Sustained Changes in Sexual Behavior by Female Sex Workers After Completion of a Randomized HIV Prevention Trial

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Introduction: Behavioral interventions in female sex workers (FSWs) are associated with changes in sexual behavior and reduced rates of sexually transmitted infections (STIs) and HIV. We examined the sustainability of such interventions.

Methods: HIV-uninfected Kenyan FSWs were enrolled in a clinical trial that provided free male condoms, community and clinic-based counseling, and STI management. After trial completion, scaled-back community-based resources remained in place. More than a year later, women were invited to complete a follow-up behavioral questionnaire and to undergo STI/HIV counseling and testing. Individual changes in sexual behavior were assessed by paired analysis.

Results: One hundred seventy-two women participated in the resurvey 1.2 years after trial termination. Client numbers had risen (paired t test, \( P < 0.001 \)), but condom use had also increased (\( P < 0.001 \)); both remained substantially lower than at enrollment. Regular partners accounted for a greater proportion of unprotected FSW sexual encounters (35% vs. 10%; \( P < 0.001 \)). Only 9 (5.2%) of 172 women had a conventional STI, and the follow-up HIV incidence of 1.6 per 100 person-years (PYs) was similar to that during the trial period (3.7 per 100 PYs). Incident STIs and HIV were associated with the frequency of unprotected sex and younger age.

Conclusions: Less intensive community-based risk reduction services after clinical trial termination may support ongoing reductions in STIs and HIV among high-risk FSWs.

Key Words: female sex worker, HIV, risk reduction, sexually transmitted infection, sustainability

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Female sex workers (FSWs) are at an extremely high risk of acquiring HIV-1 (HIV) in those regions of the world that have been most affected by the pandemic. This vulnerable group may amplify HIV transmission to the general population, such that interventions targeted at FSWs are among the most cost-effective public health strategies available to curb HIV transmission. Successful prevention strategies have included peer education and counseling to reduce high-risk sexual behavior by reducing client numbers and increasing use of male condoms, enhanced sexually transmitted infection (STI) management programs, and HIV counseling and testing. In some settings, such as the Sonagachi model of a sustainable community-level HIV intervention in FSWs and the Thailand 100% condom use program, such strategies can lead to sustained changes in sexual behavior. Studies in Cameroon demonstrated poor sustainability of changes in sexual behavior after a short-term intervention, however, with few women maintaining consistent condom use for more than 1 year after participation in a randomized trial of STI prevention.

From 1998 to 2002, we performed a randomized placebo-controlled clinical trial of monthly antibiotic prophylaxis to prevent STIs and HIV in high-risk Kenyan FSWs from the Kibera district in Nairobi. All participants in this trial were provided with peer- and clinic-based risk reduction counseling, with regular screening and treatment for symptomatic and asymptomatic STIs and with HIV counseling and testing. Enrollment was associated with rapid changes in sexual behavior, including increased condom use and reduced client numbers, and each of these factors was associated with...
reduced rates of classic STIs and HIV. Changes in sexual behavior were well sustained during the trial, although condom use declined over time in the subgroup of bar-based sex workers. To examine the sustainability of these changes after trial termination, we invited former participants to complete a resurvey questionnaire, to be tested for common STIs, and to undergo HIV counseling and testing.

METHODS

Randomized Trial Design and Risk Reduction Services

From May 1998 to January 2002, HIV-seronegative FSWs from the Kibera district in Nairobi were enrolled in a randomized, placebo-controlled, double-blind study of monthly administered azithromycin to prevent STIs and HIV. An FSW was defined as a woman who reported receiving money or gifts in exchange for sex during the month before initial screening, and participants were recruited through a pre-established FSW peer education network. All participants were provided with a variety of clinic-based HIV prevention services that included free male condoms, prompt treatment of asymptomatic STIs, twice-yearly screening and treatment of asymptomatic STIs, and sexual risk reduction counseling. At enrollment, all women were provided with 2 clinic-based hour-long risk reduction counseling sessions. After enrollment, clinic-based counseling was provided at each monthly visit, based on the perceived needs and self-reported sexual behavior of participants. During the trial, HIV counseling and testing were performed every 3 months.

