



Overview of Implementation Science and the QUERI Frameworks

Brian S. Mittman, PhD

Director, VA Center for Implementation
Practice and Research Support

VA Greater Los Angeles Healthcare System

September 15, 2011

Outline

➤ Part 1: Introduction: overview of implementation science

Part 2: Policy/practice foundations

Part 3: Implementation science frameworks

Part 4: Implementation research resources

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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

Step 1. New evidence

ORIGINAL CONTRIBUTION

JAMA-EXPRESS

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



Step 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

JAMA. 2000;283:1335-1337.

Step 2. *Guidance* for adoption

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

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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

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

Circulation 2005;112:e154-e235; originally published online Sep 13, 2005;

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CENTER FOR IMPLEMENTATION PRACTICE & RESEARCH SUPPORT

Step 2. *Incentives* for adoption

Circulation

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**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

Circulation 2005;112:1853-1887; originally published online Sep 13, 2005;

Step 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

Step 4. Trials of implementation programs

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart
Association®



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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;

Step 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
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

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Part 3: Implementation science frameworks

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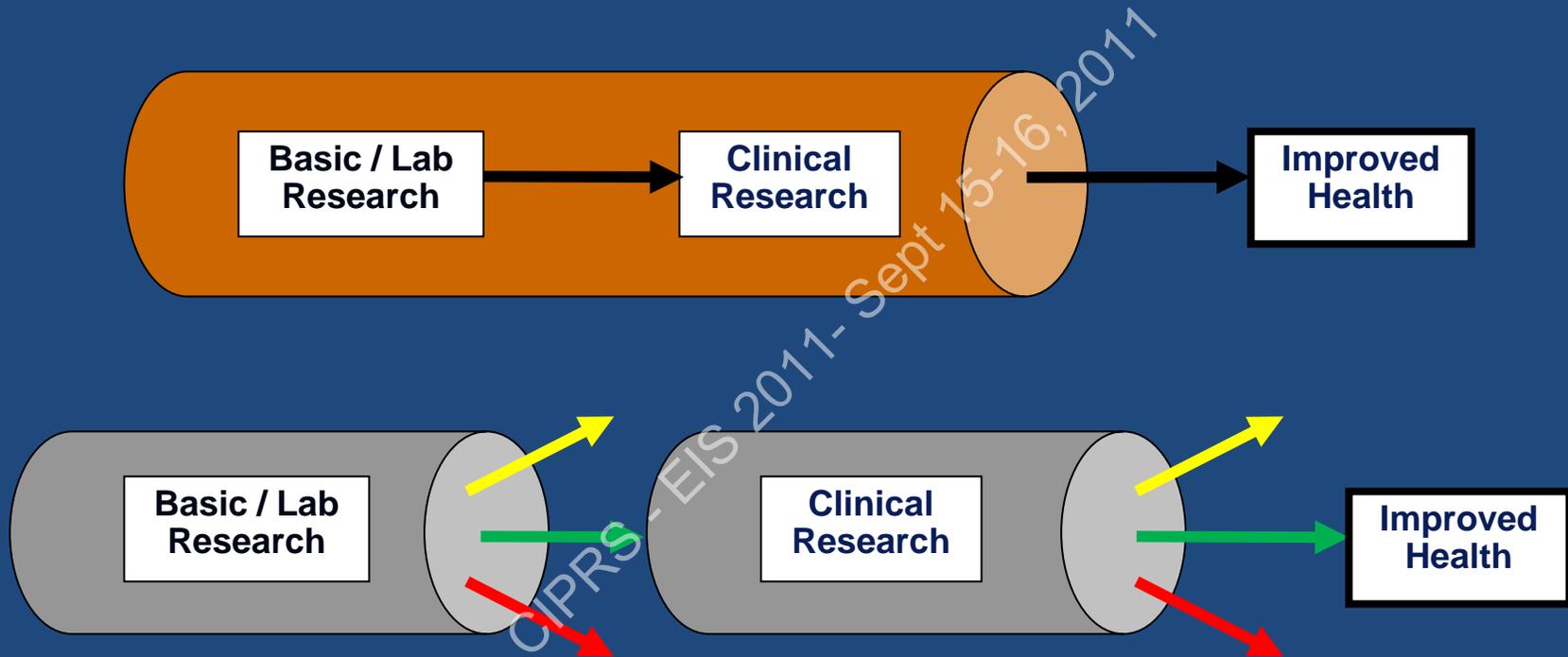
Policy/practice foundations of implementation, implementation research

