



BROWN
Alpert Medical School

Centers for Behavioral and Preventive Medicine



The Miriam Hospital
A Lifespan Partner

Conceptualizing Fidelity in Implementation Research

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Problem: Inherent tension between fidelity to Evidence-Based Practice (EBP) versus adaptation to new context

Think Tank objective:

To identify strategies to balance fidelity versus fit for translation or dissemination of evidence-based interventions

Finding a balance internal vs. external validity

Internal validity demands

- Maintain fidelity to original Evidence-Based Program
- Document program delivery as intended
- Avoid type III error (not effective because not delivered as planned)

External validity demands

- Customize to local context
- culturally relevant
- Local buy-in
- Insure real-world success
- Generalizable to larger context
- What must be retained to maintain EBP model?

Overview

- Describe our project as case example
- Review literature for recommendations on how to balance fidelity versus fit
- Describe some of our project's challenges and solutions
- Discuss questions for your input and recommendations

Diabetes Care in American Samoa

Funding:

- NIDDK, R18-DK075371
- Principal Investigator: Stephen McGarvey, PhD, MPH

Study partners:

- Warren Alpert Medical School/Brown University
- The Miriam Hospital, Providence, RI
- Tafuna Family Health Center
- American Samoa Dept. of Health
- American Samoa families with diabetes

Project Sugar 2 (PS2)

- Based in Baltimore, MD, for urban African Americans
- CHW & nurse case-manager team approach in managed care organization
- Based on Precede-Proceed Model
- Used treatment algorithms to guide decisions on content and frequency of visits, clinic & home visits, primary care coordination

Gary et al, *Diabetes Educator*. 2005;31:880-889.

