*Enhancing Implementation Science in VA 2012, Introductory Program*

# 1: Introduction to Implementation Science in VA

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May 3, 2012

# Outline

➢ Part 1:  Introduction: overview of implementation science

Part 2:  Policy/practice foundations

Part 3:  Implementation science frameworks

Part 4:  Overview of EIS 2012 Introductory Program

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.

# Poll question

Please indicate your primary affiliation and role; select one

- VA clinician researcher
- VA social scientist researcher
- *Non-VA* clinician researcher
- *Non-VA* social scientist researcher
- Non-researcher, VA
- Non-researcher , non-VA

# Poll question

If you are a researcher, please indicate your primary research focus:

- Basic science / lab research
- Clinical research (study drugs, devices, health promotion programs)
- Health services researcher (study health service use, costs, quality, accessibility, delivery, organization, financing, outcomes)
- Implementation researcher

# Poll question

Please indicate your highest role to date in implementation research:

- Principal investigator

- Co-investigator / consultant

- I have watched colleagues conduct implementation research

- None

# 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.

# Phase 2.  *Advocacy* for adoption

## 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

Sharon Ann Hunt, William T. Abraham, Marshall H. Chin, Arthur M. Feldman, Gary S. Francis, Theodore G. Ganiats, Mariell Jessup, Marvin A. Konstam, Donna M. Mancini, Keith Michl, John A. Oates, Peter S. Rahko, Marc A. Silver, Lynne Warner Stevenson, Clyde W. Yancy, Elliott M. Antman, Sidney C. Smith, Jr, Cynthia D. Adams, Jeffrey L. Anderson, David P. Faxon, Valentin Fuster, Jonathan L. Halperin, Loren F. Hiratzka, Sharon Ann Hunt, Alice K. Jacobs, Rick Nishimura, Joseph P. Ornato, Richard L. Page and Barbara Riegel

# Phase 2. *Incentives* for adoption

**Circulation**

**ACC/AHA Clinical Performance Measures for Adults With Chronic Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Heart Failure Clinical Performance Measures): Endorsed by the Heart Failure Society of America**

Robert O. Bonow, Susan Bennett, Donald E. Casey, Jr, Theodore G. Ganiats, Mark A. Hlatky, Marvin A. Konstam, Costas T. Lambrew, Sharon-Lise T. Normand, Ileana L. Pina, Martha J. Radford, Andrew L. Smith, Lynne Warner Stevenson, Robert O. Bonow, Susan J. Bennett, Gregory Burke, Kim A. Eagle, Harlan M. Krumholz, Costas T. Lambrew, Jane Linderbaum, Frederick A. Masoudi, Sharon-Lise T. Normand, James L. Ritchie, John S. Rumsfeld and John A. Spertus

# 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

# Phase 3. Measurement of adoption rates
## (US 2002-03; UK 2005)

## 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 ß-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

# 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

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3. Measurement of rates of adoption and implementation (quality) gaps

4. Research to develop and evaluate *implementation (or QI) programs* to increase implementation

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

# Barriers to implementation research progress?

- Lack of rigor; limited internal validity; too few RCTs

- Limited external validity; too many RCTs (or too many flawed RCTs); use of "black box" evaluation approaches

- Lack of theory; lack of appropriate theory

- Too many theories; lack of guidance in using theory

- Implementation phenomena are extraordinarily complex (simple vs. complex vs. wicked problems)

