OPTIMIZING IMPLEMENTATION IN RESEARCH AND PRACTICE

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DEPARTMENT OF GLOBAL HEALTH

WHAT IS IMPLEMENTATION SCIENCE?

IMPLEMENTATION SCIENCE DEFINED

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

IMPLEMENTATION SCIENCE MADE SIMPLE

What is implementation research and how does it differ from effectiveness research?

EVIDENCE BASED	PROGRAMS, PRACTICES, PRINCIPLES, PROCEDURES, PRODUCTS, PILLS, POLICIES = THE THING
Effectiveness Research	Whether THE THING **works**
Implementation Research	**Studying** how to best help people and places **do** THE THING
Implementation Strategies	The **stuff we do** to try to help people and places **do** THE THING
Main Implementation Outcomes	**How much** and **how well** they **do** THE THING

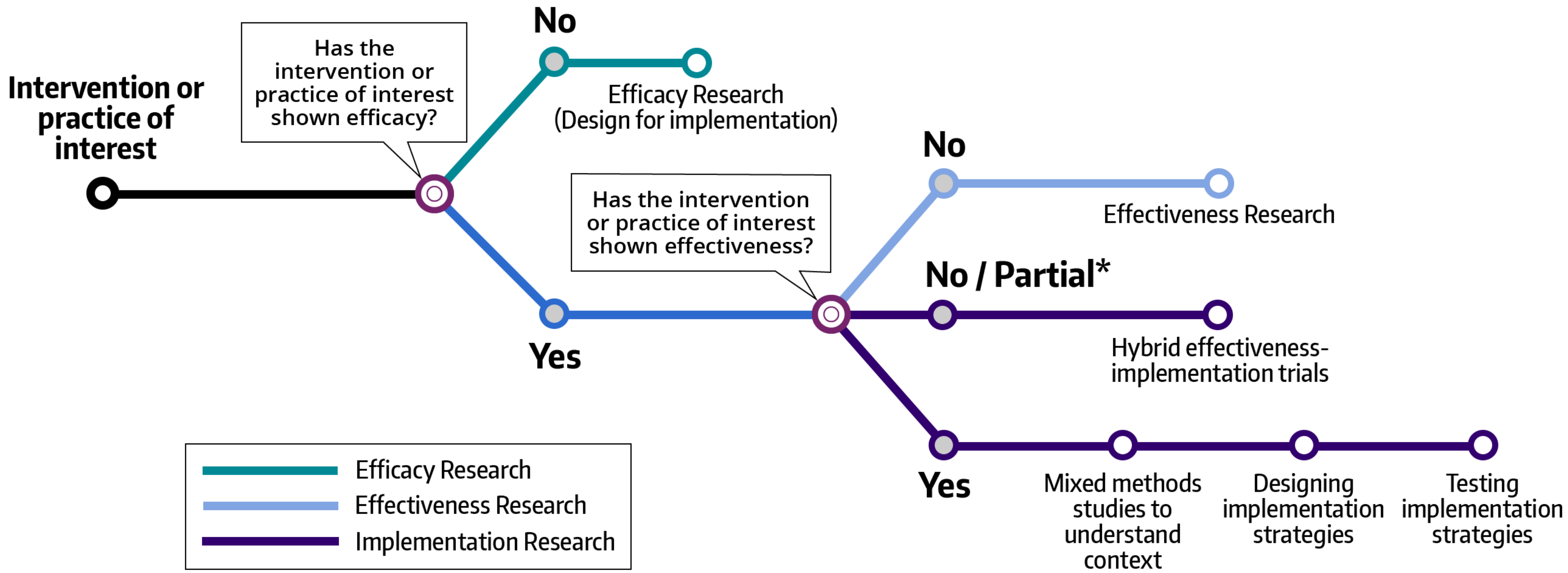
Adapted from: Curran, G.M. Implementation science made too simple: A teaching tool. *Implement Sci Commun* 1, 27 (2020). https://doi.org/10.1186/s43058-020-00001-z

Examples:

Training, audit and feedback, opinion leaders clinical reminders, decision support, task shifting

% clinicians delivering EBP, % patients receiving EBP, guideline adherence, competence

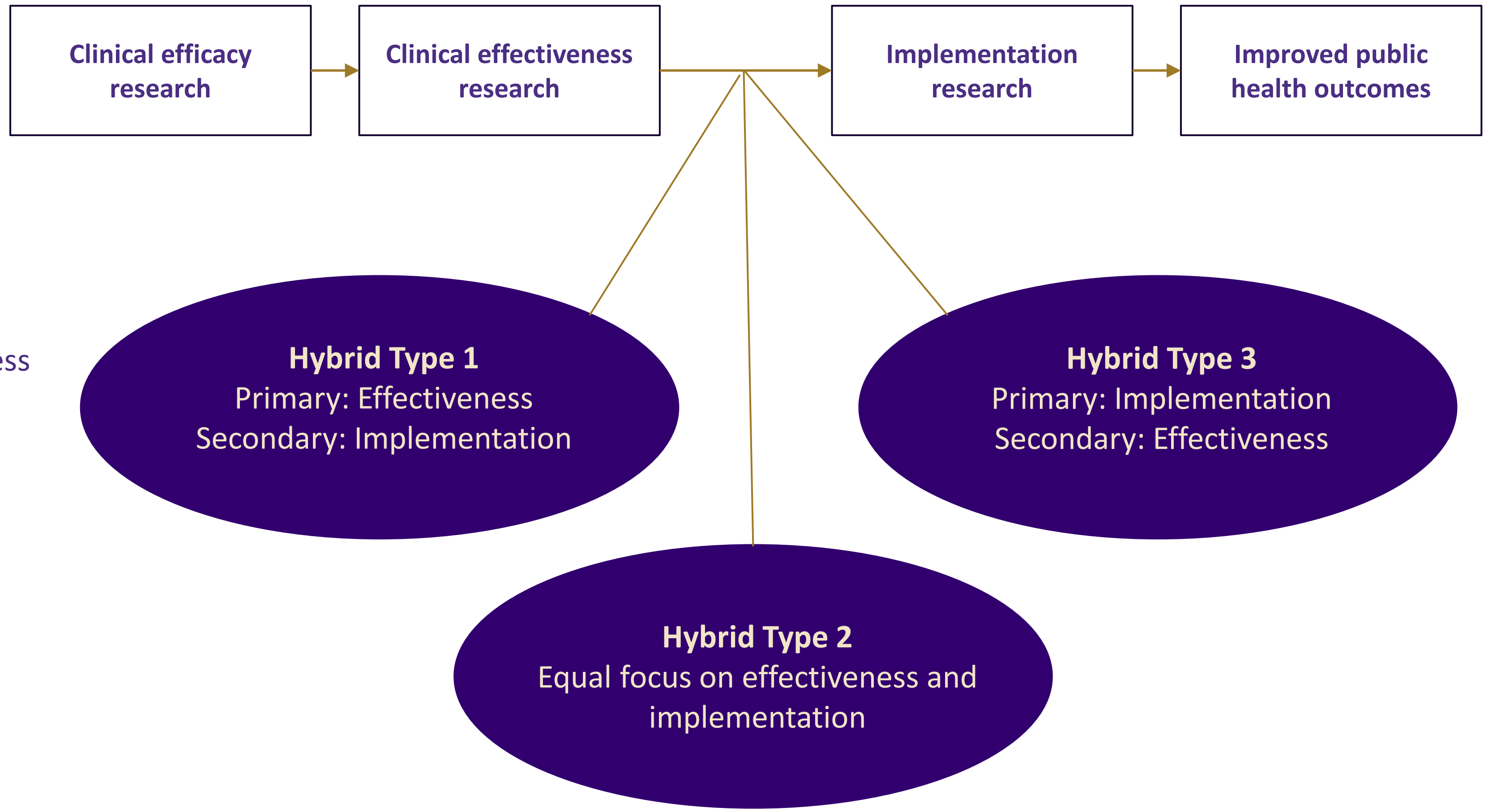
WHEN TO DO IMPLEMENTATION SCIENCE



"Hybrid designs blend design characteristics of effectiveness and implementation studies to generate timely uptake of desirable interventions, more effective implementation strategies, and more relevant information for future scale-up activities."

