Diagnostic 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. prospective comparative)
☐Population
☐Sample group descriptions
☐Disease status (e.g. suspects, diagnosed, healthy)
☐Methods (including index and reference test descriptions)
☐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 population of those suspected of illness/condition without true diagnosis
☐Recruitment method
☐Consecutive enrollment (e.g. enrolling all participants fitting criteria without selection bias)
☐Inclusion and exclusion criteria
☐Reference and index test(s) details (described to permit replication)
☐Blinding (described and at low risk for participants and examiners)
☐Credibility of examiner background and training
☐Patient characteristics (noted significant differences)
☐Process details
☐Intended comparisons
☐Pre-specified threshold/cutoff values used for reference and index test(s)
☐Time between the reference and index test(s)
☐Same reference standard used and identical measurement methods across all compared groups
☐Best-known diagnostic method used as the reference test

Statistical Analysis/Data Management
- ☐Statistical software
- ☐Statistical models
- ☐Calculations
- ☐Data organization strategies

Results
- ☐Final examined patient count
- ☐Number of patients examined with each test
- ☐Number of patients included in analysis for each test
- ☐Study duration
- ☐Data evaluated for each test and/or patient group
- ☐Positive and negative patient group counts, PPV, NPV, sensitivity, specificity, positive likelihood ratios, and negative likelihood ratios provided
- ☐Test/group comparison data
- ☐Explanation of data tables
- ☐Rate and details of patients lost to follow-up
- ☐If any, explanation of missing data
- ☐Patient adverse events, benefits, or harms (if documented/analyzed)

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 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, and why they will be recruited
- All patients, or a random sample of all available patients, displaying signs/symptoms of the target condition that have not obtained a true diagnosis should be included
- Matching techniques or statistical control for possible confounders (e.g. comorbidities) should be done upon inclusion
- The patient characteristics and disease status (e.g. undiagnosed, symptomatic, etc.) should be reported and described for all patients and groups
- A complete count of patients that were included should be reported as well as the patient count for any groups or categories of patients

Discouraged (High risk of bias)

- Healthy or pre-diagnosed patients included in the analysis
- Patients or groups with unspecified or unclear patient counts, recruitment strategies, or potential confounders

Patient Enrollment

Standard (Low risk of bias)

- The study should be approved with informed consent to meet safety, ethics, and regulation standards
- Patients should be consecutively enrolled by including all patients that fit the study criteria and agree to participate (e.g. avoiding "cherry picking")
- A detailed list of criteria that patients have to meet to be included or excluded from the study should be described

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

General Methods

Standard (Low risk of bias)

- Determine and report the duration of the recruitment and study periods
- Organize a blinding strategy through use of different examiners for evaluating patients and reading results
- Ensure those examining patients are certified to operate needed materials/devices/procedures, and describe examiner credentials
- Ensure those reading results of examinations are certified to properly document and interpret those results, and describe examiner credentials

Discouraged (High risk of bias)

- Patients or examiners that are un-blinded or have the ability to discover the results of any of the examinations used in the interpretation of results or analysis
- Examiners that are not trained, credentialed, and/or approved to use or interpret any aspect of their function in the study
- Examiners of the patients or results that are credentialed to use materials, devices, and/or procedures, but they are not properly trained on one or more aspects of those materials or procedures used in the study

Details and Procedures

Standard (Low risk of bias)

- Describe all groups and measures that will be compared and how they will be compared in the analysis of the results
- Compare each index test individually to the reference standard results
- Choose index and reference tests with referenced validity and reliability for the diagnosis of the target condition
- The reference test should be the best known method of diagnosis in current practice
- Ideally, reference and index testing would be done one immediately after the other, and standard duration between tests should at least be brief enough to not permit a change in patient status (For example: diagnosis of infection or localized pain may change over a short period of time)
- Describe how each test will be administered and interpreted including a process description that permits replication and predetermined threshold/cutoff values for diagnosis
- Threshold/cutoff values chosen through a referenced literature search or referenced values from the lab or clinical resources
- Ensure each patient will be measured in the same way across all groups being directly compared

Discouraged (High risk of bias)

- Lack of description of any of the testing procedures or comparisons of interest
- Use of inapplicable or unvalidated devices or testing procedures used for the condition of interest
- Threshold/cutoff values for particular test diagnosis that are unlisted or clinically irrelevant
- Duration that is long enough between index and reference testing that could possibly permit a change in patient status
- Patients measured differently within individual groups or across comparator groups

Statistical Modeling and Analysis

Standard (Low risk of bias)

- Reference the statistical software packages that will be used to calculate target outcome data
- 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, likelihood ratios, sensitivity, specificity, predictive values, etc.
- Create data tables (e.g. 2x2, positive and negative patient counts, etc.) and/or statistical models that will assist with comparisons and interpretation of the results

Discouraged (High risk of bias)

- Insufficient data or calculations that will not allow the reader to evaluate sensitivity, specificity, likelihood, and/or pre/post-test comparisons of target diagnostic index tests
- Invalidated equations or statistical methods used for interpretation of results

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
- Observed patient/group numbers from recruitment and testing are listed as well as the data for those included in final analysis
- Any missing data or observations are described in detail with rationale provided for those patients/groups

Discouraged (High risk of bias)

- Data presented at recruitment, during examination, and in the final analysis that is not presented or lacking agreement and/or appropriate rationale for missing data, observations, or patients/groups

Data Comparisons

Standard (Low risk of bias)

- All patient/group data is organized in a way that allows for all target comparisons and calculation of sensitivity, specificity, likelihood ratios, and predictive values
- Rationale for the structure of the data tables and for the target comparisons and data chosen is provided

Discouraged (High risk of bias)

- Data presented is insufficient for necessary calculations, and the structured data tables do not allow for target comparisons and conclusions to be made