**Translators**

①曹煜隆（北京大学人民医院，北京，中国）

Caoyulong（Peking University People's Hospital, Beijing, China）

②单娇（北京积水潭医院，北京，中国）

Shanjiao（Beijing Jishuitan Hospital, Beijing, China）

③龚志忠（清华大学，北京，中国）

Gongzhizhong（Tsinghua University, Beijing, China）

**Back-translated**

①高燕（北京大学人民医院，北京，中国）

Gaoyan（Peking University People's Hospital, Beijing, China）

②匡季秋（北京大学人民医院，北京，中国）

Kuangjiqiu（Peking University People's Hospital, Beijing, China）

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 项目 | **编号** |  | **项目细节** | **Page** |
| **题目和摘要** | | | | |
| 题目  (Title) | 1 | D;V | 应明确研究为预测模型建立研究还是验证研究，研究目标人群和预测的结局指标  Should specify the study is for model development or model validation, the target population, and the predicted outcome |  |
| 摘要(Abstract) | 2 | D;V | 概述研究目标、研究设计、研究机构、研究对象、样本量、预测因子，结局指标，统计分析方法，结果和结论  Summary of the objectives, study design, institutions, population, sample size, outcome, statistical analysis methods, results and conclusions |  |
| **前言** | | | | |
| 背景和目的  (Background and Objective) | 3a | D;V | 阐述研究背景（包括诊断和预后）以及多因素模型建立或验证的原理，包括参考的现有模型  Describe the study background (including diagnostic and prognostic) and the principle of developing or validating the multivariable prediction model, including references to existing models. |  |
| 3b | D;V | 详细说明研究目标，包括研究是建立模型还是验证模型，还是两者都有  Specify the objectives, including whether the study is the development or validation of the model, or both. |  |
| **研究方法** | | | | |
| 数据来源  (Data source) | 4a | D;V | 描述研究设计或数据来源（如随机试验、队列研究或注册研究数据等），并分别描述建立或验证模型的数据集  Describe the study design or data source (e.g. randomised trial, cohort, or registry data etc.), and describe the development and validation dataset separately. |  |
| 4b | D;V | 详细描述重要研究日期，包括开始时间、结束时间，如有可能还应有随访结束时间  Specify important research dates, including start date, end date, if possible, end of follow-up time. |  |
| 研究对象  (Population) | 5a | D;V | 详细说明研究机构的关键信息（如初级医疗机构、二级医疗机构或普通人群），包括研究中心的数量和位置  Specify the key information of research institution (e.g. primary care, secondary care, or general population), including number and location of research centres. |  |
| 5b | D;V | 描述研究对象的纳入标准  Describe the inclusion criteria for the research population |  |
| 5c | D;V | 如果干预与模型相关，详述研究对象接收干预治疗的具体细节  If the intervention is related to the model, specify the details of the received intervention |  |
| 结局指标  (Outcome) | 6a | D;V | 清晰定义预测模型所要预测的结局指标，包括如何以及何时进行评估  Clearly define the outcome to be predicted by the prediction model, including how and when to evaluate the model |  |
| 6b | D;V | 报告对预测结局指标盲法评价的所有细节  Report all details of blinded assessment of the outcome to be predicted |  |
| 预测因素  (Predictor) | 7a | D;V | 清晰定义建立多因素预测模型所使用的所有预测因素，包括如何以及何时测量  Clearly define all predictors used to develop the multivariable model, including how and when they were measured |  |
| 7b | D;V | 报告对预测因素指标盲法评价的所有细节  Report all details of blinded assessment of the predictors |  |
| 样本量  (Sample size) | 8 | D;V | 解释研究样本量是如何确定的  Describe how the study sample size was determined. |  |
| 缺失数据  (Missing data) | 9 | D;V | 描述缺失数据的处理方法（如仅分析完整数据、单一插补和多种插补等），并详细说明插补方法  Describe the method of handling missing data (e.g. complete case analysis, single imputation, and multiple imputation etc.) and details of the imputation method |  |
| 统计分析方法  (Statistical analysis method) | 10a | D | 描述预测因素的统计方法  Describe the statistical method of the predictors |  |
| 10b | D | 明确模型类型，详述建模过程（包括预测因素的选择）和内部验证方法  Define model type, describe the detail of model development (including predictor selection) and internal validation method. |  |
