

SENO-CPTIONS



Intervention Protocol Manual

A Step-by-Step Guide
to Risk Reduction
Counseling with PLWHA

OPTIONS INTERVENTION PROTOCOL MANUAL

A Step-by-Step Guide to Risk Reduction Counseling with PLWHA

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Welfare Research, Inc. (WRI) provided editorial and design assistance.

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New York State Department of Health AIDS Institute, Centers for Disease Control (CDC), and National Institutes
of Health (NIH).



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Executive Summary

Great progress has been made in both medical and behavioral science resulting in significant improvements in the prevention and treatment of HIV. Despite these successes, CDC and others have voiced concerns about the fact that the annual rate of new infections has not decreased over the past decade. Although most HIV-positive individuals reduce their risky sexual and drug use behavior when they are diagnosed with HIV, a substantial number continue to engage in risky behavior that puts others at risk for HIV infection.

With a growing number of people living longer with HIV, it is critical to develop prevention programs that help HIV-positive individuals adopt and maintain healthy behaviors to prevent the transmission of HIV to others and the coinfection of HIV-positive individuals with other pathogens. The special characteristics of the provider-patient relationship and repetitive nature of clinical care contacts suggest that the clinical care site can serve as an important setting to develop and test interventions to reduce HIV risk behaviors and transmission. Unfortunately, few interventions have been conducted within clinical care programs.

Beginning in 1999, NIH funded the Center for Health, Intervention, and Prevention (CHIP) at the University of Connecticut to develop a provider-delivered intervention that decreases HIV-infected patients' risky sexual and drug use practices. This intervention is based on the Information-Motivation-Behavioral Skills (IMB) model of HIV risk behavior change, which asserts that HIV risk behavior is caused by deficits in individuals' levels of HIV prevention information, motivation, and behavioral skills.

The Options intervention trains healthcare providers to use brief motivational interviewing (MI) techniques to address these deficits at a level consistent with the individual patient's readiness to change. The project capitalizes on the importance of the provider-patient relationship and the repeated encounters over time that characterize HIV care. The intervention incorporates brief (5-10 minute) individualized discussions of HIV risk reduction into patients' regularly scheduled clinic visits (which occur approximately once every 3 months). Outcome research has demonstrated that Options is a feasible and practical intervention that busy healthcare providers are able to implement on an ongoing basis and that it is effective at decreasing risky sexual behavior in HIV patients over the course of an 18-month follow-up.





Options Intervention Context



Introduction

“HIV infection and risky behavior continue at levels far too high. Now, more than ever, it is critical that we expand successful HIV prevention programs to bring infection rates down.”

- Dr. Helene Gayle, Former Director of CDC’s National Center for HIV, STD & TB Prevention, 13th International AIDS Conference, July 2000

Need for HIV Risk Reduction Interventions for HIV+ Individuals

In the past 20 years, great strides have been made in both medical and behavioral science resulting in significant improvements in the prevention and treatment of HIV. With the advent of antiretroviral medications to treat HIV infection, for example, the number of people dying from AIDS has decreased dramatically, and the duration and quality of life for those living with HIV has increased significantly.¹⁻³ With respect to prevention, behavioral scientists have developed effective, targeted prevention interventions that have successfully reduced risky sexual and drug use behavior among a variety of high risk populations including men who have sex with men,⁴ injection drug users, youth,^{5,6} and women who engage in high-risk behavior. Effective prevention programs have helped decrease the annual rate of new HIV infections in the U.S. from over 150,000 in the mid-1980s to approximately 40,000 per year at the present time.⁷

Despite these successes, the Centers for Disease Control and Prevention (CDC)⁸ and others have voiced concern over the fact that the annual rate of new infections has leveled off at 40,000 and has not decreased over the past decade. CDC believes that this infection rate is “unacceptably high” and consequently, in 2001, announced the development of a new HIV Prevention Strategic Plan to cut annual infections in the U.S. in half within 5 years. A major component of that plan is the SAFE (Serotatus Approach to Fighting the HIV Epidemic) initiative, which prioritizes the development and delivery of “targeted, sustained, and evidence-based HIV prevention programs” for those living with HIV.⁹



Although most HIV-positive individuals reduce their risky sexual and drug use behavior when they are diagnosed with HIV, a substantial portion of HIV-infected individuals continue to engage in risky behavior that puts others at risk for HIV infection. A review of the literature reveals that from 50% to 90% of HIV-positive individuals remain sexually active after being diagnosed with HIV,^{10–14} and that between about 20% and 50% of sexually active HIV-positive individuals do not consistently use condoms during vaginal and anal sex.^{10–13,15–19} Consistent with these findings, Kalichman²⁰ reviewed over 20 HIV prevention studies, concluding that “across a wide range of geographic areas, populations, and settings,” approximately one third of HIV-infected individuals continue to participate in risky sexual behavior following their diagnosis. With respect to injection drug use, research indicates that 15% to 45% of HIV-positive injection drug users engage in unsafe syringe and works practices (i.e., do not always use clean syringes and works).^{10–13,16,19, 21–23}

Integrating Prevention with Ongoing Clinical Care

With a growing number of people living longer with HIV, it is critical to develop prevention programs that help them adopt and maintain healthy behaviors. To date, the majority of HIV risk reduction interventions have been conducted with individuals of HIV-negative or unknown status, and only a minority of programs have targeted HIV-positive persons.⁹ The National Institutes of Health (NIH) declared that not only must prevention efforts include those who are living with HIV, it must prioritize those HIV-positive individuals in treatment. They recently stated that “HIV prevention interventions based in medical treatment settings represent a critical domestic and international priority.”²⁴ Unfortunately, few interventions have been conducted within clinical care programs despite the fact that this is where most HIV-infected individuals receive their HIV care.

The relationship between antiretroviral medication issues and HIV risk behaviors has only recently begun to be explored, but early findings underscore the importance of integrating prevention and care. Studying a national sample of women with HIV, Wilson,¹⁹ for example, found that those women with suboptimal levels of adherence (i.e., < 95% adherence) were more than twice as likely to report that they had engaged in unprotected sexual activity in the previous 6 months, compared with those who reported optimal adherence. Several other studies^{25–28} have reported similar findings, suggesting that those who engage in HIV risk behaviors are more likely to report inconsistent adherence to their antiretroviral medication regimen. In two studies conducted by Kalichman, the relationship between these two sets of behaviors was not found to be straightforward, however. For some HIV-infected individuals, suboptimal adherence was associated with an increased incidence of risky behavior,²⁹ whereas for other individuals, having an undetectable viral load (which is usually a function of adherent behavior) was correlated with the practice of risky behavior.³⁰ Regardless of what the actual relationship is between medication adherence and risky behavior, it is a relationship that underscores

the importance of integrating prevention and care for those who are HIV-infected.

Although there are potentially serious consequences associated with risky sexual or drug use behavior regardless of a person's level of adherence, these consequences are even more serious for those individuals who do not optimally adhere to their medications. Suboptimal adherence is the major cause of therapeutic failure in patients receiving antiretroviral therapy. It leads to increased viral replication followed by the selection and potential transmission of drug-resistant strains of HIV. Instances of individuals becoming infected with HIV strains that are resistant to specific antiretroviral medications and whole classes of medications are occurring with increasing frequency.^{31–33} Consequently, maximizing patients' adherence to their antiretroviral medications may reduce the likelihood of transmission of both sensitive and resistant strains of HIV.

Incorporating prevention interventions within the clinical care setting facilitates the opportunity for dealing with these and other complex relationships between risk behaviors and treatment. The special characteristics of the provider-patient relationship and repetitive nature of clinical care contacts suggest that the clinical care site can serve as an important but currently underutilized setting to develop and test interventions to reduce HIV risk behaviors and transmission. The HIV clinical care setting provides opportunities for repeated prevention intervention contacts between healthcare providers and HIV-positive patients, and it also provides the most complete access possible to the critical target population of HIV-positive individuals. However, this is an area where there has been relatively little prevention work done. Very few studies have been conducted to identify the determinants of HIV risk behavior among HIV-positive individuals, and few, if any, interventions have documented success in changing HIV risk behavior among HIV-positive individuals.

Overview of the Options Project

The goal of the Options Project was to develop an effective HIV risk reduction intervention for people living with HIV/AIDS (PLWHA) in order to prevent the transmission of HIV to others as well as to protect HIV-positive people from coinfection with additional pathogens such as herpes, syphilis, and hepatitis B and C, and from reinfection with drug-resistant strains of HIV.³⁴ Specifically, the focus of this research project was to develop a conceptually-based, empirically-targeted HIV prevention program that could effectively reduce HIV risk behavior among HIV-positive individuals in clinical care settings.

The Options risk reduction intervention is based on the Information-Motivation-Behavioral Skills (IMB) model of HIV risk behavior change,^{35–38} a model which has received extensive empirical support across populations at risk for and infected with HIV (for reviews, see articles by Fisher and Fisher³⁶ and Fisher et al.³⁹). Essentially, the IMB model asserts that HIV risk behavior



is caused by deficits in individuals' levels of HIV prevention information, motivation, and behavioral skills, and that risky behavior can be changed by ameliorating these deficits. In the Options Project, healthcare providers are trained to use brief motivational interviewing (MI) techniques⁴⁰ to address HIV positive patients' HIV prevention information, motivation, and behavioral skills deficits, at a level consistent with the individual patient's readiness to change their HIV risk behavior. This project capitalizes on the importance of the provider-patient relationship and the repeated encounters over time that characterize HIV care. The ultimate goal of the intervention is to motivate HIV-positive patients to engage in safer sexual and drug use behavior in order to maximize their own health and the health of their partners.

The Options intervention consists of incorporating brief provider-patient discussions of HIV risk reduction (e.g., condom use, clean needle use) into the routine clinical visit. (Prior to implementing the intervention, providers receive specially-designed training in motivational interviewing and risk reduction techniques.) During the first patient visit, about 5 to 10 minutes are spent on an MI-delivered dialogue between the patient and healthcare provider about the patient's risky behavior, the dynamics of their behavior, and individually-tailored goals that will move them in the direction of safer behavior. On subsequent visits, about 5 minutes are spent discussing these issues as well as any progress that the patient has made since the previous visit toward achieving their goal. It is anticipated that a patient receives the intervention approximately once every 2 to 3 months at their regularly scheduled clinic visit. Provider-patient discussions of HIV risk reduction are *individualized* for each patient based on the patient's current readiness to change their risky behavior. For example, individuals who have not yet begun to think about changing their behavior will focus on different issues and goals than those who periodically practice safer behavior.

During each clinic visit, the healthcare provider discusses HIV risk reduction or maintenance of safer behavior with the HIV-positive patient. Specifically, the provider assesses whether the patient believes that risk reduction behavior change is **important** to them and whether the patient feels **confident** that they can actually change their behavior. Then the provider asks the HIV-positive patient to decide on a realistic and attainable goal that is appropriate to the individual patient. This goal may involve an actual change in their risk behavior or it may involve an interim step that increases their readiness to change and moves them in the direction of risk behavior change. Using motivational interviewing techniques, the provider collaborates with the HIV-positive patient to help them strategize and problem-solve ways to achieve the goal that they have selected, and the patient then tries to achieve this goal before the next clinic visit. If the patient is already practicing safer behavior on a consistent basis, the provider reinforces them for their behavior and encourages the patient to maintain their safer behavior.

Options Outcome Data

The Options Project was an NIMH grant-funded study that was rigorously evaluated for its impact on behavior. Evaluation of the effectiveness of the intervention was performed by research staff from the Center for Health, Intervention, and Prevention (CHIP) at the University of Connecticut. They used a quasi-experimental nonequivalent control group design for the evaluation of this intervention. Specifically, they selected the two clinics that are the largest providers of HIV care in Connecticut, and assigned one to serve as the experimental site and the other as the control site. These clinics were similar in their patient populations, clinic environments, and procedures.

A quasi-experimental design was chosen because of concerns of cross-contamination of the control condition if both conditions were in the same clinic. Random assignment of either patients or providers within the same clinic to experimental or control conditions would likely have resulted in compensatory equalization and/or treatment diffusion, which would have posed threats to the internal validity of the study and precluded the ability to detect true treatment effects.

Approximately 250 patients were recruited from each site. Patients in the experimental condition completed self-report surveys of their sexual and drug use behavior approximately every 6 months and participated in the Options intervention with their healthcare providers for a period of 18 months. Control condition patients did not receive the Options intervention, but they did complete the surveys, and they continued to receive the care that their clinic normally provided. The surveys were administered via laptop computer in either English or Spanish. Self-report measures have been found to correlate highly with actual behavior, and research has shown that people tend to be more forthcoming on computer-delivered surveys than on paper-and-pencil surveys or in structured interviews.

With respect to intervention feasibility, the data revealed that the intervention was consistently implemented, despite providers' demanding schedules. Over a 3-year period, 23 providers implemented the protocol in 73% of routine medical visits. When the intervention was not implemented, it was usually because other patient issues took precedence such as illness or the need for hospitalization. On average, patients received one dose of the intervention about every 4 months for a total of 5.4 intervention doses over an 18-month period.

To assess intervention fidelity, providers filled out a form (called the *Patient Record Form*) at the end of each Options visit, documenting the steps of the intervention protocol that they had completed. Based on the data from these forms, providers implemented an average of 7 out of 9 of the suggested protocol steps. The steps that they were least likely to implement were steps that were considered to be less critical to the protocol. Thus, the findings suggest that providers delivered the intervention with adequate fidelity.⁴¹

More important than the feasibility and fidelity of the intervention is the effectiveness of the intervention in changing risk behavior. Because there were so few active injection drug users (73) in the study and even fewer (28) who reported sharing “dirty” syringes or works, an analysis of the effectiveness of the intervention on injection drug use behavior was not possible. Consequently, the outcome evaluation focused on sexual risk behavior, defined as unprotected vaginal, anal, and insertive oral sex. Analyses focused on assessing changes in sexual risk behavior over time in the experimental versus the control participants.⁴²

The outcome data revealed that HIV-infected patients who received the provider-delivered intervention showed a significant reduction in the number of unprotected vaginal, anal, and insertive oral sex events over a follow-up interval of 18 months ($P < 0.05$). In contrast, these behaviors increased significantly across the study interval for patients in the standard-of-care control condition ($P < 0.01$). When only unprotected vaginal and anal sex were examined (excluding oral sex), similar findings were revealed. There was a marginally significant reduction in unprotected vaginal and anal sex events among patients who received the intervention ($P = 0.09$), and a significant increase in unprotected vaginal and anal sex events among control condition patients ($P < 0.01$).⁴²

Based on analyses of the data from the original study, developing an effective risk reduction intervention that takes advantage of the relationship between patients and providers, and embedding that intervention within the clinic visit appears to be a feasible, practical, and effective option for reducing risky behavior among HIV+ patients in clinical care.^{41,42}

Reprints of the articles that describe the development, implementation, and evaluation of the Options intervention can be found in Chapter 9 of this manual.

Principles of Motivational Interviewing

“Motivational interviewing is a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence.”

- Rollnick and Miller⁴³

Motivational Interviewing as a Tool for Change

Motivational Interviewing (MI) consists of a set of empirically-supported interpersonal communication techniques designed to produce rapid internally-motivated changes in health-related behaviors.^{40,44,45} It is a patient-centered approach to enhancing individuals’ motivation to change, and one of its main underlying principles is that people cannot be forced to change their behavior if they are not ready.^{40,44,45}

Giving advice and telling the patient what to do is the typical strategy that is used in healthcare settings to encourage patients to engage in healthier behavior, but this strategy has been found to be effective in changing behavior in only 5% to 20% of patients, and it is effective only with patients who are ready and motivated to change.^{46,47} Arguing with patients who are ambivalent about why they should change their behavior typically elicits resistance and arguments from patients about why they cannot change. Thus, it is critical to work collaboratively with patients in a supportive and nonjudgmental way to help them explore, understand, and resolve their ambivalence to changing by identifying and addressing their individually-relevant obstacles to such change. There are costs and benefits to changing and not changing, and to work effectively with a patient to increase their motivation to change, it is important to understand what the costs and benefits are for that particular person.

Equally important, MI recognizes that each individual patient is potentially the best source of information about the particular barriers that they may face to behavior change or maintenance of safer behavior. The MI strategy seeks patient insight on this issue and then uses it as the basis for collaboratively formulating individually-tailored strategies for change or maintenance.

Collaboration between Healthcare Provider and Patient

The Options intervention uses Motivational Interviewing techniques to deliver HIV risk reduction information, motivation, and behavioral skills content in a way that maximizes patient “buy-in,” minimizes resistance, and has an empirically-supported likelihood of eliciting safer sexual and drug use behavior.^{42,48} Rather than taking on an authoritarian role and acting as an expert and prescribing change, in this intervention the healthcare provider leaves the responsibility for change with the patient. This does not mean that the provider is not directive. On the contrary, the provider has a clear goal in mind, which is to reduce HIV risk behavior, and they use various MI strategies to achieve that goal. Specifically, the provider (1) assesses the patient’s risk behavior in a nonjudgmental manner; (2) identifies the patient’s informational, motivational, behavioral skills, and other barriers to consistently practicing safer sexual behavior; (3) learns from the patient “what would have to happen” for them to overcome these barriers and practice safer behavior; and (4) negotiates a behavior change goal with the patient. Because the patient is viewed as the “expert” in their own individual and unique life situation, it is the patient who defines the problem and identifies the solution, with the provider serving as the facilitator of this process. In the case where the patient is unable to identify any solutions or strategies, the provider takes a more active role and offers a menu of intervention strategies from which the patient can choose.

The patient is intimately involved in every step of the process, especially in the selection of the goals. The relationship between the patient and the healthcare provider is thus a collaboration—one in which the patient and provider work together to negotiate an individualized plan for positive change.

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

- Rollnick and Miller ⁴³

Key Components of Motivational Interviewing

- **Acknowledge personal choice.** It is the individual’s personal responsibility and choice whether or not to change their behavior. A common assumption made by healthcare providers is that the patient *should change* or that the patient *wants to change*. Assessing how much the person wants to change is crucial to the success of the provider-patient interaction. Expressing one’s views about change in a relatively neutral and nonjudgmental way and emphasizing the patient’s freedom to choose, can help one avoid alienating the patient or making them defensive.
- **Respect the patient as an expert.** Whereas the provider is an expert on how people in general can change their behavior, the patient is the expert on how they themselves can change. Each patient is unique in what motivates them to change, and it is assumed that the patient has important insight and ideas for how to solve their own problems.
- **Ask simple open-ended questions** (as opposed to close-ended, or yes-no questions) to encourage exploration and decision-making.
- **Use skillful reflective listening.** Reflective listening involves the healthcare provider briefly summarizing what the patient is saying in order to show that the provider is listening to the patient and understands the meaning of what they are saying. It provides the provider with the opportunity to verify their understanding of the patient’s perspective, and it helps build rapport with the patient. It is only by carefully listening to one’s patient that the provider can learn what it will take for the patient to change their behavior.
- **Create and amplify, in the patient’s mind, any discrepancies between present behaviors (where they are now) and broader goals (where they want to be).** Most patients who are engaging in risky behavior are not malicious and do not want to infect others. And most patients want to prolong their lives and do not want to compromise their health. Consequently, if patients can come to understand that their behavior is at odds with these goals, it is likely that they will be more motivated to engage in safer behavior.
- **Embrace ambivalence.** Many patients are ambivalent about change, and they have very good reasons for not changing their high risk behavior. It is important for the provider to understand those reasons. Allowing the patient to discuss the benefits of their risky behavior can paradoxically serve as a catalyst for positive behavior change.

- **Avoid arguing, confronting, and pressuring the patient into action.** This can lead to the patient taking a defensive and rigid posture, and thus not being amenable to making any changes.
- **Support a patient's right to choose.** Approaches that support the patient's autonomy are more effective in helping a patient change than are coercive measures. A patient is more likely to adopt healthy behaviors if they "want to" than if they "ought to" or "have to." Adopting a controlling and paternalistic approach is antithetical to supporting the patient's autonomy. Patients are more likely to make healthy choices if the provider acknowledges and supports their right to choose than if the provider behaves as if they can make the patient change.⁴⁸
- **Work at the patient's pace.** It is important to work at a pace that is sensitive to the patient's needs and their readiness to change. If the healthcare provider pushes the patient ahead of where they are ready to be, the provider is likely to engender resistance on the part of the patient.
- **"Roll with resistance" to change.** Any statement made by the patient can be rephrased or reframed to create momentum toward change. Resistance (e.g., denial, arguing, objecting, refusing to engage in conversation) is influenced by the way in which the provider interacts with the patient. It is a function of the interpersonal interaction between the patient and the provider, and it can either be exacerbated or diminished depending on the provider's response to it. Resistance is a signal that the provider and patient are not in the same place. Further exploration or shifting focus may help "melt" the resistance.
- **Avoid being judgmental.** It is critical to provide nonjudgmental feedback and information to maximize the patient's motivation to engage in safer sexual and drug use practices. The role of the healthcare provider is to understand the patient's feelings and perspectives without judging, criticizing, or blaming.
- **Adopt an attitude of acceptance and respect.** By showing respect for the patient, the patient's self-esteem is supported, which frees them to change. Acceptance refers to "understanding" the patient's perspective. It does not mean approving of or endorsing their behavior.
- **Support and increase the patient's self-efficacy and their ability to cope with obstacles and succeed at change.** Self-efficacy refers to a person's confidence in their ability to make a specific change in behavior. It is important to help the patient believe that healthy outcomes are possible.
- **Negotiate goals that are realistic and attainable.** It is critical that the patient be successful in their efforts to reach their goals so that their self-efficacy and their motivation to change increases. Therefore, it is important that realistic goals be chosen. This may mean choosing smaller interim goals at which the patient can succeed rather than large behavior change goals at which they will fail.





Intervention Protocol for First Options Meeting with Patients Reporting Risk Behavior



Protocol Outline for First Options Meeting with Patient Reporting Risk Behavior

STEP 1: Set the agenda for the discussion.

- (a) Inform the patient that you would like to discuss their sex and drug use behaviors.
- (b) Ask the patient's permission to discuss their behaviors.

STEP 2: Identify the patient's current HIV risk behaviors.

- (a) Assess the patient's sexual and drug use behaviors to determine the specific HIV risk behaviors in which they are engaging.

STEP 3: If the patient reports multiple risk behaviors, ask the patient to choose one on which to focus during today's visit.

- (a) Provide a brief verbal summary of the patient's risk behaviors and the behavior on which they chose to focus.

STEP 4: Evaluate the patient's readiness to change the behavior being discussed today.

- (a) Assess **Importance**: Have the patient rate the **Importance** of changing their behavior on a scale from 0 to 10, where 0 is "not at all important" and 10 is "extremely important."
- (b) Assess **Confidence**: Have the patient rate their **Confidence** that they could change their behavior if they so chose, on a scale from 0 to 10, where 0 is "not at all confident" and 10 is "extremely confident."
- (c) Briefly summarize, or recap, both scores provided by the patient.

STEP 5: Using the following algorithm, decide whether to focus on **Importance** or **Confidence**.

- (a) If **Importance** and **Confidence** are both 9 or 10, skip the remaining discussion on **Importance** and **Confidence**, and discuss barriers to change.
- (b) If **Importance** < 7, focus on **Importance**.

- (c) If **Importance** ≥ 7 , focus on whichever one (**Importance** or **Confidence**) is rated lower.

STEP 6: Focusing on *Importance* or *Confidence*, identify the barriers to consistently practicing safer sex or drug use behavior.

- (a) If the patient's **Importance/Confidence** rating > 1 , ask the patient to explain why they did not give a **lower** score. If their rating ≤ 1 , skip this step, and move on to Step 6(b).
- (b) Ask the patient to explain what would need to happen in order for their rating to **increase**.
- (c) Responses to these two questions should elicit possible strategies on how to increase the **Importance** or **Confidence** of practicing safer behavior and thus move the patient in the direction of behavior change.

STEP 7: Briefly summarize the patient's responses, and then discuss strategies for changing their risky behavior.

- (a) Briefly summarize the patient's responses to the two above-listed questions.
- (b) Ask the patient to identify possible strategies for increasing their **Importance** or **Confidence** rating.
- (c) If the patient is unable to come up with any strategies, ask them if you can suggest some, and then offer a menu of strategies.

STEP 8: Negotiate a goal or plan of action with the patient.

- (a) Review the strategies discussed, and ask the patient to choose a goal or action plan that they would be willing to work on between now and their next visit.
- (b) To increase the patient's commitment to completing the negotiated goal, consider writing it down on the *Options Prescription* pad and then handing the *Options Prescription* to the patient. (**Note:** Use of the *Options Prescription* is optional. Many providers choose not to use it with their patients.)

STEP 9: Document what transpired during the *Options* discussion on the *Patient Record Form (PRF)*, and file the *PRF* in the patient's medical record.

- (a) Although it is not necessary to use the *Patient Record Form* per se, it is critical to document what occurred during the discussion. Documentation helps you to recall the issues that need to be addressed in subsequent *Options* discussions.

Step-by-Step Review of Options Intervention Protocol

- The intervention protocol described herein is for **initial** Options visits with HIV-infected patients who are engaging in HIV risk behavior. This chapter describes each step of the protocol, the purpose of the step, and a suggested script for how to introduce that step.
- The intervention protocol for **initial** Options visits with HIV-infected patients who are not engaging in any HIV risk behavior is similar to the protocol presented in this chapter, but it is not identical (see *Chapter 3*).
- Follow-up Options visits retain many but usually not all of the elements of the first visit and thus are often shorter in duration. Since initial and follow-up protocols differ somewhat, the protocol for follow-up visits is described separately in Chapter 4.
- It is recommended that the Options intervention be implemented only with patients who have met with their healthcare provider on at least one prior occasion and thus have an “established” relationship with them. This intervention involves discussions about very personal, intimate behaviors, and it is unlikely that patients will be forthcoming unless they have a trusting, supportive relationship with their healthcare provider. Theoretically, rapport should be present in an established relationship between a patient and their healthcare provider, but there is no guarantee of this. Consequently, it is critically important that the provider actively work to establish and maintain rapport with their patient.
 - In all interactions with the patient, it is important that the healthcare provider be considerate of the patient’s situation, priorities, and pressing needs (e.g., it’s the end of the day and they want to go home, or they’ve been in the waiting room for an hour or more).⁴⁰
- Although a healthcare provider can implement the intervention at any time during a medical visit, most providers choose to implement the intervention at the very end of the visit, after they have completed all medical aspects of the visit.

▶ **The initial *Options* discussion usually takes about 10 minutes to complete, with subsequent discussions taking 5 minutes or less.**

STEP 1: Set the agenda for the discussion

Purpose:

- To communicate to the patient that you would like to have a discussion with them about their sex and drug use behaviors.

Suggested Script:

- *“I now talk with all of my patients about their sex and drug use behavior. I know that it can be uncomfortable to talk about these things, but I think it’s important to do so because of how they can affect your health and the health of others. So I’d like to spend a few minutes talking about these things, if that’s okay with you.”*

Elaboration:

- In order for the patient not to feel singled out in this discussion about sex and drug use, inform the patient that you are having this discussion with all of your patients and that it has become part of routine care at the clinic.
- Contextualize this discussion by telling the patient that you want to talk about these issues because it is important to the patient’s and others’ health.
- To alleviate any discomfort the patient may have in talking about these very personal issues, acknowledge that these can be difficult issues to discuss.
 - It is not unusual for the patient to become somewhat anxious and/or defensive when these issues are raised, but their anxiety and defensiveness should diminish once the patient realizes that they are not going to be judged or criticized for their behavior.
- Once you have indicated that you want to discuss these issues with the patient, ask for the patient’s permission to proceed with the discussion. Throughout this discussion, it is critical that the patient experience a sense of control over what is happening and believes that their wishes are being respected; this minimizes the patient’s defensiveness and elicits greater cooperation and eventual “buy-in” to behavior change. In our years of experience with this intervention, both nationally and internationally, we have found that very few people decline to proceed with the discussion.

Additional Information about STEP 1

Alternative Sample Scripts for STEP 1:

- *“Because I care about your health, I think that it’s important for us to talk about any sex and drug use behavior in which you may be engaging. The reality is that what you do sexually and with respect to drugs can affect your health. Now I know that this can be hard to talk about, but I think that it’s really important for us to do so. Is it okay if we take a few minutes to discuss these issues?”*
- *“I’d like to ask you some questions about your sex life and your drug use, if you’re okay with that. I think that part of helping you stay healthy means looking at all aspects of your life and how they affect your health. Now I know that some people feel awkward talking about these things, particularly about sex, but please understand that it’s safe to talk about them here. I have these discussions with all of my patients, so there’s not much that I haven’t heard about. What do you think? Can we spend a little time talking about these things?”*

If a patient refuses to discuss their sex and drug use behavior:

- If the patient refuses to discuss these issues, briefly summarize their statements as a way of validating their concerns and then suggest that this discussion be resumed at the next clinic visit. Then ask the patient if there is anything else that they want to talk about today.
- Sample responses to patient who refuses to discuss sex and drug use:
 - *“You’ve said that you’d prefer not to talk about these issues today. That’s okay, but I do hope that we can talk about them sometime soon, because I believe they’re important to your health. If possible, I’d like to talk about them at your next clinic visit. Would you be willing to do that? . . . Now, is there anything else that you’d like to talk about today before we finish up?”*
 - *“I’m hearing that this is not the right time for you to talk about these issues. That’s all right. I’m wondering if you’d be willing to think about these issues between now and your next visit, and then perhaps discuss them at your next visit. Would that be okay?”*

End of Step 1

STEP 2: Identify the patient's current HIV risk behaviors.

Purpose:

- To determine what specific risky sexual behaviors (i.e., unprotected vaginal, anal, or oral sex) and drug use behaviors (e.g., sharing syringes or works), if *any*, the patient is engaging in, and the conditions under which those risky behaviors occur.

▶ **This assessment does not involve conducting an exhaustive sex and drug history; there is not sufficient time to do this nor is it necessary for this intervention.**

Suggested Script:

- *“Many of my patients find it hard to practice safer sex and safer drug use on a day-to-day basis. The reality is that these are not easy things to do. Now, I don’t know if you are having any trouble being safe, but if you are, I’d like to understand what you find difficult about it. What works for you and what doesn’t, when it comes to safer sex? . . . What works for you and what doesn’t, when it comes to safer drug use?”*

Elaboration:

- Once the patient has agreed to discuss their sex and drug use behavior, explore with the patient those unsafe sex and drug use behaviors in which the patient is engaging.
 - Although this intervention protocol can be used to motivate behavior change in a variety of domains, the primary goal of this protocol is to reduce *HIV* risk behavior, not risk behavior in general. This means that the focus of this assessment should be on risky sexual and drug use behavior that contributes to the transmission of HIV and other STIs. Using drugs may be a risky or unhealthy behavior, but it does not present an increased risk of HIV transmission unless the syringes and/or works are being shared, or the patient exhibits impaired judgment as a function of using certain recreational (or prescription) drugs and is therefore more likely to engage in HIV risk behaviors.
- The goal of this step is to determine as quickly and efficiently as possible *which* risky behavior(s), *if any*, the patient is engaging in (e.g., insertive vaginal sex without condoms), and the *conditions* under which the risky behavior(s) occurs (e.g., the particular partners, the settings, the affective states, the degree of intoxication).
 - Identify the specific types of sexual behavior in which the patient is engaging (insertive or receptive vaginal, anal, or oral sex), the number and perceived serostatus of the partners with whom they are having sex, whether or not they are using condoms with

those partners, and the conditions under which they do and do *not* use condoms. For example, are they using condoms in every sexual encounter? Only with certain partners? Only for anal sex? Only for insertive intercourse? Only during anonymous sex? Episodically? Only when they are sober?

