The Implementation Research Logic Model (IRLM)

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

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Check ISC³i 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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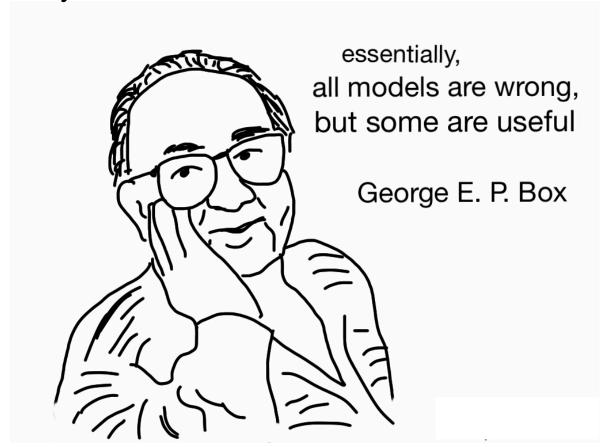
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Do We Really Need Another Model?









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







Development of the IR Logic Model

Uses and Elements







Case Applications

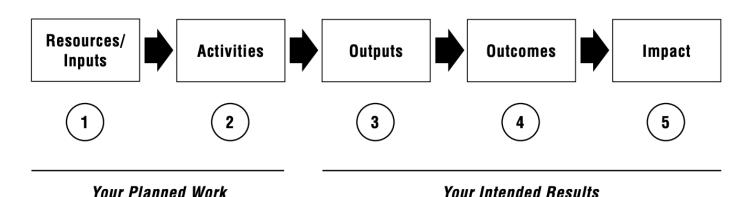
- Used in the study of implementing a new model of patient care in a new physical space Implementation strategies
- Used in the first 6 months of three already-funded implementation research projects to plan for and describe the prospective implementation research aspects of the trials
- Applied in the 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 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)

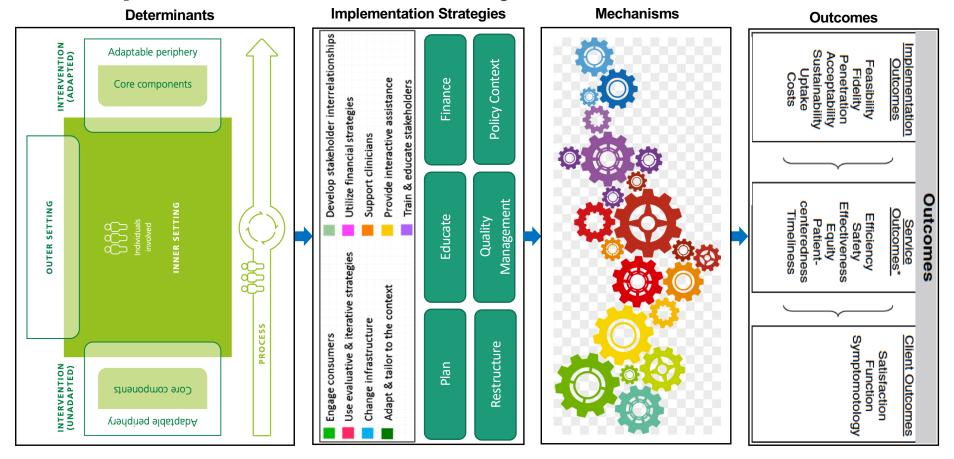




IRLM Formats

The Implementation Research Logic Model (IRLM)



