

FOCUS ON THE FUTURE

A brief, single-session intervention with
young African American males
who have sex with women,
who report symptoms of an STD and/or
have been diagnosed with an STD



Starter Kit



2012

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CAI grants permission to the CDC to maintain the intervention's geographic relevance and accuracy over time. All portions of the publication and materials related may be amended from the 2012 version packaged by CAI as determined by the CDC.

Important Information for Users

This HIV/STD risk-reduction intervention is intended for use with persons who are at high risk for acquiring or transmitting HIV/STD and who are voluntarily participating in the intervention. The materials in this intervention package are not intended for general audiences.

The intervention package includes the Starter Kit, the Implementation Manual with Facilitator's Guide and Staff Presentation, the Technical Assistance Guide, the Training of Facilitators Curriculum with accompanying Participant Handbook and Training Presentation, the Fact Sheet, marketing brochures, promotional posters, information cards, branded ditty bags, and training DVD.

Before conducting this intervention in your community, all materials must be approved by your community HIV review panel for acceptability in your project area. Once approved, the intervention package materials are to be used by trained facilitators when implementing the intervention.

How to Use this Starter Kit

The **Focus on the Future** Starter Kit was developed as a resource for agencies that wish to learn more about the intervention. The information in this document provides an overview of **Focus on the Future (FOF)**, the principles behind the intervention, and what is required in order to facilitate effective adoption of the program.

This manual is divided into the following sections: Overview of the Intervention, Science Behind the Intervention, Pre-Implementation, Implementation, and Appendices. The following is a brief overview of the sections of this document and how to use them.

Overview of the Invention

The overview section addresses the primary concerns your agency may have when becoming familiar with a new intervention. In the overview section of the manual you will find an overview of the intervention, the 5 principles behind **FOF**, the target population, venues for delivery, and benefits of the intervention to the agency and client.

Science Behind the Intervention

The science behind the intervention section outlines the social and behavioral science used in **FOF**, a review and explanation of the *core elements* and *key characteristics* of **FOF**, the behavior change logic model, and modifications to the intervention during packaging.

Pre-Implementation

The pre-implementation section addresses 3 *getting started* activities (Assessing Fit, Capacity Issues, and Budget Development), staffing requirements, and the issues that arise when preparing for implementation. This section also contains various tools, checklists, and helpful reminders your agency can use during the pre-implementation phase.

Implementation

The implementation section addresses the issues that your agency will focus on while implementing **FOF**. The implementation section contains a timeline for implementation, a summary of implementation activities, and sample budgets for the intervention.

Appendices

This includes additional materials to assist in implementing the intervention.

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Overview of the Focus on the Future (FOF) Intervention

What is FOF?

FOF is a 45 to 60 minute, individual-level, single-session, behavioral intervention for African American men who have sex with women (MSW) ages 18-29, who report STD symptoms and/or are newly diagnosed with an STD, who reported their HIV status as negative or unknown, and who inconsistently and/or incorrectly used male condoms during vaginal sex with female partners in the last 3 months. The intervention is provided in an STD clinic to clients newly diagnosed with an STD and/or who report symptoms of an STD. The intervention focuses on building the clients' knowledge, skills and attitudes to reduce subsequent STD diagnoses, increase condom and lubricant use, decrease the frequency of unprotected sex, reduce the number of female sexual partners, and increase condom use and condom negotiation self-efficacy.

During this single-session intervention, the trained Peer Health Advisor (PHA) provides information, motivation and skills directly relevant to addressing the multiple barriers to condom use that men may face. Emphasis is placed on the correct and consistent use of condoms and lubricant as a way to increase sexual pleasure and taking responsibility and an active role in reducing HIV and STDs. At the end of the intervention, men are given a small nylon bag ("ditty bag") to fill with packets of lubricant and condoms to use and to find products that have the right fit and feel. The large selection of condoms and packets of lubricant that men choose from include high-end and popular brands that are appealing to young African American men (e.g., Trojan Magnum).

Clients observe the PHA demonstrate the correct application of a condom on a model and the client practices those skills until he expresses a sense of mastery. Throughout the session, men are encouraged to feel good about using condoms and lubricant, to experience condoms as being compatible with sexual pleasure, and to actively protect themselves from future STD infection. From the conversation with the PHA, the clients learn that the high-risk behaviors that lead to the acquisition of STDs are similar to those that would put them at-risk for HIV. Clients are motivated to personally respond to the HIV epidemic through the use of a large poster illustrating the disproportionate HIV/AIDS burden experienced by African Americans in the US.

Key to the intervention is the ability of the PHA to establish rapport, a trusting relationship, and an environment that focuses on the client's future and his community's future. This is most effective when a member of the target population is chosen as the PHA to implement the intervention. Establishing a respectful and non-judgmental environment that focuses on the client's future will motivate men to fully engage in the intervention. It is also crucial that the tone of the intervention is "sex-positive" (e.g. a healthy, non-judgmental attitude towards the man's sexuality and lifestyle).

FOF is a one-time intervention, which means that clients are only eligible to participate once, even if they screen eligible to participate multiple times. It is most effective if it is integrated as a standard of care at clinics. This is because clients are more likely to participate if they view **FOF** as a part of the services that have been arranged for them during their clinic visit.

FOF at a Glance

The table below provides a brief overview of the goal, activities, and time for each of the six components of **FOF**.

Component	Goals	Overview	Time
<p>Component 1 Establish a constructive rapport and show the client respect.</p>	<p>Create a positive and comfortable environment so clients will fully engage in the following teaching/learning process;</p> <p>Establish the upcoming session as a chance to improve existing condom use skills.</p>	<p>The PHA meets the client and uses different strategies (e.g., discuss sports or music, “caring brother” or “being real” approach, etc.) to build rapport and establish a non-judgmental climate. The PHA casually inquires about how often the client uses condoms and describes the goal of the intervention, which is to help the client resolve any problems he may have with using condoms.</p>	<p>5 minutes</p>
<p>Component 2 Fill gaps in the client’s understanding of correct condom use based on a review of the Short Condom Use Survey (SCUS).</p>	<p>Understand the errors that the client has made when using condoms;</p> <p>Address errors and rectify misconceptions the client may have about correct condom use.</p>	<p>The PHA gives the client a few minutes to complete the survey. The PHA reviews the survey and gives the client positive feedback about things he is doing well and addresses errors he has made when using condoms in the past.</p>	<p>10 minutes</p>
<p>Component 3 Inquire about clients' past condom use experiences, discuss condom negotiation strategies, and increase motivation to use condoms by showing HIV rates poster.</p>	<p>Rectify issues with condom use;</p> <p>Discuss condom negotiation skills and help the client determine ones that will work for him;</p> <p>Increase client motivation to improve upon existing condom use skills by showing disproportionate HIV rates among African American males.</p>	<p>The PHA asks the client about how often he uses condoms and gives him positive reinforcement. The PHA and client have an informal discussion about experiences that the client has with condoms (e.g., tight fit, girlfriend will suspect him of cheating, etc.). The PHA presents options of how the client can introduce condoms into relationships. The client looks at the poster on the wall that illustrates how African Americans are disproportionately affected by HIV. The PHA addresses the client’s reaction to the poster in a way that will further motivate him to take action on behalf of his community.</p>	<p>10 minutes</p>

Component	Goal	Overview	Time
<p>Component 4 Provide guided practice in the correct application and use of condoms and water-based lubricant.</p>	<p>Increase clients' self-efficacy for condom and lubricant use;</p> <p>Show that oil-based lubricants do not work;</p> <p>Develop an understanding of how to introduce condoms into current and future relationships.</p>	<p>The PHA blows up a condom, ties it tightly, and rubs baby oil on it. It breaks. This is used as a jumping off point for a discussion about why the client should never use oil-based lubricants. The PHA gives the client a card with correct condom use instructions and demonstrates how to properly use a condom and lube using the penile model, delivering key health promotion messages throughout the process. The client then practices putting the condom and lube on the penile model until he has done it correctly three or four times. The PHA delivers important messages about condom use throughout the practice.</p>	<p>10 minutes</p>
<p>Component 5 Address erection and access problems.</p>	<p>Get clients to "shop ahead" for condoms and lubricant;</p> <p>Normalize the loss of an erection thereby helping clients to get beyond this problem without taking off the condom.</p>	<p>The PHA engages the client in a discussion about how erection loss is normal and strategies to overcome it. The discussion also focuses on the importance of having a supply of good fitting condoms on hand before sex occurs.</p>	<p>5 minutes</p>
<p>Component 6 Help clients achieve a satisfactory fit and feel.</p>	<p>Provide information, motivation, and skills to clients that will increase their quality of condom and lubricant use and thereby decrease the odds of condom failure;</p> <p>Close the session.</p>	<p>The client spends some time exploring the different condoms and lubricants by opening them up and feeling them. The PHA describes features that help him find a few with the best feel and fit. The client fills a small bag with any condoms/lubricant he chooses (25+ of each). The client is asked what he will remember about the conversation and then to share the information with a friend or family member.</p>	<p>10 minutes</p>
<p>Total Time</p>			<p>~50 minutes</p>

FOF is based on 5 principles. The 5 principles were chosen by the original researchers.

1. **Unconditional respect for men**

- This principle permeates the entire intervention. PHAs must show clients unconditional respect regardless of whether the past decisions they have made are compatible with the PHAs' values. This also means that the PHA needs to be respected by clients and clinic staff.
- This principle is one of the most recognized principles of sexual education. It comes from the Sexuality Information and Education Council of the United States (SIECUS) *Guidelines for Comprehensive Sexuality Education* (<http://www.siecus.org>).

2. **Options and know how**

- Key to the intervention is teaching men how to correctly use a condom and giving them a wide option of high-end and popular condoms to try at home in order to find one with the right fit and feel. They will also be given water-based lubricant to take home and try.
- This principle comes from *If the Condom Fits, Wear It: A Qualitative Study of Young African American Men* by Dr. Richard Crosby published in 2004 in the Journal of Sexual Transmitted Infections (**Appendix A**).

3. **Practice is good**

- It is important that clients get to practice putting a condom on a penile model until they have done it properly 3 or 4 times and that they get to practice this skill at their own pace.
- Clients are encouraged to practice with the 25+ condoms and 25+ packets of water-based lubricant after the session ends.
- This principle also comes from *If the Condom Fits, Wear It: A Qualitative Study of Young African American Men*.

4. **Condoms can feel better**

- The PHA needs to sexualize condoms, conveying that they are compatible with sexual pleasure and can make sex feel better. This is done by adding moisture, studding, and ribbing, as well as giving people the peace of mind that they are protecting themselves from STDs and HIV.
- This principle also comes from *If the Condom Fits, Wear It: A Qualitative Study of Young African American Men*. In this study, Dr. Crosby found that the more men use condoms, the less likely they are to report condoms interfering with sexual pleasure.

5. **Protect our future**

- This principle relates to clients protecting their own futures and the future of their communities. Some clients may feel defeated and that they do not have valuable futures. It is important that the PHA conveys that the clients have futures ahead of them and they can ensure they are healthy by making positive and knowledgeable decisions. PHAs can do this by not challenging the wisdom of the clients' past choices—the focus should be on the future and never on the past. **FOF** also places an emphasis on the high rates of HIV amongst the African American community and the importance of the client protecting his community's future.
- This principle was developed by the original developer and researcher, Dr. Crosby. He believes that men do not want to talk about condoms and disease, however they are interested in talking about themselves and how to protect their futures.

The **FOF** intervention is not a lecture, but a sex-positive, structured conversation that uses positive reinforcement, culturally appropriate terms, and a focus on the client's future. This intervention creates a context in which participants can

- Rectify misconceptions about correct condom use,
- Recall problematic events when using condoms,
- Identify and rectify common problems with condom use,
- Illustrate scenarios that involve condom negotiation,
- Consider outcomes of consistent and correct condom use in attainment of future goals,
- Ask questions about various types of condoms and lubricant,
- Practice correctly applying different types of condoms and lubricant on a penile model,
- Find a condom with the right fit and feel.

Target Population

Who is it for?

The target population for **FOF** is African American men ages 18-29, who have sex with women (MSW), who report STD symptoms and/or are newly diagnosed with an STD, who reported their HIV status as negative or unknown, and who inconsistently and/or incorrectly use condoms during vaginal sex with female partners in the last 3 months. This population is in a demographic group highly impacted by HIV whose risk is due to the lack of consistent and correct use of condoms and lubricant as a means of protection.

FOF is most effective in geographic areas with high STD rates and a high proportion of clients who are young African American males who have sex with women.

Who else can FOF be adapted for?

A man who has sex with men (MSM) in addition to having sex with women should not be excluded from **FOF**. The client is eligible as long as he self-identifies as someone who has sex with women and has used a condom during vaginal sex within the last 3 months. The focus of the intervention is to address issues with consistent and correct use of condoms and lubricants, and therefore men who have sex with men in addition to women can participate. The PHA establishes a non-judgmental rapport with clients. However, the main focus of their conversation is on condom use while having sex with women. MSM who exclusively have sex with men are not eligible to participate.

Venues and Setting for the Delivery of FOF

In the original research, **FOF** was delivered in a private room in an STD clinic. It is important that **FOF** is delivered in a private room to ensure client confidentiality. The room should have at least two comfortable seats and a table, and have a positive climate that encourages openness and trust. This could include the use of music, identifiable pictures and posters, and brochures. The room must be available to the PHA for at least 60 minutes for an uninterrupted session with each client.

Appropriate Settings to Implement FOF

FOF is intended to be implemented in STD clinic settings that can provide testing, diagnosis, and treatment for most commonly occurring STDs. During the original research, **FOF** was conducted in a public STD clinic in Louisville, Kentucky. **FOF** materials were pilot tested in four STD clinics, two in the North East and two in the South East U.S. All of these clinics had experience serving a high proportion of young African American men who have sex with women.

FOF can also be adapted for Community-Based Organizations (CBOs) that serve men who meet the eligibility criteria and that are able to diagnose and treat STDs.

Benefits to Clinic and Care Services

FOF has many benefits to the implementing clinic, including

- Complementing, expanding and enhancing the quality of existing prevention services by providing a brief, evidence-based program;
- Supporting the clinic's mission;
- Closing gaps in needed services for young African American men;
- Integrating a new prevention service that does not require a great amount of resources or effort;
- Impacting the norms and culture of the community regarding the way members think about sex (i.e., move towards a "sex-positive" model whereby condom use and lubricants are eroticized);
- Enhancing the image of the STD clinics/CBOs as
 - Attractive sites for funders to invest in;
 - Creative, innovative, and proactive sites in addressing HIV/STDs in African American males.
- Reducing the transmission of HIV/STDs in the community.

Benefits to Clients in Care

FOF is beneficial to clients receiving the intervention in the following ways

- Enhancing their quality of life by providing them with the skills to prevent infecting or re-infecting themselves with an STD or HIV and infecting their partners;
- Providing them with a wide variety of high-end lubricants and condoms to identify those that have the right fit and feel;
- Providing them with an opportunity to connect with a caring and knowledgeable peer who is interested and believes in their futures;
- Providing them with a safe environment to practice properly applying condoms and lubricant and talk through any potential barriers to consistent use;
- Reducing worry and concern when having sex, making it a more enjoyable experience;
- Allowing them to maintain their current lifestyle with regard to sex;
- Empowering them to be a part of the collective action to reverse the high HIV/STD prevalence in their demographic group;
- Alleviating the burden of HIV/STDs in the community amongst African American males;

- Providing positive ripple effects in cases where clients represent a “hub” of transmission through extensive social networks;¹
- Impacting the norms and culture of the community regarding the way they think about sex (i.e., move towards a “sex-positive” model whereby condom use and lubricants are eroticized).

¹ Guttmacher Policy Review, Spring 2009, Volume 12, Number 2. For Some Sexually Transmitted Infections, Secondary Prevention May Be Primary by Adam Sonfield.

The Science Behind the FOF Intervention

Original Research Findings

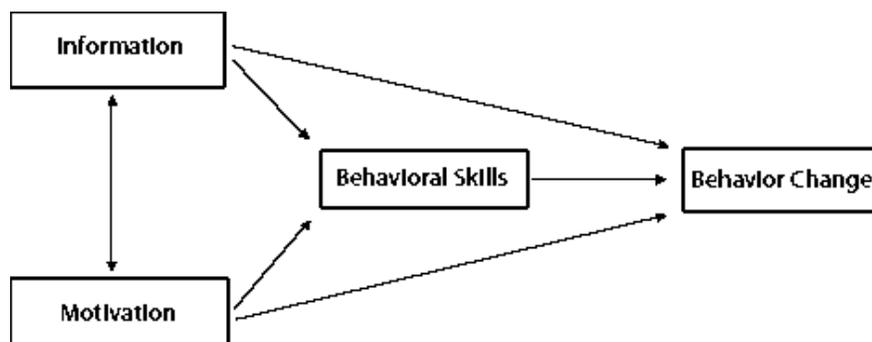
To design and test the efficacy of the intervention, Crosby et al. originated a two-year randomized control study in a public STD clinic in Louisville, KY. Results from this study showed various positive effects on the behaviors of the intervention clients.² When clients completed a three month follow-up assessment, individuals who received the **FOF** intervention were significantly less likely to have acquired a subsequent STD. A significant number reported having fewer sexual partners, significantly fewer acts of unprotected sex, and were significantly more likely to report using condoms during their last episode of sexual intercourse with a woman. They also had significantly improved proficiency scores for condom application skills. The results also suggest a substantial protective benefit for men's female sexual partners against HIV or other STD acquisition. **FOF** was shown to be effective when clients received it one time, and there is no evidence that suggests it would continue to be effective when given to the same client multiple times.

