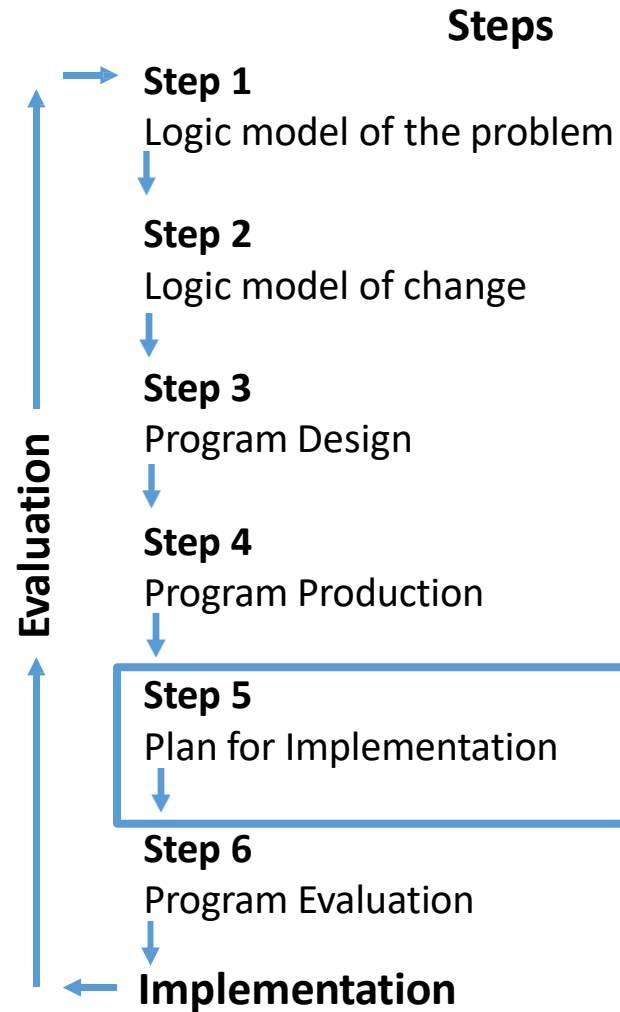
Implementation Research Logic Model



© Smith, J.D., Li, D., & Rafferty (2020)

Smith, J.D., Li, D.H. & Rafferty, M.R. The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects. *Implementation Sci* 15, 84 (2020). <https://rdcu.be/cOO44>

Intervention Mapping (2016)



Implementation Mapping Process (2019)

Task 1. Conduct a needs and assets assessment and identify adopters and implementers.

