



Introduction to Implementation Science and Programs of Implementation Research

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*Enhancing Implementation Science in VA
Denver, Colorado*

Why implementation research?

Implementation – and implementation research – are critical to:

- the success of major policy initiatives in the US and abroad (in healthcare, education, environmental protection, criminal justice, economic competitiveness, etc.) and
- achievement of the associated societal goals



Why implementation research (cont.)?

Implementation and implementation research are also critical to achievement of the institutional missions of:

- health and social service research programs and research funding programs
- professional schools (medicine, nursing, social welfare, education)
- regulatory agencies, advocacy organizations and service delivery organizations (including VHA)



Outline

Part 1: The need for increased implementation and implementation research in health and health care

Part 2: Defining and characterizing implementation research and QUERI

Part 3: Implementation research resources

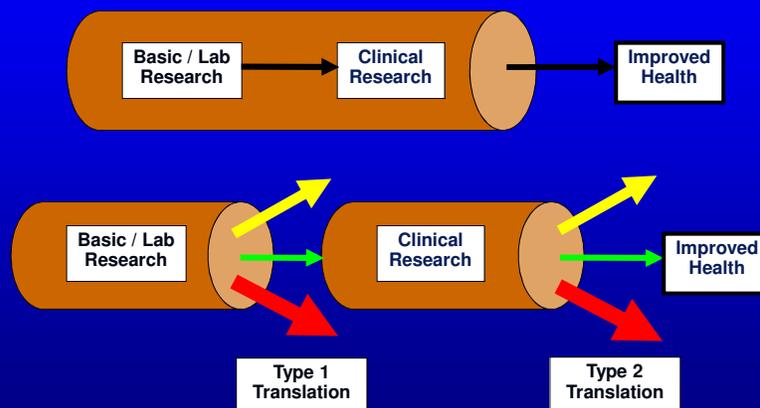


The need to accelerate implementation in health: Two streams of policy concern

- Stream 1 -- translational roadblocks; implementation gap
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



Stream 1: Translational roadblocks and inefficiency in health research



Translational roadblocks and 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 Implementation Gap (*second translational roadblock*)

- 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



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

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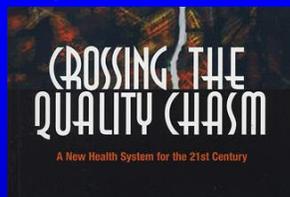
ABSTRACT

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.



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 Keeseey, 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.



Key terms and concepts

- diffusion, dissemination, implementation
- adoption, uptake
- scale-up, spread

- innovation, best practice, evidence-based practice
- clinical intervention, health system intervention

- implementation program, strategy
- quality improvement (QI)

- efficacy, effectiveness; internal vs. external validity
- complex social interventions, context



Implementation research vs. quality improvement research

Generally speaking...

- implementation research studies processes and strategies for increasing adoption, use of innovative, effective practices and research findings, whereas
- quality improvement research studies approaches for addressing quality problems (*often via implementation of innovative practices, or to close quality gaps that are equivalent to implementation gaps*)

Both fields encompass theory, research, policy and practice in organizational/professional behavior and behavior change



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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/Mittman, 2006)

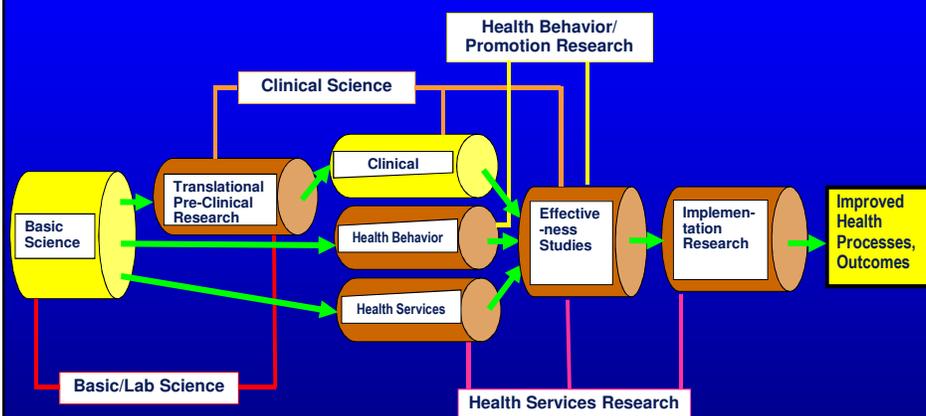


Implementation research goals

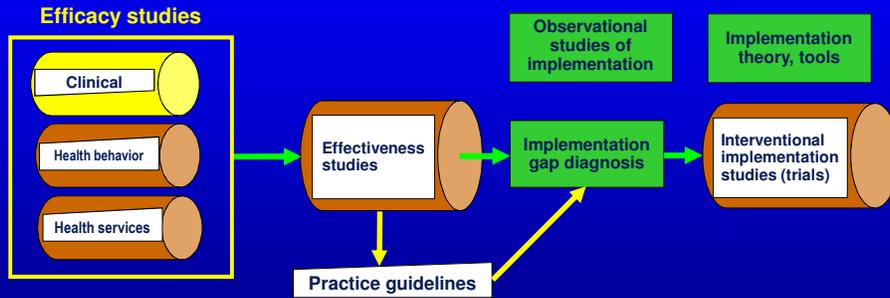
1. Develop reliable strategies for increasing use of evidence-based/effective services to improve outcomes; facilitate widespread adoption (scale-up/spread) of these strategies
2. Produce generalizable knowledge and increased understanding of implementation *processes, barriers, facilitators, strategies*
3. Develop, test and refine implementation theories and hypotheses; methods and measures
4. Facilitate improvement in participating sites



