

Closing the Gap Between Discovery and Delivery

**Dissemination and Implementation Research
PARs 039,520, 521**

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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

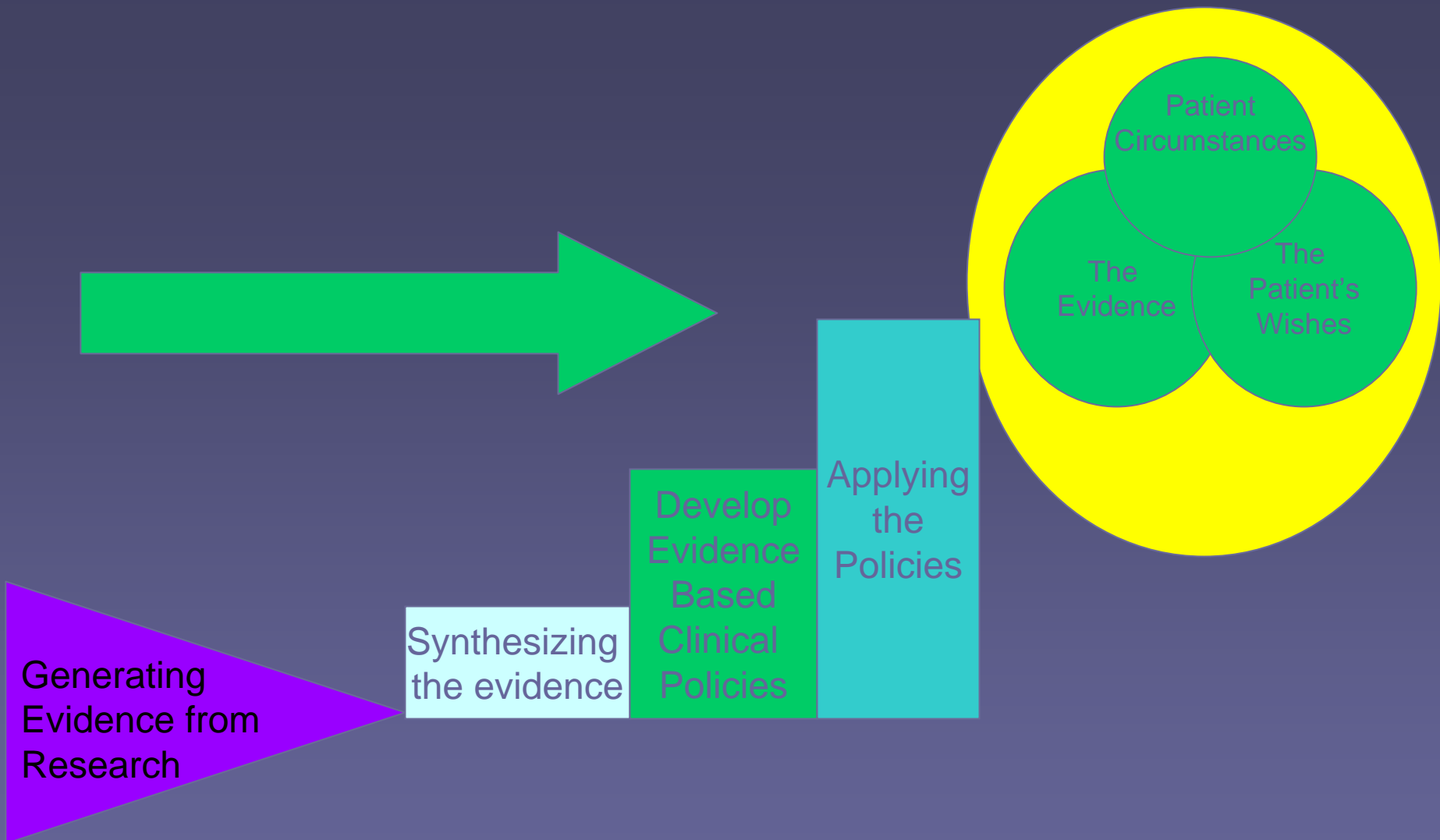
Stage 5 assumed to be beyond research...