Rabin & Brownson, Dissemination and Implementation Research in Health, 2018

THREE TYPES OF HYBRID STUDY DESIGNS



Primary aim: Determine effectiveness of an intervention
Secondary aim: Better understand context for implementation

Primary aim: Determine impact of an implementation strategy
Co-primary or secondary aim: Assess clinical outcomes associated with implementation

Primary aim: Determine effectiveness of an intervention
Co-primary or secondary aim: Determine feasibility and/or (potential) impact of an implementation strategy

HYBRID 1 EXAMPLE

Contemporary Clinical Trials 88 (2020) 105877

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

ELSEVIER

Preventing diabetes with digital health and coaching for translation and scalability (PREDICTS): A type 1 hybrid effectiveness-implementation trial protocol

Fabio A. Almeida[a,b,*], Tzeyu L. Michaud[a,b], Kathryn E. Wilson[a], Robert J. Schwab[c], Cody Goessl[a], Gwenndolyn C. Porter[a], Fabiana A. Brito[a], Greg Evans[d], Emily V. Dressler[d], Ashley E. Boggs[e], Jeffrey A. Katula[e], Cynthia Castro Sweet[f], Paul A. Estabrooks[a,b]

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[b] Center for Reducing Health Disparities, University of Nebraska Medical Center, Omaha, NE 68198, United States
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[e] Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC 27109, United States
[f] Medical Affairs, Omada Health, Inc., San Francisco, CA 94111, United States

Specific Aims:

1. Evaluate the clinical effectiveness of a digital Diabetes Prevention Program versus a small-group diabetes prevention class.
2. Assess the potential for future adoption, implementation and sustainability of a digital Diabetes Prevention Program within a regional healthcare system.

HYBRID 2 EXAMPLE

Lyon *et al. Implementation Science* (2021) 16:3
https://doi.org/10.1186/s13012-020-01064-1

Implementation Science

STUDY PROTOCOL Open Access

Check for updates

Protocol for a hybrid type 2 cluster randomized trial of trauma-focused cognitive behavioral therapy and a pragmatic individual-level implementation strategy

Aaron R. Lyon[1*], Michael D. Pullmann[1], Shannon Dorsey[1], Carol Levin[1], Larissa M. Gaias[2], Stephanie K. Brewer[1], Madeline Larson[3], Catherine M. Corbin[1], Chayna Davis[1], Ian Muse[1], Mahima Joshi[1], Rosemary Reyes[1], Nathaniel J. Jungbluth[4], Rachel Barrett[1], David Hong[5], Michael D. Gomez[6] and Clayton R. Cook[3]

Specific Aims:

1. Evaluate the effectiveness and cost-effectiveness of TF-CBT in schools versus an enhance treatment-as-usual condition.
2. Evaluate the impact and cost-effectiveness of BASIS versus attention control

HYBRID 3 EXAMPLE

Midboe *et al. Implementation Science* (2018) 13:145
https://doi.org/10.1186/s13012-018-0838-2

Implementation Science

STUDY PROTOCOL Open Access

CrossMark

Testing implementation facilitation of a primary care-based collaborative care clinical program using a hybrid type III interrupted time series design: a study protocol

Amanda M. Midboe[1*], Steve Martino[2,3], Sarah L. Krein[4,5], Joseph W. Frank[6,7], Jacob T. Painter[8,9], Michael Chandler[8,9], Allison Schroeder[6], Brenda T. Fenton[2,3], Lara Troszak[1], Taryn Erhardt[1], Robert D. Kerns[2,3] and William C. Becker[2,3]

Specific Aims:

1. Determine if implementation facilitation leads to uptake and sustained use of Primary Care-Integrated Pain Support (PIPS) collaborative clinical care program.
2. Examine the effectiveness of PIPS on clinical outcomes, including transitions to safer medication regimens and uptake of complementary and integrated health (CIH) treatments.
3. Determine the budget impact of implementation of PIPS.

WHAT ELSE CAN YOU DO WITH IMPLEMENTATION SCIENCE?

Murphy *et al. Implementation Science* 2014, **9**:31
http://www.implementationscience.com/content/9/1/31

IMPLEMENTATION SCIENCE

RESEARCH **Open Access**

Understanding diagnosis and management of dementia and guideline implementation in general practice: a qualitative study using the theoretical domains framework

Kerry Murphy[1], Denise A O'Connor[1*], Colette J Browning[2], Simon D French[3], Susan Michie[4], Jill J Francis[5], Grant M Russell[6], Barbara Workman[7], Leon Flicker[8], Martin P Eccles[9] and Sally E Green[1]

Shaw *et al. Implementation Science* 2013, **8**:106
http://www.implementationscience.com/content/8/1/106

IMPLEMENTATION SCIENCE

RESEARCH **Open Access**

Organizational factors associated with readiness to implement and translate a primary care based telemedicine behavioral program to improve blood pressure control: the HTN-IMPROVE study

Ryan J Shaw[1*], Miriam A Kaufman[1], Hayden B Bosworth[1,2,3], Bryan J Weiner[4], Leah L Zullig[1,4], Shoou-Yih Daniel Lee[5], Jeffrey D Kravetz[6,7], Susan M Rakley[2,8], Christianne L Roumie[9,10], Michael E Bowen[11], Pamela S Del Monte[8], Eugene Z Oddone[1,2] and George L Jackson[1,2]

WHAT DOES IMPLEMENTATION SCIENCE BRING TO THE TABLE?

- Focus on implementation
- Theories, models, and frameworks
- Assessment tools
- Implementation strategies
- Methods

SO, WHAT IS THE PROBLEM?

SUBOPTIMAL IMPLEMENTATION IN RESEARCH AND PRACTICE

In "implementation as usual," implementation strategies are not matched to important contextual factors.

Optimized implementation happens when strategies employed to implement evidence-based interventions truly address key barriers in the *specific* settings in which implementation occurs, and when those strategies reflect the *best possible methods* to address those barriers.

