The Implementation Research Logic Model (IRLM)

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

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Check ISC^{3}i website (https://isc3i.isgmh.northwestern.edu/) for resources and the above link to the full pre-publication article on www.medRxiv.org

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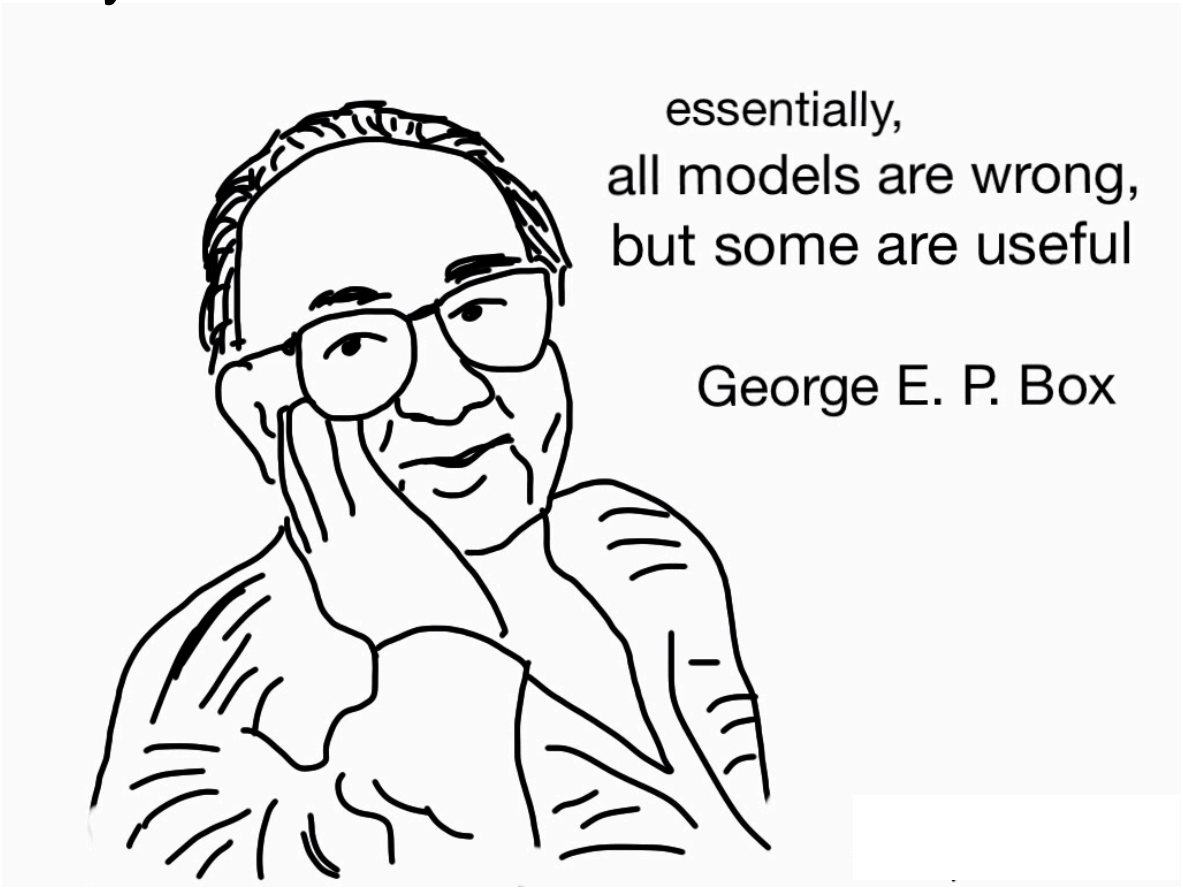
Do We Really Need Another Model?



Yes, We Need Another Model

- Logic models often required by funders (EHE supplements!)
- 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)

Logic Models (in general)

- A graphic depiction that presents the shared relationships among various elements of a program or study
- Develop agreement among diverse stakeholders of the “what” and the “how”
- Improve planning by highlighting theoretical and practical gaps
- Support the development of meaningful process indicators for tracking
- Reproduce successful studies / identify failures of unsuccessful studies

Petersen, Taylor, & Peikes, 2013

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Development of the IR Logic Model

Uses and Elements

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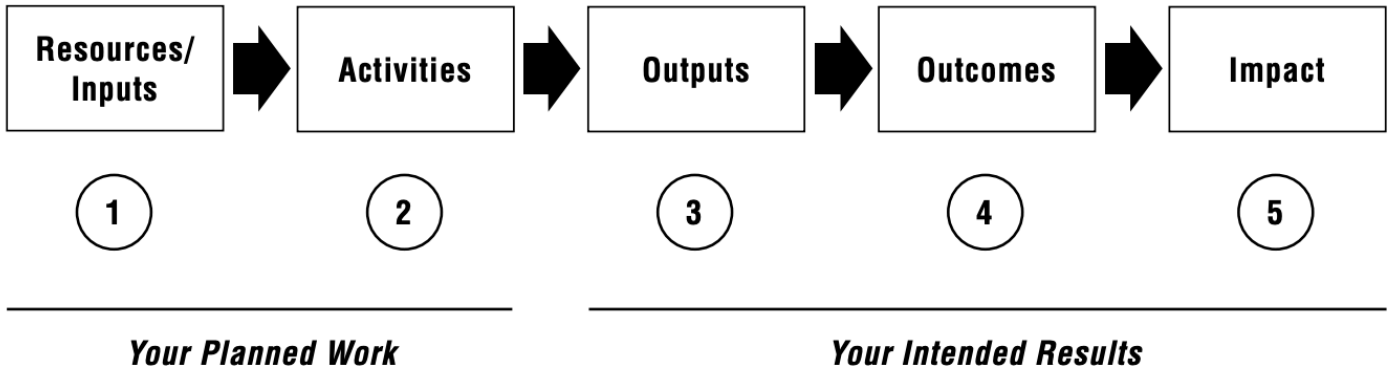
Case Applications

