


Center for Mental Health Services Research
 GEORGE WARREN BROWN SCHOOL OF SOCIAL WORK
 Washington University in St. Louis

Conceptual & Methodological Challenges and Strategies for Conducting Implementation Research

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Implementation research is team science: methods collaborators

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Implementation research is team science

Convergence of research perspectives:

- > mixed methods
- > treatment researchers
- > service systems researchers
- > research design specialists
- > measurement specialists

Transdisciplinary:

- > economics, policy, organizational researchers
- > psychologists, social workers, MD's, anthropologists,

Part I: What is implementation research, and why is IR important?

Implementation is about changing care

Response to problems in care

Research findings:

- *“Languish” on shelf for 15-20 years before incorporation into usual care*
- *Fall into the “valley of death”**
- *Are poorly and inequitably delivered*

*Simon, 2009

Where Are The Interventions?

- *In discovery*
 - *Basic and clinical research (T1)*
- *In the pipeline*
 - *awaiting implementation and dissemination (T2)*

Consequence of implementation gap:

- Less than 10% of US population with serious mental disorders receive adequate care
- Mental health care rated as "D"
- Suffering is prolonged for those with mental illness
- Nation doesn't benefit from billions of US tax dollars spent on research



Value of implementation research

- *T2 research can do more to decrease morbidity and mortality than a new imaging device or a class of drugs*
- Wolff, S. H. (2008) The meaning of translational research and why it matters. JAMA, 299 (2), 211-213.

Value of IR (cont): studies show that

- quality of care can be improved by more than 200% by implementing performance feedback systems for clinicians
- and by 400% by implementing institutional reminder systems.
- Implementation strategies can boost the effectiveness of treatments by more than 30%,
- and reduce staff turnover by 50%.

Implementation is a concern for all areas of service delivery:


- Health
- Mental Health
- Social services
- Criminal justice
- Education
- HIV-AIDS

Hence, D&I PA and conference = NIH wide

- But my examples: Mental Health, Health, & Social Services


Implementation Science: Definitions

Scientific study of the process of moving new practices into routine care

 **Definitions of Implementation Research**


*Implementation research builds... “a knowledge base about how health information, interventions, and new practices are transmitted and translated for public health and health care service use in specific settings.” **

* NIH D&I PA's (PAR 06-039)

 **Definitions of Implementation Research**

*“research that supports the movement of evidence-based interventions and approaches from the experimental, controlled environment into the actual delivery contexts where the programs, tools, and guidelines will be utilized, promoted, and integrated into the existing operational culture” **

* Rubenstein & Pugh, 2006

 **Definitions of Implementation Research**

(study of) “...the utilization of strategies or approaches to introduce or modify evidence-based interventions within specific settings. This involves the identification of and assistance in overcoming barriers to, the application of new knowledge obtained from a disseminated message or program” *

* Lomas, 1993

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Part II: Conceptual Models for Implementation Research

Theoretically informed: Implementation conceptualized as:

Innovation (Rogers)

Multi-level change
Influenced by context: organizational (culture and climate, Glisson), policy, resource, human capital

Explicit change
Conceptualized as a form of intervention

Inherently dynamic process

IR: informed by multiple disciplines

- clinical epidemiology,
- communication theory,
- behavioral science,
- public policy,
- financing,
- organizational theory,
- and informatics.

IR: multiple stakeholders

- service consumers
- families
- providers
- administrators
- funders
- legislators

Multiple stakeholders have different priorities

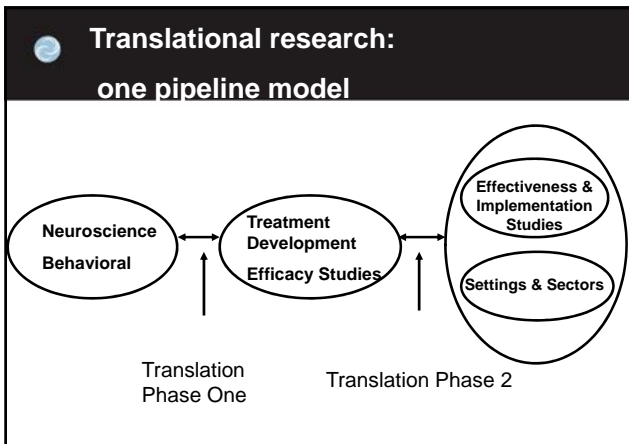
- Shumway research:
 - Stakeholder groups value and prioritize different outcomes
 - We expect that different stakeholders differ regarding implementation:
 - Rationale
 - Preferences
 - Priorities

