Dissemination and Implementation Science: What is it and Why is it critical to Translational Science?

Initiated by the Dissemination and Implementation Workgroup of the Collaboration Engagement Task Force within the Clinical Translational Science Award Program

National Institutes of Health
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Agenda

Why a webcast on Dissemination and Implementation Science?
Laura-Mae Baldwin, MD, MPH  5 minutes

Dissemination & Implementation Science: Why and what?
Enola Proctor, PhD  15 minutes

Reversing Health Disparities in Complex Health Conditions through Implementation Science
Stephen Bartels, MD, MS  15 minutes

Question and Answers  25 minutes
Clinical Translational Science Award (CTSA) Program

Over 60 medical research institutions across the U.S. that work together to speed the translation of research discoveries into improved patient care.

- Fostering innovative research
- Cultivating multi-disciplinary research partnerships
- Ensuring a pipeline of next-generation researchers through robust education and career development programs
D&I Science in the CTSA Program:

CTSA program defines translation as:  
the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes.*

Complexity and challenges—research and operational-- become clear as translational research projects move from genes, proteins and cells in laboratory settings to real-world environments.*

*Christopher P. Austin, 2018, Nature

Hence, need for distinct scientific approaches
Dissemination & Implementation Science: Why and what?

Enola Proctor
Shanti Khinduka Distinguished Professor & Implementation Science Director
Institute for Clinical and Translational Science
Washington University in St. Louis
$95 billion spent on health research annually but translation to real-world benefit is:

Incomplete
• 42% high quality care
• 30% spending unnecessary

Protracted
• 17 years
• 14% of findings
Another 17 year quest

The care that “could be”

vs

The care that “is”

The “know” –”do” gap
Dissemination and Implementation Science Imperatives: The Why?

Scientific:
• Identify and develop strategies to overcome barriers to the adoption, integration, scale-up, and sustainability of evidence based interventions, tools, policies, and guidelines

Public health:
• Recoup return on investment in life sciences and medical discoveries
• Extend benefits from prevention, early detection, and treatments to all populations

Ethical:
• Ensure that biomedical discoveries make a difference in people’s lives
**Dissemination**

Targeted distribution of information and intervention materials to a specific public health or clinical practice audience.

Intent: to spread knowledge and the associated evidence-based interventions.

**Dissemination research**

Scientific study of targeted distribution of information and intervention materials to a specific health audience.

Intent: to understand how best to spread and sustain knowledge and associated evidence-based interventions.
Implementation

The adoption of evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

Implementation research

The scientific study of HOW to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.
A Big Tent of Terms (and Circles)*

* The terms according to D.A.C.
What does dissemination research study?

Key variables:
- audience and audience segmentation
- message types (data, narrative), communication channels
- information packaging, diffusion processes

Key outcomes:
- information spread
- awareness, acceptance, belief in evidence,
- knowledge reception & retention, intent to act on information
What does implementation research study?

**Key variables:**
- behavior of healthcare professionals and support staff
- healthcare organizations (culture/ context)
- healthcare consumers and family members
- policymakers in context as key variables
- implementation strategies and processes

**Key outcomes:**
- sustainable adoption, implementation and uptake of evidence-based interventions
Features of D&I research

- Multilevel
- Cross-setting
- Transdisciplinary

Leverages expertise from:

- Health care professions (medicine, nursing, social work, psychology, pharmacy, rehab medicine)
- Comparative effectiveness and health outcomes researchers
- Practice managers
- Experts in informatics, org behavior, engineering, marketing, communications, & health policy
Scientific priorities for dissemination and implementation science

• More complete uptake of evidence-based interventions
• De-implementation of ineffective or suboptimal care
• Scale up & spread of effective interventions across health plans, systems, and networks
• Implementation of genomic testing into practice
• Sustainability/adaptation of effective practices in a changing health care context
The current state of implementation science in genomic medicine: opportunities for improvement

Megan C. Roberts, PhD, Amy E. Kennedy, PhD, MPH, David A. Chambers, DPhil and Muin J. Khoury, MD, PhD

Purpose: The objective of this study was to identify trends and gaps in the field of implementation science in genomic medicine.

