

Evaluation des interventions de prévention du VIH chez les séropositifs

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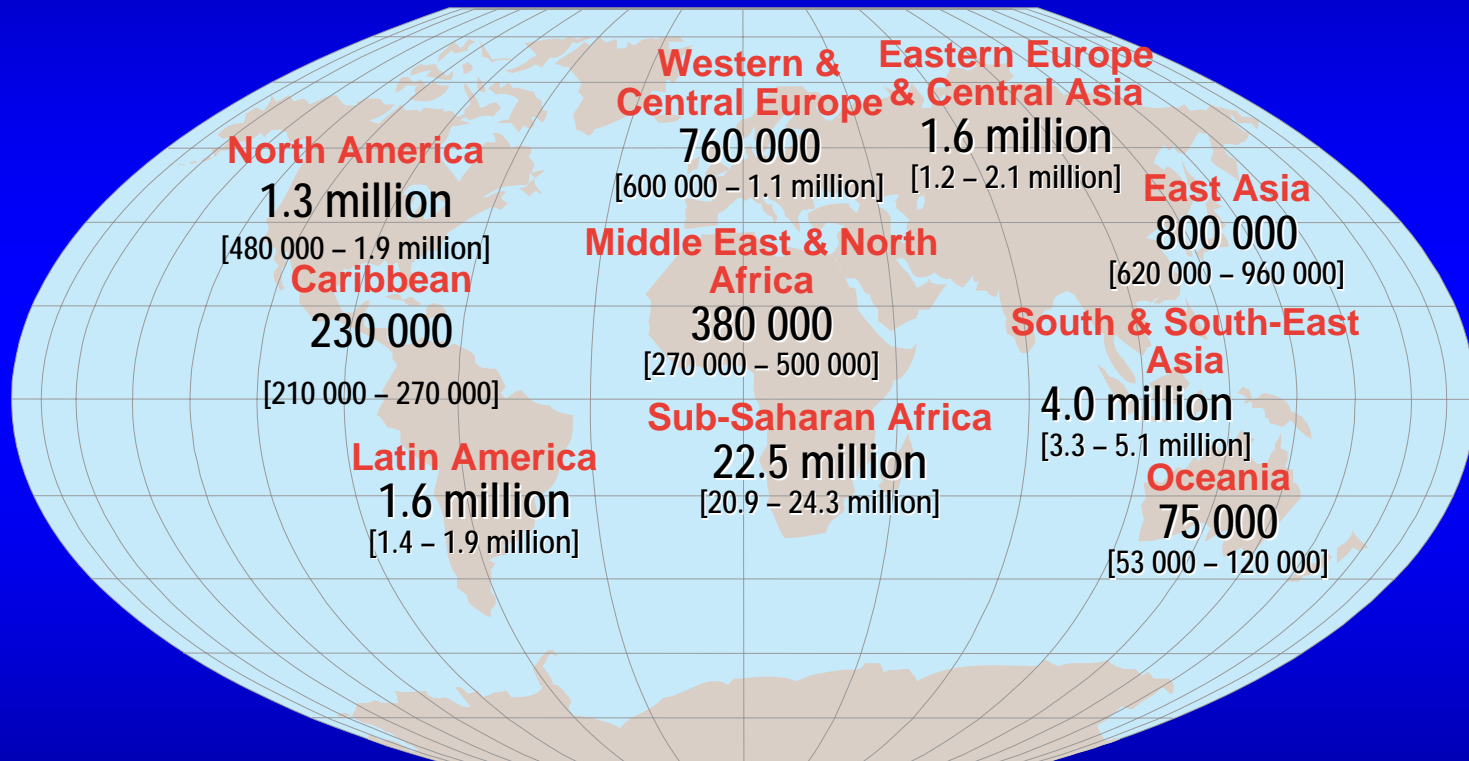
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- Over the years, I have published a number of theory- based HIV prevention interventions performed in clinics, hospitals, and in the community in the U.S. and internationally, using *experimental* and *quasi-experimental* designs.
- I would be happy to discuss any of these studies, and the methodological, practical, and theoretical challenges involved with you, or to correspond with you about them.
- Due to time constraints, my talk today will focus on a series of quasi-experimental and experimental studies I've done in the U.S. and South Africa involving **prevention for positives** interventions.
- These interventions **help seropositives to practice safer sex and drug use.**
- They are designed collaboratively by behavioral scientists, health care providers, and members of the seropositive community. They help prevent the spread of HIV to *seronegatives*, and help prevent *seropositives* from contracting other pathogens.

