

# Evaluation Methods in Implementation Research: An Introduction

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# Objectives

- Offer perspectives on what constitutes 'successful implementation'
- Define formative and summative evaluation in implementation research (IR)
- Describe 4 stages of formative evaluation (FE) in IR
- Provide overview of summative (or 'impact') evaluation approaches and methods in IR
- Provide overview on evaluating usefulness of theory selected to inform or guide implementation

# *What is Successful Implementation?*

- SI metrics and indicators from 'PARIHS Guide' Appendix 5 (see handout)
  - *Implementation plan and its realization*
  - *EBP innovation uptake: i.e., clinical interventions and/or delivery system interventions*
  - *Patient and organizational outcomes achievement*

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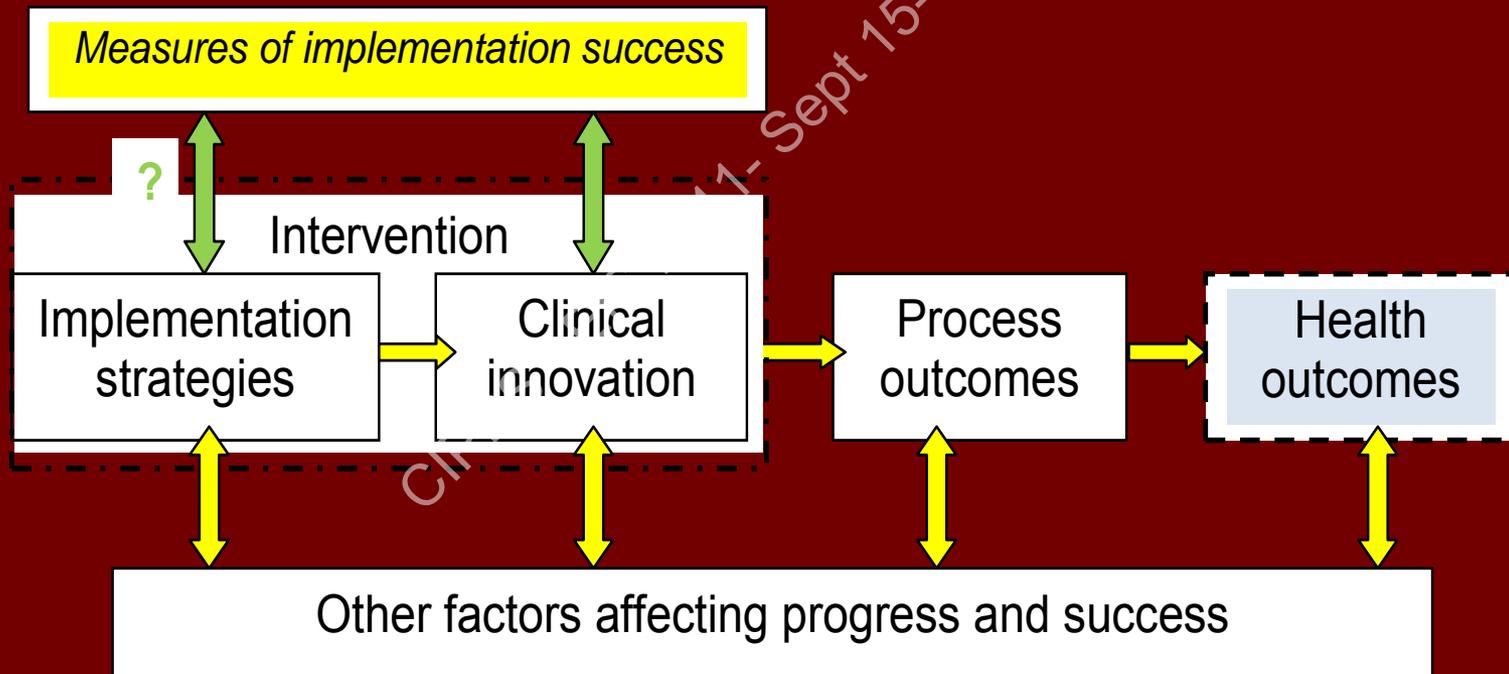
# What is implementation strategy v. innovation v. outcomes?