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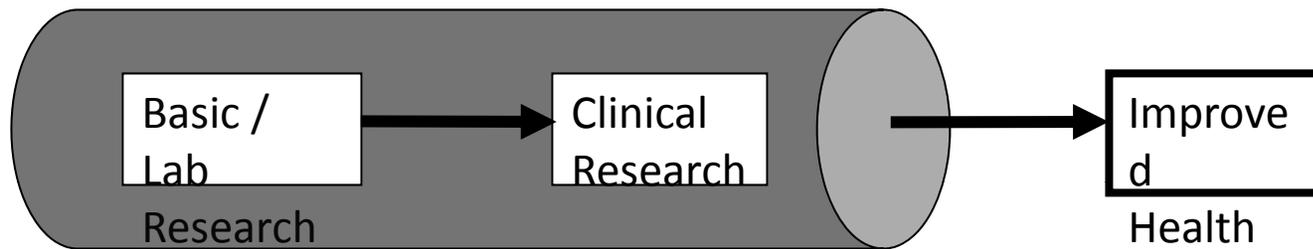
Part 3:  Implementation science frameworks
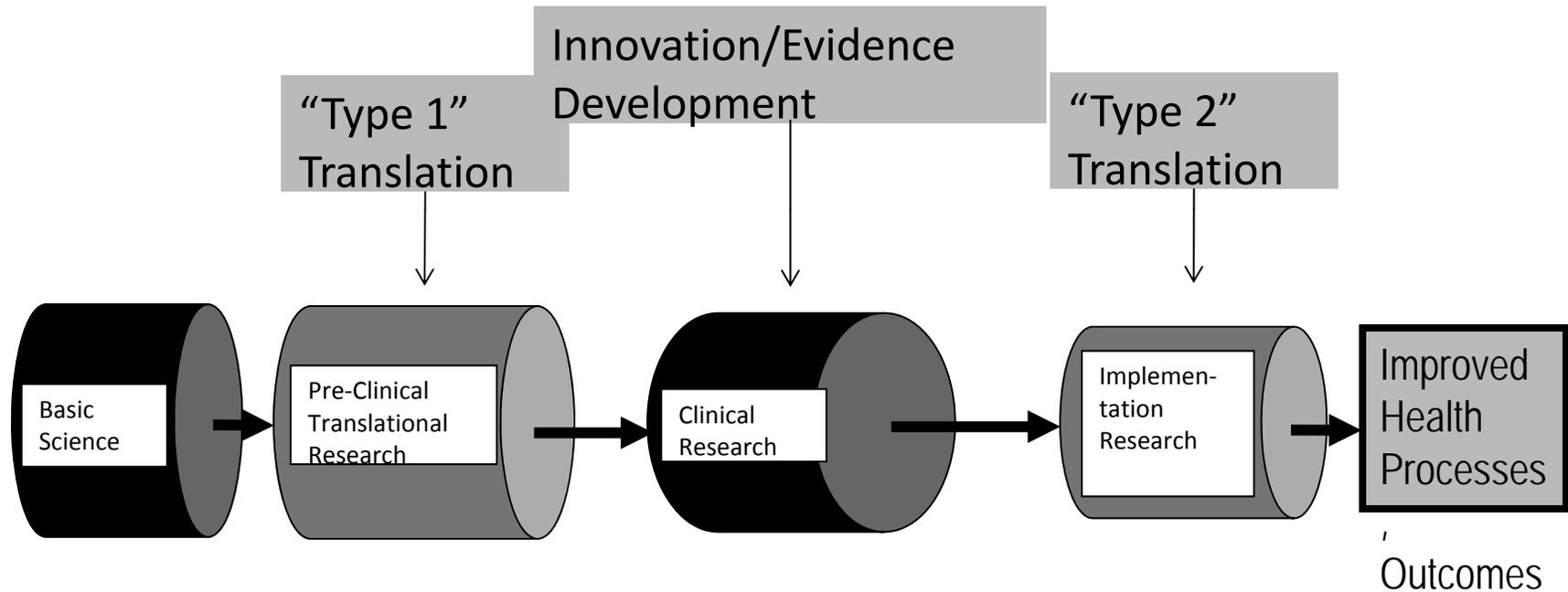
Part 4:  Overview of EIS 2012 Introductory Program

# 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*

# The <u>Implementation Gap</u>:
## A component of the *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*

# 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

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.

# Quality comparisons: VA vs. other US

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

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 <u>health services</u>.