Sex worker community meetings were organized quarterly in each of the 10 villages comprising the Kibera slum. Each was led by an FSW peer leader from that village, with the support of at least 1 member of the research team. Discussion in these meetings was focused on risk reduction, particularly on the negotiation of consistent condom use with casual and regular clients. In addition, a wider meeting of sex workers from all Kibera villages was held every 6 months at a local hall to address risk reduction issues pertaining to the sex worker community.

Clinic and Community Services Provided After Trial Termination

The randomized trial ended in January 2002. No clinic-based counseling was provided after trial termination, and routine STD screening ended. Although the clinic could still be used to access medical care for symptomatic conditions, these services were rarely used. Quarterly peer-led sex worker community meetings in all Kibera villages continued up to 2006, however, and a local project (the Urban Slum Project) started to distribute male and female condoms free of charge throughout bars, hotels and other sex work hotspots.

Posttrial Resurvey

Just longer than 1 year after trial termination, the participants still resident in the Kibera slum were invited to participate in the cohort resurvey by completing a behavioral questionnaire and undergoing HIV/STI counseling and testing. Former study participants were invited to take part in the resurvey at a village level, through the ongoing peer-led sex worker community meetings, and those interested returned to the clinic, where the study was described by the research team in their language, an information form was provided, and participants provided signed informed consent. The study protocol was reviewed and approved by Institutional Review Boards at Kenyatta National Hospital, Nairobi, Kenya; the University of Manitoba, Winnipeg, Manitoba, Canada; the University of California, San Francisco, San Francisco, California; the University of Washington, Seattle, Washington; and the University of Toronto, Toronto, Ontario, Canada.

Laboratory Methods

During the clinical trial, all FSWs underwent a complete physical examination and STI testing and treatment at enrollment, every 6 months thereafter, and whenever clinically indicated. Cervical swabs were obtained for Neisseria gonorrhoeae and Chlamydia trachomatis polymerase chain reaction (PCR) assays (AmpliCor PCR Diagnostics; Roche Diagnostic Systems, Mississauga, Ontario, Canada) and for N. gonorrhoeae culture. Trichomonas vaginalis cultures were analyzed using In Pouch TV (Biomed Diagnostics, San Jose, CA). Blood samples were obtained for HIV and syphilis serology at enrollment and every 3 months during the trial. The rapid plasma reagin test (RPR test; Becton Dickinson, Groot-Bijgaarden, Belgium) was performed for syphilis serology, and positive samples were confirmed by Treponema pallidum hemagglutination assay (TPHA; Randox Laboratories, Antrim, United Kingdom). An HIV screening enzyme-linked immunosorbent assay (ELISA) was performed using the Detect-HIV kit (BioChem ImmunoSystems, Montreal, Quebec, Canada), and positive tests were confirmed with the Recombigen HIV-1/HIV-2 enzyme immunoassay (EIA; Cambridge Biotech Corporation, Galway, Ireland). Monthly first-void urine samples were collected and tested for N. gonorrhoeae and C. trachomatis by PCR assay (AmpliCor PCR Diagnostics, Roche Diagnostics, Laval, Quebec, Canada). At the posttrial resurvey, first-void urine samples were tested for N. gonorrhoeae and C. trachomatis by means of PCR. T. vaginalis was cultured from vaginal swabs using In Pouch TV, and HIV and syphilis serology was performed. Any infections were treated according to Kenyan national treatment guidelines.

Antiretroviral programs for HIV therapy had not been scaled up in the region at the time of the original trial or of this resurvey but began to be rolled out in Nairobi in 2004. All sex workers attending peer-led sex worker community meetings in Kibera villages were informed of these programs. Women who had tested HIV-positive at any time, whether or not they were enrolled in our trial or resurvey, were referred to these programs through the sex worker clinic. No active tracing of HIV-infected participants was undertaken.

