RAISING THE BAR: ENGINEERING OPTIMIZED BEHAVIORAL INTERVENTIONS FOR INCREASED PUBLIC HEALTH IMPACT

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Part of the Medicine: Mind the Gap lecture series
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Outline

• What gap are we minding?
• A few definitions
• Developing behavioral interventions: Business as usual
• Engineering behavioral interventions: The Multiphase Optimization Strategy (MOST)
• Does optimization replace evaluation?
• Two fundamental principles
• OK, so how do you do this? Two in-progress examples
• Imagine...
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What gap are we minding?

Every year in the US:

Cigarettes responsible for

443,000 deaths

$193 billion in health care costs and loss of productivity

Poor diet and physical inactivity responsible for

400,000 deaths


What gap are we minding?

Each year
- cardiovascular diseases
- cancers
- chronic respiratory diseases
- diabetes

cause

35 million deaths worldwide

These all have important behavioral risk factors.

What gap are we minding?

The World Health Organization estimates that elimination of behavioral risk factors would prevent

up to 80% of heart disease

stroke

type 2 diabetes

and over one-third of cancers

What gap are we minding?

• Behaviors like these have a tremendous impact on public health:
  — Alcohol, tobacco, and other drug use
  — Physical inactivity and sedentary behavior
  — Eating poorly
  — Risky sexual behavior
  — Noncompliance
  — Many others

• All can potentially be modified via behavioral interventions
What gap are we minding?

• The gap between
  — The importance of the impact of behavioral factors on public health
  — The effectiveness of today’s behavioral interventions at modifying these behavioral factors
Behavioral interventions can be engineered to meet specific criteria. This will set the bar for effectiveness, efficiency, and scalability. We then can keep raising the bar, and gradually close the gap.
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Definition: behavioral intervention

• A program aimed at modifying behavior for the purpose of treating or preventing disease, promoting health, and/or enhancing well-being.

• Examples:
  — Clinic-based smoking cessation
  — Weight loss/management program
  — School-based drug abuse prevention

• Note that according to this definition, most behavioral interventions are treatment packages made up of multiple components.
Definition: Intervention component

- Any aspect of an intervention that can be separated out for study
  - Parts of intervention content
    - e.g.: topics in a drug abuse prevention curriculum
  - Features that promote compliance/adherence
    - e.g.: use of mems caps on medication
  - Features aimed at improving fidelity
    - e.g.: 800 number for program delivery staff to call with questions
More about intervention components

- Can impact effectiveness, efficiency, economy
- Some may be pharmaceutical
- Can be defined at any level: individual, family, school, etc.
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How behavioral inventions are typically developed

- Intervention components are chosen based on scientific theory, clinical experience, etc.
- Combined into a treatment package
- Package is evaluated via a randomized controlled trial (RCT)
- The *treatment package approach*
Treatment package approach

Behavioral intervention

Evaluation via RCT
What’s wrong with evaluating a treatment package via an RCT?

Absolutely nothing!
The RCT is designed to tell us

- Whether a treatment package performs better than a control or comparison
- Whether one treatment package performs better than another
Treatment package approach

Behavioral intervention

Evaluation via RCT
The RCT does not tell us

An RCT that finds a significant effect DOES NOT tell us

• Which components are making positive contributions to overall effect
• Whether a component’s contribution offsets its cost
• Whether all the components are really needed
• How to make the intervention more effective, efficient, and scalable
What the RCT does not tell us

An RCT that finds a non-significant effect DOES NOT tell us

• Whether any components are worth retaining
• Whether one component had a negative effect that offset the positive effect of others
  — Example: Williams and French’s (2011) meta-analysis suggested that focusing on overcoming barriers has a negative effect on physical activity
• Specifically what went wrong and how to do it better the next time
The treatment package approach has encouraged...

...stuffing the behavioral intervention with many components to get a significant effect

...downplaying considerations such as efficiency, cost-effectiveness, time-effectiveness, and scalability

...focusing primarily on attaining statistical significance

...paying insufficient attention to

meeting clinically meaningful criteria and

SETTING A BAR THAT CAN BE RAISED
What’s the alternative?

• When engineers build products they take an approach that is
  — Systematic
  — Efficient
  — Focused on the clear objective of optimizing the product

• Can we borrow ideas from engineering...

