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The Implementation Research Logic Model (IRLM)

A Method for Planning, Executing, Reporting, and Synthesizing Implementation Projects

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Question (poll)

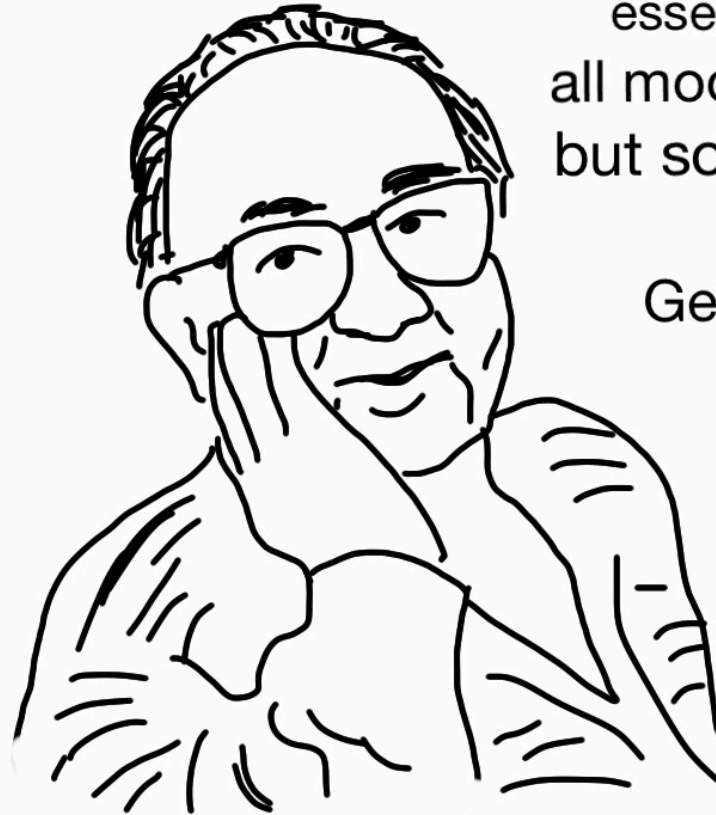
- What aspect of implementation research have you found to be the most challenging?
 - a. Demonstrating how you are integrating determinants with strategies and outcomes
 - b. Justifying the implementation strategies to be used/tested
 - c. Planning for an implementation study with diverse stakeholders and multidisciplinary researchers
 - d. Reporting comprehensively what happened in an implementation research study

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An IR specific logic model is needed

- Integrating the necessary conceptual elements of implementation research, which often involves multiple models, frameworks, and theories, is an ongoing challenge
- Transparency, Rigor, Openness, Specification, & Reproducibility
 - Rigor—the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results
 - Improving the specification of phenomena in implementation research is necessary to inform our understanding of how implementation strategies work, for whom, under what determinant conditions, and on what implementation and clinical outcomes (Smith, Li, & Rafferty, 2020)
 - Testable way of explaining phenomena by specifying relations among variables, thus enabling prediction of outcomes (Glanz & Bishop, 2010)

Do We Really Need Another Model?



essentially,
all models are wrong,
but some are useful

George E. P. Box



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DEVELOPMENT OF THE IRLM

Uses and Elements



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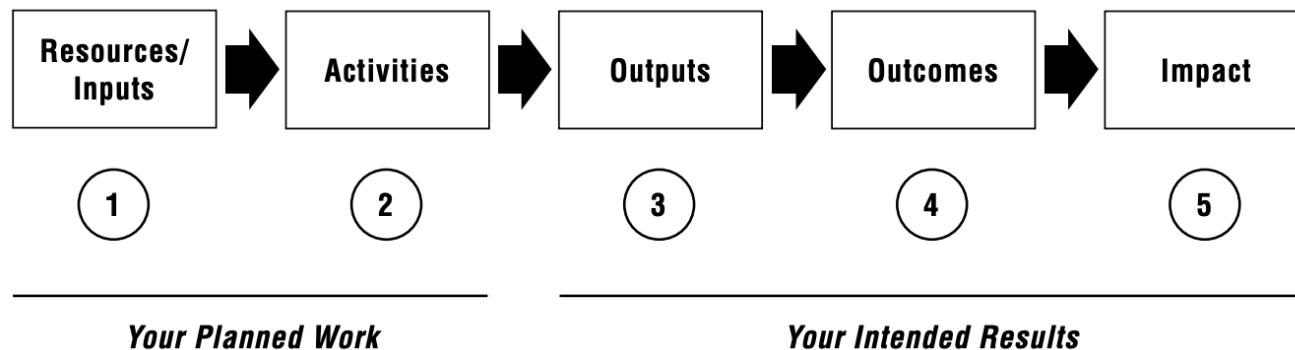
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Case Applications

- Used in the study of implementing a new model of patient care in a new physical space Implementation strategies
- Used in the first 6 months of three already-funded implementation research projects to plan for and describe the prospective implementation research aspects of the trials
- Applied in the later stages of a nearly completed implementation research project
- Used in a two-day training hosted by ISC³i — EHE planning project grantees (post-training survey results will be presented)

Structure of the IRLM

- Began with the common “pipeline” logic model format
 - Familiar to funders, investigators, readers, and reviewers
 - Adapted to integrate existing implementation science frameworks as its core elements with an eye toward facilitating causal modeling



W.K. Kellogg Foundation Evaluation Handbook (1998)

Theory and Elements of the IRLM

- Generalized theory of the IRLM :
 - (1) implementation strategies selected for a given EBP are related to the implementation determinants (context-specific barriers and facilitators)
 - (2) strategies work through specific mechanisms of action to change the context or the behaviors of those within the context
 - (3) implementation outcomes are the proximal impacts of the strategy and its mechanisms, which then relate to the clinical outcomes of the EBP
- IRLM: Aid in the specification of the relationship between foundational elements of an IR study
- Determinant(s) → Implementation Strategy → Mechanism of Action → Outcomes

Definitions of IRLM Elements

- **Determinants**
 - Factors that might prevent or enable improvements (barriers & facilitators); may act as moderators or 'effect modifiers,' or as mediators; indicating that they are links in a chain of causal mechanisms (CFIR, Damschroder et al. 2009)
- **Implementation Strategies**
 - Supports, changes to, and interventions on the system to increase adoption of EBPs into usual care (Powell et al. 2012; Powell et al. 2015)
- **Mechanisms of Action**
 - Processes or events through which an implementation strategy operates to affect desired implementation outcomes (Lewis et al. 2018)
- **Outcomes**
 - **Implementation:** the effects of deliberate and purposive actions to implement new treatments, practices, and services (Proctor et al. 2011)
 - **Clinical:** the direct effects on participants of the EBP (e.g., symptoms, infection)



