Applying Implementation Science to Improve Care

March 24, 2015
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Outline

Part 1: Introduction, motivation

Part 2: Policy/practice foundations

Part 3: Implementation science frameworks

Part 4: Key resources, implications, conclusions
What is implementation research?

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

* quality improvement programs, practice change programs (interventions)
Effects of Controlled-Release Metoprolol on Total Mortality, Hospitalizations, and Well-being in Patients With Heart Failure
The Metoprolol CR/XL Randomized Intervention Trial in Congestive Heart Failure (MERIT-HF)

Conclusions In this study of patients with symptomatic heart failure, metoprolol CR/XL improved survival, reduced the need for hospitalizations due to worsening heart failure, improved NYHA functional class, and had beneficial effects on patient well-being.

JAMA. 2000;283:1295-1302

www.jama.com
Chapter 2. *Advocacy for adoption*

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**JAMA**

*The Journal of the American Medical Association*

**Vol. 283 No. 10, March 8, 2000**

**Editorial**

**β-Blocker Therapy for Heart Failure**

*The Evidence Is In, Now the Work Begins*

Robert M. Califf, MD; Christopher M. O'Connor, MD

Chapter 2. Guidance for adoption

ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): Developed in Collaboration With the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: Endorsed by the Heart Rhythm Society


Circulation 2005;112:e154-e235; originally published online Sep 13, 2005;
Chapter 2. Medical society, healthcare system support for adoption

- American Heart Association “Get with the Guidelines”
- VA/DoD guideline development, implementation
- Kaiser Permanente, HealthPartners, other private systems

Adherence to Heart Failure Quality-of-Care Indicators in US Hospitals

Analysis of the ADHERE Registry Arch Intern Med. 2005;165:1469-1477

Gregg C. Fonarow, MD; Clyde W. Yancy, MD; J. Thomas Heywood, MD; for the ADHERE Scientific Advisory Committee, Study Group, and Investigators

Trends and inequities in beta-blocker prescribing for heart failure

Sunil M Shah, Iain M Carey, Stephen DeWilde, Nicky Richards and Derek G Cook

British Journal of General Practice, December 2008
Clinical Reminders Attached to Echocardiography Reports of Patients With Reduced Left Ventricular Ejection Fraction Increase Use of β-Blockers
A Randomized Trial

Paul A. Heidenreich, MD, MS; Parisa Gholami, MPH; Anju Sahay, PhD;
Barry Massie, MD; Mary K. Goldstein, MD, MS

Conclusions—A reminder attached to the echocardiography report increased the use of β-blockers in patients with depressed left ventricular systolic function. (Circulation. 2007;115:2829-2834.)
What is implementation research?

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

*Effectiveness of implementation and QI programs varies, but is generally low*
Outline

Part 1: Introduction, motivation

- Part 2: Policy/practice foundations
  - Translational roadblocks; implementation gap
  - Quality chasm

Part 3: Implementation science frameworks

Part 4: Key resources, implications, conclusions
The Clinical Research Crisis

- AAMC Clinical Research Summit: Clinical Research: A National Call to Action (Nov 1999)
Translational research

Basic Science  →  Clinical Research

Type 1 Translation  

Type 2 Translation  

Improved Health Processes, Outcomes
Translational research

- **Basic Science**
- **Pre-Clinical/Translational Research**
- **Clinical Research**
- **Implementation Research**

**Type 1 Translation**

**Type 2 Translation**

Improved Health Processes, Outcomes
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
The *Tower of Babel* problem

- Knowledge translation, translational research
- Research utilization, knowledge utilization
- Knowledge-to-action, knowledge transfer & exchange
- Technology transfer
- Dissemination research
- Quality improvement research, improvement science
- Delivery system science
- T-1, T-2, T-3, T-4
- Etc.
The “Quality Chasm”

- Institute of Medicine (1999, 2001)

- Quality “report cards” (US, international)
Implementation science, improvement science, delivery system science

- QI often focuses on the “here and now,” addressing a specific quality gap via rapid-cycle, iterative improvement
- IS often attempts to close an implementation gap by developing and rigorously evaluating a fixed implementation strategy across multiple sites, emphasizing theory, contextual factors, (sometimes) mediators, moderators, mechanisms
- Delivery system science is the “basic science” of implementation and improvement, examining the structure, operation and impacts of delivery systems and delivery system arrangements
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Gaps in the pipeline: *Efficacy vs. effectiveness studies*

Clinical Research (Clinical, behavioral, services)

Efficacy Studies → Effectiveness Studies → Implementation Research

Improved Health Processes, Outcomes
# Clinical research 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>Aim: evaluate a / an ...</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>Typical outcomes</td>
<td>symptoms, health outcomes, patient behavior</td>
<td>adoption, adherence, fidelity</td>
</tr>
<tr>
<td>Typical unit of analysis, randomization</td>
<td>patient</td>
<td>clinician, team, facility</td>
</tr>
</tbody>
</table>
Combining phases: *Hybrid effectiveness-implementation designs*

Clinical Research
(Clinical, behavioral, services)

- Efficacy Studies
- Effectiveness Studies
- Implementation Research

Improved Health Processes, Outcomes

E-I Hybrid Type 1
E-I Hybrid Type 2
E-I Hybrid Type 3
Gaps in the pipeline: Evidence syntheses, guidelines

Clinical Research (Clinical, behavioral, services)

- Efficacy Studies
- Effectiveness Studies

Implementation Research

Guidelines, Evidence Syntheses

Improved Health Processes, Outcomes
Gaps in the pipeline: 
**Pre-implementation studies**
*(document, diagnose quality/implementation gaps)*
Gaps in the pipeline: 
**Observational implementation studies**

- Clinical Research
  - Efficacy Studies
  - Effectiveness Studies

- Quality/impl gap dx

- Implementation Research

- Observational

- Implementation Research

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: *Phased implementation trials*

- **Phase 1**: Pilot Projects
- **Phase 2**: Efficacy Trials
- **Phase 3**: Effectiveness Trials
- **Phase 4**: "Post-Marketing"

Improved Health Processes, Outcomes
### Gaps in the pipeline: Phased implementation trials

<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>
</tr>
</tbody>
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US, international resources

- NIH grant funding, review committee, training programs
- Journals: Implementation Science, Translational Behavioral Medicine, special issues of general and specialty journals
- NIH CTSAs (selected), PBRNs (AHRQ, other), VA QUERI, NIH-funded Dental PBRN
- Patient-Centered Outcomes Research Institute (PCORI), AAMC Research on Care Community (ROCC)
- Knowledge Translation Canada, other CIHR programs
Critical resources

- Practice-based research network or other “laboratory”
- Fully engaged stakeholders
- Partnerships and partnership research approaches
- Social/behavioral science expertise
- Management/leadership skills, training, aptitude: local, regional, national policy/practice engagement
- Academic recognition