Adults and Children Estimated to be Living with HIV, 2007



Total: 33.2 (30.6 – 36.1) million

Source: UNAIDS/WHO, December 2007

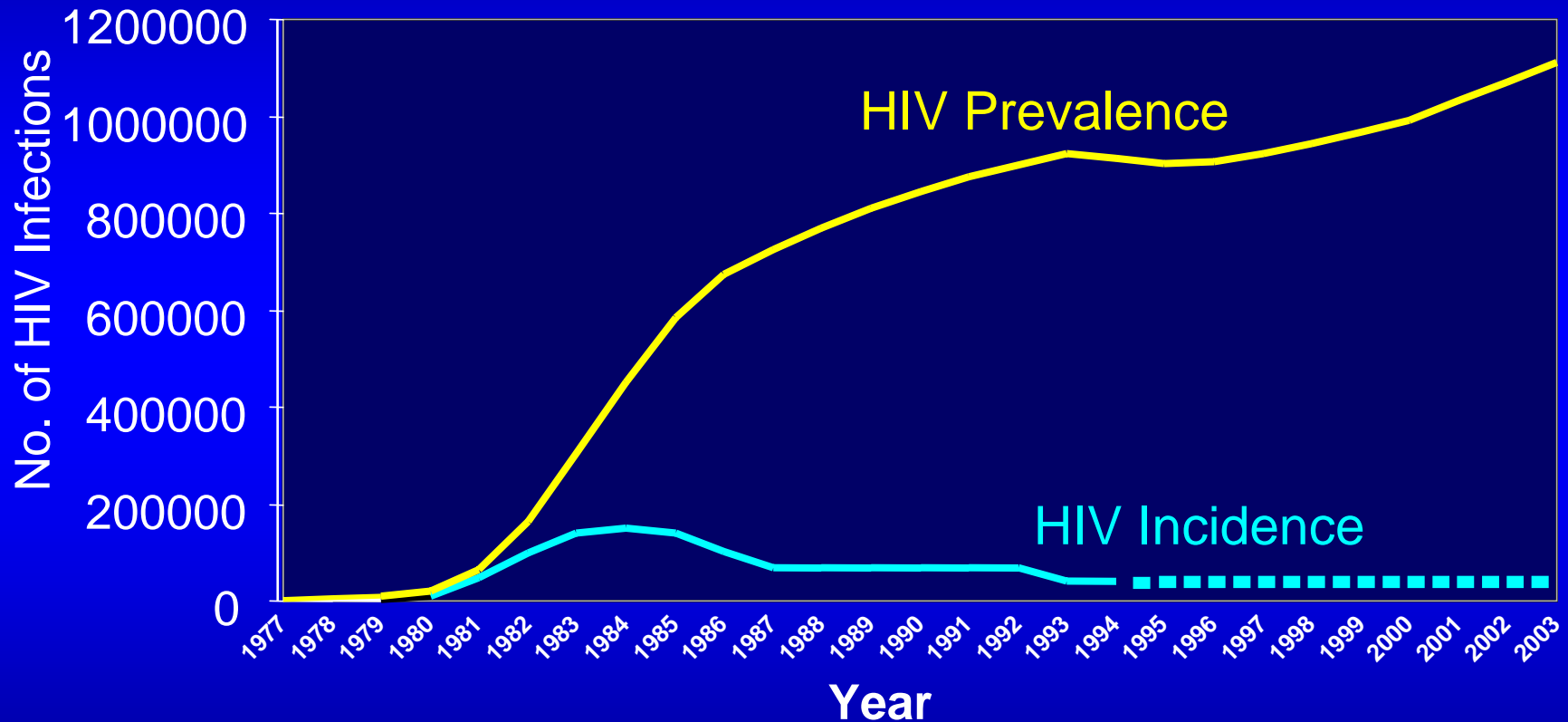
A Global Prevention “Cocktail”

- For an effective global HIV prevention portfolio, we need to consider the design of “*prevention cocktails*” that involve potent HIV prevention interventions for *seronegatives*, and potent HIV prevention interventions for *seropositives*.
- To date, worldwide, the vast majority of HIV prevention interventions have focused on *seronegatives*.

Why Prevention with Positives?

- All new HIV infections must involve an HIV seropositive individual.
- Given limited funds, it may be cost-effective to encourage HIV testing and to intervene intensively with individuals who are HIV positive.
- While most HIV seropositive individuals who know their serostatus reduce their risk levels, some do not.
- In the HAART era, prevalence rates for HIV infection will continue to climb. Prevention for positives would seem to make sense.

Estimated HIV Infection Incidence and Prevalence, by Year, 1977-2003, United States



Note: Estimates are from *Glynn et al., NHPC 2005*. Incidence based on back calculation models and seroprevalence through 1994, and estimated annual HIV incidence of 40,000 after 1994.

Using a Theory-Based Approach to Design Prevention for Positives Interventions

Weaknesses in Many Existing HIV Prevention Programs

- Many HIV prevention interventions are intuitive and atheoretical, and are *not* informed by state-of-the-art behavioral science models.
- Many interventions are not “*tailored*,” based on elicitation research, to the target population.
- Too many interventions have a *general* focus (e.g., “practice safer sex”) rather than a specific focus (e.g., “use condoms every time you have intercourse”).

(Continued)

- Too many interventions focus *only* on providing HIV prevention *information* (Information is necessary, but not sufficient, for behavior change).
- Too many interventions fail to *motivate* individuals to practice safer behavior, and fail to teach them the necessary *behavioral skills*.
- Too few HIV prevention interventions are *rigorously evaluated*.
- Very few prevention interventions that are found to be effective are *disseminated widely*.

*The Information-Motivation-
Behavioral Skills Model of HIV
Risk and Prevention*

The Information - Motivation - Behavioral Skills Model of HIV Risk and Prevention



(J. Fisher & Fisher, 1992; *Psychological Bulletin*)

**Tests of the Information--Motivation--Behavioral Skills Model with respect to Sexual Risk behavior:
(Summary of Reported Associations Among IMB Components.)**

Source	Location	Sample	Information-motivation	Information-behavioral skills	Motivation-behavioral skills	Behavioral skills-behavior	Information-behavior	Motivation-behavior	Percent variance
Anderson et al. (2006)	Urban housing developments in NY, OH, VA, WA, and WI	N=557 low income women (76% African American)			✓	✓		✓	50%
Bryan et al. (2000)	Methadone maintenance program in Hartford, CT	N=156 heroin-addicted adults receiving methadone treatment			✓		✓	✓	35%
Bryan et al. (2001)	Chennai, India	N=300 male truck drivers				✓	✓	✓	40-51% ¹
Fisher et al. (1994)	University in Storrs, CT	N=259 university students		✓	✓	✓		✓	10%
Fisher et al. (1994)	Hartford and New Haven, CT	N= 126 gay men		✓	✓	✓		✓	35%
Fisher et al. (1999)	Miami, FL	N= 87 male high school students			✓	✓		✓	75%
Fisher et al. (1999)	Miami, FL	N=61 Female high school students		✓	✓	✓			45%
Kalichman et al. (2005)	Inner-city areas of Miami-Dade County, FL	N=320 substance abusing, severely mentally ill adults	✓	✓	✓	✓		✓	not stated
Kalichman et al. (2006)	STI clinic in Cape Town, South Africa	N=191 STI clinic patients	✓			✓		✓	not stated
Robertson et al.	Juvenile detention center in a southern U.S. city	N=195 female incarcerated juvenile offenders	✓			✓		✓	not stated
Robertson et al. (2006)	Juvenile detention center in a southern U.S. city	N=328 male incarcerated juvenile offenders	✓		✓			✓	not stated

¹ Findings from Bryan et al. (2001) represent tests of relationships of information, motivation, behavioral skills with behavior, and percent of variance accounted for in condom use with wives and with commercial sex workers.

