

# Evaluation Methods in Implementation Research: An Introduction

Jeffrey L. Smith, PhD(c)  
Implementation Research Coordinator  
VA Mental Health QUERI

Email: [Jeffrey.Smith6@va.gov](mailto:Jeffrey.Smith6@va.gov)

# Audience Poll Question

- What exposure have you had to the presentation for today?
  - Attended the EIS training last July in Denver
  - Listened to the presentation online
  - Reviewed only the slides online
  - This will be my first time hearing about it

# Audience Poll Question

- How confident do you feel about evaluation methods and measures to use in conducting an implementation study?
  - *Not at all confident*
  - *Somewhat confident*
  - *Moderately Confident*
  - *Very confident*
  - *I'm ready to dive in!*

# Audience Poll Question

- Have you ever adapted or tailored an intervention using formative evaluation techniques?
  - *Yes*
  - *No*

# 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*

# How do we define implementation success? (from Lukas and Hall 'Think Tank Summary')

- **Implementation success** is the presence of the innovation as intended in the delivery context
- **Measuring implementation success** is formally determining that presence

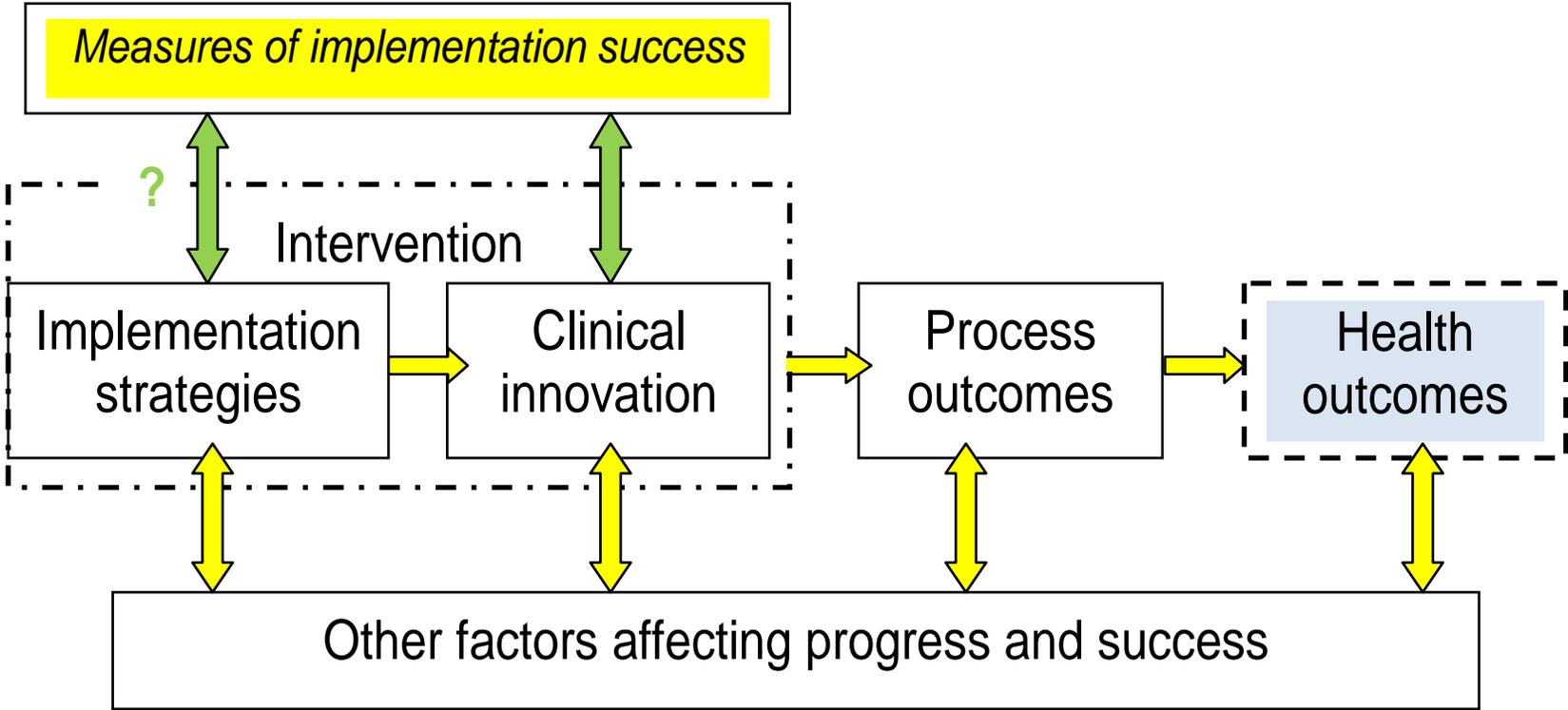
# What is implementation strategy v. innovation v. outcomes?

- Examples:

<b><i>Study</i></b>	<b><i>Implementation strategy</i></b>	<b><i>Innovation</i></b>	<b><i>Process outcome</i></b>
<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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Against what shared standards should implementation success be judged?