How it is Different from Other HIV Prevention Interventions

FOF fills a critical gap in evidence-based HIV prevention interventions currently available for young African American men who have sex with women (MSW), because it is designed to meet their needs and address their concerns regarding consistent condom use. **FOF** is one of only a few evidence-based interventions recognized by the CDC for use in STD clinic settings.

Theories and Models Used

The **FOF** intervention is based on the Information, Motivation, and Behavioral Skills Model (IMB).³ This theory asserts that HIV-related information, motivation, and behavioral skills are the fundamental determinants of HIV/STD prevention. If an individual is well-informed, motivated to act, and possesses the skills and confidence to take effective action, he or she is more likely to initiate and maintain patterns of HIV/STD preventive behavior.



The “**information**” aspect of the model addresses the cognitive domain and refers to the provision of knowledge to support the change in behavior. The “**motivation**” component targets the affective

² Crosby R, DiClemente R, et al. A brief, clinic-based, safer sex intervention for heterosexual African American men newly diagnosed with an STD: A randomized controlled trial. *Research and Practice*. 2009; 99: 1-8.

³ Fisher J, Fisher W. The information-motivation-behavioral skills model. In: DiClemente RJ, Crosby RA, Kegler M, eds. *Emerging Theories in Health Promotion Practice and Research*. San Francisco, CA: Jossey-Bass; 2002: 40-70.

domain and encourages the development of a favorable attitude towards the positive health behavior and capitalizes on existing social support systems to enhance motivation. Identifying barriers and strategies to overcome them is another way to enhance motivation. The “**behavior**” aspect of the model focuses on the psychomotor domain. Through instruction, repeated demonstrations and practice, individuals acquire the practical skills necessary to maintain the behavior change.

According to IMB, health interventions should be focused on

1. Communicating effective health information that is appropriate for the target health behavior and specific to a population,
2. Increasing personal motivation and social support, and
3. Skill-training to increase self-efficacy for performing a health behavior.

During the **FOF** intervention, information directly relevant to the quality of condom use is provided. Men also learn, by demonstration, that oil-based lubricants can quickly erode latex condoms.

Increasing motivation to use condoms is a central component of **FOF**. Throughout the session, men are encouraged to feel good about using condoms, to consider condoms as being compatible with sexual pleasure, and to actively protect themselves from future STD infection. Clients are also motivated to personally respond to the AIDS epidemic through the use of large posters illustrating the disproportionate HIV/AIDS burden experienced by African American men in the United States.

Skill acquisition is another essential component of **FOF**. Correct condom and lubrication use are demonstrated and practiced by the men until they exhibit a sense of mastery.⁴

FOF also draws from Albert Bandura’s Social Learning Theory⁵. This theory states that people learn new behavior through observational learning, imitation, and modeling. If people observe positive, desired outcomes in the observed behavior, then they are more likely to model, imitate, and adopt the behavior themselves. **FOF** utilizes a Peer Health Advisor (PHA) to model correct condom and lubricant use skills. With the PHA’s guidance, the clients then imitate those skills to build their self-efficacy for correct and consistent condom use.

Although it is not a formal theory, an important feature of **FOF** is that it can be customized to the needs of each client. Customizing is a process that matches messages and approaches with the needs and values of the client.⁶ The one-on-one interaction of **FOF** (in the context of a trusting relationship) allows the PHA to “listen and respond” to the needs of the client. The content of the program is used much like a checklist of competencies, whereby, once competency is established for a component, the PHA is able to move on to the next component. This form of customizing allows for the vast differences in learning that inevitably exist, even in highly homogenous populations. This on-the-spot customizing provides men with the skills they lack rather than leading them through a program that is customized for a group of people. Evidence clearly suggests that customized HIV prevention interventions are likely to be superior to “canned programs.”^{7,8}

⁴ Crosby R, DiClemente R, et al. A brief, clinic-based, safer sex intervention for heterosexual African American men newly diagnosed with an STD: A randomized controlled trial. *Research and Practice*. 2009; 99: 1-8.

⁵ Bandura A. Self-efficacy: Toward a unifying theory of behavior change. *Psych Rev* 1977; 84:191-215.

⁶ Petty RE, Barden J, Wheeler SC. The elaboration likelihood model of persuasion: Health promotions that yield sustained behavior change. In DiClemente, R. J., Crosby, R. A., & Kegler, M. (eds.) (pp. 71 – 99) *Emerging Theories in Health Promotion Practice and Research*. San Francisco, CA: Jossey-Bass Wiley. 2002.

⁷ Coates TJ, Aggleton P, Gutwiller F, et al. HIV prevention in developed countries. *Lancet* 1996; 348:1143-1148.

Core Elements and Key Characteristics

Core Elements are defined as “elements that embody the theory and internal logic of the intervention and most likely produce interventions’ main effects.”⁹

*Core elements are critical features of an intervention’s intent and design and are thought to be responsible for its effectiveness. Consequently, core elements should be maintained without alteration to ensure program effectiveness.*¹⁰

FOF Core Elements

Content

1. A trained PHA teaches correct condom use skills for clients. (IMB Components: Information, Behavior.)
 - The PHA will foster positive attitudes and norms towards correct and consistent condom use by providing adequate opportunity for clients to practice proper application of condoms during the session. This will improve the clients’ condom use behaviors and self-efficacy.
2. The PHA and clients discuss condom negotiation skills. (IMB Components: Behavior.)
 - The PHA addresses issues with using condoms in the clients’ lives and discusses condom negotiation strategies that they can use with partners. Being able to negotiate condom use with his partners impacts the clients’ condom use behaviors.
3. The PHA provides clients with 25+ packets of water-based lubricants and 25+ condoms of their choice from a broad selection of high-end and popular brands. (IMB Components: Motivation, Behavior.)
 - After determining which condoms might have the right fit and feel for the clients, the clients select 25+ condoms and 25+ packets of lubricant from a large variety of high-end and popular brands. Clients are also provided with a bag to carry their condoms and packets of lubricant. Having condoms with the right fit and feel, packets of lubricant, and a trendy bag with which to carry them motivates men to use condoms, thereby increasing their condom use behaviors.
4. The PHA clearly communicates the importance of the client protecting his and his community’s futures by using condoms correctly and consistently with his partner(s). (IMB Components: Behavior.)
 - The PHA equates condom use with an investment in the clients’ futures, lowering their chances of contracting or transmitting future STDs and slowing the spread of HIV/AIDS in their communities.

⁸ DiClemente RJ. Development of programmes for enhancing sexual health. *Lancet* 2001; 358:1828-1829.

⁹ Glossary. *AIDS Education and Prevention*, 12, Supplement A, 145-146, 2000.

¹⁰ Glossary. *AIDS Education and Prevention*, 12, Supplement A, 145-146, 2000.

Pedagogy

1. The PHA establishes rapport and a trusting relationship with the client at the beginning of the session. (IMB Components: Motivation.)
 - The relationship with the PHA motivates clients to fully engage in the forthcoming teaching/learning session and establishes an effective means of relating prevention messages to them.
2. The PHA shows unconditional respect for men and maintains a non-judgmental environment for the client concerning any risk behaviors disclosed. (IMB Components: Information, Motivation.)
 - The PHA maintains a “sex-positive” attitude, which is a healthy, non-judgmental attitude towards the client’s sexuality and lifestyle choices. By remaining non-judgmental, the client is motivated to fully engage in the session and feel comfortable disclosing information about his risk behaviors. In turn, the PHA can provide information about condom use issues that is customized to the client with positive reinforcement.

Implementation

1. The intervention is delivered at a point when the client is feeling vulnerable and is highly concerned about his STD infection status. This may be while he is in the clinic waiting, after a presumptive diagnosis, or after a confirmed lab result. (IMB Components: Motivation.)
 - The time when a client believes that he may be infected with an STD or after he receives a positive diagnosis is a critical period in which to address prevention with clients. It is a moment of great motivation for clients to improve their safe sex practices. Thus, the intervention should be delivered at a location that can test and diagnosis clients with STDs.
2. The PHA conducts a customized one-to-one counseling session with the client for 45-60 minutes. (IMB Components: Information.)
 - The interactive nature of the program allows the PHA to proceed at a pace and level that is developmentally appropriate for each client. Depending on the needs of the client, the duration of the intervention is a minimum of 45 minutes. Depending on the client, up to 60 minutes may be required to ensure that the appropriate information is covered during the session.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations.¹¹

*Key Characteristics are less essential to effectiveness, but essential to adaptations an agency may consider making. Key Characteristics can be altered so that an intervention can be customized to the specific needs of the at-risk community receiving the intervention and the capabilities of the organization implementing the intervention.*¹²

¹¹ Glossary. AIDS Education and Prevention, 12, Supplement A, 145-146, 2000.

¹² Glossary. AIDS Education and Prevention, 12, Supplement A, 145-146, 2000.

FOF Key Characteristics

1. A survey is completed by the client to inform the PHA of his problems with using condoms.
 - This short survey allows the PHA to customize the intervention so that it addresses the client's specific needs and concerns.
 - Tailoring Options: The client may be asked to verbally answer the questions on the survey or communicate his issues with condom use so that the PHA can address his specific concerns.
2. A visual aid (i.e., poster) hanging in the room that displays HIV prevalence among African American males in the US is used to increase men's motivation to change behaviors associated with condom use.
 - This poster helps to create a personal motivation for the client to improve his safe sex practices.
 - Tailoring Options: If hanging the poster on the wall is not an option, the poster can be shown to the clients at the appropriate time during the intervention.
3. The PHA needs to have similar everyday experiences and communication styles.
 - Identifying with the PHA is important because it increases the value of the intervention's messages.
 - Tailoring Options: A PHA who can communicate clearly and effectively should be prioritized over one who might communicate in a common way with the client, though these are related concepts.
4. The PHAs are men who come from the community for which the intervention is intended.
 - This goes beyond the concept of "matching" by race, age, and gender.
 - Tailoring Options: The PHA can be recruited from another nearby community with a similar socio-economic-cultural environment.
5. Both the PHA and the client should be seated in a private and comfortable environment.
 - The space should feel comfortable and safe so that the client feels able to communicate freely and openly about his experiences and concerns.
 - Tailoring Options: As space is often limited, a multi-purpose space may be used as long as it is private during the intervention.

While every attempt should be made to maintain fidelity to the original intervention, Key Characteristics may be adapted to accommodate the capabilities of the implementing organization. This is different from the Core Elements, which cannot be modified.

Focus on the Future (FOF) Behavior Change Logic Model

Statement of the Problem

FOF is designed for African American men who have sex with women (MSW) ages 18-29, who are newly diagnosed with an STD and/or report symptoms of an STD, who report their HIV status as negative or unknown, and have used a male condom during vaginal sex at least once in the past 3 months.

Major risk factors for HIV include: membership in a demographic group highly impacted by HIV and STDs, lack of consistent condom use as a means of protection, incorrect use of condoms, and incorrect/lack of use of water-based lubricant.

Specific Behavior Change Logic

Determinants <i>To address risk behavior/factors</i>	Activities <i>To address behavioral determinants</i>	Outcomes <i>Expected changes as a result of activities targeting behavioral risk determinants</i>	
<ul style="list-style-type: none"> • Incorrect or lack of condom use skills • Low self-efficacy related to condom use • Lack of skills using lubricant • Low self-efficacy related to the use of lubricant • Negative attitudes toward condom use • Lack of self-efficacy toward negotiating condom use • Inability to identify triggers of unsafe sex • Lack of knowledge of HIV/AIDS prevalence • Low or no risk perception regarding self • Lack of perceptions regarding risk reduction options (e.g., planning for sex, finding a condom with the right fit and feel, using lubricant, etc.) 	<p>45-60 minute individual-level, single-session behavioral intervention, delivered by a trained Peer Health Advisor.</p> <ul style="list-style-type: none"> • Recall any problematic events when using condoms • Rectify misconceptions about correct condom use • Illustrate proper condom use • Consider outcomes of consistent and correct condom use in attainment of future goals • Ask questions about various types of condoms • Practice correctly applying different types of condoms on a penile model • Illustrate scenarios that involve condom negotiation • Discuss how to overcome barriers • Understand the importance of being prepared by having 2 to 3 condoms on hand when having sex • Experiment with different types of condoms and lubricant until they find a brand and size that best serves their needs • Know where to locate condoms in the community (including types and price) 	<p>Immediate Outcomes</p> <ul style="list-style-type: none"> • Increase knowledge regarding correct condom use • Increase risk perception as it relates to unprotected sex • Increase motivation to use condoms consistently and correctly • Increase decision-making • Decrease negative attitudes towards condoms and increase positive attitudes • Improve condom use skills • Improve lubricant use skills • Increase self-efficacy related to safer sex skills (e.g., use of lubricant, planning ahead, etc.) 	<p>Intermediate Outcomes</p> <ul style="list-style-type: none"> • Reduction in subsequent diagnosis of an STD • Reduction in the number of sexual partners • Increased condom use and decreased unprotected vaginal and anal intercourse • Increased communication with partners about HIV/STI risks and condom use • Increased communication with peers about HIV/STI risks and condom use • Improved management of risky sexual situations, e.g., <ul style="list-style-type: none"> ○ Planned ahead to practice safer sex ○ Increased condom carrying • Correct and consistent condom use (less slippage, breakage, etc.) • Increased/improved condom negotiation skills • Improved planning for accessibility of condoms when needed

How to Get Started

Purpose

Pre-implementation prepares the implementing agency to perform the **FOF** intervention. It is during this period that your agency can make any necessary organizational changes, conduct an assessment, and develop program integration and monitoring and evaluation plans. Pre-implementation is also the time to explore the need for tailoring **FOF**. For this intervention, pre-implementation activities are focused on

- Determining agency need and capacity for **FOF**,
- Budgeting,
- Securing support through stakeholder “buy-in,”
- Hiring and training the necessary staff,
- Developing practices for patient eligibility screening and recruitment,
- Determining how to fit **FOF** into clinic flow,
- Determining a location for the intervention to take place,
- Obtaining and sustaining intervention supplies.

In the following pages are tools that will help your agency work through all of the pre-implementation processes.

If a CDC directly funded agency has trouble developing capacity in any of these areas (e.g., developing a budget), consult with your CDC Project Office concerning your agency’s capacity building assistance (CBA) needs and then submit a request to the CDC Capacity Building Assistance Request Information System (CRIS) website at <http://www.cdc.gov/hiv/cba>. If an agency is indirectly funded through their state or local health department, consult your health department on your CBA needs and the health department point of contact will submit a CRIS request.

Target Population Appropriate for FOF

FOF is designed for African American men ages 18-29 who have sex with women (MSW) and newly diagnosed with an STD or report symptoms of an STD. Participants should also have used a male condom during vaginal sex at least once during the past three months, and should report their HIV status as either negative or unknown. This population is at risk of transmitting or acquiring HIV due to having unprotected sex with female partners. Major risk factors include

- Membership in a demographic group highly impacted by STD/HIV,
- Lack of consistent condom use as a means of protection,
- Incorrect use of condoms and/or lubricant.

Other groups of young men in your community may also be highly impacted by STD/HIV such as young Hispanic men, Caucasian Men who have sex with Men (MSM) or MSM of color. **FOF** may be adapted for use with other communities who are highly impacted by STD/HIV; however, due to the specific type of information relevant for people living with HIV, **FOF** is not recommended to be delivered to men who know they are HIV-positive. For more information about adaptation, please refer to the “Adaptation” section.

Agency Fit and Capacity

Your agency should have the capacity to successfully implement **FOF**. Capacity is concerned with issues that relate to the agency as a whole, not only the capacity to carry out the specific intervention. It needs to be determined whether or not **FOF** will be of value to your agency and appropriate for clients, and whether or not your agency has the capacity to implement such an intervention. Use the checklist below to keep track of what steps still need to be taken before your agency is ready to implement the intervention. If other parties need to be involved to accomplish these goals you can use this checklist to keep track of their progress as well. (See **Appendix B**.)

Statement	Agree	Disagree
FOF meets the purpose, goals, and objectives of my agency.		
FOF meets the needs of the target population that my agency serves.		
My agency can secure adequate funding to successfully provide the intervention to clients.		
My agency has a history of working with the target population and has access to the target population from our existing services. (See Appendix C for a tool to determine the approximate number of eligible clients your clinic sees each day.)		
My agency is ready to implement the intervention. (See “Agency Readiness to Implement the Intervention.”)		
My agency is able to secure “buy-in” for the intervention from key staff in my agency and supporting agencies in the community, as well as from other relevant stakeholders.		
My agency has organizational support to develop and sustain FOF .		
My agency has the policies and procedures in place to support this intervention.		

Stakeholder "Buy-in"

Your agency's intervention champion can use the following stakeholder's checklist to obtain support for implementing **FOF**. The stakeholders are those people on your Board of Directors/Executive Board, in your community, at your agency, your staff, or your funding source who have a stake in the successful implementation of an intervention. The stakeholder's checklist contains those items the champion can use to convince the stakeholders that **FOF** is an intervention that your agency can and should implement because it meets the needs of the community your agency serves.