- **Note:** Although a patient's perception of a partner's serostatus is often unreliable, it is important for you to understand what the patient believes about their partner's status and how that has impacted on the patient's decisions regarding sex and safer sex.
- Determine what recreational drugs, if any, the patient is using, the mode of administration of those drugs (e.g., injecting, snorting, smoking), and if they are injecting, whether they are sharing their needles and works (i.e., cotton, cooker, water) and under what conditions. Are they bleaching their needles? Sharing their dirty needles only with their sexual partner? Sharing dirty needles when they do not have access to clean ones? Using clean needles but sharing the rest of their works (i.e., cotton, cooker, water)? Engaging in frontloading or backloading?
- Keep in mind that your definitions and the patient's definitions of "risky behavior" and "safer behavior" may differ. Specifically, if the patient indicates that they are practicing "safer behavior" 100% of the time, explore this further to determine what they mean by "safer behavior." Does this mean that they are using condoms during insertive and receptive vaginal, anal, and oral sex every time with every partner, or does it mean that they are using condoms just during some forms of sex (for example, only during anal sex, or only during insertive sex) with certain types of partners (for example, only with HIV-negative partners)? It is critical that you not take the patient's statements at face value and that you fully explore (in a supportive manner) what the patient means by "safe" or "risky" behavior.
- Create a safe environment where the patient feels comfortable enough to be forthcoming about their sex and drug use behavior.
 - Acknowledge how difficult it is to practice safer behavior on a day-to-day basis. This gives the patient permission to admit to their risky behavior, and it lessens their fear that they will be judged negatively for doing so.
 - Avoid evaluating or judging the patient for the behavior(s) in which they are engaging.
 - Be careful about the words that you use. Some words may be viewed as pejorative by the patient (e.g., "junky," "hooker," "dike," "twat," "queer").
- Use simple, open-ended questions to encourage patient exploration and decision-making (e.g., "*What type of sex do you have with your boyfriend?*") instead of "*Do you have vaginal sex with your boyfriend?*")

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- A series of close-ended (yes/no) questions takes control away from the patient and can feel like an interrogation. “Adopt a curious and eliciting interviewing style,” allowing the patient to do most of the talking (p. 109).⁴⁰ Your job is to listen to your patient and understand their perspective and not to lecture them.
 - When interacting with your patient, use reflective listening, or summary statements, to convey an interest in and understanding of what your patient is saying. Briefly summarizing back to the patient what they tell you serves two purposes:
 - It helps you to build rapport with your patient by showing the patient that you are listening to them and care about what they are saying.
 - It allows you to check in with your patient to determine whether you have clearly understood what the patient is trying to communicate and thus helps you to avoid serious conflict with them.

Additional Information about STEP 2

Alternative Sample Scripts for STEP 2:

- *“I know that practicing safer sex and safer drug use is not easy to do every day. In fact, a lot of my patients struggle with it. I’d like to get a sense of whether it’s a struggle for you, and if it is, what that struggle is like.”*
- *“There are a lot of things that can get in the way of a person being safe when they have sex or use drugs. I’d appreciate it if you would tell me what you do to protect you and your partner(s) from HIV and other sexually transmitted diseases, and what, if anything, makes it difficult to do it consistently.”*
- *“A lot of people find it very difficult to practice safer sex every day. What role does safer sex play in your life? When do you practice safer sex? When don’t you?”*
- *“Many people don’t like to use condoms. Could you tell me how the use of condoms does or does not fit into your sex life? When do you use them? When don’t you?”*
- *“Sometimes it can be very challenging to practice safer sex. Can you tell me when you are most likely to have unprotected sex? When are you most likely to use condoms?”*
- *“It can be pretty tough trying to use clean needles and works every time you shoot up. When are you most likely to share dirty syringes or works? When are you most likely to use clean syringes?”*

End of Step 2

STEP 3: *If the patient reports multiple risk behaviors, ask the patient to choose one on which to focus during today's visit.*

Purpose:

- To limit the scope of the discussion so that it is manageable within the allotted time period.

Suggested Script:

- *“You said that you are doing [risk behavior x] and [risk behavior y]. Let’s just focus on one of these areas for today. Which one would you prefer to talk about?”*

Elaboration:

- If *after* inquiring about the patient’s sex and drug use behavior, you discover that the patient has multiple risk behaviors (e.g., not using condoms with their spouse as well as sharing syringes with others), it is recommended that you focus the discussion on just one of these behaviors. There are two reasons for this:
 - You have limited time in which to have this discussion, so it is not feasible to talk in detail about more than one behavior in a single visit.
 - It can be overwhelming for a patient to simultaneously work on changing multiple behaviors; doing so increases the likelihood that the patient will fail at it.
- Be sure to identify *all* of the patient’s HIV risk behaviors *before* giving the patient a choice of which one to focus on. In other words, do not ask the patient to choose whether they want to discuss sex *or* drug use before having assessed *all* of their HIV risk behaviors. If given that choice, the patient may choose to discuss the behavior where they are taking the fewest risks and you will never know that they are taking significant risks in other areas.
- To maximize the patient’s sense of control over the process and minimize their resistance to behavior change, it is best if the patient decides on which behavior to focus.
 - Do not be concerned if when given the choice, the patient chooses to discuss the behavior that is least problematic for them. If they achieve successful behavior change with that behavior, they will likely have increased confidence for working on the more challenging behavior(s).
 - If the patient seems to be avoiding dealing with their more challenging behavior, you always have the option of asking the patient to focus on it. Many providers have made the decision themselves about which behavior will be discussed because they want the patient to work on the behavior that poses the greatest health risk to the patient or to their partner.

Additional Information about STEP 3

Alternative Sample Scripts for STEP 3:

- *“It sounds like there are a couple of areas that are worth exploring because they may impact your health—using condoms with HIV-negative partners but not with HIV-positive partners, and periodically sharing your works. Let’s just focus on one of these areas for today. Which one would you prefer to talk about today?”*
- *“We could talk about using condoms with your partners or we could talk about sharing syringes. Which one would you like to talk about today?”*
- *“So right now, you are not using condoms with your husband and you are also sharing needles with him. Let’s focus on just one of those issues for today. Which one would you prefer to talk about?”*

End of Step 3

STEP 4: Evaluate the patient's readiness to change the risk behavior discussed today.

Purpose:

- To assess the patient's readiness to change their risky behavior by determining (1) how **important** it is to the patient to change from risky to safer behavior, and (2) how **confident** the patient is that they can successfully change their risky behavior.

Suggested Script:

- *"I would like to better understand how you feel about [changing your behavior to safer behavior]. Can you help me by answering a couple of questions?"*
 1. *"On a scale from 0 to 10, where 0 is 'not at all important' and 10 is 'extremely important,' how **important** is it to you to [change your behavior]?"*
 2. *"On a scale from 0 to 10 where 0 is 'not at all confident' and 10 is 'extremely confident,' how **confident** are you that you can [change your behavior]?"*

Rating Importance and Confidence without the Numeric Scale:

- There are some patients who have difficulty with the concept of numbers and therefore find it extremely challenging to make numeric ratings of **Importance** and **Confidence**. For these patients, it is preferable to ask them to rate Importance and Confidence without using the 0-to-10 number scale.
 1. *"How **important** is it to you to use a condom when you have insertive anal sex? Is it not at all important, somewhat important, or extremely important to you? . . . And how confident are you that you could always use a condom when you have insertive anal sex? Are you not at all confident, extremely confident, or somewhere in-between?"*

Elaboration:

- It is important to know where the patient is in the process of change because this information helps determine what strategies might be most likely to help the patient move in the direction of behavior change. A patient's readiness to change their risky behavior can be determined by understanding the patient's ratings of **Importance** and **Confidence**.⁴⁰ The goal of this step is thus to briefly assess how **important** it is to the patient to change their behavior and how **confident** they are that they can do so.
- Because of the limited time that you have to implement this intervention

with each patient, it is critical that you be able to *quickly and efficiently* identify barriers that may be currently preventing the patient from consistently practicing safer sexual and drug use behavior. Motivational Interviewing provides the means to systematically identify such individual barriers to safer behavior.⁴⁰ Specifically, the constructs of **Importance** and **Confidence** can be used to evaluate a patient's readiness to change their risky behavior and to identify particular individual barriers or obstacles that are currently preventing the patient from consistently engaging in safer sexual and drug use behavior. **Steps 4, 5, and 6** of this intervention protocol involve the use of **Importance** and **Confidence** to identify an individual patient's specific barriers.

- **Importance** refers to the value that a patient places on a particular behavior, whereas **Confidence** refers to the patient's perception that they have the ability to engage in that behavior. A patient is more likely to change a particular behavior if they are "convinced of the personal value of changing" that behavior (i.e., believe that it is *important* to change) and are *confident* that they have the ability and skills necessary to make that change.⁴⁰ Thus, evaluating how **important** it is to a patient to engage in safer sexual or drug use behavior and how **confident** they are that they can do so (**Step 4**), provides invaluable individually-relevant information about the patient's readiness to change. And identifying what is preventing them from regarding the safer behavior as more **important** or from having more **confidence** that they can enact the behavior (**Step 6**), informs you about the specific barriers that may be preventing the patient from changing. In addition, these steps help to identify possible strategies for increasing the patient's readiness to change and motivating actual behavior change.
- The constructs of **Importance** and **Confidence** map well onto the patient's levels of information, motivation, and behavioral skills. When a person believes that engaging in a particular safer sexual behavior is of low **Importance**, this is usually indicative of that person having inadequate information about that behavior (e.g., the patient believes that a person who is taking ARVs cannot transmit HIV) and/or having low motivation to implement it (e.g., the patient has negative attitudes towards condom use). In contrast, when a person has little **Confidence** in their ability to engage in a particular safer sex or drug use behavior, this usually indicates that the person has insufficient objective behavioral skills (e.g., the patient doesn't know how to correctly put on a condom or how to ask their partner to use one) and/or low self-efficacy regarding performing that behavior, or it can sometimes be indicative of low motivation.

Additional Information about STEP 4

Alternative Sample Scripts for STEP 4:

- *“Right now, you’re not using condoms with any of your partners. I’m not really sure how you feel about that. Can you help me by answering a couple of questions? . . . How **important** is it to you to start using condoms? If 0 is ‘not at all important’ and 10 is ‘extremely important,’ what number would you give for the importance of using condoms? . . . If you decided right now to make a change and to use condoms with all of your partners, how **confident** are you that you would be successful at this? If 0 is ‘not at all confident’ and 10 is ‘extremely confident,’ what number would you give yourself?”*
- *“From our conversation, it sounds as if using condoms with HIV-negative partners is important to you, but using them with HIV-positive partners is less important. I would like to understand that a little better. If you were to rate the **importance** of using condoms with HIV-positive partners on a scale from 0 to 10 where 0 is ‘not at all important’ and 10 is ‘extremely important,’ how would you rate it? . . . Let’s assume for the time being that you have decided that it’s important to use condoms with your HIV-positive partners. On a scale from 0 to 10, how **confident** are you that you could use condoms with them, where 0 is ‘not at all confident’ and 10 is ‘extremely confident?’”*
- *“You told me that when you split a bag with your boyfriend, you usually share your works with him. I’m not really sure what you think about that. Can you help me by answering a couple of questions, and then we can see where to go from there? . . . How **important** is it to you to stop sharing your works with them? If 0 is ‘not at all important’ and 10 is ‘extremely important,’ how would you rate not sharing? . . . And using the same scale, with 0 being ‘not at all confident’ and 10 being ‘extremely confident,’ how **confident** are you that you could each use your own works when you split a bag?”*

End of Step 4

STEP 5: *Decide whether to focus on Importance or Confidence.*

Purpose:

- To determine which of the two dimensions of readiness (**Importance** or **Confidence**) warrants further exploration.

Algorithm:

- Use the following algorithm to decide whether to further explore **Importance** or **Confidence**:
 - If both **Importance** and **Confidence** are 9 or 10, directly explore with the patient any remaining barriers to changing their risky behavior.
 - If the rating of **Importance** < 7 (see “Elaboration,” below), explore **Importance** and ignore **Confidence** for the time being.
 - If the rating of **Importance** ≥ 7 , explore the one (i.e., **Importance** or **Confidence**) with the *lower* rating. In other words, if **Importance** is rated lower than **Confidence**, explore **Importance** and ignore **Confidence** during this clinic visit. If **Confidence** is rated lower than **Importance**, explore **Confidence** and ignore **Importance** during this clinic visit.

Elaboration:

- If the patient rates *both* **Importance** and **Confidence** as high (9 or 10), there is no need to further explore either of them. This patient already believes that practicing safer behavior is important, and they have the confidence to do so. Further exploring these constructs will provide you with little, if any, useful information, so direct exploration of any remaining barriers to behavior change is indicated.
- As long as changing a particular behavior is viewed as low to moderate in importance (<7), **Importance** should be focused upon and explored with the patient to identify the specific reasons for the low score (**Step 6** below). If the patient does not view practicing safer behavior as **important**, then it is unlikely that they are going to engage in that behavior even if they are **confident** that they can do so. On the other hand, if the **Importance** of practicing safer behavior is rated high (≥ 7) and the **Confidence** rating is lower, **Confidence** should be focused on.

Additional Information about STEP 5

Working with the Patient who Rates Both *Importance* and *Confidence* as 9 or 10:

- **For the patient who views safer behavior as Important, has the Confidence to perform it, but has *not* yet actually begun to practice the safer behavior being discussed:** This patient is *preparing* to make changes in a very substantial way but has not yet begun to make any actual behavior changes. Therefore, the next step for this patient is to *identify the barriers* that exist to actually enacting the behavior. Once you and the patient have discussed the barriers, proceed to **Step 7** and problem-solve ways to overcome them.
- **For the patient who views safer behavior as Important, has the Confidence to engage in it, and is *periodically* engaging in the safer behavior:** In this case, your task is to identify and help the patient manage any barriers or impediments to consistently performing the safer behavior on a long-term basis. You should first provide reinforcement for the safer behavior in which the patient is engaging by praising the patient for those times when they are safe. Receiving acknowledgement and praise from someone whom the patient respects serves as a strong incentive for continuing to practice safer behavior. It can also be worthwhile to ask the patient how they feel they are doing with their behavior and what benefits they are gaining from practicing safer behavior. You should then explore the barriers to more consistent practice of the behavior. Once the barriers are identified, proceed to **Step 7**, and discuss with the patient strategies for overcoming those barriers.

End of Step 5

STEP 6: Identify the barriers to consistently practicing safer sex or drug use behavior.

Purpose:

- To better understand the reasons for why the patient is not engaging in behavior change on a consistent basis and what might help to motivate behavior change.

Suggested Script:

- Once you have decided whether to focus on **Importance** or **Confidence**, use the following two questions to quickly and efficiently identify any barriers that exist to consistently practicing safer behavior.
 1. “You gave yourself a score of [#] for [**Importance** or **Confidence**]. Why did you give yourself a [#] and not a *lower* score?”
 2. “*What would have to happen* for your [**Importance** or **Confidence**] score to *increase*?”

Elaboration:

- Once you have decided whether to focus on **Importance** or **Confidence**, asking the two follow-up questions (enumerated above) about **Importance** or **Confidence** helps clarify why the patient is not consistently practicing safer behavior and suggests possible strategies for motivating and guiding their actual behavior change.
 - Asking the patient to explain why they did not give a *lower Importance/Confidence* score (Question 1, above) serves to elicit self-motivating statements for change. By talking about why their rating is not lower, the patient essentially presents arguments for change that they regard as credible. In addition, this provides you with information about potential resources the patient has with regard to practicing safer behavior. You should *not ask* this question if the patient’s rating of **Importance/Confidence** is 0 or 1. Obviously, the question does not make sense if they are already giving **Importance/Confidence** the lowest possible rating. But if the patient’s **Importance/Confidence** score is higher than 1, the patient attaches some importance to safer behavior or has some confidence that they can practice safer behavior, and you can hopefully build on that.
 - Asking the patient to explain **what would need to happen** for their **Importance/Confidence** score to *increase* (Question 2, above), elicits reasons for the lower score and for why the patient may not be engaging in safer behavior on a consistent

basis. Importantly, it directly helps identify strategies that might be effective in helping the patient change their behavior.

- When posing this question to the patient, ask them what would need to happen for their current score to increase by 1 to 3 points, not by any more than that. Asking the patient to raise their **Importance** or **Confidence** score by a large amount (e.g., from a score of 2 to a score of 10) may seem totally overwhelming to the patient and may discourage the patient from trying to modify their behavior at all.
- A **low Importance** score is usually a function of *inadequate information and/or low motivation* to engage in safer behaviors. For example, practicing safer sex may be rated by the patient as of low **Importance** because the patient is misinformed (for example, believes HIV is not transmissible with an undetectable viral load), and/or has low motivation (for example, has negative attitudes toward condom use, poor social support for condom use, and/or low perceived vulnerability that they can transmit HIV to others). To assist the patient in changing their **Importance** score, assess what the cause of the low **Importance** score is, using the questions listed above.
- A **low Confidence** score can be a function of *insufficient objective behavioral skills, low self-efficacy regarding performing safer behavior, negative attitudes about safer behavior, and/or a lack of social support for safer behavior*. A **low Confidence** score can also be a function of *the patient setting unrealistically high behavior change goals for themselves*. By exploring with the patient the specific reasons for the low **Confidence** score, you will be able to identify any perceived (social support, attitudinal, or behavioral skills) barriers or obstacles to behavior change and will be able to negotiate possible solutions for overcoming those barriers.
- **Reminder:** For the patient who rates *both Importance and Confidence* as high (9 or 10), do *not* ask the two above-listed questions. Instead, acknowledge the fact that practicing safer behavior is **important** to the patient and that the patient has the **confidence** to do so. Next, ask the patient to identify any barriers that are preventing them from always being safe, and work together to address those barriers (**Steps 7 and 8**).

Additional Information about STEP 6

Sample Scripts for STEP 6:

If focusing on *Importance*:

1. *“You gave yourself a score of 6, which suggests that using condoms has some importance for you. I am curious why you chose a 6 and not a 3 or 4.”*
2. *“What would have to happen for your **Importance** score to move up from a 6 to an 8 or a 9?”*

If focusing on *Confidence*:

1. *“You gave a score of 4 for your confidence in being able to use clean needles every time you shoot up. What is the reason that you gave a 4 and not a lower score, like a 1 or 2?”*
2. *“What would help you to feel more confident about using clean needles so that your **Confidence** is a 6 or 7 rather than a 4?”*

End of Step 6

STEP 7: Briefly summarize the patient's responses, and then discuss strategies for changing their risky behavior.

Purpose:

- To identify a strategy or menu of strategies that could overcome patient-identified obstacles to consistently practicing safer behavior and increase the patient's readiness and ability to change their risky behavior.

Suggested Script:

- “You said that your [**Importance/Confidence**] would increase if [x] happened. Do you have any ideas for how to make [x] happen?” . . . If the patient does not specify any strategies: “Would you be interested in hearing about some ways to make [x] happen?”

Elaboration:

- Once you have assessed the specific cause of the “low” **Importance/Confidence** score by asking the patient *what would have to happen* for their score to increase (**Step 6**), explore with the patient possible solutions or strategies for overcoming perceived obstacles to increasing the **Importance/Confidence** they attach to behavior change. Increasing their **Importance/Confidence** should ultimately move the patient in the direction of positive behavior change.
- Ideally, strategies for change should be elicited from the patient because they are the expert on their own life situation and will likely know best what will work or not work for them. This ensures that the strategies are appropriate for their particular situation.
 - One way to elicit strategies from the patient is by asking them about those situations when they were *successful* in engaging in safer behavior. What was different about those particular situations, and what specifically helped the patient to be successful in those situations? (Obviously, the patient should not be asked these questions if they never successfully engaged in safer behavior.)
- If the patient is unable to come up with any strategies on their own, ask the patient if you may offer some possible strategies. If you offer strategies, it is important that these strategies be provided in a way that does not elicit resistance from the patient. One approach is to ask the patient if they are interested in hearing about some things that other people have found helpful. Another approach is to tell them what other people have found helpful and then ask them if any of those strategies sounds like something that might work for them. However you do it, it is preferable that you provide a “menu” of strategies from which the patient can choose. This allows the patient to select the strategy that makes the

most sense to them in their life, increasing their sense of control over the process and the likelihood that they will follow through with the suggested action.

- If focusing on **Importance**: Asking the patient how to increase their **Importance** rating should elicit the relevant data that is needed to determine whether there are **information** deficits and/or **motivation** deficits underlying the low **Importance** score and what exactly needs to be “worked on” with the patient to increase their **Importance** score and move them in the direction of behavior change.
 - **Information Deficits**: If the patient has Information Deficits, it means that the patient needs more information about (1) the transmission of HIV and other STIs; (2) how to prevent HIV/STI transmission; and/or (3) the decision rules used to decide with whom it is “safe” to have unprotected sex (an example of a flawed decision rule is that it is “safe” to have unprotected sex with other HIV-positive individuals). Before attempting to provide any missing information or correct any misinformation, ask the patient if you can share some information with them. Be careful not to give the patient unsolicited or unwanted information, as you do not want to provide information that they do not want or are not yet ready to receive.⁴⁰ If they consent to discussing their information deficits, address and rectify any relevant information issues as appropriate. Next, ask the patient if there is any additional information of any type that they would like you to share with them.
 - **Motivation Deficits**: Motivation deficits can take many forms, including (1) negative attitudes about safer behavior (for example, *“Using condoms would be more important to me if they felt better. I just can’t feel anything when I wear one.”*); (2) perceptions of poor social support for safer behavior (for example, *“I guess that not sharing needles would be more important to me if my friends cared. But my friends don’t seem to care, so why should I?”*); and/or (3) perceptions of low vulnerability to negative outcomes to the self or others from being unsafe (e.g., *“I would probably give a higher Importance score for using condoms with my HIV+ partners if someone told me that I was at risk. But at this point, no one has shown me that I am at risk if I have unprotected sex with another positive person.”*)
- If focusing on **Confidence**: Asking the patient how to increase their **Confidence** rating should help you determine whether there are **behavioral skills** deficits and/or **motivation** deficits underlying the low **Confidence** score and to identify the specific strategies that will address those deficits and move the patient in the direction of behavior change.
 - **Behavioral Skills Deficits**: To increase or improve a patient’s **behavioral skills**, you can (1) provide written materials that teach



the needed skills (e.g., give the patient an instructional brochure on how to put on a condom), (2) demonstrate to the patient how to perform the necessary skills (e.g., show the patient how to insert a Female Condom into a pelvic model), (3) talk about specific scenarios and how to implement the needed behavioral skills in those particular scenarios (e.g., teach the patient how to negotiate safer sex with their boyfriend), or (4) refer the patient to a place where they can learn the needed skills (e.g., refer the patient to a nurse who can teach them how to clean their needles).

- **Motivation Deficits:** Another possible cause for a low Confidence rating is insufficient motivation, which can be due to negative attitudes toward safer behavior or poor social support for that behavior. To change a patient's **attitudes** about safer behavior, you can discuss strategies for overcoming the negative aspects of safer behavior, or you can teach needed behavior skills, which can alter their attitudes (e.g., teaching the patient how to eroticize safer sex can make safer sex more exciting). To increase perceived *social support* for safer behavior, you can explore with the patient those individuals in the patient's life (including yourself) who can serve as supports for safer behavior.

Additional Information about STEP 7

Sample Demonstrations of STEP 7:

- **Focusing on *Importance* (Information Deficit):**

- **Patient:** *“It would be more important to me to use condoms if I were a ‘top,’ but I’m not; I’m a ‘bottom.’ There’s not much risk to a ‘top’ who has sex with me.”*
- **Provider:** *“It sounds like you’re saying that using condoms would be more important to you if you knew that your partners, who are all ‘tops,’ were at risk for HIV.”*
- **Patient:** *“Yeah, that’s right.”*
- **Provider:** *“Actually, I have some information about this issue that I would like to share with you, if you are interested. Is that okay with you?”*

- **Focusing on *Importance* (Motivation Deficit):**

- **Provider:** *“You said that you do not like using condoms because you can’t feel as much. Do you have any ideas for how to make condoms feel better?”*
- **Patient:** *“No, not really.”*
- **Provider:** *“If you’re interested, I have some ideas that might help.”*
- **Patient:** *“Yeah, sure. Why not?”*
- **Provider:** *“Okay, great! Well, some people find that they can feel more when they put some water-based lubricant on the inside of the condom or on the head of the penis. Others choose to use thinner condoms in order to increase sensitivity. Still others have decided to use the Female Condom because they believe that it feels more like sex without a condom. Do any of these ideas sound like something that might work for you?”*

- **Focusing on *Confidence* (Behavioral Skills Deficit):**

- **Patient:** *“I would feel much more confident about not sharing my syringes with my boyfriend if he knew that I am HIV-positive. But he doesn’t know, and I don’t know how to tell him.”*
- **Provider:** *“It sounds like you would like your boyfriend to know that you have HIV, but you don’t know how to go about telling him.”*
- **Patient:** *“Yeah, I am so afraid that he’ll get angry and leave me.”*
- **Provider:** *“And that’s a realistic fear. Would you like to talk about some different ways of informing him about your HIV?”*

End of Step 7

STEP 8: Negotiate a goal or action plan with the patient.

Purpose:

- To increase the probability of behavior change by allowing the patient to choose a goal that is realistic and attainable in the context of her/his life situation.

Suggested Script:

- *“We have talked today about some possible ways to make [x] happen. Would you be willing to try any of these things between now and your next visit?”*

Elaboration:

- A plan of action can evolve naturally out of an exploration of the **Importance** or **Confidence** associated with behavior change. Discussing the reasons for the patient’s rating and what can be done to make it higher should elicit a menu of possible strategies for how to increase their **Importance** or **Confidence**. From these strategies should emerge a goal or action plan that can potentially move the patient in the direction of behavior change or at least in the direction of considering behavior change (i.e., increase their readiness to change).
- Rather than you prescribing the goal, the patient should tell you what a reasonable next step would be. They can choose a goal or action plan from among the strategies discussed. The goal must be a realistic, “do-able” one that the patient is willing to try and commit to; unless the patient is committed to the goal, it is unlikely that they will be successful at accomplishing their goal.
 - “Selection of one’s own approach from among options has the effect of enhancing perceived personal choice and control. When a person perceives that he or she has freely chosen a course of action, it is more likely that the person will persist and succeed” (p. 34).⁴⁴
- In the ideal situation, you and your patient would negotiate a specific risk behavior change goal for the next clinic visit and a plan to reach that goal (e.g., take free condoms home with them from the clinic and try using them at least once between now and their next clinic visit; disclose to their partner that they have HIV). Realistically, however, not every patient is ready to make an actual change in their risk behavior (particularly those patients who give a **low Importance** and/or a **low Confidence** rating with respect to the practice of the safer behavior being discussed). Therefore, it is important to look for smaller, more realistic goals that may represent interim steps on the journey toward the goal of consistent safer behavior (e.g., rather than the patient trying unsuccessfully to use condoms 100% of the time between now and the next visit, they could go to a store and explore the different condoms that are available, or they could read an article about how to eroticize wearing a condom, or they could learn how

to put a condom on with their mouth by practicing on their fingers). Although these steps may not represent actual changes in risk behavior, they may lead to an increase in a patient's readiness to change their behavior (i.e., to an increase in their **Importance** or **Confidence** score), which will increase the probability of eventual behavior change.

- If you and the patient cannot agree on any specific action steps that the patient can take, suggest that the patient commit to a goal of *thinking about changing* or at least *continuing the discussion* at the next visit. Success here will be determined by having “opened the door” for discussion about the risky behavior.
- It is important to remember that as you work with the patient, their goals will evolve and change over time. One of your patients may start off by agreeing to a goal of “thinking about safer sex” and may evolve over a period of several months to a goal of consistently using condoms. Another of your patients may already be practicing safer sex on a consistent basis when they have their first clinic visit and then may relapse at a later time. The key to the success of this intervention is for you to be flexible and to ensure that the goals are tailored to the needs of the patient within their life situation.
- Whatever the negotiated goal is (e.g., continuing the discussion next time, thinking about the safer behavior, taking an interim step towards the safer behavior, trying the safer behavior once, or implementing the safer behavior all the time), it is critical to ensure that it is **realistic** and **attainable**. Do not attempt to direct the patient towards a goal which they are not ready or able to achieve. **At this juncture, the patient's success is critical.**
- To increase the patient's commitment to completing the negotiated goal, consider writing it down on the *Options Prescription* pad and then handing the *Options Prescription* to the patient. (**Note:** Use of the *Options Prescription* is optional. Many providers choose not to use it with their patients.)
 - The *Options Prescription* serves as a mini-contract between you and your patient. Research has shown that having a written agreement or “contract” with the patient increases the likelihood that the patient will actually follow through on the agreed-upon goal (e.g., Gallucci & Smolinski, 2001; Haynes, McDonald, & Garg, 2002; McDonald, Garg, & Haynes, 2002).
 - To increase the patient's commitment to the agreed-upon goal, have both you and the patient sign the *Options Prescription*.

Additional Information about STEP 8

Sample Scripts for STEP 8:

- *“You told me today that it is important for you to use condoms, but your partner refuses to use them, and you don’t think he would be willing to try other latex condoms to see if he liked them better. You seemed interested, though, when I was talking about the Female Condom. What would be a realistic goal for you for the next visit in terms of the Female Condom? Would it be for you and your partner to try the Female Condom between now and then? Or if you’re not ready for that yet, then perhaps you could talk to your partner about the Female Condom and see how he feels about it. Another option would be for you to first read some literature about this condom before talking to your partner about it. Which of these three options makes the most sense to you?”*
- *“You said that in order to feel more confident about using condoms, you would have to be able to keep an erection while using a condom. We talked about a couple of different ways to help you to keep an erection. One was to masturbate with the condom on while you’re alone and there is no pressure to perform; this might help you to get comfortable enough with the condom so that you don’t feel anxious while using it and lose your erection. A second strategy that we explored was the possibility of you discussing this issue with your partner and the two of you trying to come up with a solution to the problem. Would either of these strategies be something that you would be willing to try over the next month?”*
- *“I understand that you would rate using condoms with your HIV+ partners higher in importance if you believed that unprotected sex presented a health risk to you or your partners. There is lots of information out there indicating that unsafe sex presents a health risk to HIV-positive individuals, but I know that you are skeptical about it. If you would like, I can get you some articles on the subject. Or I can give you some informational websites to check out. Or I can refer you to some other healthcare providers to talk about it. Which, if any, of these would you be willing to do between now and the next clinic visit?”*
- *“To raise your confidence score for not sharing needles, you said that you need to have greater access to clean needles. We talked about you going to the Syringe Exchange Program and finding out how to get clean needles from them. We also talked about me prescribing clean needles for you so that you can get them from the local pharmacy. Would you be willing to try one of these between now and the next clinic visit?”*
- **Sample script for patient who is unwilling to commit to a plan of action:**
“I am hearing that maybe this isn’t the right time for you to make a change. And that’s all right. I’m wondering if you’d be willing to think about some of the things that we talked about today and then discuss them again at our next visit. Would that be okay?”

End of Step 8

STEP 9: Document what transpired during the Options discussion on the Patient Record Form (PRF), and file the PRF in the patient's medical record.

Purpose:

- To ensure that there is continuity from one Options visit to the next by providing a systematic reminder of what occurred during the previous Options discussion with a patient.

Elaboration:

- The *Patient Record Form* is a brief form that was developed with the input of many healthcare providers. It is where you document what occurred during the Options discussion.
- Although it is not critical to use the *Patient Record Form* per se, it is recommended that there be a formalized and consistent format for documenting the information discussed during the Options visit.
- The *Patient Record Form* can be modified and tailored to meet the needs of your clinic staff and patient population, and it can also be incorporated into an electronic medical record system.
- At a minimum, the following information should be documented: (1) any risky sexual and drug use behaviors in which the patient is engaging, (2) the specific barriers to consistently practicing safer behavior, (3) the **Importance** and **Confidence** ratings, and (4) the agreed-upon goal or action plan that the patient intends to work on between now and the next visit.

End of Step 9

"We believe that each person possesses a powerful potential for change. Your task... is to release that potential, to facilitate the natural change processes already inherent in the individual."

Miller & Rollnick, 1991, (p. 62) ⁴⁴





Intervention Protocol for Patients Reporting No Risk Sexual or Drug Use Behavior



Step-by-Step Review of Protocol

1. Set the agenda for the discussion.

- a. Inform the patient that you would like to discuss their sexual and drug use behaviors.
- b. Ask the patient's permission to discuss these behaviors.

