Dissemination and Implementation (D&I) Science: Key Issues and Health Equity

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Adult and Child Consortium for Outcomes Research and Delivery Science
Acknowledgments and Conflicts of Interest

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University of Colorado SOM - ACCORDS D&I Science Program
RE-AIM Colleagues

FINANCIAL DISCLOSURE
National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Robert Wood Johnson Foundation (RWJF) funding

UNLABELED/UNAPPROVED USES DISCLOSURE
None
Overview

- Characteristics of D&I science
- D&I science perspective and contributions to **Health Equity**
- D&I perspective on Fidelity and **Adaptation**
- D&I Outcomes and Evidence
  My Own Health Report example
- Future directions and **Opportunities** for CTSA D&I research
Some Remedies and Key Terms

• **Implementation Science** is the study of methods to promote the integration of research findings and evidence into practice.

• **Dissemination Research** is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical audience. The intent is to understand how best to spread and sustain knowledge and interventions.

• **Implementation Research** is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community.

• **Pragmatic Research** is the use of real-world tests in real-world populations and situations.
A Big Tent of Terms (and ovals)

Population Health (and Community) Services

Dissemination Research

Health Communication Research

Implementation Research

Quality Improvement Science

Health Services Research

Pragmatic Research

QI

Adapted from Mitchell S, Chambers, D. https://doi.org/10.1200/JOP. 2017.024729
<table>
<thead>
<tr>
<th>Point #</th>
<th>Characteristic</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>SYSTEMS PERSPECTIVE</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td><strong>Context</strong> is critical</td>
<td>Research should focus on and describe context</td>
</tr>
<tr>
<td>2</td>
<td>Multilevel complexity</td>
<td>Most problems and interventions are multilevel and complex</td>
</tr>
<tr>
<td>3</td>
<td>Focus on systems characteristics</td>
<td>More emphasis needed on interrelationships among system elements and systems rules</td>
</tr>
<tr>
<td></td>
<td><strong>ROBUST, PRACTICAL GOALS</strong></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Representativeness and reach</td>
<td>Focus on reaching broader segments of population and those most in need</td>
</tr>
<tr>
<td>5</td>
<td>Generalizability</td>
<td>Study generalization (or lack of such) across settings, subgroups, staff, and conditions</td>
</tr>
<tr>
<td>6</td>
<td>Pragmatic and practical</td>
<td>Producing answers to specific questions relevant to stakeholders</td>
</tr>
<tr>
<td>7</td>
<td>Scalability and sustainability</td>
<td>From outset, greater focus on scale-up potential and likelihood of sustainability</td>
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<tr>
<td>Point #</td>
<td>Characteristic</td>
<td>Implication</td>
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<tr>
<td></td>
<td>RESEARCH METHODS TO ENHANCE RELEVANCE</td>
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</tr>
<tr>
<td>8</td>
<td>Rigorous</td>
<td>Identify and address plausible threats to validity in context of questions. Greater focus on replication.</td>
</tr>
<tr>
<td>9</td>
<td>Rapid</td>
<td>Approaches that produce faster answers</td>
</tr>
<tr>
<td>10</td>
<td>Adaptive</td>
<td>Best solutions usually evolve over time, as a result of informed hypotheses and mini-tests with feedback</td>
</tr>
<tr>
<td>11</td>
<td>Integration of methods; triangulation</td>
<td>For greater understanding, integrated Quantitative and Qualitative methods are often required</td>
</tr>
<tr>
<td>12</td>
<td>Relevance</td>
<td>Relevance to stakeholders should be top priority</td>
</tr>
<tr>
<td>F</td>
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<tr>
<td></td>
<td>FLEXIBILITY</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Multiplicity</td>
<td>Encourage and support diverse approaches with the above characteristics (all models are wrong)</td>
</tr>
<tr>
<td>14</td>
<td>Respect for diverse approaches; humility</td>
<td>Different perspectives, goals, methods and approaches are needed. Continuing the same existing approaches will produce the same unsatisfactory results.</td>
</tr>
</tbody>
</table>

Too often we have assumed, “If you build it…and if you have evidence”…
An Evidence-Based Cancer Prevention... or Pain Reduction... or Care Transition.....or (fill in blank) Story

Even if 100% effective...it’s only as good as how and whether:

- it is adopted - and where it is not adopted
- practitioners are trained to deliver it - and who is not trained
- trained practitioners consistently deliver it - and who does not
- eligible populations receive it - and which do not
- it can be sustained - and where, why and when is it not

If we assume 50% success for each step (even with perfect access/adherence/dosage/maintenance- and equal benefit throughout)

Impact: \[ \frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} = 0.03 \] = 3% benefit

Moral of the Story?