Methods: We conducted a literature review using the Centers for Disease Control and Prevention’s Public Health Genomics Knowledge Base to examine the current literature in the field of implementation science in genomic medicine. We selected original research articles based on specific inclusion criteria and then abstracted information about study design, genomic medicine, and implementation outcomes. Data were aggregated, and trends and gaps in the literature were discussed.

Results: Our final review encompassed 283 articles published in 2014, the majority of which described uptake (33.7%, n = 101) and preferences (36.4%, n = 103) regarding genomic technologies, particularly oncology (35%, n = 99). Key study design elements, such as racial/ethnic composition of study populations, were underreported in studies. Few studies incorporated implementation science theoretical frameworks, sustainability measures, or capacity building.

Conclusions: Although genomic discovery provides the potential for population health benefit, the current knowledge base around implementation to turn this promise into a reality is severely limited. Current gaps in the literature demonstrate a need to apply implementation science principles to genomic medicine in order to deliver on the promise of precision medicine.

Key Words: dissemination; genomic medicine; implementation; precision medicine; translational research

1. Less than 2% of studies incorporated implementation science frameworks or theories. Perhaps as a result, studies often neglected contextual factors that drive implementation science theory.
2. The unit of analysis in >98% of published studies were the individual, rather than the provider or health system.
3. The majority of published studies occurred within an academic medical center setting.
4. Fewer than half of the included studies reported race/ethnicity data, challenging our ability to assess racial/ethnic disparities and the generalizability of study findings across subpopulations.
5. The majority of studies were in oncology, likely reflecting the current evidence base in the field. However, as evidence accrues, research in other disease areas will be needed.
6. Most studies were observational, many reporting barriers and facilitators for genomic medicine implementation.
7. Few studies reported the use of collaborative processes (e.g., key stakeholders) and sustainability indicators.
D&I research opportunities

NIH (National Institutes of Health)
AHRQ (Agency for Health Research Quality)
IOM (Institute of Medicine)
WHO (World Healthy Organization)
World Bank
VA (Veterans Administration)
AAMC (American Association of Medical Colleges)
PCORI (Patient Centered Outcomes Research Inst)
Dissemination and Implementation Research in Health
PAR # 18-007 (R01)

• National Cancer Institute (NCI)
• National Human Genome Research Institute (NHGRI)
• National Institute on Aging (NIA)
• National Institute on Alcohol Abuse and Alcoholism (NIAAA)
• National Institute of Allergy and Infectious Diseases (NIAID)
• Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
• National Institute on Deafness and Other Communication Disorders (NIDCD)
• National Institute of Dental and Craniofacial Research (NIDCR)
• National Institute on Drug Abuse (NIDA)
• National Institute of Environmental Health Sciences (NIEHS)
• National Institute of Mental Health (NIMH)
• National Institute of Neurological Disorders and Stroke (NINDS)
• National Institute of Nursing Research (NINR)
• National Center for Complementary and Integrative Health (NCCIH)

• Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP)
• Office of Behavioral and Social Sciences Research (OBSSR)
• National Institute on Minority Health and Health Disparities (NIMHD)
The Center for Translation Research and Implementation Science (CTRIS) plans, fosters, and supports research to identify the best strategies for ensuring successful integration of evidence-based interventions within clinical and public health settings, such as health centers, worksites, communities, and schools in the United States and abroad. These strategies will build on the successes in fundamental discovery science and early-stage translational research. They also will help tackle new challenges in late-stage T4 translational research—the phase in the translational research pathway that leads to general knowledge about implementing evidence-based interventions—that helps turn discoveries into improved health.
Funding opportunities: NCATS website