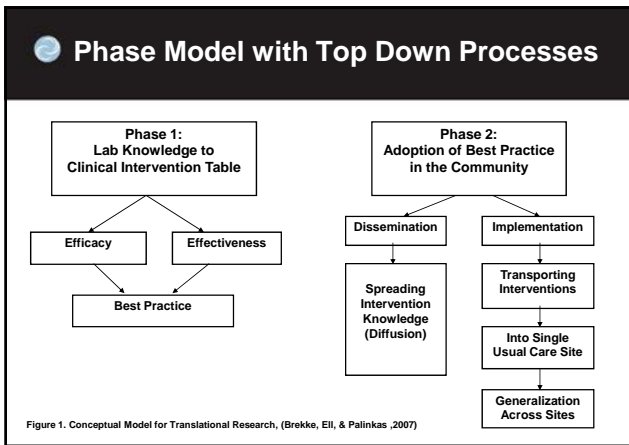
Our heuristic conceptual model draws on:

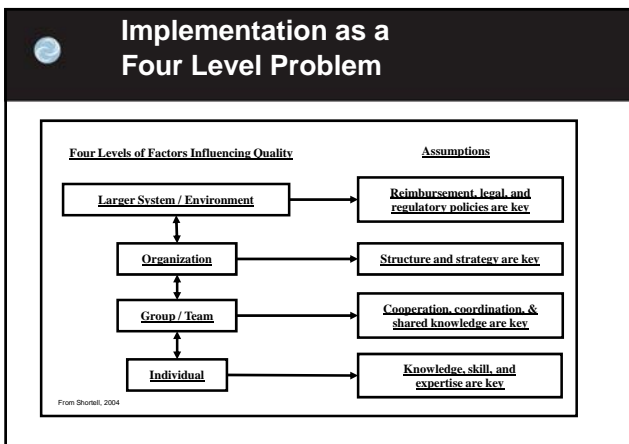
NCI's "stage" pipeline model

Shortell's multi-level model of change for performance improvement

Health services model distinctions between:
structure
process
outcomes





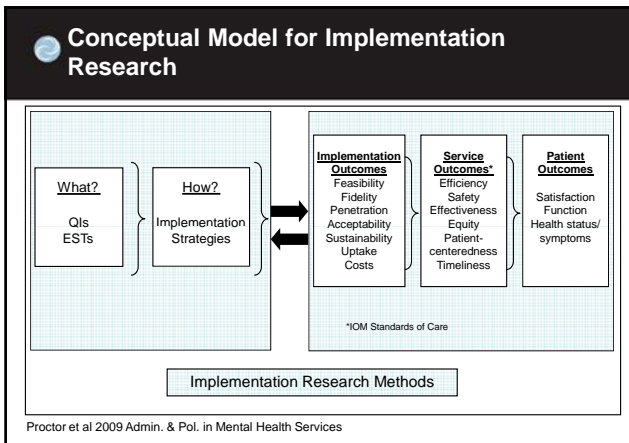


Limitations of extant conceptual models

Pipeline models:
 Underscore distinctiveness of types of T research
 Posit implementation as "last stage," afterthought

Top down models:
 Distinguish research tasks, terminology
 Unsustainable, don't engage stakeholders, don't capture multiple levels

Fail to specify variables for manipulation
 Point to "where," not "what"



Value-added of conceptual model

- Distinguishes processes and outcomes
- Two process technologies:
 - EST's
 - Implementation strategies
- Outcome distinctions
 - Implementation outcomes versus service & client outcomes
 - Types of implementation outcomes

Need: Model-guided research

- To determine effective implementation mechanisms (NIMH Road Ahead Report)
 - *Thus models must specify mechanisms, processes, outcomes*
- To test implementation in varied service settings:
 - Specialty mental health
 - Primary care
 - Criminal justice
 - Schools
 - Social Services

Exercise: key elements of improving care by implementing something new

A problem in care, involving a setting, population, intervention

An evidence-based improvement to introduce (implement): for example, an EST, QI

A strategy for introducing the improvement (IS)

Outcomes to achieve (IOs)

A context for the work

- Stakeholders
- Culture, climate


A design for testing the implementation

Break time!

