

## **Counsellor-delivered HIV risk reduction intervention addresses safer sex barriers of people living with HIV in KwaZulu-Natal, South Africa**

**Running Title:** Safer sex intervention for PLWH in South Africa

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## **Counsellor-delivered HIV risk reduction intervention addresses safer sex barriers of people living with HIV in KwaZulu-Natal, South Africa**

**Abstract:** This study developed an HIV risk reduction intervention for people living with HIV (PLWH) obtaining care at primary healthcare clinics in KwaZulu-Natal, South Africa by (i) conducting elicitation research to understand the dynamics of risk behaviour among PLWH, (ii) modifying an existing HIV risk reduction intervention based on research findings, and (iii) conducting a pilot study to evaluate feasibility, acceptability, and fidelity of the modified intervention implemented by trained lay counsellors at a rural clinic in KwaZulu-Natal. Sixty-one healthcare providers and 77 HIV+ patients from four primary healthcare clinics participated in 14 focus groups and 20 individual interviews to identify informational, motivational, and behavioural skills (IMB) factors contributing to PLWH's sexual risk behaviour. Elicitation research findings were incorporated into a revised version of *Options for Health*, an evidence-based risk reduction intervention for PLWH in clinical care. In a five-day training, lay counsellors learned strategies to address IMB barriers to safer sex identified in elicitation research. The revised intervention, which was implemented by six counsellors with 39 patients, was feasible to implement, acceptable to patients and counsellors, and implemented with good fidelity. This work makes an important contribution towards development of a theory-based HIV risk reduction intervention for PLWH linking prevention with treatment in South Africa.

**Key Words:** HIV risk reduction intervention, prevention-with-positives, counsellor-delivered, South Africa, IMB model, HIV clinical care

## Introduction

South Africa is currently experiencing one of the most severe HIV epidemics in the world, with 18.1% of the population (5.7 million people) infected with HIV, nearly 1000 AIDS deaths daily, and 1.4 million children orphaned due to AIDS (UNAIDS & WHO, 2009). Recognizing the extreme seriousness of the situation, the South African government developed a five-year national strategic plan, the goals of which are to cut the HIV incidence rate in half by 2011 and provide at least 80% of **People Living With HIV (PLWH)** with access to an appropriate package of treatment, care, and support services that will assist them in living longer and healthier lives (SANAC, 2007). To help achieve these objectives, the government has prioritized providing evidence-based HIV prevention programs to PLWH to help them reduce their risky sexual behaviour and avert transmission of the virus to others.

Although there are numerous HIV prevention interventions that have been evaluated and shown to be effective at reducing risky sexual behaviour among PLWH, nearly all of them were developed and evaluated in the United States (e.g., Gilbert et al., 2008; Healthy Living Project Team, 2007; Kalichman et al., 2001; Richardson et al., 2004; Wingood et al., 2004; Wolitski, Gomez, & Parsons, 2005). Evidence-based HIV prevention interventions for PLWH with demonstrated effectiveness in South Africa are urgently needed. One such intervention that has shown promise in South Africa is the lay counsellor-delivered *Izindlela Zokuphila/Options for Health* (Cornman et al., 2008), which is a culturally-adapted version of the U.S.-based *Options Project* (Fisher et al., 2004, 2006). The rollout of antiretroviral medications in South Africa has involved employment of lay counsellors in the public healthcare system (i.e., at primary healthcare clinics) to assist patients with adherence. *Options for Health* takes advantage of the antiretroviral rollout to address PLWH's risk reduction needs by situating an evidence-based HIV prevention intervention in the context of routine HIV clinical care.

The *Options for Health* intervention is based on the Information-Motivation-Behavioural Skills model (IMB) of HIV-preventive behaviour (Fisher & Fisher, 1992; Fisher, Fisher, & Shuper, 2009). It consists of brief, collaborative, patient-centered discussions between a trained lay counsellor and a patient during routine clinical visits, in which the counsellor uses Motivational Interviewing (MI) techniques (Miller & Rollnick, 1991; Rollnick et al., 1999) to assess the patient's sexual risk behaviour; identify the specific informational, motivational, and/or behavioural skills barriers that are preventing the patient from consistently engaging in safer sex; explore possible strategies that the patient can use to address his/her specific barriers; and then negotiate an individually-tailored and achievable behaviour change goal with the patient for the following visit (see [Supplementary-Table S1](#) for steps of intervention protocol; Cornman et al., 2008; Fisher et al., 2004, 2006).

*Options for Health* was developed, implemented, and initially evaluated with a small sample of PLWH (N=152) attending an urban clinic in Durban, South Africa, and it was found to be effective at reducing unprotected sexual behaviour (Cornman et al., 2008). One of the limitations of the initial *Options for Health* study, however, was the fact that it was conducted at a semi-private HIV care facility that required patients to pay for their clinic visits (Cornman et al., 2008). Considering that the vast majority of PLWH receive their HIV care at primary healthcare clinics that provide care free of charge (Nattrass, 2006; Harrison, 2009), the participants in the original *Options for Health* study may not have been representative of the majority of PLWH who receive HIV care in South Africa (Cornman et al., 2008). Because there is considerable need to develop an intervention that fits into the clinical context where most South African PLWH access care and that adequately addresses the needs of those who attend such facilities (McIntyre & Thiede, 2007), the current study sought to adapt the *Options* intervention for use with PLWH who receive their HIV care at primary healthcare clinics in KwaZulu-Natal, South Africa.

