Implementation Research to Reduce Disparities: Frameworks and Approaches

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Outline

Part 1: Introduction: Policy/practice foundations of implementation and implementation research

Part 2: Frameworks for implementation research

Part 3: Applying implementation research to reduce disparities and enhance equity
The need to accelerate implementation in health: Two streams of policy concern

• Stream 1 -- *translational roadblocks; implementation gap*
  barriers to rapid, efficient progression of innovations from basic science to clinical application to routine use

• Stream 2 -- *quality chasm*
  gaps in the quality, safety, equity, efficiency, timeliness and patient-centeredness of health care delivery
Stream 1: Translational roadblocks and inefficiency in health research

Basic / Lab Research → Clinical Research → Improved Health

Type 1 Translation

Type 2 Translation
The Implementation Gap (second translational roadblock)

- NIH recognition

Clinical Research to Clinical Practice — Lost in Translation?
Claude Lenfant, M.D.

- NIH Roadmap (June 2003+) and CTSA program

Translational and Clinical Science — Time for a New Vision
Elias A. Zerhouni, M.D.

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VÁQUERI
Investing in discovery/development vs. fidelity

The Break-Even Point: When Medical Advances Are Less Important Than Improving the Fidelity With Which They Are Delivered

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Steven H. Woolf, MD, MPH
Robert E. Johnson, PhD

ABSTRACT
Society invests billions of dollars in the development of new drugs and technologies but comparatively little in the fidelity of health care, that is, improving systems to ensure the delivery of care to all patients in need.
Stream #2: the “Quality Chasm”

- Institute of Medicine (1999, 2001)

- US and international quality measurement studies

The Quality of Health Care Delivered to Adults in the United States

Quality comparisons: VA vs. other US

Comparison of Quality of Care for Patients in the Veterans Health Administration and Patients in a National Sample

Steven M. Asch, MD, MPH; Elizabeth A. McGlynn, PhD; Mary M. Hogan, PhD; Rodney A. Hayward, MD; Paul Shekelle, MD, MPH; Lisa Rubenstein, MD; Joan Keesey, BA; John Adams, PhD; and Eve A. Kerr, MD, MPH

Diabetes Care Quality in the Veterans Affairs Health Care System and Commercial Managed Care: The TRIAD Study

Eve A. Kerr, MD, MPH; Robert B. Gerzoff, MS; Sarah L. Krein, PhD, RN; Joseph V. Selby, MD, MPH; John D. Piette, PhD; J. David Curb, MD, MPH; William H. Herman, MD, MPH; David G. Marrero, PhD; K.M. Venkat Narayan, MD, MSc, MBA; Monika M. Safford, MD; Theodore Thompson, MS; and Carol M. Mangione, MD, MSPH
Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services.

It includes the study of influences on healthcare professional and organizational behavior.

1. Develop and evaluate implementation programs
2. Study implementation processes, barriers, facilitators
3. Develop, test and refine implementation theories and hypotheses; methods and measures
Key terms and concepts

- diffusion vs. dissemination vs. implementation
- innovation, best practice, evidence-based practice
- clinical/health services intervention, implementation, implementation program or strategy
- quality improvement (QI)
- context
Implementation research vs. quality improvement research

Generally speaking…

• **implementation research** studies processes and strategies for increasing adoption, use of innovative, effective practices and research findings, whereas

• **quality improvement research** studies approaches for addressing quality problems (often – but not always – via implementation of effective, innovative practices)

Both fields encompass theory, research, policy and practice in organizational and professional behavior and behavior change
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1. Refined research-implementation pipeline: "Implementation research and clinical research"

- Basic Science
- Translational Pre-Clinical Research
- Clinical Science
- Clinical
- Health Behavior
- Health Behavior/Promotion Research
- Effective-ness Studies
- Implementation Research
- Improved Health Processes, Outcomes
- Health Services
- Health Services Research

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VA QUERI
Equity-related basic science, clinical science

• Behavioral science to understand fundamental human decision processes and behaviors (implicit biases, stereotypes), group decisions and behaviors, organizational structures and processes

• Health behavior/health education research to understand and change patient behavior
2. The *Classic* Six-Step QUERI Process

