Additional file 5. Items for data extraction and risk of bias assessment

List of items for which data were extracted.

|  |  |
| --- | --- |
| **Item** | **Description / examples** |
| Validated model | Framingham Wilson, Framingham ATPIII, PCE; men or women; race (PCE); LDL or total cholesterol (Framingham Wilson). |
| Study type | Only external validation; external validation and development of a new model; external validation and incremental value assessment. |
| Study design | Cohort, randomized controlled trial |
| Eligibility criteria for participants | Age, (exclusion of) comorbidities, treatment, race. |
| Study dates | Inclusion dates, end of follow-up, follow-up time. |
| Prediction horizon | Time period for which predictions were made, e.g. 10 years. |
| Geographical location | Country and continent. |
| Case-mix | Information on the frequency, or mean/median and spread of the following population characteristics of the validation study: age, gender, smoking, diabetes, treatment, hypertension, systolic blood pressure, diastolic blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, race, other diseases, linear predictor, 10-year predicted survival probability. |
| Predictors | Full definition, measurement method, blinding of measurements. |
| Predicted outcome | Full definition, including ICD-codes. |
| Sample size | Number of participants, number of events, Kaplan-Meier 10-year survival probability. |
| Performance | C-statistic, 10-year total observed/expected ratio, standard error, 95% confidence intervals, calibration plot, calibration table. Performance of the original model and after updating the model were extracted. |

List of domains and signaling questions used for risk of bias assessment.

|  |  |
| --- | --- |
| **Domain** | **Signaling question** |
| Participant selection | 1. Were appropriate data sources used, e.g. cohort, RCT or nested case-control study data? |
|  | 2. Were all inclusions and exclusions based on characteristics of participants appropriate (e.g. comorbidities, treatment)? |
| Predictors | 1. Were predictors defined and assessed in a similar way for all participants? |
|  | 2. Were predictor assessments made without knowledge of outcome data? |
|  | 3. Are all predictors available at the time the model is used? |
|  | 4. Were predictors defined and assessed in the same way as in the original Framingham model? |
| Outcome | 1. Was a pre-specified outcome definition used? |
|  | 2. Were predictors excluded from the outcome definition? |
|  | 3. Was the outcome defined and determined in a similar way for all participants? |
|  | 4. Was the outcome determined without knowledge of predictor information? |
|  | 5. Are you confident that the outcome has been correctly measured for all patients (e.g. no outcomes are missed)? |
| Sample size and participant flow | 1. Were there a reasonable number of outcome events? |
|  | 2. Was the time interval between predictor assessment and outcome determination appropriate? |
|  | 3. Were all enrolled participants included in the analysis? |
|  | 4. Were participants with missing data handled appropriately? |
| Analysis | 1. Were any complexities in the data (e.g. censoring, competing risks) accounted for appropriately? |
|  | 2. Was the model *not* recalibrated before validation? |

This is a preliminary version of the PROBAST tool for risk of bias assessment of prediction model studies1,2.

**References**

1. Wolff RF, Moons KGM, Riley RD, Whiting PF, Westwood M, Collins GS, Reitsma JB, Kleijnen J, Mallett S: PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies. Ann Intern Med 2019, 170(1):51-58.
2. Moons KGM, Wolff RF, Riley RD, Whiting PF, Westwood M, Collins GS, Reitsma JB, Kleijnen J, Mallett S: PROBAST: A Tool to Assess Risk of Bias and Applicability of Prediction Model Studies: Explanation and Elaboration. Ann Intern Med 2019, 170(1):W1-w33.