New and Future Directions in Implementation Science:

Some Things to Consider in Your Next Grant or Two

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www.ucdenver.edu/implementation
"First, I want to give you an overview of what I will tell you over and over again during the entire presentation."
Overview

1. Definitions and Scope
2. * Nine Key Lessons for Implementation Science (IS) Research Success
3. Details and Examples of IS: PRECIS, RE-AIM
4. Types Barriers, Alternative designs
5. Recent NIH Meeting on Reporting
6. IS Models
7. IS Measures
8. *Tips for IS Grant Proposals
9. Resources, Q&A, Discussion
Types of Translation Research: T0 to T4

- T0: Population Health Impact
- T1: Discovery and Basic Theory
- T2: Development of Promising Tests and Initial Testing or Interventions
- T3: Evidence-based Reviews, Recommendations, Policies
- T4: Implementation in Healthcare Systems and Prevention Programs

## Diffusion-Dissemination-Implementation Continuum

<table>
<thead>
<tr>
<th>Discovery/ Development</th>
<th>Delivery</th>
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<tbody>
<tr>
<td><strong>Diffusion</strong></td>
<td><strong>Implementation</strong></td>
</tr>
<tr>
<td>1. Research diffusion</td>
<td>1. Research implementation</td>
</tr>
<tr>
<td>...the passive process by which a growing body of information about an intervention, product, or technology is initially absorbed and acted upon by a small body of highly motivated recipients (Lomas, 1993).</td>
<td>...the utilization of strategies or approaches to introduce or modify evidence-based interventions within specific settings. This involves the identification of and assistance in overcoming barriers to, the application of new knowledge obtained from a disseminated message or program (Lomas, 1993).</td>
</tr>
<tr>
<td>2. Diffusion research</td>
<td>2. Implementation research</td>
</tr>
<tr>
<td>...centers on the conditions which increase or decrease the likelihood that a new idea, product, or practice will be adopted by members of a given culture (Rogers, 1995).</td>
<td>...research that supports the movement of evidence-based interventions and approaches from the experimental, controlled environment into the actual delivery contexts where the programs, tools, and guidelines will be utilized, promoted, and integrated into the existing operational culture (Rubenstein &amp; Pugh, 2006).</td>
</tr>
<tr>
<td><strong>Dissemination</strong></td>
<td></td>
</tr>
<tr>
<td>1. Research dissemination</td>
<td></td>
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<tr>
<td>...active process through which the information needs (pull) of target groups working in specific contexts (capacity) are accessed, and information is &quot;tailored&quot; to increase awareness of, acceptance of, and use of the lessons learned from science (Kerner, 2007).</td>
<td></td>
</tr>
<tr>
<td>2. Dissemination research</td>
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<tr>
<td>...the study of processes and variables that determine and/or influence the adoption of knowledge, interventions or practice by various stakeholders (Lomas, 1997).</td>
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[http://cancercontrol.cancer.gov/is/definitions.html](http://cancercontrol.cancer.gov/is/definitions.html)
Funding Opportunities in Implementation Science and Pragmatic Research

NIH ongoing R01/R on Dissemination and Implementation Research in Health #13-055  http://grants.nih.gov/guide/pa/files/P-13-055.html

NIH Trans-institute ‘common fund’ Health Care Systems Collaboratory www.nihcollaboratory.org

Recent set of announcements from NIDDK on pragmatic research, natural experiments -http://grants.nih.gov/guide/pa/files/P-13-366.html

Multiple PCORI announcements, including one of large pragmatic trials to be released early Feb.  www.pcori.org

