

Research to Reality: The Evidence Integration Triangle

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National Institute of Health

Outline

Need for Implementation Research

 What Do We Know About Dissemination & Implementation (D&I) Science?

- How to Make Sense out of this Complexity?
 - The Evidence Integration Triangle (EIT)

How to Learn More- and GET FUNDED?

Future Directions and Opportunities to Get Involved

EIT

Translation Continuum



The Need

Bench



Bedside



Clinic

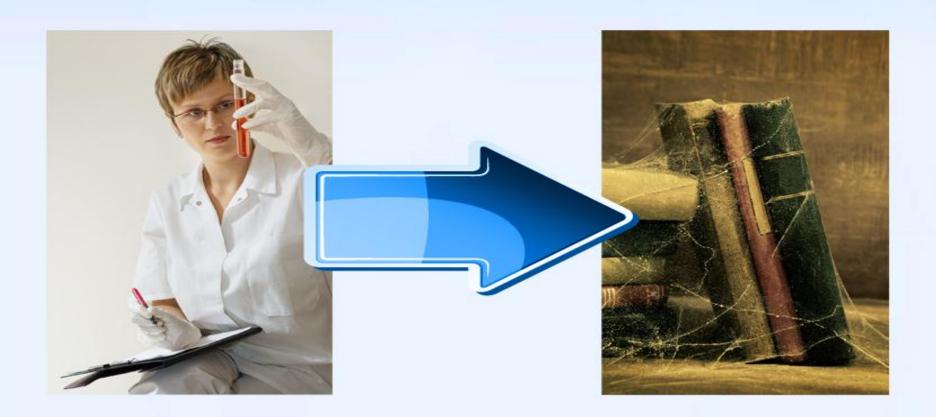


Community



Population & Policy

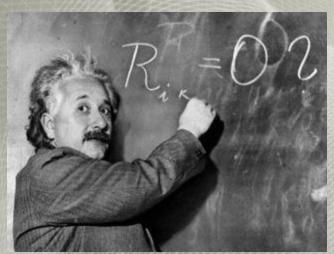
Bench to Bookshelf



Current Situation in United States¹

- Underperforming health care system²
- Balkanized and silo approaches
- Expensive, unsustainable cost, increasing
- Inequitable: Health disparities
- CRISIS and OPPORTUNITY

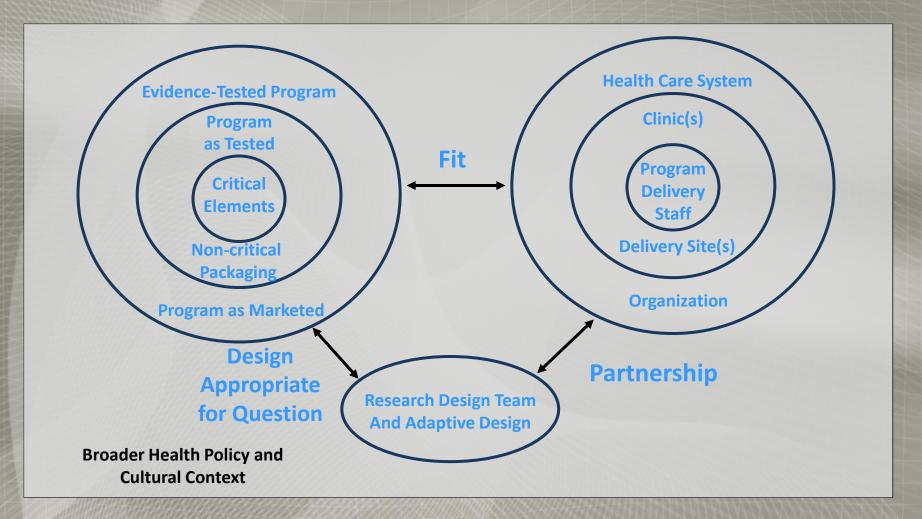
"The significant problems we face cannot be solved by the same level of thinking that created them."



