Systematic review

To edit the record click *Start an update* below. This will create a new version of the record - the existing version will remain unchanged.

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

The impact of HIV infection diagnosis on sero-adaptive behaviors in men who have sex with men in the United States: protocol for a systematic review and meta-analysis

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

05/01/2018

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

30/09/2018

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No

Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Mohsen Malekinejad

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:
Dr Malekinejad

7. * Named contact email.

Give the electronic mail address of the named contact.

mmalekinejad@gmail.com

8. Named contact address

PLEASE NOTE this information will be published in the PROSPERO record so please do not enter private information

Give the full postal address for the named contact.

University of California San Francisco, 3333 California Street, Suite 265, San Francisco, CA 94118

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+115108168555

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of California, San Francisco (UCSF)

Centers for Disease Control and Prevention (CDC)

Organisation web address:
www.ucsf.edu
www.cdc.gov

11. Review team members and their organisational affiliations.

Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.

Dr Mohsen Malekinejad. UCSF

Ms Erin Barker. UCSF (independent contractor)

Mr Hacsi Horvath. UCSF

Dr James G. Kahn. UCSF

Ms Sopiko Jimsheleishvili. UCSF

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

This project is supported by Cooperative Agreement (Grant No: U38PS004649) from the US Centers for Disease Control and Prevention (CDC)

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members.

Dr Angela Hutchinson. CDC

Dr Ram Shrestha. CDC

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

Do HIV-infected men who have sex with men in the United States change their sexual behavior after learning they have HIV?

16. * Searches.

Give details of the sources to be searched, search dates (from and to), and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

PubMed (Jan 1, 1996 - Jan 2018), EMBASE (Jan 1, 1996, Jan 2018), PsycINFO (Jan 1 1996 - Jan 2018).

17. URL to search strategy.

Give a link to the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies).

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Human Immunodeficiency Virus transmission

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Adults and adolescents in the United States who have been tested for HIV infection and received HIV- positive results; AND are self characterized (or reported by study authors) as being men who have sex with men (MSM). This would include men who have sex with transgender women, young MSM (as defined by investigators), and men who have sex with men and women (MSMW). Eligible study populations could be of any antiretroviral therapy (ART) status.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Our objective is to assess the effect of participants' knowing their HIV-infected status, in terms of changing sexual behavior. The exposure will be knowledge of one's HIV infection. The comparator will be no such knowledge. We will include any modality of HIV testing, including: voluntary counseling and testing, provider-initiated counseling and testing, couples' HIV counseling and testing, community- and outreach-based testing, and other modalities as identified. We will exclude studies that provided multifaceted interventions that may influence risk behaviors unless the effect of those additional interventions can be isolated or statistically taken into account.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

-- HIV sero-positive individuals unaware of their HIV infection
-- Pre-HIV testing (HIV-tested participants, before testing)
-- No knowledge of one's HIV infection, when one is in fact infected

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

A range of non-randomized study designs will be eligible for inclusion:

-- Prospective cohort studies
-- Retrospective cohort studies - with clear indication of timing of HIV diagnosis and assessment of outcomes
-- Case-control studies and cross-sectional studies - with clear indication of timing of HIV diagnosis and assessment of outcomes
-- Before and after study (pre- and post-STI infection in same participants)

We will exclude: Case series, case reports.

Other eligibility criteria:

We will exclude qualitative, modeling, and narrative reviews, and studies without relevant quantitative primary

epidemiological data. We will use systematic reviews of relevant topics for hand-searching purposes.

Studies published in any language will be eligible, but all studies must be conducted in the United States. We will include studies from Canada and other high-income countries if we do not find 5 or more US-based studies.

In the first instance, we will only include published or in-press peer-reviewed studies. We will exclude unpublished studies, abstracts, and conference proceedings. We will consider including unpublished data if we do not identify 5 or more peer-reviewed studies.

Note: given the nature of the research question, we do not anticipate randomized controlled trials addressing this question. However, observational studies nested in RCTs will be included.

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24. * Primary outcome(s).

Give the pre-specified primary (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

We will include the following sexual behaviors although studies may use different wording to refer to these concepts:

-- Avoid sexual intercourse (abstinence)
-- Switch to oral intercourse
-- Avoid unprotected sex
-- Serosorting
-- Seropositioning
-- Encouraging HIV-uninfected partner to take PrEP
-- Withdrawal before ejaculation
-- Using viral load as a measurement of transmission risk
-- Condom serosorting

Timing and effect measures
We will capture outcomes reported at any point of follow-up.

25. * Secondary outcome(s).