Part III: key ingredients in IR

- Implementation strategies
- Implementation outcomes
- Contextual factors
- Design

Implementation requires strategic interventions



- Won't happen by admonition, or order
- Will require deliberate and targeted action
 - Thus need for empirically tested implementation strategies

Implementation strategies

- Preponderance of descriptive research:
 - Identifying barriers to implementation
 - Observations of "usual" care in changing practice (naturalistic spread, implementation)
- Need to derive strategies for implementation
 - from theory
 - from descriptive studies

Implementation strategies: current knowledge

“Packages” of components:*

- Professional interventions:
 - Educational materials and meetings
 - Local consensus processes
 - Academic detailing (information to providers)
 - Local opinion leaders
 - Client-mediated interventions (score feedback to providers)
 - Audit and feedback (summary of clinical performance)
 - Reminders
 - Marketing
- *Gilbody et al, JAMA, 2003; 289, pp 3145-3151

Implementation strategies: current knowledge

“Packages” of components:

- Organizational interventions:
 - Revision of professional roles (boundary shifting, expansion of roles)
 - Team building, including clinical multidisciplinary teams
 - (Gilbody et al, JAMA, 2003; 289, pp 3145-3151)
 - ARC intervention (Glisson) to change organizational climate and culture

Implementation strategies: current knowledge

Top down versus bottom up

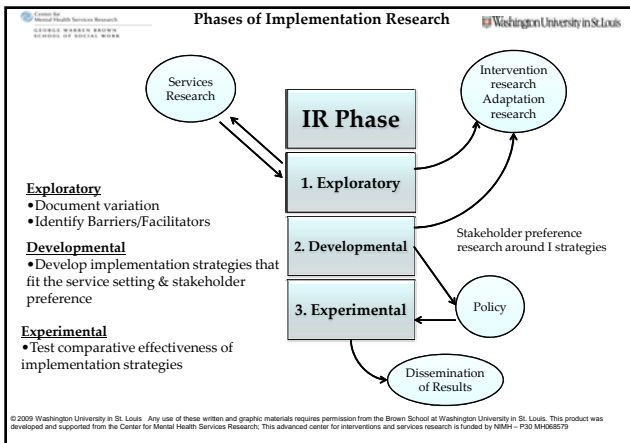
Overlap across approaches

Little empirical evidence for components

Little if any tests of comparative effectiveness

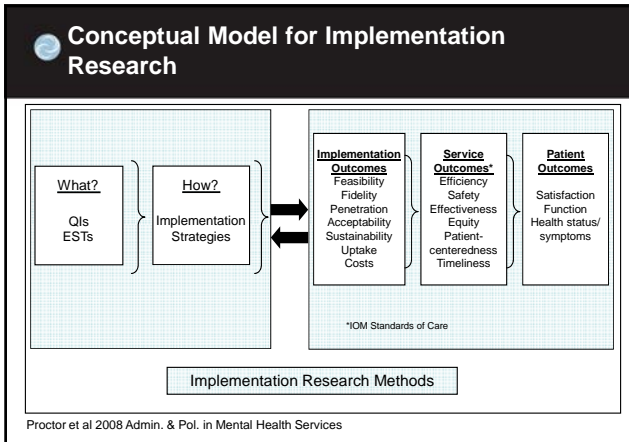
Important research questions:

- discovering barriers to the delivery of evidence-based treatment
- mapping pathways to the uptake and sustainability of those treatments in the real world
- and testing the comparative effectiveness of implementation strategies.



Part III: key ingredients in IR-Implementation outcomes

- How to conceptualize and measure success of implementation processes?
- Distinct outcomes needed
- Outcomes are distinct from clinical outcomes
 - Could have an effective intervention, poorly implemented
 - Could have an ineffective treatment, successfully implemented



- See handout: taxonomy of implementation outcomes
- Which outcomes are of interest to your research?
 - To the stakeholders in the setting of care?

- ### Part III: key ingredients in IR- Contextual factors
- Who are the patients/ clients/ consumers?
 - How prevalent is the social/ health problem being addressed?
 - Who are key stakeholders? What is their usual pattern of care? Training? Investment in change?
 - How large is the “implementation gap?”
 - How universal or generalizable is the setting? (national system? network?)

Part III: key ingredients in IR-Contextual factors

- What factors need to be controlled?
- What variance needs to be maximized?
- What are moderator variables?

Part III: key ingredients in IR-Design

Cross sectional, or multiple waves of data collection?