2. Assess the patient's current sex and drug use behaviors.

- a. Determine the specific sex and drug use behaviors in which the patient is engaging.
- b. If the patient is not engaging in any sex or drug use, assess why they are not having sex.
 1. It is important that prior to reinforcing a patient's "abstinence," you understand why they are not having sex. There are many reasons why people do not have sex, and it is often not because patients are trying to protect others. For example, there are some people who are "safe" only because they have not had the opportunity to have sex, and there are others who are too frightened of transmitting their HIV to have sex with anyone. People who are "safe" as a function of lack of opportunity or of fear may be likely to engage in risk behavior once the opportunity arises or the fear dissipates. If a patient is reporting no risk behavior, it cannot be assumed that this person is motivated to maintain their safer behavior. Therefore, it is vital to understand why they are engaging in safer behavior and to assess how **Important** it is for the patient to maintain their safer behavior and how **Confident** they are that they have the ability to do so.
 2. If the patient's motivation for abstaining from having sex is to protect their own health and the health of their partners, it is critical that you reinforce and encourage them to continue their safer behaviors.

3a. If the patient is consistently practicing safer sex and drug use behavior (i.e., is using condoms consistently, is abstaining from sex, and/or is not sharing syringes or works), reinforce their safer behavior, and evaluate their readiness to maintain it.

- a. Assess **Importance**: Have the patient rate the **importance** of maintaining their safer behavior on a scale from 0 to 10, where 0 is “not at all important” and 10 is “extremely important” (e.g., *On a scale from 0 to 10, with 0 being “not at all important” and 10 being “extremely important,” how important is it to you to continue to use condoms during sex?*).
- b. Assess **Confidence**: Have the patient rate their **confidence** that they can maintain their safer behavior on a scale from 0 to 10, where 0 is “not at all confident” and 10 is “extremely confident” (e.g., *On a scale from 0 to 10, with 0 being not at all confident and 10 being “extremely confident,” how confident are you that you can continue to use condoms during sex?*).

1. **Examples of Scripts:**

- “You said that you are using a new syringe each time you shoot up. That’s great that you are not sharing your syringes with anyone. I would like to understand a bit more about how you feel about this. On a scale from 0 to 10, with 0 being “not at all important” and 10 being ‘extremely important,’ how important is it to you to continue to use new syringes? . . . On a scale from 0 to 10, with 0 being ‘not at all confident’ and 10 being ‘extremely confident,’ how confident are you that you can continue to use a new syringe each time?”
 - “You told me you are choosing not to have sex right now. On a scale from 0 to 10, with 0 being “not at all important” and 10 being ‘extremely important,’ how important is it to you to continue to abstain from having sex? . . . On a scale from 0 to 10, with 0 being ‘not at all confident’ and 10 being ‘extremely confident,’ how confident are you that you can continue to abstain from having sex?”
- c. Briefly summarize, or recap, both scores provided by the patient.
 - d. **Note:** Some providers feel that the **Importance** question can at times seem artificial or awkward when the patient is not engaging in any risk behavior. This is particularly true when the patients are abstaining from sex. When asked how important it is to abstain from sex, some patients have reacted to the question by assuming that their providers regard their behavior as abnormal. If that is the case, then you can choose not to ask the **Importance** question, and just ask the **Confidence** question instead. For example, “On a scale from 0 to 10, where 0 is ‘not at all confident’ and 10 is ‘extremely confident,’ how confident are you that you can continue to abstain from sex?”

3b. If the patient responds that they are currently not having sex, but would like to do so in the future, evaluate their readiness to engage in safer sexual behavior when they do have sex.

- a. Determine if the patient believes that it is important to engage in safer sex, is motivated to do so, has the self-efficacy to do so, and has a plan for how that will be achieved once the opportunity arises. In this situation, it does not make sense to ask them to rate how **Important** it is to continue to *not* have sex; they have already said that they would like to have sex in the future. The goal is not for them to continue to abstain from sex, unless that is something they are motivated to do. The priority here is to ensure that they have a plan for how they will practice safer sex when they do eventually have sex. There are a couple of options for how to interact with the patient here. One option is to ask them to rate the **Importance** of practicing safer sex and the **Confidence** that they can do so, once they do have sex. Another option is to ask them to rate how confident they are that they will not have sex between now and the next visit. If they answer anything less than 9, there needs to be a discussion about a plan for safer sex.
 1. Assess **Importance**: Have the patient rate the importance of engaging in safer sexual behavior on a scale from 0 to 10, where 0 is “not at all important” and 10 is “extremely important” (e.g., “*You said that you currently are not having sex but would like to do so in the future. If it’s okay with you, I would like to ask you a couple of questions so that I can better understand how you feel about safer sex. On a scale from 0 to 10, with 0 being ‘not at all important’ and 10 being ‘extremely important,’ how important is it to you to use condoms when you do have sex?*”).
 2. Assess **Confidence**: Have the patient rate their confidence that they can maintain their safer behavior on a scale from 0 to 10, where 0 is “not at all confident” and 10 is “extremely confident” (e.g., “*On a scale from 0 to 10, with 0 being ‘not at all confident’ and 10 being ‘extremely confident,’ how confident are you that you will be able to use condoms consistently when you do have sex?*”).
 3. Briefly summarize, or recap, both scores provided by the patient.
- b. **Note**: Once you have established that your patient has a plan for how they are going to engage in safer sexual behavior once do they have sex, it does not make sense to keep asking them these questions each time that they come in for a visit. On follow-up visits, you should check in with them to find out if anything has changed (e.g., did they have sex between the last visit and this one). If not, then reinforce their safer sex plan, and agree to check in again at their next visit.

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4. Using the following algorithm, decide whether to focus on *Importance*, on *Confidence*, or on other issues.
 - a. For the patient who views safer behavior as important (9 or 10), has the confidence that they can successfully engage in the behavior (9 or 10), and has actually been consistently performing the behavior for a significant period of time, provide positive reinforcement for their efforts and encourage them to continue to maintain their safer behavior. In addition, it is recommended that the patient work on preventing relapse by identifying potential triggers and problem-solving strategies for managing those triggers.
 1. **Positive Reinforcement:** It cannot be overemphasized how important it is to reinforce patients for their successes. Receiving acknowledgement and praise from someone whom patients respect and admire serves as a strong incentive for continuing to practice safer behavior.
 - a. **Examples of Scripts:**
 - “You should be proud of yourself and the great job you’re doing protecting yourself and your partners.”
 - “You’ve really done a tremendous job practicing safer behavior.”
 2. **Relapse Prevention:** Ask the patient if there is anything that could get in the way of their maintaining their safer behavior that they would like to discuss today. In other words, help the patient assess their potential HIV risk triggers—the people, places, and feeling states that they find to be challenging in the practice of safer behaviors—and then problem-solve possible strategies for effectively managing these triggers.
 - a. **Example of a Script:**
 - “It sounds like you are doing a terrific job practicing safer behavior. You should be proud of yourself. I am curious if there are any situations that you find to be challenging or more difficult to stay safe in.”
 - b. **Note:** Once you have worked on relapse prevention with the patient, and there is a successful plan in place for how to deal with challenging situations, it is not necessary to continuously assess their triggers. If the patient is practicing safer behavior and has the confidence to continue to do so, check in with the patient on a regular basis, reinforce their safer behavior, and then agree to check in on the next visit. This check-in should not take more a couple of minutes to do.

- b. **For the patient who is not having sex, but would like to do so, who views safer behavior as important (9 or 10), and has confidence that they can successfully engage in safer behavior (9 or 10), the provider needs to assess what plan, if any, the patient has for ensuring that they will practice safer behavior once they do have sex.** In addition, it is recommended that this patient try to anticipate any barriers to safer behavior and problem-solve strategies for overcoming these barriers.
 - 1. **Example of a Script:**
 - “You said that it is important to you to practice safer sex when you do eventually have sex, and you are confident that you can do so. How will you ensure that you have safer sex when the opportunity arises? . . . Do you anticipate any situations that may be particularly challenging for practicing safer sex?”
 - c. **When Importance and Confidence are not both equal to 9 or 10: If Importance < 7, focus on Importance. If Importance ≥ 7, focus on whichever one (Importance or Confidence) is rated lower.**
- 5. Identify the barriers to consistently practicing safer sex and drug use behavior. Note:** Only ask these two follow-up questions if the patient’s *Importance* and *Confidence* ratings are not both equal to 9 or 10.
- a. If their rating ≥ 2, ask the patient to explain why they did not give a **lower** score. If their rating < 2, skip this step, and move on to 5b. (e.g., *You gave a rating of 6 for your confidence in continuing to use condoms. Why did you choose 6 and not 3 or 4?*)
 - b. Ask the patient to explain what would need to happen for their rating to **increase**. (e.g., *Although you haven’t been engaging in any risky sexual behavior, you rated the importance of continuing to be safe as 5. What would need to happen for that importance rating to increase to a 7 or 8?*)
 - c. Responses to these questions should elicit possible strategies for the provider on how to increase the scores and thus help the patient maintain their safer sex and drug use practices.
- 6. Briefly summarize the patient’s responses to the two above-listed questions, and then with their permission, discuss with them various strategies for increasing their Importance and/or Confidence rating.**
- a. **Note:** This step should be skipped if the patient’s *Importance* and *Confidence* ratings are both 9 or 10.
 - b. If the patient is working on relapse prevention, the focus should be on discussing strategies that would help the patient to maintain their safer sexual and/or drug use practices rather than on *Importance* and/or *Confidence*.



7. Negotiate a goal or plan of action with the patient.

- a. Based on the strategies just discussed, ask the patient for possible goals that they would be willing to work on between now and the next visit. If they do not suggest any goals, offer various alternatives among which they can choose.
- b. Ask the patient to choose which goal they would like to work on. If they are consistently practicing safer sex and drug use behavior, an appropriate goal would be to continue with that behavior.
- c. To increase the patient's commitment to completing the negotiated goal, consider writing it down on the *Options Prescription* pad and then handing the *Options Prescription* to the patient. (**Note:** Use of the *Options Prescription* is optional. Many providers choose not to use it with their patients.)

8. Document what transpired during the Options discussion on the *Patient Record Form (PRF)*, and file the *PRF* in the patient's medical record.

- a. Although it is not necessary to use the *Patient Record Form* per se, it is critical to document what occurred during the discussion. Documentation helps you recall the issues that need to be addressed in subsequent *Options* discussions.



Intervention Protocol for Follow-Up Options Visits



Introduction

The focus of the follow-up visit is on the goal that was set at the previous visit. The healthcare provider should: (1) review the goal; (2) explore what progress if any was made toward reaching that goal; (3) reinforce any progress that was made toward reaching that goal; (4) discuss barriers and impediments if no or limited progress was made; (5) reassess **Importance** and/or **Confidence** (if relevant); and (6) negotiate a new or revised goal.

This visit should be of shorter duration since it is not necessary to repeat all of the steps that were implemented at the initial visit. If no goal was set at the previous visit, then this visit should proceed in a similar fashion to the initial visit, with an assessment of risk behavior, an evaluation of **Importance** and **Confidence**, a discussion of strategies for increasing **Importance** or **Confidence**, and an agreement on a goal or action plan for the next visit. It is important to remember that the goal for a patient who is practicing safer behavior is continued practice of that safer behavior.

Step-by-Step Review of Protocol

1. **Review the *Patient Record Form* from the last visit.** Before beginning the Options discussion with the patient, briefly review the *Patient Record Form* from the last visit for the following information: (a) identified risk behaviors, if any, (b) conditions under which risk behaviors occurred, (c) **Importance** and **Confidence** scores, and (d) agreed-upon goal or plan of action.
 - a. If no goal was agreed upon at the last visit, return to the protocol used for initial visits and follow those steps as outlined. Depending upon what happened at the last visit, either continue from where you left off or begin again with the first step.
2. **Explore the progress that was made by the patient toward achieving the goal that was agreed upon at the previous visit.** Be careful not to sound judgmental or evaluative when asking about the patient's progress. The patient must feel comfortable and secure enough with you to admit that they did not achieve the goal, if that is the case. By asking the patient "*what if any* progress that they made" or "*how much progress* did they make," the

provider conveys an expectation of progress while also allowing the patient to admit that they did not achieve the goal or only partially achieved the goal.

a. **Examples of Scripts:**

- “The last time that you were here, you set a goal for yourself. You decided to [specific goal]. I’m wondering what, if any, steps you were able to take toward achieving that goal?”
- “The last time we were together, you agreed to work on the goal of [specific goal] between the last visit and today’s visit. What progress, if any, did you make toward reaching that goal?”
- “At your last visit, you set a goal of [specific goal]. How have things gone for you since then?”
- “The last time that you were here, you said that you didn’t think that using condoms with your partner was important, but you said that you would think about it between then and now. Did you think about it, and if so, what are your thoughts now on the matter?”
- “The last time that we met, you indicated that you were using condoms every time that you had anal sex. Has anything changed since then?”

b. **Note:** If the patient was not having sex as of the last visit (and was not using recreational drugs), the provider should determine if anything has changed since that visit (e.g., “Last time we met, you said that you were not having sex. I was wondering if anything has changed since then.”).

3. If the patient fully achieved their goal . . .

a. If the patient fully achieved their goal, praise them for their accomplishment. It is critical that you strongly reinforce the patient for the work that they did as this likely serves as an important source of motivation for the patient. It is also a good idea to ask how the patient feels about what they accomplished. It is an opportunity for the patient to brag a bit and reinforce themselves for what they did. If the patient minimizes what they accomplished, then it may be a sign that they are not very committed to the goal and that relapse may occur.

1. **Examples of Scripts:**

- “You did a terrific job! You should be proud of yourself!”
- “You made a lot of progress since our last meeting. Great work! How do you feel about what you accomplished?”

2. **Note:** If the goal for the patient was to “think about” their behavior between the previous meeting and the current meeting, then you should be careful about how much you praise the

patient. It is important that the praise not sound excessive relative to the goal that was accomplished because you could risk sounding insincere.

- b. If the patient was not engaging in any risky behavior as of the last visit, and has continued to avoid risky behavior since then, reinforce this.
 1. Be careful about reinforcing abstinence if that was not the patient's goal at the last visit. If the patient has not had sex since the last visit but wanted to have sex, it is important *not* to praise the patient for not having sex. In this case, the focus should be on whether the patient is still committed to having safer sex when they do have sex. If the patient has a safer sex plan, you can assess the **Importance** of implementing the plan and the **Confidence** that they can do so.
 - a. If the ratings at the last visit for the safer sex plan were 9 or 10, it is not necessary to do a formal reassessment. Rather, you can summarize the ratings from the last visit, and ask if they changed any, or simply ask if the patient is committed to the plan that they previously discussed.
 2. If at the last visit, the patient rated both the **Importance** of practicing safer behavior (e.g., using condoms, abstaining from sex) and the **Confidence** that they could continue to do, as a 9 or 10, it is not necessary to reassess those ratings at the follow-up visit. This Options visit can be a simple check-in to assess whether or not anything has changed since the last visit.
 3. If the patient is not engaging in any sexual behavior, but you are concerned that the patient is not committed to abstinence, you can ask the patient to rate their confidence that they will not have sex between now and the next visit. If the rating is anything less than a 9 or 10, discuss creating a safer sex plan with the patient.
- c. If the patient reached their “end” goal (i.e., engaging in safer behavior on a consistent basis), praise the patient on *their* behavior and shift the focus to maintenance and relapse prevention. This can be done by assessing the patient's ratings of **Importance** and **Confidence** with respect to *maintaining* their safer behavior.
 1. If the patient rates both **Importance** and **Confidence** as a 9 or 10, then you can ignore **Importance** and **Confidence**, and instead talk to the patient about any challenging situations that might arise in the future and how to handle them. In this situation, the goal for the next session would be to continue to practice safer behavior and perhaps to work on relapse prevention.
 2. If instead, one or both of the ratings for maintaining their safer behavior is less than 9, further explore the ratings according to the algorithm provided in the protocol for initial visits. Strategies should be explored for increasing the **Importance** or **Confidence**

rating so that the patient does not relapse and continues their safer behavior into the future. A goal should be negotiated based on the discussion of the ratings.

3. If the patient initially reported engaging in two (or more) risky behaviors and they have successfully eliminated one of their risky behaviors, the patient has the option of focusing on one of their other risky behaviors. In this case, use the protocol for initial visits and focus on this other risky behavior.
- d. If the patient achieved a goal that is an interim step toward the “end” goal (e.g., interim step = discussing condom use with her husband; “end” goal = using condoms consistently with her husband), you can ask the patient whether their **Importance** and **Confidence** ratings changed any as a function of having accomplished their goal (e.g., “Last time that we met, you rated the importance of using condoms with your husband as a 10, but your confidence as a 5. Has either of your ratings changed since you talked to your husband about condoms?”). Then follow the remainder of the protocol steps from the initial visit, discussing strategies for increasing the patient’s **Importance/Confidence** rating, and negotiating a new goal. The new goal may be another interim step toward the “end” goal (e.g., interim step = trying a variety of condoms to determine which one they like best), or it may be the “end” goal itself this time.
 1. Although the patient may have accomplished a goal, this does not automatically mean that they are ready for the next step. Spending some time talking about the goal, what it felt like to achieve the goal, and what was difficult about achieving the goal can provide you with valuable information about whether the patient is ready to move on to the next step or should just maintain their current behavior for a while.
 2. **Note:** It is also possible to negotiate a new goal without reevaluating the **Importance** and **Confidence** ratings. Sometimes it is relatively easy to determine what the next step is without involving **Importance** and **Confidence** ratings. However, if you need assistance in understanding the barriers to further progress, a reassessment may be beneficial.

4. If the patient partially achieved their goal . . .

- a. If the patient partially achieved their goal, reinforce the patient for whatever progress that was made toward the goal and then explore the barriers that got in the way of the patient fully achieving their goal. It is critical for you to work together with the patient to assess whether the goal was too ambitious for the patient. It is much more effective to agree on a less ambitious goal so that the patient has a successful experience and is motivated to continue to pursue behavior change. An experience of failure can be very discouraging for a patient and can negatively impact on the patient’s motivation level.

1. **Examples of Scripts:**

- “So you and your husband did not try using the Female Condom, but you did have a discussion about it. That is great that the two of you were able to talk about it. That is a good first step. I am curious to know what happened in that discussion and what got in the way of you actually trying the Female Condom.”
- “So you said that you exchanged your dirty needles at the NEP van for new ones, but you ended up not using them. I am glad to hear that you went to the van and actually made the exchanges. I know that was not an easy thing for you to do. How did you feel about doing it? What got in the way of your actually using those needles?”

- b. After discussing the barriers that got in the way of the patient fully accomplishing their goal, you can reassess the patient’s **Importance** and **Confidence** with respect to achieving their goal, discuss strategies for reaching their goal, and then renegotiate a new or revised goal for the following clinic visit.

1. **Note:** It may not be necessary for you to reassess **Importance** and **Confidence** if the discussion about barriers provides you and the patient with enough information to know what the needed strategies and goals are.

5. **If the patient did not achieve their goal (or any portion of their goal). . .**

- a. If the patient did not achieve the goal that they set during the last visit, explore with the patient the barriers that got in the way of achieving that goal. It is critical that you avoid being judgmental or evaluative of the patient in this discussion. Rather than viewing this as a failure, it should be regarded as an opportunity to learn about and better understand how to help the patient move forward toward healthier behavior.

1. **Examples of what to say:**

- “So you had some difficulty attaining the goal that you set for yourself during your last visit. Well, you’re not alone. Many people find it hard to change these behaviors. Would it be all right if we talked about it? . . . Let’s try to understand what happened and what got in the way of achieving your goal.”
- “You indicated that you had some difficulty with the goal that we set last visit. I was wondering if you would be willing to tell me how you feel about that.”
- “Let’s talk about the goal that you set at your last visit and whether or not it was a realistic goal. Perhaps it was too ambitious for your first goal.”

2. **Examples of what not to say:**

“So you totally failed at achieving your goal that we set last time.”

“It doesn’t sound like you care at all about being safe. If you did, you would have worked on this goal.”

“Doesn’t it matter to you that you may be infecting others? Why didn’t you live up to our agreement?”

- b. After discussing the barriers to reaching the goal, you can follow an abbreviated version of the procedures described for the initial visit by reevaluating the patient’s **Importance** and **Confidence** scores for the chosen behavior, discussing strategies for increasing their **Importance/Confidence** score, and then renegotiating an *attainable, specific goal* for the next visit.
 1. **Note:** It may not be necessary for you to reassess **Importance** and **Confidence** if the discussion about barriers provides you and the patient with enough information to know what the needed strategies and goals are.

6. **As with the initial visit, document what transpired during the Options discussion on the *Patient Record Form (PRF)*, and file the PRF in the patient’s medical record.** This step should occur at the end of every Options visit.

7. **If likely to increase the patient’s commitment to completing the goal, write the goal down on the *Options Prescription* pad and hand the prescription to the patient.**

- a. **Note:** As mentioned in other sections of this manual, use of the *Options Prescription* is optional.

Behavior Change Can be a Slow Process

It is critical to be patient throughout this process of behavior change. Some patients will progress very rapidly, and some will move slowly. Progress will depend on where the patient is in the process of change. If the patient has not even thought about change, progress has been made if the patient starts critically examining *their own* behavior and begins exploring the possibility of change. If the patient has been consistently practicing safer behavior, then success is the patient continuing to do so without relapse. What is considered progress or success will vary from patient to patient. Some patients will need to take baby steps toward the goal of practicing safer behavior and others will reach that goal at warp speed. It is important that you not become frustrated if the patient is moving very slowly. The critical element here is to be able to have a dialogue with the patient about risky behavior and to support the patient as they explore these issues.

Be Prepared for Relapse

Over time, it is to be expected that a patient will relapse with respect to their practice of safer behavior. It is difficult and challenging to be safe on a day-to-day basis as motivation ebbs and flows. When a patient does relapse, it is critical that you not chastise or judge the patient for their relapse. The relapse should be acknowledged and discussed. You can even validate the fact that safer behavior is challenging to do on a consistent basis, and that many people find it difficult to do. However, this should not be used as an excuse by the patient to forego safer behavior. Assess with the patient what happened during the relapse and treat it as a learning experience where they can determine what changes need to be made in the future. A relapse is an opportunity to explore what the patient's triggers for risky behavior are and to determine how to anticipate and manage those triggers.





Options Implementation Forms



Options Implementation Tools

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Patient Record Form

The *Patient Record Form* is an example of a standardized form on which the healthcare provider can document what transpired during an Options visit, including the risk behaviors identified (*if any*), the conditions under which the risk behaviors occur, **Importance** and **Confidence** ratings, and the agreed-upon goal or action plan. Once completed by the provider, the *Patient Record Form* is filed in the *patient's medical record*. At the *subsequent visit*, the provider reviews the *Patient Record Form* as a reminder of what occurred at the last visit. The form thus serves multiple purposes; besides providing intervention prompts to the provider, it is a measure of intervention fidelity and implementation frequency, and it contains patient information that the provider needs in order to effectively implement the intervention from one clinic visit to the next.

Versions of this form have been successfully used in over 25 clinics throughout the United States as well as in South Africa and Mozambique. It can be tailored to the needs of a clinic, and with the assistance of IT staff, it can be modified for use in electronic medical records.

When providers first begin implementing the Options intervention, they sometimes need assistance in remembering the steps of the protocol. They can use the *Patient Record Form* as a prompt, or they can use the *Quick Reference Guide for the Options Intervention* or the *Options Pocket Guide*. If they use a paper copy of the *Patient Record Form*, they can put the *Reference Guide* on the back of that form. If instead, they have electronic medical records, a copy of the guide can be incorporated into the electronic records. A third option is to use the *Options Pocket Guide*, which is a palm-sized version of the guide that the provider can carry in their pocket.

The *Patient Record Form*, *Quick Reference Guide*, and *Options Pocket Guide* can be obtained from this manual.



Quick Reference Guide for the Options Intervention

1. Set the Agenda.

“There are a couple of things that I talk about with all of my patients—sex and drug use I would like to spend a few minutes talking about these issues, if that is okay with you.”...

2. Assess Risk Behavior.

“Many of my patients are finding it challenging to practice safer sex and safer drug use on a day-to-day basis... Now, I don’t know if these are issues for you, but if they are, I would appreciate it if you would help me understand what this struggle is like for you ... What works for you and what doesn’t, when it comes to safer sex... What works for you and what doesn’t, when it comes to safer drug use?”

3. Summarize risky behaviors, and ask patient to choose one on which to focus.

“You said that you are doing [risk behavior x] and [risk behavior y]. Let’s just focus on one of these areas for today. Which one would you prefer to talk about?”

4. Assess Importance and then Confidence.

“I would like to better understand how you feel about [changing behavior]. Can you help me by answering a couple of questions?”...

1) *“On a scale from 0 to 10 where 0 is ‘not at all important’ and 10 is ‘extremely important,’ how important is it to you to [change this behavior]?”...*

(2) *“On a scale from 0 to 10 where 0 is ‘not at all confident’ and 10 is ‘extremely confident,’ how confident are you that you can [change this behavior]?”*

5. Decide on whether to assess importance or Confidence, using the following algorithm:

- If both IMPORTANCE and CONFIDENCE = 9 OR 10, explore with the patient any barriers to change.
- If the rating of IMPORTANCE < 7, explore IMPORTANCE and ignore CONFIDENCE for the time being.
- If the rating of IMPORTANCE ≥7, explore the one with the lower rating.

6. Based on the algorithm, further explore Importance OR Confidence.

(1) *“You gave yourself a score of [#] for [importance/confidence]. Why did you give yourself a [#] and not a lower score?”*

(2) *“What would have to happen in order for your [importance/confidence] score to increase?”*

7. Briefly summarize patient’s responses, and then discuss specific strategies for raising patient’s score. If patient does not offer any strategies, ask permission to provide strategies, and then provide a menu of strategies.

*“You said that your [importance/confidence] would increase if [x]. Would you be interested in hearing about [x]? **or** Would you be interested in learning about ways to [x]?”*

8. Negotiate a Goal or Action Plan with the patient: Have the patient select a goal from a menu of goals for the next clinic visit.

“You have talked today about some possible ways to [x]. Would you be willing to try any of these alternatives between now and our next visit?”

Optional: Document the agreed-upon goal or action plan on the Prevention Prescription or Action Plan, and hand it to the patient.

9. Document Goal or Action Plan on the Patient Record Form and file it in the patient’s medical record.

Options Intervention Steps

STEP 1: Set the agenda for the discussion.

STEP 2: Identify patient's current HIV risk behavior(s).

STEP 3: If patient reports multiple risk behaviors, ask patient to choose ONE to focus on today.

STEP 4: Use Importance and Confidence ratings (0-10) to assess patient's readiness to change.

STEP 5: Decide whether to focus on Importance or Confidence:

- If both are 9 or 10, discuss barriers to change.
- If Importance < 7, focus on Importance.
- If Importance \geq 7, focus on the lower rating.

STEP 6: Identify barriers to consistently practicing safer sex or drug use.

- If Importance/Confidence rating > 1, ask patient to explain why did not give a lower rating. If rating \leq 1, skip this question.
- Ask patient what would need to happen for rating to increase.

STEP 7: Summarize patient's responses, and discuss strategies for changing risky behavior.

STEP 8: Negotiate realistic/attainable goal with patient to address risk behavior. **OPTIONAL:** Write it on *Options Prescription* pad, and give to patient.

STEP 9: Document Options discussion on *Patient Record Form*, and file it in patient's medical record.

Options Prescription / Options Action Plan

At the end of each Options discussion, the healthcare provider can document the agreed-upon goal or action plan on a document entitled: *Options Prescription* or *Options Action Plan*. The provider, or the provider and patient together, can sign the form, indicating their commitment to working together toward this goal. The provider then gives the *Prescription* or *Action Plan* to the patient to take with them. This document can function as a mini-contract, or agreement, between the provider and patient, indicating the specific goal that the patient will try to accomplish between now and the next clinic visit. It can also serve as a form of reinforcement for the patient who is practicing safer behaviors, acknowledging the good work that the patient is doing in protecting their own health and the health of others. Lastly, it serves to convey the importance of following through on the goal. When a healthcare provider writes a medication prescription for a patient, the provider is acknowledging the importance of the patient taking their medications. When a provider writes a behavior change prescription, the provider is conveying that working on the behavior change goal is as important as taking one's medications.

In practice, use of the *Prescription / Action Plan* was quite variable. The majority of healthcare providers preferred to create a verbal agreement between themselves and the patients. Only a minority of providers chose to use a paper form.

The *Options Prescription* and the *Options Action Plan* can be obtained from this manual.

OPTIONS

P
R
E
S
C
R
I
P
T
I
O
N
S



Prevention
Prescription

Date: _____

Name: _____

Plan: _____

Signature

OPTIONS

**P
P
C
I
O
N
S
E
S**



Action
Plan

Date: _____

Name: _____

Plan: _____

Signature

Signature



Transcripts of Options Protocol Demonstrations



Transcripts

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Transcript of Protocol Demonstration with HIV+ Gay Male Who Barebacks: First Options Visit

Deborah H. Cornman, Ph.D.

Associate Director

Center for Health, Intervention, and Prevention

University of Connecticut

STEP: Set the Agenda

Debbie: I have to say, Larry your blood work looks great—undetectable. And CD4 at 1390. You are doing terrific. Keep up the great work that you are doing. Now, what I want to do is shift gears a little bit. There are a couple of things that I am now talking about with all my patients—sex and drug use. And I know that these are not easy issues to talk about, but I think they are important ones, because they are important to your health. So I'd like to spend a few minutes talking about these issues if that's okay with you.

Larry: Yeah, okay.

STEP: Assess Risk Behaviors

Debbie: Good, thanks. Many of my patients are finding it challenging to practice safer sex and safer drug use on a day-to-day basis and the reality is it's not easy to do; it's difficult to do. Now I don't know if these are issues for you or not, but if they are, I would like to understand what that struggle is like for you. What's it like for you practicing safer sex? What works, what doesn't?

Larry: Well, sometimes it just takes, you know, the fun out of it. Condoms don't feel right. I don't get the pleasure I do when I'm either barebacking, or just, you know, taking the spontaneity out of sex—when you have to think about too many things, and you know.... And sometimes I do, and sometimes I don't and I know I probably should, but, you know, I just like to have sex. I don't like it when I have to worry about it all the time.

Debbie: So, sometimes you are using condoms and sometimes you're not.

Larry: Right.

Debbie: And when are you choosing to use condoms?

Larry: You know, I, I tend not to use a condom when it's just oral sex, which I do some, but when it comes to, you know, I'm on the top, I'm usually the one who needs to wear a condom, and, you know, it takes away from the pleasure, and takes away from the spontaneity and the impulsiveness of the moment and so, you know, only if I have a lot of plans in place, do I really think about it that much.

Debbie: So when it's more spontaneous you are saying you are not using condoms.

Larry: Right, right.

Debbie: But if you plan, you are more likely to use condoms.

Larry: Yeah, A lot of time either I won't have them or he won't have them, or we'll go into a place where we can't access them or get them really easily and, you know, we just go for it, you know, there's usually not a whole lot of talk about it.

STEP: Summarize Risk Behaviors

Debbie: Okay, so, you're not using condoms during oral sex. You're using it during anal sex when you plan for it and you anticipate it's coming.

Larry: Right, exactly. It might be somebody I've been with before, and planning a more lengthy date, or something, or dinner or something, and I know it's gonna end in sex. Then I'll plan, cause I know I probably should at all times.

Debbie: Now your partners are positive? Negative?

Larry: I don't know, I don't know. I meet a lot of them online.

Debbie: Okay.

Larry: And we just kind of meet somewhere for coffee or something.

Debbie: Okay, and what's happening in terms of your alcohol and drug use?

Larry: Oh! Still sober!

Debbie: How long now?

Larry: A little over three years.

Debbie: Congratulations! That's great! Keep up the good work! So, let's focus a little more on the anal sex if that's okay with you. Can I ask you a couple more questions?

Larry: Yeah, sure.

STEP: Assess Importance and Confidence

Debbie: If you were to rate how important it is to you to use condoms, during anal sex, on a scale from 0 to 10 where 0 is not at all important and 10 is extremely important, how would you rate how important it is to use condoms?

Larry: Well, I know it's important, you know. I think, in my mind, or intellectually I believe that it's, it's probably a 7 or 8 as far as importance. I don't always think, though. I don't always, you know, think about that.

