What made the intervention work?
Mediation analyses of HIV prevention interventions

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HIV Risk Reduction Interventions

- Many behavioral interventions designed to reduce sexual risk behavior have been developed for various at-risk populations.
- These interventions, based on behavioral theory, contain many theoretically-derived activities representing different theoretical elements.
- For most of these interventions, we do not know which elements may have been responsible for intervention effectiveness.
Elements of SCT and TPB

Social Cognitive Theory
- Self-efficacy to perform behavior (SE)
- Expected outcomes of behavior (OEs)

Theory of Planned behavior
- Attitudes (expected outcomes and value of outcomes)
- Norms (approval of behavior by close others and motivation to comply)
- Perceived behavioral control (SE)
Examples of application of theory in HIV interventions

- Build skills and self-efficacy via modeling and practice, e.g., using condoms, negotiating use with partner
- Change expected outcome beliefs, e.g., that condoms reduce pleasure
- Build peer norms/approval within groups
Most behavioral HIV interventions have multiple theoretical components

- Mediation analysis provides a way to identify effective and ineffective components.

- Not as rigorous as randomizing people to receive individual components, but much more efficient!

- May help to refine interventions to become more cost-effective by emphasizing mediator-based components with demonstrated importance for a particular population and de-emphasizing others.
To conduct mediation analyses, your theoretical elements must:

- Be instantiated in the intervention
- Be measured in evaluation assessments
Mediation analysis

- Uses measures of theoretical factors driving the intervention and assessed in study (potential mediators)
- Identifies factors changed significantly by the intervention (step 1)
- Tests whether inclusion of mediator attenuates strength of intervention effect on dependent variable (step 2)
Independent Variable

Treatment condition

Dependent Variable

Unprotected sex
Independent Variable

Treatment condition

Mediators

Dependent Variable

Unprotected sex
Generic Mediation Model

- BL Assessment
  - Sex risk Mediators

- Randomization

 Intervention Mediators & NS factors

  - Mediator 1
  - Mediator 2
  - Mediator 3

  - Nonspecific factors (demand; attention; assessment reactivity)

 Comparison Nonspecific factors

  - (demand; attention; assessment reactivity)

 FU assessment

  - Sex risk Mediators

 FU assessment

  - Sex risk Mediators
Goals of talk

- Describe three HIV intervention studies with different populations
- Briefly review methods and outcome results
- Show results of mediation analyses for each of these studies
SISTER TO SISTER:
THE BLACK WOMEN’S HEALTH
PROMOTION PROJECT

RESPECT YOURSELF
PROTECT YOURSELF
...BECAUSE YOU ARE WORTH IT!!
Sister-to-Sister

- **Outcome paper:**

- **Mediation paper:**
Sister-to-Sister

- NINR-funded study conducted at a hospital in inner-city Newark NJ
- 564 African American women randomized to single-session intervention conditions: Skill-building, Information, Control
- Follow-up for one year
- Skill intervention produced significant effects on behavior; STD incidence at 12 months
Sister-to-Sister Potential Mediators

- Condom knowledge
  Intervention: Provide factual information
  Assessment e.g.: *The condom should be unrolled before it is put on.*

- Hedonistic condom OEs
  Intervention: Show ways to make condoms more pleasurable
  Assessment e.g.: *Condoms interrupt the flow of sex.*

- Partner reaction OEs
  Intervention: Develop negotiation strategies specific to partner
  Assessment e.g.: *My partner will be angry if I ask him to use a condom.*

- Partner approval OEs
  Intervention: Develop negotiation strategies specific to partner
  Assessment e.g.: *Would your partner approve or disapprove of condom use?*
Sister-to-Sister Potential Mediators (cont.)

- SE for sexual impulse control
  Intervention: Encourage practice, e.g., to stop sex to get a condom
  Assessment, e.g.: *I can say no to sex if my partner and I do not have a condom.*

- SE for carrying condoms
  Intervention: Give condom keychain.
  Assessment, e.g.: *It is easy for me to have condoms with me.*

- SE for condom use
  Intervention: Modeling and practice of condom use; negotiation
  Assessment, e.g.: *I am sure I could get my partner to use condoms, even if he does not want to.*
Condom knowledge
- Hedonistic condom OEs
- Partner reaction OEs
- Partner approval OEs
- SE for sexual impulse control
- SE for carrying condoms
- **SE for condom use**

**BL Assessment** → **Randomization**

**Intervention** → **Mediators & NS factors** → **3; 6-month FU**
- Sex risk Mediators

**Comparison** → **Nonspecific factors** → **3; 6-month FU**
- Sex risk Mediators

**12-month FU**
- Sex risk Mediators

OE=outcome expectancy  SE=self-efficacy
Summary: Sister-to-Sister

- Skills intervention effective in changing risk behavior
- Partner resistance and self-efficacy significant in univariate mediation analyses
- Only self-efficacy remained significant in multivariate mediation analysis
- Suggests the primacy of women’s skills at negotiation over partner characteristics, contrary to common opinion
LET US PROTECT OUR FUTURE
South African Adolescent Health Promotion Project

- **Outcome paper:**

- **Mediation paper:**
South African Adolescent Health Promotion Project

- NIMH-funded study conducted in Mdantsane, Eastern Cape, SA
- Cluster-randomized trial involving 9 matched pairs of schools
- Participants were 1,057 6th-grade learners (mean age = 12.4 yrs); schools randomized to six-session HIV Risk Reduction intervention or Health Promotion attention control
Results of SA Adolescent Health Promotion Study

Significant intervention effects were observed for:

- Vaginal intercourse in last 3 months
- Unprotected sex in last 3 months
- Multiple sex partners in last 3 months