Phase I:
Elicitation Research

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graph TD; A[Phase I:  
Elicitation Research] --> B[Phase II:  
Individually Tailored IMB Intervention]; B --> C[Phase III:  
Evaluation/Outcome Research];
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Phase II:
Individually Tailored IMB Intervention

Phase III:
Evaluation/Outcome Research

Table 2. Effective Sexual Risk-Reduction Interventions Using the Information-Motivation-Behavioral Skills (IMB Model).¹

Source	Location	Sample	IMB model-based Intervention
Anderson et al. (2006)	Urban housing developments in NY, OH, VA, WA, and WI	N=557 low income women (76% African American)	Five 90-minute group workshops emphasizing HIV-related information, positive attitudes, and condom use and negotiation skills. The intervention also included community-based activities and the formation of a community-based Women's Health Council.
Avants et al. (2004)	Methadone maintenance program in New Haven, CT	N=220 Injection drug users	Twelve-session harm reduction group intervention emphasizing AIDS education, the development of a personalized risk-reduction plan, and skills development.
Belcher et al. (1998)	Low-income, inner city community in Atlanta, GA	N=74 women (95% African American)	Single-session HIV prevention intervention focusing on HIV-related education, problem solving, communication skills, self-efficacy, assertiveness training, and development of action plans.
Boyer et al. (2001)	US Marines in the Western Pacific	N=619 male US Marines	Four 2-hour interactive group sessions focusing on STI/HIV risk-related knowledge, alcohol use, and skills training.
Boyer et al. (2005)	US Marines stationed in the US and abroad	N=2,157 female US Marine recruits	Four 2-hour group sessions addressing HIV-risk-related IMB factors through didactic teaching, interactive group activities, and videos.
Carey et al. (1997)	Syracuse, NY	N=102 women (76% African American)	Four 90-minute group sessions involving motivational interviewing techniques, HIV-related knowledge enhancement, and interpersonal skills building.
Carey et al. (2000)	CBO in Syracuse, NY	N=102 women (88% African American)	Four 90-minute group sessions involving motivational interviewing techniques, HIV-related knowledge enhancement, and interpersonal skills building.
Cohen (2000)	University in Austin, TX	N=288 university students	Two-session intervention emphasizing HIV/AIDS information, condom demonstrations, and self-management techniques.
Cornman et al. (submitted for publication)	Urban HIV-care clinic in KwaZulu-Natal, South Africa	N=152 HIV+ patients on ARVs receiving clinical care	Multiple 15-minute intervention sessions delivered by counselors during routine care aimed at increasing HIV-related knowledge, changing negative attitudes, building skills, and setting goals.
Cornman et al. (2007)	Chennai, India	N=250 male truck drivers	Single-session group interactive workshop that focused on addressing information deficits, decreasing negative condom attitudes, and rehearsing condom use skills.

¹ Due to space limitations, information presented in Table 2 provides only very brief descriptions of studies and interventions. Please refer to the cited studies for complete descriptions of samples, IMB model-based interventions, and sexual risk-reduction outcomes.

Table 2. (continued)**Effective Sexual Risk-Reduction Interventions Using the Information-Motivation-Behavioral Skills (IMB Model).¹**

Source	Location	Sample	IMB model-based Intervention
Fisher et al. (1996)	University in Storrs, CT	N=744 undergraduate dormitory residents	Three 2-hour sessions involving a slide show to present HIV-related information; group discussions to enhance attitudes; and video-based and in-vivo skills training.
Fisher et al. (2002)	4 inner-city high schools in CT	N=1577 High school students	Five-session classroom-based intervention providing HIV-related information, attitudinal change videos, and video-based and hands on skills training.
Fisher et al. (2006)	2 of the largest HIV clinics in CT	N=497 HIV+ patients receiving clinical care	Multiple 5-10 minute intervention sessions delivered by clinicians during routine care addressing IMB barriers, ambivalence to behavior change, and risk-reduction goals.
Jaworski et al. (2001)	University in Syracuse, NY	N=78 female university students	Single-session intervention emphasizing STI information, advantages of risk-reduction, and skills training.
Kalichman et al. (2005)	STI Clinic in Milwaukee, WI	N=612 STI Clinic patients	Single 90-minute counseling session emphasizing HIV-related information and personal responsibility and providing personalized feedback and skill straining.
Kalichman & Cherry (1999)	STI Clinic in Atlanta, GA	N=106 male STI Clinic patients (100% African American)	Single 3-hour group-based session providing HIV-related information along with motivational and skills training (for either latex or polyurethane condoms).
Kalichman et al. (1999)	STI Clinic in Atlanta, GA	N=117 male STI Clinic patients (100% African American)	Two 3-hour video-based intervention sessions involving HIV-related information, motivational training, and skills acquisition and practice.
Kalichman et al. (1999)	STI Clinic in Atlanta, GA	N=81 female STI Clinic patients (100% African American)	Single 2.5 hour workshop emphasizing HIV-related information, female condom use and skills, and communication skills.
Kiene & Barta (2006)	University in Storrs, CT	N=157 university students	Two-session computer-based intervention emphasizing HIV-related information, advantages of using condoms, normative support, behavioral skills, and goal setting.
Margolin et al. (2003)	Methadone maintenance program in New Haven, CT	N=90 HIV+ Injection drug users	Twice-weekly, 2 hour HIV harm-reduction sessions involving skills training, cognitive remediation strategies, and behavioral games.

