Implementation Research Designs and Methods: Testing Implementation Strategies

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Objectives

- Learn the fundamentals of the Implementation Research Logic Model (IRLM)
- Understand the basic goals of research to scale up effective clinical and health interventions
- Explore using the IRLM for studies of scale up
  - Present a “scale up extension” of the IRLM
  - Hypothetical case example

The Delivery System Matters

"The use of effective interventions without [effective] implementation strategies is like a serum without a syringe; the cure is available, but the delivery system is not."

Fixsen, Blase, Duda, Naoom, Van Dyke, 2010

Hybrid Approaches

Effectiveness Research

Implementation Strategies to Support the Delivery System

Intervention Effectiveness

Symptoms, Functioning, Quality of Life, Infections, etc.

Clinical/Prevention/ Health Promotion **Intervention**

Evidence-Based Clinical/Preventive/Health Interventions

- **The 7 P's**
  - **Pill** (PrEP)
  - **Program** (PROMISE)
  - **Practice** (routine HIV screening in clinical settings)
  - **Principle** (HIV Treatment as Prevention)
  - **Product** (condom)
  - **Policy** (housing for people at high risk for HIV)
  - **Procedures** (male circumcision)

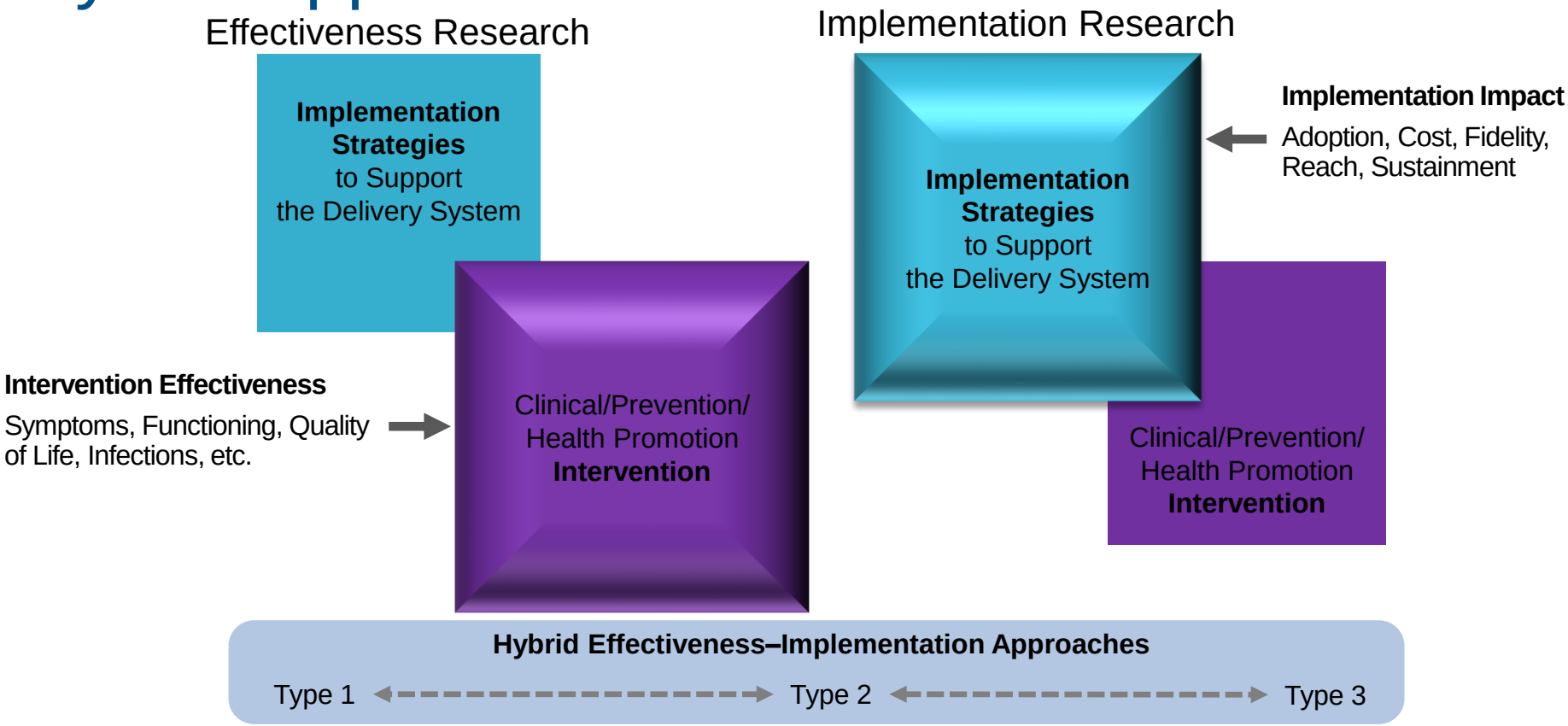
Brown et al., 2017

Implementation Strategies

- Implementation Strategies are an intervention on the system to increase adoption of evidence-based innovations into usual care
  - 9 categories derived from 75 discrete evidence-informed strategies
- Theory- or logic-driven connection between the implementation strategy and the barriers (that it will attempt to overcome) and the facilitators (that it will attempt to leverage) (CFIR → ERIC study)
- Rarely 1-to-1 (i.e., 1 strategy often is linked to multiple determinants; > 1 strategy to address 1 barrier; increasing 1 implementation outcome could be the result of ≥1 determinant and require ≥ strategy)

