## The subsequent steps for use of the PROBAST+AI tool.

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| **Step** | **Task** | **When to complete** |
| 1 | Specify the intended purpose of the prediction model assessment or of the prediction model systematic review | Once per assessment or systematic review |
| 2 | Classify the type of prediction model study (development or evaluation or both) | Once for each prediction model of interest in each publication assessed, for each relevant outcome |
| 3 | Assess quality and applicability to the intended purpose of the prediction model for model development, for each domain  &  Assess risk of bias and applicability to the intended purpose of the prediction model for model evaluation, for each domain | Once for each model development for each distinct prediction model in a publication  Once for each model evaluation for each distinct prediction model in a publication |
| 4 | Assess the overall quality and applicability for model development, and separately, the risk of bias and applicability for model evaluation | Once for each assessed prediction model in a publication, and separately for model development and for model evaluation. |

Directly based on PROBAST-2019 (www.probast.org). We strongly recommend reading the Explanation and Elaboration Light (Supplementary Table 4) and the Explanation and Elaboration document of PROBAST-2019[[1]](#footnote-1). We also recommend checking the example papers on www.probast.org.

**Step 1: Use the PICOTS guidance to specify your intended purpose or aim of the prediction model assessment, and the review question in case a systematic review of prediction model studies is conducted**

PICOTS:

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| **Item** | **Explanation** |
| **Population** | Define the target population (e.g., patients) in whom the assessed prediction models are to be applied. The target population not only directs search strings and in/exclusion criteria of prediction models or prediction model studies in case of a systematic literature review, but also directs the applicability assessment. |
| **Index model(s)** | Define the targeted prediction models to be assessed, which may be a single prediction model (the index model) of which the predictive accuracy is meta-analysed across multiple external evaluation studies of that index model but may also address multiple prediction models (developed or evaluated) for the targeted population, outcome or setting, depending on the assessor’s or prediction model review focus. |
| **Comparator model(s)** | Define the other prediction models whose predictive ability is compared to that of the index model. |
| **Outcome(s)** | Define the outcomes or endpoints that are predicted by the index (and possibly comparator) prediction models in the target population. |
| **Timing** | 1. Define the moment or time-point (e.g., in the patient work-up) at which the prediction with the prediction models is made (i.e., the start point or T0 of the use of the models).  2. Define the time or follow-up period in which the outcomes are being predicted by the prediction models in the targeted population (prediction horizon). |
| **Setting and intended use of the prediction model** | Define the healthcare setting or context to which the index prediction models apply. The prediction ability of models may change across healthcare settings or contexts. |

*The following table should be completed once per prediction model review.*

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| **Population** | Trauma patients presenting at accident and emergency |
| **Index model(s)** | Any model |
| **Comparator model(s)** | Not applicable |
| **Outcome(s)** | All-cause mortality |
| **Timing** | 1. At arrival at the emergency room  2. In-hospital or within 30 days |
| **Setting and intended use of the prediction model** | Hospital setting; To identify patients with traumatic bleeding who are at risk of early death and hence to inform timely care decisions |

**Step 2: Classify the type of prediction model assessment**

Use the following table to classify the assessments as model development, model evaluation, or combination (see also Box 1 in the paper). Different signalling questions apply for different types of prediction model assessments. If the assessment does not fit one of these classifications, then PROBAST+AI should not be used.

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| **Classify the assessment based on its aim** | | | |
| *Type of prediction study* | *Explanation* | *PROBAST+AI boxes to complete* | *Tick as appropriate* |
| Development only | Prediction model development only, i.e., without evaluation of its performance. | Model development | ✘ |
| Evaluation only | External validation of one or more existing models in new data | Model evaluation | ✘ |
| Combination | Prediction model development combined in the same study (publication) with the evaluation of its apparent performance, internal validation performance, or external validation performance. | Model development and evaluation | ✓ |

**Step 3: Assess quality and applicability or risk of bias and applicability**

This table should be completed once for each publication being assessed and for each relevant outcome in the prediction model review

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| **Publication reference** | Perel P et al. Predicting early death in patients with traumatic bleeding: development and validation of prognostic model. BMJ 2012 Aug 15;345:e5166. doi: 10.1136/bmj.e5166 |
| **Models of interest** | CRASH-2 |
| **Outcome of interest** | All-cause mortality |

**PROBAST+AI: MODEL DEVELOPMENT**

Each domain of the model development part is judged for concerns about quality (low, high, or unclear concern). Each domain includes signalling questions to help make judgements. Signalling questions are rated as yes (Y), probably yes (PY), probably no (PN), no (N), no information (NI), and in some cases not applicable (NA, items marked with an asterisk\*). All signalling questions are phrased so that ‘yes’ or ‘probably yes’ indicate low concerns for quality (= high quality).