• ... and build optimized behavioral interventions?
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The Multiphase Optimization Strategy (MOST)

- An engineering-inspired framework for development, optimization, and evaluation of behavioral interventions
- Using MOST it is possible to engineer a behavioral intervention to meet a specific optimization criterion

Collins, Murphy, Nair, & Strecher, 2005; Collins, Murphy, & Strecher, 2007; Collins, Baker, Mermelstein, Piper, Jorenby, Smith, Schlam, Cook, & Fiore, 2011
Treatment package approach

Behavioral intervention

Evaluation via RCT

component component
component component
component component
Treatment package approach

component

component component

component component

Evaluation via RCT
Multiphase Optimization Strategy (MOST)
Multiphase Optimization Strategy (MOST)

Empirically-based optimization

Optimized behavioral intervention

Evaluation via RCT
Multiphase Optimization Strategy (MOST)

Empirically-based optimization

Optimized behavioral intervention

Evaluation via 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
Selecting an optimization criterion

• Your definition of “best possible, given constraints”
• This is the goal you want to achieve
• Once achieved, it is the bar that sets a standard for later efforts
One possible optimization criterion:

• Efficient intervention with no “dead wood”
• CONSIDER a school-based drug abuse prevention program.
  —Suppose: The investigators want to be confident that every component is necessary to reduce waste of time and money.
  —Achieve this by selecting only active intervention components.
Another possible optimization criterion

• Most effective intervention that can be delivered for $\leq$ some $$

• CONSIDER a smoking cessation intervention.
  — Suppose: Insurers say they will pay for a smoking cessation intervention that costs no more than $500/person to deliver, including materials, pharmaceuticals, and staff time.
  — Achieve this by selecting set of components that represents the most effective intervention that can be delivered for $\leq$ $500$. 
Another possible optimization criterion

• Most effective intervention that can be delivered in $\leq$ some amount of time

• CONSIDER a clinic-based intervention to prevent HIV risk behaviors in MSM

  — Suppose: Interviews with clinic staff suggest that the program has the best chance of being implemented well if it takes no more than 6 minutes to deliver.

  — Achieve this by selecting set of components that represents the most effective intervention that can be delivered in $\leq 6$ minutes.
Other possible optimization criteria

• Cost-effectiveness
• A criterion based on a combination of cost and time
• Most effective without exceeding a specified level of participant burden
• Or any other relevant criterion
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Evaluation and optimization:
Both important; not the same thing.

<table>
<thead>
<tr>
<th>Optimization: Is the intervention the <em>best possible, given constraints?</em></th>
<th>Evaluation: Is the intervention’s effect statistically significant?</th>
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<tbody>
<tr>
<td>No</td>
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<td>No</td>
<td>May wish to optimize using effect size as criterion</td>
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<td>Yes</td>
<td>Different intervention strategy needed</td>
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Evaluation:
Is the intervention’s effect statistically significant?
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Resource management principle

• Conduct research to gain the most scientific information relevant to the research questions at hand, without exceeding available resources.
  — This is what I need to find out: ______
  — These are the resources I have: ______
  — HOW CAN I MANAGE MY RESOURCES STRATEGICALLY TO FIND OUT WHAT I NEED TO KNOW?
Continuous optimization principle

• No intervention is ever permanently optimized
• As soon as one cycle of MOST is completed, a new one should start
• Can always make the intervention better
  — More effective, as effective but cheaper, less burdensome, etc.
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Example 1 of MOST: “Opt-in” weight reduction intervention study

Objective: Develop a highly effective weight reduction intervention aimed at adults

Funded by NIDDK.

Program official: Christine Hunter

Bonnie Spring
Northwestern University
Opt-in theoretical model

**Core Intervention**
- Education
- Goal Setting
- Skill Building
- Tech Tools

**Experimental Components**
1. Phone Coaching (12 v 24)
2. Text Messages (Y v N)
3. PCP Communication (Y v N)
4. Buddy Training (Y v N)
5. Meal Replacements (Y v N)

**Social Cognitive Mechanisms**
- Self-Efficacy
- Self-Regulation
- Supportive Accountability
- Facilitation

**Adherence**

**Weight Loss**
MOST as implemented in opt-in

- Component screening experiment
- Optimization criterion: Most effective ≤ $500
- Optimized treatment package
- Evaluation via RCT

Components:
- # coaching sessions
- PCP comm.
- Meal repl.
- Text msgs.
- Buddy training
The component screening experiment

• Purpose: efficient screening of intervention components
  — Weed out underperforming components
  — Get a sense of magnitude of each component’s effect
  — Examine whether effect of a component is augmented or reduced in presence of another