List the pre-specified secondary (additional) outcomes of the review, with a similar level of detail to that required for primary outcomes. Where there are no secondary outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review

None

Timing and effect measures
To address the effect of HIV diagnosis knowledge over time, we will capture outcomes from all reported time-points during follow-up period, e.g., at one month, three months, six months, 12 months, or as reported by investigators.

26. Data extraction (selection and coding).

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Selection of studies

We will first compile all electronic records in an Endnote library. After removing duplicate records, one author will perform a broad first cut of all downloaded material from the electronic searches to exclude citations that are “plainly” irrelevant. This can be done in Endnote by filtering studies that have “clearly” irrelevant keywords in their titles. In the current review, these could include such terms as “qualitative,” “in-vitro,” “rhesus,” and other such terms suggesting clear irrelevance. A second author will review titles and confirm irrelevance of citations excluded in this way, using pre-specified criteria. Next, one author using pre-specified criteria will read the titles, abstracts and descriptor terms of the remaining downloaded citations to identify potentially eligible studies. A second author will review excluded records. Records deemed eligible by either of the reviewers will be promoted to be reviewed at the full text level. We will obtain full text copies for all citations identified as potentially eligible, and two authors will independently inspect these to establish the relevance of the study according to the pre-specified inclusion criteria. The two authors will examine studies for relevance based on design, types of participants, and outcome measures, and will then decide which studies meet inclusion criteria. Where there is disagreement between the two authors prior to the full-text level, the record will be promoted to the next level. When there is disagreement at the full-text level, the eligibility will be established by discussion with a neutral arbiter. Authors will indicate explicit reasons for exclusion only at the full-text level. As authors will examine relevance of retrieved electronic records, they will set aside systematic reviews with overlapping PICO questions, and will hand search their bibliographies to identify relevant primary studies.

Data extraction:

From all studies meeting inclusion criteria, one author will extract data into a standardized, pre-piloted data extraction form. The second author will review and cross-check extracted data against the papers. We will resolve any disagreement by discussion or by involving a neutral third party to adjudicate.

The following characteristics will be extracted from each included study:

-- Study details: Complete citation, study location, study design characteristics and other relevant details.
-- Details of participants: Age group, psychosocial factors (e.g., substance abuse), psychiatric (e.g., depression) or other comorbidities (e.g., hepatitis C), receiving other interventions such as PrEP.
-- Details of intervention: Modality of testing (e.g., clinic-based, community-based etc.), specific intervention characteristics and other relevant details.
--- Outcome details: Numerators and denominators associated with each outcome, or effect measures (risk ratio, odds ratio) and associated confidence interval and P Values, definitions and descriptions of outcomes provided in papers, details of how outcomes were assessed.
-- Methodological details: Recruitment methods, method of randomization if an RCT, numbers of participants entering the study, comparability of groups, study inclusion and exclusion criteria, length of follow-up, losses to follow-up, withdrawals or drop-outs.
-- Bias assessment data: Other details necessary to perform a bias risk assessment using the Cochrane tool described below, or the criteria for observational studies described below.

27. * Risk of bias (quality) assessment.

State whether and how risk of bias will be assessed (including the number of researchers involved and how discrepancies will be resolved), how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

Two review authors will independently assess risk of bias for each included study. Since we do not expect to find randomized controlled trials with relevant data for our research question, we will apply four criteria recommended by the GRADE Working Group (Schünemann 2013) for observational studies. We will resolve any disagreement by discussion or by involving a neutral third party to adjudicate. We will generate summary figures to illustrate risk of bias in each study and across all included studies.

-- Failure to develop and apply appropriate eligibility criteria (comparability of groups)
-- Flawed measurement of either exposure or outcome
-- Failure to adequately control confounding
-- Incomplete or inadequately short follow-up

28. * Strategy for data synthesis.

Give the planned general approach to synthesis, e.g. whether aggregate or individual participant data will be used and whether a quantitative or narrative (descriptive) synthesis is planned. It is acceptable to state that a quantitative synthesis will be used if the included studies are sufficiently homogenous.

We will conduct descriptive analysis in order to provide an overall understanding of existing literature on the topic of interest. If possible, we will calculate summary statistics using meta-analytic methods. We will conduct meta-analysis, if appropriate, using Cochrane's Review Manager software. We will also use STATA (V15) if needed. We will generally use a random effects model even if statistical heterogeneity might be low (I^2 less than 45%) because of expected clinical and contextual heterogeneities or because included populations may still be quite different. If heterogeneity is extremely high (I^2 more than 85%), we may consider stratifying analyses by key variables (see below) and potential confounders. If relevant data from one or more studies cannot be pooled with data from other studies, we will undertake a narrative synthesis of these data.