1. The implementation gap
2. The quality chasm

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The implementation gap (second translational roadblock)



The Implementation Gap:

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

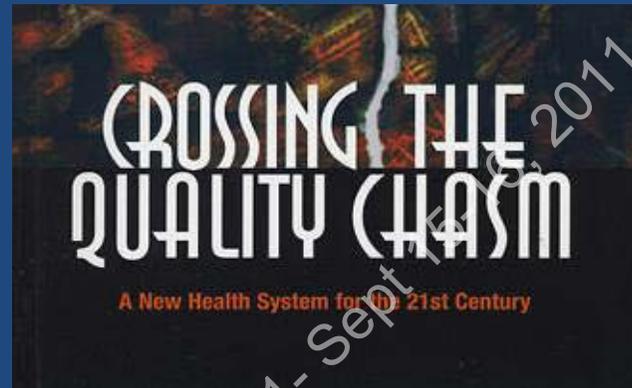
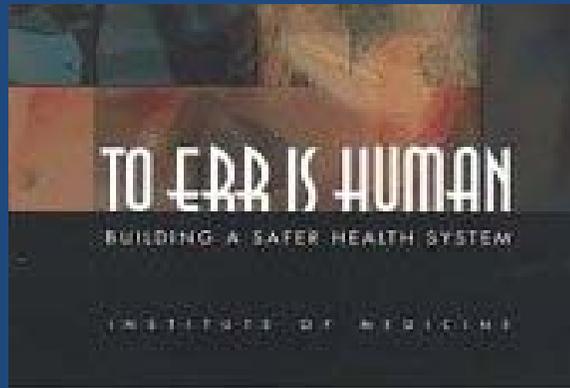
**Clinical Research in the United States
at a Crossroads**

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

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.

Eccles and Mittman, 2006

Implementation research goals

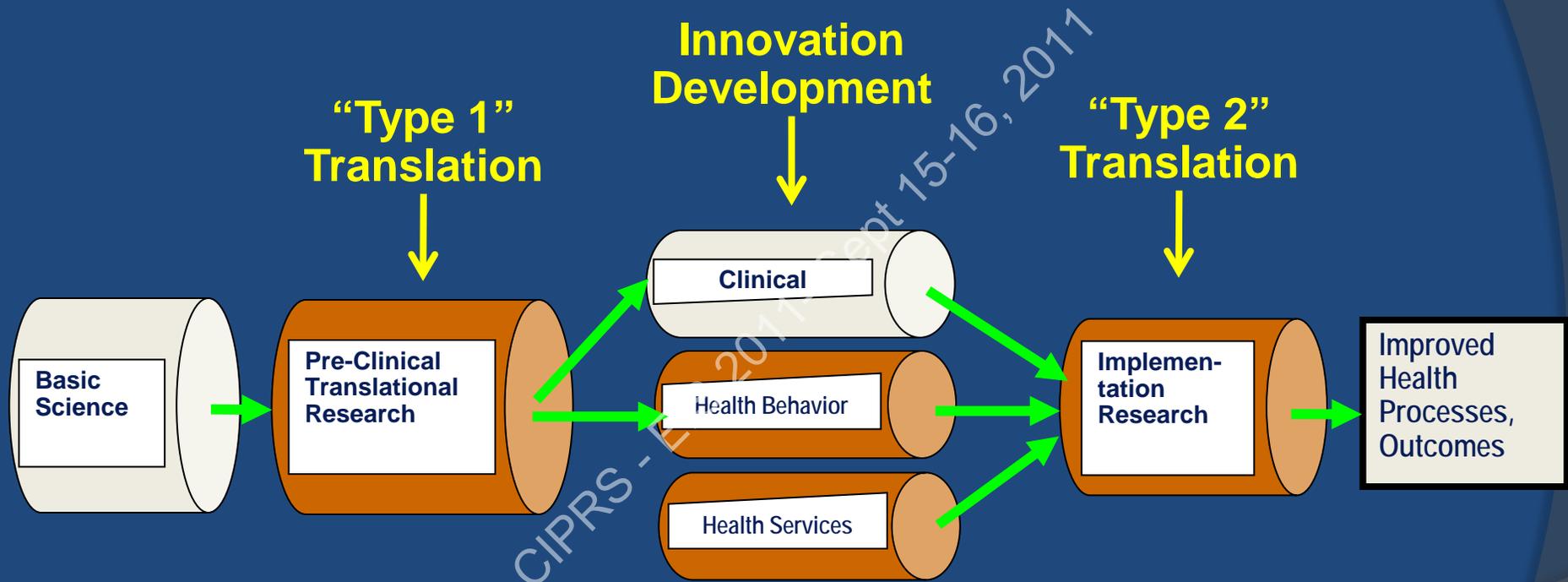
1. Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies
2. Produce insights and generalizable knowledge regarding implementation *processes, barriers, facilitators, strategies*
3. Develop, test and refine implementation theories and hypotheses; methods and measures

