



Dissemination and Implementation Research

Catherine M. Stoney, Ph.D.
National Heart, Lung, and Blood Institute
March 14, 2016


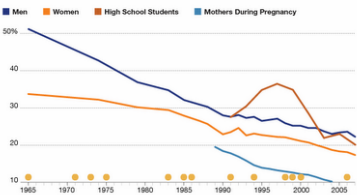


Smoking rates in the US from 1965-2007

Tobacco Timeline: U.S. Smoking Rates Since 1965


In 1964, the U.S. surgeon general released the first report that linked smoking to cancer. Since then, as advertising restrictions became more stringent and public smoking bans more widespread, the overall number of American men and women who smoke has steadily declined.

Roll your mouse over the circles to see smoking milestones in the past half-century.



How to improve tobacco cessation?

- Patient-level treatments
- Practitioner-level treatments
- Social education
- Environmental structures
- Legal & regulatory statutes



What we will be talking about

- **The Problem:**
 - State of the health care system in the US today
 - Current gap between **research and practice**
- **The Big Picture:**
 - The research & translational spectrum
- **A Solution:**
 - Definitions, principles, and characteristics of D&I research
- **Example:**
 - D&I research
- **Design:**
 - Types of designs for D&I research
 - Unique design considerations
- **The Future:**
 - Directions and opportunities



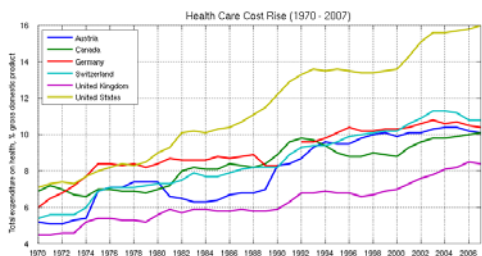
Current Health Care Situation in the US

- Underperforming health care system
- Balkanized and silo approaches to care, lack of integration of care
- Expensive, unsustainable cost, increasingly inaccessible
- Inequitable, significant health disparities
- Evidence-based

Adapted from: Institute of Medicine, 2003.
McGlynn EA et al., 2003.



Health Care Costs are Rising



Moving Research to Practice

Research, research, research, research, research

**“it takes 17 years, on average,
...for 14 % of research
...to translate into practice”**

NIH National Heart, Lung, and Blood Institute

Balas EA, 1998.

Research to Practice Pipeline

The 17-year odyssey

Priorities for research funding

Peer review of grants

Publication priorities and peer review

Academic appointments, promotion, and tenure criteria

Research synthesis

Evidence-based medicine movement

Guidelines for evidence-based practice

Practice

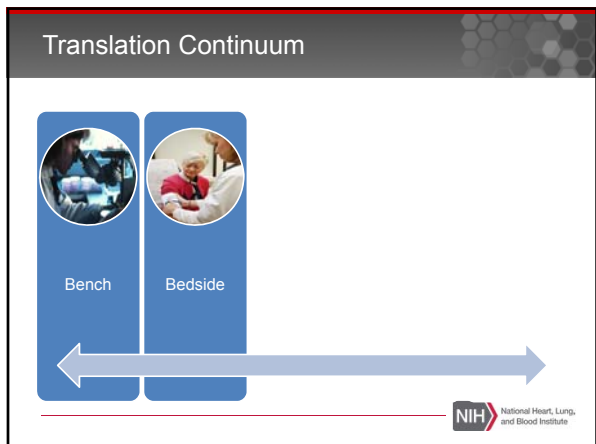
Funding; population needs, demands; local practice circumstances; professional discretion; credibility and fit of the evidence.

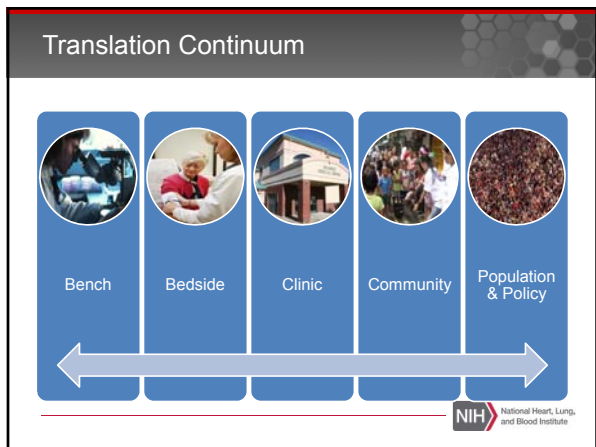
NIH National Heart, Lung, and Blood Institute