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IRLM FORMATS

A Few Examples



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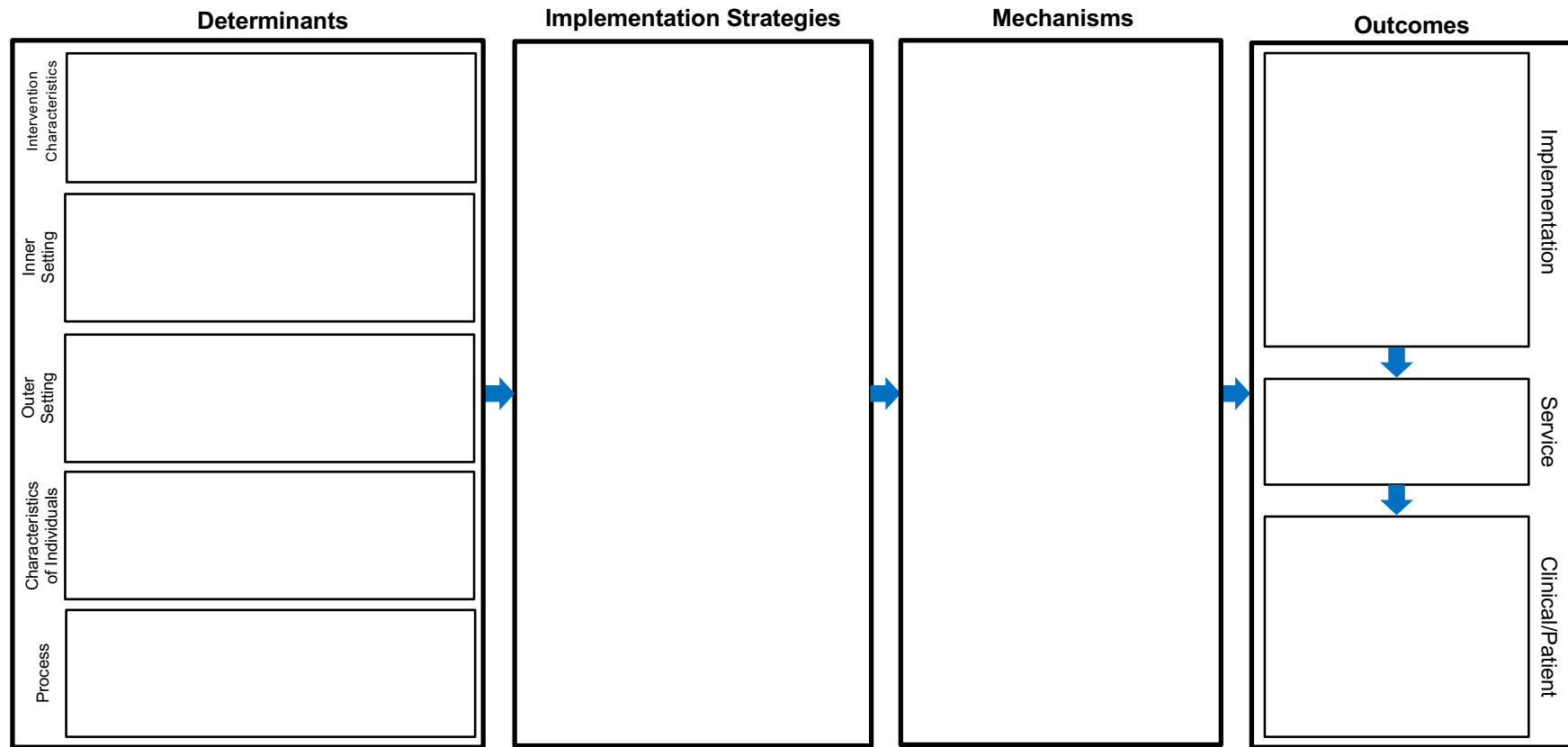
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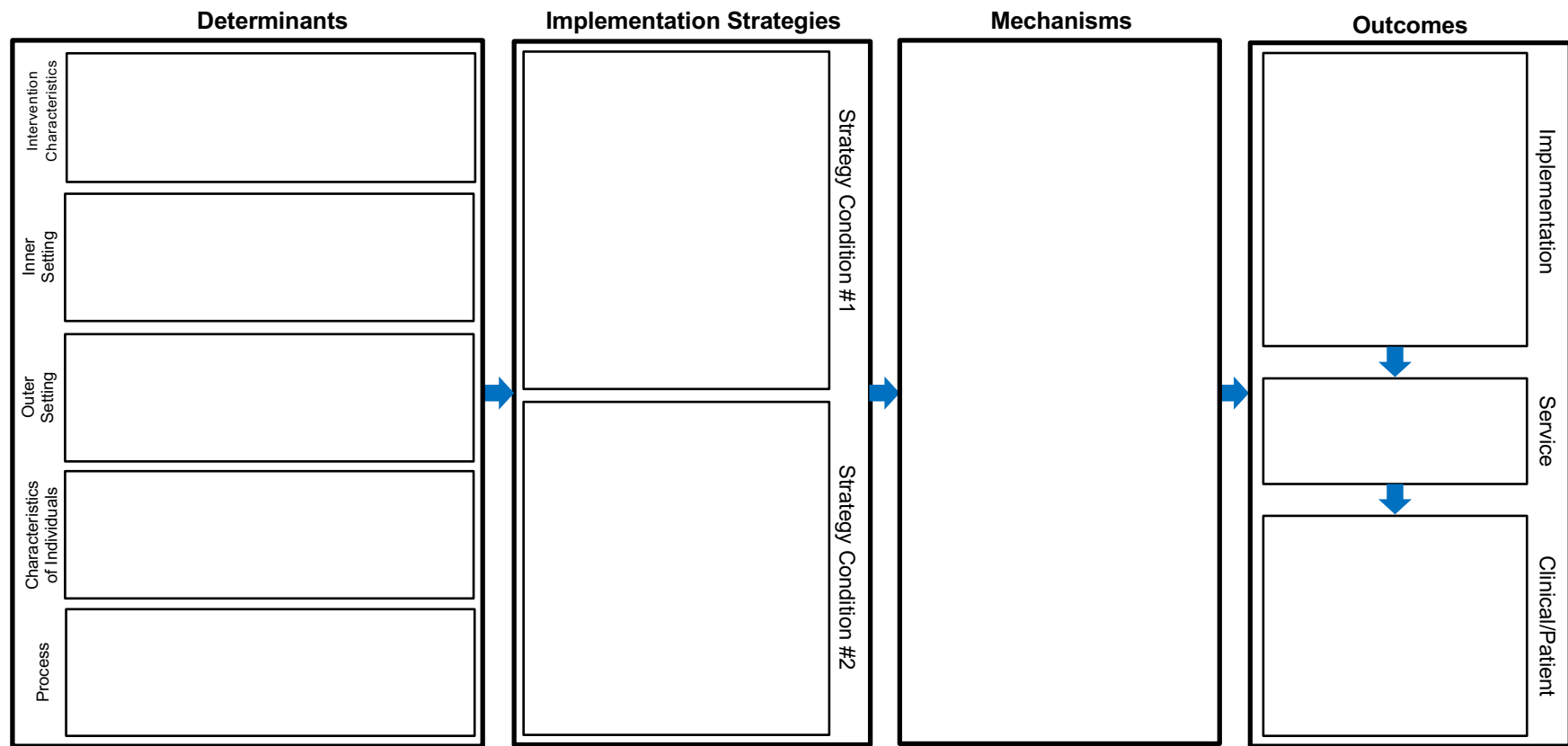
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The Implementation Research Logic Model (IRLM)