- **Notice of Change of Application Due Date to PA-16-328 "Limited Competition: Administrative Supplements to Enhance Network Capacity: Collaborative Opportunities for the CTSA Program (Admin Supp)"** (link is external) NOT-TR-18-017 · Posted Date: 01/30/2018

- **Collaborative Innovation Award, Clinical and Translational Science Award (CTSA) Program (U01 Clinical Trial Optional)** (link is external) PAR-18-244 · Posted Date: 11/21/2017

- **Limited Competition: Exploratory CTSA Collaborative Innovation Awards (R21 Clinical Trial Optional)** (link is external) PAR-18-245 · Posted Date: 11/21/2017
Funding opportunities: NCATS website

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  PAR-18-245 · Posted Date: 11/21/2017
11th Annual Conference on the Science of Dissemination and Implementation in Health

DATE & TIME  December 3-5, 2018  LOCATION  Renaissance Washington D.C.

Call for Abstracts
Reversing Health Disparities in Complex Health Conditions through Implementation Science

Steve Bartels, MD, MS
Herman O. West Professor of Geriatrics, Professor of Psychiatry and Community & Family Medicine
Co-Director, SYNERGY Community Engagement Core
Co-PI CDC Health Promotion Research Center at Dartmouth
The Problem:
An Epidemic of Premature Death in Middle-aged Persons with Mental Illness

The average life expectancy in the US has steadily increased to 77.9 years (increasing by almost 5 years since the 90s alone)
At the same time..........

Mentally ill die 25 years earlier, on average
By Marilyn Elias, USA TODAY

Adults with serious mental illness treated in public systems die about 25 years earlier than Americans overall, a gap that’s widened since the early ’90s when major mental disorders cut life spans by 10 to 15 years, according to a report due Monday.

For people with major mental illness:
The average life expectancy is 53 yrs.
“50 is the New 75”
The Hidden Health Disparity of Early Mortality for Patients with Major Mental Illness

Mean Years of Potential Life Lost

<table>
<thead>
<tr>
<th>Year</th>
<th>AZ</th>
<th>MO</th>
<th>OK</th>
<th>RI</th>
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<td>1997</td>
<td>26.3</td>
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<td></td>
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<td>28.5</td>
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<tr>
<td>1998</td>
<td>27.3</td>
<td>25.1</td>
<td></td>
<td>28.8</td>
<td>29.3</td>
<td></td>
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<tr>
<td>1999</td>
<td>32.2</td>
<td>26.8</td>
<td>26.3</td>
<td>29.3</td>
<td>26.9</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>31.8</td>
<td>27.9</td>
<td></td>
<td>24.9</td>
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</tr>
</tbody>
</table>

Compared with the general population, persons with major mental illness lose 25-30 years of normal life span.

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online] 2006 Apr [date cited]. Available at: URL:http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm
Cardiovascular Disease Is Primary Cause of Death in Persons with Mental Illness

![Chart showing percentage of deaths in various states with different causes of death]
Integrated Health Promotion and Health Behavior Change: In SHAPE

- Nurse Evaluation and Consultation
- Initial Fitness Assessment
  - Individualized fitness and healthy lifestyle assessment
- Individual Meetings with a “Health Mentor”
- Vouchers to Local Fitness Centers
- Individual and group nutrition education
- Smoking cessation referrals
- Group Education/Motivational “Celebrations“

*Promoting Health and Functioning in Persons with SMI: CDC - R01 DD000140 (PI: Bartels)*
*Health Promotion and Fitness for Younger and Older Adults With SMI: R01 MH078052-01 (PI: Bartels)*
Clinically Significant Improved Fitness and Weight Loss Among Overweight Persons With Serious Mental Illness

1st RCT (n=133):
At 12 months: 49% in intervention group achieved either clinically significant increased fitness (>50 m on 6MWT) or weight loss (5% or greater)
REPLICATION TRIAL: 2nd RCT Boston, Mass (Multiple Sites: n=210; half underserved minorities)