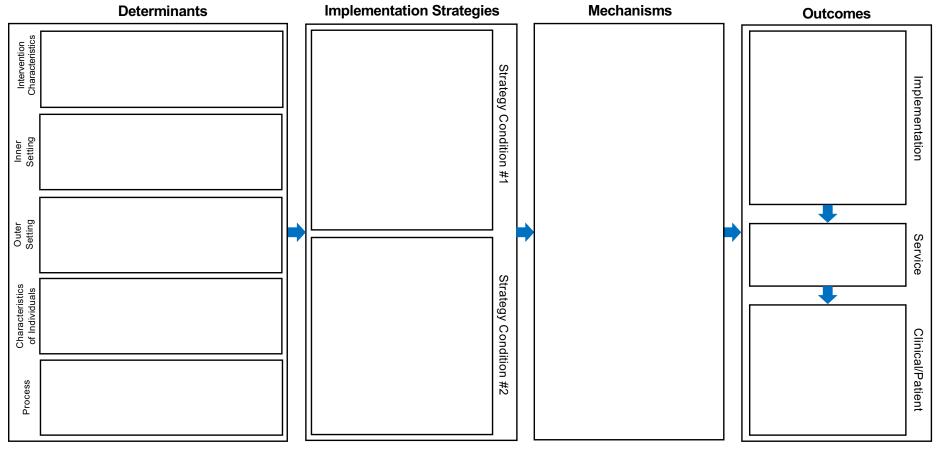






IRLM for Comparative Implementation



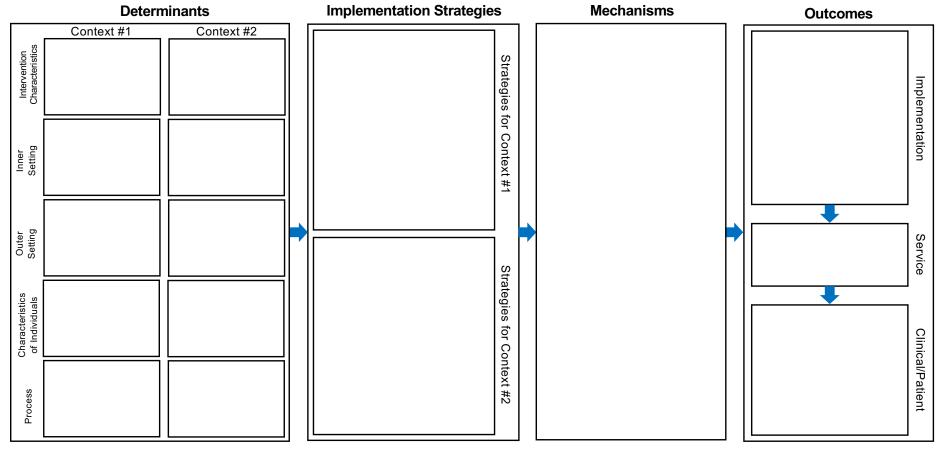








IRLM for Multi-Context Implementation of Single Intervention

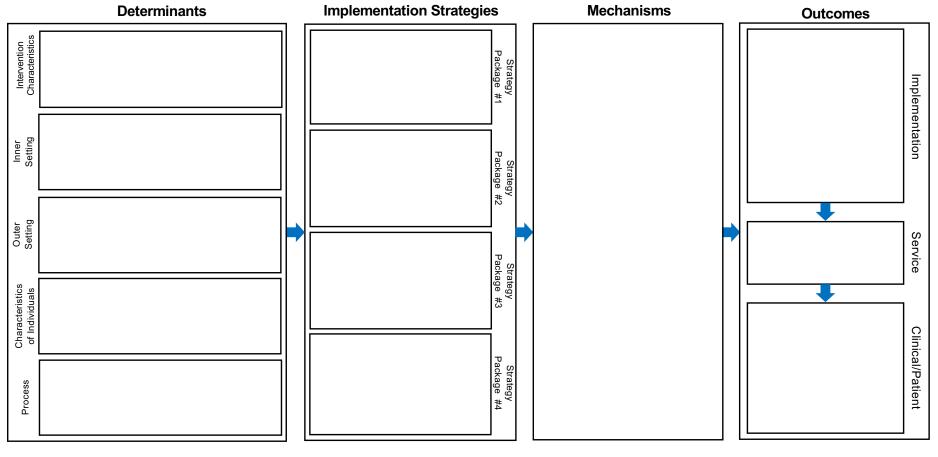








IRLM for Implementation Optimization Trial (4 clusters; 1 setting)