To adapt this intervention, the IMB approach for collaboratively designed behaviour change interventions was used (Fisher, Cornman, Norton, & Fisher, 2006). The first step was to conduct elicitation research into the dynamics of HIV risk behaviour among PLWH who attend primary healthcare clinics and the challenges of implementing an HIV risk reduction intervention in these facilities. The findings from this research informed the modifications that were made to the *Options* intervention to ensure that it adequately addressed the HIV prevention needs of PLWH and was feasible to implement in busy primary healthcare clinics. Specifically, the intervention protocol and training curriculum were reviewed, and any content that was redundant or not relevant to the current population was removed, existing content was modified, and new content was added to address any determinants not sufficiently covered in the original intervention. Next, a pilot study was conducted in which the revised *Options* intervention was taught to several counsellors who implemented it with HIV+ patients in a primary healthcare clinic in KwaZulu-Natal, and it was evaluated for acceptability, feasibility, and fidelity. Findings from the pilot study were then reviewed and additional modifications made to the intervention as needed. The final step is currently underway, which comprises evaluating the intervention's effectiveness in a large-scale randomized controlled trial.

This paper presents the findings from the initial steps of the intervention adaptation process. First, the findings from the elicitation research are summarized as well as how these findings were incorporated into the revised and tailored *Options* intervention. This is followed by a description of the pilot study, including the extent to which the modified intervention was acceptable to patients and healthcare providers and was able to be implemented with fidelity in a demanding clinical care environment.

## **Elicitation Research**

### ***Method***

### *Participants*

In 2007, a convenience sample of 77 PLWH (41 women, 36 men) with a mean age of 36.2 years (range 23 to 58), receiving care at one of four primary healthcare clinics (one urban, one peri-urban, two rural) in the uMgundundlovu Health District of KwaZulu-Natal, South Africa, participated in either focus groups discussions or individual interviews. Nearly all the participants (94.7%) were from the Zulu ethnic group, their mean monthly income was 1340 Rand (~US\$190), 77.6% were unemployed, and over half the patient participants (56.6%) lived in informal housing (i.e., shacks). Almost all the participants (96.0%) were receiving antiretroviral therapy at enrollment. Study inclusion criteria for patient participants were HIV infection, receiving HIV care at one of the participating clinics, and 18 years of age or older.

Additionally, 61 healthcare providers (31 nurses, 20 lay counsellors, one doctor, one pharmacist, and eight “others”) were recruited from the same clinics to participate in focus group discussions. The mean age of the providers was 37 years (range 21 to 65), 86.9% were women, and 90.2% were Zulu. Over 80% of the providers had obtained the equivalent of a high school diploma (Standard 10/Matric) or higher, and the average time working at the clinics was 4.2 years (range one month to 35 years). At the time of study enrollment, these four participating clinics collectively provided care to over 2300 PLWH on antiretroviral medications. Individual providers met with and provided care to an average of 92 PLWH per week (range six to 300 PLWH/week).

### *Procedures*

Staff at the participating clinics referred interested HIV+ patients to trained multilingual research assistants who described the study to the patients, indicated that participation was voluntary, and obtained informed consent. No patients refused to take part in focus group discussions or structured interviews. Healthcare providers who participated in focus group discussions also provided informed consent prior to their participation. Patients who participated

in focus group discussions or individual interviews were given 50 Rand (~ US\$7.20) to cover their transportation costs, and food was provided. Healthcare providers were not given any monetary compensation, but food was provided during the focus groups.

Fifty-seven PLWH participated in one of eight patient focus group discussions (one female and one male focus group at each of the four clinics), and an additional 20 HIV+ patients (11 women, nine men) participated in structured individual interviews. Providers participated in one of six provider focus group discussions at the four clinics. Patient focus groups and individual interviews were conducted in isiZulu by trained, gender-matched research assistants, and provider focus groups were facilitated in English by a Ph.D.-level clinical psychologist with extensive experience conducting focus groups internationally. All participants completed a brief demographic survey prior to participating in focus groups and individual interviews.

As a means of reducing the effects of social desirability and fostering greater openness, focus group discussions with PLWH used semi-structured, open-ended questions to assess participants' perceptions of the prevalence of sex and sexual risk among PLWH, as well as the IMB barriers that made it challenging for PLWH to consistently engage in safer sex with their partners. Indirect questioning where participants are asked to answer questions about similar "others" rather than themselves has been used frequently in marketing and other social sciences and found to decrease socially desirability bias (Fisher, 1993). Individual interviews with PLWH asked them about their own sexual behaviour and the barriers that made safer sex challenging for them. They were intended to augment the information provided in focus groups and give people the opportunity to provide information they might be uncomfortable revealing in a group setting.

Focus groups with healthcare providers assessed not only the topics discussed in the patient focus groups but also if and how providers addressed safer sex with their HIV+ patients, their perceived effectiveness at doing so, and the resources they needed to be more effective. In

addition, providers were presented with a summary of the *Options for Health* intervention protocol and asked about the feasibility of implementing it and for any suggested changes to it.

Standard focus group procedures were employed to address the specified research foci (e.g., Krueger & Casey, 2000; Marshall & Rossman, 1999). The protocols used for the patient and provider focus groups represented adaptations and extensions of previous qualitative research conducted by our research team in HIV care settings (e.g., Fisher et al., 2004). Focus group discussions and individual interviews were approximately 1½ to 2 hours in duration and were audiotaped. All procedures described herein (for elicitation research and pilot study) were approved by the Institutional Review Board at the University of Connecticut and the Biomedical Research Ethics Committee at the University of KwaZulu-Natal. The study was also approved by the Research Committee for the Department of Health for the province of KwaZulu-Natal.

