Introduction to Implementation Science &
the Implementation Research Logic Model

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## Conflict of Interest Disclosures for J.D. Smith

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Agenda

• Introduction to core concepts of implementation research (IR)
• Implementation Research Logic Model
  • Why IR needs a unique logic model
  • Components of the IR Logic Model
    • Determinants
    • Implementation Strategies
    • Mechanisms of Action
    • Outcomes
  • Example of the IR Logic Model to a hypothetical study of HIV intervention implementation
Introduction to Implementation Science

Core concepts and definitions
The Research-to-Practice “Chasm”

- **17 years** to move effective interventions into practice
- **14%** of interventions reach their intended population in the real-world

Institute of Medicine, 2001

Balas et al., 1998
Let’s Start Very Non-Scientific

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether THE THING works
- D&I research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the stuff we do to try to help people/places **DO THE THING**
- Implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

Slide courtesy of Geoff Curran, 2019
Terminology

- **Implementation practice** is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within and across specific systems (local knowledge).

- **Implementation research** evaluates the use of strategies to integrate interventions into real-world settings to improve patient outcomes (generalizable knowledge).

- **Implementation science** is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice.

Brown et al. 2017; NIH, 2019
Could a program work?

Does a program work?

Making a program work

Efficacy studies

Effectiveness studies

Preintervention

Implementation Practice

Implementation

Preparation

Exploration

Implementation Research

4 Phases: Aarons et al., 2011

Local knowledge

Generalizable knowledge

Time

Real-world relevance

Quality improvement

Traditional Translational Pipeline

Brown et al., ARPH 2017

Feinberg School of Medicine
IR has a Different Emphasis Than Other Types of Research

Effectiveness vs. Implementation

Evaluate Health Outcomes

Evaluate Adoption, Reach, Fidelity, Speed of Delivery, Cost of Support

System to Support Adoption and Delivery w Fidelity

Intervention (EBP)

Influences what to measure, what to model, how to test, and what to evaluate

IR has a Different Emphasis Than Other Types of Research

Effectiveness vs. Implementation

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The Delivery System Matters in Implementation

“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
Interventions vs. Implementation Strategies

• Evidence-Based Clinical or Preventive Intervention: 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
Interventions vs. 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

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<th>Educate</th>
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<th>Restructure</th>
<th>Quality Management</th>
<th>Policy Context</th>
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<tr>
<td>Engage consumers</td>
<td>Use evaluative &amp; iterative strategies</td>
<td>Change infrastructure</td>
<td>Adapt &amp; tailor to the context</td>
<td>Develop stakeholder interrelationships</td>
<td>Utilize financial strategies</td>
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<td>Support clinicians</td>
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<td>Train &amp; educate stakeholders</td>
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ERIC Study
Powell et al. 2015

Powell et al. 2012
Assumptions about IR

• There is sufficient evidence to implement one of the P’s

• Implementation needs to be evaluated as a P is rolled out

• IR is about the context of implementation
  • Service delivery system and agents
  • Defined population(s) served
Bridging Research and Practice
Models for Dissemination and Implementation Research

Rachel G. Tabak, PhD, Elaine C. Khoong, BS, David A. Chambers, DPhil, Ross C. Brownson, PhD

Context: Theories and frameworks (hereafter called models) enhance dissemination and implementation (D&I) research by making the spread of evidence-based interventions more likely. This work organizes and synthesizes these models by (1) developing an inventory of models used in D&I research; (2) synthesizing this information; and (3) providing guidance on how to select a model to inform study design and execution.

Evidence acquisition: This review began with commonly cited models and model developers and used snowball sampling to collect models developed in any year from journal articles, presentations, and books. All models were analyzed and categorized in 2011 based on three author-defined variables: construct flexibility, focus on dissemination and/or implementation activities (D/I), and the socioeconomic framework (SEF) level. Five-point scales were used to rate construct flexibility from broad to operational and D/I activities from dissemination-focused to implementation-focused. All SEF levels (system, community, organization, and individual) applicable to a model were also extracted. Models that addressed policy activities were noted.

Evidence synthesis: Sixty-one models were included in this review. Each of the five categories in the construct flexibility and D/I scales had at least four models. Models were distributed across all levels of the SEF; the fewest models (n=8) addressed policy activities. To assist researchers in selecting and utilizing a model throughout the research process, the authors present and explain examples of how models have been used.