• It is about the denominator
• All ‘steps’ or dimensions are important for population health
• At each step, there are both threats to and opportunities for health equity
Population Health - It’s about equity

Yellow = participated
Evaluating complex interventions: Confronting and guiding (vs. ignoring and suppressing) heterogeneity and adaptation

October 9, 2018

Brian S. Mittman, PhD
Department of Research and Evaluation, Kaiser Permanente Southern California
Quality Enhancement Research Initiative (QUERI), U.S. Department of Veterans Affairs
Suzanne Dworak-Peck School of Social Work, University of Southern California
Clinical and Translational Science Institute, University of California at Los Angeles
Implementing complex interventions: “Adaptation happens”

• Complex interventions usually can be, will be and should be adapted
• Adaptation should be:
  – embraced, studied, and guided rather than
  – ignored, and/or
  – suppressed
Adaptation Defined

1. Adaptation can be defined as the \textit{deliberate or accidental (i.e., drift) modification of the program, including:}

   a. deletions or additions (enhancements) of components

   b. refinements in the nature of included components

   c. adjustments in the manner/intensity of the administration of program components (called for in the program manual, curriculum or core components analysis)

   \textit{d. cultural and other modifications due to local circumstances}

2. Adaptation of programs often occurs to improve the fit (or compatibility) of a program to a new setting, or to increase the cultural appropriateness of a program.

3. Adaptations to evidence-based interventions are common and inevitable (some researchers suggest) to meet the needs of a specific context.

4. Adaptations might lessen the effectiveness of the program if they compromise the core elements and underlying logic of a program.
‘Tug of War’

Internal Validity  Fidelity  Adaptation  External Validity
Sources of Intervention Adaptation

- **INTERVENTION**
  - Who delivers the intervention; fit with other interventions; financing source

- **SERVICE SETTING ADAPTATIONS**
  - Age-appropriateness; health literacy; responsive to individual needs; comorbid conditions

- **TARGET AUDIENCE ADAPTATIONS**
  - Number of sessions; dose; technological format; session length

- **MODE OF DELIVERY ADAPTATIONS**
  - Cultural sensitivity; imagery used; consistency with belief system

- **CULTURAL ADAPTATIONS**
  - Core components of intervention identified through testing; mechanisms of action

- **CORE COMPONENTS**

Development of a framework and coding system for modifications and adaptations of evidence-based interventions

Shannon Wilsey Stirman\textsuperscript{1,2,3,}, Christopher J Miller\textsuperscript{1,2,5}, Katherine Toder\textsuperscript{4} and Amber Calloway\textsuperscript{6}

Abstract

\textbf{Background:} Evidence-based interventions are frequently modified or adapted during the implementation process. Changes may be made to protocols to meet the needs of the target population or address differences between the context in which the intervention was originally designed and the one into which it is implemented (Addict Behav 2011, 36(6):630–635). However, whether modification compromises or enhances the desired benefits of the intervention is not well understood. A challenge to understanding the impact of specific types of modifications is a lack of attention to characterising the different types of changes that may occur. A system for classifying the types of modifications that are made when interventions and programs are implemented can facilitate efforts to understand the nature of modifications that are made in particular contexts as well as the impact of these modifications on outcomes of interest.

\textbf{Methods:} We developed a system for classifying modifications made to interventions and programs across a variety of fields and settings. We then coded 258 modifications identified in 32 published articles that described interventions implemented in routine care or community settings.

\textbf{Results:} We identified modifications made to the content of interventions, as well as to the context in which interventions are delivered. We identified 12 different types of content modifications, and our coding scheme also included ratings for the level at which these modifications were made (ranging from the individual patient level up to a hospital network or community). We identified five types of contextual modifications (changes to the format, setting, or patient population that do not in and of themselves alter the actual content of the intervention). We also developed codes to indicate who made the modifications and identified a smaller subset of modifications made to the ways that training or evaluations occur when evidence-based interventions are implemented. Rater agreement analyses indicated that the coding scheme can be used to reliably classify modifications described in research articles without overly burdensome training.

