

# Balancing Fidelity and Adaptation

**If We Want More Evidence-Based Practice,  
We Need more Practice-Based Evidence**

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# Disclosure

- Speaker's Name: Lawrence W. Green
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- Speaker's Title: Balancing Fidelity and Adaptation: If We Want More Evidence-Based Practice, We Need more Practice-Based Evidence.
- Speaker Disclosures
  - Relevant financial relationships: None\*
  - Relevant non-financial relationships: None

\*Two slides contain graphics from a co-authored book on which I earn royalties.



# Definitions

- **Fidelity:** Adherence in the implementation of an intervention to exactly what the RCT or next-best evidence demonstrated to be efficacious under controlled experimental conditions.
- **Adaptation:** Cautious but purposeful revision of the experimentally tested intervention to make it fit better with the patients and circumstances in which it would be (or is being) applied.

# Three Paradoxes

- **The internal validity--external validity paradox**
  - The more rigorously controlled a study testing the efficacy of an intervention, the less reality-based it may become, so it cannot be taken to scale or generalized
- **The specificity – generalizability paradox**
  - The more relevant and particular to the local context, the less generalizable to other contexts
- **The subgroup analysis paradox**
  - For many practitioners and policy makers, the most useful data from a trial are subgroup differences, but statisticians, and hence editors, have resisted subgroup analyses of trials because the subgroups were not randomized

# What Needs to be Covered

- **Why is fidelity an issue?**
  - Practitioner resistance to evidence-based guidelines
    - Perception that it is an unrealistic burden on their practice
    - Perception that it is based on research too far removed from their realities
  - Researchers' belief (Hubris? Conflict of interest?) in the certainty and universality of their findings
  - Experience in some sectors that what is passing as evidence-based practice is not what the evidence showed
- **What needs to be considered in arriving at conclusions concerning fidelity Vs. adaptation?**
  - Differences between clinical/behavioral
  - Community/population