Stakeholder checklist

1. Identify your stakeholders

- Your agency's Board of Directors/Executive Board (if applicable)
- Staff members from your agency who will have a role in the operation of the intervention
 - i. Administrators who will obtain support
 - ii. Supervisors who will monitor the intervention
 - iii. Staff who will interact with participants at any level
- Local agencies from which you could recruit PHAs
 - iv. Agencies offering support groups for African American men ages 18-29 who have sex with women
 - v. Health care providers and mental health professionals serving African American men ages 18-29 who have sex with women
 - vi. Social service agencies reaching African American men ages 18-29 who have sex with women
 - vii. Organizations of African American men ages 18-29 who have sex with women and organizations that may have members who are African American men ages 18-29 who have sex with women
- Organizations which could provide assistance or other resources
 - viii. Merchants for incentives, refreshments
 - ix. Agencies that can provide a venue for the intervention
 - x. Agencies that can provide transportation
 - xi. Advisory board to help tailor intervention
 - xii. Other collaborating agencies to provide information for resource packets
- Agencies with which your agency needs to maintain good community or professional relations
 - xiii. State and local health department
 - xiv. Local medical and mental health associations
 - xv. Sexually transmitted disease (STD) clinics and services
 - xvi. Community-based organizations
 - xvii. Your funding source(s)
 - xviii. Others

2. Getting stakeholders informed, supportive, and involved
- Getting them informed about the intervention
- i. Decide in advance what specific roles you want each stakeholder to play.

Who will you ask to

 1. provide financial support,
 2. refer African American men ages 18-29 who have sex with women to the intervention,
 3. assist with implementation of the intervention,
 4. be a resource to which you can refer participants,
 5. help tailor the intervention for your target population,
 6. provide a room in which the sessions can be held,
 7. supply refreshments for participants,
 8. donate small incentives or prizes for participants,
 9. speak supportively about **FOF** in conversations with their associates?
 - ii. Send letters that tell stakeholders about **FOF** and its importance, that your agency is/will be making the intervention available, and, what specific role(s) you think that they might play in the success of the intervention, and offer an opportunity for them to learn more.
 - iii. Call in 2 weeks and assess their interest. If they are interested, schedule a time to meet (e.g., one-on-one, lunch-and-learn at your agency with a group of other stakeholders, presentation at their agency for several of their staff or association members).
 - iv. Hold the meeting, to describe **FOF** and answer questions.
- Getting their support
- v. Describe several specific roles they could play.
 - vi. Emphasize the benefits of their involvement to themselves, their agency, the community, and answer questions.
 - vii. Invite them to commit to supporting **FOF** by taking on one or more roles. Keep track of commitments.
- Getting them involved
- viii. Soon after meeting, send a thank you letter that specifies the role(s) to which they committed. If they did not commit, send a letter thanking them for their time and interest and ask them to keep the letter on file in case they reconsider later.
 - ix. For persons who committed to a role that is important to pre-implementation, put them to work as soon as possible.
 - x. For persons who committed to involvement later in the process, send them brief progress updates and an idea of when you will be calling on their support.

- xi. Hold periodic celebratory meetings for supporters to acknowledge your appreciation for and the value of their contributions; update them on the intervention's progress, and keep them engaged.

Program Review Panel

If CDC will be funding all or part of your agency's implementation of **FOF**, your agency must follow the Requirements for Contents of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control and Prevention (CDC) Assistance Programs. You also must submit the program's modules, content, information collection forms, participant handouts, videos and other program materials you plan to use for approval by a local Program Review Board (PRB). The PRB's assessment will follow the CDC Basic Principles found in 57 Federal Register 26742. If all of your funding for **FOF** is coming from another source, check with that source for their policy on PRB approvals.

We recommend that you first find out what the local PRB's procedures are from your state health department and work within them. It may be helpful to your PRB to provide an overview or executive summary of the intervention with other relevant materials. Also providing a copy of the research article may be useful for PRB members who are interested in the scientific evidence supporting the intervention.

Emphasize the activities that are Core Elements of the intervention. Emphasize that these elements are required in order to get results similar to those of the original research. Be prepared to answer questions, to make things clear, or refer PRB members to sections of the package materials for information.

If all of your funding for **FOF** is from another source, check with that source for their policy on approvals.

Identifying Appropriate Staff

To implement **FOF** your agency will need to involve a number of existing staff, as well as integrate the new staff member hired specifically for the intervention, the PHA. Specifically, **FOF** requires the participation of each of the following individuals

- *Clinic Director*: Preparing the agency for **FOF**, securing funds and "buy-in," hiring a PHA, organizing training for all necessary staff, quality assurance, budget management, establishing and executing the evaluation plan, and communicating with the agency manager, etc.
- *Clinic Manager*: Supervises the PHA or the PHA's supervisor, helps to evaluate agency policies and procedures as they apply to **FOF**, obtains supplies for the intervention, determines space to be used for the intervention, evaluates agency readiness for

implementation, debriefs weekly with the PHA and PHA's supervisor on intervention successes and challenges, etc.

- *PHA's Supervisor*: Receives training on **FOF**, supervises the PHA, debriefs weekly with the PHA, reviews the PHA's performance, supports the PHA, etc. See the section below for more guidance on providing supervision to the PHA.
- *Clinical, Nursing, Social Work, Disease Investigation Specialist (DIS), and Triage Staff*: These staff understands the clinic's flow for each day and incorporates the provision of **FOF** by the PHA based on the client's eligibility. These staff members receive orientation on the screening for eligibility and referral processes for **FOF**, screen clients for eligibility, recruit clients, etc.
- *PHA*: Receives training on **FOF**, conducts the **FOF** intervention and serves as a consultant on safe sex practices to clients after intervention. See the section below for more guidance on hiring the PHA.

Hiring the PHA

Recruiting an appropriate PHA is a key component of **FOF**. Filling the position is more complicated than simply finding someone who fits the required profile. The PHA needs to be someone who is non-judgmental, has a sex-positive attitude, able to quickly establish a rapport with each client, and create an environment of trust and respect that encourages open and honest communication during each session. PHAs should have the following characteristics

- African American man who is able to talk honestly and share experiences about heterosexual intercourse;
- 21 to 35-years-old (older candidates are preferred as they may have more experience and appear to be more of an authority to clients);
- Comes from and currently resides in the area surrounding the agency;
- Relates to men quickly (i.e., easily builds rapport, has a good sense of humor, etc.);
- Outgoing, friendly and caring personality;
- Non-judgmental of others' lifestyles and choices;
- Able to look at sexual behaviors non-judgmentally (a sex-positive attitude);
- Comfortable talking about condoms, sex and STDs;
- Motivated to improve his community;
- Openness and receptive to training/learning.
- Because the person hired for the position will be responsible for reading the Facilitator's Guide on a regular basis, using a survey with clients, and creating a list of stores in the area where clients can purchase condoms and lubricant, the Peer Health Advisor must be literate. In order to address the candidates literacy level during the interview, you can
 - Ask the candidate to read a pamphlet that you have in the clinic out loud,
 - Ask the candidate to write an answer out to one of the questions.

When recruiting the PHA, it is advised that you do not use online or print advertising. It is difficult to target the desired population using these strategies, and you will waste time and effort filtering through an inflated pool of applicants. Instead, agencies should use their own networks to search for candidates. Staff may know of ideal candidates in the community, including previous or current clients at the agency. Agencies may also reach out to other organizations that they partner with to identify candidates.

Supervising the PHA

PHAs require supervisors who will work to successfully integrate them into the clinic team, meet with them to debrief about the intervention, and provide support in other ways. There are several components that make up the foundation of supportive supervision, such as building a trusting relationship between the supervisor and the PHA and allowing the PHA to explore feelings and reactions that emerge from facilitating the intervention. The following outlines the general principles of conducting supportive supervision.

- The supervisor ensures the PHA is integrated into the agency team, which can be done by
 - Taking him around the clinic to meet other staff members, describing his role at the clinic;
 - Introducing him during the pre-implementation “Staff Buy-in” meeting;
 - Letting other staff know how to contact him with questions about the intervention;
 - Having the PHA share the successes of the program during staff meetings;
 - Sharing the program’s successes in agency newsletters.
- The supervisor sets aside time to meet with the PHA weekly.
 - The supervisor recognizes that this supervision time is dedicated to the PHA.
 - The supervisor creates a safe space. There are no interruptions during supervision, if possible, and the PHA is encouraged to share any concerns.
 - The supervisor sets a time that is consistent and convenient for the supervisor and PHA.
 - The focus of the supervision meeting remains on the development needs and concerns of the PHA.
 - The supervisor and PHA set the agenda together.
 - The supervisor is open to exploring the feelings and reactions of the PHA that can help him reflect on working with clients who are part of their community.
 - The supervisor uses open-ended questions to help the PHA share their work with clients.
 - The supervisor is responsive and empathic and encourages the PHA to use his or her insight into the community to respond to client issues.
 - The supervisor provides guidance and resources.
 - The supervisor remains non-judgmental in his or her approach.

During supervision meetings, discussion topics can include

- Sessions
 - Approximately how long is each session taking?

- What questions do clients ask or what do they say that you struggle responding to?
- What common stories/problems/scenarios/characteristics are clients presenting you with that often need to be addressed during **FOF**?
- What impressions are you receiving or comments are you hearing from clients after they complete the intervention?
- What do you find clients respond well to? How can you build on that?
- How is your level of supplies? (Sufficient? Getting low?)
- What referrals are you making (to other staff within the clinic)?
- Clinic Flow
 - How many clients do you see each day?
 - How much down time do you have each day, on average?
 - What do you do during your down time?
 - How do you think we could recruit more men to the intervention or recruit more effectively?
- Training and Intervention Materials
 - How well did the training prepare you to deliver the intervention?
 - What materials that you received during the training have you been referring to (e.g., Facilitator's Guide, video, cheat sheet, etc.)? How often?
 - Are clients calling you to ask questions? If yes, what types of questions?
 - Have clients mentioned anything about how they are being referred to the program? Are clients asking about **FOF** before being told about the program by clinic staff?
- Integration at the Clinic
 - Does everyone at the clinic understand your role and what you do?
 - Have you met everyone at the clinic?
 - Do you feel like a part of the clinic team?
- Review of the 6 Components of the FOF Intervention (see pages 8-9)
 - What strategies do you use to build rapport?
 - How do you use the survey that the clients complete to address the client's problems throughout the session?
 - How do the clients feel about condom negotiation? What comes up?
 - How do clients react to the posters? How do you address their reactions?
 - How do clients feel about practicing correct condom use on the penile model? How do you make them feel more comfortable touching the model, condoms and lube?
 - How many times do clients put the condom on the model?
 - How do clients react to the discussion about erection loss?
 - How do clients feel about or react to the list of stores in the area to buy condoms/lube?
 - How do clients react to the number of condoms and lube that you show them? How do you ensure that you are not favoring one condom or lube over another?
 - What condoms/lubes are popular? What reasons do clients have for their preferences?
 - How do you close the session?

Facility Requirements

FOF requires that the intervention take place in a private room with a door at an agency or clinic that provides STD/HIV screenings and is located in a geographic area with a high incidence of STDs among African American men who have sex with women. It does not need to be a large space, but it should have enough room for both the PHA and the client to sit comfortably in chairs at a desk or table. Selecting a space that has a sink for clients and PHAs to wash their hands after practicing correct condom use on the penile model would be ideal.

There should also be a cabinet, closet or room to store the supplies necessary for the intervention. The ditty bags and the high volume and variety of high-end and popular condoms and lubricant that are associated with **FOF** are appealing to both clients and staff. Therefore, it is important to keep supplies locked up in a closet or room that only a known number of staff have access to. It would be ideal if only the PHA and his supervisor have access to the supplies. Consider having the lock to the closet or room where the supplies for the intervention will be kept changed prior to implementing the intervention.

Policies and Procedures

During pre-implementation, your agency should evaluate current policies and procedures in order to determine their capacity to support the needs of **FOF**. Some policies may need to be revised in order to accommodate the intervention, and some new procedures may be required all together. Examples of these include

- Patient confidentiality,
- Integrating **FOF** into clinic flow,
- Screening for eligibility,
- Recruiting clients,
- Referral tracking,
- Managing supplies,
- Ordering supplies,
- Safety and security plan,
- Planning for potential issues,
- PHAs' Clinic Responsibilities.

Clinic Readiness to Implement the Intervention

It is important that your agency assesses its readiness and that the necessary requirements needed in order to implement this intervention with fidelity are in place. At the point of assessing readiness, your agency should be confident that their setting is appropriate for implementation of **FOF**. If you

have any concerns about whether or not your agency has an appropriate setting to deliver **FOF**, refer to the “Appropriate Agencies to Implement **FOF**” and “Agency Fit and Capacity” materials found in the “Overview” section.

Clinic Readiness Checklist

After understanding what is required for implementing **FOF**, your agency can use the following checklist to assess if your agency has the capacity to implement the intervention with fidelity. The checklist will also identify what areas may need to be developed or identify what stakeholders are needed to acquire specific resources. Use the checklist to keep track of what steps still need to be taken before your agency is ready to implement the intervention. If other parties need to be involved to accomplish these goals you can use this checklist to keep track of their progress as well.

Clinic Readiness Checklist

Capacities and Resources Needed for FOF	Yes/No/ Referral
<i>Staffing Requirements</i>	
<ul style="list-style-type: none"> ● Clinic Director <ul style="list-style-type: none"> ○ Do you have a clinic director who is willing to prepare the clinic for FOF, secure funds and “buy-in,” hire a PHA, organize training for all necessary staff, provide quality assurance, manage the budget, establish and execute the evaluation plan, and communicate with the clinic manager? 	
<ul style="list-style-type: none"> ● Clinic Manager <ul style="list-style-type: none"> ○ Do you have a clinic manager who is willing to supervise the PHA or the PHA’s supervisor, help to evaluate clinic policies and procedures as they apply to FOF, obtain supplies for intervention, determine space to be used for the intervention, evaluate clinic readiness for implementation, and debrief weekly with the PHA or PHA’s supervisor on intervention successes and challenges? 	
<ul style="list-style-type: none"> ● PHA’s Supervisor <ul style="list-style-type: none"> ○ Is there someone at the clinic who is willing to receive training on FOF, supervise the PHA, debrief weekly with the PHA, review the PHA’s performance, and support the PHA? 	
<ul style="list-style-type: none"> ● PHA <ul style="list-style-type: none"> ○ Is there someone you know of who meets the criteria to be a successful PHA, is willing to receive training on FOF, conduct FOF, and serve as a consultant on safe sex practices to clients after FOF? 	
<i>Training Requirements</i>	
<ul style="list-style-type: none"> ● Is the PHA able to attend a 3-day training on FOF and the supervisor able to attend a 1/2-day training? 	

<ul style="list-style-type: none"> Is the clinic committed to orient the staff about the FOF intervention, integration of FOF into clinic flow, screening eligible client processes, etc.? 	
<i>Resources Required</i>	
Do you have the following resources?	
<ul style="list-style-type: none"> Ability to purchase and securely store 1 realistic penile model, 1-2 less realistic penile models, bottles of baby oil, 600+ condoms (a variety of desirable and/or high-end brands), 600+ 3 to 8 m water-based lubricants packets (a variety of desirable and/or high-end brands), paper towels, hand sanitizer, pens/pencils, ditty bags (small draw-string bags for clients to put 25+ condoms and 25+ lubricants of their choosing). 	
Capacities and Resources Needed for FOF	Yes/No/Referral
<i>Resources Requirements (Continued)</i>	
<ul style="list-style-type: none"> Available private office/room to conduct FOF session uninterrupted for at least 60 minutes at a time. 	
<ul style="list-style-type: none"> Available wall space in the FOF room to hang the color poster that reveals the dramatic difference in AIDS rates for African Americans versus the rest of the population (nationally). 	
<ul style="list-style-type: none"> Ability to print and prepare wallet-sized cards (outlining the 8 steps for correct condom use on one side and contact information of the PHA and clinic on the other). 	
<ul style="list-style-type: none"> Ability to develop a list of stores in the surrounding area that carry a variety of high-end condoms and lubricants with the address, hours, and prices listed. 	
<ul style="list-style-type: none"> Ability to copy the Short Condom Use Survey (SCUS) and list of stores in the area. 	
<ul style="list-style-type: none"> Access to a laptop computer, iPod/speakers or CD player (optional). 	
<ul style="list-style-type: none"> Availability to purchase/obtain refreshments (water, soda, snacks) (optional). 	
<ul style="list-style-type: none"> A sink for the PHA to wash the penile models daily. 	
<i>Policies and Procedures</i>	
Are the following policies and procedures currently in place and able to satisfy the needs of FOF ? (Which need to be amended, and which need to be created?) For example	
<ul style="list-style-type: none"> Patient confidentiality, 	
<ul style="list-style-type: none"> Integrating FOF into clinic flow, 	
<ul style="list-style-type: none"> Screening for eligibility, 	
<ul style="list-style-type: none"> Recruiting clients, 	
<ul style="list-style-type: none"> Referral tracking, 	
<ul style="list-style-type: none"> Managing supplies, 	

• Ordering supplies,	
• Safety and security plan,	
• Planning for potential issues,	
• PHAs' Clinic Responsibilities.	

