

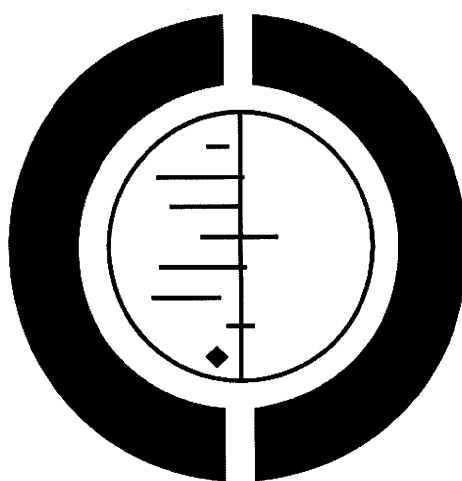
## 資料 1

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# **Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries (Protocol)**

Ota E, Wariki WMV, Hori N, Mori R, Shibuya K



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[Intervention Protocol]

## **Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries**

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### **ABSTRACT**

This is the protocol for a review and there is no abstract. The objectives are as follows:

1. To identify the studies done on behavioural interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries
2. To evaluate the effect of behavioural interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries.

## BACKGROUND

### Description of the condition

The HIV/AIDS epidemic continues to expand worldwide. Globally, there were an estimated 33 million people [range 30 million-36 million] living with HIV in 2008, and the annual number of new HIV infections declined from 3.0 million [range 2.6 million-3.5 million] in 2001 to 2.7 million [2.2 million-3.2 million] in 2007 (UNAIDS 2008). Overall, 2.0 million people [range 1.8 million-2.3 million] died due to AIDS in 2007, compared with an estimated 1.7 million [1.5 million-2.3 million] in 2001 (UNAIDS 2008).

Some of the most worrisome increases in new infections are now occurring in various high-income countries, such as in Western Europe (UNAIDS 2008; UNAIDS 2009). The rate of newly reported HIV infection in Europe nearly doubled between 2000 and 2007 (van de Laar 2008). In the United States, the Centers for Disease Control and Prevention estimated that annual HIV incidence has remained relatively stable since the early 1990s, although the annual number of new HIV infections in 2006 (56,300) was approximately 40% greater than previously estimated (Hall 2008). In Canada, official epidemiological estimates suggest that annual HIV incidence may have increased between 2002 and 2005 (Public Health Agency of Canada 2007).

Sex workers are defined as female, male and transgender adults and young people who receive money or goods in exchange for sexual services, either regularly or occasionally, and who may or may not consciously define those activities as income-generating (UNAIDS 2002). The World Health Organization (WHO) defines sex workers as one of four key populations globally for HIV/AIDS health initiatives, estimating that there are tens of millions of sex workers worldwide, with clients in the hundreds of millions (WHO 2006). Sex workers are at high risk for infection with HIV, and their clients may serve as a "bridging population" by spreading HIV to the general population (Ghys 2001). Talbot argued that the number of HIV-infected sex workers in an individual country is highly significant for explaining the HIV prevalence levels across countries (Talbot 2007). National estimates of median HIV prevalence among sex workers was 0.4% (range 0.1%-1.4%) in Western Europe in 2000, (Vandepitte 2006). It has been estimated that there are around 80,000 female sex workers (FSWs) in Britain (Scambler 2007) and that less than 2% of London's FSWs are HIV-positive (Day 2006a; Day 2006b), notwithstanding reports that almost half (43%) of new diagnoses of HIV in the United Kingdom in 2005 occurred in London (UNAIDS/WHO 2006).

In general, the living and working conditions of sex workers could result in a variety of interrelated risk factors for HIV infection: a large number of different sexual partners, and hence exposure to many other sexually transmitted infections (STIs) that could increase the probability of acquiring or transmitting HIV; unprotected sexual activity, often because clients or private partners

refuse to use condoms; and drug injection by either the woman or her sexual partners (Estebanez 1993).

Migrant sex workers have become a bridge population in the global spread of HIV/AIDS in various high-income countries (Parrado 2004, O'Connor 1996), and their mobility causes problems for the establishment of support networks and ongoing medical care (Church S 2001, Wolffers 2002, Mardh 1999). An Australian study showed a higher risk of STIs and lower rates of condom use for international sex workers than for local sex workers (O'Connor 1996). Higher HIV rates are also found in foreign transsexual sex workers in Rome (Spizzichino 2001).