Conclusions: These findings may enable researchers to better identify and select models to inform their D&I work.

Theories, Models, and Frameworks

• Determinant frameworks: barriers and facilitators of implementation process/outcomes (CFIR, PARIHS, Theoretical Domains Framework)

• Process models: specifies stages/phases of implementation (EPIS, Knowledge-to-Action, Ottawa Model)

• Evaluation frameworks: aspects of implementation that can be measured to determine success of implementation (RE-AIM, PRECEDE-PROCEED, Proctor et al. 2009)

• Classic theories: theories originating in other fields (Diffusion of Innovation, social networks, behavior change, organizational)

• Implementation theories: developed by implementation researchers (Implementation Climate, Absorptive Capacity, Organizational Readiness)
Development of the IR Logic Model

Uses and Elements
Disclaimer

essentially,
all models are wrong,
but some are useful

George E. P. Box
Development of the IR Logic Model

• Based on the CDC and AHRQ logic model format and components
• Pipeline model
  • Other: Outcome chains
• Leverage existing frameworks, models, and taxonomies by focusing on their integration in a new logic model
• Pilot work
  • Ce-PIM/AbilityLab
  • Keep It Up! 3.0 (Brian Mustanski)
  • Emory (Patrick Sullivan & Aaron Siegler)
  • Raising Healthy Children Study (CORD 2.0)
• Principled use, not rule-governed
• Model from Smith & Polaha (2017)
Logic Models (in general)

• 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

Uses:
• Planning the project
• Organizing a project proposal/grant application/study protocol
• Presenting findings from a completed project (post hoc application)
• Synthesizing the findings of multiple projects

Petersen, Taylor, & Peikes, 2013
Related Approaches

• **Program Theory** (Funnell & Rogers, 2011)
  • Explicit model on how a project/strategy contributes to a chain of intermediate results and finally to the intended or observed outcomes
    • **Theory of Change** — central processes or drivers by which change comes about; formal theory or tacit understanding
    • **Theory of Action** — explains how projects/strategies are constructed to activate the Theory of Change

• **Implementation Mapping** (Bartholomew, Fernandez, et al.)
  • Primarily focused on the design and selection of implementation strategy(s)
  • Series of matrices
Elements of an IR Logic Model

1. Determinants of practice
2. Implementation strategies
3. Mechanisms of action
4. Outcomes

• IR Logic Model: Specification of the relationship between components of an IR study
  Determinant(s) → Implementation Strategy → Mechanism of Action → Outcomes
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; TICD, Flottorp et al. 2013)
Determinants

- Patient needs and resources
- Cosmopolitanism
- Peer pressure
- External policies and incentives

For definitions visit: https://cfirguide.org/constructs/

Knowledge/Beliefs about the Intervention
- Self-efficacy
- Individual stage of change
- Individual identification with the organization
- Other personal attributes

Structural characteristics
- Networks and communication
- Culture
- Implementation climate
  - Tension for change
  - Compatibility
  - Relative priority
  - Organizational incentives/rewards
  - Goals and feedback
  - Learning climate

Readiness for implementation
- Leadership engagement
- Available resources
- Access to knowledge/information

Engaging
- Opinion leaders
- Formal internal implementation leaders
- Champions
- External change agents

Planning
- Executing
- Reflecting and Evaluating

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

For definitions visit: https://cfirguide.org/constructs/

Adaptable periphery
- Core components
- Adaptable components
- Adaptable periphery

OUTER SETTING

INNER SETTING

INTERVENTION (UNADAPTED)

INTERVENTION (ADAPTED)
Elements of an IR Logic Model

Implementation Strategies
• interventions on the system to increase adoption of evidence-based innovations into usual care (Powell et al. 2015)
• 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)
• Characteristics of the Strategy
  • The Actor, the Action, the Action Target, Temporality, Dose, Outcome Affected, Justification for use (Proctor, Powell, & McMillen, 2013)
  • Fidelity to the strategy itself
Elements of an IR Logic Model

Specifying Implementation Strategies in the IR Logic Model

• Comprehensive
  • Strategies already in place (pre)
  • Strategies added/used that were unplanned (during; post)