Various CDC, AHRQ, foundations announcements

Many national and local CTSA translation projects
### Implementation Science Recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description and Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Consider stakeholder perspectives</td>
<td>Research should be designed from stakeholder perspective, especially the end users. There are multiple stakeholders.</td>
</tr>
<tr>
<td>2. Design for dissemination and sustainability</td>
<td>From the outset, ask if this intervention can ever work in real-world settings. How can you design for maximum adoption? Consider evaluability assessments</td>
</tr>
<tr>
<td>3. Consider multi-level context</td>
<td>Context consists of historical, policy, organizational, team and interpersonal factors. Context changes over time and is best assessed using repeated, mixed methods</td>
</tr>
<tr>
<td>Recommendation</td>
<td>Description and Reference</td>
</tr>
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<td>----------------</td>
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</tr>
<tr>
<td>4. Address external (as well as internal) validity</td>
<td>Document the relevance, uptake, and experience <strong>across multiple levels</strong>. How well do results generalize across patient, staff, setting, and policy contexts?</td>
</tr>
<tr>
<td>5. Resource and cost issues are central</td>
<td>It is always about costs—but costs are also time, not just dollars. One person’s costs are another’s profits. Consider the key perspective(s).</td>
</tr>
<tr>
<td>6. Variation and Adaptation (of interventions and guidelines) happen</td>
<td>Key need to document and understand adaptations—not all of which are bad. Balance between fidelity and adaptation.</td>
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</table>
# Implementation Science Recommendations (3)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description and Reference</th>
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</thead>
<tbody>
<tr>
<td>7. Complexity is real—and needs to be addressed</td>
<td>Interventions have multiple effects—intended and unintended. As above, adaptation will occur.</td>
</tr>
<tr>
<td>8. Don’t just “look under the lamp post”: Consider the denominator</td>
<td>Assess and understand who does not participate and why, who drops out and why.</td>
</tr>
<tr>
<td>9. We need more practical models, methods, and measures</td>
<td>All of these need to be understood by stakeholders, be user friendly, broadly applicable and actionable</td>
</tr>
</tbody>
</table>
Traditional RCTs study the effectiveness of treatments delivered to carefully selected populations under ideal conditions. This makes it difficult to translate results to the real world. Even when we do implement a tested intervention into everyday clinical practice, we often see a “voltage drop”—a dramatic decrease in effectiveness.

“"If we want more evidence-based practice, we need more practice-based evidence.”

Green LW. Am J Pub Health 2006

Research to Practice Pipeline

Basic Idea

» A **pragmatic** trial is a real-world test in a real-world population, whereas an **explanatory** trial is a specialized experiment in a specialized population and often optimal setting

» Pragmatic does not mean being less rigorous

Practical (Pragmatic) Trials: Key Contextual Characteristics

- Multiple, heterogeneous settings
- Diverse and representative populations
- **Comparison conditions** are real-world alternatives
- Multiple outcomes important to decision and policy makers
- Begins with and focus on **Stakeholder perspective**

Thorpe KE et al., Can Med Assoc J, 2009, 180: E47-57
Tunis SR et al. Practical clinical trials...JAMA 2003;290:1624-1632
Glasgow RE et al. Practical clinical trials...Med Care 2005;43(6):551-557
# Key differences between Traditional Randomized Control Trials (RCT) and Pragmatic Controlled Trials (PCT)

<table>
<thead>
<tr>
<th></th>
<th>A traditional RCT tests a hypothesis under ideal conditions</th>
<th>A PCT compares treatments under everyday clinical conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GOALS</strong></td>
<td>To determine causes and effects of treatment</td>
<td>To improve practice and inform clinical &amp; policy decisions</td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo using rigid study protocols &amp; minimal variation</td>
<td>Tests two or more real-world treatments using flexible protocols &amp; local customization</td>
</tr>
<tr>
<td><strong>PARTICIPANTS</strong></td>
<td>Highly defined &amp; carefully selected</td>
<td>More representative because eligibility criteria are less strict</td>
</tr>
<tr>
<td><strong>MEASURES</strong></td>
<td>Require data collection outside routine clinical care</td>
<td>Brief and designed so data can be easily collected in clinical settings</td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td>Rarely relevant to everyday practice</td>
<td>Useful in everyday practice, especially clinical decision making</td>
</tr>
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</table>
The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

A helpful tool to illustrate the degree to which a trial is pragmatic or explanatory. 10 domains plotted on a “spoke-and-wheel” diagram:

1. Eligibility criteria
2. Intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison)
6. Follow-up intensity
7. Primary outcome
8. Participant compliance
9. Practitioner adherence
10. Primary analyses

PRECIS Summary across 3 studies

- PRECIS: An efficient way to summarize how pragmatic vs. explanatory projects are on multiple dimensions
- For comprehensive reporting, parallel external validity/pragmatic criteria (e.g., engagement with stakeholders; report on resources required) are needed/helpful
- Both sets of criteria can be coded reliably after minimal training and can detect differences in study design
- Helps to increase TRANSPARENCY and inform researchers, potential adopting settings, and decision makers