### Description of the interventions

Several studies have indicated that many clients of sex workers refuse to use condoms during sexual relations (Estebanez 1993). The effect of behavioural intervention strategies could be increased by aiming for goals that are achieved by use of multilevel approaches, such as increases in condom use, with populations both uninfected and infected with HIV (Coates 2008). Female condom interventions may help empower women to protect themselves when they are unable to avoid sexual relations with HIV-infected partners or cannot persuade their partners to use a condom. In Amsterdam, a survey of men recruited from an STI clinic who had had relations with sex workers in the preceding four months found that less than half of these men always used condoms during vaginal intercourse with sex workers; only 7% used condoms with their private sexual partners (Hooykaas 1989).

Injecting drug use is the major risk factor associated with HIV infection among sex workers in Western countries (Estebanez 1993). In most cases, infection among injecting drug users probably results from sharing contaminated syringes or needles; however, some women may have acquired HIV through sexual contact with a drug-using partner. And non-injected recreational drugs may also cause people to fail to practice safer sex, contributing to HIV transmission. A number of investigators have reported that the disinhibiting effects of alcohol and other drugs decrease the likelihood of using condoms and may increase the tendency to engage in higher-risk forms of sexual activity (Robertson 1988, Plant 1990, Harcourt 1990). Among 118 sex workers studied in New York in 1985-1987, 31% of those who injected drugs versus only 7% of those who did not were HIV positive (Wallace 1987). A European survey of 866 sex workers from nine European centres (Amsterdam, Antwerp, Athens, Copenhagen, Lisbon, London, Paris, Vienna and eight cities in Spain) carried out in 1990-1991 found that HIV seroprevalence was 32% among women who were injecting drug users and <2% among women who did not inject drugs (European Working Group 1992). Similarly, a survey of 208 street-based sex workers in Glasgow found that 59% injected drugs (McKeganey 1990).

In regions where HIV infection is rare among FSWs, surveillance of risk behavior and STIs will indicate the potential for spread

of HIV infection (UNAIDS/WHO 2006). Surveillance for behaviour, STI and HIV among sex workers is important because the results may indicate success or failure of the national response to the epidemic, including targeted programs to encourage safe sex between sex workers and clients (Ghys 2001). Interventions to change behavior among sex workers and their clients have been identified as a strategy to reduce HIV transmission. Fisher et al (Fisher 2006a, Fisher 2006b) concluded that critical components of interventions included not only information but also motivation and skills. Vaginal use of topical microbicides by women helps reduce the transmission of HIV (Poynten 2009) and other STIs (Behets 2008). Interventions for management of STIs were based on clinical diagnosis and serologic tests for herpes simplex virus type 2 (HSV-2) with a monoclonal blocking enzyme immunoassay (Kamali 2003).

### How the interventions might work

Meta-analysis in developing countries have shown that behavior change interventions effectively reduce HIV transmission for sex workers (Merson 2000). Voluntary HIV counseling and testing has been associated with increased condom use, reduced number of partners, and decreased HIV and in sex workers and clients (Merson 2000). This effect results from behavior change subsequent to education, support, and the knowledge of one's HIV status. Care programmes and participation in research can have a similar effect (Michael 2005).

Male condoms reduce HIV and STI transmission in sex workers (Holmes 1994, Hanenberg 1994, Donovan 2004) and prevent STI complications such as pelvic inflammatory disease (Ness 2004). A reliable and accessible supply of good quality condoms is essential (UNAIDS 2002, Merson 2000, Michael 2005). Condom promotion, distribution, and social marketing result in increased condom use and reduced STI and HIV infection rates, especially in female sex workers (Merson 2000). Local culture, language, and traditions should also be considered (Gerofi 1995). Female condoms have successfully prevented pregnancy and reduced STI transmission in analytical studies, (Fontanet 1998, Denlaud 1997, French 2003) and there is in-vitro evidence and biological plausibility for HIV prevention (Denlaud 1997). Female condoms empower women by enabling them to negotiate safe sex, by promoting healthy behavior, and by increasing self-effectiveness and sexual confidence (Gollub 2000). Female condoms are accepted by sex workers (Denlaud 1997, Michael 2005), but major difficulties include cost and poor availability.

Education for sex workers can improve healthy behavior by delivering the basic facts about disease, dispelling myths, and offering healthy lifestyle and work options (Michael 2005). Education can effectively reduce drug use, disease, violence, debt and exploitation (Vanwesenbeeck 2001, UNAIDS 2002; O'Connor 1996; Merson 2000). Peer education has resulted in substantial increases in STI and HIV knowledge, condom use, and safer sex

practices, and reduced incidence of HIV and STIs (Vanwesenbeeck 2001, UNAIDS 2002, Michael 2005).

