Implementation Science in 2013

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Overview

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

- Pragmatic Approaches and eHealth Review

- Reflections, Needs and Pragmatic Example
  - My Own Health Report 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—Inequity 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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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

Stakeholders
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
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 REVIEW 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

Maximum and minimum PRECIS scores based on only studies for which all domains were scored.

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

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.

- 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.
<table>
<thead>
<tr>
<th>Domain</th>
<th>Final Measure (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overall Health Status</td>
<td>1 item: BRFSS Questionnaire</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 income, marital status, education, address, insurance status, veteran’s status. Multiple sources including: Census Bureau, IOM, and National Health Interview Survey (NHIS)</td>
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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
**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
   - [x] 4 or more times

b. How many servings of **fruits/vegetables** did you eat each day?
   - [ ] 5 or more
   - [x] 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
   - [x] 1-2 drinks
   - [x] 3 or more

**MRN:** ____________________________

**Extreme Stress**

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**Database of text messages and triggers**

**Summary display and printout for patient**

**Action Plan printout**

**Summary display and printout for physician**

**Research analysis**

**Report data stored in database**
**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](http://cancercontrol.cancer.gov/IS/pdfs/MOHR_Executive_Summary_2-22-2013.pdf)
## Pragmatic Features

<table>
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<th>Feature</th>
<th>Description</th>
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<tr>
<td><strong>Relevant</strong></td>
<td>Diverse, real-world primary care settings; and staff who do all the intervention</td>
</tr>
<tr>
<td><strong>Rigorous</strong></td>
<td>Cluster randomized, delayed intervention design</td>
</tr>
<tr>
<td><strong>Rapid</strong></td>
<td>One year from concept, planning, and execution, low cost, and cost informative</td>
</tr>
<tr>
<td><strong>Resource</strong></td>
<td>Low cost; studying costs and cost-effectiveness under different delivery conditions</td>
</tr>
<tr>
<td><strong>Informative</strong></td>
<td>Report on adaptations, failures, lessons learned</td>
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“The significant problems we face cannot be solved by the same level of thinking that created them.”

A. Einstein
Russ’ Observations and Reflections

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

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

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

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

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

Traditional Timeframe for Research in Comparison to Technology

- Wii
- iPhone
- Android
- iPad
- Siri/4S

2005
2006
2007
2008
2009
2010
2011
2012

- Grant Submitted
- Grant Awarded
- Develop & Pilot Test
- Recruit & Randomize
- Follow-ups
- Analyze & Publish
- Replications, Reviews & Adoption

2-10 years
Environmental Scan of Practice/Industry Based
- Focus on lessons learned
- Snowball networking

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 X₁, X₂

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
- 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.
What Else Do We Need?

- Harmonized measures: Common measures would help cross-study comparisons, reviews, etc.

- Convergence of results across diverse methods: e.g., RCTs, observational data, simulation modeling, natural experiments, practice-based evidence, quantitative and qualitative, etc.
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)
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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

NIH D&I Funding Announcements: 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.
RESEARCH TESTED INTERVENTION PROGRAMS (RTIPS)

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](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.

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

Population Focus: Medically Underserved, Older Adults (65+ years)

Self-rating Quiz

Scores should be interpreted using this scale:

- 5-10: Excellent
- 4-5: Good, could use a little work
- 3-3: Fair, needs additional planning
- < 3: Poor, needs serious attention

It may be helpful to have several members of your team take this self-rater quiz and then compare and discuss your answers.

Find more resources for improving your scores.

Dissemination Capability

1.0 = low  5.0 = high

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

http://rtips.cancer.gov/rtips/index.do
Evidence means different things to different people—it 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: NCIdccpsISteam@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
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- Scalability—potential to impact large numbers
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- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice