Implementation Science
Perspectives on Opportunities and Challenges for ISRII

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Implementation Science
National Cancer Institute

ISRII 6th Scientific Meeting
Chicago – May 2013
Overview

- Implementation Science Perspectives on ISRII
  - Evidence Integration Triangle
  - RE-AIM and Health Equity Issues

- Pragmatic Approaches and eHealth Review

- Reflections, Needs and Pragmatic Example
  - My Own Health Report (MOHR) study

- Funding, Conclusions, Q&A
NCI Implementation Science  
Team Vision

To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.

IS Team Website: http://cancercontrol.cancer.gov/IS/
**RE-AIM Realist* or Precision Medicine Question**

- 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>
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</tbody>
</table>

IS Team Presentation on Health Inequities: [http://cancercontrol.gov/IS/presentations.html](http://cancercontrol.gov/IS/presentations.html)
Evidence Integration Triangle (EIT)

Intervention Program/Policy
(Prevention or Treatment)
(e.g., key components; principles; guidebook; internal & external validity)

Participatory Implementation Process
(e.g., stakeholder engagement; CBPR; team-based science; patient centered)

Practical Progress Measures
(e.g., actionable & longitudinal measures)

Multi-Level Context
- Intrapersonal/Biological
- Interpersonal/Family
- Organizational
- Policy
- Community/Economic
- Social/Environment/History

Feedback

Evidence Integration Triangle (EIT)

**Evidence Integration Triangle (EIT) - A Patient-Centered Care Example**

**Intervention Program/Policy**
Evidence-based decision aids to provide feedback to both patients and health care teams for action planning and **health behavior counseling**

**Evidence**
US Preventive Services Task Force recommendations for health behavior change counseling; goal setting & shared decision making

**Stakeholders**
Primary care (PC) staff, patients and consumer groups; health care system decision makers; groups involved in meaningful use of EHRs

**Participatory Implementation Process**
Iterative, **wiki activities** to engage stakeholder community, measurement experts and diverse perspectives

**Practical Progress Measures**
Brief, **standard patient reported data items** on health behaviors & psychosocial issues -- actionable and administered longitudinally to assess progress

**Multi-Level Context**
- Dramatic increase in use of EHR
- Primary Care Medical Home
- CMS funding for annual wellness exams
- Meaningful use of EHR requirements
PRAGMATIC METHODS
The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

Describes ten domains that affect the degree to which a trial is pragmatic or explanatory.

1. Participant eligibility criteria
2. Experimental intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison) outcome
6. Follow-up intensity
7. Primary trial outcome
8. Participant compliance
9. Practitioner adherence
10. Analysis of primary

eHealth RESULTS

- Little variability in PRECIS scores across all studies
- Most fell midway along the PRECIS continuum composite mean = 3.12 (domain range, 2.7-3.6)
- Few reported practical feasibility criteria composite mean = 1.98 (domain range, 1.5 to 2.8 )
- Practical feasibility scores rated lower than PRECIS
- Significant differences by intervention settings, target population, year published, and translation phase
- Trend analysis
  - Significant increase—Experimental intervention flexibility domain
  - Significant decrease—Intervention resources domain

Average PRECIS Scores for All Studies by Domain

PRECIS SUMMARY

- PRECIS: An efficient way to summarize how pragmatic vs. explanatory projects are on multiple dimensions

- For comprehensive reporting, parallel external validity/pragmatic criteria 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
Pragmatic Measures

1. **Required Criteria**
   - Important to stakeholders
   - Burden is low to moderate
   - Broadly applicable, has norms to interpret
   - Sensitive to change

2. **Additional Criteria**
   - Actionable
   - Low probability of harm
   - Addresses public health goal(s)
   - Related to theory or model
   - “Maps” to “gold standard” metric or measure

Dissemination and Implementation Measures Initiative

- To engage research community and stakeholders in sharing, commenting on, and rating measures of key D&I constructs.

- To provide a resource for investigators in writing grants and designing studies, and eventually, data sharing among interested parties to advance science.