Pre-Implementation Timeline

The following timeline outlines when the required tasks should take place in order to successfully prepare to implement the **FOF** intervention. The responsible staff and materials are also listed.

Task	Person(s) Responsible	Materials	Timeline
<p>Determine Agency Fit and Capacity</p> <ul style="list-style-type: none"> • Agency should meet the following criteria <ul style="list-style-type: none"> ○ Ability to diagnose and treat STDs; ○ Serves a large number of the target population <ul style="list-style-type: none"> ▪ Males , ▪ Ages 18-29, ▪ African American, ▪ Men who have sex with women (MSW), ▪ Newly diagnosed with an STD or report symptoms of an STD, ▪ Uses condoms , ▪ Condom use is incorrect or inconsistent; ○ Has a private space where one-on-one; intervention can take place; ○ Has a cupboard, closet or room to securely store supplies for the intervention; ○ Able to secure funding to successfully provide the intervention (this timeline may be ongoing); <ul style="list-style-type: none"> ▪ Able to purchase materials such as high-end/popular condoms and lubricants, small bags, and a penile model; ▪ Able to hire, compensate, and supervise a PHA; ○ Able to promote the program within the community; ○ Has a system in place to track referrals to the program; ○ Management and staff will “buy-in” to the intervention; ○ Follows CDC Standard of Care guidelines (e.g., screening, treating, post-test/risk reduction counseling); ○ Ability to do case study reviews without difficulty for monitoring and evaluation purposes. 	<p>Clinic Director</p> <p>Clinic Manager</p> <p>Clinic Manager</p> <p>Local and State Health Departments</p> <p>Stakeholders</p> <p>Clinic Director</p> <p>Clinic Manager</p>	<p>See Appendix C for a tool to determine the number of eligible clients your clinic sees per day</p> <p>Clinic Floor Plan</p> <p>Funding Opportunity Announcements</p>	<p>Week 1-2</p>

Task	Person(s) Responsible	Materials	Timeline
Develop Budget <ul style="list-style-type: none"> • Use budget template to plan expenses. <ul style="list-style-type: none"> ○ Staff ○ Facility ○ Equipment ○ Supplies 	Clinic Director, Clinic Manager, Fiscal Managers/ Officers	See Estimated and Blank Cost Sheet	Week 3-4
Obtain Stakeholder “Buy-in” <ul style="list-style-type: none"> • Engage stakeholders for support and participation in the planning and execution of the intervention • See Stakeholder Checklist <ul style="list-style-type: none"> ○ List of internal and external partners to reach out to for support in “buy-in,” recruitment, and funding • Review Program Review Board requirements 	Clinic Director, Clinic Manager, PHA Supervisor	See Stakeholder Checklist	Week 5
Identify Appropriate Staff to Implement the Intervention <ul style="list-style-type: none"> • Identify current staff members who will participate in the day to day execution of the intervention. This may include <ul style="list-style-type: none"> ○ Clinic Manager: Oversees the intervention implementation; ○ PHA Supervisor: Oversees the PHA; could be the clinic manager, social worker, nurse, etc.; ○ Clinician, nurses, social workers, DIS, triage staff: Screens and refers clients to the PHA for intervention; ○ New or existing PHA, if applicable . 	Clinic Director, Clinic Manager, PHA’s Supervisor, Clinicians/ Nurses/ Social Workers/ DIS/Triage	Staff Directory	Week 6
Create Data Collection System <ul style="list-style-type: none"> • If funded by CDC, agencies need to collect data that can be imported into the NHME system. See the Monitoring and Evaluation Section for more details. 	Clinic Director, Clinic Manager	“Monitoring and Evaluation” Section of the IM	Week 7

Task	Person(s) Responsible	Materials	Timeline
Review Policies and Procedures <ul style="list-style-type: none"> • Make sure the current policies and procedures are appropriate for FOF, and make adjustments, if necessary, to accommodate the program. 	Clinic Director, Clinic Manager	Clinic Policies and Procedures See “Policies and Procedures”	Week 8
Set-up a “Buy-in” Meeting at the Agency <ul style="list-style-type: none"> • Conduct a meeting with all staff to introduce and gain support for FOF. 	Clinic Manager	See “Staff Buy-in”	Week 9
Hire a PHA to implement the intervention <ul style="list-style-type: none"> • Revise the Job Description included in the IM. • Develop or adapt the marketing materials included in the IM to advertise the position. • Explore existing networks of appropriate individuals. • Interview candidates using the interview tool in the IM. • Hire a PHA. 	Clinic Director, Clinic Manager, PHA’s Supervisor	Refer to “Identifying Appropriate Staff”	Week 10
Integrate the PHA into Agency Team <ul style="list-style-type: none"> • Introduce the PHA and his role to all staff at the agency. 	Clinic Manager		Week 11
Train the PHA and Supervisor <ul style="list-style-type: none"> • Register the PHA and supervisor for a CDC FOF Training of Facilitators session – 3-day training. • Attend Training of Facilitators Program. • Debrief with PHA and supervisor about the Training of Facilitators Program. 	Clinic Manager, PHA’s Supervisor, PHA	CDC Website	Week 12
Train the Clinic Staff <ul style="list-style-type: none"> • Register clinic staff for training on the intervention and how to integrate the PHA into the healthcare team. 	All Clinic Staff	CDC Website	Week 12

Implementation Overview

The implementation overview addresses two topics: a programmatic timeline and an implementation summary for the intervention.

Programmatic Timeline (1st year only)

The programmatic timeline describes ongoing implementation activities rather than planning and pre-implementation activities.

Activity	Timeline
Distribute and review Client Surveys.	Once every day
PHA meets with Supervisor.	Once every week
Monitoring and evaluation.	Once every week
Monitor levels of supplies (condoms, lubricant, ditty bags, etc.) and purchase supplies as required.	Once every week
Distribute and review Staff Surveys.	Once every month
Address staff “buy-in” (see “Staff Buy-in” in the Pre-Implementation Section of the IM).	Once every month
Provide the PHA with formal feedback based on an observed FOF session with a client (video-taped, tape recorded, male staff member sits in on session to observe, etc.).	Once every month
Review and update “List of stores in the surrounding area that carry a variety of high-end condoms and lubricants with their addresses, hours and prices listed.”	Once every 2 months
Quality assurance staff meets to discuss ways to improve implementation.	Once every 4 months
HIV Rates Pie Chart.	Once a year (or as updated statistics are released by the CDC)

Implementation Summary

This chart will help your agency prepare for the implementation of **FOF** by listing what inputs need to be gathered, what activities need to be conducted, and what outputs will be expected. The inputs section is a summary of the elements your agency should have in place before beginning to implement **FOF**. Once you have these resources, you can begin working on the activities section, which, when executed faithfully, should create the tools in the output section that allow you to offer **FOF** to the target population in your community.

INPUTS <i>Resources needed to implement and conduct intervention activities</i>	ACTIVITIES <i>Actions required to prepare for and conduct the intervention</i>	OUTPUTS <i>Deliverables or products that result from implementation activities</i>
<ul style="list-style-type: none"> • Agency capacity to conduct FOF • A PHA who comes from and resides in the community and relates to men positively and quickly • Clinic Manager who will assist with pre-implementation activities and conduct quality assurance activities • Confidential and safe meeting space to conduct all FOF sessions without interruptions • Agency, staff, and other stakeholder (local agencies with target client population, organizations that can provide material support) “buy-in” and involvement in assisting agency to implement FOF • Commitment to and completion of three days of intensive training on FOF intervention. • Ability to screen for eligibility • Ability to integrate FOF into clinic flow • Local/state public health officials’ support for FOF implementation • Community and consumer support for FOF implementation 	<ul style="list-style-type: none"> • Closely review FOF curriculum/intervention and understand theory and science behind it • Assess agency capacity to conduct FOF and identify technical assistance needs • Request technical assistance from Project Officer, CBA Coordinator • Introduce and orient staff to FOF • Identify appropriate staff to implement the intervention (Assess need for adaptation of intervention and contact Project Officer for further assistance) • Obtain and utilize consumer, community stakeholder input on FOF intervention • Inform local/state public health officials about FOF to gain their support • Prepare implementation plan with measurable goals and process and outcome objectives • Develop program monitoring plan to improve program and for quality assurance • Identify logistics for FOF (e.g., times, days, space) • Train and build skills of FOF PHA, his supervisor, and staff who will refer clients 	<ul style="list-style-type: none"> • Implementation plan, tailored to target population including measurable goals and process and outcome objectives • Written process/procedures to integrate FOF into flow of agency services and programs • Written FOF referral process • Evaluation plan including tools, evaluation data, data analysis, and summary reports with interpretation • Documentation of regular program monitoring and program improvement in accordance with monitoring plan • % of planned # of participants referred for FOF in [timeframe] • % of planned # of FOF sessions held in [timeframe] • % of planned # of FOF participants who satisfy target population characteristics in [timeframe]

<p style="text-align: center;">INPUTS</p> <p style="text-align: center;"><i>Resources needed to implement and conduct intervention activities</i></p> <p style="text-align: center;">(continued)</p>	<p style="text-align: center;">ACTIVITIES</p> <p style="text-align: center;"><i>Actions required to prepare for and conduct the intervention</i></p> <p style="text-align: center;">(continued)</p>	<p style="text-align: center;">OUTPUTS</p> <p style="text-align: center;"><i>Deliverables or products that result from implementation activities</i></p> <p style="text-align: center;">(continued)</p>
<ul style="list-style-type: none"> • Input of agency staff, consumers, and community stakeholders into planning and implementation • External technical assistance 	<ul style="list-style-type: none"> • Plan and implement process/procedures to integrate FOF into flow of agency services and programs • Design participant referral process including who refers and how • Purchase/obtain a variety of high-end male condoms, packets of lubricant, male penis models for demonstration and skill building during the session • Purchase/obtain a small bag (e.g., ditty bag) for the client to put condoms and lubricant in at the end of the session • Conduct FOF intervention 	

Budget

Budget Narrative

In order to implement the intervention, personnel, space in the facility, equipment, supplies, and the PHA recruitment need to be included in the budget.

Personnel

A Clinic Director and Clinic Manager will be needed at 5% full time employee (FTE) during pre-implementation and at 2% during the implementation period. Clinicians, nursing, social workers, DIS, and triage staff will be required to spend 1% FTE in order to become familiar with the intervention and screen and recruit eligible clients to **FOF**. A Supervisor needs to be assigned to the PHA. This individual will spend 7% FTE attending the 3-day training and supervising the PHA. Finally, the PHA will be hired from the surrounding community and paid approximately \$10/hour to be trained to carry out the **FOF** intervention. The amount of personnel time may vary depending on agency location.

Facility

FOF requires that the intervention take place in a private room at the agency location. It does not need to be a large space, but it should have enough room for both the PHA and the client to sit comfortably at a table or desk. There should also be cabinet, closet or room to store the supplies necessary for the intervention. The ditty bags and the high volume and variety of high-end and popular condoms and lubricant that are associated with **FOF** are appealing to both clients and staff. Therefore, it is important to keep supplies locked up in a closet or room that only a known number of staff have access to. It would be ideal if only the PHA and his supervisor have access to the supplies. Consider having the lock to the closet or room where the supplies for the intervention will be kept changed prior to implementing the intervention.

Equipment

In terms of equipment, your agency will need a photocopier (to copy the SCUS and list of stores that carry high-end condoms and lubricant) and a computer to print relevant materials. Additionally, the PHA will need to have access to a phone so clients can call him if they encounter issues with condom use. The agency can assign a phone within the facility for the PHA to use, a cell phone can be purchased for the PHA to use, or the PHA can be reimbursed for using his personal phone.

Supplies

A number of supplies need to be purchased for **FOF**. Paper is required to copy the SCUS and list of stores that carry high-end condoms and lubricant. Clients will use pens when filling in the SCUS. Key to the intervention is supplying clients with a variety of high-end/popular condoms and lubricants. Each client will receive 25+ condoms and 25+ packets of lubricant. Additional condoms and packets of lubricant will need to be purchased so the client can practice correctly putting condoms on a penile model and to explore the different features of condoms and lubricant. When purchased through bulk purchasing sites for the pilot study, this worked out to \$7.30/client for

condoms and \$6.55/client for lubricant. Your agency will need to purchase small bags for the clients to put their condom and lubricant samples in. Paper bags can be used, however, it is preferred that agencies use small nylon or velvet bags (“ditty bags”). Providing clients with a higher-end bag to put their samples in makes them feel like a valued and important client of the clinic. A lifelike penile model that accurately represents the anatomy of the target population is required during the skills building component. Having one or two less lifelike models are important to have on hand in the case a client refuses to practice using the lifelike model. Baby oil is needed for the demonstration about the dangers of using oil-based lubricants. A poster with National HIV Rates and PHA contact cards need to be printed in color. Paper towels and hand sanitizer are important to have on hand for clients and the PHA to clean their hands after practicing correct condom use. Finally, if able, your agency can supply the PHA with speakers to play music during the session and with refreshments to offer the clients. Both of these supplies will help the PHA build trust and rapport, which may increase the impact of the intervention.

Two budgets have been included for your consideration. The first is a budget that includes estimated figures and represents the cost of implementing **FOF** for one year (or 1250 clients). The second budget is a blank, user-friendly tool without figures to assist you when developing a budget with your respective figures.

Cost Sheet – Estimated

Categories for Provider Costs to Implement Intervention									
Categories	Pre-Implementation (start-up)			Implementation (intervention delivery)			Cost per Participant N=1250	Total cost	
Personnel (time spent on intervention)									
	# Staff Required	% time or # hrs	weeks	# Staff Required	% time or # hrs	weeks			
Salaried									
Clinic Director	1	5%	2	1	2%	50	In Kind	In Kind	
Clinic Manager	1	15%	2	1	5%	50	In Kind	In Kind	
Other Clinic Staff	TBD	1%	2	TBD	1%	50	In Kind	In Kind	
Hourly									
Peer Health Advisor	1	40	2	1	40	50			
Compensation	% allocated	\$/hr	weeks	% allocated	\$/hr	weeks			
Peer Health Advisor		\$10.00	2		\$10.00	50	\$16.64	\$20,800.00	
Facilities (time used for intervention)									
	# Required	# hrs/week	weeks	#	# hrs/week	weeks			
Small Private Meeting Space/ Peer Health Advisor Office	1	40	2	1	40	50	In Kind	In Kind	
Equipment (time used for intervention)									
	# Required	% time	weeks	# Required	% time	weeks			
Copier	1	1%	2	1	1%	50	In Kind	In Kind	
Computer	1	10%	2	1	1%	50	In Kind	In Kind	
	# Required	\$ allocated/week	weeks	# Required	\$ allocated/month	weeks			
Phone	1	\$6	1	1	\$6.00	50	\$0.24	\$306.00	

<u>Categories</u>	<u>Pre-Implementation (start-up)</u>			<u>Implementation (intervention delivery)</u>			<u>Cost per Participant</u> N=1250	<u>Total cost</u>
Supplies								
	<u>Units</u>	<u>x</u>	<u>Price/unit</u>	<u>Units</u>	<u>x</u>	<u>Price/unit</u>		
Condoms	Client(s)*	1	\$7.30	Client(s)*	1250	\$7.30	\$7.31	\$9,132.30
Lubricants	Client(s)*	1	\$6.55	Client(s)*	1250	\$6.55	\$6.56	\$8,194.05
Penile Model - Rubber	Model(s)	1	\$11.00	Model(s)	0	\$11.00	\$0.01	\$11.00
Penile Model - Wooden	Model(s)	1	\$8.00	Model(s)	0	\$8.00	\$0.01	\$8.00
Penile Model - Plastic Banana	Model(s)	1	\$5.28	Model(s)	0	\$5.28	\$0.00	\$5.28
Ditty Bags	Bag(s)	5	\$1.25	Bag(s)	1250	\$1.25	\$1.26	\$1,568.75
Baby Oil	20oz Bottle(s)	1	\$4.50	20oz Bottle(s)	10	\$4.50	\$0.04	\$49.50
External Audio Speakers	Set(s)	1	\$22.00	Set(s)	0	\$22.00	\$0.02	\$22.00
MP3 Player	Player(s)	1	\$30.00	Player(s)	0	\$30.00	\$0.02	\$30.00
Printer Ink - Black	Cartridge(s)	1	\$122.00	Cartridge(s)	3	\$122.00	\$0.39	\$488.00
Printer Ink - Cyan	Cartridge(s)	1	\$122.00	Cartridge(s)	2	\$122.00	\$0.29	\$366.00
Printer Ink - Magenta	Cartridge(s)	1	\$122.00	Cartridge(s)	2	\$122.00	\$0.29	\$366.00
Printer Ink - Yellow	Cartridge(s)	1	\$122.00	Cartridge(s)	2	\$122.00	\$0.29	\$366.00
Printer Paper	Cartridge(s)	1	\$48.99	Cartridge(s)	3	\$48.99	\$0.16	\$195.96
Posters	Poster(s)	7	\$55.00	Poster(s)	0	\$55.00	\$0.31	\$385.00
Contact cards	Contact card(s)	1250	\$0.22	Contact card(s)	0	\$0.22	\$0.22	\$275.00
Total Cost								
Personnel			\$800.00			\$20,000.00	\$16.64	\$20,800.00
Facilities			In Kind			In Kind	In Kind	In Kind
Equipment			\$6.00			\$300.00	\$0.24	\$306.00
Supplies			\$1,298.87			\$20,164.97	\$17.17	\$21,463.84
Phase Total			\$2,104.87			\$40,464.97	\$34.06	\$42,569.84
Final Total:								\$42,569.84

