Behavioural Medicine for Global Health: Challenges and Opportunities

William Riley, Ph.D.
Associate Director for Behavioral and Social Sciences Research
Director, Office of Behavioral and Social Sciences Research
National Institutes of Health
Influence of Behavioral Clinical Trials

Nearly 100K Behavior RCTs

Broad Influence
Challenges and Opportunities

• Basic to Applied Translation (T1)
• Methods
  • Comparators
  • Self-report of Unblinded Participants
  • Efficiency
• Post-Study Challenges
  • Publication Lags
  • Building a More Cumulative Science
  • Implementation
• Challenges and Opportunities with COVID-19
Improving T1 Translation

Preliminary Analyses of FY18 NIH Behavioral Intervention Grants

• 66% evaluating adaptations of existing interventions (different group, different delivery, different problem)
• 20% comparative effectiveness or D&I research
• 14% evaluating novel intervention components or packages

“The goal of the NIH Science of Behavior Change (SOBC) Common Fund Program is to provide the basis for an experimental medicine approach to behavior change that focuses on identifying and measuring the mechanisms that underlie behavioral patterns we are trying to change.”

N =580

84
169*
109*
145*
116

0
100
200
300

Novel...
Adapte...
Adapte...
Adapte...
Existing...

The NIH Science of Behavior Change Program: Transforming the science through a focus on mechanisms of change

Lisbeth Nielsen\textsuperscript{a,}, Melissa Riddle\textsuperscript{b}, Jonathan W. King\textsuperscript{c}, the NIH Science of Behavior Change Implementation Team, Will M. Akin\textsuperscript{d}, Wen Chen\textsuperscript{d}, David Clark\textsuperscript{d}, Elaine Collier\textsuperscript{d}, Susan Czajkowski\textsuperscript{e}, Layla Esposito\textsuperscript{f}, Rebecca Ferrer\textsuperscript{g}, Paige Green\textsuperscript{h}, Christine Hunter\textsuperscript{i}, Karen Kehl\textsuperscript{i}, Rosalind King\textsuperscript{j}, Lisa Onken\textsuperscript{k}, Janine M. Simmons\textsuperscript{l}, Luke Stoeckel\textsuperscript{l}, Catherine Stoney\textsuperscript{l}, Lois Tully\textsuperscript{l}, and Wendy Weber\textsuperscript{l}
Selecting Appropriate Comparators

- Positioning trial in an applicable research framework
- Defining the primary purpose
- Choosing the optimal comparator
  - Works at all?
  - Relative to clinically relevant alternatives?
  - How or why it works?
- Address barriers
- Address limitations
- Finalize choice

REVIEW

The selection of comparators for randomized controlled trials of health-related behavioral interventions: recommendations of an NIH expert panel

Kenneth E. Freedland\textsuperscript{a,*}, Abby C. King\textsuperscript{b}, Walter T. Ambrosius\textsuperscript{c}, Evan Mayo-Wilson\textsuperscript{d}, David C. Mohr\textsuperscript{e}, Susan M. Czajkowski\textsuperscript{f}, Lehana Thabane\textsuperscript{g}, Linda M. Collins\textsuperscript{h}, George W. Rebok\textsuperscript{d}, Shaun P. Treweek\textsuperscript{i}, Thomas D. Cook\textsuperscript{j}, Jack D. Edinger\textsuperscript{k}, Catherine M. Stoney\textsuperscript{l}, Rebecca A. Campo\textsuperscript{m}, Deborah Young-Hyman\textsuperscript{n}, William T. Riley\textsuperscript{m}, for the National Institutes of Health Office of Behavioral and Social Sciences Research Expert Panel on Comparator Selection in Behavioral and Social Science Clinical Trials
Unblinded Participants and Self-Report

• Fastidious about PI and RA blinding
• But unable to blind participants
• Larger effects from subjective vs. objective outcomes
• Outcomes need to extend beyond self-report

“Measuring MVPA via self-report versus accelerometry produces considerably different results in a sample of young adolescents.”
R3 Research

• 7 yrs from grant submission to publication – much changes and findings may be dated by the time they are published.
• Need faster recruitment, designs, infrastructures and review
• Noted that in response to the SARS outbreak, the Canadian Institutes of Health Research developed and issued a funding announcement that resulted in submissions within 2 weeks, and that were approved for funding within 10 days of submission