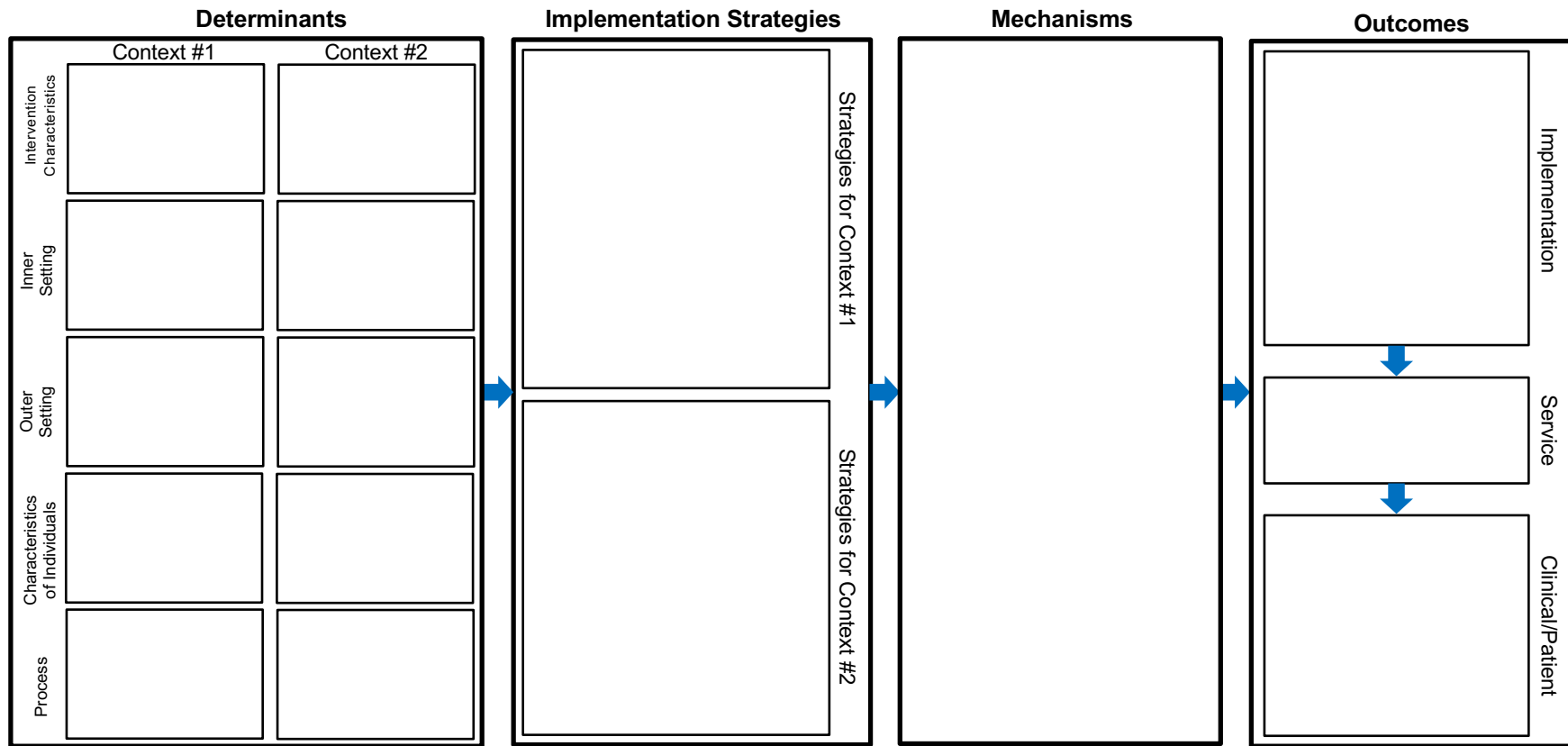
Smith, Li. & Rafferty, 2020, *Implementation Science*