Any signalling question rated as ‘no’ or ‘probably no’ flags the potential for sincere concerns regarding quality of that domain. You will need to use your judgement to determine whether the entire domain should be rated as ‘high’, ‘low’, or ‘unclear’ concern regarding quality. The Explanation & Elaboration Light (Supplementary Table 4) contains further information and examples on rating signalling questions and concerns regarding quality for each domain of the model development process.

The first three domains are also rated for concerns regarding applicability (low/high/unclear) of the prediction model (study) to the review question or to intended use of the assessed prediction models (as defined in step 1).

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| **DOMAIN 1: Participants and data sources** | |
| **A.** **Quality** | |
| *Describe the sources of data and criteria for participant selection:*  Patients from the CRASH-2 trial – 20,127 trauma patients with or at risk of significant bleeding within  eight hours of injury. Took place in 274 hospitals in 40 countries. Randomized trial comparing tranexamic vs.  placebo. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **1.1 Were appropriate data sources used?** | **Y** |
| **1.2 Was an appropriate study design used?** | **PY** |
| **1.3 Did the in- and exclusions of study participants result in a representative dataset?** | **PY** |
| **Concern regarding quality of selection of participants and data sources** | **QUALITY CONCERN:**  ***low*** |
| ***Rationale of quality rating:***  No information on inclusions and exclusions from the CRASH-2 trial (development dataset), unlikely to have a major impact. The CRASH-2 trial is referenced (Lancet 2010;376:23-32). | |
| **B.** **Applicability** | |
| Describe included data sources, participants, setting, and dates:  As before, no dates reported for the CRASH-2 trial (development dataset) but the trial is referenced. | |
| **Concern that the (data of the) included participants do not match the review question or the assessor’s intended use of the prediction model** | **APPLICABILITY CONCERN:**  ***low*** |
| ***Rationale of applicability rating:***  Participants and setting seem to fit review question | |

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| **DOMAIN 2: Predictors** | |
| **A.** **Quality** | |
| *List and describe predictors included in the final prediction model, how they were defined and assessed, and their timing of assessment:*  Demographic characteristics (age and sex), characteristics of injury (type of injury and time from injury to  randomisation), and physiological variables (Glasgow coma score, systolic blood pressure, heart rate,  respiratory rate and central capillary refill time). Predictors seem to have been pre-specified (within CRASH-2),  all predictors were measured at baseline (taken from patients’ entry forms completed before randomisation). If data pre-processing was performed, this was probably performed similarly for all participants, as data came from the same clinical trial. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **2.1 Were predictors defined and assessed in a similar way for all participants?** | **PY** |
| **2.2 Was any pre-processing of predictors similar for all participants?** | **PY** |
| **2.3 Were predictor assessments made without knowledge of outcome data?** | **Y** |
| **2.4 Were the predictors included in the model available at the time the model was intended to be used?** | **Y** |
| **Concern regarding the quality of the predictors or their assessment** | **QUALITY CONCERN:**  ***low*** |
| ***Rationale of quality rating:***  No major issues identified. | |
| **Applicability** | |
| **Concern that the definition, pre-processing, assessment, or timing of assessment of the predictors in the model do not match the review question or the assessor’s intended use** | **APPLICABILITY CONCERN:**  ***low*** |
| ***Rationale of applicability rating:***  All predictors were measured at baseline (taken from patients’ entry forms completed before randomisation) | |