Community development has been successful in the promotion of safe sex, identification of injustice, support for HIV-infected workers, enhancement of self-esteem, cooperation with police and controllers, provision of legal and financial training, initiation of alternative income-generation schemes, and support for migrants and human rights (UNAIDS 2002, UNAIDS 1999, Michael 2005). Successful initiatives have resulted in enhanced self-esteem; improved negotiating skills; ability to refuse clients; access and use of condoms; training to recognize, avoid, and escape violence; STI and HIV preventive services; safe houses; drop-in centres; and STI treatment through pharmacies (Vanwesenbeeck 2001, UNAIDS 2002, UNAIDS 1999, Williamson 2001).

### Why it is important to do this overview

The settings in which sex workers work, however, as well as the behavioural characteristics of these sex workers and their clients, may differ between the high-income developed world and low- and middle-income developing world. Hence, the intervention strategies may also be different.

Behavioural interventions are being undertaken in various parts of high-income countries (Dorfman 1992). However, there has been no systematic review that has examined and summarized their effects.

## OBJECTIVES

1. To identify the studies done on behavioural interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries
2. To evaluate the effect of behavioural interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Studies which have evaluated the effect of behavioural interventions on any one of the outcome measures, specified below, and for methodological rigor based on study design (randomized controlled trials and certain quasi-experimental designs) in high-income countries, will be included. Randomised controlled trials in which the unit of randomisation is individuals and clusters (groups

or communities) will be included. From non-randomized studies, certain quasi-experimental prospective designs with a control group are considered eligible only if they include independent comparison groups where assignment to treatment status is not based on need or volition, and separate baseline measurements are also taken, as in the Untreated Control Group Design with Pretest and Posttest (Cook 1979).

Examples of studies that are not eligible are those that compared:

- People who chose to participate in an intervention with those who did not
- Baseline and follow-up measures with no separate comparison condition
- Only follow-up measures without baseline measures when either individuals or groups were assigned to treatment condition by a non-random process

High-income countries are those that are technologically advanced and enjoy a relatively high standard of living. For the purposes of this review, we will consider these to be the 66 countries identified by The World Bank as having "high-income economies" (World Bank).

### Types of participants

1. Sex workers (female, male, and transgender)
2. Clients of sex workers (female and male)

### Types of interventions

behavioural or social interventions designed to promote sexual risk reduction and thereby to reduce transmission of HIV or other STIs. These interventions may be delivered to individuals, groups, or communities.

### Types of outcome measures

Primary outcomes:

-Change in biological variables for prevention among FSWs and their male clients, including HIV incidence, HIV prevalence, STI incidence, STI prevalence

Secondary outcomes:

-Change in self-reported behavior or change in observed behavior (e.g. knowledge, attitudes, intentions, self-reported sexual behavior, biological outcomes).

These outcome measures include:

1. Condom use (male/female)
2. Needle change
3. Increasing self-efficacy for protective behavior
4. Improving communication with partners (male clients and private partners) regarding safer sexual practices
5. Use of microbicides (post-exposure and pre-exposure)
6. Treatment of STIs and reproductive tract infections
7. Less risky types of sex

### Search methods for identification of studies

Intervention strategies for behavioural changes may be heterogeneous and influenced by social, demographic, and cultural factors, according to local situations. Reporting strategies for the effect of these interventions might not be uniform and there may be considerable grey literature and local publications dealing with this issue. Hence, relevant studies will be identified by the following procedures:

a) Electronic databases: To begin with, a comprehensive list of electronic databases will be made in consultation with the HIV/AIDS Review Group Coordinator, the Trial Search Coordinator and some of the experts in HIV/AIDS research and service projects working in high-income countries. Opinions from policy makers and healthcare administrators also will be sought regarding sources of databases. This list will serve as the key document for extraction of data from electronic databases.

The Cochrane Central Register for Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, MEDLINE, PsycInfo, ERIC, Web of Science, the National Research Register, CINAHL, Dissertation Abstract International (DAI), EMBASE, and Cochrane HIV/AIDS Group specialized register will be included in the database list. The publication sites of the World Health Organization, the US Centers for Disease Control and Prevention, and other international research sites also will appear in the database list.

An extensive search strategy string will be developed in consultation with the Trial Search Coordinator of the HIV/AIDS Review Group. All possible keywords will be included in the string to get an exhaustive electronic literature search. Journals in all languages will be included in the search. Articles from other languages will be translated into English with the help of experts, and data will be extracted.

b) Handsearching: Because some of the publications might not have appeared in electronic databases, a handsearching strategy will be developed and adapted for high-income countries.

c) Personal communication: Key personnel and organizations working in HIV/AIDS interventions in high-income countries, including members of the various networks of sex work researchers and activists in high-income countries including the United Kingdom and the United States, will be contacted for published and unpublished references and data.

d) Cross-references: The quoted references of studies identified by the above procedure will be further scrutinized to locate more studies.

e) Conference proceedings of national and international conferences related to HIV/AIDS will be searched.