- 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 ISC^{3}i — EHE planning project grantees (post-training survey results will be presented)

Structure of the IRLM

- Began with the common “pipeline” logic model format used by AHRQ, CDC, NIH, PCORI, and others
  - 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

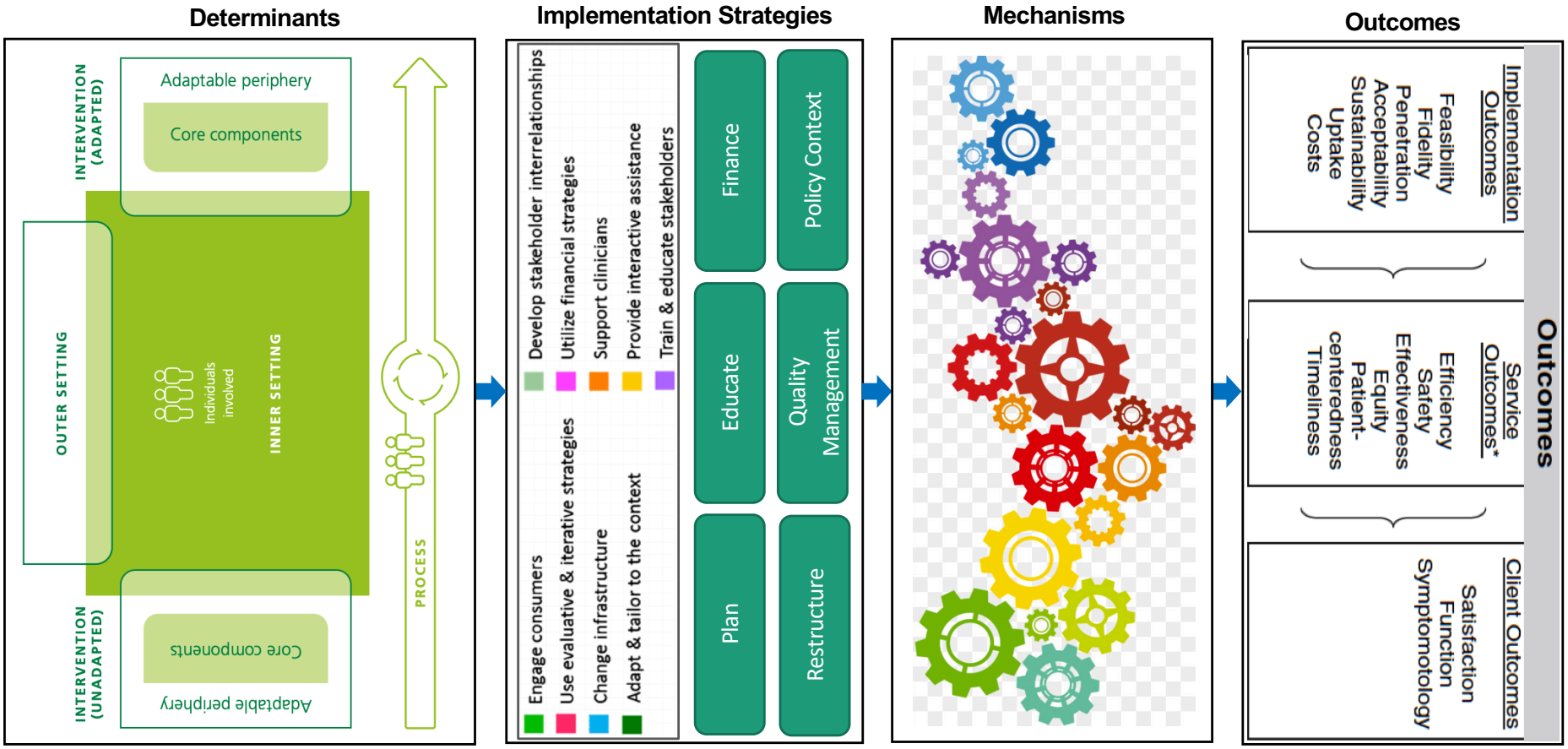
  Determinant(s) → Implementation Strategy → Mechanism of Action → Outcomes

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)

IRLM Formats

The Implementation Research Logic Model (IRLM)