Potential for Translation? RE-AIM

› Internal validity perspective:
  • The **magnitude of effect** as the key indicator of readiness for translation and adheres to the principles of **evidence rating** for determining efficacy

› External validity perspective:
  • Attention to intervention features that can be **adopted** and delivered broadly, have the ability for **sustained** and consistent **implementation** at a reasonable cost, **reach** large numbers of people, especially those who can most benefit, and produce **replicable** and **long-lasting effects**


Goal of Applied Interventions à la RE-AIM is to:

» Increase *REACH*: participation rate and who participates
» Increase *EFFECTIVENESS*: broad impacts and who benefits
» Increase *ADOPTION*: which settings can deliver the program?
» Increase *IMPLEMENTATION*: balance between fidelity, costs, and local adaptations
» Increase *MAINTENANCE*: can results be sustained at individual and setting levels?
Precision (Personalized) Medicine Questions in IS

Determine:

‣ What percent and types of patients are **Reached**;

‣ For whom among them is the intervention **Effective**; in improving what outcomes; with what unanticipated consequences;

‣ In what percent and types of settings and staff is this approach ** Adopted**;

‣ How consistently are different parts of it ** Implemented** at what cost to different parties;

‣ And how well are the intervention components and their effects **Maintained**?

## RE-AIM—Health Equity Implications

<table>
<thead>
<tr>
<th>RE-AIM Issue</th>
<th>Disparity</th>
<th>Overall Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>30%</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>0 (equal)</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>Adoption</td>
<td>30%</td>
<td>49% of benefit</td>
</tr>
<tr>
<td>Implementation</td>
<td>30%</td>
<td>34% of benefit</td>
</tr>
<tr>
<td>Maintenance</td>
<td>30%</td>
<td>24% of benefit</td>
</tr>
</tbody>
</table>

[www.re-aim.org](http://www.re-aim.org)
Current RE-AIM Uses

- Popularized by Glanz, Rimer book & Larry Green(s)
- Used by public health, CDC, HRSA, RWJF, VA & QUERI projects
- Used in over 250 publications and many grant proposals
- Development of “Calculators,” “Quizzes,” Self-test- available at www.re-aim.org
- Used in NIH, RWJF, AoA, CDC grant, Peers for Progress applications
- eLearning onlineTraining:
  http://www.centertrt.org/index.cfm?fa=webtraining.reaim
Cost Evidence

- Replication costs and scalability costs are arguably most needed
- Perspective—patient and adopting setting
- Costs should be comprehensive, standard and transparent
- “One persons costs are another’s profits”
- Cost-effectiveness analyses need not be overwhelming*--cost per incremental unit change
- Should be harmonized and include costs frequently not counted that need to be — e.g., recruitment, overhead, training, preparation and supervision

RE-AIM Summary Points

» RE-AIM is an outcomes framework that can be used for planning, implementation and evaluation

» Each RE-AIM dimension is an opportunity for intervention

» RE-AIM can be used for efficacy, effectiveness, and implementation science projects

» All dimensions can be addressed within a given study (though likely not all intervened upon)

» Methods exist to combine and summarize RE-AIM outcomes

» www.re-aim.org
Design Options in IS

Natural Experiments

Stepped Wedge, Sequential intervention Designs emphasizing replication

Hybrid designs - implementation-effectiveness

Rapid, recursive research and QI

Designs to prioritize outcomes such as reach, cost-effectiveness, feasibility, sustainability

Diabetes CD-ROM Reach and Effectiveness Study

- Innovative Hybrid 2 X 2 design adult diabetes patients:
- Design:
  - First step: From diabetes registry, Randomize to Choice or RCT Recruitment methods
  - Second step: Within randomization arm, assign to in-person class or mail CD
- Results:
  - CD Had 4 times the reach
  - Equivalent behavioral and biologic outcomes
  - No interaction of Choice by Condition

Barriers to Implementation

➢ Features of Research Design

➢ Features of Program/Intervention/Policy

➢ Features of Implementation Setting

➢ Interactions among the above

Integrated Dynamic, Multi-level Research-Practice-Policy Partnership Contextual Systems Approach

Evidence-Tested Program
- Program as Tested
- Critical Elements
- Non-critical Packaging
- Program as Marketed

Fit

Organization
- Delivery Site(s)
- Program Delivery Staff

Partnership

Design Appropriate for Question

Research Design Team And Adaptive Design

Adapted from Estabrooks P. et. al. AJPM, 2005, 31: S45
Take-Home Points and Brief Discussion

