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An Introduction to Effectiveness, Dissemination And Implementation Research

From the Series: *CTSI Guides to Community-Engaged Research*

This guide is an introduction to the emerging fields of **effectiveness research, diffusion research, dissemination research and implementation sciences**, the latter three having been categorized by the NIH and CDC as key components of '**translation research'**.

This is one of a series of guides developed by the CTSI **Community Engagement Program** (CE) on conducting community-engaged and translational research.

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The purpose of this guide is to:

- Introduce the reader to basic principles of and definitions of effectiveness and translation research in order to promote a shared language and facilitate dialogue.
- Provide a framework for researchers to include effectiveness research, diffusion research, dissemination research and implementation sciences in their current work.
- Provide both a framework, practical information, and grant language that will encourage established UCSF investigators to prepare grant applications related to effectiveness and translation research and to encourage fellows and junior faculty to consider developing their career focus in these fields.
- Provide the reader with a set of resources for further readings, links to funding opportunities, helpful citations, and names of experts.
- Promote interest among and between members of the UCSF scientific community; policymakers and practitioners at the local, regional, and state-wide level; and community members to engage in a new kind of research – one that will help transform health and medicine through discovery by closing the gap between discovery and delivery.
- Raise awareness of informal and formal consultative services for those interested in pursuing this line of inquiry.

Defining Key Terms

According to the Centers for Disease Control and National Institutes of Health, the following terminology is defined:

- *Translation research* characterizes the sequence of events (i.e., process) in which a proven scientific discovery (i.e., evidence based public health intervention) is successfully institutionalized (i.e., seamlessly integrated into established practice and policy). Translation research does not encompass pure biomedical or formative basic science research (e.g., discovery of a new gene, metabolic pathway or etiology research). It also does not include the conduct of an initial or replication intervention efficacy or effectiveness trial. Translation Research is comprised of many complex components which include specialized fields of study. Specifically, translation research is comprised of dissemination research, implementation research and diffusion research. Translation research involves the study of how best to transfer evidence-based knowledge into routine or representative practice, and by definition requires involvement and input of the end-user in the pipeline. *Translation research* should not be confused or conflated with the more broadly used *translational research*, the term NIH uses to refer to the upstream pipeline model of bench science to effectiveness research. Rather, translation research takes effectiveness studies and attempts to understand the process that moves discoveries to sustained adoption.
- *Reach* has been characterized as a measure of the accessibility of an intervention across multiple dimensions: participation rates across communities, clinics, providers, and patients; representativeness of patients/individuals enrolled; and patient engagement with (e.g. uptake of, use of) an intervention.
- *Dissemination* is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience.
- *Dissemination Research* is the systematic study of how the targeted distribution of information and intervention materials to a specific public health audience can be successfully executed so that increased spread of knowledge about the evidence-based public health interventions achieves greater use and impact of the intervention.
- I*mplementation* is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.
- *Implementation research* is the systematic study of how a specific set of activities and designed strategies are used to successfully integrate an evidence-based public health intervention within specific settings (e.g., primary care clinic, community center, school).
- *Diffusion research* is the systematic study of the factors necessary for successful adoption by stakeholders and the targeted population of an evidence-based intervention which results in widespread use (e.g., state or national level) and specifically includes the uptake of new practices or the penetration of broad scale recommendations through dissemination and implementation efforts, marketing, laws and regulations, systems-research and policies.

Evidence-based interventions are a key component of translation research. We define and describe the characteristics of an evidence-based intervention:

- *Intervention* is an intentional action (singular or constellation) designed for an individual, a community, or a region that alters a behavior, reduces risk or improves outcome. Interventions can be a medical or behavioral therapy, modification to the natural or built environment, including engineering controls, public heath policy, public health program, health communication, or public health law.
- *Efficacy* refers to the intervention's ability to do more good than harm among the target population in an ideal setting (e.g., randomized clinical control trial or community-level trial).
- *Effectiveness* refers to the intervention's ability to do more good than harm for the target population in a real world setting.
- *Evidence-based* means that the intervention has undergone sufficient scientific evaluation to be proven to be efficacious or effective (e.g., intervention is considered valid or "proven" because it is strongly linked to desirable outcome).
- *Practical Clinical Trials*: trials of evidence-based, reproducible interventions across a range of settings, providers and patients designed to enable rigorous, real-world evaluation with respect to reach and effectiveness.

In the context of an intervention it is extremely important to clarify the concept of "adaptation", "adoption", "fidelity", "outcomes and impacts", "scalability" and "sustainability " which are interrelated and not mutually exclusive terms.