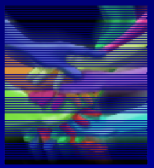
Table 2. (continued)
Effective Sexual Risk-Reduction Interventions Using the Information-Motivation-Behavioral Skills (IMB Model).¹

Source	Location	Sample	IMB model-based Intervention
Metzler et al. (2000)	Public Health STI Clinics in Oregon	N=339 adolescents	Five 60-90 minute individual counselor-participant sessions emphasizing goal setting; assertiveness training, social skills training, and behavioral self-management.
Otto-Salaj et al. (2001)	Community mental health clinics in Milwaukee, WI	N=189 men and women from outpatient programs	Seven-session small group intervention (+2 booster sessions) emphasizing HIV/AIDS risk, self-efficacy, condom use skills, and safer-sex role-plays.
Peeler (2000)	University in Pullman, WA	N=386 university students	15-session interventions (self-management and peer norm) emphasizing HIV-related information, condom use skills, role-playing, self-management skills training, and enhancement of positive peer norms.
Rosengard (1992)	University in Storrs, CT	N=701 university students	Three-session intervention emphasizing AIDS information, attitudes, social norms, and skills training.
Rotheram-Borus et al. (1998)	Social service agency in New York, NY	N=151 adolescents	Seven 1.5 hour intervention sessions emphasizing HIV knowledge, perceived risk, self-efficacy, negotiation and condom use skills, and goal setting.
St. Lawrence et al. (1995)	Southern US City	N=246 Adolescents (100% African American)	Eight 1.5-2 hour weekly group sessions emphasizing HIV-related information, values, empowerment, perceived vulnerability, and communication and condom use skills.
St. Lawrence et al. (2002)	Residential drug treatment programs in MS	N=161 substance-dependent adolescents	Twelve 90-minute group sessions emphasizing HIV risk-related knowledge, personal responsibility, condom and negotiation skills, and personal vulnerability.
Simbayi et al. (2004)	STI Clinic in Cape Town, South Africa	N=228 STI clinic patients	Single 60-minute counseling session emphasizing HIV-related knowledge, motivation and commitment to change, and behavioral self-management and communication skills.
Walter & Vaughn (1993)	High schools in New York, NY	N=1201 9 th and 11 th grade students.	Six in-class sessions emphasizing AIDS transmission and prevention information, appraisal of perceived risk, personal values, condom skills, and negotiation skills.
Weinhardt et al. (1998)	Public psychiatric hospital in upstate NY	N=22 female outpatients living with mental illness	Ten daily 75-minute treatment sessions focusing on HIV-related information, vulnerability, negotiation skills, and sexual assertiveness training.

Three Prevention for Positives Intervention Studies

- **A Quasi-Experiment in two HIV care clinics in Connecticut, USA.** (J. Fisher et al., 2004, 2006).
- **A Pilot Experiment within a single HIV care clinic in Durban, South Africa.** (D. Cornman et al., submitted for publication).
- **A Randomized Control Experimental Trial in 16 primary care clinics in and around Pietermaritzburg, South Africa.** (J. Fisher et al., in process).

These three studies have complementary strengths and weaknesses.



U.S. Quasi-Experiment

- Two *comparable hospital-based clinics* in two large cities in Connecticut, U.S.A., comprising the two largest HIV clinics in Connecticut.
- Clinics were comparable in terms of populations served, services, structure, and standard-of-care for prevention for positives.
- Patients in one clinic received the *prevention for positives* intervention; those in the other received the *standard-of-care*.
- N = 494 HIV positive patients.

Fisher, J.D., Cornman, D.H., Osborn, C.Y., Amico, K.R., Fisher, W.A., & Friedland, G.H. (2004). Clinician-initiated HIV risk reduction intervention for HIV-positive persons: formative research, acceptability, and fidelity of the Options project. *JAIDS*, 37(2), S78-S87.

Fisher, J.D., Fisher, W.A., Cornman, D.H., Amico, K.R., Bryan, A., & Friedland, G. (2006). Clinician-Initiated Intervention Delivered During Routine Clinical Care Reduces Risky Sexual Behavior of HIV+ Patients. *JAIDS*, 41(1), 44-52.



Health Care Providers

(e.g., physicians, advanced practice nurses,
physician assistants)

were chosen to perform the intervention

- Many have a trusting relationship with their patients.
- Many have repeated contacts with their patients over long periods of time.
- *But interactions between providers and patients about prevention are infrequent, and are intuitively and not theoretically-based.*

Conceptual Basis: IMB model and Motivational Interviewing

Motivational Interviewing

“The strategies of Motivational Interviewing are more persuasive than coercive, more supportive than argumentative. The clinician seeks to create a positive atmosphere that is conducive to change. The overall goal is to increase the patient’s intrinsic motivation, so that change arises from within rather than being imposed from without. When this approach is done properly, it is the patient who presents the arguments for change, rather than the clinician.”

Miller and Rollnick (1991, p. 52)

Options Protocol for *each patient visit*

- Set the *agenda* to discuss safer sex.
- *Assess risk behavior.*
- Determine how to proceed by first having patients rate the “*Importance*” of changing their risk behavior, and then their “*Confidence*” that they could change it.
- Further explore either “*Importance*” or “*Confidence.*”
- Elicit a *menu of specific strategies* from the patient for raising his or her score.
- Negotiate a *goal or action plan* with the patient.
- Give a “*behavioral prescription*” to the patient.

OPTIONS

S
E
R
V
I
C
E
S



Prevention Prescription

Date: _____

Name: _____

Plan: _____

Signature



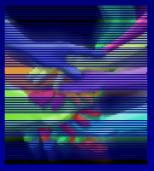
Options Project Intervention Outcomes at Eighteen Months



- Intervention efficacy for changing *sexual risk behavior* was assessed by modeling risk behavior as a function of intervention condition, time, and the interaction between condition and time.
- *Generalized Estimating Equations* (GEE) within a general linear model framework were used for the data analyses, because of both the correlated nature of the longitudinal data and its Poisson distribution (count data).