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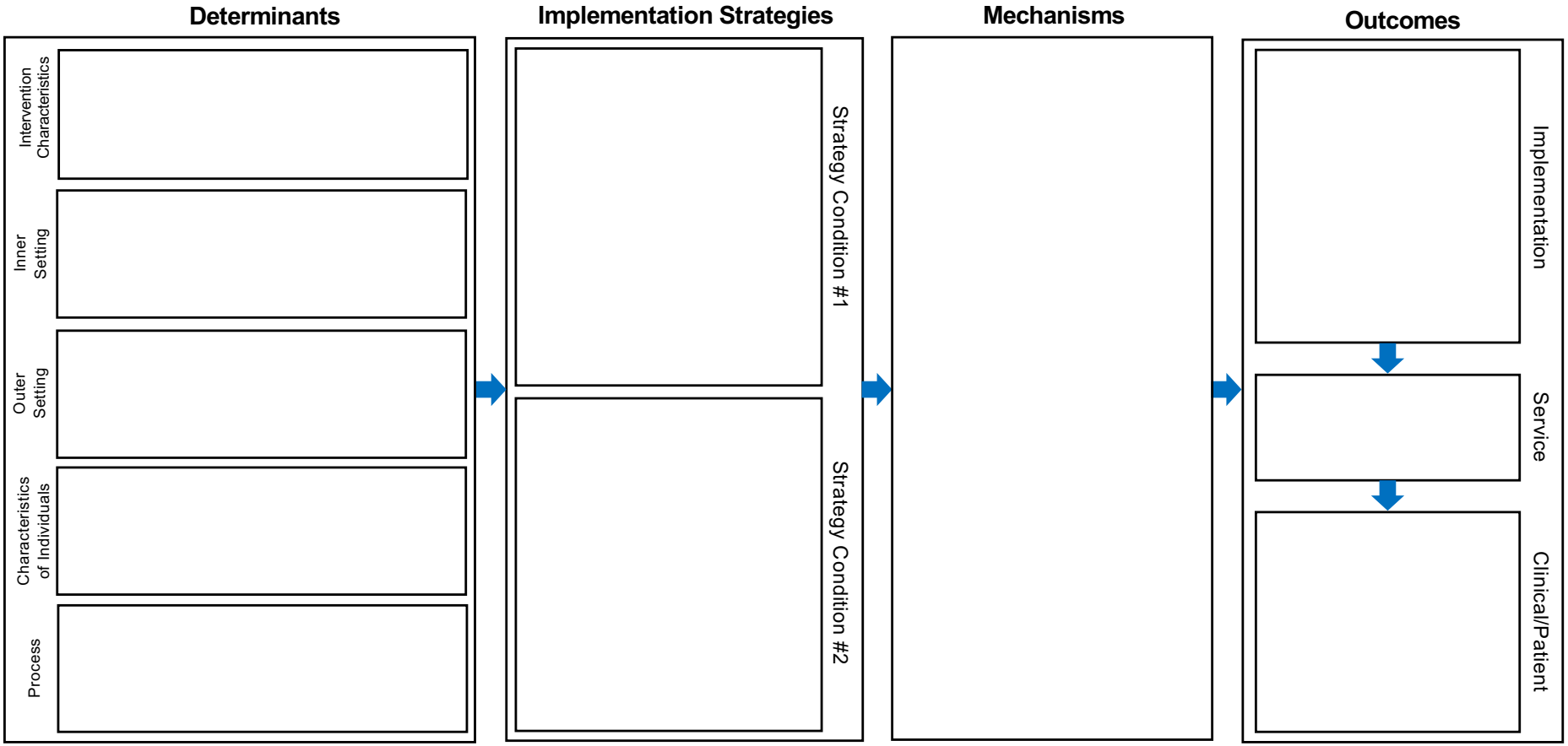
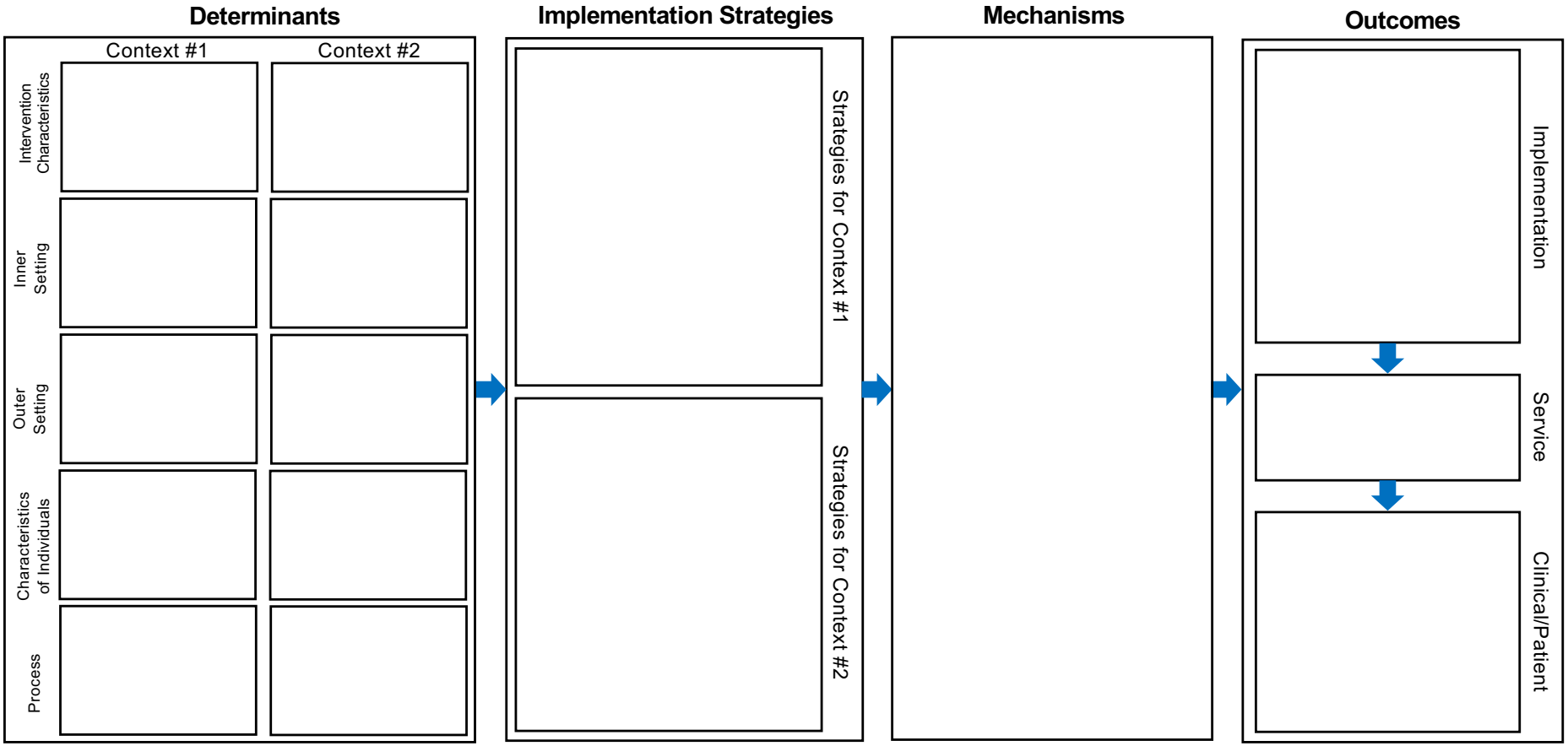
IRLM for Comparative Implementation