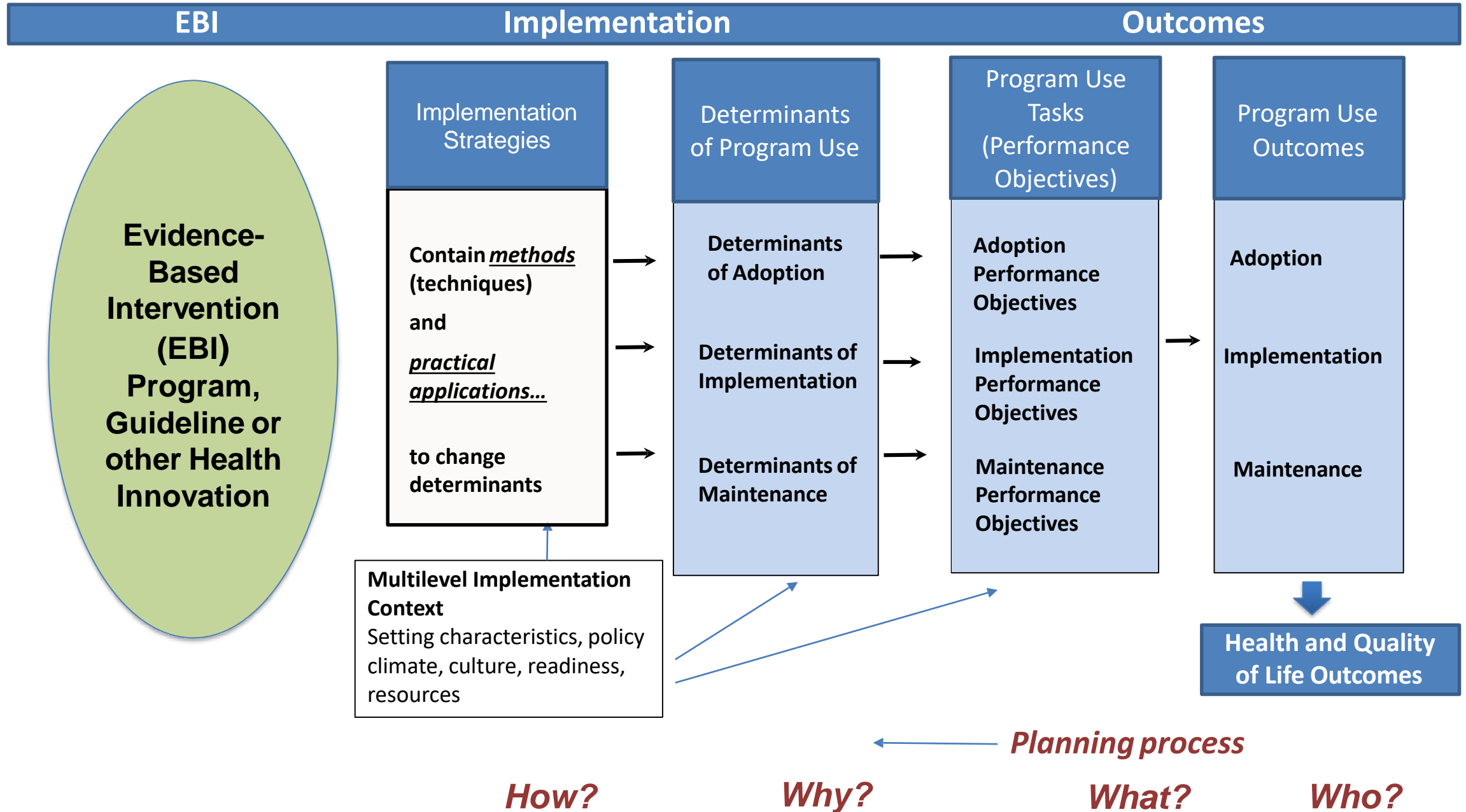
Task 2. Identify adoption and implementation outcomes, performance objectives, and determinants; create matrices of change.

Task 3. Choose theoretical methods; Select or create implementation strategies.

Task 4. Produce implementation protocols and materials.

Task 5. Evaluate implementation outcomes.

