Quality Assessment Checklist

COVID-19 Vaccines Mandate

We will be using Covidence to assess the studies by using a customizable checklist. The checklist was created based on the STROBE and ROBINS-E checklist/tool and includes 7 domains (2 questions on Generalizability and 5 questions on Risk of Bias) and 13 questions on Overall Reporting.

Important to note that this checklist is based on two adapted Quality Assessments / Guidelines to speed up the 'quality assessment' process mandated by FOPH. This checklist only provides an objective classification of studies. It does not provide an in-depth assessment or risk-of-bias of studies and should not be considered as a replacement of approved Assessments / Guidelines.

A traffic light system will be used to classify the studies as High, Mid-, or Low Confidence as shown below.

Traffic Light System & Criteria:

- Green → High Confidence
  - Study is complete, comprehensive and adequately reports methods, biases, and results
- Yellow → Mid-confidence
  - Study is comprehensive but moderately reports methods, biases, and results
- Red → Low Confidence
  - Study is incomplete and does not adequately reports methods, biases, and results

This will be decided by:

1) Calculating the total number of YES per section
   a. Generalizability Section
      i. Maximum of YES = 3
      ii. Minimum of YES = 0
   b. Risk of Bias Section
      i. Maximum of YES = 5
      ii. Minimum of YES = 0
2) Determining the classification per section using the following criteria where:
   a. Generalizability Section
      i. Green → Yes = 3
      ii. Yellow → 3 > Yes > 0
      iii. Red → Yes = 0
   b. Risk of Bias Section
      i. Green → Yes = 5
      ii. Yellow → 3 < Yes < 4 (Yes is greater than 3 and less than 4)
      iii. Red → Yes ≤ 3
3) Determining the final classification of the study by combining the result of both generalizability and risk of bias sections using the following criteria where:
   a. Green + Green = High Confidence
   b. Green + Yellow = Mid-Confidence
   c. Yellow + Yellow = Mid-Confidence
   d. Green + Red = Mid-Confidence
   e. Yellow + Red = Low-Confidence
   f. Red + Red = Low-Confidence

In addition, the Overall Reporting Quality of the study will be assessed separately using a simpler system of Good/Poor quality where:

Good Reporting → Yes ≥7

Poor Reporting → Yes < 7

PS: the reviewer does not need to follow the Reporting Section if they are experienced in identifying good/poor reporting studies. The questions are available in case of need.

Covidence Checklist:

Generalizability Section:

Question	Elaboration	Answer
Sample Size Does the study include a large sample size? If the population size is small, then smaller sample sizes are to be expected (e.g., cancer patients, immunocompromised individuals)	When determining your sample size, it is important to consider the size of the entire population you want to study. A population is the entire group that you want to draw conclusions about. The population size may be known (such as the total number of employees in a company), or unknown (such as the number of pet keepers in a country), but there's a need for a close estimate, especially when dealing with a relatively small or easy to measure groups of people.	YES NO UNSURE
International Location Was the study conducted at a multi-country scale?	Did the study include participants from multiple countries?	YES NO UNSURE
Local Location Was the study conducted at a multi-centric scale?	Did the study include participants from multiple locations within country? (e.g., multiple health care centers, hospitals…)	YES NO UNSURE

Risk of Bias Section:

Question	Elaboration	Answer
Bias Due to Confounding Did the authors use an appropriate analysis method that controlled for all important confounding domains?	Appropriate methods to control for measured confounders include stratification, regression, matching, standardization, and inverse probability weighting. They may control for individual variables or for the estimated propensity score. Inverse probability weighting is based on a function of the propensity score. Each method depends on the assumption that there is no unmeasured or residual confounding. Examples of COVID-19 Vaccine confounding: health care seeking, exposure risk, misclassification of outcomes due to diagnostic errors, prior SARS-CoV-2 infection, and spurious inferences of waning.	YES NO UNSURE
Bias in Participant Selection Was the selection of participants into the study (or into the analysis) based on participant characteristics observed before the start of intervention / exposure window being studies? If not, did the analysis corrected for all potential selection biases?	This domain is concerned only with selection into the study based on participant characteristics observed after the start of intervention. Selection based on characteristics observed before the start of intervention can be addressed by controlling for imbalances between experimental intervention and comparator groups in baseline characteristics that are prognostic for the outcome (baseline confounding). Selection bias occurs when selection is related to an effect of either intervention or a cause of intervention and an effect of either the outcome or a cause of the outcome. Therefore, the result is at risk of selection bias if selection into the study is	YES NO UNSURE