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*
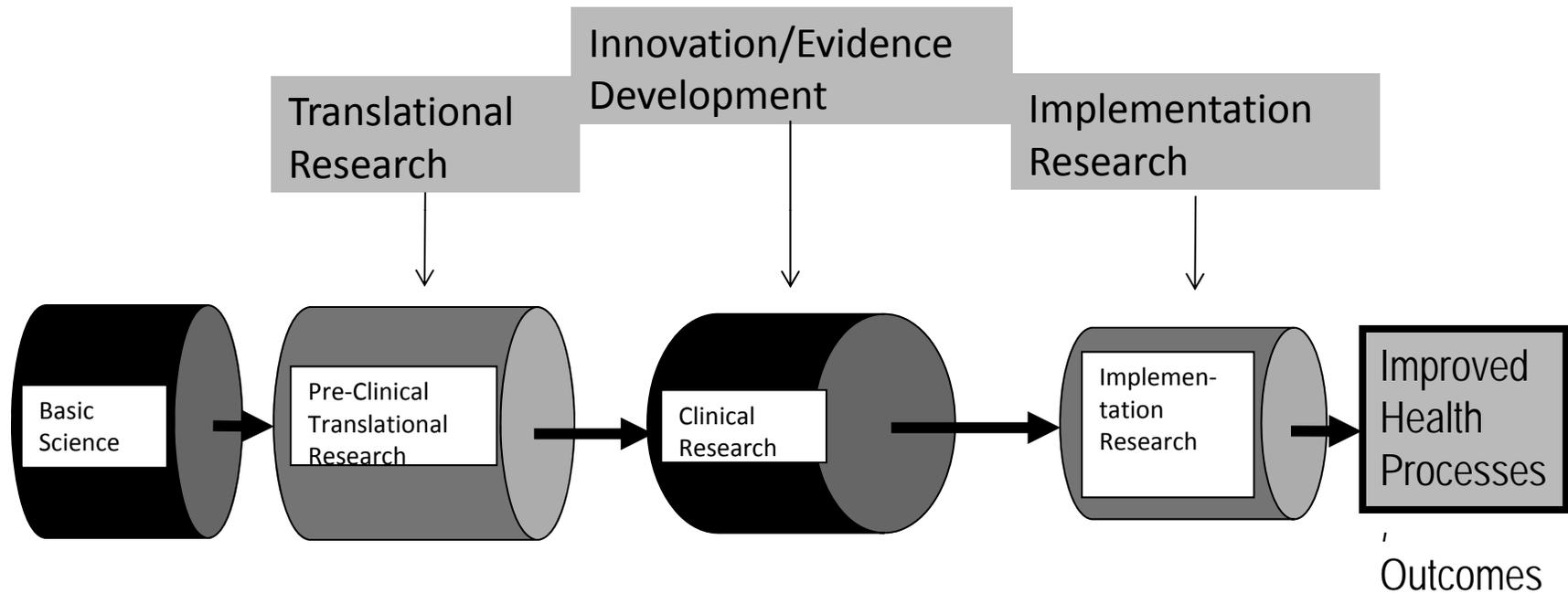
# Gaps in the pipeline:
## *Effectiveness and Hybrid E-I studies*