Implementation Mapping Logic Model



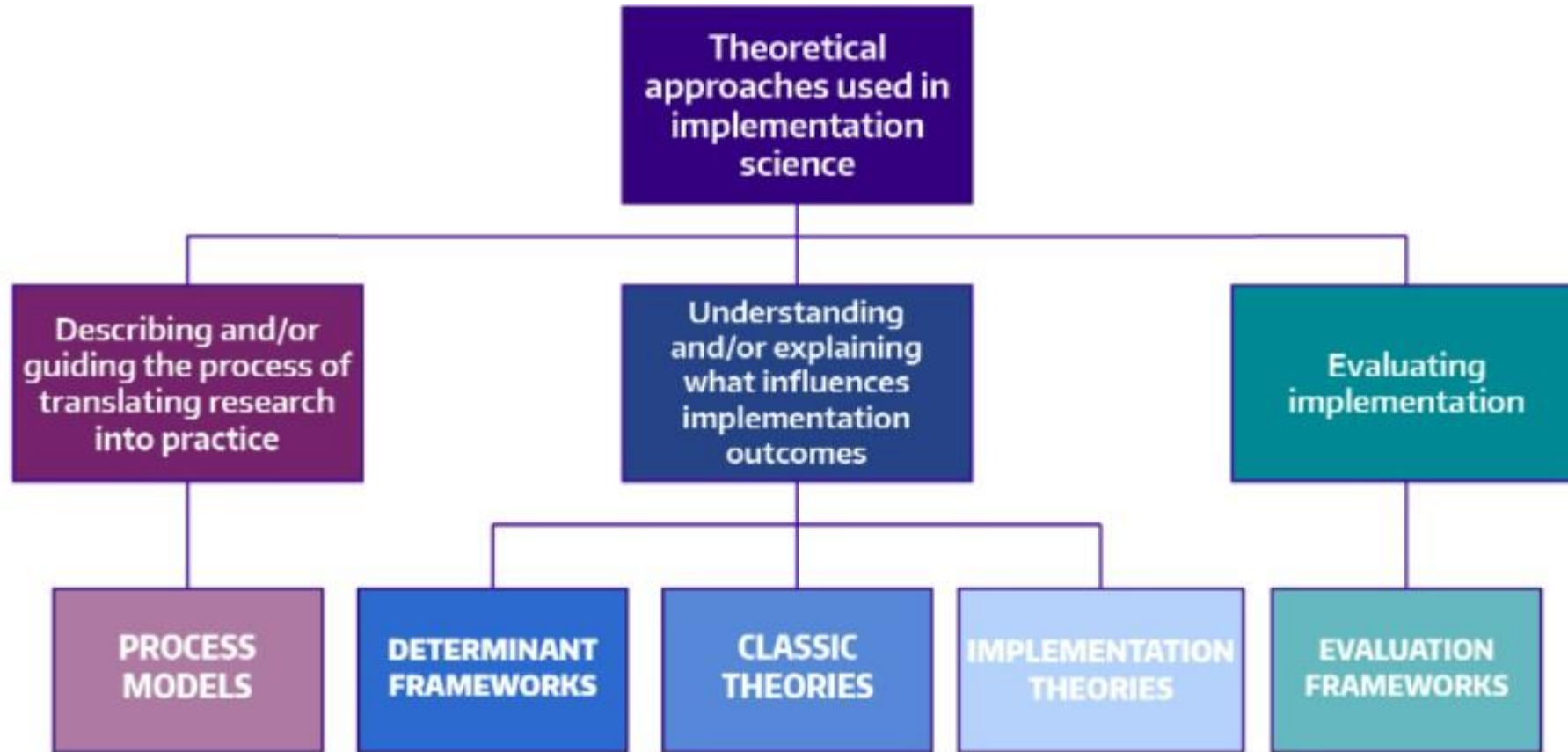
Step 3

Pick an Implementation Science Theory, Model, or Framework

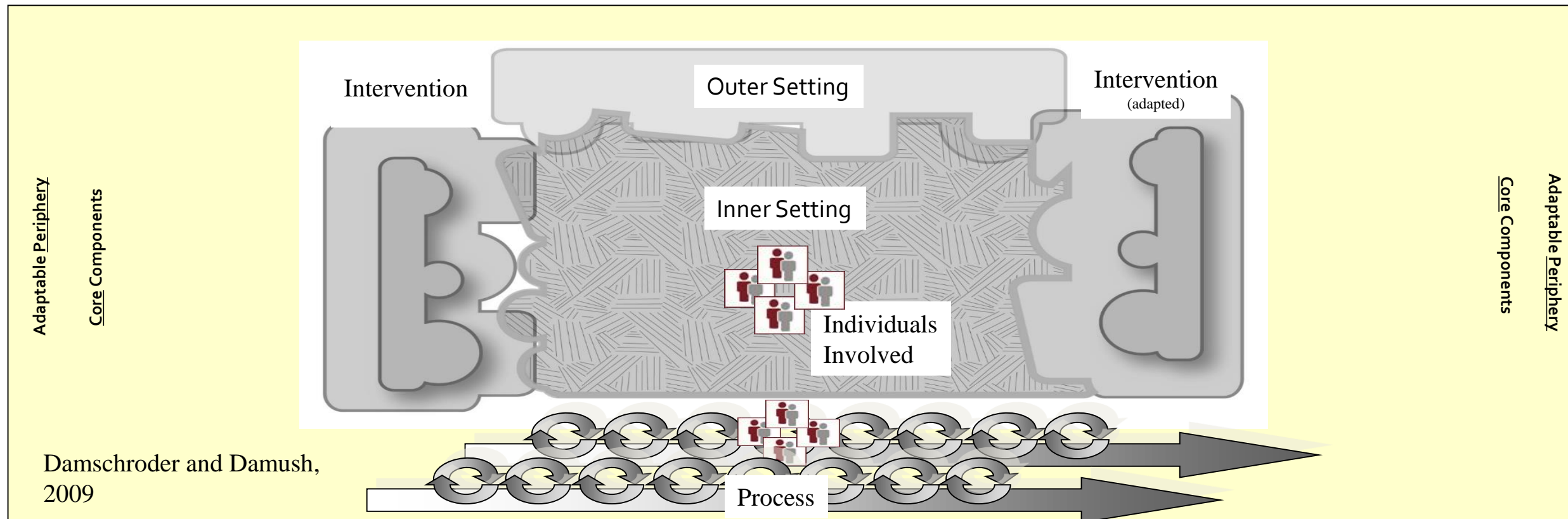
Use of Theory – Cornerstone of Implementation Science

- Use of theories and frameworks:
 - ▣ Provide systematic structure for the development, management, and evaluation of studies.
 - ▣ May help to enhance the effectiveness of interventions.
 - ▣ Ensures the inclusion of essential IS strategies.
 - ▣ Enhances the interpretability of findings; explain why an intervention works (or doesn't).
 - ▣ Helps to link aims, research designs, measures and analytic strategies.
 - ▣ Provides an opportunity to advance theories in the field.
 - ▣ May be a source of innovation (e.g., use of models from outside of health).

Implementation Science Models and Frameworks



Consolidated Framework for Implementation Research (CFIR)



Damschroder L, Aron D, Keith R, Kirsh S, Alexander J, Lowery J. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science* 2009; 4:50.

Example: Use of CFIR and Practice Change Model

Research Question:
 What are the practice, organizational, and contextual factors associated with meeting ABCS performance goals/targets among smaller primary care practices?

Marino M, Solberg L, Springer R, McConnell KJ, Lindner S, Ward R, Edwards ST, Stange KC, Cohen DJ, Balasubramanian BA. Cardiovascular Disease Preventive Services Among Smaller Primary Care Practices. Am J Prev Med. 2022 May;62(5):e285-e295.

Domain	Construct – Measure	Data Source
Resources for change (PCM) Inner setting – Internal capabilities (CFIR)	<u>Structural characteristics</u> ¹⁷¹ (social architecture or organization, physical space, staffing, roles) – Organizational Readiness for Change Assessment (ORCA) <u>Networks & communication</u> ^{65,172} – ORCA <u>Culture</u> (mindfulness, diversity, heedful interactions, mutual respect, social and task activities, communication, teamwork) – Adaptive Reserve Scale <u>Characteristics of individuals, practice