IRLM for Multi-Context Implementation of Single Intervention



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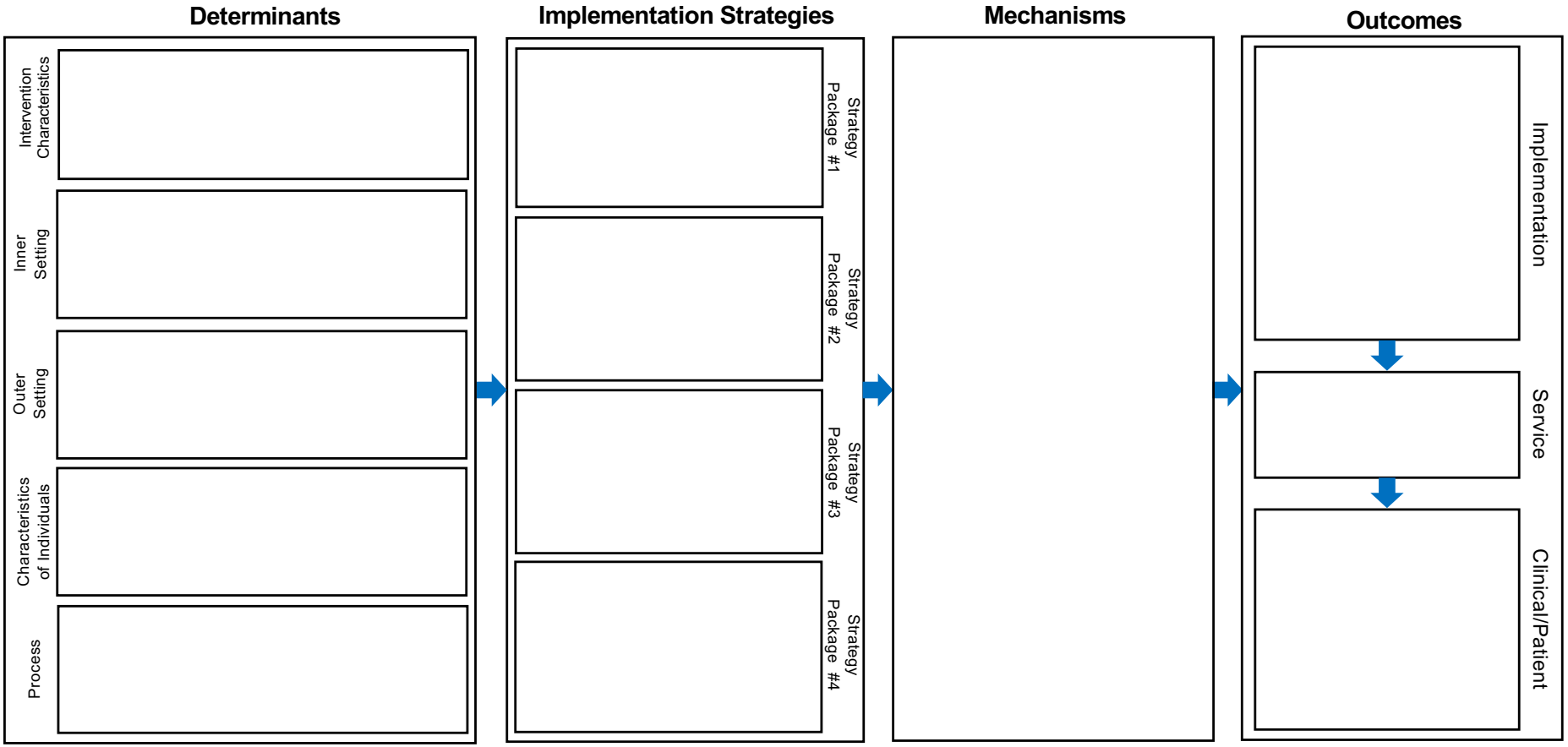
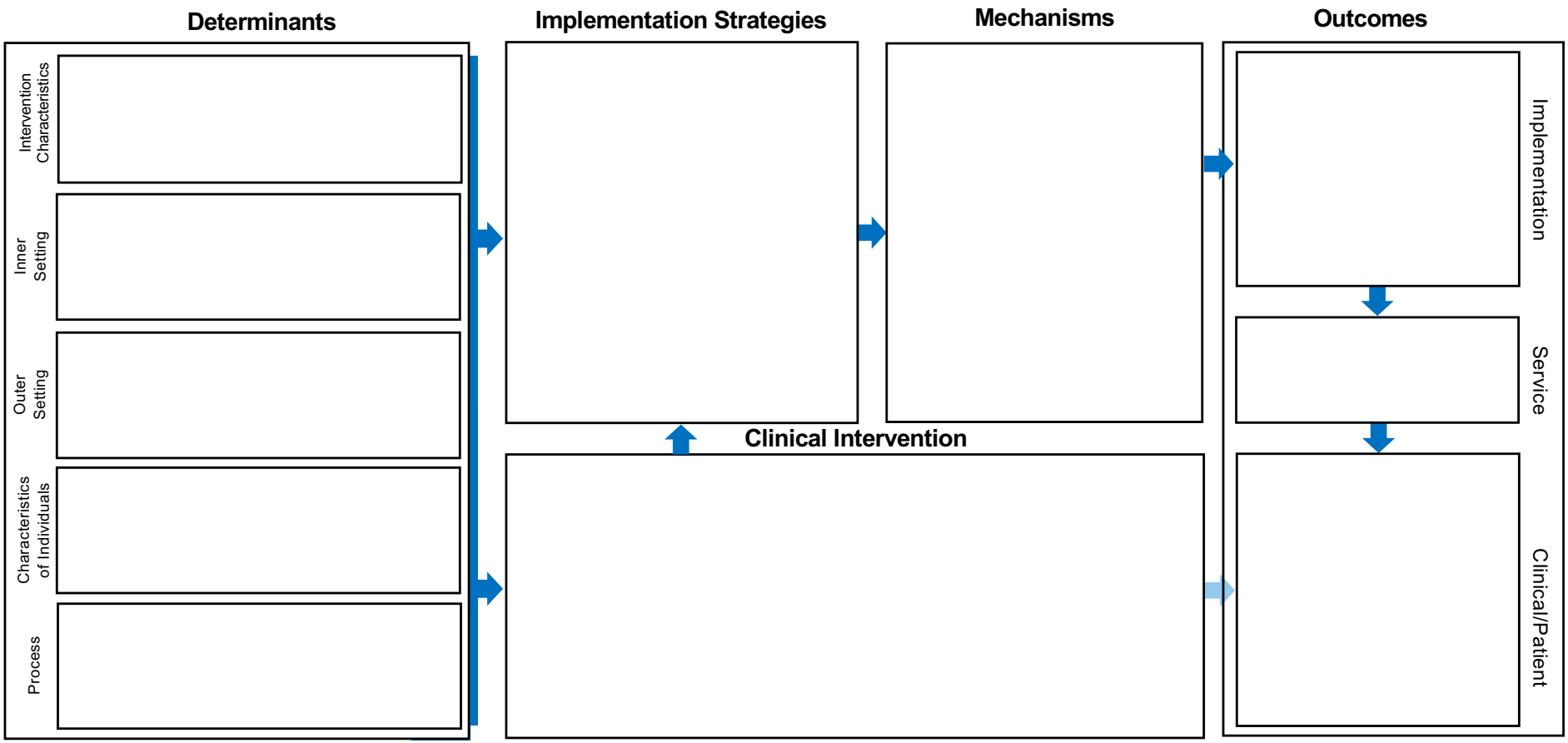
IRLM for Implementation Optimization Trial (4 clusters; 1 setting)



IRLM with Clinical Intervention



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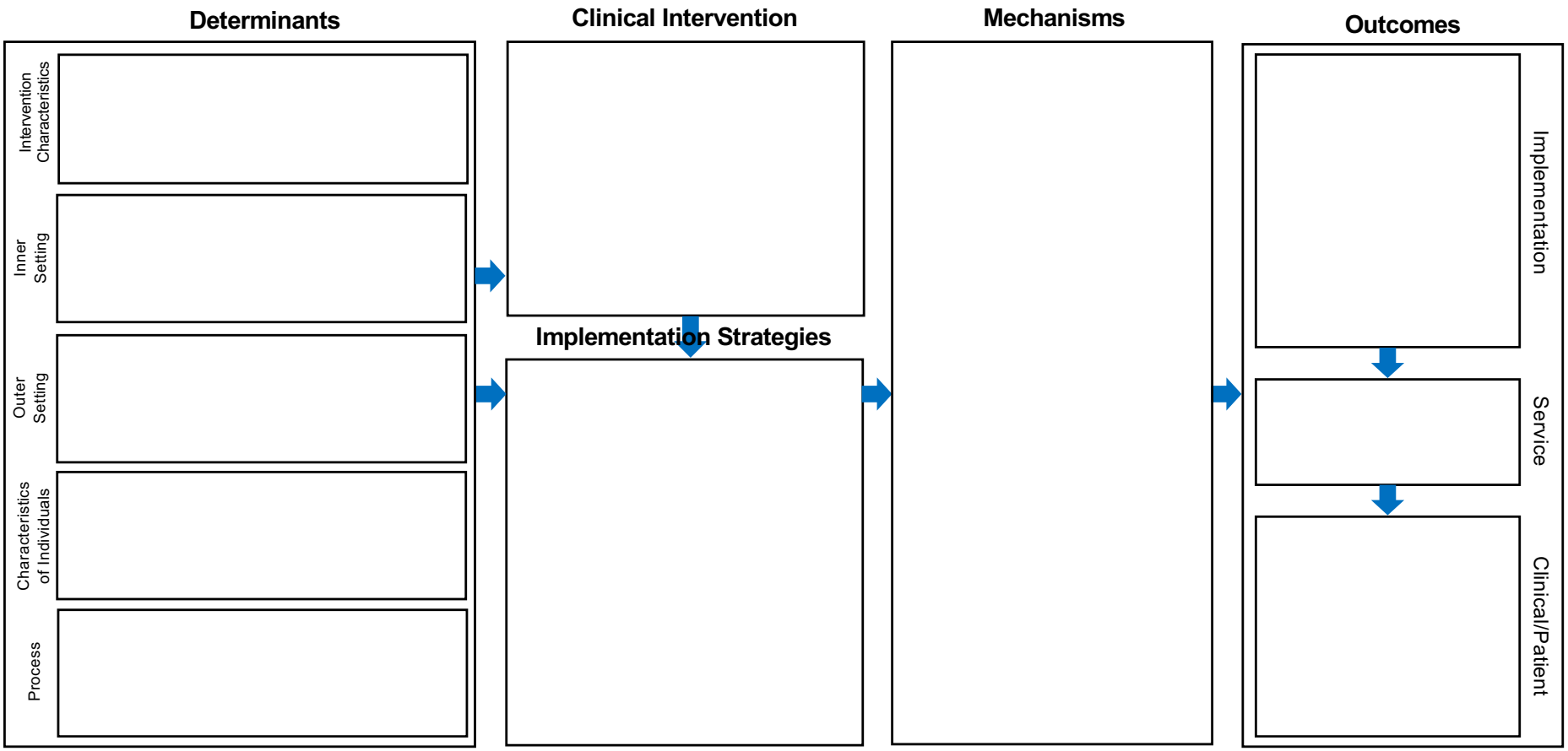
IRLM with Clinical Intervention (v2)



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Using the IRLM

Guiding Principles

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)

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

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

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

