What Types of Evidence Do We Need to Produce Relevant and Sustainable Interventions??

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NCI Implementation Science Team Mission

The mission of the Implementation Science (IS) Team is to build and advance the field of Implementation Science by:

- Promoting science that is **rigorous, transparent and relevant** in the real world;
- Fostering **rapid learning** strategies for improving individual and population health; and
- Building **partnerships** for the development, dissemination and implementation of evidence-based measures, initiatives and programs.

Evidence Needed: 2R’s and ‘RCCT’

- Relevant
- Rigorous and
- Rapid
- Cost
- Convergent
- Transparent

Relevant (Contextual and Practical)

- Relevant to stakeholders (patients/family, clinicians, administrators, policy makers)
- Relevant samples - representative of real world, including patients with co-morbid conditions
- Relevant settings - similar to those in practice (not just the most advanced and well resourced)
- Relevant clinicians - including those who have other duties and competing demands
RE-AIM Implications: Transparent Reporting

CONSORT Pragmatic Trials Reporting Criteria\(^1,\, 2\)

- Real-world *stakeholder* questions
- *Multiple outcomes*...of interest to stakeholders—costs and Return on Investment
- Real-world *comparison conditions*—consider “Minimal Intervention Needed for Change” (MINC)
- *Multiple settings*—replications
- CONSORT “PLUS” flow diagram\(^3\)

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\(^3\)http://cancercontrol.cancer.gov/IS/reaim/figures-and-tables.html
Rigorous…. and a word about RCTs

• Address most likely challenges to validity and conclusions for THAT question

• Both external and internal validity are important

• Design should fit the question- NOT vice-versa

• An RCT is not an RCT is not an RCT

• CONSORT delineation of Pragmatic trials is an important advance

• RCT is not the only design that is experimental- and it does NOT guarantee causality

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Rigorous Designs

- Multiple Baseline Across Settings
- Interrupted Time Series (with replication)
- RCT- individual, cluster randomized, mTCT
- N of 1
- Regression-discontinuity
- Cross-over
- Prospective Meta-analyses
- Comparative Case Study
- Natural experiments- with replication and addressing contextual factors
- Preference
- Many hybrid and quasi-experimental designs
Rapid Evidence

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

• EMR, 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 L et al, Health Affairs, Web Exclusive Collection, w107-w118, doi:10.1377/hlthaff.26.2.w107

Glasgow R, Chambers D. Clinical Translational Science, 2012, in press
How to Evaluate Technologies that Outpace Research?

YouTube

2005

Grant Submit and Award

iPhone

2006

Development and Pilot Testing

Android

2007

Recruit and Randomize

iPad

2008

Follow-ups

2009

Analyze and Publish

2010

2011

Rapid

Relevant

Rigorous

Cost

Convergent

Transparent

William Riley, NHLBI
Cost Evidence

- Replication costs and scalability costs are arguably most needed
- Perspective- patient and adopting setting
- Costs should be comprehensive and transparent
- ‘One persons costs are another’s profits’
- Cost-effectiveness analyses need not be overwhelming\(^1\)- 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\(^1\)

Public Health Cost Questions to Ask....

• In this world of “the 4 P’s” of personalized medicine.... ALSO ask the 4 “W’s”:

  ✔ Who Benefits
  ✔ Who Suffers
  ✔ Who Pays
  ✔ Who Profits
Convergent Evidence

- Much to learn from well conducted *observational studies*
- Huge amount of potential for *simulation modeling*- esp. re: interactions and unintended consequences\(^1,2\)
- *Evaluability*\(^3\)- aka initial ‘sniff test’
- Mixed methods\(^4\) and *qualitative*
- Practice-based evidence on *efficiency and feasibility*
- Emphasis on *replication and consistency*
- Combine with *experimental*

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 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 outcome

Future Evidence Needs- Keys to Advance Translation

• Context- key factors that may be moderators
• Scalability
• Sustainability
• Health inequities impacts
• Patient/citizen/consumer and community perspective
• Multi-level interactions, especially between policy and practice
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

EIT Conclusions

• The evidence-based movement is a good start, but only gets us so far

• To make greater progress, two other elements also need attention:
  ▪ Practical MEASURES to track progress, and
  ▪ Implementation PROCESSES that use partnership principles
  ▪ These 3 legs of the ‘EIT” are each necessary but not sufficient by themselves

http://cancercontrol-dev.cancer.gov/IS/presentations/
The same research methods, policies, paradigms and approaches that produced today’s inequities are not likely to reduce them

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

A. Einstein
Questions? Comments?

I am all ears

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NCI Implementation Science Website: http://cancercontrol.cancer.gov/IS/