- *Adaptation* refers to the modifications of the intervention itself or the necessary alterations in the supporting infrastructure.
- *Adoption* refers to the uptake of the desired intervention into the target population or uptake by the implementers.
- *Fidelity* refers to "the adherence of actual treatment delivery to the protocol originally developed" or "the degree program developers implement programs as intended by the developers"
- *Integration* refers to the informed combination of evidence-based knowledge and local contextual knowledge into community applications
- *Outcomes and impacts* are the end results of public health interventions which include effects that people experience and care about, such as change in the ability to function, improved health, quality of life, satisfaction, or cost.
- *Scalability* describes the adoption of an intervention resulting in wider usage that retains or improves its effectiveness, affordability, and sustainability.
- *Sustainability* is achieved when the evidence-based intervention is routinely executed. Long-term sustainability can be dependent upon funding availability and policies which support a functional infrastructure that maintains fidelity of the evidence-based intervention (e.g., training, laws, and reimbursement for services).

Examples of *dissemination research topics* include:

- Analysis of factors influencing the creation, package, transmission and receipt of valid health research knowledge
- Experimental studies to test effectiveness of individual and systemic strategies acquisition and maintenance of knowledge, use of knowledge in decision-making and practice

- Studies testing alternative strategies for service delivery systems targeting rural, minority, and other underserved populations

Examples of *implementation research topics* include:

- Studies of efforts to implement prevention, early detection, or diagnostic interventions into existing care systems or community settings
- Studies on the fidelity of implementation efforts, including the identification of those components of the intervention for which fidelity is meaningful
- Longitudinal studies on the factors that contribute to sustainability of interventions in practice
- Development of outcome measures and suitable methodologies for dissemination and implementation that accurately assess success of the approach (not just clinical outcomes)

A recent NIH review panel summarized characteristics of outstanding dissemination and implementation studies:

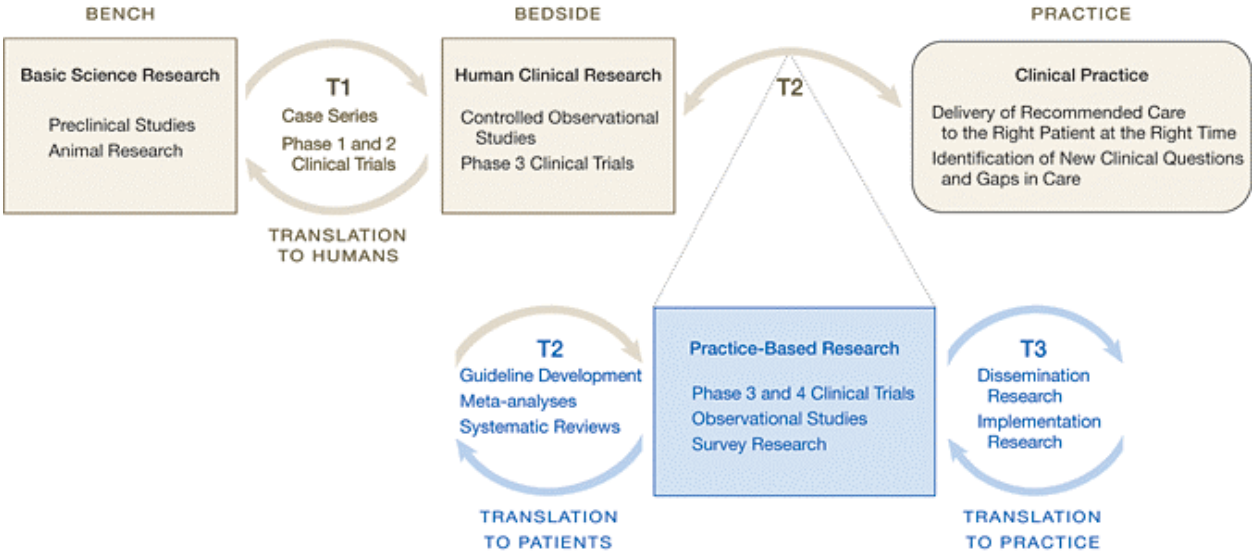
- Focuses on an important public health or clinical problem
- Efficacy data strongly supports value of dissemination and implementation
- Thorough understanding of dissemination and implementation principles and theories
- Dissemination and implementation approaches have potential for **broad reach**
- Team strong on intervention and dissemination expertise, multidisciplinary
- Address innovative hypothesis; uses innovative methods; challenges existing public health paradigm
- Study has potential to contribute to dissemination and implementation knowledge base and advance the field
- Dissemination to expanded /hi risk target populations
- Specific dissemination products will be created

Click here to view presentations and videos with examples of dissemination/implementation research. Click here for details on the recent NIH conference, Building the Science of Dissemination and Implementation in the Service of Public Health.

