

Developing a Quality Assurance/Quality Improvement Framework for Evidence-based Programs

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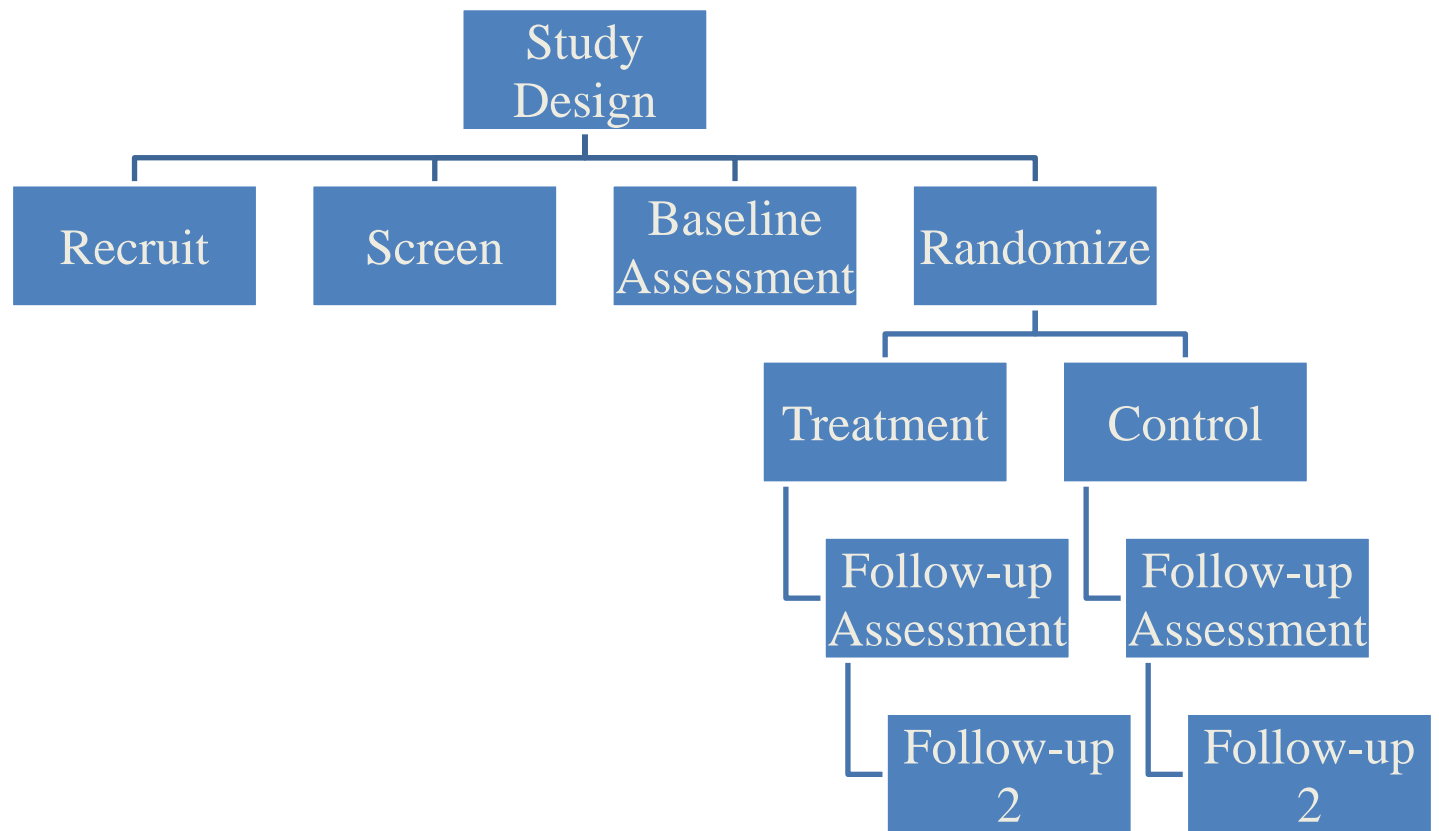
The origins and rise of evidence-based programs: *what are they?*