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<td>1.</td>
<td>Identify high risk/high burden conditions</td>
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<td>2.</td>
<td>Identify best practices</td>
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<td>3.</td>
<td>Define existing practice patterns in VA and variations from best practices</td>
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<td>4.</td>
<td>Identify (or develop) and implement programs to promote best practices</td>
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<td>5.</td>
<td>Document outcome and system improvements</td>
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<td>6.</td>
<td>Document improvements in health related quality of life</td>
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VA QUERI research-implementation pipeline: Pre-implementation and implementation studies

Efficacy Studies

- Clinical
- Health Behavior
- Health Services

Effectiveness Studies

Practice Guidelines

Observational studies of implementation

Document and diagnose gaps

Implementation Trials

Implementation research
Preparing for implementation: Observational *pre-trial* research

Step O: Observational Studies of Implementation

- natural experiments (policy initiatives, diffusion of innovation studies)
- focus on contextual influences, implementation (practice change) mechanisms, processes
- emphasize external over internal validity
- measure implementation (fidelity) and its influences within hybrid effectiveness-implementation studies
Preparing for implementation: Observational pre-implementation research

Step 3: Measure and Diagnose Quality/Performance Gaps

3A. measure existing practice patterns and outcomes and identify variations from evidence-based practices and benchmark outcomes (*quality, outcome and performance gaps*)

3B. identify determinants of current practices

3C. diagnose quality gaps

3D. identify barriers and facilitators to improvement
3. QUERI Four-Phase Implementation Research Framework

**Efficacy Studies**
- Clinical
- Health Behavior
- Health Services

**Effectiveness Studies**

**Observational studies of implementation**

**Implementation Trials**

**Implementation research**

**Document and diagnose gaps**

**Practice Guidelines**

**Phase 1**
Pilot Projects

**Phase 2**
Small-Scale Efficacy Trials

**Phase 3**
Large-Scale Effectiveness Trials

**Phase 4**
“Post-Marketing” Monitoring, Refinement
3. QUERI Four-Phase Implementation Research Framework

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<tr>
<th>Phase</th>
<th>Study Type</th>
<th>Form of Evaluation</th>
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<tr>
<td>Pre-trial</td>
<td>Program</td>
<td>Conceptual design of implementation program and underlying design (logic) model from theory, prior empirical research</td>
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<td>Phase 1</td>
<td>Pilot / Formative</td>
<td>Pilot test, assess feasibility, formative evaluation and refinement, develop intervention/evaluation protocols</td>
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<td>Phase 2</td>
<td>Efficacy</td>
<td>Small-scale rigorous trial in controlled settings with ongoing intervention support; emphasis on internal validity</td>
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<tr>
<td>Phase 3</td>
<td>Effectiveness</td>
<td>Large-scale rigorous trial under routine conditions in varied settings; emphasis on external validity</td>
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<tr>
<td>Phase 4</td>
<td>Monitoring</td>
<td>Ongoing monitoring and feedback</td>
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D. Design and methods (continued)

- Evaluation details: impact evaluation
  - outcomes (patient, system outcomes)
  - contextual factors
- Evaluation details: formative/process evaluation
  - describe mechanisms of impact
  - analysis plans (to explain mechanisms and variations)
- Evaluation details: other
  - sustainability, spread/scale-up potential and pathway
  - economics
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Implementation research and disparities/equity: pre-implementation studies

- Basic science, conventional HSR to study fundamental patterns of clinician/health system behavior
- “QUERI Step 3” to document and explain current practices and practice gaps (disparities); document barriers and facilitators to improvement
Implementation research and disparities/equity: pre-trial studies

• “QUERI Step O”: observational studies of natural experiments and policy/practice initiatives to improve equity
  – examine mechanisms, contextual influences

• “QUERI Step E” and hybrid effectiveness/implementation studies
  – assess “best practice” effectiveness in diverse routine care settings
  – examine determinants of variations in effectiveness and determinants of adoption/fidelity
Implementation research and disparities/equity: implementation trials

1. Implementation trials to improve quality across the board or for high-disparity areas of care ("rising tide"): broad-focus QI for CRC; QI programs to increase appropriateness of colonoscopy

2. Implementation trials to improve quality for under-served groups: QI to increase appropriate use of colonoscopy in under-served groups

3. QI / implementation trials addressing specific causes of disparities: multi-faceted programs to address clinician beliefs, patient activation and participation

For #3: distinguish effectiveness from implementation research; local implementation vs. scale-up/spread

Build on implementation science theory, conceptual frameworks