Lessons from COVID-19 Research Response

• Rapid review and funding process
• Rapid development infrastructure
• Rapid trials infrastructure

Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise

William T Riley¹, Russell E Glasgow¹, Lynn Etheredge² and Amy P Abernethy³

Figure 1 Consumer technology advances missed during a typical RCT published in 2012.
Publication Lags

- NIH trials funded in 1979 – 93% published within 9 yrs (Dickerson et al., 1993) [Interview of PIs]
- Phase I oncology trials – 67% published in 7.5 yrs (Camacho et al., 2005)
- IRB approved trials in Univ Hospital Bern – 52% published with 8 yrs (von Elm, et al, 2008)
- AMD ct.gov trials – 54% published within 2 yrs (Prenner et al., 2011)
- Clinicaltrials.gov registered trials – 46% published within 30 mos. (Ross et al., 2012)
- Large RCTs in ct.gov – 71% published within 2 yrs (Jones, et al., 2013)
- NHLBI Trials – 57% published within 30 mos. (Gordon, et al, 2013)


NIH R01/U01, 2008-2014
- 655 had zero pubs at 60 mos
- 5% of BSSR grants
- 2% of non-BSSR grants

Figure 3 Survival curve for BSSR predictor. 0= non-BSSR, 1= BSSR
"despite numerous controlled trials of various interventions for a given problem, the field has little guidance on how to improve upon previously studied interventions, adapt them to specific populations, contexts, or delivery mechanisms, or streamline them to facilitate use in real-world settings with constrained resources.

Ma et al (2020) Effectiveness of cognitive behavioural therapy for chronic obstructive pulmonary disease patients: A systematic review and meta-analysis
Implementation Challenges

• Well documented across all healthcare – “Valley of Death” (Meslin et al., 2013)

• Translation of social and behavioral interventions into practice present unique challenges:
  • Lack of a market-driven delivery system with accompanying regulatory structure
  • Inadequate health insurance reimbursement for effective interventions
  • When reimbursed - based on time, not quality or empirical basis
  • Settings in which behavioral interventions are delivered are much more diverse than medicine, and most have competing interests and strained resources
  • Behavioral interventions are complex and resource intensive, requiring considerable training and time to deliver with fidelity

• Strategies to Address Implementation Challenges
  • Interventions and Research Designs that Facilitate Adoption
  • Practice-based Research
  • Evaluating while Disseminating
  • Digital Technologies
  • Transition from Packages to Principles
COVID Social/Behavioral Research

- Most current mitigation efforts are social/behavioral interventions (risk communication, handwashing, paid sick leave, social distancing)
  - Based on varying levels of evidence from prior epidemics on adherence and transmission
  - Some with limited generalizability to an epidemic of this nature
  - Most with insufficient precision or quantification to better inform models
  - Some not implemented consistent with existing evidence
- Most with insufficient evidence to quantify “adverse events” such as rapid economic downturn, unemployment, social isolation, life disruption, limited healthcare access (cost-benefit analysis)
- The adverse effects of these mitigation strategies have downstream health effects:
  - Stress, mental health, and suicide
  - Substance abuse
  - Stress-related physical conditions
  - Domestic abuse, child abuse
  - But some positive outcomes as well (motor vehicle accidents, youth violence).

Achieving control of simulated outbreaks under different transmission scenarios
Interventions to Ameliorate Downstream Health Effects

- Inadequate access to healthcare
- Exacerbation of Health Disparities
- Telehealth and Digital Interventions

COVID-19 Competitive and Administrative Supplements

- Adherence to mitigation
- Mitigation risk reduction
- Economic impacts
- Social impacts
- Downstream health impacts
- Interventions to ameliorate impacts
- Healthcare access
- Natural experiments

[https://obssr.od.nih.gov/research-support/funding-announcements/](https://obssr.od.nih.gov/research-support/funding-announcements/)
Skate to where the puck is going

How to:
• Optimize unwinding of mitigation to maintain lower transmission rates while improving economic and social recovery
• Provide services to the backlog of “elective” care
• Help families manage complicated bereavement
• Reduce COVID-19 recovery complications
• Communicate risk in the context of better therapeutics, vaccines
• Minimize vaccine hesitancy, especially given the rapid pace of vaccine development and testing
Questions? Bill Riley: william.riley@nih.gov

@NIHOBSSR

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