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| **QUIPS Risk of Bias Assessment Instrument for Prognostic Factor Studies** | | |  |  |
| *Modified from:* Hayden JA, Côté P, Bombardier C. Evaluation of the Quality of Prognosis Studies in Systematic Reviews. Annals of Internal Medicine. 2006;144:427-437, with the assistance of the QUIPS-LBP Working Group.  **Instructions**: Complete the QUIPS tool for the article by Aloisio et al. Focus on the prognostic factor albumin and the outcome mortality (ignore ICU admission).  Rate the quality of reporting (Yes, Partial, No, Unsure) in the blue boxes and the risk of bias (Low, Moderate, High, Unclear) in the green boxes. Provide rationale for your rating of the quality of reporting in the white boxes and rationale for RoB assessment in the grey box. Other grey boxes can be left empty. You can ignore the “Key characteristics (LIST)”. | | |  |  |
| **Author and year of publication** | Aloisio 2020 |  |  |  |
| **Study identifier** |  |  |  |  |
| **Reviewer** |  |  |  |  |
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| **Biases** | **Issues to consider for judging overall rating of "Risk of bias"** | **Study Methods & Comments** | **Rating of reporting** | **Rating of "Risk of bias"** |
| Instructions to assess the risk of each potential bias: | These issues will guide your thinking and judgment about the overall risk of bias within each of the 6 domains. Some 'issues' may not be relevant to the specific study or the review research question. These issues are taken together to inform the overall judgment of potential bias for each of the 6 domains. | Provide comments or text exerpts in the white boxes below, as necessary, to facilitate the consensus process that will follow. |  |  |
| **1. Study Participation** | **Goal: To judge the risk of selection bias (likelihood that relationship between *PF* and *outcome* is different for participants and eligible non-participants).** |  |  |  |
| *Source of target population* | The source population or population of interest is adequately described for key characteristics (LIST). |  |  |  |
| *Method used to identify population* | The sampling frame and recruitment are adequately described, including methods to identify the sample sufficient to limit potential bias (number and type used, e.g., referral patterns in health care) |  |  |  |
| *Recruitment period* | Period of recruitment is adequately described |  |  |  |
| *Place of recruitment* | Place of recruitment (setting and geographic location) are adequately described |  |  |  |
| *Inclusion and exclusion criteria* | Inclusion and exclusion criteria are adequately described (e.g., including explicit diagnostic criteria or  “zero time” description). |  |  |  |
| *Adequate study participation* | There is adequate participation in the study by eligible individuals |  |  |  |
| *Baseline characteristics* | The baseline study sample (i.e., individuals entering the study) is adequately described for key characteristics (LIST). |  |  |  |
| **Summary Study participation** | **The study sample represents the population of interest on key characteristics, sufficient to limit potential bias of the observed relationship between PF and outcome.** | **Rationale for RoB assessment**: |  |  |
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| **2. Study Attrition** | **Goal: To judge the risk of attrition bias (likelihood that relationship between *PF* and *outcome* are different for completing and non-completing participants).** |  |  |  |
| *Proportion of baseline sample available for analysis* | Response rate (i.e., proportion of study sample completing the study and providing outcome data) is adequate. |  |  |  |
| *Attempts to collect information on participants who dropped out* | Attempts to collect information on participants who dropped out of the study are described. |  |  |  |
| *Reasons and potential impact of subjects lost to follow-up* | Reasons for loss to follow-up are provided. |  |  |  |
| *Outcome and prognostic factor information on those lost to follow-up* | Participants lost to follow-up are adequately described for key characteristics (LIST). |  |  |  |
| There are no important differences between key characteristics (LIST) and outcomes in participants who completed the study and those who did not. |  |  |  |
| **Study Attrition Summary** | **Loss to follow-up (from baseline sample to study population analyzed) is not associated with key characteristics (i.e., the study data adequately represent the sample) sufficient to limit potential bias to the observed relationship between PF and outcome.** | **Rationale for RoB assessment**: |  |  |