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| **DOMAIN 3: Outcome** | |
| **A.** **Quality** | |
| *Describe the outcome, how it was defined and determined, and the time interval between predictor assessment and outcome determination:*  The primary outcome was all cause mortality within four weeks of injury.  The development dataset was part of an RCT so some patients received the trial intervention between predictor measurement and outcome measurement. This was accounted for in the model by including treatment as a covariate in the model. For model development (CRASH-2 data), the outcome was defined as all-cause mortality, in-hospital or within 28 days of discharge. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **3.1 Were outcomes defined and assessed appropriately?** | **Y** |
| **3.2 Were outcomes defined and assessed in a similar way for all participants?** | **Y** |
| **3.3 Were outcome assessments made without use or knowledge of predictor data?** | **PN** |
| **3.4 Was the time interval between predictor assessment and outcome assessment appropriate?** | **Y** |
| **Concern regarding quality of the outcome or its determination** | **QUALITY CONCERN:**  ***low*** |
| ***Rationale of quality rating:***  Potential for the outcome (“all-cause mortality”) to be determined with predictor information available is unlikely to have a major influence as this is an objective outcome. | |
| **B.** **Applicability** | |
| *At what time point was the outcome determined:*  Patients’ outcomes were recorded at discharge, at death in hospital, or 28 days after injury, whichever  occurred first.  *If a composite outcome was used, describe the relative frequency/distribution of each contributing outcome:*  N/A | |
| **Concern that the outcome, its definition, assessment, or timing of assessment do not match the review question or the assessor’s intended use** | **APPLICABILITY CONCERN:**  ***low*** |
| ***Rationale of applicability rating:***  All-cause mortality was the outcome of interest for the review. The outcome of the primary study  matches the outcome of interest of the review. | |

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| **DOMAIN 4: Analysis** | |
| **Quality** | |
| *Describe the numbers of participants, number of candidate predictors, number of outcome events:*  20,127 participants, 9 candidate predictors, 3076 deaths | |
| *Describe how the prediction model was developed (e.g., with respect to modelling technique,*  *predictor selection, and classification or risk group definition):*  All candidate predictors were initially included in multivariable logistic regression. Analyses were adjusted for  treatment, by including treatment arm as a co-variable. A variable for economic region (low, middle, or high-  income country, as defined by the World Bank) was also included. The final model was developed using a  backwards stepwise approach. | |
| *Describe the performance measures of the prediction model, e.g., (re)calibration, discrimination,*  *(re)classification, net benefit, and whether they were adjusted for optimism:*  Discrimination (c-statistic) and calibration. Optimism was assessed by bootstrap re-sampling. | |
| *Describe missing data on predictors and outcomes as well as methods used for handling*  *these missing data:*  Data were missing for <1% of participants for age, systolic blood pressure, heart rate, respiratory rate and Glasgow coma score. Data for capillary refill time were missing for 3% of patients. No information on missing data for sex, type of injury and time from injury to randomisation.  “Complete case analysis as amount of missing data was very low” | |
|  | **Y/ PY/ PN/ N/ NI/ NA** |
| **4.1 Was there evidence that the sample size was reasonable?** | **Y** |
| **4.2 Were continuous and categorical predictors handled appropriately?** | **Y** |
| **4.3 Were participants with missing or censored data handled appropriately in the analysis?** | **N** |
| **4.4 If methods to address class imbalance were used, was the model or the model predictions recalibrated?\*** | **NA** |
| **4.5 Were methods used to address potential model overfitting?** | **Y** |
| **Concern regarding quality of the analysis** | **QUALITY CONCERN:**  ***low*** |
| ***Rationale of quality rating:***  In the development of the model complete case analysis was used, however, the frequency of missing data was very low (RCT data), and the authors used multiple imputation in the validation set so they know the usefulness of this method to handle missing data. If the complete case analysis in the model development was likely to distort the result, they probably would have used multiple imputation there as well. Therefore the risk of bias is considered low. No other problematic issues are present with respect to this domain. | |

**PROBAST+AI: MODEL EVALUATION**

Each domain of the model evaluation part is judged for risk of bias (low, high, or unclear). Each domain includes signalling questions to help make judgements. Signalling questions are again rated as yes (Y), probably yes (PY), probably no (PN), no (N), no information (NI), and in some cases not applicable (NA, items marked with an asterisk\*). All signalling questions are phrased so that ‘yes’ or ‘probably yes’ indicate low risk of bias. Any signalling questions rated as ‘no’ or ‘probably no’ flags the potential for high risk of bias in that domain. You will need to use your judgement to determine whether the entire domain should be rated as ‘low’, ‘high’, or ‘unclear’ risk of bias.