\textbf{Conclusions:} This coding system can complement research on fidelity and may advance research with the goal of understanding the impact of modifications made when evidence-based interventions are implemented. Such findings can further inform efforts to implement such interventions while preserving desired levels of program or intervention effectiveness.

\textbf{Keywords:} Implementation, Modification, Adaptation, Sustainability

BY WHOM are modifications made?
- Individual practitioner/facilitator
- Team
- Non-program staff
- Administration
- Program developer/ purveyor
- Researcher
- Coalition of stakeholders
- Unknown/unspecified

WHAT is modified?
Content
(Modifications made to content itself, or that impact how aspects of the treatment are delivered)
Context
(Modifications made to the way the overall treatment is delivered)

TRAINING AND EVALUATION
(Modifications made to the way that staff are trained in or how the intervention is evaluated)

At what LEVEL OF DELIVERY
(for whom/what are modifications made?)
- Individual patient level
- Group level
- Individual practitioner level
- Clinic/unit level
- Hospital level
- Network level
- System level

Context modifications are made to which of the following?
- Format
- Setting
- Personnel
- Population

What is the NATURE of the Content modification?
- Tailoring/tweaking/refining
- Adding elements
- Removing/skipping elements
- Shortening/ condensing (pacing/timing)
- Lengthening/extending (pacing/timing)
- Substituting
- Reordering of intervention modules or segments
- Integrating the intervention into another framework (e.g., selecting elements)
- Integrating another treatment into EBP (not using the whole protocol and integrating other techniques into a general EBP approach)
- Repeating elements or modules
- Loosening structure
- Departing from the intervention (‘drift’)
Adapting the Stirman et al. Framework Using the RE-AIM Model and Clinical Experience

### WHY: What was the purpose of the adaptation?
- Increase reach, participation, access
- Increase effectiveness
- Increase adoption by more clinics/settings or make intervention more aligned with organizational goals
- Increase implementation/ability of staff to deliver intervention successfully

### WHEN: When during the project the adaptation was made?
- During planning stages, before intervention began
- Early, during first few weeks of intervention
- During the middle stages
- At or close to the end of project

### HOW: How or on what BASIS was this change made?
- Based on our vision or values
- Based on a framework (for example, PCMH)
- Based on our knowledge or experience of working with patients
- Based on QI data, summary information or results
- Based on pragmatic/practical considerations (for example, “this is the only way it would work”)
- Based on financial incentives/payment
- Based on feedback or suggestions (Practice Facilitator/coach or other)
- Other

### IMPACT: What are (subjective) short-term results of the adaptation?
- Are they positive, negative, no real impact?
- Did the changes impact:
  - Reach/participation/access
  - Effectiveness
  - Adoption
  - Implementation/ability of staff to deliver intervention successfully
  - Maintenance

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<table>
<thead>
<tr>
<th>BY WHOM are modifications made?</th>
</tr>
</thead>
<tbody>
<tr>
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<td>- Team</td>
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<td>- Non-program staff</td>
</tr>
<tr>
<td>- Administration</td>
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<tr>
<td>- Program, developer/curriculum</td>
</tr>
<tr>
<td>- Researcher</td>
</tr>
<tr>
<td>- Coalition of stakeholders</td>
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<td>- Unknown/unspecified</td>
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<tr>
<td>- System level</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>At what LEVEL OF DELIVERY (for whom/what are modifications made?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Individual patient level</td>
</tr>
<tr>
<td>- Group level</td>
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<tr>
<td>- System level</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>What is the NATURE of the Content modification?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Tailoring/reshaping/refining</td>
</tr>
<tr>
<td>- Adding elements</td>
</tr>
<tr>
<td>- Removing/trimming</td>
</tr>
<tr>
<td>- Shortening/condensing (pacing/timing)</td>
</tr>
<tr>
<td>- Lengthening/extending (pacing/timing)</td>
</tr>
<tr>
<td>- Substituting</td>
</tr>
<tr>
<td>- Recording of intervention modules or segments</td>
</tr>
<tr>
<td>- Integrating the intervention into another framework (e.g., selecting elements)</td>
</tr>
<tr>
<td>- Integrating another treatment into EBP (not using the whole protocol and integrating other techniques into a general EBP approach)</td>
</tr>
<tr>
<td>- Repeating elements or modules</td>
</tr>
<tr>
<td>- Loosening structure</td>
</tr>
<tr>
<td>- Departing from the intervention (shift)</td>
</tr>
</tbody>
</table>

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Methods to Assess Adaptation- use >1 Method

1. Observational techniques
2. Focused interviews
3. Questionnaires, checklists and logs
4. Content analysis of key documents and curricula
5. Study databases and clinical databases
Sample Interview Questions

WHAT component or part of the intervention was changed in this adaptation? In other words, what was the nature of the change?
  – For instance, was it a change to program content, format, delivery mode, staff delivering it, patients eligible, where, when or how it was delivered or what?

