# Methods to address bias reporting template

Form for reporting on methods used to minimise risk of bias

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| Type of bias | How bias was addressed or assessed |
| Selection bias at study entry | Selection bias at study entry can arise for several reasons including selection of patients based on eligibility criteria related to the exposure and outcome, or from deviations between the date the patient meets eligibility criteria, the date treatment is assigned, and the start of follow-up. Common types of time-related bias are prevalent-user bias, lead time bias, immortal time bias and depletion of susceptibles. Discuss the potential for selection bias at study entry and how this was addressed or investigated through study design, statistical analysis or sensitivity analysis. |
| Selection bias at study exit  | A common cause of selection bias because of how individuals exit a study is informative censoring. This may be because of loss to follow-up or the occurrence of censoring events. Discuss the possibility of informative censoring and how this was addressed in the analysis.  |
| Addressing confounding | Describe the risk of confounding from unmeasured (or unknown) confounders, poorly measured confounders, or time-varying confounding. This should be informed by a systematic identification of potential confounders, clear causal assumptions including the possibility of time-varying confounding, and differences in baseline characteristics between comparison groups.Show how you dealt with any identified risk of confounding through study design (such as selection of a suitable active comparator) and analysis (using an appropriate statistical model, accounting for time-varying confounding). If possible, provide empirical data on the balance of baseline characteristics after adjustment.If concerns remain about residual confounding, show its impact on results has been assessed using sensitivity or bias analysis.Confirm that no covariates were inappropriately adjusted to induce bias. For example, show that no covariates on the causal pathway between interventions and outcomes were adjusted for (overadjustment). This may result from the use of covariates measured after the index date. Avoid adjustment for colliders or instruments. This can be informed by causal diagrams. |
| Detection bias | Describe the potential for detection bias resulting from differences in healthcare practices across comparison groups (for example, because of differential frequency or intensity of follow up, or different tests) or length of follow up. Describe how these have been dealt with through study design (for example, use of comparator with similar follow up) or analysis (for example, adjustment for healthcare use before index date). |
| Measurement error and misclassification | Describe the potential for bias from measurement error or misclassification (this should be informed by assessment of data suitability). Consider which variables are inaccurate, whether this is random or systematic, and how it differs across comparison groups.Show you addressed risks of bias through statistical analysis (for example, by incorporating external data or calibration) or assessed its impact on results using sensitivity or bias analysis. |
| Missing data | Describe the potential for bias from missing data (this should be informed by assessment of data suitability). Consider which variables have missing data, whether this is random or systematic, and how it differs across comparison groups.Show how you have addressed risks of bias using statistical methods (such as multiple imputation) and demonstrating their validity. If missingness may not be explainable by observed variables or has unknown mechanisms, sensitivity or bias analysis can be used to explore the impact of different missing ‘not at random’ assumptions.  |
| Reverse causation | Describe the risk of reverse causation between the intervention and the outcome arising from causal relationships between variables, time lag between recording of data on interventions and outcomes, or care pathways.Describe how risk of reverse causation was addressed through study design (for example, induction periods or longitudinal follow up), analysis (for example, instrumental variables), or assessed through sensitivity analysis.  |