Debbie: If you were to rate how confident you are if you could use a condom, every time you have anal sex, on a scale from 0 to 10 where 0 is not at confident and 10 is extremely confident, how would you rate it?

Larry: Kind of low. I'd say, 4 or 5.

Debbie: 4 or 5?

Larry: Yeah, I don't necessarily like condoms, so...

Debbie: So in terms of importance, it's a 7 or 8, somewhat high, relatively high, and in terms of confidence it's a 4 or 5.

Larry: Yeah, that's correct.

STEP: Ask Why Importance or Confidence Score Not Lower

Debbie: So why a 4 or 5 and not a 2 or 3?

Larry: Well, I mean, like I said, when I plan what's going on, then I make sure that condoms are available. But it's when I just meet someone for the first time, or I run into them at a book store, or a bar or whatever, and we decide we wanna have sex, then I'm not thinking about safe sex, I'm thinking about sex.

STEP: Ask How to Increase Importance or Confidence Score

Debbie: Right. So what would need to happen to raise that 4 or 5 to a 6 or 7?

Larry: Well, condoms would have to be a whole lot more enjoyable. You know, there's not a whole lot of pleasure there, they don't feel right, I can't always, you know, get off or anything like that, and um...

STEP: Summarize Responses, and Discuss Strategies for Raising Score

Debbie: So it's a sensation for you?

Larry: Yeah, it's something that could happen where it's more, you know, there's something in place when the spontaneity hits, or the impulse hits, you know, that would be your cue, or something there that would tell me uh...

Debbie: Do you normally carry condoms with you?

Larry: Sometimes.

Debbie: Sometimes. Okay. But the primary thing is how they feel. You're not very motivated to use them

Larry: Yeah, I mean, unless, the person really insists that we go find some or...

Debbie: Where do you get your condoms?

Larry: Oh, drugstore.

Debbie: There are a couple ideas I have about how to increase sensation if you're interested in that.

Larry: Well, yeah, if it will make, you know, sex better and more enjoyable.

Debbie: One idea is to put lubricant in the tip of the condom or on the head of the penis, that's been known to increase sensation, I don't know if you've tried that.

Larry: No, no. I don't think that really works that well.

Debbie: So that's not an option. Another thing is to try a variety of condoms. I don't know how many condoms you've experimented with, but there are actually a variety of condoms.

Larry: I've always used the same kind, you know, always I just grab something from the drugstore.

Debbie: I heard that you go online, and there are certain websites that you can go to that can provide you with all sorts of condoms, information about condoms. If you have a size issue, a sensation issue, there's all sorts of information out there. That's another possibility. And I guess the other option I can think of right now is the Reality Condom. Have you heard about it at all?

Larry: I thought that was for women, that's all I've heard.

Debbie: It was designed to be used both during vaginal and anal sex. It only has FDA approval for vaginal sex; it does not have FDA approval for anal sex. But the regular latex condom does not have FDA approval for anal sex, so... the same boat. But, a lot of people like it, men and women, and I've talked to quite a few gay men who have really liked it because it does not adhere to the penis, it's inside the rectum, it adheres to the anal walls, rectal walls, and so, um, there's a lot of freedom for the penis when it's going in and out, it's not constricting. And it's a polyurethane condom so that's supposed to conduct heat better, and you can use oil-based lubricants. (hmm) So that's an option, and though they are expensive to buy we do have them available free here, and there are other places, we can give you a list of places where you can go and get them for free. But you tell me what you think. Is this a good option?

Larry: Do I put it in? Do they put it in?

Debbie: Either way. You can do it.

Larry: Impulsively, in the moment? Or put it in ahead of time?

Debbie: No you don't have to. It can go in up to 8 hours ahead of time, but you don't have to do it that way. So you can put it in him, he could put it in himself. There have been some who have put it on their penises, and then inserted their penis in. There's an inner ring that you might want to take out that people don't like to bang against, but when you put it in the vagina you need the ring. When you put it in the anus, there's no need for that inner ring. So that's an option.

Larry: Well, it's something to think about.

STEP: Negotiate Goal or Action Plan

Debbie: So any of those, you wanna look into.

Larry: Well, I'll check out the websites if you wanna give them to me, about condoms, I don't mind checking that out cause I go online all the time anyway.

Debbie: Okay, yeah.

Larry: And you know, the Reality Condom, if someone could explain it to me.

Debbie: Yeah I can. If you have time, you can go and talk to the nurse. I'll take you right out there and meet with the nurse and she'll give you all the information about it. Some people find it's a great alternative to the regular latex condom.

Larry: Yeah, as long as it's pleasurable and I enjoy it.

Debbie: Yeah, that's the goal!

Larry: Yeah, absolutely.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Debbie: All right, so what I'll do is, I'll write down the name of the site. Condomania.com is one of the places. It's great. And then I'll hook you up with the nurse right now if you have a few minutes.

Larry: Yeah.

Debbie: Okay, and we'll talk about how that goes between now and the next visit, does that make sense?

Larry: Yeah.

Debbie: Okay. And we should meet again in a month's time.

Larry: Okay.

Debbie: All right.

Larry: That'll be great.

Debbie: Great work! Thanks, Larry. I'll see you next month.

Larry: Okay, very good. Thanks.

Transcript of Protocol Demonstration with HIV+ Gay Male Who Barebacks: Follow-up Options Visit

Deborah H. Cornman, Ph.D.

Associate Director
Center for Health, Intervention, and Prevention
University of Connecticut

Debbie: So everything continues to go okay with your meds.

Larry: Yeah, yeah, I take my medicine. That's no problem.

STEP: Review Progress on Goal Agreed-upon at Previous Visit

Debbie: Okay. Last time your blood work looked great, so that's good. I want to again talk about the last time when you set a goal, about going to the websites, about going online, about checking out some condoms. And we also made arrangements so you would meet with the nurse about the Reality Female Condom. I just wondered how that went.

Larry: Well, I went online, and that's easy; I can do that in the privacy of my own home. And I ordered some condoms that looked interesting, some that were thinner, that might give me a little more enjoyment when I'm having sex, and I got some. And they're better, they're better than what I was getting at the drugstore. They tend to be somewhat expensive, but not bad, not bad. It's a good alternative. I'm trying to think more. Of course, I don't like thinking when it comes to having sex.

Debbie: Yeah. Right.

Larry: But that's all right.

Debbie: Okay. So did it help with the sensation issue? Or not help?

Larry: Yeah, yeah, some, and I haven't checked out all the websites you gave me, just a couple. So, maybe I'll do a little more looking there.

Debbie: And what happened with the Reality Condom? Not an option?

Larry: Yeah, yeah, I tried it a couple times, you know. Again, there's too much thinking, a lot of fumbling around trying to figure it out, and...you know, it seemed to be too messy, and a lot of lube.

Debbie: It's a lot of lube.

Larry: Yeah, just too many mechanics about using it, so it's not something I would probably use on a regular basis.

Debbie: Hmm, well it does take practice, that's something about the Reality Condom. It does take some practice. But that's not something you want to try?

Larry: Not right now. I imagine if I got involved with somebody whose, you know, then maybe we would consider it on a regular basis, but... you know... this is... the way I'm doing sex now just doesn't make sense.

STEP: Reassess Importance and Confidence Scores from Previous Visit

Debbie: Okay. So last time you said, when you were talking about your confidence in using a condom every time you had anal sex, you said it was like a 4 or 5. On a scale of 0-10, is it any different? Or is it the same?

Larry: Well I'm feeling a little more, I don't know what the words, you know, educated or something about the different condoms, so that helps, that helps some. And I found some that feel better, so I might be more inclined to know that, you know, when I'm gonna have sex it's gonna be enjoyable, and not something that won't be because of the condom. So I might tend to be a little more willing and confident that I can use it.

Debbie: So what would you say, has it gone up from a 4 or 5?

Larry: Yeah, you know, maybe a little bit, you know maybe up to a 6, but it's only been a month so... you know maybe, maybe as I explore more options, it might work. As long as it's not something that takes a lot of, like I said, the mechanics, and the fumbling, and trying to figure, too much thinking, if it just becomes automatic.

Debbie: So you would rather stay with the male condom rather than the Reality Condom.

Larry: Yeah, yeah, I think I'm a little more familiar with that, and like I said, unless I get involved in a relationship, I don't want to either explain or figure it out every time that I decide that I want to use that.

Debbie: Did you go online to condomania.com?

Larry: That was one of the ones, yeah.

Debbie: Did you see the ones that are tailored to your particular size?

Larry: Yeah, yeah, but size has never been the problem.

Debbie: It's the sensation for you.

Larry: Yeah, it's the fact that, you know, you're covering it up, you're wearing it, so, takes a little bit away, but the thin ones, seem noticeably ... different.

Debbie: So that's helped some. So last time you talked about having some issues around being available all the time. Has that changed at all? You know when you have spontaneous sex, you don't necessarily have condoms around?

Larry: I find myself, you know, now that I've found condoms that seem to be somewhat pleasurable, I find myself carrying them more often, having them available, either in my car, or somewhere, so I'm using them certainly more than I have been. So it doesn't seem to be so much thinking or worrying about whether it's gonna be enjoyable or not, I just kind of do it.

STEP: Renegotiate New Goal or Action Plan

Debbie: So, it's, is it your intention to check out more places, more types of condoms, or you think you found the condoms you want?

Larry: Well, you know, I didn't know there were so many different kinds out there, you know, so much available, so I'll just keep looking, yeah.

Debbie: So, that will be the goal for the next time we meet, you'll continue to experiment with different condoms and...

Larry: Yeah, it's actually kind of fun to see what's out there. I didn't know there were so many.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Debbie: Okay, Great. So, I'll just write that down. That's the goal for next time we meet. And, since you are doing so well, medically, we'll meet in two months instead of a month?

Larry: Yeah, yeah that would be good. Yeah, that would give me plenty of time to check other things out.

Debbie: Okay, great.

Larry: Absolutely.

Debbie: So I'll see you in two months.

Larry: All right.

Debbie: Look forward to it. Keep up the good work.

Larry: Thanks, I appreciate it.

Transcript of Protocol Demonstration with HIV+ Sexually Active Heterosexual Female

Deborah H. Cornman, Ph.D.

Associate Director

Center for Health, Intervention, and Prevention

University of Connecticut

STEP: Set the Agenda

Debbie: Kaye, your lab work looks great. You're still undetectable and your CD4 counts are high, so what you're doing, you need to continue to do. You're doing a great job; keep up the good work. I want to switch gears a little bit. There are a couple things I want to talk about that I'm talking about now with all my patients, and that's sex. I'm talking about sex and drug use, and I know that these are not easy issues to talk about but I think they're important ones, important to your health. So I'd like to spend a few minutes talking about these if that's okay with you.

Kaye: Sure.

STEP: Assess Risk Behaviors

Debbie: Okay. And in terms of safer sex and safer drug use, I know that it's challenging to do that on a day-to-day basis. The reality is that it's not an easy thing to do, to constantly practice safe sex, to think about it to engage in safer drug use behavior, but I don't really know if these are issues for you. I know something about your drug use behavior, but if they are issues, I'd like to know what that struggle is like for you. So let's talk about sex, what works for you and what doesn't when it comes to safer sex.

Kaye: Well, you know I been with my boyfriend for about six years now, and he knows that I'm positive, but sometimes we use condoms, but he don't like them, you know.

Debbie: He doesn't like them?

Kaye: No.

Debbie: What's his issue with condoms?

Kaye: He just don't like to use them. I don't know. He just says he'd rather, you know, he loves me, you know and I love him, and when I bring up condoms, he gets mad.

Debbie: He gets mad?

Kaye: Yeah.

Debbie: Does it scare you at all, make you nervous or you just don't want to get in an argument with him?

Kaye: I don't want to get in an argument, and you know, that's like my best friend, so you know, we've been together for a long time, so I don't want to make him angry. You know, it's a good relationship.

Debbie: Yeah.

Kaye: I don't want to give him anything either, so I don't know...

Debbie: Now he's negative, as far as we know.

Kaye: He was tested like, I don't know, maybe a year, couple years ago, and he was negative.

Debbie: So he hasn't been tested since then?

Kaye: No. I've been clean though, I've been clean for about a year.

Debbie: Yeah, I wanted to ask how that was going.

Kaye: Good, good. I'm in the program and stuff

Debbie: You're on methadone.

Kaye: I'm on the methadone.

Debbie: And that's going well?

Kaye: Yeah, and I go to the outpatient class that they have. I'm getting ready to graduate from that.

Debbie: Well, congratulations!

Kaye: Thanks.

Debbie: That's an accomplishment, so that's going well.

Kaye: Yup.

STEP: Assess Importance and Confidence

Debbie: All right, so is it okay if we talk some about the sexual behavior with your partner?

Kaye: I don't know, you know, how I can get him to use condoms.

Debbie: Well, let me ask you a couple questions so I can understand what's going on better. First of all, if you were to rate how important it is to use condoms with him on a scale from 0 to 10, where 0 is not at all important and 10 is extremely important, how important would it be to you?

Kaye: For me, like 8, important.

Debbie: Pretty important. And how confident are you that you can get him to use condoms, on the same scale to 10, where 0 is not at all confident and 10 is extremely confident?

Kaye: Like 4, maybe.

STEP: Ask Why Importance or Confidence Score Not Lower

Debbie: So, it's lower. But you said a 4 for confidence, so you have a little bit of confidence, why a 4 and not a 2 or a 1?

Kaye: Because he'll use them sometimes, he just don't like to. And I don't want to make him angry.

Debbie: When does he use them?

Kaye: Sometimes he'll drink or something, and you know, then I can convince him to wear them.

Debbie: Okay, so when he's been drinking, then you have some influence over him.

Kaye: But he don't drink a lot.

STEP: Ask How to Increase Importance or Confidence Score

Debbie: What would need to happen to get your confidence up, from like a 4 to a 6 or 7, make you feel more confident about getting him to use condoms?

Kaye: I don't know, maybe somebody can talk to him.

Debbie: Maybe somebody else can talk to him?

Kaye: Yeah, I mean, he knows everything and he supports me a lot. Like I said, he loves me, and I love him, too. I don't want him to get anything. I asked him to come to my support groups, he said he's gonna come, but he hasn't come yet.

Debbie: Do you think he has any concerns about getting the virus?

Kaye: I don't think he thinks I can give it to him.

STEP: Discuss Strategies for Raising Score

Debbie: This is an idea: would he be willing to come in to a visit and talk to me? You can join him or just by himself, either one. Do you think that would be helpful to sit down and talk with me?

Kaye: I think that'd be helpful. I don't know if he's gonna come in. I'll talk to him. Like I said, he really supports me, you know...

Debbie: Well it sounds like he cares about you, and sounds like you have some concerns about possibly infecting him.

Kaye: I don't know what I would do if he would get infected. You know, that would be on my conscience. I don't want to have nobody else get this, you know.

STEP: Negotiate Goal or Action Plan

Debbie: Right. And I would hate to see you go through that. It's clear that you care about him. Well, the possibility is to talk to him and come in for an appointment, and we could schedule it as soon as you want. Does that sound like a reasonable goal for next time?

Kaye: Sure. I'll talk to him.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Debbie: Okay. Why don't we just write down what the agreed-upon goal is, if that's okay with you.

Kaye: Okay.

Debbie: So, you'll talk to him, if he's willing to come in, then just call up and make an appointment. I can see you whenever you want to come in, as soon as next week.

Kaye: Okay.

Debbie: If you would like, we can just do a special meeting.

Kaye: Mornings would be good.

Debbie: That's fine. Just tell the people at the front desk what time you want to meet with me.

Kaye: Okay.

Debbie: That sounds good? I'll talk to you, and you talk to him. Hopefully, he'll agree and then we'll meet and discuss this.

Kaye: All right. Thanks.

Debbie: Hang in there. Just give me a call and we'll set it all up, okay?

Kaye: All right. Thank you.

Debbie: All right. Keep up the good work. We'll get it to work.

Kaye: Thanks.

Transcript of Protocol Demonstration with HIV+ Male Injection Drug User

Deborah H. Cornman, Ph.D.

Associate Director
Center for Health, Intervention, and Prevention
University of Connecticut

Debbie: Your lab work looks great, Greg.

Greg: Thanks.

STEP: Set the Agenda

Debbie: No thank you, you're doing a great job. You're still undetectable and CD4 count looks great, so keep up the good work. What you're doing is working. What I'd like to do now is spend some time talking about sex and drug use. I'm talking about that with all my patients now, and I know this can be uncomfortable to talk about, but I think it's important to talk about it. It's important to your health. So if it's okay with you, I'd like to spend a few minutes talking about these issues.

Greg: Sure that's fine.

STEP: Assess Risk Behaviors

Debbie: Okay. The reality is that a lot of my patients are finding it challenging to practice safer sex and safer drug use on a day-to-day basis. It's not an easy thing to do every day for the rest of your life. Now, I don't know if these are issues for you or not, I have some understanding of your drug use behavior, but if they are issues, I'd like to know what that struggle is like for you. Let's start talking about your sex life. What works for you and what doesn't when it comes to safer sex?

Greg: Well, we um, I got my steady girlfriend, same lady I've been having for awhile. We use protection sometimes, sometimes. When we start drinking, we get a little rowdy and we don't use protection. We don't use a condom, but it's not always, it's only sometimes. But it's with my girlfriend so it's the same lady.

Debbie: Now she's positive, is that right?

Greg: Yes, she is.

Debbie: She's positive. So how often would you say that that happens?

Greg: Probably I would say 40% of the time.

Debbie: 40% of the time you're not using condoms. And that's during vaginal sex, anal sex?

Greg: Vaginal sex.

Debbie: Vaginal sex, ok. And what about your drug use?

Greg: Well, I'm still using but I really don't want to go into any program or none of that. And when I'm using nowadays, I'm only using with my girlfriend. I don't go out with my friends any more. So, we do share the needles but it's my girlfriend again, so I don't have to worry about it.

Debbie: You're using heroin exclusively?

Greg: Yeah.

Debbie: About how many bags a day are you using?

Greg: 6.

Debbie: And so, you, you share syringes, you're sharing bags?

Greg: Yes, but just with my girlfriend, nobody else.

STEP: Summarize Risk Behaviors, and have Patient Choose One to Discuss Further

Debbie: Okay, all right. So you've talked about that 40% of the time you're having sex without condoms, and then you're sharing syringes with your girlfriend.

Greg: Yeah, but it's just her.

Debbie: Let's just focus on one of those topics today. Which one would you like to focus on?

Greg: I don't want to talk about sex with my girlfriend. We can talk about my drug use.

Debbie: Talk about your drug use. Okay, well, I just want to understand a little bit more about what's going on with the drug use and how you feel about the sharing of syringes, so if I could ask you a couple questions?

Greg: Sure, sure.

STEP: Assess Importance and Confidence

Debbie: If you were to rate how important it is to you not to share syringes with your girlfriend, on a scale from 0 to 10, where 0 is not at all important and 10 is extremely important, how important would you rate it?

Greg: I would say it's a 0. It's my girlfriend.

Debbie: Not important—it's your girlfriend. And how confident are you that you could not share syringes? If you decided it was important, how confident are you that you could not share syringes with your girlfriend, on a scale of 0 to 10 where 0 is not at all confident, and 10 is extremely confident.

Greg: Taking into consideration it's my girlfriend, I would say a 7, but I would have to know a little bit more about why not. I mean, because it's only one person, it's my girl.

Debbie: So, in order for it to be, it's not important at all, it's your girlfriend, you care about her, you love her. You have some confidence—6 or 7, is that what you said?

Greg: Yes, 7.

STEP: Ask How to Increase Importance or Confidence Score

Debbie: So what would need to happen for you to be, for it to be more important to not share syringes?

Greg: (shrug) Show me why not. It's my girl, it's not like I can say, hey, I don't want to share with you any more. She's going to feel like I'm rejecting her. So I need to know why I shouldn't be doing that. I'm not doing it with everybody else on the street.

Debbie: Which is great that you're not sharing with anybody else. Is it okay if I share some information, and some of my concerns, about sharing with her?

Greg: Sure, sure.

Debbie: One of my concerns is the possibility of re-infection. You two...

Greg: What do you mean?

Debbie: With a different strain of HIV. You two are not taking the same drug regimen. Right?

Greg: No, we're not taking the same.

Debbie: They're different, so there's a possibility that one of you can develop resistance, and you have already developed resistance to some medications, that you could transmit that resistant strain to your girlfriend, which could happen actually through sex or through sharing syringes. And then she could become resistant to that drug, and that medication wouldn't work for her. If she's got resistance to a particular medication, she could transmit that resistance to you, and then those drugs wouldn't work for you.

Greg: So, you're trying to tell me that I can get worse than what I am now, or I can make my girlfriend worse?

Debbie: Yes, that's my concern is that by sharing syringes, that yes, you could be sharing a drug resistant strain of HIV with her, or she could share it with you and then that limits the drugs that would work for you, limit the drugs that work for her, and could hurt your health down the road.

Greg: Even if it's just... I'm sharing only with her, and nobody else?

Debbie: Yeah, because her HIV is not the same as your HIV.

Greg: Wow.

Debbie: She's got a different history than you have in terms of the medication, and then anything else. You've both been tested for Hepatitis C, and you're both negative as I recall.

Greg: Yeah, yeah, we're both...

Debbie: So there's not a concern about that. But there's always a possibility, too, that if you or she got something else, you could share it through the syringes. And so that's my concern about sharing the syringes.

Greg: I don't want to cause her any harm, I mean...

Debbie: Well, I know you care about her a lot. Does that make a difference in terms of how important it is to you, in terms of sharing

Greg: Yes, if what you're telling me is true, it is, it's important—I don't want to cause her any problems.

STEP: Discuss Strategies for Raising Score

Debbie: I know you don't. I know you care about her. There are a couple ways we could go. I could give you some literature to read, to support what I've said. You could talk to your girlfriend about this. She could come in here, the three of us could meet. What makes sense?

STEP: Negotiate Goal or Action Plan

Greg: That'd be good, if you could give me something in writing, some literature. Then I can go and talk to her, and then we can make an appointment, so that she don't feel like I'm trying to, that I'm making this up, because I don't want to share my drugs with her.

Debbie: So you like the idea of all three? I can get you some information to read, and then you can go and talk with her, and then we can set up an appointment for the three of us to talk?

Greg: Yes, if we could do that, it's gonna be tough for me to explain to her everything in detail.

Debbie: Ok, that's fine. We can do that. So that sounds like a great goal for next time and what we can do is, why don't you talk to her. I don't know if I have the literature available right now. I'll get you the literature. I have your address, and I can send it to you or you can come pick it up. But once you talk to her, and she wants to come in, just set up an appointment immediately. Let's not wait until your next regular visit. Set it up as soon as possible, because I think this is important.

Greg: Yeah, I need to do it as soon as possible.



Debbie: Okay, so I'll get you the information, and you'll talk to her. And then the three of us will meet, as soon as you can set up an appointment with me. Okay?

Greg: Thank you, I appreciate your help.

Debbie: Thank you, I appreciate it too. We'll get that all set up, and we'll set up the meeting. And, meanwhile, in terms of your medical regime, keep taking the drugs like you're taking them. You're doing a great job.

Greg: I'm just a little bit shocked about the information about the reinfection. Sometimes we don't find this information. It's not easy.

Debbie: Oh I know, it's not always available. But I'll get it for you. I'll send it to you as soon as I get the information for you. I've got it back at the office, my other office. Okay?

Greg: Thanks

Debbie: All right, thanks a lot.

Transcript of Protocol Demonstration with HIV+ Sexually Abstinent Female

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Debbie: Well, Heather, everything looks good with your lab work. You continue to be undetectable, and the CD4 count is right where we want it. So keep up the good work with the medication. It looks great.

Heather: Great.

STEP: Set the Agenda

Debbie: I'd like to shift gears a little bit. There are a couple things that I am now talking about with all of my patients—sex and drug use. And I know that these are not easy issues to talk about, but I think they are very important ones, important for your health. So, I'd like to spend a few minutes talking about those issues, if that's okay with you.

Heather: Yeah, that's okay.

STEP: Assess Risk Behaviors

Debbie: Okay, good. Thanks, I appreciate it. And I know safer sex and safer drug use is a challenging thing to do on a daily basis. The reality is, it's not easy to do. Many of my patients are finding it difficult. Now I don't know if these are issues for you or not, but if they are I'd like to understand what that struggle is like for you, what works for you and what doesn't work for you in terms of safer sex, if you are having sex.

Heather: Well, right now, I'm not having sex. It's just not on my list of priorities. So, yeah, it's just, there are just bigger things in my life right now than sex, so I just don't even really think about it.

Debbie: Is that something you'd like to have in the future?

Heather: Oh yeah, I mean, I miss it at times (giggles). But overall, I know that I just have a lot going on in my life right now and sex is just not one of those things that I think about on a regular basis.

Debbie: So it's not a priority right now.

Heather: No.

Debbie: In terms of alcohol and drug use, anything going on there? Are you drinking?

Heather: No. I mean, I'm sober, basically. I don't remember, I actually don't remember the last time I had a drink, so...

Debbie: And no recreational drug use?

Heather: No.

STEP: Summarize Risk Behaviors

Debbie: Okay. I'd like to talk a little bit more about the sexual behavior if that's all right with you.

Heather: Sure, that's fine.

Debbie: Because I think you said you were not interested in having sex right now, but you might want to in the future somewhere down the road. So I would like to just talk about that future, in terms of making a plan for that future (okay), because it would be nice somewhere down the road if you did have a satisfying sexual life. So if I could ask you a couple questions about that, to better understand where you are...

Heather: Yeah, sure.

STEP: Assess Importance and Confidence

Debbie: So, if you did, somewhere down the road, if you did have sex, how important would it be for you to use a condom every time you had sex? On a scale of 0 to 10 where 0 is not at all important and 10 is extremely important?

Heather: Definitely a 10. Most definitely.

Debbie: 10, okay. And, how confident are you that you could use a condom every time you had sex, on a scale from 0 to 10 where 0 is not at all confident and 10 is extremely confident?

Heather: Definitely a 10. I mean, you and I have talked about my situation with my ex-husband, and you know, he wasn't honest with me about his, his status, about being HIV-positive. And it is very important to me, if I'm going to have a relationship with someone else, that I'm very clear with them about using condoms. It's very important to me.

STEP: Summarize Responses, and Discuss Strategies for Raising Score

Debbie: So it's extremely important, 10, and you are confident that you can make that happen.

Heather: Most definitely.

Debbie: Okay, well, I like how adamant you are about that, and I commend you on your motivation to practice safer behavior in the future some time. I know you are not having sex now, but do you have a plan in place for, if you

did, when you do have sex in the future? What you would do? Where you would get condoms?

Heather: Well, I mean, I know you can pick some up at the drug store. My husband and I, we never used condoms, so I guess I don't really have a plan set up, because I just don't think about sex right now. But, I mean, I can see your point, I mean, if I'm going to find someone in the future that would probably be a good idea to have.

Debbie: There are a variety of places you can get condoms, including here. You can get them for free. And then there are also places in the community so you wouldn't actually have to pay for them. You may not have the variety here that you would in some other places, but there are free condoms here. My other question, I guess, would be, do you know how to put a condom on a man's penis?

Heather: I think so... I'm pretty sure, I mean I've done it before, but now I guess I don't know (giggles).

Debbie: All right, you may, I don't know. The reason I'm asking is because we do have someone here who can teach you to do that, and I understand you aren't having sex now, but in the future it might be nice to know how to do that, for when you do get a relationship.

Heather: Well, I definitely want to do it right, so yeah, that wouldn't hurt to try that out, to have someone, you know, show me how actually do it, so that I know I'm doing it properly.

STEP: Negotiate Goal or Action Plan

Debbie: Okay. So a plan for next time... Or I could set it up right now if you want. You could meet with the nurse; you could learn about condoms. You could also get a list of where free condoms are available so that somewhere down the line, when you do have a relationship, you would be prepared. Does that make sense?

Heather: Yeah.

Debbie: Do you want to do that now? Or would you set up for another time? I don't know when you would have time to do this.

Heather: Well, I have time today. I mean, if I could meet with the nurse today.

Debbie: Okay, so does that make sense for a goal... You meet with the nurse, and then when you check in next time, we will see where you are in terms of your relationship issues?

Heather: Sure. (giggles)

Debbie: And hopefully hear good news!

Heather: Yeah.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Debbie: Yeah, that'll be nice. All right, so I'll just jot down what your goal is, you'll meet with the nurse, she'll give you a list of places where you can get free condoms including here, and she'll just refresh your memory in terms of how to put a condom on.

Heather: Okay, that sounds good.

Debbie: All right, and then we'll meet in a month.

Heather: Okay, thank you very much.

Debbie: Keep up the great work. Great to see you again.

Heather: Thanks.

Transcript of Protocol Demonstration with HIV+ Gay Male Who Uses Crystal Meth

Frederick Altice, M.D.

Associate Professor of Medicine
Section of Infectious Diseases–AIDS Program
Yale University School of Medicine

STEP: Set the Agenda

Rick Altice, M.D.: Jim, it looks as though your T-cells are quite stable, as we talked about—they're still over 300. Your viral load is still sitting at about 4000 to 5000, so that is really unchanged and is stable. Now, I'd like to talk a little bit, if you don't mind, about your sexual and drug use behavior, if that's okay with you.

Jim: Okay, we can talk about it, we can talk about it.

Rick Altice, M.D.: The reason why I'd like to do this is because it is an important part of your overall health in terms thinking of this in a more comprehensive manner. And thank you for allowing us to go into this. If you don't mind, one of the things that you've shared with me in the past is that on weekends you might go and use some crystal meth with a bunch of guys, and you've identified that you don't always take your medications during that time. Do you mind if we go back and just talk about the last time that happened?

STEP: Assess Risk Behaviors

Jim: Okay. No, yeah, it's all right.

Rick Altice, M.D.: When was it?

Jim: Let's see, the last time was about two weeks ago; it wasn't this past weekend, but the weekend before. It was probably about a two-day run. I worked late at the bar and then got off my shift. Actually I started getting tired, so I actually used a little bit before I finished my shift. And then some guys from work, we went over and we went to one of the after hours clubs. And then from there, a few of us went over to a house, and we had a session, and then by the time I got home, it was late. I was a little bit tired, kind of went into the next day, so I probably missed a couple doses of my meds, but I went right back on track again.

Rick Altice, M.D.: When you all got together, you said you were using some crystal meth. You took a little bit before you left. How were you using it?

Jim: Most of the guys, we started out snorting it at the bar. And then when we were at the house party, then we were booty bumping. And doing other...

Rick Altice, M.D.: Smoking it?

Jim: Some of the guys were smoking.

Rick Altice, M.D.: You weren't, though?

Jim: No, I don't.

Rick Altice, M.D.: Was there injecting at all?

Jim: Not that I know of, no. I know guys who do that, but not...

Rick Altice, M.D.: But you've never done that, all right. And, during that session—it was a couple of days or something like that—did you engage in any unprotected anal intercourse?

Jim: Oh yeah.

Rick Altice, M.D.: Either as top or bottom?

Jim: Oh yeah.

Rick Altice, M.D.: Yes to both?

Jim: Yes, yes to both.

Rick Altice, M.D.: All right, and when you were doing that, were you using any sort of condoms at all?

Jim: Early in the night, one guy asked if I would use one when I topped him so I did. That didn't last long. I ended up pairing off with someone else that wanted to bareback, and I just didn't want to use them. If somebody wants to use it, find somebody who will do it.

STEP: Assess Importance and Confidence

Rick Altice, M.D.: What I'd like to do is talk about topping and bottoming, and using or not using condoms. I'd like to really assess two different issues: (1) How important it is for you to use a condom when you're engaging in anal intercourse, topping or bottoming, and then (2) I really want to address confidence. So using a scale of 0 to 10, where 0 is not important at all and 10 is extremely important, how important is it for you to use a condom when you engage in anal intercourse?

Jim: When I'm on a crystal run? Or like in this situation like that? Not at all.

Rick Altice, M.D.: It's not important at all?

Jim: It's not important at all.

Rick Altice, M.D.: Can you assign a number to that?

Jim: I guess I'd have to say 0.

Rick Altice, M.D.: Okay.