staff</u> ^{173,174} (knowledge & beliefs, self-efficacy, individual stage of change, individual identity with organization, other personal attributes) – Evidence-based Practice Attitudes Scale <u>Readiness for implementation</u> ⁶⁵ (leadership engagement, resources) – Adapted from Klein et al, Change Process Capability Questionnaire (CPCQ) <u>Access to knowledge & information</u> (planning, engaging champions, reflection and evaluation) – Adaptive Reserve <u>Change Capability and Use of evidence-based Strategies</u> – CPCQ	Practice Information Form (PIF) (collected by our team in cooperation with R18s) Practice Member Questionnaire (PMQ) (collected by our team in cooperation with R18s)
External motivators (PCM) Outer setting (CFIR)	<u>Patient needs and resources</u> ¹⁷⁵ – Patient-centered Interaction subscale from the PCMH Self-Assessment Survey <u>External policies and incentives</u> ¹⁷⁶ – 7 item External Incentive Index <u>Cosmopolitanism</u> – how well networked with others; key stakeholders perspectives on external motivators	Practice Member Questionnaire (PMQ) (collected by our team in cooperation with R18s)
Opportunities for change [perceived]	Key stakeholders' perspectives on opportunities for change	Context Assessment Template
Intervention Characteristics Process of Implementation (Aim 3)	Relative advantage – adapted from Scott et al (measure to assess uptake of a heart health kit) ¹⁷⁷ Complexity – adapted from Pankratz et al ¹⁷⁸	Context Assessment Template
Other practice characteristics ^{24,166,179,180}		
Location	State, oversight organization	Practice Information Form
Practice characteristics	Type, ownership, size, number of clinicians, number of staff, use of EHRs, clinical information systems	
Staff involved in CVD care	Staff role(s); team- vs. provider-based approach	
Patient panel	Size, demographics of patient panel (race/ethnicity, age, insurance)	
Workload	Monthly #, types of encounters	
Provider characteristics	Age, gender, year graduated, number of years at practice, specialty	