A. Einstein

The Need

Integrated Dynamic, Multilevel Research-Practice Partnerships Systems Approach



Implementation and Dissemination Research Characteristics (Russ' view)

- Contextual
- Complex
- Multi-component programs and policies
- Non-linear
- Transdisciplinary
- Multi-level

Rapid Learning Approaches

Data Collected:

- With real (and complex) patients
- By real-world staff
- Under real-world conditions and settings
- And evaluated through real-time data (often with Electronic Health Records)

The Need

Recommended Purpose of Research (ala RE-AIM)

Funding

Collect evidence to document interventions that can:

- Reach large numbers of people, especially those who can most benefit
- Be widely adopted by different settings
- Be consistently implemented by staff members with moderate levels of training and expertise
- Produce replicable and long-lasting effects (and minimal negative impacts) at reasonable cost

Ultimate Impact of an Insurance-sponsored Weight Management Program in West Virginia¹

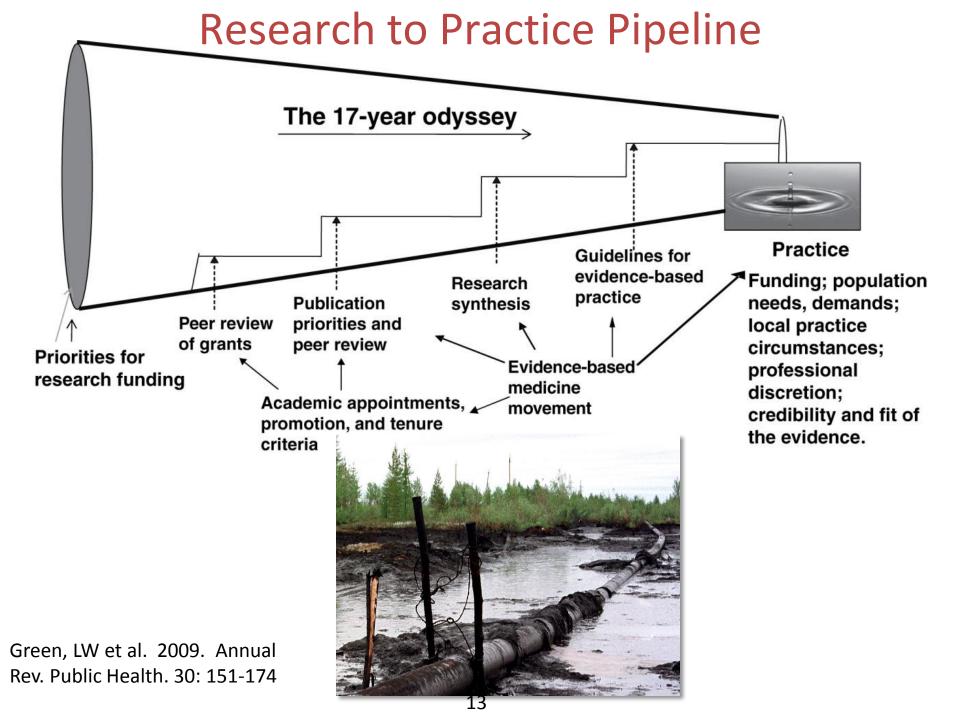
The Need

Dissemination Step	Concept	% Impacted
8.8% of Weight Management sites participated	Adoption	8.80%
5.9% of members participated	Reach	0.52%
91.4% program components implemented	Implementation	0.47%
43.8% of participants showed weight loss	Effectiveness	0.21%
21.2% individuals maintained benefit (individual)	Maintenance	0.04%

¹Abildso CG, Zizzi SJ, Reger-Nash B. Evaluating an Insurance-Sponsored Weight Management Program With the RE-AIM Model, West Virginia, 2004-2008. Preventing Chronic Disease Public Health Research, Practice, and Policy. 2010. 7(3).

STEP	TRANSLATION ISSUES INVOLVED	LENGTH OF TIME
Initial Research	Choice of measures; generalizability.	1-5 years
Replication Research	Degree measures harmonized, samples similar study(ies).	1-3 years
Synthesis Reviews	Criteria used for: inclusion, quality, outcomes, realist review?	1-2 years?
Guideline Created	Implementation guides? Adaptation guides, feasibility.	1-3 years?
Other Guidelines?	Consistency with original, costs and ease of implementation.	1-2 years?
Adoption of Guidelines	Politics, costs, adaptation.	6 months?
Implementation of Guidelines	Readiness, capacity, incentives, tracking, guidelines.	3-12 months
Patient "Adherence"	Competing demands, cost, meaning.	1 – X months
Sustainability	Evolution over time, "drift."	2 - ? years
Complete Cascade	Partnership, relevance, adaptation are cross- cutting issues.	8-17+ years

Future Directions/D&I Opportunities



The Need

Intervention Program/Policy

(Prevention or Treatment)

(e.g. design; key components; principles; external validity)

Evidence

Stakeholders

- Intrapersonal/Biological
- Interpersonal
- Organizational

- Policy
- Community/Economic
- Social/Environment

The Need

(Prevention or Treatment)

(e.g. design; key components; principles; external validity)

Evidence

Stakeholders

Practical Measures

(e.g. actionable & longitudinal measures)