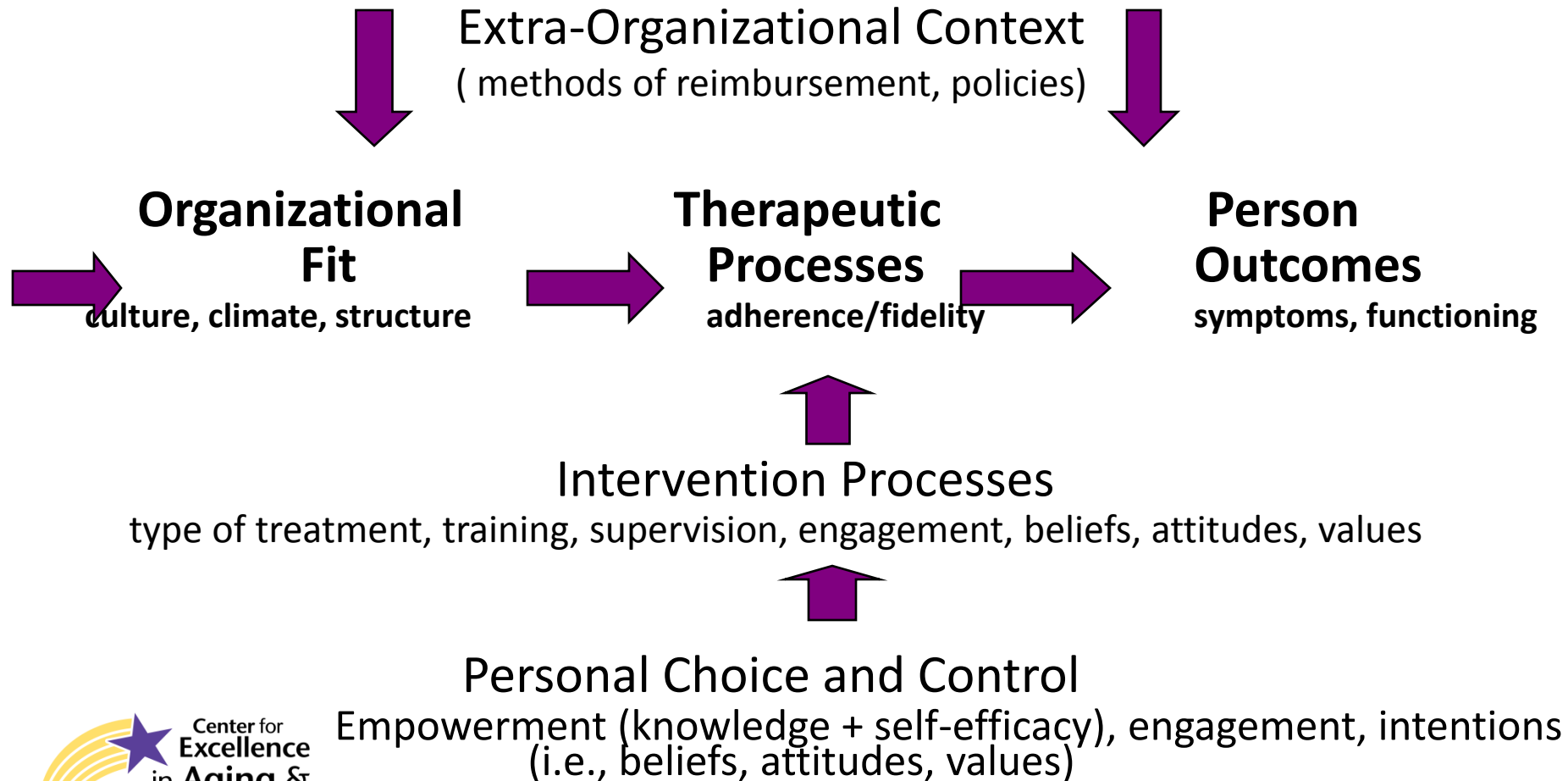
Randomized Control Trials

- Known as the gold standard for evaluating efficacy of interventions.
- Randomly assigning subjects to an intervention eliminates any bias from unknown characteristics of the sample that might contribute to treatment effects by balancing these characteristics evenly across intervention groups.