Jim: Or maybe a 1, like in that situation, where somebody asked me if I'd put it on and you know, I thought he was hot and I wanted to be with him, so I did. But no, other than that.

Rick Altice, M.D.: It's not important.

Jim: It's not important.

Rick Altice, M.D.: And just to keep with that same scale, where 0 is not confident at all, and 10 is extremely confident, how confident are you that if you wanted to use a condom, every time, that you could use it?

Jim: If I wanted to?

Rick Altice, M.D.: Yes, under those circumstances on crystal meth.

Jim: If I wanted to, maybe a 4. Maybe.

Rick Altice, M.D.: Maybe a 4.

Jim: Maybe. It just doesn't seem to be, it's just not an issue. To me, most of the time, I assume everybody I'm with is positive anyway. And in the group, if someone wants to, you know, that's their responsibility to mention the condom, and that's not up to me. If they're there, and they're engaging in that whole scene, I'm assuming that they know the risk.

STEP: Ask How to Increase Importance or Confidence Score

Rick Altice, M.D.: Let me just go back to that importance score of 0 or 1 as you put it. It's very clear that you don't see it as a very important issue. Is there any sort of information that would help you move that score from say a 0 or a 1, to even a 3 or a 4 or a 5? I mean, you obviously don't rate this as very important, but there must be reasons for that. So what would actually change this to be more important for you?

Jim: Quite honestly, I don't really know what would change it. I mean, I know the things that are out there. I know about the STDs, and I've talked to counselors about different ways to use condoms to make it more pleasurable, and to me, it just takes away from it. And right now, the priority in my life is that I'm living my life and those are my moments. I work hard, I play hard, and that's important for me. I'm not going to change that. I'm 36 years old. I've been dealing with this, being told to be safe for so long, I'm quite frankly, no disrespect, but sometimes I just get to the point where I'm tired. There doesn't seem to be any guarantee. I mean even if I was safe, it's not going to make the HIV go away.

Rick Altice, M.D.: It's not going to make your HIV go away?

Jim: No, and the STDs, there's medication. So I get an STD, I take the medication, it goes away, I'm fine.

Rick Altice, M.D.: So you don't feel as though there's any harm to you, potentially, by not using a condom, because almost everything that you can think of that you can get is treatable. Is that correct?

Jim: Well, other than, maybe getting exposed what we talked in the past about other strains of HIV. But I don't really know how much is true. You know, some of it's theory.

STEP: Summarize Responses, and Discuss Strategies for Raising Score

Rick Altice, M.D.: We have talked a little bit about how you remain at risk for getting a secondary infection. We do know that some folks can get strains of a more resistant virus than you have, and potentially your T-cells could go down and your viral load could go up as a consequence of that. You could have some pretty significant medical consequences that actually might interfere with your work and your well-being. Does that in any way impact the way you think about this?

Jim: I'd have to think about it. I mean, it's not something I necessarily haven't heard before, you know. A lot of times it can be, it can come across like a scare tactic, but I guess it's something that I can consider.

STEP: Negotiate Goal or Action Plan

Rick Altice, M.D.: You're absolutely right, sometimes it is perceived as a scare tactic. To be quite honest with you, that's not my goal. Fear never works, with regard to reducing behaviors. What we really have to focus is on how you can think about living a healthier life and avoiding the things that would be detrimental to you. So I don't really want to focus on the fear factor, but there are some health information issues that you need to be aware of before you can make good decisions for yourself. What I'd like to do, if it's all right with you— I'd like to be able to revisit this from time to time when you come back into clinic so we can talk about it, if that's all right with you.

Jim: As long as it's not something that we talk about every time I come back. I mean, I'll be honest with you. I'll be upfront with you and if to me, if I felt my use was becoming more frequent, if it was something that was a problem, then I would be willing to at least revisit it, and so on.

Rick Altice, M.D.: Why don't we do this, I'll ask your permission each time, and if you're ready to deal with it, we'll deal with it at that session, and if you are not ready to deal with it, we'll skip it for that time and maybe perhaps touch on it the next time. Is that fair enough?

Jim: That's fair enough.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Rick Altice, M.D.: What I'll do then, if you don't mind me just writing a prescription. I write prescriptions for all your medications, and also I'd like to write a prescription for prevention, if you will. Please tell me if I'm correct. I will ask for your permission to re-discuss this in the future (writing on pad). And of course, if any other questions or things come up in the meantime, I'd be happy to field those questions and try to help you through any of those sorts of things that come up.

Jim: Okay, thank you.

Transcript of Protocol Demonstration with HIV+ Female Sex Worker

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Section of Infectious Diseases–AIDS Program
Yale University School of Medicine

Rick Altice, M.D.: Your T-cells are just under 500, and your viral load's only about 35,000. So, you know, good news is good news.

Dianna: Great.

STEP: Set the Agenda

Rick Altice, M.D.: All right. What I'd like to do is I'd like to change gears if it's all right with you, and I'd like to talk a little bit about some sexual and drug use behaviors.

Dianna: Yeah, okay.

STEP: Assess Risk Behaviors

Rick Altice, M.D.: All right. I know that in the past you've told me that you exchange sex for money, and I'd like to just explore that a little bit with you. I know that you have paying customers. Have you had any instances of unprotected sex, either oral, anal, or vaginal in that setting?

Dianna: Well, when I do it with my customers, I am known for, like it's condoms or nothing, now. There's no way I'm gonna, you know.

Rick Altice, M.D.: And you manage to use condoms for oral sex as well?

Dianna: Oh yeah. I have a good trick. Yeah.

Rick Altice, M.D.: Tell me about that.

Dianna: Just put it in my mouth, and roll it down with my mouth, and actually, the guys think it's kind of cool, you know.

Rick Altice, M.D.: Very interesting. Then you would say that using a percentage, you are using condoms with your paying customers 100%?

Dianna: Oh, absolutely.

Rick Altice, M.D.: Absolutely 100%?

Dianna: Yup.

Rick Altice, M.D.: Are there ever any instances where you don't use condoms, either with paying customers or anyone else that might be special to you?

Dianna: Like I've told you, if I'm in the streets, and you come to me, you've got to use condoms. Well my boyfriend now, I'm just afraid to ask him to start using.

Rick Altice, M.D.: How long have you been with this boyfriend?

Dianna: Almost 2 years now.

Rick Altice, M.D.: Almost 2 years. And is he the only other person besides your paying customers with whom you have sex?

Dianna: Oh yeah, yeah.

Rick Altice, M.D.: Just him. Does he know about your HIV?

Dianna: Oh no, oh no. I'm afraid that he might leave me. I really love him.

STEP: Summarize Risk Behaviors

Rick Altice, M.D.: Let me just clarify what you and your boyfriend are doing. You're engaging in unprotected... when I say engaging, I mean having unprotected sex with him. You're not using condoms at all with him?

Dianna: Oh no, when we do whatever, I mean.

Rick Altice, M.D.: And when you say "whatever," are you having vaginal sex with him?

Dianna: In the regular place? Yeah.

Rick Altice, M.D.: Okay. And how about anal sex? Is he putting his penis into your rectum?

Dianna: Yeah.

Rick Altice, M.D.: Okay. And what about oral sex?

Dianna: Yeah. I give him blowjobs.

Rick Altice, M.D.: You give him blowjobs. All right. And you don't ever use a condom with any of those three behaviors?

Dianna: (nods affirmatively)

Rick Altice, M.D.: Okay.

Dianna: I want to!

Rick Altice, M.D.: You want to, all right. What I'd like to do is focus on unprotected vaginal and even anal intercourse, if that's all right.

Dianna: Yeah, okay.

STEP: Assess Importance and Confidence

Rick Altice, M.D.: I'd like to get a sense of how important it is to you to use a condom every single time that you have sex, where 0 is not important at all and 10 is extremely important. How important is it to you to use a condom every time?

Dianna: Really important.

Rick Altice, M.D.: So using 10 as extremely and 0 as not important at all...

Dianna: 8.

Rick Altice, M.D.: Okay, good. And I want to change that a little bit. Using the same scale, how confident are you that you can, the two of you, use a condom every time you have sex, with 10 being extremely confident and 0 not confident at all?

Dianna: Well, I'm just so afraid to lose him, so I would probably say like a 4, if that.

STEP: Ask Why Importance or Confidence Score Not Lower

Rick Altice, M.D.: A 4. All right, now a 4 is kind of in the middle. How come you didn't say you have zero confidence—I have no confidence at all?

Dianna: I think about that, you know, out there in the streets. I make sure that, you know, I make it quite clear. I just don't understand why I don't have the guts at home.

Rick Altice, M.D.: So the reason why you're confident at a 4 level is because you're successful at using it 100% of the time on the streets. But with this special guy, it's different.

Dianna: Yup.

STEP: Ask How to Increase Importance or Confidence Score

Rick Altice, M.D.: Okay. Let's just explore that a little bit about the confidence. Have you tried anything with him in the past to try to move him towards condom use, in other words, to encourage him?

Dianna: Well, yeah, like when I learned the trick with the condom on the mouth, you know I tried it on him, and it was fun, you know.

Rick Altice, M.D.: Right.

Dianna: But then when it came to like doing the real thing, actually giving him a blowjob with it, he just didn't want it.

Rick Altice, M.D.: He wants it without a condom.

Dianna: Yes.

Rick Altice, M.D.: Do you have any friends or anyone else who have some things that do work?

Dianna: Well, one of the girls told, you know, the guy she's with and uh, he seems okay, you know so, that gave me a little hope.

Rick Altice, M.D.: So disclosing gives you hope, but you're fearful of that.

Dianna: I just don't want to lose him, you know. He's a really nice guy.

Rick Altice, M.D.: And as far as you know, he's negative, or you just don't know.

Dianna: You know sometimes I wish that he would like get tested, because he might be positive. If he's positive, then you know, we wouldn't have to worry about it.

Rick Altice, M.D.: And you've never asked him, is that correct?

Dianna: Oh no. I just wish he would get tested.

STEP: Summarize Responses, and Discuss Strategies for Raising Score

Rick Altice, M.D.: So you think that maybe him getting tested might help. What would that do for you if he were to test, and let's say he were negative? How would that change things for you?

Dianna: Well, then I would say, you know, I'm trying to protect you and take care of you, because I love you kind of thing. You know what I mean.

Rick Altice, M.D.: Uh-huh. Let's go back to the issue of wanting to tell him.

Deanna: Okay.

Rick Altice, M.D.: Because you indicate that you would like to tell him, but you're very fearful.

Dianna: Gosh, just talking about it (laughs).

Rick Altice, M.D.: I understand. Is it okay if I offer some suggestions that I've heard that work for other people?

Dianna: Yeah.

Rick Altice, M.D.: Okay. These may not be right for you, but some people have actually found it useful to talk with the folks in the partner notification program. Are you familiar with that?

Dianna: Are they going to tell him my name?

Rick Altice, M.D.: Well, let me just talk a little bit about what it means.

Dianna: Okay.

Rick Altice, M.D.: The partner notification program can work with you on three different levels. One, they can meet with you and counsel you about how you can tell him. Second, I understand that they can meet with you and then meet with you and your partner that doesn't sound like a good option—no. Then the third thing they can do is they can meet with him independently, never use your name, and just say he has been exposed to HIV and in that situation, they recommend that he gets tested and that he engage in safer behavior because he has been put at risk. So those would be three of the things that they'd be able to do with you and your partner to help with that. Do you think that would be an option that you're willing to explore?

Dianna: I don't know.

Rick Altice, M.D.: Not to tell him that way, but to meet with the folks and see if they have suggestions that they find that work really well.

Dianna: I think meeting them might be okay, you know? But they're not gonna to come to my house or anything, right?

Rick Altice, M.D.: You can set up where you'll meet with them and how you do that. You would negotiate with them. I'll make sure you have a number before you leave. Have you ever asked him why he doesn't like to use condoms?

Dianna: No, no.

Rick Altice, M.D.: One of the things that you could do is you could ask him why he has such negative feelings about condoms.

Dianna: I just don't want to give this virus to anybody.

Rick Altice, M.D.: There is also a female-controlled way to use condoms. Have you heard of the Female Condom before?

Dianna: Yeah. We joke about it.

Rick Altice, M.D.: What do you mean when you say you joke about it?

Dianna: Well it's because it's just so ugly-looking, you know?

Rick Altice, M.D.: I've heard that before, too. Have you actually tried to use one?

Dianna: It's hard on the streets to use the Female Condoms but, you know, some girls leave it in there.

Rick Altice, M.D.: Does he perform oral sex on you before he...?

Dianna: No, he likes his stuff.

Rick Altice, M.D.: He likes his stuff. That means he just likes to put it in. So he doesn't even check around down there very much. Does he put his hand down there?

Dianna: No.

Rick Altice, M.D.: No. One difference with the Reality Condom is that as long as he's not checking things out beforehand, there might be a way for you to be able to try it.

Dianna: Yeah, but what if he finds it, you know?

Rick Altice, M.D.: Yeah, that might be a serious concern. Are you interested in learning more about the Female Condom or is that something maybe we should just talk about at a different time?

Dianna: I kind of like the talking right now.

STEP: Negotiate Goal or Action Plan

Rick Altice, M.D.: You like the talking. All right. And if I understand you correctly, that it'd be useful to maybe talk at least to the partner notification folks, at least just to learn about some options, is that correct?

Dianna: Yeah, okay.

Rick Altice, M.D.: If it's all right, I would like to kind of summarize where we are, and I'd like to write a prescription for prevention, in the same way I write a prescription for a medication. And I'd like to write it down on this sheet. I think that we agreed to set you up with the partner notification group. And next time we get together, you'll report back how well that has worked, and if that option doesn't work we can explore other ideas about disclosure. Does that seem like a reasonable plan?

Dianna: Yup.

STEP: Document Goal on Options Prescription Pad and Patient Record Form

Rick Altice, M.D.: Let me just write this out. I'm going to set you up with the partner notification program. All right. Seem like a plan?

Dianna: Yeah.

Rick Altice, M.D.: Are you okay?

Dianna: I'm just scared, you know. He's such a good guy, you know?

Rick Altice, M.D.: Many people are very fearful about disclosure, and you're not alone in that. We'll try to work together over time to see if we can come up with a plan that will keep you safe and him safe, throughout the whole process.

Dianna: Great.

Rick Altice, M.D.: All right Dianna, so good to see you, as always.

Dianna: Thank you.





Managing Resistance to Change



Definition of Resistance

“Effective helpers neither court reluctance or resistance nor are surprised by it.”

- G. Egan⁵⁰

Resistance is typically observed in those patients who either are ambivalent about changing or are not interested in changing at all. It can take the form of arguing, interrupting, denying the problem, or ignoring the provider (see *Table 1*). How resistant a patient is during a visit is a function not only of what the patient brings to the visit but also of the interaction between the patient and the provider. Miller and Rollnick contend that “patient resistance is a provider problem” and that how the provider deals with the patient’s resistance is critical to the provider’s effectiveness in motivating change.⁴⁴ The more resistant a patient is, the less likely that they will change. Therefore, it is critical that the provider “avoid eliciting or strengthening resistance.”

Confrontational or coercive styles of interaction have been found to elicit more resistance from patients than styles that are low in confrontation.^{51,52} In a study of counselor-patient interactions around alcohol use, Miller and Sovereign found that the more the counselor confronted the patient, the more the patient was drinking a year later, whereas the more the counselor supported and listened to the patient, the more the patient changed in a healthy direction (i.e., consumed less alcohol).⁵² In other words, how the provider handles the patient’s ambivalence greatly influences the degree of patient resistance and the motivation to change.

Arguing with a patient about why they should change often results in an ambivalent patient shifting over to the other side of the ambivalence and arguing why they *should not* or *cannot* change. People do not like to be told what to do and will typically become resistant if they feel that their freedom is being limited or restricted in some way. Patients are more likely to change their behavior in a healthy direction if they “want to” rather than if they “ought to” or “have to.”⁴⁹ In other words, if patients believe that they have freely chosen a particular course of action, they will be more committed to it than if they are coerced into taking that course of action.

Table 1:

Four Categories of Patient Resistance Behavior

1. Arguing: The patient contests the accuracy, expertise, or integrity of the provider.

- a. *Challenging:* The patient directly challenges the accuracy of what the provider has said.
 - b. *Discounting:* The patient questions the provider's personal authority and expertise.
 - c. *Hostility:* The patient expresses direct hostility toward the provider.
-

2. Interrupting: The patient breaks in and interrupts the provider in a defensive manner.

- a. *Talking over:* The patient speaks while the provider is still talking, without waiting for an appropriate pause or silence.
 - b. *Cutting off:* The patient breaks in with words obviously intended to cut the provider off (e.g., "Now wait a minute. I've heard about enough.").
-

3. Denying: The patient expresses an unwillingness to recognize problems, cooperate, accept responsibility, or take advice.

- a. *Blaming:* The patient blames other people for her or his problems.
 - b. *Disagreeing:* The patient disagrees with a suggestion that the provider has made, offering no constructive alternative. This includes the familiar "Yes, but . . .," which explains what is wrong with suggestions that are made.
 - c. *Excusing:* The patient makes excuses for his or her own behavior.
 - d. *Claiming impunity:* The patient claims that he or she is not in any danger (e.g., from sharing needles).
 - e. *Minimizing:* The patient suggests that the provider is exaggerating risks or dangers, and that it "really isn't so bad."
 - f. *Pessimism:* The patient makes general statements about self or others that are pessimistic, defeatist, or negativistic in tone.
 - g. *Reluctance:* The patient expresses reservations and reluctance about information or advice given.
 - h. *Unwillingness to change:* The patient expresses a lack of desire or an unwillingness to change, or an intention not to change.
-

4. Ignoring: The patient shows evidence of not following or ignoring the provider.

- a. *Inattention:* The patient's response indicates that she or he has not been following or attending to the provider.
 - b. *Nonanswer:* In answering a provider's query, the patient gives a response that is not an answer to the question.
 - c. *No response:* The patient gives no audible or nonverbal reply to a provider's query. (An example of a patient's nonverbal reply is nodding her/his head.)
 - d. *Sidetracking:* The patient changes the direction of the conversation that the provider has been pursuing.
-

Note: This behavior coding system was developed by Chamberlain et al.,⁵³ modified by Miller⁵⁴ for use in the treatment of alcohol problems, and then revised slightly for this manual. A copy of Miller's coding system can be found in Miller and Rollnick's book entitled, *Motivational Interviewing: Preparing People to Change Addictive Behavior*.⁴⁴

Strategies for Minimizing Resistance

There are numerous strategies for minimizing resistance. Some of them are listed below. Other options are enumerated in Miller and Rollnick's 1991 book about Motivational Interviewing.⁴⁴

1. Do not start talking about how to change the patient's behavior if they are ambivalent about changing or have not even thought about changing. Telling the patient how to make changes when the patient is not interested in changing or is ambivalent about it, can negatively impact their motivation to change. The patient must be committed to change before they can begin to explore *how* to change. Therefore, it is critical to evaluate the patient's readiness to change before discussing strategies for change. Strategies should be individualized to the patient's unique situation, and this cannot happen in an effective way until the patient's situation and perspective are understood.
2. Once you sense or observe resistance, change your tactics or approach. Resistance indicates that you and the patient are not in the same place. You may be pushing the patient to do something for which they are not yet ready. Arguing is counterproductive and simply pushes the patient farther away from making changes. A modification in your approach or interpersonal style will likely lead to a change in client resistance.
3. If the patient exhibits resistance, you can respond by acknowledging the patient's disagreement, anger, or different perspective. Rather than challenging their perspective and continuing the battle or power struggle (the confrontation vs. denial struggle), acknowledge and validate their perceptions or emotions. This should diffuse any conflict, lessen the defensiveness or resistance, and allow further exploration.⁴⁴ This does not mean that you agree with the patient's perspective but rather that you understand what their perspective is.

Examples:

- **Patient:** *Who are you to tell me what to do? You don't know what it is like to be dope-sick and to need a fix.*
- **Provider:** *It sounds like you are pretty angry with me right now.*
- **Patient:** *I don't know why we are talking about this. I don't have a problem.*
- **Provider:** *So you really feel that safer sex and drug use aren't issues for you. You feel that you can manage them fine without any help.*
- **Patient:** *I couldn't change even if I wanted to. My life is too much of a mess.*
- **Provider:** *So right now, you can't see any way that you could change with your life being so chaotic.*

4. Many patients become resistant when they feel that their freedom is being restricted or denied. They react by asserting their freedom and refusing to cooperate. You can respond to this by assuring the patient that, ultimately, the decision to change is theirs. It is important that you do this in a supportive rather than a confrontational or argumentative way.

Example:

- **Patient:** *This is my life. I will do what I want to do.*
- **Provider:** *You're right. If you decide that you don't want to change, then you won't. If you want to change, then you will. It is your choice. I can't change you even if I wanted to.*

5. If the patient is presenting one side of their ambivalence and arguing against change, you can try to elicit the other side of the ambivalence (i.e., the side that wants to change). This can be done by restating or summarizing the patient's perspective (i.e., the one arguing against change) in an exaggerated or more extreme form. If the provider presents the patient's perspective in a more extreme form, the patient is likely to back off and to move toward the other side of the ambivalence, which is toward change. It is critical that the provider not be too extreme in their presentation of the patient's perspective. If the provider is viewed as sarcastic or mocking, the patient could become hostile and even more resistant.⁴⁴

Examples:

- **Patient:** *I'm never going to be able to use condoms. Once I am turned on, condoms are the last thing that I'm thinking about!*
- **Provider:** *So what you're saying is that once you're aroused, you have absolutely no control over what you do. At those times, nothing or no one can stop you from having sex.*
- **Patient:** *What do I care? I've already got HIV!*
- **Provider:** *You've got HIV, so it doesn't really matter if you get any other diseases. You don't care whether you get Kaposi's Sarcoma, or hepatitis, or some other sexually transmitted disease.*

6. When working on a “plan of action,” you should try to elicit goals and strategies from the patient rather than prescribing them. If, instead, you offer the goals and strategies, it is preferable that you provide a **menu** of strategies from which the patient may choose. This increases their sense of freedom and choice—and increases their commitment to the goal and the likelihood that they will follow through. You should **offer new perspectives or goals for the patient to consider**; you should not impose them. The patient should have the freedom to accept that which they find valuable and to reject the rest. It is ultimately the patient's responsibility to make changes in their behavior, not yours.

If we accept the premise that all resistance is composed of ambivalence and that it reflects the first reaction to change rather than the last, we can then view resistance as one step of many in the process of changing to healthier behavior. Although we need to look out for and minimize resistance, we should not be surprised by it or view it as a sign of failure in the consultation. If you can “roll with resistance” and avoid argument, you will be likely to see the resistance dissipate over time and the patient eventually move in the direction of behavior change.







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Clinician-Initiated HIV Risk Reduction Intervention for HIV-Positive Persons

Formative Research, Acceptability, and Fidelity of the Options Project

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Objective: To conduct research on levels and dynamics of HIV risk behavior among HIV-positive patients in clinical care, use this research to design a clinician-initiated HIV prevention intervention for HIV-positive patients, and evaluate the acceptability of the intervention to clinicians and patients and the fidelity with which it can be delivered by clinicians.

Methods: Study 1 (elicitation research) involved focus groups with HIV-positive patients and HIV care clinicians to understand the dynamics of HIV risk behavior among HIV-positive patients and how to integrate HIV prevention into routine clinical care. Study 2 (acceptability and intervention fidelity) involved the evaluation of 1455 medical visits by experimental intervention patients (N = 231) for acceptability and fidelity of the clinician-initiated HIV prevention intervention.

Results: Elicitation research with patients and clinicians identified critical HIV prevention information, motivation, and behavioral skills deficits in HIV-positive patients as well as risky sexual behavior. These findings were integrated into a theory-based HIV prevention intervention initiated by clinicians that proved acceptable to clinicians and patients and that clinicians were able to implement with adequate fidelity.

Conclusion: HIV prevention interventions by clinicians treating HIV-positive patients can and should be integrated into routine clinical care.

Key Words: HIV prevention, HIV-positive, clinical intervention

(*J Acquir Immune Defic Syndr* 2004;37:S78–S87)

In the United States, an estimated 1 million persons are infected with HIV and approximately 40,000 new HIV infections occur each year.¹ To date, the primary strategy for HIV

prevention remains the reduction or elimination of HIV risk behaviors, predominantly among HIV-negative individuals. Strategies for reducing HIV risk behaviors among people who are aware they are HIV-positive are a critical additional component of overall HIV prevention efforts^{1–4} and have recently become a prominent part of the overall US HIV prevention strategy.

Although many individuals who know they are HIV infected reduce or eliminate HIV risk behaviors, significant numbers continue to engage in behaviors that could transmit HIV to others and lead to their own coinfection with other pathogens.^{1,5,6} Considerable risk for transmission of HIV between HIV-positive individuals and partners who may be HIV-negative has been documented.^{6–12} Finally, HIV transmission from treated HIV-positive persons to treatment-naïve HIV-negative persons may spread antiretroviral-resistant strains of HIV.^{13,14}

Although the clinical setting represents an ideal context for HIV risk behavior change interventions for HIV-positive individuals, clinician efforts to intervene systematically to reduce HIV transmission risk among HIV-positive patients are rare,^{15,16} as is research to develop and test such interventions. Our recent literature review found that only a few HIV risk reduction interventions for HIV-positive individuals have been performed in clinical settings¹⁷ and that none of these have yet reported final outcome data.

The current work was based on the Information-Motivation-Behavioral skills (IMB) model of preventive behavior,^{18,19} which has received extensive support in correlational studies and in experimental intervention research.¹⁹ The IMB model asserts that HIV prevention information, HIV prevention motivation, and HIV prevention behavioral skills are the fundamental determinants of HIV preventive behavior.¹⁸

According to the model, HIV prevention information that is directly relevant to preventive behavior (ie, HIV transmission and prevention information) is a prerequisite for such behavior. The information component also includes HIV prevention heuristics and implicit personality theories—simple decision rules that permit HIV-positive individuals to make relatively automatic and cognitively effortless (but often incor-

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rect) decisions about a partner's HIV status and, by extension, about whether to engage in HIV preventive behavior. Use of such heuristics seems to be strongly negatively related to HIV preventive practices.^{20–22}

Motivation to engage in HIV preventive acts is an additional determinant of HIV preventive behavior and influences whether HIV-positive individuals are inclined to act on what they know about HIV risk and prevention. HIV prevention motivation includes an HIV-positive individual's personal motivation to practice HIV preventive behaviors (eg, attitudes toward personally practicing specific HIV preventive acts^{23,24}) and his or her social motivation to engage in HIV prevention (eg, perceptions of social support for performing such acts²⁴).

Behavioral skills for performing HIV preventive acts are a third critical determinant of HIV preventive behavior. The behavioral skills component of the IMB model is composed of an individual's objective ability and perceived self-efficacy concerning performance of the sequence of HIV-preventive behaviors involved in effective prevention.^{18,25}

The IMB model specifies that the effects of HIV prevention information and motivation are expressed mainly through the deployment of HIV prevention behavioral skills in the initiation and maintenance of HIV preventive behavior. HIV prevention information and motivation may also have direct effects on preventive behavior in cases in which complicated or novel behavioral skills are not necessary.¹⁸ Finally, information and motivation are viewed as independent constructs in the model, insofar as well-informed individuals are not necessarily well motivated and well-motivated persons are not necessarily well informed.^{18,26}

The IMB model's constructs are viewed as highly generalizable determinants of HIV preventive behavior across diverse populations and HIV preventive behaviors.¹⁸ The model proposes that the particular information, motivation, and behavioral skills implicated in prevention vary as a function of the population and the preventive behavior in question. Further, it specifies procedures for conducting elicitation research to identify specific information, motivation, and behavioral skills content relevant to understanding a specific population's practice of a specific HIV preventive behavior and for using this content to develop targeted interventions to change that behavior.^{26,27} Specifically, open- and closed-ended techniques (eg, focus groups, questionnaires) are used to elicit the information, motivation, and behavioral skills dynamics of HIV risk and preventive behavior in the target population. Incorporating these findings into intervention design is essential to creating maximally effective HIV prevention interventions tailored to the identified needs of a target population.¹⁸ Such theoretically based and empirically targeted interventions are then implemented and rigorously evaluated to ensure that HIV prevention goals are attained.

The current work involves elicitation research and the subsequent development, implementation, and evaluation of

the acceptability, feasibility, and fidelity of the Options intervention, an IMB model-based clinician-initiated HIV risk reduction intervention for HIV-positive persons in clinical care. Study 1 involved elicitation research focus groups to identify HIV-positive patients' and their health care clinicians' perceptions of the information, motivation, behavioral skills, and other determinants and dynamics of HIV transmission risk behavior in an HIV-positive clinical care population. Patients and clinicians were also asked to suggest how best to integrate HIV prevention interventions that address patients' HIV risk dynamics into patients' routine clinical care. How these findings were incorporated into the design of the Options project, and the specifics of the intervention that resulted, are described. Study 2 presents data on the extent to which the Options intervention was acceptable to patients and clinicians and was able to be implemented with fidelity in a demanding clinical care environment.

STUDY 1: ELICITATION RESEARCH

Method

Participants

At the end of 1999, a convenience sample of 20 HIV-positive patients from the Nathan Smith Clinic (NSC) of the Yale–New Haven Hospital (New Haven, CT) were recruited by clinic staff for participation in the elicitation research. The patients were predominantly black ($n = 9$) and non-Hispanic white ($n = 9$), followed by Latino ($n = 2$). Most patients had at least a high school diploma ($n = 13$), were living in poverty with incomes of \$10,000 or less ($n = 13$), and had received their HIV diagnosis more than 7 years before the research ($n = 14$).

Procedures

The patients participated in 1 of 4 focus groups depending on their gender and mode of HIV acquisition: gay/bisexual men ($n = 4$), injection drug-using (IDU) men ($n = 5$), IDU women ($n = 5$), and non-IDU heterosexual women ($n = 6$). Two additional focus group discussions were conducted with primary care clinicians from the same clinic. Ten clinicians attended the first focus group, and 6 attended the second. Of the 16 clinicians (8 male and 8 female) who participated, 14 were physicians, 1 was a physician's assistant, and 1 was a nurse practitioner.

Standard focus group procedures²⁸ were used to address the research foci described previously. In the patient and clinician focus groups, the protocols were adaptations and extensions of previous qualitative research conducted with HIV-positive patients by our research team.^{20,21} All sessions were audiotaped and were approximately 2 hours in duration. All HIV-positive participants were given \$20 as compensation for their time and travel. Procedures described herein were approved by relevant University and Hospital Institutional Review Boards (IRBs), and patients were informed that their re-

search participation or nonparticipation would not in any way affect their health care.

Results

Analysis

All focus group session audiotapes were transcribed verbatim and coded for content. The method of analytic induction and comparative analysis²⁹ was used to find common patterns. Analytic induction involves scanning the focus group interview transcripts for themes or categories, developing a working scheme after examination of initial cases, and then modifying the scheme on the basis of subsequent cases.³⁰ Negative instances that do not fit the initial constructs are sought to expand, adapt, or restrict the original construct.

Findings from the patient and clinician focus groups revealed important HIV prevention information, motivation, and behavioral skills deficits and reports of HIV risk behavior among HIV-positive patients.

HIV Prevention Information Deficits

The consensus among the clinicians in the focus groups was that HIV-positive patients were relatively well informed about HIV transmission and prevention but had difficulty in using that information. In addition, the clinician and patient focus groups revealed that there continue to be patient misconceptions that need to be addressed. One misconception that was identified as prevalent among HIV-positive patients was the belief that having an undetectable viral load means one cannot transmit HIV to others. HIV-positive patients and clinicians thought that individuals who have this belief are more likely to engage in HIV risk behaviors when their viral load is undetectable, because, as one participant said, "You figure I'm undetected, so I can't hurt nobody." The misconception that an undetectable viral load means a person is not infectious has been associated with unsafe sexual practices³¹ and should be addressed by clinicians in clinic-based risk reduction interventions.

Clinicians also reported that many HIV-positive patients are confused as to whether they should use condoms when they are in HIV-seroconcordant relationships. Clinicians contended that many patients believe there is minimal or no risk associated with having unprotected sex with another HIV-positive individual. Similarly, some participants in the patient focus group reported that many HIV-positive people do not believe that there are any health risks associated with 2 HIV-positive people having unprotected sex or sharing syringes. As one said, "They think like, what's the big deal? We've both got HIV."