## ***Results***

### *Analysis*

Upon completion of the focus group discussions and individual interviews, research staff transcribed the audiotapes verbatim, and the resulting transcripts were translated into English. All translations were reviewed by the isiZulu-speaking facilitator for accuracy prior to content coding. Patient and provider focus groups were then coded by two raters using a theory-driven approach (Krippendorff, 1980; Weber, 1990) supplemented by data-driven strategies (Glaser, 1998). Each utterance (content spoken by a single person immediately following and prior to another individual speaking) from the transcribed focus groups was content-coded by two raters using a non-orthogonal coding structure that was developed a priori based on barriers and facilitators of safer sexual behaviour identified by the IMB model and in the recent literature. These theory-driven content areas were then modified and supplemented by emergent content from the data collected. Modifications to the coding categories were followed by reviews of all

previously coded transcripts in an iterative process. Codes were compared and any disagreements on how an utterance was coded were discussed. Inter-rater reliability statistics were not recorded, but disagreements in coding were rare, and consensus was always reached. Coding of focus group content via this mixed approach resulted in 28 separate content codes that were not mutually exclusive (i.e., an utterance could be coded with multiple codes). Individual interviews were reviewed separately for any additional themes beyond what was identified in the focus groups.

Consistent with findings from other studies (Cornman et al., 2008; Kiene et al., 2006; Olley et al., 2005), participants in the focus groups and individual interviews reported that few PLWH in their communities abstained from sexual activity, many had multiple partners, and a substantial proportion of them did not use condoms during sex. They also identified important informational, motivational, and behavioural skills barriers that prevented PLWH from consistently engaging in safer sex. And focus group discussions with providers revealed several challenges that providers faced when trying to do risk reduction counselling with HIV+ patients. There was remarkable consistency within and across the patient and provider focus groups and the individual interviews regarding the barriers they believed made it challenging for PLWH to consistently engage in safer sex. Consequently, the findings were collapsed across groups and are being presented in summary form, with any differences within and between the groups noted.

#### *Patients' Informational Barriers to Safer Sex*

(1) *Misconceptions about HIV.* The consensus among the patients and providers in the focus groups was that although PLWH were relatively well-informed about HIV transmission and prevention, many of them had misconceptions that served as barriers to safer sex. One misconception identified by all focus groups as prevalent among PLWH was the belief that HIV could be cured. The cures discussed included: (a) traditional healers, (b) herbal medicines, (c) God and prayer, (d) antiretroviral medications, and (e) sex with a virgin, child, dog, goat, or an

“old lady who has stopped menstruating.” Further, focus group participants indicated that there were many PLWH who believed their HIV was cured if they felt healthy or had an undetectable viral load.

(2) *Misconceptions about Condoms.* In addition to misconceptions about an HIV cure, participants reported that many PLWH had misconceptions about condoms, including the belief that condoms: (a) had been purposely infected with HIV “by the White people to spread the virus” and “kill Blacks,” (b) had small holes in them that allowed the virus to pass through, and (c) contained “small insects and worms” that were transferred to a person’s “private parts” during sex. There were also reports from healthcare providers that many HIV+ patients incorrectly believed that there were no health risks if two PLWH had unprotected sex with one another.

#### *Patients’ Motivational Barriers to Safer Sex*

(1) *Negative Attitudes towards Condoms.* Focus group participants agreed that most HIV+ men had negative attitudes about condoms and did not want to use them. Although HIV+ women were regarded as more motivated to use condoms than men, there were many women, purportedly, who also had negative attitudes about condoms. Participants reported that both men and women complained that they “couldn’t feel anything” when they used condoms and that condoms gave them a rash and “made it itchy.” An additional complaint from some women was that condoms caused “sores or cuts in the vagina.” In contrast, many men reportedly did not like condoms because condoms made it difficult to maintain an erection or ejaculate, were too small or too tight, were too large and fell off, or caused them pain. According to the participants, men disliked government condoms even more than commercial condoms because they “smelled bad,” “burst” too easily, or were “too wet.”

(2) *Fear of Disclosure.* Lack of disclosure of one’s HIV status was identified by all focus groups as a major barrier to condom use. Participants agreed that those who did not disclose their HIV

status to their partners were less motivated to use condoms because they feared that introducing a condom into their relationship would reveal their HIV status. Participants reported that both men and women feared being rejected by their partners if they disclosed. In addition to fearing rejection, HIV+ women feared getting “blamed” for bringing HIV into the family if they disclosed. Even if a woman contracted HIV from her partner, she would likely be the one who would be held responsible for the two of them having the virus and could be punished verbally and physically. In contrast, some HIV+ men were reportedly hesitant to disclose to their partners because they believed that their partners “would tell everyone that they have the virus,” and they would experience stigma and discrimination as a result. In addition, some of the providers said that many men were hesitant to reveal their HIV status because “if they tell their partners they’ve got AIDS, they might see a certain weakness in them,” and men were supposed to be strong.

