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PROSPERO International prospective register of systematic reviews

Values and preferences of women living with HIV who are pregnant or considering pregnancy on choice of antiretroviral therapy during pregnancy

Lyubov Lytvyn, Reed Siemieniuk, Susan Bewley, Sophie Dilmitis, Allyson Ion, Reza D Merza, Malgorzata Bala, Rene Rodriguez Gutierrez, Paul Elias Alexander, Hassan Mir, Rizwana Buthool, Gordon Guyatt

Citation
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Review question(s)
What are the values and preferences as they relate to choosing antiretroviral therapy among women living with HIV who are pregnant or considering pregnancy?

Searches
We will search MEDLINE, EMBASE, and PsycINFO from 2000, using a combination of keywords and MeSH terms for “HIV” AND “pregnancy” AND “antiretroviral therapy”, and using a search filters for patient values and preferences developed by Wessels et al, which includes terms related to health behaviours, patient values, and patient preferences. We will review the references of the included studies for other potentially eligible studies. We will search for grey literature through Google.

Types of study to be included
Inclusion criteria: Both quantitative and qualitative studies reporting values and preferences about taking ART medication during therapy, including:
1. Health state value studies (e.g. measures between 0, i.e. death, and 1, i.e. perfect health, elicited through techniques such as standard gamble, time trade off, and visual analog scale for a specific outcome);
2. Direct choice studies (e.g., choice when presented with decision aid, probabilistic trade off techniques, discrete choice, conjoint analysis willingness to pay, randomized controlled trials on preferences);
3. Studies on non-utility measurement of health states (e.g. surveys);
4. Qualitative studies (e.g. focus groups, semi-structured interviews).
Exclusion criteria:
1. Studies that are not written from the perspective of women living with HIV (e.g. health system, healthcare worker);
2. Studies reporting overall health-related quality of life (not specific to certain outcomes);
3. Non-primary studies (e.g. clinical practice guidelines, reviews, commentaries, communications, letters, or viewpoints);
4. Case report, and case series;
5. Cost-effectiveness studies;
6. Analyses of data that are not patient reported (e.g. databases of health records);
7. Studies on use of nevirapine only;
8. Studies reporting overall access to/use of care, without discussion of ART (e.g. studies of factors affecting whether a woman would use an available service, or studies about access to services).

Condition or domain being studied
ART choice among women living with HIV who are pregnant or considering pregnancy.

Participants/ population
Women living with HIV, diagnosed at any time, and are of childbearing age (15-45 years), in any geographic region, in any setting (e.g. HIV clinic, primary care).

Intervention(s), exposure(s)
Initiate, continue, or change ART regimen during pregnancy, for any duration (short-course prophylaxis, cART).

Comparator(s)/ control
Not applicable.

Context
Studies on values and preferences after the first recommendation for ART drugs for preventing vertical transmission in 2000.

Outcome(s)
Primary outcomes
Quantitative measurements of values and preferences (standard gamble, time trade off, visual analogue scale, willingness to pay, conjoint analysis, discrete choice, contingent choice method, pairwise comparison, ranking, probability trade off, direct choice), and qualitative measurements of values and preferences (studies that inform on preferences, views, experiences, attitudes, or perceptions). The results of this study will be used to inform a guideline on different ART regimens for pregnant women. Thus, values and preferences related to maternal health (mortality, adverse effects, AIDS-related illness, viral load suppression, treatment interruptions/gaps or switch of ART, hepatitis B resistance) and child health (neonatal mortality or stillbirth, mortality at 1 year, preterm delivery [<37 weeks], early preterm delivery [<34 weeks], birth weight [low birth weight], head circumference [small head circumference], HIV infection, hepatitis B infection, long-term child development, adverse effects) will be of particular importance. However due to the exploratory nature of the study, outcomes of interest will not be limited to specifics and we expect that we will need to infer values and preferences specific to our outcomes from evidence of related outcomes. The review's aim is to inform a clinical practice guideline regarding two ART regimens.
Secondary outcomes
None.

Data extraction, (selection and coding)
Two reviewers will independently extract data using a standardized form in Microsoft Excel. Data from qualitative studies, in the form of quotations and descriptions of findings in results sections and abstracts, will be extracted using thematic synthesis. Barriers and facilitators related to ART choice will be extracted, including patient-reported reasons for compliance. Data from components of mixed-methods studies will only be extracted if they satisfy inclusion criteria. Disagreements will be resolved through discussion and consensus, or by consulting a third party if necessary. The following details will be extracted: first author, publication year, number of participants, participant demographics (e.g. age, length of time living with HIV, whether they have previously or are currently taking ART and what regimen, current and previous pregnancies, availability of treatment [e.g. government funded program, private insurance/benefits, clinical trial], and other data as provided such as drug use, sexual orientation, whether they are sex workers, disabilities, co-infections, experience of violence, history of mental health issues, etc.), methods used to extract data (e.g. standard gamble, survey techniques, semi-structured interview), and values and preferences outcomes.

Risk of bias (quality) assessment
To asses quality, we will use the Newcastle Ottawa Scale for observational studies, and the CASP tool for qualitative studies. For randomized controlled trials, we will use the Cochrane Collaboration risk of bias tool to assess the risk of bias.

Strategy for data synthesis
For quantitative measures (e.g. utilities and health status values), we will pool studies to generate an estimate and associated 95% confidence intervals using the inverse variance method (random effect model) in ReviewManager software. For qualitative measures, reviewers will categorize codes from extracted data to build descriptive themes.

Analysis of subgroups or subsets
None planned.

Dissemination plans
We will submit this systematic review to peer-review journals for publication. This review will inform guidelines on the use of therapies for women living with HIV who are pregnant or considering pregnancy. We will share our findings through national and/or international conferences and workshops.

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Anticipated or actual start date
10 February 2017

Anticipated completion date
31 March 2017

Funding sources/sponsors
None

Conflicts of interest
None known

Language
English

Country
Norway

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Female; HIV Infections; Humans; Infectious Disease Transmission, Vertical; Pregnancy; Pregnancy Complications, Infectious

Stage of review
Ongoing

Date of registration in PROSPERO
15 February 2017

Date of publication of this revision
15 February 2017

Stage of review at time of this submission	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