GEM-D&I Homepage: www.gem-beta.org/GEM-DI

D&I workspace launched on GEM in March 2012

120 measures available, across 45 constructs.
# Pragmatic EHR Measures for Primary Care

<table>
<thead>
<tr>
<th>Domain</th>
<th>Final Measure (Source)</th>
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<tbody>
<tr>
<td>1. Overall Health Status</td>
<td>1 item: BRFSS Questionnaire</td>
</tr>
<tr>
<td></td>
<td>2. Eating Patterns 3 items: Modified from Starting the Conversation (STC)</td>
</tr>
<tr>
<td></td>
<td>3. Physical Activity 2 items: The Exercise Vital Sign</td>
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<tr>
<td></td>
<td>4. Stress 1 item: Distress Thermometer</td>
</tr>
<tr>
<td></td>
<td>6. Sleep 2 items: a. Adapted from BRFSS</td>
</tr>
<tr>
<td></td>
<td>b. Neuro-QOL [Item PQSLP04]</td>
</tr>
<tr>
<td></td>
<td>7. Smoking/Tobacco Use 2 items: Tobacco Use Screener</td>
</tr>
<tr>
<td></td>
<td>[Adapted from YRBSS Questionnaire]</td>
</tr>
<tr>
<td></td>
<td>8. Risky Drinking 1 item: Alcohol Use Screener</td>
</tr>
<tr>
<td></td>
<td>9. Substance Abuse 1 item: NIDA Quick Screen</td>
</tr>
<tr>
<td></td>
<td>[Smith PC et al. <em>Arch Int Med</em> 2010;170(13):1155-1160]</td>
</tr>
<tr>
<td></td>
<td>10. Demographics 9 items: Sex, date of birth, race, ethnicity, English fluency,</td>
</tr>
<tr>
<td></td>
<td>occupation, household income, marital status, education, address, insurance status,</td>
</tr>
<tr>
<td></td>
<td>veteran’s status. Multiple sources including:</td>
</tr>
<tr>
<td></td>
<td>Census Bureau, IOM, and <em>National Health Interview Survey (NHIS)</em></td>
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</table>
Pragmatic Study Methods: Key Characteristics

- Questions from and important to stakeholders
- Multiple, heterogeneous settings
- Diverse populations
- Comparison conditions are real-world alternatives
- Multiple outcomes important to decision and policy makers

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
My Own Health Report (MOHR)
Automated Assessment Tool

Patient Fills Out Tool

Patient Health Update
Check the box next to your answer.

Q1. Over the past 7 days:
   a. How many times did you eat fast food meals or snacks?
      - less than 1 time
      - 1-3 times
      - 4 or more times
   b. How many servings of fruits/vegetables did you eat each day?
      - 5 or more
      - 3-4 servings
      - 2 or less
   c. How many soda and sugar sweetened drinks (regular, not diet) did you drink each day?
      - Less than 1
      - 1-2 drinks
      - 3 or more

Report data stored in database

Summary display and printout for patient
Action Plan printout
Summary display and printout for physician

Database of text messages and triggers

Research analysis
MOHR Project—Key Points

http://www.myownhealthreport.org/

- Cluster randomized trial of 9 pairs of clinics. Approximately half of clinics community health centers, others AHRQ-type PBRN clinics
- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- **WHAT is delivered**—e.g., automated assessment tool, feedback, goal setting materials, follow-up are **STANDARD**;
- **HOW this is delivered** is customized to setting
- **Study goal** = Sustainable, routine use of intervention

Fact Sheet Available at: http://cancercontrol.cancer.gov/IS/pdfs/MOHr_Executive_Summary_2-22-2013.pdf
### Pragmatic Features

<table>
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<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Relevant</td>
<td>Diverse, real-world primary care settings; and staff who do all the intervention</td>
</tr>
<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</td>
<td>Low cost; studying costs and cost-effectiveness under different delivery conditions</td>
</tr>
<tr>
<td>Informative</td>
<td>Report on adaptations, failures, lessons learned</td>
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</tbody>
</table>
“The significant problems we face cannot be solved by the same level of thinking that created them.”