- Fidelity -- Adherence, Scope/reliability, Intensity/dose, Quality of program, Participant responsiveness, Sustainability
- RE-AIM – Reach, Effectiveness, Adoption, Implementation, Maintenance

# 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*
  - *Used to assess success, effectiveness, or goal achievement of an intervention*

<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’
    - erroneous study results occur because intervention not implemented as planned (Type III error)
  - Avoid explanation and outcome attribution failure
    - FE helps identify what did / did not happen in implementation plan
    - Identify factors in setting, anticipated and unanticipated, that influenced implementation
  - Enhance understanding of study outcomes to more accurately interpret project findings and inform future implementation efforts

# Four Stages of FE

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

# 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 or implementation of proposed adoption strategy
  - Strategy feasibility, including perceived utility of project
- Goals
  - Identify determinants and potential problems and try to address in implementation strategy; refine proposed strategy as feasible
  - Avoid negative unintended consequences
  - Engage clinical stakeholders in defining the problem and potential remedies; innovative solutions may emerge from within

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

- Stand-alone developmental FE for diagnostic assessment of process / 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 actual execution
- Enables researchers to...
  - Avoid ‘Type III’ errors, where intervention not implemented as planned or designed
  - Understand nature and implications of local adaptation
  - Describe and understand major barriers to implementation and what it takes to achieve desired change
  - Identify and implement new intervention components or refine original strategy to optimize potential for success
  - Identify critical details necessary to replicate implementation strategy in other clinical settings

# Critical Measures of Implementation

- Integrity of innovation
  - Fidelity to planned implementation strategy
  - Dose of intervention delivery, when variability is possible
  - Requires clear operational definitions of intervention components
- Exposure to innovation
  - Degree to which intervention is experienced by targeted users
  - Dose of exposure, when variability is possible
  - Requires clear operational defs for measuring intervention exposure
- Intensity of implementation
  - Eg, implementation or intensity scores for multifaceted interventions
  - Eg, 'goal attainment scaling' when strategy allows local adaptation or choice of alternative interventions across sites