Mounting an Intervention RCT Study



Model of Influences on Effective Implementation & Sustainability



Research Phase

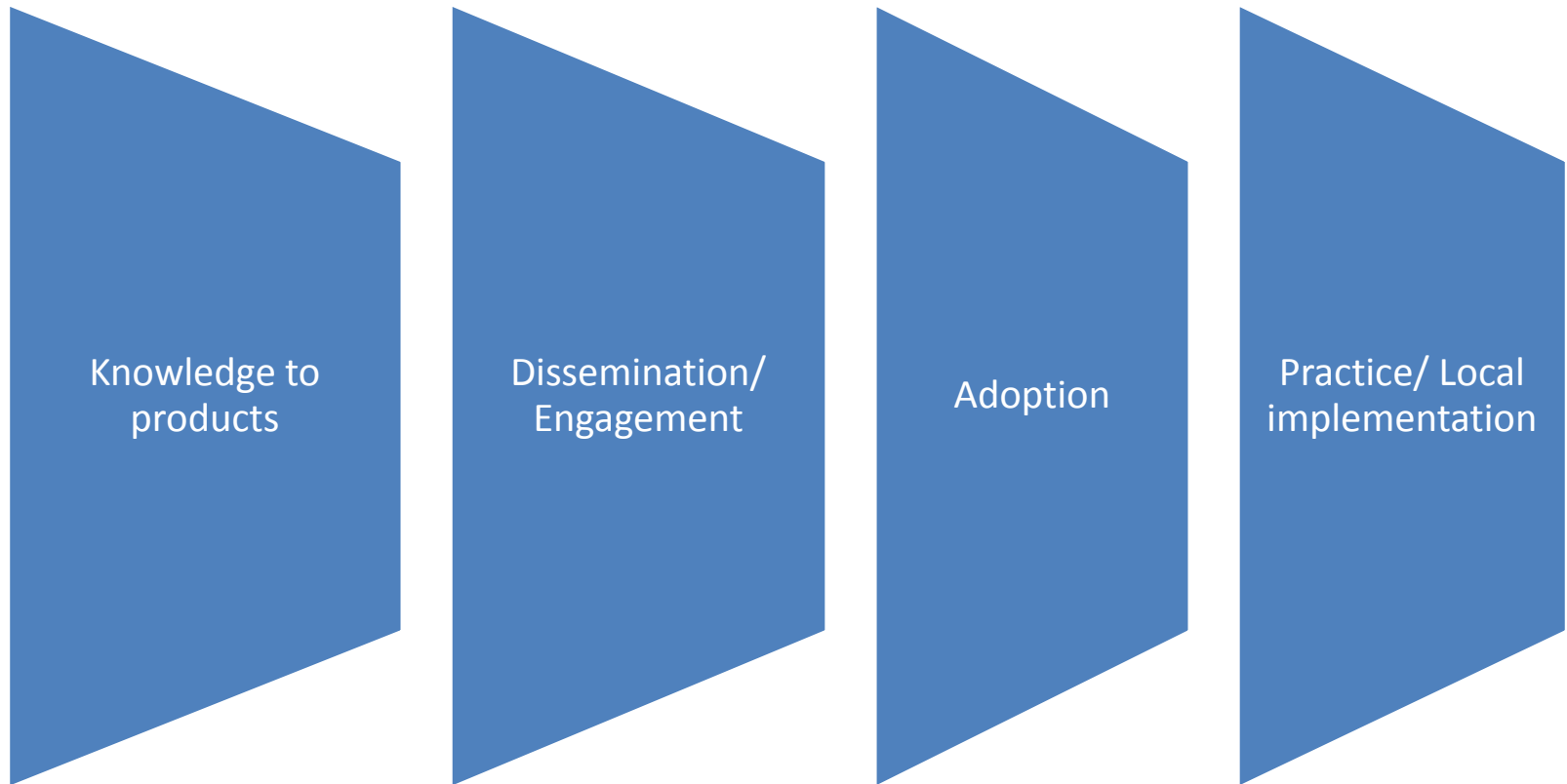


- Discovery

- Efficacy

- Effectiveness/Implementation Research

Translation Phase



Translational Research

- Type I – development and testing of treatment approaches generated through laboratory and pre-clinical research
- Type II – Enhancing the adoption of effective practices in the community

What Does Translation Require

- Real world application
- Effectiveness – Extensiveness – Efficacy – Engagement in quality implementation
- Infrastructure – policy, networks and embedding in delivery systems
- Guidelines, standards and quality assurance

(Adapted from Spoth, 2008)

Best Practices Evidence-based Good Programming



Best Practices

- Processes, practices, or systems widely recognized as improving the performance and efficiency of organizations in a target area, such as health promotion. (NCOA, 2005)
- Best practices in health promotion are those sets of processes and activities that are consistent with health promotion values/goals/ethics, theories/beliefs, evidence, and understanding of the environment, and that are most likely to achieve health promotion goals in a given situation (<http://www.bestpractices-healthpromotion.com/id12.html>)

NCOA Model Programs

Programs include the essential elements for successful behavior change:

- goal-setting
- problem-solving
- action-planning
- ongoing support
- Monitoring

*NCOA – National Council on Aging



NCOA Model Programs

Effective organizational and program planning strategies for:

- social marketing
- staff recruitment and training
- participant recruitment and retention
- partnering
- program sustainability
- evaluation



What is Evidence?

Lonigan, Ebert & Johnson, 1998;
Chambless et al., 1998

At least two controlled group design studies or a large series of single-case design studies

Minimum of two investigators (to be well-established)