ERIC Study
Powell et al. 2015

Hybrid Approaches



test the thing, observe/gather information on doing the thing

test the thing, test/study strategies to do the thing

test strategies to do the thing, observe/ gather information on the thing

Approach, NOT Design

- Changing the language from hybrid “design” to hybrid “approach”
  - Helps folks recall that this is an approach that can be used with a variety of research designs

Research Aims by Hybrid Approach Type

Study Characteristic	Hybrid Type I	Hybrid Type II	Hybrid Type III
Research Aims	***Primary Aim:*** Determine effectiveness of an intervention ***Secondary Aim:*** Better understand context for implementation	***Primary Aim*:** Determine effectiveness of an intervention ***Co-Primary* Aim*:** Determine feasibility and/or (potential) impact of an implementation strategy *or “secondary”…	***Primary Aim*:** Determine impact of an implementation strategy ***Secondary Aim*:** Assess clinical outcomes associated with implementation

Why should we consider hybrid designs?

- Maybe we can speed this up a little?
  - Sequential examination can be slow
  - Don’t wait for “perfect” intervention effectiveness data before moving to implementation research
  - We can “backfill” effectiveness data while we test/evaluate implementation strategies
- How do intervention/innovation outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from “both sides”?

Characteristics and Challenges of Designing Implementation Trials

- External validity > internal validity
- Minimize disruptions to and burden on the systems
- Randomization occurs at “higher levels” of the service system (e.g., provider, clinic, county, etc.)
  - Small number of “units”
  - Nesting within multiple levels of the system(s)
  - Interactions between
- Experimental Designs: The implementation strategy/strategies are manipulated (serve as the IV)

Hwang, Birken, Melvin, Rowheder, & Smith, 2020, *J Clin Trans Sci*

Choosing a Design

- What design type is required to answer your implementation research question(s)?
  - Implementation preparation aim?
  - Consider at what level in the system the primary outcome is measured (aligned with the level the strategy is targeting)
- Do you have sufficient units to answer your implementation research question(s)?
- Can you randomize the units?
- Is “implementation as usual” an acceptable comparison to your community/clinical partners?

Different Types of Designs

- Formative/Developmental
  - Understanding context, selecting, tailoring, and adapting strategies for later testing
- Non-experimental
  - Observational studies (policy)
- Within-site designs:
  - Generally simpler, typically not randomized (compare to pre or to no implementation)
- Between-site designs:
  - Replication/aggregation, comparison of implementation strategies, randomization can reduce bias, produces generalized knowledge
- Within- and between-site designs:
  - Roll-out designs (e.g., stepped wedge)
  - Randomize timing (and potentially to implementation strategy)

Hwang, Birken, Melvin, Rowheder, & **Smith**, 2020, *J Clin Trans Sci*

Within-Site Designs

- Post Design
- Pre-Post Design
- Interrupted Time-Series
  - Rarely randomized
  - Single site can demonstrate feasibility and initial impact (more sites are needed for full evaluation)

  - Any hybrid approach can be used
  - Most commonly see either a Type I or a Type III as these designs lend themselves to a primary focus

Hwang, Birken, Melvin, Rowheder, & **Smith**, 2020, *J Clin Trans Sci*

Between-Site/Within- and Between-Site Designs

- Novel implementation strategy vs routine practice
- Comparative Implementation
  - Two novel implementation strategies for the same clinical/preventive intervention (7 Ps)

- Two/Three-arm cluster randomized trials
- Roll-out designs (Stepped-wedge)
- Factorial designs/SMART
  - Non-Randomized or Randomized

- Any hybrid approach can be used
  - If unit of randomization is patient > Type I (maybe a Type II)
  - If unit of randomization is clinician/clinic/CBO > Type II/Type III
  - Exceptions of course because Hybrid approaches are not dictated by trial/study design
  - Interesting design examples combining cluster and patient-level randomization (Raising Healthy Children, NU IMPACT)