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

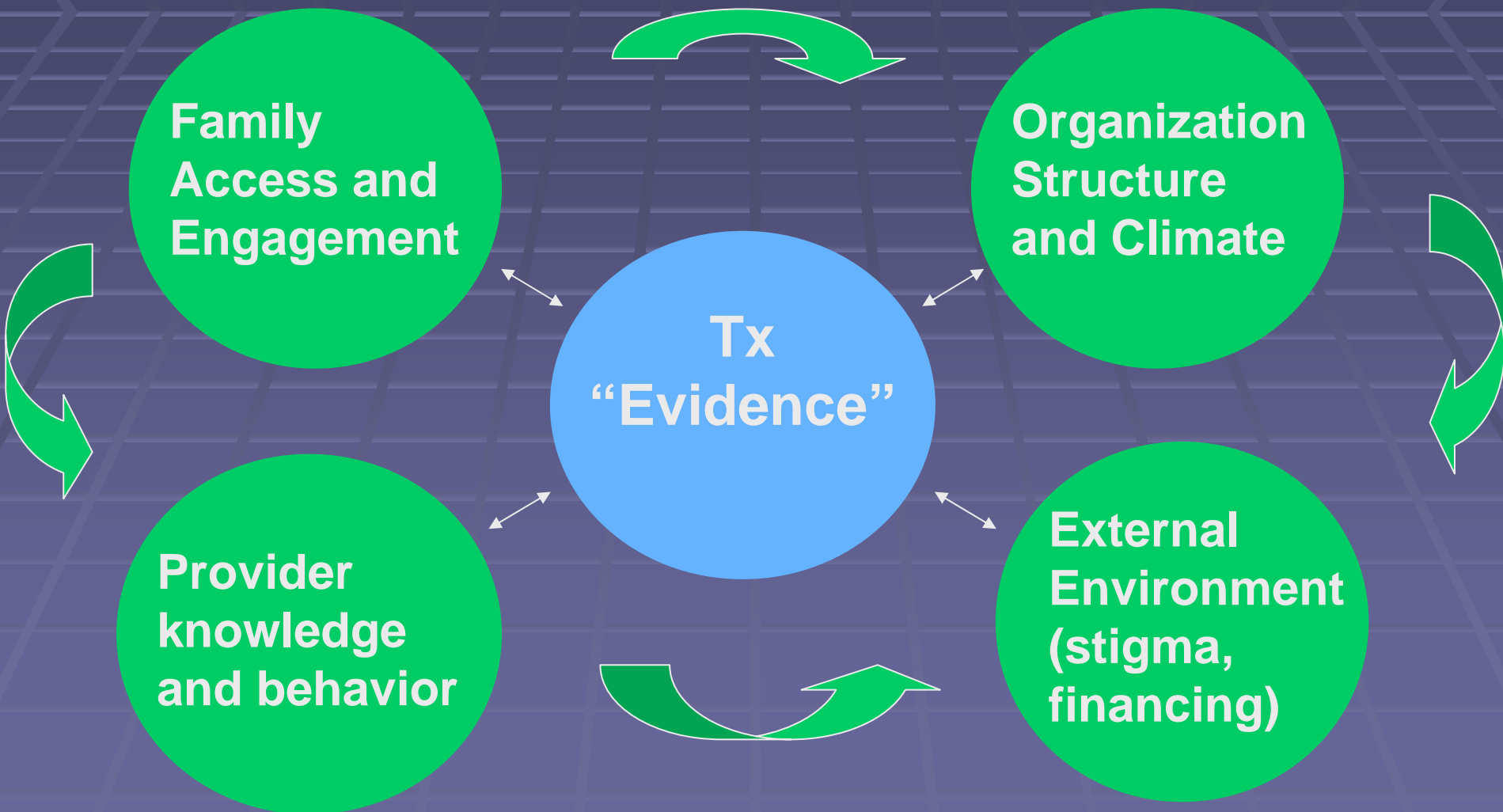
Implementation Here and Now

- 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.)



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



Real-World Implementation:

The influence of content, context, and process

Implementation

Content

- Evidence development & testing
- Evidence interpretation & packaging

Process

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

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)

Adapted from Pettigrew et al, 1992
by Chambers, Ringeisen, Hoagwood
& Patel, 2002

NIMH Dissemination & Implementation (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 Evidence-Based Programs (EBP) 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?

