Models & Methods in Behavioral Intervention Development Research

Chair: Susan Czajkowskia, Ph.D.

Speakers:

Lynda Powell, Ph.D.

Bonnie Spring, Ph.D.
Changing unhealthy behaviors is the “single greatest opportunity to reduce premature deaths…”

When we succeed in changing behavior, we improve health…

A 7% weight reduction and 2.5 hour per week activity increase led to a 58% reduction in the cumulative incidence of Type 2 diabetes in insulin-resistant individuals.

DPP Research Group, *NEJM*, 2002
...but behavior change is hard to achieve & even harder to maintain

Trials of Hypertension Prevention II:
Weight loss over 36 months in 2382 overweight pre-hypertensives

(Stevens et al. *Ann Intern Med*, 2001)
The challenge: developing more effective & sustainable health-related behavioral interventions

Just as with development of better drugs, devices & surgical techniques, building better behavioral interventions depends on our ability to translate knowledge about human behavior, gained through basic behavioral & social science research, into more effective behavioral interventions.
Translational Research

“The process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease” (Zerhouni, 2003).

Defines a *continuum* of research (“bench” to “bedside” to “public health application”)

2 major types of translational research:

- **Translation I:** *Basic science discoveries are used to develop new treatments for disease (“bench to bedside”)*
- **Translation II:** *Research aimed at improving utilization of proven therapies in clinical practice & community settings (“bedside to public health”)*

Both types are important to both biomedical & behavioral research

Often involves interdisciplinary research teams

Bi-directional in nature
- Findings from basic science can be translated into public health applications
- Observations in clinical/community settings can inform earlier stages of research (basic science)
The standard NIH Translational Research model

T1 Translation

Bench ↔ Bedside

T2 Translation

Public Health

Bench ↔ Bedside → Public Health
Behavioral Translational Research model

T1 Translation

bBSSR  Behavioral Intervention

T2 Translation

Public Health
Our current situation:
Not a continuum of research leading to public health impact but parallel paths leading to ???

Basic behavioral & social science research

Behavioral & psychosocial intervention studies

Public health & community studies
Obesity Related Behavioral Intervention Trials (ORBIT) RFA program

■ 7 research centers & a Coordination Unit
■ Interdisciplinary project teams of basic and applied biological, clinical, behavioral and social scientists

■ Goals of the ORBIT program:
   ■ To translate findings from basic research on human behavior to develop more effective interventions to reduce obesity & improve obesity-related health behaviors
   ■ To promote an intervention development process for the behavioral sciences that is analogous to Type I translation in the biomedical sciences

Orbit
Translating Ideas into Interventions: The Process of Developing Behavioral Interventions
NIH-sponsored Workshop
December 6-7, 2010

- What model or framework can we use to guide the behavioral intervention development process?

- Which study designs & methods are most appropriate for the development of behavioral interventions?

- How do we create environments that foster creativity & encourage the development of innovative behavioral interventions?
“Translating Ideas into Interventions” Workshop
Models of Behavioral Intervention Development Group

Nancy Adler, Ph.D.
Lynda Powell, Ph.D.
Brian Wansink, Ph.D.
June Stevens, Ph.D.
Bonnie Spring, Ph.D.
Lisa Onken, Ph.D.

Sonia Arteaga, Ph.D.
Patty Mabry, Ph.D.
Sarah Kobrin, Ph.D.
Melissa Riddle, Ph.D.
William Riley, Ph.D.
Mary Charlson, M.D.
Why do we need a model to guide the behavioral intervention development process?

- To facilitate use of a standardized, widely-accepted approach to designing, developing and optimizing health-related behavioral interventions (as is true for drug development)

- To encourage the development of behavioral interventions that are well-characterized, appropriately tested & optimized prior to testing in Phase III trials – ultimately leading to better, more powerful behavioral interventions with greater potential for public health impact

- To provide guidance to researchers, funding agencies, & reviewers regarding how best to develop, test and optimize behavioral interventions

- To highlight the importance of T1 & behavioral development research, leading to greater academic recognition of this area, additional funding & training opportunities, and more behavioral researchers pursuing translational and interventional research
T1 research – biomedical (drug development) model

Investigation of biologic mechanisms of underlying disease

Identification of biologic targets for intervention

Moving animal findings to human application

Drug Development

Phase I (safety: “dose-finding”)

Phase II (biologic activity: “dose-response”)

Phase III (efficacy & effectiveness)