## ■ Examples:

<i>Study</i>	<i>Implementation strategy</i>	<i>Innovation</i>	<i>Process outcome</i>
<b>Bipolar CCM</b>	Replicating effective programs (REP)	Collaborative chronic care model (CCM)	Guideline concordant treatment for bipolar disorder
<b>Organizational collaboration for hand-hygiene</b>	External facilitation	Organizational model for strengthening implementation of evidence-based practices	Hand-hygiene compliance

Adapted from: Lukas CV, Hall C. Challenges in Measuring Implementation Success. 3rd Annual NIH Conference on the Science of Implementation and Dissemination: Methods and Measurement. March 15-16, 2010. Bethesda, MD.

# Does the concept of implementation success apply to implementation processes as well as to the innovation?



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# Definitions

## ■ Formative evaluation

- *Rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts* (Stetler et al, 2006<sup>†</sup>)

## ■ Summative (impact) evaluation

- *Systematic process of collecting and analyzing data on impacts, outputs, products, outcomes and costs in an implementation study*

<sup>†</sup> Stetler CB, Legro MW, Wallace CM, Bowman C, Guihan M, Hagedorn H, Kimmel B, Sharp ND, Smith JL. The role of formative evaluation in implementation research and the QUERI experience. *Journal of General Internal Medicine* 2006; 21 (Suppl 2):S1-8.

# Need for FE in Implementation Research

- Capture information on factors that hinder or facilitate successful implementation
- Address interpretive weaknesses
  - Avoid 'implementation assessment failure'
  - Avoid explanation and outcome attribution failure
  - Enhance understanding of study outcomes

# Four Stages of FE

- Developmental
- Implementation-Focused
- Progress-Focused
- Interpretive

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# Developmental FE

- aka "local needs assessment", "organizational diagnosis"
- Involves data collection on...
  - Actual degree of less-than-best practice (need for improvement)
  - Determinants of current practice
  - Potential barriers / facilitators to practice change
  - Feasibility of (initial) implementation strategy
- Goals
  - Identify determinants and potential problems and try to address in implementation strategy; refine strategy as needed
  - Avoid negative unintended consequences
  - Engage clinical stakeholders in defining the problem and potential remedies

# Tension... What is Appropriate Use of Developmental FE?

- Stand-alone developmental FE for diagnostic assessment of determinants of current practice prior to implementation trial  
(use it later)

vs.

- Developmental FE used SOLELY within the context of an ongoing implementation trial  
(use it now)

# Implementation-Focused FE

- Occurs during implementation of project plan
- Focuses on assessing discrepancies between implementation plan and execution
- Enables researchers to...
  - Ensure fidelity (both to implementation strategy and clinical intervention)
  - Understand nature and implications of local adaptation
  - Identify barriers to implementation
  - Identify new intervention components or refine original strategy to optimize potential for success
  - Identify critical details necessary to replicate implementation strategy in other clinical settings

# Progress-Focused FE

- Occurs during implementation of project plan
- Focuses on monitoring indicators of progress toward implementation or clinical QI goals
  - audit/feedback of clinical performance data
  - progress in relation to pre-determined timelines for implementing intervention components
- Used to inform need to modify or refine original strategy
- May also be used as positive reinforcement for high performing sites; negative reinforcement for low performers

# Interpretive Evaluation

- Uses data from other FE stages and data collected from stakeholders at end of project
- Obtain stakeholder views on:
  - Usefulness / value of intervention
  - Barriers / facilitators to implementation success or failure
  - Satisfaction with implementation process
  - Recommendations for further refinements to intervention
- Can provide working hypotheses on implementation success / failure