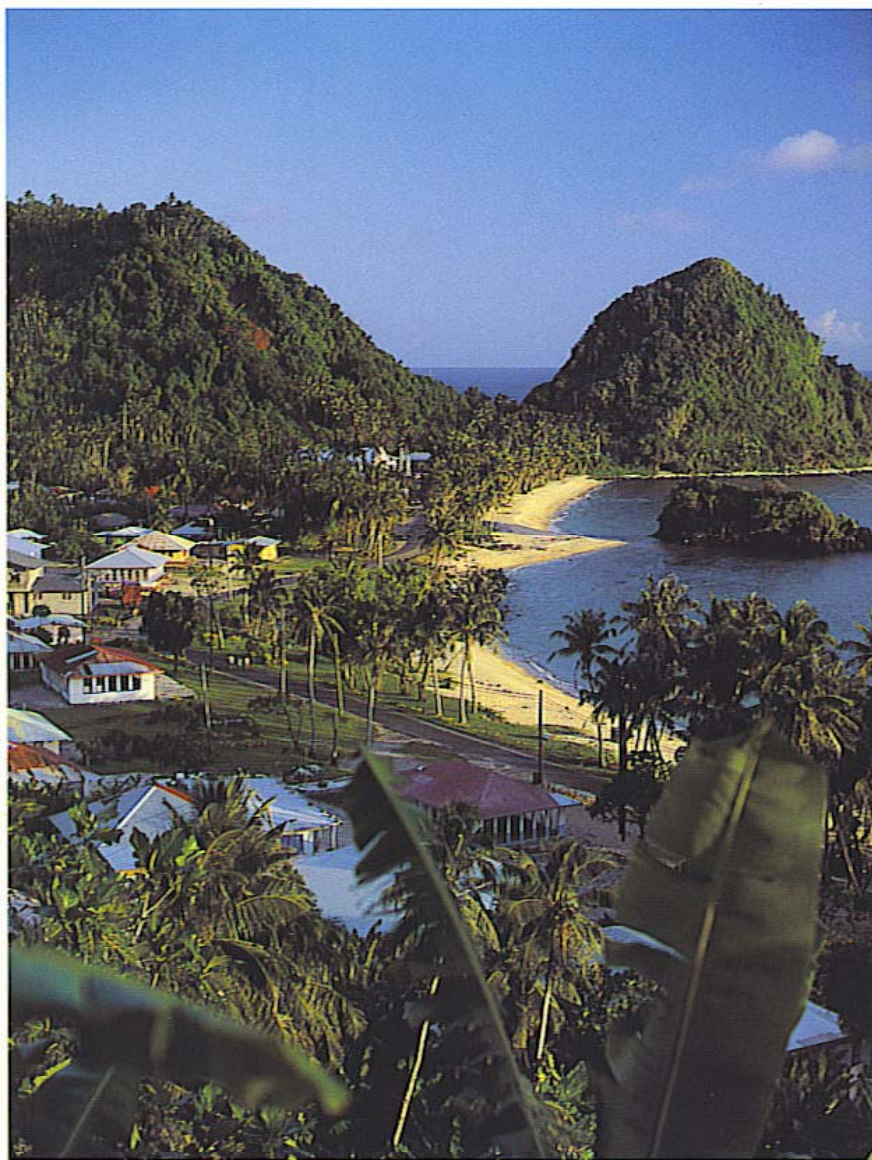
Diabetes Care in American Samoa

Fa'amoemoega ma se amataga fou
Hope and New Beginnings



2600 miles southwest of Hawaii

6 inhabited islands



American Samoa 

- Midway between Hawaii and New Zealand
- U.S. Territory since 1900
- 67,000 population
- 83% ethnic Samoans; 10% other AAPI; 1% white
- 57% below poverty level
- “medically underserved area”
- “health professional shortage area”

Why Diabetes Care in American Samoa?

- 94% of people 25-64 in American Samoa were overweight or obese in 2004
- Type 2 diabetes in American Samoa has increased rapidly with change in way of life and high obesity rates.
- 21.5% Am Samoa adults (>18 yrs) have diabetes vs. 10.7% in U.S. adults overall
- No reported diabetes interventions with American Samoans

