

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

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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-naive 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 domains³⁹⁻⁴¹ 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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