WHO was responsible for first suggesting or initiating this change?
  – Was this the person(s) the one(s) implementing the change? If not, who implemented the adaptation?

WHEN during the ____ program was this adaptation first made?

WHY was this adaptation made?
  – For example, to get more people to participate, to make the program attractive to more settings, to increase its effectiveness, to make it easier to deliver, to make it easier to maintain or reduce costs, etc.?
## Sample Tracking Form

<table>
<thead>
<tr>
<th>Date of modification</th>
<th>4/15/2018</th>
<th>6/2/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description of modification</strong></td>
<td>Survey questions reordered; moved Rose Dyspnea questionnaire to the end.</td>
<td>Revised patient letter to include information about automated pre-procedural phone calls.</td>
</tr>
<tr>
<td><strong>Reason for modification</strong></td>
<td>To improve fluidity of the survey and enhance data capture</td>
<td>To prepare patients for data collection</td>
</tr>
<tr>
<td><strong>Modifications made by WHOM</strong></td>
<td>Researcher</td>
<td>Researcher</td>
</tr>
<tr>
<td><strong>WHAT is modified</strong></td>
<td>Order of data collection</td>
<td>Content of the intervention</td>
</tr>
<tr>
<td><strong>At what LEVEL OF DELIVERY</strong></td>
<td>Individual patient level</td>
<td>Individual patient level</td>
</tr>
<tr>
<td><strong>CONTEXT modification are made to…</strong></td>
<td>Intervention format</td>
<td>Intervention format</td>
</tr>
<tr>
<td><strong>What is the NATURE of the content modification</strong></td>
<td>Tailoring/tweaking/refining</td>
<td>Tailoring/tweaking/refining</td>
</tr>
<tr>
<td><strong>WHEN during the project was the adaptation made</strong></td>
<td>During planning stages before intervention was begun</td>
<td>During planning stages before intervention was begun</td>
</tr>
<tr>
<td><strong>WHY was the adaptation made</strong></td>
<td>Increase effectiveness</td>
<td>Increase implementation/ability of staff to deliver intervention successfully</td>
</tr>
<tr>
<td><strong>IMPACT – what are the (subjective) short-term results of the adaptation</strong></td>
<td>Positive: impact effectiveness</td>
<td>Positive: impact implementation/ability of staff to deliver intervention successfully</td>
</tr>
</tbody>
</table>
Understanding adaptations to patient-centered medical home activities: The PCMH adaptations model

Tristen L. Hall, MPH,1 Jodi Summers Holthrop, PhD, MCHES,2 L. Miriam Dickinson, PhD,3 Russell E. Glasgow, PhD4

Abstract
Primary care practices have increasingly adopted the patient-centered medical home (PCMH) model and often adapted quality improvement efforts to fit local context. This paper implemented a modified framework for understanding adaptations in the context of primary care PCMH transformation efforts. We combined an adaptations model by Stilman et al. that categorized adaptations to evidence-based interventions in research studies with dimensions from the RE-AIM framework, as well as items specific to PCMH. The resulting constructs were translated into a “plain English” adaptations interview. We conducted interviews with 27 practices and used resulting descriptive categories to inform exploratory analyses of the relationships between adaptation characteristics and improvement outcomes in PCMH domains of team-based care and data capacity. Practices most commonly focused on development and use of disease registries and enhancements to team-based care (not disease-specific.

Implications
Practice: Adoptions to quality improvement and PCMH transformation components are common and can result in positive impacts on effectiveness.

Policy: Effective primary care quality improvement and PCMH transformation initiatives must anticipate the potential for and evaluate the impact of adaptations during program implementation.

Research: Future research is needed to further investigate, improve, and test the generalizability of models to describe and understand adaptations that primary care practices make in the course of PCMH transformation and similar quality improvement initiatives.