Confusion also exists around the HIV transmission risks of oral sex. Some clinicians remarked that many people, particularly HIV-positive gay men, believe that there is essentially no risk associated with unprotected oral sex and conse-

quently do not use condoms during this activity. This perception was supported by comments made by many of the HIV-positive gay men, who believed that condoms only need to be used during anal and vaginal sex. As one reported, "I've not come across anyone who uses condoms for oral sex." Several participants in the focus groups that did not include gay men also indicated that condom use for oral sex was rare, because most people believe that oral sex presents a low HIV risk. This confusion is not surprising, because there has been controversy about the HIV transmission risks of oral sex.³²⁻³⁴ Consequently, clinicians should expect their patients to want clarification concerning the risks associated with oral sex.

Some clinician focus group participants indicated that patients use incorrect heuristics and implicit theories for deciding who is likely to be HIV-positive. One said, "Some patients will use where the encounter takes place as an indicator of who is positive. If you go to a gay bar or are in prison, depending on the crime, the assumption is that you are a high-risk person, so that you might likely be HIV-positive." This perception was supported by some participants in the patient focus groups. One gay man said, "Lots of positive men just assume that the guy that they meet in the park or at the bookstore is positive. So they figure, why bother using condoms?" Other patients believed that those who are willing to engage in risky sexual or drug use behavior are probably HIV infected. Use of incorrect heuristics has been associated with increased risky behavior.^{20,21}

An additional informational deficit that emerged during the patient focus groups was the belief among women patients that it is difficult for an HIV-positive woman to transmit HIV to an HIV-negative man during unprotected sex. Most women endorsed this belief and seemed heavily invested in it being true, because many were finding it difficult to motivate their HIV-negative male partners to use a condom during sex or because they did not want to reveal to their partners that they were HIV-positive.

HIV Prevention Motivation Deficits

The prevailing attitude among HIV-positive patients in the focus groups was favorable toward always using condoms during vaginal and anal sex but unfavorable toward condom use during oral sex. In addition, participants indicated their belief that most HIV-positive patients are sexually active and that abstinence is not an acceptable prevention strategy. This suggests that it might be difficult for clinicians to persuade their HIV-positive patients to abstain from sex and that they are likely to be more successful if they focus on encouraging them to use condoms during vaginal and anal sex.

During focus group discussions, HIV-positive patients identified several motivational barriers to using condoms with their partners. These included being in a long-term relationship, desiring emotional closeness, feeling apathetic about risky behavior, believing that condoms inhibit pleasure, and

not wanting to “face up to the reality of being HIV-positive.” Some participants said that HIV-positive people have an illusion of safety in their long-term relationships and that they are “less likely to use condoms if they perceive a relationship as intimate or close.” This was echoed in clinician focus groups, with several clinicians reporting that their patients’ intimate relationships interfere with their ability to practice safer sex. As one said, “Committed relationships are more immutable to protection. Using a condom is very inconsistent with committed sex.” This finding is in accord with some reports in the literature.³⁵

Outside of committed relationships, patients reported that a desire for emotional closeness decreases the likelihood that condoms are used consistently. One male participant said, “Some women are so desperate for companionship that they don’t want you to use a condom.” Other HIV-positive male patients pointed out that they do not use condoms because their “sexual partners do not care about being infected.” The same pattern was reported by HIV-positive female patients. A large number complained that their male sexual partners do not care about whether they get infected and insist on having unprotected sex; consequently, they have great difficulty in getting them to use condoms. As a female participant put it, “My last 3 partners were negative. These men refused to use rubbers. And the man before that was HIV-positive, and he refused to wear a rubber with me, also.” Some of the female participants also talked about “women not wanting to enforce condom use because they don’t want to be rejected.”

Clinicians identified similar motivational barriers to patients having safer sex but raised an additional issue that was not offered by patients—that many patients in relationships practice risky sexual practices because of fear of being verbally or physically abused by their partners. One said, “Patients are powered and pressured. Maybe not using condoms isn’t a choice.” Another stated, “People are not going to say ‘no condom, no sex’ when they know they’ll get slapped around.” Others talked about how the power differential that often exists in intimate relationships in terms of economics inhibits patients’ ability to engage in preventive behavior. As one said, “One person will be the supplier of the drugs and the other will engage in risky behavior because of the fear of being expelled from the relationship.”

Patient focus group participants reported that some HIV-positive individuals rationalize their risky behaviors by maintaining an “I don’t care” or apathetic attitude. In effect, a number of participants expressed being less motivated to use condoms because they already have the virus. As one said, “HIV-positive drug users that already have HIV don’t have any concern about it now because they already have it.” Other participants made statements along the lines of “You’ve already got HIV. You figure what else could happen to you?”

Additional patient focus group participants said that HIV-positive people fail to practice safer sex because condoms

inhibit pleasure. One said, “Some people just don’t like using condoms; they don’t get the sensation or the feeling that they’re looking for.” Further, patients said condoms were not used by some HIV-positive people because they do not want to face up to their HIV-positive status; condoms remind them that they have HIV, and they do not want to be reminded of that. One said, “There’s guilt and shame. Putting a condom on tends to break a person out of the denial phase of their status and makes them face that.”

HIV Prevention Behavioral Skills Deficits

In the patient focus groups, many patients reported that they did not know how to negotiate condom use with their partners, particularly when their partners refused to use them. Focus groups with clinicians corroborated that many HIV-positive patients do not engage in safer sex because of their inability to negotiate condom use effectively. One clinician said, “Some women report having informed a male sex partner who is HIV-negative of their status. And then he says, ‘Baby, I don’t care. I’ll go down with you’ or ‘I love you too much to use a condom.’” Another reported, “I have one patient who...has unprotected sex because her partner knows her status and doesn’t care to use a condom.” As noted earlier, most clinicians indicated that their patients were relatively well informed about HIV transmission and prevention but did not know how to use or apply that information.

An additional behavioral skills deficit that was reported in the patient and clinician focus groups was the inability of many HIV-positive individuals to use condoms when drunk or high. As one clinician put it, “I think people know exactly how to use a condom but in the heat of the moment their alcohol or drug use interferes.” This sentiment was echoed by some of the patients, as exemplified by the following statement: “If I’m with someone who’s drunk, they’re much more sloppy with it.”

Sexual and Drug Use Behavior in the HIV-positive Patient Sample

All but 2 of the patients in the focus groups reported being sexually active. Those who were not active were women who indicated that they currently had no interest in sex and that “other things are more important in my life right now.” Some of the sexually active women reported having a difficult time getting their partners to use condoms and had basically “given up on even trying.” The sexually active men reported using condoms almost all the time with HIV-negative partners but only some of the time with HIV-positive partners. (Note, however, that HIV-positive individuals’ assumptions of their partners’ serostatus are often inaccurate.^{36,37}) Almost none of the participants indicated that they used condoms during oral sex, and they reported that unprotected oral sex is common practice among HIV-positive individuals.

With respect to injection drug use, most of the patient participants in the IDU focus groups reported that they were

currently on methadone. Only 3 indicated that they were continuing to inject drugs (heroin or cocaine). Two patients said they shared syringes but only with HIV-positive partners. They seemed to believe that most HIV-positive individuals do not share their syringes or works but that some occasionally do so when they are “dope sick.”

Overall, the findings of the elicitation research with respect to HIV risk demonstrate that HIV-positive patients have critical HIV prevention information, motivation, and behavioral skills deficits as well as risky behavior that could be beneficially addressed via clinician-based interventions.

Feasibility of a Clinician-Initiated HIV Risk Reduction Intervention

Patients and clinicians discussed the feasibility of a clinician-initiated HIV risk reduction intervention. Both were concerned with whether there would be sufficient time to address sex and drug use behavior adequately during a routine health care visit. Patients expressed a positive attitude toward talking about HIV risk reduction with their clinicians but had some concerns about the hierarchic relationship between patients and clinicians and expressed a desire for such discussions to be more of a “partnership.” They also voiced concerns about being judged negatively by their clinicians if they admitted to engaging in unsafe practices. In addition, during the patient focus groups, it was revealed that there are many HIV-positive individuals who distrust their clinicians because of a history of experiencing discrimination from the medical profession. Examples included health care clinicians who would not examine their HIV-positive patients without wearing a surgical mask and gown as well as doctors arguing over who was going to examine a patient because no one wanted to touch him or her.

Clinicians indicated that they rarely talk about risk reduction with their HIV-positive patients, although most recognized the importance of doing so. In addition to time constraints, clinicians indicated that the barriers to conducting risk reduction discussions with their patients include financial constraints (no reimbursement), discomfort in talking about sex and drug use, concerns that interventions could require them to interact with their patient and the patient’s partner, the belief that they cannot influence patients’ behavior, and lack of knowledge about sex and drug use and about how to assess and address these issues. A few clinicians also indicated that cultural barriers interfere with their ability to discuss HIV prevention with their patients. One stated, “I have patients who look at me and see this small, white, Jewish woman, and they’re not about to tell me about their sexual history.” Another followed up on this point by saying, “I deal with a lot of Latina women who are submissive. To empower them to use condoms is almost impossible. This is scary considering that, if you’re married, sex outside of the marriage [in men] is culturally accepted.”

HIV care clinicians also indicated that they needed training in how to do risk reduction counseling with their patients, including how to motivate people to change, what language and terminology to use when discussing sex and drug use, and what risk reduction strategies to teach patients. As one put it, “I don’t think we know a lot about this, so I don’t know what to tell people.”

When the proposed Options intervention was presented, clinicians generally expressed a positive reaction to it. One stated, “This project allows patients to feel safe and comfortable, and it’s reasonable, time wise.” Overall, clinicians indicated a willingness to participate in the project as long as they had sufficient training. There were 2 clinicians who stated that they did not believe that doing risk reduction counseling with their patients was their responsibility, however. One of these clinicians said, “They didn’t come to see me for public health information; they came to see me for their health.”

Discussion

The elicitation research consisted of focus groups with HIV-positive patients and HIV care clinicians to explore the dynamics of HIV risk behavior among HIV-positive patients. It also assessed how both groups thought a clinician-based HIV prevention intervention could best be implemented in the context of routine clinical care. The findings revealed critical informational, motivational, and behavioral skills deficits that must be addressed in clinician-initiated HIV risk reduction interventions, although the generalizability of the results is limited by the small sample size. Given the HIV prevention deficits observed, it is reassuring that patients and clinicians generally agreed they would welcome a clinician-based HIV prevention intervention if it was properly structured and addressed the patient and clinician concerns expressed in the focus groups. Specifically, the intervention needed to be brief and feasible to implement in a clinical setting and had to provide clinicians with the comfort and skills to discuss sex and drug use in a nonjudgmental collaborative fashion with their patients.

Using these findings to inform intervention development and the IMB model and motivational interviewing (MI)³⁸ as theoretical foundations, we created a brief intervention, the Options protocol, to be initiated by HIV care clinicians with HIV-positive patients at each regularly scheduled medical visit. The protocol is essentially a “shell” or framework that the clinician uses first to elicit the dynamics of HIV risk behavior for each patient and then to create a tailored HIV risk reduction intervention for that patient. It consists of a brief (5- to 10-minute), collaborative, patient-centered discussion in which the clinician introduces a discussion of sexual and drug use risk behavior into the clinical care visit using MI, a patient-centered, supportive, and nonjudgmental technique designed to enhance individuals’ motivation to change. MI was chosen for this intervention because it has received extensive support

for its ability to motivate behavior change in a variety of health domains^{39–41} and because it specifically addresses patients' desire for their clinician to be nonjudgmental and for their interactions with the clinician to be more like a partnership.

In the Options protocol:

1. The clinician briefly but thoroughly assesses the patient's sexual and drug use risk behavior.
2. The patient and clinician select which of these 2 types of behaviors to focus on further.
3. The patient and clinician then identify the conditions under which the risk behavior occurs (eg, the patient has unprotected anal sex when he or she drinks).
4. The clinician selects a specific behavior (eg, using condoms every time the patient has anal sex) that the patient will rate on "importance" and "confidence" (see below), consistent with MI techniques.
5. The clinician evaluates the patient's readiness to change the behavior by asking him or her to rate the importance of changing it on a scale from 0 to 10.
6. The clinician then has the patient rate the confidence that he or she can change the behavior on a scale from 0 to 10.
7. The clinician elicits specific strategies from the patient for moving toward safer behavior.
8. The clinician also negotiates an individually tailored behavior change goal or plan of action with the patient for the following visit.
9. The clinician writes the goal on a prescription pad and hands it to the patient.

These discussions of HIV risk reduction are individualized for each patient based on his or her current readiness to change risk behavior. The importance and confidence ratings are critical to the determination of the patient's readiness to change and to identifying their particular barriers to change. Whereas the information, motivation, and behavioral skills deficits characteristic of the overall patient population were identified in the elicitation research (and are reported earlier), the purpose of the importance and confidence ratings is to ascertain the particular deficits that need to be rectified to increase or maintain HIV preventive behavior for a specific patient. By asking the patient to rate how important it is for him or her to change risk behavior and how confident he or she is that it can be changed and then assessing the patient's perception of what needs to occur to increase his or her importance and confidence ratings, the clinician can determine the information, motivation, and behavioral skills deficits for that patient that need to be remediated in the intervention. Specifically, if a patient reports that engaging in safer behavior is not important to him or her, it generally reflects an information or motivation deficit. If it is important but the patient is not confident that he or she can practice safer behavior, it often reflects a behavioral skills deficit. Once the clinician and patient understand what the patient's deficits are, they then explore strategies for over-

coming them. By asking the patient what needs to be done to increase his or her importance and confidence ratings, the clinician can ascertain precisely what the patient, who is viewed as the expert on his or her situation, needs in order to address the factors associated with his or her HIV risk behavior.

Note that for many patients who are not practicing risky behavior at the time of their visit with their clinician, the goal of the visit is to maintain safer behavior. For these patients, importance and confidence ratings are taken with respect to maintaining safer behavior rather than for changing risky behavior. For these individuals, interventions contain elements that can increase the importance of, and their confidence in, maintaining safer behavior over time.

Before implementing the Options protocol, clinicians were trained for 4 hours in how to work collaboratively with their patients to elicit and address the deficits needing to be remediated to increase or maintain a patient's HIV prevention behavior. In addition to receiving step-by-step instruction in the risk reduction protocol, they were trained for an additional 2 hours in the various sexual and injection drug use behaviors in which their patients engage and were provided with strategies that they could use to teach their patients how to minimize the health risks associated with those behaviors.

STUDY 2: ACCEPTABILITY AND FIDELITY RESEARCH

Methods

Participants

This study involved 231 HIV-positive patients who had at least 1 medical visit over the course of their participation in the Options project. All patients attended the same large HIV specialty clinic that was the site of Study 1. The mean age of the participants was 43 years (range: 26–70 years), 53% were male, and two thirds were black or Hispanic (52% black and 17% Latino/a). Twenty-seven percent were white, and 9% reported "other" racial identities. Most (79%) reported being heterosexual, followed by gay/lesbian (13%) and bisexual (8%). Forty-seven percent reported acquiring HIV through heterosexual sex, 36% by sharing needles or works, 13% from homosexual sex (of the 29 participants reporting this transmission route, 27 were male and 2 were female), and 4% through a blood transfusion, paralleling the HIV transmission routes in the geographic locale where this research took place. Nearly half (48%) reported they had known their HIV status for 10 years or more. Twenty-three percent of the participants had education beyond high school; almost three quarters (73%) of the participants had yearly family incomes of \$10,000 or less; and although most (87%) had stable housing, 13% were living in homeless shelters, on the street, or in abandoned buildings.

Patient Recruitment

To participate in this research, an individual had to be HIV-positive, in clinical care at the NSC at Yale–New Haven

Hospital, and at least 18 years of age. The study was described as the evaluation of a new counseling program that focused on reducing HIV risk behavior among HIV-positive individuals in clinical care in order to maximize their health and that of their partners. Participants received no monetary incentive for participation in the intervention sessions, although they were compensated for participating in the evaluation research, which was conducted separately from the intervention.

Clinician Training

Over the course of the study, 23 clinicians (20 physicians, 2 physician assistants, and 1 nurse practitioner) were trained in the intervention protocol. Training comprised of 3 basic components: (1) the intervention workshop, a 4-hour didactic and interactive training session on the intervention protocol and MI techniques; (2) the sex and drugs workshop, a 2-hour workshop on sexual and injection drug use behaviors and risk reduction strategies; and (3) a 1-hour 1-on-1 booster session involving role plays of the protocol, including feedback. These are described elsewhere (Fisher JD, Fisher WA, Cornman DH, et al. Clinician-initiated intervention delivered during routine clinical care reduces risky sexual behavior of HIV-positive patients; unpublished manuscript).

Intervention Feasibility, Acceptability, and Fidelity Measures

The extent to which the Options project intervention was **feasible** and **acceptable** to clinicians was assessed by comparing the total number of visits by consented patients during the study with the number in which the protocol was administered by clinicians. Acceptability to patients was calculated by comparing the rate of patient refusal to participate in the Options protocol with the total number who participated in the protocol, through the use of data gathered for each clinic visit from the provider. (Note that an explicit element in MI is the clinician asking the patient if he or she is willing to engage in safer sex discussions. It is made clear that it is okay with the clinician if the patient does not wish to proceed.)

The **fidelity** with which the Options intervention was delivered by clinicians was assessed through the use of a 1-page form (Patient Record Form [PRF]) that clinicians completed at the end of every patient visit. Clinicians used the PRF to document which of the 9 intervention steps described earlier (eg, risk assessment, ratings of importance and confidence) they had implemented with the patient as well as the goal or action plan they had negotiated for the next visit. Each time a patient had a scheduled medical visit, a blank PRF as well as the PRF from the previous visit (if it was not the first Options visit) was attached to the medical chart. The clinician referred to the previous PRF to remind him or her of what had transpired at the last Options visit. To assess intervention fidelity, each step completed by the clinician was scored and totaled such that total scores could range from 0 (no Options steps implemented) to 9 (all Options steps completed).

As an additional measure of fidelity, we also administered exit questionnaires with randomly chosen patients immediately after their medical visits. These assessed the “tone” of the visit (eg, whether it was conducted consistent with MI precepts) and whether patients recalled the Options protocol steps being implemented. Given that participants were not trained in MI or in protocol steps and could not be expected to identify their presence definitively, questions were more general than on the PRF and were intended as secondary measures of intervention fidelity. For this purpose, an 18-item measure was created containing items assessing the patient’s perceptions of how the clinician conducted Options discussions (eg, “During today’s visit, did your clinician praise you for what you are doing to keep you and your partner[s] safe from HIV and other diseases transmitted through sex and/or drug use?”) and the presence of certain Options protocol elements (eg, importance and confidence ratings) in the medical visit. The measure also contained general questions regarding patients’ perceptions of their clinicians’ supportiveness (eg, “How comfortable did you feel discussing sex and/or drug use with your provider?”) that were rated on a 0 (not at all) to 10 (very) scale. After the initial Options visit, exit questionnaires included 3 additional items addressing goal setting and attainment from previous visits (eg, “During your last clinic visit, did you and your provider decide upon a goal that you would work on between the last visit and today?”). Patients were told their clinician would not see their responses to the exit questionnaire.

Results

Acceptability of the Options Intervention

From October 4, 2000 to August 1, 2003, the clinicians trained in the Options protocol completed PRF forms for a total of 1455 medical appointments with 231 patients. Of the 1455 medical visits, 73% (1068) included an implementation of the Options protocol. Results indicated that other issues (primarily serious medical conditions competing for the clinician’s time) took precedence over protocol implementation for 23% (336) of the medical visits. Because there was an opportunity for repeated exposure to Options over subsequent visits, however, only 14 participants (6% of the total sample) failed to receive an Options intervention during their participation in the research because of other issues persistently being more pressing during medical visits than the intervention. Further, only a small proportion (3% [47 visits]) of all tracked patient visits involved a patient refusing to participate in the Options intervention. In sum, the Options protocol was implemented in most of medical visits, competing issues did not preclude many participants from receiving an Options intervention during another medical visit, and patient refusal to engage in the intervention was rare. Thus, the Options intervention was well accepted as a component of routine HIV care in a high-volume inner-city HIV care setting.

Intervention Fidelity

The extent to which the Options intervention was delivered according to protocol was evaluated using the PRF data from the 1068 patient visits in which the intervention was implemented. As previously noted, the PRF gathers information regarding the inclusion of 9 steps in the delivery of the Options protocol. At a gross level, intervention fidelity was assessed by evaluating the average number of steps implemented during intervention deliveries and the percentage of patient visits that included more than half of these steps (5 or more). At a more refined level, we assessed the implementation rate for each step. This provided a more fine-grained assessment of intervention fidelity.

On average, intervention protocol delivery involved approximately 6 of the 9 protocol steps (mean [M] = 6.46, SD = 1.75) and ranged from 2 to 9 steps. Seventy-seven percent of the patient visits included more than half of the protocol steps. Because the 9 steps detailed in the PRF are not viewed as equally critical and some are not appropriate in particular contexts, we also reviewed the implementation of each step individually. An assessment of sexual and drug use risk behavior (step 1) was included in 95% of the protocol implementations, as was the decision whether to discuss sexual or drug use risk behavior further (step 2). Choosing a behavior to be rated on importance and confidence (step 4) was included in 88% of protocol implementations, and rating the importance of and confidence in changing or maintaining that behavior (steps 5 and 6 [83% and 82%, respectively]) was frequently included in protocol implementation. Assessing the conditions under which the risk behavior occurs (step 3 [46%]), generating strategies to increase importance and confidence (step 7 [53%]), selecting a goal or plan for the next visit (step 8 [66%]), and giving the patient a prescription with a behavioral goal (step 9, [39%]) were less commonly included in protocol delivery.

It is likely that some of these steps were omitted because of the clinician's perception that they were not relevant in certain cases. For example, when importance and confidence are both rated at high levels, discussing methods to increase these ratings is not appropriate. If a patient is in maintenance, discussing the conditions under which the risk behavior occurs is not relevant. Overall, the frequency with which protocol steps were included in intervention delivery suggests that clinicians generally followed the Options protocol. This, coupled with strong evidence that clinicians found the protocol to be acceptable and implemented it regularly and that patients overwhelmingly found it to be acceptable, bodes well for its widespread implementation.

The patient exit questionnaires, which were collected between November 2000 and July 2003 from 181 participants, also suggested that clinicians were implementing the protocol appropriately. Patient reports indicated that most Options medical visits were consistent with the protocol and that re-

fusal rates were quite low. Specifically, 72% of participants (n = 145) reported discussing sexual behavior with their clinician, with 80% of these (n = 115) going on to discuss condom use. Moreover, the refusal rate for discussing sexual behaviors with clinicians was low (6%, n = 2). In addition, 58% (71 of 123) of participants reported discussing injection drug use with their clinicians. Again, there was a low refusal rate (2%, n = 4). Of those who discussed injection drug use behavior with their clinician, 64% also discussed clean needle use, only 1% (n = 1) refused to discuss drug use-related issues, and 26% reported that such discussions were "not applicable" to them.

Exit questionnaires revealed that in most Options visits, clinicians had patients rate the importance of and their confidence in adopting the preventive behavior at focus, with 63% of patients reporting having rated "importance" and 65% reporting having rated "confidence." Further, 67% reported discussing specific strategies they could use to raise their importance or confidence score. Most (73%) selected a goal to work on for the next visit, with 54% receiving a written behavioral prescription. Moreover, the goals selected were viewed as realistic by patients. On average, participants rated the likelihood of reaching their goal as 8.46 (SD = 2.24) on a scale of 0 (unlikely) to 10 (very likely). Further, and consistent with MI, goals seemed to be largely a collaboration between the patient and clinician. Of those selecting goals, 66% (98 of 148 patients) collaborated with their clinician to select a goal, 35% (37 of 148 patients) selected their own goals, and 9% (13 of 148 patients) reported that the clinician selected the goal. For those who had selected a goal at their previous visit, 87% reported discussing progress toward that goal and 66% reported discussing barriers to goal achievement.

Overall, exit questionnaires revealed that patients reported positive experiences during their medical visits, that included the Options protocol. Most (72%) reported receiving praise from their clinician for efforts at working toward risk reduction goals. On average, on a scale from 0 (not at all helpful) to 10 (very helpful), patients rated their clinicians as quite helpful (M = 9.08, SD = 1.89) and very understanding (M = 9.30, SD = 1.49). In sum, exit questionnaires support our acceptability and fidelity findings and suggest that the clinicians used the patient-focused style of delivery that was a major component of the clinician's training.

GENERAL DISCUSSION

The present research explored the dynamics of HIV risk behavior in HIV-positive patients in clinical care. Focus groups revealed that HIV-positive patients have HIV prevention information, motivation, and behavioral skills deficits that may lead to risky behavior. Information deficits included believing that HIV cannot be transmitted when viral load is undetectable, that unprotected sex is safe with an HIV-positive partner, that people willing to engage in risky behavior are likely to be HIV-positive, and that HIV-positive women are

unlikely to transmit HIV to men. Moreover, motivation to practice prevention was reduced for individuals who were in a long-term relationship, desired emotional closeness, had a partner who did not care about prevention or who was emotionally or physically abusive, believed that condoms inhibit pleasure, or were in denial about their HIV status. With respect to behavioral skills, patients had difficulty in effectively negotiating condom use with partners who were not inclined to use them and believed that they did not have the skills to practice safer sex when under the influence of substances. Given the profile of HIV risk dynamics observed in the HIV-positive patient population, it is reassuring that patients and clinicians generally agreed that they would welcome a clinician-based HIV prevention intervention, given that it was properly structured and addressed the concerns that patients and clinicians expressed in the focus groups.

Based on our elicitation findings and relevant theory, we created the Options protocol, which incorporates what we learned into an intervention that takes into account the sensitivities and sensibilities of patients and clinicians. This is critical, because in the era of antiretroviral therapy (ART), in which patients are likely to see their clinicians with some regularity, clinicians have a unique opportunity to integrate prevention with care. Studies show that, to date, this opportunity has been missed (Morin SF, Koester KA, Maiorana A, et al. Missed opportunities: prevention with HIV-infected patients in clinical care settings; unpublished manuscript). Nevertheless, our data suggest that under the proper conditions, patients would welcome such an intervention and that most clinicians would as well.

The Options intervention individualizes the patient-clinician interaction to the specific HIV risk dynamics and HIV prevention needs of the patient, and involves a true "patient-clinician" collaboration in addressing the patient's HIV risk reduction needs. The data presented in the current study suggest that the Options intervention is feasible and acceptable to patients and clinicians. Moreover, clinicians can be trained in this protocol in a relatively short time. We note that in vivo observation of clinicians and discussions with research staff suggest that any initial discomfort clinicians may have had with discussing risk behavior with their patients was effectively addressed via clinician training and workshops. In fact, many of the participating clinicians adopted Options protocol strategies with all their patients, even those who were not enrolled in the study. Moreover, the exit questionnaires, which assessed the patient's perspectives of their clinician's use of the Options protocol, provided support for the acceptability and fidelity findings. They also suggest that patients regarded their clinician as understanding, helpful, and collaborative while he or she was implementing the protocol and working with them toward risk reduction goals.

Overall, the Options protocol was found to be acceptable and capable of being delivered with fidelity in clinical care. Of

ultimate import, however, is the extent to which it was effective in reducing HIV risk behaviors in HIV-positive patients. Importantly, our recently completed outcome analyses revealed that patients exposed to the protocol reduced HIV sexual risk behaviors significantly over time, whereas those in a standard-of-care control clinic did not evidence reductions in risk behaviors (Fisher JD, Fisher WA, Cornman DH, et al. Clinician-initiated intervention delivered during routine clinical care reduces risky sexual behavior of HIV-positive patients; unpublished manuscript). This suggests that if widely implemented, the Options protocol may play an important role in establishing a standard of care effectively linking prevention with treatment, and, in this way, may help to contain the spread of HIV.

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Clinician-Delivered Intervention During Routine Clinical Care Reduces Unprotected Sexual Behavior Among HIV-Infected Patients

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Objective: To evaluate the effectiveness of a clinician-delivered intervention, implemented during routine clinical care, in reducing unprotected sexual behavior of HIV-infected patients.

Design: A prospective clinical trial comparing the impact of a clinician-delivered intervention arm vs. a standard-of-care control arm on unprotected sexual behavior of HIV-infected patients.

Setting: The 2 largest HIV clinics in Connecticut.

Participants: A total of 497 HIV-infected patients, aged ≥ 18 years, receiving HIV clinical care.

Intervention: HIV clinical care providers conducted brief client-centered interventions at each clinical encounter that were designed to help HIV-infected patients reduce unprotected sexual behavior.

Main Outcome Measures: Unprotected insertive and receptive vaginal and anal intercourse and unprotected insertive oral sex; unprotected insertive and receptive vaginal and anal intercourse only.

Results: HIV-infected patients who received the clinician-delivered intervention showed significantly reduced unprotected insertive and receptive vaginal and anal intercourse and insertive oral sex over a follow-up interval of 18 months ($P < 0.05$). These behaviors increased across the study interval for patients in the standard-of-care control arm ($P < 0.01$). For the measure of unprotected insertive and receptive vaginal and anal sex only, there was a trend toward a reduction in unprotected sex among intervention arm participants over time ($P < 0.09$), and a significant increase in unprotected sex in the standard-of-care control arm ($P < 0.01$).

Conclusions: A clinician-delivered HIV prevention intervention targeting HIV-infected patients resulted in reductions in unprotected

sex. Interventions of this kind should be integrated into routine HIV clinical care.

Key Words: HIV/AIDS, HIV prevention, clinician-delivered intervention, HIV-infected patients, sexual risk behavior, unprotected sex

(*J Acquir Immune Defic Syndr* 2006;41:44–52)

New HIV infections have not declined significantly in the United States¹ and many other nations² in recent years, in large part owing to the continuing risky sexual behavior and injection drug use practices of a proportion of HIV-positive persons.^{3–11} Failure to reduce the incidence of HIV risk behavior among HIV-infected persons has arguably been an outcome of nearly exclusive focus on delivering HIV prevention interventions to HIV-negative as opposed to HIV-positive persons¹² throughout most of the history of the HIV pandemic.

To address the lack of HIV prevention interventions designed to support HIV-positive persons' practice of HIV-preventive behavior, efforts to develop effective prevention interventions for HIV-infected persons have now become a major clinical and public health focus.^{7,13–22} The implementation of HIV prevention interventions for HIV-positive persons is particularly relevant in the current context of effective and potent antiretroviral therapy that has transformed HIV into a chronic disease with an extended period of potential infectiousness with both sensitive and resistant virus.^{23–25}

Although many HIV-infected individuals avoid risky behaviors that can transmit the virus to others, substantial numbers of HIV-infected persons continue to engage in HIV transmission-risk behaviors.^{5–7,9,10,26–29} Research indicates that approximately 33% of HIV-positive persons engage in behaviors that place uninfected individuals at risk for infection,^{4–6,8,11} and HIV transmission-risk behavior rates appear to be similar across HIV-infected men who have sex with men, HIV-infected injection drug users, HIV-infected heterosexual men and women, and HIV-infected individuals who are and who are not seeking health services.⁸

The challenge of developing effective and feasible interventions to promote safer sex and drug injection practices among HIV-infected individuals has been designated by the Centers for Disease Control,¹³ National Institutes of Health,³⁰ and the Global HIV Prevention Working Group¹⁴ as a critical priority at this point in the HIV pandemic. In this respect, it has

Received for publication December 28, 2004; accepted October 12, 2005.
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Supported by research grant RO1 MH59473 from the National Institute of Mental Health, Bethesda, MD.

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been specifically recommended that HIV prevention interventions be integrated into clinical care for HIV-infected patients.^{13,14} It has been noted that “clinicians providing medical care to HIV-infected persons can play a key role in helping their patients reduce risk behaviors and maintain safer practices and can do so with a feasible level of effort, even in constrained practice settings. Clinicians can greatly affect patients’ risks for transmission of HIV to others by performing a brief screening for HIV transmission-risk behaviors; communicating prevention messages; discussing sexual and drug-use behavior; positively reinforcing changes to safer behavior; referring patients for such services as substance abuse treatment; facilitating partner notification, counseling, and testing; and identifying and treating other STDs”¹³ (see also Gayle et al¹⁴).