Use of a treatment manual

Uniform therapist training and adherence

Tested with clinical samples

Tests of clinical and functional outcomes

Long-term outcomes beyond termination of treatment



Grading the Quality of Evidence:

Biglan, Mrazek, Carnine, & Flay (2003)

- Grades 1-7
 - 1 = multiple RCTs or multiple time series experiments by two or more independent teams + data on implementation effectiveness
 - 2 = multiple RCTs or multiple time series experiments by two or more independent teams
 - 3 = multiple RCTs or multiple time series experiments but no independent teams
 - 4 = 1 RCT or time series
 - 5 = comparisons between groups without randomization
 - 6 = pre-post comparison for one group
 - 7 = endorsement by authorities

Health Promotion & Evidence-Based Practice

- Some are highly rated as evidence-based
- Many do NOT meet criteria for evidence-based
- For others the quality of the evidence would not be highly rated

...Consideration of Program/Treatment Fidelity issues is still important

Components of an Evidence-Based Health Promotion Program

- Specific target population
- Specific, measurable goal(s)
- Stated reasoning and proven benefits
- Well-defined program structure and timeframe
- Specifies staffing needs/skills
- Specifies facility and equipment needs
- Builds in program evaluation to measure program quality and health outcomes

NCOA, 2006

Practice opportunity: Case studies

- Please select a reporter
- List the essential elements of the program
- List the organizational and program planning strategies that the program includes
- Rate the strength of the program based upon the Biglan scale
- List any other components that contribute to the program's evidence-base

Grading the Quality of Evidence:

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Case Study A

- The Arthritis Foundation Exercise Program
 - Essential Elements
 - Organizational and Program Planning Strategies
 - Biglan Comparison
 - Other components that contribute to the program's evidence-base

