Closing the Gap Between Discovery and Delivery

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Transforming Health and Medicine Through Discovery

An Introduction to the National Institutes of Health
NIH Mission

*Uncover new knowledge that leads to better health for everyone by:*

- Supporting peer-reviewed scientific research at universities, medical schools, hospitals, and research institutions throughout United States and overseas
- Conducting research in its own laboratories
- Training research investigators
- Developing and *disseminating* credible health information based on scientific discovery
It takes 17 years to turn 14 per cent of original research to the benefit of patient care.

E.A. Balas, 2000
Research Into Practice

- The dance continues…
- Fed, Foundation, State, Local Initiatives
- Policy mandates around provision of Evidence Based Practices
- Appropriateness of manualized interventions
  - fidelity vs. adaptation
- Tested Interventions under-utilized… Used Interventions under-tested
Assumptions About Scientific Development

- Stage 1: Basic Research
- Stage 2: Treatment Development
- Stage 3: Efficacy
- Stage 4: Effectiveness
- Stage 5: Adaptation to Real World

Stage 5 assumed to be beyond research…
Major Challenges

- Building interventions that are more service-oriented
- Understanding optimal construction of interventions
- Improving likelihood of implementation during intervention testing
- Improving the science of implementation
Emerging lists of “best practices”

Continued assumption of linear development of interventions
  - encouraged by funding streams

Anecdotal information on implementation

Some efforts to produce models & theories to test implementation

Much discussion of barriers (papers, meetings, initiatives, studies, etc.)
Generating Evidence from Research

Synthesizing the evidence

Develop Evidence Based Clinical Policies

Applying the Policies

The Path from the Generation of Evidence to the Application of Evidence (Haynes and Haines, 1998, BMJ)
Intervention “evidence”: Only one piece of the picture

- Family Access and Engagement
- Provider knowledge and behavior
- Organization Structure and Climate
- External Environment (stigma, financing)
- Tx “Evidence”
Real-World Implementation: The influence of content, context, and process

**Implementation**

**Content**
- Evidence development & testing
- Evidence interpretation & packaging

**Context**

*External:*
- Political and Professional
- Economic (e.g., reimbursement)
- Social (e.g., stigma)

*Internal:*
- Org culture & structure
- Practice setting characteristics
- Local stakeholders (e.g., attitudes and behaviors)

**Process**
- Behavior change strategies
  - client motivation/behavior
  - provider practices
- Systemic processes
  - supervisory practices
  - quality improvement
- Engagement
  - teachers, physicians, families

Adapted from Pettigrew et al, 1992 by Chambers, Ringeisen, Hoagwood & Patel, 2002
NIMH D&I Research Experience

- Portfolio began in 2001 with 3 grants
- PA written in 2002
- Aimed at research on practice change at
  - Consumer level
  - Provider level
  - Organizational level
  - Ecological level (local, regional, state, national)
- Currently 30 grants in portfolio
Examples of NIMH D&I Research

- Can computerized decision support system improve guideline adherence for depression?
- Can behavioral interventions targeting MDs increase use of EBPs for aggression?
- Why do non-EBPs get implemented in care settings while EBPs do not?
- Does a community database enhance fit of EBPs with local settings?
Examples of NIMH D&I Research

- Can informed consumers enhance their likelihood of receiving EBPs?
- Can QI be used as a platform for implementing EBPs?
- How can clinicians be trained to deliver EBPs?
- Can one assess organizational readiness to deliver EBPs?
NIMH Spotlight: State Implementation of EBPs

- Focus: Can state mental health systems implement EBPs?
- 2003 RFA—state planning grants
- 2005 RFA—exploratory/developmental implementation research grants
- 2006—Statewide implementation studies
  - Already ongoing in TN, OK, CA
Dissemination And Implementation Research Program (82-SEDR)

This program includes studies that will contribute to the development of a sound knowledge base on the effective transmission of mental health information to multiple stakeholders and of the process by which efficacious interventions can be adopted within clinical settings. Research on dissemination will address how information about mental health care interventions is created, packaged, transmitted, and interpreted among a variety of important stakeholder groups. Research on implementation will address the level to which mental health interventions can fit within real-world service systems. Related topics include multilevel decision-making perspectives about services and interventions in community settings, with special focus on translating behavioral science into applied research in these areas.

Areas of Emphasis

- Development of innovative ways of disseminating information to stakeholders (such as new technologies, use of multimedia approaches).
- Novel methods development to address the multidimensional components of dissemination and implementation (consumer, practitioner, clinic, organization, state).
- Implementation studies addressing organizational outcomes around sustainability.