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Step 4

Identify Implementation Strategies

Implementation Strategies Are...



Methods or techniques used to enhance the adoption, implementation, and/or sustainability of a clinical or public health program or practice

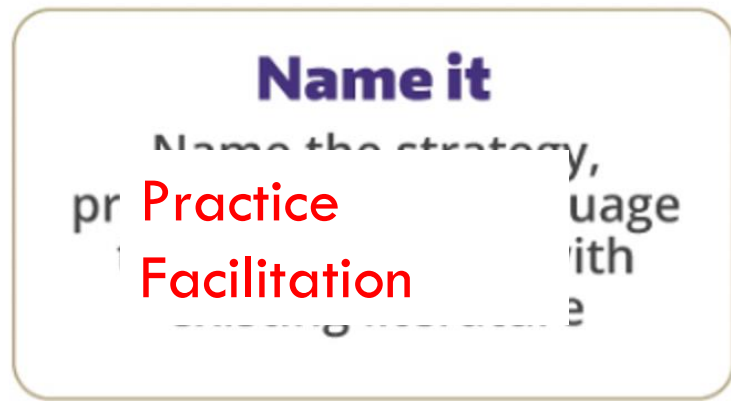
OR

The '**how to**' component of changing healthcare or public health practice.

Implementation Strategies

Types of Strategies	Examples
<u>Discrete</u> - often involve one action or process such as an educational session.	Education or training sessions
<u>Multifaceted</u> - often combine two or more discrete strategies in a package of implementation strategies.	Providing interactive assistance - Facilitation - Technical assistance
<u>Blended</u> - composed of multiple discrete strategies that have been packaged and/or protocolized.	Population-based registry + new clinical workflow + facilitation