Case Study B

- The Chronic Disease Self-Management Program
 - Essential Elements
 - Organizational and Program Planning Strategies
 - Biglan Comparison
 - Other components that contribute to the program's evidence-base

Case Study C

- EnhanceFitness
 - Essential Elements
 - Organizational and Program Planning Strategies
 - Biglan Comparison
 - Other components that contribute to the program's evidence-base

Let's Take a Break...back in 15
minutes please



Assuring your program through QA/QI methods



Challenges in the Delivery of Evidence-Based Programs

- Delivery in original studies was often supervised by the creator
- Delivery was often by PhD students, research team members and/or other trained practitioners
- The original manual assumed background knowledge and/or a grounding in professional theories and practices
- Limited attention paid to treatment fidelity and how it should be measured
- Translational efforts to date relied heavily upon paid, trained staff or have been under the supervision of the program creator

Translation for Peers and Communities

- Delivery needs to move beyond dependence on the supervision of the program creator(s)
- Delivery cannot assume prior knowledge and professional training of staff nor can it depend on it
- Training and delivery manuals should clearly specify every step of delivery and every piece of knowledge required for a quality translation of the program

Translation for Peers and Communities

Training should be standardized:

- A specific, approved training program for leaders is necessary.
- A specific, approved train the trainer curriculum is ideal.
- Both must include guidance on demonstration requirements so that persons may be certified as leaders/trainers.

Translation for Peers and Communities

Clear guidelines on negotiable and non-negotiable components of the program intervention:

- What constitutes successful completion of the program/intervention
- What are successful measures of program/treatment fidelity

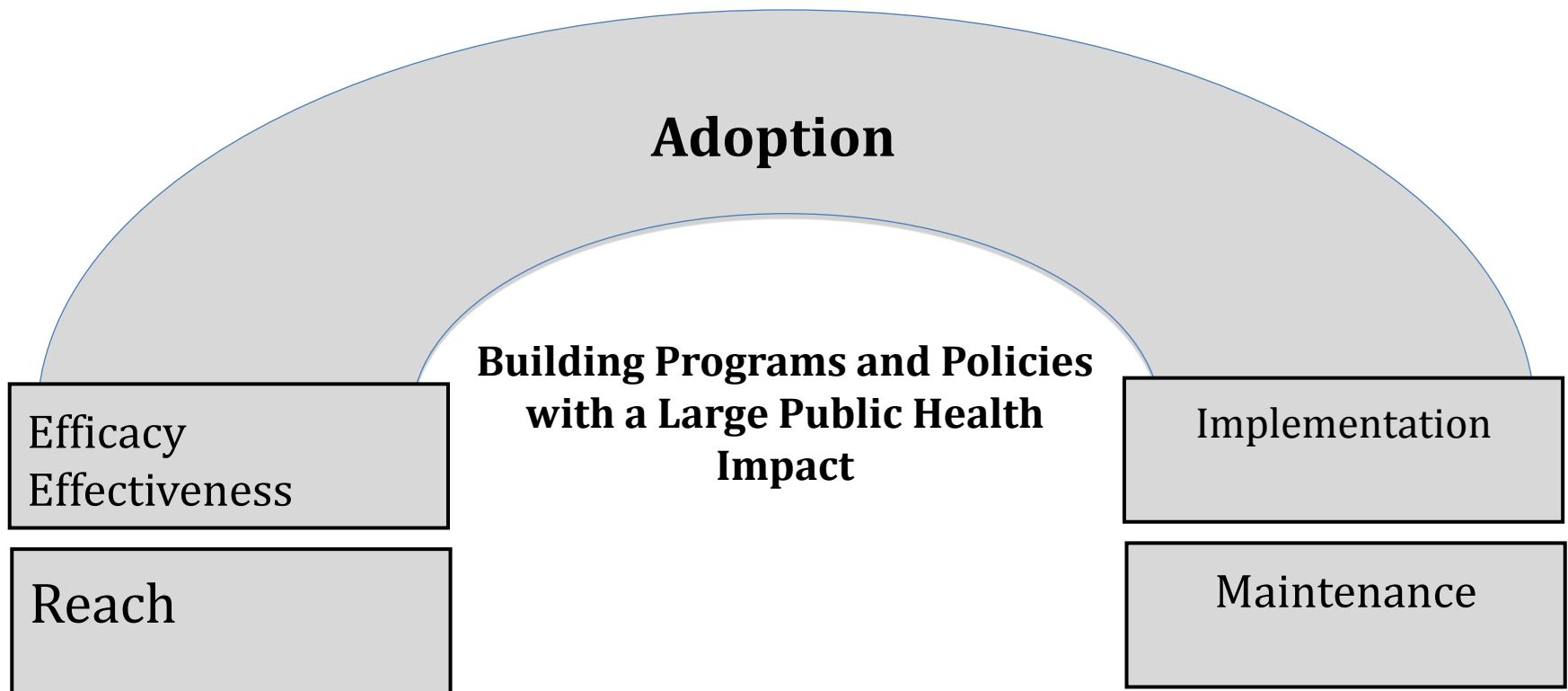
Translation and Program/Treatment Fidelity

