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Quality Enhancement Research Initiative

Achieving the Promise of CER: The Role of Implementation Science

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June 8, 2010

Implementation Science is integral to CER: it is critical for achievement of the CER initiative's policy, practice and research goals.

This presentation describes three specific roles for Implementation Science to explain and support this argument.

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The role of implementation science in CER

1. Implementation science to support implementation of CER findings
2. Integration of implementation research activities into CER studies
3. Applying implementation science principles to CER studies comparing “delivery system interventions”

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Outline

Part 1: The importance of implementation and implementation science in achieving CER goals

Part 2: Integrating implementation research into CER

Part 3: Applying implementation science principles to CER on healthcare delivery systems/interventions

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The need to accelerate implementation: Two streams of policy concern

- Stream 1 -- *translational roadblocks*

  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

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Stream 1: The Implementation Gap and *Clinical Research Crisis*

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

- IoM Clinical Research Roundtable (2000-2004)

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*

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The Implementation Gap: A component of the *Clinical Research Crisis*

- NIH recognition


SHATTUCK LECTURE

Clinical Research to Clinical Practice — Lost in Translation?

Claude Lenfant, M.D. N Engl J Med 2003;349:868-74.

- NIH Roadmap (June 2003+) and CTSA program


Translational and Clinical Science — Time for a New Vision

Elias A. Zerhouni, M.D. N ENGL J MED 353;15 WWW.NEJM.ORG OCTOBER 13, 2005

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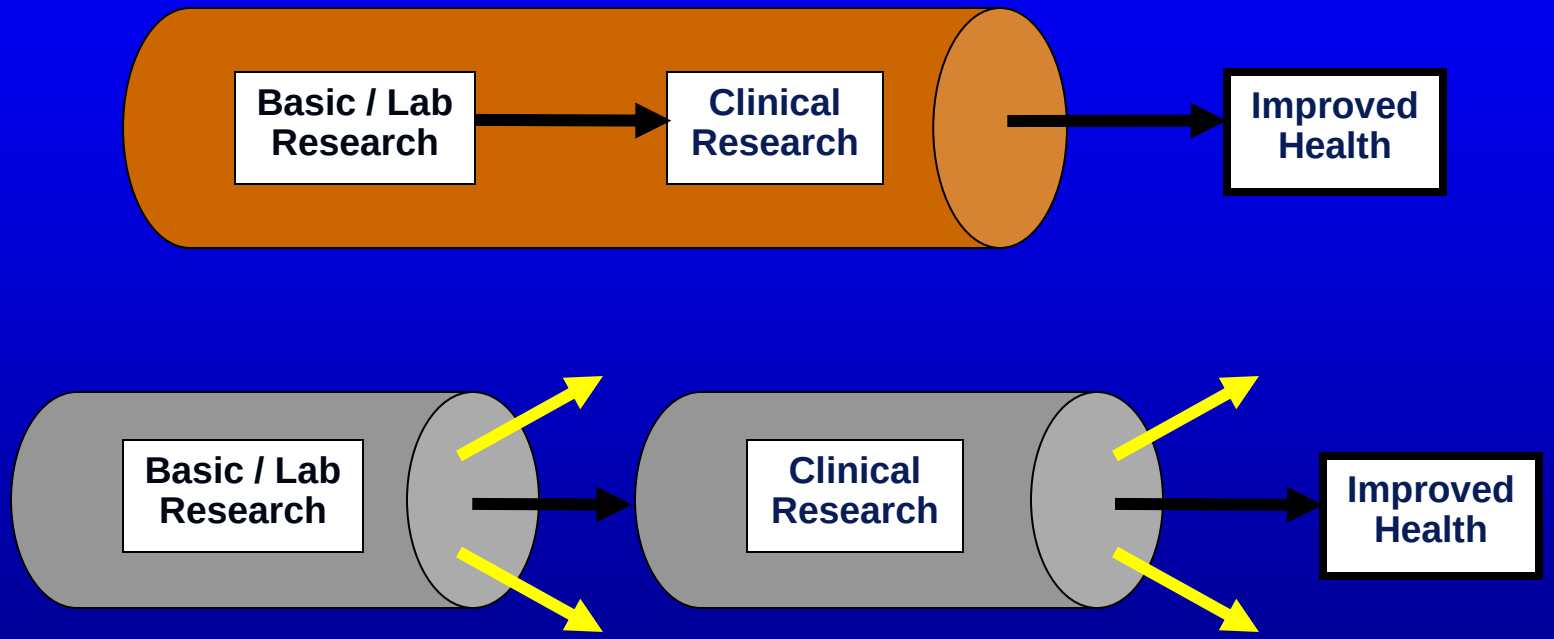
Translational roadblocks and inefficiency in health research: simplified depiction



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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

ANNALS OF FAMILY MEDICINE • WWW.ANNFAMMED.ORG • VOL. 3, NO. 6 • NOVEMBER/DECEMBER 2005

Steven H. Woolf, MD, MPH[1]

Robert E. Johnson, PhD[2]

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.