Examples: Suboptimal Implementation

- Healthcare system employs untailored ("what we always do") strategies to implement hereditary cancer risk assessment program; program uptake remains low.
- Safety-net clinic uses inefficient workflow to implement mailed fecal immunochemical test (FIT) program; program reach suffers.
- Healthcare system uses general, untested patient outreach materials that do not address women's barriers to completing home-based HPV test; completion rates do not increase

SUBOPTIMAL IMPLEMENTATION IN RESEARCH AND PRACTICE

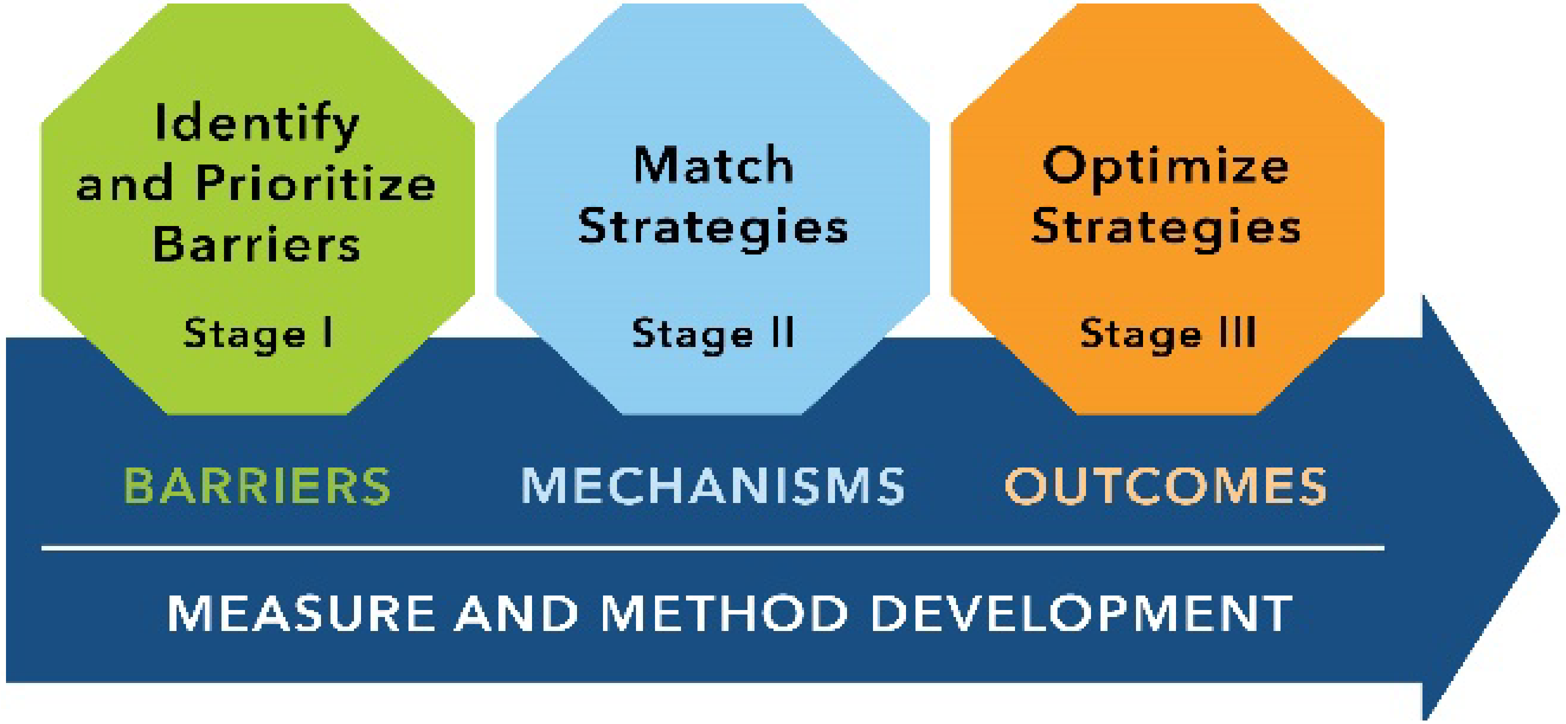
Implementation science can help:

1. Generate robust methods for assessing context, prioritizing barriers, and matching strategies to barriers.
2. Generate useful guidance on designing and deploying strategies for optimal effectiveness, efficiency, or fit with local resources.

<u>But only if we address 4 critical barriers:</u>

1. Underdeveloped methods for barrier identification and prioritization.
2. Incomplete knowledge of strategy mechanisms.
3. Underutilization of methods for optimizing strategies.
4. Poor measurement of implementation constructs

OPTIMIZING IMPLEMENTATION IN RESEARCH AND PRACTICE



IMPACT OPTICC MECHANISMS

HOW ARE WE ADDRESSING THE "GRAND CHALLENGE" OF OPTIMIZING IMPLEMENTATION?

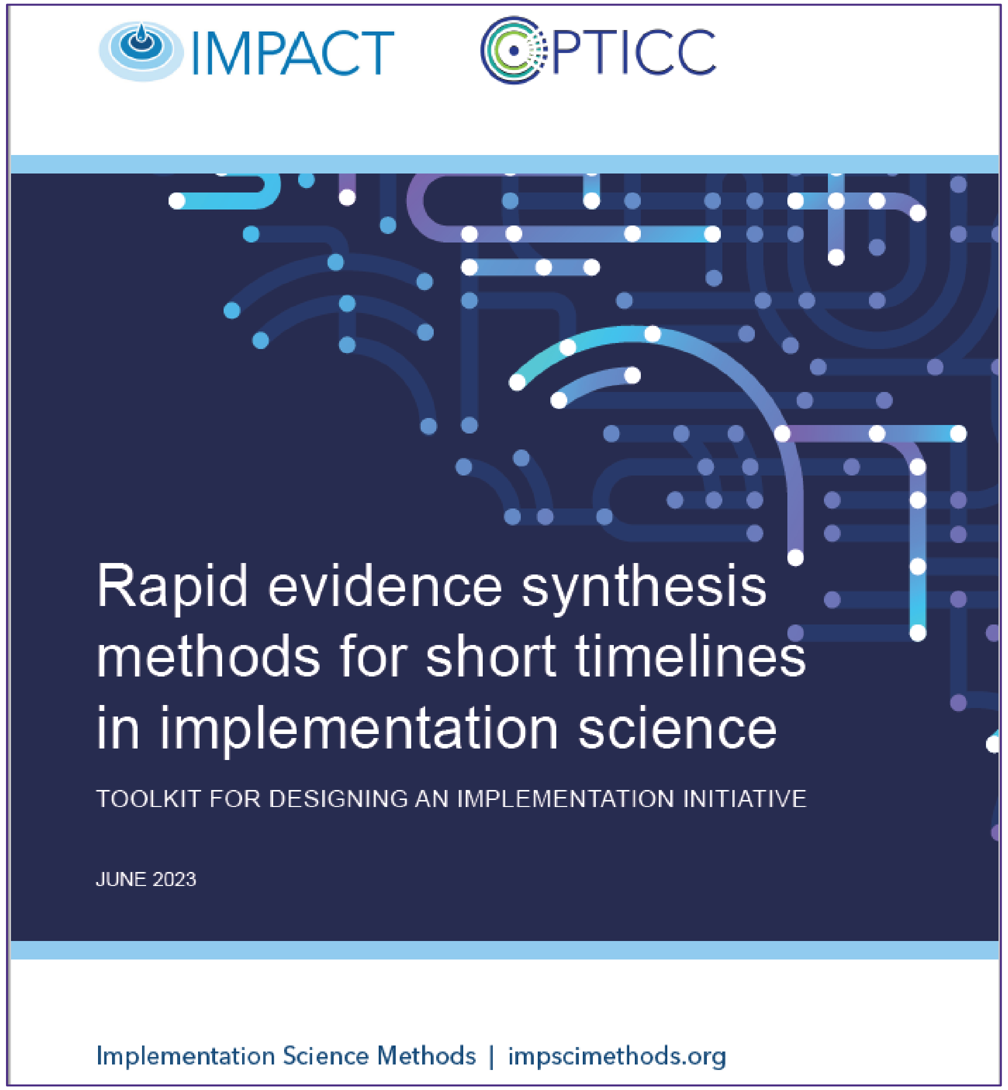
STAGE 1: METHODS TO IDENTIFY AND PRIORITIZE IMPLEMENTATION BARRIERS

Problems with Currently Used Methods:

1. They typically do not consider relevant barriers identified in the literature.
2. They are subject to issues of recall, bias, and social desirability
3. They do not sufficiently engage the end user in the EBI prior to assessment
4. Barrier prioritization relies on stakeholder ratings of perceived qualities which may have little to do with impact.