Recent NIH Program Announcements (click for more information)

- PAR-06-520 for R03
- PAR-06-521 for R21
- PAR-07-086 for R01

Underpinnings of Dissemination and Implementation Research



The graphic representation above (Westfall et al 2007) shows where "translation research" is situated in the pathway of harnessing science to promote health (the T3 loop).

Scientific development for human health has been conceived as occurring through 5 steps:

- Basic research
- Treatment Development
- Efficacy
- Effectiveness
- Adaptation to Real World

The transfer from stages **3 to 4 to 5** that is central to the **Discovery-Delivery Continuum** traditionally has been considered to be either a minor area of scientific inquiry or beyond research entirely. More recently, increasing attention is being paid to the barriers that impede movement across these stages. There now is growing attention being paid to the science needed to understand and intervene to promote dissemination and implementation. It is clear that intervention 'evidence' is only one piece of a multi-step process. Real-world implementation is influenced by **content** (evidence development and testing; evidence interpretation and packaging), **context** (political and professional, economic, social, organizational, attitudes and behavior of local stakeholders) and **process** (behavior change strategies, supervisory/management practices, and engagement).

The goals of implementation and dissemination research are to generate new insights and generalizable knowledge regarding dissemination and implementation processes, facilitators, barriers, strategies; to apply, test, and refine models, theories, hypotheses, and principles; to produce reliable strategies for improving health-related processes and outcomes for both local and other settings and groups.

What is the problem, and why do we need to perform effectiveness, dissemination and implementation research?

"Tested interventions are underutilized. Used interventions are under-tested." - Chambers and Kerner 2007

Barriers to translation

The gap between clinical research and practice in many areas of health care and public health is well-documented, large, and growing. There are many interacting reasons for the general failure for health research to translate into practice, including economic and social policy, as well as scientific factors. In this document, we focus on those elements of the scientific process that can present **barriers to dissemination and implementation,** because they are most proximal to program developers and researchers. These include characteristics of:

- The intervention studied
- The target settings
- The research/evaluation design
- Interactions of all 3 above

Many of the problems associated with the points above result from the practice of sacrificing external validity in the hope of maximizing internal validity that is the hallmark of efficacy rather than effectiveness, research. Most studied interventions that have proven efficacious have tended to be intensive and demanding of both staff and participants, limiting generalizability. Some threshold level of intensity of intervention is likely necessary, but program designers should be developing programs of the minimal intensity needed for change, rather than maximum intensity. Of note, studies of the relationship between efficacy of interventions and program **reach** have shown an inverse relationship between participation rates and magnitude of change among participants. In other words, the more participation by diverse populations, the less change the intervention has been able to effect. One possible solution is to replace intensive interventions that engage fewer people with more extensive approaches that involve low cost interventions with frequent contact that engage more people (Rose's theorem).

Two additional barriers are that programs are (a) not packaged or manualized so that they are straightforward to implement and (b) implementation materials do not permit any deviation from the original efficacy study protocol or do not describe the modifications that are permissible. Program designers should collect more process evaluation data to help make recommendations regarding program modifications, and funders should support the time and effort it takes to conduct these important translation steps.

Other elements of the research design can limit translation. When small and unrepresentative samples of patients, staff, and setting are included, results do not generalize. Practices such as run-in periods or excluding patients with co-morbidities further limit external validity and prevent uptake by practitioners and policymakers. Attention now should be focused on inclusion of more typical settings and intervention personnel. In addition, studies only rarely address outcomes important to policymakers, such as cost-effectiveness or other economic outcomes. **This lack of "fit" (mismatch) between an intervention /research design on the one hand and the realities inherent to the ultimate target practice setting and the information needed by policymakers on the other hand, leads to low adoption and implementation** (e.g. the program is not seen as feasible, or as being responsive to local concerns). Community-based participatory research (CBPR), methods and 'practical clinical trials' each offer means of enhancing the relevance and effectiveness of public health interventions.

Contextual Issues

Factors that influence decision-makers with respect to translation include such issues as the magnitude and time course of the health issue of focus; the personal, social, and economic costs of the problem; the political will and resources to tackle the problem; the **robustness, replicability, relevance, and representativeness** of the data; the quality and consistency of the evidence; and the potential costs of inaction. Researchers can and should do more to present contextual and external validity evidence to aid decision makers. **External validity** refers to 'inferences about the extent to which a causal relationship holds over variations in persons, settings, treatments, and outcomes.' Information on the 4 categories of (1) program reach on representativeness, (2) implementation and adaptation, (3) outcomes for decision-making and (4) maintenance and institutionalization should be integrated into research designs and reports.