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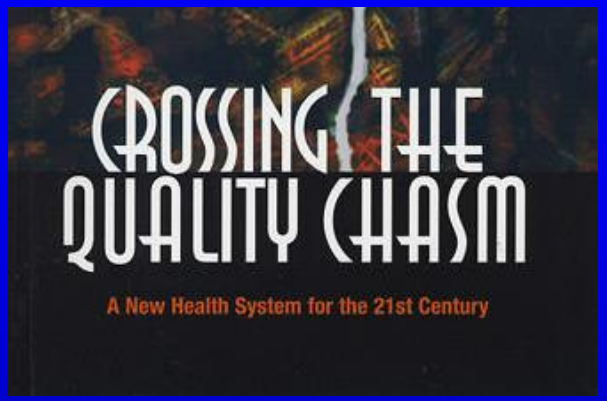
Stream 2: The Quality Chasm in healthcare delivery

- Institute of Medicine (1999, 2001)



- US and international quality measurement studies

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

Elizabeth A. McGlynn, Ph.D., Steven M. Asch, M.D., M.P.H., John Adams, Ph.D., Joan Keesey, B.A., Jennifer Hicks, M.P.H., Ph.D., Alison DeCristofaro, M.P.H., and Eve A. Kerr, M.D., M.P.H. N Engl J Med 2003;348:2635-45.

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Quality comparisons: VA vs. other US

Ann Intern Med. 2004;141:938-945.

IMPROVING PATIENT CARE

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

Ann Intern Med. 2004;141:272-281.

IMPROVING PATIENT CARE

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

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Implementation research definition

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

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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

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To succeed the CER initiative requires
(1) development of valid, useful CER findings,
(2) widespread adoption and implementation
of these findings

CER findings are not self-implementing

CER implementation requires implementation
research

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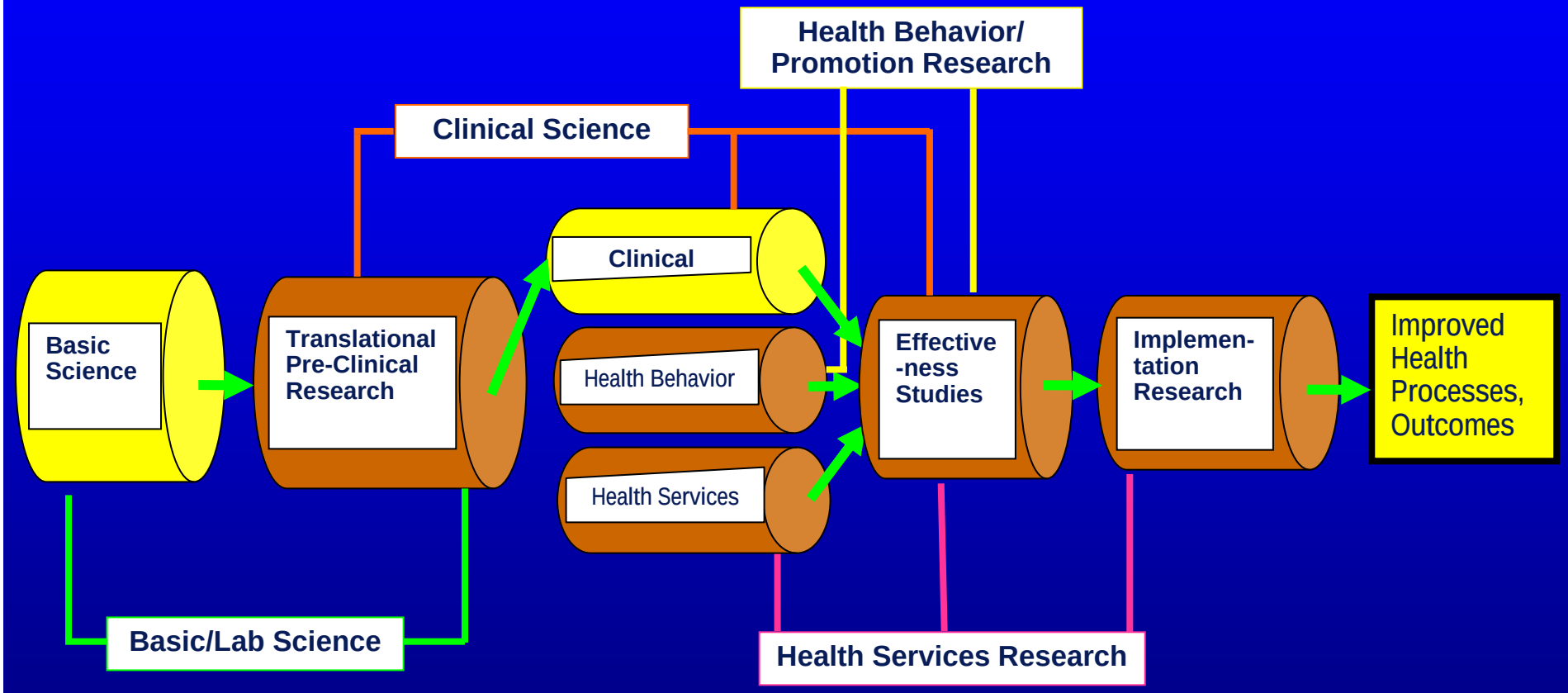
1. Refined research-implementation pipeline: *Implementation research* and *clinical research*