IRLM for Comparative Implementation



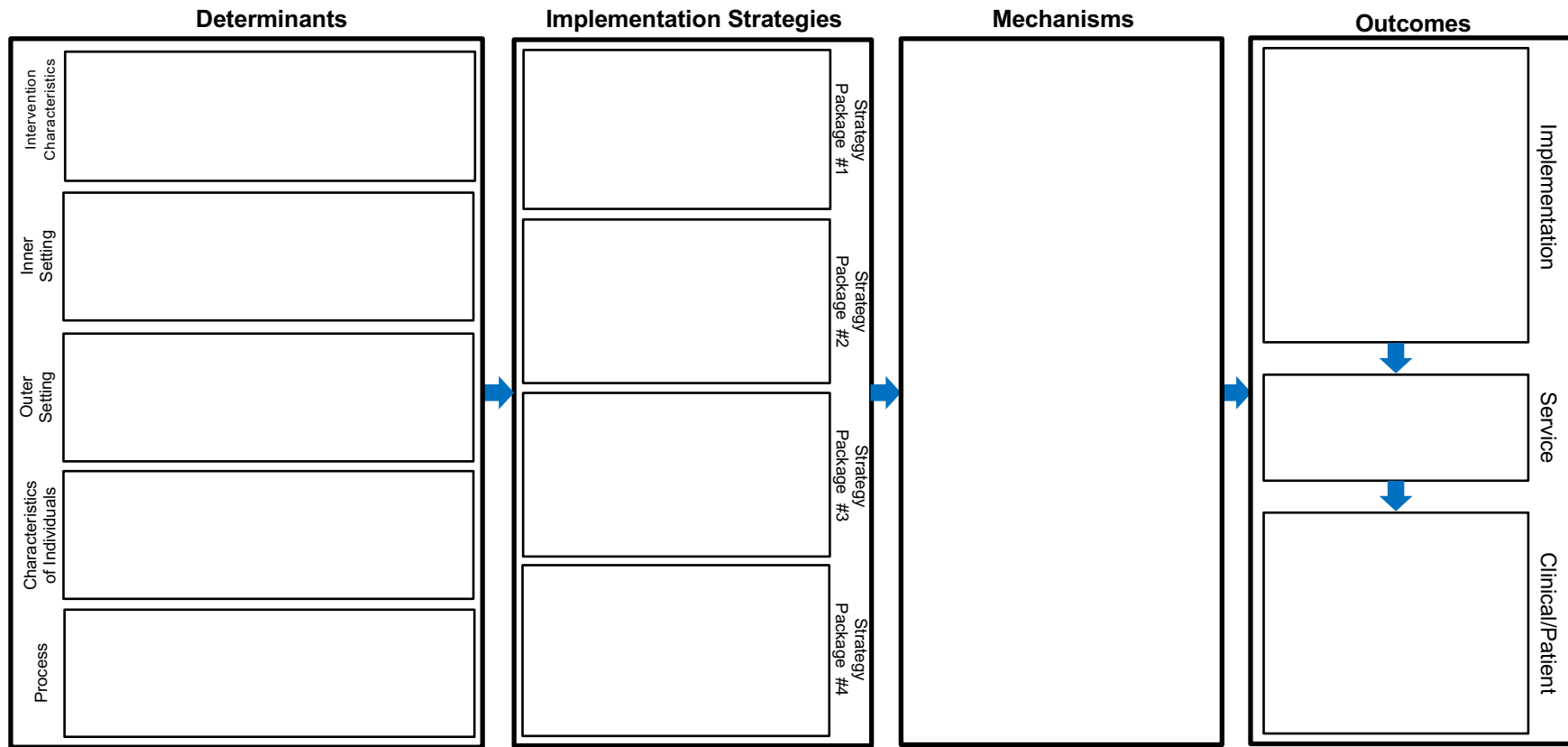
Smith, Li. & Rafferty, 2020, *Implementation Science*

IRLM for Multi-Context Implementation of Single Intervention



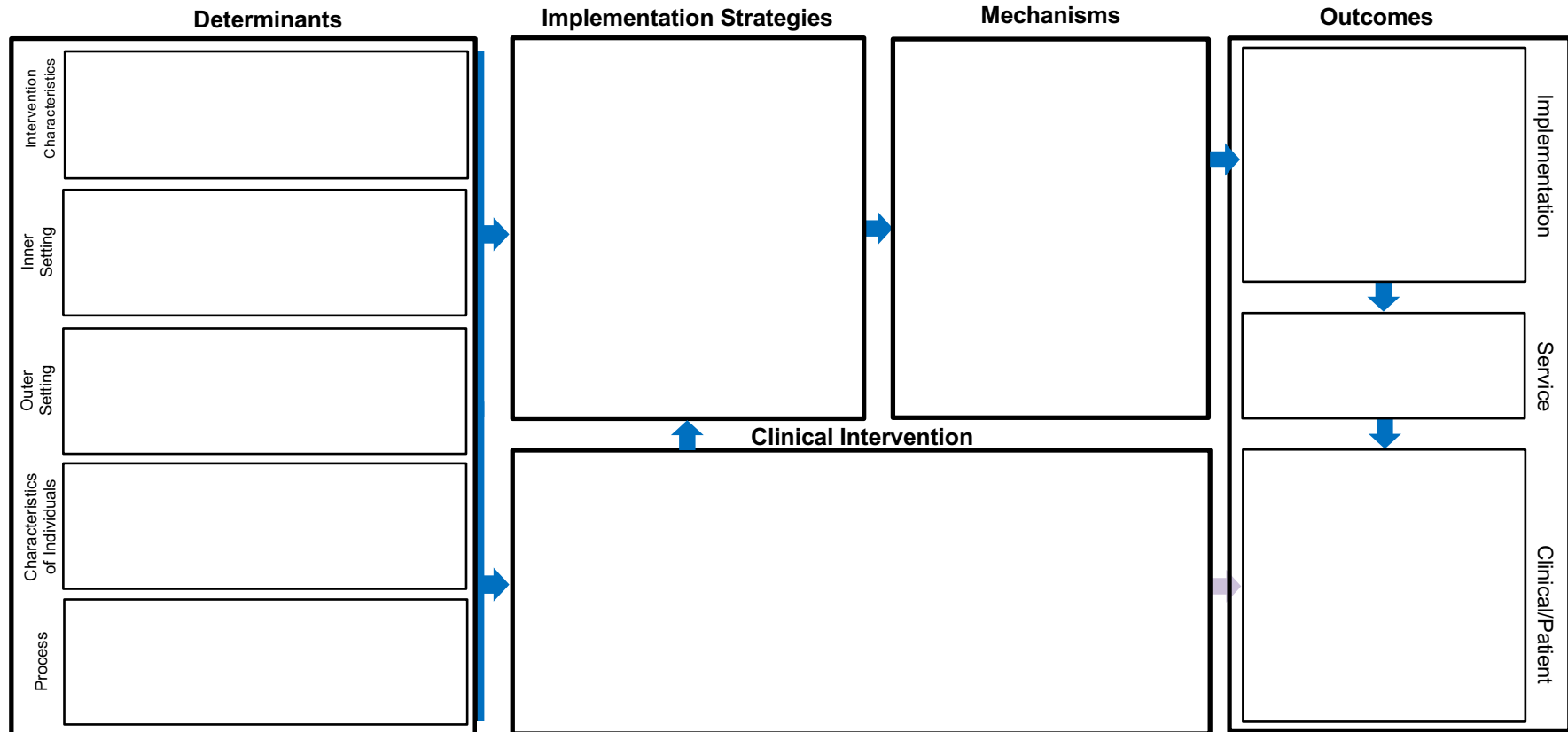
Smith, Li. & Rafferty, 2020, *Implementation Science*