(3) *Lack of Partner Support for Safer Sex.* Both patients and providers reported that another major barrier to safer sex for HIV+ women was the belief that men had the power in relationships, and it was men’s role to make the decisions about when to have sex, the type of sex to have, and whether condoms were used. Female patients indicated that they were “scared” to express their opinion about sex to a man because “a woman must be under a man,” and “he does not want to hear what you have to say.” Women in two of the patient focus groups indicated that many HIV+ women felt obligated to engage in sex without condoms with their husbands because their husbands had paid “lobola” (bride price) for them. A woman refusing to have sex without a condom could be viewed as disrespectful towards her partner, labeled a “cheater” or a “bitch,” and “beaten,” “raped,” or abandoned by her partner. Because “most women [were] financially dependent on men,” many reportedly had sex without condoms so their partner would not abandon them and leave them destitute. These findings are consistent with published studies indicating that gender power imbalances are characteristic of many relationships in South Africa

and that women who are in these types of relationships are much less likely to suggest condom use to their partners (Kalichman et al., 2005; Kalichman & Simbayi, 2004; Langen, 2005).

Women were not the only ones, however, whose motivation to use condoms was negatively impacted by lack of partner support. Participants in the patient focus groups agreed that some men had female partners who did not want them to use condoms because using condoms signified that the men “did not trust them.” In addition, many male patients reported that men felt pressure from their partners, families, and communities to have children. “I think the reason why we males do not use condoms is peer pressure. If you do not have a child, you are not man enough.” This was not unique to men, however, as many HIV+ women desired to have children or felt pressure from their partner, in-laws, or family to get pregnant.

#### *Patients' Behavioural Skills Barriers to Safer Sex*

Several behavioural skill deficits were noted by focus group participants. Specifically, participants reported that PLWH had difficulty using male and female condoms correctly, negotiating safer sex, disclosing their HIV status, and engaging in safer sex when under the influence of alcohol or marijuana (“dagga”).

(1) *Difficulty Using Male and Female Condoms Correctly.* Only 11 (five women, six men) of 20 participants who were individually interviewed, rated their confidence in correctly using a condom as 10 on a 10-point scale (1=“not at all” confident to 10=“very confident”). When asked what would need to happen to increase their confidence, they indicated they would need more training. Focus group participants estimated that even fewer PLWH knew how to use the female condom correctly. Of 11 women interviewed, 6 had never used a female condom, and the remaining 5 had tried it on at least one occasion but were not currently using female condoms because they and/or their partner preferred male condoms. Some women in the patient focus groups incorrectly believed that the female condom could get lost inside their body during sex or

that it had to be inserted 8 hours prior to sex. Other women in the patient focus groups and individual interviews complained about the female condom being “difficult to put in,” making a “squeaky” or “annoying” noise during sex, “moving around too much,” and being “uncomfortable” or “painful” to use. Several men in the patient focus groups had never heard of female condoms, and none of the nine men who were individually interviewed had ever had sex with a partner who used one. The majority of the men in the patient focus groups were not aware that female condoms were available free-of-charge at the clinics, and some of them incorrectly believed that female condoms “needed to be held in place” during sex. It was clear that both women and men needed additional training in how to use female condoms correctly.

(2) *Limited Ability to Negotiate Condom Use.* Patients in the focus groups reported that PLWH struggled with how to effectively negotiate condom use with their partners, particularly when their partners refused to use them. It was especially challenging for women because of the power imbalance in relationships and the potentially serious negative outcomes if negotiations did not go well. Both patients and providers believed that even carrying condoms could be risky for a woman because if a man discovered them in her possession, “he would think she had been somewhere...having sex with someone else” or that “she was selling her body.” When asked about the feasibility of women physically putting condoms on their partners, most of the female patients indicated they were “afraid” to do so because of how men might react. “There are people who think if you are comfortable [putting a condom on a man], you are a prostitute, and they will leave you.” In contrast, many men in the patient focus groups reported they would like women to put condoms on them. Not only would it make them “happy” because “it would mean that she is a loving person” and “shows that she cares for [him],” it would “excite” them sexually. In order for a woman to do this, however, she would first need to ask the man’s permission.

(3) *Difficulty Managing HIV Disclosure and Condom Use.* As previously stated, both men and women found it difficult to introduce condoms into a relationship without first disclosing their HIV status, and disclosing was challenging due to possible negative consequences. Patients and providers had very few ideas about how to successfully introduce condoms into a relationship without raising suspicions about one's HIV status. The one strategy that providers felt worked well for disclosing HIV status and minimizing blame was for a patient to bring his/her partner to the clinic and both get tested together so they could simultaneously find out their serostatus; this strategy had apparently been used frequently at the clinics.

(4) *Limited Ability to Manage Safer Sex and Alcohol/Marijuana Use.* Estimates of the proportion of PLWH who drank alcohol ranged from 80 to 90%, and all focus groups agreed that alcohol was a barrier to condom use and a facilitator of sexual behaviour. This is consistent with a South African study which found that drinking moderate to large amounts of alcohol prior to sex increased the likelihood and rate of unprotected sex (Kiene et al., 2008). Estimates of marijuana ("dagga") use were quite variable with some providers estimating that nearly half of their HIV+ patients used it, and some female patients stating that almost all HIV+ men used it. Although all patients in the focus groups believed that marijuana use increased the likelihood of risky sexual behaviour, there was disagreement among providers as to its effects. Most providers believed that "if the person is smoking dagga, this is when he thinks using condoms is useless," but there were other providers who felt that alcohol but not marijuana use negatively impacted on condom use.