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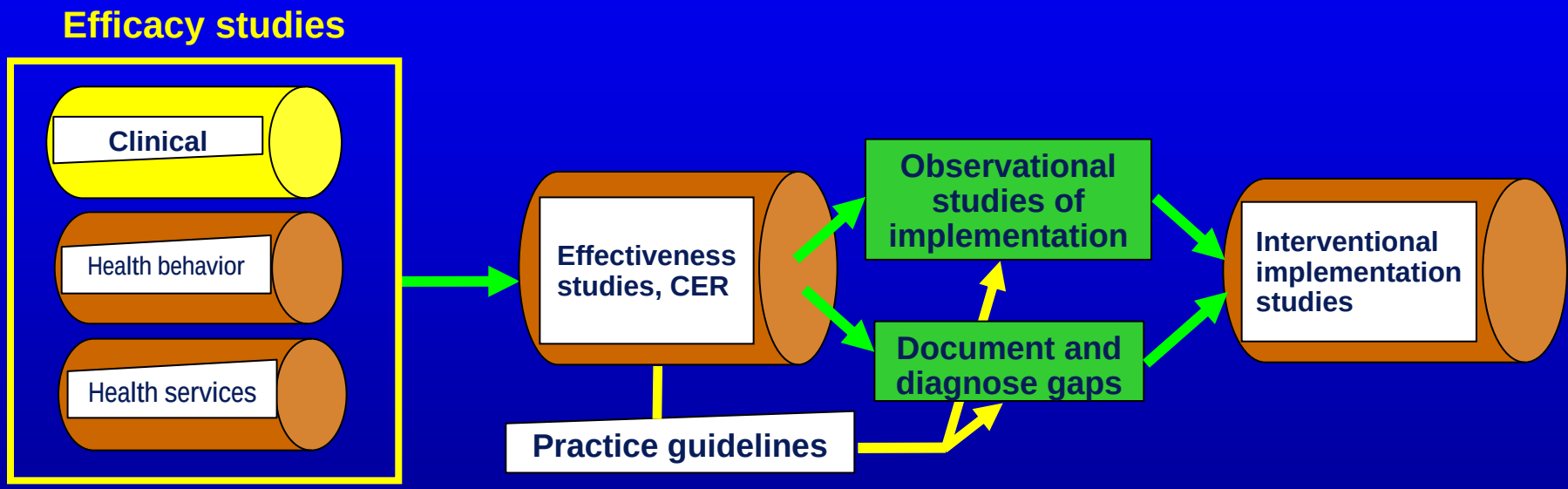
VA QUERI research-implementation pipeline: Pre-implementation studies



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Transitioning from effectiveness to implementation research

- The standard, simplified *pipeline* places effectiveness research (and guideline development) as separate from, and prior to, implementation research … it assumes that findings/guidelines are "handed off" to implementation researchers
- Effectiveness studies offer an ideal opportunity for early (pre-) implementation research: document current practices and identify determinants, diagnose quality gaps, assess acceptance and barriers/facilitators to adoption of new findings/guidelines

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Hybrid effectiveness-implementation studies: selected examples

1. Standard effectiveness trial (comparing clinical treatments) plus assessment of barriers/facilitators to adoption
2. Standard effectiveness trial plus focused (non-randomized) implementation activities with pilot study-type evaluation
3. Implementation trial (comparing implementation programs) with patient outcome data collection and analysis (effectiveness)

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Comparative effectiveness studies of *complex social interventions*

Two very different questions

1. Does it work? What is the *effect size*?
   Should I use it or not? (formulary decision)

2. How, when, why and where does it work?
   What factors (contextual) influence effectiveness?
   How should I use it?

Impact- vs. mechanism-oriented research

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Implementation science and comparative effectiveness studies of delivery systems

- Delivery system interventions are complex social interventions
- Delivery system interventions do not have an inherent property of effectiveness that can be estimated
- CER studies of delivery interventions should follow implementation science principles and frameworks, emphasizing process (vs. impact) evaluation, mechanisms and processes vs. “effectiveness,” contextual factors, etc.

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