Implementation research frameworks: Strengthening research programs and projects

1. Pipeline concepts guide the development of an integrated portfolio and sequence of pre-implementation and implementation studies
2. Additional frameworks guide the design, conduct and reporting of individual studies

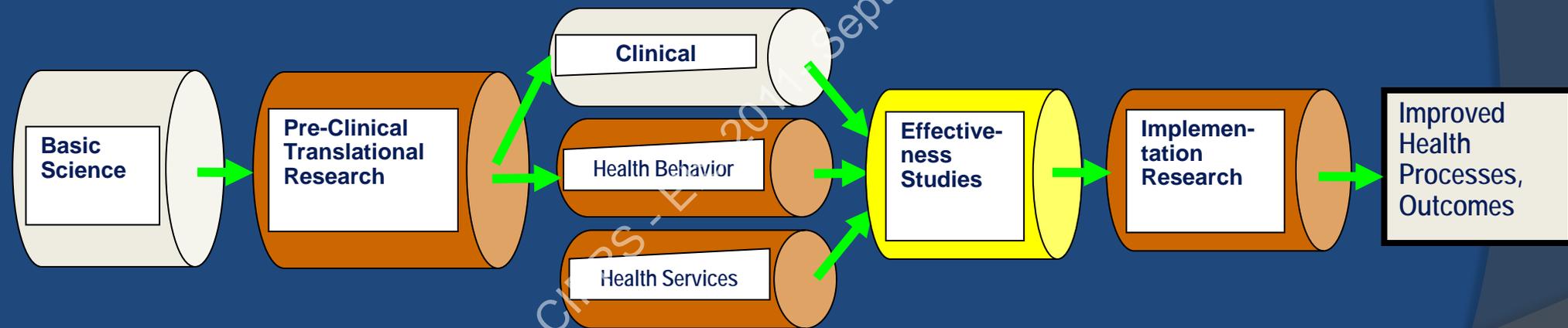
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Refined research-implementation pipeline: *Implementation research and clinical research*