51% achieved either clinically significant increased fitness (>50 m on 6MWT) or weight loss (5% or greater)

Pragmatic Replication Trial of Health Promotion Coaching for Obesity in Serious Mental Illness and Maintenance of Outcomes

Stephen J. Bartels, M.D., M.S.
Sarah L. Pratt, Ph.D.
Kelly A. Aschbrenner, Ph.D.
Laura K. Barre, M.D.
John A. Naslund, M.P.H.
Rosemarie Wolfe, M.S.
Haixi Xie, Ph.D.
Gregory J. McHugo, Ph.D.
Daniel E. Jimenez, Ph.D.
Ken Jue, M.S.S.A.
James Feldman, M.D., M.P.H.
Bruce L. Bird, Ph.D.

Objective: Few studies targeting obesity in serious mental illness have reported clinically significant risk reduction, and none have been replicated in community settings or demonstrated sustained outcomes after intervention withdrawal. The authors sought to replicate positive health outcomes demonstrated in a previous randomized effectiveness study of the In SHAPE program across urban community mental health organizations serving an ethnically diverse population.

Method: Persons with serious mental illness and a body mass index (BMI) >25 receiving services in three community mental health organizations were recruited and randomly assigned either to the 12-month In SHAPE program, which included membership in a public fitness club and weekly meetings with a health promotion coach, or to fitness club membership alone. The primary outcome measures were weight and cardiorespiratory fitness (as measured with the 6-minute walk test), assessed at baseline and at 3, 6, 9, 12, and 18 months.

Results: Participants (N=210) were ethnically diverse (46% were nonwhite), with a mean baseline BMI of 36.3 (SD 6.2). At 12 months, the In SHAPE group (N=104) had greater reduction in weight and improved fitness compared with the fitness club membership only group (N=106). Primary outcomes were maintained at 18 months. Approximately half of the In SHAPE group (51% at 12 months and 46% at 18 months) achieved clinically significant cardiovascular risk reduction (a weight loss ≥5% or an increase of >50 meters on the 6-minute walk test).

Conclusions: This is the first replication study confirming the effectiveness of a health coaching intervention in achieving and sustaining clinically significant reductions in cardiovascular risk for overweight and obese persons with serious mental illness.
The Challenge of Implementing Evidence-Based Interventions from Clinical Trials in Real World Settings

Replicability

Voltage Drop
It’s Hard Enough to Change Health Behaviors

But Even Harder to Change the Behavior of Organizations

What does it take to implement health promotion?

(especially when it is not in the mission, competency, scope of practice, or financing of a health care organization)
Can Behavioral Health Organizations Change Health Behaviors?
Rediscovering the Neck
Statewide Learning Collaborative to Reduce Early Mortality in Persons with Mental Illness (NIMH R01 MH089811)

- Statewide Learning Collaborative including all 10 regional mental health centers with Monthly Meetings including program leaders and In SHAPE Health mentors

- Aggregate implementation outcomes and nested 4-site comparison design

1) Person-level outcomes
2) Provider-level outcomes
3) System-level outcomes
Implementation of a Lifestyle Intervention for People With Serious Mental Illness in State-Funded Mental Health Centers

Stephen J. Bartini, M.D. M.S., Kelly A. Aschkenas, Ph.D., Sarah I. Pratt, Ph.D., John A. Nadas, Ph.D., Emily A. Scherer, Ph.D., Lisa Zubkoff, Ph.D., Michael J. Cohen, M.A., Gail E. Williams, B.A., Rosemarie S. Wollte, M.S., Kenneth Jue, M.S.A., Mary F. Brunette, M.D.

Objective: The purpose of this study was to evaluate health outcomes of a state-supported implementation of community mental health settings of an evidence-based lifestyle intervention for overweight and obese adults with serious mental illness.

