The settings in which commercial sex workers work, however, as well as the behavioral 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 the effect of all these interventions. Hence, we propose to conduct this systematic review with the following objectives:

Objectives

To evaluate the effect of behavioral interventions to reduce the transmission of HIV infection among commercial sex workers (males, females, and trangenders) and their clients (males, females, and transgenders) in high-income countries

Methods

Criteria for considering studies for this review

Types of studies

Studies which have evaluated the effect of behavioral interventions on any one of the outcome measures, specified below, and for methodological rigor based on study design (randomized controlled trials and certain quasiexperimental designs) in high-income countries, will be included. Non-randomized studies are considered eligible only if they include independent comparison groupswhere 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 & Campbell).

Examples of studies that are not eligible for those that compared:
- people who chose to participate in an intervention to 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. Commercial sex workers (male, females, and transgenders)
2. Clients of commercial sex workers (male, females, and transgenders)

Types of interventions

Behavioral interventions: Interventions aimed at changing individual behaviors only, without explicit or direct attempts to change the norms of the target population as a whole.
Social interventions: Interventions designed to change not only individual behaviors, but also social norms or peer norms. These are strategies such as structural and resource support, which are usually used to bring changes in social norms and/or peer norms.
Policy interventions: Interventions aimed at changing individual behavior or peer/social norms or structures, through administrative or legal decisions. Examples may include needle exchange programs, condom distribution in public settings, and mandatory HIV education in all schools of a district.

Types of outcome measures

primary outcome

-Change in biological variables for prevention (HIV incidence, HIV prevalence, STI incidence, STI prevalence)

secondary outcome

-Studies that reported any type of outcome measure related to HIV transmission would be included (knowledge, attitudes, intentions, self-reported sexual behavior, biological outcomes and so forth).

These outcome measures include:

1. Condom use (male/female)
2. Number of sexual partners
3. Increasing self-efficacy for protective behavior
4. Improving communication with partners regarding safer sexual practices.
5. Use of microbicides (post exposure and pre exposure)
6. Treatment of sexually transmitted infections and reproductive tract infections etc.
7. Needle sharing

Search methods for identification of studies

Intervention strategies for behavioral changes may be heterogeneous and influenced by social, demographic and cultural factors, according to local situations. Reporting strategies of effect of these interventions might not be uniform and there may be lot of 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 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 health care administrators also will be sought regarding source 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, AIDSLINE, 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 and 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) Hand-searching: Since many of the publications from developing countries might not have appeared in electronic databases, a hand-searching 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 will be contacted for published and unpublished references and data.

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

e) Conference proceedings of national and international conferences related to 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 adressed behavioral interventions in high-income countries will be identified. High-income countries include all high-income countries in 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 studys inclusion or exclusion, and the reasons for this. 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 trials ID, 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 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 include.

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 use the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identify substantial heterogeneity (I^2 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 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 2001). For random-effects 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 'unreasonably 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.

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

Contributions of authors

Erika Ota (EO) and Windy Wariki (WW) were designed, set up, and drafted the protocol. Rintaro Mori (RM), Narumi Hori (NH), and Kenji Shibuya (KS) were revised the article and KS and 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.

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Figures

Sources of support

Internal sources

- No sources of support provided

External sources

- No sources of support provided

Feedback

Appendices

添付資料７

コクランレビュープロトコール

1. Changes in out-of-pocket payments on utilisation of health care services

Changes in out-of-pocket payments on utilisation of health care services

Protocol information

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Background

Changing economic climates globally have forced governments to reconsider health care budgets and this has led to alternative strategies being tested for their ability to control health care expenditure while still maintaining or promoting health. Among these strategies are changes in cost-sharing with patients at the point of service delivery. Out-of-pocket (OOP) fees charged to patients are proposed as an efficient device for controlling unnecessary healthcare use as well as a means of raising revenue for health services in economically deprived settings (Shaw 1995). However, OOP payments create financial barriers preventing millions of people each year from seeking and receiving needed health care services (Preker 2002;Hjortsberg 2003).

Barriers to health care use are often defined with respect to availability, accessibility, and affordability (Penchansky 1981) so patient fees may constitute a significant barrier to appropriate use by their impact on the affordability of health care access. Perceived quality of services, socio-cultural factors, distance and travel cost, and cost of services are the additional factors that also can deter patients from seeking health care services (Asenso-Okyere 1998; McIntyre 2006; Obrist 2007; Onwujekwe 2008; Roovali 2006). Fees for health care constitute a significant barrier to appropriate use by their impact on the affordability of health care access (Souteyrand 2008; Mesko 2003; Wagstaff 2003; WHO 2000). There seems to be no universal logic determining the extent to which OOP payments are used by health care systems, or the level at which they are set. In considering changes to health services, health policy makers and planners around the world need to understand the effect on service use of a change in the amount of money patients pay for that service. If OOP payments are reduced, will utilisation increase, and if so, by how much? Conversely, if higher fees are imposed, will this discourage use of health services? And in both these circumstances, how is the health of patients affected?

