Translational Science in the Behavioral Domain: More interventions please... but enough with the efficacy!

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Disclosures

• Financial: Carilion Clinic

• Scientific Biases:
  • Efficacy trials are necessary to determine the impact of behavior on health outcomes, but not for behavior change trials
  • An RCT is not the the gold standard design for research-practice translation
  • Do not believe that an intervention has to have a clinically meaningful effect to have an impact
The translational pipeline

- Efficacy to determine if the intervention achieves behavior change
- Effectiveness to determine if it does so when delivered to representative participants
- Effectiveness to determine if it does so when delivered by representative staff in community or clinical organizations
- Broad acceptability (i.e., a large number of people in community or clinical settings)

Flay, 1986
How does the pipeline work?

- Active Choices & Active Living Every Day
- First RCT published in 1991—consistent efficacy in increasing regular physical activity
- One was small group based one telephone based
How does the pipeline work?

- RWJF-Active for Life® (AFL)
- Competitive grants for community organizations to deliver either Active Choices or ALED awarded in 2001
- Goals:
  - Reach diverse populations (it did)
  - Test the effectiveness (it was)
  - If effective to translate Active Choices and ALED into sustained delivery across the grantee communities beyond the life of the grant

How does the pipeline work?

• With a high level of resources, ongoing training and support for 5 years, and a highly motivated set of community organizations…. only 7 of 12 Sites were confident they would to maintain the program post grant funding
How does the pipeline work?

• One more quick example from the obesity treatment literature…
• Stand Up if you believe that there are treatment options for childhood obesity that can achieve clinically meaningful reductions in weight status and demonstrate sustained effects for up to 10 years
• Stay standing if you believe these interventions have been widely translated into typical community settings
While the pipeline translational model espouses a movement towards external validity it still values:

- Simple over complex
  - To every complex question, there is a simple answer…and it is wrong.~ H. L. Mencken
- Control over Context
  - In theory there is no difference between theory and practice, in practice there is ~ Yogi Berra
- Randomization over Reality
  - If we want more evidence-based practice we need more practice based evidence ~ Larry Green
- Best possible over best available evidence

The pipeline rarely works

And it is too SLOW!
It is time for a new paradigm

• Move from a paradigm that emphasizes:
  • The magnitude of effect as the key indicator of readiness for translation and adheres to the principles of evidence rating for determining efficacy

• Move to one that emphasizes:
  • Attention to intervention features that can be adopted and delivered broadly, have the ability for sustained and consistent implementation at a reasonable cost, reach large numbers of people, especially those who can most benefit, and produce replicable and long-lasting behavior changes
Outcomes for the new paradigm

- **Reach**: The number, percent of target audience, and representativeness of those who participate
- **Effectiveness**: Change in outcomes and impact on quality of life and any adverse outcomes
- **Adoption**: Number, percent and representativeness of settings and educators who participate
- **Implementation**: Extent to which a program or policy is delivered consistently, and the time and costs of the program
- **Maintenance\(_i\)**: Sustained change in outcomes and impact on quality of life and any adverse outcomes
- **Maintenance\(_o\)**: Extent of discontinuation, modification, or sustainability of intervention
Important RE-AIM concepts

- All dimensions have equal importance when applied to translational science
- All dimensions provide a target for intervention
- All dimensions are likely inter-related
- Combining metrics could lead to more informed decision making.
Translational research agenda

- More interventions to improve reach, adoption, implementation, and maintenance of evidence-based interventions
- Identification of new research designs that can provide relevant and actionable information for practice organizations and professionals
- Development of metrics that combine RE-AIM indicators and link metrics to public health changes
Key Translational Issues:

- Shift from focus on the numerator to the denominator
- Generalizability to target population
- Avoid contributing to disparities
- Common comparison for decision making including unintended consequences
- Robustness when combined with adoption: what works best for whom, and under what conditions
A Reach Trial

- Cluster randomized controlled trial (n=28)
- Two conditions
  - Both described similarly in kick off presentations
  - Both included an email component (but differed on frequency)
  - Highlighted incentives in intervention worksites
Reach

- Number
  - 6204 Employees
  - 1806 Participants
  - Proportional Reach
## Representativeness

- Compared to brief health survey of total employee population (~70% response rate)
- Overall=Study representativeness
- Incent=Incentive intervention representativeness

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Adoption, Implementation, Maintenance

Translational Issues:

• Will the intervention fit in a typical practice setting?
• Generalizability to delivery agents
• Initial start-up and ongoing costs
• Understanding structure and who makes adoption decisions (and how they are made)
• Characteristics of the intervention, setting, culture, and organization that facilitate or impede implementation
An Adoption Trial

Participatory Dissemination
Targeted Model

Efficacy to Effectiveness to
Demonstration to
Dissemination Model

Versus

Fit Extension

Active Living Everyday

Physical activity program

As tested

Critical elements

Appropriate for question

Broader health policy and cultural context

Delivery site(s)

Organization

Clinic

Program delivery staff

Partnership

Research design

184 assessments for Active for Life

184 assessments for Active for Life

466 not included in study
- 132 delivered none
- 197 not completed program or completed program but did not start intervention
- 309 did not start program in timeframe

301 not included in study
- 201 did not meet eligibility
- 152 did not start program in timeframe

135 completed pre-post surveys
331 completed post-survey

204 started program and completed post-survey; 215 completed post-survey

14 withdrew from program and evaluation and were not post-survey; 11 withdrew from program only

95 did not return post-survey

16 returned post-survey but were excluded from analysis because of missing data for dependent variables or covariates

216 included in pre-post analyses

370 included in pre-post analyses

Fit Extension

Active Living Everyday

CARLIONCLINIC
Adoption

N=56 Health Educators

Health Educators interested
N=36

64% Adoption at study level
No significant diffs between adopters and non adopters

R

ALED
N= 18

Fit Ex
N=18

Telephone Introduction

Online Training

In person training
Adoption-Programs

- Adopters did not differ from non-adopters on age, ethnicity, or years of service.

\[ \chi^2(1) = 7.2, \ p < .01 \]
Translational Science Research Designs

- Project Move! An adaptation of DPP for weight loss in the VA.