Specifying and Reporting Implementation Strategies for Replicability

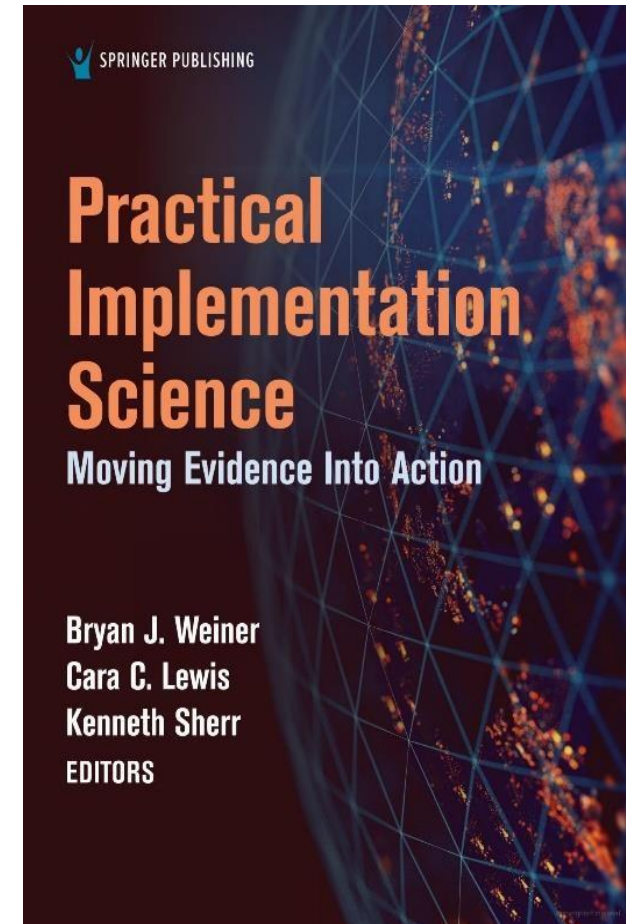


approach to supporting improvement in clinics focusing on building organizational capacity for continuous improvement



Developing and Selecting Strategies

- Group Model Building
- Conjoint Analysis
- Concept Mapping
- Implementation Mapping – Dr. Fernandez is the developer



Step 5

Select Research Method

Types of methods

- Quantitative - QUAN
 - ▣ Surveys
 - ▣ Clinical quality measures
 - ▣ Healthcare Utilization
- Qualitative – QUAL
 - ▣ Interviews
 - ▣ Direct Observation
 - ▣ Focus Groups
- Mixed methods – “integrate” QUAL and QUAN
 - ▣ Sequential
 - ▣ Convergent

Example

Aim 1: Conduct a hybrid type III Effectiveness-Implementation Cluster-Randomized Trial

Randomize 30 primary care clinics to Basic Support (control) or Enhanced, In-Person Support (implementation strategy), receiving Basic Support plus QI facilitation (up to 4 hours/month for 15 months) and assistance from expert consultants

Hypotheses: Adult patients with DMII in practices randomized to In-Person Support will demonstrate significantly greater decrease (improvement) in PHQ-9 and HbA1c scores at 15 months post-baseline as compared to Basic Support - **QUAN**

Aim 2: Conduct Mixed Method Evaluation of Implementation

We will select 12 clinics (6 higher-; 6 lower-change) and observe and interview clinic staff, then use comparative analysis to identify factors that influenced implementation, outcomes, and sustainability - **QUAL**

Primary Research Question: What patient, organizational, intervention and external factors explain why some practices implement and sustain changes aligned with ADA recommendations, while others do not? – **QUAL and QUAN**