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| **3. Prognostic Factor Measurement** | **Goal: To judge the risk of measurement bias related to how PF was measured (differential measurement of PF related to the level of outcome).** | Prognostic factor of interest: albumin |  |  |
| *Definition of the PF* | A clear definition or description of 'PF' is provided (e.g., including dose, level, duration of exposure, and clear specification of the method of measurement). |  |  |  |
| *Valid and Reliable Measurement of PF* | Method of PF measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). |  |  |  |
| Continuous variables are reported or appropriate cut-points (i.e., not data-dependent) are used. |  |  |  |
| *Method and Setting of PF Measurement* | The method and setting of measurement of PF is the same for all study participants. |  |  |  |
| *Proportion of data on PF available for analysis* | Adequate proportion of the study sample has complete data for PF variable. |  |  |  |
| *Method used for missing data* | Appropriate methods of imputation are used for missing 'PF' data. |  |  |  |
| **PF Measurement Summary** | ***PF* is adequately measured in study participants to sufficiently limit potential bias.** | **Rationale for RoB assessment**: |  |  |
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| **4. Outcome Measurement** | **Goal: To judge the risk of bias related to the measurement of outcome (differential measurement of outcome related to the baseline level of PF).** | Outcome of interest: mortality |  |  |
| *Definition of the Outcome* | A clear definition of outcome is provided, including duration of follow-up and level and extent of the outcome construct. |  |  |  |
| *Valid and Reliable Measurement of Outcome* | The method of outcome measurement used is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and confirmation of outcome with valid and reliable test). |  |  |  |
| *Method and Setting of Outcome Measurement* | The method and setting of outcome measurement is the same for all study participants. |  |  |  |
| **Outcome Measurement Summary** | ***Outcome of interest* is adequately measured in study participants to sufficiently limit potential bias.** | **Rationale for RoB assessment**: |  |  |
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| **5. Covariate adjustment** | **Goal: To judge the risk of bias due to inappropriate covariate adjustment (i.e. the effect of PF is distorted by another factor that is related to PF and outcome).** |  |  |  |
| *Important covariates Measured* | All important covariates, including treatments (key variables in conceptual model: LIST), are measured. |  |  |  |
| *Definition of the covariate* | Clear definitions of the important covariates measured are provided (e.g., including dose, level, and duration of exposures). |  |  |  |
| *Valid and Reliable Measurement of covariates* | Measurement of all important covariates is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). |  |  |  |
| *Method and Setting of Covariate Measurement* | The method and setting of covariate measurement are the same for all study participants. |  |  |  |
| *Method used for missing data* | Appropriate methods are used if imputation is used for missing covariate data. |  |  |  |
| *Appropriate Accounting for Covariates* | Important covariates are accounted for in the study design (e.g., matching for key variables, stratification, or initial assembly of comparable groups). |  |  |  |
| Important covariates are accounted for in the analysis (i.e., appropriate adjustment). |  |  |  |
| **Covariate adjustment Summary** | **Important covariates are appropriately accounted for, limiting potential bias with respect to the relationship between *PF* and *outcome*.** | **Rationale for RoB assessment**: |  |  |
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| **6. Statistical Analysis and Reporting** | **Goal: To judge the risk of bias related to the statistical analysis and presentation of results.** |  |  |  |
| *Presentation of analytical strategy* | There is sufficient presentation of data to assess the adequacy of the analysis. |  |  |  |
| *Model development strategy* | The strategy for model building (i.e., inclusion of variables in the statistical model) is appropriate and is based on a conceptual framework or model. |  |  |  |
| The selected statistical model is adequate for the design of the study. |  |  |  |
| *Reporting of results* | There is no selective reporting of results. |  |  |  |
| **Statistical Analysis and Presentation Summary** | **The statistical analysis is appropriate for the design of the study, limiting potential for presentation of invalid or spurious results.** | **Rationale for RoB assessment**: |  |  |
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