**Decision rules for high and unclear PROBAST ratings**

Generally, within the domains, if criteria suggest both a “high” and an “unclear” ROB, the category “high” should be chosen for being more specific.

Table S1: Decision rules for high and unclear PROBAST ratings

|  |  |
| --- | --- |
| Domain 1: Participants | |
| ROB category | **Rules** |
| High | * Case-control studies: hospital controls or cases from only one center * Cohorts: self-selected screening population, no population sampling * Pooled studies and meta-analyses:   + If at least one study is included that should be rated as high |
| Unclear | * No or limited information on the study participants * Pooled studies and meta-analyses: * If no references to the studies included were provided |
|  | |
| Domain 2: Predictors | |
| ROB category | **Rules** |
| High | * Pooled studies: default is **high ROB**, as heterogeneity between studies is assumed. Exceptions:   + Justification was given that there was no heterogeneity e.g. because identical protocols were used to assess risk factors 🡪 **low ROB**   + Example from our studies: different assessment of number of nevi (nevi count on arms versus nevi count on whole body), but use of quantiles for risk model instead of absolute nevi counts [1] 🡪 **low ROB** |
| Unclear | * Case-control studies: Use of risk factors for which recall bias is possible (especially risk factors related to UV exposure like “sunburns” and “sunbed use”) * No or limited information on the selection and assessment of predictors |
|  | |
| Domain 3: Outcome | |
| ROB category | **Rules** |
| High | * Multiple outcomes, not only melanoma (e.g., “severely dysplastic naevus/cannot exclude melanoma“ [2]) * Melanoma diagnosis not verified/histological confirmed (e.g. “suspected melanoma” [3]) * Self-reported outcome e.g. lifetime melanoma via surveys |
| Unclear | * No or limited information on outcome |
|  | |
| Domain 4: Analysis | |
| ROB category | **Rules** |
| High | * + No validation (internal or external) Exception: prespecified models   + No performance evaluation   + Limited sample size concerning number of predictors |
| Unclear | * + No or limited information on analysis   + Components of the analysis whose impact on the results is unclear. E.g., ordinal incorporation of PRS [4], rounding of model coefficients to define the risk score [5], handling of ordinal variable as continuous variable [6] |
|  | |
| Overall ROB (according to the given rules in the PROBAST tool [7]) | |
| Low ROB: | If all domains were rated low ROB.  If a prediction model was developed without any external validation, and it was rated as low risk of bias for all domains, consider downgrading to high ROB.  Such a model can only be considered as low ROB, if the development was based on a very large data set and included some form of internal validation |
| High ROB: | If at least one domain was judged to be at high ROB. |
| Unclear ROB: | If an unclear risk of bias was noted in at least one domain and all other domains were rated low ROB. |

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