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Implementation Science and Improvement Science: Differences, Similarities and Synergy

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A brief history

- Quality assessment, small-area variations (1970s)
- “Changing physician behavior” (1980s)
- Industrial quality improvement , QI research, AHRQ (1990s)
- Quality chasm, translational roadblocks, NIH (2000s)
- Implementation research, *Implementation Science* (2000s)
- Health reform/ACA (CER, CMS/CMMI, AAMC (2010s)
- Theory/methods development (role of theory; contextual influences; mediators, moderators, mechanisms): ongoing



The Implementation Gap

- 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

- 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

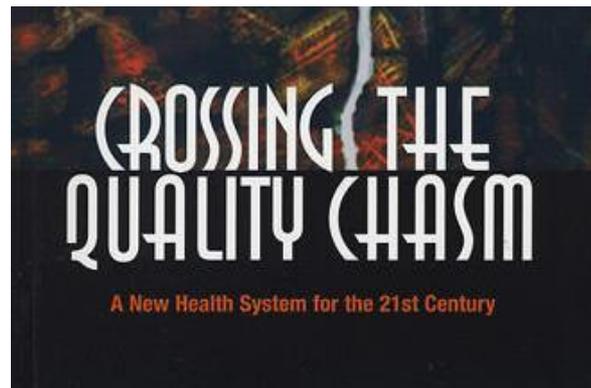
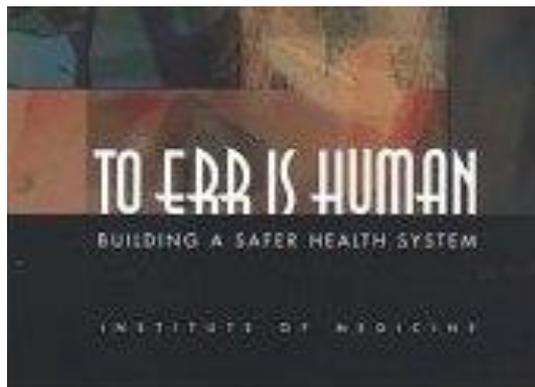
Translational and Clinical Science — Time for a New Vision

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



The Quality Chasm

- 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.



Healthcare quality improvement (QI) research

- Motivated by quality gaps (gaps in clinical effectiveness, patient safety, equity, value, access)
- Approaches include industrial quality improvement techniques (CQI, TQM, PDSA, Lean, Six Sigma)
- QI research is often **problem-driven**
- Quality problems include logistical/administrative issues (e.g., lost medical records, delayed surgery starts)
- QI research also addresses implementation of clinical practice guidelines and innovative care models (chronic care model), treatments, disease mgmt, prevention strategies, etc.



Healthcare* implementation research

- Motivated by recognition that research results and innovations are under-utilized (*translational roadblocks*)
- “Research results” derive from clinical research (efficacy, effectiveness), health promotion/prevention research, health services research
- Activity guided by clinical research approaches and based on explicit implementation science conceptual, theoretical frameworks (vs. industrial QI methods)
- Implementation research is often **solution-driven**



Contributions to learning and improvement

- ⦿ Insights into *requirements or conditions* for change; barriers to change (environment, organization, team, ind'l)
- ⦿ Reliable, robust strategies (interventions) for directly improving care: *FDA-approved, formulary-listed* strategies
- ⦿ Processes for guiding improvements in care (PDSA/rapid-cycle improvement); analytical approaches and tools for monitoring and guiding improvement
- ⦿ Insights into the behavior of delivery systems and organizations, teams, clinicians/staff



Improvement vs. implementation science

- ◎ QI often focuses on the “here and now” – immediate, local improvement needs via rapid-cycle, iterative improvement;
- ◎ IS often attempts to develop, deploy and rigorously evaluate a fixed implementation strategy across multiple sites, emphasizing theory, contextual factors, (sometimes) mediators, moderators, mechanisms
- ◎ IS aims to develop generalizable knowledge



Improvement vs. implementation science

- ◎ QI is *pragmatic*, improvement-oriented (often at the cost of limited confidence in interpretation and attribution and in generalizable knowledge);
- ◎ IS is *scientific*, research/knowledge-oriented (often at the cost of improvement outcomes and practical knowledge)
- ◎ Arguably: neither has made much headway in achieving either goal



Improvement vs. implementation science

- ◎ QI often ignores contextual factors, fundamental insights into organizational/professional behavior, cross-site differences and implications for improvement success; QI offers tools for persisting until improvement is achieved, driven by a desire to solve a specific quality problem
- ◎ IS often ignores heterogeneity and dominance of context over intervention main effects, and – too often – mediators, moderators, mechanisms and adaptation



Implementation and improvement science: conceptual, theoretical foundations

- The fundamental basis – foundation – for both fields includes theory, empirical research and research methods addressing the:
 - organization and delivery of healthcare (and other) services
 - knowledge, beliefs, attitudes and practices (behaviors) of healthcare (and other) professionals and staff
- Use of “health care delivery science” captures this common foundation



Studying complex social interventions

Implementation and improvement strategies and programs are *complex social interventions* characterized by:

- Variability and heterogeneity of program (intervention) content across time and place
- Heterogeneity of program implementation across time and place
- Strong contextual influences (leadership, culture, experience/capacity, staff/budget sufficiency), variability and heterogeneity of context across time and place
- Weak main effects (other than for *robust* programs)



Studying complex social interventions

- Robust CSIs are amenable to RCTs to estimate mean effect sizes – effectiveness – and the strength of a small number of contextual influences
- We prefer to study robust CSIs because “that’s where the light is”
- The value and applicability of methods for estimating “effectiveness” decreases with increases in the
 - magnitude of contextual influences
 - degree of heterogeneity and variability of programs and settings
- and with decreases in the main effect size



Studying complex social interventions: What is our goal?

Two very different questions

1. Does it work? Is it “*effective*”?
Should it be approved?
Included in the formulary?
Should I use it?
2. How, why, when and where does it work?
How should I use it?
How do I make it work?

*For many QI and implementation strategies,
Q1 is meaningless*