- The “adoption of effective practices in the community” and the reliance on volunteers and community practitioners for their delivery requires the separation of the program intervention from clinical and program creator management with the assurance that the intervention will continue to be delivered as intended.
- How can this be delivered? With a focus on effective practice.....

Tools for Effective Practice

- Attention to the RE-AIM framework: implementation and maintenance
- A QA/QI approach
- An understanding of and a belief in the value of program/treatment fidelity

RE-AIM BUILDING BLOCKS THAT TOGETHER PRODUCE PUBLIC HEALTH IMPACT



The RE-AIM Questions

Implementation

- Can different levels of staff implement the program successfully?
- Are different components of the intervention delivered as intended?

Maintenance

- Can organizations sustain a *quality* program over time?

QA/QI

Quality assurance, is concerned with assuring that activities that require good quality in delivery are being performed effectively. “Good quality” is established through comparison with an external standard.

Quality Improvement is concerned with raising the quality of program delivery. “Improvement” is established primarily by comparing current performance with past performance with a goal of better attaining the “Quality Assurance” set standard.

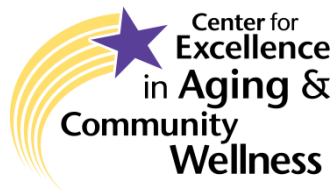
Believing in Program/Treatment Fidelity

..... a *Type III error*, this is the mistake of concluding an intervention is ineffective when it was not implemented in full (Basch, Sliepcevich, Gold, Duncan, & Kolbe, 1985; Glasgow, 2002) Frank et al., 2008

.....Despite the importance of fidelity and consequences encountered when it is breached, techniques used in monitoring fidelity have historically been underreported

(Bellg et al., 2004; Borrelli et al., 2005; Calsyn, 2000; Hogue, Liddle, Singer, & Leckrone, 2005; Moncher & Prinz, 1991; Resnick, Inquito et al., 2005; Santacroce et al., 2004)....

Frank et al., 2008



Treatment (Program) Fidelity Recommendations

Adopt a universal definition of *fidelity*, include adherence, dose, quality of program delivery, participant responsiveness and program differentiation

Standardize measures and methods for fidelity assessment to include both self report and observer data

Treatment (Program) Fidelity Recommendations

Increase research on factors influencing fidelity

- Provider characteristics
- Participant characteristics
- Match between providers, participants and the program;
- Administrative, community & environmental characteristics which influence and promote fidelity of implementation

Insist that fidelity be assessed and reported.