Methods: Weight and fitness outcomes were evaluated for 122 overweight or obese adults with serious mental illness in four community mental health centers (CMHCs) that were participating in a phased statewide implementation of the In SHAPE lifestyle intervention. Six- and 12-month outcomes were compared between two CMHCs that implemented In SHAPE in the first 12 months and two CMHCs with similar characteristics that implemented In SHAPE in a subsequent phase in the statewide implementation 12 months later.

Results: Participants in the two In SHAPE sites (N = 63 participants) lost significantly more weight (p < .001) and showed greater improvement in fitness (p < .01) compared with participants at the two usual care control sites (N = 59 participants). At six months, nearly half (49%) of the In SHAPE participants and 12 months more than half (60%) of In SHAPE participants showed clinically significant cardiovascular risk reduction defined as ≥30% weight loss or improved fitness (≥50 m [164 feet] increase on the six-minute walk test). The difference between the In SHAPE and control groups was not statistically significant.

Conclusions: This natural experiment demonstrated promising public health benefits of a practical implementation of health promotion programming for overweight and obese adults with serious mental illness and offers a potential model for reducing risk of early mortality among individuals served by state-funded mental health centers nationwide.

Psychiatric Services in Advance (DOI: 10.1176/appi.ps.201700368)

Clinically Significant Cardiovascular Risk Reduction by Sites
In Shape (n=2) vs. Control (n=2)
(5% weight loss or increase of 50M in 6MWT)

<table>
<thead>
<tr>
<th>% Clinically Significant Risk Reduction</th>
<th>6 Month</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>In Shape CMHCs</td>
<td>49%</td>
<td>60%</td>
</tr>
<tr>
<td>Control CMHCs</td>
<td>37%</td>
<td>35%</td>
</tr>
</tbody>
</table>
Weight/Fitness Cardiovascular Risk Reduction by Site
(% with either $\geq$ 5% weight loss or increase of $\geq$ 50 meters on 6 minute walk test)

CMHC #1: In SHAPE
CMHC #2: In SHAPE
CMHC #3: Health Home
CMHC #4: Usual Care

p=.005

Best Case Scenario in Health Promotion RCTs
What Will it Take to Implement and Spread this Preventive Intervention Nationally?

What is the most effective implementation strategy?
Are Learning Collaboratives the Most Effective Approach to Implementing a New Practice that Requires a Significant Change in Organizational Culture?

Randomized

48 mental health organizations:
Three phases of 16 organizations over two years
Estimated Patient Participants: 2400

Virtual Learning Collaborative
- Coaching organizations to work together to share processes and outcomes, engage in group problem solving, and apply systems improvement

Training and Individual Technical Assistance
- Individually tailored, phone-based implementation technical assistance

R01MH102325, PI: Bartels
Site Selection

Sites selected for each phase to achieve an optimal mix of the following:

- Organizational readiness
- Geographic distribution
- Diversity of patient population
- Organizational size
- Urban vs. rural
# Participation Over 24 Months

<table>
<thead>
<tr>
<th>Learning Collaborative (18 months)</th>
<th>Ongoing engagement with research team (until 24 months)</th>
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<tr>
<td>Individual Technical Assistance (18 months)</td>
<td>Ongoing engagement with research team (until 24 months)</td>
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</table>
Prediction Model for InSHAPE Study

Organizational Factors
- Funding,
- Prioritization, Leadership,
- Workforce Development,
- Workflow Re-engineering,
  Reinforcement

Implementation Strategies
- Technical Assistance
  or
- Learning Collaborative

Fidelity to InShape Model

Health Outcomes
- (BMI, 6-minute walk, etc.)
DARTMOUTH’S IN SHAPE IMPLEMENTATION STUDY

NATIONAL COUNCIL FOR BEHAVIORAL HEALTH
STATE ASSOCIATIONS OF ADDICTION SERVICES

Stronger Together.