If investigators only performed an apparent performance evaluation of the model, the responses to the signalling questions of domain 1, 2, and 3 in the Model Development section, can directly be copied and pasted to domain 1, 2, and 3 of this Model Evaluation section. However, the risk of bias judgement in the estimated model performance measures (e.g., their calibration or discrimination) still needs to be made.

Domain 4 should be evaluated separately for each type of model evaluation/validation assessed (apparent performance, internal validation, external validation). Shaded boxes indicate where signalling questions do not apply and should not be answered. The Explanation & Elaboration Light (Supplementary Table 4) contains further information and examples on rating signalling questions and risk of bias for each domain of model evaluation.

The first three domains are also rated for concerns regarding applicability (low/high/unclear) of the prediction model (study) to the review question or the intended use of the assessed prediction model(s) (as defined in step 1).

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| **DOMAIN 1: Participants and data sources** | |
| **A.** **Risk of bias** | |
| *Describe the sources of data and criteria for participant selection:*  Data from Trauma Audit and Research Network (TARN) including 60% of relevant hospitals in England and Wales and some hospitals in Europe, collected between 2000 and 2008, were used. TARN collects data on  patients who arrive at hospital alive and who meet any of the following criteria: death from injury at any point  during admission; hospital stay >3 days; need for intensive or high dependency care; need for between  hospital transfer for specialist care. The validation data set excluded patients with isolated limb injuries and  those over 65 years with isolated femoral neck or pubic ramus fracture. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **1.1 Were appropriate data sources used?** | **Y** |
| **1.2 Was an appropriate study design used?** | **PY** |
| **1.3 Did the in- and exclusions of study participants result in a representative dataset?** | **Y** |
| **Risk of bias introduced by the selection of participants and data sources** | **RISK OF BIAS:**  ***low*** |
| ***Rationale of risk of bias rating:***  (risk of) significant bleeding was not a specific entry criterion in the validation dataset, so researchers  selected only patients with an estimated blood loss of at least 20%. This sounds like a reasonable and sensible  approach***.*** | |
| **B.** **Applicability** | |
| Describe included data sources, participants, setting, and dates:  Data set excludes participants older than 65 years and those with isolated femoral neck or pubic ramus fractures. | |
| **Concern that the (data of the) included participants do not match the review question or the assessor’s intended use of the prediction model** | **APPLICABILITY CONCERN:**  ***low*** |
| ***Rationale of applicability rating:***  Participants and setting seem to fit review question even though some exclusions were made | |

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| **DOMAIN 2: Predictors** | |
| **A.** **Risk of bias** | |
| *List and describe predictors included in the evaluated model, e.g., definition and timing of*  *assessment:*  The physiological data available in TARN are identical to those in CRASH-2, in that for every patient the  heart rate, systolic blood pressure, Glasgow coma score, respiratory rate, and capillary refill time on arrival are  entered by the hospital data coordinators. All predictors were measured on arrival. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **2.1 Were predictors defined and assessed in a similar way for all participants?** | **PY** |
| **2.2 Was any pre-processing of predictors similar for all participants?** | **PY** |
| **2.3 Were predictor assessments made without knowledge of outcome data?** | **PY** |
| **2.4 Were the predictors included in the model available at the time the model was intended to be used?** | **PY** |
| **Risk of bias introduced by the predictors or their assessment** | **RISK OF BIAS:**  ***low*** |
| ***Rationale of risk of bias rating:***  No major issues identified. TARN is used for clinical auditing, so we expect that definitions, assessment and pre-processing are similar between participants. | |
| **B.** **Applicability** | |
| **Concern that the definition, pre-processing, assessment, or timing of assessment of the predictors in the model do not match the review question or the assessor’s intended use** | **APPLICABILITY CONCERN:**  ***high*** |
| ***Rationale of applicability rating:***  All predictors were measured at baseline (by hospital data co-ordinators at time of arrival), however, the predictor ‘hours since injury’ was frequently missing and therefore excluded from the model. | |

