UCLA CTSI

Part 1: Introduction to Implementation Science

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Outline

- Part 1: Introduction: overview of implementation science
- Part 2: Policy/practice foundations
- Part 3: Implementation science frameworks
Increased investment and activity in implementation and implementation research are critical to achievement of key societal goals in health and health care:

- Reducing gaps in quality and outcomes:
  - quality of life; excess mortality, morbidity;
  - gender/racial equity, use of effective care and prevention
- Improving efficiency, reducing cost
- Addressing obesity, substance abuse, etc.
What is implementation research?

1. Development of 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 (or QI) programs to increase implementation

The next few slides illustrate this sequence for a key innovation in heart failure treatment
Phase 1. New evidence

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
Phase 2. Advocacy for adoption

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

Phase 2. Guidance for adoption
Phase 2. *Incentives for adoption*
Phase 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
Phase 4. Trials of implementation programs

Improving Guideline Adherence: A Randomized Trial Evaluating Strategies to Increase β-Blocker Use in Heart Failure
Maria Ansari, Michael G. Shlipak, Paul A. Heidenreich, Denise Van Ostaeyen, Elizabeth C. Pohl, Warren S. Browner and Barry M. Massie
*Circulation* 2003;107:2799-2804; originally published online May 19, 2003;
Phase 4. Trials of implementation programs

Health Services and Outcomes Research

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. Development of new evidence, innovation
2. Initial efforts to promote implementation
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4. Research to develop and evaluate implementation (or QI) programs to increase implementation

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

Part 1: Introduction: overview of implementation science

➤ Part 2: Policy/practice foundations

Part 3: Implementation science frameworks
Policy/practice foundations of implementation, implementation research

1. The implementation gap

2. The quality chasm
The implementation gap
(second translational roadblock)
Refined research-implementation pipeline: 
*Implementation research and clinical research*

- **Basic Science**
- **Pre-Clinical Translational Research**
- **Clinical Research**
- **Innovation/Evidence Development**
- **Implementation Research**
- **Improved Health Processes, Outcomes**

**“Type 1” Translation**

**“Type 2” Translation**
The **Implementation Gap:**
A component of the *Clinical Research Crisis*

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


*Central Challenges Facing the National Clinical Research Enterprise*  
*JAMA. 2003;289:1278-1287*

*Clinical Research in the United States at a Crossroads*  
*Proposal for a Novel Public-Private Partnership to Establish a National Clinical Research Enterprise*  
*JAMA. 2004;291:1120-1126*
The “Quality Chasm” in US healthcare delivery

- 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 Keseys, 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
Outline

Part 1: Introduction: overview of implementation science

Part 2: Policy/practice foundations

- Part 3: Implementation science frameworks

Part 4: Overview of program
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 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
Implementation research frameworks: Planning, designing, conducting, reporting

1. Pipeline diagrams *(and gaps)*

2. QUERI six-step process *(pre-implementation, implementation)*

3. QUERI 4-phase framework *(phased trials)*

4. SDP template *(not covered today)*
Refined research-implementation pipeline: *Implementation research and clinical research*
Gaps in the pipeline: Effectiveness and Hybrid E-I studies

- Efficacy studies
  - Clinical
- Health Behavior
- Health Services

- Effective-ness Studies
- Implementation Research

- Hybrid effectiveness-implementation studies

- Guidelines, Evidence Syntheses
- Improved Health Processes, Outcomes
Gaps in the pipeline: Pre-implementation studies

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

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

Step M: Develop measures, methods and data resources

Step C: Develop clinical evidence, effective practices

Step E: Effectiveness studies
Annotated QUERI Six-Step Process

Step 1: Select Diseases/Conditions/Patient Populations

1A. Identify and prioritize (via a formal ranking procedure) high risk/high burden clinical conditions

1B. Identify high priority clinical practices/outcomes within a selected condition

Step 2: Identify Evidence-Based Guidelines/Recommendations

2A. Identify evidence-based clinical practice guidelines and recommendations

2B. Identify evidence-based clinical practices

Prioritize recommendations for implementation (based on gap, importance for outcomes, feasibility of improvement)
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: *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
Annotated QUERI Six-Step Process

Step 4: Implement Improvement Programs

4A. Identify quality improvement strategies, programs and program components or tools to address quality gaps (e.g., via literature reviews)

4B. Develop or adapt quality improvement strategies, programs, program components or tools (e.g., educational resources, decision support tools)

4C. Implement quality improvement strategies and programs

Step 5/6: Evaluate Improvement Programs

5. Assess improvement program feasibility, implementation and impacts on patient, family and system outcomes

6. Assess improvement program impacts on health related quality of life (HRQOL)
Gaps in the pipeline: Phased implementation trials

Efficacy studies

Clinical

Health Behavior

Health Services

Effectiveness Studies

Document and diagnose quality gaps

Implementation Practice

Improved Health Processes, Outcomes

Phase 1 Pilot Projects

Phase 2 Small-Scale Efficacy Trials

Phase 3 Large-Scale Effectiveness Trials

Phase 4 “Post-Marketing” Monitoring, Refinement
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<thead>
<tr>
<th>Phase</th>
<th>Study Type</th>
<th>Form of Evaluation</th>
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<tbody>
<tr>
<td>Pre-trial</td>
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<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; 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; 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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