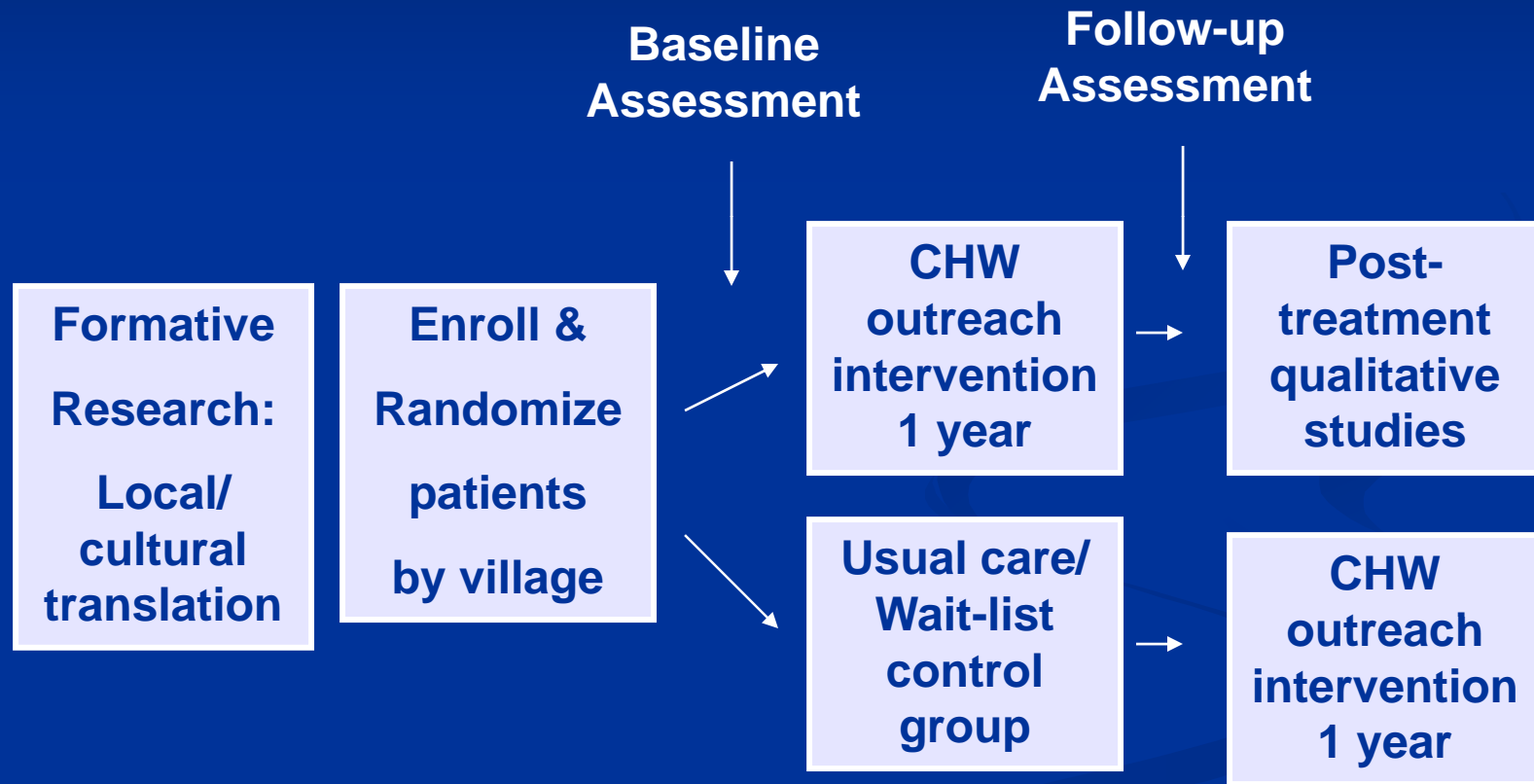
Fa'amoemoega ma se Amataga Fou Hope and New Beginnings



Study Aims:

- Improve diabetes control
- Improve cardiovascular disease risk factors
- Improve diet and exercise behaviors
- Improve process of care – adherence to American Diabetes Association guidelines

Research Design



Recommendations from literature to balance EBP fidelity vs. fit

■ Theoretical fidelity approach^{1,3}

- Identify critical theoretical components a priori
- Adaptation maintains emphasis on these components
- Measure adherence to key components

■ Essential ingredients approach^{1,2,4}

- Expert panel identifies components necessary consistent with original research
- Other components are modifiable

1. Glasgow. *Research on Soc Work Pract.* 2009, 19:560-68.

2. Bauman LJ. *Am J Community Health.* 1991, 19:619-39

3. Rovniak et al, *Am J Health Promotion.* 2005, 20:85-95.

4. Ory et al. *Alzheimer and Dementia.* 2007, 3:S57.

Recommendations from literature, contin “Planned Adaptation approach”

- **Step 1: Examine EBP theory of change**
 - Identify core mechanisms that link theory to program activities
 - Or, use meta-analyses for key components
 - Identify moderators that may enhance or diminish outcomes
 - Identify any secondary pathways for change

Planned Adaptation approach, continued

- **Step 2: Identify population differences**
 - Examine whether core components of theory apply to the new population
 - Examine whether differences may act as moderators that may impact change pathways
 - If “yes” to these questions, new efficacy trial may be needed in new population

Planned Adaptation approach, continued

- **Step 3: Adapt program content**
 - Consider adaptations for new population
 - Insure core components are not altered
- **Step 4: Adapt evaluation strategy**
 - Measure core mechanisms of change from original program theory
 - Measure adaptations made in program content to accommodate new population