In 2014, the National Institute of Mental Health funded Dr. Steve Bartels and Dartmouth College team to conduct a hands-on initiative to determine how to best implement evidence-based health promotion to decrease obesity and reduce cardiovascular risk for persons with mental illness. Half of the participating organizations selected for this study will receive training and individual technical assistance for 12 months, and half will receive training and implementation support by participating in a learning collaborative for 18 months.

Benefits to Participating Organizations: The organizations selected to participate will receive (at no cost)

- Training in the In SHAPE Program;
- Personal trainer certification reimbursement for one designated Health Mentor at a local or online AFAA, NASM, ACE, or ACSM chapter;
- Implementation support through expert technical assistance, and ongoing weekly Health Mentor supervision;
- An iPad to assist the Health Mentor in tracking participant progress and program outcomes.

For more information on In SHAPE:

- Visit: www.kenjoe.com/In SHAPE
- Watch: youtube.com/watch?v=R3K3y2zaotko&feature=youtu.be

Have additional questions or want more information? Contact Nina Marshall, Director of Public Policy, at NinaM@TheNationalCouncil.org.

In SHAPE Implementation Study
INTEGRATING HEALTH PROMOTION FOR OBESITY IN MENTAL HEALTH ORGANIZATIONS

Download Frequently Asked Questions

Watch a recording of our In SHAPE Informational Webinar

Applications for the In SHAPE Implementation Study are not being accepted at this time.

The Problem: People with serious mental illness (SMI) in publicly funded mental health organizations have a reduced life expectancy of 25-30 years compared to the general population. Obesity and tobacco use are major causes of this dramatic health disparity. Obesity rates are twice as prevalent among persons with SMI compared to those without SMI — placing this high-risk, high-cost group at substantial risk for diabetes and cardiovascular disease.

The Project: Through a competitive application process, 48 mental health organizations from across the United States will be selected to implement In SHAPE within their organizations — a wellness program designed to improve the physical health of people with serious mental illness, and participate in a research study to advance understanding of how to better address the physical health needs of individuals with serious mental illness.

http://www.thenationalcouncil.org/training-courses/dartmouths-shape-implementation-study/
Implementation Project
“Translational” Health Care Delivery Science
*From Community Need to Effectiveness and Implementation Research*

**Community Development**
- Identification of Need, Community Coalition
- Development of InSHAPE Model (2002)

**Effectiveness Research**
- Effectiveness RCT Studies (CDC, NIMH) (2006-2012)

**Implementation Research**
- Statewide Implementation Study (2009-2014); Statewide Medicaid Incentives Grant (2011-2016)
- Nationwide Implementation Project (2014-2018)
CTSAs: From Discovery to Translational Implementation Team Science

“Cross-disciplinary team science…a promising approach to accelerate scientific innovation and the translation of scientific findings into effective policies and practices.”

National Cancer Institute Team Science Toolkit
Examples of Dissemination and Implementation Research Across the Disease and Translational Spectrum

- Implementing and interpreting genomic screening
- Adoption of biomarker-based treatment algorithms
- Bioinformatics and predictive modeling
- Hybrid effectiveness implementation clinical trails
- mHealth Technology
- Global Health
CTSAs: From Discovery to Translational Implementation Science

1) Implementation Science enhances the impact of Discovery Science by advancing uptake. Only a fraction of evidence-based practices and research findings are applied in routine health care.

2) Implementation Science improves the process of Discovery Science. The impact of research can be increased when downstream application, usability, and scalability inform the design.

3) Implementation Science accelerates the pace of improving health care and health outcomes from research. On average, it takes 17 years from discovery to implementation in routine practice.

4) Implementation Science supports the CTSA’s role engaging in state and regional partnerships and public health impact. Community-engaged research and partnerships are common components of high impact implementation science.

5) CTSA’s are uniquely positioned to advance the development of the next generation of Translational Implementation Team Scientists. A key workforce component to enhance the future public health impact of the nation’s Clinical Translational Science Institutes.
Questions?