Statistical Analysis

For all statistical analyses comparing factors at baseline (enrollment) and follow-up time points, baseline data were only included for the subset of FSWs who participated in the posttrial resurvey. Self-reported condom use, weekly number of reported clients, and hormonal contraceptive use over the
past month were all recorded in the baseline, follow-up, and resurvey periods. Casual clients were defined as single-time only customers; regular partners were self-identified by FSWs as longer term intimate partners (often a “boyfriend” or husband). Information regarding the charge for sex and specific high-risk sex acts (eg, anal sex, sex during menses) was only collected at enrollment and at the time of resurvey. Condom use was reported on a semiquantitative scale (0 = never [0%], 1 = rarely [1% to 24%], 2 = sometimes [25% to 49%], 3 = often [50% to 74%], 4 = almost always [75% to 99%], and 5 = always [(100%)]. Changes in continuous variables over time were evaluated within an individual using the Wilcoxon signed rank test. Groups were compared using the Wilcoxon signed rank test (for continuous variables) or the χ² test (for dichotomous variables) in SPSS version 10.0 for windows (SPSS, Chicago, IL). Only women who were active in sex work with at least 1 weekly client were included in the analyses of sexual behavior.

RESULTS

Cohort Characteristics at Study Follow-Up

All resurveyed FSWs had completed the baseline enrollment questionnaire, had been followed for varying intervals of time through the randomized trial, and had completed the resurvey questionnaire. One hundred seventy-two FSWs were resurveyed after the trial was terminated, of whom 144 (84%) currently exchanged sex for money. Their mean age at resurvey was 33.5 years (±8.8 years), and the mean time elapsed from the last clinical trial visit to resurvey was 1.2 years (range: 1.0 to 5.3 years). One participant was married, and the rest were divorced/separated/widowed (58%) or never married (41%). The mean reported prior duration of sex work was 10.5 years (±6.7 years). To assess how representative these 172 FSW participants were of the original clinical trial cohort, baseline demographics, sexual behavior, and STI prevalence data at original trial enrollment were compared between those who were subsequently resurveyed (n = 172) or were not (n = 294). Those taking part in the resurvey had been older at trial enrollment (30.0 vs. 27.8 years; P = 0.002), perhaps reflecting decreased mobility with increasing age. There were no significant differences in charge for sex or baseline sexual behavior, however, as defined by condom use with casual or regular clients, number of casual or regular clients, or the proportion reporting anal sex or sex during menses (Table 1); neither were there any differences in the prevalence of infection by N. gonorrhoeae, C. trachomatis, or T. vaginalis (Table 2).

Sexual Behavior With Casual Clients

At resurvey, the mean charge for sex had increased significantly from trial enrollment (201 vs. 131 Kenyan shillings [Ksh] (75 Ksh = 1 US dollar); P < 0.001). As previously reported, the average reported number of casual clients per week fell dramatically during the trial from 16.2 at enrollment to 2.8 at the last study visit (paired samples t test, P < 0.001). This number had increased significantly by the time of resurvey (from 2.8 to 6.1; P < 0.001; Fig. 1), although casual client numbers remained much lower at resurvey than they had been at the original trial enrollment (6.1 vs. 16.2; P < 0.001). Condom use with casual clients had also increased during the clinical trial (from 2.6/5 to 3.7/5 on our semiquantitative scale; P < 0.001). Rather than declining after trial termination, however, condom use had actually continued to increase (from 3.7/5 to 4.3/5; P < 0.001; see Fig. 1).

Between trial termination and the posttrial resurvey, there was an increase in the number of unprotected casual encounters that just reached statistical significance (from 23.3 to 35.6 per year; P = 0.05).

