#### REGISTERED TITLES

- Abacavir-based triple nucleoside regimens for maintenance therapy in patients with HIV
- Abstinence-promotion interventions for HIV prevention in developing countries
- Antidepressants to treat depression in people with HIV/AIDS
- Behavioural interventions for preventing HIV in refugee camps
- Boosted protease inhibitor 'monotherapy' for treating HIV/AIDS
- · Interventions for preventing HIV-related sexual violence
- Motivational interviewing for reducing morbidity and mortality in people with HIV
- Timing for initiation of antiretroviral therapy in asymptomatic, treatment-naive adults with HIV
- Timing for initiation of antiretroviral therapy in HIV-positive patients being treated for tuberculosis
  - Topical microbicides for preventing HIV infection
  - Treatment for herpes zoster ophthalmicus in people with HIV infection
  - Vaccines for prevention of HIV infection

# 添付資料 6

# コクランレビュープロトコール

- 1. Behavioral interventions to reduce the transmission of HIV infecti on among commercial sex workers and their clients in high-inco me countries
- 2. Behavioral interventions to reduce the transmission of HIV infecti on among commercial sex workers and their clients in low-incom e and middle-income countries

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

# **Protocol information**

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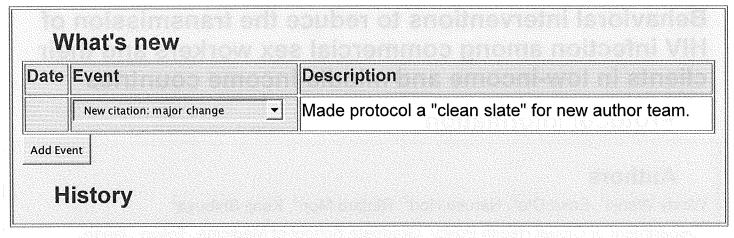
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# **Abstract**

# Plain language summary

# **Background**

#### **Description of the condition**

UNAIDS recently have reported, in 2008, there were an estimated 2.7 million (range 2.4-3.0 million) people became newly infected with HIV, bringing the total number of people living with HIV to 33.4 million (range 31.1-35.8 million) people and overall, 2.0 million (range 1.7-2.4 million) AIDS-related deaths occurred worldwide (UNAIDS 2009). Most of the newly infected occurred in low- and middle-income countries. Sub-Saharan Africa remains the most heavily affected region and mainly as a result of heterosexual transmission (WHO 2009).

Sex workers (female sex workers and male-to female transgender population) and their clients (including truck drivers, security men, sailors, dock workers and police) are the specific populations at risk of HIV exposure and has long performed an important role in the heterosexual transmission of HIV. They are rarely targeted by unique HIV prevention interventions (Vuylsteke 2009) The term sex workers constitutes a meaningful single population for epidemiological purposes, but it encompasses a wide group of female sex workers, men sex workers, and transgender with a wide variety of settings (e.g. brothels, informal settings, and on the street). 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). Transmission among sex workers and their clients is helping to drive a much broader epidemic of heterosexually acquired HIV, 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 high number and turnover of partners, low levels of condom use, high sexually transmitted infection (STI) prevalence, unsafe practices such as douching and use of inappropriate lubricants.

The number of countries reporting on indicators specially relating to sex workers significantly increase between 2005 and 2009. In Sub-Saharan Africa, HIV prevalence among sex workers ranging form 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 (Khobotlo 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. Survey 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. Result of a randomized controlled trial in Jamaica have shown that 25% among AIDS patients had exposure to sex workers (Weir 2008).

Unprotected sex commercial is the most important risk factor for the spread of HIV in several parts of Asia. In Viet Nam, 33% male sex workers recruited from more than 70 sites in Ho Chi Minh City tested HIV positive (Nguyen, 2008). HIV prevalence among male sex workers is more than twice as high as among their female counterparts and is currently trending upwards in Thailand and Indonesia (UNAIDS 2009). Sex worker is common among male transgender people in Pakistan (Khan 2008). High HIV infection prevalence among transgender sex workers also reported from studies conducted Phnom Penh, Cambodia (22%), in 2003 (Girault 2004) and in Jakarta, Indonesia (59.3%) (Pisani 2004). In India, high HIV and STI prevalence were found among street-based female sex workers (30% and 27%, respectively) and among those who working 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 commercial sex workers in other part of Indonesia, these men could well be agents of rapid spread of the virus throughout Indonesia (Fajans 1995).

In 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 has ranged from 1.3% to 7% (UNAIDS 2009), in Egypt, 0.8% (Shawky 2009), in Algeria, Morocco and Yemen estimate that, 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 Caribbean have 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 in the past (Caceres 2009). Surveys in Guatemala and El Salvador have determine HIV prevalences among female sex workers of 4.3% and 3.2%, respectively (Soto 2007).