Contact

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DSIR Division Offices, Units, and Branches

- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs (8T-SB)
- Office of Research Training and Career Development (8K-RTT)
- Clinical Trials Operations and Biostatistics Unit (CTOB)
- Adult Treatment and Preventive Intervention Research Branch (83-AT)
- Child and Adolescent Treatment and Preventive Intervention Research Branch (84-CT)
- Services Research and Clinical Epidemiology Branch (82-SE)

Quick Links

- GO TO Division of Services and Intervention Research (DSIR)
- GO TO Services Research and Clinical Epidemiology Branch (82-SE)
THE CANCER CONTROL CONTINUUM

Cancer Control Continuum

Focus

Prevention
- Tobacco Control
- Diet
- Physical Activity
- Sun Exposure
- Virus Exposure
- Alcohol Use
- Chemoprevention

Detection
- Pap Test
- Mammography
- FOBT
- Endoscopy
- PSA Informed Decision Making

Diagnosis
- Informed Decision Making
- Clinical Follow-up Imaging

Treatment
- Health Services and Outcomes Research
- Clinical Trials

Survivorship
- Palliation
- Coping
- Health Promotion

Cross Cutting Issues

- Communications
- Surveillance
- Social Determinants and Health Disparities
- Genetic Testing
- Decision-Making
- Evidence-Based Health Care
- Quality of Cancer Care
- Epidemiology

National Cancer Institute
The Discovery – Delivery Continuum

Discovery

Development

Delivery

Translational Research

Research Translation

Context

Counts

Public Health Practice

Primary Care Practice

Disease Specialty Practice
“The transfer of evidenced-based knowledge into routine or representative practice”

What is Evidence......?

- Surveillance Data
- Systematic Reviews of Multiple Intervention Research Studies
- Expert Opinion/Narrative Reviews
- A Single Intervention Research Study
- Program Evaluation
- Word of Mouth/Media/Marketing
- Personal Experience

...like beauty, it's in the eye of the beholder
“The informed combination of evidence-based knowledge and local contextual knowledge into community applications.”

NCI Steps towards D&I Research

Dissemination Supplements to Efficacy Studies
- NCI-funded intervention investigators invited to submit competitive one year supplement applications
  - With efficacy established
  - $125,000 direct costs to cover dissemination planning and implementation

AHRQ & NCI PAR-04-041: Translating Research into Primary Care Practice

Trans-NIH Dissemination and Implementation PAR
- Round 1 for NCI: 10 R01s, 2 R21s;
- Round 2 for NCI: 6 R01s, 4 R21s, 1 R03
Dissemination Supplements: Closing the Discovery to Delivery Gap

- A peer review mechanism to identify applications with:
  - Sufficient efficacy data
  - Viable plan for evaluating dissemination potential
- DCCPS invited NCI-funded intervention investigators to submit competitive 1-year R01 supplement applications
  - $125,000 direct costs
  - To cover dissemination planning and implementation
- Successful applicants were provided resources to:
  - Support market research and cost-effectiveness research
  - Conduct and evaluate product promotion
  - Disseminate intervention products with appropriate evaluation

39 applications - 12 funded
Content Analysis of D&D Supplement Reviews*

Characteristics of Applications Rated Outstanding and Excellent:

1. Efficacy data strongly supports value of dissemination
2. Applicant demonstrated thorough understanding of dissemination principles and theories
3. Dissemination approaches had potential for broad reach
4. Investigative team strong both on intervention and dissemination expertise
5. Findings from study had potential to contribute to dissemination knowledge base
6. Collaboration of research team with dissemination partners
7. Dissemination to expanded (often higher risk) target population considered strength in innovation
Characteristics of Applications Rated Very Good or Below:

1. Efficacy data limited, missing or do not justify dissemination
2. Limited understanding of dissemination theory or how to apply it to design and evaluation
3. Conceptual framework lacking or poorly described
4. Overly ambitious for one-year time frame
5. Evaluation methods did not focus on dissemination
6. Replication not synonymous with dissemination
7. Intervention modified; too different from original intervention
8. No letter of commitment from practice partner organizations
9. Investigative team lacked dissemination research expertise
10. Dissemination approaches not innovative
11. Limited information regarding plans for sustainability
Most applications focused on efficacy rather than dissemination

Little process data with which to evaluate dissemination

Efficacy & effectiveness of USPSTF recommendations questioned within study section

Human subjects concerns (who is being studied?)

RCT’s preferred design for almost all studies

Explicit vs. Tacit Knowledge
Review group discussion prior to grant receipt

- Downplay importance of testing “new” interventions
- Focus on dissemination
  - Expanded use of efficacious interventions
    - e.g., reminders for screening

At review - Persistent preoccupation with RCT testing of interventions...... but three successes

- EMR-assisted smoking cessation
- EMR-assisted screening mammography recruitment
- Touch screen kiosk for healthy living
The New PAR

- PAR-06-520, 06-521, 07-086: Dissemination and Implementation in Health
  - NIMH, NCI, NHLBI, NIDA, NIAAA, NIDCR, NIDCD, NINR, OBSSR, ODS
- Special Emphasis Panel for D and I
- SEP reviews R03, R21, R01 applications
- Submission every other round
Dissemination and Implementation Research

- **Dissemination** is “the targeted distribution of information and intervention materials to a specific public health or clinical practice audience.”
- **Implementation** is “the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.”

