Diagnostic Study Planning Guide

As you plan your study, record your intentions for each of the suggested items prior to data collection to ensure that you have the detail required for your future manuscript. Each unchecked box may result in higher risk of bias of study results, lowering the quality of your final publication. Additional details for each domain are provided below the checklists.

Suggested Study Design: Prospective Comparative

Title

Author(s)/Affiliation

Date

Patient Recruitment Additional Details

- ☐ Recruitment setting/location
- ☐ Recruitment criteria
- ☐ Recruitment methods
- ☐ Population of un-diagnosed clinical suspects of the condition
- ☐ Patient demographics/characteristics of each comparison group

Patient Enrollment Additional Details

- ☐ Informed consent and study approval status
- ☐ Consecutive enrollment
- ☐ Inclusion criteria
- ☐ Exclusion criteria

Materials Additional Details

- ☐ Measurement tools/instruments
- ☐ Referenced validity of measurement tools

General Methods Additional Details

- ☐ Duration of the study
- ☐ Blinding strategy for examiners and participants
- ☐ Credibility of examiner background and training

Details and Procedures Additional Details

- ☐ Intended comparisons
- ☐ Best-known diagnostic method chosen for the reference standard
- ☐ Valid and applicable index test(s) chosen for evaluation
- ☐ Minimal time between reference and index testing
- ☐ Process details for application of all tests
- ☐ Predetermined threshold/cutoff values for reference and index test(s)
- ☐ Equal measurement methods across all groups

Statistical Modeling and Analysis Additional Details

- ☐ Software chosen for statistical analysis
- ☐ Data organization methods
- ☐ Equations/calculations for group data comparisons
- ☐ Data tables and/or statistical models

General Results Additional Details

- ☐ Patient/group data observed
- ☐ Patient/group data included in final analysis
- ☐ Rate and details of patients lost to follow-up
- ☐ Rationale for missing data

Data Comparisons Additional Details

- ☐ Complete data for all comparisons
- ☐ Individual and/or group data for each administered test
- ☐ Explanation for data tables
- ☐ Positive and negative patient group counts
- ☐ Positive and negative predictive value calculations
- ☐ Calculations for sensitivity, specificity, and positive & negative likelihood ratios

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