The HIV clinical care setting may be an efficient and effective context in which to situate HIV prevention interventions for HIV-infected persons because it provides repeated opportunities for supportive prevention contacts between clinicians and patients and capitalizes on the often trusting relationship between them. The HIV clinical care setting also affords the most complete access possible to the population of HIV-infected individuals who are capable of transmitting the virus to uninfected others. At present, however, very few HIV prevention interventions have been systematically implemented and evaluated in the HIV clinical care setting.^{12,15,17–19}

The current research involves the design, implementation, and evaluation of a clinician-delivered HIV risk reduction intervention, targeting HIV-infected patients’ risky sexual and drug use behaviors, and delivered in the context of routine HIV clinical care. This approach exploits the efficiencies and strengths of the HIV clinical care setting and the opportunities it affords for repeated clinician–patient prevention interactions and is designed to be amenable to widespread and cost-effective dissemination.

METHODS

Participants

HIV-infected participants were recruited at the 2 largest HIV clinics in Connecticut, including 1 site in New Haven and 1 in Hartford. Inclusion criteria for the study protocol were documented HIV infection; receiving HIV clinical care; and age ≥ 18 years. Exclusion criteria were physical or mental disability sufficient to interfere with involvement in the research protocol.

Subjects were recruited with poster displays in examination and waiting rooms soliciting participation; brochures that contained similar information; solicitation from nurses and clinic staff; and by way of clinicians who described the study to their patients. Interested patients were introduced to research staff who described study details and obtained informed consent. Participation in this study was voluntary. Institutional review boards at the University of Connecticut, Yale University School of Medicine, and Hartford Hospital approved the research protocol.

Study Design

This prospective clinical trial employed a quasi-experimental research design^{31–33} in which clinics were assigned to intervention (New Haven) or standard-of-care control (Hartford) arms. This design was selected to avoid cross-contamination between intervention and control arms had both conditions been implemented within the same clinical site. Moreover, implementing both the experimental and control conditions of this study at a single site could have potentially caused patients in the control group to feel disadvantaged and resentful. The intervention and control sites were selected on the basis of their similarity in population served (eg, both serve approximately 800 HIV-positive patients from inner city populations) and structure of services (eg, both are hospital-based comprehensive HIV clinics staffed by clinicians and nurses, with social work and mental health services available, and assign patients to individual practitioners who provide HIV primary care services to their own panel of patients). We note that the intervention and standard-of-care control sites were carefully compared and found to be similar on several potential confounders, including clinic environments and procedures, overall characteristics of patient populations, standards of care, lack of preexisting HIV prevention efforts, and modes of HIV transmission. To further assess for bias in outcome measures associated with preexisting differences between sites, we conducted tests for pretest equivalence and were prepared to statistically adjust for any measured variable on which the clinics differed and that was related to our primary outcome measures.^{31–33}

Procedures

On average, at the intervention and control arm sites, patients saw their providers for regularly scheduled visits about every other month. Standardized sexual and injection drug use behavior assessments^{4,34,35} and measures of other relevant factors were conducted at baseline and at approximately 6-month intervals for a follow-up period of approximately 18 months (4 assessments). Computer-administered self-interviews (CASI)³⁶ assessed patients’ demographics, HIV prevention information, motivation, behavioral skills, and sexual and injection drug use behaviors. Measures were administered in either English or Spanish, at the patient’s choice, with an accompanying audio track to assist those who had difficulty reading. On average, 2 HIV prevention intervention sessions were delivered per patient between each assessment of patient behavior. Subjects were compensated \$25 for each CASI assessment but received no compensation for participating with their HIV care provider in the clinician-delivered HIV prevention intervention. Study participants were informed that their HIV care providers would at no time have access to data from their CASI assessments.

The clinician-initiated intervention protocol, known as the “Options/Opciones Project,” was based on the information–motivation–behavioral skills model, an empirically validated approach to HIV risk reduction.^{37–40} It was delivered using techniques drawn from motivational interviewing,⁴¹ an empirically validated, brief, patient-centered strategy for promoting risk behavior change in clinical settings. Intervention content was also informed by focus group discussions with

HIV-infected patients ($n = 20$) and HIV care clinicians ($n = 17$) who reviewed and commented upon this intervention approach while it was under development. Details of intervention development have been described elsewhere.⁴²

The Options/Opciones Project HIV risk reduction intervention consisted of brief (5- to 10-minute), collaborative, patient-centered discussions between clinician and patient, conducted during routine clinical visits and repeated at each visit, over a study interval of approximately 18 months. Clinicians verbally assessed HIV-positive patients' sexual and injection drug use behaviors, evaluated patients' readiness to change risky (or maintain safer) behaviors, sought to understand patient ambivalence about change, and elicited strategies from patients for moving toward change or maintaining safer behavior. Clinician and patient then negotiated an individually tailored behavior change (or maintenance) goal or plan of action, and sessions ended with the patient being given a "prevention prescription," written on a prescription pad, which summarized the agreed-upon-goal to be reached by the next visit. Clinicians were directed to attempt to implement the intervention at the end of every regular clinical visit with every enrolled patient unless pressing medical concerns precluded intervention delivery.

Participants in the standard-of-care control arm met with their clinicians for scheduled visits and received standard medical care, which did not systematically include discussion of HIV prevention. Such discussions were not prohibited during the study, however, and occurred on an ad hoc basis.

Clinician Training

Over the course of this research, 23 HIV care clinicians (20 physicians, 2 physician assistants, and 1 nurse-practitioner) were trained to deliver the Options/Opciones Project intervention to criterion. Intervention training consisted of 3 hours of didactic teaching and interactive practice in intervention delivery with HIV-infected standardized patient volunteers. A 1-hour one-on-one follow-up session with role plays was also conducted with each clinician, after the core intervention training, and before he or she began to deliver the intervention. In addition, clinicians participated in a 2-hour workshop on sexual and injection drug use behavior and risk reduction strategies. Clinicians were provided with a complete intervention manual and had access to an intervention "cheat sheet," outlining intervention procedures, attached to each intervention arm patient's medical chart.

Intervention Fidelity

Intervention fidelity was assessed with clinicians' reports of their delivery of 9 specific intervention protocol steps at each visit and via patient completion of exit questionnaires following intervention visits. These findings are discussed in detail in a separate report⁴² that provides convergent evidence of intervention fidelity from clinician and patient reports and indicates that the intervention was delivered in 73% of all HIV clinical care visits. Most of the cases in which it was not delivered were due to the presence of pressing medical concerns.

Outcome Measures

Several intervention outcome measures were used in this research. As a broad measure of potential HIV transmission-risk sexual behavior, the total number of unprotected vaginal and anal sexual events (receptive and insertive) together with the total number of unprotected insertive oral sexual events (participant's penis in a partner's mouth) over the prior 3-month period was calculated. (Unprotected receptive oral sex by an HIV-infected person is associated with minimum HIV transmission risk^{43,44} and was not included in this index.) We also constructed a more rigorous and conservative measure of HIV transmission-risk sexual behavior that included only unprotected vaginal and anal sexual events. We label this transmission-risk measure as "more rigorous and conservative" for 2 reasons. First, HIV transmission via unprotected oral insertive behavior by an HIV-infected person is relatively inefficient, especially when ejaculation is unknown. Second, because of its relative inefficiency, some respondents may view engaging in oral sex (to the exclusion of other unprotected acts) as a risk reduction measure. Our intervention's motivational interviewing techniques recognize the importance of such individual subjectivities in determining respondent risk reduction goals.

In addition to considering the behavior itself, transmission risk is by implication based on the assumption of HIV being transmitted from an infected to a noninfected individual. Despite the fact that respondents' perceptions and assumptions regarding their partner's serostatus may be highly inaccurate and speculative,^{5,6,26,45} we decided to include this variable in constructing additional exploratory risk measures. Presumed partner serostatus and sexual risk behavior were combined in 4 different ways: number of unprotected vaginal, anal, and insertive oral sexual acts with an HIV-negative or HIV status-unknown partner; number of unprotected vaginal and anal sexual acts with an HIV-negative or HIV status-unknown partner; number of HIV-negative and HIV status-unknown sexual partners with whom the respondent reported unprotected vaginal, anal, or insertive oral sex; and number of HIV-negative and HIV status-unknown sexual partners with whom the respondent reported unprotected vaginal or anal sex. Current injection drug use behavior was too infrequent in this sample for use as an intervention outcome measure.

Analytic Approach

At each wave of data collection, unprotected sexual events were summed for each participant. We analyzed baseline unprotected sexual behaviors (both unprotected vaginal, anal, and insertive oral sexual events *and* unprotected vaginal and anal sexual events) to assess possible differences between participants who were in the intervention vs. standard-of-care control arms as well as to determine whether there were differences between participants who were retained vs. not retained across all 4 waves of data collection. Analyses of variance for continuous measures⁴⁶ and logit modeling (PROC CATMOD)⁴⁷ analyses for categorical measures⁴⁸ were conducted to examine whether pretest differences between study arms or differential attrition between arms had taken place.

To assess intervention outcomes, we modeled 2 primary measures of unprotected sexual behavior (unprotected vaginal,

anal, and insertive oral sex events *and* unprotected vaginal and anal sex events) as a function of study arm (intervention or control), time, and the study arm \times time interaction. Preliminary analyses supported this approach as individual providers appeared to have no independent effects on outcomes and there were no “dosing” effects. Generalized estimating equations (GEE) were used to account for the correlated nature of the longitudinal data (ie, repeated observations across subjects)⁴⁹ as well as the Poisson distribution of our outcome measure.^{50–52} In these analyses we specified a lag-1 autoregressive error structure on the repeated observations and included an overdispersion parameter to improve the fit of the model, as GEE can underestimate standard errors when overdispersion is present.^{50,51}

We estimated 2 primary models, and as described earlier, one was more broadly based and the other more rigorous and conservative. The former involved total number of unprotected vaginal, anal, and insertive oral sexual events, and the latter involved total number of unprotected vaginal and anal sexual events. Moreover, we estimated 4 exploratory models (total number of unprotected vaginal, anal, and insertive oral sexual events with HIV-negative and HIV status-unknown partners; total number of unprotected vaginal and anal sexual events with HIV-negative and HIV status-unknown partners; total number of HIV-negative and HIV status-unknown partners involved in unprotected vaginal, anal, and insertive oral sexual events; and total number of HIV-negative and HIV status-unknown partners involved in unprotected vaginal and anal sexual events). These analyses employed SAS version 8.02 (SAS, Inc., Cary, NC) using the PROC GENMOD procedure, with missing observations estimated via the all-possible-pairs method associated with PROC GENMOD.^{49,52,53}

RESULTS

Patient Characteristics

Between October 2000 and August 2003, 497 patients participated in this study. Research at both sites occurred over the same interval. Mean age of participants was 43 years (range: 22–70 years); 288 (58%) were male and 209 (42%) were female; 187 (38%) were African American, 174 (35%) Hispanic, and 107 (22%) were white. A total of 219 participants (44%) had some high school education; 180 (36%) had a high school diploma or equivalent; and 97 (20%) had some college education or a college degree. The majority of participants, 344 (69%), had yearly family incomes of $<$ \$10,000. Most participants had stable housing, although 39 (8%) were living in homeless shelters, on the street, or in abandoned buildings.

Self-reported routes of HIV infection (valid $n = 488$) included acquiring HIV through heterosexual sex ($n = 223$, 46%), sharing contaminated injection paraphernalia ($n = 194$, 40%), male same-sex contact ($n = 56$, 12%), and blood transfusion ($n = 12$, 3%). Nearly half ($n = 235$, 47%) of study participants reported that they had known about their HIV status for ≥ 10 years, and 323 of the 483 participants queried (67%) indicated that they were currently prescribed antiretroviral medications. One or more biologic measures were

available for 419 participants (84%). Median CD4 count for these participants was 356 cells/mm³, with a range of 0–1705 (SD = 308); 266 (78%) of the 342 participants for whom viral load data were available had virus detectable at ≥ 400 copies/mL; and $> 3/4$ ($n = 228$, 86%) of those with detectable viral loads had viral loads of ≥ 1500 copies/mL.

Baseline Unprotected Sexual Behavior

At baseline assessment, 114 (23%) of 490 participants in this HIV clinical care sample reported unprotected vaginal, anal, or insertive oral sex during the preceding 3 months (7 participants had missing values on this variable). Aggregate number of such unprotected sexual events was substantial: HIV-infected study participants reported a total of 2408 unprotected vaginal, anal, or insertive oral sexual events during the past 3 months, with 1785 of these being unprotected vaginal or anal sexual events. Aggregate number of partners involved in unprotected vaginal, anal, or insertive oral sexual events over the past 3 months was also substantial: HIV-infected study participants reported engaging in such unprotected sexual acts with a total of 351 partners during this interval.

Baseline Differences Between Intervention and Control Arms

Statistical tests were conducted to detect possible baseline differences between patients in the intervention compared with the standard-of-care control arm (Table 1). There were significant differences ($P < 0.05$) between intervention and control arm participants at baseline on race, whether participants received public assistance, whether participants had education beyond high school, route of HIV infection, CD4 counts, and whether they were prescribed antiretroviral therapy. None of these variables were associated with number of reported unprotected vaginal, anal, and insertive oral sexual events, nor were any significantly associated with the more conservative sexual risk measure (unprotected vaginal and anal sex). For completeness, we also tested a series of models in which these variables served as moderators of treatment effects on the broader and the more conservatively defined primary outcome measures, and in all cases the test of the time \times condition \times covariate was nonsignificant (all P values ≥ 0.25). Therefore, no covariates are included in any of the intervention outcome analyses.

Attrition Analyses

Of 497 patients completing baseline assessments, 490 provided complete baseline data. A total of 403 of these participants provided data at the second risk behavior assessment; 321 provided complete assessments for 3 waves of data; and 231 provided assessments at all 4 time points. Thus, a total of 1445 separate assessments were collected over the course of the study, leaving 543 missing data points. We examined the reasons for missing data, and its potential impact on the evaluation of treatment outcome, understanding that attrition in a population in which there is substantial health status, geographic, and resource instability is to be expected.^{19,54,55} For the 266 participants who were unable to complete

TABLE 1. Tests for Baseline Differences Between Intervention and Control Arms

Variable	Intervention (n = 252)	Control (n = 245)	Test of Pretest Equivalence
Gender (female)	45%	39%	χ^2 (1, n = 497) = 2.13, $P = 0.14$
Race			χ^2 (3, n = 495) = 80.46, $P < 0.001$
African American	51%	25%	
Hispanic	17%	53%	
White	28%	15%	
Other	4%	7%	
Age	43.24 (7.5)	43.51 (7.9)	F (1,489) = 0.14, $P = 0.71$
Income (making \leq \$10,000 per year)	72%	74%	χ^2 (1, n = 472) = 0.46, $P = 0.50$
Receiving welfare or public assistance	77%	63%	χ^2 (1, n = 497) = 11.07, $P < 0.001$
Education (completed high school or less)	24%	15%	χ^2 (1, n = 496) = 6.11, $P = 0.01$
Route of HIV Infection			χ^2 (3, n = 488) = 8.07, $P = 0.04$
Heterosexual sex	46%	45%	
IDU	35%	44%	
Homosexual sex	15%	10%	
Blood transfusion	4%	1%	
Sexual Orientation			χ^2 (2, n = 497) = 2.36, $P = 0.31$
Heterosexual	79%	77%	
Homosexual	11%	15%	
Bisexual	10%	8%	
On antiretroviral therapy	73%	60%	χ^2 (1, n = 484) = 8.04, $P = 0.005$
CD4 ⁺ cell counts	471 (326)	368 (290)	F (1,405) = 11.232, $P = 0.001$
Detectable viral load	77%	79%	χ^2 (1, n = 342) = 0.194, $P = 0.660$

IDU, intravenous drug use.

assessments for all 4 time points, 101 (38%) terminated their care at the clinic, 70 (26%) received no further assessment because of conflicting schedules or failure to appear for scheduled visits; 43 (16%) could not complete a final assessment before the study terminated; 39 (15%) died during the study period; and a few withdrew because they were too sick to continue (3 participants, 1%), objected to the personal nature of the assessment items (3 participants, 1%), or for no stated reason (7 participants, 3%).

Attrition analyses were performed to statistically determine whether any systematic attrition by study arm had occurred. Based on these analyses, there was no differential attrition by study arm noted for either of the 2 primary baseline sexual risk behaviors (unprotected vaginal, anal, and insertive oral sexual events, or vaginal and anal events), HIV transmission route, age, gender, sexual orientation, race, education, income, or housing status (all P values >0.15). Those who dropped out of the study did not differ from those who remained on any of these factors, and attrition was also consistent within the intervention and control populations. Individuals who were engaging in risky behavior at baseline were no more likely to leave the study than those who were not and were no more likely to leave the intervention than the control arm of this research.

Intervention Outcome Analyses

Analysis of intervention impact on the broad outcome measure of total number of unprotected vaginal, anal, and insertive oral sexual events revealed a significant study arm effect ($b = 0.62$, $SE = 0.24$, $P = 0.01$; intervention arm

participants reported more unprotected sexual events at baseline assessment than did standard-of-care control arm participants), modified by a significant study arm \times time interaction ($b = -0.51$, $SE = 0.15$, $P < 0.001$). Notably, as can be seen in Figure 1 and Table 2, unprotected vaginal, anal, and insertive oral sexual events decreased significantly over time among HIV-infected patients who received the clinician-delivered HIV prevention intervention ($b = -0.51$, $SE = 0.23$, $P < 0.05$). In contrast, unprotected vaginal, anal, and insertive oral sexual events increased steadily and significantly over

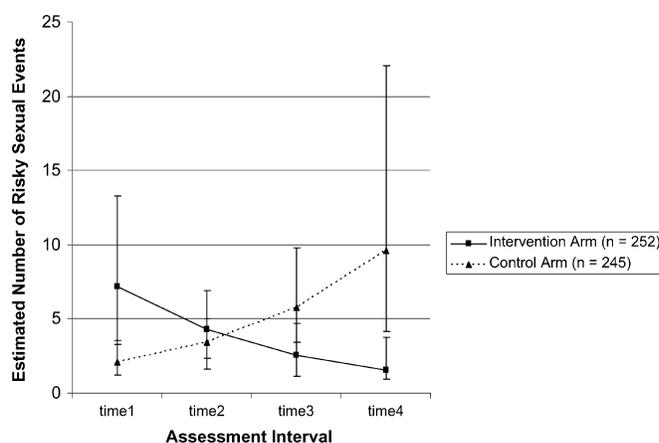


FIGURE 1. Estimated mean number of unprotected anal, vaginal, and insertive oral sexual events in intervention vs. control arms over time.

TABLE 2. Estimated Mean* Unprotected Sexual Events Within Study Arms Over Time†

Measure	Study Arm	Time 1	Time 2	Time 3	Time 4	Time by Condition	Time Effect Within Condition
Unprotected vaginal, anal, and insertive oral sexual events	Intervention	7.15 (0.31)	4.27 (0.24)	2.56 (0.31)	1.53 (0.46)	$b = -0.51, SE = 0.15, P < 0.001$	$b = -0.51, SE = 0.23, P < 0.05$
	Control	2.06 (0.28)	3.44 (0.20)	5.75 (0.27)	9.61 (0.42)		$b = 0.51, SE = 0.19, P < 0.01$
Unprotected vaginal and anal sexual events	Intervention	5.33 (0.35)	3.50 (0.28)	2.30 (0.33)	1.51 (0.47)	$b = -0.52, SE = 0.16, P = 0.002$	$b = -0.42, SE = 0.25, P = 0.09$
	Control	1.49 (0.29)	2.74 (0.20)	5.06 (0.28)	9.34 (0.45)		$b = 0.61, SE = 0.21, P < 0.01$
Unprotected vaginal, anal, and insertive oral sexual events with HIV-negative or HIV status-unknown partners	Intervention	10.56 (0.25)	8.57 (0.16)	6.96 (0.15)	5.65 (0.23)	$b = -0.22, SE = 0.09, P < 0.01$	$b = -0.20, SE = 0.13, P = 0.11$
	Control	5.66 (0.18)	7.21 (0.16)	9.19 (0.20)	11.72 (0.26)		$b = 0.24, SE = 0.12, P < 0.05$
Unprotected vaginal and anal sexual events with HIV-negative or HIV status-unknown partners	Intervention	8.20 (0.28)	7.16 (0.18)	6.24 (0.16)	5.45 (0.23)	$b = -0.21, SE = 0.09, P = 0.02$	$b = -0.14, SE = 0.13, P = 0.30$
	Control	4.52 (0.19)	6.00 (0.16)	7.97 (0.20)	10.58 (0.28)		$b = 0.28, SE = 0.13, P < 0.05$
Number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal, anal, and insertive oral sexual events	Intervention	1.78 (0.31)	1.14 (0.19)	0.72 (0.14)	0.46 (0.21)	$b = -0.27, SE = 0.16, P = 0.09$	$b = -0.44, SE = 0.25, P = 0.08$
	Control	1.18 (0.34)	1.30 (0.28)	1.43 (0.34)	1.58 (0.48)		$b = 0.10, SE = 0.20, P = 0.62$
Number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal or anal sexual events	Intervention	0.49 (0.49)	0.21 (0.25)	0.09 (0.32)	0.04 (0.60)	$b = -0.61, SE = 0.32, P = 0.06$	$b = -0.87, SE = 0.58, P = 0.14$
	Control	0.31 (0.58)	0.44 (0.38)	0.63 (0.47)	0.90 (0.75)		$b = 0.36, SE = 0.27, P = 0.19$

*Data derived from GEE models (see "Methods").

†Time points separated by an average 7.9 months.

time for HIV-infected patients in the standard-of-care control arm of this research ($b = 0.51, SE = 0.19, P < 0.01$). Note that this interaction remains significant when these analyses are performed separately for male ($P = 0.002$) and female ($P = 0.04$) patients. Means displayed in Figure 1 and Table 2 are predicted group means from the GEE analysis, with missing observations estimated via the all-possible-pairs method associated with PROC GENMOD. Trimming outliers from the control group at the final wave of measurement did not change the significance of this interaction effect.

We repeated this intervention outcome analysis with our more conservative measure, focusing on unprotected vaginal and anal sexual events only. Number of unprotected vaginal and anal sexual events showed a significant effect of study arm ($b = 0.64, SE = 0.28, P < 0.05$), similar to the study arm effect reported for the broader measure, and a significant study arm \times time interaction ($b = -0.52, SE = 0.16, P = 0.002$). This interaction indicates a marginally significant reduction in unprotected vaginal and anal sex among intervention arm patients over time ($b = -0.42, SE = 0.25, P = 0.09$) and a significant increase in unprotected vaginal and anal sex among standard-of-care control arm patients ($b = 0.61, SE = 0.21, P < 0.01$). As can be seen in Table 2, unprotected vaginal and anal sexual events for HIV-infected intervention arm patients decreased steadily over the study period. In contrast, HIV-infected control arm participants showed steady increases in unprotected vaginal and anal sex over the study interval.

In additional, exploratory analyses, we examined intervention impact on number of unprotected sexual events reported with partners who were perceived to be HIV negative or HIV status unknown. For number of unprotected vaginal, anal, and oral insertive sexual events with partners perceived to be HIV negative or HIV status unknown, there was a significant study arm effect ($b = 0.31, SE = 0.15, P = 0.04$), similar to that reported for the broad measure reported earlier, and a significant study arm \times time interaction ($b = -0.22, SE = 0.09, P = 0.01$). The study arm \times time interaction indicates that HIV-positive intervention arm patients tended to reduce their number of unprotected vaginal, anal, and insertive oral sexual events with HIV-negative or HIV status-unknown partners over time ($b = -0.20, SE = 0.13, P = 0.11$). Conversely, standard-of-care control arm patients significantly increased unprotected vaginal, anal, and insertive oral sexual events with partners perceived to be HIV negative or HIV status unknown over the study interval ($b = 0.24, SE = 0.12, P < 0.05$) (Table 2). When conducting this analysis for the number of unprotected vaginal and anal sexual events only, with partners thought to be HIV negative or HIV status unknown, there was a marginal effect of study arm ($b = 0.30, SE = 0.16, P < 0.07$) and a significant study arm \times time interaction ($b = -0.21, SE = 0.09, P = 0.02$). The pattern of this interaction indicated a nonsignificant trend for reduction in unprotected vaginal and anal sex among intervention arm patients with partners perceived to be HIV negative or unknown ($b = -0.14, SE = 0.13, P = 0.30$) and a significant increase in unprotected vaginal and anal sex

among standard-of-care control arm patients with partners perceived to be HIV negative or HIV status unknown ($b = 0.28$, $SE = 0.13$, $P < 0.05$) (Table 2).

Exploratory analysis of the number of partners perceived to be HIV negative or HIV status unknown with whom the patient was involved in unprotected vaginal, anal, and insertive oral sexual events did not show a study arm effect ($b = 0.21$, $SE = 0.16$, $P = 0.38$) but did reveal a marginal study arm \times time interaction ($b = -0.27$, $SE = 0.16$, $P = 0.09$). The study arm \times time interaction indicates a nonsignificant trend for intervention patients to decrease the number of HIV-negative and HIV status-unknown partners with whom they were involved in unprotected vaginal, anal, and insertive oral sexual events over time ($b = -0.44$, $SE = 0.25$, $P = 0.08$). In contrast, there was no change in the number of HIV-negative or HIV status-unknown partners involved in this type of event reported by patients in the standard-of-care control condition ($b = 0.10$, $SE = 0.20$, $P = 0.62$). For number of HIV-negative or status-unknown partners with whom the patient was involved in unprotected vaginal or anal sex only, no study arm effect was observed ($b = 0.23$, $SE = 0.36$, $P = 0.53$), although there was a trend for a study arm \times time interaction ($b = -0.61$, $SE = 0.32$, $P = 0.06$). Whereas neither the intervention nor the standard-of-care control arm participants demonstrated significant change in the number of HIV-negative or status-unknown partners with whom they were involved in unprotected vaginal or anal sex events over time ($b = -0.87$, $SE = 0.58$, $P = 0.14$ and $b = 0.36$, $SE = 0.27$, $P = 0.19$, respectively), the direction of these effects (Table 2) was consistent with those described above. Intervention arm participants tended to reduce the number of HIV-negative and HIV status-unknown partners with whom they had unprotected vaginal or anal sex, whereas control arm participants tended to increase the number of HIV-negative and HIV status-unknown partners with whom they had unprotected vaginal or anal sex.

DISCUSSION

The current findings are among the first to demonstrate that a clinician-delivered HIV prevention intervention, implemented during the course of routine clinical care, can be effective in reducing a broad measure of HIV-infected patients' unprotected vaginal, anal, and insertive oral sexual behavior. The pattern of results reported for a more conservative and rigorous measure, involving unprotected vaginal and anal intercourse only, showed a similar trend toward a reduction in unprotected sex for HIV-positive patients in the intervention arm of this study. The current research also demonstrates that this clinician-delivered intervention approach is both feasible to implement and acceptable to patients. Numerous HIV care clinicians were readily trained in the intervention protocol, which is brief to deliver (5–10 minutes) and which was successfully implemented during the majority of patients' routine clinical visits in a high-volume, inner city HIV care setting. (For further information about the intervention development, clinician training, and intervention implementation, see Fisher et al.⁴²)

The clinician-delivered intervention under study resulted in a significant reduction in total unprotected vaginal,

anal, and insertive oral sexual events reported by HIV-positive patients and a trend for reductions in a more conservative outcome measure of unprotected vaginal and anal sexual events only. In contrast, standard-of-care control patients showed significant increase in unprotected sexual behavior, whether defined both broadly (unprotected vaginal, anal, and insertive oral events) or conservatively (unprotected vaginal and anal sexual events). Primary analyses thus demonstrated a consistent pattern of results in which intervention participants decreased unprotected sexual events and standard-of-care control participants increased unprotected sexual activity. An identical pattern of results appeared in each of our exploratory analyses of intervention outcome. Examination of reported outcome measure means (Table 2) shows a consistent pattern of reduced unprotected sex for intervention participants and increased unprotected sex for standard-of-care controls that is repeated for each outcome measure assessed: unprotected vaginal, anal, and insertive oral sex for all partners; unprotected vaginal and anal sex for all partners; unprotected vaginal, anal, and insertive oral sex with partners perceived to be HIV negative or HIV status unknown; unprotected vaginal and anal sex with partners perceived to be HIV negative or HIV status unknown; number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal, anal, or insertive oral sex; and number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal and anal sex.

Although we believe our finding for an intervention-induced reduction in total unprotected vaginal, anal, and insertive oral sex events is of both statistical and clinical significance (the mean of such unprotected events declined from an estimated 7.5 per HIV-positive patient at baseline to an estimated 1.5 such unprotected events per patient at follow-up), we have no ready explanation for why statistical significance of intervention effects was inconsistent for the remaining outcome measures, other than to speculate that this is potentially an artifact reflecting a lack of power or large standard errors due to the variability of risk in the sample. Future research replicating this type of clinician-delivered intervention over time, exploring new types of interventions that can be implemented by other types of clinicians (eg, nurses, social workers), and directly assessing reasons for increases in unprotected sexual behavior among HIV-positive persons not in such interventions, is needed to strengthen our understanding of intervention impact and of the natural history of safer sexual behavior.

With the welcome success of antiretroviral therapy, there is a growing cohort of relatively healthy and long-lived HIV-infected persons who are nonetheless capable of transmitting both sensitive and antiretroviral-resistant virus to uninfected others.^{7,13,30,56,57} At the same time, there is a paucity of empirically validated strategies for assisting HIV-infected persons to maintain safer sexual behavior and a lack of identified delivery channels that could effectively reach large numbers of HIV-infected persons.^{12,17–19} The only published study to date involving safer sex interventions for HIV-infected patients in a clinical care setting¹⁹ found that counseling by providers emphasizing the negative effects of unsafe sex can reduce unprotected sexual behavior in patients with high levels of risk

behavior. Taken together, the current and the existing study suggest the value of incorporating HIV prevention elements into routine clinical interactions between HIV-infected patients and providers. Because the clinical care setting provides the most universal access possible to HIV-infected persons and offers repeated opportunities for clinician–patient HIV prevention interactions,^{13,14} it appears to be both desirable and potentially effective to integrate HIV care and HIV prevention. The finding that HIV-infected persons in our standard-of-care control setting significantly *increased* their unprotected sexual behavior across time is consistent with recent observations of increases in unprotected sexual behavior^{58–61} and so-called safer sex fatigue among HIV-positive individuals,⁶² and underscores the cost of failing to intervene and the urgency of linking HIV prevention with HIV care on a broad basis.

Limitations of the current research include the use of a limited number of clinical settings, a relatively small sample size, reliance on self-reports of unprotected sexual behavior, and characteristics of quasi-experimental research approaches. Systematic efforts were made to address and minimize each of these potential limitations. Specifically, clinical sites for the current research were chosen on the basis of their broad representativeness of high-volume, inner city HIV clinical care settings. Assessments of sexual behavior were computer based and completely confidential, and patients were directly assured that their clinical care providers would never see reports of their sexual behavior. A considerable literature, moreover, attests to the validity of reports of safer and unprotected sexual behavior.^{63–66} Finally, we note that the quasi-experimental approach we adopted, deemed most appropriate to this research, resulted, as is often the case, in instances of initial non-equivalence between control and intervention research arms. Statistical tests to detect effects of such initial inequivalence clearly indicate that there was no differential effect on intervention outcome of any of the factors on which intervention and control arms initially differed, including Hispanic/Latino ethnicity or gender, age, income, being on welfare, education, sexual orientation, CD4 count, detectability of viral load, or being on highly active antiretroviral therapy. Moreover, concerns about initial nonequivalence on risk behavior are greatly lessened by the crossover interaction pattern consistently observed in our results across 4 waves of assessment and on several outcome variables.