	related to both the intervention and the outcome.	
Bias in Classification of Interventions / Exposures Were intervention/exposure groups clearly defined and recorded at the start of the intervention/exposure?	In general, if information about interventions received is available from sources that could not have been affected by subsequent outcomes, then differential misclassification of intervention status is unlikely. Collection of the information at the time of the intervention makes it easier to avoid such misclassification. Examples of COVID-19 Vaccination Classification: Use of laboratory-confirmed outcomes in VE evaluations such as use of real-time reverse-transcription polymerase chain reaction (rRT-PCR) for laboratory testing of participants. Specimens should be taken within 10 days of disease onset.	YES NO UNSURE
Bias in Missing Data Were complete data on exposure status, confounding variables, and outcome data available for all, or nearly all, participants? If not is there evidence that results were robust to the presence of missing data?	Evidence for robustness may come from how missing data were handled in the analysis and whether sensitivity analyses were performed by the investigators, or occasionally from additional analyses performed by the systematic reviewers. It is important to assess whether assumptions employed in analyses are clear and plausible. Both content knowledge and statistical expertise will often be required for this. For instance, use of a statistical method such as multiple imputation does not guarantee an appropriate answer. Review authors should seek naïve (complete-case) analyses for comparison, and clear differences between complete-case and multiple imputation-based findings	YES NO UNSURE

	should lead to careful assessment of the validity of the methods used.	
Bias in Selection of Reported Results Is the reported effect estimate unlikely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple exposure measurements within the exposure domain?	Because of the limitations of using data from non-randomized studies for analyses of effectiveness (need to control confounding, substantial missing data, etc), analysts may implement different analytic methods to address these limitations. Examples include unadjusted and adjusted models; use of final value vs change from baseline vs analysis of covariance; different transformations of variables; a continuously scaled outcome converted to categorical data with different cut-points; different sets of covariates used for adjustment; and different analytic strategies for dealing with missing data. Application of such methods generates multiple estimates of the effect of the intervention versus the comparator on the outcome. If the analyst does not pre-specify the methods to be applied, and multiple estimates are generated but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	YES NO UNSURE

Reporting Section:

Question	Elaboration	Answer
Objectives Does the study state specific objectives, including any prespecified hypotheses?	N/A	YES NO UNSURE
Study Design Does the study present key elements of study design early in paper?	N/A	YES NO UNSURE
Setting Does the study describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection?	N/A	YES NO UNSURE
Participant Selection Does the study give the eligibility criteria, and the sources and methods of selection of participants? If applicable, does the study give matching criteria and number of case/exposed and control/unexposed	N/A	YES NO UNSURE
Variables Does the study clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers? Does the study give diagnostic criteria, if applicable?	N/A	YES NO UNSURE
Bias Does the study describe any efforts to address potential sources of bias?	N/A	YES NO UNSURE

Statistical Methods Does the study describe all statistical methods, including those used to control for confounding and used to examine subgroups / interactions?	N/A	YES NO UNSURE
Missing Data If data was missing, does the study explain how missing data were addressed? (If data was complete select YES)	N/A	YES NO UNSURE
Number of Participants Does study reports numbers of individuals at each stage of study - e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed?	N/A	YES NO UNSURE
Outcome Data Does the study report numbers of outcome events or summary measures over time?	N/A	YES NO UNSURE
Main Results Does the study give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval)? Does the study make clear which confounders were adjusted for and why they were included?	N/A	YES NO UNSURE
Other Analyses Does the study report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses?	N/A	YES NO UNSURE

Limitations Does the study give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence?	N/A	YES NO UNSURE