Sexual Behavior With Regular Partners

Sexual behavior by FSWs with their regular partners (boyfriends) is more refractory to change than with casual clients, because negotiating condom use is difficult in the

TABLE 1. Demographics at Original Trial Enrollment for FSWs Who Did or Did Not Take Part in the Posttrial Resurvey

<table>
<thead>
<tr>
<th></th>
<th>Took Part in Resurvey (n = 172)</th>
<th>Declined Resurvey or Lost to Follow-Up (n = 294)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>30.0</td>
<td>27.8</td>
<td>0.002</td>
</tr>
<tr>
<td>Duration of sex work (y)</td>
<td>5.8</td>
<td>4.9</td>
<td>0.05</td>
</tr>
<tr>
<td>Casual clients/week</td>
<td>15.9</td>
<td>15.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Charge for sex (KShs)</td>
<td>130.2</td>
<td>140.4</td>
<td>0.5</td>
</tr>
<tr>
<td>Condom use (0–5 scale)</td>
<td>2.5</td>
<td>2.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Condom use with all clients (%)</td>
<td>18.0</td>
<td>16.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Report a regular client (%)</td>
<td>48.8</td>
<td>48.6</td>
<td>1.0</td>
</tr>
<tr>
<td>Condom use with regular client (0–5 scale)</td>
<td>1.0</td>
<td>1.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Douche (%)</td>
<td>68.6</td>
<td>69.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Practice anal sex (%)</td>
<td>12.8</td>
<td>16.7</td>
<td>0.3</td>
</tr>
<tr>
<td>Practice sex during menses (%)</td>
<td>20.3</td>
<td>19.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

TABLE 2. Prevalence of STIs at Original Trial Enrollment for FSWs Who Did or Did Not Take Part in the Posttrial Resurvey

<table>
<thead>
<tr>
<th></th>
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<th>Declined Resurvey or Lost to Follow-Up (n = 294)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia trachomatis</td>
<td>13/170 (7.6%)</td>
<td>30/262 (11.4%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae</td>
<td>14/172 (8.1%)</td>
<td>31/294 (10.5%)</td>
<td>0.4</td>
</tr>
<tr>
<td>Treponema pallidum</td>
<td>7/172 (4.1%)</td>
<td>12/293 (4.1%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Bacterial vaginosis</td>
<td>77/162 (47.5%)</td>
<td>146/276 (52.9%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Hormes simplex virus</td>
<td>type 2</td>
<td>127/167 (76.0%)</td>
<td>0.2</td>
</tr>
</tbody>
</table>

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context of an intimate relationship; nonetheless, sex with regular partners may lead to HIV exposure and infection.\textsuperscript{23,24} In the clinical trial, data regarding sexual behavior with regular partners were collected at enrollment, and these were compared with self-reported data at resurvey. Among the 144 women who had remained active in sex work, 68 (47\%) of 144 had reported a regular client at enrollment, whereas 107 (74\%) of 144 did so at resurvey. The mean number of regular clients had increased from 0.9 at enrollment (range: 1 to 5 clients) to 1.3 (range: 1 to 5 clients) \((P < 0.001)\). Self-reported condom use with regular clients was consistently lower than with casual clients, however, at enrollment (1.1/5 with regular clients vs. 3.2/5 with casual clients; \(P < 0.001\)) and at resurvey (3.5/5 with regular clients vs. 4.3/5 with casual clients; \(P < 0.001\)). Assuming 1 sexual encounter per week with regular clients, we calculated the number of annual unprotected encounters with a regular client. There was a trend toward reduced unprotected regular client encounters over time, although this was not statistically significant (25.5 per year at trial enrollment vs. 19.2 per year at resurvey; \(P = 0.1\)). The proportion of all unprotected sexual encounters that were with a regular client, as opposed to a casual client, increased over the same time frame (from 10.3\% at enrollment to 34.6\% at resurvey; \(P < 0.001\)), however.