- Intrapersonal/Biological
- Interpersonal
- Organizational

- Policy
- Community/Economic
- Social/Environment

Intervention Program/Policy

(Prevention or Treatment)

(e.g., design; key components; principles; external validity)



Implementation Process

The Need

(e.g., stakeholder engagement team-based science; CBPR; patient centered care)

Practical Measures

(e.g., practical, actionable & longitudinal measures)

- Intrapersonal/Biological
- Interpersonal
- Organizational

- Policy
- Community/Economic
- Social/Environment

The Need

Intervention Program/Policy – The "What"

EIT

- Identify key components or theoretical principles
- Need for detailed implementation guides, lessons learned manuals
- Need to focus and report on both internal and external validity (need to add relevance to rigor)

"If we want more evidence-based practice, we need more practice-based evidence."

Most focus on treatment; less on prevention; least on policy

Practical Measures – the "So What"

Measures need to be:

- Brief and practical
- Collected longitudinally to assess progress
- Reliable and valid
- Sensitive to change

SBM Releases Public Policy Statement

The Public Health Need for Patient-Reported Measures and Health Behaviors in Electronic Health Records

- Have national norms, easily understood and ACTIONABLE
- Culturally appropriate across groups
- Reflect multiple stakeholder perspectives

Society of Behavioral Medicine Health Policy Statement on Public Health Need for Patient Reported Measures. http://www.sbm.org/policy/patient-reported measures.pdf National Cancer Institute

- Partnership and Community Based Participatory Research (CBPR) approaches¹
- Patient-centered Care Approach
- Team science in action^{2,3}

The Need

Iterative, self-correcting

¹ Guidelines and Categories for Classifying Participatory Research Projects in Health: http://lgreen.net/guidelines.html

²Gray, D. O. (2008). In C. L. S. Coryn& M. Scriven (Eds.), Reforming the evaluation of research. New Directions for Evaluation, 118, 73–87.

³Mâsse, LC, et al. Am J Prev Med. 2008; 35 (2S): S151-S160.

CURRENT IDEAL

The Need

Intervention Program/Policy

(Prevention or Treatment)

(e.g., design; key components; principles; external validity)





Implementation Process

(e.g., stakeholder engagement; team-based science; CBPR; patient centered care)

Practical Measures

(e.g., actionable & longitudinal measures)

Multi-Level Context

- Intrapersonal/Biological
- Interpersonal
- Organizational

- Policy
- Community/Economic
- Social/Environment

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Intervention Program/Policy

(Prevention or Treatment)

(e.g., design; key components; principles; external validity)



Implementation Process

(e.g., stakeholder engagement; team-based science; CBPR; patient centered care)

Feedback

Practical Measures

(e.g., actionable & longitudinal measures)

Multi-Level Context

- Intrapersonal/Biological
- Policy

Interpersonal

• Community/Economic

Organizational

Social/Environment National Cancer Institute

Practical (Pragmatic) Trials: Key Contextual Characteristics

- Multiple, heterogeneous settings
- Representative populations
- Comparison conditions are real-world alternatives

EIT

Multiple outcomes important to decision and policy makers

Thorpe KE et al., Can Med Assoc J, 2009, 180: E47-57 Tunis SR et al. Practical clinical trials...JAMA 2003;290:1624-1632 Glasgow RE et al. Practical clinical trials... Med Care 2005; 43(6):551-557 "For every complex problem there is a simple solution ... and it is wrong."



H.L. Mencken

Bridging the Gap: A Synergistic Model

Getting Evidence-based Cancer Control Interventions into Practice

GOAL: To increase the adoption, reach and impact of evidence-based cancer control



Documenting, improving, and communicating the intervention for wide population use



Delivery Capacity

Building the capacity of relevant systems to deliver the intervention



Market Pull/Demand

Building a market and demand for the intervention



Increase the number of systems providing evidence-based cancer control Increase the number of practitioners providing evidence-based cancer control Increase the number of individuals receiving evidence-based cancer control



<u>ULTIMATE GOAL:</u>

Improve population health and well-being

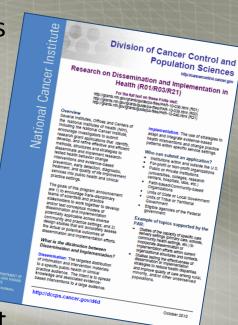
Tracy Orleans (RWJF) – Designing for Dissemination Conference Presentation, 9/02



"By God, gentlemen, I believe we've found it—the Fountain of Funding!"