Systematic, Multimethod Assessment of Adaptations Across Four Diverse Health Systems Interventions

Borsika A. Rubio1,2,4,5, Marina McCreight1, Catharine Battaglia1, Romam Ayale1, Robert E. Burke1, Paul L. Nace1, Joseph W. Frank1 and Russell E. Glasgow2

1 Denver Health Center of Innovation for Women’s Centered and Value-Added Care (I-IW), Denver, CO, United States; 2 Department of Family Medicine & Adult and Child Consortium for Outcomes Research and Delivery Science (ACORDS), University of Colorado, Aurora, CO, United States; 3 Denver Health Center of Innovation for Women’s Centered and Value-Added Care (I-IW), Denver, CO, United States; 4 Department of Family Medicine & Adult and Child Consortium for Outcomes Research and Delivery Science (ACORDS), University of Colorado, Aurora, CO, United States; 5 University of Colorado, School of Medicine, Aurora, CO, United States; 6 University of Colorado, School of Medicine, Aurora, CO, United States; 7 University of Colorado, School of Medicine, Aurora, CO, United States; 8 University of Colorado, School of Medicine, Aurora, CO, United States; 9 University of Colorado, School of Medicine, Aurora, CO, United States

Background: Many health outcomes and implementation science studies have demonstrated the importance of tailoring evidence-based care interventions to local context to improve fit. By adapting to local culture, history, resources, characteristics, and priorities, interventions are more likely to lead to improved outcomes. However, it is unclear how best to adapt evidence-based programs and promising innovations. There are few guides or examples of how to best categorize or assess health-care adaptations, and even fewer that are brief and practical for use by non-researchers.

Materials and methods: This study describes the importance and potential of assessing adaptations before, during, and after the implementation of health systems interventions. We present a promising multimodal and multimethod approach developed and being applied across four different health systems interventions. Finally, we discuss implications and opportunities for future research.

Results: The four case studies describe in the conditions addressed, interventions, and implementation strategies. They include two nurse coordinator-based transition of care interventions, a data and training-driven multimodal pain management project, and a cardiac patient-reported outcomes project, all of which are using audit and feedback. We used the same modified adaptation framework to document changes made to the interventions and implementation strategies. To create the modified framework, we started with the adaptation and modification model developed by Stilman and colleagues and expanded it by adding concepts from the RE-AIM framework. Our assessments address the initiative domains of WHO, HOW, WHEN, WHAT, and WHY to classify and organize adaptations. For each case study, we discuss how the modified framework was operationalized, the multiple methods used to collect data, results to date and approaches utilized for data analysis. These methods include a real-time tracking system and structured interviews at key times during the intervention. We provide...
Examples of Adaptations Documented in TAQ Projects to Date

- Change in recruitment materials and protocol (*change in intervention*)
- Change in who contacts patient (*task shifting*)
- Change in feedback procedures (*implementation strategy change*)

TAQ = Triple Aim QUERI
PCORI Methodology Guideline SCI-3:
Specify how adaptations to the form of the intervention and comparator will be allowed and recorded

• Researchers should specify:
  – allowable adaptations in form and/or function
  – a description of how planned and unplanned adaptations will be managed, measured and reported over time

• Any planned adaptations should:
  – have a clear rationale
  – ideally be supported by theory, evidence or experience
  – maintain fidelity to the core functions of the intervention

• Upon study conclusion, researchers should provide guidance on:
  – allowable adaptations; or
  – unproductive adaptations
## Types of Adaptations

<table>
<thead>
<tr>
<th>Focus of Adaptation</th>
<th>Planning</th>
<th>During</th>
<th>Dissemination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
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<td>Implementation</td>
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<td></td>
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<tr>
<td>Strategy</td>
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<tr>
<td>Setting</td>
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Adaptation, Fidelity, and Tailoring Interest Group

- Began January 2016 as part of the IRG
- 61 members currently .... **YOU ARE INVITED TO JOIN**
- Representation from many VA QUERI research programs
- Co-chaired by Borsika Rabin, MPH, PhD, PharmD and Russell Glasgow, PhD; Facilitated by Christine P. Kowalski, MPH
- Meet monthly to discuss topics related to adaptation, tailoring and fidelity with attention to clinical application. Discussions include how to define interventions and implementation strategies, as well as how to describe and document adaptations.

