



Implementation Science in an Era of Health Reform and Patient-Centered Comparative Effectiveness Research: New Threats, New Expectations, New Opportunities

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Implementation (and science) imperatives

- ◎ mortality/morbidity gaps (underuse)
- ◎ quality of life gaps, disparities
- ◎ direct harms (overuse, inappropriate use)
- ◎ waste, value, cost, economic harms
- ◎ research ethics: societal impacts and benefits vs. grants/pubs/tenure; “breakthrough” vs. “follow-through”

New programs, opportunities, progress

- ◎ NIH: funding and review, training, conferences; ARRA-related growth in NIH I/C interest in CER and implementation science
- ◎ AHRQ, VA, PCORI, CMS, foundations, VHOs: funding, conferences
- ◎ Journals: *Implementation Science*, *Translational Behavioral Medicine*, special issues of general and specialty journals
- ◎ AAMC (ROCC), AHC innovation/implementation initiatives, CTSAs (selected), HMORN and other research networks

New programs, opportunities, progress (cont.)

- ◎ Professional and medical societies (e.g., AcademyHealth, American College of Cardiology, ASCO); VHO collaborations (AHA/ACC)
- ◎ KT Canada/CIRH, UK NIHR CLAHRCs, UK Health Foundation, Australian Primary Care CREs, other western health systems
- ◎ General trends:
 - importance of engagement and partnerships
 - support for effectiveness (vs. efficacy) studies
 - partnership and funding by policy/practice stakeholders (esp. integrated delivery systems/ACOs)

New expectations

- ◎ US health reform: visibility of CMS/CMMI, PCORI
- ◎ Patient/stakeholder engagement; partnership research: stakeholder awareness, scrutiny
- ◎ Policy/practice funder (and consumer) expectations
- ◎ Assumptions, expectations of new and career change researchers
- ◎ International emphasis on research impact assessment; possible US interest (GAO, OMB?) and (re-)examination of mission and output of NIH, CTSAs, universities?

Resources, requirements for progress

1. Capacity, workforce: interest, skill and expertise, support
2. Funding
3. Journals, conferences
4. Regulatory guidance, pathways
5. Appropriate inputs (innovations, research findings)
6. Partnership opportunities, guidance
7. Implementation leverage, ability
8. Theory, research approaches and methods

1. Capacity, workforce

- ⦿ Academic legitimacy, prestige; local (department, school, campus) and professional/community
- ⦿ Training programs (PhD, fellowship, mid-career) and trainers (faculty); interdisciplinary, cross-campus programs
- ⦿ Pilot and bridge funding, career development awards
- ⦿ Uncertain core competencies and required knowledge, skills; explicit vs. tacit knowledge and experiential learning
- ⦿ Insufficient recruitment and involvement of relevant disciplines, departments

2. Funding / 3. Journals, conferences

- ◎ Is funding a problem of supply, demand, or both?
 - do funding lines differ? why?
 - consensus on research designs and methods
- ◎ Journal, conference capacity seem adequate (for now)

4. Regulatory issues

- ◎ Bypassing vs. fixing regulatory processes
 - risk level (intervention vs. evaluation); clinical vs. HSR
 - operations/QI activity vs. research
 - multi-site studies and “engagement”

5. Implementation inputs (innovations, findings)

- ◎ Efficacy vs. effectiveness findings; external validity, generalizability, transferability
- ◎ Practice-based evidence, practical/pragmatic clinical/behavioral trials
- ◎ Designing for dissemination: “reach” goals vs. more modest (achievable) goals

6. Partnership research

- ◎ Partnership research
 - unfamiliar, time-consuming, frustrating
 - academic performance standards are a disincentive
 - VA QUERI integration stems from unique advantages (internal partners, internal funding, supportive rewards)
 - PBRNs, CTSA community engagement, academic ACOs, PCORI are contributing to progress
 - key questions remain (true acceptability of practice-based research, level of participation required: “seeding trials”)

7. Implementation/improvement leverage, ability

- ⦿ Interventional implementation research requires an ability to change practice (to conduct studies, show success, generate policy/practice relevant output)
- ⦿ What if theory and observational research suggest that this is rarely possible?

Necessary conditions for practice change

1. Valid, legitimate (accepted) evidence
2. Evidence of deviations
3. External expectations, interest (monitoring), pressure
4. Supportive professional norms
5. Etiology of practices, deviations
6. Information, evidence, education
7. Feasible methods/systems

Necessary conditions for practice change: *gaps in researcher influence*

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8. Theory, research approaches and methods

- A. Core terms, concepts, definitions
- B. Theory and conceptual frameworks
- C. Research portfolio composition, study sequencing
- D. Research approaches, designs and methods: evaluating and studying complex social interventions

A. Core terms, concepts, definitions

- ◎ Multiple origins, foundations
- ◎ Heterogeneous labels, subfields
- ◎ Consistency vs. “let a thousand flowers bloom”: internal vs. external orientation and needs
- ◎ Research synthesis, shared learning
- ◎ Slow (and limited) progress toward establishing a more coherent, coordinated research community and field

B. Theoretical and conceptual foundations

- ⦿ Lack of adequate theory (number, scope, utility)
- ⦿ Excess volume of theories
- ⦿ Lack of guidance in using theory
- ⦿ Good progress in cataloguing, synthesizing (CFIR)
- ⦿ *Measurement development work well underway*
- ⦿ *Study designs/approaches remain problematic*

C. Diversity of empirical studies; sequencing

- ◎ Pre-implementation studies (documenting and diagnosing implementation gaps, identifying barriers and facilitators to practice change)
- ◎ Interventional implementation studies: Phase 1 pilots, Phase 2 efficacy studies, Phase 3 effectiveness studies, Phase 4 scale-up/spread and “post-marketing” research
- ◎ Observational studies (emphasizing external validity, large samples, policy/practice led implementation, routine vs. artificial conditions)
- ◎ QUERI (and other) frameworks

D. Research approaches, designs, methods for evaluating implementation strategies

Disagreements and debates over research approaches, designs and methods

vs.

Lack of consensus (or clarity of communication) regarding research questions and goals (and research approaches best able to address these)

Studying complex social interventions

Implementation 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 (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 of methods for estimating “effectiveness” is inversely related to:
 - the magnitude of contextual influences (vs. main effects)
 - the level of program heterogeneity and variability

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/most implementation strategies, Q1 is meaningless



Developing insights and guidance for implementation

- ⦿ How do I choose an appropriate implementation strategy given my context?
- ⦿ How do I implement (deploy) the strategy to increase effectiveness?
- ⦿ How do I adapt and customize the strategy to increase effectiveness (initially and over time)?
- ⦿ How do I modify/manage the organization or setting to increase effectiveness (initially and over time)?
- ⦿ **How, why, when and where does it work?**

Conclusions

Effective response to new opportunities and challenges requires:

- ⦿ Features of the evidence, research, innovations we implement
- ⦿ External barriers (IRB, funding, study sites/subjects)
- ⦿ Professional, institutional factors (disciplines, terms, concepts)
- ⦿ Theoretical and conceptual foundations
- ⦿ Research approaches, designs, methods