



WHAT TYPES OF EVIDENCE ARE NEEDED?

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EVIDENCE THAT IS...

Contextual

Practical

Robust

PERSPECTIVES AND ISSUES TO CONSIDER

- **Philosophy of Science (Contextualism vs. Reductionism)**
- **State of Science and Methodology (Internal and External Validity)**
- **Future Directions for SBM (Usefulness and Practical Value)**

PHILOSOPHY OF SCIENCE

Key Issue: Will **further** progress be made by isolating, simplifying, and holding conditions constant (reductionism) ...

OR by

Studying programs in context and the impact of different contextual factors (contextualism)

Most other (“hard”) sciences have moved
beyond a reductionistic approach

*“Behavioral science...especially
within the U.S., has focused primarily
in individual health-related behaviors,
without due consideration of the social context
in which health behaviors occur.”*

Glass & McAfee

A CONTEXTUAL APPROACH IS CONGRUENT WITH...

- Social-ecological models;
- Multi-level programs;
- Systems thinking and approaches;
- Complex interventions and complexity theory; and
- Transdisciplinary approaches.

“Linear thinking dominates theories of science, health and change. It...isolates factors that are really interconnected, and simplifies things that are really complex.”

“Systems thinking sees dynamic interactions between related things...knowledge generated in one context may not be relevant in others.”

OUR CURRENT SITUATION

“The law of halves” ... a story

THE REALITY OF TRANSLATING AN EVIDENCE-BASED *(Fill in Blank)* INTERVENTION

<u>ISSUE</u>	<u>RE-AIM ELEMENT</u>	<u>SUCCESS RATE</u>	<u>POPULATION- WIDE IMPACT</u>
Settings that Participate	ADOPTION	40%	40%
Patients Who Accept	REACH	40%	16%
Program Delivery	IMPLEMENTATION	40%	6.4%
RCT Efficacy Results	EFFECTIVENESS	40%	2.6%
Longer-term Effects	MAINTENANCE (Individual Level)	40%	1.0%

MORAL OF THE STORY?

“Focus on the **Denominator**”

(not just the numerator)

(Each step of the dissemination
sequence, or each “RE-AIM”
dimension is important)

DEFINITIONS

External Validity – “Inferences about the extent to which a causal relationship holds over **variations in persons, settings, treatments and outcomes.**” (Shadish et al, 2002)

External Validity – “To what populations, settings, treatment variables and measurement variables can this effect be **generalized?**” (Campbell & Stanley, 1963)

Shadish WR, Cook TD, Campbell DT. Experimental and quasi-experimental design...Boston: Houghton Mifflin, 2002

Campbell DT, Stanley JC. Experimental and quasi-experimental designs for Research. Chicago, IL: Rand McNally, 1963.

STATE OF OUR SCIENCE

Only 1 of the 22 CONSORT criteria pertain to external validity, and that criterion is very vague and subjective

CONSORT Item 22 = “*Generalizability (external validity) of the trial findings*”

www.consort-statement.org

JAMA, 2001;285:1987-1991

CONSISTENT CONCLUSIONS FROM MULTIPLE REVIEWS

The evidence base on internal validity far exceeds that on external validity:

- Oldenburg, Ffrench, Sallis, 2000: 1210 health behavior studies
- Glasgow et al., 2004: 119 health behavior change studies
- Klesges et al., 2007: 19 childhood obesity prevention studies

Oldenburg, Ffrench, Sallis. *The Science of Health Promotion* 2000;14(4):253-257

Glasgow RE et al. *Ann Behav Med* 2004;27(1):3-12.

Klesges L et al. Submitted Review. Contact: lisa.klesges@stjude.org

RECOMMENDED PURPOSE OF RESEARCH (ala RE-AIM)

Collect evidence to document 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**

“If we want more evidence-based practice, we need more practice-based evidence.”

