Implementation Science: Methods, Models and Opportunities to Integrate Evidence, Policy and Practice

Russell E. Glasgow, Ph.D.,
Deputy Director,
Implementation Science Team
Division of Cancer Control and Population Sciences
National Cancer Institute
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.

http://cancercontrol.cancer.gov/is/
Models, Methods and Measures for Implementation Science

♦ Example “Population Case Study”
♦ Need and Models:
  • Commonalities, EIT (and RE-AIM if requested)
♦ Methods Issues:
  • Pragmatic Trials
  • Types of Evidence Needed: “2 R’s and RCT”
♦ Measurement Issues:
  • Criteria for Pragmatic Measures
  • Example applications
♦ Opportunities, Resources and Discussion
Definitions

“Dissemination is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidence-based interventions.”

“Implementation is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific....settings”

NIH Grant information Program Announcement PAR 10-038
Why is Implementation Science Needed?

- Not reaching patients with complex problems and those most in need
- Not testing in settings and with staff that are typical to most clinical situations
- Health care and outcomes are inequitable
- Not addressing issues important to clinicians, policy makers, and patients
- Many “evidence-based”; treatment not feasible in most real-world settings
- Bottom Line—research not seen as RELEVANT
Most Common Type of Research?
Bench to Bookshelf
Example Cancer Screening IVR Calls Implementation Study

- Large scale (n = 5,905) RCT of efficient automated phone call patient reminder system for Colorectal Cancer Screening (CRC)
- Used PRISM framework and partnership with HMO operations to design feasible, sustainable program
- Intervention patients 1.5 times more likely to receive CRC screening than controls—REPLICATES parallel findings for mammography, which increased screening rates by 1.6 times
- Found cost-effective and adopted/sustained by HMO

Why is This Good Implementation Science?

♦ Engaged stakeholders from beginning
♦ Topic and outcomes are important to stakeholders
♦ Intervention is practical, relatively low cost and potentially generalizable
♦ Population-based study, so applies to all members
♦ Sustainable and program replicates earlier work and was sustained
Characteristics of Priority Real-World Health Implementation Research Issues

♦ Contextual
♦ Complex
♦ Multi-component programs and policies
♦ Non-linear
♦ Transdisciplinary
♦ Multi-level and multi-method
♦ Addresses “wicked”, messy, important problems

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<th>Models</th>
<th>Methods</th>
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<th>Conclusions</th>
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Models and Perspectives

![Diagram of models and perspectives](image-url)
Evidence Integration Triangle (EIT)

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

- **Stakeholders**

- **Evidence**

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

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

- **Feedback**

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

Many D & I Models

Theories of Intervention/Change
- Diffusion of Innovations
- PARiHS
- PRECEDE-PROCEED
- PRISM

Models of Evaluation
- RE-AIM
- CFIR (formative evaluation)
Abundance of D&I Models—61 at least. But There are Key Common Points:

- Context is critical
- Begin with stakeholders—take their perspective
- Design for dissemination—from beginning
- Need balance between fidelity to evidence based program and adaptation to local setting

Key Common Points (cont.)

♦ There is more than evidence needed for successful adoption, implementation and sustainability

♦ Implementation science is a multi-level affair

♦ Select the DESIGN and the MODEL that best fits your question— not one “right model”, but that you use it well

Definitions

♦ A pragmatic (or practical) trial seeks to answer the question, “Does an intervention work under usual conditions?”

♦ An explanatory (or efficacy) trial seeks to answer the question, “Can an intervention work under ideal conditions?”
Pragmatic Implementation Studies: Key Contextual 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
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

A. PRAGMATIC STUDY

- Flexibility of the comparison intervention
- Practitioner expertise (experimental)
- Practitioner expertise (comparison)
- Follow-up intensity
- Outcomes
- Participant compliance
- Practitioner adherence
- Eligibility criteria
- Primary analysis

B. EXPLANATORY STUDY

- Flexibility of the comparison intervention
- Practitioner expertise (experimental)
- Follow-up intensity
- Outcomes
- Participant compliance
- Practitioner adherence
- Eligibility criteria
- Primary analysis
Types of D & I Methods and Evidence Needed: 2R’s and “RCT”

- Relevant
- Rigorous and
- Rapid
- Cost informative
- Transparent
How to Evaluate Technologies that Outpace Research?