Principle 3: Specify Critical Study Design Elements

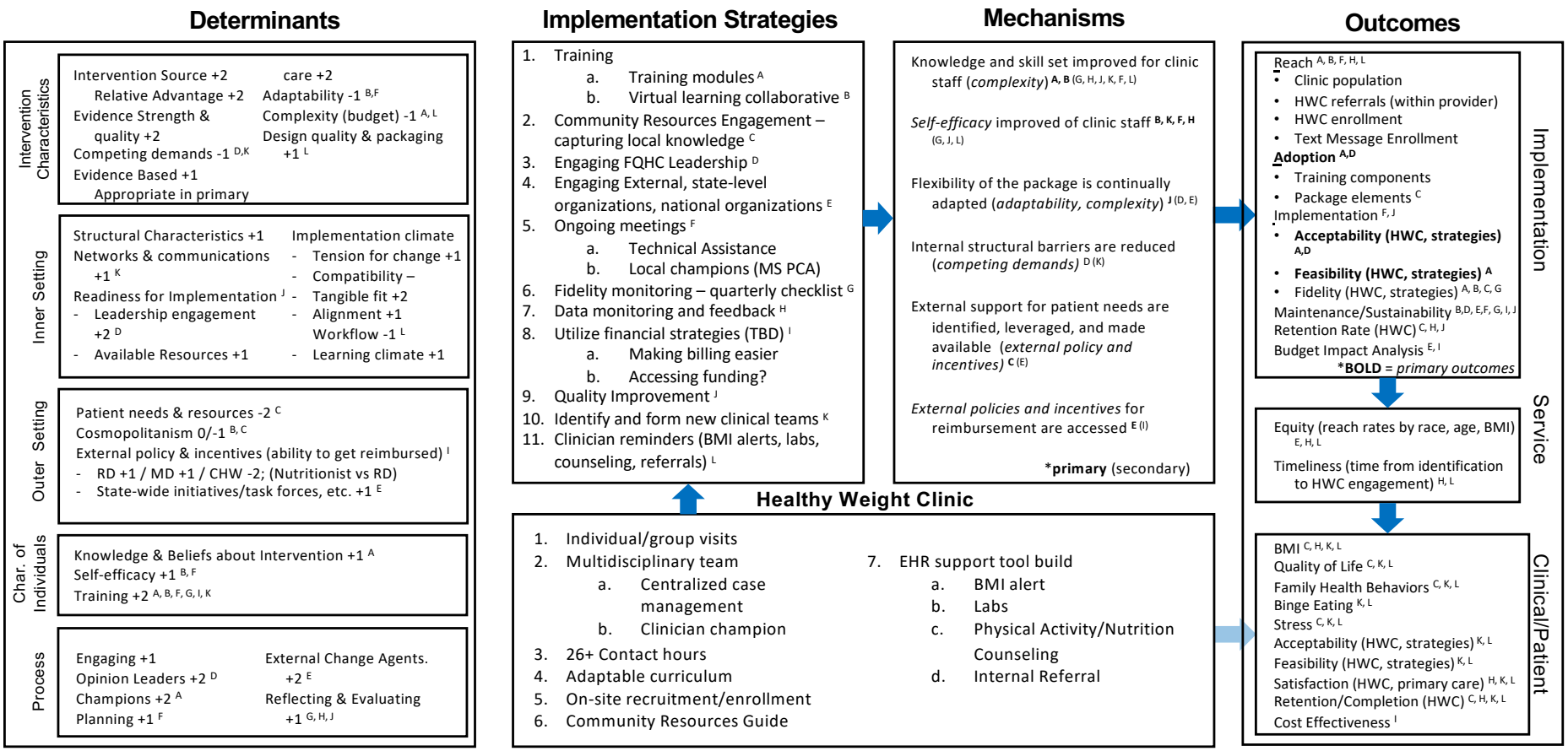
- *For quasi/experimental designs*
  - Clearly label the independent variable(s) (i.e., the strategies that are introduced or manipulated or that otherwise differentiate study conditions)
    - important for internal validity and for differentiating conditions in multi-arm studies
- *For comparative 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

