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## HIV/Sexually Transmitted Disease Risk Reduction: Strategies for Enhancing the Utility of Behavioral and Biological Outcome Measures for African American Couples

The NIMH Multisite HIV/STD Prevention Trial for African American Couples Study Group

### Abstract

**Objective**—Numerous studies have discussed the value of including biological outcome measures as a complement to behavioral outcome measures to assess the efficacy of HIV risk-reduction interventions. This article highlights strategies used to minimize the limitations of including both self-reported sexual behaviors and biologically confirmed sexually transmitted diseases as primary outcome measures in an HIV/sexually transmitted disease (STD) prevention program for African American serodiscordant couples (EBAN).

**Design**—Couples receiving an HIV intervention condition (EBAN) were compared with couples receiving a time-equivalent General Health Promotion condition on behavioral and biological outcomes. Both behavioral and biological data were collected at baseline, immediately postintervention, and at 6 and 12 months postintervention.

**Methods**—Literature reviews, consulting other researchers who conducted couples studies, our investigative team's experience in previous HIV interventions, and formative work were used to develop procedures to minimize potential limitations associated with the inclusion of behavioral and biological outcome measures for EBAN.

**Results**—Given the strengths of including behavioral and biological outcome measures, the EBAN study chose to have both measures serve as primary outcomes. The primary behavioral outcome for the trial is the proportion of protected vaginal and anal intercourse episodes that occurred within the index couple in 90 days before each follow-up assessment and over the 12-month postintervention follow-up period. The primary biological outcome is the proportion of participants (male or female study partners) with an incident STD (chlamydia, gonorrhea, or trichomoniasis) over the 12-month postintervention follow-up period.

**Conclusions**—Employing procedures to minimize limitations of using self-reported sexual behaviors and STDs as complementary primary outcomes enhances their utility as measures of the efficacy of HIV/STD prevention interventions.

### INTRODUCTION

People living with HIV are now living longer and more sexually active lives.<sup>1</sup> Many individuals who test positive for HIV reduce or eliminate behaviors that can transmit HIV to others.<sup>2,3</sup> However, these reductions are not absolute because individuals who reduce HIV risk behaviors may not maintain these practices for a lifetime. Several studies have demonstrated that approximately one-third of persons diagnosed with HIV infection may continue to engage in sexual practices.<sup>4</sup> These behaviors place their HIV-negative sexual partners at risk of disease acquisition and themselves and other HIV-positive sexual partners at risk for exposure to infection with a different strain of HIV. Decreasing the number of unprotected sexual acts between individuals living with HIV and persons of unknown or HIV-negative status is the most targeted method of reducing sexual transmission of HIV.<sup>5</sup> Therefore, evaluating the

impact of a behavioral intervention for HIV-serodiscordant couples requires measuring sexual risk behaviors targeted by the intervention.

Historically, HIV prevention interventions have relied almost exclusively on individuals' self-reported behavior change to assess intervention efficacy.<sup>6</sup> Typical self-reported behaviors that have served as the cornerstone of assessing intervention efficacy include frequency of condom use, number of different sexual partners, or frequency of drug use when engaging in sexual behavior.<sup>6</sup> EBAN trial investigators believe that using a measure of self-reported sexual behavior is crucial because it is the most frequently used behavioral outcome in HIV prevention trials. Additionally, the study assessed a set of theoretically derived mediating variables through which change in self-reported risky sexual behaviors is hypothesized to occur. However, for numerous reasons, trial investigators were cautious about relying entirely on the measurement of self-reported sexual behaviors to assess programmatic efficacy. First, several observational studies exploring the relationship between behavioral and biomedical outcomes have failed to show a strong relationship between individuals' risk behaviors and sexually transmitted disease (STD) acquisition.<sup>7</sup> Additionally, some HIV interventions have not observed a strong relationship between individuals' sexual behaviors and STD acquisition.<sup>8</sup> Furthermore, there is ample empirical evidence suggesting that self-report of sexual behavior may be subject to potential reporting biases, such as inaccurate recall bias (encoding, distortion, retrieval, and reconstruction)<sup>9-11</sup> and social desirability bias.<sup>12-13</sup>