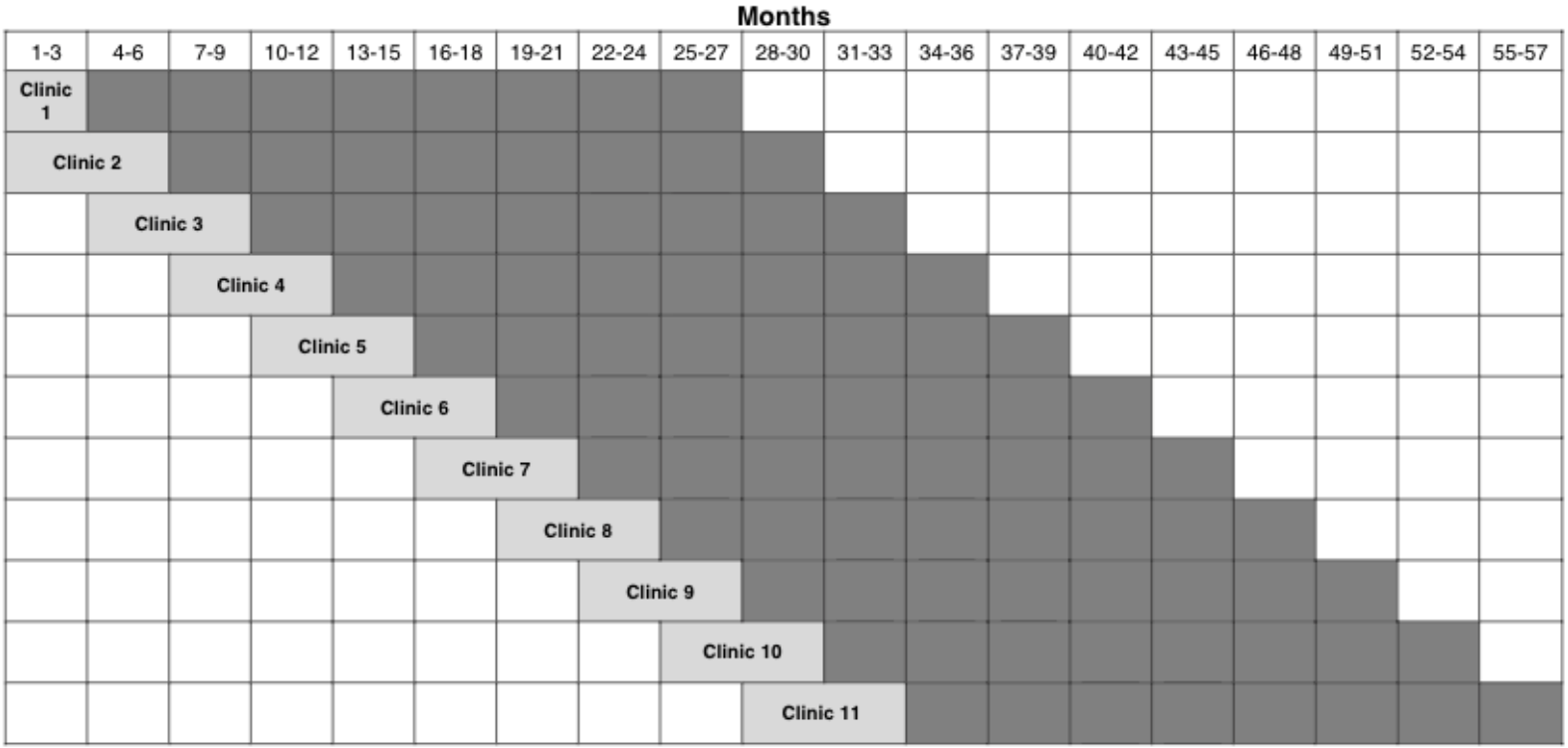
Collaborative Care Model Trial

- Matched-pair randomized roll-out trial using a hybrid Type 2 effectiveness-implementation approach
- Comparing Collaborative Care Model (CoCM) for depression and anxiety with services as usual

- Implementation Strategies
  - In-person training
  - Ongoing booster trainings
  - EHR modifications (for ease of referral and tracking program status)
  - Audit and feedback from program status tracker
  - Financial/billing solutions (Wolk et al., 2021, *Medical Care*)
  - Illinois law for CoCM reimbursement
- Analysis Plan
  - **Effectiveness:** CoCM effects on reducing depression/anxiety symptoms (compared to non-enrolled and pre)
  - **Implementation:** Reach and adoption (closely examining health equity in outcomes) and sustainability (compared to pre and within and across the clinics)
  - Mixed methods to examine PCP and support staff acceptability, appropriateness and feasibility of CoCM and our implementation strategy