The search strategy will be iterative in that references of the included studies will be searched for additional references.

## Data collection and analysis

The methodology for data collection and analysis is based on the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2009).

### Selection of studies

All studies that have addressed behavioural interventions in high-income countries will be identified. High-income countries include all high-income countries in the World Bank. A high-income country is one with an annual gross national income (GNI) per capita equivalent to \$11,906 or greater in 2009 (World Bank). The abstracts of all identified studies will undergo initial screening in an inclusive manner, based on the objectives of the study, and will be short-listed. The full articles of short-listed studies will be obtained and scrutinized independently by two sets of reviewers for possible inclusion. Scrutiny for inclusion will be based on the type of study, type of participants, type of interventions, and outcome measures. A standard proforma will be developed and used for documenting the decision process. Each set of reviewers will independently document in the proforma the determination of the study's inclusion or exclusion and the reasons. In case of disagreement, a fifth reviewer will serve as arbitrator. Thus, the agreed-upon studies will be included in the review. In the case of excluded studies, a summary statement will be made about the reasons for exclusion.

### Data extraction and management

The data from selected studies will be extracted by two teams independently, using a pre-designed data extraction sheet. The data extraction sheet contains details of key entries, namely the trial's identification, its methods, types of participants, the intervention, and the outcomes.

We will use data collection forms to extract data on study design. For eligible studies, two review authors will extract the data using the agreed upon form. We will resolve discrepancies through discussion or, if required, we will consult an additional review author. We will enter data into Review Manager software (RevMan 2008) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

### Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). We will resolve any disagreement by discussion or by involving an additional assessor.

- 1) Sequence generation (checking for possible selection bias)
- 2) Allocation concealment (checking for possible selection bias)
- 3) Blinding (checking for possible performance bias)
- 4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)
- 5) Selective reporting bias
- 6) Other sources of bias
- 7) Overall risk of bias

### Measures of treatment effect

Dichotomous data: We will present results as a summary risk ratio with 95% confidence interval.

Continuous data: We will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome but use different methods.

### Unit of analysis issues

individually randomized trials, cluster-randomized trials and cross-over trials will be included.

### Dealing with missing data

For included trials, we will note levels of attrition. We will explore the impact of including trials with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. For all outcomes we will carry out analysis on an intention-to-treat basis. The denominator for each outcome in each trial will be the number randomized minus any participants whose outcomes are known to be missing.

### Assessment of heterogeneity

We will use the  $I^2$  statistic to measure heterogeneity among the trials in each analysis. If we identify substantial heterogeneity ( $I^2 > 50\%$ ), we will explore it by prespecified subgroup analysis.

### Assessment of reporting biases

Where we suspect reporting bias, we will attempt to contact study authors, asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such trials in the overall assessment of results by a sensitivity analysis.

### Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2008). We will use fixed-effect inverse variance meta-analysis for combining data where trials are examining the same intervention and the trials' populations and methods are judged sufficiently similar. Where we cannot explain heterogeneity between trials' treatment effects, we will use random-effect meta-analysis.

### Subgroup analysis and investigation of heterogeneity

If we can include a number of trials, we plan to carry out subgroup analysis for the primary outcome of the HIV incidence, HIV prevalence, STI incidence and STI prevalence. For fixed-effect meta-analysis, we will conduct planned subgroup analysis, classifying whole trials by interaction tests as described by Deeks (Deeks 2001). For random-effect meta-analysis, we will assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

### Sensitivity analysis

We will perform sensitivity analysis based on trial quality, separating high-quality trials from trials of lower quality. For the purposes of this sensitivity analysis, we will define "high quality" as a trial having adequate allocation concealment, and classify as "unrea-



sonably expected loss to follow-up” as less than 20%, given the stated importance of attrition as a quality measure (Tierney 2005). If we include any cluster-randomized trials, other sensitivity analysis may also be desirable. If cluster trials have been incorporated with an estimate of the ICC borrowed from a different trial, we will perform a sensitivity analysis to see what the effect of different values of the ICC on the results of the analysis would be.

## ACKNOWLEDGEMENTS

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\* Indicates the major publication for the study

**WHAT'S NEW**

Last assessed as up-to-date: 21 April 2010.

Date	Event	Description
2 September 2010	New citation required and major changes	New protocol, new author team.

**HISTORY**

Protocol first published: Issue 2, 2006

Date	Event	Description
15 February 2010	New citation required and major changes	Made protocol a “clean slate” for new author team.
11 November 2008	Amended	Converted to RevMan 5, and re-published without new citation.