Over the past several decades, improvements in the formatting and framing of sexual behavior questions have enhanced the validity of self-reported sexual behaviors. Research shows that estimates of sexual behavior are more likely to be valid if surveys enquire about behaviors that occur during shorter recall periods.<sup>11,13</sup> Use of cues, such as activities and important events, have also been beneficial.<sup>9,14,15</sup> Additionally, the advent of audio computer-assisted self-interviewing (ACASI) has reduced barriers to literacy, minimized social desirability bias, and has been shown to yield higher rates of self-reported sexual behaviors than interviewer-administered or self-administered surveys.<sup>13,16</sup> Even with these advances, assessment of sexually transmitted infections (STIs) has been advocated as a complementary measure for evaluating programmatic efficacy.<sup>17,18</sup>

Historically, the primary drawback of using biological markers, such as STDs, was the logistics of data collection. Data collection was typically feasible only in a clinical environment, such as a doctor's office or an STD treatment center, and often required trained clinicians utilizing invasive procedures. Recently, however, major developments have been made in STD diagnostic procedures, in particular the introduction of DNA amplification assays that have high sensitivity and specificity. With the availability of these DNA amplification techniques that can identify bacterial STDs in urine specimens, in particular prevalent STDs such as chlamydia and gonorrhea, it is now possible to detect STDs in a noninvasive manner in a broad range of nonclinical settings.<sup>19-24</sup> The development of this diagnostic technology paved the way for greater utilization of STDs as a clinical end point in evaluating HIV prevention interventions.

Furthermore, including STIs as an end point in HIV prevention trials recognizes the impact of STD on HIV transmission. Specifically, HIV-positive persons with an STD may be more likely to transmit HIV to others due to the effects of the STD on HIV infectivity, such as increased shedding of HIV. Furthermore, HIV-negative persons with an STD may be more susceptible to a subsequent exposure to HIV because the STD may compromise the mucosal or cutaneous surfaces of the genital tract that normally act as a barrier against HIV.<sup>25</sup>

The use of biological end points, while representing an objective and quantifiable marker of high-risk sexual behavior, is not without controversy nor is it a panacea for avoiding bias

associated with self-report. It is important to recognize that reliance on incident STDs as a measure of program efficacy may not be an appropriate outcome for every study. It is unlikely, for instance, that the incidence of STDs will be changed in a short-term study conducted in a population with little sexual activity or in a community with a low prevalence of STDs.<sup>26</sup> Conversely, populations with a high degree of sexual activity and a high prevalence of STDs are ideal for studying the effects of behavioral interventions on STD incidence. Moreover, studies incorporating biological markers as the primary outcome measure need to be conducted with samples that are sufficiently large and a follow-up of sufficient duration to provide adequate statistical power to detect differences in STD incidence.<sup>26</sup>

A review of randomized controlled trials of individual-level, population-level, and multilevel interventions for preventing STIs identified 41 trials that met inclusion criteria and used STD outcomes as objective measures of intervention efficacy.<sup>27</sup> Among individual- and group-level interventions, 32 targeted acquisition, 4 targeted transmission, and 1 targeted complications of STIs. The most common intervention modality used was behavioral interventions; 11 of the 41 of the interventions were designed to reduce high-risk sexual practices. Notably, few of the studies in this review have been conducted among HIV-positive individuals.<sup>27</sup> One trial was efficacious in reducing STDs among individuals living with HIV<sup>28</sup> and another trial reported a reduction in STD symptoms in couples.<sup>29</sup> There have not been any published HIV prevention trials conducted among African American serodiscordant couples using biological outcome markers as measures of efficacy. The EBAN trial investigators sought to use a primary biological outcome measure to complement the use of a behavioral outcome measure to assess intervention efficacy given the moderate degree of risky sexual behaviors,<sup>4</sup> and STDs,<sup>30</sup> among individuals living with HIV; the experience of the EBAN trial investigators in using STDs to assess HIV intervention efficacy<sup>28,31</sup>; the 12-month follow-up period to assess incident STD acquisition; the large study sample of African American couples (N = 536 couples); and the public health significance of reducing STD acquisition among African American HIV-serodiscordant couples.<sup>32</sup>

This article describes approaches used to minimize limitations in using self-reported sexual behavior and objective STD data as primary outcomes in an HIV/STD prevention program for African American serodiscordant couples (EBAN).