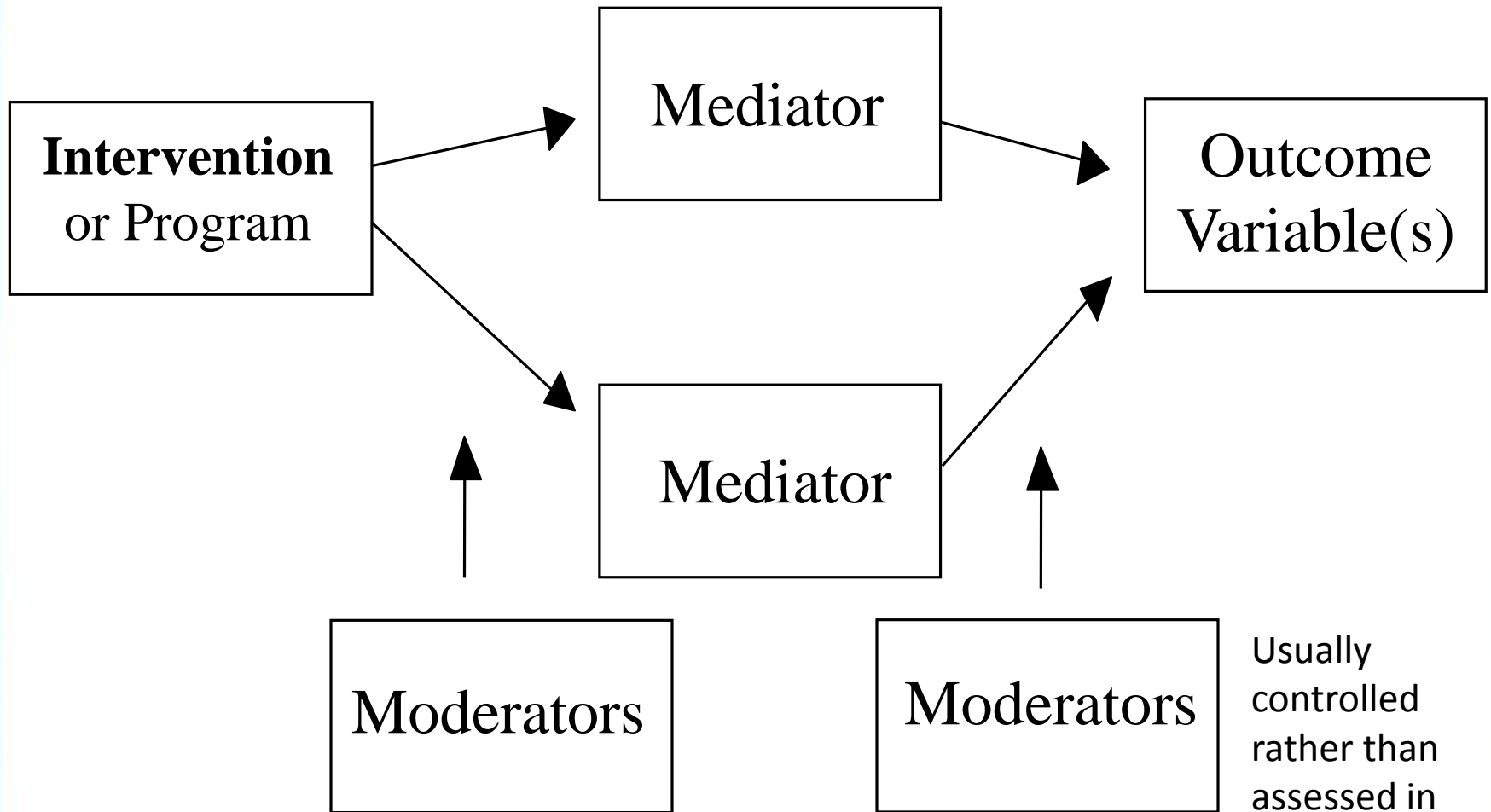
# Why “Fidelity” Has Become an Issue

- Researchers test an intervention for its efficacy
- Rigorous test (efficacy) qualifies it for official lists of “evidence-based practices” and systematic reviews that produce guidelines
- Practitioners try to incorporate it into their programs in other populations, circumstances
- Poor fit produces failure of program
- Practitioners are blamed for not implementing with “fidelity”
- Now buy the producers’ training

\* Green LW, Glasgow RE, ...external validity...*Evaluation & the Health Professions*, Mar. 2006.