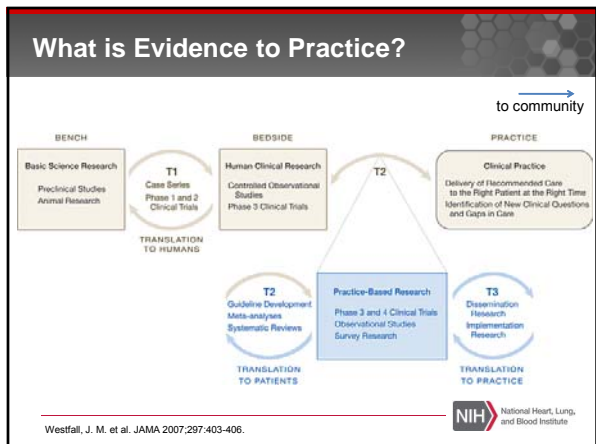
The Goal of Dissemination and Implementation Research

- The ultimate goal of D&I research is to extend and adapt generally accepted and effective interventions that have previously been carried out in well-controlled settings and test in broader populations or settings (i.e., real-world settings like the workplace, schools, community centers and clinics, neighborhoods, etc).
- Understand, study and test how to translate **Evidence into Practice**

NIH National Heart, Lung, and Blood Institute







What is Implementation Research?

- Implementation is the use of specific strategies to adopt and integrate evidence-based and guideline-based health interventions for the purpose of changing patterns of care within specific “real world” settings. Interventions developed in efficacy settings typically must be adapted to broader settings. **Implementation research tests these adaptations and other strategies.**



What is Dissemination Research?

- Dissemination is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intention is to spread knowledge and associated evidence-based interventions.
- **Dissemination research tests these active process to determine if they result in increased awareness, acceptance, and use of the lessons learned from science.**




A rose by any other name....

- Diffusion of Innovations
- Knowledge to Action
- Knowledge Transfer
- Knowledge Translation
- Research to Practice
- Research Utilization
- Scale up
- Translational Research



Questions Addressed by D&I Research

- How to achieve widely accepted and evidence-based interventions in a variety of real-world settings
- Potentially modify interventions to be consistently accepted and implemented by individuals with varying training and expertise
- Enhance feasibility, provider and patient adherence, and community uptake while producing reliable effects at reasonable cost
- Determine how to reach large numbers of people in real-world settings, especially those who can most benefit




Dissemination and Implementation Research

- Bridges research and practice in real-world settings
- Strikes a balance between rigor and relevance in study designs, methods and outcomes




The Balance Between Relevance and Rigor (Internal and External Validity)

<p>Risk of Type I Error (false positive - α)</p> <hr style="border: 1px solid black;"/> <p>External Validity Maximize Generalizability</p> <p>Across participants Across situations Across time and place</p>	<p>Risk of Type II Error (false negative - β)</p> <hr style="border: 1px solid black;"/> <p>Internal Validity Maximize Control</p> <p>History effects Bias of all sorts Experimenter effects Measurement effects</p>
---	---




Dissemination & Implementation Research Characteristics & Challenges

- Contextual
- Complex (non-linear)
- Multi-component
- Transdisciplinary
- Multi-level
- Timing
- Sequencing of implementation studies
- Study Designs
- Study Methods




Typical Outcomes in D&I Research

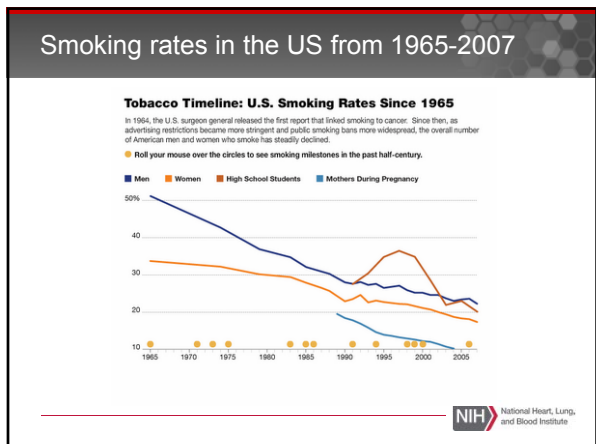
- Primary outcomes are related to D&I **strategies**.
 - Provider acceptance and adherence
 - Patient/community adherence and adoption
 - Uptake into practice
 - Formation of community partnerships
 - Penetration of guidelines more globally/diffusion
 - Actionable measures
- Cost, cost-effectiveness
- Effectiveness of the intervention
- Sustainability
- Evaluation of impact and unintended consequences