The Major Cross-NIH D&I Funding Announcement

- R01 PAR 10-038 (\$500k per annum up to five years
 - RO3 PAR 10-039 (\$50K per annum up to two years
 - R21 PAR 10-040 (\$275K up to two years)
- Participating Institutes: NIMH, NCI, NIDA, NIAAA, NIAID*, NHLBI, NINR, NIDDK*, NINDS*, NIDCD, NIDCR, & Office of Behavioral & Social Sciences Research
- Starting October 2010, new standing review commit Dissemination and Implementation Health Research
- Three submission dates per year: February, June, October



The Need

Key Features

- "To identify, ... and refine effective and efficient methods....
- and strategies to disseminate and implement research-tested ...

 interventions and prevention... and Quality of Life improvement services......

in public health and clinical practice settings"

The Need

Other D &I Mechanisms

- CTSA funding at many medical schools
- Partnerships with Prevention Research Centers

Some CDC Mechanisms

AHRQ Funding- especially via PBRNs and EHR Related

Other NIH and private funding (ACS, etc.)

Key Content Issues Funded

 Implementation of evidence-based interventions in healthcare and community settings

Workplace health promotion

 Survey of state (provincial) tobacco plans and implementation research to reach and assist underserved populations

Key Questions Asked By Reviewers

- Is this program or policy ready for dissemination?
- Is team really transdisciplinary?
- Will this advance the field; how is it innovative?
- Is there a good plan for sustainability or broader dissemination of the project?

Content Issues Seldom Addressed (Research Opportunities)

- Comparative Effectiveness Research
- Dissemination to large number of settings
- Proposals addressing complex patients, complex and multilevel problems
- Health policy issues
- Dissemination & implementation of systematic review evidence

Annual D&I Meetings

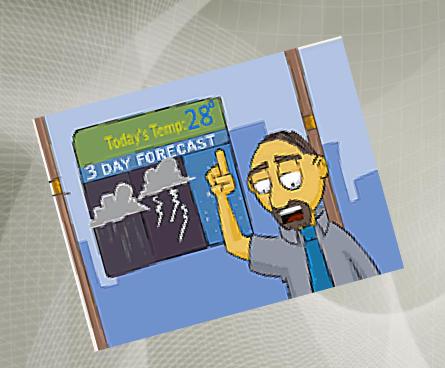
- "State of the D&I Science" Venue
- Three meetings held since 2007
 - Participation increased from 350 registrants in 2007 to over 900 in 2010
 - Past themes have included: "Building Capacity" and "Methods and Measures"

Next meeting: Bethesda, MD March 21-22, 2011

Theme: Policy and International Contributions

Registration: http://conferences.thehillgroup.com/obssr/DI2011/index.html

PREDICTING THE FUTURE...





"You Don't Need a Weatherman
To Know Which Way the Wind Blows"
-Bob Dylan

Evolving Issues

- Simulations, MODELING, system dynamic models
- Time-lagged REPLICATIONS
- Natural experiments
- Well-documented quality improvement studies
- RAPID LEARNING and electronic medical records (EHR) databases¹
- Practical and pragmatic trials²

¹Etheredge LM, Health Affairs, 2007, Web Exclusive Collection: w107-118

Challenges and Conclusions

- The future is multiple (conditions, behaviors, interactive modalities)
- The future is complex (and we ignore complexity at our peril)¹

 "All models (and designs) are wrong" ²— and greater tolerance, respect, and creativity is needed

 We need to UN-learn much of what we have been taught to answer the tough questions

Evidence that...