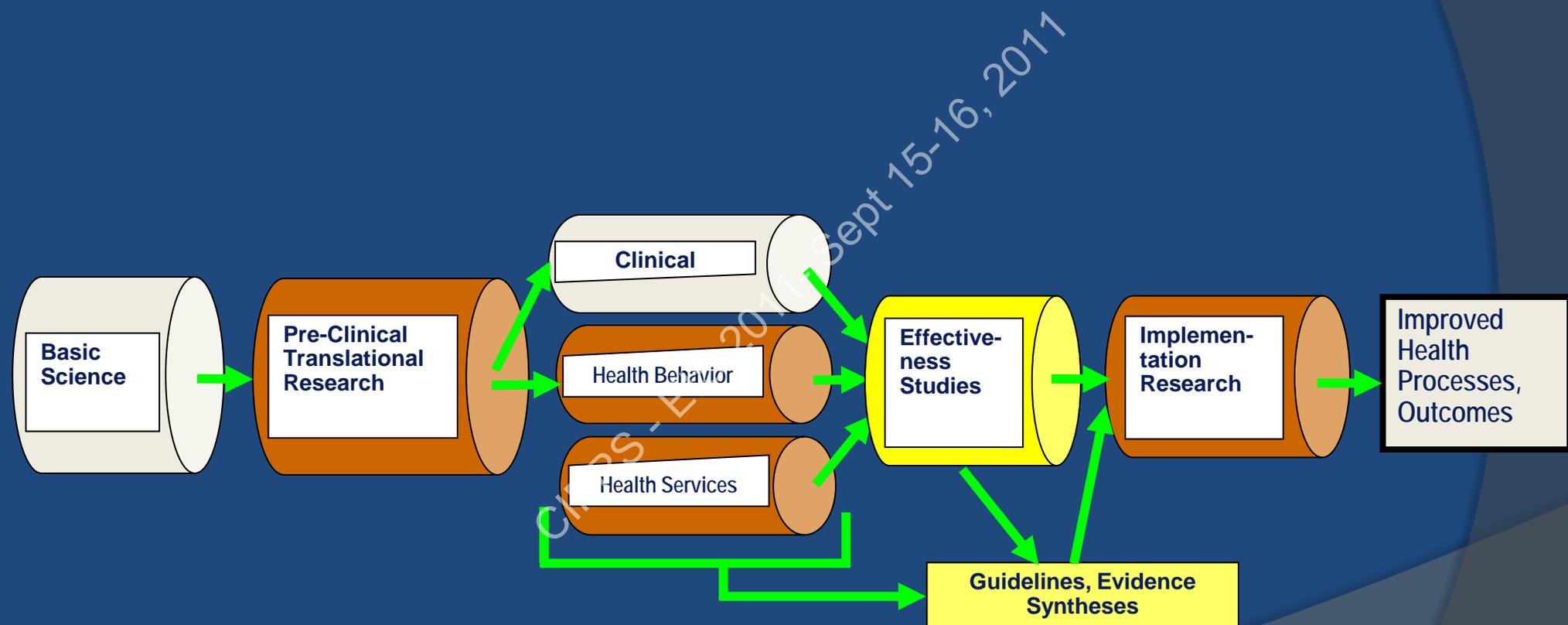
Gaps in the pipeline:

1. *Effectiveness studies*
(to be discussed in hybrid lecture)