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| **DOMAIN 3: Outcome** | |
| **A.** **Risk of bias** | |
| *Describe the outcome, how it was defined and determined, and the time interval between predictor assessment and outcome determination:*  The primary outcome was all cause mortality within four weeks of injury.  Validation uses TARN data, which records mortality at any point during admission as an outcome. | |
|  | **Y/ PY/ PN/ N/ NI** |
| **3.1 Were outcomes defined and assessed appropriately?** | **Y** |
| **3.2 Were outcomes defined and assessed in a similar way for all participants?** | **Y** |
| **3.3 Were outcome assessments made without use or knowledge of predictor data?** | **PN** |
| **3.4 Was the time interval between predictor assessment and outcome assessment appropriate?** | **Y** |
| **Risk of bias introduced by the outcome or its determination** | **RISK OF BIAS:**  ***low*** |
| ***Rationale of risk of bias rating:***  Potential for the outcome (“all-cause mortality”) to be determined with predictor information available and  the difference in follow-up definition (in-hospital or within 28 days of discharge – development, versus at any  point during admission [duration not defined] – validation) are unlikely to have a major influence. | |
| **B.** **Applicability** | |
| *At what time point was the outcome determined: Although not reported in the article, the TARN database only has information collected during hospital stay.*    *If a composite outcome was used, describe the relative frequency/distribution of each contributing outcome:*  N/A | |
| **Concern that the outcome, its definition, assessment, or timing of assessment do not match the review question or the assessor’s intended use** | **APPLICABILITY CONCERN:**  ***low*** |
| ***Rationale of applicability rating:***  All-cause mortality was the outcome of interest for the review. The outcome of the primary study  matches the outcome of interest of the review. | |

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| **DOMAIN 4: Analysis** | | | |
| **Risk of bias** | | | |
| *Describe numbers of participants, number of predictors, outcome events and events per predictor:*  Apparent performance/internal validation: 20,127 participants, 9 candidate predictors, 3076 deaths (342 events per predictor)  External validation: 14,220 trauma patients, 765 deaths | | | |
| *Describe the performance measures of the evaluated model, e.g., (re)calibration, discrimination,*  *(re)classification, net benefit, and whether they were adjusted for optimism:*  Discrimination (c-statistic) and calibration; optimism in apparent performance was assessed by bootstrap re-sampling. | | | |
| *Describe any participants who were excluded from the analysis:*  Apparent performance/internal validation: Participants with missing data were excluded from the analysis. | | | |
| *Describe missing data on predictors and outcomes as well as methods used for handling*  *these missing data:*  Apparent performance/internal validation: Data were missing for <1% of participants for age, systolic blood pressure, heart rate, respiratory rate and Glasgow coma score. Data for capillary refill time were missing for 3% of patients. No information on missing data for sex, type of injury and time from injury to randomisation.  External validation: Missing data percentages ranged from 0% for age to 84% for capillary refill time. Authors conducted “multiple imputations to substitute the missing values of the predictors included in the prognostic model by using the procedure of imputation by chained equations in Stata Release 11”. However, the results state “For the external validation, we used the same variables as were included in the derivation model except hours since injury, as this variable had a very large number of patients with missing data.” so it looks like this predictor was excluded after multiple imputation. | | | |
|  | **Y/ PY/ PN/ N/ NI/ NA** | | |
| **4.1 Was model evaluation based on only apparent performance avoided?** | **Y** | | |
|  | **A** | **I** | **E** |
| **4.2 Was there evidence that the sample size was reasonable?** | **Y** | **Y** | **Y** |
| **4.3 Were participants with missing or censored data handled appropriately in the analysis?** | **N** | **N** | **N** |
| **4.4 If methods to address class imbalance were used, was the evaluation done in a dataset without imbalance correction?\*** | **NA** | **NA** | **NA** |
| **4.5 If data splitting was done to create training and test datasets, was there evidence that data leakage was avoided?\*** | **NA** | **NA** | **NA** |
| **4.6 If resampling methods were used to evaluate model performance, were all model development steps replicated in the resampling process?\*** | **NA** | **Y** | **NA** |
| **4.7 Was the predictive performance of the model evaluated appropriately, e.g., calibration, discrimination, and net benefit?** | **PY** | **PY** | **PY** |
| **Risk of bias introduced by the analysis** | **RISK OF BIAS:**  ***high*** | | |
| ***Rationale of risk of bias rating:***  Apparent performance and internal validation (using bootstrapping) was done with complete case-analysis. Multiple imputation was used for missing data in the external validation dataset, however in the results it is stated that one predictor is excluded from the analyses because of a large amount of missing data. Excluding a variable that is part of a prediction model will result in higher or lower predicted probabilities and thus bias the performance of the model.. For apparent performance, only discrimination is evaluated, for internal and external validation only discrimination and calibration (no net benefit). | | | |