• Single-arm studies
  • Non-experimental: identify those of interest (pre); identify those with greatest relevance/impact (post)
  • Experimental: identify those added/manipulated for the trial (the IV)

• Multi-arm studies
  • Non-experimental: identify differences between arms (pre and post)
  • Experimental: identify those added/manipulated for the trial (the IV) for each arm/condition
  • Comparative implementation: identify those added/manipulated AND those that differ between arms/conditions
Elements of an IR Logic Model

Mechanisms of action

- Process or event through which an implementation strategy operates to affect desired implementation outcomes (Lewis et al. 2018)

Slide courtesy of Cara Lewis (April 2019)
Examples of Causal Chains

- Relative Advantage of EBI
  - Adoption of EBI
    - Incentivize Use of EBI
      - Determinant of practice
        - Implementation strategy
      - Implementation outcome
      - Clinical outcome
    - Delivery with Fidelity
      - Acceptable
        - Self-efficacy
          - Knowledge
            - Train & Educate
              - Mediator
                - Incentivize Use of EBI
                  - Adoption of EBI
                    - Determinant of practice
                      - Implementation strategy
            - Moderator
Elements of an IR Logic Model

Implementation Outcomes
The effects of deliberate and purposive actions to implement new treatments, practices, and services (Proctor et al. 2011)
1) indicators of implementation success
2) proximal indicators of implementation processes
3) key intermediate outcomes in relation to service or clinical outcomes

Interactions among IR outcomes
• Public health impact: effect * reach
• Figure
IR Outcomes are Distinct from Clinical Outcomes

Proctor et al. 2009; 2011

Short-term/proximal → Long-term/distal
Can the program be ADOPTED?

Can providers deliver it with FIDELITY?

Will the program REACH the intended population?

Will organizations SUSTAIN it over time?

Evidence-Based Intervention

Implementation Outcomes = Population Benefit

50% threshold… 6% population benefit

Gaglio, Shoup, & Glasgow, 2013
Effectiveness–Implementation
Hybrid Designs
A bit of a special case
Definition and Purpose

- Simultaneous evaluation of the effectiveness of the clinical intervention and its implementation
- ≥2 levels of data collection (patient & system)
- Emphasis on E and I differentiates hybrid types (continuum)
- Speed translation and efficiently take programs to scale

Curran et al. 2012
Hybrid Types

• **Type I:** Explore *implementability* of an intervention while we are testing its effectiveness (towards real world implementation strategies)

• **Type II:** Test implementation strategies *during* effectiveness trials (simultaneous look at both)

• **Type III:** Test implementation strategies while also documenting clinical/prevention intervention outcomes (evaluating them as they relate to uptake and fidelity)
Application/Purpose of Each Type

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<th>Type</th>
<th>Primary Aim</th>
<th>Secondary Aim</th>
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<tr>
<td>Type I</td>
<td>Determine effectiveness of an intervention</td>
<td>Better understand context for implementation</td>
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<tr>
<td>Type II</td>
<td>Determine effectiveness of an intervention</td>
<td>Determine feasibility and/or (potential) impact of an implementation strategy</td>
</tr>
<tr>
<td>Type III</td>
<td>Determine impact of an implementation strategy</td>
<td>Assess clinical outcomes associated with implementation</td>
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- Use Type I or Type II when effectiveness of the P has yet to be established
- Allowed to “backfill” effectiveness data while testing implementation strategies
- Use Type II or III when a relationship between implementation and effectiveness is unknown or hypothesized to occur (head-to-head trial)
- Power and level of randomization are key considerations

Curran et al. 2012; Landsverk, Brown, Smith et al. 2017
Hybrid Type I Example: PrEP as a Long-Acting Injectable

• Assumption: Efficacy trials were recently completed – no effectiveness trials
• Test effectiveness of long acting PrEP provided in-house within STD clinics AND gather information about implementation

Specific Aims
Aim 1. Test the comparative effectiveness of long acting PrEP compared to one-a-day PrEP.
Aim 2. Gather information about implementation (adoption, acceptability, adherence, fidelity).
Aim 3. Evaluate relations between implementation and effectiveness (e.g., does adherence account for variation in PrEP effectiveness? Are patients more likely to remain adherent to long acting PrEP?)
Logic Model for Implementation Research

Determinants

- Intervention Characteristics
- Inner Setting
- Outer Setting
- Characteristics of Individuals
- Process