Efficacy studies

Clinical

Hybrid effectiveness-
implementation studies

Health Behavior

Health Services

Effective-
ness
Studies

Implemen-
tation
Research

Improved Health
Processes,
Outcomes

Guidelines,
Evidence
Syntheses
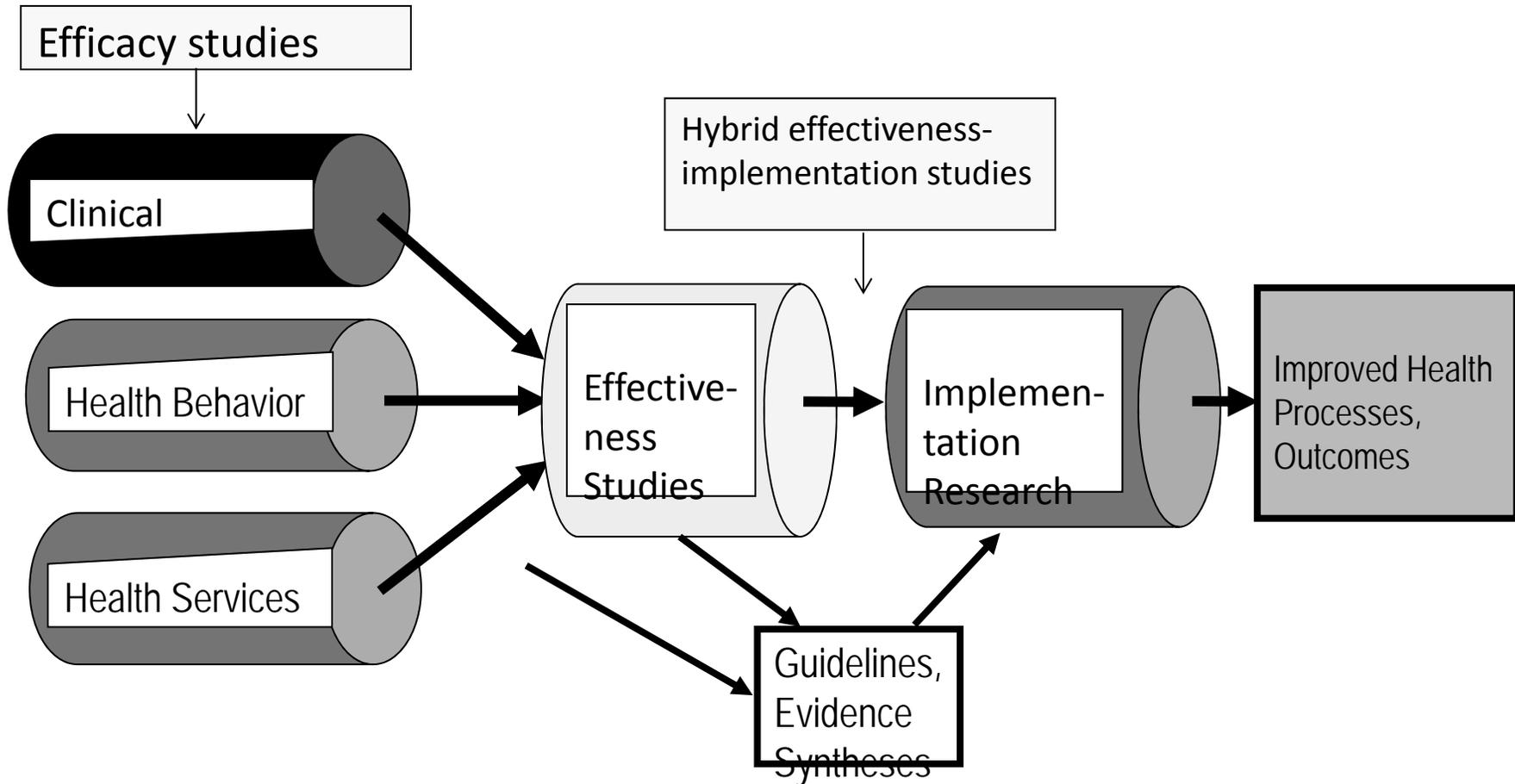
# Gaps in the pipeline:
## *Pre-implementation studies*
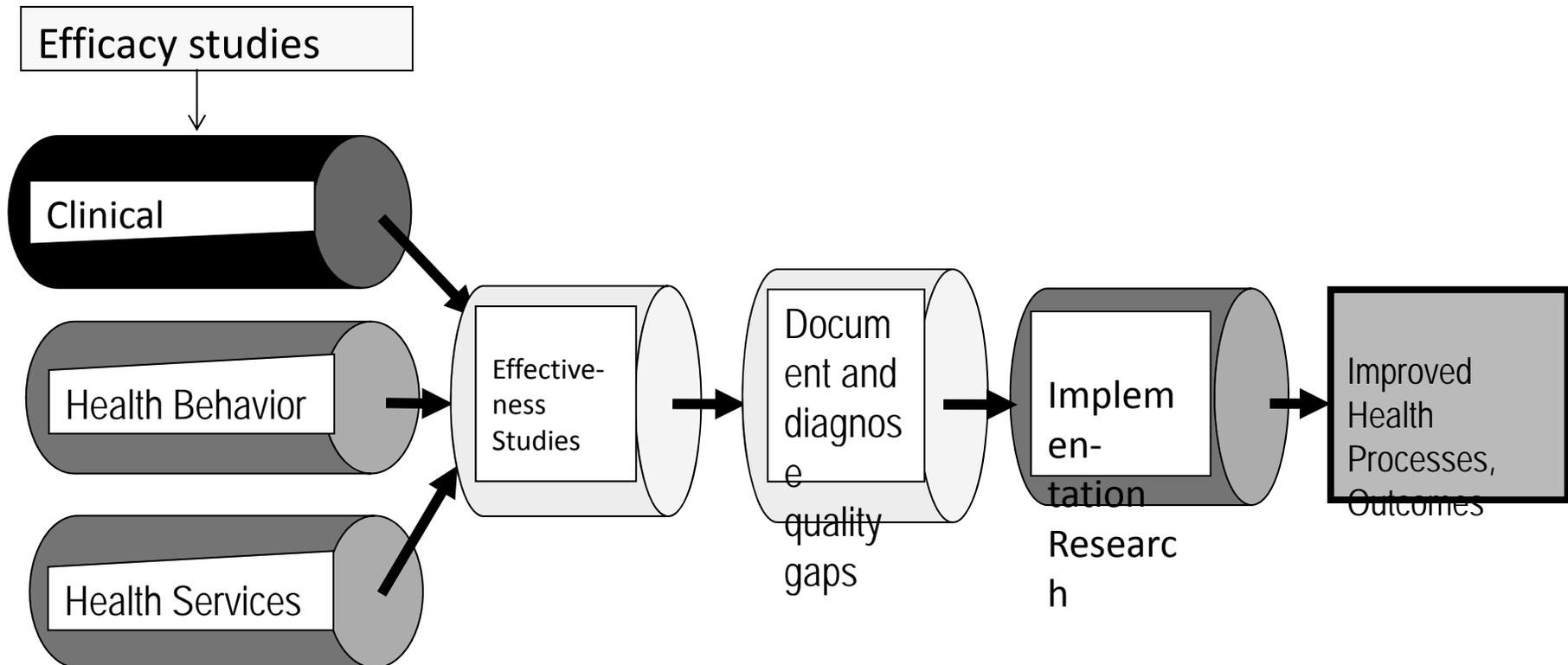
# The *Classic* Six-Step QUERI Process