# FE Assessment Methods / Tools

## ■ Quantitative

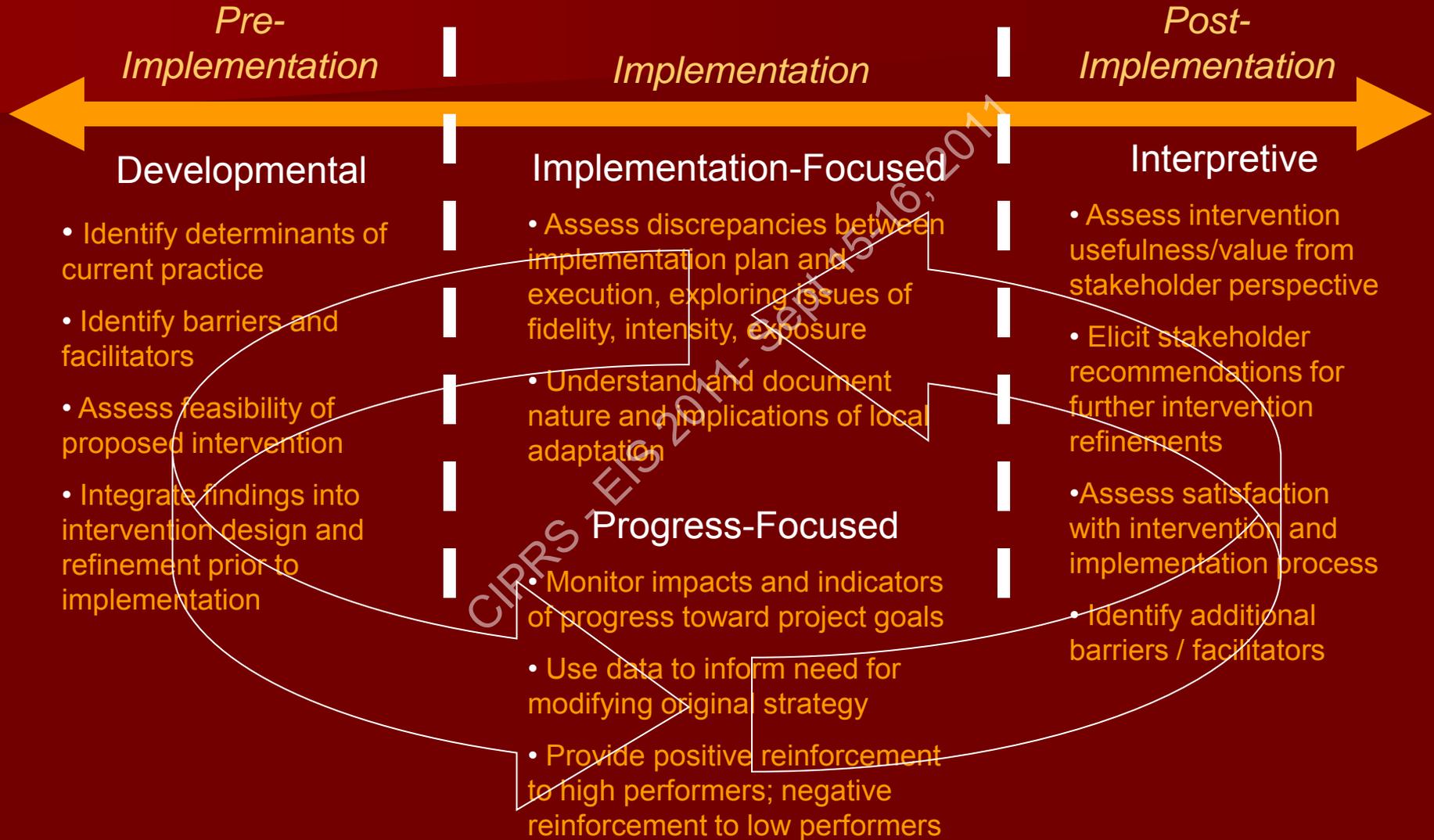
- Structured surveys / tools
  - Instruments assessing organizational culture, readiness to change, provider receptivity to EBPs
  - Intervention fidelity measures
- Audit / feedback of clinical performance data