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 ☺

Completed IRLM

MA Childhood Obesity Research Demonstration Project (CORD3.0) (Taveras, PI)



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Using the IRLM for Different Purposes and Stages of Research

Planning, Executing, Reporting, Synthesizing

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 that are likely to be feasible and effective (Waltz et al. 2015)

- Posit conceptually derived mechanisms of action based on determinants, strategies, and targeted outcomes

Executing

- Majority of the parameters will be known
- However, through completing the IRLM prior to the start of studies, we found that:
  - IRLM helped to reveal important contextual factors
  - Additional implementation strategies were needed to complement the primary ones proposed
  - Mechanisms needed to be added and measured
- Completed IRLM serves as ”protocol” and can form the basis for ongoing tracking of what occurs, what is altered, deviations, etc.

Reporting

- Nearly all elements of the IRLM will be known
- Means of showing what happened during the study
- Accurate reporting of the hypothesized relationships that were observed
- Facilitates communication of the findings

Synthesizing

- **Purpose:** 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

- Being applied in a NCI-funded research consortium

Supporting Text and Resources

- Preliminary data for determinants
- Measures
- Strategy/ies (Proctor, Powell, & McMillen, 2013)
- "Paths" supported by theory (e.g., Lewis et al. 2018)
- Trial design
- Implementation plan/process model (e.g., EPIS)

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

By utilizing superscripts, subscripts, 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.

Acceptability and Usability of the IRLM

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

ISC^{3}i's Ending the HIV Epidemic "Summit"

- Two-day in-person training in Chicago, IL, in October 2019
- N=132 participants
  - N=129 pre-training survey
  - N=66 post-training survey (42 investigators, 24 implementation partners; 68.2% Female)
- 10 items related to the IRLM plus one about the general logic of implementation research
  - Items rated on a 4-point scale (0=*not at all*, 1=*a little*, 2=*moderately*, 3=*very much*)

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

1)	Improving the rigor and reproducibility	77.7%, M=3.05, *SD*=.885
2)	Serving as a “roadmap” for the project	74%, M=3.08, *SD*=.950
3)	Clearly reporting and specifying the project plan	67.8%, M=2.94, *SD*=.909
4)	Understanding connections between determinants, strategies, mechanisms, and outcomes	66.3%, M=2.92, *SD*=.957
5)	Identifying gaps in the IR logic of their project	64.2%, M=2.86, *SD*=1.021
6)	Deepening their knowledge of IR methods	62.9%, M=2.83, *SD*=.959
7)	Planning the project	61.3%, M=2.82, *SD*=1.088
8)	Developing consensus and understanding of the project among diverse stakeholders involved	58.8%, M=2.75, *SD*=1.090
9)	Identifying gaps in research questions/analyses	51.3%, M=2.54, *SD*=1.032

