TRIPOD Checklist: Prediction Model Development and Validation

Section	Item		Checklist description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract					
Title	1	D;V	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.	3/1-2	Title/1
Abstract	2	D;V	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.	3/4-31	Abstract/1-4
Introduction					
Background and objectives	3a	D;V	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.	4-5/43-87	Introduction/1-3
	3b	D;V	Specify the objectives, including whether the study describes the development or validation of the model or both.	4-5/72-87	Introduction/3
Methods					
Source of data	4a	D;V	Describe the study design or source of data (e.g., randomized trial, cohort, or registry data), separately for the development and validation data sets, ifapplicable.	5/90-103	Methods/1
	4b	D;V	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.	5/90-103	Methods/1
Participants	5a	D;V	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.	5/90-103	Methods/1
	5b	D;V	Describe eligibility criteria for participants.	5/90-103	Methods/1
	5c	D;V	Give details of treatments received, if relevant.	Supplementary Table	Supplementary Table
Outcome	6a	D;V	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.	5/90-103	Methods/1
	6b	D;V	Report any actions to blind assessment of the outcome to be predicted.	5/90-103	Methods/1
Predictors	7a	D;V	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.	5-7/121-177	Methods/3-6
	7b	D;V	Report any actions to blind assessment of predictors for the outcome and other predictors.	5-7/121-177	Methods/3-6
Sample size	8	D;V	Explain how the study size was arrived at.	5-8/121-180	Methods/3-7

Missing data	9	D;V	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.	5-6/121-136	Methods/3
Statistical analysis methods	10a	D	Describe how predictors were handled in the analyses.	5-7/121-177	Methods/3-6
	10b	D	Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation.	5-7/121-177	Methods/3-6
	10c	V	For validation, describe how the predictions were calculated.	6/137-163	Methods/4-5
	10d	D;V	Specify all measures used to assess model performance and, if relevant, to compare multiple models.	6/137-163	Methods/4-5
	10e	V	Describe any model updating (e.g., recalibration) arising from the validation, if done.	6/137-163	Methods/4-5
Risk groups	11	D;V	Provide details on how risk groups were created, if done.	6/137-163	Methods/4-5
Development vs. validation	12	V	For validation, identify any differences from the development data in setting, eligibility criteria, outcome, and predictors.	6/137-163	Methods/4-5
Results					
Participants	13a	D;V	Describe the flow of participants through the study, including the number of participants with and without the outcome and, if applicable, a summary of the follow-up time. A diagram may be helpful.	7/183-195	Results/1
	13b	D;V	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.	7/183-195	Results/1
	13c	V	For validation, show a comparison with the development data of the distribution of important variables (demographics, predictors and outcome).	7/183-195	Results/1
Model development	14a	D	Specify the number of participants and outcome events in each analysis.	7-8/196-254	Results/2-6
	14b	D	If done, report the unadjusted association between each candidate predictor and outcome.	7-8/196-254	Results/2-6
Model specification	15a	D	Present the full prediction model to allow predictions for individuals (i.e., all regression coefficients, and model intercept or baseline survival at a given time point).	7-8/196-254	Results/2-6
	15b	D	Explain how to the use the prediction model.	7-8/196-254	Results/2-6
Model performance	16	D;V	Report performance measures (with CIs) for the prediction model.	7-8/196-254	Results/2-6
Model-updating	17	V	If done, report the results from any model updating (i.e., model specification, model performance).	7-8/196-254	Results/2-6
Discussion					
Limitations	18	D;V	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).	10/315-320	Discussion/3

Interpretation	19a	V	For validation, discuss the results with reference to performance in the development data, and any other validation data.	9-10/298-320	Discussion/3
	19b	D;V	Give an overall interpretation of the results, considering objectives, limitations, and results from similar studies, and other relevant evidence.	9-10/298-320	Discussion/3
Implications	20	D;V	Discuss the potential clinical use of the model and implications for future research.	9-10/298-320	Discussion/3
Other information					
Supplementary information	21	D;V	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.	2/Data availability	Data availability/NA
Funding	22	D;V	Give the source of funding and the role of the funders for the present study.	2/Funding, Authors'	Funding, Authors'