### Data Collection

In this 2-armed randomized controlled trial, data collection for the primary behavioral outcome and the primary biological outcome was generated from 3 data sources over 4 assessment points. Specifically, data were collected from participants at the baseline, the immediate postintervention assessment, and the 6- and 12-month follow-up assessments. Urine and vaginal swabs were used to identify 3 STDs. ACASI was administered to assess the primary behavioral outcome, and the administration of ACASI in this trial is discussed in greater detail in the article *Designing an Audio Computer Assisted Self Interview (ACASI) System in a Multisite Trial: A Brief Report*. Table 1 provides a description of the data collection modalities used in this trial.

### DEFINING THE PRIMARY BEHAVIORAL OUTCOME

A number of indices are typically used as the primary behavioral outcome; however, proportion of protected intercourse episodes is one of the most commonly used measures to assess outcome efficacy in HIV prevention trials. Therefore, to facilitate comparability to other studies of HIV prevention, this definition of the primary behavioral outcome was adopted in this trial. Specifically, the primary behavioral outcome is defined as “the proportion of vaginal and anal intercourse episodes that occurred within the index couple that were protected in the past 90 days and over the 12-month postintervention follow-up period. Protection is defined as the

number of times that either a male condom or a female condom was used by the index couple divided by the number of times the index couple had vaginal or anal sex in the prior 90 days and over the 12-month postintervention follow-up period.”

### **Enhancing the Validity and Reliability of Self-Reported Sexual Behavior Data in Couples**

Given the trial’s primary behavioral outcome, couples’ self-reports of sexual behavior must be assessed. In using self-report measures, there are 2 psychometric properties that are important: (1) reliability—which indicates that the results are consistent and not random—and (2) validity—which indicates that the investigator and the respondent understand the meaning of the question in the same way. Findings from several studies indicate that there is a fair to good concordance for whether a couple has ever used a condom among HIV-discordant couples.<sup>31-32</sup> Reports of less frequently occurring behaviors (eg, oral sex) within a couple are less consistently recalled.<sup>32</sup> The validity and reliability of sexual behavior in couples’ sexual behavior may be influenced by many variables, including (1) the cultural and gender mores of the social group to which the couple belongs, (2) the manner in which information on sexual behavior is obtained, (3) the level of social desirability bias, (4) the couple’s memory or recall of their sexual practices, and (5) the prevalence of condom-use errors. The trial sought to address each of these 5 challenges to enhance the validity and reliability of the primary behavioral outcome measure.

### **Emphasizing Cultural Congruence and Gender Sensitivity in the Assessment Procedures**

Unfortunately, the legacy of failing to provide informed consent with African Americans has had negative ramifications for many African Americans involved in research studies.<sup>35</sup> To enhance the willingness of couples to provide valid and reliable information about their sexual behavior, participants were assured of the confidentiality of their data as part of the informed consent. After providing informed consent, a male research assistant escorted all male study participants to a private room in which the ACASI, beverages, and African American art or other ethnic crafts were displayed. Likewise, an African American female research assistant escorted all female study participants to a separate private room that contained similar materials present in the room for men. The aim of these procedures was to create a culturally attractive and comfortable setting for participants. Additionally, the trial investigators sought to enhance participants’ confidence in the researchers and study staff’s gender sensitivity and cultural competency.

