Prognostic Manuscript Preparation Guide

Track your progress by checking the box for each suggested field that is presented with a detailed description in your study. Refer to the Research Road Map for manuscript submission criteria regarding journal specific requirements.

Title

Author(s)/Affiliation

Date

Title
☐Relevant title

Author & Details
☐Last name, first initial, credentials of all authors (e.g. degree, job title, department, and location)

Abstract
☐Background
☐Goals/objectives
☐Study Design (e.g. randomized controlled trial)
☐Population
☐Sample group descriptions
☐Disease status (e.g. suspects, diagnosed, healthy)
☐Methods
☐Results (Key findings and statistical data)
☐Conclusion (Take-home message, implications, etc.)

Keywords
☐Search terms (Ex. Disease name or abbreviation, instrument name or abbreviation, main intervention, key anatomy, etc.)

Introduction
☐Background
☐Rationale
☐Main objectives
☐Applicability

Methods and Materials
☐Informed consent/study approval
☐Number and description of study centers
☐Number and description of sample groups
☐Duration of study
☐Instruments/tools used
☐Validity of measurement tools
☐Recruited participants representative of the target population and without true diagnosis
☐Prognostic factors of interest
☐Recruitment method
☐Consecutive enrollment (e.g. enrolling all participants fitting criteria without selection bias)
☐Inclusion and exclusion criteria
☐Credibility of examiner background and training
☐Baseline patient characteristics (noted significant differences)
☐Process details for tests and measurements
☐Measurement methods for prognostic factors and diagnosis (described and identical for all groups)
☐Pre-specified threshold/cutoff values used
☐Time between examinations
☐If any, follow-up times (described and identical for all groups)
☐Intended comparisons
☐Potential confounder descriptions and measurements
☐Patient adverse events, benefits, or harms (if documented/analyzed)

Statistical Analysis/Data Management

- ☐ Predictor selection method (e.g. Past literature, stepwise model, etc.)
- ☐ Statistical software, models, and variables
- ☐ Calculations and equations
- ☐ Strategy for statistical assumptions verification testing and management/control of missing data

Results

- ☐ Final examined patient count
- ☐ Study duration
- ☐ If any, follow-up times and data gathered at those times
- ☐ Scale Directionality of all outcome measurement tools
- ☐ Odds ratios (OR), risk ratios (RR), risk differences (RD), Log Odds, hazard ratios (HR) or any other validated/appropriate summary statistic and each respective CL (regardless of significance)
- ☐ Group comparison data
- ☐ Explanation of data tables
- ☐ Limited confounding with statistical control
- ☐ Rate and details of patients lost to follow-up
- ☐ Selective reporting avoided (data for pre-specified prognostic factors)
- ☐ If any, explanation of missing data
- ☐ Intent to treat population (if applicable)

Discussion

- ☐ Strengths
- ☐ Limitations
- ☐ Author interpretations
- ☐ Clinical implications

Conclusions

- ☐ Summary statement of main findings and/or interesting results

Acknowledgements

- ☐ Recognition for those involved in any aspect of the study

Disclosures/Conflicts of Interest

- ☐ Disclosure of any author conflicts of interest, funding, or influence risks

Ethics, Quality, or Safety Concerns

- ☐ Any risks, harms, or ethical concerns with this study or implications of this study

Funding Sources

- ☐ Any organizations, groups, or individuals associated with the funding of this study

References

- ☐ All references used/cited in development of this study
- ☐ Study protocol contact location, and/or accessibility

Appendix

- ☐ Any forms, charts, and/or tables used but not included in the content

ADDITIONAL DETAILS

Patient Description

Standard (Low risk of bias)

- Study participants are representative of the larger population of interest
- Exposed and unexposed patient groups are described, distinguishable, and have not yet been diagnosed or confirmed to have the target outcome/illness

Discouraged (High risk of bias)

- Healthy and pre-diagnosed patients included in the analysis (non-nested case control design)

Patient Recruitment

Standard (Low risk of bias)

- Patients should be recruited and examined prospectively at one location or similar locations (e.g. multi-center study in three county hospitals in Southern Illinois)
- Patients should be recruited following a pre-defined criteria for how, when, why, and by whom they will be recruited
- Matching techniques should be done upon inclusion if you do not plan to statistically control for potential confounders
- A complete count of patients that were included should be reported as well as the patient count for any groups or categories of patients
- The patient characteristics and disease status (e.g. undiagnosed, symptomatic, etc.) should be reported and described for all patients/groups

Discouraged (High risk of bias)

- Patients or groups with unspecified or unclear patient counts, recruitment strategies, or uncontrolled potential confounders

Patient Enrollment

Standard (Low risk of bias)

- The study should be approved with informed consent to meet safety, ethics, and regulation standards
- A description should be provided of how, and within what population, enrollment will be conducted
- Patients should be consecutively enrolled by including all patients that fit the criteria and agree to participate (e.g. avoiding "cherry picking")
- A detailed list of criteria should be set for patients to be included or excluded from the study

Discouraged (High risk of bias)

- Unapproved or unorganized studies with uninformed patients
- Enrollment of patients by convenience sampling or non-consecutive enrollment
- Including or excluding patients with limited details or rationale
- Including patients with possible confounders (e.g. comorbidities, variant patient characteristics) with no statistical method for control or matching technique

Materials

Standard (Low risk of bias)