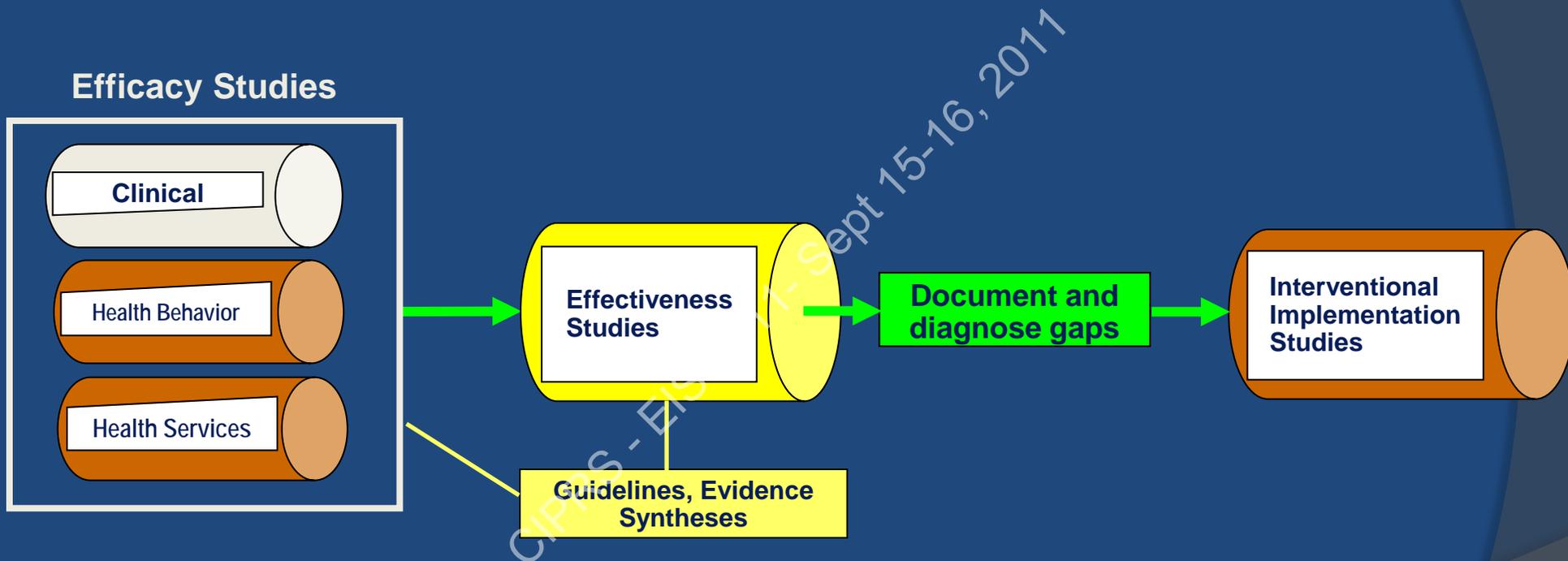
Gaps in the pipeline:

1. *Effectiveness studies*
(to be discussed in hybrid lecture)



Gaps in the pipeline:

2. *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

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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

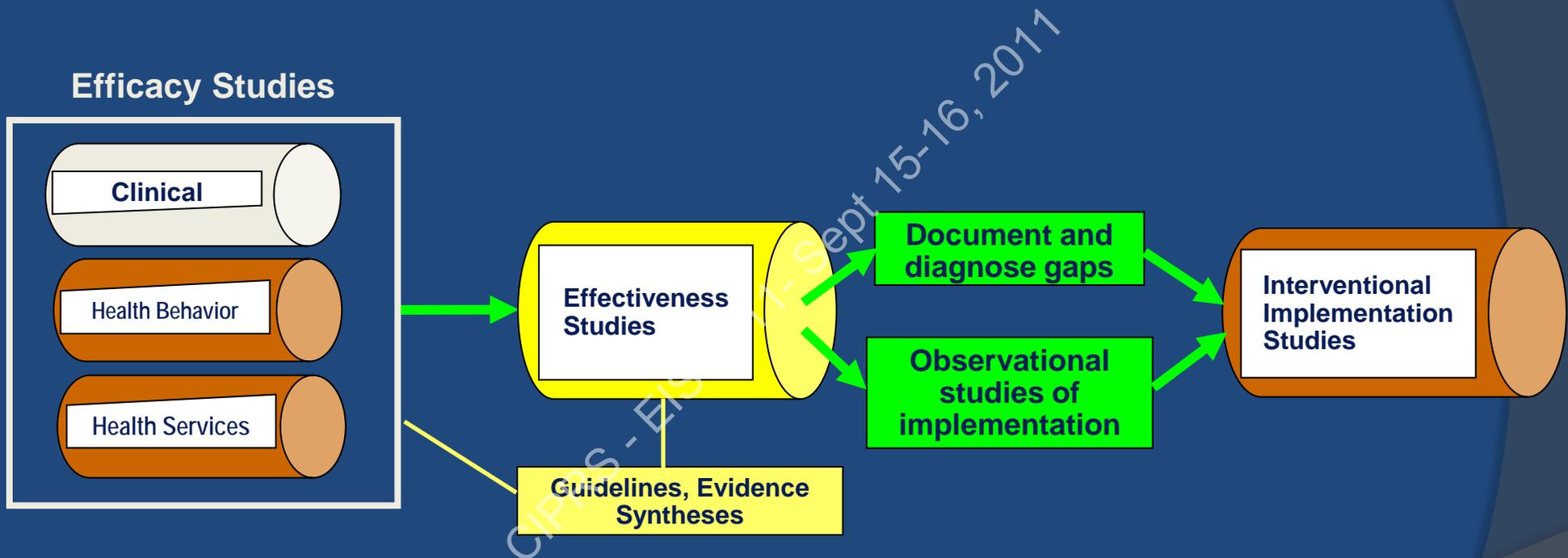
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Modified Research-Implementation Pipeline