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



Research-implementation pipeline: Implementation and pre-implementation studies



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VA QUERI

MODIFIED QUERI PIPELINE 2010 (with 2003 steps)

GROUNDWORK / PRE-QUERI (Steps C, E, 2, M)	PRE- IMPLEMENTATION (Steps 3A, B, C, D)	IMPLEMENTATION PLANNING, PRE-TRIAL (Step 4A, 4B)	IMPLEMENTATION TRIALS (Steps 4C, 5, 6)	OBSERVATIONAL IMPLEMENTATION EVALUATIONS (Step O)
<ul style="list-style-type: none"> Efficacy research Effectiveness studies Syntheses, guidelines Data, research methods development 	<ul style="list-style-type: none"> Document, diagnose gaps 	<ul style="list-style-type: none"> Identify, develop implementation "interventions," tools 	<ul style="list-style-type: none"> Evaluate implementation programs (pilots to spread) Encompasses formative evaluation, sustainability, cost, etc. 	<ul style="list-style-type: none"> Contextual influences Implementation processes Economic assessment

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Observations on pipeline models

- Research and implementation activities rarely proceed in a linear manner
- Implementation research can (should) be applied to a broad range of interventions, innovations, effective programs, etc.
- Observational studies of (naturally occurring) implementation processes maximize policy/practice relevance and value, external validity, ability to study contextual factors

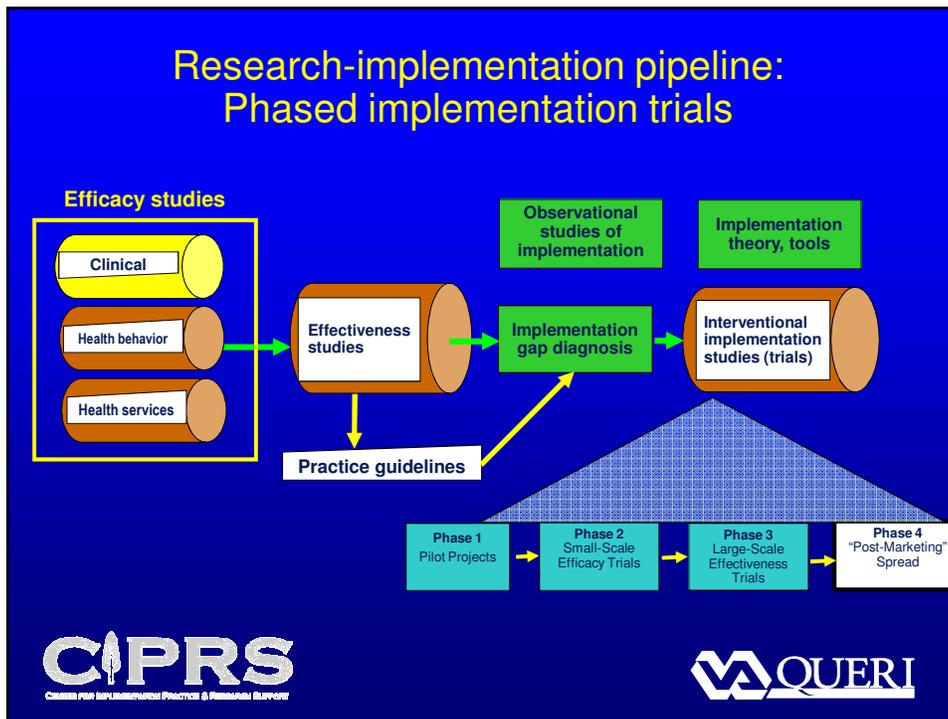


Observations on pipeline transitions

- Implementation trials should be preceded by adequate pre-implementation research (vs. “empirical treatment” approaches to implementation program design)
- Hybrid effectiveness/implementation studies (vs. separate phases ... e.g., “hand-off” of guidelines to implementation researchers) permit implementation gap diagnosis, preparation for implementation trials



Research-implementation pipeline: Phased implementation trials



QUERI Four-Phase Implementation Trial Framework

<u>Phase</u>	<u>Study Type</u>	<u>Form of Evaluation</u>
Pre-trial	Program	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	Scale-up/spread: general support, monitoring

Issues in studying implementation

- Distinguishing implementation vs. pre-implementation research
- Distinguishing implementation programs from clinical interventions and other effective practices
- Completing pre-implementation steps
- Relying on theory
- Recognizing heterogeneity, variability, contextual effects



Key features of implementation trials

- Heterogeneity of settings, interventions; context dependence, weak main effects
- Process/mechanism vs. outcome/impact focus
- Formative evaluation
- Adaptation vs. fidelity; protocol-driven adaptation
- External validity vs. internal validity
- Cluster randomization (clinician, facility, system)
- Sustainability, scale-up/spread potential, economic evaluation
- Reliance on theory (implementation program, evaluation)



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Implementation research resources

Journals: *Implementation Science*; quality/safety; general medical/HSR/PH-HP

Conferences: NIH D/I, KU/KT; SGIM, AcademyHealth, SBM, AHA/ACC

Training: NIMH IRI, Canada KT, CIPRS

Centers: QUERI, KP Colorado, EPOC, CTSA's (limited)

University departments: GIM/HSR, Fam Med, Prev Med, Geriatrics, Nursing, SPH (Community Health, Health Services); management, education, public administration

Professional associations: SGIM, AcademyHealth, SBM



Implementation research resources

- RE-AIM, UK MRC, other frameworks
- Green/Glasgow external validity criteria
- Experimental/quasi-experimental designs, cluster RCTs
- Stetler et al, formative evaluation, process evaluation
- Economic evaluation
- CONSORT-like statements, templates
- Diffusion, dissemination, implementation theories, models
- Qualitative research methods
- Publication guidelines (protocols, main findings, adjunctive analyses)