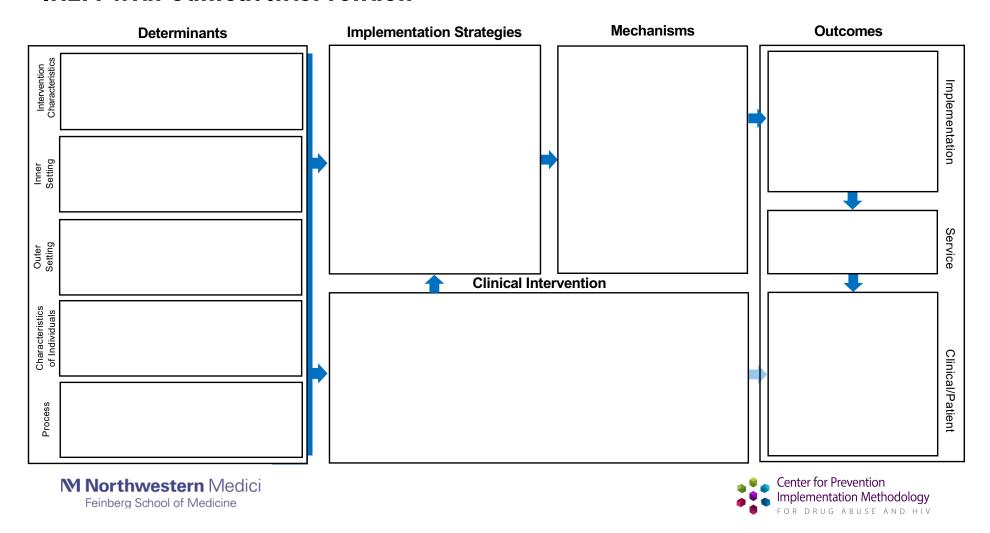






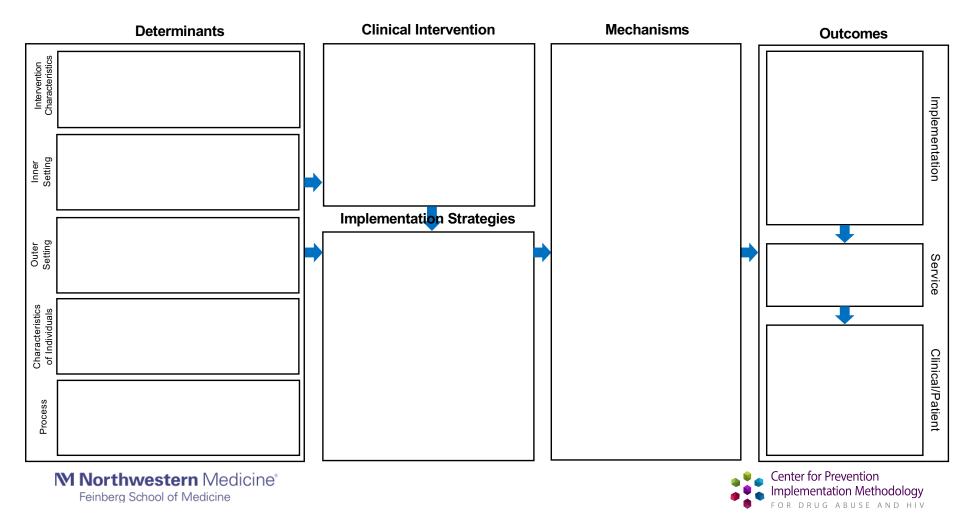
IRLM with Clinical Intervention





IRLM with Clinical Intervention (v2)







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 healthrelated 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)

Determinants

care +2 Intervention Source +2 Relative Advantage +2 Adaptability -1 B,F Evidence Strength & Complexity (budget) -1 A, L quality +2 Design quality & packaging Competing demands -1 D,K Evidence Based +1