- Describe the details (range, direction, source, etc.) and reference the validity and/or reliability of any scales, questionnaires, categorization techniques, medical devices, etc. that will be used at any stage of the study duration

Discouraged (High risk of bias)

- Use of invalidated or unapproved scales, questionnaires, devices, etc. to categorize and measure patient outcomes or prognostic factors

General Methods

Standard (Low risk of bias)

- Determine and report the duration of the recruitment and study periods
- Ensure examiner credentials are provided with proper certification to analyze and/or interpret patient factors and outcomes
- Describe pre-defined primary and secondary prognostic factors and outcomes of interest
- Measure all patients/groups in the same way and with the same tools; this also applies to the method of diagnosis for recruitment

Discouraged (High risk of bias)

- Examiners that are not trained, credentialed, and/or approved to use or interpret any aspect of their function in the study
- Investigating outcomes or prognostic factors that are not predefined and described
- Patients/groups measured at different time-points or through use of different outcome or prognostic measures

Details and Procedures

Standard (Low risk of bias)

- Describe how each prognostic factor of interest will be measured including a process description that permits replication and predetermined threshold/cutoff values for predictor and outcome variables
- Choose valid and referenced threshold/cutoff values for diagnosis confirmation, inclusion, and/or outcome response
- Choose time-points for follow-up that are clinically relevant and allow for proper analysis of the population at risk
- Ensure each patient will be measured in the same way and at the same time-points across all groups being directly compared
- Describe all groups and measures that will be compared and how they will be compared in the analysis of the results
- Describe dosage and administration of rescue medication if applicable as a potential confounder

Discouraged (High risk of bias)

- Lack of description of any of the measurement procedures or comparisons of interest
- Use of inapplicable or invalidated devices or outcome measures used for the condition of interest
- Threshold/cutoff values for diagnosis or outcome measurement that are unlisted or clinically irrelevant
- Unlimited allowance of rescue medication or rescue medication that may have confounding effects on the intervention or outcome of interest
- Patients measured differently within individual groups or across comparator groups

Statistical Modeling and Analysis

Standard (Low risk of bias)

- Describe how, and by whom, the data was documented and organized to prepare for analysis
- Describe any equations that will be used in preparation and analysis including: power analysis, odds ratios, risk ratios, confidence limits, significance, etc.
- Create data tables (e.g. odd/risk ratios with confidence limits at each follow-up time) and statistical models (e.g. regression analysis) that will assist with comparisons, control for possible confounding or baseline differences, and interpretation of the results for desired conclusions
- Be sure to use at least 10 participants per group for every factor included in the final regression analysis
- Clearly describe statistical methods, potential confounders included in the model, and statistical control methods (e.g. multiple OLS regression, matching with paired t-test, etc.)
- Clearly describe methods used for predictor selection for inclusion in the model (e.g. forward stepwise selection, past literature, etc.) - If stepwise method used, model stability validation done through bootstrap re-sampling or other comparable method.
- Clearly describe methods to deal with missing data (Imputation, LOCF, ITT, etc.) as well as statistical assumptions testing.

Discouraged (High risk of bias)

- Insufficient data or calculations that will not allow the reader to clearly observe significance or raw data to evaluate odds or risk ratios (e.g. patient counts, confidence limits, etc.)
- Unclear, invalid, or absent description of statistical tests, model building, variable selection strategy, or statistical assumptions testing method.
- Incomplete description of all the variables included in final statistical model
- Missing predictor/outcome data and management/control strategy

General Results

Standard (Low risk of bias)

- All patient/group data needed to analyze all target comparisons is organized in a way that allows complete analysis of all necessary calculations
- The number of patients with missing predictor and/or outcome data from recruitment to final analysis is presented
- Target prognostic factor and outcome results are consistent with pre-determined target factors and outcome measures listed in the study protocol/methods
- All outcome and prognostic factor measurements are made on validated tools or scales with range and direction indicated (e.g. VAS pain scale: 0-100 where 100 is best)
- Any missing data or observations are described in detail with rationale provided for those patients/groups
- Statistical results/models account for missing predictor/outcome data through imputation (e.g. multiple imputation, LOCF, etc.) or models that allow for missing values (e.g. mixed models).
- Differences and significance of rescue medication consumption between intervention groups if applicable

Discouraged (High risk of bias)

- Data presented at recruitment, during follow-up, or in the final analysis that lacks agreement and/or lacks appropriate rationale for missing data, observations, or patients/groups
- Missing data or observations without adjustment and appropriate rationale
- Outcomes presented in analysis that are not predefined and listed in the study protocol/ methods
- Lack of statistical model and/or rationale to account for missing predictor/outcome data when accompanied by a large loss to follow-up

Data Comparisons

Standard (Low risk of bias)

- All patient/group data are evaluated at the same time-point and are organized in a way that allows for all target comparisons and calculations (e.g. dichotomous events/non-events, odds/risk ratios, etc.) including confidence limits and determination of significance for each calculation
- Rationale provided for the structure of the data tables, statistical model, target comparisons, and data presented is
- Description of potential confounders and statistical control for these confounders is provided

Discouraged (High risk of bias)

- Data presented supports conclusions but is insufficient for necessary calculations, and the structured data tables and statistical modeling do not allow for target comparisons and conclusions to be made
- Group data not presented individually and/or target time-points that do not include consistent reporting with all other time-points