HIV prevention efforts may be having an impact among sex workers and their clients. Several successful interventions had been reported in order to change the behavior among sex workers and their clients to reduce the heterosexual spread of HIV including interventions to change behavior, condom promotion, and effort to improve condoms availability to reduce the risk of infection and decrease vulnerability to HIV, or sexual-health education 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

#### How the intervention might work

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

- 1) The effect of behavioural strategies could be increased by aiming for many goals (e.g., delay in onset of first intercourse, reduction in number of sexual partners, increases in condom use, etc) that are achieved by use of multilevel 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 intervention may help empower women to protect themselves in situation in which they are unable to avoid sexual relation with HIV infected partners or cannot persuade their partners to use a condom. Use of topical vaginal microbicides agents which have in vitro and some in vivo, such as nonoxynol-9 (N-9) that is the most extremely tested (Wilkinson 2002) help reduce the epidemic of HIV and AIDS, substances that a women could insert in vagina before sexual intercourse, clinically important to prevent the transmission of HIV and STIs (Elias 1996; Behets 2008; Poynten 2009).
- 2) Management of STIs were based on clinical diagnosis and sera test for herpes simplex virus type 2 (HSV2) with a monoclonal blocking enzyme immunoassay (Kamali 2003).
- 3) Peer education enlist 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 behaviour.

# Why it is important to do this review

Researches in some countries suggested that prevention projects that result in increased condom use during paid sex could significantly reduce HIV transmission. For example, Cambodia's decline in HIV prevalence occurred at the same time that consistent condom use during commercial sex rose from 53% in 1997 to 96% in 2003 (Gorbach 2006), in China consistent use condom had a 70% reduction HIV infection (Wang 2009). Other countries with epidemic driven by sex workers such as Mombasa and Uganda (Morris 2006), Chile (Barrientos 2007) and India (Basu 2004) have experienced decline in HIV prevalence when the sex workers and their clients consistently use condoms. However, increasing of condom use depend on the availability of condom (Bradley 2010). Therefore, making condoms available in rooms is most effective strategy to increase condom use (Egger 2000). Consistent condom use was significantly more likely among male partners who perceived that some or all of their male social network members used condoms consistently (Barrington 2009).

Beside condoms, vaginal microbicides were found effective on reducing transmission of HIV among sex workers (Van Damme 2002; Behets 2008).

Treatment for STI was found more effective to reduce the transmission of HIV and STI when combined with consistently and correct use of condom (Laga 1994; Ghys 2001).

Peer education has resulted in substantial increases in STD and HIV knowledge, condom use, as well as reduced incidence of HIV and STDs (Ford 2000).

Various interventions strategies have been adopted to reduce HIV transmission among commercial sex workers and their clients in low- and middle-income countries, however, the effectiveness of different strategies intended to encourage and facilitate protective behavior among sex workers and their clients and cost effectiveness, 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 commercial sex worker (males, females, and transgenders) and their clients (males, females and transgenders) in low-income and middle-income countries.

Through this systematic review, we would like to find out if behavioral interventions such as condom use, microbicides use, and behavior modification are effective in reducing the transmission of HIV when the interventions are delivered in sex worker settings.

Our research questions are:

- 1) What behavioral interventions to reduce risk of HIV transmission among commercial sexual worker have been tested in randomised controlled trials studies?
- 2) What are the effect of behavioral interventions contrasted against minimal or no intervention comparison conditions?

# **Methods**

# Criteria for considering studies for this review

# Types of studies

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

# Types of participants

Commercial sex workers (male, females, and transgenders) and clients of commercial sex workers (males, females, and transgenders) are the target population.

# Types of interventions

We will include only studies concerned with behavioral Interventions for reducing the transmission of HIV in commercial sex workers setting, including behavioral interventions,

social interventions and policy interventions. Behavior interventions are defined in this systematic review as interventions that aim to change individual behaviors to prevent HIV infection. These interventions studies will be compared with 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. These include strategies such as community mobilization, and structural and resource support that is usually used to bring 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. Example include promoting condom availability, etc.

# Types of outcome measures

#### **Primary outcomes**

Change in biological variables for prevention among commercial 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) use of microbicides (post exposure and pre exposure);
- e) 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 intervention 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 contact and make consultation with the HIV/AIDS Review Group Coordinator, the Trial 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, AIDSLINE, CINAHL, Dissertation Abstract International (DAI), EMBASE, LILACS, BIOSIS, SCISEARCH, INDMED, Proquest, and various South Asian abstracting databases will 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 the database list.