**Step 4: Assess the overall concerns regarding quality, risk of bias and applicability of the prediction model**

Use the following tables to reach overall judgements about concerns regarding quality and applicability for the model development process, and separately about risk of bias and concerns regarding applicability for the model performance evaluation. Complete for each assessed model.

**Model development**

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| **OVERALL CONCERN REGARDING QUALITY OF THE PREDICTION MODEL DEVELOPMENT** | |
| **Low concern regarding quality** | If all four domains were rated low concern regarding quality. |
| **High concern regarding quality** | If at least one domain was rated high concern regarding quality . |
| **Unclear concern regarding quality** | If at least one domain was rated unclear concern regarding quality and no domains were rated high concern. |

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| **OVERALL CONCERN FOR APPLICABILITY OF THE PREDICTION MODEL DEVELOPMENT** | |
| **Low concern for applicability** | If all three domains were rated low concern for applicability. |
| **High concern for applicability** | If at least one domain was rated high concern for applicability. |
| **Unclear concern for applicability** | If at least one domain was rated unclear concern for applicability and no domains were rated high concern. |

**Model evaluation**

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| **OVERALL RISK OF BIAS OF THE PREDICTION MODEL EVALUATION** | |
| **Low risk of bias** | If all four domains were rated low risk of bias. |
| **High risk of bias** | If at least one domain was rated high risk of bias. |
| **Unclear risk of bias** | If at least one domain was rated unclear risk of bias and no domains were rated high risk of bias. |

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| **OVERALL CONCERN FOR APPLICABILITY OF THE PREDICTION MODEL EVALUATION** | |
| **Low concern for applicability** | If all three domains were rated low concern for applicability. |
| **High concern for applicability** | If at least one domain was rated high concern for applicability. |
| **Unclear concern for applicability** | If at least one domain was rated unclear concern for applicability and no domains were rated high concern. |

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| **OVERALL JUDGEMENT OF PREDICTION MODEL** | |
| **Overall judgement of quality (development)** | **QUALITY CONCERN:**  *low* |
| *Summary of quality concern:*  Model was developed on a large prospective, pragmatic, randomised controlled trial. Treatment was accounted for in the model. Large dataset with a large number of events. Complete case analysis was performed, but the frequency of missing was low. Backward selection after the inclusion of all predictors is an accepted approach. | |
| **Overall judgement of risk of bias (evaluation)** | **RISK OF BIAS:**  *high* |
| *Summary of sources of potential bias:*  One predictor was excluded from the model which will have biased performance. Otherwise, no major problems were identified. | |
| **Overall judgement of applicability (development)** | **APPLICABILITY CONCERN:**  *low* |
| *Summary of applicability concern:*  The model has been developed on data from a randomized clinical trial. The concern is that RCTs may  include a selective population, typical younger, less comorbidity and medication use. In this case, these  concerns may be limited given the acute onset of the condition (trauma) and it was a large pragmatic trial. | |
| **Overall judgement of applicability (evaluation)** | **APPLICABILITY CONCERN:**  *high* |
| *Summary of applicability concern:*  Data from a large ongoing registry of trauma patients with similar data collection. However, one  predictor is missing in the evaluation dataset. | |

1. Moons KGM, Wolff RF, Riley RD, Whiting PF, Westwood M, Collins GS, et al. 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 [↑](#footnote-ref-1)