But NOT for virginity; consistent condom use
South African Adolescent Project Potential Mediators

- **Abstinence prevention OE**
  Intervention: Provide accurate information regarding HIV transmission
  Assessment, e.g.: *If I have sex, I am likely to get AIDS.*

- **Abstinence career OE**
  Intervention: Discuss outcomes of sex (pregnancy, AIDS) as barriers to career development
  Assessment, e.g.: *If I do NOT have sex before I matriculate, I will be able to focus on getting a good job.*

- **Parental approval-sex**
  Intervention: Discussions with parents as homework
  Assessment, e.g., *My father would think it is okay for me to have sex in the next three months.*
Risk reduction knowledge
Intervention: Provide accurate information
Assessment e.g.: *A person can have the AIDS virus and give it to other people even if the person does not look sick.*

SE abstinence
Intervention: Practice sex refusal in role plays
Assessment, e.g.: *How sure are you that you could refuse to have sex with a person, even if you loved him?*
Cultural HIV myths
Intervention: Provide accurate information
Assessment, e.g.: *People who are jealous of you can give you AIDS by putting a curse on you.*

SE avoid risky situations
Intervention: Charting a safe course on a map with dangers lurking
Assessment, e.g.: *How sure are you that you could refuse a gift offered to you by a person that you thought might want to have sex with you?*
**South African Adolescent Health Promotion Project**

**Intervention → Mediators & NS factors**
- Abstinence prevention OE
- Abstinence career OE
- Parental approval-sex
- Risk reduction knowledge
- SE abstinence
- SE avoid risky situations
- Cultural HIV myths

**3; 6-month FU → 12-month FU**
- Sex risk Mediators

**BL Assessment → Randomization**

**Comparison → Nonspecific factors**

**3; 6-month FU → 12-month FU**
- Sex risk Mediators

OE=outcome expectancy  SE=self-efficacy
Summary: SA Adolescent Health Promotion

- For young adolescents in South Africa, parental (dis)approval of sex is important—may be an effect of parental intervention component.

- Self-efficacy for avoiding risky situations (e.g., where they may be offered goods in exchange for sex) seems to be more important than self-efficacy for abstinence generally—may be related to young age.
Seropositive Urban Men’s Intervention Trial

- Outcome paper:

- Mediation paper:
SUMIT

- CDC-funded randomized controlled trial conducted in New York City and San Francisco
- Participants were 811 HIV-seropositive ethnically diverse gay and bisexual men
- Intervention was six group sessions; control was one educational session
SUMIT Results

- Significant effect obtained for unprotected receptive anal sex
- No effect for unprotected insertive anal sex with negative or unknown serostatus partners (by far the highest transmission risk behavior)
SUMIT Potential Mediators

- Partner HIV status assumptions
  Intervention: Show photographs of infected and uninfected men and guess status
  Assessment, e.g., *I can usually tell if a guy is HIV positive without asking him.*

- Perceived peer norms
  Intervention: Norms for safer sex expressed and shared during intervention
  Assessment, e.g.: *How many of the HIV+ men you know (do the sexual behavior) with partners who are HIV-negative or whose status they do not know?*

- Condom use SE
  Intervention: Provide practice in condom use
  Assessment, e.g., *I can use a condom even if I’ve met someone I really want to like me.*
SUMIT Potential Mediators (cont.)

- OEs Hedonistic condom OEs
  Intervention: Show ways to make condoms more pleasurable
  Assessment, e.g.: *Condoms can make me lose my hard-on.*

- Anxiety and depression
  Intervention: Provide information on mental health symptoms and referrals
  Assessment, e.g.: *How often have you been bothered in the past week by feeling suddenly scared for no reason; feeling worthless.*

- Personal responsibility
  Intervention: Stress the importance of refraining from transmission risk behaviors
  Assessment, e.g.: *I feel responsible for protecting my partners from HIV.*

- Self-evaluative OEs
  Intervention: Stress the importance of refraining from transmission risk behaviors
  Assessment, e.g.: *I feel good about myself when I have safer sex.*
Seropositive Urban Men’s Intervention Trial

- **Intervention**: Mediators & NS factors
  - Ptr HIV assumptions
  - Perceived peer norms
  - Condom use SE
  - Hedonistic condom OEs
  - Anxiety
  - Depression
  - Personal responsibility
  - Self-evaluative OEs

- **Comparison**: Nonspecific factors

- **3-month FU**: Sex risk Mediators

- **6-month FU**: Sex risk Mediators

**Notes**:
- OE = outcome expectancy
- SE = self-efficacy
Change in UIAI with HIV -/? Partners (2 conditions combined)

Perceived Responsibility

Mean Change

positive responders
negative responders

Study Timepoints

3 months
6 months

Perceived Responsibility

-0.4
-0.3
-0.2
-0.1
0
0.1
0.2

3 months
6 months

Study Timepoints

Mean Change

positive responders
negative responders
Change in UIAI with HIV -/? Partners (2 conditions combined)

Self-evaluative OEs

Mean Change

Study Timepoints

3 months 6 months

positive responders

negative responders
Summary: SUMIT

- For seropositive men, holding a self-standard to protect others from infection is the most important determinant of transmission risk behavior.
- Had we succeeded in changing this through intervention, the intervention might have proven effective.
Conclusions

- Mediation analysis is an efficient and cost-effective way to obtain suggestive evidence for essential and nonessential components of interventions.
- Suggests ways to refine interventions for particular populations.
- Systematicity in data suggests socially desirable responding not cause for intervention effects.
- In the studies reviewed here, different populations appear to require different intervention components; this may prove to generalize to other behavioral domains.
Disclaimer

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.
Thank You!