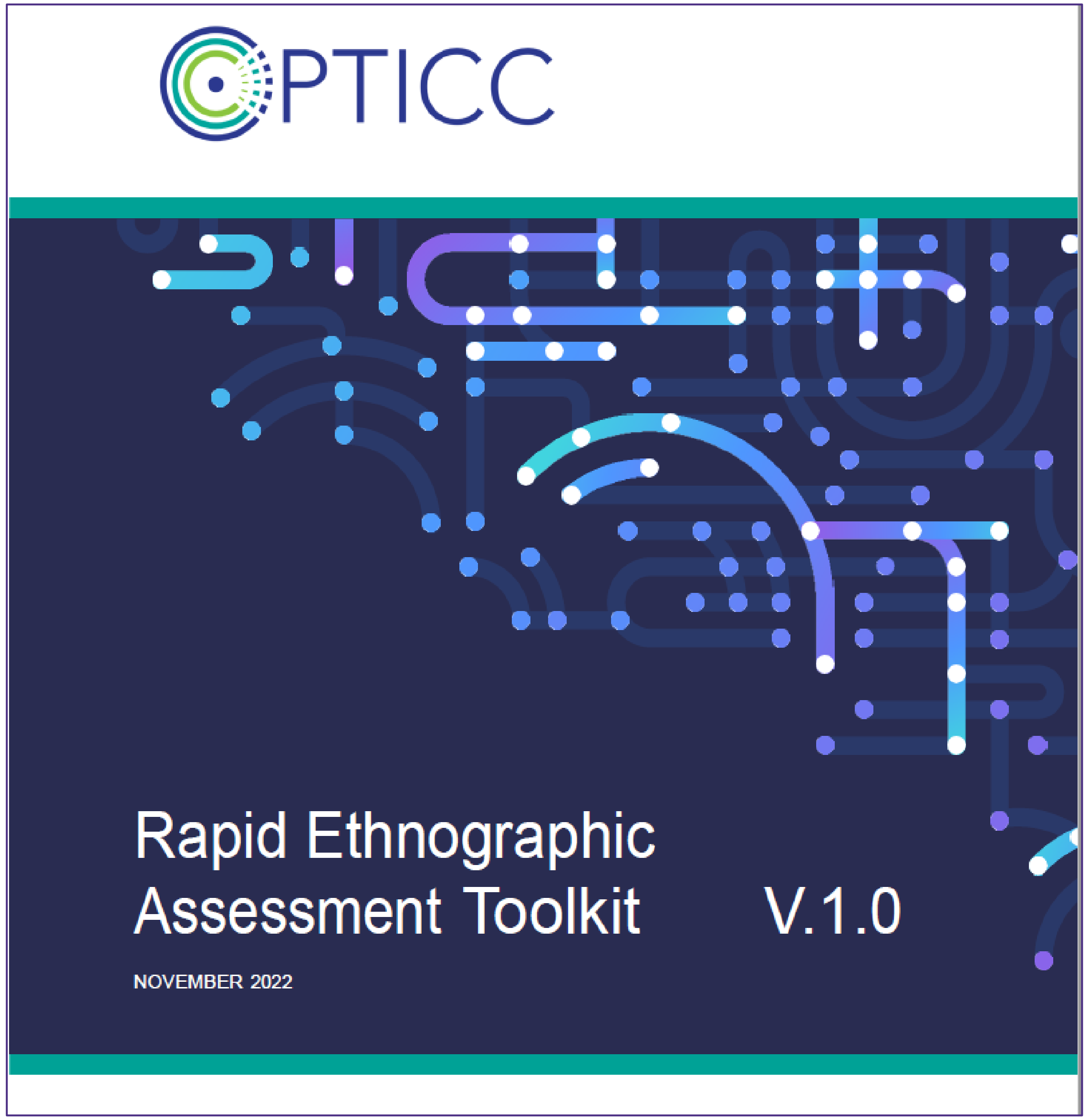
STAGE 1: METHODS TO IDENTIFY AND PRIORITIZE IMPLEMENTATION BARRIERS

Rapid evidence synthesis is a series of methods that adapts systematic review methods for shorter timelines than for a full systematic review.



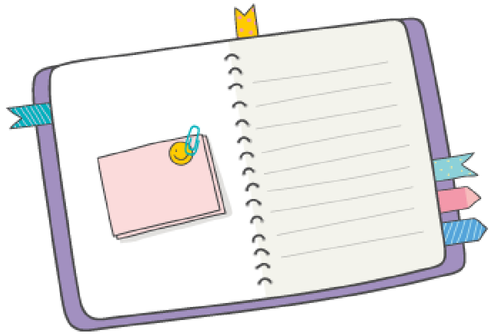
STAGE 1: METHODS TO IDENTIFY AND PRIORITIZE IMPLEMENTATION BARRIERS

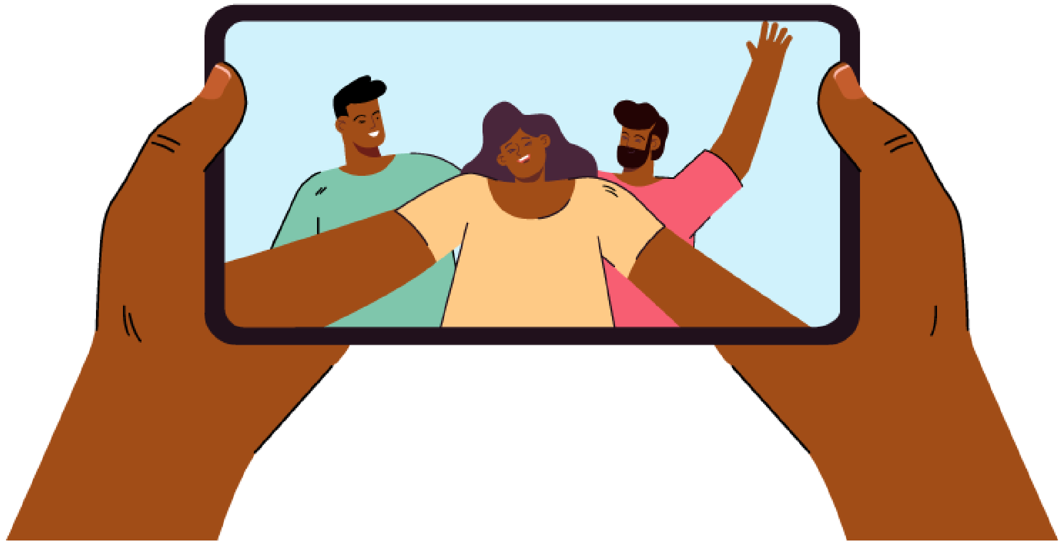
Rapid ethnographic assessment is used to efficiently gather ethnographic data about determinants by seeking to understand the people, tasks, and environments involved from stakeholder perspectives. This is achieved primarily by engaging stakeholders as active participants and applying user-centered approaches to efficiently elicit information.