Larry W. Green, 2004

Green LW & Ottosen JM. From efficacy to effectiveness...Proceedings from NIDDK Conference: *From Clinical Trials to Community*, 2004

WE NEED MORE “PRACTICAL CLINICAL TRIALS”

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

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

Glasgow RE, Magid DJ, et al. *Med Care* 2005;43(6):551-557

Glasgow RE, et al. *Ann Behav Med* 2006;31(1):5-13

MEASURES FOR PRACTICAL TRIALS

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

“What little systematic evidence we now have confirms that RCTs often lack external validity...this issue is neglected by current researchers, medical journals, funding agencies...and governmental regulators alike.”

Rothwell PM, Lancet, 2005; 365:82-93

WHAT SPECIFICALLY DO WE NEED TO KNOW ABOUT EXTERNAL VALIDITY?

- Program or Policy **Reach** and Sample **Representativeness**
- Program or Policy **Implementation** and **Adaptation**
- **Outcomes** Important to **Decision Makers**
- **Maintenance** and **Institutionalization**

Glasgow RE, Green LW, et al. *Ann Behav Med* 2006;31(2):105-108

Green LW, Glasgow RE. *Evaluation and the Health Professions* 2006;29(1):126-153

WHAT IS THE MOST IMPORTANT FUTURE CHALLENGE FOR BEHAVIORAL MEDICINE/HEALTH RESEARCH/SBM?

Translation of Research into Practice: Implementation and Dissemination

“The need to examine the efficacy of alternative modes of diffusion with the same care and rigor as is devoted to the development of models being diffused.”

“Lack of consideration of external validity is the most frequent criticism by clinicians of RCTs, systematic reviews, and guidelines.”

Rothwell PM, *Lancet*, 2005;365:82-93

The Current System is **BROKEN**: Research does NOT Currently Translate into Practice:

- Application of evidence-based SAMSA “model” program based on efficacy RCT completely ineffective in applied context*
- Replication of same smoking cessation program found efficacious in efficacy trial did not work—even in exact same setting with same patient group—in effectiveness study.**

* Halfours et al, *Am J Public Health*, 2006;96:2254-2259

** Stevens, Glasgow, et al, *Medical Care*, 2000;39:451-459

The “3 Rs” of Integrating Research into Practice

- Representativeness (Reach, Adoption)
- Robustness (Effectiveness across subgroups—especially re: disparities)