*For information or to join contact: Christine.Kowalski@va.gov*
Understanding and Assessing Adaptations: Models, Methods, Measures

Faculty: Borsika Rabin, UCSD/VA; Russ Glasgow, CU/VA; Greg Aarons, UCSD; Ana Baumann, Wash U; Ulrica von Thiele Schwarz, Karolinska Institute

Description: A workshop to focus on the assessment of adaptations in implementation research with special focus on general description of the role of adaptations in real world settings. It will include common models for conceptualization and methodological considerations for the systematic, prospective, pragmatic assessment of adaptations across diverse contexts. Presenters will discuss types of adaptations (including adaptations to interventions and implementation strategies), ways in which adaptations can be documented through the lifetime of a research project, and will share existing methods and instruments for the assessment of adaptations.
### Types of Outcomes in Implementation Research

<table>
<thead>
<tr>
<th>Implementation Outcomes</th>
<th>Service Outcomes</th>
<th>Client Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Acceptability</td>
<td>• Efficiency safety</td>
<td>• Satisfaction</td>
</tr>
<tr>
<td>• Adoption</td>
<td>• Effectiveness</td>
<td>• Function</td>
</tr>
<tr>
<td>• Appropriateness</td>
<td>• Equity</td>
<td>• Symptoms</td>
</tr>
<tr>
<td>• Costs</td>
<td>• Patient-centerededness</td>
<td></td>
</tr>
<tr>
<td>• Feasibility</td>
<td>• Timeliness</td>
<td></td>
</tr>
<tr>
<td>• Penetration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sustainability</td>
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</tbody>
</table>
Evidence-Based...on what? (Issues often ignored)
External Validity/ Pragmatic/ Equity Outcomes

- Participant representativeness
- Setting representativeness
- Context and setting
- Heterogeneity/Disparities in Outcomes
- Community/setting engagement
- Adaptation/change over time
- Sustainability
- Costs/feasibility of treatment
The 5 Rs to Enhance D&I Science and Likelihood of Translation

Research that is:

- Relevant
- Rapid and recursive
- Redefines rigor
- Reports resources required
- Replicable

EXAMPLE D&I STUDY and OUTCOMES: My Own Health Report (MOHR) Program

Cluster randomized pragmatic trial of web-based, brief health behavior and mental health risk assessment and feedback intervention in nine diverse, low-resourced pairs of primary care practices

Implementation Science (RE-AIM) Outcomes included:

- **Reach** of the MOHR program across patients
- Whether safety net practices would adopt MOHR
- How practices would implement MOHR
- Costs and adaptations for MOHR
- Effectiveness of the MOHR program on behavior change goal setting

# Pragmatic Patient Report Measures for Primary Care & EHR

<table>
<thead>
<tr>
<th>Domain</th>
<th>Final Measure (Source)</th>
</tr>
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<tbody>
<tr>
<td>1. Overall Health Status</td>
<td>1 item: BRFSS Questionnaire</td>
</tr>
<tr>
<td>2. Eating Patterns</td>
<td>3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al.</td>
</tr>
<tr>
<td>5. Anxiety and Depression</td>
<td>4 items: Patient Health Questionnaire—Depression &amp; Anxiety (PHQ-4) [Kroenke K, et al.</td>
</tr>
<tr>
<td></td>
<td><em>Psychosomatics</em> 2009;50(6):613-621]</td>
</tr>
<tr>
<td>6. Sleep</td>
<td>2 items: a. Adapted from BRFSS</td>
</tr>
<tr>
<td></td>
<td>b. Neuro-QOL [Item PQSLP04]</td>
</tr>
<tr>
<td>7. Smoking/Tobacco Use</td>
<td>2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]</td>
</tr>
<tr>
<td>10. Demographics</td>
<td>9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household</td>
</tr>
<tr>
<td></td>
<td>income, marital status, education, address, insurance status, veteran’s status. Multiple</td>
</tr>
<tr>
<td></td>
<td>sources including: Census Bureau, IOM, and <em>National Health Interview Survey (NHIS)</em></td>
</tr>
</tbody>
</table>
**Basic patient and clinician feedback and goal setting advice**

**Electronic and paper**

**High Risk Patients:** On average had 5 of 11 risks
## Demographics of Intervention and Control Patients in My Own Health Report