**Place of Work and Sustainability of Reductions in Sexual Risk Taking**

As previously reported in the larger cohort,\textsuperscript{32} initial increases in condom use were similar for all FSWs but were less well sustained in club-based and bar-based sex workers than in those working from their own home. At resurvey, the greatest increase in client numbers was seen in bar-based sex workers (home-based sex workers, increase of 2.2 clients since trial termination; club-based sex workers, increase of 3.8 clients since trial termination; bar-based sex workers, increase of 5.2 clients since trial termination; \(P = 0.001\); Fig. 2A). Self-reported condom use did not differ between bar-based sex workers and those based elsewhere (see Fig. 2B), however.

**Self-Reported Sexual Behavior and Sexually Transmitted Infection/HIV Incidence**

Prevalent classic STIs and newly acquired HIV were uncommon at resurvey. During the original clinical trial, 17 (9.9\%) of 172 women had acquired HIV during a mean of 2.7 years of follow-up, for an HIV incidence of 3.7 per 100 person-years (PYs). There were 3 new HIV cases at resurvey among 155 women (two thirds in women currently active in sex work), for an HIV incidence of 1.6/100 PYs. These rates were not significantly different \((P = 0.3, 2\text{-sample comparison of Poisson rates; Table 3})\), and the trend to reduced HIV incidence may reflect concurrent reductions in national adult HIV prevalence.\textsuperscript{25} At resurvey, there were only 6 prevalent cases of \textit{N. gonorrhoeae}, 3 of \textit{C. trachomatis}, and no cases of \textit{T. vaginalis}. STI incidence could not be compared between periods because of differences in sampling frequency. Again, however, restricting analysis to resurveyed FSWs, STI prevalence at resurvey was consistently lower than at original trial enrollment (see Table 3; 2.4\% vs. 7.5\% for \textit{Chlamydia}, \(P = 0.03\); 4.2\% vs. 8.1\% for gonorrhea, \(P = 0.1\); and 0\% vs. 14.2\% for trichomoniasis, \(P < 0.001\), Wilcoxon signed rank test).

During resurvey, FSWs with a prevalent STI or newly acquired HIV infection reported a higher number of unprotected sexual exposures to casual clients over the past year (83.2 vs. 37.4; \(P = 0.009)\). In addition, they were younger (27.3 vs. 33.5 years of age; \(P = 0.009)\) and had been engaged in sex work for a shorter time (6.6 vs. 10.4 years; \(P = 0.02\)). The number of unprotected sexual encounters...
with regular clients was not associated with new STI/HIV infection (25.7 vs. 24.8 unprotected encounters per year; \( P = 0.9 \)).

**DISCUSSION**

Risk reduction interventions in FSW groups have been associated with profound changes in sexual behavior, \(^9\)\(^{19}\) and modeling suggests that FSW-targeted interventions are the most cost-effective way to prevent HIV sexual transmission.\(^3\) After the FSW clinical trial in Cameroon, however, only a few women sustained consistent condom use for more than 1 year.\(^20\) Within a similar time frame, our data suggest that if low level community services can be maintained (in this case, provision of free condoms at bars through an independent initiative and quarterly peer-led community meetings at the village level), changes in sexual behavior may be maintained without intensive clinic-based counseling and STI management. Further follow-up is required to see how long these changes can be sustained. Although client numbers increased after trial termination, condom use also increased, such that the frequency of unprotected sexual exposures to casual clients was unchanged and rates of HIV and classic STIs were low.
TABLE 3. Rates of STIs and HIV During the Original Trial and at Posttrial Resurvey

<table>
<thead>
<tr>
<th>STI</th>
<th>Original Trial</th>
<th>Posttrial Resurvey</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia trachomatis (%)</td>
<td>13/170 (7.6)</td>
<td>4/168 (2.4)</td>
<td>0.03</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae (%)</td>
<td>14/172 (8.1)</td>
<td>7/168 (4.2)</td>
<td>0.1</td>
</tr>
<tr>
<td>Trichomonas vaginalis (%)</td>
<td>23/170 (13.5)</td>
<td>0/168 (0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HIV (incidence per 100 PYs)</td>
<td>3.7</td>
<td>1.6</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*Prevalence at original trial enrollment or at posttrial resurvey screening.
†Incidence during the original trial period or during the posttrial period.