#### *Provider Barriers to Risk Reduction Counselling*

Nearly three-quarters (73%) of the healthcare providers reported they had discussions about safer sex with their HIV+ patients at every clinic visit, but the discussions were not based on any model of health behaviour change nor were they typically tailored to the specific needs of the patient. According to providers, these discussions ranged from five to 30 minutes in duration,

with most providers spending five minutes talking about safer sex and counsellors having the greatest amount of time to spend with patients. Providers agreed that training counsellors in the *Options* risk reduction intervention could be beneficial to the patients and counsellors.

Barriers to providers having effective risk reduction discussions with their HIV+ patients included: (1) discomfort discussing sex with their patients, especially anal and oral sex, (2) judgmental attitudes towards patients who engaged in unprotected sex, got pregnant, had multiple partners, or had partners of the same gender, and (3) inability to get patients to be forthcoming about their desires to have children prior to getting pregnant. Overall, providers reported extremely low self-efficacy in their ability to influence patients' sexual behaviour. As one provider stated, "It's hard.... You come in and work with them, and they leave and they forget everything you said." Providers seemed to be well-versed in the large number of barriers that were preventing their patients from engaging in safer sex, but had limited resources and strategies for addressing those barriers. Structural barriers to having risk reduction discussions included lack of confidential counselling space, limited time, too much paperwork, and a shortage of staff.

#### *Modifications to Intervention Protocol and Counsellor Training*

Based on the findings from this elicitation research and the Durban study (Cornman et al., 2008), the *Options* intervention protocol and counsellor training workshop that were used in the Durban study were modified to more effectively address the HIV risk reduction needs of HIV+ patients and the counselling needs of lay counsellors in primary healthcare clinics in KwaZulu-Natal. The original *Options* intervention protocol consisted of an eight-step framework that counsellors used to identify the specific barriers that were preventing a patient from consistently engaging in safer sex and then to create a personalized HIV risk reduction goal with the patient to address his/her barriers and move him/her in the direction of safer sexual behaviour. Based on the feedback provided by counsellors in the current study and the Durban study, three of the eight

steps were simplified for ease of understanding, and the remaining five steps were not altered. Further, whereas the original *Options* protocol included sample scripts in English for each step of the intervention, the revised protocol also included scripts in isiZulu.

The most significant changes were made to the *Options for Health* counsellor training workshop, which was extensively modified to teach lay counsellors how to more effectively address each of the informational, motivational, and behavioural skills barriers to safer sex identified in the elicitation research and to assist them with the counselling barriers that were discussed in the provider focus groups. More specifically, the training was redesigned to provide counsellors with a compendium of strategies they could use to help HIV+ patients address their specific safer sex barriers. To accommodate the additional training modules that were necessary to accomplish this and to provide more time for role-play and rehearsal, the training was expanded from three days to five days.

The original three-day training workshop (Cornman et al., 2008) included modules on (a) the development of the *Options* intervention, (b) IMB model of HIV prevention, (c) Motivational Interviewing, (d) the eight-step *Options* intervention counselling protocol, and (e) the different sexual and drug use behaviours in which patients may engage, the health risks associated with those behaviours, and strategies for minimizing those risks. New modules that were added to the five-day training to address the barriers identified in the elicitation research included modules on HIV disclosure and stigma, gender dynamics, safer sex negotiation, effective communication skills, reproductive decision-making, and basic couples counselling. For the first time, training was also provided in the anatomy of the female and male reproductive systems so that counsellors could address various patient concerns such as the fear that female condoms would get pushed inside during sex and lost in the body. In addition to these new modules, interactive exercises were added to the training to increase counsellors' comfort with talking about different types of

sexual behaviour, including anal sex, oral sex, and same-gender sex. Also added to the training was a values clarification exercise to help counsellors learn about their own personal biases and prejudices, and how those might negatively influence their ability to do effective counselling.

To address the mistakes that some patients make when using male and female condoms, counsellors were provided with extensive step-by-step training in how to correctly use female and male condoms, and strategies for addressing each of the various patient complaints about them (e.g., decreased sensation, breakage, noise during use); this was included in the original Durban training and was expanded in this pilot study to provide additional practice. A brochure with step-by-step instructions in isiZulu on how to use male and female condoms was newly created for counsellors to distribute to patients.

To increase counsellors' self-efficacy for doing risk reduction counselling, they engaged in multiple role-plays daily, practicing how to work with different types of clients presenting with a variety of barriers to safer sex. They also watched and analyzed video simulations of the protocol, which were newly created for this study. The simulations consisted of seven *Options* protocol demonstrations with four patients with different risk profiles (four initial sessions, three follow-up sessions). Following the training, telephone support and routine onsite booster sessions (weekly for the first four weeks and then every other week for eight weeks) were conducted to provide additional technical assistance to the lay counsellors; this was not provided as part of the original training. ([See Supplementary Table S1 for the revised intervention protocol steps and Table S2 for how each of the barriers was addressed in the revised intervention.](#))

## **Pilot Study**

### ***Method***

#### *Participants*

In 2008, when the modifications to the intervention protocol and training workshop had

been completed, a pilot study was conducted at a South African Department of Health-accredited antiretroviral therapy clinic in the uMgundundlovu Health District of KwaZulu-Natal, to evaluate the intervention for its feasibility, acceptability, and fidelity; this primary healthcare clinic was selected for the representativeness of its patients and healthcare staff. A total of six lay counsellors (five women, one man) who were working at the clinic as antiretroviral adherence counsellors, participated in the revised *Options* training. As is required of all counsellors working in primary healthcare clinics, these counsellors had completed a standardized 10-day training course provided by the Department of Health (DOH) prior to being hired, and then once hired, participated in supplemental DOH trainings each year on a variety of topics (e.g., pre- and post-test HIV counselling, HIV risk reduction counselling, PMTCT). The *Options* training thus built on the counselling foundation that these counsellors already had.