IS MORE



IS LESS

Contextual

Practical, efficient

Robust, generalizable

Comparative

Comprehensive

Representative

Isolated

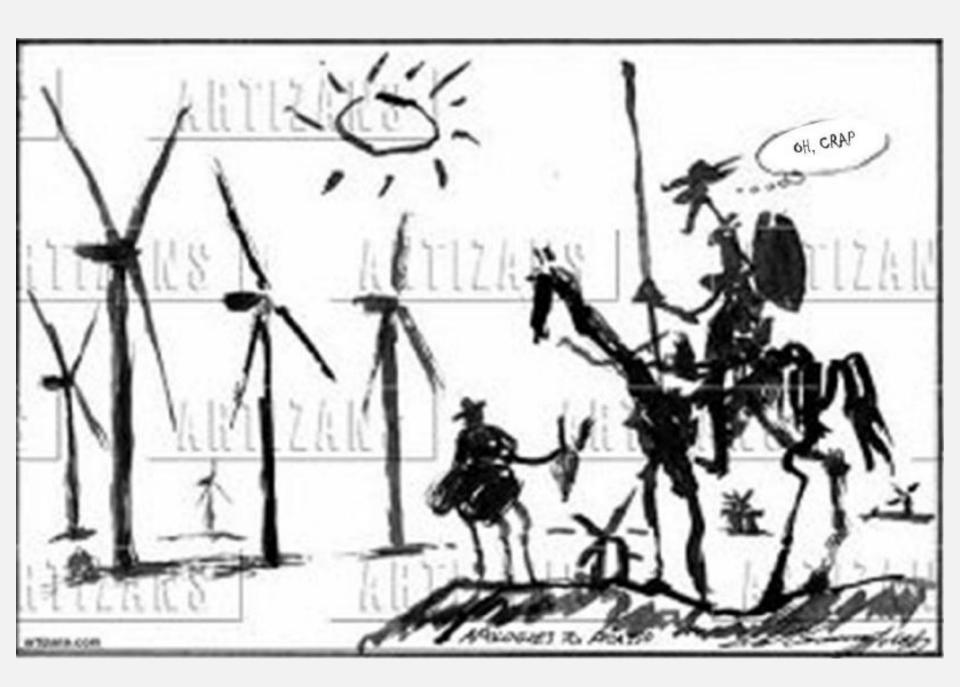
Abstract, intensive

Singular (setting, staff, population)

Academic

Single outcome

From ideal settings



COMMENTS, QUESTIONS, ETC.

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NCI Implementation Science Website:

http://cancercontrol.cancer.gov/d4d/

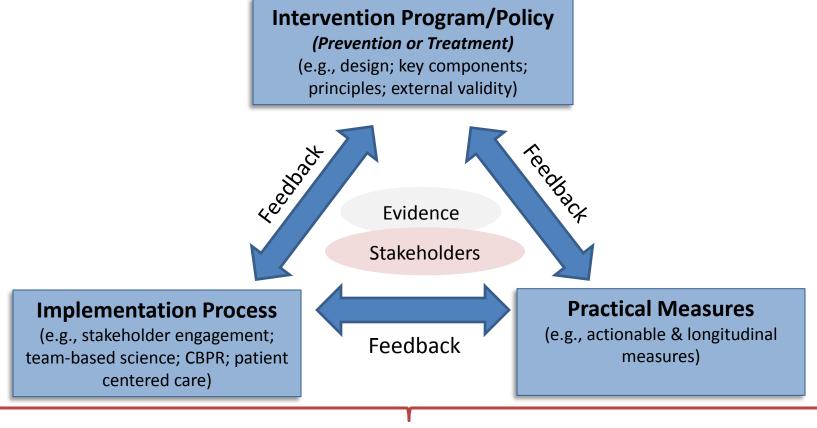




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Evidence Integration Triangle

Translation Across the Continuum



- Intrapersonal/Biological
- Interpersonal
- Organizational

- Policy
- Community/Economic
- Social/Environment

Key Pragmatic and Translation Content Issues in Need of Study by Research Design, Intervention and Evaluation Issues

Research Issue	Key T3-T4 Complex Issues in Need of Study				
	Practical and Feasible	Key Contextual	Transparent	Design Fits Question	
	Interventions	Factors	Reporting		
Experimental Design	Addresses issues relevant to decision makers Representative settings and participants Includes complex patients and realistic comparison treatment(s)	Heterogeneous or typical settings Study of moderating factors Includes qualitative features.	Reports Modification and adaptation to recruitment and design across sites local customization.	Tits specific question Dynamic Adaptive Rapid and efficient Information for scale-up and robustness analyses Simulations	
Intervention Characteristics	Designed for broad adoption and implementation Efficient MINC* Stepped care Scalable.	Flexible Provides guidelines for fidelity and customization Deliverable by variety of staff in typical settings	Reports on: • Adoption • Implementation • Modifications • Subgroup effects • "CONSORT Plus"** information.	Designed for healthcare settings of future QI blends that get smarter over time Sustainable with typical resources.	
Evaluation Measures and Analyses	Analyses of modifier and subgroup effects Effects of Tx intensity and staff expertise Cost, cost-effectiveness, and sensitivity analysis.	Report policy, economic, and political context Assess impact on	Reach by Condition Unintended Quality- of-life impacts Implementation by condition and over time Maintenance at setting and individual levels.	Evaluate systems impacts and unintended consequences Understand multilevel effects and mediators "Post-mortem" interviews long-term sustainability and program evaluation	

WHY? (Targets for Change?)

- Much research not relevant to patients, practitioners, policy makers
- Vested interests (FDA model)
- Way we were trained "unlearning"
- Complex, "wicked issues"¹
- Insufficient funding (98.5% NIH budget for basic)

Future Directions/D&I Opportunities