IRLM for Implementation Optimization Trial



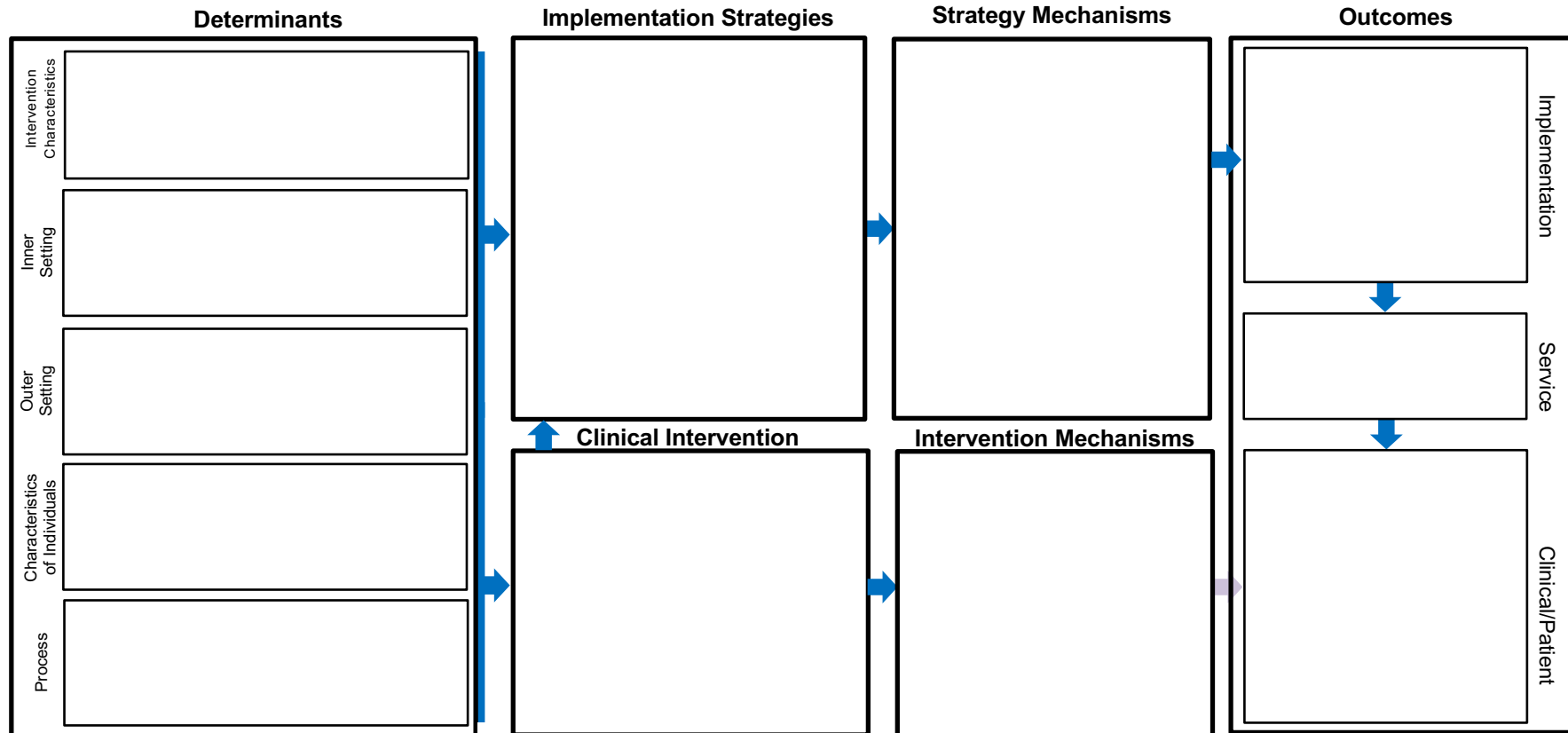
Smith, Li. & Rafferty, 2020, *Implementation Science*

IRLM with Clinical Intervention



Smith, Li. & Rafferty, 2020, *Implementation Science*

IRLM with Clinical Intervention and Intervention Mechanisms



Smith, Li. & Rafferty, 2020, *Implementation Science*



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USING THE IRLM FOR DIFFERENT PURPOSES AND STAGES OF RESEARCH

Planning, Executing, Reporting, Synthesizing



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- **Planning**
 - Often begins with the known parameter(s) of the study
 - Working from the two “bookends” of the IRLM (context and outcomes often known; strategies, mechanisms, and even the EBP often are not)
 - Work with community partners and/or organization stakeholders to fill in the implementation strategies
- **Executing**
 - Completed IRLM serves 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

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POPULATING AND USING THE IRLM

Guiding Principles

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Principle 1: Strive for Comprehensiveness

- Determinants
 - Include all relevant determinants and not simply limit reporting to those that are hypothesized to be related to the strategies and outcomes
 - Valence should be noted
 - Simply adding plus (+) or minus (–) signs for facilitators and barriers, respectively
 - Using a coding system, such as that developed by Damschroder et al. 2013, to indicate the relative strength of the determinant
 - 2 (strong negative impact)
 - 1 (weak negative impact)
 - 0 (neutral or mixed influence)
 - 1 (weak positive impact)
 - 2 (strong positive impact)
 - Try not to use study-specific adjectives or change the name of the determinant (e.g., greater relative priority, addresses patient needs, good climate for implementation)

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Principle 1: Strive for Comprehensiveness

- Implementation strategies
 - First, list all strategies in the system
 - Second, strategies should be labeled to indicate whether they were:
 - (a) in place in the system prior to the study;
 - (b) initiated prospectively for the purposes of the study (particularly for experimental study designs);
 - (c) removed as a result of being ineffective or onerous; or
 - (d) introduced during the study to address an emergent barrier or supplement other strategies because of low initial impact
 - Relevant for IRLM used during planning, as an ongoing tracking system (article in process), for retrospective application to a completed study, and in the final reporting of a study

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Principle 1: Strive for Comprehensiveness

- Outcomes
 - List all measured outcomes.

Principle 2: Indicate Key Conceptual Relationships

- Indicate the relationships between elements in a manner aligning with the specific theory of change for the study
 - Provide some form of notation to indicate these conceptual relationships using superscripts (preferred), color-coding, arrows (limited), or a combination of the three
 - Such notations in the IRLM facilitate reference in text to the study hypotheses, tests of effects, causal chain modeling, and other forms of elaboration
 - When presenting the IRLM using presentation programs (e.g., PowerPoint, Keynote, Prezi), colors and arrows can be helpful, and animations can make these connections dynamic and sequential without adding to visual complexity

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Principle 3: Specify Critical Study Design Elements

- *Primary Outcomes*
 - Indicate the primary outcome(s) at each relevant level of the study design (i.e., clinician, clinic, organization, county, state, nation)
 - The levels should align with the specific aims and the level(s) targeted by the implementation strategy/ies
 - Suggestion: Include downstream health services and clinical outcomes even if they are not measured, as these are important for understanding the logic of the study and the ultimate health-related targets

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Principle 3: Specify Critical Study Design Elements

- *For quasi/experimental designs*
 - Clearly label the independent variable(s) (i.e., the strategies that are introduced or manipulated or that otherwise differentiate study conditions)
 - important for internal validity and for differentiating conditions in multi-arm studies
- *For comparative implementation trials*
 - Indicate the determinants, strategies, mechanisms, and (potentially) the outcomes that differentiate the conditions
 - Might need to use an IRLM for each arm when the strategies either occur across two delivery systems or are simply were very different, by design
- *For implementation optimization designs*
 - Specify the different combinations, packages, or conditions being tested