# Theory: Mechanisms as Mediator Variables, Context as Moderators

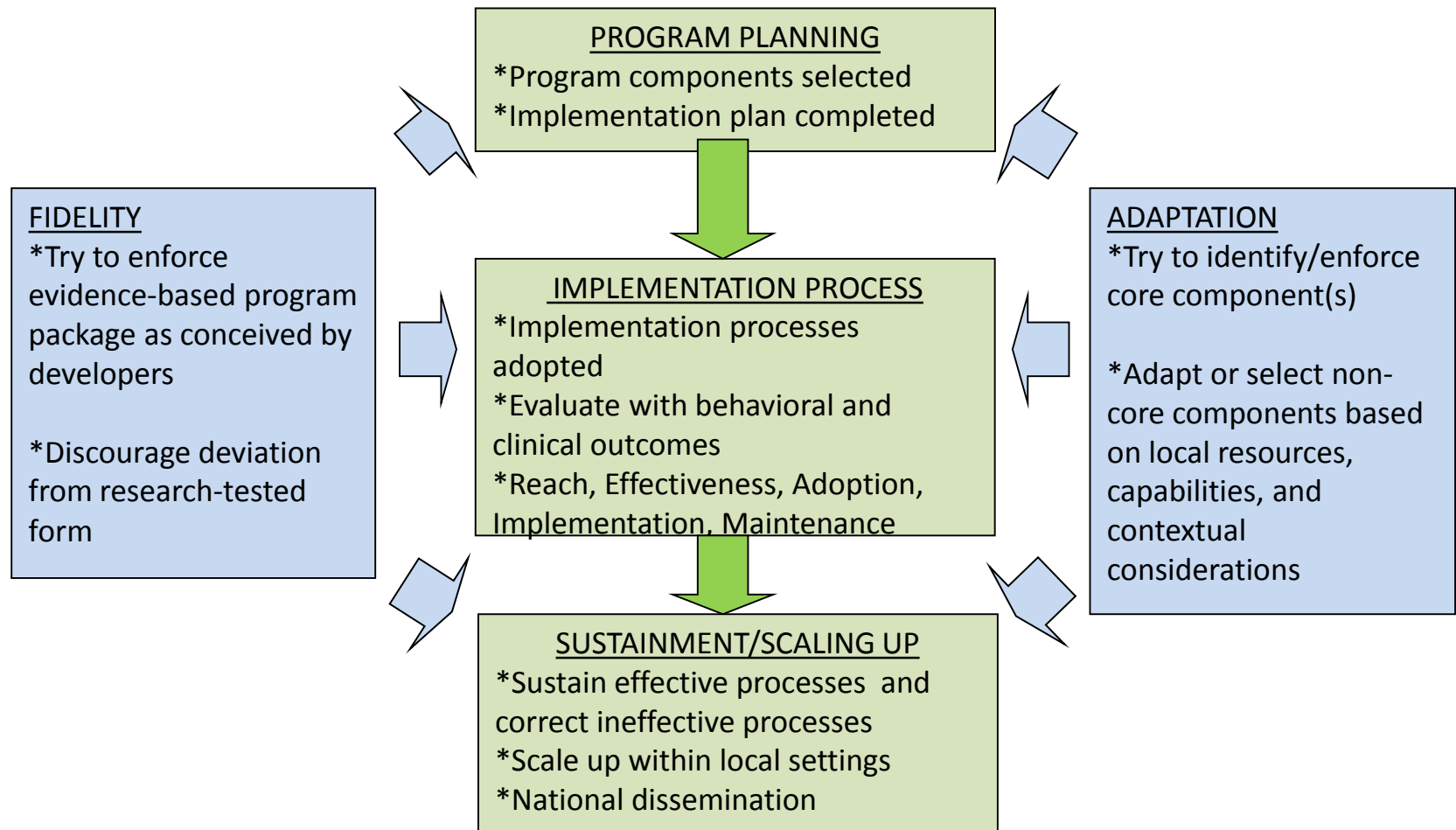


Usually controlled rather than assessed in RCTs.

Source: Green LW, Kreuter MW, *Health Program Planning: An Educational and Ecological Approach*. 4th ed. New York: McGraw-Hill, 2005, p. 204; Green LW, Glasgow RE, 2006.



# Searching for Answers in the Study of Fidelity and Adaptation



Adapted from Chapter 14, Figure 14-1 in Brownson, Proctor, Colditz (eds.).  
*Dissemination and Implementation Research in Health*. NY: Oxford U.Press.



## Making Adaptation a Process, not an Event

The first **clinical** question (Potter M et al, UCSF. 2004):

What kind of primary care colorectal cancer screening outreach program could be:

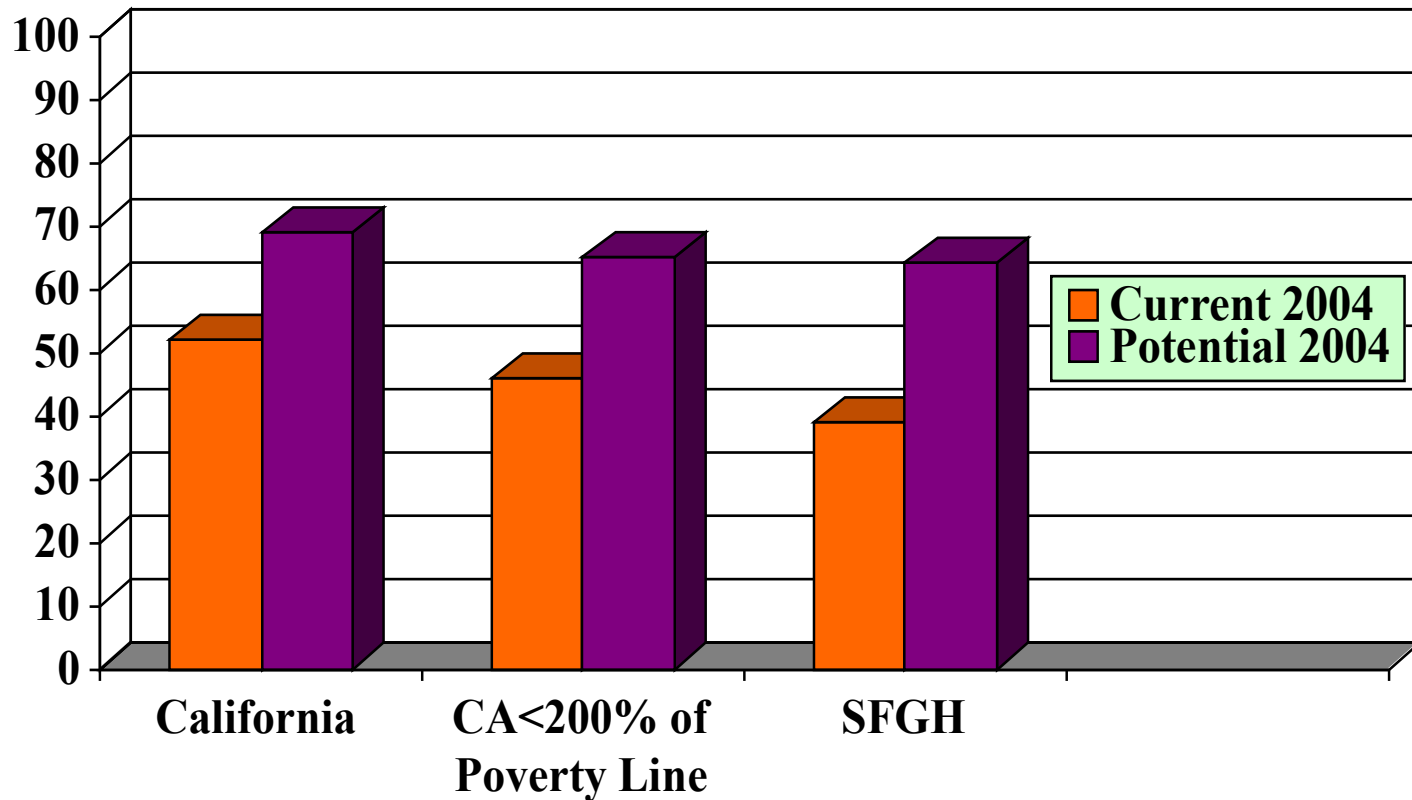
- (a) effective for the target population
- (b) acceptable to clinicians and staff
- (c) feasible to implement with limited resources
- (d) sustainable after the researchers leave
- (e) adaptable and scalable for diverse settings