## ■ Qualitative

- Semi-structured interviews w/ clinical stakeholders (pre-/post-)
- Focus groups
- Direct (non-participant) observation of clinical structure and processes in site visits
- Document review

## ■ Mixed Methods (ie, Quantitative + Qualitative)

# Stages of FE



# Summative Evaluation in Implementation Research

## ■ Outcomes Assessment

- A priori measures defined at outset of project to assess intervention impact or effectiveness
- Defined at patient-, provider-, clinic-, facility-, and/or system-level... depending on intervention target
- Involves use of administrative data, chart review, and/or primary data collection

## ■ Cost Assessment

- Assess costs associated with implementation strategy to inform decision makers on value and feasibility of implementing the intervention

# Summative Evaluation – Outcomes Assessment

- Process of care measures
  - Assess intervention effect on targeted clinical practice / utilization measures
    - Increase use of targeted EBP?
    - Decrease use of ineffective, inefficient practices?
- Clinical outcome measures
  - Assess intervention effect on patient outcomes
    - Symptom reduction/remission, functioning, health-related quality of life
- Are outcomes observed similar to intervention effects in earlier efficacy / effectiveness trials?

# Summative Evaluation – Cost Assessment

- Budget Impact Analysis (BIA)
  - Purpose: Estimate financial consequences of adoption and diffusion of an intervention within a specific health care setting or system
  - Document and assess costs to system associated with intervention design and implementation
    - Include provider time and utilization measures (eg, clinic visits, pharmacy costs)
    - Utilize administrative data, chart review
  - See HERC guidelines for cost analysis in QUERI

# RE-AIM Evaluation Framework

## PURPOSES

- Broaden and standardize criteria used to evaluate clinical QI programs
- Evaluate issues relevant to program adoption, implementation, and sustainability
- Help close the gap between research studies and practice

# RE-AIM TO HELP PLAN, EVALUATE, AND REPORT STUDIES

*R* →

Increase

Reach

*E* →

Increase

Effectiveness

*A* →

Increase

Adoption

*I* →

Increase

Implementation

*M* →

Increase

Maintenance

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# RE-AIM DIMENSIONS AND DEFINITIONS

DIMENSION	DEFINITION
REACH	<ol style="list-style-type: none"><li data-bbox="909 565 1711 665">1. Participation rate among eligible individuals</li><li data-bbox="909 694 1711 793">2. Representativeness of participants</li></ol>
EFFICACY / EFFECTIVENESS	<ol style="list-style-type: none"><li data-bbox="909 1048 1736 1148">1. Effects on primary outcome(s) of interest</li><li data-bbox="909 1176 1736 1275">2. Impact on quality of life and negative outcomes</li></ol>

# RE-AIM DIMENSIONS AND DEFINITIONS (cont.)

DIMENSION	DEFINITION
ADOPTION	<ol style="list-style-type: none"><li>1. Participation rate among possible settings</li><li>2. Representativeness of settings participating</li></ol>
IMPLEMENTATION	<ol style="list-style-type: none"><li>1. Extent to which intervention delivered as intended</li><li>2. Time and costs of intervention</li></ol>
MAINTENANCE (sustainability)	<ol style="list-style-type: none"><li>1. Long-term effects of intervention</li><li>2. Impact of attrition on outcomes</li><li>3. Extent of continuation or modification of treatment</li></ol>

# Evaluate Usefulness of Theory

In terms of...

- Planning the implementation strategy
- Conducting evaluations
- Identifying unanticipated elements critical to SI but may be unexplained by selected theory
- Gaining additional insights about the theory
- Helping to understand findings, including relationships between domains or constructs

# Summary

- Formative evaluation can be key to effective intervention design and success, interpretation and replication of results
- Summative evaluation is used to assess relevant clinical outcomes and costs associated with implementation of EBPs
- Formative and summative evaluation are complementary in developing, implementing, evaluating and refining implementation interventions
- Important to evaluate usefulness of selected theory