During the last century there were a few occasions when a country's health system altered in such a way that patients' OOP payments for health services were universally changed. Britain and Canada provide the most striking examples of this phenomenon. In Britain, government policies removed patient fees for health care when the National Health Service (NHS) was introduced in 1948. Three studies provided an estimate of the effect of this change on health care utilisation (Titmuss 1959; Logan 1950; Stewart 1973). Since most workers were exempt from fees-for-service prior to the NHS, this group was used as "··· a kind of a control" (Titmuss 1959) in the review of changes in physician consultation. There was some overall increase in the number of consultations provided following the NHS introduction and this increase was greatest among women and the elderly - the population groups previously facing the greatest OOP expenses for consulting a doctor. In 1970 a compulsory universal health care plan was introduced in Quebec, Canada. A before and after household survey showed a significant shift in consultation patterns following the introduction of Medicare, with lower income groups consulting more often and higher income groups less often (Enterline 1973). However, the United States has provided possibly the most readily identified systematic attempt to examine the effect of different levels and types of payments for health services in the Health Insurance Experiment, a randomised controlled trial undertaken by the RAND Corporation in the 1970s (Lohr 1986). Another randomized controlled trial conducted in Ghana showed a positive impact on health care-seeking behavior among the fee exempt households (Ansah 2009). In Uganda, removal of user fees improved health service utilization (Xu 2006), however, in another study, accessibility to curative services increased but for preventive services (e.g. growth monitoring), the number of attendants decreased (Wilkinson 2001). In addition, according to a systematic review, financial protection (i.e. insurance) improves access and utilization of health care among children with special health care need (Jeffrey 2006).

Instances of system-wide fee change are relatively uncommon but there are a growing number of literatures reporting changes in utilisation of specific health care services, such as vaccination (Ronne 1997), mammography (Fletcher 1993), chiropractic services (Shekelle 1996), and prescription drugs (Liebowitz 1985) following changes in the OOP payments patients are levied for these services.

To assess the impact of changes in out-of-pocket payments on utilisation of health services, the literature on both health systems and specific health services will be considered.

Objectives

The five main objectives of this review are:
1. To assess whether utilisation of a health service increases, decreases, or stays the same when out-of-pocket payments for a health service are removed;
2. To assess whether utilisation of a health service increases, decreases, or stays the same when out-of-pocket payments for a health service are introduced;
3. To assess whether utilisation of a health service increases, decreases, or stays the same when out-of-pocket payments for a health service are increased or decreased;
4. To assess whether health status of patients using a health service increases, decreases, or stays the same when out-of-pocket payments for a health service change;
5. To assess whether patient satisfaction with a health service increases, decreases, or stays the same when out-of-pocket payments for a health service change.

Specific hypotheses:

Health service utilisation

1. Health service use increases when out-of-pocket payments by patients using the service are reduced or removed;
2. Health service use decreases when out-of-pocket payments by patients using the service are increased or introduced;

Health status

3. Health status of patients using a health service increases when patient out-of-pocket payments decrease;

Patient satisfaction

4. Patient satisfaction with a health service increases when patient out-of-pocket payments decrease.

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, controlled before and after studies, and interrupted time series studies.

Types of participants

Patients using any formal health services in primary care or hospital settings, and in urban or rural areas. Health services will include consultations with doctors or nurses, products such as pharmaceuticals and immunisations, and investigations such as laboratory services and x-rays. Whole country or whole community populations may be included in one of the eligible study designs.

Types of interventions

The intervention under investigation in this review is introduction of a patient out-of-pocket payment where previously there was no fee; the removal of a patient out-of-pocket payment; or the change of a patient

out-of-pocket payment (that is, an increase or decrease in amount charged to patients).

Types of outcome measures

The primary outcome of interest is change in utilisation of the health service for which the out-of-pocket payment is changed.

Secondary outcomes will include patients' satisfaction with the health service for which the out-of-pocket payment is changed; use of alternative services; changes in severity of condition treated; changes in mortality.

Search methods for identification of studies

The search strategy will involve:
1. A search of the specialised register of the Cochrane Effective Practice and Organisation of Care Group, identifying studies published before the end of 2000.
2. A search of the web sites of the RAND Corporation, the World Bank, the World Health Organisation, USAID and other sites identified by any part of the search process.
3. A search of the bibliographies of research reports identified by the above methods for reference to other studies suitable for inclusion.
4. Contacting the authors of key reports for information about other studies missed by the above methods.
5. Contacting known or advised experts in the field.

Data collection and analysis

The abstracts identified by the above searches will be scanned to exclude theoretical notes, discussions and editorials, and reports of studies clearly outside the scope of this review. Copies of the remaining reports will be obtained by the Center for Policy Studies in Family Practice and Primary Care and assessed by Susan Dovey and at least one other person to determine whether the inclusion criteria are met. In cases of uncertainty, others in the review team will be involved in the assessment and if no conclusion can be reached, the author(s) of the report will be contacted.

All eligible studies will be reviewed by at least two reviewers and relevant data abstracted according to the standard EPOC checklist.

The likely heterogeneity of studies identified by this process may preclude meta-analysis. If meta-analysis is possible, we will use the methods advised by the EPOC group. If meta-analysis is not possible we will combine studies using a qualitative narrative synthesis. However, the effect by out-of-pocket payment may be different because of the variation in the nature of the available settings, and therefore a sub-group analysis based on the income of the countries/states would be appropraite.

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Contributions of authors

Based upon the protocol prepared by SD and others, RM and SS revised the background and criteria. KS advised and commented on draft as a content specialist.

Declarations of interest

None known.

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Figures

Sources of support

Internal sources

- American Academy of Family Physicians, USA
- University of Otago, New Zealand

External sources

- No sources of support provided

Feedback

Appendices