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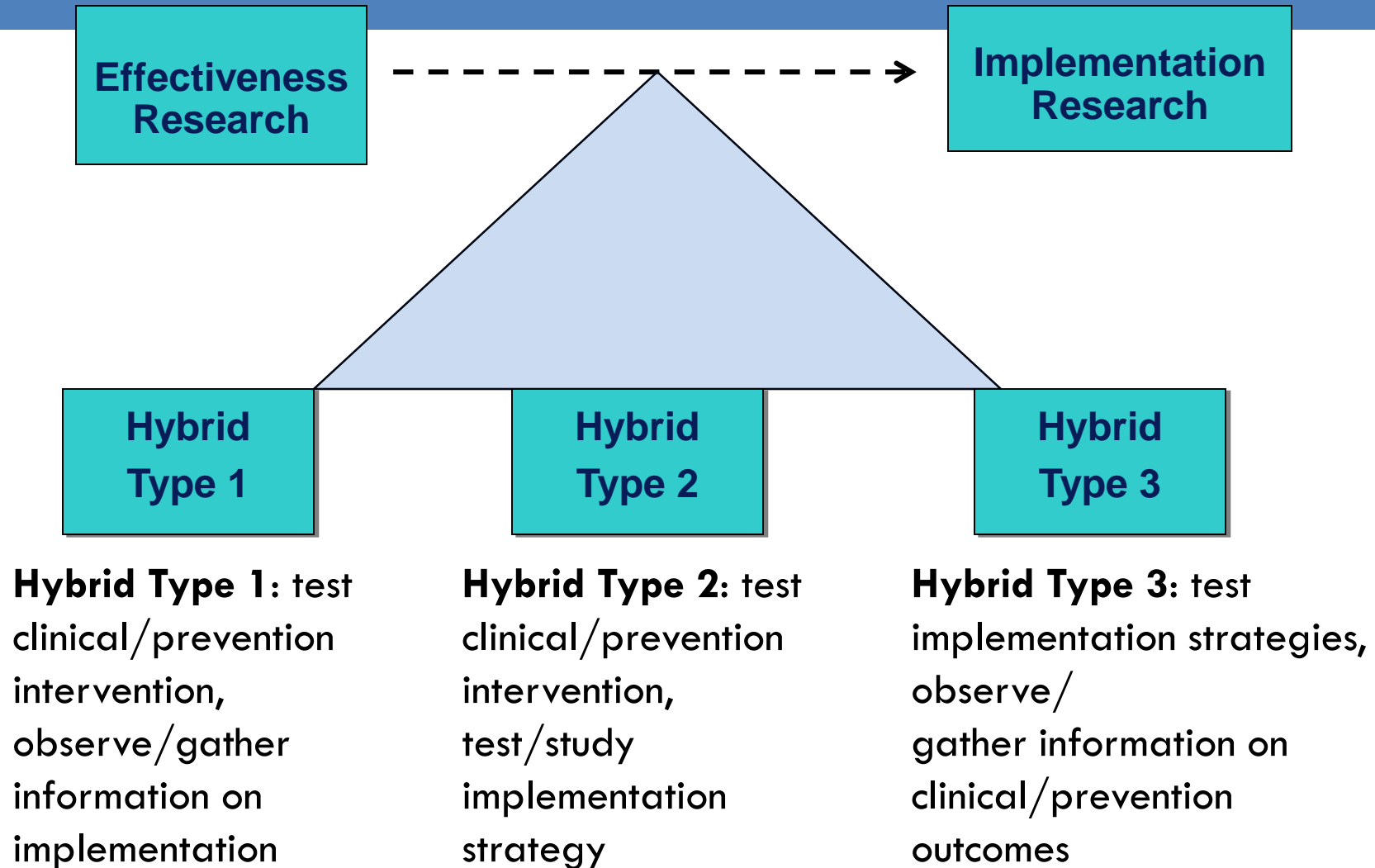
Step 6

Select Study Design

Traditional Study Designs

Experimental Designs	Randomized-controlled trial Cluster-randomized trial Stepped-wedge cluster-randomized trial SMART Adaptive designs
Quasi-Experimental Designs	Pre-post study Regression-discontinuity designs Interrupted time-series
Observational	Cross-sectional Prospective cohort Positive Deviance

Hybrid Implementation-Effectiveness Designs



Example

Aim 1: Conduct a hybrid type III Effectiveness-Implementation Cluster-Randomized Trial

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Hypothesis: Adult patients with DMII in practices randomized to In-Person Support will demonstrate significantly greater decrease (improvement) in PHQ-9 and HbA1c scores at 15 months post-baseline as compared to Basic Support

Aim 2: Conduct Mixed Method Positive-Deviance Evaluation of Implementation

We will select 12 clinics (6 higher-; 6 lower-change) and observe and interview clinic staff, then use **comparative analysis** to identify factors that influenced implementation, outcomes, and sustainability

Primary Research Question: What patient, organizational, intervention and external factors explain why some practices implement and sustain the strategies, while others do not?