*Assumes 35 high-end condoms and 35 foils of water-based lube per client (25 of each to take home and 10 of each to open and practice with)

Categories for Provider Costs to Implement Intervention - Template								
Categories	Pre-Implementation (start-up)			Implementation (intervention delivery)			Cost per Participant N=1250	Total cost
Personnel (time spent on intervention)								
Salaried Clinic Director Clinic Manager Other Clinic Staff	# Staff Required	% time or # hrs	weeks	# Staff Required	% time or # hrs	weeks		
Hourly Peer Health Advisor Compensation Peer Health Advisor	% allocated	\$/hr	weeks	% allocated	\$/hr	weeks		
Facilities (time used for intervention)								
Small Private Meeting Space/ Peer Health Advisor Office	# Required	# hrs/week	weeks	#	# hrs/week	weeks		
Equipment (time used for intervention)								
Copier Computer	# Required	% time	weeks	# Required	% time	weeks		
Phone	# Required	\$ allocated/week		# Required	\$ allocated/month	weeks		

<u>Categories</u>	<u>Pre-Implementation (start-up)</u>		<u>Implementation (intervention delivery)</u>		<u>Cost per Participant</u> N=1250	<u>Total cost</u>
Supplies						
	<u>Units</u>	<u>x</u>	<u>Price/unit</u>	<u>Units</u>	<u>x</u>	<u>Price/unit</u>
Condoms	Client(s)*			Client(s)*		
Lubricants	Client(s)*			Client(s)*		
Penile Model - Rubber	Model(s)			Model(s)		
Penile Model - Wooden	Model(s)			Model(s)		
Penile Model - Plastic Banana	Model(s)			Model(s)		
Ditty Bags	Bag(s)			Bag(s)		
Baby Oil	20oz Bottle(s)			20oz Bottle(s)		
External Audio Speakers	Set(s)			Set(s)		
MP3 Player	Player(s)			Player(s)		
Printer Ink - Black	Cartridge(s)			Cartridge(s)		
Printer Ink - Cyan	Cartridge(s)			Cartridge(s)		
Printer Ink - Magenta	Cartridge(s)			Cartridge(s)		
Printer Ink - Yellow	Cartridge(s)			Cartridge(s)		
Printer Paper	Cartridge(s)			Cartridge(s)		
Posters	Poster(s)			Poster(s)		
Contact cards	Contact card(s)			Contact card(s)		
Total Cost						
Personnel						
Facilities						
Equipment						
Supplies						
Phase Total						
Final Total:						

*Assumes 35 high-end condoms and 35 foils of water-based lube per client (25 of each to take home and 10 of each to open and practice with)

Adaptation

Adaptation is the process of modifying an evidence-based intervention to meet a particular population's needs while maintaining fidelity to the intervention's core elements and original intent. Prior to considering adapting an intervention, it is important to consider all available evidence-based interventions to make sure you have selected the intervention that best suits the needs of the target population you want to serve. Matching the HIV-prevention needs of your target population—specifically, risk behaviors and determinants of risk—with an intervention that addresses these problems should be done first. If you determine that there is no existing evidenced-based intervention that can meet your target population's needs, then it may be time to consider adaptation. This means that, for example, you may need to adapt an intervention, originally designed to serve a specific target population, for persons of a different race, ethnicity, or age.

The adaptation process consists of a number of analytical steps ranging from a community assessment which includes an assessment of your target population's HIV-prevention needs and determinants of behavior change, to reviewing the existing intervention, community support and norms, to making necessary changes to fit your target population, to pilot testing new materials. A critical component of the process is working with members of your target population and key stakeholders during each step to ensure that your target population's needs are addressed and that the materials are culturally and linguistically competent and age appropriate.

Some things to consider when deciding whether to adapt an existing intervention include: a) how the existing intervention's problem statement and determinants of behavior change, as depicted in the behavior change logic model, fit with your target population's HIV-prevention needs; b) how immediate and intermediate outcomes depicted in the behavior-change logic model fit with the intended behavior change goals for your target population; and, c) whether the existing content, prevention messages, intervention activities, delivery strategies, and materials are suitable and relevant for your target population.

When going through the adaptation process, it is important to keep the original intent of the intervention as depicted in its behavior change logic model. That is, the intervention should continue to address the same needs identified in the problem statement, target the same determinants of behavior change and aim for the same intended outcomes. The specific manner or method by which this is accomplished in the intervention may need to be modified. Understanding the behavior-change logic model and the core elements and key characteristics of the intervention is important so the adaptation process can be done successfully. Core elements cannot be changed. They must be maintained because they are based on the underlying theory or internal logic of the intervention and are believed to be critical to the intervention's success in achieving its outcome objectives, including the behavior changes you want clients to achieve. The intervention's key characteristics can be modified. In general, the intervention content, activities, delivery strategies, and materials can be modified as needed, as long as these changes don't affect the core elements.

It is not recommended that you adapt an intervention for a different risk behavior. For example, an intervention that seeks to change risky sexual behaviors cannot easily be modified to change injection drug use behaviors. To address this problem, selecting a different intervention that better fits your target population and their risk behaviors is strongly recommended. Adaptation is generally not recommended for a population with a different HIV-serostatus or a different gender because of differences in content, prevention messages, and contextual issues.

If you have program evaluation funds, sound management recommends that you conduct process monitoring and process evaluation with the adapted intervention once it is implemented. This will assist you in determining if your target population is being reached as anticipated and if the adapted intervention is being delivered completely, consistently, and with fidelity to your clients.

If your agency is funded by the Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, you must include your project officer in discussions and decisions about the adaptation process, and your project officer should provide approval for the adapted intervention to be implemented with clients. Your project officer can also discuss capacity-building assistance available from the CDC (<http://www.cdc.gov/hiv/cba>). If you are “indirectly” funded by CDC through your health department, check with health department staff to request assistance on adaptation.

APPENDICES

ORIGINAL ARTICLE

If the condom fits, wear it: a qualitative study of young African-American men

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Objective: To extend the current knowledge base pertaining to condom failure among young African-American men by assessing their experiences with male condom use.

Methods: Qualitative assessments were conducted with 19 African-American men (aged 18-29 years) who had just been diagnosed with an STI and reported using condoms in the previous 3 months.

Results: Five categories were identified from the data. These categories pertained to: (1) the "fit and feel" of condoms; (2) condom brand and size; (3) application problems; (4) availability of condoms and lubricants; and (5) commitment to condom use. Common themes included reasons why men believed condoms would break or slip off during sex. Comfort problems, including tightly fitting condoms and condoms drying out during intercourse, were mentioned frequently. Condom associated erection problems were often described. Many men also noted that condom use reduced the level of sexual satisfaction for their female partners. Men noted that finding the right kind of condom was not always easy and it became apparent during the interviews that men typically did not acquire lubrication to add to condoms. Despite their expressed problems with using condoms, men were, none the less, typically emphatic that condom use is an important part of their protective behaviour against STIs.

Conclusion: Men were highly motivated to use condoms; however, they experienced a broad range of problems with condom use. With the exception of losing the sensation of skin to skin contact, the vast majority of these problems may be amenable to behavioural interventions.

Previous studies have investigated errors and problems that may occur when young men use condoms.¹⁻⁶ These studies have focused on two critical events that lead to condom failure: breakage and slippage. Only two studies have sampled men from a high risk population (men were sampled from an STI clinic).^{2,4} One study enrolled men (18-54 years) attending STI clinics in Sydney, Australia. The study found that breakage and slippage were particularly common for a small number of men.⁴ The other enrolled primarily African-American men (15-29 years) from a US STI clinic and found that 78% of those diagnosed with gonorrhoea reported at least one of five events during the previous month (started sex without condom, removed condom before sex was over, flipped the condom over, breakage, or slippage). Among men attending the clinic but not diagnosed with an STI, 74% reported at least one of these events.²

Two observations regarding these studies are noteworthy. Firstly, each brought attention to a neglected aspect of STI prevention (that is, the value of correcting user errors). However, the initial findings have not been subsequently investigated to gain a more in-depth understanding. Clearly, identifying common user errors and problems among men is an important task, but one that does not currently lend itself entirely to the use of closed response data collection instruments. Secondly, only one study² sampled men from a priority population for STI prevention in the United States. Evidence clearly suggests that African-American men (especially younger men) are particularly likely to be infected by HIV.⁷⁻⁹ Of interest, a nationally representative US study found that African-American men were four to five times more likely to experience condom slippage and breakage than men of other races.⁴

The purpose of this study was to extend the current knowledge base pertaining to condom failure among young African-American men by qualitatively assessing experiences

using the male condom. Because young African-American men are disproportionately infected by STIs, we selected this population for initial study. Further, we sampled men newly diagnosed with an STI; thus, the findings may be useful in the development of clinic based prevention efforts.

METHODS

Study sample

From June through August 2003, 19 men attending an STI clinic were enrolled. Men were recruited during days and times that were arbitrarily selected. Eligibility criteria were: (1) African-American, (2) 18-29 years of age, (3) diagnosis (confirmed or presumptive) of an STI during the clinic visit, (4) reported they were not knowingly HIV positive, and (5) used a condom with a female partner in the past 3 months. Before discharge from the clinic, medical staff determined eligibility based on the first three requirements. Twenty men were referred to a male interviewer who established eligibility based on the latter two requirements. One man stated that he had not used condoms in the past 3 months. All of the remaining 19 eligible men volunteered to participate and provided written informed consent. The institutional review board at Emory University approved the study protocol. A \$30 incentive was provided.

Data collection

Interviews occurred in a private room adjacent to the examination rooms. The interviewer (RC) informed men that he wanted to "find out what kind of problems guys experience when they use condoms." Men were asked to describe any of the problems they may have experienced. The interviewer used prompts (as sparingly as possible) to help men think about problems that may have occurred. Prompts were simple phrases such as, "any problems putting the condom on?" or "do condoms ever slip off during sex?" Prompts were designed to normalise user errors and

problems thereby potentially encouraging men to accurately disclose user related issues. Also, when men provided answers that were unclear or complex, the interviewer asked for clarification and (in many instances) summarised the response for men to verify. Interviews lasted 15–35 minutes, were recorded on audiotape, and were professionally transcribed.

Data analysis

Data were sorted into categories by the first author (RC). The second author (CG) conducted an independent and concurrent review of the data. The identified categories were then verified by the remaining authors (WY and SS).

RESULTS

Five categories were identified: (1) “fit and feel”; (2) brand and size; (3) application problems; (4) availability issues; and (5) commitment to use. Themes (typically focusing on negative events) relating to these categories are presented below.

Category 1: “fit and feel”

One commonly reported problem was that condoms dry out. Men described this problem from their perspective and their sex partners’ perspectives. Nearly all of the men describing dryness problems suggested that the issue was primarily a comfort problem for their partners as opposed to themselves (one exception to this was two men who noted that unlubricated condoms typically “pinch” their pubic hairs, causing extreme discomfort). One man astutely observed that a dry condom remains stationary on him while it is constantly moving in and out of the woman’s vagina. Men were aware that women disliked the sensation of intercourse when condoms became dry. As one man said, “I’m the type of person where if you’re not feeling it, I’m not feeling it.” Another man said that his female partners may “grin and bear it” when condoms dry out but even if sex continues “dimaxing can be difficult under those circumstances.”

Men related several strategies used to rectify dryness. For example, several men said they would simply take the condom off (often at the woman’s request) and continue sex. One man noted that he would “switch out” one condom for another (a fresh one) during any given session of sexual intercourse. He (like a few others) noted that condoms typically don’t dry out until sex has lasted 20 minutes or more. He described recently “switching out” condoms three times during a single sexual encounter and then stated his current infection resulted from an occasion where he had taken off a dry condom and continued sex without another condom (“that’s why I’m here today—I didn’t have the sense to put another one on”).

Men were keenly aware that levels of vaginal secretions vary widely among women and they generally stated that dry condoms are more of an issue when secretions “dry up.” This awareness that sex could become better or worse as a function of two factors (vaginal secretion and the amount of condom lubrication) was common.

Some men added lubrication to their condoms. Several said they use their saliva (as one said, “I kiss it”) and many mentioned their occasional use of KY jelly. One man was very committed to using baby oil: “It (baby oil) suits me better”—“It creates more slip and slide.” He noted that the baby oil helps him keep his erection. Others noted they would use any kind of lotion they could find to lubricate condoms. As one man stated, “If it dries out I’ll usually put lotion on whatever I can find.”

Several suggested that stopping sex to add lubrication was a hassle and could ruin the mood. Yet, men also said that sex

with a dry condom is not as pleasurable and many believed that the dryness was responsible for breakage.

Category 2: condom brand and size

A common theme was that finding the right condom promotes improved use. As one man stated, “Condoms rarely break or slip off once you find the kind that suits you ... everybody has that one (brand) that they like best ... if you’re gonna use em’ make sure you’re comfortable.” One man emphatically stated, “If the condom is not comfortable when you start, it will probably break before you dimax.”

Men reported that some brands/sizes of condoms cause discomfort and erection problems. These problems were typified by one man (diagnosed with syphilis) who described his problem with condoms by saying, “my penis can’t breathe” and another man who said, “they be chokin’ you.” The first man, like many other men in the study, noted that most brands and sizes fit too tightly and this can ruin sex. Men also commonly suggested that tight fitting condoms break (“pop”). With few exceptions, men reporting discomfort said that condoms from the clinic are too tight. They noted that an expensive brand (Magnum) is very comfortable and does not pop.

Loss of erection from tight fitting condoms was common. One man said that 90% of the reason that he sometimes does not use condoms is to avoid erection problems. Several stated that erection problems, caused by condoms, could be so frustrating that they would (despite knowing better) take off the condom and continue sex. Men attributing erection problems to condom use often described pain (from the tight fit), pinching (of the pubic hairs by the rim), and their fears of breakage with tight fitting condoms (as one man said, “small condoms pop almost every time”). Again, men noted that selecting the right brand was the key to avoiding these problems.

Men commonly blamed tight fitting condoms for slippage. One man stated that condoms only slip off when they are too small. Another stated, “the ones that are too tight are the ones most likely to ride up (and slip off).” Most men reporting problems with tightness noted that the unrolled condom did not cover the length of the penis. One stated that he got genital warts because the condom did not cover part of his penis. Some indicated that condoms would slip off as a result of being only partially unrolled. A few also said that they don’t always unroll the condom all the way because doing so pinches their pubic hairs. Of interest, one man stated that he was “trapped between sizes” and described how regular condoms are too tight, but the larger condoms slip off. Finally, several men noted at least one past experience when a condom had slipped off during intercourse and remained inside a partner’s vagina. Men described this event vividly and talked about the condom getting “lost” inside the vagina, where it was not easy to retrieve. In fact, one man talked about he and his partner going to the emergency room to have a condom retrieved.

Interestingly, one man suggested that it was very important to “find the right condom for the right female.” He went on to note that some of his partners liked Magnums and some liked Trojans. He noted he had to keep these preferences straight in order to please “his women.”

Category 3: application and use problems

The most common application error that men described in conjunction with breakage was trapped air. As one man said, “I don’t pay attention to that (air in the condom)—I didn’t even know you was supposed to.” Another described his “trick” for expelling air; he would work the air pocket down to the rim and lift the rim just enough to let the air out. Some stated that tight fitting condoms were especially likely to trap

air and one specifically noted a lack of condoms breakage since learning to expel trapped air.

Most men stated they did not have problems putting condoms on. However, further discussion suggested that men had unknowingly been making application errors. One man stated: "I just slap em' on." Nearly all of the men noted they would often place the condom on the penis with the wrong side facing up (this prevents proper unrolling). Although a few knew that the condom should then be discarded (because of pre-ejaculate), most said they turned the condom over and unrolled it.

Some men described the types of lubricants they used on condoms and freely included Vaseline and other oil based substances as valid options—not making a distinction between these and water based lubricants. Men also noted (without apparent concern) that condom packages had been opened with teeth and sharp fingernails.

A majority described at least one example of having the condom break and frequently linked breakage with application errors. Several stated that breakage had been a common occurrence and others believed their current STI resulted from breakage. Men typically said that they had fewer condoms "pop" as they became more experienced using condoms. One was particularly poignant, noting that when you are younger you are thinking about having sex, not how to use the condom. He suggested that experience is typically the teacher: "You're not gonna go out and ask someone, 'hey man how do you put on a condom'—you just take it on yourself to (learn)." Another said, "they used to break all of the time because I was inexperienced ... I had to learn how to put one on—I learned by reading the package." Indeed, a majority noted learning on their own, through friends, or by reading packages. None the less, several had learned how to apply condoms in highschool health classes (many recalled this vividly).