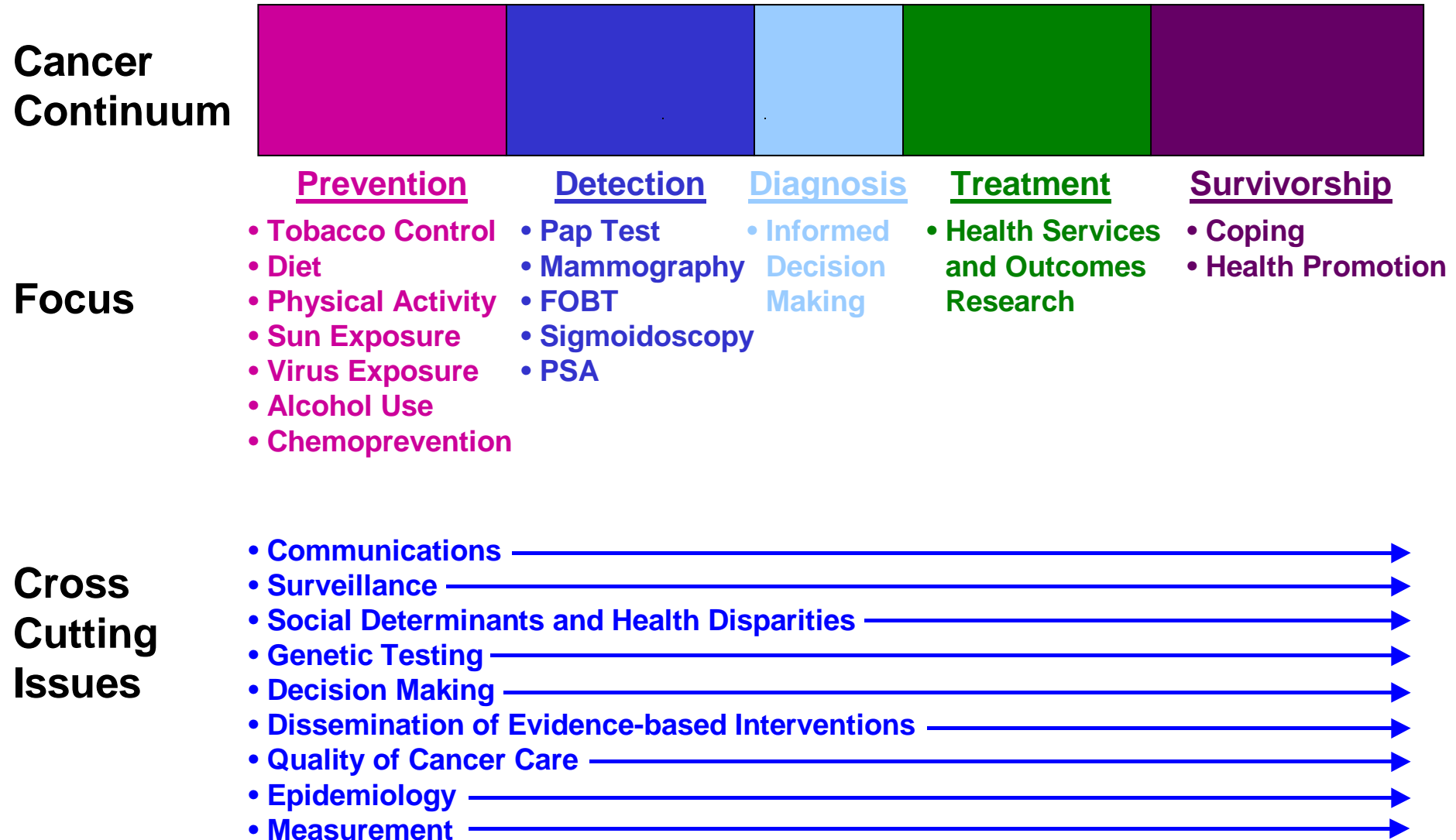
Examples of NIMH D&I Research

- 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?

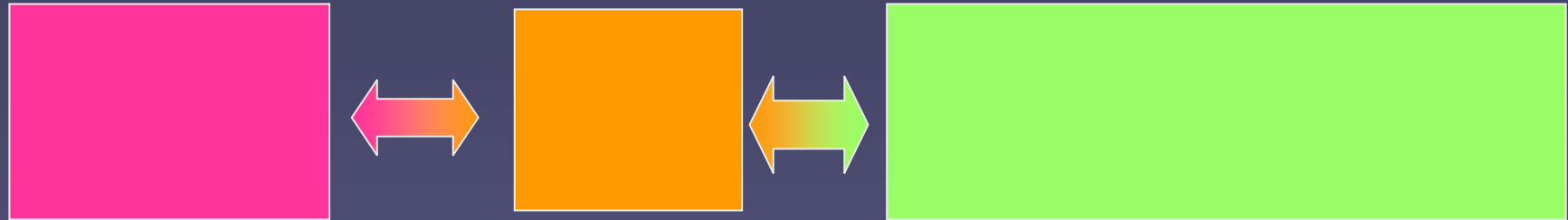
NIMH Spotlight: State Implementation of EBPs