DCAS hybrid approach

- **Key components from meta-analyses:**
 - Treatment algorithms, case-management, community outreach, one-on-one interventions, multiple contacts over time
- **Project Sugar RE-AIM eval:**
 - Algorithms, one-on-one counseling, monitoring in home, multiple contacts, PCP coordination
- **Precede-Proceed components**
 - predisposing (knowledge, beliefs),
 - enabling (skills, resources)
 - reinforcing factors (family, health care providers)
- **Dose (minutes, visits x risk level)**
- **Visit content (from menu of patient goals)**

DCAS challenges to measuring fidelity

- Meta-analyses components are “hard-wired” into intervention – visit frequency monitoring applies
- Theory components were not directly measured in EBP, mediation analysis not done, difficult to measure motivation, skills
- Staff value intervention more than data collection
- Staff turnover threatens dose, data collection consistency and quality
- Healthcare system changes
- Natural disasters

Think Tank questions

- How is fidelity in translation and dissemination research similar or different from fidelity in efficacy studies?
- How far can we go from the original EBP when adapting to new context before it no longer resembles the original and is no longer valid? What has to be retained?
- What key components do you measure for fidelity?
- How do we monitor/record unanticipated barriers that occur after the implementation is underway?
- Changes in staff, leadership or the healthcare system, and natural disasters in the setting all impact intervention delivery. How are such barriers construed in implementation research?
- How far “out of the box” can we go in finding solutions to barriers that will keep the program going?
- How do we report these lessons learned when publishing fidelity of interventions and publishing research findings?
- Final thoughts

Think Tank questions

- How is fidelity in translation and dissemination research similar or different from fidelity in efficacy studies?

Think Tank questions

- How is fidelity in translation and dissemination research similar or different from fidelity in efficacy studies?
 - Adaptation permitted for implementation of key components – e.g. algorithm cut points
 - Increased emphasis on external validity, broader inclusion criteria
 - Simplified process measures – “hard wired”

Think Tank questions

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Think Tank questions

- How far can we go from the original EBP when adapting to new context before it no longer resembles the original and is no longer valid? What has to be retained?
 - Key mechanisms of change – mediation analyses
 - Expert opinion/meta-analyses components of success in prior interventions
 - EBP components most frequently implemented

Think Tank questions

- What key components do YOU measure for fidelity?

Think Tank questions

- What key components do YOU measure for fidelity?
 - “Dose of treatment delivered – e.g. count of contacts, minutes, materials delivered
 - Visits according to patient categories/risk
 - Visit objectives covered – e.g. content, topic of patient goals
 - Safety/adverse events – case examples
 - Participant satisfaction with delivery

Think Tank questions

- How do YOU monitor/record unanticipated barriers that occur after the implementation is underway?

Think Tank questions

- How do YOU monitor/record unanticipated barriers that occur after the implementation is underway?
 - Team meeting minutes
 - Qualitative data collection with staff, and participants

Think Tank questions

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Think Tank questions

- Changes in staff, leadership or the healthcare system, and natural disasters in the setting all impact intervention delivery. How are such barriers construed in implementation research?
 - “Grist for the mill” –sustainable interventions should be able to navigate more typical real world events, interruptions
 - Do they compromise key components?

Think Tank questions

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Think Tank questions

- How far “out of the box” can we go in finding solutions to barriers that will keep the program going?
 - As long as core components are retained
 - Cross-training to cover staff shortages
 - Peer fidelity monitoring

Think Tank questions

- How do we report these lessons learned when publishing fidelity of interventions and publishing research findings?

Think Tank questions

- How do we report these lessons learned when publishing fidelity of interventions and publishing research findings?
 - Target new journals with translation/ dissemination emphasis
 - Use “commentary” or “framing health matters” option for some journals
 - Advocate new emphases in our professional societies for their journals

Final thoughts?

- Take home messages or “pearls”?

Final thoughts?

- Take home messages or “pearls”?
 - Focus on mechanisms of change
 - Identify what is most salient to participants in this setting