• This information is then used to optimize the intervention
Choice of design for component screening experiment is critical

- Any experimental design is a possibility BUT...
- ...must be selected based on Resource Management Principle!!!
Resource management principle

• To select a design, consider several, and examine
  —The scientific information each will provide
    • And whether it is what you want!
  —What each design costs
    • Number of subjects
    • Number of experimental conditions
• NOTE that the starting point is the resources you have
Experimental Design possibility 1

- Conduct an experiment for each component

<table>
<thead>
<tr>
<th>Experiment 1</th>
<th>12 coaching sessions</th>
<th>24 coaching sessions</th>
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<tbody>
<tr>
<td>Experiment 2</td>
<td>No text messages</td>
<td>Text messages</td>
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<tr>
<td>Experiment 3</td>
<td>No PCP communication</td>
<td>PCP communication</td>
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<td>Experiment 4</td>
<td>No buddy training</td>
<td>Buddy training</td>
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<tr>
<td>Experiment 5</td>
<td>No meal replacements</td>
<td>Meal replacements</td>
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</tbody>
</table>
Experimental design possibility 2

- Comparative treatment experiment

<table>
<thead>
<tr>
<th>24 coaching sessions</th>
<th>Text messages</th>
<th>PCP communication</th>
<th>Buddy training</th>
<th>Meal replacements</th>
<th>All set to low: 12 coaching sessions, No text mgs, No PCP, No buddy training, No meals</th>
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</thead>
<tbody>
<tr>
<td>All others set to low</td>
<td>All others set to low</td>
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## Comparison of experimental design possibilities 1 and 2

<table>
<thead>
<tr>
<th>Design</th>
<th>N to achieve power ≥ .8</th>
<th>Number of experimental conditions</th>
<th>Can interactions be examined?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1: Five individual experiments</td>
<td>2,800</td>
<td>10</td>
<td>No</td>
</tr>
<tr>
<td>Option 2: Comparative treatment</td>
<td>1,680</td>
<td>6</td>
<td>No</td>
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</tbody>
</table>
Experimental design possibility 3

• Factorial experiments 101: $2 \times 2$, or $2^2$, factorial design

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<tr>
<th>Component A</th>
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<th>On</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off</td>
<td>A, B off</td>
<td>A on, B off</td>
</tr>
<tr>
<td>On</td>
<td>A off, B on</td>
<td>A, B on</td>
</tr>
</tbody>
</table>

• Factorial experiments can have
  ≥ 2 factors
  ≥ 2 levels per factor
Experimental design possibility 3

- The Opt-In study would require a $2^5$, or 2X2X2X2X2, factorial experiment.
- This would involve 32 experimental conditions.
- HOW COULD THAT EVER BE POWERED?
Comparison of experimental design possibilities 1-3

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<td>Option 3: Factorial experiment</td>
<td>560</td>
<td>32</td>
<td>Yes, all</td>
</tr>
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</table>

• BUT we felt we could not handle more than 16 conditions.
Experimental design possibility 4

- **Fractional** factorial experiment
- Special type of factorial experiment
  - A *fraction* of the experimental conditions are run
  - Powered exactly the same as an ordinary factorial experiment
  - Important trade-offs that we will discuss shortly
## Comparison of experimental design possibilities 1-4

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<td><strong>560</strong></td>
<td><strong>32</strong></td>
<td>Yes, all</td>
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<td>Option 4: Fractional factorial experiment</td>
<td><strong>560</strong></td>
<td>16</td>
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<tr>
<td>Experimental Condition</td>
<td>Core Intervention</td>
<td># Phone Coaching Sessions</td>
<td>PCP Communication</td>
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Overall $N=560$, per-condition $n=35$. How can 35 per condition be enough?
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Main effect of # Phone Coaching Sessions *based on overall N of 560*
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**Main effect of PCP Communication based on overall N of 560**
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Main effect of Text Messages *based on overall N of 560*
## Design for Opt-In Component Screening Experiment

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Main effect of Meal Replacements *based on overall N of 560*
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Main effect of Buddy Training based on overall N of 560
Fractional factorial designs: Trade-offs

• There are no free lunches in statistics.