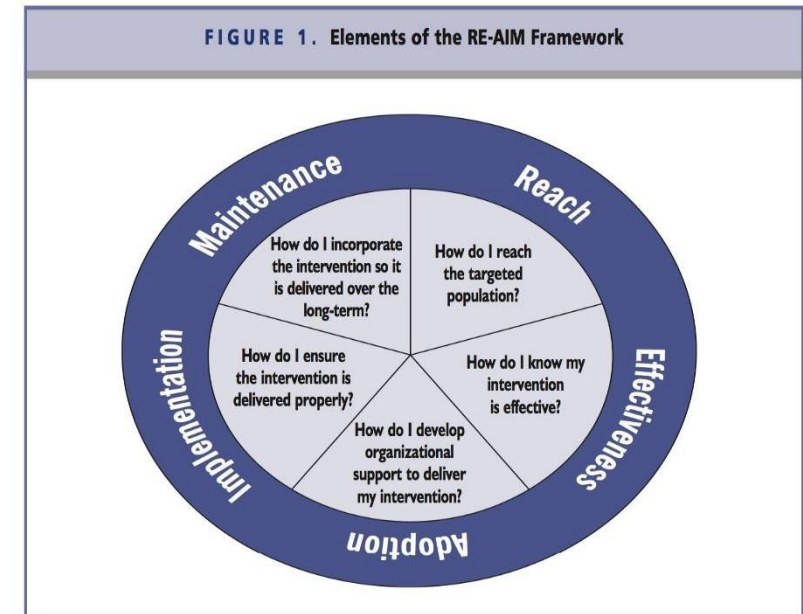
Step 7

Choose measures and evaluation approach

The RE-AIM Framework

- **RE-AIM is an acronym that consists of five elements:**
 - **R**each the target population
 - **E**fficacy or effectiveness
 - **A**doption by target settings or institutions
 - **I**mplementation - consistency of delivery of intervention
 - **M**aintenance of intervention effects in individuals and populations over time

RE-AIM





Step 8-10

Secure Funding

Conduct Study

Disseminate Results

Implementation Science in Simple Terms

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether THE THING works
- D&I research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the stuff we do to try to help people/places **DO THE THING**
- Implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

Curran, 2020, *Implementation Science Communications*

THE THING = HPV vaccine or Care Coordination

Training Opportunities



Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC)

- 8 free, self-paced modules intended to be an introduction to implementation science methods and approaches regardless of disease area

<https://cancercontrol.cancer.gov/is/training-education/training-in-cancer/TIDIRC-open-access>



University of Washington

- 11-week, online course covering the fundamentals of Implementation Science (estimated 6-9 hours per week)
- Individuals or site groups can register

<https://impsciuw.org/implementation-science/learn/uw-opportunities/>

Training Opportunities



Special Programme for Research and Training in Tropical Diseases

- Massive open online course (MOOC) on implementation research
- 5 modules, 6 weeks, multiple languages

[https://tdr.who.int/home/our-work/strengthening-research-capacity/massive-open-online-course-\(mooc\)-on-implementation-research](https://tdr.who.int/home/our-work/strengthening-research-capacity/massive-open-online-course-(mooc)-on-implementation-research)

Cancer Prevention and Control Research Network

- Self-paced, all materials available online

<https://cpcrn.org/training>



Training Opportunities

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL



UNC at Chapel Hill

- No cost, self-paced tutorials with a particular focus on research methods applied in dissemination & implementation research

<https://impsci.tracs.unc.edu/get-informed/tutorials/>



COLUMBIA UNIVERSITY
HERBERT IRVING COMPREHENSIVE
CANCER CENTER

Columbia University

- Mini, video-based course introducing implementation science to researchers

<https://www.cancer.columbia.edu/research/researchers/community-based-research/implementation-science-mini-course>

Training Opportunities



Washington University in St. Louis

- The Institute for Implementation Science Scholars (IS-2) is a mentored training program for investigators interested in applying dissemination and implementation (D&I) methods and strategies to reduce the burden of chronic disease and address health inequities.

<https://is2.wustl.edu/apply/>

Additional conferences, workshops, and other trainings can be found at:

- <https://societyforimplementationresearchcollaboration.org/dissemination-and-implementation-training-opportunities/>
- <https://impsci.tracs.unc.edu/get-informed/trainings/>

Summary



Thank You!

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