### **Administering ACASI**

The advent of ACASI has reduced barriers to literacy, minimized social desirability bias, and has been shown to yield higher rates of reporting risky sexual behaviors than interviewer-administered or self-administered surveys.<sup>13,16</sup> However, ACASI had not previously been used with African American couples. Therefore, before implementing the trial we piloted the ACASI with 32 couples to assess the feasibility and reliability of using ACASI to administer the study interview (see article on ACASI as part of this issue). Additionally, to enhance the reliability and validity of self-reported sexual behaviors the EBAN trial used the following procedures: (1) defined the terms vaginal, anal, and oral sex, so participants would not have to translate the meaning of these more technical terms into more commonly used nomenclature for sexual practices, (2) clarified what was meant by the number of times a person has sex (if a person had sex more than one time in a given day we would count each time they had sex as an episode), (3) added the word “about” when asking participants how many times they engaged in specific sexual behavior to reduce extrapolating to thinking about every episode of sex, (4) added a pop-up screen on the ACASI that indicated the number of times a person has sex, (5) programmed the ACASI so that it would not proceed if the number of times a participant used condoms is greater than the number of times they reported sex, (6) provided clear

instructions informing participants that the time frame for reporting their sexual behaviors changed, (7) used instruments that have established reliability and validity with African Americans, and (8) whenever possible, used complete scales rather than partial measures to assess a study construct.

### **Minimizing Social Desirability Bias**

To minimize socially desirable responses, a motivational statement at the introduction of the ACASI sexual behavior section appealed to participants' sense of altruism and indicated that the results of this study would be important for the African American community. Additionally, a social desirability scale<sup>36</sup> was embedded in the ACASI to assess social desirability tendency. Finally, the training of assessment staff discussed methods for enhancing validity of self-reported sexual behaviors, and staff were trained to be warm and nonjudgmental toward study participants and to encourage candid responding.

### **Enhancing Recall**

Couples' self-reported sexual practices may be inaccurate because of lack of recall.<sup>37</sup> Responses may unintentionally be inaccurate due to the difficulty of remembering when particular behaviors occurred. Increased bias of sexual behavior has been attributed to longer periods of recall between the interview and the sexual activity under question.<sup>38</sup> Very recent recall periods (ie, in the past 2 weeks or the past month) allow for less recall bias but may not capture infrequent sexual events. Therefore, to enhance recall of our primary behavioral outcome and other sexual behaviors assessed, the EBAN trial (1) used the Timeline Followback method, which incorporates the use of recall-enhancing techniques, such as calendars for a specific recall period (90-day calendar), to provide visual cues to aid in retrospective recall of sexual behaviors<sup>13</sup>; (2) assessed sexual behaviors at 4 time periods (past 90 days, past 30 days, typical week, and at last sexual intercourse); and (3) provided the dates corresponding to the 90-day and 30-day recall interval on the ACASI screen.<sup>13,37</sup>

### **Assessing Condom-Use Errors**

Although sexual behavior may be accurately recalled, there may still be concerns regarding correct condom use.<sup>37,40</sup> Self-reports of condom use vary considerably in quality and level of detail due to a lack of understanding of the term "use."<sup>41</sup> A couple may indeed have used a condom but did not use it consistently or correctly, thereby negating its protective effects. Typical condom-use errors include failure due to slippage, placing the condom on the penis after initiation of sex, removing the condom before the end of the sexual episode, and placing the incorrect side of the condom on the penis and needing to take it off, invert it, and re-place it on the penis.<sup>42-45</sup> In each of these cases, study participants may have recalled that they used a condom, but attributable to condom-use errors, it may not be protective against STDs. Research has shown that condom-use error is associated with increased STDs.<sup>44,46</sup> In addition to condom user errors, as described above, another problematic concern is condom failure or the frequency of condom breakage. However, to minimize threats to internal validity, the trial assessed the frequency of condom breakage and slippage for males and the ability of participants to correctly apply condoms.

## **DEFINING THE PRIMARY BIOLOGICAL OUTCOME**

The primary biological outcome is the proportion of participants (male study partners or female study partners) with an incident STD (chlamydia, gonorrhea, and trichomoniasis) over the 12-month postintervention follow-up period. The EBAN trial investigators sought to address several factors that are crucial in using STDs as indicators of intervention efficacy. Specifically, these factors included (1) choosing a quality referral laboratory, (2) selecting appropriate STDs to comprise the primary outcome, (3) ensuring successful STD treatment at baseline, and (4)

addressing components of STD transmission dynamics in the study design. These are discussed below.