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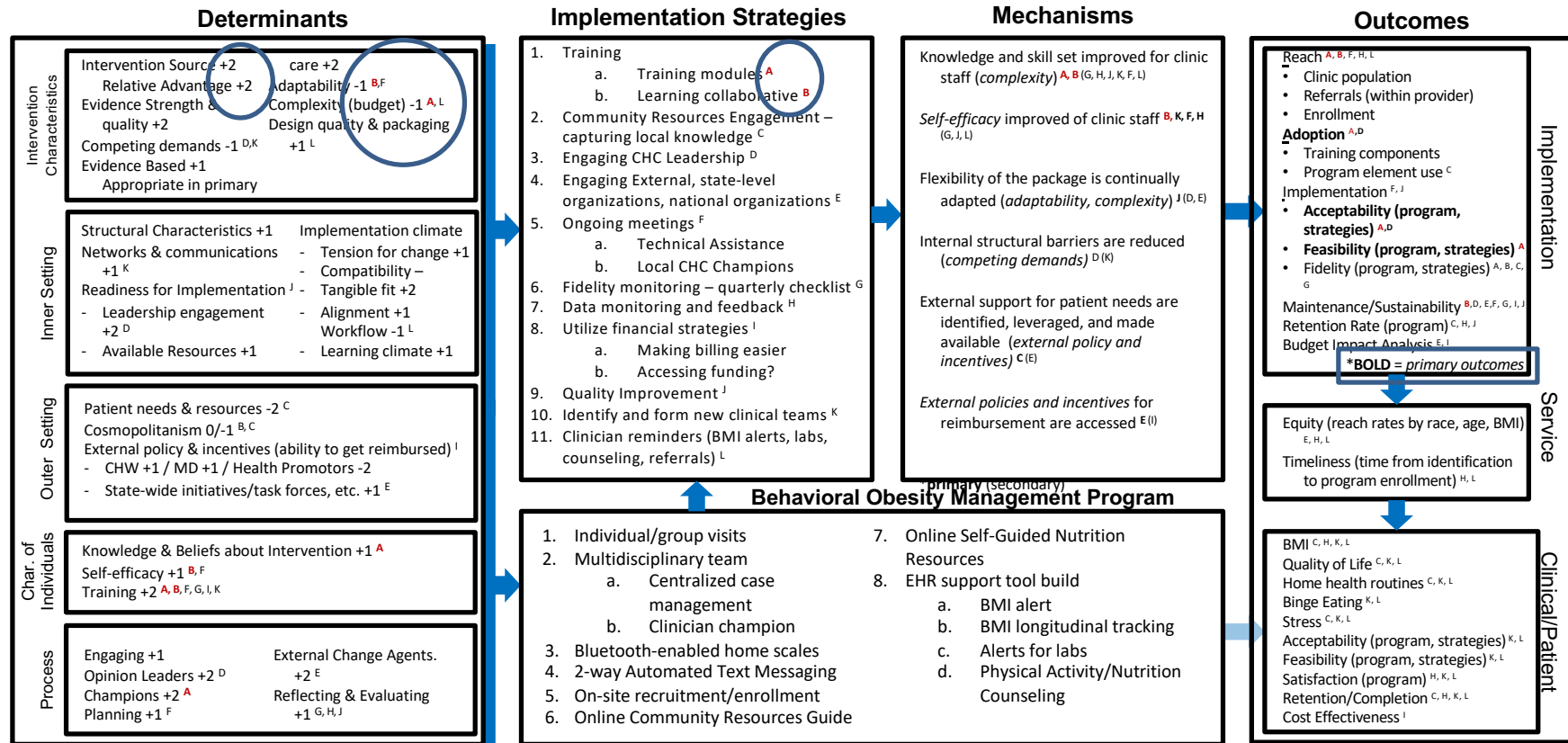
Principle 3: Specify Critical Study Design Elements

- *Additional specification options*
 - Users of the IRLM can specify any number of additional elements that may be important to their study
 - Notate those elements of the IRLM that have been or will be measured versus those that were based on the researcher's prior studies or inferred from findings reported in the literature
 - Indicate when implementation strategies differ by level or unit within the study (in large multisite studies, strategies might not be uniform across all units, particularly those strategies that already exist within the systems)
 - Be creative 😊

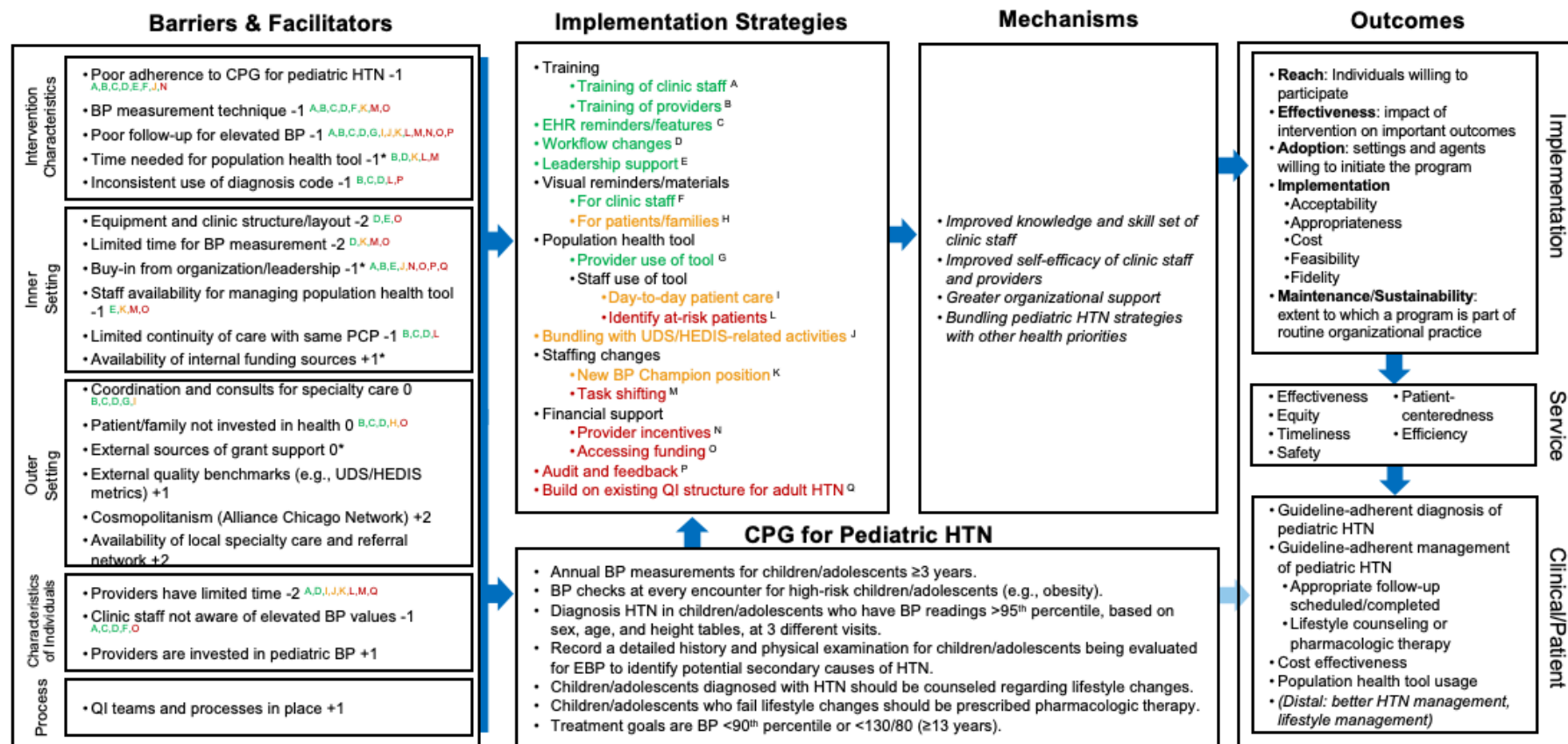
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Completed Hypothetical IRLM