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n=1513)</th>
<th>Control (n=1400)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (female)</td>
<td>67%</td>
<td>68%</td>
</tr>
<tr>
<td>Latino</td>
<td>27%</td>
<td>29%</td>
</tr>
<tr>
<td>African American</td>
<td>10%</td>
<td>11%</td>
</tr>
<tr>
<td>Less than high school High school</td>
<td>18% 33%</td>
<td>19% 32%</td>
</tr>
<tr>
<td>Medicaid or no insurance (Mdn)</td>
<td>51%</td>
<td>49%</td>
</tr>
</tbody>
</table>

Clinics in 8 states; largely community health centers
Adoption

18 Practices agreed to adopt MOHR

- 30 practices approached (adoption 60%)
- 7 of 9 sites recruited, first practices approached
  ✓ Decliners participating in other studies, worried about workload or doing HRAs
- Participating practices represented a diverse spectrum of low-resourced primary care settings, most were safety net or community health centers
Overall **Reach**: 1768 of 3591 patients (49.2%)

Reach of different approaches (**adaptation** of contact methods to fit setting):

- **Mailed** (patient completed)
  - 4 sites  average 30%

- **Phone** (nurse completed)
  - 1 site  64%

- **Lobby** (patient + staff completed)
  - 1 site  44%

- **Lobby** (MA or coordinator completed)
  - 4 sites  average 75%
Implementation adaptations (content standard)

Practices used four main implementation strategies:

- Web at home (n=3), phoned patients (n=1), completed in office on paper (n=1) or electronically in office (n=4)
- 4 asked patients only and 5 asked staff to help complete MOHR with some patients
- 8 needed research team or some health systems assistance
- 8 asked clinicians to counsel patients, 4 had some follow-up, 1 had no counseling or follow-up

Delivery of MOHR took 28 minutes (range 16-31), including assessment, feedback and counseling (most time for counseling)
Effectiveness: Primary Outcome

Did anyone help you set a goal?

<table>
<thead>
<tr>
<th>Topics</th>
<th>% Yes</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Eating/Diet</td>
<td>51.7</td>
<td>34.1</td>
</tr>
<tr>
<td>Physical Activity/Exercise</td>
<td>49.5</td>
<td>37.9</td>
</tr>
<tr>
<td>Tobacco/Smoking</td>
<td>22.6</td>
<td>19.7</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>17.1</td>
<td>13.1</td>
</tr>
<tr>
<td>Drug Use</td>
<td>13.5</td>
<td>11.4</td>
</tr>
<tr>
<td>Stress Level</td>
<td>31.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Anxiety/Depression</td>
<td>32.1</td>
<td>23.1</td>
</tr>
<tr>
<td>Sleep</td>
<td>29.6</td>
<td>24.4</td>
</tr>
</tbody>
</table>
Effectiveness: Secondary Outcome
Have you made any positive changes?

<table>
<thead>
<tr>
<th>Topics</th>
<th>% Yes</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Eating/Diet</td>
<td>62.9</td>
<td>49.9</td>
</tr>
<tr>
<td>Physical Activity/Exercise</td>
<td>55.1</td>
<td>48.2</td>
</tr>
<tr>
<td>Tobacco/Smoking</td>
<td>17.3</td>
<td>16.6</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>15.2</td>
<td>14</td>
</tr>
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<td>Sleep</td>
<td>30.2</td>
<td>24.4</td>
</tr>
</tbody>
</table>
Moral of this Example

- Success demands tailoring and *Adaptation* at the levels of:
  - patient
  - clinician
  - setting

- Opportunity to contribute patient report measures to big data elements that are not usually available: currently adding social determinants of health to MOHR
### How Does MOHR Address the 5 Rs?

<table>
<thead>
<tr>
<th>Relevant</th>
<th>Diverse, real-world primary care settings, and staff who do all the interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigorous</td>
<td>Cluster randomized, delayed intervention design</td>
</tr>
<tr>
<td>Rapid</td>
<td>One year from concept, planning, and execution; low-cost and cost-informative</td>
</tr>
<tr>
<td>Resource Informative</td>
<td>Low cost; studying costs and cost-effectiveness under different delivery conditions. Still too time-consuming.</td>
</tr>
<tr>
<td>Replicable</td>
<td>To low-resource primary care setting wellness visits?</td>
</tr>
<tr>
<td>Transparent</td>
<td>Reports on context, multi-level participation, adaptations, failures, lessons learned</td>
</tr>
</tbody>
</table>
In Summary, D & I Science is about:

- Multi-level, *contextual* issues and external validity
- Relevant, *pragmatic* models, research methods and measures
- Real-world implementation and *adaptation*
- Reducing, or at least not exacerbating *health inequities*
- *Designing* for dissemination, sustainability and equity

- *Normal science (T1– T2) is necessary but not sufficient*
Replicability (and Generalizability)

Important to report conditions under which program was delivered

• To what extent is the program \textit{replicable}:
  ✓ In similar settings?
  ✓ In different settings?