- There is a pressing need for a DIFFERENT type of research: PRAGMATIC approaches—that translate more rapidly and are more relevant to stakeholders

- Using a model (whether RE-AIM or other IS model) to help plan, guide implementation, and evaluation can help focus efforts on key issues for translation success

- There are many opportunities for this type of research, especially among research networks and for coalitions to study context (e.g., the HCS Collaboratory, VA centers, FQHCs, PBRNs, the Y, MOHR, etc.)
Models for Implementation Science

» Models – theories and frameworks

» What can they do:
  > Ensures inclusion of essential D&I strategies
  > Enhance the interpretability of study findings
  > Provide systematic structure for the development, management, and evaluation of interventions/D&I efforts

» Wealth of existing models for D&I
  > 61 identified by Tabak et al in a review
  > Additional models with practitioner/clinician focus

Model Categories
Construct Flexibility (CF)
1: Broad
Loosely outlined and defined constructs; allows researchers greater flexibility
2
3
4
5: Operational
Detailed, step-by-step actions for D&I research

Dissemination and / or Implementation (D/I)
D only
Focus on active approach of spreading EBIs to target audience via determined channels using planned strategies
D > I
Equal focus on dissemination and implementation
D = I
Equal focus on dissemination and implementation
I > D
Focus on process of putting to use or integrating evidence-based interventions within a setting
I only

Socio-ecological Framework (SEF)
System: Hospital system, government
Community: Local government, neighborhood
Organization: Hospitals, service organizations, factory
Individual: Personal characteristics

http://www.cdc.gov/prc/images/dni-models_large.jpg
# Models utilized in IS R01s

<table>
<thead>
<tr>
<th>Model</th>
<th>Frequency (%)</th>
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</thead>
<tbody>
<tr>
<td>Rogers’ Diffusion of Innovations + RE-AIM</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Nonspecific reference</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Rogers’ DOI alone or in combination with other</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>RE-AIM alone or in combination</td>
<td>7 (15%)</td>
</tr>
<tr>
<td>Specific theory/framework:</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>- Cooperation Extension System</td>
<td></td>
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<tr>
<td>- Community Readiness Model</td>
<td></td>
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<tr>
<td>- Quality Assurance Model (2)</td>
<td></td>
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<tr>
<td>- Self-regulation Theory of Health Behavior</td>
<td></td>
</tr>
<tr>
<td>- Collaborative Depression Core Model</td>
<td></td>
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<tr>
<td>- Cognitive Behavioral Theory</td>
<td></td>
</tr>
<tr>
<td>- Advanced Recovery Theory</td>
<td></td>
</tr>
<tr>
<td>- Program Change Model</td>
<td></td>
</tr>
<tr>
<td>No theory/framework</td>
<td>22 (48%)</td>
</tr>
</tbody>
</table>

# Assessment for IS research

When, where, how, with whom, under what circumstances, and why does this program/intervention/treatment work?