Obesity Management Intervention implemented in Community Health Centers (CHCs)



IRLM for Pediatric Hypertension/BP



*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

Question (put answer in the chat)

- What aspect of the IRLM do you anticipate being the most challenging if you were to use it for an upcoming or ongoing implementation research project?
 - e.g., specifying relationships between elements; being comprehensive; getting stakeholders to understand it; figuring out what are the strategies and what are the interventions; time required to complete it; etc.

Supporting Text and Resources

- Data re: determinants
- Measures
- Strategy specification (Proctor, Powell, & McMillen, 2013)
- “Paths” supported by theory (e.g., Lewis et al. 2018)
- Trial design description and methods
- Implementation plan/process model (e.g., EPIS)

Text	Table	Figure
✓	✓	✓
✓	✓	
✓	✓	
✓	✓	✓
✓		✓
✓	✓	✓

By utilizing superscripts, subscripts, color, and other notations within the IRLM, it is easy to refer to (a) hypothesized causal paths in theoretical overviews and analytic plan sections; (b) planned measures for determinants and outcomes; and (c) specific implementation strategies in text, tables, and figures.



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ACCEPTABILITY AND USABILITY OF THE IRLM

Results of a Post-Training Survey of EHE
Planning Project Grantees



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ISC³I's Ending the HIV Epidemic Summit

- Coordinating and technical assistance center for grantees funded under the national *EHE* plan
- 2-day in-person training in Chicago, IL, in October 2019
- *N*=132 participants from 63 projects
 - *n*=129 pre-training survey
 - *n*=66 post-training survey 6 weeks after
 - 42 investigators, 24 implementation partners; 68.2% women
 - 44.6% indicated having completed a full draft of the IRLM for their project
- 10 items related to the IRLM plus one about the general logic of implementation research
 - Rated on a 4-point scale from 1 (*not at all*) to 4 (*very much*)

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IRLM was either “moderately” or “very” helpful in:

1) Improving the rigor and reproducibility	77.7%, <i>M</i> =3.05
2) Serving as a “roadmap” for the project	74.0%, <i>M</i> =3.08
3) Clearly reporting and specifying the project plan	67.8%, <i>M</i> =2.94
4) Understanding connections between determinants, strategies, mechanisms, and outcomes	66.3%, <i>M</i> =2.92
5) Identifying gaps in the IR logic of their project	64.2%, <i>M</i> =2.86
6) Deepening their knowledge of IR methods	62.9%, <i>M</i> =2.83
7) Planning the project	61.3%, <i>M</i> =2.82
8) Developing consensus and understanding of the project among diverse stakeholders involved	58.8%, <i>M</i> =2.75
9) Identifying gaps in research questions/analyses	51.3%, <i>M</i> =2.54

Note. All SDs = 0.89–1.09

Additional Results

- 74.1% ($M=3.02$, $SD=.886$) said the worksheets provided during the summit were “*moderately*” or “*very*” helpful in completing the IRLM
- 77.6% ($M=3.18$, $SD=.827$) said their knowledge on the logic of implementation research increased “*moderately*” or “*very much*” after the two-day training



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RESOURCES FOR USING THE IRLM

- Quick Reference Guide, Worksheets, Templates, Examples
- IRLM Website



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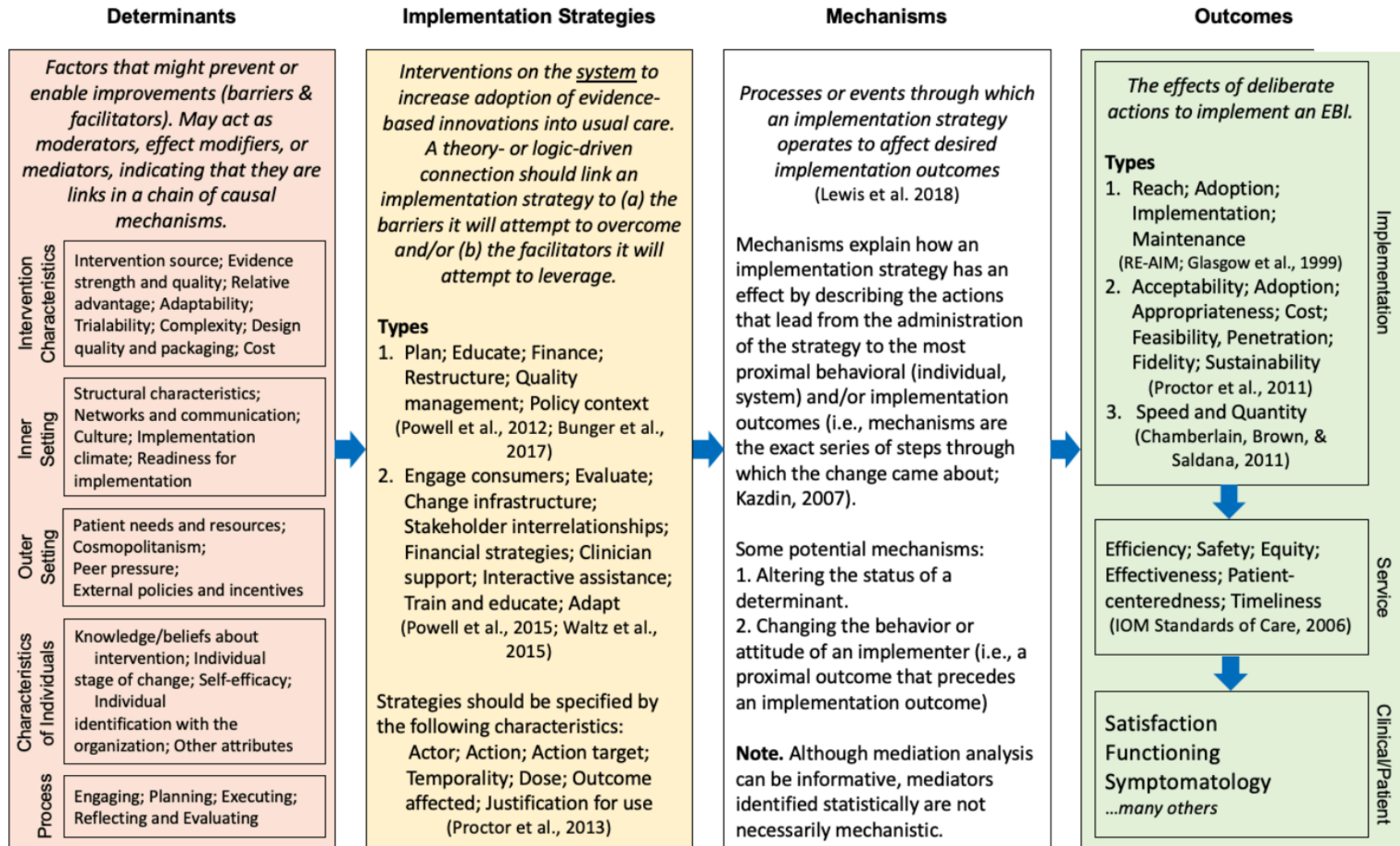
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Quick Reference Guide



