

Sex and Gender in Systematic Reviews Planning Tool

A considerable body of research shows that the effects / outcomes of drugs and other health interventions differ between men and women. Questions about possible sex and gender differences should be asked and the particular relevance determined or ruled out.

This tool will help reviewers ask and answer these questions when planning a systematic review.

When a hand appears in the tool – it is a cue to stop & consider sex/gender. This consideration is intended to lead you to: (1) revise your approach; (2) highlight key gaps; (3) contextualize your findings.



PLANNING A SYSTEMATIC REVIEW

1. Review Section: Background

- 1a. Are sex and/or gender relevant or not relevant to the SR question? YES NO
- 1b. Have you discussed why sex and/or gender differences may or may not be expected? YES NO



If you answered "NO" to any of the above questions CONSIDER:

- Is there evidence in the literature to suggest sex/gender differences in the subject area?
- Is it *likely* that the intervention will affect men and women differently?
- Is the intervention widely applied across broad population groups? If so, have differences by sex or gender been examined?
- Is the intervention only applied to men *OR* women? If so, are there issues about being a man or a woman (social roles) that may influence the intervention's effectiveness?

2. Review Section: 'Criteria for considering studies for this review'

- 2a. Do the inclusion/exclusion criteria for studies consider sex and/or gender differences? YES NO
- 2b. If relevant, have you justified or explained why some population groups are excluded from the review? YES NO
- 2c. Have you planned to address the possibility of **differences in outcomes** between men and women? YES NO
- 2d. Have you planned to examine whether **outcome measures** are different for men and/or women? YES NO



If you answered "NO" to any of the above questions CONSIDER:

- If women or men as a group were *excluded*, a rationale should be provided.
- If subgroups of men or women were *excluded* (e.g., older men) a rationale should be provided.
- If women and men are *included*, is it also necessary to consider different outcomes?

3. Review Section: Methods of the review

- 3a. Does the data extraction form include sections to extract data for men and women separately? YES NO
- 3b. Does the data extraction form include sections to extract data by sex for withdrawals and dropouts? YES NO



If you answered "NO" to any of the above questions CONSIDER:

- If the review includes both men and women data should be extracted by sex.
- If the published report does not include data by sex but includes both men and women, efforts should be made to contact primary authors.
- If data extraction by sex *cannot* be done, provide a rationale.
- Are there possible reasons why men or women may be more likely to withdraw from the study?

4. Review Section: Results and Analysis

- 4a. Will you distinguish between findings for men and women in your results? **YES** **NO**
- 4b. Will you analyze the finding taking sex and/or gender into account? **YES** **NO**
- 4c. If reported, will information about adverse effects of drugs or interventions be sex-disaggregated? **YES** **NO**
- 4d. If sub-group analysis by sex and/or gender could not be completed, will you explain why? **YES** **NO**
(e.g. insufficient data in primary studies)



If you answered "NO" to any of the above questions, CONSIDER:

- If data was extracted by sex, provide a rationale as to why results/findings are not distinguished.
- Have you contacted primary authors to request sex disaggregated data?
- Are there possible reasons that men and women may experience reported adverse outcomes differently?

5. Review Section: Discussion and Conclusion

- 5a. Will you address whether the primary studies analysed or failed to analyse results by sex? **YES** **NO**
- 5b. Will you address the sex and/or gender implications for clinical practice? **YES** **NO**
- 5c. Will you address the sex and/or gender implications for policy and regulation (e.g. drug labeling)? **YES** **NO**
- 5d. Will you address the sex and/or gender implications for research? **YES** **NO**



If you answered "NO" to any of the above questions CONSIDER:

- Return to questions in previous sections – are there gaps in our knowledge?
- Call attention to BOTH what we *know* and *don't know* about this intervention for men and women.

6. Review Section: Table of Included Studies

- 6a. Will you provide detailed information on study samples including sex, age, ethnicity breakdowns in your table of included studies? **YES** **NO**



If you answered "NO" to the above question CONSIDER:

- Are answers to other tool questions consistent with information provided in the included studies table?
- If men and women are included in the primary studies (as reported in the table) will rationales be provided for **reporting or not** reporting findings by sex?
- What are the implications for your review if basic demographic information was not reported in primary studies? Will these implications be included in the discussion?