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

Implem-en-tation Practice

Implem-en-tation Trials

Improved Health Processes, Outcomes
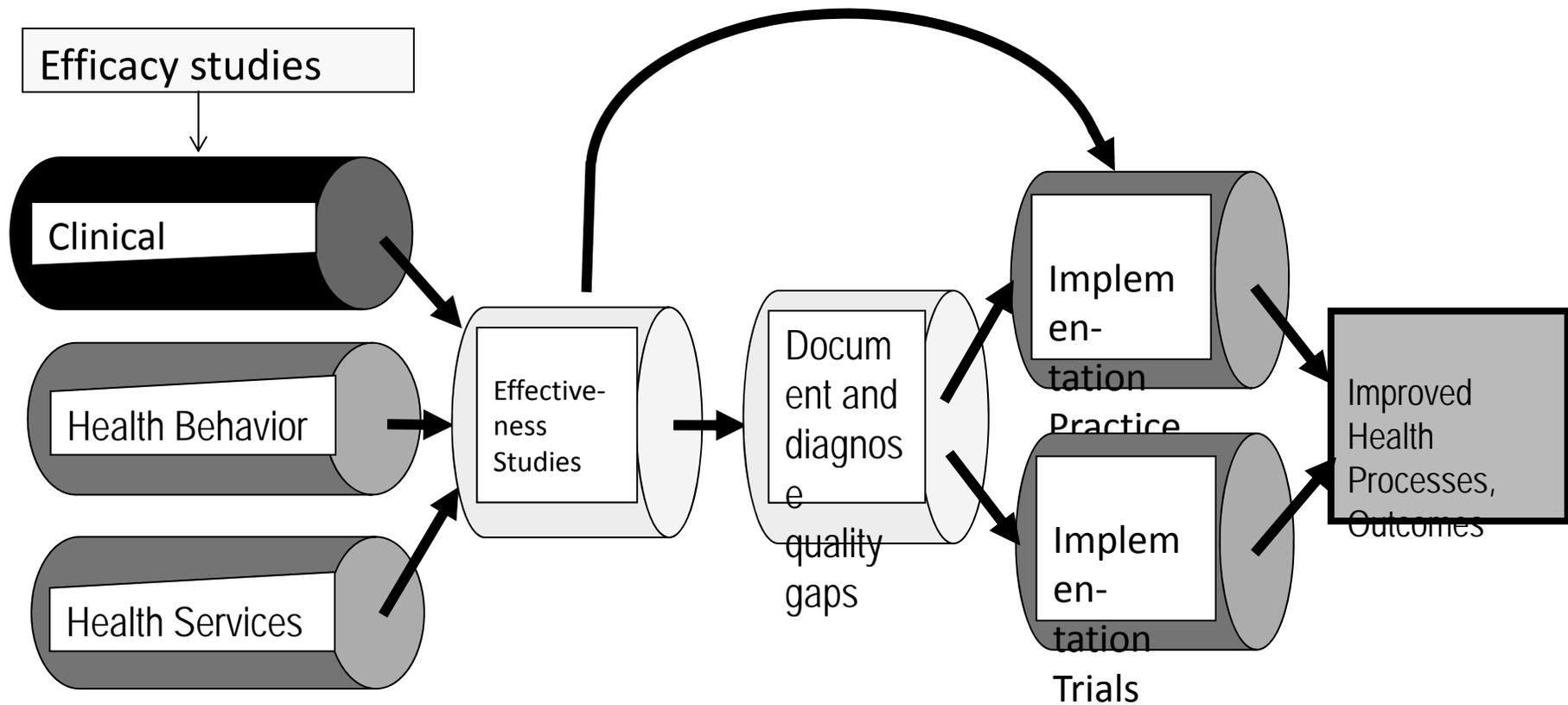
# Observational studies of implementation processes (QUERI Step O)