- **YouTube**: 2005
- **iPhone**: 2006
- **Android**: 2007
- **iPad**: 2008
- **2009**: Follow-ups
- **2010**: Analyze and Publish
- **2011**: Grant Submit and Award

**Development and Pilot Testing**

**Recruit and Randomize**

**Analyze and Publish**

William Riley, NHLBI and NCI
Rapid Evidence

♦ Need rapid learning research—especially for pressing issues such as obesity, HIV, explosion of health care spending, health inequities, and cancer survivorship

♦ EMRs, and their potential enhancements, make possible “rapid learning health care systems”*
  • Real-time data on millions of real-world patients in real-world health care settings, treated under usual conditions

Etheredge LM. Health Affairs 2007;Web Exclusive Collection(26):w107-w118.
Transparent Evidence on…..

♦ Info 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*

“The significant problems we face cannot be solved by the same level of thinking that created them.”

A. Einstein
Pragmatic Measures
Need for Better and Harmonized Measures in Dissemination and Implementation Research

♦ Most studies use their own measures, often unknown characteristics, and quite different measures same construct

♦ Without standard or more harmonized measures, difficult to do reviews, syntheses, compare across studies

♦ Are different purposes of measurement—e.g.:
  • “Gold standard”—when this is primary focus for grant, need “best possible measure”, have staff to ensure quality
  • “Practical measure”—for use in busy, low-resource settings; when one of a large set of measures; has to be brief and feasible
D&I and Patient Reported Measures Initiatives

GEM-Dissemination and Implementation Initiative (GEM-D&I)

Health care policy and health information environment variables relevant to dissemination and implementation research and practice are dynamic and change rapidly. This creates both enormous opportunities and specific challenges as the D&I community works to identify the outcomes and associated measures evidence base to inform D&I research and practice.

The GEM-Dissemination and Implementation Initiative (GEM-D&I) is a project initiated and co-developed by the Cancer Re...

Useful Links & Documentation

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<th>GEM-DI - Acknowledgements</th>
<th>application/pdf</th>
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https://www.gem-beta.org/ (GEM Homepage)
http://cancercontrol.cancer.gov/IS/resources.html (IS Team Website)
In the billions of dollars spent on EHRs in the last several years, one thing is missing: Patient-Reported Measures.

Advent of patient-centered medical home and “meaningful use” of EHRs.

Impossible to provide patient-centered care if no patient measures, goals, preferences, concerns collected.

With recent advances in measurement, meaningful use incentives, time is right.
PATIENT REPORT EHR MEASURES
PROJECT PHASES

♦ SBM content experts identify 2-3 candidate measures in each of 13 key domains

♦ Widespread web-based wiki activity: www.gem-beta.org

♦ “Town Hall” Meeting at NIH: Day 1 town hall followed by Day 2 invited stakeholder decision makers

♦ Post Meeting and Beyond: Pilot study followed by Pragmatic Trial of actual implementation

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<tr>
<th>Domain</th>
<th>Final Measure (Source)</th>
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<tbody>
<tr>
<td>1. 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 <em>National Health Interview Survey (NHIS)</em></td>
</tr>
<tr>
<td>2. Overall Health Status</td>
<td>1 item: BRFSS Questionnaire</td>
</tr>
<tr>
<td>7. Sleep</td>
<td>2 items: a. Adapted from BRFSS</td>
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<td></td>
<td>b. Neuro-QOL (Item PQSLP04)</td>
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<tr>
<td>8. Smoking/Tobacco Use</td>
<td>2 items: Tobacco Use Screener (Adapted from YRBSS Questionnaire)</td>
</tr>
<tr>
<td>10. Substance Abuse</td>
<td>1 item: NIDA Quick Screen [Smith PC et al. <em>Arch Int Med</em> 2010;170(13):1155-1160]</td>
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Participatory Implementation Process
Iterative, wiki activities to engage stakeholder community, measurement experts and diverse perspective. Clinics help to design interventions.