| 10c | V | 描述模型验证中预测值的计算方法  Describe the method of predictions calculated in model validation. |  |
| 10d | D;V | 详述模型预测效果的所有评估方法，如相关可比较不同的预测模型  Specify all methods to evaluate model performance, if relevant, to compare different prediction models |  |
| 10e | V | 描述验证模型后模型的更新（如再校正等）  Describe the updated model after model validation (e.g. recalibration etc.) |  |
| 风险分层  (Risk stratification) | 11 | D;V | 如果进行了风险分层，提供如何建立风险分层的细节  Provide details on how risk stratification was created, if risk stratification is done. |  |
| 建立vs验证  (Development vs validation) | 12 | V | 识别建模数据集与验模数据集在研究机构、纳入标准、结局指标和预测因素上的任何差异  Identify the differences between the development dataset and the validation dataset in research institutions, inclusion criteria, outcome and predictors |  |
| **结果** | | | | |
| 研究对象  (Population) | 13a | D;V | 描述研究对象纳入研究的过程，包括有结局或无结局的研究对象数量以及随访情况，建议制作流程图  Describe the process of population were included in the study, including the number of patients with or without outcome, and follow-up status, flow chart is recommended |  |
| 13b | D;V | 描述研究对象的特征（包括人口学资料、临床特征与有效的预测因素），以及缺失预测因素与结局指标研究对象的数量  Describe the characteristic of the population (including demographic data, clinical features, and valid predictors), and the number of patients with missing predictors and outcome |  |
| 13c | V | 比较建模数据集与验模数据集在重要变量上的分布差异，如人口学资料、预测因素和结局指标等  Compare the differences between development datasets and validation datasets on important variables, such as demographic data, predictors and outcome |  |
| 模型建立  (Model development) | 14a | D | 明确每次分析中的研究对象和结局事件的数量  Specify the number of patients and outcome events in each analysis |  |
| 14b | D | 可报告每个未校正的候选预测因素与结局指标的关系  Report the relationship between each unadjusted candidate predictor and outcome |  |
| 模型详述  (Model interpretation) | 15a | D | 提供可对个体进行预测的完整预测模型，（如所有的回归系数、模型截距或既定时间点的基线生存率等）  Provide the full prediction model that can be used to predict individuals, (e.g. all regression coefficients, intercept, or baseline survival at a given time point) |  |
| 15b | D | 解释如何使用预测模型  Explain how to use the prediction model |  |
| 模型效能  (Model Effectiveness) | 16 | D;V | 报告预测模型的预测效果参数及其可信区间  Report the performance measures and their confidence intervals for the prediction model |  |
| 模型更新  (Model updating) | 17 | V | 报告模型更新的结果，即更新后的模型参数和模型预测效果  Report the results of the updated model, that is model parameters and model performance |  |
| **讨论** | | | | |
| 局限性  (Limitation) | 18 | D;V | 讨论研究的局限性（如非随机抽样、预测结局指标平均事件不足、缺失数据等）  Discuss the limitations of the study (e.g. non-random sampling, lack of events per predictor, missing data, etc.) |  |
| 解释  (Interpretation) | 19a | V | 与建模数据集或其他数据集的预测效果对比，报告验模数据集的预测效果  Report the performance of the validation data, compared with the performance in the development datasets or other datasets |  |
| 19b | D;V | 结合研究目的、局限性、其他类似研究结果和其他相关证据，对研究结果进行总体讨论  General discussion of the results, combined with objectives, limitations, results from other similar studies, and other relevant evidence |  |
| 意义  (Implications) | 20 | D;V | 讨论模型的潜在临床应用和对未来研究启示  Discuss the potential clinical application of the model and its implications for future research |  |
| **其他信息** | | | | |
| 补充信息  (Supplementary information) | 21 | D;V | 提供补充资料和信息，如研究方案、网页计算器和数据集  Provide the supplementary documents and information, such as research protocol, web calculator, and datasets |  |
| 资助  (Funding) | 22 | D;V | 提供研究资金来源和资助方在本研究中的角色  Provide funding source and the role of funders in this study |  |

\*仅与预测模型开发相关的项目标注为D，仅与预测模型验证相关的项目标注为V，与预测模型开发和验证均相关的项目标注为D;V。