Effect size

Studies use different metrics to report effect sizes. To make data across studies comparable and combinable, to the extent feasible and scientifically permissible, we will transform all data to risk ratios (RR). When this is not possible, we will report data in their original form. We will prioritize data that are adjusted for confounding factors. When such data are not reported, we collect unadjusted data.

Unit of analysis

The unit of analysis for the SR will be the individual study; we will not examine patient-level data.

Dealing with missing data

We will contact study authors if it is necessary to obtain data missing from published reports.

Assessment of heterogeneity

In pooled data, we will use the I^2 statistic and tau^2 statistic to assess heterogeneity among the studies in each analysis. If we identify substantial heterogeneity (e.g., I^2 more than 45%) in pooled data for primary outcomes, we will explore it by pre-specified stratified analysis (see below). If heterogeneity persists, we will perform sensitivity analyses (see below), present results separately and propose explanations for the observed heterogeneity.

Assessment of reporting biases

Where we suspect reporting bias, we will attempt to contact study authors and ask 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 studies in the overall assessment of results by a sensitivity analysis. If any meta-analysis in our review includes 10 or more studies, we will assess the potential for publication bias for the studies using a funnel plot. If appropriate and depending on the heterogeneity of data, we will statistically test for the funnel plot asymmetry. We will attempt to minimize the potential for publication bias through rigorous review methods and by using comprehensive search strategies, including evaluating published literature in all languages.

Sensitivity analysis

Where relevant, we will conduct sensitivity analysis to investigate the effect of excluding studies with high overall risk of bias, studies with arbitrary inclusion criteria, and studies with other methodological issues.

29. * Analysis of subgroups or subsets.

Give details of any plans for the separate presentation, exploration or analysis of different types of participants (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of intervention (e.g. drug dose, presence or absence of particular components of intervention); different settings (e.g. country, acute or primary care sector, professional or family care); or different types of study (e.g. randomised or non-randomised).

In pooled results with substantial heterogeneity (I^2 more than 45%), and as the data may allow, we will explore heterogeneity through subgroup analyses of the following:

-- Length of time since diagnosis (short vs. long term effect)
-- Participants being on treatment vs. not
-- Study design and risk of bias of studies
-- Type of sexual partner (low risk vs. high risk) or with known vs. unknown HIV serostatus

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness	No
Diagnostic	No
Epidemiologic	No
Individual patient data (IPD) meta-analysis	No
Intervention	No
Meta-analysis	No
Methodology	No
Network meta-analysis	No
Pre-clinical	No
Prevention	No
Prognostic	No
Prospective meta-analysis (PMA)	No
Qualitative synthesis	No
Review of reviews	No
Service delivery	No
Systematic review	Yes
Other	No

effect of HIV diagnosis knowledge

Health area of the review

Alcohol/substance misuse/abuse	No
Blood and immune system	No

Cancer	No
Cardiovascular	No
Care of the elderly	No
Child health	No
Complementary therapies	No
Crime and justice	No
Dental	No
Digestive system	No
Ear, nose and throat	No
Education	No
Endocrine and metabolic disorders	No
Eye disorders	No
General interest	No
Genetics	No
Health inequalities/health equity	No
Infections and infestations	Yes
International development	No
Mental health and behavioural conditions	No
Musculoskeletal	No
Neurological	No
Nursing	No
Obstetrics and gynaecology	No
Oral health	No
Palliative care	No
Perioperative care	No
Physiotherapy	No

Pregnancy and childbirth	No
Public health (including social determinants of health)	No
Rehabilitation	No
Respiratory disorders	No
Service delivery	No
Skin disorders	No
Social care	No
Surgery	No
Tropical Medicine	No
Urological	No
Wounds, injuries and accidents	No
Violence and abuse	No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

There is not an English language summary

32. Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

United States of America

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

No I do not make this file publicly available until the review is complete

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

We will prepare peer-review manuscripts

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

HIV diagnosis, sero-adaptive risk behaviors, men who have sex with men

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

We reviewed (unpublished) the effect of HIV diagnosis knowledge on HIV transmission, condom use and sexual partnership among an HIV high risk population including men who have sex with men. The protocol for that review was not registered in PROSPERO. While this new review is informed by our existing review, it is different on multiple levels including focusing on sero-adaptive behaviors among only MSM in the US.

38. * Current review status.

Review status should be updated when the review is completed and when it is published.

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.