Structural Characteristics +1 Networks & communications

Appropriate in primary

Implementation climate Tension for change +1

Readiness for Implementation J - Tangible fit +2 Leadership engagement

Compatibility -Alignment +1

Available Resources +1

Workflow -1 L - Learning climate +1

Patient needs & resources -2 C Cosmopolitanism 0/-1 B, C

External policy & incentives (ability to get reimbursed) |

RD +1 / MD +1 / CHW -2; (Nutritionist vs RD)

- State-wide initiatives/task forces, etc. +1 E

Char. Individu

Inner

Knowledge & Beliefs about Intervention +1 A Self-efficacy +1 B, F Training +2 A, B, F, G, I, K

Engaging +1 Opinion Leaders +2 D Champions +2 A

External Change Agents. +2 E

Planning +1 F

Reflecting & Evaluating

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Implementation Strategies

1. Training

Training modules A

Virtual learning collaborative B

2. Community Resources Engagement capturing local knowledge ^c

Engaging FQHC Leadership D

Engaging External, state-level organizations, national organizations E

Ongoing meetings F

Technical Assistance

Local champions (MS PCA)

Fidelity monitoring – quarterly checklist ^G

Data monitoring and feedback ^H

Utilize financial strategies (TBD)

Making billing easier

Accessing funding? 9. Quality Improvement J

10. Identify and form new clinical teams K

11. Clinician reminders (BMI alerts, labs,

counseling, referrals) L

Knowledge and skill set improved for clinic

Self-efficacy improved of clinic staff B, K, F, H

Flexibility of the package is continually adapted (adaptability, complexity) J (D, E)

(competing demands) D(K)

identified, leveraged, and made available (external policy and incentives) C(E)

External policies and incentives for

Healthy Weight Clinic

1. Individual/group visits

2. Multidisciplinary team

Centralized case management

Clinician champion

3. 26+ Contact hours

4. Adaptable curriculum

On-site recruitment/enrollment

6. Community Resources Guide

7. EHR support tool build

Labs

Physical Activity/Nutrition Counseling

Outcomes

Reach A, B, F, H, L

Clinic population

· HWC referrals (within provider)

· HWC enrollment

· Text Message Enrollment

Adoption A,D

· Training components

Package elements ^C

Implementation F, J

Acceptability (HWC, strategies)

Feasibility (HWC, strategies) ^A

· Fidelity (HWC, strategies) A, B, C, G

Maintenance/Sustainability B,D, E,F, G, I, I Retention Rate (HWC) C, H, J

Budget Impact Analysis E, I

*BOLD = primary outcomes

Implementation

ervice

Clinical/Patient

Equity (reach rates by race, age, BMI)

Timeliness (time from identification to HWC engagement) H, L

BMI C, H, K, L Quality of Life C, K, L

Family Health Behaviors C, K, L Binge Eating K, L

Stress C, K, L

Acceptability (HWC, strategies) K, L Feasibility (HWC, strategies) K, L

Satisfaction (HWC, primary care) H, K, L Retention/Completion (HWC) C, H, K, L

Cost Effectiveness 1



Mechanisms

staff (complexity) A, B (G, H, J, K, F, L)

Internal structural barriers are reduced

External support for patient needs are

reimbursement are accessed E(I)

*primary (secondary)

BMI alert

Internal Referral



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	
✓	√	√	
✓	✓		
✓	√		
✓	√	√	
√		√	
✓	✓	√	

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







ISC³i'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
- 2) Serving as a "roadmap" for the project
- 3) Clearly reporting and specifying the project plan
- 4) Understanding connections between determinants, strategies, mechanisms, and outcomes
- 5) Identifying gaps in the IR logic of their project
- 6) Deepening their knowledge of IR methods
- 7) Planning the project
- 8) Developing consensus and understanding of the project among diverse stakeholders involved
- 9) Identifying gaps in research questions/analyses