## **CONTRIBUTIONS OF AUTHORS**

Erika Ota (EO) and Windy Wariki (WW) designed, set up, and drafted the protocol. Narumi Hori (NH), Rintaro Mori (RM), and Kenji Shibuya (KS) revised the article and KS supervised development of the protocol. All authors read and approved the final protocol. NH is a content specialist, who has been working in the field of HIV/AIDS education. RM has experiences in systematic reviews in NICE guidelines and Cochrane reviews in the field of Pregnancy and Childbirth. KS is an expert of global health field including both high- and low-income settings.

## **DECLARATIONS OF INTEREST**

We declare that we have no conflict of interest.

## **SOURCES OF SUPPORT**

### **Internal sources**

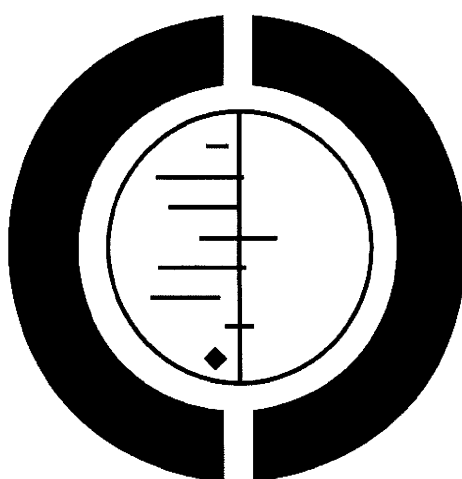
- Health Labour Sciences Research Grant, Japan.

### **External sources**

- No sources of support supplied

# **Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low-income and middle-income countries (Protocol)**

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**Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low-income and middle-income countries (Protocol)**

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[Intervention Protocol]

## **Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low-income and middle-income countries**

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### **ABSTRACT**

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to evaluate the effectiveness of behavioral interventions for reducing the transmission of HIV infection among sex workers (male, female, and transgender) and their clients in low- and middle-income countries. Through this systematic review, we aim to discover if behavioral interventions such as condom use and behavior modification are effective in reducing the transmission of HIV when the interventions are delivered in sex worker settings. We will investigate what behavioral interventions to reduce risk of HIV transmission among commercial sexual workers have been tested in RCTs.

## BACKGROUND

### Description of the condition

In 2008, the Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that an estimated 2.7 million people (range 2.4-3.0 million) became newly infected with HIV, bringing the total number of people living with HIV to 33.4 million (range 31.1-35.8 million). Overall, 2.0 million (range 1.7-2.4 million) AIDS-related deaths occurred worldwide (UNAIDS 2009). Most newly acquired infections occurred in low- and middle-income countries, and sub-Saharan Africa remains the most heavily affected region, mainly as a result of heterosexual transmission (WHO 2009).

Sex workers are defined as “female, male and transgender adults and young people who receive money or goods in exchange for sexual services, either regularly or occasionally, and who may or may not consciously define those activities as income-generating” (UNAIDS 2002). The term “sex workers” constitutes a meaningful single population for epidemiological purposes, but it encompasses female sex workers, male sex workers, and male-to-female transgender sex workers in a wide variety of settings (e.g. brothels, massage parlours, informal settings, and on the street). Sex workers and their clients, including truck drivers, security workers, sailors, dock workers, police, migrant workers and businessmen, are highly at risk for HIV exposure. Transmission among sex workers and their clients helps to drive a much broader epidemic of heterosexually acquired HIV (UNAIDS 2009), resulting in extensive transmission among individuals who engage in low levels of risk behavior. The lifetime probability of a sex worker becoming infected by HIV is high due to multiple risk factors, including a large number and turnover of partners, low levels of condom use, high prevalence of sexually transmitted infections (STIs), and unsafe practices such as douching and use of inappropriate lubricants. They are rarely targeted by HIV prevention interventions (Vuylsteke 2009) but have unique prevention requirements because of their socially stigmatised (Padilla 2008) and often precarious lifestyle due to economic pressure (Gu 2008).

