Russ Glasgow, Ph.D.
Kaiser Permanente Colorado
Critical Issues in eHealth Research Conference
June 10, 2005
# ACKNOWLEDGEMENTS

**KPCO Colleagues**

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<td>Liz Bayliss, M.D.</td>
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**“RE-AIM Colleagues”**

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<td>Sheana S. Bull, Ph.D.</td>
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Kaiser Permanente Colorado, Clinical Research Unit

Mission:  *To Develop, Conduct, and Translate High-Quality Research into Practice*
OVERVIEW

1. “Journalist Questions” and Terminology
2. Decision Maker Issues – Practical eHealth Trials
3. Evaluation and “RE-AI M” Needs
4. The Road Ahead: Key Challenges and Opportunities
WHO, WHAT, WHEN, WHERE, AND HOW

Who Gets Invited and Who Comes? (Digital Divide Stereotypes)
- Define eligibility and exclusions
- What percent of those invited participate?
- What are the characteristics of participants?

Compare to:
  a) Non-participants or
  b) Representative sample(s)
**WHO, WHAT, WHEN, WHERE, AND HOW**

Key Issues for Representativeness:

- Race, ethnicity, and SES
- Computer experience
- Health literacy*
- Contextual issues related to health care setting
- What are barriers to participation?

WHO, WHAT, WHEN, WHERE, AND HOW

How is the IT Program Designed?

- Theoretical Basis and Behavioral Architecture
- How User Friendly and Consumer-Based Is it?
- Level of Interactivity
- Adopted to Fit the Context

WHO, WHAT, WHEN, WHERE, AND **HOW**

*How* Do (Different) Participants Use the Technology?

- Which components or sections, content?
- Qualitative and quantitative syntheses
- Moderator variables
- Critical importance of formative evaluation and *usability labs*
WHO, WHAT, WHEN, WHERE, AND HOW

**What** Happens Over Time?
- Do patients stay involved?
- Do they use the resources differently over time (initiation, change, maintenance)?
- How long do outcomes persist?
- Who drops out and why?
“Making Progress in the **Relevance** and **Application** of research; as well as in the process for acquiring and using it in **Decision Making** needs a **cultural change** by both researchers and decision makers.”

Jonathan Lomas
Key elements of “Practical Clinical Trials”

- Representative Patients
- Multiple Settings
- Controls address “standard of care;” other alternatives
- *Outcomes or measures relevant to clinicians and decision makers*

WHO, **WHAT**, WHEN, WHERE, AND HOW

*What* Outcomes are Produced?

- Behavior Change (patients and clinicians)
- Biological Changes
- Quality of Life and **Unanticipated Consequences**
- Health Care Utilization and Patient/Provider Interactions
- Economic Outcomes

BEHAVIOR CHANGE

- Brief, practical measures*
- Often triangulate when no “gold standard”
- Focus on sensitivity to change
- Measures of patient, staff, change agents (e.g., family), system and policy changes

ECONOMIC OUTCOMES
Use Standardized Methods

- Assess cost of intervention delivered*
- Estimate replication costs**
- Optional, more sophisticated analyses of cost-effectiveness, cost-utility, cost-benefit, return on investment
- “Costs are not costs are not costs”

IN DESIGNING FOR PRACTICAL eHEALTH TRIALS, be:

- Practical in intervention delivery
- Broad in what you measure
- Transparent (TREND*) in reporting
- Summarize results in terms understandable to clinicians (NNT) and policy makers

www.hetinitiative.org
RE-AIM TO HELP **PLAN**, EVALUATE, AND REPORT STUDIES

- **R** Increase Reach
- **E** Increase Effectiveness
- **A** Increase Adoption
- **I** Increase Implementation
- **M** Increase Maintenance

www.re-aim.org
SIMPLE QUESTIONS FOR DI SSEMI NATION

1. Who comes? (Reach and Representativeness)

2. What Outcomes are Produced? (Effectiveness) (Intended and Unintended)

3. Where Will Program Work? (Adoption and Representativeness)

4. How Consistently is Program Delivered? (Implementation)

5. How Long Will Effects Last? (Maintenance)

“My question is: Are we making an impact?”
RE-AIM AND RELATED GENERALIZATION ISSUES

To Whom Do Results Apply?
- At Setting, Clinician, and Patient Level
- Contextual and Moderating Factors
- Rakowski “Focal Point” Concept

SETTING LEVEL

Which Settings and Health Professionals Adopt?