Breakage was common. Many men noted they could "feel it" when the condom broke and said they would immediately stop sex. One man said that he felt it break and he stopped sex then had another condom on within 10 seconds (he believed this caused his current chlamydia infection). Another told about his efforts to stop sex after breakage, but his female partner only began thrusting harder. Conversely, other men stated they often continued having sex after breakage, despite knowing better: "I kept going, but I didn't ejaculate"; another said, "I can feel the difference when it breaks...if it's with a regular partner I'll usually keep going." Whether men stopped or continued was often described as a function of whether the female partner was known and trusted.

Category 4: availability of condom and lubricants

Although men often expressed clear preferences for certain brands, they also said these brands might not be easily accessible or affordable. The comments of one man were typical: "Dry condoms are bad (implying they break); I've bought them by mistake—you have to use them." This comment is informative in that the man (like others in the study) was implying that once you acquire a condom you should use it. This may be a financial issue (that is, not to waste a condom) or an availability issue. Several men noted that they would obtain condoms from a clinic (despite problems with fit) simply because they were free. Others suggested that cost is less important than availability and described past problems finding well lubricated (and properly fitting) condoms. One man summarised the availability issue nicely by saying, "I may get stuck buying those old dry rubber ones." A quote from one captures sentiments expressed by many, "Late at night you don't have time to look around—you use what you can get."

A few noted that lubricants are not easy to carry around and that while they preferred to use a water based lubricant with a condom, this was not always available.

Category 5: commitment to condom use

Despite problems with "fit," application, and availability, men commonly endorsed condom use as an essential practice in their lives. A comment from one was typical: "I'm not a fan of condoms, but I have to use them to keep from getting STDs." Another remarked: "I try to use them (condoms) because I hate coming here." One noted that he was already at a disadvantage (relative to life expectancy) because he is African-American and that using condoms was necessary to him as a means of avoiding STIs that could make his life even shorter: "Having HIV puts an expiration date on you."

While commitment was strong, men described a number of problems that interfered with intentions. Men noted that they could become too aroused to think clearly enough to use a condom. One man stated, "Grinding before sex is a problem because you forget and slip it in. It is possible to stop and put a condom on but unless she insists, it may not happen—this is why I got my STD." Another noted that being drunk or high was likely to make him "want sex with my lady so bad" and that if she didn't care about using a condom then why should he care. Another (noting erection problems from condoms) said, "I'm not really feeling the person." He repeatedly suggested that he had to "bear down" and mentally discipline himself to use condoms. His comment and experience of condom use is typical of men who suggested that condom use is usually their intent but not always their behaviour.

Despite temptations not to use condoms, many expressed intention to use condoms on every occasion of sexual intercourse, except with a "main" partner (this was seemingly linked to strong fears of getting an STI from an "other" partner). The comments of one man are especially worth noting: "Once I do not use a condom with a girl, then we work into not using them at all." He subsequently suggested that he (or his partners) would feel that there was nothing left to lose by not using condoms.

DISCUSSION

This qualitative study of men newly diagnosed with an STI, produced unique data that provide multiple insights about condom failure. To avoid breakage and slippage—for example, men may have a strong brand and size preference for condoms. Men believed that many negative events they described (including slippage and erection problems) were related to lack of adequate lubrication. Application errors were common. Indeed, men frequently suggested that negative events might be caused by these errors.

Men were generally dedicated to using condoms despite difficulties (for example, erection problems, discomfort, dryness, loss of pleasure). Men were keenly aware of their vulnerability to STIs and they did not mitigate the value of condom use. Yet, men had developed personalised standards for using condoms and some of these practices may be problematic for disease prevention.

A key strength of the qualitative design is the rich narrative. The relative importance for two of the factors (how well the condom fit and how well it felt during sex) was unanticipated given research findings from previous studies.¹⁻⁶ Yet, these factors appear to be critically important with respect to events that precipitate condom failure. Indeed, the men seemed to be saying that condoms are important and should be used, but they expressed a desire to have condoms fit well and have adequate lubrication. The common theme that condoms are important is not surprising given the realities of high STI prevalence among young

Key messages

- Men typically suggested that tight fitting condoms led to erection difficulties, slippage, and breakage. Although most men were aware that larger condoms could be purchased, they typically described problems with accessibility and cost. STI clinics might benefit men by providing a wide selection of various brands and sizes of condoms
- Problems caused by the inadequate lubrication of condoms were frequently mentioned by men in the study. The problems described (erection difficulties, slippage, and breakage) may easily precipitate user error (for example, taking the condom off) or condom failure that leads to the acquisition (or transmission) of an STI. Providing men with instruction and adequate supplies of lubrication may be beneficial
- Despite their description of various errors and problems associated with using condoms, men in this study were generally committed to using condoms. This commitment is positive and could form the basis for clinic based counselling protocols designed to help men refine their condom use skills

African-American men; however, we cannot rule out the possibility of a self presentation bias given these men were newly diagnosed with an STI (and were being interviewed directly afterwards).

Men's responses often suggested that achieving sexual pleasure was at odds with their desire to prevent acquisition of STIs. Although issues pertaining to loss of sensation could be reduced (for example, acquisition of correctly fitting and well lubricated condoms), the overall loss of skin to skin contact was clearly a concern. STI clinic practitioners could address these issues in the process of counselling their young African-American clients. However, further research is needed to determine how couples resolve these issues and whether one partner is more insistent on using condoms.

The findings also suggest that clinic based programmes could help men avoid problems with condom use. For example, breakage, slippage, and erection problems might be avoided by providing men with a wide selection of condoms and encouraging men to find a brand and size that fits and has adequate (and lasting) lubrication. Among low income clients, clinics may benefit men (thereby reducing STI transmission) by allowing them to return and replenish their supply of a favoured condom. STI clinics could also offer men supplies of lubrication (in pocket sized packages). One to one instruction may also be important as a strategy to help men apply condoms more efficiently. Providing this instruction immediately after men are diagnosed with an STI may be particularly effective as this opportunity represents a "teachable moment."

Limitations and further research

Findings based on this purposive sample should not be assumed to fairly represent the larger population of young African-American men newly diagnosed with an STD. Thus,

while intriguing, the current findings should none the less be considered exploratory, especially given the possibility that men have exaggerated their commitment to condom use (that is, self presentation bias) and shifted the blame for condom failure to the product rather than user errors. Further research should build on the study findings to construct structured qualitative interviews that specifically collect event specific data (in a context that avoids self presentation bias).

CONCLUSIONS

Within the limitations of this qualitative study, findings suggest that men in this sample were highly motivated to use condoms, even before their current STI. Despite using condoms, men none the less acquired an STI, possibly due to user error. As opposed to product failure (an irresolvable problem), forms of user failure may be amenable to behavioural interventions. From a policy perspective, STI clinics may benefit men by providing a variety (that is, different brands and sizes) of free condoms and easy to carry packages of lubrication. From a patient education perspective, further research is needed to determine if men can benefit from a brief, interactive, education programme designed to rectify practices that may otherwise lead to user failure or the discontinuation of condom use.

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Appendix B: Agency Fit and Capacity Checklist

Use the checklist below to keep track of what steps still needs to be taken before your agency is ready to implement the intervention. If other parties need to be involved to accomplish these goals you can also use this checklist to keep track of their progress as well.

Statement	Agree	Disagree
FOF meets the purpose, goals, and objectives of my agency.		
FOF meets the needs of the target population that my agency serves.		
My agency can secure adequate funding to successfully provide the intervention to clients.		
My agency has a history of working with the target population and has access to the target population from our existing services. (See Appendix K for a tool to determine the approximate number of eligible clients your clinic sees each day.)		
My agency is ready to implement the intervention. (See “Agency Readiness to Implement the Intervention.”)		
My agency is able to secure “buy-in” for the intervention from key staff in my agency and supporting agencies in the community, as well as from other relevant stakeholders.		
My agency has organizational support to develop and sustain FOF .		
My agency has the policies and procedures in place to support this intervention.		

Appendix C: Modeling Anticipated Demand for FOF Based on a Calendar Year

When integrating **FOF** into your clinic system, it is important to consider how many eligible clients that your clinic serves on a daily basis. Using data from your clinic, complete the tool below to determine the number of clients from the **FOF** target population that a PHA would be able to see in one day at your agency.

If your clinic does not have this data readily available, a staff member can be designated to collect this information for a set period of time (e.g., 2 weeks). See **Appendix A.IX** for a “SAMPLE Client Eligibility Tracking Log” that can be used to record this data. If this data is unavailable and your clinic is unable to collect it, you may make assumptions or your best guess whenever necessary.

1. How many **African American Males** between the **ages of 18 and 29** (inclusive) did you serve in the last calendar year?

2. Of the group in question 1, how many had a **negative or unknown HIV status?**

3. Of the group in question 2, how many **tested positive for an STD** or were **presumptively treated for an STD?**

4. Of the group in question 3, how many **have sex with women?** (Note: include those who have sex with men in addition to women. Do not include those who have sex exclusively with men.)

5. Of the group in question 4, how many have **used a condom in the last 3 months?**

This is the eligible population

6. How many weeks is your clinic open per year?
Note: On average, a clinic is open 42 weeks per year when you exclude holidays and other closings.

7. How many days per week is your clinic open?

8. Multiply the total in **question 6** by **question 7**. This gives you the number of days your clinic is open per year. x =

This is the number of days your clinic operates

Question 6

Question 7

9. Take the total in **question 5** and divide it by the total in **question 8**. This gives you the number of eligible clients that your Peer Health Advisor could deliver the **FOF** intervention to each day.

$$\boxed{} \div \boxed{} = \boxed{}$$

Question 5 Question 8

This is the number eligible clients your clinic sees each day

Using the information gathered from completing the above tool and the guiding questions below, you will determine how eligible clients who enter your clinic will receive the **FOF** intervention.

Considerations

- Ideally the PHA can conduct one **FOF** intervention per hour.
- Consider the number of hours each day that you are open.
- Based on the number of hours that your clinic is open each day and the number of eligible clients you anticipate to see at your clinic each day, think about whether it is possible to offer **FOF** to all eligible clients or only some.

Appendix D: Marketing Materials

The following documents can be used to market the intervention to potential clients or important staff and stakeholders at your agency. These can be used to engage staff and communicate the benefits of **FOF** to the agency and the target population. The documents are a tool that can be used to introduce parties to the principles, and strategies of the intervention and begin to build the necessary “buy-in” among key staff.

How effective is FOF?

The original research demonstrated that participation in FOF:

- ◆ Reduces subsequent STDs
- ◆ Increases reported condom use
- ◆ Decreases the number of sexual partners
- ◆ Decreases the number of acts of unprotected sex
- ◆ Increases proficiency scores for condom application skills

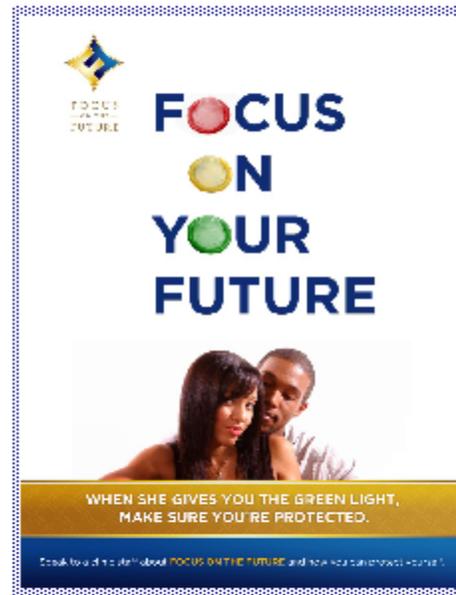
What experiences have agencies had with FOF?

- ◆ "I think this should be mandated (at my agency)" - Social Work Supervisor
- ◆ "(FOF) has been an instrumental tool in stemming the tide of disease" – Disease Investigation Specialist
- ◆ "This is what I've been waiting for!" - Registered Nurse

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FOCUS
— ON THE —
FUTURE

A Brief Intervention for Young African American Men



What is FOF?

FOF is a 45 to 60 minute, individual-level, single session, behavioral intervention that focuses on providing information, motivation and skills to address clients' condom use barriers. This one-on-one conversation between a client and a trained peer, which occurs in an clinical STD setting, allows the intervention to be customized to the clients' individual needs.



Focus on the Future teaches clients:

- ◆ Strategies to address condom use errors and negative condom use experiences
- ◆ Condom negotiation strategies
- ◆ Correct condom and water-based lubricant skills
- ◆ The features of and where to buy a variety of high-end condoms and lubricants so they can find ones with the right fit and feel

Who is FOF for?

Eligible clients for FOF are African American men ages 18-29, who have sex with women (MSW), have used a condom in the last three months, are not knowingly HIV-positive, and either report STD symptoms or have been diagnosed or treated for an STD.

Who facilitates FOF?

FOF is facilitated by a trained Peer Health Advisor (PHA), who is a 21-35 year old African American MSW from the community. Peers are able to build rapport quickly with clients and clients are often more receptive to peers' messages.



What are the goals of FOF?

The overall goal of FOF is to build clients' self-efficacy for using condoms correctly and consistently. This is done by:

- ◆ Discussing condom negotiation skills, the importance of using water-based lubricant, planning for sex, and overcoming negative experiences when using condoms (e.g., condoms breaking, erection loss, etc.)
- ◆ Highlighting that more cases of HIV infection have been reported among African American men compared to other groups of people in the US, in order to motivate clients to take collective action
- ◆ Giving clients the opportunity to practice correctly applying a condom to a model at least 3 times
- ◆ Giving clients 25+ fun and unique condoms and 25+ packets of lubricant to take home

How effective is FOF?

Research shows that participation in FOF will:

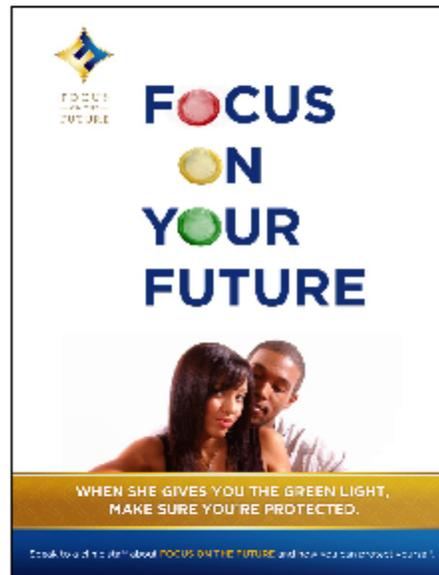
- ◆ Reduce your chances of getting a new STD
- ◆ Increase the chances you'll use a condom
- ◆ Increase your condom use skills

What do participants say about FOF?

- ◆ "No one has ever talked to me about this stuff before."
- Participant
- ◆ "This program makes me want to use condoms." - Participant
- ◆ "We need to have this program everywhere—in schools, barber-shops, outside the clubs."
- Participant

For more information contact:

CLINIC NAME
CLINIC ADDRESS
CLINIC ADDRESS
CLINIC CONTACT INFO
CLINIC CONTACT INFO



PHA NAME
PHA CONTACT INFO
PHA CONTACT INFO
FOF is funded by the CDC under
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FOCUS
— ON THE —
FUTURE

A Brief Sexual Education Program for Young African American Men on Safer Sex & Condom Use



What is FOF?

FOF is a 45 to 60 minute, one-on-one, one-time conversation that focuses on giving you information, motivation and skills to address issues with using condoms. This is a one-on-one talk between a you and a another young man from the community, which allows the conversation to be customized to your individual needs.

What are the Principles of FOF?

- ◆ Unconditional respect for men
- ◆ There are many options for condoms and lubricants available. It is important to find ones with the right fit and feel for you
- ◆ Practicing condom use is important
- ◆ Condoms can feel good during sex
- ◆ You can protect your future and your community's future



Who is FOF for?

FOF is for African American men ages 18-29, who have sex with women, who have used a condom in the last three months, who are not knowingly HIV-positive, and who either have the symptoms of an STD or have been diagnosed or treated for an STD.

Who facilitates FOF?

During your session you will talk with a Peer Health Advisor (PHA), who is a 21-35 year old African American man from the community. PHAs are not health-care professionals, they are guys like you who want to protect the community.



What are the goals of FOF?

The overall goal of FOF is to make you better at using condoms correctly and consistently. This is done by:

- ◆ Helping you introduce condoms in the bedroom, showing you why you should use water-based lubricant, helping you plan for sex, and teaching you how to overcome negative experiences when using condoms (e.g., condoms breaking, erection loss, etc.)
- ◆ Giving you the opportunity to practice correctly applying a condom to a model
- ◆ Giving you 25+ fun and unique condoms and 25+ packets of lubricant to take home for free!



