Expanding the Research Tool Box: A new framework for building effective and efficient interventions

Kari Kugler, PhD, MPH
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Conflict of Interest

Kari C. Kugler, PhD, MPH discloses activities with other organizations such as:

- National Institutes of Health (NICHD, NIAAA, NIDA) [5]
- United States Department of Education [5]
- United State Department of Agriculture [5]
- Office of Adolescent Health [5]
- University of Southern California and University of Illinois [2]

Click here for details of the disclosure selections: http://www.rheumatology.org/Learning-Center/CME-MOC/Policies-Disclosures
Outline

- Behavioral intervention example
- Traditional approach
- MOST approach
- Research considerations
- Take away messages
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- Take away messages
Hypothetical intervention to reduce STIs among college students

Loosely based on a study R01 AA022931 (PI Collins)
Behaviors are complex, so interventions often include multiple components

- Intervention component: Any aspect of an intervention that can be separated out for study
  - Parts of intervention content (e.g., change norms, increase self-efficacy)
  - Features that promote compliance/adherence (e.g., weekly text messages or brief phone counseling)
  - Features aimed at improving fidelity (e.g., training modules for staff)
Outline

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Preparation phase

- Review existing literature
- Devise a conceptual model
- Identify intervention components
- Conduct pilot work
Evaluation phase

- Typically conduct a 2-arm randomized controlled trial (RCT)
  - Compare packaged intervention to a delayed control or standard of care
Traditional approach

Excellent for evaluating whether the packaged intervention performs better than a control or standard of care.
If the RCT shows a significant effect, we still do not know

- Which components are making positive contributions to overall effect
- Whether all the components are really needed
- Whether a component’s contribution offsets its cost
- How to make the intervention more effective, efficient, scalable and/or sustainable
Or if the RCT shows a non-significant effect, we do not know

- Whether any components are worth retaining
- Whether one component had a negative effect that offset the positive effect of others
- Specifically what went wrong and what the next steps should be
What’s the alternative?

- Start by specifying
  - the ideal we would like to accomplish
  - the constraints that limit what we can accomplish
What’s the alternative?

- Then systematically build
  - The ideal: The most effective intervention possible
  - That:
    - Only includes active components
    - Can be delivered for less than $200/participant
    - Takes no more than 10 minutes of staff time to deliver
    - Takes the average participant no more than two hours to complete
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The Multiphase Optimization Strategy (MOST)

- An engineering-inspired framework for development, optimization, and evaluation of behavioral and biobehavioral interventions (BBI)
- Developed by Linda Collins and colleagues
MOST includes three phases

- **Preparation phase**
  - Same as traditional approach, but also includes identification of an optimization criterion

- **Optimization phase**
  - Fully powered experimentation to optimize a BBI

- **Evaluation phase**
  - Fully powered experimentation to evaluate effectiveness
The MOST approach

Self-efficacy

Norms

Text messages

Component screening experiment

Optimized intervention

RCT
Definition: Optimization

- “The process of finding the best possible solution... subject to given constraints” (The Concise Oxford Dictionary of Mathematics)
  - Optimized does not mean best in an absolute or ideal sense
  - Instead, realistic because it includes constraints
- Optimization always involves a clearly stated optimization criterion
Component screening experiment

- Goal: To empirically determine which components, individually and in combination, are active
  - “Active” can be defined by statistical significance, effect size, etc.