- No covariates were identified in our assessments for pre-test non-equivalence, nor did we find significant differential attrition by condition.
- Our **primary** outcome assessment evaluated intervention impact on *unprotected vaginal, anal, and insertive oral sex events* over a maximum of 4 waves of data collection.



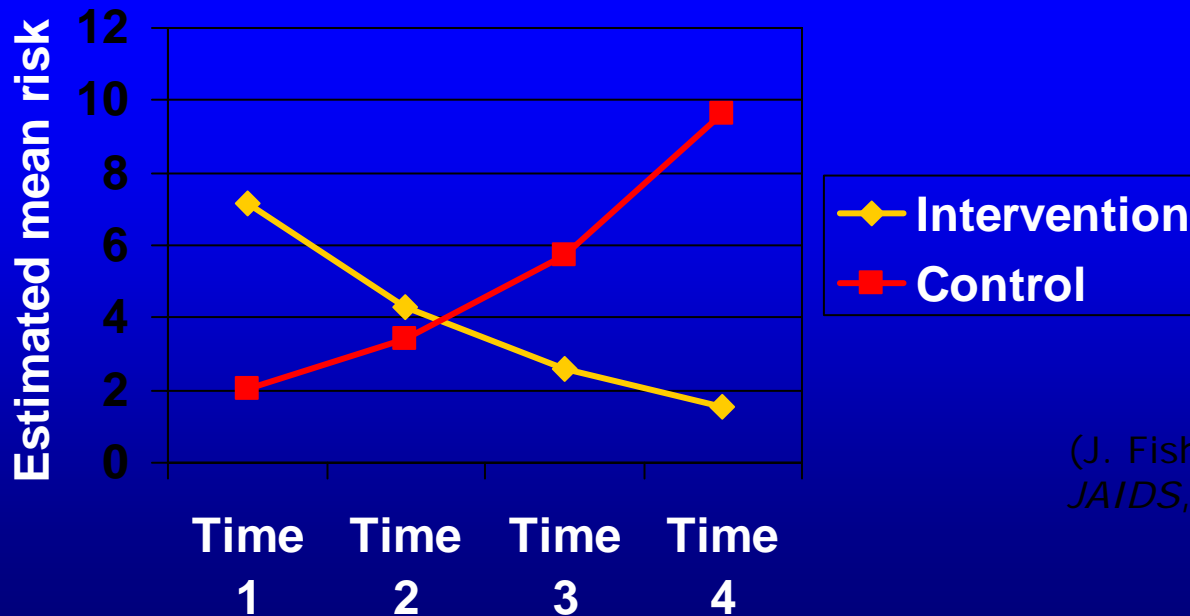
GEE Results

- For the mean of unprotected vaginal, anal, and insertive oral sex events, **THE TIME X CONDITION INTERACTION WAS SIGNIFICANT** ($b = -.51, se = .15, p < .001$).
- Risk behavior was significantly **reduced** in the intervention group ($b = -.51, se = .23, p < .05$) but significantly **increased** over time in the control group ($b = .51, se = .19, p < .01$).

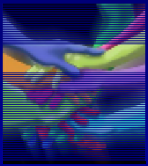
Estimated Means by Study Arm from GEE linear model

MEASURE: UNPROTECTED VAGINAL, ANAL, AND ORAL INSERTIVE SEXUAL EVENTS

Estimated (GEE) Group Means



(J. Fisher et al.,
JAIDS, 2006)



- Demonstrates that our approach to linking prevention to care for seropositives is **feasible, acceptable**, can be done with **fidelity**, and can *change risky behavior*.
- Our two-site quasi-experimental design is ideal for an *initial* study.
- Limitations: only 2 sites; reliance on self-reports; and other typical limitations of quasi- experiments.
- But our sites were representative sites; where there was nonequivalence between sites, it did not differentially affect intervention outcome.
- Crossover interaction across four waves reduces concerns about nonequivalence.

Durban Pilot Experiment



- McCords Hospital HIV Care Clinic in Durban, South Africa.
- HIV Counselors (5) were *randomly* assigned to *intervention* or *standard-of-care* control condition.
- Patients were *randomly* assigned to counselors.