Dissemination & Implementation Approaches

- Patients
 - Self-management
 - Behavioral counseling
 - Self-monitoring and feedback
- Health care providers
 - Clinical guidelines
- Technological
 - Home monitoring
 - Internet or phone-based intervention
- Health care system
 - Chart reminders
 - Team approaches
 - Decision support
- Community
 - Community health workers
 - Pharmacy
 - Worksite resources





Smoking Rates are High in Military Recruits

- Until 1975, cigarettes were included in K-rations and C-rations
- Smoking was banned in submarines – at the end of 2010
- Today, over 30% of members of the military smoke; smoking while in active duty is even higher

NIH National Heart, Lung, and Blood Institute

The Problem

- The DOD has identified tobacco cessation as a US military priority
- Quit lines and nicotine replacement are both effective in increasing quit rates in well-controlled trials
- Recruits still smoke at alarmingly high rates
- Can these strategies be effectively implemented in US military recruits?

NIH National Heart, Lung, and Blood Institute

What are the questions and challenges that need to be addressed?

- Recruitment is a significant challenge
 - Following chain of command
 - Obtaining appropriate approvals
 - Coordinating with installation
 - Establishing a point-of-contact
- Choosing the right intervention
 - Interventions known to be efficacious
 - Quit lines
 - NRT
- Can these be effective when self-paced?
- Can these be delivered in a cost-effective manner?



Smoking Cessation Among Military (n~1400)

	All participants	Self-Paced	Counselor
Age	39.2 + 13.9	39.1 + 14.2	39.3 + 13.7
Gender	42.3% female	41.0% female	43.6% female
Air Force	70.0%	70.3%	69.0%
Years Smoked	18.7 + 13.2	18.7 + 13.1	18.6 + 13.2
Number of cigarettes	17.8 + 8.7	17.6 + 8.2	18.0 + 9.1
Number of quit attempts	1.6 + 2.3	1.4 + 2.6	1.5 + 2.1

Richey et al., 2012



Abstinence Rates by Condition


	Post-Test (n= 785)	12-month F/U (n=611)
Counselor-Initiated	55.8%	33.1%
Self-Paced	26.7%	23.5%



Key Findings

- The overall cessation rates are high – about twice that expected.
- Even among the self-paced group, cessation and maintenance of cessation is high after 1 year.
- This is a low-cost, effective strategy for this population.


Pezzin et al., 2010



Design Strategies Used in D&I Research


- RCTs
- Simulations, modeling, dynamic systems science models
- Natural experiments
- Use of EHRs
- Pragmatic trials
- Often utilize cluster randomized designs
- Community Based Participatory Research Approaches (CBPR)*
- Patient-centered care approaches

*Guidelines and Categories for Classifying Participatory Research Projects in Health: <http://green.net/guidelines.html>



Design Considerations in D&I research

- Questions specific to D&I research:
 - In implementation research, the question is about the implementation strategy of an established (albeit modified) intervention or strategy
 - In dissemination research, the question is focused on the dissemination strategy and outcomes.
- Consider where the state of your science falls on the research continuum
- Utilize team science approaches, multidisciplinary, integrated care



Design Considerations in D&I research – con't

- Often community based (work-sites, schools, community clinics, churches, community hospitals, HMOs), participatory approaches
- Able to incorporate personalized aspects of treatment using patient-centered care approaches
- Incorporates multi-level context: personal, organizational, community, policy, environmental and social contexts
- Conducted with real (non-selected) patients, often with complex co-morbidities – take all comers



Design Considerations in D&I Research – cont.

- Multi-component treatments delivered by real-world health care, community, worksite workers, under real world conditions and settings
- Can be vitally important to measure secular trends and potential confounders
- Designed for broad adaptation and implementation
- Scalable (cost-effective)
- Deliverable by variety of personnel in typical settings
- Can sometimes be evaluated through real-time data (for example, with Electronic Health Records)

Tunis, et al., 2007.



Key Take Home Points

- D&I research is contextual and non-linear
- Successful programs evolve and are about “fit”, acceptance, flexibility
- D&I research is multi-level and complex, and concerns settings, staff, delivery, scale, and sustainability
- D&I research involves multiple conditions, behaviors, complex and multi-component interventions
- Main outcomes are related to dissemination and implementation **processes**
- This is essential work for successfully bridging research to practice.



D&I Opportunities

- “State of the D&I Science” venue
- Annual or semi-annual meeting in Bethesda, sponsored by NIH and other partners
- Free and open to the public
- Training Institute for Dissemination and Implementation Research in Health (<http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2015/index.html>)
- Several NIH funding initiatives
- Center for Translational Research and Implementation Science (CTRIS), National Heart, Lung, and Blood Institute
- Implementation Science, National Cancer Institute