The number of countries reporting on indicators relating to sex workers significantly increased between 2005 and 2009. In sub-Saharan Africa, HIV prevalence among sex workers ranged from zero in Comoros and Sierra Leone to 49.4% in Guinea-Bissau. Seven African countries (Benin, Burundi, Cameroon, Ghana, Guinea-Bissau, Mali and Nigeria) have reported that more than 30% of all sex workers were living with HIV (UNAIDS 2009; Gomes do Espirito Santo 2005). Recently, about one quarter of all sex workers (26%) in Lesotho were reported to have had a symptomatic STI (Khubotlo 2009). In Swaziland, transmission during heterosexual contact (including sex within stable couples, casual sex and sex work) is estimated to account for 94% of incident infections (Mngadi 2009). In 2008, Lowndes et al have reported between 13% and 29% of men in West Africa may have paid for sex in the previous year (Lowndes 2008). Surveys in Kenya (Gelmon 2009), Uganda (Wabwire-Mangen 2009) and Rwanda (Asiimwe 2009)

suggested that sex workers and their clients accounted for an estimated 14.1%, 10% and 46% of incident HIV infections, respectively. Results of a randomised controlled trial (RCT) in Jamaica have shown that 25% among AIDS patients had had exposure to sex workers (Weir 2008).

Unprotected commercial sex is the most important risk factor for the spread of HIV in several parts of Asia. In Viet Nam, 33% of male sex workers recruited from more than 70 sites in Ho Chi Minh City tested positive for HIV (Nguyen 2008). Prevalence of HIV among male sex workers is more than twice that of their female counterparts and is currently trending upwards in Thailand and Indonesia (UNAIDS 2009). Sex work is common among male-to-female transgender people in Pakistan (Khan 2008). High prevalence of HIV infection among transgender sex workers also has been reported in studies conducted in Phnom Penh, Cambodia (22%) in 2003 (Girault 2004) and Jakarta, Indonesia (59.3%) (Pisani 2004). In India, high HIV and STI prevalences were found among street-based female sex workers (30% and 27%, respectively) and among those who work in brothels (34% and 13%, respectively) (Buzdugan 2010). Clients of commercial sex workers are also at high risk of transmission. Given their high mobility and frequent sexual encounters with sex workers in other parts of Indonesia, these men could be agents of rapid spread of the virus throughout Indonesia (Fajans 1995).

In the Middle East and North Africa, surveys of bar-based sex workers in Djibouti have found HIV prevalence rates as high as high 26%, while in Yemen it has ranged from 1.3% to 7% (UNAIDS 2009); in Egypt, 0.8% (Shawky 2009); in Algeria, Morocco and Yemen, respectively, 3.9%, 2.1% and 1.6% of their national population (UNAIDS 2009). The percentage of sex workers who report having used a condom during the most recent episode of intercourse ranged from 44.4% in Jordan to 61.1% in Yemen (UNAIDS 2009).

Surveys in the Caribbean identified high infection rates, particularly in Guyana and Jamaica in 2005 (27% and 9%, respectively) (UNAIDS 2009).

In Latin America, particularly in Peru, 44% of men report having had sex with a sex worker (Caceres 2009). Surveys in Guatemala and El Salvador have determined HIV prevalence among female sex workers of 4.3% and 3.2%, respectively (Soto 2007).

Prevention efforts may have an effect among sex workers and their clients. Several successful interventions have been reported among sex workers and their clients to reduce the heterosexual spread of HIV, including interventions to change behavior, promote condoms, improve condom availability, and educate about sexual health and effective management of STIs.

### Description of the intervention

- 1) Promotion of safer sexual behavior among sex workers and clients: condom availability and correct use



- 2) Promotion and availability of STI prevention and care services
- 3) Peer education among sex workers and clients
- 4) Structural interventions that mobilize sex workers to seek changes socially, including forces of community empowerment

#### How the intervention might work

In low- and middle-income countries in which the per capita allocation for health care spending may be very low, anti-HIV therapies are invariably beyond the reach of all but the privileged few. This situation highlights the need for effective, low-cost tools for HIV intervention that can be used in this setting.

1) The effect of behavioral strategies could be increased by aiming for important goals, such as delay in onset of first intercourse, reduction in number of sexual partners, increases in condom use, that are achieved using multi-level approaches (e.g. couples, families, social and sexual networks, institutions, and entire communities) with populations both uninfected and infected with HIV (Coates 2008). Female condom interventions may help empower women to protect themselves when they are unable to avoid sexual relations with HIV-infected partners or cannot persuade their partners to use a condom.

2) Management of STIs was based on clinical diagnosis and serologic tests for herpes simplex virus type 2 (HSV-2) with a monoclonal blocking enzyme immunoassay (Kamali 2003).

3) Peer education enlists members of a specific group to help effect behavioral change among their peers (Cornish 2009; Steen 2009). Its initial goal is usually to modify individuals' knowledge, attitudes and beliefs to bring about healthy behavior.

4) Structural interventions which mobilize sex workers to engage in HIV prevention may address other factors, such as economic security, stigma reduction, community-based organizing (Ghose 2008) and rights-based advocacy (Wolffers 2003).