- Used a qualitative comparative analysis during scale up of the intervention

- Primary outcomes: Determining necessary and sufficient implementation conditions that lead to greater weight loss

Kahwati et al, 2012
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<th>High interface between screening and treatment</th>
<th>Use of standard curriculum</th>
<th>Use of multidisciplinary team approach involving a dietitian and at least one other discipline</th>
<th>High program complexity</th>
<th>Use of weight loss maintenance component</th>
<th>Used group care delivery format</th>
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Implementation

- No two sites shared the same pattern of implementation
- All high success sites used a standardized curriculum and group sessions to deliver the intervention
- ~50% of the low success sites did too.
- Successful patterns of implementation
  - High program complexity combined with high staff involvement
  - Low accountability to facility leadership
  - Active physician champion combined with low accountability to facility leadership
  - The use of quality improvement strategies combined with not using a waiting list
Translational Science Research Designs

- Can we ever get a good estimate of reach when participants have to agree to be randomly assigned to conditions?

- Can we adapt trial designs to answer more than one RE-AIM question at a time?
- Diabetes Prevention Program
- 16 one-on-one session
- Monthly individual and group education sessions
- Group exercise offering
- Tracking, Feedback, Follow-up
Combining two or more RE-AIM dimensions may be useful for making policy comparisons and decisions.

- **Individual Level Impact**
  - RE: Reach X Effectiveness
  - RE2: Problem Prevalence X RE (Attributable Individual Level Impact)
  - RE3: Incremental cost of treatment-control/Incremental RE of Treatment-control (Efficiency)

- **Setting Level Impact**
  - AI: Setting Adoption X Staff Adoption X Implementation
  - AI2: AI X number of target settings X Average number served per setting

- **RE-AIM Average**
An Example

- Examine individual level calculations for a commercial internet and incentives-based worksite weight loss program.

- Compare these calculations using some worksite data, and realistic data from a worksite weight loss small group intervention and individual counseling.

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<th></th>
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<th>Small Group</th>
<th>Individual</th>
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<tr>
<td>Total Employees</td>
<td>10523 (68% Women)</td>
<td>10523 (68% Women)</td>
<td>10523 (68% Women)</td>
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<tr>
<td>% Eligible</td>
<td>64%</td>
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<tr>
<td># Informed</td>
<td>10523</td>
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6 Month Weight Loss

- Which program should a worksite choose?
Which program should a worksite choose?
Cost per participant

Which program should a worksite choose?

- Internet+
- Small Group
- Individual

Dollars
Clarifying Reach

Calculations

- Participation Rate & Representativeness
  - Participation Rate
    \[
    \text{Participation Rate} = \frac{\text{No. of people willing to participate}}{\text{No. of people eligible}} \times 100
    \]
  - Representativeness:
    \[
    \text{Representativeness} = \text{the median ES across the representativeness comparisons across characteristics of participants versus those declining participation}
    \]

Reach Summary

- Participation Rate – Median ES for representativeness
Clarifying Effectiveness

- Calculations
- Composite Intervention Effective

\[(E) = (\text{MES}_{\text{primary outcome}} - \text{MES}_{\text{negative outcome}} - \text{MES}_{\text{differential impact}})\]

Assesses not only standardized effect size, but takes into account potential negative and differential effects.
Reach by Effectiveness

Definition: RE is a composite measure for assessing the reach and effectiveness of an intervention at the individual level.

\[ RE1 = \text{Reach} \times \text{Effectiveness} \]

\[ = 0.89 \times 0.37 \]

\[ = 0.33 \]
Definition: RE efficiency measures the efficiency and reach in terms of money.

Per participant cost of treatment = $54

Incremental impact of RE 1 = 0.33

RE 3 = Cost of treatment
       Incremental RE1 of treatment
       = 54/ 0.33
       = 163.64
Reach by Effectiveness by Cost

Dollars

- Internet+
- Small Group
- Individual
A more understandable description

Reach cost effectiveness example using the same internet program data:

• Approximately 10% of the employee population will benefit
• Those who benefit will lose 9.5 pounds on average (~5% weight loss).
• Women will be more likely to be successful
• The cost is $160 per successful employee
Translation of research into practice is not simply the movement of an intervention from efficacy to effectiveness

Lots of targets for interventions

As much can be learned from an intervention that spreads quickly and is ineffective as can be learned from the alternative

New and novel designs and outcomes are needed…and there are designs and outcomes available.
Mission:
Producing a Public Health Impact through Physical Activity, Nutrition, & Weight Management Interventions

Translational Obesity Research Center
Three Graduate Training Tracks:

1. Basic
2. Behavioral & Community
3. Human Clinical Physiology and Metabolism

Core Courses in:

- Translational Science
- Team Science
- Research Methods

Areas of Research Emphasis

1. Causes and consequences of obesity and related disorders
2. Breaking the link between obesity and its associated health risks
3. Obesity management dissemination and implementation

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