Smith, Fu et al. 2022, *Contemp Clin Trials Commun*

Figure 1. *Prospective randomized roll-out schedule and study periods*

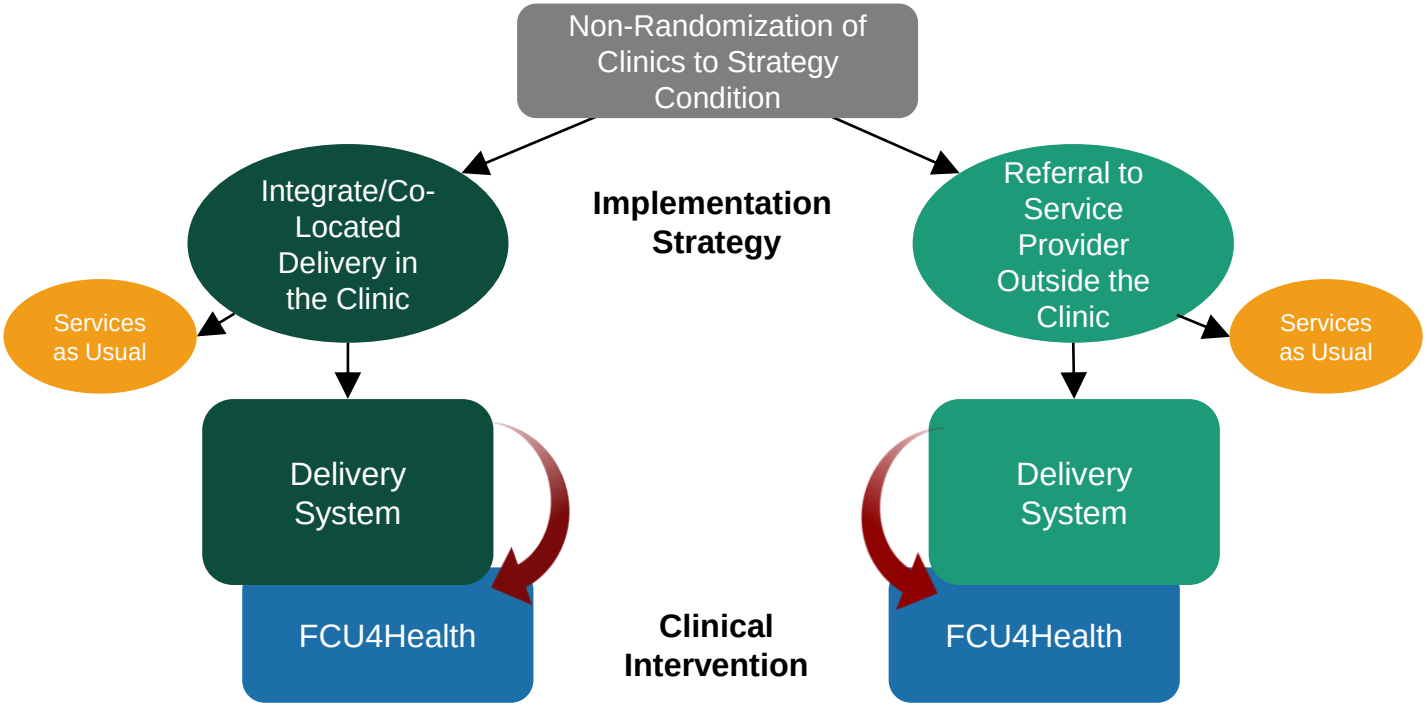


Notes. Light gray = Pre 'go-live' implementation period. Dark gray = Post 'go-live' implementation and sustainment periods. See text for changes to this prospective roll-out schedule. This figure is adapted from Figure 2 in Smith and Hasan (2020). Quantitative approaches for the evaluation of implementation research studies. *Psychiatry Research*, 283:112521–112529. doi: https://doi.org/10.1016/j.psychres.2019.1125

Smith, Fu et al. 2022, *Contemp Clin Trials Commun*

Example: Raising Healthy Children

Cluster non-randomized with embedded patient-level RCT hybrid Type 2



Smith et al 2018, *Implement Sci*

Comparison of Implementation Strategies

Identified in EMR (BMI≥85th%) – During visits by PCPs and case finding (calls by recruiters)

Training, Consultation, Fidelity Monitoring, Certification Processes

FCU4Health Program Components and Content

Randomization to Services as Usual after Assessment (within organization)

Integrated/Co-Located Delivery

- Existing BH staff deliver FCU4Health
- CHWs conduct assessments
- Delivery: home visiting > in-clinic

Referral to External Provider

- Hired BH staff (study employees)
- Undergraduates conduct assessments
- Delivery: home visiting > community