Izindlela Zokuphila/Options for Health **Intervention Participants**

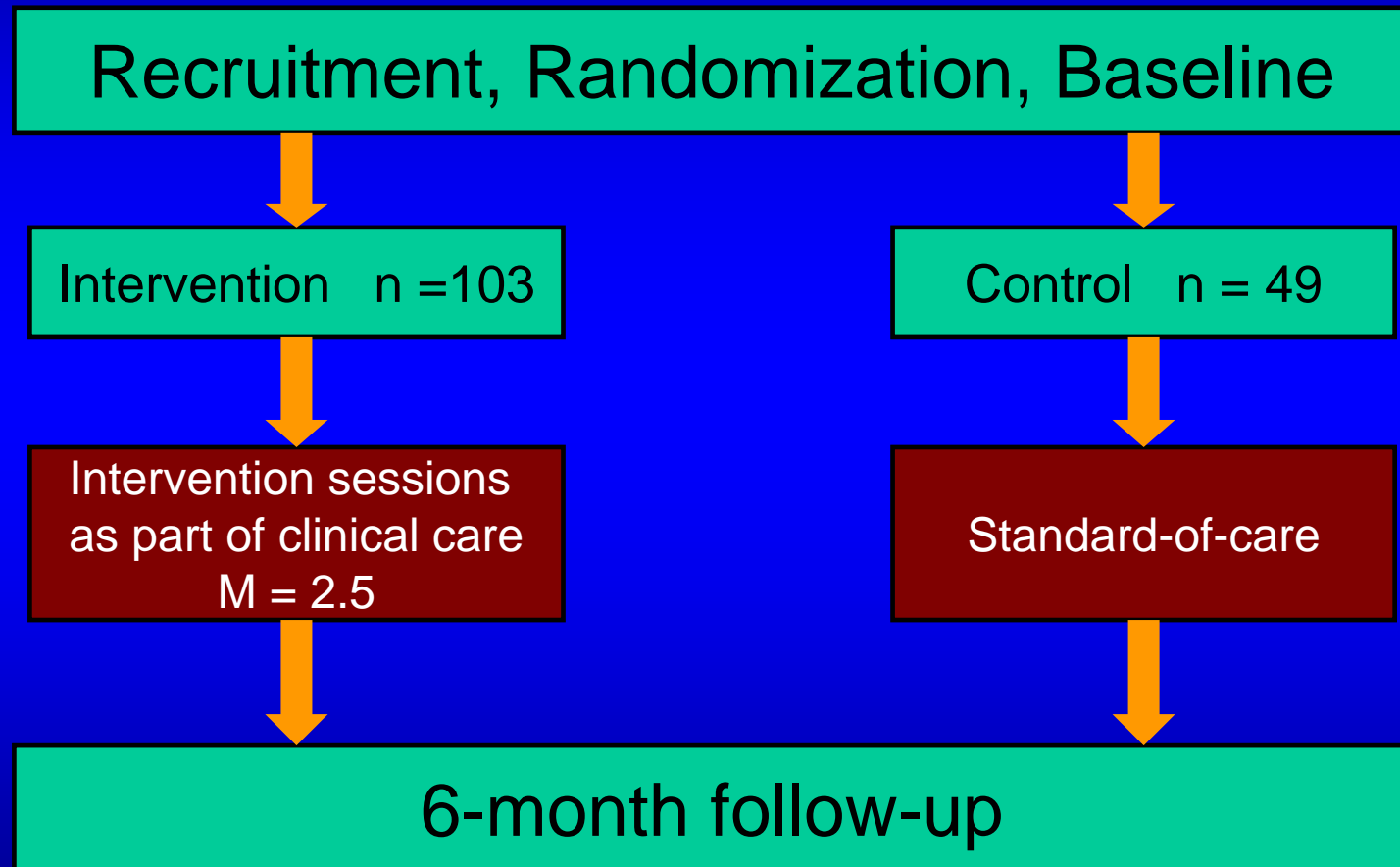
- HIV-positive patients
- N = 152 (69 males, 83 females)
- Mean age 34
- Ethnicity: 92% Zulu, 2% Indian
- 73% currently on ARVs
- 71% unemployed
- Income: 56% said they did not have enough money for food or basics





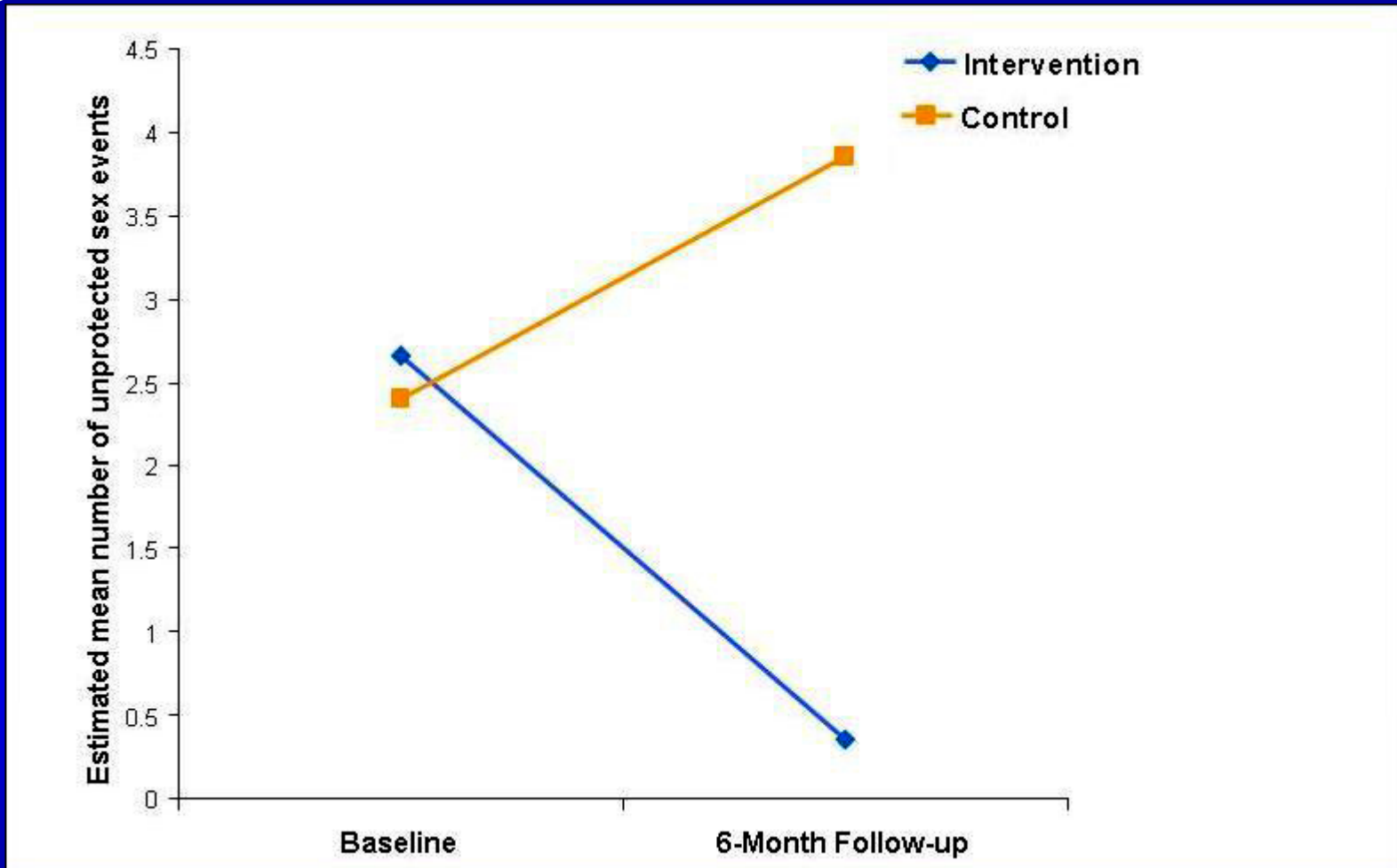
Izindlela Zokuphila/Options for Health

Intervention Methods





Time by Condition Interaction



Poisson multilevel regression change over time analyses.