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Possible answers for IS research</th>
</tr>
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<tbody>
<tr>
<td>• What to assess?</td>
<td>• Diverse set of outcomes (including adverse outcomes and cost)</td>
</tr>
<tr>
<td>• How frequently, when, and for how long?</td>
<td>• Process measures (mediators, moderators)</td>
</tr>
<tr>
<td>• With what kind of instruments?</td>
<td>• Measures at multiple levels, collected from various stakeholders at multiple time points</td>
</tr>
<tr>
<td></td>
<td>• Mix of quantitative and qualitative approaches and measures</td>
</tr>
<tr>
<td></td>
<td>• Practical measures</td>
</tr>
<tr>
<td>Challenge</td>
<td>Opportunities</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Challenge 1: Inconsistent terminology for IS</strong></td>
<td>Need to further map and possibly harmonize the meaning and classification of terms across sub-areas and geographical regions1</td>
</tr>
<tr>
<td>Inconsistency and variation in terminology and classification for D&amp;I</td>
<td></td>
</tr>
<tr>
<td><strong>Challenge 2: Constructs of critical importance for IS</strong></td>
<td>Catalogue and classification of IS models exist2</td>
</tr>
<tr>
<td>Still somewhat unclear what factors really matter for D&amp;I</td>
<td>Some commonalities across studies, models, stakeholder demand for areas of importance (context, broad outcome/process measures)3, 4</td>
</tr>
<tr>
<td>Devil is in the details – different meanings/operationalizations/measures for same concept</td>
<td>Implementation process outcomes identified5</td>
</tr>
<tr>
<td><strong>Challenge 3: Cataloguing, assessing, and harmonizing existing IS measures</strong></td>
<td>Number of ongoing efforts to do this:</td>
</tr>
<tr>
<td>Need to understand what measures exist for D&amp;I and what are their characteristics (meta data)</td>
<td>SIRC Instrument Review Project – systematic review and expert approach</td>
</tr>
<tr>
<td>If each use own measures – makes knowledge accumulation challenging</td>
<td>GEM D&amp;I Initiative – wiki/crowd-sourcing approach with focus on practical ratings</td>
</tr>
<tr>
<td></td>
<td>Jonathan Tobin - CTSA D&amp;I measures efforts</td>
</tr>
<tr>
<td></td>
<td>Nina Wallerstein – CBPR model validation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Challenge 4: Qualitative information matters (at least) as much as quantitative data</strong>&lt;br&gt;No standardized guidance on assessment of qualitative instruments for quality&lt;br&gt;Use of common instruments is even more challenging</td>
<td>Need to identify unobtrusive, observational approaches&lt;br&gt;A few examples/guidance for use and integration of qualitative data:&lt;br&gt;OBSSR: Best Practices for Mixed Methods Research in the Health Sciences&lt;br&gt;My Own Health Record project and AHRQ context instruments (Kurt Stange, Russ Glasgow)(^1)&lt;br&gt;CFIR wiki(^2)&lt;br&gt;Albright et al. Importance of Mixed Methods in Pragmatic Trials and Dissemination and Implementation Research(^3)</td>
</tr>
<tr>
<td><strong>Challenge 5: Need for practical/feasible and actionable measures</strong>&lt;br&gt;Need to balance traditional gold standard criteria with the criteria for practicality/feasibility for use in real world settings especially when measuring multiple behaviors, multiple people, multiple conditions&lt;br&gt;Need to ensure that what is measured does matter to end-users (actionable, in-line with their priorities, measured at the right level)</td>
<td>Examples and guidance:&lt;br&gt;GEM D&amp;I Initiative criteria for feasibility(^4)&lt;br&gt;Glasgow &amp; Riley paper on practical measures(^5)&lt;br&gt;EMR brief measure campaign using GEM(^6)&lt;br&gt;Jonathan Tobin - CTSA D&amp;I measures effort</td>
</tr>
</tbody>
</table>

Ongoing efforts for measure synthesis and harmonization

» Seattle Implementation Research Collaborative Instrument Review Project
  > Conduct a systematic review of D&I instruments
  > Three primary outcomes for this project series include:
    • Comprehensive library of D&I instruments
    • Rating system reflecting the degree of empirical validation of instruments
    • Consensus battery of instruments.
  > To date, 450 instruments. Rating is ongoing.
  > To learn more: http://www.seattleimplementation.org/sirc-projects/sirc-instrument-project/

» The NCI Grid-enabled Measures D&I initiative:
  > Uses crowd-sourcing approach
  > 130 different implementation science measures across 74 constructs, their associated characteristics and a rating of these measures for quality and practicality.
  > To learn more: http://www.gem-beta.org/GEM-DI
Instrument Review Project

The SIRC Instrument Review Project: A Systematic Review of Dissemination and Implementation Science Instruments

Video of Instrument Review Taskforce at SIRC 2011
Power Point Presentation from ABCT
SIRC_IRP Update_2013 (video of full presentation coming soon).

Exciting advances have been made in the field of dissemination and implementation (D&I). However, much like the science-practice gap that motivates our field, a communication gap exists among stakeholders at the forefront of this work. Measurement issues have slowed the progression of the field of D&I given the laborious process of systematically developing psychometrically sound yet feasible and cost-effective ways to assess our efforts. The lag that occurs between initial development, implementation, and then publication delays the process further, resulting in instances in which independent research teams are devoting considerable resources to unnecessarily redundant work. As a consequence, progress toward the development of commonly used instruments has been very slow, limiting the extent to which researchers have access to and are able to

http://www.seattleimplementation.org/sirc-projects/sirc-instrument-project/
Welcome to GEM, a web-based collaborative tool containing behavioral, social science, and other relevant scientific measures.