An extensive search strategy string will be developed in consultation with 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, since 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 contracted 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

The search strategy will be undertaken by one review authors Rintaro Mori (RM) to identify studies of potential interest. Two review authors Windy Wariki (WW) and Erika Ota (EO) will independently assess for inclusion all of the potential studies we identify as a result of the search strategy. Scrunity for inclusion will be based on the type of study, type of participants, type of interventions, and outcome measure. We will resolve any disagreement through discussion and , if required, third reviewer Narumi Hori (NH) will be consulted. We will include the agreed-upon studies in the review and as for excluded

studies, we will make a summary statement about the reasons for exclusion. Two authors Kenji Shibuya (KS) and RM will read 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 will extract the data using the agreed 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

Randomised-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 analysis, on an intention-to-treat basis. The denominator for each outcome in each trial will be the number randomized minus any participants whole outcomes are known to be missing.

# **Assessment of heterogeneity**

We will test for heterogeneity between studies using a I<sup>2</sup> statistic in each analysis. If we identify substantial heterogeneity (I<sup>2</sup> greater than 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-effects meta-analysis.

#### Subgroup analysis and investigation of heterogeneity

If appropriate, we will look at 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).

#### 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 'unreasonably expected loss to follow up' as less than 20%, given the stated importance of attrition as a quality measure (Tierney 2005).

#### Results

Results

Discussion

**Authors' conclusions** 

# **Acknowledgements**

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

# Contributions of authors

WW and EO were designed, set up, and drafted the protocol. RM, NH, and KS were revised the article. KS and RM were supervised development of the protocol. All authors read and approved the final protocol.

# **Declarations of interest**

We declare that we have no conflict of interest.

Differences between protocol and review

### **Published notes**

Characteristics of studies

Summary of findings tables

# Additional tables: another government but not necessary and government.

Add Table

References to studies

Other references

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

# **Protocol information**

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#### What's new

Date / Event	Description
15 February 2010	Made protocol a "clean slate" for new author team.
New citation: major change	

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Behavioral interventions to reduce the transmission of HIV infection among commercial May-2010

#### History

Date / Event	Description
11 November 2008	Converted to RevMan 5, and re-published without new citation.
Amended	The Mark Andrew Andrew Countries of Africa and Antick Countries and Anti

# Background

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

Globally, the percentage of women among people living with HIV has remained stable (at 50%) for several years, although womenfs share of infections is increasing in several countries(<u>UNAIDS 2008</u>). Some of the most worrisome increases in new infections are now occurring in populous countries, such as Indonesia, the Russian Federation, and various high-income countries(<u>UNAIDS 2008</u>).

The rate of newly reported HIV infection in Europe nearly double between 2000 and 2007 ( van de Laar et al., 2008). In the USA, the Centers for Disease Control and Prevention estimated that annual HIV incidence has remained relatively stable since the rarly 1990s, although the annual number of new HIV infections in 2006 (56,300) was approximately 40% greater than previously estimated ( Hall HI et al., 2008). In Canada, official epidemiological estimates suggest that annual HIV incidence may have increased between 2002 and 2005 (Public Health Agency of Canada 2007).

In the high-income countries, commercial sex workers constitute an important high-risk group in the transmission of HIV infection. The WHO defines sex workers as one of four key populations globally for health initiatives with respect to HIV/AIDS, estimating that there are probably tens of millions of sex workers worldwide, with clients in the hundreds of millions (WHO 2006). It has been estimated that there are around 80,000 female sex worker(FSW) in Britain (Scambler, G., 2007). It is estimated that less than 2% of Londonfs FSW are HIV-positive (Day, S., & Ward, H. 2006a; Day, S., & Ward, H. 2006b), not withstanding reports that almost half(43%) of new diagnoses of HIV in the UK in 2005 occurred in London (UNAIDS & WHO 2006).

Sex workers are not only a priority population for HIV prevention programmes in their own right-thier clients have long been recognized as a potential epidemiological bridge to other populations (<u>UNAIDS 2009</u>). In Ghana, sex workers, their clients and the sexual partners of clients were estimated to account for 2.4%, 6.5% and 23%, respectively, of all HIV infections in 2008 (<u>Bosu WK et al., 2009</u>).

Interventions to change behavior among commercial sex workers and their clients have been identified as a strategy to reduce HIV transmission. Fisher et al. (Fisher JD 2006a, Fisher JD 2006b) concluded that critical intervention components included not only information but also motivation and skills. The effect of behavioural strategies could be increased by aiming for many goals (eg, delay in onset of first intercourse, reduction in number of sexual partners, increases in condom use, etc) that are achieved by use of multilecel approaches (eg couples, families, social and sexual networks, institutions, and entire communities) with populations both uninfected and infected with HIV (Coates 2008). Female condom intervention may help empower women to protect themselves in situation in which they are unable to avoid sexual relation with HIV infected partners or cannot persuade their partners to use a condom. Use of topical microbicides help reduce the epidemic of HIV and AIDS, substances that a women could use in her vagina before sexual intercourse to prevent the transmission of HIV (Poynten 2009) and sexually transmitted infection (STI) (Behets 2008). Management of STIs were based on clinical diagnosis and sera test for herpes simplex virus type 2 (HSV2) with a monoclonal blocking enzyme immunoassay (Kamali 2003).