A Brief, Clinic-Based, Safer Sex Intervention for Heterosexual African American Men Newly Diagnosed With an STD: A Randomized Controlled Trial

Richard Crosby, PhD, Ralph J. DiClemente, PhD, Richard Charnigo, PhD, Gregory Snow, and Adewale Troutman, MD

In the United States, AIDS case rates are approximately 8 times higher among African American men than among White men.^{1,2} African American men have the highest prevalence and incidence rates of AIDS of all demographic classifications of US residents. Particularly in the South,^{3–5} African American men are also disproportionately affected by sexually transmitted diseases (STDs).⁶ Given these disparities, an important public health imperative is to develop and test interventions designed to reduce the risk of HIV or other STD acquisition among African American men—especially young African American men, who are at the greatest risk of infection.^{7,8} The imperative applies to both African American men who have sex with men and those who have sex with women. In general, however, heterosexual men of all racial/ethnic origins have been largely neglected with respect to the development and evaluation of HIV prevention interventions.^{9–11}

Few studies have specifically investigated clinic-based approaches to reducing HIV or other STDs among young African American men who have sex with women. For example, in a recent review of effective behavioral interventions for HIV infection, Lyles et al. identified 18 programs that met established methodological criteria.¹² Of these 18, 14 were designed for persons who were not knowingly HIV positive, and of these 14, none was designed for heterosexual African American men. The Centers for Disease Control and Prevention currently endorses a brief (60-minute) clinic-based program delivered in a small-group format designed to promote safer sex among African American and Hispanic men of all ages.¹³ To evaluate program efficacy, investigators used a clinic record review (mean of 17 months) to monitor subsequent STDs. Men randomized to the intervention (22.5%) were less likely to acquire a subsequent STD than were men in the routine-care group (26.8%).¹⁴

Objective. We evaluated the efficacy of a brief, clinic-based, safer sex program administered by a lay health adviser for young heterosexual African American men newly diagnosed with a sexually transmitted disease (STD).

Methods. Subsequent to STD diagnosis, eligible men (N=266; aged 18–29 years) were randomized to either a personalized, single-session intervention (delivered by a lay health adviser) or standard of care. We conducted behavioral assessments at baseline and 3 months postintervention (retention was 74.1%). We also conducted a 6-month clinic record review.

Results. Compared to men randomized to the control condition, those receiving the intervention were significantly less likely to acquire subsequent STDs (50.4% vs 31.9%; $P=.002$) and more likely to report using condoms during last sexual intercourse (72.4% vs 53.9%; $P=.008$). They also reported fewer sexual partners (mean 2.06 vs 4.15; $P<.001$) and fewer acts of unprotected sex (mean 12.3 vs 29.4; $P=.045$). Based on a 9-point rating scale, men in the intervention group had higher proficiency scores for condom application skills (mean difference=3.17; $P<.001$).

Conclusion. A brief clinic-based intervention delivered by a lay health adviser may be an efficacious strategy to reduce incident STDs among young heterosexual African American men. (*Am J Public Health.* 2009;99:S96–S103. doi: 10.2105/AJPH.2007.123893)

Although organizing groups of 3 to 8 men demonstrates efficacy, this may be problematic in many STD clinics from an operational perspective. In a multicenter randomized controlled trial, a one-to-one tailored counseling intervention was evaluated among STD clinic patients.¹⁵ Patients randomized to the enhanced counseling and the brief counseling conditions were less likely to acquire subsequent STDs over a 6-month follow-up (estimated odds ratio [OR]=0.69 and 0.71, respectively). The trial had a low participation rate (44%) and high attrition (49%). Although the trial demonstrated a treatment advantage, there was a marginal treatment effect for the primary behavioral outcome, unprotected vaginal sex. Subsequent reanalysis of the data indicated that intervention effects were not uniform across age groups. For example, among adolescents younger than 20 years, the 12-month STD incidence was 17.2% in the enhanced (intervention) group versus 26.6% in the control group. However, among young adults aged 20 to 25 years,

intervention effects were markedly smaller (13.1% vs 14.8%).¹⁶

In another study, a single-session clinic-based intervention produced significant effects in a subset analysis of young men (aged 20–30 years) and African American men over a 6- to 9-month follow-up period,¹⁷ whereas in a 6-session, video-based intervention, reductions were observed in self-reported unprotected vaginal sex among African American men recruited from an urban STD clinic.¹⁸ Unfortunately, the former study was not designed specifically for African American men and was evaluated using a nonrandomized design, whereas the latter study used a small-group intervention format, which limits its utility for clinic-based implementation, and did not assess subsequent STD acquisition. Finally, a clinic-based study using a 1-month (3-session) intervention format failed to observe significant differences in STD acquisition.¹⁹

We sought to test the efficacy of a clinic-based, safer sex program specifically designed

for young heterosexual African American men newly diagnosed with an STD and residing in the southern United States. The trial tested the hypothesis that men randomized to the intervention group would be significantly less likely than would be controls to acquire a subsequent STD and to engage in unprotected sex. Hypotheses pertaining to fewer sexual partners and greater condom application skills for men receiving the intervention were also tested.

METHODS

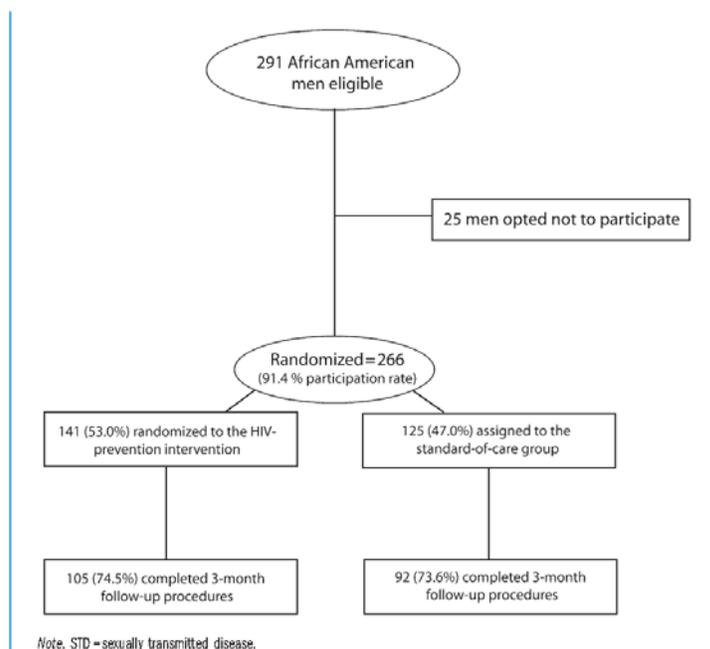
Participants

The study was conducted September 2004 through May 2006. Men were recruited from a public STD clinic located in a southern US city. Recruitment occurred following diagnosis and treatment for STDs. Nurses assessed potential eligibility by determining whether men (1) were newly diagnosed with an STD, (2) self-identified as African American, and (3) were aged 18 to 29 years. Potentially eligible men were asked if they would be interested in volunteering for a study. Those indicating any level of interest (N=306) were escorted to the project's lay health adviser (in an adjacent office), who further screened men for eligibility by determining whether men were English speaking and by asking 2 questions: (1) Are you knowingly HIV positive? and (2) Have you used a male condom at least once in the past 3 months for sexual intercourse (defined as "penis in the vagina") with a woman?

Of the 306 potentially eligible men screened by the lay health adviser, 15 were deemed ineligible based on their responses to the second set of eligibility criteria. These inclusion criteria were important because the brief nature of the intervention was designed specifically to improve the quality and consistency of condom use among men reporting recent experience with condom use. Of the 291 men deemed eligible, 266 (91.4%) were randomized to the 2 trial conditions (Figure 1).

Study Design

In a 2-arm randomized control trial, we used concealment of allocation techniques to minimize allocation bias.²⁰ Before implementing the trial, a random sequence was determined, and envelopes containing allocation cards (coded for intervention or control) were sealed, randomly



Note. STD = sexually transmitted disease.

FIGURE 1—Allocation of study participants in a randomized, controlled trial of a brief, clinic-based intervention to promote STD protective behaviors: Southern United States, September 2004 Through May 2006.

sequenced, and piled; the top envelope on the pile was always used to determine assignment to group. The trial was conducted using a 3-month follow-up assessment and a 6-month medical-records review to assess intervention efficacy.

Intervention Methods

Based on recent evidence suggesting that young African American men experience multiple difficulties with condoms,^{21,22} we designed the intervention to promote men's quality, correctness, and consistency of condom use. A 1-year formative phase was used to develop the intervention. In an initial elicitation study (that used the same inclusion criteria as the trial), we collected qualitative data pertaining to men's barriers in achieving correct and consistent condom use.²¹ We used the findings to develop the brief (approximately 45–50 minutes long) intervention, which we then tested and revised based on identified gaps.

The program (named Focus on the Future) was based on a lay health adviser model. Evidence suggests that lay health advisers are instrumental in achieving intervention success among various populations of African Americans across a broad range of health behaviors.²³ The essence of the model is that the most effective change agents are people who come from the community for which the intervention program is intended. This goes beyond the concept of "matching" by race, age, and gender.²⁴

A young African American male who had grown up and resided in the main catchment area served by the clinic was selected, hired, and trained to implement the intervention. His everyday experiences and communication style were indeed no different from those of the men participating in the intervention. The lay health adviser was selected based on his ability to effectively discuss sex and condom use with men in a nonjudgmental manner. Part of this

ability included being adept at quickly establishing rapport with men by finding common ground between them. Once selected, he attended a 3-day training seminar designed to provide him the skills and information needed to deliver the single-session intervention.

The single session was predicated on the information, motivation, and behavioral skills model.²⁵ Information directly relevant to the quality of condom use was provided. For example, men learned that condoms come in a variety of sizes and shapes, and they learned about the value of periodically adding water-based lubricants to condoms during sexual intercourse. Men learned, by demonstration from the lay health adviser, that oil-based lubricants can quickly erode latex condoms. Enhancing men's motivation to use condoms was an integral component of the session. Throughout the session, the adviser encouraged men to feel good about using condoms, to experience condoms as being compatible with sexual pleasure, and to actively protect themselves from future STD acquisition. The lay health adviser constantly attempted to equate condom use with an investment in the men's future.

The participants were also motivated to personally respond to the AIDS epidemic through our use of large posters illustrating the disproportionate HIV/AIDS burden experienced by African American men. An equally important, but implicit, objective was to have the adviser be responsive to men's questions, problems, and concerns regarding safer sex with their female partners. Men were prompted to think about ways they could initiate condom use with existing partners. Skill acquisition was also emphasized. Correct condom and lubrication use were demonstrated and practiced by men until they expressed a sense of mastery. Men were encouraged to use condoms they felt fit them comfortably and provided them with a sense of security. Based on formative work,²¹ we decided to provide men with pocket-size vials of water-based lubricants as well as 12 or more condoms of their choice from a broad selection of brands and sizes.

All men enrolled in the study received nurse-delivered messages regarding condom use per Centers for Disease Control and Prevention guidelines.²⁶ These messages were typically delivered in only a few minutes and essentially informed men that condoms are an

effective means of preventing subsequent STD acquisition when used consistently. As patients of the clinic, all men were allowed to take up to 12 condoms—with only 1 size and brand available—from the clinic as they exited. In addition to the disease-specific diagnosis and treatment the men received, these procedures comprised clinical standard of care. Men randomized to the control group received only this standard of care, whereas men randomized to the intervention group received this standard of care and participated in the Focus on the Future program.

Data Collection

Immediately following diagnosis and study enrollment, men completed a self-administered questionnaire that the lay health adviser gave them. To avoid problems associated with low literacy, questions were recorded onto a compact disc that men could play using a portable headset. Next, men completed a directly observed condom-application skills assessment. The same procedures were repeated at the follow-up assessment. Men were compensated \$40 for the first assessment and \$60 for the second.

Primary Outcome Measure

Subsequent diagnosis of an STD constituted the primary outcome. Because this publicly funded clinic was the only low-cost option for men in the entire urban catchment area, a medical-records review was used to assess this outcome.

Other Outcome Measures

Four behavioral outcomes were assessed: (1) number of female sexual partners in the past 3 months, (2) condom use during the last act of penetrative (penile–vaginal or penile–anal) sexual intercourse with a female partner, (3) frequency of unprotected penetrative sexual intercourse with a female partner in the past 3 months, and (4) proficiency in using condoms as determined through direct observation of men's ability to apply condoms to a stationary, life-size, rubber penis model. For the fourth behavioral outcome, a 9-item checklist was refined based on previous research conducted by R.J.D.²⁷ This checklist comprised “yes” versus “no” indicators completed by the lay health adviser as men demonstrated the task of condom application.

Statistical Analyses

Demographic and baseline attributes among intervention and control participants were compared via the 2-sample *t* test with unrestricted variances for quantitative variables and the χ^2 test for dichotomous variables. Demographic and baseline attributes among participants who dropped out of the study and participants who remained in the study were compared similarly.

The outcomes of reinfection at any time within the 6 months and condom use at the last sexual act preceding the 3-month follow-up were analyzed via logistic regression. Remaining outcomes were analyzed via linear regression. Univariate analyses used only intervention or control status as a predictor, and multivariable analyses used intervention or control status and several covariates.

First, a dichotomized version of monthly income was used as a covariate. Monthly income served as a proxy indicator of socioeconomic status. Despite the relatively low average income of the sample, we suspected that socioeconomic status may nonetheless be an important determinant of safer sex practices and reinfection. Second, whether men were diagnosed as having 1 versus multiple STDs at baseline served as a covariate; this provided an objective marker of past sexual risk behavior among this sample of high-risk men. Given the strong predictive power of past behavior to predict future behavior, we determined that this measure was an important covariate. Third, the corresponding baseline measure of the outcome variable (except for reinfection) was always included as a covariate. Fourth, the outcome of reinfection was considered to be confounded by condom use and condom use skills; thus, follow-up values for these 2 variables were included as covariates.

Because outcome variables (except reinfection) had missing values because of attrition, the primary data analyses (described in the previous paragraph) were performed twice: first with only complete cases (participants for whom there were no missing values) and then with multiple imputation²⁸ as implemented in the MI and MIANALYZE procedures of SAS version 9.1 (SAS Institute, Cary, North Carolina).

Finally, because there were some extreme outlying observations with respect to the first

and third behavioral outcomes, sensitivity analyses were performed to complement the primary analyses. One set of sensitivity analyses entailed the removal of records with extreme outlying values, and the other involved logarithmic transformations to mitigate the outliers' influence. All analyses were conducted in SAS version 9.1.

RESULTS

Baseline Comparability of Groups

We assessed differences between men randomized to the intervention and control conditions for demographic and other key variables at baseline (Table 1). The only significant difference observed was demonstrated condom application skills, with men in the control condition scoring lower than men in the intervention condition.

Attrition

Among the 266 participants, 69 (25.9%) did not return to complete the 3-month follow-up assessment (Figure 1). However, we were still able to determine if these men acquired a subsequent STD. Comparing the 197 participants who remained in the study with the 69 who dropped out, there were no significant differences in sociodemographics or baseline attributes (Table 2). Further, the proportions of men dropping out were not significantly different between the 2 groups (intervention or control). Finally, men dropping out were not significantly different from men completing the study with respect to STD reinfection rates.

Effects of the Intervention

With 1 exception, the 5 outcome measures achieved univariate significance in both the complete case and multiple imputation analyses (Table 3). We used the complete case analysis to compare men in the control group and found that those in the intervention group were significantly less likely to acquire a subsequent STD within the 6-month follow-up interval (50.4% vs 31.9%; univariate OR estimate=0.46; 95% confidence interval [CI]=0.28, 0.76). Men in the intervention scored higher on the condom application skills assessment (mean difference estimate=3.17; 95% CI=2.81, 3.53; relative difference=

TABLE 1—Demographic and Other Baseline Attributes of Enrollees in a Risk-Reduction Intervention Evaluation of African American Men Aged 18 to 29 Years Newly Diagnosed With an STD, by Group Assignment: Southern United States, September 2004 Through May 2006

	Intervention (n=141), Mean ±SD or No. (%)	Control (n=125), Mean ±SD or No. (%)	P
Age, y	23.1 ± 3.4	23.4 ± 3.1	.49
Net monthly income >\$1000	38 (27.0)	42 (33.9) ^a	.22
Current relationship is monogamous	68 (48.6) ^b	60 (48.0)	.92
Current relationship is not monogamous	59 (42.1) ^b	54 (43.2)	.86
Previously taught how to use condoms	127 (90.1)	110 (88.7) ^a	.72
Multiple STDs diagnosed at baseline	41 (29.3) ^b	27 (22.1) ^a	.19
Baseline diagnosis included chlamydia	55 (39.0)	50 (40.3) ^a	.83
Baseline diagnosis included gonorrhea	87 (61.7)	76 (61.3) ^a	.94
Demonstrated condom use skills	3.83 ± 2.24 ^c	2.60 ± 1.67 ^d	<.001
Number of female sexual partners, past 3 months ^e	2.91 ± 2.73	3.08 ± 2.43	.60
Unprotected acts of sexual intercourse, past 3 months ^f	16.0 ± 47.3 ^b	14.3 ± 21.0 ^g	.72
Used condoms last time sexual intercourse occurred	74 (52.5)	53 (42.4)	.10

Note. STD = sexually transmitted disease. All results pertain to men who self-identified as heterosexual.

^aOut of 124 participants with data for variable for which not all participants had data.

^bOut of 140 participants with data for variable for which not all participants had data.

^cOut of 131 participants with data for variable for which not all participants had data.

^dOut of 112 participants with data for variable for which not all participants had data.

^eMedian and interquartile range were 3.0 and 1.0, respectively, for the control group and 2.0 and 1.0, respectively, for the intervention group. Excluding 4 participants in the control group and 3 in the intervention group who claimed more than 100 unprotected acts of sexual intercourse at baseline or follow-up or who claimed more than 25 partners at baseline or follow-up, mean and standard deviation are 3.02 and 2.29 for the control group and 2.70 and 1.71 for the intervention group.