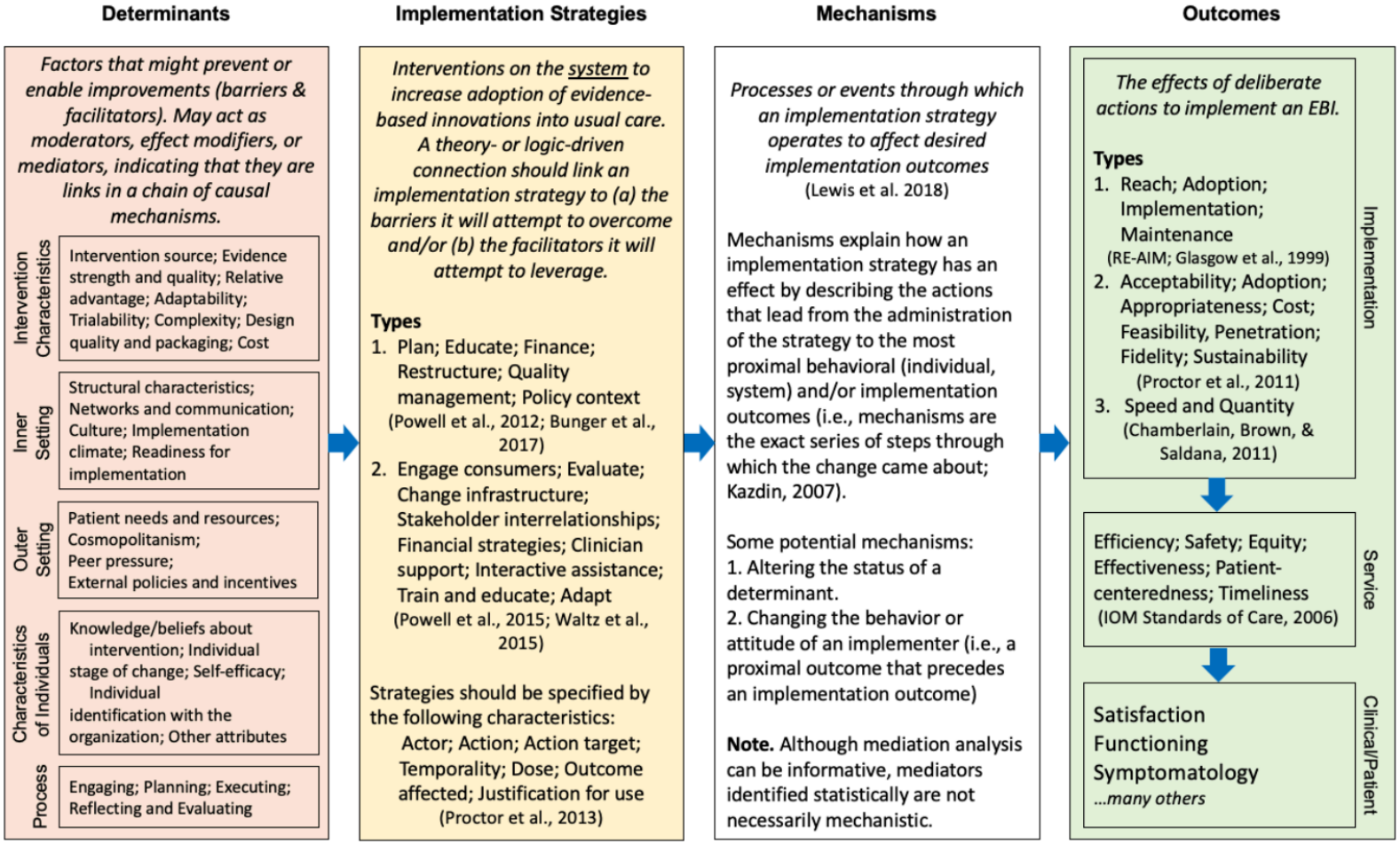
Additional Results

- The worksheets provided during the summit were either "*moderately*" or "*very*" helpful in completing the IRLM (74.1%, M=3.02, *SD*=.886)
- Knowledge on the logic of implementation research had increased either "*moderately*" or "*very much*" after the two-day training (77.6%, M=3.18, SD=.827)
- At the time of the survey (respondents were about 2.5 months into their one-year planning projects), 44.6% indicated that they had already been able to complete a full draft of the IRLM
- No statistically significant difference between investigators and implementation partners on any question (planning, reporting/specifying, knowledge of IR logic ⬆ investigators)

Resources for Using the IRLM

Quick Reference Guide, Worksheets, Templates, Examples

Quick Reference Guide



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Smith, Li, & Rafferty, 2

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	Complexity
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	Cost
	Outer Setting
	Patient needs an resources
	Cosmopolitanism
	Peer pressure
	External policies incentives

	Inner Setting
	Structural character
	Networks and communication
	Culture
	Implementation clin - *Tension for char* - *Compatibility* - *Relative priority* - *Incentives & rew* - *Goals and feedb* - *Learning climate*
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	Self-efficacy
	Individual identifica with the organizatio
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	Process
	Engaging - *Opinion leaders* - *Formal internal implementation* - *Champions* - *External change*
	Planning
	Executing
	Reflecting and evalu

Implementation Research Logic

IRLM — Impleme

Smith, Li, & Rafferty, 2020

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	(Effectiveness)
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	Implementation
	Maintenance
	Proctor et al., 2
	Acceptability
	Adoption
	Appropriateness
	Cost
	Feasibility
	Fidelity
	Penetration/Upt
	Sustainability

Implementation Research Lo

IRLM — Implen

Smith, Li, & Rafferty, 20

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√	Strategy
	Bunger et al., 2017;
	Planning
	Education
	Finance
	Restructure
	Quality manageme
	Policy

	Expert Recommendations for Implementing Change (ERIC; Powell et al., 2015; Waltz et al., 2015)
Use evaluative and iterative strategies	- 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
Provide interactive assistance	- Facilitation - Provide local technical assistance - Provide clinical supervision - Centralize technical assistance
Adapt and tailor to context	- Tailor strategies - Promote adaptability - Use data experts - Use data warehousing techniques
Develop stakeholder interrelationships	- 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
Train and educate stakeholders	- Conduct ongoing training - Provide ongoing consultation - Develop educational materials - Distribute educational materials - Use train-the-trainer strategies - Create a learning collaborative
Support clinicians	- Facilitate relay of clinical data to providers - Remind clinicians - Develop resource sharing agreements - Revise professional roles - Create new clinical teams
Engage consumers	- 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
Utilize financial strategies	- Fund and contract for the clinical innovation - Access new funding - Alter incentive/allowance structures - Make billing easier - Alter patient/consumer fees
Change infrastructure	- Mandate change - Change record systems - Change physical structure and equipment - Change service sites

Concluding Thoughts

Concluding Thoughts

- Visual depiction of implementation project
- Usability is high for seasoned and novice implementation researchers alike
- Could increase the rigor and transparency of complex studies that ultimately could improve reproducibility
- Common structure to increase consistency
- Method for more clearly specifying links and pathways to test theories

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- Simplified format – balance depth and detail
- May inhibit creative thinking if applied too rigidly

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