Adapted from Lomas (1993)
Dissemination Research Topics

- Analysis of factors influencing the creation, packaging, transmission and reception of valid health research knowledge.
- Experimental studies to test the effectiveness of individual and systemic dissemination strategies, focusing on relevant outcomes (e.g., acquisition of new knowledge, maintenance of knowledge, attitudes about the dissemination strategies, use of knowledge in practice decision-making).
- Studies testing the utility of alternative dissemination strategies for service delivery systems targeting rural, minority, and/or other underserved populations.
- Studies on how target audiences are defined, and how evidence is packaged for specific target audiences.
Implementation Research Topics

- Studies of efforts to implement prevention, early detection, and diagnostic interventions, as well as treatments or clinical procedures of demonstrated efficacy into existing care systems to measure the extent to which such procedures are utilized, and adhered to, by providers and consumers.

- Studies on the fidelity of implementation efforts, including the identification of components of implementation that will enable fidelity to be assessed meaningfully.

- Longitudinal and follow-up studies on the factors that contribute to the sustainability of research-based improvements in public health and clinical practice.
D & I Research Topics

- Studies of the capacity of specific care delivery settings (primary care, schools, community health settings, etc.) to incorporate dissemination or implementation efforts within current organizational forms.
- Studies that focus on the development and testing of theoretical models for dissemination and implementation processes.
- Development of outcome measures and suitable methodologies for dissemination and implementation approaches that accurately assess the success of an approach to move evidence into practice (i.e., not just clinical outcomes).
PAR Review Criteria - Significance

1. Does this study address an important problem?
   - If the aims of the application are achieved, how will scientific knowledge, public health or clinical practice be advanced?

2. What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

3. Do intervention efficacy data justify dissemination and implementation?

4. If aims of proposed project achieved, how will dissemination and implementation knowledge be advanced?

5. How broad a reach (to the population that will benefit from the knowledge/intervention) will be achieved by the dissemination and implementation of the intervention through the knowledge/service delivery contexts selected?
1. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?

2. Has the applicant made appropriate changes in the intervention design based on the current state-of-the-art and or contextual factors relevant to dissemination and/or implementation?

3. Does the applicant demonstrate an understanding of dissemination and implementation research principles?

4. Are the procedures to evaluate the dissemination or implementation program appropriate?

5. How appropriate are the plans to sustain effective dissemination and implementation approaches once the research-funding period has ended?
1. Is the project original and innovative?
   - For example: Does the project challenge existing paradigms, public health or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?

2. Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

3. Does the proposed dissemination or implementation research contribute new and innovative design approaches to the study of dissemination or implementation process and/or outcomes?
PAR Review Criteria - Investigators

1. Are the investigators appropriately trained and well suited to carry out this work?

2. Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

3. Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

4. Does the investigator team include specific dissemination and implementation expertise?

5. Relevant letters of support from key partner dissemination and implementation organizations, which plan to adopt the intervention, are expected.
1. Does the scientific environment in which the work will be done contribute to the probability of success?

2. Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?

3. Is there evidence of institutional support?

4. Do the proposed approaches take advantage of unique features of the intervention delivery environment or employ useful, collaborative arrangements?

5. Is there evidence of institutional support to sustain dissemination or implementation interventions once the research funding ends?
Q: Are methodological approaches other than randomized trials acceptable (e.g., quasi-experimental, qualitative, case studies)?

A: Yes. Because the design of a dissemination and implementation research project requires equal attention be paid to the external validity and the internal validity of the strategies being tested, this program announcement encourages consideration of a broad range of methodological approaches. The ones selected should be justified as most appropriate for the specific research question(s) being examined or hypotheses being tested.
Q: How much flexibility do I have in intervention delivery, adapting to my delivery context, versus maintaining the fidelity of intervention delivery as implemented in the original efficacy/effectiveness trial?

A: The impact of a particular intervention will vary both in terms of the fidelity with which the intervention is delivered and the extent to which the intervention is appropriately adapted to fit the service delivery contexts and the characteristics of the population being served. Applications are encouraged to explicitly address the balance between fidelity (internal validity) and adaptation to improve contextual fit (external validity) in the dissemination and implementation of evidence-based interventions.
Q: One of the criteria described in the Significance section of the PAR emphasizes the importance of the proposed study having a positive impact on public health and community. My research focuses on understanding the mechanisms that underlie effective dissemination approaches (basic dissemination science). Is it appropriate for me to apply to this PAR.

A: Yes. This proposal strongly encourages proposals that span the continuum of scientific inquiry from basic dissemination and implementation science (e.g., building and/or testing models) to applied dissemination and implementation trials.
Q: Does this program announcement apply to international populations outside of the U.S., or is this exclusively for study of populations within our borders?

A: As noted in the section on eligible institutions, foreign institutions may apply. During the peer review of international studies, the relevance of the study of international populations to US populations often emerges and the applicant should address this relevance in the application when appropriate.
THE DISCOVERY-DELIVERY CONTINUUM

Discovery  |  Development  |  Delivery  |  Policy

Efficacy-Replication Research  \downarrow  D&I Research

Diffusion  |  Replication  |  Knowledge Synthesis  |  Dissemination  |  Implementation