Results

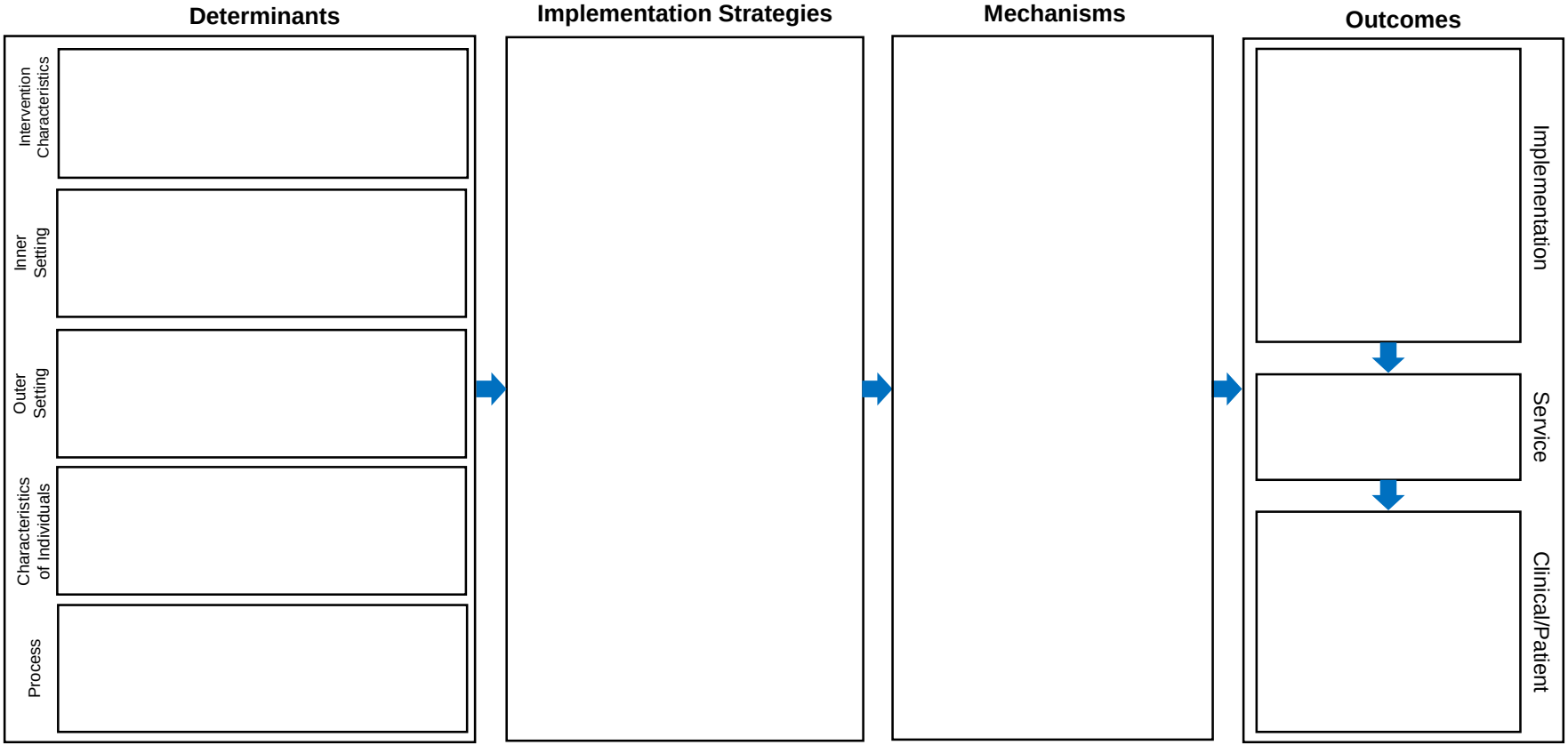
- Failure of Integrated/Co-Located Care model
- Switched to all participating clinics participating in referral-based model
  - 5 FQHCs
  - Children's hospital outpatient clinic
  - Military Health Clinic
  - Private Peds Practices
- FCU4Health effective (Smith et al. 2021; Berkel at al. 2021a)
- High fidelity to the model (Berkel et al. 2021b)

Using the IRLM for Different Purposes and Stages of Research

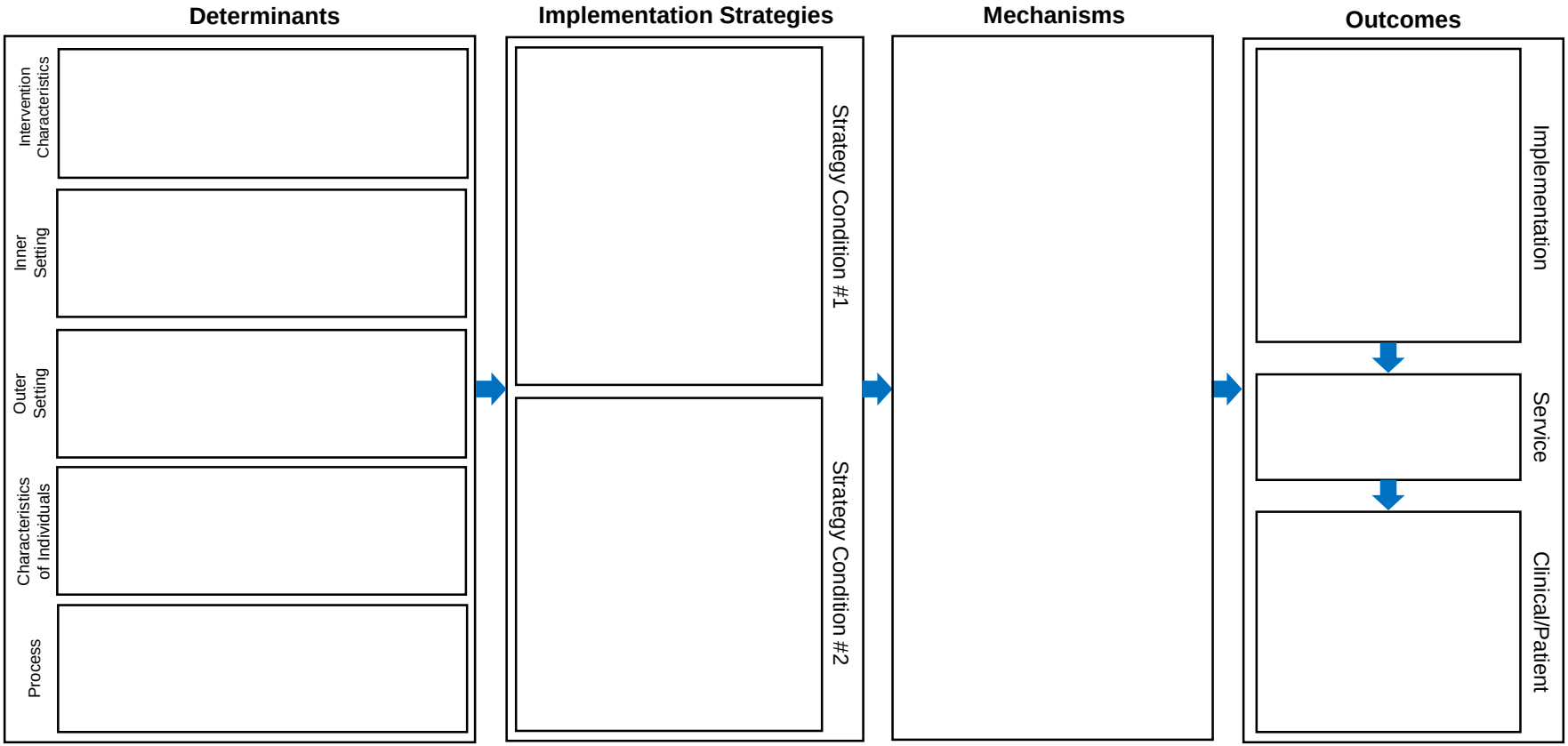
Planning, Executing, Reporting, Synthesizing