The goal of GEM is to support and encourage a community of users to drive consensus on best measures and share the resulting data from use of those measures.

GEM enables users to:

- Add constructs or measures to the database
- Contribute to and update existing information (metadata) about constructs and measures
- Rate and comment on measures to drive consensus on best measures
- Access and share harmonized data
- Search for and download measures

Learn more about GEM

Measures at a Glance

: http://www.gem-beta.org/GEM-DI
<table>
<thead>
<tr>
<th>GOLD STANDARD MEASURE RATING CRITERIA - For Primary Research Focus</th>
<th>PRACTICAL MEASURE RATING CRITERIA - For Real-World Application&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reliable:</strong> Especially test-retest (less emphasis on internal consistency)</td>
<td><strong>Feasible</strong>: Brief (generally 2 to 5 items or less); easy to administer/score/interpret</td>
</tr>
<tr>
<td><strong>Valid:</strong> Construct validity, criterion validity, performed well in multiple studies</td>
<td><strong>Important to Practitioners and Stakeholders</strong>: Relevant to health issues that are prevalent, costly, challenging; helpful for decision makers or practice</td>
</tr>
<tr>
<td><strong>Broadly Applicable:</strong> Available in English and Spanish, validated in different cultures and contexts; norms available; no large literacy issues</td>
<td><strong>Actionable</strong>: Based on information, realistic actions can be taken, e.g., immediate discussion, referral to evidence-based on-line or community resources</td>
</tr>
<tr>
<td><strong>Sensitive to Change</strong>: Longitudinal use, for performance tracking over time</td>
<td><strong>User Friendly</strong>: Patient interpretability; face valid; meaningful to clinicians, public health officials, and policy makers</td>
</tr>
<tr>
<td><strong>Public Health Relevance:</strong> Related to Healthy People 2020 goals, key IOM objectives or national priorities</td>
<td><strong>Low Cost</strong>: Publicly available or very low cost to use, administer, score, and interpret</td>
</tr>
<tr>
<td></td>
<td><strong>Enhances Patient Engagement</strong>: Having this information is likely to further patient engagement</td>
</tr>
<tr>
<td></td>
<td><strong>Do No Harm</strong>: Can likely be collected without interfering with relationships, putting respondents at risk, or creating unintended negative consequences</td>
</tr>
</tbody>
</table>

(Rabin et al. *Implement Sci* 2012 7:119)
Characteristics of Strong IS Research Studies

1. **Significance:** The proposal meets the goal of D&I PAR to improve practice through research.

2. **Use of mixed methods:** The proposal utilizes mixed methods (quantitative and qualitative), as encouraged by the PAR.

3. **Sampling strategy and selection criteria:** Regardless of the method, sampling strategies and selection criteria are well-articulated and justified.

4. **Sustainability:** The proposal addresses the sustainability of the project or innovation.

5. **Feasibility and Generalizability:** D&I is concerned with real-world applicability of interventions and innovation. Strong proposals promote interventions that are feasible and practical for real-world settings.

Content analysis of funded NCI IS grants: [http://cancercontrol.cancer.gov/IS/pdfs/DandI-PAR-Grant-FundedContentAnalysis.pdf](http://cancercontrol.cancer.gov/IS/pdfs/DandI-PAR-Grant-FundedContentAnalysis.pdf)
Characteristics of Strong IS Research Studies

6. Targeting diverse, underserved and understudied populations and settings.

7. Potential for advancing the methods for dissemination and implementation.

8. **Community Collaboration:** To be relevant to real-world settings, D&I research must foster collaboration with communities and community-based organizations.

9. **Strong Study Teams:** Proposals feature strong, experienced, inter-disciplinary study teams.

10. **Conceptual frameworks:** proposals present relevant and specific frameworks, theories or models to guide their work.

**+2 weaknesses:**

1. The proposal fails to clearly articulate its overall significance, aims, relevance to the field of D&I, or generalizability to broader settings and populations.