77.7%, M=3.05, *SD*=.885

74%, M=3.08, *SD*=.950

67.8%, M=2.94, *SD*=.909

66.3%, M=2.92, SD=.957

64.2%, M=2.86, *SD*=1.021

62.9%, M=2.83, *SD*=.959

61.3%, M=2.82, *SD*=1.088

58.8%, M=2.75, SD=1.090

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





Implementation Science Coordination, Consultation & Collaboration Initiative

Determinants

Factors that might prevent or enable improvements (barriers & facilitators). May act as moderators, effect modifiers, or mediators, indicating that they are links in a chain of causal mechanisms.

ntervention aracteristics

Intervention source; Evidence strength and quality; Relative advantage; Adaptability; Trialability; Complexity; Design quality and packaging; Cost

Inner Setting Structural characteristics; Networks and communication; Culture; Implementation climate; Readiness for implementation

Outer Setting Patient needs and resources; Cosmopolitanism; Peer pressure; External policies and incentives

Characteristics of Individuals

Knowledge/beliefs about intervention; Individual stage of change; Self-efficacy; Individual identification with the organization; Other attributes

Process

Engaging; Planning; Executing; Reflecting and Evaluating

Implementation Strategies

Interventions on the <u>system</u> to increase adoption of evidence-based innovations into usual care. A theory- or logic-driven connection should link an implementation strategy to (a) the barriers it will attempt to overcome and/or (b) the facilitators it will attempt to leverage.

Types

- Plan; Educate; Finance;
 Restructure; Quality
 management; Policy context
 (Powell et al., 2012; Bunger et al., 2017)
- Engage consumers; Evaluate; Change infrastructure; Stakeholder interrelationships; Financial strategies; Clinician support; Interactive assistance; Train and educate; Adapt (Powell et al., 2015; Waltz et al., 2015)

Strategies should be specified by the following characteristics: Actor; Action; Action target; Temporality; Dose; Outcome affected; Justification for use (Proctor et al., 2013)

Mechanisms

Processes or events through which an implementation strategy operates to affect desired implementation outcomes (Lewis et al. 2018)

Mechanisms explain how an implementation strategy has an effect by describing the actions that lead from the administration of the strategy to the most proximal behavioral (individual, system) and/or implementation outcomes (i.e., mechanisms are the exact series of steps through which the change came about; Kazdin, 2007).

Some potential mechanisms:

- 1. Altering the status of a determinant.
- 2. Changing the behavior or attitude of an implementer (i.e., a proximal outcome that precedes an implementation outcome)

Note. Although mediation analysis can be informative, mediators identified statistically are not necessarily mechanistic.

Outcomes

The effects of deliberate actions to implement an EBI.

Types

- Reach; Adoption; Implementation; Maintenance
- (RE-AIM; Glasgow et al., 1999)
- Acceptability; Adoption; Appropriateness; Cost; Feasibility, Penetration; Fidelity; Sustainability (Proctor et al., 2011)
- Speed and Quantity (Chamberlain, Brown, & Saldana, 2011)

Efficiency; Safety; Equity; Effectiveness; Patientcenteredness; Timeliness (IOM Standards of Care, 2006)