A recent study at McMaster explored the value of the research literature on behavior change related to healthy diets. Among 2,872 studies, including 16 systematic reviews, only 5 studies were appropriately designed and/or reported on the range of outcomes so as to influence policy and practice. **Practical clinical trials** (e.g. trials of evidence-based, reproducible interventions across a range of settings, providers and patients designed to enable rigorous evaluation with respect to reach and effectiveness), provide one means to achieve these ends. Key characteristics of such trials include study of heterogeneous and representative patient samples; multiple and diverse settings; multiple measures relevant to decision-makers (cost and quality of life); and comparison conditions more relevant to real-world decisions (current standard of care or alternative approaches) instead of placebo controls. **Heterogeneity is encouraged and purposeful**, rather than minimized, to achieve diversity and representativeness. Practical clinical trials reflect more of the complexity and context of the real world, e.g. participants with multiple co-morbid conditions and staff who have completing demands and varying levels of expertise.

Recommendations

As described by Glasgow and Emmons (Annual Review of Public Health 2007), "to enhance integration of research and practice, we need to change how we perform research program development, evaluation, and reporting. It will be much easier for local practitioners and policymakers to judge program relevance if researchers (a) pay greater attention to context and external validity and (b) partner with relevant decision-makers and target audiences at the outset. This is only one of many

strategies needed to increase translation of evidence-based interventions, but it is a critical component and excellent starting point."

Summary Recommendations to enhance integration of research and practice (Glasgow and Emmons 2007):

- Anticipate and address likely barriers to dissemination
- Appreciate and integrate multiple types of evidence
- Adopt research designs, such as practical clinical and behavioral trials across settings, that address concerns of clinicians and policymakers
- Conduct broader evaluations that include multiple outcomes, address generalizability, and report on contextual factors
- Do not expect a program to work perfectly initially, but plan for adaptation and refinement to fit local conditions and merging issues

Definitions and Questions to Ask to Assess Applicability (Green and Glasgow 2006)

RE-AIM Dimension	Definition	Questions to Ask
Reach (individual level)	Participation rate among intended audience and representativeness of these participants	What percentage of the target population came into contact with or began program? Did program reach those most in need? Were participants representative of your practice setting?
Effectiveness (individual level)	Impact on key outcomes and quality of life Consistency of effects across subgroups	Did program achieve key targeted outcomes? Did it produce unintended adverse consequences? How did it affect quality of life? What did program cost as implemented and what would it cost in your setting?
Adoption (setting and/or organizational level)	Participation rate and representativeness of settings in the evaluation	Did low-resource organizations serving high-risk populations use it? Did program help the organization address its primary mission? Is program consistent with your

		values and priorities?
Implementation (setting and/or organizational level)	Level and consistency of delivery across program components and different staff members	How many staff members delivered the program? Did different levels of staff implement the program successfully? Were different program components delivered as intended?
Maintenance (individual and setting levels)	At individual level: Long-term effectiveness At setting level: Sustainability and adaptation of program	Did program produce lasting effects at individual level? Did organizations sustain the program over time? How did the program evolve? Did those persons and settings that showed maintenance include those most in need?

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Helpful Web Resources:

Cancer Control PLANET. Website: http://cancercontrolplanet.cancer.gov/

Cancer Control and Populations Sciences: Research Dissemination and Diffusion Website: http://cancercontrol.cancer.gov/d4d

Consolidated Standards of Reporting Trials (CONSORT) statement. www.consort-statement.org

Implementation Science is an Open Access, peer-reviewed online journal that aims to publish research relevant to the scientific study of methods to promote the uptake of research findings into routine health care in both clinical and policy contexts. Website: http://www.implementationscience.com/

National Cancer Institute, Division of Cancer Control and Population Sciences, Research Dissemination and Diffusion Web Site. www.dccps.cancer.gov/d4d

The National Registry of Evidence-Based Programs and Practices of SAMSHA. Website: http://www.nrepp.samhsa.gov/

NorthStar - making quality improvement easier. www.rebeqi.org/?pageID=34&ItemID=35

Ottawa Statement on Trial Registration. www.ottawagroup.ohri.ca

VA implementation science resource: Website: http://www1.va.gov/hsrd/QUERI/

REBEQI: Research-based continuing education and quality improvement. www.rebeqi.org

RE-AIM: a systematic way for researchers, practitioners, and policy makers to evaluate health behavior interventions. It can be used to estimate the potential impact of interventions on public health. This is an excellent web resource. http://www.re-aim.org/

Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement. www.trend-statement.org