Implementation Strategies

Mechanisms

Outcomes

- Implementation
- Service
- Clinical/Patient

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IR Logic Model Guiding Principles

• Include all relevant determinants and strategies
  • Comprehensiveness, transparency, rigor, alternative explanations
• Indicate/Notate relationship between elements
  • Color-coding, superscript/subscript (connect to text and tables)
• Label independent variable(s) (i.e., strategies) as appropriate
• Note the Primary Outcome(s) at each level
• Operationalize the outcome(s) when space allows
• Comparative implementation trials
  • Indicate the determinants стрategies/mechanisms differentiating arms
  • Identify the shared primary outcome(s) by both arms
  • Combined when similar or 1 IR Logic Model per arm when dissimilar
Supporting Text and Resources

- Preliminary data for determinants
- Measures
- Strategy/ies (Bartholomew et al.; Powell et al., 2017; Proctor, Powell, & McMillen, 2013)
- “Paths” supported by theory (e.g., Lewis et al. 2018)
- Trial design
- Implementation plan/process model (e.g., EPIS)
A (very basic) Example Application of the IR Logic Model

An urban primary healthcare system wants to increase PrEP prescribing
Pre-Exposure Prophylaxis (PrEP) (Truvada)

• When taken consistently, PrEP has been shown to reduce the risk of HIV infection in high-risk populations by up to 92%.

• 2014 CDC Comprehensive Clinical Practice Guidelines
  • HIV-uninfected individuals who engage in behaviors that place them at substantial risk of HIV acquisition:
    • Sexually active adult men who have sex with men (MSM)
    • Adult injection drug users (IDU)
  • Delivery
    • Every 3 months — repeat HIV testing to confirm patient is still HIV negative; provide a prescription or refill authorization for no more than 90 days (until the next HIV test); assess adherence and side effects
    • Every 6 months — assess renal failure; conduct STI testing
Premise for Example IR Study

- A large health system with 54 primary health care clinics in a high HIV prevalence urban area wants to increase PrEP uptake by 50%.

- Leaders in the health system have decided to compare whether referring potentially-eligible patients to specialty STI/HIV clinics for PrEP or providing PrEP in their clinics will result in better outcomes.

- Health system has partnered with an implementation scientist to devise a study to test this question.
Research Question

Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?
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Implementation Strategies
Research Question

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Implementation Outcomes
Research Question
Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Comparison-based trial design
Specific Aims

1. Train primary care physicians to identify and prescribe PrEP as part of routine preventive care.
2. Increase primary care provider adoption of PrEP screening and prescribing.
3. Identify most effective practice for reaching PrEP eligible patients (i.e., integrated within routine care or referral to specialty STI/HIV clinics).
Hypotheses

H₁: Provider, clinic, and PrEP-related factors will be related to primary care physicians’ adoption. Training can overcome these potential barriers.

H₂: Improving leadership support of provider delivery of PrEP will improve rates of adoption.

H₃: Providing PrEP in primary care will lead to more prescriptions than referring out.
Implementation Outcome Metrics

**Adoption:** Providers’ prescribing PrEP

**Reach:** Proportion of eligible patient’s prescribed PrEP

**Acceptability:** Providers’ perspective

**Appropriateness:** Provider and patient perspectives

**Feasibility:** Time with patients; wait times; total patients

**Cost:** Is PrEP provision in the clinic cost-beneficial/cost neutral for revenue as well as effects achieved?
Example: Timeline for Pre-Post Design to Evaluate Impact

- PrEP prescribing rates are low
- Referrals to PrEP are low

Implementation Strategies
- Training of PCPs to identify eligible patients
- Training in prescribing PrEP
- Audit and feedback (routine)

Primary Outcomes
1. PrEP prescribing (adoption)
2. Proportion of eligible patients prescribed PrEP (reach)
3. Appropriateness (PCP/patient)
4. Acceptability (PCP)
5. Feasibility (workflow etc.)
6. Cost
PrEP Implementation Project IR Logic Model

**Determinants**

- **Intervention Characteristics**
  - Highly effective +
  - Insurance coverage +/-
  - Relative advantage +/-
  - HIV/STI testing/refills –
  - Adherence –