STAGE 1: METHODS TO IDENTIFY AND PRIORITIZE IMPLEMENTATION BARRIERS

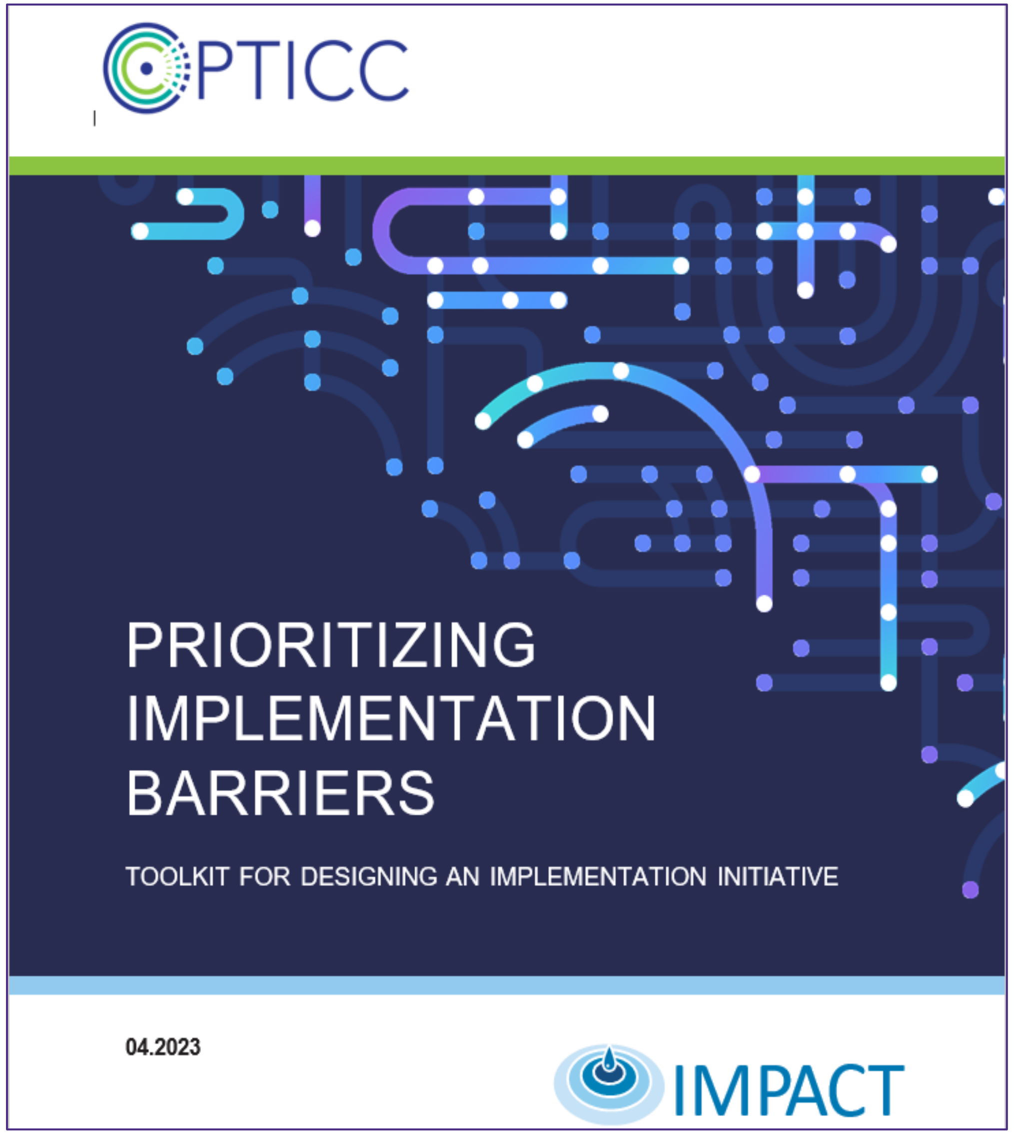
Design probes are user-centered research toolkits that utilize items such as disposable cameras, albums, and illustrated cards. End users are prompted to take pictures, make diary entries, draw maps, or make collages in response to tasks such as “Describe a typical day” or “Describe using [the evidence-based intervention]”.





STAGE 1: METHODS TO IDENTIFY AND PRIORITIZE IMPLEMENTATION BARRIERS

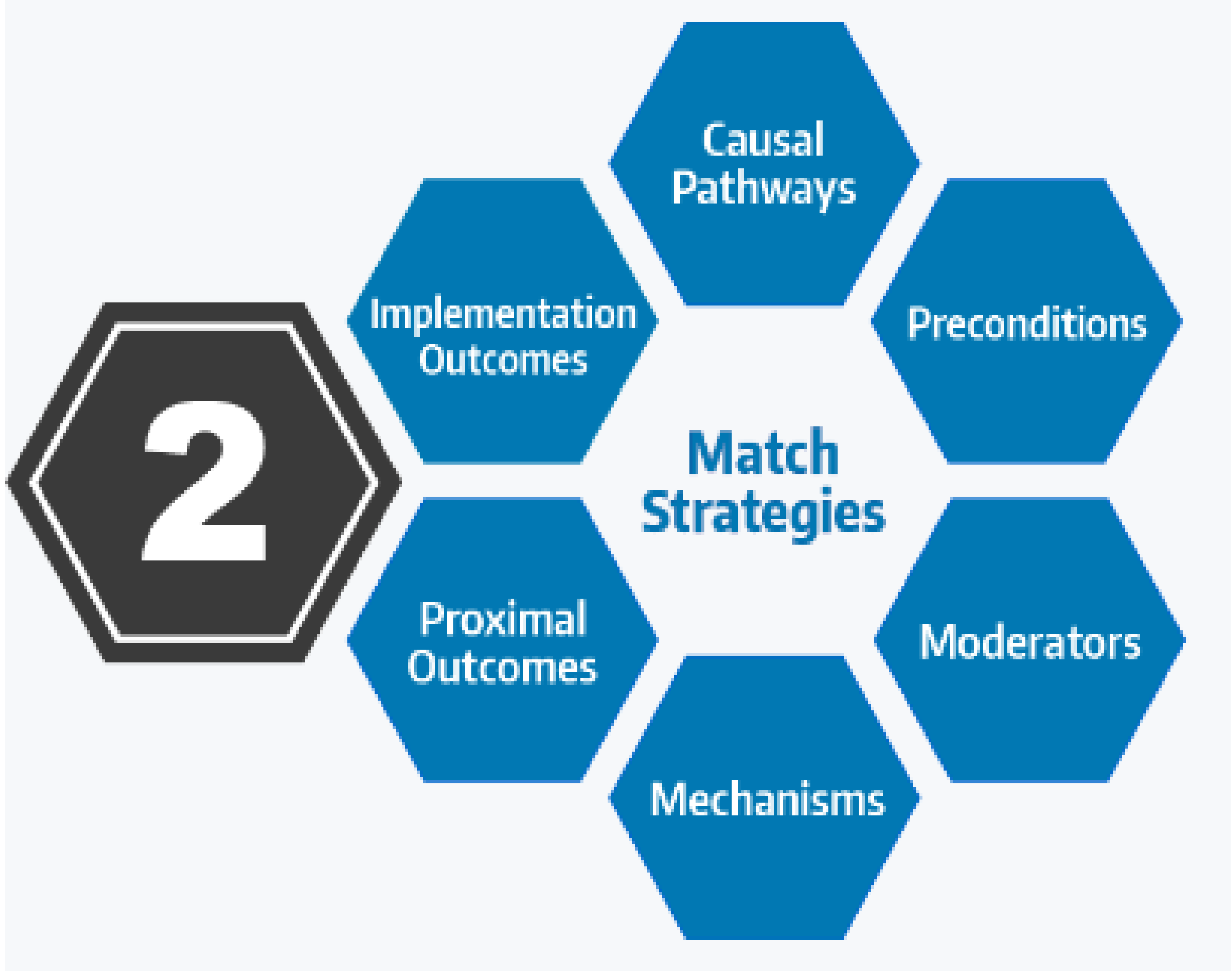
Expanded set of criteria for prioritizing implementation determinants (e.g., barriers) to facilitate selection of strategies that target "high priority" determinants



