

OUTCOMES FOR TRANSLATIONAL RESEARCH

- What Outcomes are Most Important?
 - Russ Glasgow
- Quality-of-Life Outcomes
 - Venkat Narayan
- Methodological issues in Economic Evaluation
 - David Meltzer
- Panel Discussion with Audience

What Outcomes are Most Important for Translational Research?



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OVERVIEW

- Practical and Sensitive Measures
- Mediators, Moderators, and Logic Models
- Complexity → Multiple Outcomes
- Proposed General Package of Measures

WHAT IS PRACTICAL?

- Reliable and valid
- Succinct and/or engaging
- Relevant to setting and question
- Broadly applicable -- literacy, culture, language

WHAT IS PRACTICAL?

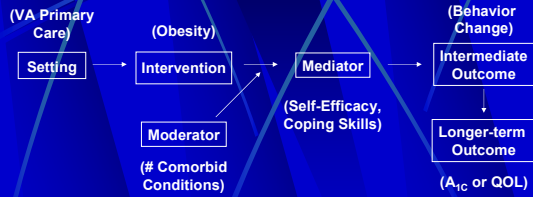
Sensitive to Change

(Responsive to Intervention Effects)

LOGIC MODEL FOR UNDERSTANDING

- Combines contextual and moderating factors with mediators, intermediate, and long-term outcomes

SAMPLE LOGIC MODEL



COMPLEXITY: THE MAGIC DIET PILL

Dissemination Step	Concept	% Impacted
50% of Clinics Use	Adoption	50%
50% of Clinicians Prescribe	Adoption	25%
50% of Patients Accept Medication	Reach	12.5%
50% Follow Regimen Correctly	Implementation	6.2%
50% of Those Taking Correctly Benefit	Effectiveness	3.2%
50% Continue to Benefit After 6 Months	Maintenance	1.6%

MORAL OF THE STORY?

“Focus on the Denominator”

All steps in the sequence (RE-AIM Dimensions) are important

ACTUAL TRANSLATIONAL DATA

Dissemination Step	Hypothetical Pill	Brief Smoking Cessation*	Diabetes Self-Management Research**
<i>Adoption by Clinics</i>	50%	? High	5 – 100%
<i>Adoption by Clinicians in Clinics</i>	50%	80%	5 – 100%
<i>Reach (Participation by patients)</i>	50%	70%	50 – 75%
<i>Implementation</i>	50%	8 - 74%	60 – 99%
<i>Effectiveness</i>	50%	10%	Variable
<i>Maintenance</i>	50%	10 – 53%	? High

* Smoking cessation primary care estimates: Courtesy of Dr. Michael Goldstein
 ** Diabetes data from studies by Glastow, et al., 1997, 2000, and 2003

A PLANNING AND EVALUATION MODEL TO “RE-AIM” PLANS AND STRATEGIES

- To broaden the criteria used to evaluate health promotion programs to include external validity
- To evaluate issues relevant to program adoption, implementation, and maintenance
- To help close the gap between research studies and practice by
 - Informing design of interventions
 - Providing guides for decision makers

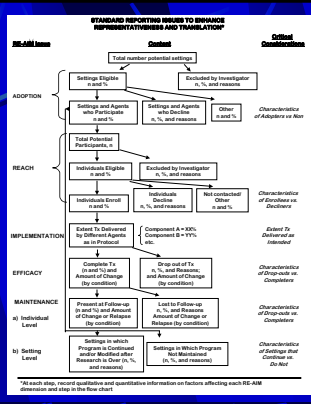
RE-AIM DIMENSIONS AND DEFINITIONS

	DIMENSION	DEFINITION
Individual Level	REACH	<ol style="list-style-type: none"> 1. Participation rate among eligible individuals 2. Representativeness of participants
	EFFICACY / EFFECTIVENESS	<ol style="list-style-type: none"> 1. Effects on primary outcome of interest 2. Impact on quality of life and negative outcomes

RE-AIM DIMENSIONS AND DEFINITIONS (cont.)

	DIMENSION	DEFINITION
Setting Level	ADOPTION	<ol style="list-style-type: none"> 1. Participation rate among possible settings 2. Representativeness of settings participating
	IMPLEMENTATION	<ol style="list-style-type: none"> 1. Extent to which intervention delivered as intended 2. Time and costs of intervention
Both	MAINTENANCE	<ol style="list-style-type: none"> 1. (Individual) Long-term effects of intervention (≥ 6 months) 2. (Individual) Impact of attrition on outcomes 3. (Setting) Extent of continuation or modification of treatment

www.re-aim.org



WHY MULTIPLE MEASURES?

Many outcomes not strongly correlated

- Behavioral with Biological
- Biological with Quality of Life
- Different Behavioral Measures
- Reach with Effectiveness
- Etc.

WHY MULTIPLE MEASURES?

Clinicians and Policy Makers Focus on Different Issues than Much Efficacy Research

- Biological vs. Economic Outcomes
- Short vs. Long Term
- Patient Centered vs. Provider/System
- Patient Level vs. Setting Level

PRACTICAL CLINICAL TRIALS MEASURES*

1) Diverse Study Samples (*Reach*)

- Few exclusion criteria
- Representative on racial, ethnic, age, gender, and other sociodemographic factors
- Representative of typical and complex patients
- Includes those in primary care having comorbidities, other meds, depression

*Tunis SR, Stryer DB, Clancy CM (2003) JAMA 290:1624-1632

PRACTICAL CLINICAL TRIALS MEASURES (cont.)

2) Multiple, Representative Settings (*Adoption*)

- Includes multiple community settings
- Includes typical (non-research) staff
- Representative of primary care
- Study variations in process and outcomes across settings

PRACTICAL CLINICAL TRIALS MEASURES (cont.)

3) Practical, Feasible Intervention Alternatives

- Document time
- Document expense
- Document intervention delivery (*Implementation*) by staff with different levels of training and expertise

PRACTICAL CLINICAL TRIALS MEASURES

4) Includes Multiple Relevant Health Outcomes

- More than knowledge and A_{1c}
- Outcomes relevant to patients, purchasers, clinicians, policy makers, and the public
- Includes quality of life
- Includes economic outcomes

PROPOSED TRANSLATIONAL RESEARCH MEASUREMENT PACKAGE

- 1) Contextual factors
- 2) Implementation
- 3) Generalization (*Reach, Adoption, Maintenance*)
- 4) Behavior change (multiple levels?)
- 5) Economic outcomes
- 6) Quality of life

CONCLUSION

The world is complex,
contextual, and multiply
determined.

Measures for translational research
should also incorporate
these characteristics

*“To every complex question,
there is a simple answer.....
and it is wrong”
H. L. Mencken*