Implementation Research Logic IRLM — Determinants Smith, Li, & Rafferty, 2015 Determinants of implementation research Often, researchers think of implementation research as a mediator, moderator or mediator-moderator. It comes from the Consolidated Framework for Implementation Research (CFIR). 1. From the list of CFIR constructs, select the constructs that apply to your project. It is important to select at least 10 constructs. 2. Circle any determinants that you think are most important for your project. 3. For each determinant, write a brief description of how it applies to your project. Determinants Intervention Characteristics Intervention source Evidence strength/quality Relative advantage Adaptability Trialability Complexity Design quality and packaging Cost Outer Setting Patient needs and resources Cosmopolitanism Peer pressure External policies and incentives	Inner Setting Structural characteristics Networks and communication Culture Implementation climate - Tension for change - Compatibility - Relative priority - Incentives & rewards - Goals and feedback - Learning climate Readiness for implementation - Leadership engagement - Available resources - Access to knowledge Characteristics of Intervention Knowledge/beliefs about intervention Individual stage of change Self-efficacy Individual identification with the organization Other attributes Process Engaging - Opinion leaders - Formal internal implementation - Champions - External change agents Planning Executing Reflecting and evaluating	Implementation Research Logic IRLM — Implementation Smith, Li, & Rafferty, 2015 Implementation outcomes: treatments, practices, and success, (2) proximal indicators of service and clinical/patient outcomes Unlike clinical/patient outcomes, service provider and typic researchers, whereas other researchers, whereas other To identify implementation outcomes, researchers should consider downstream/ distal/long-term outcomes. 1. For the evidence-based intervention, list the outcomes you are interested in (e.g., patient health, quality of care, costs, etc.). Add these to your list of outcomes. 2. From the list of service provider outcomes, list the outcomes you are interested in (e.g., provider satisfaction, burnout, etc.). Add these to your list of outcomes. Service outcome Efficiency Safety Effectiveness Equity Patient-centeredness Timeliness	3. From the list of implementation outcomes, select the outcomes that apply to your project. For each outcome, write a brief description of how it applies to your project. Implementation Outcomes RE-AIM Framework Reach (Effectiveness) Adoption Implementation Maintenance Proctor et al., 2011 Acceptability Adoption Appropriateness Cost Feasibility Fidelity Penetration/Uptake Sustainability	Implementation Research Logic IRLM — Implementation Smith, Li, & Rafferty, 2015 Implementation outcomes: treatments, practices, and success, (2) proximal indicators of service and clinical/patient outcomes To avoid inevitable conflicts, researchers should consider downstream/ distal/long-term outcomes. When implementing an intervention, researchers should consider the following strategies exist in the literature: 1. From either taxonomy or CFIR, select the constructs that apply to your project. a. For help selecting constructs, see the ERIC Matchmaking tool: https://eric.ed.gov/?q=eric+matchmaking 2. For each strategy category, select the strategies that apply to your project. a. A full list of strategies: https://link.eric.ed.gov/l?pk=ED509486 b. A full list of implementation strategies: https://impd.org/implementation-strategies/ 3. Add your discrete strategies to your list of implementation strategies. Strategy Bunger et al., 2017: Planning Education Finance Restructure Quality management Policy	Expert Recommendations for Implementing Change (ERIC; Powell et al., 2015; Waltz et al., 2015) Use evaluative and iterative strategies Provide interactive assistance Adapt and tailor to context Develop stakeholder interrelationships Train and educate stakeholders Support clinicians Engage consumers Utilize financial strategies Change infrastructure - Assess for readiness and identify barriers and facilitators - Audit and provide feedback - Develop and implement tools for quality monitoring - Conduct local need assessment - Obtain and use patients/consumers and family feedback - Facilitation - Provide local technical assistance - Provide clinical supervision - Centralize technical assistance - Tailor strategies - Promote adaptability - Use data experts - Use data warehousing techniques - Identify and prepare champions - Organize clinician implementation team meetings - Recruit, designate, and train for leadership - Inform local opinion leaders - Build a coalition - Obtain formal commitments - Conduct ongoing training - Provide ongoing consultation - Develop educational materials - Distribute educational materials - Use train-the-trainer strategies - Create a learning collaborative - Facilitate relay of clinical data to providers - Remind clinicians - Develop resource sharing agreements - Revise professional roles - Create new clinical teams - Involve patients/consumers and family members - Intervene with patients/consumers to enhance uptake and adherence - Prepare patients/consumers to be active participants - Increase demand - Use mass media - Fund and contract for the clinical innovation - Access new funding - Alter incentive/allowance structures - Make billing easier - Alter patient/consumer fees - Mandate change - Change record systems - Change physical structure and equipment - Change service sites
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IRLM Website



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<https://cepim.northwestern.edu/implementationresearchlogicmodel/>



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THANK YOU!



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