STAGE 2: METHODS MATCH STRATEGIES TO IMPLEMENTATION BARRIERS

Problems with Currently Used Methods:

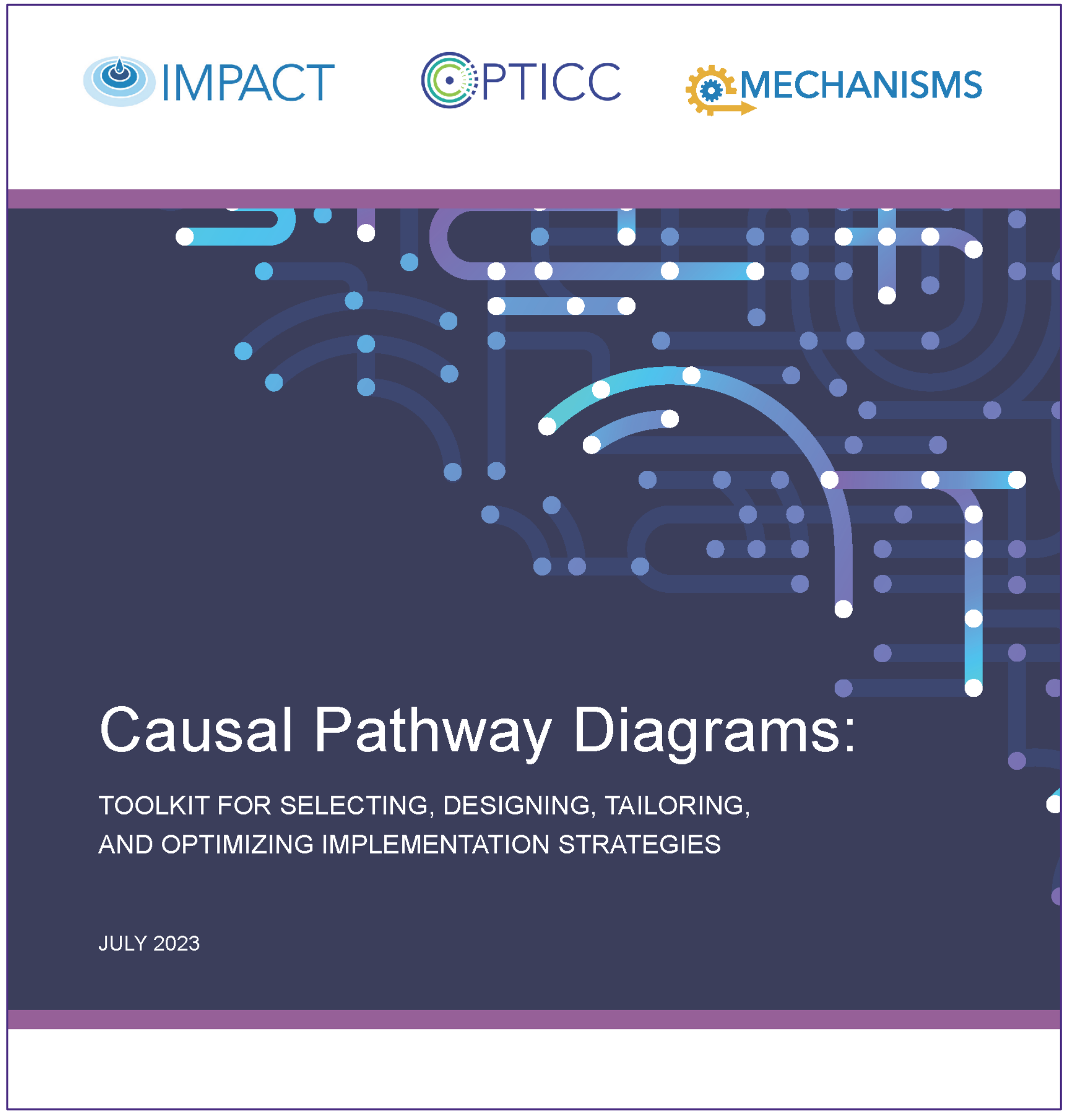
1. Although strategies have been compiled, labeled, and defined, their mechanisms remain largely unknown.
2. CFIR-ERIC Matching Tool based on low expert consensus
3. Intervention mapping requires more technical expertise than implementation researchers have and more resources than settings have.
4. DAGs and path models are useful for other purposes
5. Implementation Research Logic Model requires a "logical leap."