Program/Treatment Fidelity

Five components:

- design,
- training,
- delivery,
- receipt,
- enactment

Resnick, et al., 2005

Treatment Fidelity

Design:

- Can a study adequately test hypotheses in relation to the intervention's underlying theory?
- Why and in what ways do the authors think people's behaviors will change and can the why and how be demonstrated?

Training:

- Is there a manual that addresses and specifies all aspects of delivery?
- Are people implementing the intervention satisfactorily trained to deliver that intervention?
- Is adherence to training manual demonstrated?
- Is the training of leaders consistent?

Treatment Fidelity

- **Delivery:** Is delivery to participants consistent with the manual and is it demonstrated that participants are only receiving in the intervention what the manual says they should be receiving ?
- **Receipt:** Have the participants received and understood what it is intended they should receive and understand ?
- **Enactment:** Is there carryover into daily life?

Three Key Issues

1. ***Evidence-based*** Health Promotion Programs
2. ***Quality Assurance and Quality Improvement*** in community delivered programs
3. Importance of ***Program/Treatment Fidelity***

Let's Do Lunch...back in one hour
please



The Effective Practice Standard Model (EPS)



Quality Evidence-Based Health Promotion Programs

- Is it possible to deliver an evidence-based health program in the community without regard to program/treatment fidelity issues?
- Is it possible to deliver a quality health promotion program in the community without regard to program/fidelity?
- Yes to both...

- BUT...to deliver a quality evidence-based health program....you must consider program fidelity as the guiding principle and standard for quality assurance at a minimum AND
- You should consider program fidelity as the guiding principle for quality improvement processes

Merging Approaches to Create an Effective Practice Standard (EPS)

- Quality delivery of programs responds to RE-AIM implementation and maintenance concerns and questions
- Constant quality improvement in fidelity will assure quality of delivery
- Quality improvement to assure quality delivery is best guided by a Protocol for Program/Treatment Fidelity that includes:
 - Training for leaders
 - Self evaluation and peer review guides
 - Periodic external validation of fidelity

Let's Discuss...

What are some examples of program fidelity methods that can be used to assure minimum program quality?

What are some examples of program fidelity methods that can be used to improve program quality?

Components of the Effective Practice Standard Model

- Training
- Self-evaluation
- Peer review
- External validation
- Evaluation measures and methods

Training

- Standardized curriculum
- Non-negotiable intervention elements
- Training on QA/QI self, peer and external evaluation strategies

Self Evaluation

- Self-Assessment and feedback with Master Trainer, Peer or TA Center Staff
- Annual skills self-assessment with feedback
- Check-in (telephone) with Master Trainer or another identified individual during, and immediately after, program completion

Peer Review

- Peer-to-peer mentoring
- Written survey of co-leader at the end of the program offering
- Site visits to implement program fidelity monitoring
- Check-in with Master Trainer or another identified individual during, and immediately after, program completion
- Leader “booster” sessions that provide Q&A and problem-solving opportunities for leaders
- Co-leader evaluation

External Validation

- Site visits from Master Trainers or other trained observers
- Monitor attendance
- Observation of program delivery using formalized fidelity monitoring procedures
- Annual update/skill assessment meetings
- Availability of technical assistance from Master Trainers throughout the program life
- Participant evaluation of program and instructor
- Assessment of participant outcomes in comparison to the original study results

Measures and Methods

- Checklists/Rating scales to objectively quantify accuracy in delivery
- Manuals, training, supervision & observation protocols to standardize QA/QI activities
- Consultation with designer of original program to determine
 - 1) core “non-negotiable” elements and
 - 2) appropriateness of local adaptations

Practice opportunities



Case study

In small groups, use the QA/QI worksheet to evaluate the effective practice standards of the given program.

Case Study A

- The Arthritis Foundation Exercise Program
 - Does this program meet criteria for evidence-based programming? – How do you know?
 - What are the training requirements?
 - Is there a built-in process for quality assurance?
 - What additional strategies for quality assurance and improvement did you uncover?
 - What methods can you use to ensure a quality program in the field?