- As important as individual level representativeness
- Parallel questions about eligibility, participation as at individual level
- Key issues:
  
  Low resource and rural settings
  Barriers to setting participation (silto effect)

RE-AIM AND RELATED GENERALIZATION ISSUES

The “3 Rs” of Translation/Dissemination

- **Representativeness** (Reach, Adoption)
- **Robustness** (Effectiveness across subgroups)

  Cronbach’s generalization across persons, time, measures

- **Replicability** (Implementation) in representative settings


See [www.re-aim.org](http://www.re-aim.org) for displays and evaluation questions.
NEW RE-AIM METRICS

1) Individual Level Impact (RE) = Reach x Composite Effectiveness

   a) Reach = [Participation rate - Median ES\textsubscript{differential characteristics}]

   b) Composite Effectiveness =

      [Median ES\textsubscript{key outcomes} - Median ES\textsubscript{negative outcomes/QOL} - Median ES\textsubscript{differential impact}]

Glasgow, et al. (2005) Evaluating the Overall Impact of Health Promotion Programs...
Health Education Research, In press.
NEW RE-AIM METRICS

2) Efficiency = Cost of Intervention (over control) 
   [Reach x Composite Effectiveness]

3) Setting Level Impact (AI) = 
   Adoption x Implementation 
   [Multi-level Adoption (rate and robustness at 
   setting and clinician levels) x Composite 
   Implementation]

To determine the characteristics of interventions that can:

- **Reach** large numbers of people, especially those who can most benefit
- Be widely **adopted** by different settings
- Be consistently **implemented** by staff members with moderate levels of training and expertise
- **Produce** replicable and long-lasting effects (and minimal negative impacts) at reasonable **cost**
That Would Be Nice, But…
... is it really feasible to do all this in a given report?
YES! See examples that do much or all of this.

Ahern/RWJF eHealth Technologies Program -
www.hetinitiative.org


CHALLENGES TO DISSEMINATION

- Hard to determine applicability to local setting
- Insufficient detail or specificity in protocol
- Protocol does not fit local expertise, patients, resources, time or culture
- Protocol not delivered as in EB study
THE ROAD AHEAD: DIRECTIONS AND CHALLENGES

1. Overcoming “Silo” Effects in eHealth, of:
   - One health condition
   - One target behavior
   - One technology
   - One setting
   - One discipline
THE ROAD AHEAD: DIRECTIONS AND CHALLENGES

2. Understanding the role of interpersonal contact in eHealth
   - Level, timing, and types of health professional contact
   - Role of peer support (chat rooms, bulletin boards, etc.)
   - Lay health coaches (Senior Net, etc.)

3. The “4th R” - Respect for Creative Designs

- eHealth interventions are dynamic, not static
- Respect for designs in addition to traditional RCTs
- Evaluation designs to fit the question
- Documentation of how eHealth programs EVOLVE over time*

4. Advice for “Politicians” (and eHealth Researchers)
   - Focus on the **Denominator** (of settings, clinicians, patients)
   - Everything is **Contextual** (customize and document it)
   - **Plan** for **Generalization** and **Adaptation** (don’t hope for it)
   - Look for Interfaces with **Policy**
   - Think like and involve your **Target Audience**

### SOME MODELS FOR TRANSLATION RESEARCH

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<td>Precede-Proceed</td>
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<td>Behavioral Trials</td>
<td>Glasgow, Davidson, Dobkin, Ockene, Spring (from EBBM committee, 2005; <em>Ann Behav Med</em>, in press)</td>
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<td>RE-AIM</td>
<td><a href="http://www.re-aim.org">www.re-aim.org</a></td>
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CONCLUSION

The world is complex, contextual, evolving, and multiply determined.

Designs and measures for eHealth translational and dissemination research should address these characteristics