Feasibility Pilot Studies

Bench

Bedside
Proposed Model of Behavioral Intervention Development Process

- **Phase I**
  - (a) Definition
  - (b) Design

- **Phase II**
  - (a) Proof of concept
  - (b) Pilots

- **Phase III**
  - Efficacy & Effectiveness

**Behavioral Intervention development**

**Basic Behavioral & Social Sciences Research**

- Investigation of biological, behavioral, social, &/or env. factors & their influence on behavioral RFs
- Identification of behavioral targets for intervention

**Behavioral Intervention**
Proposed Phases of Behavioral Intervention Development

**Phase I: Definition & Design**

- Phase I(a) -- Define the scientific basis for the intervention, its mechanisms & targets
- Phase I(b) -- Design the intervention and define its essential features

**Phase II: Proof of Concept & Pilot Studies**

- Phase II(a) -- Determine if the intervention can produce clinically significant improvement in the proposed behavioral risk factor target
- Phase II(b) – Determine:
  - whether the intervention’s effects can be replicated in larger samples using a control condition
  - what is the appropriate control condition & how does it behave
  - whether the intervention is feasible & acceptable to the target population
  - estimates of acceptability of the trial protocol, the effect size of the treatment relative to the control on a proposed clinical endpoint, and screening to enrollment ratios
## Proposed Model of Behavioral Intervention Development Process: Phase I – Definition & Design

<table>
<thead>
<tr>
<th>PHASE</th>
<th>CENTRAL GOAL</th>
<th>EXAMPLES OF QUESTIONS</th>
<th>METHODS</th>
<th>MILESTONE</th>
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</thead>
</table>
| Phase Ia: Definition | Provide scientific basis for intervention |  - Important clinical question identified?  
  - Relevant basic science theories & findings?  
  - Intervention targets?  
  - Behavioral / biological mechanism(s) of action?  
  - Surrogate endpoints?  
  - Clinically significant cut-points? |  - Existing data:  
  - -- epidemiologic  
  - -- meta-analyses  
  - Basic behavioral science literature  
  - Behavioral event modeling  
  - Observational studies  
  - Experiments | Formulation of a hypothesis  
 Creation of intervention content and targets |
| Phase Ib: Design | Design and Refine                   |  - Basic components?  
  - Dose/duration?  
  - Mode of delivery?  
  - Safety?  
  - Tolerability?  
  - Acceptability?  
  - Culturally appropriate?  
  - Tailoring for subgroups?  
  - Tailoring based on treatment response? |  - Formative qualitative research:  
  - - focus groups  
  - - interviews  
  - - ethnographic  
  - ABA designs  
  - Time series  
  - Factorial/Fractional factorial  
  - Adaptive treatment designs  
  - Systems science/modelling | Satisfaction that intervention is optimized and formal testing should begin |
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<tbody>
<tr>
<td>Phase IIa: Proof-of-</td>
<td>Clinically significant signal</td>
<td>● As currently designed, does this intervention produce a clinically significant signal?</td>
<td>Quasi-experimental, treatment-only</td>
<td>Confidence that the intervention as designed can produce a clinically significant signal</td>
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<td>Concept</td>
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<td>● Does it alter:</td>
<td>design</td>
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<td></td>
<td></td>
<td>- surrogate markers?</td>
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<td>- intervention targets?</td>
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<td></td>
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<td>● If not, can optimization produce a stronger signal?</td>
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<tr>
<td>Phase IIb: Pilot</td>
<td>Clinically significant signal</td>
<td>● Can clinically significant benefit be replicated?</td>
<td>Randomized design</td>
<td>Confidence that:</td>
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<tr>
<td>Studies</td>
<td>over noise (control)</td>
<td>● Is there a signal over noise (control)?</td>
<td></td>
<td>--the intervention can produce a clinically significant signal on a behavioral risk factor above a control</td>
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<td></td>
<td>Preparation for</td>
<td>● Does the control group behave well?</td>
<td></td>
<td>--the trial protocol is feasible</td>
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<td>Phase III efficacy Trial</td>
<td>● Response in subgroups?</td>
<td></td>
<td>--the control group is appropriate</td>
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<td>● Estimates needed for efficacy trial</td>
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<td></td>
<td>-- effect size</td>
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<td>-- acceptability &amp; feasibility</td>
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Proposed Behavioral Intervention Development Model: Key Features

- Progression from basic to more clinical/applied stages
- Flexibility in terms of number & types of studies within phases
- Duration of each stage can vary depending on # and needs of studies
- Each phase includes milestones/criteria for moving to next phase of the intervention development process
- Flow is bi- not uni-directional -- may need to go back to previous phases depending on findings at any given stage