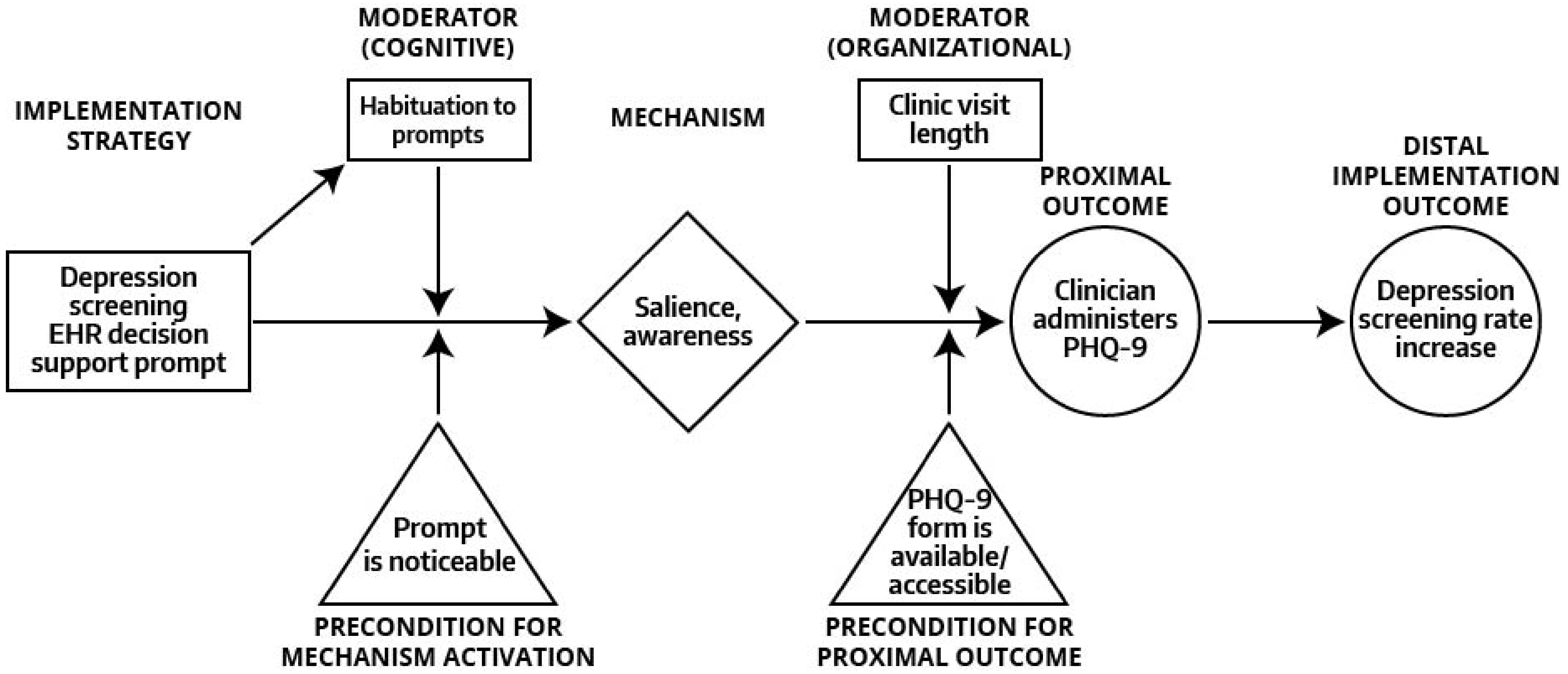
STAGE 2: METHODS TO IDENTIFY AND IMPLEMENTATION BARRIERS

Causal Pathway Diagrams (CPDs) as a visualization tool to represent the:

- Strategy and its core components
- Mechanism(s) through which it the strategy is thought to operate
- Determinants it is intended to address
- Contextual factors that may impede or facilitate the strategy's effectiveness
- Outcomes that should be expected if the strategy is operating as intended.



THEORIZING IMPLEMENTATION STRATEGIES



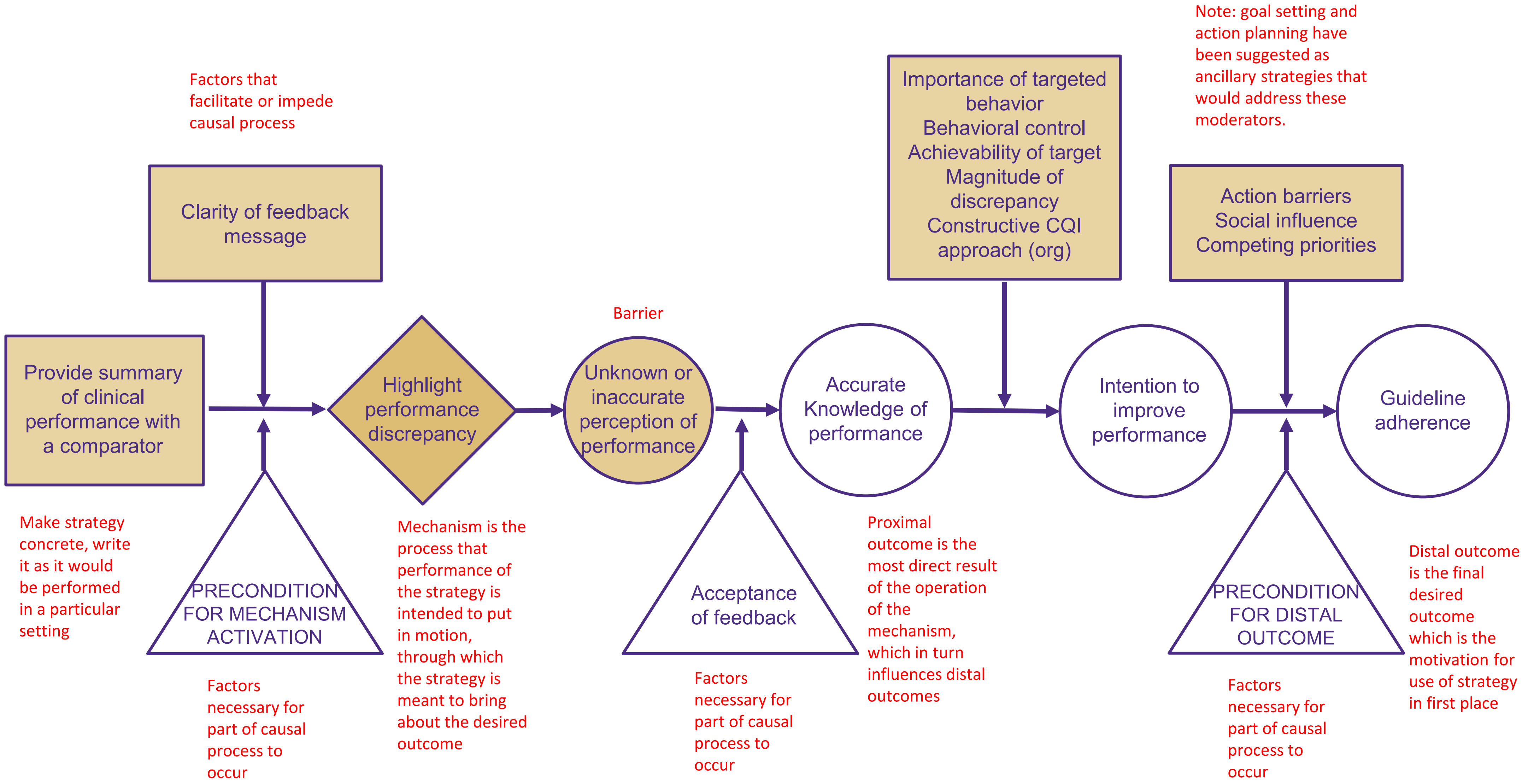
https://www.frontiersin.org/articles/10.3389/fpubh.2018.00136/full

MECHANISMS: The MECHANics of Implementation Strategies and MeasureS

Generate and assess plausibility of CPDs for 30 Expert Recommendations for Implementing Change (ERIC) Strategies

Deep Dive 1	Deep Dive 2	Deep Dive 3
Task shifting	Conduct educational outreach visits	Organize implementation teams
Clinical reminders	Create implementation blueprint	Use practice facilitation
Create a learning collaborative	Provide ongoing consultation	Innovation championing
Conduct educational meetings	Assess and redesign workflow	Use patient/family testimonials
Local opinion leaders	Use train-the-trainer strategies	Computerized decision support
Model and simulate change	Implementation leadership	Visit other sites/shadow experts
Provide clinical supervision	Tailor the strategy	Change service delivery site/setting
Promote adaptability/adaptation	Alter payment structures	A network-focused strategy (TBD)
Provide incentives	Distribute educational materials	A sustainability strategy (TBD)