### Choosing a Quality Referral Laboratory

To reduce the potential for variances in STD results and to meet the criteria of a quality referral laboratory,<sup>47,49</sup> the EBAN trial investigators decided to use a single laboratory, the Emory University Department of Microbiology and Immunology laboratory, as the referral laboratory for the STD testing and analysis. This laboratory functioned under a uniform set of organized, comprehensive guidelines for diagnostic testing. A comprehensive manual outlining standardized procedures for specimen collection, handling, preparation, shipment, testing, and reporting was created for the trial and maintained by the laboratory staff and the trial investigators. Additionally, quality assurance measures such as staff training, specimen confirmatory testing, and inter-laboratory specimen testing were performed on a regular basis.

### Selecting Appropriate STDs to Comprise the Primary Outcome

Including STDs as a primary outcome is more useful when the STDs are prevalent in the target population. In the EBAN trial, STDs were selected that were among the most prevalent among African American HIV-serodiscordant couples at each site and which could be easily treated to ascertain incident infections acquired over the follow-up period. Scant research has examined STD prevalence among HIV-serodiscordant couples in the United States. However, prior research by EBAN trial investigators indicated that nearly 20% of African American HIV-positive women had a prevalent infection with chlamydia, gonorrhea, or trichomonas.<sup>28</sup> Thus, in the EBAN trial, acquiring an incident nonviral STI was the primary outcome, this outcome was defined as a laboratory-confirmed test for a new chlamydia, gonorrhea, or trichomonas infection, at either the 6- or the 12-month follow-up assessment. Specimens for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* were assessed using the Becton Dickinson ProbeTec ET Amplified DNA Assay (Becton, Dickinson and Company, Sparks, MD) and *Trichomonas vaginalis* was assessed using Taq-Man polymerase chain reaction.<sup>50</sup>

### Ensuring Successful STD Treatment of the Couple at Baseline

The goal of many HIV prevention trials that use STDs as their primary biological outcome is to determine the efficacy of the intervention in reducing incident STDs.<sup>25</sup> This is often accomplished by testing participants at baseline for prevalent curable STDs (ie, chlamydia, gonorrhea, or trichomoniasis) and treating participants who test positive for an STD. Categorizing the participant as STD-negative at baseline is critical in HIV prevention trials as it allows for STDs that are acquired during the follow-up period to be correctly classified as incident STDs. Therefore, ensuring successful STD treatment at baseline is crucial. Participants testing positive for an STD were treated with directly observable single oral dose therapy. If one member of the couple tested positive for any of the study STDs assessed, the infected partner was notified and scheduled for an appointment for treatment. Participants testing STD positive received standard of care preventive counseling as per CDC guidelines regardless of their HIV status. These practices were conducted to ensure that both members of the couple were negative for the STDs assessed in the study at baseline.

### Incorporating an Understanding of STD Transmission Dynamics in the Study Design

It is important to recognize at least 3 distinct components of STD transmission dynamics, including the transmissibility of infection upon exposure between an infected and an uninfected person, the likelihood of sexual exposure between infected and uninfected individuals, and the duration of infection among infected individuals.<sup>5,51</sup> This concept is highlighted in Anderson and May's equation  $R_0 = \beta CD$ , where  $R_0$  is the rate of spread in a population,  $\beta$  is the

transmission probability,  $C$  is the average contact rate, and  $D$  is the average duration of infectiousness.