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 recs. for health behavior change counseling; evidence on goal setting & shared decision making.

Stakeholders:
Primary care (PC) staff, patients and consumer groups; PC associations; groups involved in meaningful use of EHRs, EHR vendors.

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
- CMS funding for annual wellness exams
- Primary Care Medical Home
- Meaningful use of EHR requirements
http://cancercontrolplanet.cancer.gov/
Go Sun Smart (GSS)

The Need

Excessive exposure to ultraviolet radiation (UVR) from sunlight is both the primary and the most easily prevented cause of skin cancer. Total lifetime exposure to UVR is positively associated with several types of skin cancer, including basal cell carcinoma, squamous cell carcinoma, and possibly melanoma. Intermittent and severe exposure (i.e., sunburning) may also be linked to the development of melanoma.

Although exposure to UVR in...  Show more »
The Trans-NIH D&I Funding Announcement
(International investigators eligible)

♦ R01 - PAR 10-038 ($500k per annum up to five years)
  R03 - PAR 10-039 ($50K per annum up to two years)
  R21 - PAR 10-040 ($275K up to two years)

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

♦ Standing review committee, Dissemination and Implementation Health Research

♦ Three submission dates per year:
  February, June, October
Other Implementation Science Funding Opportunities

♦ Small Business Initiative (SBIR and STTR) grants
♦ NIH Health Care System Collaboratory grants; other NHLBI and NIDDK R18 grants
♦ NIH research networks—CRN, etc.
♦ AHRQ grants and networks
♦ PCORI patient centered research grants
♦ VA Health Services Research grants
♦ Foundation funding—especially related to health disparities
Future Evidence Needs and Opportunities—Keys to Advance Translation

♦ Context—measures of key features; designs to adapt to changing context

♦ Sustainability- research on the DSF vs. other models using pragmatic measures

♦ Patient/citizen/consumer and community perspective and engagement throughout using the EIT and feedback to the community

♦ Study of multi-level interactions, especially between policy and practice using evaluability and simulation modeling
### Other Opportunities for Implementation Science Approaches

- Application to Comparative Effectiveness Research (CER-T)…PCORI, the NIH HCS Collaboratory and other

- Reporting criteria or recommendations for pragmatic trials that merge with PRECIS model?

- ? Your IDEAS WELCOMED

Thorpe KE, et al. A pragmatic–explanatory continuum indicator summary (PRECIS)…*CMAJ*; MAY 12, 2009; 180(10)
Take Home Points

♦ There is a pressing need for a DIFFERENT type of research—pragmatic designs, methods and models that produce results more rapidly, and are more relevant to stakeholders

♦ The implementation science field is still emerging, but there is agreement on key common points and goals

♦ There are many opportunities for this type of research, especially among research networks and for coalitions to study context
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
Questions/Comments

Contact me: glasgowre@mail.nih.gov

IS Team Website: http://dccps.cancer.gov/is/
RE-AIM Realist *Evaluability* Questions

♦ 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 program and its effects likely to be **Maintained**?

Integrated Dynamic, Multi-level Research-Practice Partnerships

Systems Approach

- Evidence-Tested Program
  - Program as Tested
    - Critical Elements

- Healthcare System
  - Clinic(s)
    - Program Delivery Staff
  - Delivery Site(s)
    - Organization

- Research Design Team And Adaptive Design

Matching of intervention strategies to principles in a way that could be fiscally sustained in these settings

Fit

Design Appropriate for Question

Partnership

Broader Health Policy and Cultural Context

Methods

- Example
- Models
- Measures
- Conclusions