#### Why it is important to do this review

Research in some countries has suggested that prevention projects resulting in increased condom use during paid sex could significantly reduce HIV transmission. In some examples, Cambodia's decline in HIV prevalence occurred when rates of consistent condom use during commercial sex rose from 53% in 1997 to 96% in 2003 (Gorbach 2006); and in China, consistent use of condoms resulted in a 70% reduction in HIV infections (Wang 2009). Other countries with epidemics driven by sex workers, such as Mombasa and Uganda (Morris 2006), Chile (Barrientos 2007) and India (Basu 2004), have experienced declines in HIV prevalence when sex workers and their clients consistently use condoms. Increasing condom use, however, depends greatly on condom availability (Bradley 2010). Therefore, making condoms available in rooms where paid sex occurs is the most effective strategy to increase condom use (Egger 2000). In addition, consistent condom use

was significantly greater among males who perceived that some or all of the members of their male social networks used condoms consistently (Barrington 2009).

Treatment for STIs was found to be more effective in reducing HIV and STI transmission when combined with consistent and correct use of condoms (Laga 1994; Ghys 2001).

Peer education has resulted in substantial increases in STI and HIV knowledge and use of condoms and in reduced incidence of HIV and STIs (Ford 2000).

Various intervention strategies have been adopted to reduce HIV transmission among sex workers and their clients in low- and middle-income countries; however, the cost-effectiveness and effectiveness of different strategies intended to encourage and facilitate protective behavior among sex workers and their clients is not known.

## OBJECTIVES

The objective of this review is to evaluate the effectiveness of behavioral interventions for reducing the transmission of HIV infection among sex workers (male, female, and transgender) and their clients in low- and middle-income countries. Through this systematic review, we aim to discover if behavioral interventions such as condom use and behavior modification are effective in reducing the transmission of HIV when the interventions are delivered in sex worker settings. We will investigate what behavioral interventions to reduce risk of HIV transmission among commercial sexual workers have been tested in RCTs.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We will include all RCTs and/or quasi-randomized controlled studies describing behavioral interventions done in sex worker settings on any one of the outcome measures specified below in low- and middle-income countries. The randomised units could be individual or clustered. Low- and middle-income countries are those in which most people have a lower standard of living, with access to fewer goods and services, than do most people in high-income countries. There are currently about 125 of these low- and middle-income countries with populations over one million; in 1997, their total population was more than 4.89 billion (World Bank).

### **Types of participants**

Sex workers (male, female, and transgender) and their clients are the target population.

### **Types of interventions**

We will include only studies on behavioral interventions for reducing the transmission of HIV in sex worker settings, including behavioral interventions, social interventions and policy interventions. Behavioral interventions are defined in this systematic review as interventions that aim to change individual behaviors to prevent HIV infection. These intervention studies will be compared with studies having no interventions.

**Behavioral interventions:** Interventions aimed at changing individual behaviors only, without explicit or direct attempts to change the norms of the community or the target population as a whole.  
**Social interventions:** Interventions designed to change not only individual behaviors but also social norms or peer norms, including strategies such as community mobilization and structural and resource support that are usually used to bring about changes in social and peer norms.

**Policy interventions:** Interventions aimed at changing individual behavior or peer and social norms or structures through administrative or legal decisions. Examples would include promoting condom availability.

### **Types of outcome measures**

#### **Primary outcomes**

Change in biological variables for HIV/STI prevention among sex workers and their clients, including:

- a) HIV incidence
- b) HIV prevalence
- c) STI incidence
- d) STI prevalence

#### **Secondary outcomes**

Change in self-reported behavior or change in observed behavior, including:

- a) Condom use (male/female)
- b) Types of sexual practices
- c) Frequency of sexual encounters
- d) Treatment of STIs, reproductive tract infections, etc.

### **Search methods for identification of studies**

Different sources of published and unpublished research literature will be searched to locate studies relevant to behavioral interventions to reduce HIV infection among sex workers and their clients. Reporting strategies of the effect of these interventions might not be uniform, and there may be much grey literature and local publications dealing with this issue. The following databases and conference proceedings will be searched using a comprehensive search

strategy without restricting for language or publication status for relevant trials.

#### **1) Electronic databases**

We will consult with the HIV/AIDS Review Group Coordinator and the Trials Search Coordinator to search the Cochrane HIV/AIDS Group's Trials Register and experts in HIV/AIDS research and service projects working in low- and middle-income countries. Opinions from policy makers and healthcare administrators will also be sought to locate relevant databases. This list will serve as the key document for extraction of data from electronic databases. The Cochrane Central Register for Controlled Trials (CENTRAL), the Cochrane HIV/AIDS group specialized register, the Cochrane database of systematic reviews, MEDLINE, CINAHL, Dissertation Abstract International (DAI), EMBASE, LILACS, BIOSIS, SciSearch, INDMED, Proquest, and various South Asian abstracting databases will be included in the database list. The publication sites of the World Health Organization, the US Centers for Diseases Control and Prevention, and other international research and non-governmental organizations also will appear in the database list.