Units of analysis?
organization?
providers?
mixed?

Observational study, or manipulation?

How many arms?

Mixed methods?

Part III: key ingredients in IR-Design

Real world challenges:

- agency/ provider reluctance to randomization
- small "n" (changing even one agency is a challenge)
- nesting: clients, within providers, within teams/ supervisors, within agency, within one policy context

Part III: key ingredients in IR-Design

“Unhappy tension” with RCT for implementation research (Donald Berwick: JAMA, 2008)

Alternatives to RCT:

- Randomized encouragement trial (RET) and “practical clinical trials: Duan, 2002: randomizes, facilitating choice and preference
- Sequential Multiple Assignment Randomized Trial (SMART), experimentally examines strategy choices and allows multiple comparisons (TenHave, 2003, General Hospital Psychiatry)


Data sources, methods of collection

Mixed research methods:


- Record abstraction
- Stakeholder preference assessment
- Qualitative research methods
- Multi-level analysis
- Data management unit

Mixed methods of data collection & analysis


- Document collection & review
- Key informant interviews to identify modifiable dimensions (e.g., of implementation strategy)
- Conjoint analysis (CA) to quantify stakeholder preferences
 - Measurement approach from psychology, used in marketing and product development; participants rate dimensions
- Group model building with stakeholders

 **Simulation:
a “third way of doing science”**


- Implementation research is complex, unwieldy, expensive
- Implementation involves complex social & human systems
 - Non-linearity
- Tools: Agent based modeling (ABM) & Systems Dynamics (SD):
 - computational approaches for understanding systems and system change

 **Simulation models:**

- Scoping models
 - Early stage, based on lit & conceptual models
 - ID major variables
 - Stakeholder group model building
- Research models
 - Based on estimated model parameters, specified nonlinear relationships, confidence building tests
 - Test implementation models, strategies, outcomes




Exercise completion


 **Part IV**

Challenges of IR

Priority research questions

 **Implementation Science**

- Emergent area of science
 - Basic and clinical research dominates NIH
 - “T2” is science, not an afterthought to science

 **Challenges for Implementation Science**

Informing choice of implementation strategy
Menu of options from national studies

Multiple levels of analysis
policy, organizational, medical team, practice

Multiple stakeholders
payers, administrators, patients, providers, families

Design challenges in testing effects of practice change
small “n,” randomization, contamination

Selecting and measuring implementation outcomes

Implementation research advancing "in real time"

- NIMH Associate Director for Dissemination and Implementation
- NIH PA's on D & I
- Cross-NIH (ad hoc) review committee
- Small, growing number of R01's on D&I
- NIH (OBSSR) annual conference on D&I
- *Implementation Science* journal

Challenges for IR

- Only tiny fractions of peer reviewed journal articles address implementation and dissemination
- only 1-2% of the federal research budget is allocated to implementation research.
- Methods are described as
 - idiosyncratic,
 - bootstrapped,
 - and insufficiently informed by theory and research

Implementation = treatment, service system, & policy concern

Spread of EHR's - national priority
Bipartisan policy support & ARRA priority

Yet Adoption is slow
Jha et al. studied variation in EHR implementation
< 2% of hospitals have comprehensive system
8-12% have a basic element

Barriers

- Cost: Inadequate capital for purchase, maintenance costs
- Unclear return on investment
- Physician resistance
- Inadequate IT staff

* Jha et al., NEJM, 2009, 360

Important questions for empirical testing

Relationships between EST's and Implementation strategies:
Are implementation strategies effective across different EST's?
Core components of implementation strategies
Relationships among outcomes
Among implementation outcomes
Between IO's, service outcomes, client outcomes
Generalizability of models across settings

Training for IR, a still-developing field


Theory is debated
Methods underdeveloped
Rapid change in publication outlets
Funding is limited; no standing review committee

Training challenges

Few extant centers and institutional training programs
Trans-disciplinary approach
IR has no disciplinary home
Dual goals: develop human and intellectual capital


 **Implementation Research Institute**

- Two year program for new implementation researchers
- Funded by an NIMH R25 grant (NIMH - R25 MH080916-03)
- First institute: June, 2010, at George Warren Brown School of Social Work, Washington University in St. Louis
- National faculty & scholars
- Information and application:
<http://cmhsr.wustl.edu/Training/RI/Pages/ImplementationResearchTraining.aspx>

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