

# 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?**

**Russell E. Glasgow, Ph.D.  
Kaiser Permanente Colorado**

# 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

---

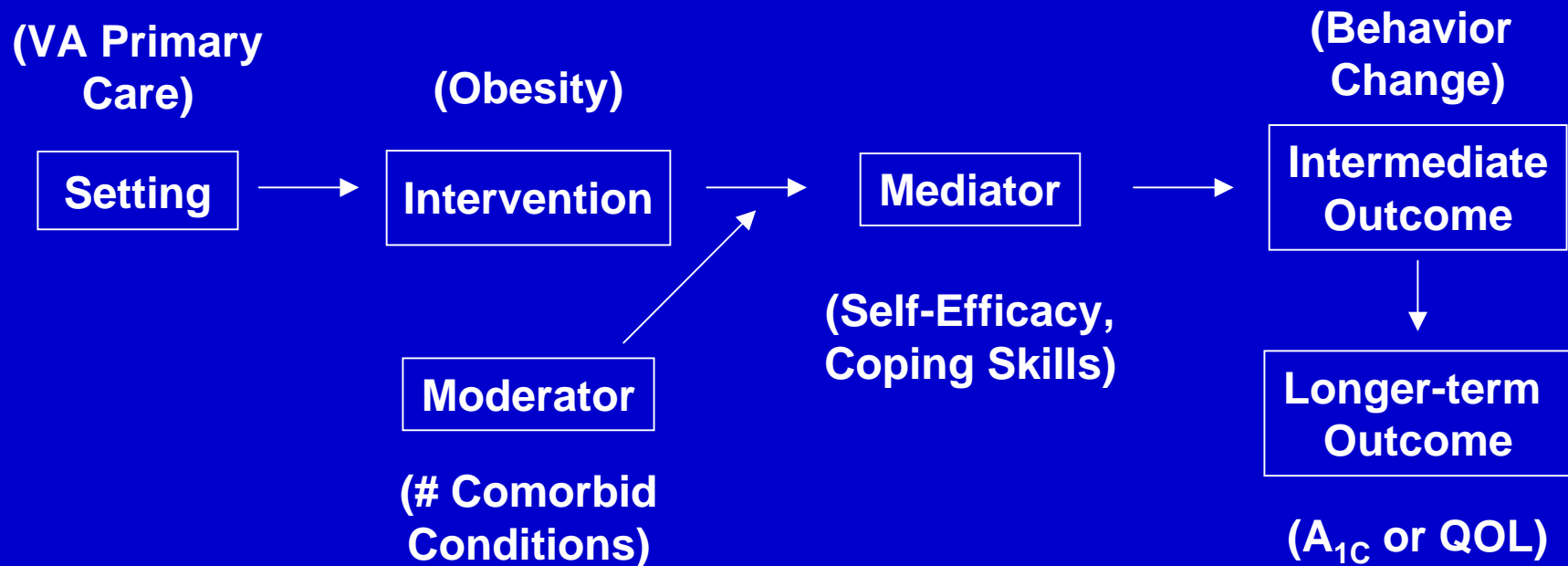
---

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

# SAMPLE LOGIC MODEL

---

---



# COMPLEXITY: THE MAGIC DIET PILL

---

---

<u>Dissemination Step</u>	<u>Concept</u>	<u>% Impacted</u>
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

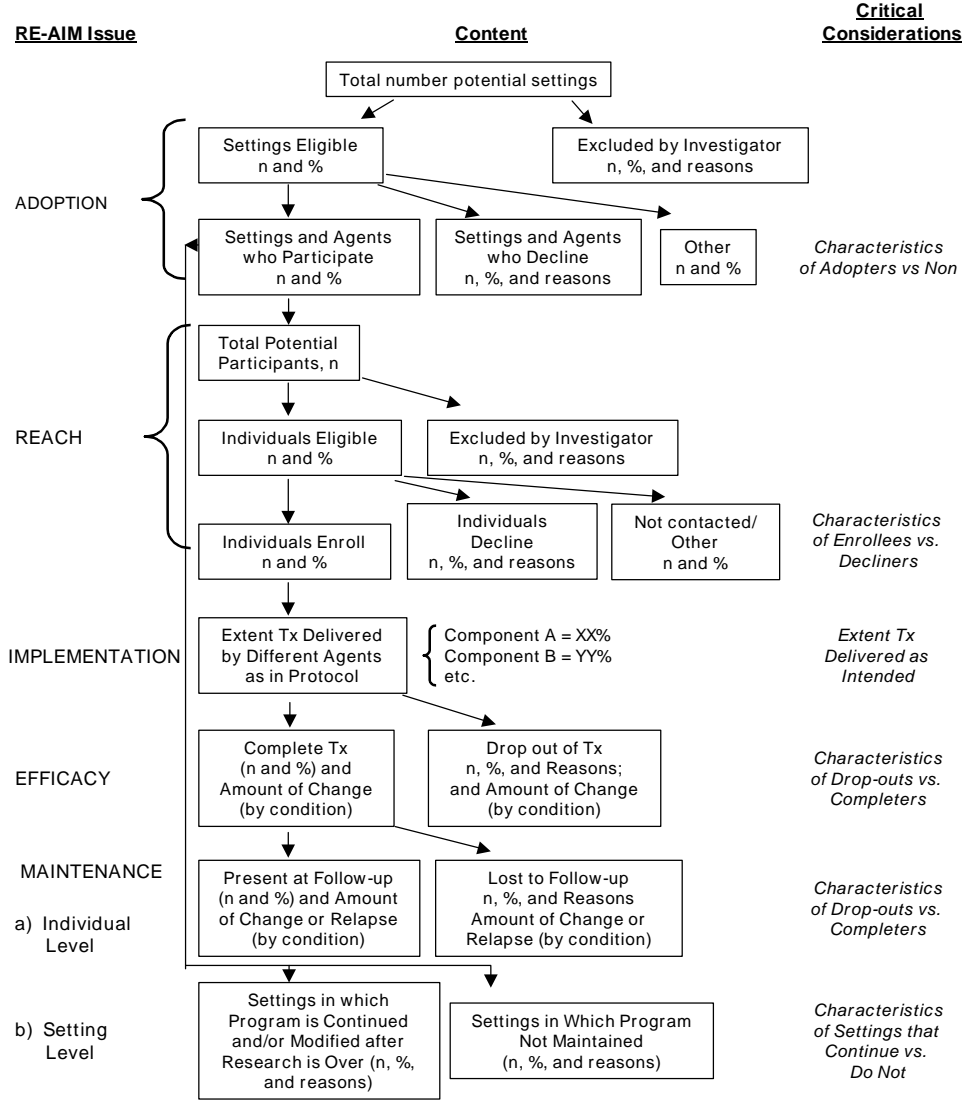
# RE-AIM DIMENSIONS AND DEFINITIONS

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

# RE-AIM DIMENSIONS AND DEFINITIONS (cont.)

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

**STANDARD REPORTING ISSUES TO ENHANCE REPRESENTATIVENESS AND TRANSLATION\***



\*At each step, record qualitative and quantitative information on factors affecting each RE-AIM dimension and step in the flow chart

# 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

# 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 fidelity
  - 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***