2. The proposal fails to adequately articulate its framework, theoretical background and conceptual models.

Content analysis of funded NCI IS grants: [http://cancercontrol.cancer.gov/IS/pdfs/DandI-PAR-Grant-FundedContentAnalysis.pdf](http://cancercontrol.cancer.gov/IS/pdfs/DandI-PAR-Grant-FundedContentAnalysis.pdf)
## Ten Key Ingredients for implementation research proposals

<table>
<thead>
<tr>
<th>Proposal Ingredient</th>
<th>Key Question</th>
<th>Review Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The care gap or quality gap</td>
<td>The proposal has clear evidence that a gap in quality exists?</td>
<td>Significant impact</td>
</tr>
<tr>
<td>2. The evidence based treatment to be implemented</td>
<td>Is the evidence for the program, treatment, or set of services to be implemented demonstrated?</td>
<td>Significance innovation</td>
</tr>
<tr>
<td>3. Conceptual model and theoretical justification</td>
<td>The proposal delineates a clear conceptual framework/theory/model that informed the design and variables being tested?</td>
<td>Approach innovation</td>
</tr>
<tr>
<td>4. Stakeholder priorities, engagement in change</td>
<td>Is there a clear engagement process of the stakeholders in place?</td>
<td>Significance impact Approach Environment</td>
</tr>
<tr>
<td>5. Setting’s readiness to adopt new services/treatments/programs</td>
<td>Is there clear information that reflects the settings readiness, capacity, or appetite for change, specifically around adoption of the proposed evidence-based treatment?</td>
<td>Impact Approach Environment</td>
</tr>
<tr>
<td>6. Implementation and strategy/process</td>
<td>Are the strategies to implement the intervention clearly defined, and justified conceptually?</td>
<td>Significance impact innovation</td>
</tr>
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<td>7. Team experience with setting, treatment, implementation process</td>
<td>Does the proposal detail the team’s experience with the study setting, the treatment whose implementation is being studied, and implementation processes?</td>
<td>Approach investigator team</td>
</tr>
<tr>
<td>8. Feasibility of proposed research design and methods</td>
<td>Does the methods section contain as much detail as possible, as well as lay out possible choice junctures and contingencies, should methods not work as planned?</td>
<td>Approach investigator team</td>
</tr>
</tbody>
</table>
| 9. Measurement and analysis section | Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory?  
Is a measurement plan clear?  
Does the analysis section demonstrate how relationships between constructs will be tested? | Approach investigator team |
| 10. Policy and funding environment; leverage or support for sustaining change | Does the proposal address how the implementation initiative aligns with policy trends? | Impact significance |
Overarching note:
What drives your impact score?

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Regression</th>
</tr>
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<tbody>
<tr>
<td>Approach</td>
<td>6.7</td>
</tr>
<tr>
<td>Significance</td>
<td>3.3</td>
</tr>
<tr>
<td>Innovation</td>
<td>1.4</td>
</tr>
<tr>
<td>Investigator</td>
<td>1.3</td>
</tr>
<tr>
<td>Environment</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

Resources

- QUERI trainings; resources; webinars: http://www.queri.research.va.gov/
- NCI (for NIH)- web resources; research tested programs; webinars: http://www.cancer.gov/
- KT Canada: http://ktclearinghouse.ca/ktcanada
- RE-AIM website (including measures; self-quizzes, literature, examples): www.re-aim.org
- CRISP: www.ucdenver.edu/implementation and D&I in Health Training Guide and Workbook (available upon request)
- Make Research Matter: http://makeresearchmatter.org/
Take-Home Points 2

» There are many IS models:
  > No one right model
  > Matching to research questions is key
  > Adaptation of models might be necessary
  > Full integration of models is key

» There is important need and gap for practical measures:
  > Need to know more about existing measures and assessment approaches (METADATA)
  > Need to develop measures and assessment approaches for certain key areas (e.g., CONTEXT)

» Key lessons learned and tips from recent and past IS grantees are available suggesting what was successful and what should be done better

» A rich array of resources available on these topics at local, national, international level
WHAT DO YOU THINK?

We want YOUR input, reactions, lessons learned.

GET IN TOUCH:
Russ: russell.glasgow@ucdenver.edu
Borsika: borsika.rabin@ucdenver.edu
A New “Bold Standard”? The 5 Rs

- Relevant
- Rapid and Recursive
- Rigorous (redefined to include robustness and generalizability)
- Resource Need Informative
- Replication is built in / emphasized

 Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Revision under review—available by request
Transparent Evidence on...

- Information needed to replicate or implement
- Resources required—costs for patients and delivery setting perspectives
- How were settings, clinicians, and patients selected—(who was excluded and why)
- Adaptation—changes made to protocol, to intervention, to recruitment, etc.

Differences across settings