AUDIT AND FEEDBACK



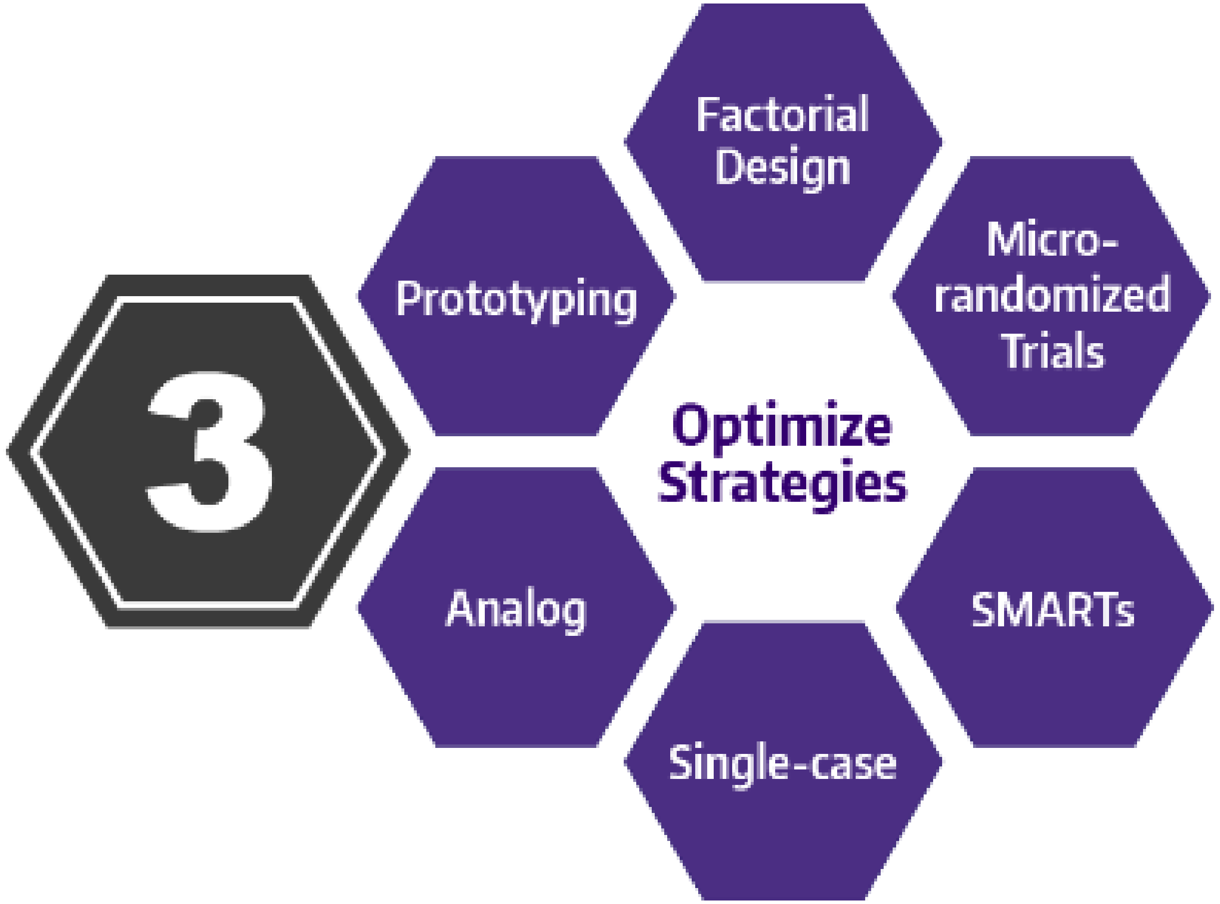
NOTE: The moderators depicted are determined by other factors, see below. Ancillary (supporting) strategies could target these moderators.

- Acceptance of feedback ← accuracy of data, trustworthiness of feedback agent, relevance of benchmark/target, ego threat, transparency/verifiability
- Clarity of feedback message ← Interpretability of feedback (e.g., layout), clarity of signal (e.g., explicit target)
- Importance of targeted behavior ← clinical importance, professional relevance
- Behavioral control ← actionability of feedback (e.g., simplicity of behavior, specificity of feedback, self-efficacy
- Constructive CQI approach (e.g., non-punitive)
- Action barriers: a catch-all for barriers to improving performance (e.g., workflow, time, disincentives, uncertainty about what to do, etc.)
- Social influences: a catch-all for social factors that positively or negatively influence efforts to improve performance (e.g., leadership support, champions, teamwork, organizational culture, communication and collective problem-solving)

STAGE 3: METHODS TO OPTIMIZE STRATEGIES

Problems with Currently Used Methods:

1. Reliance on RCTs and focus on distal implementation outcomes limits opportunities to assess strategy effects on barriers.
2. RCTs of multicomponent strategies provide limited information about component effectiveness.
3. Jump from pilot study to RCT leaves little room for optimizing strategy design (e.g., format, source, dosage)



STUDIES USING STAGE III METHODS

OPTICC or IMPACT Study	Stage 3 Method
Optimizing a chatbot for increasing breast cancer screening rates among Black and African American women.	HCD Online factorial experiment
Ride-share transportation program for patients with abnormal FIT pilot study.	Ideation
Patient-centered approach to tailoring HPV self-sampling for cervical cancer screening (PATH)	Online factorial experiment
Optimization of a theory-driven, blended pre-implementation strategy for school-based mental health clinicians	Rapid Analog Method (RAM) Factorial experiment
Promoting portal use among Black women to address barriers to breast cancer screening	Co-design SMART (proposed)

THE GOAL

Supplemental Slide

STAGE 3: METHODS TO OPTIMIZE STRATEGIES

Table 4: Challenge III Designs

Design	Description/Benefits
Factorial	Factorial designs are best for optimizing complex strategies[54,56] because they efficiently screen multiple components for an effect on target outcomes. Each component is a "factor" that can take several "levels" (e.g., yes vs. no; delivery source). Participants are randomized to cells corresponding to different combinations of levels of each factor allowing for analysis of main effects and interactions with fewer participants compared to RCTs.
MRTs	Micro-randomized trials (MRTs) evaluate strategy components delivered repeatedly (e.g., automated reminders about assessments). Each time ("decision point") that a component can be delivered (e.g., patient visit), provision or non-provision of the component is randomized, allowing multiple components to be randomized concurrently. MRTs are a highly efficient design that takes advantage of within-subject and between-subject comparisons to estimate marginal main effects, changes in component effect over time, and moderating effects.
SMARTs	Sequential Multiple Assignment Randomized Trials (SMARTs) optimize adaptive strategies[57,58] and help researchers determine decision rules for delivering a sequence of strategies that satisfy a set of optimization criteria, usually effectiveness and cost. Participants are initially randomized to two strategies that differ in intensity or cost and at predetermined times, non-responders are re-randomized to another set of strategy options; this can occur multiple times. SMARTs are highly efficient because analyses can use different sample subsets to answer different research questions (e.g., differences between strategies and the optimal way to support non-responders).
SCEDs	Single-Case Experimental Designs (SCEDs) gather evidence about strategy effects by observing changes in outcomes of interest for each participant (or unit, e.g., clinic). SCEDs are inherently within-subject designs with participants acting as their own controls, achieved through sequencing strategy exposures and comparing outcomes for periods when a participant was exposed to those when no strategy was provided. SCED designs include ABAB and multiple baseline. SCEDs require as few as six participants to provide information about effects, making it highly efficient with the low participant requirement making SCEDs promising for preliminary implementation studies in a single clinic.[59,60]