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Part 3: Evaluating Implementation Programs and Studying Implementation Processes

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Evaluating implementation programs: Impact vs. process/mechanism focus

Two very different questions for simple interventions vs. complex social interventions

1. Does it work? Is it “effective”?  
   Should it be approved?  
   Included in the formulary?  
   Should I use it?

2. How, why, when and where does it work?  
   How should I use it?  
   How do I make it work?
Studying complex social interventions

Implementation strategies and programs are complex social interventions characterized by:

- Variability and heterogeneity of program (intervention) content across time and place
- Heterogeneity of program implementation across time and place
- Strong contextual influences (leadership, culture, experience/capacity, staff/budget sufficiency), variability and heterogeneity of context across time and place
- Weak main effects (other than for robust programs)
Studying complex social interventions

- Robust CSIs are amenable to RCTs to estimate mean effect sizes (and the strength of a small number of contextual influences)

- We prefer to study robust CSIs because “that’s where the light is”

- The value and applicability of methods for estimating “effectiveness” decreases with greater:
  - magnitude of contextual influences
  - degree of heterogeneity, variability of programs and settings

- and with decreases in the magnitude of the main effect
Developing insights and guidance for implementation

- How do I choose an appropriate implementation strategy given my context?
- How do I implement (deploy) that strategy to increase effectiveness?
- How do I adapt and customize that strategy to increase effectiveness (initially and over time)?
- How do I modify/manage the organization or setting to increase effectiveness (initially and over time)?
- How, why, when and where does it work?
Fidelity vs. adaptation

- Complex social interventions can be adapted and customized to increase effectiveness. 
  *They should be adapted and customized.*

- Organizations and settings can often be managed to increase effectiveness. 
  *They should be managed.*

- Implementation research should generate *guidance* for implementation as a process, in addition to (and often instead of) producing effect size estimates to guide one-time selection decisions.
Developing insights and guidance for implementation

Selecting research approaches, designs and methods

- Trials facilitate effectiveness estimates; observational studies facilitate study of barriers, facilitators, mechanisms, mediators, moderators
- Process evaluation can develop insights into mechanisms
- Theory-based evaluation, realistic evaluation, related approaches from program evaluation offer additional value
- Guidance in selecting, applying and further developing these approaches is needed
- Implementation strategies exist on a continuum; research approaches should be matched to their features
Other challenges to implementation & research

- Multi-level, multi-factor barriers, facilitators, mechanisms
- Need for multi-faceted strategies and continuous attention (vs. “that didn’t work; let’s try something else” and the quest for “the answer”)
- Leaders’ (and researchers’) limited influence over key levels
- Requirement for full engagement and partnerships
Guidance for implementation program evaluations: QUERI Service-Directed Project (SDP) Template

Motivation

- implementation projects are hybrid research/practice initiatives involving complex social/behavioral phenomena
- implementation projects require a unique set of design features, methods, skills and competencies

Goal of the SDP Template

- provide guidance in designing, conducting and documenting implementation trials
QUERI Service-Directed Project Template

A. Specific aims
   • Implementation and science aims (short-, long-term)
   • Hypotheses: intervention impacts and processes; conceptual model

B. Background and significance
   • Clinical issue (morbidity, mortality, burden)
   • Effective practice (clinical evidence): strength, acceptance, implementation gaps (magnitude, potential to close) (QUERI Steps 2, C, E, 3A)
   • Implementation processes: evidence, insights
C. Previous studies

- Current practices: determinants, barriers and facilitators to change
- Implementation strategy: appropriateness, theory basis, empirical evidence base and status (phase in 4-phase framework)
D. Design and methods

- Theoretical/conceptual framework and its basis
  - Plans for diagnostic analysis: practice determinants; barriers and facilitators to change
  - Discussion of key conditions, requirements for change
    - Legitimacy of clinical evidence
    - Motivation for change (expectations, pressure)
    - Norms (organizational, professional, consumer)
    - Clinician, staff, consumer education and skills
    - Financial, administrative, logistical and technical barriers and facilitators
D. Design and methods (continued)

- Theoretical/conceptual framework (continued)
  - Over-arching theoretical model/framework and specific logic/program model based on practice determinants and barriers/facilitators to practice change, e.g.,
    - Organizational delivery requires organization theory; individual clinician practices require theories from social psychology
    - Knowledge gap requires education
    - Gaps in practice norms, attitudes, beliefs require social influence
  - Implementation generally requires multi-level, multi-component programs rather than interventions
D. Design and methods (continued)

• Implementation program details and theoretical basis
  ○ Overview and list of key elements tied to theoretical framework
  ○ Details of operationalization of each element
    • education program design, delivery
    • social influence strategy
    • delivery system redesign; distinguish care model from change strategy (as applicable)
  ○ Formative evaluation, tailoring/adaptation, monitoring, refinement
QUERI SDP Template

D. Design and methods (continued)

- Usual care (comparison) condition
- Evaluation details
  - Experimental design (RCT, ITS, pre/post)
  - Sites, sampling, recruitment, randomization
  - Balance between internal and external validity (and artificial vs. real-world conditions): decisions regarding sites and sampling, implementation program delivery (e.g., staffing), etc.; driven, in part, by Phase 1 vs. 2 vs. 3 status of trial
D. Design and methods (continued)

- Evaluation details: impact evaluation
  - Outcomes (patient, system outcomes)
  - Contextual factors

- Evaluation details: formative/process evaluation
  - Identify mechanisms of impact and measures: variables, measures, data collection protocols
  - Influences on mechanisms: variables, measures, data
  - Analysis plans and methods

- Evaluation details: other
  - Sustainability, spread/scale-up potential and pathway
  - Economics
  - Clinical intervention effectiveness *(if hybrid E/I study)*
D. Design and methods (continued)

- Management plan
  - Intervention management plan
  - Evaluation management plan
  - Staff qualifications: intervention, evaluation