- 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

THE CANCER CONTROL CONTINUUM



The Discovery – Delivery Continuum



Discovery

Development

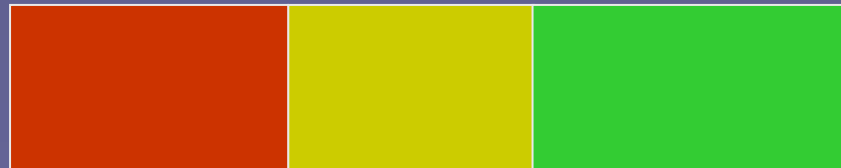
Delivery

Translational Research

Research Translation

Context

Counts



Public
Health
Practice

Primary
Care
Practice

Disease
Specialty
Practice

TRANSLATION

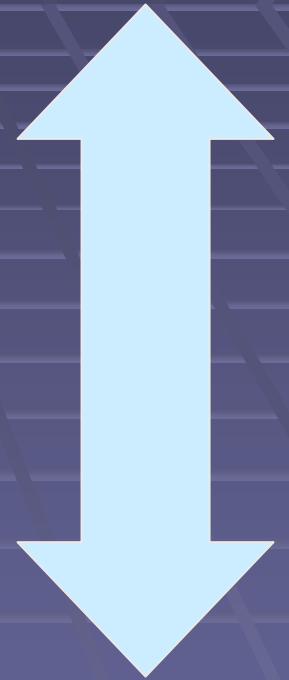


“The transfer of evidenced-based knowledge into routine or representative practice”

What is Evidence.....?

- Surveillance Data
- Systematic Reviews of Multiple Intervention Research Studies
- An Intervention Research Study
- Program Evaluation
- Word of Mouth
- Personal Experience

OBJECTIVE



SUBJECTIVE

...like beauty, it's in the eye of the beholder

INTEGRATION



“The informed combination of evidence-based knowledge and local contextual knowledge into community applications.”

Adapted from Glasgow, R SBM (2005) 26th Annual SBM Meeting, Symposium #22: Disseminating Behavioral Medicine Research: Making the Translational Leap.

AHRQ & NCI PAR-04-041: Translating Research into Primary Care Practice (Round 1)

- Most applications focused on efficacy rather than dissemination
- Little process data with which to evaluate dissemination
- Efficacy & effectiveness of US Preventive Services Task Force (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

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
- Div of Cancer Control & Population Sciences 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

12 funded applications

Content Analysis of Dissemination & Diffusion (D&D) Supplement Summary Statements

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

Content Analysis of D&D Supplement Summary Statements

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

TRANS NIH-PAR

The New PAR

- PAR-06-039, 520, 521: Dissemination and Implementation Research in Health
 - NIMH, NCI, NHLBI, NIDA, NIAAA, NIDCR, NIDCD, NINR, OBSSR, ODS
- Special Emphasis Panel (SEP) for D and I
- SEP accepts R01, R03, R21s
- 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 introduce or change evidence-based health interventions 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?

PAR Review Criteria - Approach

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?

PAR Review Criteria - Innovation

1. Is the project original and innovative?
 - For example: Does the project challenge existing dissemination or implementation paradigms in 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.

PAR Review Criteria - Environment

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?

Scientific / Research FAQs

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.

Scientific / Research FAQs

Q: I have preliminary data on the efficacy of an intervention that is likely to have a very large public health impact in a high priority area. Is it appropriate at this stage to move to a dissemination trial?

A: If the preliminary data are so compelling that completion of the efficacy or effectiveness trial is extremely unlikely to change the intervention impact observed, then it may be appropriate to consider submitting. However, this program announcement is designed to expand the knowledge base about how to disseminate and implement interventions that have been rigorously tested and that have been shown to be effective. Thus, the applicant is encouraged to discuss with their NIH institute-specific intervention research project program director the extent to which the preliminary data may justify a dissemination/implementation research project proposal at this time.

Scientific / Research FAQs

Q: My intervention impacts a relatively small (but high risk) population. Is it appropriate for me to submit an application?

A: Whether in the public health or clinical practice contexts the population impact of a particular intervention will vary both in terms of the size of the intervention effect and the reach to the population at risk. A small intervention effect applied to a large at risk population may be viewed as similar to a large intervention effect seen for a small but high-risk population. Applications are encouraged that address dissemination and implementation of evidence-based interventions that impact large underserved populations and/or specific high risk groups.

Scientific / Research FAQs

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: Both in public health or clinical practice, 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.

Scientific / Research FAQs

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.

Scientific / Research FAQs

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.