Satisfaction Functioning Symptomatology ...many others Clinical/Patient

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mplementation Research L	Inner Setting	Implementation Research Logic 3			Expert Recommendations for Impl	ementing Change (ERIC; Powell et al., 2015; Waltz et al., 2015)
RLM — Deter	Structural character	IRLM — Impleme	to your project. F	IRLM — Implen	Use evaluative and iterative	- Assess for readiness and identify barriers and facilitators
Smith, Li, & Rafferty, 2	Networks and	C	√ Implementatio	Smith, Li, & Rafferty, 20	strategies	- Audit and provide feedback
Determinants of imple	communication		RE-AIM Framev	In implementation rese		- Develop and implement tools for quality monitoring
Often, researchers thi	Culture	Implementation outcome		- An evidence-based in		- Conduct local need assessment
mediators, moderator	Implementation clir	treatments, practices, an	Reach	- An implementation in		- Obtain and use patients/consumers and family feedback
comes from the Consc		success, (2) proximal indi service and clinical/patier		To avoid inevitable con	Provide interactive assistance	- Facilitation
. From the list of CF	- Compatibility	service and clinical/patien	/=cc \	- To avoid illevitable coil		- Provide local technical assistance
project. It is impor	- Relative priority	,	(Effectiveness)	When implementing ar		- Provide clinical supervision
project. It is impor	- Incentives & rev	1 11		strategies exist in the I		- Centralize technical assistance
2. Circle any determi		1 11			Adapt and tailor to context	- Tailor strategies
Circle any determin	- Goals and feedb	I II	Adoption	From either taxono		- Promote adaptability
For each determin	- Learning climate			considering for you		- Use data experts
. Tor cuerr determin	Readiness for			a. For help sele		- Use data warehousing techniques
V Determin	implementation		Implementation	ERIC Matchi 2. For each strategy ca	Develop stakeholder	- Identify and prepare champions
Intervention Cha	- Leadership engo	1 11		a. A full list of	interrelationships	- Organize clinician implementation team meetings
Intervention soul	- Available resour	1 11		https://link.		- Recruit, designate, and train for leadership
	 Access to knowl 	<u>(4</u>		b. A full list of		- Inform local opinion leaders
Evidence strengt	Characteristics of Ir	1		https://impl		- Build a coalition
quality	Knowledge/beliefs	4	Maintenance	3. Add your discrete s		- Obtain formal commitments
Relative advanta	intervention	Unlike clinical/patient out		PrEP example proje	Train and educate stakeholders	- Conduct ongoing training
	Individual stage of o	service provider and typid		providers/staff on F		- Provide ongoing consultation
Adaptability		researchers, whereas oth				- Develop educational materials
	Self-efficacy	1, ., .,		√ Strategy (- Distribute educational materials
Trialability	· · · · · · · · · · · · · · · · · · ·	To identify implementation		Bunger et al., 2017;		- Use train-the-trainer strategies
	Individual identifica	downstream/ distal/long-	Proctor et al., 2	Planning		- Create a learning collaborative
Complexity	with the organization	1. For the evidence-base	Acceptability	1	Support clinicians	- Facilitate relay of clinical data to providers
	Other attributes	outcomes you are inte	Acceptability			- Remind clinicians
	Other attributes	outcomes, etc. Add th				- Develop resource sharing agreements
Design quality an			A.11'	Education		- Revise professional roles
packaging	B	2. From the list of servic	Adoption	Education	France consumers	- Create new clinical teams
Cost	Process	project. Add these to			Engage consumers	- Involve patients/consumers and family members
	Engaging		Appropriateness			Intervene with patients/consumers to enhance uptake and adherence
Outer Setting	- Opinion leaders			Finance		
Patient needs an	- Formal internal					Prepare patients/consumers to be active participants Increase demand
resources	implementation	Efficiency A		Restructure		- Use mass media
Coomanalitaria	- Champions	Safety A	Cost]	Utilize financial strategies	- Fund and contract for the clinical innovation
Cosmopolitanism	 External change 		Feasibility		Othize illialitial strategies	- Access new funding
Poor procesure	Planning	re		Quality manageme		- Access new funding - Alter incentive/allowance structures
Peer pressure		Equity Pr	Fidelity]		- Make billing easier
		11 1 ' ' 1 11				- Alter patient/consumer fees
External policies	Executing	- Patient- Pr			Change infrastructure	- Mandate change
incentives	Reflecting and evalu		Penetration/Upt	Dalia.	Change initiastructure	- Change record systems
incentives	and a standard	centeredness ne	Sustainability	Policy		Change physical structure and equipment
- 1		Timeliness Re	Justaniability	II I I		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
- Simplified format balance depth and detail
- May inhibit creative thinking if applied too rigidly



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