A convenience sample of 40 PLWH was recruited for participation in the pilot study. To participate, an individual had to be HIV+, receiving HIV care at the participating clinic, currently prescribed antiretroviral medications, and at least 18 years of age. Study participants were recruited, screened, and consented to participate in the study by trained isiZulu-speaking research assistants. To ensure that the revised intervention was feasible to use with both risky and non-risky patients, all participants completed a screening instrument prior to being enrolled in the study that assessed whether they had engaged in unprotected vaginal sex in the past six months. Recruitment continued until 20 PLWH (10 women, 10 men) who reported having risky sex and 20 PLWH (10 women, 10 men) who reported no risky sex were enrolled in the study. Twenty-six patients who reported no sexual risk in the past six months were screened out of the study because the no-risk group had already been fully enrolled. No one who was eligible to participate in the pilot study refused to take part in it.

All participants completed an ACASI-delivered questionnaire at the start of the study that assessed their demographic information, sexual behaviour, and antiretroviral regimen. Following the baseline measure, participants participated in a maximum of two *Options* discussions with a trained counsellor at consecutive medical visits, and they completed an Exit Questionnaire at the end of each discussion, which was administered by one of the research assistants. Participants received no monetary incentive for their participation in the intervention sessions or for the Exit Questionnaires, but they were compensated 30 Rand (~ US\$4.30) for completing the screening instrument and an additional 70 Rand (~ US\$10.00) for the baseline assessment.

The mean age of the participants was 36.5 years of age (range 21 to 78), 92.5% self-identified as Zulu, and 72.5% were currently unemployed. Almost all participants (90.0%) lived in the surrounding rural area, and 75.0% resided in informal housing. Self-report data indicated that the patients had been on antiretroviral medications for an average of 2.4 years (range five months to 10 years). Over three-quarters of the study participants (82.5%) reported sexual activity in the past one to three months, and 22.5% reported that they were trying to have a child with their current sexual partner. At enrollment into the study, the majority of participants (75.0%) reported coming to the clinic monthly, and no one came less often than once every three months. About two-thirds of the participants (67.5%) reported meeting with a counsellor monthly to talk about antiretroviral medications and adherence, 20.0% met with a counsellor every two to three months, and 12.5% reported that they never met with a counsellor when they came to the clinic for care.

#### *Assessment of Intervention Feasibility, Acceptability, and Fidelity*

The feasibility of the *Options* intervention was assessed by comparing the total number of visits that participants made to the clinic during the study with the number of visits in which the intervention was implemented by the counsellors. Intervention acceptability to patients was

determined by comparing the number of times patients refused to participate in an *Options* discussion with the total number of times that patients had this discussion with their counsellors; this information was documented on the “Options Record Form” (ORF), the one-page form that counsellors completed at the end of every patient visit to document what transpired during the *Options* discussion. Intervention acceptability was also assessed through two patient focus groups (one male and one female group) and one counsellor focus group that were conducted at the conclusion of the pilot study to gather feedback on the intervention. Patients were given 50 Rand (~ US\$7.20) for their participation in the focus group, and food was provided. Counsellors received no monetary compensation, but food was provided during the focus group discussion.

To assess intervention fidelity, members of the research team reviewed each ORF to determine which of the eight intervention steps counsellors implemented with the patients (Table 1). Each step completed by the counsellor was scored and totaled such that total scores could range from zero (no *Options* steps implemented) to eight (all *Options* steps completed). An additional measure of fidelity consisted of Exit Questionnaires that were completed by patients following each *Options* discussion with their counsellor. The 16-item questionnaire assessed patients’ perceptions of what occurred during the counselling session, how they felt about the counsellor’s counselling ability, and whether they found the discussion to be helpful.

## **Results**

### *Feasibility and Acceptability of the Options for Health Intervention*

Analysis of the ORF data revealed that 39 of the 40 enrolled HIV+ patients (97.5%) participated in at least one *Options* risk reduction discussion (one participant did not return to the clinic following enrollment). There was a total of 74 *Options* discussions, consisting of 39 initial sessions and 35 follow-up sessions. The mean time between initial and follow-up sessions was 30 days (range 11 to 56 days). Of the four patients who participated in an initial session but not a

follow-up session, three were working and did not return to the clinic before the study ended, and one patient withdrew from the study after the first *Options* session, claiming that she did not need additional counselling. Thus, all the patients who remained enrolled in the study participated in an *Options* discussion each time that they came to the clinic during the study period. Except for the participant who withdrew from the study, none of the participants ever refused to have an *Options* discussion, and there was always a counsellor available to have that discussion with a participant. These findings strongly support the feasibility of this intervention being integrated into routine clinical care and implemented by trained lay counsellors.