- Internal vs. external validity
- Artificial vs. real-world conditions
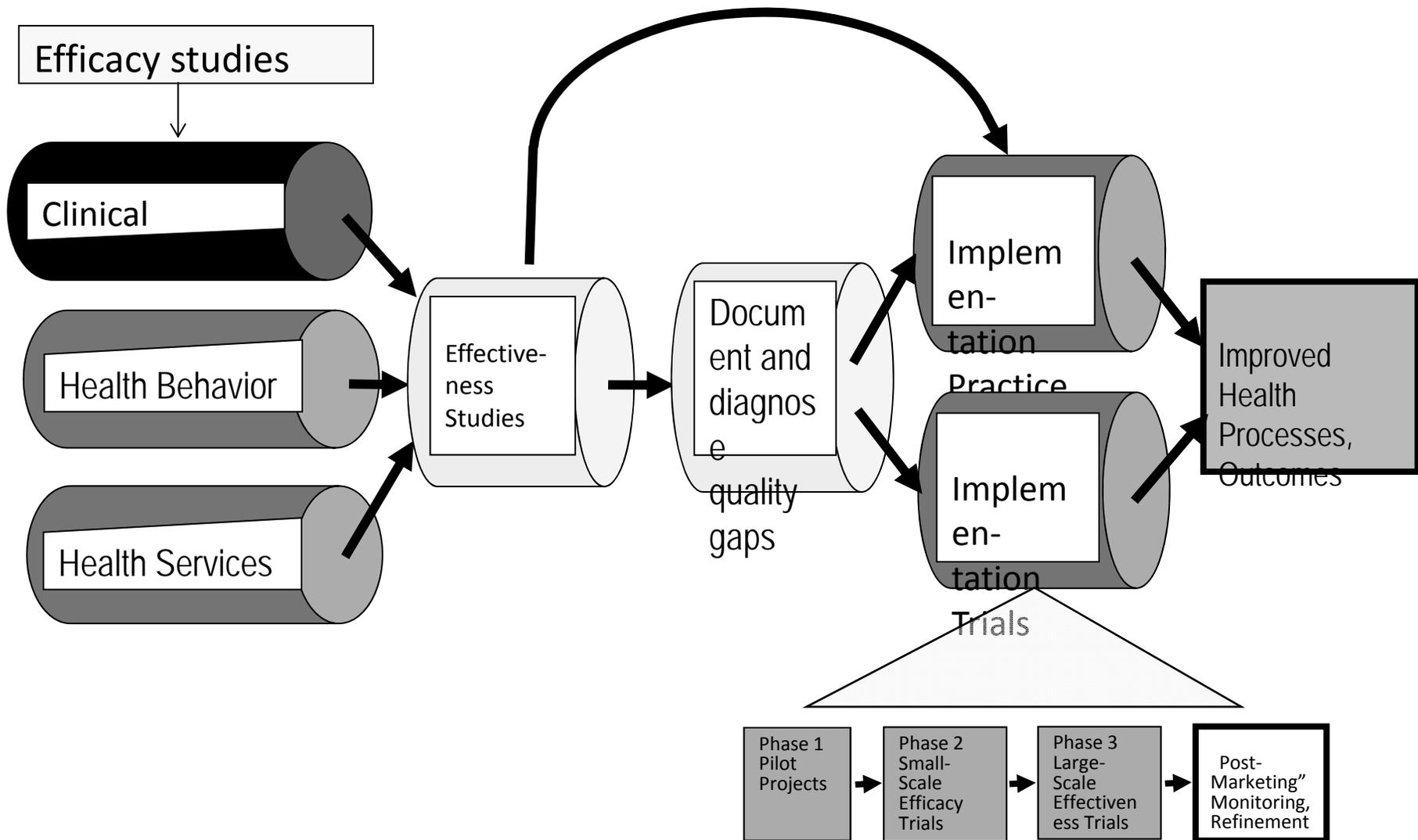
# Annotated QUERI Six-Step Process

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

Effective-ness Studies

Docum ent and diagnos e quality gaps

Implem en-tation Practice

Implem en-tation Trials

Improved Health Processes, Outcomes

| Phase 1 Pilot Projects | Phase 2 Small-Scale Efficacy Trials | Phase 3 Large-Scale Effectiven ess Trials | Post-Marketing" Monitoring, Refinement |
|---|---|---|---|

# QUERI Four-Phase Implementation Research Framework

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

# Gaps in the pipeline:
## *Challenges in implementation trials*

Most implementation trials fail to account for:

- Heterogeneity of settings, interventions, effects
- Context dependence, weak main effects
- Process and mechanism (vs. outcome/impact) focus
- Protocol-driven intervention adaptation
- External validity vs. internal validity, artificiality of trials
- Sustainability and scale-up/spread potential, economic evaluation
- Implementation phenomena are <u>different</u> (e.g., *representative sampling paradox*)

# Poll question

Which of the following types of research have you conducted? (select all that apply)

- QUERI Step 3 pre-implementation research
- Small-scale / pilot implementation trials (Phase 1)
- Larger efficacy-oriented implementation trials (Phase 2)
- "Regional roll-out" or "spread" trials (Phase 3)
- Observational studies of implementation processes (Step O)
- Formative or process evaluation in implementation science

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# EIS 2012 Lectures

1. Overview, QUERI Steps/Phases

2. Hybrid Effectiveness-Implementation Studies; QUERI Step 3

3. Designing Implementation Strategies, Part 1

4. Designing Implementation Strategies, Part 2

5. Evaluating Implementation Strategies and Studying Implementation Processes, Part 1

6. Evaluating Implementation Strategies and Studying Implementation Processes, Part 2