1. MAINSTREAM HSR&D GROUNDWORK	2. PRE-IMPLEMENTATION STUDIES	3. IMPLEMENTATION PLANNING, PRE-TRIAL	4. IMPLEMENTATION TRIAL, WITH EVALUATION	5. FREE-STANDING IMPLEMENTATION EVALUATIONS
<ul style="list-style-type: none"> ▪ Efficacy/effectiveness studies (Step C) ▪ Syntheses (Step C) ▪ Data source, measure, tool development (Step M) 	<ul style="list-style-type: none"> ▪ Document and diagnose <i>general gaps</i> (Steps 3A -3D) 	<ul style="list-style-type: none"> ▪ Identify/develop/evaluate <i>implementation</i> interventions, toolkits, and related materials (Step 4A, 4B) 	<ul style="list-style-type: none"> ▪ Conduct and study improvement-focused implementation (e.g., SDPs), ranging from feasibility pilots to national roll-outs (Steps 4C/5/6, Phases 1 to 4) 	<ul style="list-style-type: none"> ▪ Observational Studies (Step O) ▪ Formative Evaluation ▪ Summative Evaluation ▪ Economic Assessment ▪ Evaluation of Theory(s) Used

Gaps in the pipeline:

3. *Observational implementation studies*



Additional QUERI steps

Step C: Develop clinical evidence, effective practices

Step E: Effectiveness studies

Step M: Develop measures, methods and data resources

Step O: Observational studies of implementation processes

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Modified Research-Implementation Pipeline

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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