- Most often a factorial experiment is most efficient experimental design
Factorial experiments 101

- Example: $2 \times 2$, or $2^2$, factorial design

<table>
<thead>
<tr>
<th>Component A</th>
<th>Component B</th>
</tr>
</thead>
<tbody>
<tr>
<td>On</td>
<td>On</td>
</tr>
<tr>
<td></td>
<td>A,B on</td>
</tr>
<tr>
<td>On</td>
<td>Off</td>
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<tr>
<td></td>
<td>A on, B off</td>
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<td>A off, B on</td>
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<tr>
<td></td>
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- Factorial experiments can have
  - $\geq 2$ factors
  - $\geq 2$ levels per factor
Hypothetical factorial experiment

<table>
<thead>
<tr>
<th>Condition Number</th>
<th>Intervention Components</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>SELF-EFFICACY</td>
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<tr>
<td>1</td>
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<td>8</td>
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### Experimental Conditions for $2^3$ Factorial Experiment

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</table>
Analyzing a factorial experiment

- Conduct an ANOVA using linear regression
- Examine main effects and interaction effects
  - E.g., What is the effect of receiving norms component, averaged across the other components?
  - E.g., Does the effect of receiving norms component if receive text messages, averaged across self-efficacy component?
Assemble the optimized intervention

- **Goal:** To assemble the best intervention possible with no inactive components

- **Other optimization criteria**
  - Cost (e.g., < $200/participant)
  - Staff time (e.g., < 10 minutes)
  - Participant time (e.g., 2 hours)

- Researchers determine which optimization criterion to use
The MOST approach

- Self-efficacy
- Norms
- Text messages

Component screening experiment

Optimized intervention component

RCT
Evaluate optimized intervention

- Conduct RCT comparing optimized intervention to control or standard of care
  - If effective → release optimized intervention
  - If not effective → go back and re-evaluate theoretical model, components selected, and conduct another component screening experiment
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Factorial experiments

- Make efficient use of subjects, but require more experimental conditions than other RCTs
  - Variations of factorial experiment can reduce number of experimental conditions
- Can add additional component without increasing sample size!
- Designed to detect main effects and interactions, not to examine pair-wise comparisons
Optimization phase includes other designs

- Adaptive interventions
  - Use a sequential multiple assignment randomization trials (SMARTs)
- Just-in-time adaptive interventions
  - Use microrandomized trials (mRTs)
  - Use control engineering techniques
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Take-away messages

- MOST is a new approach for building more effective and efficient behavioral interventions
  - Requires an additional step of optimization
  - Factorial experiments are efficient study design for optimization
- MOST can help move science forward faster to provide a greater public health impact
  - As constraints are changed, can ask new questions
Thank you!

- Questions or comments, please contact me
  - Kari C. Kugler
  - kck18@psu.edu
- Visit Methodology Center website:
  - http://methodology.psu.edu
Extra slides
**Optimization and evaluation are not the same**

<table>
<thead>
<tr>
<th>Evaluation and optimization: Both important; not the same thing.</th>
<th>Evaluation: Is the intervention’s effect statistically significant?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Optimization:</strong> Is the intervention the <em>best possible, given constraints?</em></td>
<td>No</td>
</tr>
<tr>
<td>No</td>
<td>May wish to optimize using effect size as criterion</td>
</tr>
<tr>
<td>Yes</td>
<td>Different intervention strategy needed</td>
</tr>
</tbody>
</table>
Screening experiment

- Choose most efficient study design that permits examination of main effects and interaction effects of components

<table>
<thead>
<tr>
<th>Study design</th>
<th>Sample size</th>
<th># Experimental Conditions</th>
<th>Estimate interactions?</th>
</tr>
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<tbody>
<tr>
<td>Individual experiments</td>
<td>Larger</td>
<td>10</td>
<td>No</td>
</tr>
<tr>
<td>Single control group</td>
<td>Smaller</td>
<td>6</td>
<td>No</td>
</tr>
<tr>
<td>Factorial experiment</td>
<td>Smallest</td>
<td>32</td>
<td>Yes</td>
</tr>
<tr>
<td>Fractional factorial experiment</td>
<td>Smallest</td>
<td>8-16</td>
<td>Yes, but limited</td>
</tr>
</tbody>
</table>
Neat features of factorial experiments

- Can assign a ‘constant’ component so that everybody gets something
- Can randomize groups to condition
- Can be applied to implementation and dissemination studies
- Because have more empirical evidence of the black box, researchers can take information from one study and apply to their situation more easily