Case Study B

- The Chronic Disease Self-Management Program
 - Does this program meet criteria for evidence-based programming? – How do you know?
 - What are the training requirements?
 - Is there a built-in process for quality assurance?
 - What additional strategies for quality assurance and improvement did you uncover?
 - What methods can you use to ensure a quality program in the field?

Case Study C

- The EnhanceFitness Program
 - Does this program meet criteria for evidence-based programming? – How do you know?
 - What are the training requirements?
 - Is there a built-in process for quality assurance?
 - What additional strategies for quality assurance and improvement did you uncover?
 - What methods can you use to ensure a quality program in the field?



Case Vignette



Case vignette - you decide?

- **Vignette:** Two leaders were facilitating a workshop in a local church whose cultural expression was very different from their personal experiences.

At the first workshop, leaders noticed that unlike many previous workshops they had led where participants were often very animated and talkative with leaders after the closing, the participants of this workshop remained silently seated while the leaders cleaned up and exited the facility.

The leaders were troubled by this and concerned that perhaps the workshop content or facilitation had offended some of the participants.

You Decide?

- What do you think is going on here?
- How do you know – what data or evidence do you have to support your conclusion?
- What data do you need to address this issue?
- How would you proceed if you were the decision maker for this program?

Let's Take a Break...back in 15
minutes please



Evidence-based Program Challenges: Implementation, Delivery and Sustainability

- Resources
 - If we build it *will they come?*
- Recruitment
 - When we build it *who will come?*
- **Program quality and fidelity**
 - **When they come *will it matter?***

Partners are the Key to Success

- Program Partners
- Fidelity Partners
- Evaluation Partners



Program Partners: Delivery

- What is needed for program delivery and who can supply it?
 - Trained Leaders/instructors
 - Participant Materials
 - Workshop/program Locations
 - Incentives, snacks, stipends, transportation, etc.

Program Partners: Marketing/Recruitment

- Who will market the Program?
 - Market Targets –
 - The Demand Side – Participants
 - The Supply Side – Partners and Feeder Organizations

Fidelity Partners: Training and Technical Assistance

- Who will ensure the program delivered is faithful to the design intended by the developers and faithful to the evidence-base?
 - Training – Sustaining Qualified and Certified Trainers
 - Technical Assistance – Meeting Standards Established by the Program Developer(s)

Fidelity Partners: Quality Assurance/Improvement

- How will we track quality measures?
 - Attendance Monitoring
 - Workshop/program Observations
 - Participant Satisfaction
 - Leader/instructor Feedback
 - Ongoing Support to Leaders/instructors

Evaluation Partners: Valued Outcomes

- What are the valued outcomes for each partner?
 - Quality of Life Measures
 - Activation Measures
 - Health Improvement Outcomes
 - Healthcare Utilization Outcomes
 - Others?

EPS – So what?

- How do we address the issues that are uncovered?
 - What are we going to do about what we know?
 - Are there systemic issues that need to be addressed?
 - Are there individual issues that need to be addressed?
 - Are there cultural issues that need to be addressed?

Developing your own QA/QI Work Plan

- Use the provided work plan to begin developing your own QA/QI strategies.
- Work with other people from your organization OR find someone who is implementing the same program(s).
- Be prepared to share what you've learned with the group.

What challenges did you encounter
when creating a work plan?



Developing Sustainable QA/QI

- What do we want to do?
- Who will do it?
- How will we measure it?
- Who will review it?
- How will we act on what we learn?
- How will we pay for it?

Brainstorming opportunity

What are some resource challenges to implementing QA/QI for your program(s)?

Problem solve solutions



If a tree falls in the forest
and it's already sold,.. Is
quality a problem?*

*Dilbert



Put another
way: if we
got the grant
to deliver the
program and
everyone
knows it's a
good
program –
what's
quality got to
do with it?

For more information or a copy of
these slides:

<http://ceacw.org>



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