Bottom Line and \textbf{ULTIMATE USE QUESTION}:

“\textit{What program/policy components are most effective for producing what outcomes for which populations/recipient} when implemented by \textit{what type of persons using what implementation} strategies under \textit{what conditions}, with \textit{how many} resources and \textit{how/why} do these results come about?”
QUESTIONS, COMMENTS
D&I Science Funding Opportunities

- PCORI—and “true” patient/family-centered research
- Programs to reduce health inequities
- Guidelines implementation, especially across networks
- Patient health records—patient portal to EHR
- Collection and meaningful use of patient report measures (including social determinants) for care and research
- Efficiency, cost-effectiveness and comparative effectiveness research on care planning, etc.
Areas Ripe for Exploration

• *Sustainability* of programs in a changing context
• Scaling up practices across different health plans, systems, networks and nations: partnerships
• *De-Implementation*: discontinuing wasteful and harmful practices
• *Adaptation*/evolution of programs over time
• *Adaptive designs* (implementation as an iterative, step-wise approach)
• Integration of D&I and quality improvement

The Long Road to Learning Healthcare Systems and Communities (and why we need D&I approaches)

• Standard research, as usual, takes too long
• Research is often not feasible or aligned to address critical health and health care problems
• Research is often not designed with stakeholders nor sustainable
• Teams lack practical tools/technical assistance and strategies
• Large programs are often rolled out without adequate planning
• Need to study and learn from variation
• Treatments work differently across people and settings
Precision Medicine (Health) Opportunities for D&I Science

• How does clinical practice incorporate and adapt PMI findings?
• How do you implement evidence that will evolve?
• What does it cost and what are the opportunity costs?
• How do you train and support the workforce?
• How do you ensure that PM reduces, not exacerbates inequities?
T1-T4 Research
Which type (T) is most common?
Bench to Bookshelf
General Resources

• re-aim.org
• https://rtips.cancer.gov/rtips/index.do
• www.ucdenver.edu/accords/implementation
• www.Dissemination-Implementation.org
D&I Science Models

Over 100 D&I Frameworks:
Most Commonly used models in NIH grants: RE-AIM and DOI (now also CFIR)

Many commonalities across models and theories
Reasons to Document Adaptations

- Provide contextual process data to interpret outcomes (i.e., how adaptations contribute to outcomes)
- Consider refinements to the recommended intervention and implementation strategies based on observed changes
- Create an organized list and categorization of adaptations that future implementers can consider for success
- To develop and test replicable, easy-to-use documentation methods for recording adaptations
Dissemination & Implementation Models in Health Research & Practice

This interactive website was designed to help researchers and practitioners to select the D&I Model that best fits their research question or practice problem, adapt the model to the study or practice context, fully integrate the model into the research or practice process, and find existing measurement instruments for the model constructs. The term 'Models' is used to refer to both theories and frameworks that enhance dissemination and implementation of evidence-based interventions more likely.

Select
Search, view, and select D&I Models

Adapt
Read strategies for adapting D&I Models to research or practice context

Integrate
Read strategies for incorporating D&I Models into the full spectrum of your project

Measure constructs
Find a list of constructs and links to measurement tools associated with the D&I Models

http://www.dissemination-implementation.org/
Practical, Robust Implementation and Sustainability Model

Diabetes CD-ROM Reach and Effectiveness Study

• Innovative Hybrid 2 x 2 ‘preference’ design with adult diabetes patients

• Design
  – First step: Randomize to choice or RCT recruitment methods
  – Second step: Within these conditions, randomize to in-person class or mailed CD-ROM

• Results
  – CD-ROM condition produced four times the reach
  – Equivalent behavioral and biologic outcomes
  – No interaction of Choice by Condition