Design and Methods Challenges in Evaluating Dissemination and Implementation Programs

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Our mission and societal obligations

Healthcare professionals, policy leaders, delivery systems and researchers should endeavor to:

- Deliver high-quality, effective, appropriate care in a manner
  - appropriate to patient values and preferences, and
  - balancing benefits and harms, including physical, psychological and economic harms

- Recent economic conditions and healthcare reform have significantly increased pressure and interest in improving quality and affordability across all delivery settings and clinical domains
How are we doing?

Despite continued development and availability of effective practices and guidance, a large body of evidence reveals:

- Significant patterns of under-use of effective interventions (prevention, treatment, management)
- Considerable over-use of ineffective and inappropriate interventions (for which harms exceed benefits)
- An extensive list of “quality gaps” – underuse, overuse, misuse – requiring practice change (quality improvement, enhanced implementation)
Implementation research goals

1. Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies

2. Produce insights and generalizable knowledge regarding implementation processes, barriers, facilitators, strategies

3. Develop, test and refine implementation theories and hypotheses; methods and measures
How are we doing?

1. Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies: *not very well*

2. Produce insights and generalizable knowledge regarding implementation processes, barriers, facilitators, strategies: *reasonably well*

3. Develop, test and refine implementation theories and hypotheses; methods and measures: *not very well*
Implementation research goals

1. Develop reliable [effective] strategies for improving health-related processes and outcomes
   - Assumes “reliable strategies” can be developed or found

Unfortunately:
- Implementation outcomes are strongly influenced by contextual factors; implementation strategy main effects are often weak
- Implementation strategies and processes are strongly influenced by contextual factors, leading to significant variations across time and place
- Implementation strategy impacts are often indirect (mediated), and thus attenuated and variable
Impacts of implementation strategies:

Scenario A: Strong effects, moderate variance
Impacts of implementation strategies:

Scenario B: Strong effects, very low variance

Number of Sites

Increase in Adherence

-25 -20 -15 -10 -5 0 5 10 15 20 25 30 35 40 45 50 55 60 65
Impacts of implementation strategies:

Scenario C: Strong effects, high variance

![Bar chart showing increase in adherence with high variance](chart.png)
Impacts of implementation strategies:

Scenario D: Weak effects, very low variance

Number of Sites

Increase in Adherence
Impacts of implementation strategies:

Scenario E: Weak effects, high variance

Number of Sites

Increase in Adherence
Research approaches for studying context-dependent, time-varying, adaptable complex social interventions

- Selected quantitative approaches
  - standard regression analysis: covariates, interaction terms
  - mediation analysis: structural equation modeling

- Selected qualitative approaches
  - theory-based evaluation
  - realistic/realist evaluation
Key sources of heterogeneity, weak main effects, null findings

- Contextual factors affect implementation outcomes; main effects of the implementation strategy are often weak
  - Contextual influences (covariates)

- Contextual factors affect implementation (1) strategies and (2) processes (impacts) – leading to variation across time and place
  - Adaptive (and unstable) treatments (1)
  - Moderator effects (2)

- Implementation strategy impacts are often indirect (mediated), attenuated and variable
  - Mediator effects
Contextual, mediator, moderator effects

- External prof'l norms
- Opinion leader
- Education & training
- Leadership support
- Financial incentives
- Income, aspirations
- Leadership engagement
- Leadership support
- Motivation, activation
- Knowledge, skill
- Guideline adherence
- Adherence
- Attitudes, norms
- Knowledge, skill
- Motivation, activation
- External prof'l norms

Contextual influence

Impact, outcome

Leadership engagement

Opinion leader

Education & training

Guideline adherence

Leadership support

Motivation, activation

Knowledge, skill

Income, aspirations

Financial incentives

Implementation strategy

Contextual influence

Impact, outcome

Leadership engagement

Opinion leader

Education & training

Guideline adherence

Leadership support

Motivation, activation

Knowledge, skill

Income, aspirations

Financial incentives
Considerable guidance available (observational designs, interaction effects, propensity scores, etc.)

A moderator is a variable that affects the relationship between an independent and dependent variable.

Examples: income level/aspirations moderate the effect of financial incentives on clinician practices; budget, leadership and culture moderate the impact of a QI initiative on quality.

Evidence regarding moderator variables provides insights into variations in program effectiveness: where, when, why and for whom programs are effective.
Mediators and mediation

- A **mediator** is a variable that explains or carries the relationship between an independent and dependent variable.

\[
\begin{align*}
A & \rightarrow^{++} B \\
A & \rightarrow^{++} M \rightarrow^{++} B
\end{align*}
\]

- Example: leadership activation mediates the impact of a leadership engagement intervention on quality.

- Evidence regarding mediator relationships explains variations in program effectiveness, apparent weaknesses in effectiveness, and guides actions to increase effectiveness.
Moderators and mediators: selected references


Heterogeneity of treatment effects


Related concepts and published discussions

Personalized medicine, patient-centered outcomes research


Related concepts and published discussions

Adaptive trials

Related concepts and published discussions

Theory-based evaluation, realistic evaluation


Related concepts and published discussions

Theory-based evaluation, realistic evaluation

Generating, testing and refining program theories is “not a logical-deductive exercise. Rather, it is an interpretive task and will be achieved only through much negotiation and contestation.”

(Greenhalgh et al, 2009)

“Two practical lessons we have learnt through the project management plan include the need to ensure ... adequate time for discussion and debate, and developing flexible, yet transparent approaches for tracing iterative processes.”

(Jo Rycroft-Malone, 2010)
Related concepts and published discussions

Path analysis, structural equation modeling


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
- Strong mediator effects (indirect impacts)
- 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 of methods for estimating “effectiveness” is inversely related to:
  - the magnitude of contextual influences (vs. main effects)
  - the level of program heterogeneity and variability
Studying complex social interventions: What is our goal?

Two very different questions

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?

For many or most implementation strategies, Q1 is meaningless
Implications: Developing and using insights and guidance for implementation

- How do I choose an appropriate implementation strategy given my context?
- How do I implement (deploy) the strategy to increase effectiveness?
- How do I adapt and customize the 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?