We only examined changes in sexual behavior on an individual level. All FSWs seen at resurvey had also been enrolled and followed for several years in the preceding clinical trial. Therefore, changes in sexual behavior (or a lack thereof) may also relate to changing life circumstances as women mature. At the level of the entire sex worker community, more intensive behavioral interventions may still be necessary to have an impact on younger sex workers, who may be new to sex work in the community, and to change sexual behavior in this higher risk group. This concept was supported in our cohort by the observation that younger FSWs were at a greater risk for STI/HIV acquisition.

At resurvey, a greater proportion of sex work focused on regular clients, who accounted for a much greater proportion of unprotected sex acts. Despite increased casual client numbers after trial termination, HIV and STI rates remained low, perhaps because of consistent condom use. Sexual behavior with regular clients was more refractory to change, perhaps because of the more intimate nature of these relationships. Despite the substantial increases in the proportion of unprotected sex attributable to regular client encounters, it was only unprotected sex with casual clients that was associated with HIV/STI rates. Although regular clients are believed to represent an important bridging population for HIV and other STIs between sex workers and the general population, this may be critically dependent on the number of partners with whom the sex workers have concurrent sexual relationships. Because we did not collect behavioral or biologic data from male clients in this study, we are not able to explore why unprotected sex with regular partners seemed to be a less important risk factor for STI/HIV acquisition than with casual clients.

We cannot demonstrate whether the behavioral changes that we observed over time represented a natural evolution of sex work practices as women age or reflected changes in FSW practice at a community/population level induced by our intervention. The sex worker peer interventions aim to empower FSWs to change their sexual behavior; to provide a forum to exchange ideas on how to negotiate consistent condom use with clients; and to develop strategies to reduce risk with regular clients, who often provide less conventional support, such as school fees, rent, or groceries. By mobilizing an entire FSW community, peer interventions also aim to empower FSWs at a community level to charge more money for sex, as seen over time in our study, which may enable women to reduce client numbers. We cannot demonstrate whether the FSW behavioral changes that we observed were limited to FSW individuals enrolled and followed through our study or were occurring at a larger community level, however.

The self-reported data collected regarding condom use relied on a relatively crude semiquantitative scale. This may be less reliable than other methods, such as the cumulative reporting of condom use at last act, although the latter methods are also far from perfect, but it allowed us to assess temporal changes in condom use with clients, because this was the method used in our original clinical trial. Although various biases might affect the validity of self-reported, semiquantitative condom use data, it is reassuring that the same scale in this cohort previously correlated with the rate of acquisition of HIV and STIs in a stepwise fashion.

Although our risk reduction intervention provided a framework for sustained changes in sexual behavior, it falls short of the best practices suggested by the Joint United Nations Program on HIV/AIDS (UNAIDS). The latter suggests incorporating a situation analysis and mapping exercise for design and subsequent monitoring and evaluation of programs; coordination of responses and resources, including a national planning exercise and prioritization of interventions; identification and inclusion of a range of project partners, including sex workers, communities, private enterprises, and sectors other than health; and taking a longer term and broader perspective on ways to decrease vulnerability of sex workers by addressing the conditions (including economic and gender issues) surrounding sex work. It is perhaps reassuring to see that programs such as ours, with fewer resources than would be required for such an intervention, may still be associated with significant and sustained changes in sexual behavior, however.

Overall, our study suggests that the provision of less intensive community-based risk reduction services after clinical trial termination can lead to sustained changes in sexual behavior, with reduced STI and HIV rates among FSWs. Although reductions in client numbers were less well sustained, condom use with casual clients actually increased, and unprotected sex with the latter group was most highly associated with STI/HIV acquisition.

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