- **Inner Setting**
  - Implementation climate +
  - Available workforce +
  - Leadership support +/-
  - HIV/STI testing +/-
  - Workflow disruption –

- **Outer Setting**
  - CDC Guidelines +
  - PrEP 4 Love Campaign +
  - Ending the HIV Epidemic +
  - Patient need/demand +
  - LHD STI Clinics +/-

- **Characteristics of Individuals**
  - Commitment +
  - Provider self-efficacy +/-
  - Stigma –
  - Knowledge/beliefs/attitudes about PrEP –

- **Process**
  - Planning for PrEP +
  - Opinion leaders +
  - Champions +
  - Evaluation +
  - External impl. Support –

**Implementation Strategies**

- Training Providers/Staff
  - PrEP efficacy
  - Identify eligible patients
  - Discuss sexual behaviors with patients
  - Stigma surrounding PrEP
  - Addressing patient barriers to adherence

- Integration into Routine Care
  - Workflow evaluation
  - PDSA cycles/CQI

**Mechanisms**

- Providers/Staff
  - Knowledgeable about PrEP guidelines
  - Destigmatized
  - Comfort inquiring about and discussing sexual behaviors
  - Self-efficacy to prescribe PrEP and follow guidelines

- Value of providing PrEP
- Accountability
- Peer and Leadership recognition of providers

**Outcomes**

- **Provider Adoption**
  - Prescribe PrEP
  - Repeat HIV test
  - **Reach**
    - % of eligible patients receive PrEP Rx
    - % of patients on PrEP with 90-day RX refill
    - % of patients on PrEP with 6 month STI test

- **Appropriateness**
- **Acceptability**
- **Fidelity (PrEP Guidelines)**

- **Safe**
- **Patient-centered**
- **Equitable**
- **Timely**

- % Filling first Rx
- % Adherent to PrEP
- % Refilling PrEP Rx
- # positive STI tests
- # new HIV infections*

*primary outcomes
Feedback on the IR Logic Model

• Completing the IR logic models for our project helped both study arms systematically think through the steps needed to ultimately achieve the implementation outcomes. From the researcher standpoint, delineating the mechanistic pathways between each strategy and the outcomes creates a set of hypotheses that can be further explored in the current study or tested in future research. From the practical/staff perspective, identifying relevant determinants and selecting appropriate strategies to address those determinants helped inform the development of trainings and resources needed for CBO staff (in the CBO arm) and for our own staff (in the DTC arm) to successfully implement KIU! This process, in turn, will inform how we design and scale out technical assistance for KIU! in the future.

• For our staff with limited background in IR, there was a learning curve to understand and complete the IR logic models. We found breaking it down into the smaller components/behaviors helpful for their understanding. Once trained, they agreed the exercise was useful for ensuring the comprehensiveness of their respective implementation plans.

– Brian Mustanski, PhD & Dennis Li, PhD
Concluding Thoughts
Strengths and Limitations of the IR Logic Model

- 1-2 page visual depiction of project
- Increase transparency/comprehensiveness of a complex process
- Common structure to increase consistency and transparency
- Aids in demonstrating rigor and reproducibility components
- Clearer specification of links and pathways to test theories
- Tool for academic–practice collaboration and partnership development
- Planning and tracking process over time

- Simplified format – balance depth and detail
- May inhibit creative thinking if applied too rigidly
IR Logic Model Activity
Complete the IR Logic Model for your Project

• Work in pairs (PD and implementation partner)
• 3 sessions during this training
  • Outcomes
  • Determinants
  • Strategies & Mechanisms

• 2 worksheets/cheat sheets for quick reference

• **Goal while here:** Solid start that can be added to and refined

• Faculty will be circling to answer questions
Some Additional IR Resources
Implementation Science Trainings

Brown, Smith, Benbow, & Villamar (2016)

Basics of Implementation Science methodology with an example of its use to support diverse sexual transmitted infection (STI) clinics around the country in delivering PrEP to prevent spread of HIV infections.

Brown, Smith, & Benbow (2017)

Covers the defining characteristics of trials testing implementation, provides a basic understanding of experimental designs for implementation research, and outlines the key challenges of designing and conducting an implementation trial.

http://cepim.northwestern.edu/trainings/
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**Mission:** To reach, teach, and inspire innovations in prevention science and implementation science methodology at a national and international level.

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References


