

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*

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

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.

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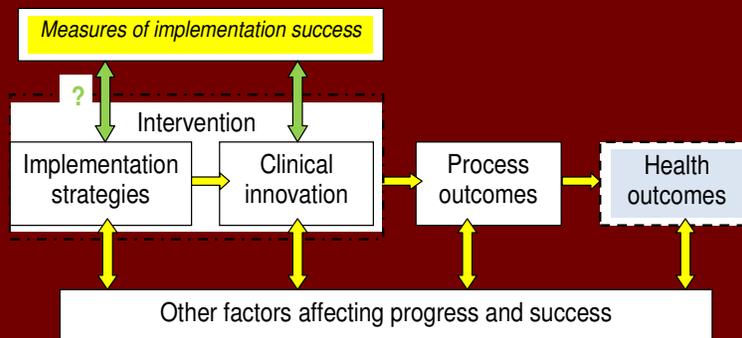
What is implementation strategy v. innovation v. outcomes?

■ Examples:

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

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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

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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[†])
- **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*

[†] 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

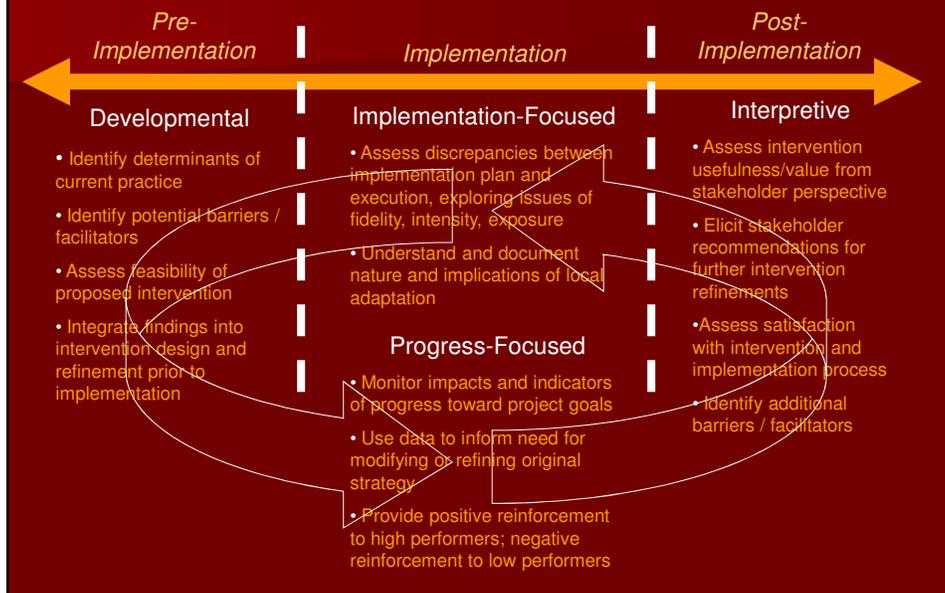
Progress-Focused FE

- 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

Glasgow, et al. *Ann Behav Med* 2004;27(1):3-12

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

DIMENSION	DEFINITION
REACH	<ol style="list-style-type: none"> 1. Participation rate among eligible individuals 2. Representativeness of participants
EFFICACY / EFFECTIVENESS	<ol style="list-style-type: none"> 1. Effects on primary outcome(s) of interest 2. Impact on quality of life and negative outcomes

www.re-aim.org

RE-AIM DIMENSIONS AND DEFINITIONS (cont.)

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

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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