- ***Planning***
  - Work with community partners and/or organization stakeholders to fill in the implementation strategies
  - Often begins with the known parameter(s) of the study
- ***Executing***
  - Completed IRLM can serve as ”protocol” and can form the basis for ongoing tracking of what occurs, what is altered, deviations, etc.
- ***Reporting***
  - Show what happened during the study; reporting of the hypothesized relationships that were observed; facilitates communication of findings
- ***Synthesizing***
  - Draw conclusions for the implementation of an EBP/similar EBPs in a particular context (or across contexts) that are shared and generalizable to provide a guide for future research and implementation

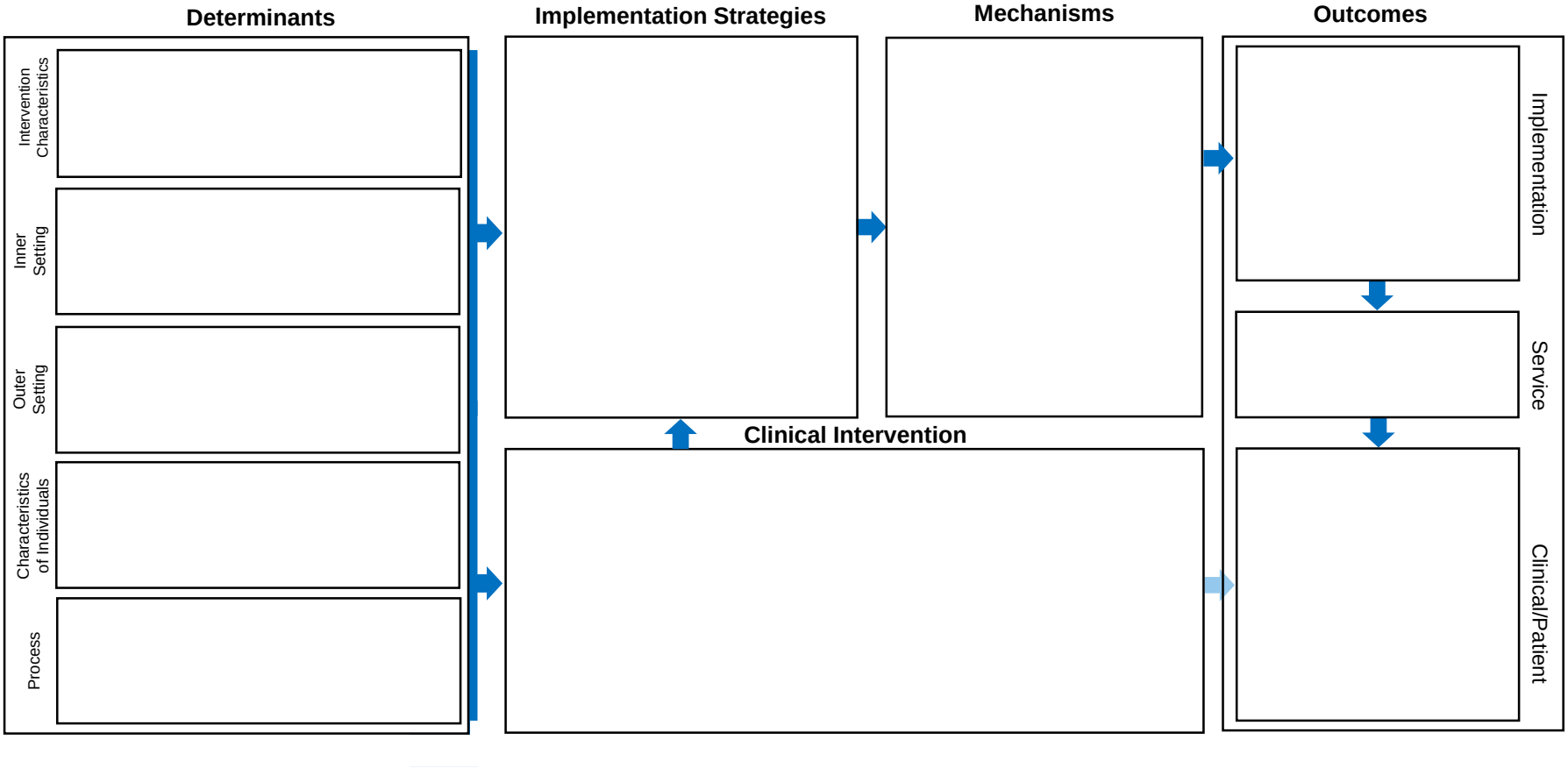
Standard Implementation Research Logic Model (IRLM)