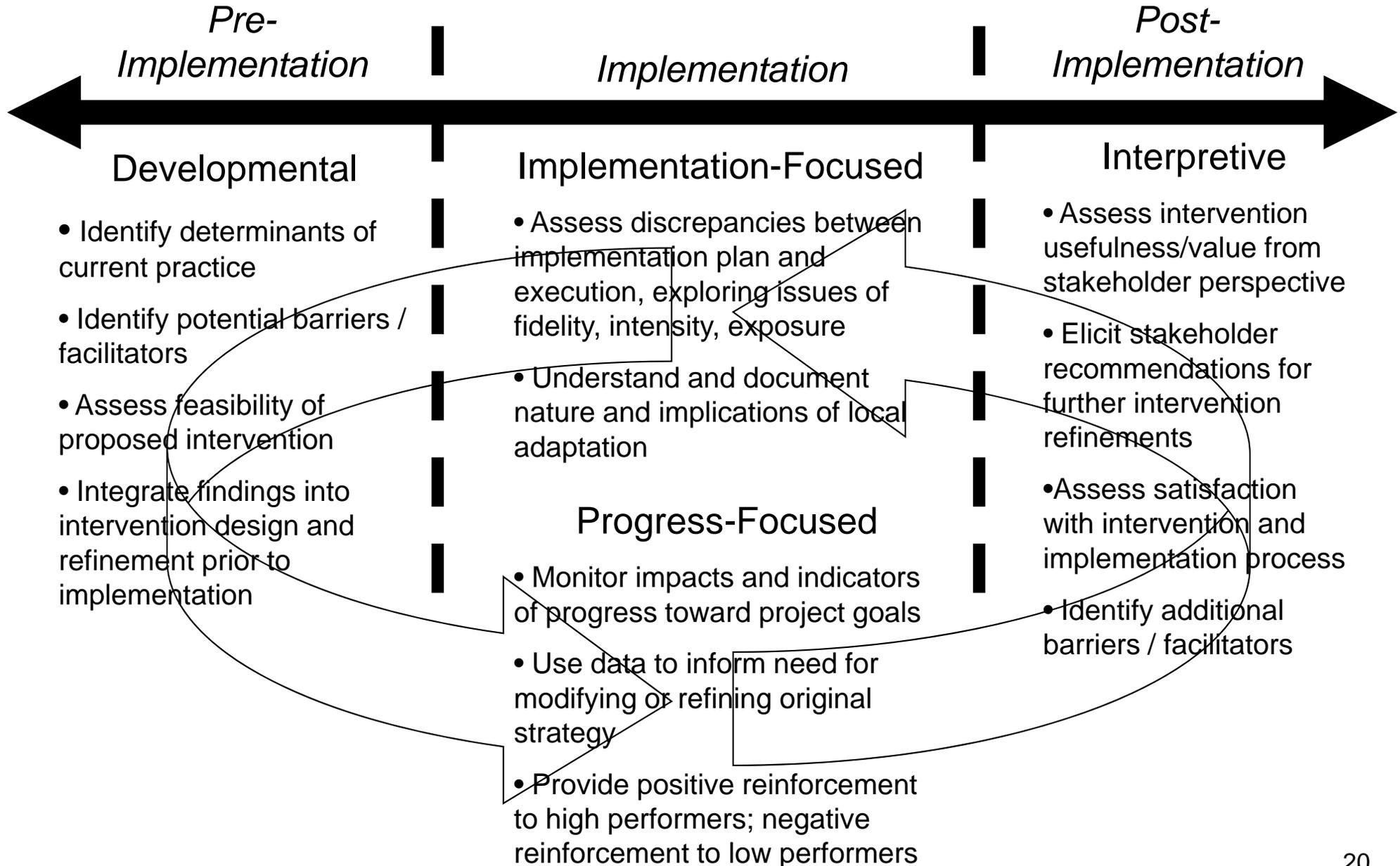
# Progress-Focused FE

- Occurs during implementation of project plan (concurrent with implementation-focused FE)
- Focuses on monitoring impacts and 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
- Can be used to inform need for modifying or refining original implementation strategy
- Can also be used as positive reinforcement for high performing sites; negative reinforcement for low performers

# Interpretive Evaluation

- Uses data from other FE stages; data on stakeholder experiences can also be collected at end of project
- Obtain stakeholder views on:
  - Usefulness / value of intervention (as a whole, or individual components)
  - 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, particularly when implementation and evaluation plans grounded in a conceptual framework (for theory building / refinement)

# Stages of FE



# FE Assessment Methods / Tools

- Quantitative
  - Structured surveys / tools
    - Instruments assessing organizational culture, readiness to change, provider receptivity to EBPs (eg, ORCA, OCM, others)
    - Intervention fidelity measures... including dose, intensity measures
  - Audit / feedback of administrative data on clinical performance on quality measure(s) of interest
- Qualitative
  - Semi-structured interviews w/ clinical stakeholders (pre-/post-)
  - Focus groups
  - Direct observation of clinical structure/processes in site visits
  - Document review
- Mixed Methods (ie, Quantitative + Qualitative)
  - Can provide richer explanation of study results to enhance understanding of key factors in implementation success / failure

# Summative Evaluation in Implementation Research

- **Outcomes Assessment**
  - A priori measures defined at outset of project that will be used to assess clinical/system intervention effectiveness
  - May be defined at patient-, provider-, clinic-, facility-, and/or system-level... depending on clinical/system 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
    - Particularly important to assess in QUERI Phase 1 and 2 studies
- Are outcomes observed similar in magnitude 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 given inevitable resource constraints
  - Document and assess costs to system associated with intervention design and implementation
    - Include costs of provider time, utilization (eg, clinic visits, pharmacy costs) associated with intervention implementation
    - Utilize administrative data, chart review
  - See HERC guidelines for cost analysis in QUERI

# RE-AIM Evaluation Framework

## PURPOSES

- To broaden and standardize criteria used to evaluate programs
- To evaluate issues relevant to program adoption, implementation, and sustainability
- To help close the gap between research studies and practice by
  - Informing design of interventions and selection of key outcome measures
  - Suggesting standard reporting criteria

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

<i>R</i> →	Increase	<u>R</u> each
<i>E</i> →	Increase	<u>E</u> ffectiveness
<i>A</i> →	Increase	<u>A</u> doption
<i>I</i> →	Increase	<u>I</u> mplementation
<i>M</i> →	Increase	<u>M</u> aintenance

# RE-AIM DIMENSIONS AND DEFINITIONS

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DIMENSION	DEFINITION
REACH	<ol style="list-style-type: none"><li data-bbox="989 646 1860 753">1. Participation rate among eligible individuals</li><li data-bbox="989 786 1860 899">2. Representativeness of participants</li></ol>
EFFICACY / EFFECTIVENESS	<ol style="list-style-type: none"><li data-bbox="989 1179 1887 1286">1. Effects on primary outcome(s) of interest</li><li data-bbox="989 1318 1887 1430">2. Impact on quality of life and negative outcomes</li></ol>

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# 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 or poorly described by selected theory
- Gaining additional insights about the framework / theory
- Helping to understand findings, including relationships between dimensions or constructs; complexity of implementation.

# Summary

- Formative evaluation can be key to effective intervention design and success, interpretation and replication of results in implementation projects
- Summative evaluation is used to assess relevant outcomes and costs associated with implementation of evidence-based practices
- Together, formative and summative evaluation are complementary in developing, implementing, evaluating and refining implementation interventions
- Important to evaluate usefulness of theory as routine part of IR studies as well

# Questions? Comments?

- Please open the Q&A tab located at the top left of your screen, to submit a question or comment.

# Audience – Poll question (after Q&A)

- Think back to the level of confidence you indicated at the beginning of this presentation. Now, how confident do you feel about evaluation methods and measures to use in conducting an implementation study??
  - *Less confident than before hearing this presentation*
  - *I'm feeling about the same*
  - *Slightly more confident*
  - *Much more confident*

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