The first **research** question (2005):

*In average risk adults over 50, is the time of influenza vaccination a missed opportunity to offer colorectal cancer screening with annual fecal occult blood tests?*

Potential increase in CRC screening for adults 50-80  
if offered with influenza vaccination  
(Combines CA BRFSS and SF General Hospital Data)





The **second research** question (2006):

*Can we show that a “FLU-FOBT Program” in a flu shot clinic can work?*

# SF General Hospital – Family Health Center



# Results – SFGH Flu Shot Clinic Randomized Trial

## *6-month outcome for all participants*


### Intent-to-treat analysis, all patients

	FLU Only Arm N=246	FLU-FOBT Arm N=268
CRCS Up-to-Date Before (Oct 2006)	52.9%	54.5%
CRCS Up-to-Date After (Mar 2007)	57.3%	84.3%
Change: p<0.001	+4.4 points	+29.8 points

Odds Ratio for Unscreened Becoming Screened in  
Multivariate Analysis: 11.3 (5.8-22.0)

CRCS up to date: FOBT within 12 months, FSIG within 5 years or colonoscopy within 10 years  
*Potter MB et al., Annals of Family Medicine, 2009.*





The next research questions (Potter et al., 2008-2012)  
*in pursuit of external validity:*

1. *Can it work with less hand-holding?*
2. *Can it be integrated with primary care?*
3. *Can it work in managed care?*
4. *Can it work in pharmacies?*
5. *Can it be sustained where it is introduced?*

# FLU-FOBT and FLU-FIT Projects

- San Francisco Dept of Public Health
  - CDC R18 (2008-2011) **“Translation of an Evidence-Based Colorectal Cancer Screening Intervention to Primary Care Settings Where Disparities Persist”**
- Kaiser Permanente Northern California
  - HMO Cancer Research Network (2008-2009) **“Preparation for the FLU-FIT Program at Kaiser Permanente Santa Clara”**
  - ACS Research Scholars Grant (2009-2012) **“Colorectal Cancer Screening with FOBT/FIT During Annual Flu Shot Clinics at Kaiser Permanente”**
- Walgreens Pharmacies
  - Alexander and Margaret Stewart Trust (2008-2009) **“A Pharmacy-Based Intervention to Increase Colorectal Cancer Screening”**



One word answers to the research questions (*email if you want more complete answers!*):

1. *Can it be implemented with less hand-holding?* -- yes
2. *Can it be integrated with primary care in resource-limited community health centers?* -- yes
3. *Can it work in managed care?* -- yes
4. *Can it work in pharmacies?* -- probably
5. *Can it be sustained where it is introduced?* -- often

# FLU-FOBT publications since 2009

- Potter MB, Phengrasamy L, Hudes ES, McPhee SJ, Walsh JM. Offering annual fecal occult blood tests at annual flu shot clinics increases colorectal cancer screening rates. *Ann Fam Med*. 2009;7:17-23.
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**Clinical Outcome:** >25,000 FOBT/FIT Kits dispensed thru our research sites from 2007-2011.



# Aligning Evidence with Practice\*

- *Matching* ecological levels of a system or community with RCT evidence of *efficacy* for interventions at those levels
- *Mapping* theory to the causal chain to fill gaps in the evidence for *effectiveness* of interventions
- *Pooling* experience to blend interventions to fill gaps in evidence for the effectiveness of programs in similar situations
- *Patching* pooled interventions with indigenous wisdom and professional judgment about plausible causes & interventions to fill gaps in the *program* for the specific population

\*Green & Kreuter, *Health Program Planning: An Educational & Ecological Approach*. 4th ed. NY: McGraw-Hill, 2005, Chapter 5.  
Green & Glasgow, 2006.



# Take Home

- Be suspicious of demands for fidelity when the intervention is on behavior, complex organizations, or communities
- Draw evidence from the practitioners, patients, organizations or communities in which the intervention would be adopted or adapted
- Try to identify the core elements (functions) of the intervention(s) that must be implemented with fidelity, as distinct from the adaptable (forms) that could be matched and varied with the context and persons
- Measure forms (duration, strength, intensity, content) of the implementation

# Some References

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