IRLM for Comparative Implementation

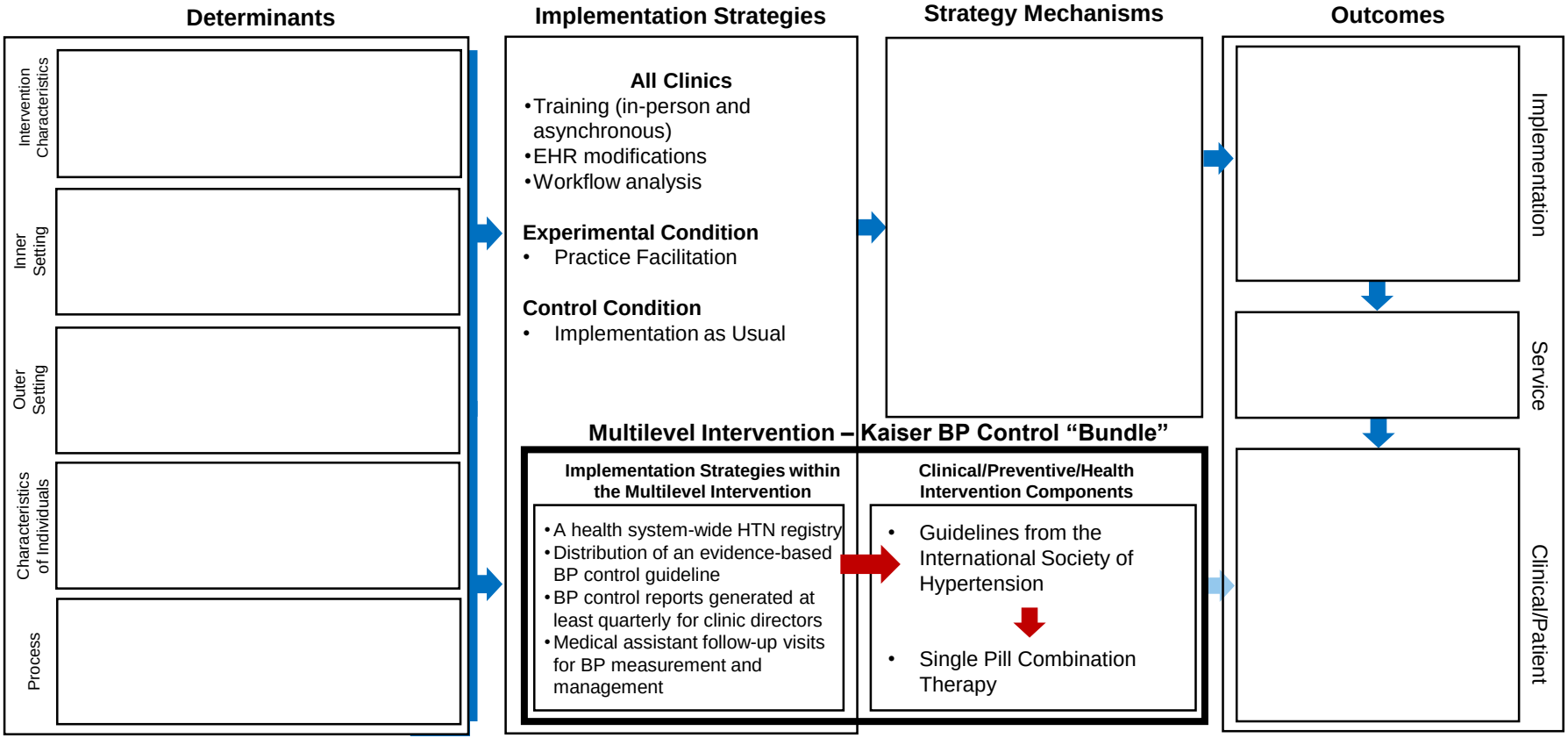


IRLM with Clinical Intervention



IRLM for a Multilevel Intervention

An intervention at two or more levels of individuals, clinical teams, institutions and/or community settings that measures outcomes at three or more of these levels