• WHAT WE GAIN USING A FRACTIONAL FACTORIAL DESIGN IN OPT-IN
  — Reduce number of experimental conditions by half
  — Ability to examine five components instead of four

• WHAT WE GIVE UP:
  — Certain effects are estimated as a “bundle” with certain other effects
Fractional factorial designs: Trade-offs

• In this design
  — Each main effect is bundled with one four-way interaction
  — Each two-way interaction is bundled with one three-way interaction

• Logic:
  — Our theoretical model does not predict large three-way and four-way interactions
  — Therefore, “bundled” estimate will be primarily due to main effect or two-way interaction
Fractional factorial designs: Trade-offs

<table>
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<th></th>
<th>Higher-order effects negligible</th>
<th>Higher-order effects large</th>
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<tr>
<td>Complete factorial chosen (four components)</td>
<td>Resources wasted; cannot investigate important research questions</td>
<td>Move science forward faster</td>
</tr>
<tr>
<td>Fractional factorial chosen (five components)</td>
<td>Move science forward faster</td>
<td>Possibility of some incorrect decisions about component selection</td>
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- Sometimes maximizing efficiency calls for taking calculated risks
- There are opportunity costs associated with the “less risky” option
- *This is the Resource Management Principle in action*
Fractional factorial designs: Trade-offs

• You do not escape this bundling with designs like the comparative treatment

<table>
<thead>
<tr>
<th>24 coaching sessions</th>
<th>Text messages</th>
<th>PCP communication</th>
<th>Buddy training</th>
<th>Meal replacements</th>
<th>All set to low: 12 coaching sessions No text mgs No PCP No buddy training No meals</th>
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<tr>
<td>All others set to low</td>
<td>All others set to low</td>
<td>All others set to low</td>
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• Example: this bundles the main effect of Coaching with ALL interactions involving Coaching
Using data from the experiment to optimize

• Conduct an analysis of variance, obtain estimates of effects of each of the components

• Use this information to select components to include in the intervention
  — Discard components that do not perform adequately
  — Use size of effects in combination with other data (e.g. cost) to select components that will make up optimized intervention
Status of Opt-In project

- Finalizing intervention protocols and manual of operations
- Expect to start the experiment late summer/early fall
After we have optimized and evaluated this intervention

• We will have set a bar for weight loss interventions
• Our work will establish which components work
• Future work (by us or others) can build on this to develop
  — equally effective for less money
  — OR more effective for $500
  — OR “Here is a more meaningful optimization criterion: ____”
• Continuous optimization principle in action
Example 2 of MOST: Clinic-based smoking cessation study

Objective: Develop a highly effective clinic-based smoking cessation intervention

Funded by NCI

Program official: Glen Morgan

Tim Baker    Mike Fiore
University of Wisconsin
Some interesting features of Example 2

• Study being implemented in health care settings
• Involves both behavioral and pharmaceutical components
• Developing two different interventions using two different optimization criteria:
  — Abstinence-optimized: no inactive components; includes all components that are demonstrated to work in our experiments
  — Cost-optimized: most effective that can be achieved for \( \leq \$500 \) per person
Baker & Fiore’s phase-based model of the smoking cessation process

MOTIVATION (3 weeks prior up to quit day) → PRECESSION (quit day to 2 weeks after) → MAINTENANCE (2 weeks to 6 months after quit day)
Components being considered for the smoking cessation intervention

- Precessation nicotine patch (No, Yes)
- Precessation ad lib nicotine gum (No, Yes)
- Precessation in-person counseling (No, Yes)
- Cessation in-person counseling (Minimal, Intensive)
- Cessation phone counseling (Minimal, Intensive)
- Maintenance medication duration (Short, Long)
Components being considered for the smoking cessation intervention

- These 6 components examined in one screening experiment
- In addition, there is another screening experiment that examines 5 components aimed at maintenance
- Thus we are examining 11 components aimed at precession, cessation, maintenance
- Also another screening experiment examining 4 components aimed at motivation for smokers not ready to quit
MOST as implemented in smoking cessation study

- Precess. NRT: patch
- Precess. counseling
- Cess. phone couns.
- Precess. NRT: gum
- Cess. in-pers couns.
- Maint. med. duration

Abstinence-optimized: No inactive components

Component screening experiments

OPTIMIZATION

Abstinence-optimized treatment package

Evaluation via RCT
MOST as implemented in smoking cessation study

Precess. NRT: patch
Precess. counseling
Cess. phone couns.