Overall, it appears that our clinician-delivered HIV prevention intervention targeting HIV-infected patients has potential to reduce unprotected sexual behavior in this population and that consideration should be given to incorporating this type of intervention into clinical care. There has recently been a widespread call for the integration of prevention and clinical care,^{13,14} and our work has demonstrated that such an approach can be both feasible and effective (see also Richardson et al¹⁹). Nonetheless, we recognize the importance of conducting additional research on the development and validation of means for promoting HIV prevention among HIV-infected individuals both within and outside of the clinical care setting. This research could ultimately involve large, randomized clinical trials including additional clinical sites and biologic outcomes, now that initial work has shown that this approach has promise.

ACKNOWLEDGMENTS

The authors acknowledge with thanks the assistance of Jack Ross, MD, in conducting this research, and the extremely helpful comments of Frederick Altice, MD, and an anonymous reviewer, concerning earlier drafts of this manuscript.

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HIV Drug Resistance and HIV Transmission Risk Behaviors Among Active Injection Drug Users

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Summary: HIV⁺ injection drug users in clinical care may harbor and transmit drug-resistant HIV. We performed a retrospective study of HIV drug resistance and risk behavior among HIV⁺ injection drug users in care to determine the number of needle-sharing events that involved and the proportion of sharing partners exposed to drug-resistant HIV. Among 180 HIV⁺ injection drug users, 55 (31%) reported injecting drugs in the previous month, and 22 of these (40%) shared needles and/or works 148 times with 296 partners, of whom 271 (92%) were thought to be HIV⁻ or status unknown. Further, 55 (31%) drug users harbored resistant HIV, including 5 (3% of total) who also shared needles and/or works a total of 27 times with 44 partners (18% of all sharing events and 15% of all exposed partners). A small proportion of injection drug users receiving clinical care engage in injection risk behavior and carry resistant HIV; however, because of multiple partners and needle-sharing events, they expose a substantial number of individuals to drug-resistant HIV. Strategies to reduce injection drug use risk behaviors among patients in clinical care are needed to reduce the transmission of sensitive and resistant HIV.

Key Words: HIV risk behavior, injection drug use, HIV drug resistance

(*J Acquir Immune Defic Syndr* 2005;40:106–109)

The HIV epidemic remains volatile, with rising rates of drug resistance and continuing transmission risk behavior resulting in significant public health and clinical consequences.^{1–4} Previous studies have documented that HIV⁺ injection drug users who are aware of their HIV diagnosis may still share injection drug needles and/or works.^{5–15} These patients have the potential to harbor and transmit drug-resistant HIV. Most extant studies of injection drug use HIV transmission risk behavior in patients in care have been limited

and have not examined the number of needle-sharing events that involve HIV drug-resistant strains, nor have they provided information about the number and perceived HIV serostatus of sharing partners.

To improve our understanding of the characteristics and relation between injection drug risk behavior and drug resistance, we performed a cross-sectional study to determine the prevalence of HIV drug resistance in HIV⁺ injection drug users receiving clinical care, the frequency with which they shared needles and/or works, and the number and perceived serostatus of needle-sharing partners they exposed to drug-resistant HIV. This information is important in estimating the likelihood of transmission of resistant HIV in this population and providing essential information for prevention strategies.

METHODS

Participants

Patients who were enrolled in the Options Project study, a longitudinal study of HIV transmission risk in HIV⁺ patients in clinical care, were recruited from 2 large HIV clinical care sites in Connecticut from 2000 to 2002.¹⁵ Inclusion criteria for the Options Project study and the resistance substudy were being at least 18 years old, healthy enough to complete the procedures, and free from obvious signs of dementia. All 497 Options Project–enrolled patients were offered participation in the resistance substudy, which involved agreeing to have a resistance test performed on archived plasma samples. All participants provided written informed consent. The study was approved by the Institutional Review Boards at the University of Connecticut and Hartford Hospital and by the Human Investigations Committee at Yale University.

Injection Drug Use

Information for this cross-sectional analysis was collected on general demographics, transmission risk categories, and risk behavior specific to injection drug use behavior over the previous month. Participants completed a risk behavior survey via a computer-administered self-interview with audio (ACASI) administered in English or Spanish at a private location within the clinic. The following definitions were used. Active injection drug use was defined as having injected drugs in the previous 1-month period. Injection drug use HIV transmission risk behavior was defined as the sharing of injection needles and equipment without cleaning them first with bleach. A set of assessment items addressed these types of risk behavior. Patients reporting sharing needles or equipment in

Received for publication October 18, 2004; accepted February 7, 2005.

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J. Fisher is supported by National Institute of Mental Health grant 1R01 MH59473-02, and M. J. Kozal is supported by a Veterans Administration Career Development Award.

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the last month on any of the assessment items were classified as engaging in risk behavior. High-risk injection drug use HIV transmission behavior was defined as risk behavior with partners believed by the subject to be HIV⁻ or of unknown status.

Laboratory and Resistance Testing

Antiretroviral treatment history, HIV viral loads (VLs), and CD4 cell counts were extracted from patients' medical records. Plasma was collected for VL determinations and genotypic resistance testing within the period covered by the behavioral survey. HIV genotypic resistance tests were performed if the VL was >400 HIV RNA copies/mL. Patients with a nondetectable VL (<400 HIV RNA copies/mL) did not have a resistance test performed and are listed separately in the analyses. Standard DNA sequencing (ABI) was used to detect HIV genotypic resistance using consensus population sequencing of the HIV-1 *pol* gene.¹⁶ A resistance mutation was defined as a major mutation causing resistance using the definitions of the International AIDS Society 2003.¹⁷ Neither secondary mutations nor polymorphisms (eg, reverse transcriptase polymorphism V118I) listed for reverse transcriptase or protease inhibitors were included. Resistance patterns, CD4 cell counts, HIV VLs, and behavioral data were merged by coded identifier.

Data Analysis

HIV⁺ injection drug use and high-risk behavior across the sample and specific to those with resistance were explored descriptively, and where sufficient group sizes permitted, we assessed the degree to which any of the patient characteristics differed between active injection drug users who shared needles and/or works in the last month versus those who did not share. Patients engaging in needle-sharing behavior were characterized in terms of demography, clinical parameters, HIV drug resistance, and the prevalence and amount of various types of needle-sharing behavior over the preceding 1-month period. All data were analyzed using SPSS, version 11.0.1 (SPSS, Chicago, IL).¹⁸

RESULTS

Patient Characteristics

Four hundred four of the 497 Options Project-enrolled patients (81%) consented and enrolled in the Options Project resistance substudy, 180 (45%) of whom had a history of injection drug use. Of these 180 participants, 63 (35%) were female, 149 (83%) were heterosexual, 15 (8%) were of same-sex orientation, 16 (9%) were bisexual, 70 (39%) were African American, and 56 (31%) were Latino. Most patients (79%) had an annual income less than \$10,000, and only 16% had some college education. The demographic, health functioning, and risk values obtained from the current sample did not differ markedly from the values generated from the entire Options Project parent study sample.

Injection Drug Use Transmission Risk Behavior and HIV Drug Resistance

Of the 180 HIV⁺ patients with a history of injecting drugs, 55 (31%) were engaged in active drug use (injected

drugs in the last month). For the nonactive injection drug users, 13 (7%) reported injecting drugs within the last 2 to 6 months, 18 (10%) injected drugs in the last 6 to 12 months, and 94 (52%) had not injected drugs for >12 months. There were no significant demographic differences between those who were and were not engaged in active drug use. Heroin was the most common drug injected (80%), followed by cocaine (51%), speedball (heroin plus cocaine, 43%), and other drugs (12%). Overall, 18 (33%) of the 55 HIV⁺ active injection drug users had a nondetectable HIV VL, with the remaining 37 active users having a mean VL of 67,069 HIV RNA copies/mL (median = 19,713 HIV RNA copies/mL; range: 1387–750,000 HIV RNA copies/mL). Thirty-five (64%) were receiving highly active antiretroviral therapy, and 18 (33%) of the 55 active injection drug users had HIV drug resistance.

With respect to injection drug use HIV transmission risk behavior, 22 (40%) of the 55 active injection drug users (40%) reported sharing needles and/or equipment in the previous month. The only significant difference between active injection drug users who did and did not engage in needle sharing was gender. A higher proportion of female active users reported sharing (67%) in comparison to active male injection drug users (30%) ($P = 0.013$). Those with and without injection drug use HIV transmission behavior were similar across all other demographic characteristics and Short Form 12 (SF12) mental and physical functioning scores. Of the 22 sharers, 16 (73%) had a detectable HIV VL (mean = 41,204 HIV RNA copies/mL, median = 35,318 HIV RNA copies/mL) and only 8 (36%) stated that they were currently taking antiretroviral therapy. Active injection drug users who shared did not differ substantially from those who did not report sharing over the last month with respect to the proportion with nondetectable VLs (27% vs. 36%, respectively; $P =$ not significant).

Five (23%) of the 22 HIV⁺ active users who shared had drug-resistant HIV. The number of patients engaging in risk, number of risk events, and high-risk events involving resistant variants and number of partners exposed to drug-resistant HIV can be found in Table 1. Briefly, the 22 HIV⁺ active drug users who were engaged in HIV transmission behavior reported sharing needles and/or works 148 times with 296 with partners, of whom 271 (92%) were believed to be HIV⁻ ($n = 138$) or status unknown ($n = 133$) and thereby were exposed to high-risk injection drug use transmission behavior. For these 22 sharers, the median number of sharing events in the prior month was 3.5 (range: 1–56 events), exposing a median of 1 partner (range: 1–170 partners). Of the 296 partners, 44 (15%) were exposed by the 5 patients with drug-resistant HIV during 27 sharing events (18% of total events). For these 5 patients with resistance and risk, the median number of sharing events in the prior month was 3 (range: 1–16 events), exposing a median of 2 partners (range: 1–25 partners). Note that the number of partners can be larger than the number of events, given that a patient can have multiple sharing partners during a sharing episode. Seven (32%) of the 22 sharers reported injecting at “shooting galleries” in the last month. With only 5 sharers with resistance and 17 sharers without resistance in the current sample, reliable comparisons of patient characteristics between these 2 groups were not possible.

TABLE 1. Active HIV⁺ Injection Drug–Using Patients Who Shared Needles and Equipment (N = 22), Injection Drug Use HIV Transmission Risk Events, and Partners Exposed in a 1-Month Period

Active HIV ⁺ IDU Patients* Who Shared Needles and/or Works (N = 22)	Total IDU Transmission Sharing Events† (N = 148)	High-Risk‡ Transmission Sharing Events† (N = 109)	Total Partners Exposed† (N = 296)	High-Risk‡ Partners Exposed† (N = 271)
HIV drug resistant (n = 5)	27 (18%)	19 (17%)	44 (15%)	36 (13%)
HIV genotype wild type§ (n = 11)	57 (39%)	29 (27%)	77 (26%)	65 (24%)
HIV viral load non-detectable (n = 6)	64 (43%)	61 (56%)	175 (59%)	170 (63%)

*Active injection drug use (IDU) was defined as having injected drugs in the previous 1-month period.

†IDU HIV transmission risk behavior was defined as reports of sharing injection needles or equipment on any of a set of items targeting IDU sharing behaviors. Patients were given a range of sharing event possibilities to select from; for example, if “11–15 times” was chosen, the median value (eg, 13) was recorded for that patient. Patients reporting sharing in the last 1-month period were assigned a minimum value of 1 for events and partner totals. These values were summed for patients in each category to give the total events and partners.

‡High-risk injection drug use HIV transmission behavior was defined as risk behavior with partners believed by the subject to be HIV⁺ or of unknown status.

§Wild-type HIV, no drug resistance mutations detected.

DISCUSSION

This study provides a description of needle-sharing behavior among HIV⁺ injection drug users who have drug-resistant HIV, the number of needle and/or equipment sharing risk events that involve drug-resistant strains, and the number and perceived HIV serostatus of needle-sharing partners. The results indicate that a small proportion of active injection drug users in clinical care carry resistant HIV and engage in injection drug use HIV transmission risk behavior; however, because of multiple event-related sharing partners, this small number can expose a substantial number of partners during unsafe needle and/or works sharing events.

Continued sharing of injection drug paraphernalia has been shown previously to be common among HIV⁺ injection drug users, ranging anywhere from 13% to 66%.^{5,6,13} Our findings are within this range (40%) and extend this observation to HIV⁺ injection drug users with drug-resistant strains seen in the clinical care setting. Recently, Sethi and colleagues¹⁴ evaluated HIV⁺ injection drug users who were at higher risk for HIV transmission and found that those who engaged in risk had drug-resistant HIV at 14% of the study visits. Our study expands on this important finding by describing the number of injection drug use risk events that involve drug-sensitive and drug-resistant strains and provides information about the number and perceived HIV serostatus of the exposed needle-sharing partners. Taken individually and collectively, this information provides a more complete picture of HIV drug resistance transmission risk in this population. Of particular note is the finding that the number of partners exposed to sensitive and resistant HIV can be substantially larger than the number of events, given that a patient can have multiple sharing partners during each sharing episode.

Subjects who engage in injection drug use can have considerable variability in the number of times they inject in a month. A large national survey of 10,000 injection drug users demonstrated that there was considerable variation among cities in the mean number of times an injection drug user injected per month, ranging from a high of 253 injections per month (~8 injections per day) to a low of 19 injections per month (~1 per day).¹⁹ The differences in injection rates were associated with ethnicity, type of drug injected (eg, heroin

users ~101 times per month, speedball users ~133 times per month), and years of experience.¹⁹ In our study, the patients who shared averaged ~5.8 sharing events per month, which is likely a small fraction of the total injection events that they engaged in per month. Among the 22 patients who reported sharing, 7 (32%) answered that they injected at “shooting galleries” in the last month, a practice that would place them at high risk for having many partners. It should be noted that needle and/or equipment sharing encompasses not only sharing needles but cooker sharing, backloading, front loading, rinse water sharing, filter sharing, and sharing syringe parts to mix drugs with water.¹⁹

The risk of transmission of drug-resistant HIV to newly infected patients is of great concern because it can affect treatment responses and clinical outcome.^{3,4} In addition, there is a risk of possible superinfection with resistant strains among those sharing with partners who may be HIV⁺.^{20–22} Thus, the continued HIV transmission risk behavior described in this report poses substantial risk for the HIV⁺ patient in clinical care as well as his or her partners. Additionally, 10 of the 22 sharers engaged in 262 unprotected sex events with 17 partners in a 3-month period, compounding the risk of transmission.²³ It is important to note that although we focused this report on the risk of transmission of resistant HIV, substantial and, indeed, greater risk of transmission of nonresistant HIV was characterized as well in this population.

A limitation of this study is our inability to perform HIV counseling and testing among the exposed partners of the patients to determine the actual rate of transmission of resistant virus. The study design provided strict confidentiality to the patients to facilitate full disclosure of their injection drug use risk behaviors. In addition, although specimens were obtained at the time of the behavioral survey, the analysis of resistance was not performed in real time but in batches well after the reported behavior took place as a designed retrospective analysis to determine the prevalence of drug resistance and not for clinical use. Patients were likely unaware that they were exposing partners to resistant strains. Indeed, only a few patients who shared could report their VL status. In this study, we used strict criteria for an active user (use within previous

month) so that we could ensure the HIV drug resistance information obtained was within the window of the sharing events. To obtain detailed behavioral and virologic information on active users is a challenge. Thus, although the sample size of 55 active users with 22 (40%) reporting sharing in the last month may seem small, the results demonstrate that the risk of transmission of drug-resistant strains, even from this small proportion of injection drug users in clinical care, is substantial. Further, our results likely underestimate the overall risk, because the study was cross-sectional, it only evaluated events during a 1-month time frame, and many patients with HIV drug resistance and injection drug use history relapse into drug use over time. Despite these limitations, this study is among the first to provide data linking risk behavior and drug resistance among injection drug users with HIV disease.

In conclusion, a small number of active injection drug users carry drug-resistant HIV and engage in risk behavior; however, because of multiple event-related sharing partners, they expose a substantial number of partners during unsafe needle and/or works sharing events. HIV⁺ injection drug users in clinical care are accessible for and should receive targeted prevention efforts within the care setting, a strategy now advocated as central to national HIV prevention efforts.^{1,2,24,25} In addition, treatment of ongoing drug use²⁶ and provision of sterile needles and paraphernalia²⁷ have been shown to decrease HIV transmission among injection drug users and would likely contribute to the reduction of transmission of resistant HIV in this population and their at-risk partners.

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Antiretroviral resistance and high-risk transmission behavior among HIV-positive patients in clinical care

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Background: HIV-positive patients receiving antiretroviral therapy (ART) who engage in HIV transmission behaviors may harbor and transmit drug-resistant HIV. However, little is known about the risk behaviors of these patients, potential partners exposed and the relationship of these to ART resistance.

Objective: To determine the relationship of HIV drug resistance and continuing HIV transmission risk behavior among HIV-positive patients in care.

Methods: A retrospective, cross-sectional study of HIV transmission risk behavior and HIV drug resistance data from 333 HIV-positive patients.

Results: Among a diverse population of 333 HIV-positive patients, 75 (23%) had unprotected sex during the previous 3-months, resulting in 1126 unprotected sexual events with 191 partners of whom 155 were believed by patients to be HIV-negative or of unknown status. Eighteen of the 75 (24%) had resistant HIV and 207 unprotected sexual events, exposing 18% of the HIV- or status unknown partners. There was no difference in the proportion of patients engaging in unprotected sex who had undetectable viral load (VL) (22%): VL > 400 copies/ml without resistance (20%) and VL > 400copies/ml with resistance (26%). Resistance and risk behavior was predicted only by lower mental health scores (odds ratio, 10.3; 95% confidence interval, 1.7–18.6).

Conclusion: A substantial minority (23%) of patients in clinical care engaged in HIV sexual transmission risk behavior. A small subset of these also had ART-resistant HIV. However, this core group (approximately 5% of all patients) accounted for a large number of high-risk HIV transmission events with resistant virus, exposing a substantial number of partners.

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AIDS 2004, **18**:2185–2189

Keywords: HIV drug resistance, HIV transmission risk behaviour

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Note: This study was presented at the XII International HIV Drug Resistance Workshop, Los Cabos, Mexico, 13 June 2003.

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Received: 4 March 2004; revised: 2 July 2004; accepted: 3 August 2004.

Introduction

The prevalence of antiretroviral (ART)-resistant HIV in newly acquired infections in North America and Europe is estimated to range from 8 to 26% [1–11]. Patients receiving ART in clinical care who carry resistant virus and engage in high-risk sexual HIV transmission risk behaviors (unprotected sex with HIV-negative persons), are likely to be a major source of new resistant infections. Little is known about these patients, the dynamics of their risk behaviors, partners exposed and the relationship of these to ART resistance. A better understanding of the dynamics of risk behavior and drug resistance among patients in clinical care is essential for the development of targeted prevention strategies to reduce transmission of both sensitive and resistant HIV.

To address this issue, we performed a study of ART resistance, risk behavior and the relationship of resistance and transmission risk in patients with HIV who are being followed in clinical care.

Methods

Participants

Patients who were already enrolled in the Options Project study, an ongoing longitudinal study of HIV transmission risk in HIV-positive patients in care, were recruited from two HIV clinics in Connecticut. The inclusion criteria for the ART resistance sub-study were: written informed consent, at least 18 years old, and healthy enough to complete the procedures. The study was approved by the Human Investigations Committees at the University of Connecticut, Hartford Hospital and Yale University.

Behavioral survey

At baseline before any behavioral intervention, participants completed the Assessment of HIV+ Risk Behavior (AHRB) survey. AHRB is a computer-administered self-interview with audio (ACASI) administered via laptop computers in private locations within the clinic setting. AHRB assessed for demographics, transmission risk categories, the constructs of the Information-Motivation-Behavioral Skills model [12–14], mental and physical health functioning measured by the SF-12 [15], and sexual risk behavior over the last 3-months.

The following definitions were used.

No or low-risk sexual HIV transmission behavior: either no reported sexual events or 100% condom use.

Sexual HIV transmission risk behavior: unprotected sexual events (penile–vaginal and penile–anal for females and

penile–vaginal, penile–anal and insertive penile–oral sex for men) with all partners (oral sex was restricted to partners considered to be HIV-negative or status unknown).

High-risk sexual HIV transmission behavior: transmission risk behavior with a partner believed by the subject to be HIV-negative or whose status was unknown.

Laboratory and resistance testing

HIV viral load (VL), treatment history, and CD4 cell counts were extracted from patients' medical records. HIV genotypic resistance tests were performed if the VL was > 400 HIV RNA copies/ml. The parent study did not require a plasma sample to be drawn at the time of the risk behavior interviews. Thus, we included only patients with a plasma sample available within a 3-month window of the risk survey.

Standard DNA sequencing of the HIV-1 *pol* gene was used to detect HIV genotypic resistance (ABI, Applied Biosystems, Foster City, CA, USA) [16]. A resistance mutation was defined utilizing the definitions of the International AIDS Society (2002) [17]. Resistance and baseline behavioral data were merged by coded identifier.

Data analysis

Data was analyzed using SPSS version 11.0.1 (SPSS, Inc., Chicago, Illinois, USA). ART-resistant individuals were characterized by demography, physical and mental health functioning, and the prevalence and amount of various types of risk over the preceding 3-month period. These characteristics were compared between those with and without resistant HIV, by univariate analyses using *t*-tests for continuous and chi-square tests for categorical variables. Differences were considered significant at the 0.05 or less level. Those variables that demonstrated significant univariate relations were then used in a multivariate logistic model [18] assessing the presence or absence of resistance, with associated odds ratios for each variable assessed. Sexual HIV transmission risk for the entire sample and for those with ART-resistant HIV was descriptively explored. The same strategy was used within the group of participants with resistant HIV, with and without reported risk behavior.

Results

Patient characteristics

There were 497 patients in the parent Options Project study, 404 of whom consented to the resistance sub-study. Seventy patients who agreed to the sub-study did not have a plasma sample available within the frame for resistance testing and thus were not included. These

patients did not differ from the patients included in the analysis in respect to demography, clinical parameters and risk behavior. Of the 334 patients with a VL and a behavioral survey result 46% were female, 79% heterosexual, 40% African American, 33% Latino and 73% reported being on ART at the time of the survey. Heterosexual sex was reported by 47%, injection drug use by 41%, male-to-male sex by 9% and 3% reported blood transfusion as their mode of HIV acquisition.

ART resistance and sexual HIV transmission risk behavior

Overall, 53% (178 of 334) of the participants had an HIV VL > 400 copies/ml. Of the 178 patients with a detectable VL, 121 (68%) were on ART. Twenty-seven percent (89 of 334) of the entire sample had ART resistance. Most patients had resistance to a single class of antiretrovirals (54%), whereas 36% were resistant to two classes, and 10% to three classes.

Of the 334 participants, 333 provided complete responses to the baseline sexual risk behavior survey and 170 (51%) of these patients had engaged in any sexual activity in the previous 3-months. Of these, 49% (164 of 333) engaged in penetrative penile–vaginal or penile–

anal sex. Twenty-three percent of patients (75 of 333 patients) engaged in sexual risk behavior, reporting one or more unprotected vaginal, anal or oral sex event over the preceding 3 months. There was no difference in proportion of patients engaging in unprotected sex between those with and without detectable VLs (23 versus 22%, *P* = 0.77). Further, a similar proportion of patients with a non-detectable VL (34 of 156 = 22%), a VL > 400 copies/ml without ART resistance (23 of 88 = 26%) and with ART resistance (18 of 89 = 20%) engaged in unprotected sex, *P* = 0.614.

The 75 patients engaging in sexual risk behavior reported a total of 1126 unprotected sexual events in the prior 3 months involving a minimum of 191 partners (Fig. 1). Eighteen of the 75 (24%) patients engaging in unprotected sex had ART-resistant virus. These 18 patients with ART resistance and sexual risk behavior had a mean CD4 T-cell count of 325×10^6 cells/l (SD, ± 159) with a mean VL of 88 286 copies/ml (SD, $\pm 177 226$). Eighteen percent of all reported unprotected sexual risk events (207 of 1126) were by patients who had resistant virus. Of the 207 reported unprotected events 166 (80%) involved unprotected vaginal or anal sex. Finally, these patients

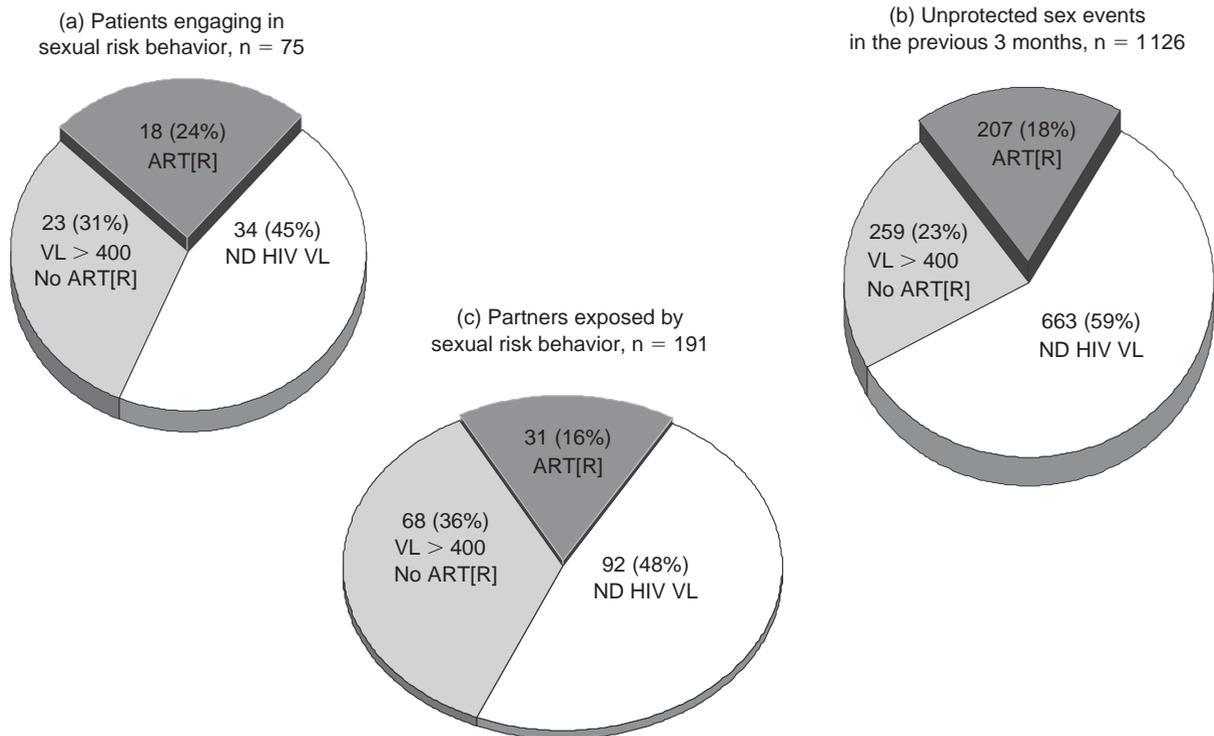


Fig. 1. HIV-positive patients in clinical care with non-detectable and detectable HIV viral load (VL) and with and without antiretroviral therapy (ART) resistance engaging in HIV sexual transmission risk behavior: number and percentage of high-risk transmission events and number and percentage of partners exposed. (a), The number and proportion of patients engaging in risk behavior; (b), the number and proportion of unprotected events; and (c), the number and proportion of partners exposed. The number and proportion of patients, events involving and partners exposed to ART-resistant [R] HIV strains are shaded darker gray. ND, non-detectable.

reported having unprotected sexual events with 16% of all partners engaging in unprotected sex (Fig. 1).

With regard to partner HIV status, in a 3-month period 48 patients (14%) reported engaging in 703 high-risk sexual events with a total of 155 HIV-negative or status-unknown partners. Among these 48 patients, 15 (31%) had resistant HIV. These 15 patients had 149 unprotected high-risk sexual events and exposed 28 HIV-negative or status-unknown partners. Thus overall 4.5% of patients (15 of 333) had ART resistance and also engaged in high-risk sexual behavior.

Characteristics of patients with ART resistance with and without sexual HIV transmission risk behavior

The patients with resistant HIV with and without risk behavior were compared by demographics, physical and mental health functioning, and clinical parameters. There were no differences by gender, ethnicity, stability of housing, years of being HIV-positive, mean CD4 cell counts, or VL. However, those with resistance reporting sexual risk were younger (40.11 versus 44.21 years, respectively; $P=0.036$) and reported higher average levels of education (1.22 versus 0.73, respectively; $P=0.07$; 1 = a high school education). Bisexual orientation was more common in the group with resistance and high-risk behavior (22 versus 1.4%, $P=0.001$), although the number of patients with this characteristic was small. Finally, participants with resistance and sexual risk scored significantly lower on mental health functioning on the SF-12 than non-risk resistant participants ($P=0.008$). Relevant variables were entered into a multivariate logistic regression model (age, mental health scores, sexual orientation, educational attainment, and yearly income). Only mental health functioning appeared as an independent predictor of sexual risk behavior (odds ratio, -10.34 ; 95% confidence interval, -18.20 to -1.72 ; $P=0.02$). Thus, for each unit decrease in mental health functioning, the odds of being classified in the resistant virus with HIV transmission group increased 10-fold.

Discussion

This study provides one of the first descriptions of sexual HIV transmission risk behaviors among HIV-positive patients in care, with both antiretroviral sensitive and resistant virus. The results indicate that there is substantial opportunity for transmission of both sensitive and resistant HIV to at-risk partners from patients in care. Among these HIV-positive patients 23% engaged in unprotected sexual risk behavior during the previous 3 months, with the total number of unprotected sexual events exceeding 1000. Further, a substantial proportion of these events were with partners

who were thought by the subjects to be HIV-negative or of unknown HIV status. When the resistance and behavioral risk data was linked, 24% of patients who engaged in unprotected sex did so with resistant virus. Thus, patients who had both resistance and engaged in high-risk sexual behaviors represented only a small proportion of the entire study population (approximately 5%). Although this proportion is small, the total number of potential transmission events and partners at risk of acquisition of resistant HIV is quite substantial. This study also offers insight into the characteristics of patients with antiretroviral resistance reporting sexual risk behaviors. When assessed in a multivariate model the only independent predictor of risk behavior was lower mental health functioning. Thus, of those variables that might differentiate these patients from others and thus direct prevention efforts, lower mental health functioning, probably in the form of depression, appears to be of special importance. Recent studies have also demonstrated that ongoing risk behavior may be linked with other behaviors or conditions. Researchers have found an association between risk behavior and a history of trading sex for money and drugs [19], being female [20] and, among HIV-positive men who have sex with men, depression and sildenafil use [21,22].

Interestingly, in this study patients with non-detectable VLs and those with and without resistance had the same levels of sexual risk behavior, suggesting that, in this clinic population, the presence of VL or resistance status did not appear to affect the likelihood of engaging in risk behavior. This is consistent with a recent meta-analysis of HIV sexual risk behavior studies by Crepaz and colleagues, who reported that patients receiving ART did not exhibit increased sexual risk behavior, even when achieving an undetectable VL; however, patients beliefs about ART and VL was associated with risk behavior [23]. Our study is limited in that it was a retrospective, cross-sectional analysis of behavior and resistance in patients from a single geographic region. Nevertheless, all risk groups were represented and the demography and risk profile is typical for urban areas of the United States where the HIV epidemic is mature [5]. Another limitation is that we did not identify and test exposed partners to determine true rates of resistance transmission, which would be critical in determining the transmissibility of resistant virus.

HIV-positive patients in care and engaging in risk behaviors should be a major focus of new, targeted prevention strategies that integrate prevention and clinical care [24,25]. Results from this study suggest that a likely source of resistant infections is a small core group of patients within the clinic setting that have both resistance and high risk HIV transmission behaviors (approximately 5% of the population). Of those

variables that might differentiate antiretroviral-resistant patients engaging in risk behavior from resistant patients who are not, mental health functioning appears critical, and addressing mental health issues may be the key to reducing transmission risk behaviors.

Acknowledgements

We would like to thank all the patients who participated in the study and the HIV clinicians who referred their patients.

Sponsorship: This work received financial support from the University of Connecticut NIH (grant: NIMH 1R01 MH59473-02) (J.F.) and a Veterans Administration Career Development Award (M.J.K.).

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