A. Einstein
Observations and Reflections

... On Evidence
Types of Evidence Needed: A New “Bold Standard”? The 5 R’s

- Relevant (to stakeholders)
- Rapid
- Rigorous (redefined to include robustness and replication)
- Resources Reported
- Recursive—iterative; ongoing learning

Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request
Relevance

- Studies with or generalizable to:
  - Real-world settings, including low-cost sites
  - Range of staff intervention models
  - Range of end users, consumers, participants
  - Typical conditions of administration and assessment
- Can get quick idea from CONSORT PRECIS criteria

Rapid

- Pace of research (17 years for 14% of data to translate) is way too slow

- Need changes in design, review, measures, publication, and culture

- Many evolving, adaptive designs; several from different fields

Riley WR, Glasgow, Etheredge, Abernathy, revision under review 2013
Development/Validation Steps Involving Rapid eHealth Learning Networks

2007

Environmental Scan of Practice/Industry Based
- Focus on lessons learned
- Snowball networking

2008

Rapid Literature Review
- Inclusive of grey lit.
- Focus on key & recent
- Nomination

Evaluability Assessment
- RE-AIM
- Cost
- Future direction
- Context
- Health technology

Small Rapid Studies
- A-B
- N of 1
- Fractional factorial
- Program changes
- Version $X_1$, $X_2$

2009

Application Tests in Diverse Settings
- Stepped wedge
- Pragmatic studies
- Replication
- CER
- Relevant RCTs

Dissemination / Evaluation
- Continuous monitoring
- Alerts
- Communities of Practice
- Continuous Quality Improvement

Target Timeframe:
- Rapid Literature Review: 1-3 months
- Evaluability Assessment: 2-6 months
- Small Rapid Studies: 6-12 months

Acronyms:
RE-AIM= Reach Effectiveness, Adoption, Implementation, and Maintenance
CER= Comparative Effectiveness Research
RCT= Randomized Control Trial
Rigorous (Devil is in the Details)

- Replication is *sina qua non* of causality—and severely unappreciated

- Balance of internal and external validity

- Consider and address most likely potential confounding factors
Resource Informative

- Need to know *implementation costs* (as conducted) and *replication costs* (under different conditions)

- Need to report staff time, training, *recruitment*, supervision, delivery costs

- Do **NOT** need complete, comprehensive societal analyses of downstream consequences, etc.
Recursive (Iterative)

- Across the T1-T4 cycle
- In Quality Improvement (QI) sense of continuous improvement
- Programs and policies hardly ever work perfectly when initially implemented, or as in the efficacy study
- Evidence Integration Triangle captures some of the needed iteration
All Models (and Methods) are Wrong…
....Some are useful

“To every complex question, there is a simple answer… and it is wrong.”

~H. L. Mencken
Types of Evidence Needed: A New “Bold Standard”? The 5 R’s

- Relevant (to stakeholders)
- Rapid
- Rigorous (redefined to include robustness and replication)
- Resources Reported
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Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request
Funding and Resources
The Trans-NIH D&I Funding Announcement (International Investigators Eligible)

- R01 - PAR 13-055 ($500k per annum up to five years)
- R03 - PAR 13-056 ($50K per annum up to two years)
- R21 - PAR 13-054 ($275K up to two years)

- Participating Institutes: NIMH, NCI, NIDA, NIAAA, NIAID, NHLBI, NINR, NIDDK, NINDS, NIDCD, NIDCR, NCCAM, NHGRI*, NIA* & Office of Behavioral & Social Sciences Research

- Standing review committee, Dissemination and Implementation Health Research

- Three submission dates per year: February, June, October

- New Institute Added to PAR in 2013

http://cancercontrol.cancer.gov/funding_apply.html#is
Implementation Science Funding Opportunities

- PCORI—and “true” patient/family-centered research
- “Team Science” and collaborative approaches to care transformation
- Guidelines implementation, especially across networks
- Patient Health Records—patient portal to EHR
- Collection and meaningful use of patient report measures for care and research
- Efficiency, CEA and CER on care planning, etc.
Criteria for Inclusion on RTIPs

- Intervention outcome finding(s) must be published in a peer-reviewed journal.