Cost-optimized:
Most effective \( \leq \$500 \)

Cost-optimized treatment package

Component screening experiments

Component screening experiments used in both optimizations

Evaluation via RCT
Choosing a design using the resource management principle

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<th>N to achieve power ≥ .8</th>
<th>Number of experimental conditions</th>
<th>Can interactions be examined?</th>
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<td>8, 16, or 32 depending on design chosen</td>
<td>Selected subset can be estimated</td>
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- We chose a fractional factorial design requiring 32 conditions
Experimental design chosen for smoking cessation study

- Fractional factorial with six factors
- 32 experimental conditions (i.e., half fraction)
- Main effects bundled with five-way interactions

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<th>Nicotine Patch</th>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>Intensive</td>
<td>Intensive</td>
</tr>
</tbody>
</table>
About implementation

• How do you conduct three factorial experiments
  — Simultaneously
  — In real-world health care settings
  — With a total of 80 experimental conditions?

• Takes careful planning and organization, use of computers, sufficient well-trained staff...

• ...it CAN BE DONE!!!
Status of smoking cessation project

• All subjects recruited and assigned; completing data collection and preparation

• All together
  — 15 intervention components
  — 3 separate component screening experiments
  — 80 experimental conditions
  — 1,700 subjects
After we have optimized and evaluated this intervention

• We will have set a bar for clinic-based smoking cessation interventions

• Future work by us (or others) can attempt to develop
  — as effective for less money
  — OR more effective for $500
  — OR more effective for more money
  — OR as effective, less burdensome
  — OR...

• Continuous optimization principle in action
Outline

• What gap are we minding?
• A few definitions
• Developing behavioral interventions: Business as usual
• Engineering behavioral interventions: The Multiphase Optimization Strategy (MOST)
• Does optimization replace evaluation?
• Two fundamental principles
• OK, so how do you do this? Two in-progress examples
• Imagine...
Imagine these optimized interventions

• Internet-delivered intervention to prevent drug abuse in NCAA athletes, optimized for effectiveness (this is funded by NIDA)

• Brief clinic-based intervention to reduce HIV risk behaviors in MSM, optimized to be most effective that takes under 6 minutes to deliver
Imagine these optimized interventions

- Intervention to increase compliance with a cancer treatment regimen, optimized to be most effective with least cognitive burden

- Workplace-based intervention to reduce sitting time, optimized to be most effective while being least disruptive to productivity
Imagine these optimized interventions

• Intervention to get arthritis patients to maintain moderate physical activity, optimized to be most effective that can be delivered in a single one-hour session

• Intervention to improve control of symptoms in end-stage heart disease, optimized to be most effective for <$300/patient

• And many many more!
Imagine the state of the art if MOST were widely implemented

• Every evidence-based intervention is optimized, so it is the best possible, given specific constraints.
Imagine the state of the art if MOST were widely implemented

• Interventions are engineered with clinically important outcome criteria, efficiency, economy, and scalability in mind.

• Every evidence-based intervention is immediately scalable
  — because important implementation constraints have been included in the optimization criterion.
Imagine the state of the art if MOST were widely implemented

- It is known which intervention components work, so interventions are transparent.
  - A coherent base of scientific knowledge is accumulating.
- Once a component screening experiment has been conducted, the ANOVA is made public, so if desired others can optimize using a different criterion.
Imagine the state of the art if MOST were widely implemented

• Many fewer RCT’s end up showing null results.
• The resource management principle is used, so that every NIH dollar yields the most scientific information obtainable.
Imagine the state of the art if MOST were widely implemented

• Every time a behavioral intervention is optimized, a clear bar is set for effectiveness, efficiency, and economy.

• Any new intervention must demonstrate that it is incrementally better than the preceding one, and specifically in what ways.
Imagine the state of the art if most were widely implemented

- In this way the bar is raised with each new evidence-based intervention.
- There is incremental progress over time, with interventions steadily gaining public health impact.
The gap

• Every year
  — 443,000 deaths in the US due to smoking
  — 400,000 deaths in the US due to poor diet/inactivity
  — 35,000,000 deaths worldwide from noncommunicable diseases that stem from largely behavioral causes
  — And much additional morbidity, mortality, and economic loss directly or indirectly due to behavioral factors

• Imagine closing the gap!
Behavioral interventions can be engineered to meet specific criteria. This will set the bar for effectiveness, efficiency, and scalability. We then can keep raising the bar, and gradually close the gap.
For more information:

http://methodology.psu.edu/ra/most

This web site has

— suggested reading
— FAQ
— Advice for people writing grant proposals involving MOST

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