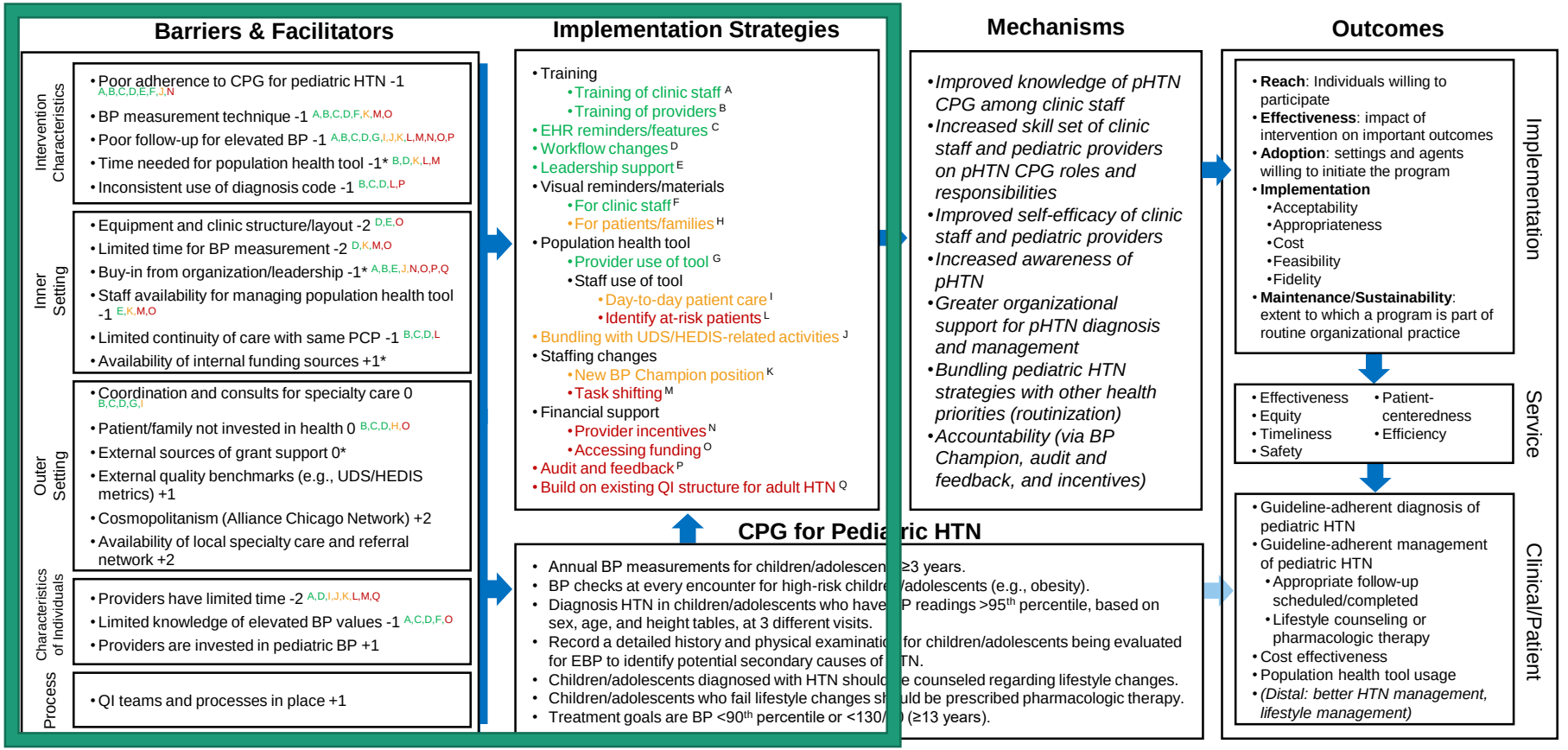


IRLM Principles of Use

1. Strive for Comprehensiveness
2. Indicate Key Conceptual Relationships
3. Specify Critical Study Design Elements

More detail in Smith, Liu, & Rafferty, 2020, *Implementation Science*

IRLM for Pediatric HTN Guideline Implementation in Primary Care



Notes. *Significant variation between clinics. Tier 1 = High priority, high effectiveness, higher feasibility; Tier 2 = Moderate priority, moderate effectiveness, moderate feasibility; Tier 3 = Lower priority, moderate effectiveness, low feasibility. IRLM is incomplete per the guidelines of Smith, Li, & Rafferty (2020); depiction is accurate to the progress made with the Stakeholder Advisory Panel (SAP) to this stage of the project, as described in this article.

Knapp et al. 2022 *Implementation Science Communications*

Thank you!

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