Cronbach’s generalization across persons, time, measures

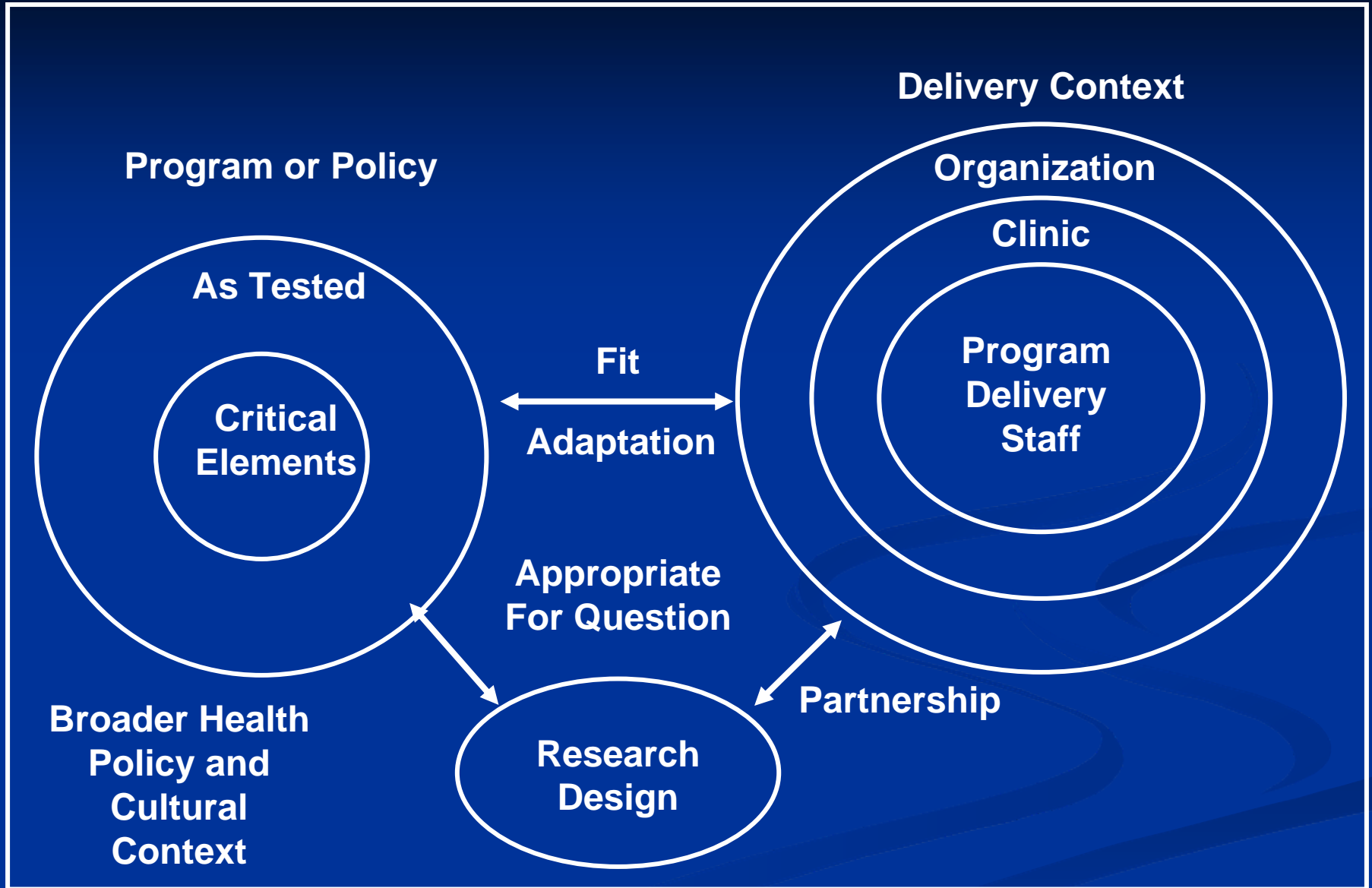
- Replicability (appropriate Implementation and adaptation) in representative settings

These produce Rigor AND Relevance

Cronbach LH, et al. *The dependability of behavioral measurements: Theory of generalizability for scores and profiles*. New York, John Wiley & Sons, 1972

Stange K. *Rigor and Relevance*. Available from kurt.stange@cwru.edu.

Simplified Systems Model for Translational Research – Adopted from Best et al



Advice for Clinicians, Decision Makers, and Researchers

- Focus on the Denominator (of settings, clinicians, patients)
- **Plan** for Generalization and Adaptation (don't hope for it)
- Look for Interfaces with Policy
- **Partner** with your Target Audience and Stakeholders...from the outset
- Everything is Contextual (customize and document it)

Klesges LM, et al. *Ann Behav Med* 2005;29:66S-75S

Green LW & Glasgow RE. Evaluating the Relevance, Generalization...*Evaluation and The Health Professions* 2006;29(1):126-153.

CHALLENGES AND CONCLUSIONS

- The future is **multiple** (conditions, behaviors, interactive modalities)
- The future is **complex** (and we ignore complexity at our peril)*
- “**All models (and designs) are wrong**”** – and greater tolerance, respect, and creativity is needed
- We need to **UN-learn** much of what we have been taught to answer the tough questions

* Glasgow RE, Emmons KM. *Annual Review of Public Health* Dec 6, 2006 epub ahead of print

** Sterman JD. *Syst Dynam Rev* 2002;18:501-531

EVIDENCE THAT...

IS MORE

IS LESS

Contextual

Isolated

Practical, efficient

Abstract, intensive

Robust, generalizable

Singular (Setting, staff,
population)

Comparative

Academic

Comprehensive

Single outcome

Representative

From ideal settings

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

A. Einstein