^fMedian and interquartile range were 6.5 and 18.0, respectively, for the control group and 4.0 and 13.0, respectively, for the intervention group. Excluding 4 participants in the control group and 3 in the intervention group who claimed more than 100 unprotected acts of sexual intercourse at baseline or follow-up or who claimed more than 25 partners at baseline or follow-up, mean and standard deviation are 13.51 and 18.08 for the control group and 11.75 and 19.44 for the intervention group.

^gOut of 123 participants with data for variable for which not all participants had data.

^hOut of 114 participants with data for variable for which not all participants had data.

+145%). Also, men in the intervention reported significantly fewer sexual partners (2.06 vs 4.15, mean difference estimate = -2.10; 95% CI = -3.22, -0.98; relative difference = -51%), significantly fewer acts of unprotected sex (12.3 vs 29.4; mean difference estimate = -17.1; 95% CI = -33.6, -0.5; relative difference = -58%) and were significantly more likely to report using condoms during their last episode of sexual intercourse (72.4% vs 53.9%; univariate OR estimate = 2.25; 95% CI = 1.24, 4.07). Of note, these results remained relatively unchanged with multiple imputation, with the exception of unprotected sex, which narrowly missed significance.

Multivariable analysis yielded more robust intervention effects on subsequent STD

acquisition (Table 3). Men randomized to the intervention had about 68% lower odds of acquiring a subsequent STD (adjusted OR estimate = 0.32; 95% CI = 0.12, 0.86). Furthermore, findings from the multiple imputation analyses indicated that men in the intervention group had a higher score on the condom application assessment (mean difference estimate = 3.19; 95% CI = 2.81, 3.56), had fewer female sexual partners (mean difference estimate = -1.87; 95% CI = -2.96, -0.79), and were more likely to report condom use at last sexual episode (adjusted OR estimate = 2.06; 95% CI = 1.07, 3.96). One outcome did not achieve statistical significance in multivariable analyses, namely, number of episodes of unprotected sex in the past 90 days

TABLE 2—Differences Between Men Completing Follow-up Assessments and Those Not Completing Follow-up Assessments in a Risk-Reduction Intervention Evaluation of African American Men Aged 18 to 29 Years Newly Diagnosed With an STD: Southern United States, September 2004 Through May 2006

	Stayed in (n=197), Mean ±SD or No. (%)	Dropped out (n=69), Mean ±SD or No. (%)	P
Age, y	23.4 ± 3.3	23.0 ± 3.3	.47
Net monthly income >\$1000	61 (31.1) ^a	19 (27.5)	.58
Current relationship is monogamous	88 (44.9) ^a	40 (58.0)	.06
Current relationship is not monogamous	88 (44.9) ^a	25 (36.2)	.21
Previously taught how to use condoms	179 (91.3) ^a	58 (84.1)	.09
Multiple STDs diagnosed at baseline	52 (26.7) ^b	16 (23.9) ^c	.65
Baseline diagnosis included chlamydia	73 (37.2) ^a	32 (46.4)	.18
Baseline diagnosis included gonorrhea	122 (62.2) ^a	41 (59.4)	.68
Demonstrated condom use skills	3.39 ± 2.16 ^d	2.90 ± 1.84 ^e	.09
Number of female sexual partners, past 3 months	3.13 ± 2.81	2.61 ± 1.78	.08
Unprotected acts of sexual intercourse, past 3 months	16.6 ± 42.0 ^f	11.6 ± 17.9 ^g	.21
Used condoms last time sexual intercourse occurred	90 (45.7)	37 (53.6)	.26
Assigned to intervention group	106 (53.3)	36 (52.2)	.87
Reinfection	78 (39.6)	30 (43.5)	.57

Note. STD = sexually transmitted disease. All results pertain to men who self-identified as heterosexual.

^aOut of 196 participants with data for variable for which not all participants had data.

^bOut of 195 participants with data for variable for which not all participants had data.

^cOut of 67 participants with data for variable for which not all participants had data.

^dOut of 181 participants with data for variable for which not all participants had data.

^eOut of 62 participants with data for variable for which not all participants had data.

^fOut of 171 participants with data for variable for which not all participants had data.

^gOut of 66 participants with data for variable for which not all participants had data.

(mean difference estimate = -11.9; 95% CI = -31.3, 7.5).

Both sets of sensitivity analyses preserved the conclusions from the primary analyses that men in the intervention had significantly fewer female sexual partners than did men in the control group (Table 4). The sensitivity analyses involving logarithmically transformed number of unprotected acts preserved the mixed conclusions from the primary analyses, in particular statistical significance with univariate complete cases but lack thereof with multivariable multiple imputation. The sensitivity analyses entailing removal of records disagreed with the primary analyses only in that statistical significance was not achieved with univariate complete cases.

DISCUSSION

The findings of our study clearly show the efficacy of this brief clinic-based intervention

for young heterosexual African American men at risk of STD or HIV acquisition in terms of lower rates of subsequent STD acquisition, reduction in STD- or HIV-associated sexual behaviors, and improvement in condom application skills. The practical value of the findings is paramount, because they demonstrate marked reductions in STD incidence without the use of lengthy, resource-intensive programs. Moreover, the reduction in incidence over the 6-month postintervention period produced a larger effect size than did those observed in previous trials of brief, clinic-based interventions for African American men.^{14-19,29} The observed protective value relative to subsequent infection was also greater than that derived from a recent meta-analysis of clinic-based STD prevention programs (effect size: .32 vs .85).²⁹ The treatment advantage may be attributable to multiple factors, such as tailoring to a relatively homogeneous population of men, intervening only with men who reported previous

experience in using condoms, and the use of a lay health adviser model. The effect may also be partially explained by the observation that men randomized to the intervention group reported significantly fewer sexual partners at follow-up (an unexpected finding).

In an era when the Centers for Disease Control and Prevention has stated, "In the United States, the HIV/AIDS epidemic is a health crisis for African Americans,"³⁰ the findings offer one approach to addressing this marked racial disparity. The findings also suggest a protective benefit for men's female sexual partners, who are typically African American. Because power imbalances in heterosexual relationships may favor males, intervention with African American men may also protect African American women against HIV or other STD acquisition.³¹ Indirect effects may also occur by lowering the prevalence of STDs within African American women's sexual networks.³² In turn, reductions in STD prevalence and incidence among African American men and women may mitigate the racial disparity in HIV/AIDS prevalence and incidence by removing STDs as a cofactor.³³⁻³⁶

The brief nature of the intervention also warrants comment. Implementation of small-group interventions or multisession interventions may not be optimally efficient in STD clinics. Because clinics are designed to provide patients with a series of one-to-one interactions with clinical staff, triaging young African American men newly diagnosed with an STD into an additional one-to-one session with a lay health adviser is a relatively simple expansion of the existing clinical paradigm. In addition, the use of a lay health adviser to implement the intervention may be a cost-effective strategy. The relative ease of implementation and higher cost-effectiveness may address the problem of effectively translating evidence-based research into practice.³⁷⁻⁴⁰

Limitations

There are a number of limitations to the study. First, as is true for all sexuality research, findings are limited by the validity of retrospective self-report, although this limitation is somewhat mitigated by the medical-records review findings pertaining to STD reinfection. Further, as is typically true for STD or HIV behavioral randomized trials, the use of a nonprobability sample limits the ability to generalize the findings to young heterosexual

TABLE 3—Intervention Versus Control Group Outcomes Assessed 3 Months Postintervention in a Risk-Reduction Intervention Evaluation of African American Men Aged 18 to 29 Years Newly Diagnosed With an STD: Southern United States, September 2004 Through May 2006

	Intervention (n=141), No. (%) Mean ± SD (No.)	Control (n=125), No. (%) Mean ± SD (No.)	Univariate Measure of Effect		Multivariable Measure of Effect	
			OR Estimate (95% CI)	P	AOR Estimate (95% CI)	P
Reinfection ^a	45 (31.9)	63 (50.4)	0.46 (0.28, 0.76)	.002	0.32 (0.12, 0.86)	.02
Condom use skills ^{b,c}	5.35 ± 1.21 (104)	2.18 ± 1.30 (84)	3.17 (2.81, 3.53)	<.001	3.21 (2.80, 3.63)	<.001
Condom use skills ^d			3.17 (2.79, 3.54)	<.001	3.19 (2.81, 3.56)	<.001
Partners in past 3 months ^{e,f}	2.06 ± 1.66 (105)	4.15 ± 5.59 (91)	-2.10 (-3.22, -0.98)	<.001	-2.09 (-3.18, -0.99)	<.001
Partners in past 3 months ^{d,f}			-1.85 (-2.97, -0.74)	.002	-1.87 (-2.96, -0.79)	.001
Unprotected acts of sexual intercourse, past 3 months ^{g,h}	12.3 ± 25.8 (99)	29.4 ± 79.3 (84)	-17.1 (-33.6, -0.5)	.045	-13.4 (-35.6, 8.8)	.23
Unprotected acts of sexual intercourse, past 3 months ^h			-14.9 (-31.0, 1.3)	.07	-11.9 (-31.3, 7.5)	.21
Condom used at last act of sexual intercourse ⁱ	76 (72.4)	49 (53.9)	2.25 (1.24, 4.07)	.008	2.26 (1.08, 4.48)	.03
Condom used at last act of sexual intercourse ⁱ			2.27 (1.23, 4.19)	.009	2.06 (1.07, 3.96)	.03

Note. STD = sexually transmitted infection. For quantitative variables, the measure of effect is a mean difference (expected score for intervention participant minus expected score for control participant, adjusted in the multivariable analyses for covariates specified below) and was estimated by linear regression. For dichotomous variables, the measure of effect is an odds ratio (odds in favor for intervention participant divided by odds in favor for control participant, adjusted in the multivariable analyses for covariates specified below) and was estimated by logistic regression. Complete case analyses used only those participants for whom there were no missing values on variables in the regression model. Multiple imputation analyses used all participants. All results pertain to men who self-identified as heterosexual. For variables on which not all participants had data, the numbers in parentheses identify how many participants did have data.

^aMultivariable analysis controls for monthly income level, having 1 vs 2 or more STDs diagnosed at study enrollment (mixed STDs), follow-up values for condom skills, and follow-up values for condom use at last act of sexual intercourse.

^bMultivariable analysis controls for income, mixed STDs, and the baseline value of condom skills.

^cComplete case analysis.

^dMultiple imputation.

^eMedian and interquartile range are 2.0 and 3.0, respectively, for the control group and 2.0 and 2.0, respectively, for the intervention group. Excluding 4 participants in the control group and 3 in the intervention group who claimed more than 100 unprotected acts of sexual intercourse at baseline or follow-up or who claimed more than 25 partners at baseline or follow-up, mean and standard deviation are 3.52 and 4.04 for the control group and 2.00 and 1.47 for the intervention group.

^fMultivariable analysis controls for income, mixed STDs, and the baseline value for number of female sexual partners in the past 3 months.

^gMedian and interquartile range are 4.5 and 21.0, respectively, for the control group and 1.0 and 11.0, respectively, for the intervention group. Excluding 4 participants in the control group and 3 in the intervention group who claimed more than 100 unprotected acts of sexual intercourse at baseline or follow-up or who claimed more than 25 partners at baseline or follow-up, mean and standard deviation are 17.24 and 28.77 for the control group and 11.12 and 21.96 for the intervention group.

^hMultivariable analysis controls for income, mixed STDs, and baseline values for skill, unprotected sex, and condom use at last act of sexual intercourse.

ⁱMultivariable analysis controls for income, mixed STDs, and the baseline values for skills and condom use at last act of sexual intercourse.

African American men newly diagnosed with an STD in other clinics of the United States. Another concern was the attrition rate. That 26% of the enrolled men did not return for the follow-up assessment (despite potential compensation of \$60 and lack of employment) suggests that these men may experience instability in their daily lives, perhaps as a consequence of poverty and discrimination. However, differences between dropouts and men completing the study were not observed, and attrition was not a problem relative to the primary study outcome, because we were able to collect these data by medical record review.

Although urine-based polymerase chain reaction testing for subsequent STD acquisition may have been a more rigorous approach, the use of archival data is not uncommon, even in large-scale trials that employ polymerase chain

reaction testing.⁴¹ Although we could not ascertain whether men were diagnosed with subsequent STD infections elsewhere with this study design, options for alternative sources of clinical care were limited and most likely would be comparably distributed between study groups. The relatively short duration of the follow-up period pertaining to behavioral outcomes is also a limitation, given that maintenance of intervention effects could not be assessed over longer periods. Also noteworthy is that the program was specifically designed to improve the quality, correctness, and frequency of use among men recently using condoms, thereby excluding those entirely rejecting condom use. This planning decision was made based on our awareness that a 40-minute intervention is unlikely to change behaviors of men who never use condoms. However, a complete lack of condom use ("never

use") among young African American men is not the norm; nationally representative data indicate that fewer than 1 of every 6 young African American men reported never using condoms during a 12-month recall period.⁴²

It must also be acknowledged that the use of multiple raters would have allowed us to establish intrarater reliability for the measure of demonstrated condom application skills; this limitation should be considered in the larger context of the study findings (that is, the "skills variable" was only 1 of several supporting outcomes). Finally, the study design cannot determine what portion of the observed effect was attributable to the provision of condoms to men in a variety of sizes and brands. This is less a limitation than a product of the intervention's purpose of increasing men's pleasure in using condoms by providing a range of options.

TABLE 4—Results of Sensitivity Analyses for Selected Outcomes Measures Used to Compare Men Randomized to the Intervention Versus Control Groups in a Risk-Reduction Intervention Evaluation of African American Men Aged 18 to 29 Years Newly Diagnosed With an STD: Southern United States, September 2004 Through May 2006

	Univariate		Multivariable	
	Measure of Effect, Estimate (95% CI)	P	Measure of Effect, Estimate (95% CI)	P
Observations with extreme outlying values excluded^a				
Partners in past 3 months ^{c,d}	-1.52 (-2.37, -0.67)	<.001	-1.37 (-2.18, -0.55)	.001
Partners in past 3 months ^e	-1.28 (-2.14, -0.43)	.004	-1.19 (-2.01, -0.36)	.006
Unprotected acts of sexual intercourse, past 3 months ^{c,f}	-6.1 (-13.7, 1.4)	.11	-1.0 (-9.8, 7.9)	.83
Unprotected acts of sexual intercourse, past 3 months ^{g,f}	-4.6 (-12.0, 2.8)	.21	-3.3 (-11.9, 5.4)	.43
Response variable transformed logarithmically to reduce the impact of outlying values^b				
Partners in past 3 months ^{c,d}	-0.33 (-0.49, -0.17)	<.001	-0.32 (-0.47, -0.17)	<.001
Partners in past 3 months ^e	-0.29 (-0.48, -0.10)	.004	-0.29 (-0.48, -0.11)	.004
Unprotected acts of sexual intercourse, past 3 months ^{c,f}	-0.53 (-1.00, -0.07)	.03	-0.32 (-0.88, 0.24)	.26
Unprotected acts of sexual intercourse, past 3 months ^{g,f}	-0.50 (-0.99, 0.00)	.051	-0.42 (-1.00, 0.17)	.15

Note. STD = sexually transmitted disease.

^aFour participants in the control group and 3 participants in the intervention group were excluded who claimed more than 100 unprotected acts at baseline or follow-up or who claimed more than 25 partners at baseline or follow-up.

^bThe transformed value is the natural logarithm of 1 plus the original value. Point and 95% confidence interval estimates for measures of effect are not directly comparable to those obtained in the absence of a logarithmic transformation; the main feature of interest is whether the P value is in qualitative agreement with the corresponding P value in Table 2 (i.e., both <.05 or both >.05).

^cMultivariable analysis controls for income, mixed STDs, and the baseline value for number of female sexual partners in the past 3 months.

^dMultivariable analysis controls for income, mixed STDs, and baseline values for skill, unprotected sexual intercourse, and condom use at last act of sexual intercourse.

Conclusions

The weight of evidence suggests that a brief, clinic-based intervention may be efficacious in reducing subsequent acquisition of STDs among young heterosexual African American men newly diagnosed with an STD. The use of a lay health advisor may help keep intervention costs low, thereby enabling program dissemination in resource-poor environments. As the United States⁴⁰ and other countries⁴³ implement clinic-based counseling in settings that provide STD screening, the option of postdiagnostic counseling conducted by a lay health adviser may prove useful. Adaptation and application of the program in geographic areas (domestically and globally) experiencing epidemics of STD or HIV may be worth pursuing in future studies. ■

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Contributors

R. A. Crosby originated the study, acquired funding for the study, developed the study protocol, provided oversight for the study, authored the article, and performed revisions of the article. R. J. DiClemente originated the study, developed the study protocol, provided consultation during the data collection phase of the study, and participated in authoring and performing revisions of the article. R. Charnigo provided oversight of data management and cleaning, analyzed the data, interpreted the findings, and participated in authoring and performing revisions of the article. G. Snow implemented all study protocols for recruitment, data collection, randomization, intervention, retention, and follow-up assessment. A. Troutman provided administrative support for the study, access to the sample, and guidance pertaining to the intervention.

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Human Participant Protection

Study procedures were approved by the Office of Research Integrity at the University of Kentucky. The trial was registered with the clinicaltrials.gov protocol registration system (No. NCT00314028) and monitored by a data safety monitoring board.

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