- The study must have produced one or more positive behavioral and/or psychosocial outcomes ($p \leq .05$) among individuals, communities, or populations.

- Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. The intervention must have messages, materials, and/or other components that include English and can be disseminated in a U.S. community or clinical setting.

- The intervention has been conducted within the past 10 years.

How You Can Get Involved:


2. Contact the RTIPs team for questions, comments, additional information: http://rtips.cancer.gov/rtips/contact.do

EVIDENCE-BASED PROGRAM AND RE-AIM RESOURCES

Purpose: Designed to increase breast cancer screening among low-income Korean-American women (2010)

Program Focus: Awareness building, Behavior Modification, and Self-efficacy

Population Focus: Medically Underserved

Reaching (s): P30CA16042, R25CA87949, U.S. Army Medical Research and Material Command (Grant number(s): DAMD17-03-1-0676)

Self-rating Quiz

Scores should be interpreted using this scale:

- 5-10: Excellent
- 7-8: Good, but could use a little work
- 5-6: Fair, needs additional planning
- < 5: Poor, needs serious attention

Dissemination Capability

1.0 = low  5.0 = high

http://re-aim.org/resources_and_tools/index.html

RE-AIM Scores

- Reach: 30.0%
- Effectiveness: 33.3%
- Adoption: 33.3%
- Implementation: 56.7%

http://rtips.cancer.gov/rtips/index.do
Evidence means different things to different people – is almost a cultural difference

We need:

- Balance and respect for different types of evidence
- To think and evaluate broadly
- To consider evidence from multiple perspectives, and especially of potential target audience
Contact me: glasgowre@mail.nih.gov

IS Team Website:
http://dccps.cancer.gov/is/

IS Team Email:
NCIdccpslSteamp@mail.nih.gov
ADDITIONAL SLIDES
RE-AIM Evaluability Questions or Planning for Dissemination

- What percent and what types of patients are likely to Receive this program;
- For whom among them is the intervention Effective; in improving what outcomes; what broader effects and potential negative consequences?
- What percent and what types of settings and practitioners are likely to Adopt this program;
- How consistently are different parts of the program likely to be Implemented across settings, clinicians, and patient subgroups…and at what cost;
- And how well is the eHealth program and its effects likely to be Maintained?

Future Evidence Needs and Opportunities—Keys to Advance Translation

- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Health equity impacts
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice
Future Evidence Needs and Opportunities—
Keys to Advance Translation (cont.)

- Health equity impacts
- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice
T1 case series efficacy trials

Clinical and behavioral scientists

T2 effectiveness studies
Clinical guideline development
Systematic reviews

Health services and public health scientists

T3 effectiveness studies
Implementation guideline development
Systematic reviews
Mathematic modeling

Dissemination and implementation scientists

Basic scientists

Proximal Stakeholders

Distal Stakeholders

Decision makers in public health, clinical practice, community organizations, workplaces, schools, government, and residents

T4 use of evidence-based intervention and implementation strategies in the real world

Gaglio et al (2013) submitted
Summary: Experience Using PRECIS

Results: Consistent results were found across all three diverse applications. These pragmatic criteria can be reliably rated, reveal differences across dimensions and studies, and studies are rated as more pragmatic on the original PRECIS criteria than on the added external validity criteria.

Conclusions: Such measures should be used more consistently to help plan pragmatic studies, evaluate progress, increase transparency of reporting, and integrate literature intended to help translate research into practice and policy.
Average Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) scores for Practice-Based Opportunities for Weight Reduction (POWER) Trials, Systematic Review of eHealth Cancer Prevention and Control Interventions, and My Own Health Report (MOHR)

Gaglio B, et al. How pragmatic is it? Lessons learned using PRECIS…Submitted to Med Care