* Items relevant only to the development of a prediction model are denoted by D, items relating solely to a validation of a prediction model are denoted by V, and items relating to both are denoted D;V. We recommend using the TRIPOD Checklist in conjunction with the TRIPOD Explanation and Elaboration document.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

The REMARK checklist

Item to be reported		Reported on Page Number/Line Number	Reported on Section/Paragraph
INTRODUCTION			
1	State the marker examined, the study objectives, and any pre-specified hypotheses.	4-5/72-87	Introduction/3
MATERIALS AND METHODS			
Patients			
2	Describe the characteristics (e.g., disease stage or co-morbidities) of the study patients, including their source and inclusion and exclusion criteria.	5/91-103	Methods/1
3	Describe treatments received and how chosen (e.g., randomized or rule-based).	5/91-103	Methods/1
Specimen characteristics			
4	Describe type of biological material used (including control samples) and methods of preservation and storage.	5/104-120	Methods/2
Assay methods			
5	Specify the assay method used and provide (or reference) a detailed protocol, including specific reagents or kits used, quality control procedures, reproducibility assessments, quantitation methods, and scoring and reporting protocols. Specify whether and how assays were performed blinded to the study endpoint.	5/104-120	Methods/2
Study design			
6	State the method of case selection, including whether prospective or retrospective and whether stratification or matching (e.g., by stage of disease or age) was used. Specify the time period from which cases were taken, the end of the follow-up period, and the median follow-up time.	5-7/121-177	Methods/3-6
7	Precisely define all clinical endpoints examined.	5-7/121-177	Methods/3-6
8	List all candidate variables initially examined or considered for inclusion in models.	5-7/121-177	Methods/3-6
9	Give rationale for sample size; if the study was designed to detect a specified effect size, give the target power and effect size.	5-7/121-177	Methods/3-6
Statistical analysis methods			
10	Specify all statistical methods, including details of any variable selection procedures and other model-building issues, how model assumptions were verified, and how missing data were handled.	5-7/121-177	Methods/3-6
11	Clarify how marker values were handled in the analyses; if relevant, describe methods used for cutpoint determination.	5-7/121-177	Methods/3-6

RESULTS			
Data			
12	Describe the flow of patients through the study, including the number of patients included in each stage of the analysis (a diagram may be helpful) and reasons for dropout. Specifically, both overall and for each subgroup extensively examined report the numbers of patients and the number of events.	7/183-195	Results/1
13	Report distributions of basic demographic characteristics (at least age and sex), standard (disease-specific) prognostic variables, and tumor marker, including numbers of missing values.	7/183-195	Results/1
Analysis and presentation			
14	Show the relation of the marker to standard prognostic variables.	7/196-254	Results/2-6
15	Present univariable analyses showing the relation between the marker and outcome, with the estimated effect (e.g., hazard ratio and survival probability). Preferably provide similar analyses for all other variables being analyzed. For the effect of a tumor marker on a time-to-event outcome, a Kaplan-Meier plot is recommended.	7/196-254	Results/2-6
16	For key multivariable analyses, report estimated effects (e.g., hazard ratio) with confidence intervals for the marker and, at least for the final model, all other variables in the model.	7/196-254	Results/2-6
17	Among reported results, provide estimated effects with confidence intervals from an analysis in which the marker and standard prognostic variables are included, regardless of their statistical significance.	7/196-254	Results/2-6
18	If done, report results of further investigations, such as checking assumptions, sensitivity analyses, and internal validation.	8/233-247	Results/5
DISCUSSION			
19	Interpret the results in the context of the pre-specified hypotheses and other relevant studies; include a discussion of limitations of the study.	8-10/256-320	Results/1-3
20	Discuss implications for future research and clinical value.	9-10/298-320	Results/3

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