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

What is implementation strategy v. innovation v. outcomes?

Examples:

| Study                              | Implementation strategy                            | Innovation                                      | Process outcomes                        |
|------------------------------------|---------------------------------------------------|------------------------------------------------|
| 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 |


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

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*

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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

**Developmental**
- Identify determinants of current practice
- Identify potential barriers / facilitators
- Assess feasibility of proposed intervention
- Integrate findings into intervention design and refinement prior to implementation

**Implementation-Focused**
- Assess discrepancies between implementation plan and execution, exploring issues of fidelity, intensity, exposure
- Understand and document nature and implications of local adaptation

**Progress-Focused**
- Monitor impacts and indicators of progress toward project goals
- Use data to inform need for modifying or refining original strategy
- Provide positive reinforcement to high performers; negative reinforcement to low performers

**Interpretive**
- Assess intervention usefulness/value from stakeholder perspective
- Elicit stakeholder recommendations for further intervention refinements
- Assess satisfaction with intervention and implementation process
- Identify additional barriers / facilitators

**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 (e.g., 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

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
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| **REACH** | 1. Participation rate among eligible individuals  
2. Representativeness of participants |

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<th>Dimension</th>
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| **EFFICACY / EFFECTIVENESS** | 1. Effects on primary outcome(s) of interest  
2. Impact on quality of life and negative outcomes |
RE-AIM DIMENSIONS AND DEFINITIONS (cont.)

<table>
<thead>
<tr>
<th>DIMENSION</th>
<th>DEFINITION</th>
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<tbody>
<tr>
<td>ADOPTION</td>
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<tr>
<td>1.</td>
<td>Participation rate among possible settings</td>
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<td>2.</td>
<td>Representativeness of settings participating</td>
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<td>IMPLEMENTATION</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Extent to which intervention delivered as intended</td>
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<td>2.</td>
<td>Time and costs of intervention</td>
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<td>MAINTENANCE (sustainability)</td>
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<tr>
<td>1.</td>
<td>Long-term effects of intervention</td>
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<td>2.</td>
<td>Impact of attrition on outcomes</td>
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<td>3.</td>
<td>Extent of continuation or modification of treatment</td>
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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.