EIS- Intro Program Session 5: Evaluation Overview and Designs (Evaluation Components)

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Objectives

- Describe goals of evaluation in implementation science
- Offer perspectives on what constitutes ‘successful implementation’
- Describe 4 stages of formative evaluation
- Provide overview of summative (or ‘impact’) evaluation
- Introduce RE-AIM framework to guide selection of evaluation measures
Goals of Evaluation in Implementation Science

- Conduct formative (or process) evaluation
  - Rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts (Stetler et al, JGIM 2006; 21(Suppl 2):S1-8.)

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

- Evaluate usefulness of selected theory, in terms of...
  - Planning implementation strategy
  - Unanticipated elements critical to SI, but unexplained by selected theory
  - Helping to understand findings and relationships between domains or constructs
What is Successful Implementation?

- Implementation plan and its realization

- EBP innovation uptake
  - i.e., clinical interventions and/or delivery system interventions

- Patient and organizational outcomes achievement
Does the concept of implementation success apply to implementation strategy as well as to the innovation?

Four Stages of Formative Evaluation (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 (including context)
  - 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 stakeholders in defining problem and potential solutions
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
  - Identify new intervention components or refine original strategy to optimize potential for success
  - Identify critical details necessary to replicate implementation strategy in other 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 or value of intervention
  - Barriers and facilitators to implementation success or failure
  - Satisfaction with implementation strategy
  - Recommendations for refinements to implementation strategy

- Can provide working hypotheses on implementation success / failure
FE Assessment Methods / Tools

- **Quantitative**
  - Structured surveys / tools
    - Instruments assessing context (e.g., 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** (i.e., Quantitative + Qualitative)
Stages of FE

Pre-Implementation

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

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

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

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

Post-Implementation
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 (e.g., clinic visits, pharmacy costs)
    - Utilize administrative data, chart review
RE-AIM Evaluation Framework

PURPOSES

- Broaden and standardize criteria used to evaluate clinical QI programs
- Guide consideration and selection of evaluation measures
- Evaluate issues relevant to program adoption, implementation, and sustainability

## RE-AIM Dimensions

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<tr>
<th>Dimension</th>
<th>Definition</th>
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| **REACH** | 1. Participation rate among eligible individuals  
2. Representativeness of participants |
| **Efficacy / Effectiveness** | 1. Effects on primary outcome(s) of interest  
2. Impact on quality of life and negative outcomes |

http://cancercontrol.cancer.gov/is/reaim/
## RE-AIM DIMENSIONS (cont.)

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

- Formative and summative evaluation are complementary in developing, implementing, evaluating and refining strategies to increase use of EBPs.

- Formative evaluation can be key to effective design and success of implementation strategies.

- Summative evaluation used to assess relevant clinical outcomes and costs.

- RE-AIM framework can be helpful in selecting evaluation measures.