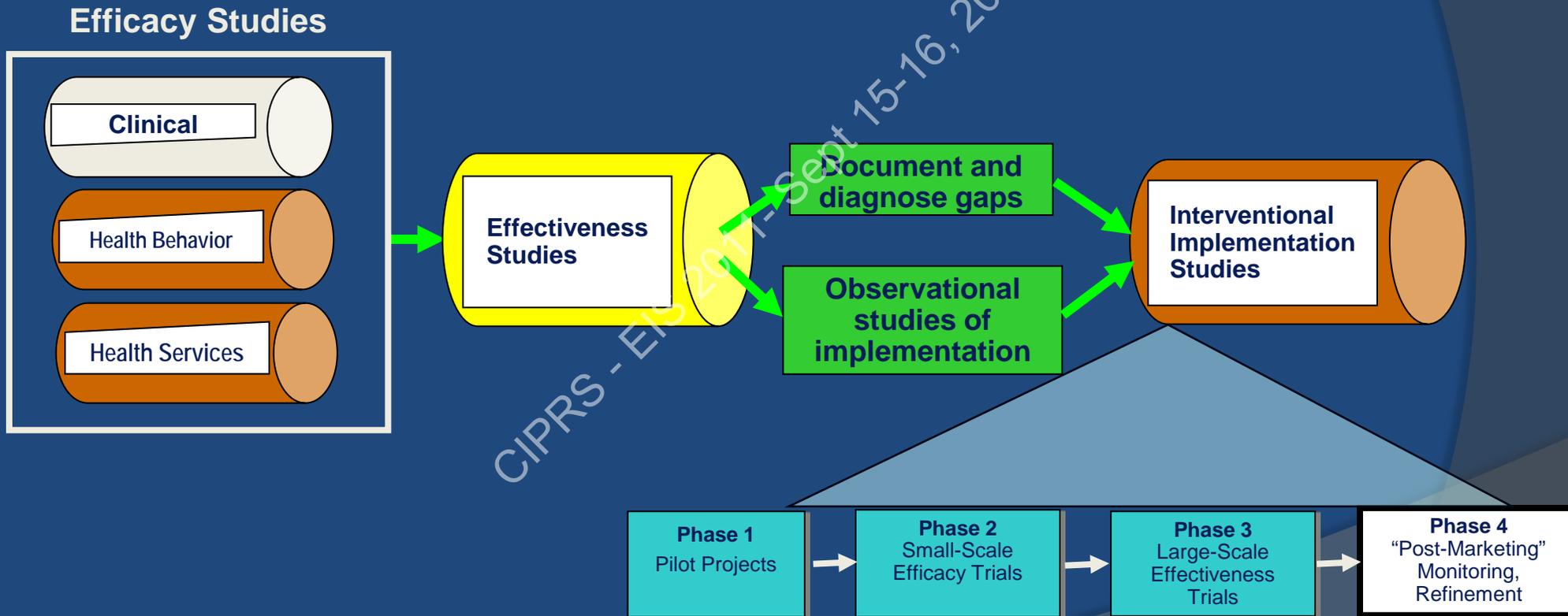
Updated QUERI Pipeline

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

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Gaps in the pipeline:

4. *Phased implementation trials*



QUERI Four-Phase Implementation Research Framework

<u>Phase</u>	<u>Study Type</u>	<u>Form of Evaluation</u>
Pre-trial	Program design	Conceptual design of implementation program and underlying (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; emphasis on internal validity
Phase 3	Effectiveness	Large-scale rigorous trial under routine conditions in varied settings; emphasis on external validity
Phase 4	Monitoring	Ongoing monitoring and feedback

Gaps in the pipeline:

5. *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
- ⦿ Sustainability and scale-up/spread potential, economic evaluation
- ⦿ Implementation phenomena are different (e.g., *representative sampling paradox*)

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National, international resources

- NIH Conference on the Science of Dissemination and Implementation (2007, 2009, 2010, 2011, 2012 planned)
- NIH funding announcements
- NIH- and AHRQ-funded training programs
- Journals: *Implementation Science*, *Translational Behavioral Medicine*, special issues of general and specialty journals
- NIH CTSAs (selected)
- PBRNs (AHRQ, other)
- VA QUERI
- Knowledge Translation Canada, other CIHR programs

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Local resources

Health Sciences:

- Community Health, Health Behavior
- Health Services, Management
- GIM, Family/Prev Medicine, Subspec
- Nursing, Dentistry, Allied

Main Campus:

- Psychology, Sociology, Anthropology, Political Science, Economics
- Management, Education, Public Policy

Critical resources

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

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New opportunities

- AAMC implementation science initiative
- Standing study section at NIH; ongoing and new PARs
- Evolution of NIH CSTAs and “type 2 translation” focus
- Comparative Effectiveness Research and Patient-Centered Outcomes Research Institute (PCORI): CER studies of “delivery system interventions”

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Selected challenges and new directions in implementation science

- Social/behavioral science theory: identify, refine, guide use of existing theory (*and develop new theory?*)
- Increased study of natural experiments, processes
- Challenges of evaluating “complex social interventions”: implications for expt’l, obsv’l research approaches
- Methods for synthesizing diverse, complex evidence
- Partnership research: bridging science and practice goals, balancing internal vs. external validity