Consistent with this understanding of STD dynamics, the EBAN trial STD preventive counseling and treatment procedures emphasized several points. First, the counseling addressed the importance of reducing behaviors related to transmission of infection between the HIV-infected and the uninfected partner, including abstaining from sex until the completion of STD therapy. Additionally, given the importance of duration of infection or infectiousness, having partners receive timely STD treatment was a priority for the trial. Conducting a couples-level HIV intervention afforded the EBAN investigators a unique opportunity to provide timely STD treatment to both members of the sexual dyad. This STD treatment strategy is not often feasible in individual-level HIV interventions. Strategies aimed at enhancing partner STD treatment are outlined in Table 2. These strategies were developed by a multidisciplinary team composed of infectious disease physicians, infectious disease nurses, public health professionals, and social science researchers from the 4 study sites.

Over the past few years, an increasing number of HIV prevention studies have addressed the relationship between behavioral and biomedical outcomes of STD transmission. However, one of the most novel aspects of the EBAN trial was the investigators' ability to address these critical issues of STD transmission dynamics among African American serodiscordant couples.

## CONCLUSIONS

The EBAN trial is one of the largest randomized controlled trials of a behavioral intervention to reduce the risk of HIV among African American serodiscordant couples. Among the highlights of the assessment procedures developed for this study are the use of 2 complementary primary outcome measures (behavioral and biological) to assess trial efficacy. Additionally, this trial employed multiple strategies to minimize potential threats to reliability and validity of the primary behavioral outcome measure. Moreover, this trial employed numerous strategies to minimize challenges in enhancing timely STD treatment in couples.

Behavioral outcomes provide useful data regarding the immediate target for the behavioral intervention and are useful in low STD/HIV prevalence populations. However, there is not always a high correspondence between engagement in risky sexual behaviors and acquisition of incident STDs.<sup>7</sup> Moreover, self-reported sexual behaviors are subject to numerous biases.<sup>9–13</sup> Conversely, biological outcomes provide a direct impact of the intervention on STD incidence and can also provide important policy information for assessing the cost-effectiveness of the intervention in preventing STDs among HIV-serodiscordant couples. The trial investigators advocate the collection of both behavioral and biological end points when assessing HIV intervention efficacy. Although this strategy may be more costly, timely, and complex, it provides a more complete assessment of the impact of an intervention. However, to reap the benefits of using behavioral and biological outcomes of HIV intervention efficacy, procedures are required to address the limitations of each measure. EBAN trial investigators sought to enhance the rigor of the study measures by developing such procedures and practices.

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**Table 1**

Modes of Data Collection for the Primary Behavioral and Biological Outcome

Data Sources	Purpose of Data Collection	Time Point of Data Collection	Who Oversees Data Collection
ACASI	Assess self-reported primary behavioral outcome, mediators, and several moderators	(1) Baseline	ACASI assistant
		(2) Immediate posttest	
		(3) 6-month follow-up	
		(4) 12-month follow-up	
Vaginal swab specimen	Assess STD status in females	(1) Baseline	Clinical research coordinator
		(2) Immediate posttest	
		(3) 6-month follow-up	
		(4) 12-month follow-up	
Urine specimen	Assess STD status in males	(1) Baseline	Clinical research coordinator
		(2) Immediate posttest	
		(3) 6-month follow-up	
		(4) 12-month follow-up	

**Table 2**

## Timing of STD Treatment to Prevent STD Reinfection

Scenario	Partner 1	Partner 2	Timing of STD Treatment to Prevent Reinfection
A	Tests positive for an STD	Tests positive for same STDs as partner 1	Treat partner 1 and partner 2 together at time 1
		Tests STD negative but requests treatment	
B	Tests positive for an STD	Tests negative for all STDs <i>and</i> reports being sexually abstinent since initial STD testing	Treat partner 1 at time 1 and partner 2 does not need treatment
		Both partners self-report having protected sex	
C	Tests positive for an STD	Tests positive for same STDs as partner 1 and the partners do not present together for treatment	Treat partner 1 at time 1 and treat partner 2 within 24 hours of partner 1; or treat both partners together at time 2
		Tests STD negative but requests treatment	
D	Tests positive for an STD	Tests STD negative but requests STD treatment	Treat partner 1 at time 1 and partner 2 treated at time 2 (>24 hours after partner 1)
		Reports being sexually abstinent since initial STD testing	
		Both partners self-report having protected sex	