(1) *Patient Focus Groups*. At the end of the pilot study, two focus groups were conducted with a total of 14 randomly selected patients (seven women, seven men) who had participated in *Options for Health*, to elicit their feedback on the risk reduction counselling intervention, including any suggested changes to it. Both patient groups reported that the conversations were helpful, they gained important information and skills from them, and they were more motivated to engage in safer sex following the discussions. Specifically, women spoke about the benefits of learning about female condoms and how to talk with their partners about safer sex while men found the conversations about condoms and substance use to be useful. Men and women in both groups also found that having their goals written down on an “Action Plan” was helpful as a reminder of what they were working on or as a tool they could use to initiate conversation with their partners.

None of the men reported that the *Options* discussions made them feel uncomfortable or embarrassed. The women, on the other hand, reported being anxious at the start of the first *Options* discussion because they did not know where the counsellor was heading with the discussion, and they were initially fearful of being judged negatively. However, they became more comfortable as the discussion progressed and the counsellors treated them with respect. There was also a difference of opinion on the relevance of the gender of the counsellor. Although

the counsellor's gender did not appear to matter to the men, some women said that talking with a male counsellor made it more difficult for them to be forthcoming. Further, both groups agreed that they were initially surprised when asked about different types of sexual behaviour (oral, anal, and same-gender sex) because they were not accustomed to discussing these issues, but they also reported that the counsellors were open, comfortable, and competent when doing so, which helped them relax.

Overall, both groups reported that *Options for Health* was extremely useful, they felt the program should continue so that they could get more of their concerns addressed, and they thought it was important to offer the program to others at the clinic. They recommended that *Options* be expanded to include conversations about stigma and discrimination, nutrition, and the immune system. The findings from these two focus groups support the acceptability of the *Options* intervention to HIV+ patients attending primary healthcare clinics.

(2) *Counsellor Focus Group*. A total of six lay counsellors (five women, one man) and one lay counsellor supervisor (Professional Nurse who spoke about *Options*' impact on clinic flow) participated in the counsellor focus group at the end of the pilot study. They indicated feeling comfortable relatively quickly implementing the intervention (after the first two patients) and that *Options* worked equally well with both male and female patients regardless of patients' specific problems with safer sex. The counsellors also reported that *Options* helped patients understand the importance of safer sex, and it was useful in motivating patients to practice safer behaviour. They believed patients were honest about their behaviour and were able to speak openly with the counsellors about issues that were not normally talked about in their culture, including oral, anal, and same-gender sex. The ORF data supported this, with 24.1% of participants acknowledging they sometimes or never used condoms during sex, four patients reporting they were having anal sex, and one patient indicating he was having unprotected oral sex.

The counsellors and Professional Nurse agreed that *Options* fit well into the clinic flow and did not disrupt the provision of clinical care. The most challenging issues for counsellors to discuss with patients involved disclosure and reproductive decision-making, and they recommended providing additional training in how to work with patients who want to have a child. Overall, these findings support the acceptability of the intervention to lay counsellors.

### *Intervention Fidelity*

The extent to which the *Options* intervention was delivered according to the protocol was evaluated using the ORF data provided by the counsellors and the Exit Questionnaire data provided by the patients. As previously noted, the ORF was the form on which counsellors documented what transpired during the *Options* discussion. Out of the eight steps in the intervention protocol, the ORF data indicated that counsellors implemented a mean of 7.7 steps (median of 8.0 steps) with the study participants across all *Options* visits (initial and follow-up). Seven of the eight steps were implemented 97% of the time or more. The eighth and final step, which consisted of documenting the agreed upon goal on the “Action Plan” form and handing it to the patient, was carried out least often at 74.3% of the time (87.2% during initial visits, 60.0% during follow-up visits). It should be noted, however, that patients were given the option of not taking the “Action Plan” with them if they had confidentiality concerns, and several patients opted not to take it. In the follow-up sessions, 77.1% of the goals agreed upon during the initial sessions were reported as having been fully achieved, 11.4% were partially achieved, and there was no progress made on 11.4% of the goals. Although no efficacy data was collected, the fact that most of the risk reduction goals had been achieved suggests that progress towards consistent safer sexual practices was being made by many patients. Overall, the findings from the ORFs (summarized in Table 1) suggest that the intervention protocol was implemented with fidelity.

Thirty-nine patients completed an Exit Questionnaire after their initial *Options* session, and 35 patients completed one after their follow-up session. A review of the 74 Exit Questionnaires revealed that what transpired during the *Options* discussions (in terms of steps implemented), was very consistent with the ORF data provided by the counsellors (see Table 1), suggesting high fidelity of implementation. Specifically, participants reported that counsellors implemented a mean of 7.2 steps (median of 8.0 steps). Of note, 71.0% of the patients who said they left the session with a goal, reported either developing it themselves or collaboratively with the counsellor, indicating that most goals were not merely prescribed by the counsellor. Further, 93.9% of those who had a goal at the initial session reported discussing their progress on that goal at their follow-up session.

The Exit Questionnaires also revealed that patients had very positive feedback about these discussions. Using a 10-point rating scale (1="Not at all" to 10="Very"), patients indicated, on average, that they felt "very comfortable" ( $M = 9.68$ ,  $SD = 1.22$ ) talking with their counsellor about sex, and they found their counsellor to be "very helpful" ( $M = 9.79$ ,  $SD = 1.15$ ) and "very understanding" of their feelings and concerns ( $M = 9.46$ ,  $SD = 1.66$ ) when discussing sex. Most respondents (84.3%) felt that their counsellor had "a lot" of knowledge about safer sex, and the remaining 15.7% responded that they did not know how much knowledge their counsellor had. There was no negative feedback about the discussions and no suggested changes.