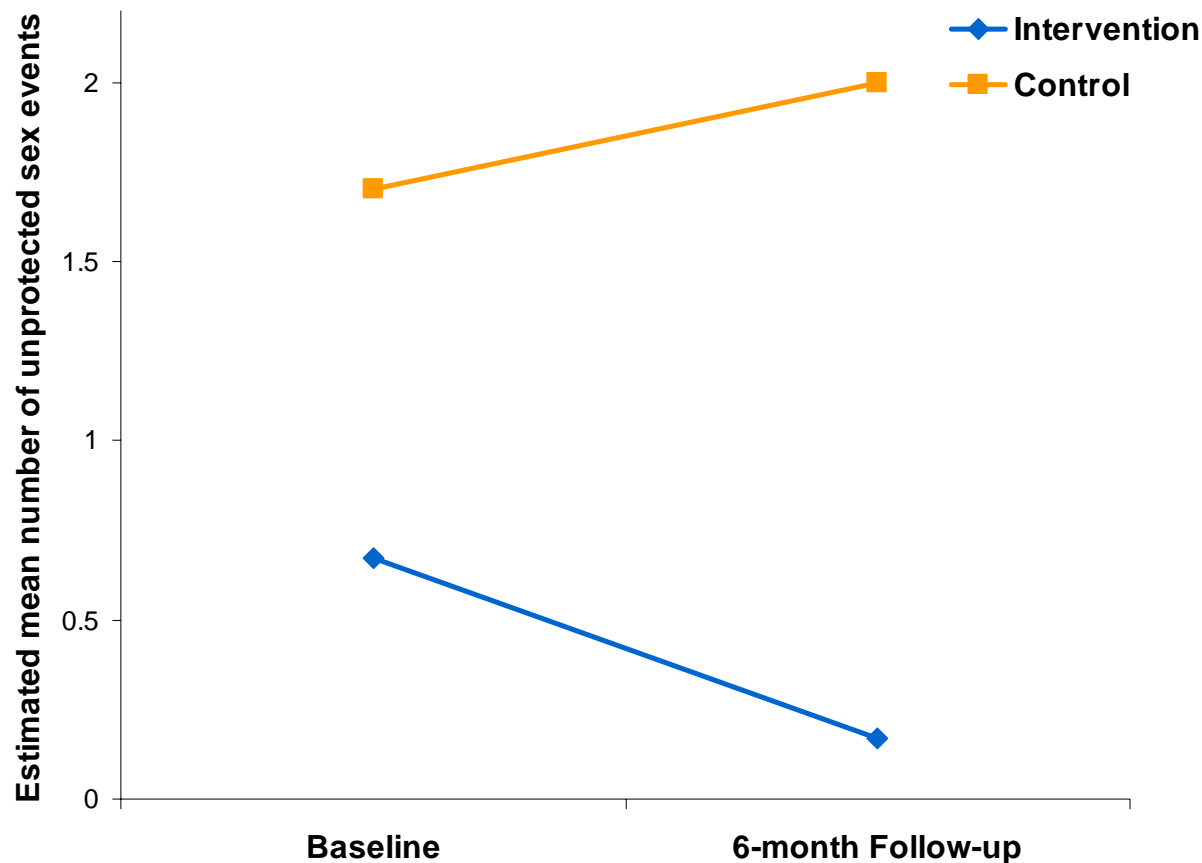
Interaction: *Event Rate Ratio* = .11 (.01 - .87)

Cornman DH, Kiene SM, Christie S, Fisher WA, Shuper PA, Pillay S, Friedland GH, Thomas CM, Lodge L, Fisher JD. Clinic-based intervention reduces unprotected sexual behavior among HIV-infected patients in KwaZulu-Natal, South Africa. (manuscript submitted for publication)



Time by Condition Interaction

With HIV-Negative & Status Unknown Partners



Poisson multilevel regression change over time analyses

Interaction: *Event Rate Ratio* = .10 (.01 - .1.0)

Cornman DH, Kiene SM, Christie S, Fisher WA, Shuper PA, Pillay S, Friedland GH, Thomas CM, Lodge L, Fisher JD. Clinic-based intervention reduces unprotected sexual behavior among HIV-infected patients in KwaZulu-Natal, South Africa. (manuscript submitted for publication)



- The South African single-site pilot study shows the potential of our prevention for positives intervention when adapted to the South African clinical care context.
- It is **acceptable, feasible**, may be implemented with **fidelity**, and can *change risky behavior*.
- Limitations:
 - Single site
 - Potential for contamination and crossover
 - Limited number of patients and counselors
 - Limited intervention dosage
 - Limited follow-up interval
 - Self-report data



Last year, we started work with our South African collaborators on a large NIMH-funded, randomized controlled trial of our Izindlela Zokuphila/Options for Health Intervention at 16 primary care sites in Pietermaritzburg, South Africa.

This research addresses many of the limitations of the previous studies:

- Large-scale RCT.
- Representative sample of clinical care sites (and counselors).
- Includes self-report and biological (STI) measures.
- Significant intervention dosage.
- Longer follow-up.

Such an extensive and expensive study probably only makes sense after the sorts of smaller scale confirmatory studies discussed earlier.

