Developing an Integrated Implementation Research Agenda: Guidance from Prevailing Frameworks

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Mastering implementation science: key topics

1. What is implementation science? *(aims, scope)*
2. Why is it important? *(policy, practice, science goals)*
3. How does it relate to other types of health research?
4. What are the components of a comprehensive, integrated program of implementation research?
5. How does one plan, design, conduct and report different types of implementation research studies – and appropriately follow up?
Learning implementation science: key topics

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What is implementation research?  
*The usual story*

1. Clinical research produces new evidence, innovation
2. Initial efforts to promote implementation
3. Measurement of rates of adoption and implementation (quality) gaps
4. Research to develop and evaluate *implementation programs* to increase adoption

* quality improvement programs, practice change programs (interventions)
The implementation gap
(second translational roadblock)
Refined research-implementation pipeline

“Type 1” Translation

Pre-Clinical Translational Research

Innovation/Evidence Development

Clinical Research

“Type 2” Translation

Implementation Research

Improved Health Processes, Outcomes

Basic Science

Clinical Research

Implementation Research

Improved Health Processes, Outcomes
Refined research-implementation pipeline

Innovation/Evidence Development

“Type 2” Translation

Clinical Research

Implementation Research

Improved Health Processes, Outcomes
Clinical research (trials) vs. implementation research

<table>
<thead>
<tr>
<th>Study feature</th>
<th>Clinical research</th>
<th>Implementation research</th>
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</thead>
<tbody>
<tr>
<td>Study aim: evaluate a ...</td>
<td>clinical intervention</td>
<td>implementation strategy</td>
</tr>
<tr>
<td>Typical intervention</td>
<td>drug, procedure, therapy</td>
<td>clinician, organizational practice change</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>symptoms, health outcomes</td>
<td>adoption, adherence, fidelity</td>
</tr>
<tr>
<td>Typical unit of analysis, randomization</td>
<td>patient</td>
<td>clinician, team, facility</td>
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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.

Eccles and Mittman, 2006
Implementation science aims

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
The *Tower of Babel* problem

- Knowledge translation
- Translational research
- Research utilization
- Technology transfer
- Knowledge-to-action
- Dissemination research
- Quality improvement research
- Knowledge transfer and exchange
- Etc.
Implementation research vs. QI research

- QI often focuses on the “here and now” – immediate, local improvement needs via rapid-cycle, iterative improvement, addressing a quality problem.

- IS often attempts to develop, deploy and rigorously evaluate a fixed implementation strategy across multiple sites, emphasizing theory, contextual factors, (sometimes) mediators, moderators, mechanisms, addressing an implementation gap.

- IS aims to develop generalizable knowledge.
Refined research-implementation pipeline

Innovation/Evidence Development

“Type 2” Translation

Clinical Research

Implementation Research

Improved Health Processes, Outcomes
Gaps in the pipeline:
1. *Health behavior, health services research*
Gaps in the pipeline: 2. Effectiveness studies

- Efficacy studies
- Clinical
- Health Behavior
- Health Services
- Effective-ness Studies
- Implementation Research
- Guidelines, Evidence Syntheses
- Improved Health Processes, Outcomes
Gaps in the pipeline:

3. *Pre-implementation studies*

- Efficacy studies
- Clinical
- Health Behavior
- Health Services
- Effectiveness Studies
- Document and diagnose quality gaps
- Implementation Research
- Improved Health Processes, Outcomes
Expanded QUERI Six-Step Process

Step 3: Document and Diagnose Quality/Performance Gaps

3A. Measure existing practice patterns and outcomes across VHA 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
Gaps in the pipeline:
4. *Observational implementation studies*

- Efficacy studies
- Clinical
- Health Behavior
- Health Services
- Effective-ness Studies
- Document and diagnose quality gaps
- Implementation Practice
- Implementation Trials
- Improved Health Processes, Outcomes
Observational implementation studies

- Naturally-occurring (policy/practice-led) vs. artificial (researcher-led) implementation processes
- Maximize external validity
- Large sample sizes; maximize power to detect contextual influences
- Examine local adaptation processes and effects
Gaps in the pipeline:

5. Phased implementation trials
## QUERI Four-Phase Implementation Research Framework

<table>
<thead>
<tr>
<th>Phase</th>
<th>Study Type</th>
<th>Form of Evaluation</th>
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<tbody>
<tr>
<td>Pre-trial</td>
<td>Program design</td>
<td>Conceptual design of implementation program and underlying (logic) model from theory, prior empirical research</td>
</tr>
<tr>
<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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<tr>
<td>Phase 2</td>
<td>Efficacy</td>
<td>Small-scale rigorous trial in controlled settings with ongoing intervention support; emphasis on internal validity</td>
</tr>
<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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