The findings from the Exit Questionnaires were thus consistent with the findings from the "Options Record Forms," and together suggest that the eight protocol steps were implemented in the vast majority of visits. In addition, the context of the intervention delivery was consistent with Motivational Interviewing principles in that patients reported feeling very comfortable during the discussions and viewed the counsellors as very helpful, understanding, and knowledgeable.

## **Conclusion**

With the high incidence and prevalence of HIV in South Africa (Rehle et al., 2007; UNAIDS & WHO, 2009), it is critical to provide evidence-based HIV prevention interventions that can be used effectively with South African PLWH to reduce their risky sexual behaviour and decrease the transmission of HIV to others. The current study sought to adapt an existing version of the *Options for Health* intervention (Cornman et al., 2008) for use with PLWH who obtain their HIV care at primary healthcare clinics, which is where the majority of PLWH in South Africa receive their care. Elicitation research was first conducted at four primary healthcare clinics, the risk reduction intervention was then modified based on the findings of that research, and a pilot study was carried out to evaluate the feasibility, acceptability, and fidelity of the resulting intervention as implemented by trained lay counsellors at a primary healthcare clinic in KwaZulu-Natal.

The elicitation research demonstrated that HIV+ patients had critical HIV prevention informational, motivational, and behavioural skills deficits that needed to be addressed. It was also clear that providers needed additional training in how to do nonjudgmental, patient-centered risk-reduction counselling that included a compendium of strategies they could use with their patients to help them overcome their barriers to safer sex. The findings from the elicitation research resulted in minor changes to the intervention protocol but major revisions to the counsellor training curriculum. The counsellor training workshop was expanded to include training not only in the intervention protocol but also in the strategies needed to address each of the barriers to safer sex that were identified in the elicitation research.

Once developed, the intervention was piloted and evaluated for feasibility, acceptability, and fidelity. The data from this pilot study suggests that the *Options for Health* intervention is feasible to implement in a primary healthcare clinic and is acceptable to both patients and counsellors. Moreover, it appears that lay counsellors can be trained in this protocol in a

relatively short period of time, and the data provided by the counsellors and patients suggests that counsellors can implement this intervention with fidelity in a busy South African public clinic.

Limitations of the elicitation research include the fact that focus group participants reported on their perceptions of other PLWH's informational, motivational, and behavioural skills barriers to safer sex rather than their own, which could have resulted in a misrepresentation of the prevalence of these barriers. Limitations of the pilot study include the use of a single clinic, a limited number of counsellors, a relatively small sample size, and a short follow-up period. In addition, fidelity was assessed via self-reports provided by the counsellors and patients of what occurred in the discussions rather than by objective assessments conducted by independent trained researchers. To more fully evaluate this intervention, a large-scale randomized controlled trial (RCT) is required that includes a representative sample of counsellors, patients, and clinical care sites; the use of biological outcomes; and a longer follow-up period. An RCT of this intervention is currently underway in 16 clinics in KwaZulu-Natal, South Africa.

This study demonstrates the multi-step process that is required to adapt a theory-based HIV prevention intervention so that it addresses the specific risk reduction needs of a particular population. One must first understand the risk dynamics of that population including the specific informational, motivational, and behavioural skills barriers to safer sex and the strategies for overcoming those barriers as well as the context in which the intervention will be implemented (e.g., available resources, structural barriers, training needs). This study carried out the initial steps in the development of an HIV risk reduction intervention for PLWH that links prevention with treatment in primary healthcare clinics in South Africa. The findings thus far are promising, and if the intervention is found to be effective in the RCT that is underway, this intervention can play an important role in helping to prevent the spread of HIV throughout South Africa.

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Table 1: Summary of Steps Implemented in *Options for Health Sessions*

	Description of Step (time it takes to implement step)	ORFs: All Visits (N=74)		Exit Interviews: All Visits (N=74)		ORFs: First Visits (N=39)		ORFs: Follow-Up Visits (N=35)	
		N	%	N	%	N	%	N	%
Step 1	Introduce the discussion about sex (30 seconds)	74	100.0%	72	97.3%	39	100.0%	35	100.0%
Step 2	Assess sexual risk behaviours (5-7 minutes)	74	100.0%	72	97.3%	39	100.0%	35	100.0%
Step 3	Rate Importance of engaging in safer behaviour (30 seconds)	73	98.6%	68	91.9%	38	97.4%	35	100.0%
Step 4	Rate Confidence of engaging in safer behaviour (30 seconds)	73	98.6%	70	94.6%	38	97.4%	35	100.0%
Step 5	Identify specific barriers to safer behaviour (3-4 minutes)	72	97.3%	68	91.9%	38	97.4%	34	97.1%
Step 6	Discuss strategies for overcoming barriers (3-5 minutes)	73	98.6%	70	94.6%	38	97.4%	35	100.0%
Step 7	Agree on specific goal for safer behaviour (2 minutes)	72	97.3%	67	90.5%	38	97.4%	34	97.1%
Step 8	Document goal on "Action Plan" form, and hand to patient (30 seconds)	55	74.3%	49	66.2%	34	87.2%	21	60.0%
Mean Number of Steps Implemented (SD)		7.65 (.77)		7.24 (1.59)		7.74 (.85)		7.54 (.66)	
Median Number of Steps Implemented		8.0		8.0		8.0		8.0	