We hope to demonstrate that Izindlela-Zokuphila is a model for linking prevention with care that can be used in the context of ARV rollouts that bring seropositives into care throughout Africa.

Our Research Team



Our Research Team

- Quarraisha Abdool Karim
- Demi Adelaja
- K. Rivet Amico
- Bill Barta
- Sarah Christie
- Richard Colon
- Deborah Cornman
- Rebecca Ferrer
- Jeffrey D. Fisher
- William Fisher
- Gerald Friedland
- Timothy Gorin
- Zandile Jojo
- Susan Kiene
- Umesh Laloo
- Anthony Lemieux
- Sue MacDonald
- Gethwana Mahlase
- Morris Ndlovu
- Wynne Norton
- Sandy Pillay
- Caroline Redding
- Lindsay Shepherd
- Paul Shuper
- Laramie Smith
- Cindy Trayling
- Lindiwe Xulu

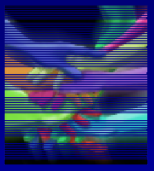
“South Africa has faced extraordinary challenges before, and it has prevailed. Now we must face our greatest challenge – protecting the next generation from AIDS. This will take no less than a new social revolution – one that will break the powerful stigma of AIDS so we can seek help without fear; one that will change the way we think about sex and behave so we can save our lives; one that will support government’s treatment plan to provide life-saving treatment for all who need it. The challenge is to see AIDS as a crisis that requires our combined attention and efforts.”

--- Nelson Mandela



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Pre-Intervention Injection Drug Use Across Sites

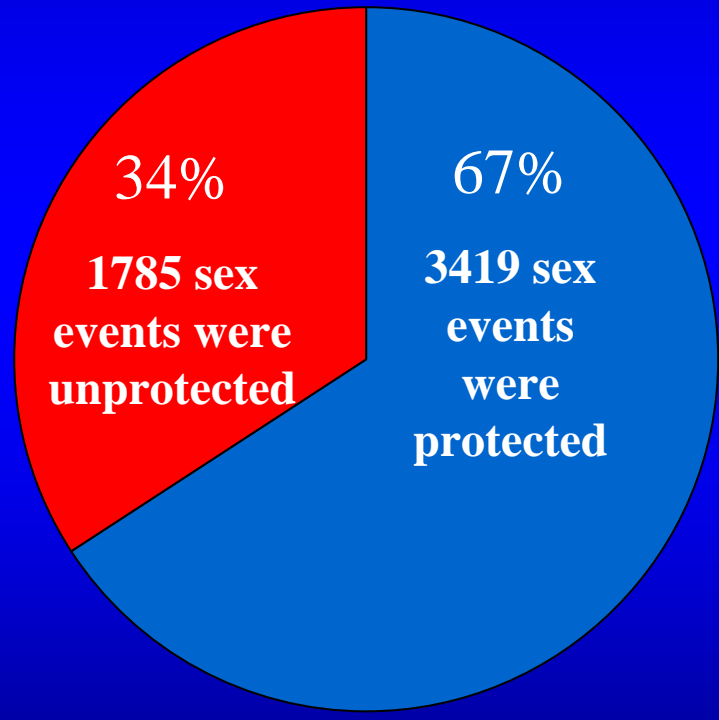
- About 60% of participants who were questioned reported *ever* having used injection drugs, while 32% reported injection drug use *in the past month*.
- Of those who used injection drugs in the past month, 38% borrowed or lent uncleaned works or needles during this interval.
- On the other hand, 64% of those who had ever used injection drugs had been in recovery for a year or more.

Sexual Events in the Preceding Three Months Across Sites (N=490 participants)

- 49% (240) of the entire, HIV+ sample reported engaging in a vaginal and/or anal sexual event in the preceding three months.
- 40% (95) of these individuals reported some degree of risk (*events with no condom use*) during one or more of these events.

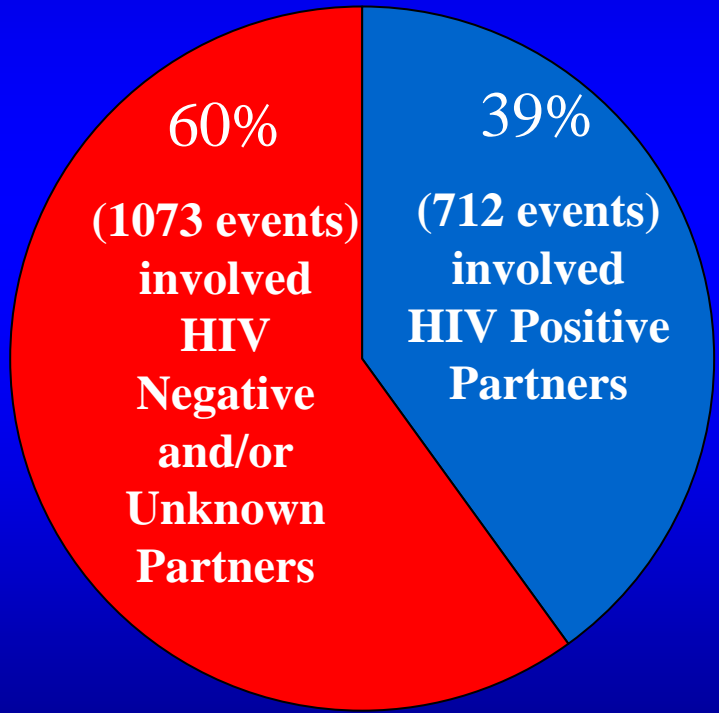


In the preceding three months, 240 participants engaged in 5204 Vaginal and/or Anal Sex events





Of the 1785 unprotected sex events reported by the 95 participants reporting risky sexual behaviors:





Potential Partners Exposed to HIV

In the past three months, participants engaged in risky vaginal and/or anal sex with a *minimum* of 199 partners of negative or unknown HIV status.

