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| Sex and Gender Methods Review | | | | |
| **Literature review** | | | | |
|  | Y | P | N | n/a |
| Clear articulation of any sex or gender differences/issues that are relevant to the research question or context e.g. epidemiology, risk factors, differential outcomes. |  |  |  |  |
| Is a theoretical conceptualization of sex/gender and key issues discussed? |  |  |  |  |
| **Research Question** |  |  |  |  |
| Clear articulation of a sex/gender research question as a primary or secondary research question; or statement that the purpose includes controlling for/measuring the effect of sex/gender in the primary research question. |  |  |  |  |
| Sex and or gender issues salient to the research questions are identified and included in the research question and/or evident in the design. |  |  |  |  |
| **Study Design** |  |  |  |  |
| Sampling, inclusion and exclusion criteria consider sex/gender and diverse populations of men and women |  |  |  |  |
| Description of the recruitment strategies to accrue the appropriate sample of men and women |  |  |  |  |
| Choice of treatment; or measures of exposure/covariates are not gender biased |  |  |  |  |
| Description of how sex and gender were measured; and measures were appropriate |  |  |  |  |
| Choice of outcome measures or diagnostic/ validation tests are not gender biased |  |  |  |  |
| **Analysis** |  |  |  |  |
| A description of how sex/gender are handled is stated in the data analysis plan (sex-disaggregated or stratified analyses, pathway modeling, use of sex and gender variables as confounders or in interaction terms) |  |  |  |  |
| Are sex/gender considered at an individual and organizational/system and/or societal level (e.g. gender relations, socially constructed roles) |  |  |  |  |
| Potential interactions/confounding between sex and gender are considered in design and/or tested. |  |  |  |  |
| The validity/representativeness of the results for men and women is presented/evaluated. For clinical trials this includes disaggregated reporting of dropouts, adherence and outcomes. Predictors and outcomes in other studies should be reported as disaggregated |  |  |  |  |
| **Interpretation** |  |  |  |  |
| The extent to which the conclusions are valid for men and women is stated |  |  |  |  |
| The extent to which the conclusions are valid across gender diverse populations is stated. |  |  |  |  |
| Potential confounding, interaction, and/or interplay between sex and gender are discussed. |  |  |  |  |
| How the results should be applied/translated based on sex/gender is discussed/stated. |  |  |  |  |
| **OVERALL: Are Sex and Gender adequately addressed in the study?** |  |  |  |  |
| Comments | | | | |

This tool was designed to assess the risk of bias in how sex/gender is included in research studies. It can be used on etiologic or prognosis cohort studies (exposure/outcome) or interventional (intervention/outcome) studies. Y=yes; P=partial; N=no; if the item is not applicable given the area of research, then it is marked as n/a

Based on the items evaluated, the evaluator decides whether overall sex and gender have been adequately addressed in the research (unbiased) (Y), partially addressed (potentially biased), or not adequately addressed (N), free of bias. If the item relevant but is not addressed or is unknown, then the answer is no.

For example, in prognostic studies it is important to know that the treatments provided to the cohort or other exposures and the outcome measures, do not have gender biases that might distort the observed relationships. If this is specifically discussed and citations that the measures are not gender biased is provided than this is a yes. A justification or citation that men and women tend to respond differently on an outcome measure might be considered partial. If there is no evidence or rationale to suggest that gender bias is not a problem, than it is in no.

Reviewers should discuss these items and what constitutes a yes partial or no specific to the research question before conducting analysis across studies.

Since it is not possible to address all aspects of sex and/or gender in any one study, it is up to the reviewers to pre-state what are the critical issues that should be documented and addressed within studies, for that particular research question; and to give appropriate credit for inclusion of salient aspects, acknowledging that not everything can be measured in one study.

This is a overall decision based on calibrating the items and considering their relative importance to the validity of the science.