An extensive search strategy string will be developed in consultation with the Trial Search Coordinator of the HIV/AIDS Review Group. All possible keywords will be included in the string to get an exhaustive electronic literature search.

#### **2) Handsearching**

We will develop and conduct a handsearch of key HIV/AIDS research journals because many of the publications from low- and middle-income countries might not have appeared in electronic databases.

#### **3) Personal communication**

Key personnel and organizations working in HIV/AIDS intervention programs in low- and middle-income countries will be contacted for published and unpublished references and data.

#### **4) Conferences proceedings**

We will search conference proceedings for relevant abstracts.

#### **5) Cross-references**

The quoted references of studies identified by the procedures above will be further scrutinized to locate more studies. The search strategy will be iterative, in that references of the included studies will be searched for additional references.

### **Data collection and analysis**

The methodology for data collection and analysis is based on the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2009).

#### **Selection of studies**

Two review authors (WW and EO) will independently assess for inclusion of the potential studies we identify as a result of the search strategy. Scrutiny for inclusion will be based on the type of study, type of participants, type of interventions, and outcome measures. WW and EO will resolve any disagreement through discussion

and, if required, a third reviewer (RM) will be consulted. We will include the agreed-upon studies in the review and for excluded studies we will make a summary statement about the reasons for exclusion. Three authors (KS, RM, and N) as the experts will be informed of the included studies and conduct the data extraction independently.

#### **Data extraction and management**

We will use data collection forms to extract data on study design. For eligible studies, two review authors (WW and EO) will extract the data using the agreed upon form. We will resolve discrepancies through discussion or, if required, we will consult an additional review author (RM). We will enter data into Review Manager software (Revman 2008) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

#### **Assessment of risk of bias in included studies**

Two review authors (WW and EO) will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). We will resolve any disagreement by discussion or by involving an additional assessor (RM).

- 1) Sequence generation (checking for possible selection bias)
- 2) Allocation concealment (checking for possible selection bias)
- 3) Blinding (checking for possible performance bias)
- 4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)
- 5) Selective reporting bias
- 6) Other sources of bias
- 7) Overall risk of bias

#### **Measures of treatment effect**

Dichotomous data: We will present results as a summary risk ratio with 95% confidence interval.

Continuous data: We will use the mean difference if outcomes are measured in the same way among trials. We will use the standardised mean difference to combine trials that measure the same outcome but use different methods.

#### **Unit of analysis issues**

Randomised-controlled trials and/or quasi-randomized controlled trials

#### **Dealing with missing data**

For included trials, we will note levels of attrition. We will explore the impact of including trials with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes we will carry out analyses on an intention-to-treat basis. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

#### **Assessment of heterogeneity**

We will test for heterogeneity between studies using an  $I^2$  statistic in each analysis. If we identify substantial heterogeneity ( $I^2 > 50\%$ ), we will explore it by prespecified subgroup analysis.

#### **Assessment of reporting biases**

Where we suspect reporting bias we will attempt to contact study authors, asking them to provide missing outcome data. Where this is not possible and the missing data are thought to introduce serious bias, we will explore the impact of including such trials in the overall assessment of results by a sensitivity analysis.

#### **Data synthesis**

We will carry out statistical analysis using the Review Manager software (Revman 2008). We will use fixed-effect inverse variance meta-analysis for combining data where trials are examining the same intervention and the trials' populations and methods are judged sufficiently similar. Where we cannot explain heterogeneity between trials' treatment effects, we will use random-effect meta-analysis.

#### **Subgroup analysis and investigation of heterogeneity**

If appropriate, we will look at subgroup analysis for the primary outcome of HIV incidence, HIV prevalence, STI incidence and STI prevalence. For fixed-effect meta-analysis, we will conduct planned subgroup analysis classifying whole trials by interaction tests as described by Deeks (Deeks 2001).

#### **Sensitivity analysis**

We will perform sensitivity analysis based on trial quality, separating high-quality from lower-quality trials. For the purposes of this sensitivity analysis, we will define 'high quality' as a trial having adequate allocation concealment, and classify as 'unreasonably expected loss to follow-up' as less than 20%, given the stated importance of attrition as a quality measure (Tierney 2009).

## **Results**

## **ACKNOWLEDGEMENTS**

As part of the pre-publication editorial process, this protocol has been commented on by all authors.

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