



PRISMA 2020 Checklist

Section/topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
TITLE				
Title	1	Identify the report as a systematic review.		
ABSTRACT				
Abstract	2	See the PRISMA 2020 for Abstracts checklist (Table 2).		
INTRODUCTION				
Rationale	3	Describe the rationale for the review in the context of existing knowledge.		
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.		
METHODS				
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.		
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.		
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.		
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.		
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.		
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.		
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.		

Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.		
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.		
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis.		
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.		
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.		
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.		
	13e	Describe any methods used to explore possible causes of heterogeneity among study results.		
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.		
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).		
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.		
RESULTS				
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.		
	16b	Cite studies that met many but not all inclusion criteria ('near-misses') and explain why they were excluded.		
Study characteristics	17	Cite each included study and present its characteristics.		
Risk of bias in studies	18	Present assessments of risk of bias for each included study.		
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.		

Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.		
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.		
	20c	Present results of all investigations of possible causes of heterogeneity among study results.		
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.		
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.		
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.		
DISCUSSION				
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.		
	23b	Discuss any limitations of the evidence included in the review.		
	23c	Discuss any limitations of the review processes used.		
	23d	Discuss implications of the results for practice, policy, and future research.		
OTHER INFORMATION				
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.		
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.		
	24c	Describe and explain any amendments to information provided at registration or in the protocol.		
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.		
Competing interests	26	Declare any competing interests of review authors.		
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.		

Table 2 PRISMA 2020 for Abstracts checklist

Section/topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
TITLE				
Title	1	Identify the report as a systematic review.		
BACKGROUND				
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.		
METHODS				
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.		
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.		
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.		
Synthesis of results	6	Specify the methods used to present and synthesize results.		
RESULTS				
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.		
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).		
DISCUSSION				
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).		
Interpretation	10	Provide a general interpretation of the results and important implications.		
OTHER				
Funding	11	Specify the primary source of funding for the review.		
Registration	12	Provide the register name and registration number.		

STARD 2015

Section & Topic	Item No	Item	Reported on Page Number/ Line Number	Reported on Section/ Paragraph
TITLE OR ABSTRACT				
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)		
ABSTRACT				
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)		
INTRODUCTION				
	3	Scientific and clinical background, including the intended use and clinical role of the index test		
	4	Study objectives and hypotheses		
METHODS				
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)		
Participants	6	Eligibility criteria		
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)		
	8	Where and when potentially eligible participants were identified (setting, location and dates)		
	9	Whether participants formed a consecutive, random or convenience series		
Test methods	10a	Index test, in sufficient detail to allow replication		
	10b	Reference standard, in sufficient detail to allow replication		
	11	Rationale for choosing the reference standard (if alternatives exist)		
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory		
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory		
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test		
	13b	Whether clinical information and index test results were available to the assessors of the reference standard		

Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy		
	15	How indeterminate index test or reference standard results were handled		
	16	How missing data on the index test and reference standard were handled		
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory		
	18	Intended sample size and how it was determined		
RESULTS				
Participants	19	Flow of participants, using a diagram		
	20	Baseline demographic and clinical characteristics of participants		
	21a	Distribution of severity of disease in those with the target condition		
	21b	Distribution of alternative diagnoses in those without the target condition		
	22	Time interval and any clinical interventions between index test and reference standard		
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard		
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)		
	25	Any adverse events from performing the index test or the reference standard		
DISCUSSION				
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability		
	27	Implications for practice, including the intended use and clinical role of the index test		
OTHER INFORMATION				
	28	Registration number and name of registry		
	29	Where the full study protocol can be accessed		
	30	Sources of funding and other support; role of funders		

AIM

STARD stands for “Standards for Reporting Diagnostic accuracy studies”. This list of items was developed to contribute to the completeness and transparency of reporting of diagnostic accuracy studies. Authors can use the list to write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

Explanation

A **diagnostic accuracy study** evaluates the ability of one or more medical tests to correctly classify study participants as having a **target condition**. This can be a disease, a disease stage, response or benefit from therapy, or an event or condition in the future. A medical test can be an imaging procedure, a laboratory test, elements from history and physical examination, a combination of these, or any other method for collecting information about the current health status of a patient.

The test whose accuracy is evaluated is called **index test**. A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is typically done by comparing the distribution of the index test results with those of the **reference standard**. The reference standard is the best available method for establishing the presence or absence of the target condition. An accuracy study can rely on one or more reference standards.

If test results are categorized as either positive or negative, the cross tabulation of the index test results against those of the reference standard can be used to estimate the **sensitivity** of the index test (the proportion of participants with the target condition who have a positive index test), and its **specificity** (the proportion without the target condition who have a negative index test). From this cross tabulation (sometimes referred to as the contingency or “2x2” table), several other accuracy statistics can be estimated, such as the positive and negative **predictive values** of the test. Confidence intervals around estimates of accuracy can then be calculated to quantify the statistical **precision** of the measurements.

If the index test results can take more than two values, categorization of test results as positive or negative requires a **test positivity cut-off**. When multiple such cut-offs can be defined, authors can report a receiver operating characteristic (ROC) curve which graphically represents the combination of sensitivity and specificity for each possible test positivity cut-off. The **area under the ROC curve** informs in a single numerical value about the overall diagnostic accuracy of the index test.

The **intended use** of a medical test can be diagnosis, screening, staging, monitoring, surveillance, prediction or prognosis. The **clinical role** of a test explains its position relative to existing tests in the clinical pathway. A replacement test, for example, replaces an existing test. A triage test is used before an existing test; an add-on test is used after an existing test.

Besides diagnostic accuracy, several other outcomes and statistics may be relevant in the evaluation of medical tests. Medical tests can also be used to classify patients for purposes other than diagnosis, such as staging or prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

DEVELOPMENT

This STARD list was released in 2015. The 30 items were identified by an international expert group of methodologists, researchers, and editors. The guiding principle in the development of STARD was to select items that, when reported, would help readers to judge the potential for bias in the study, to appraise the applicability of the study findings and the validity of conclusions and recommendations. The list represents an update of the first version, which was published in 2003. More information can be found on <http://www.equator-network.org/reporting-guidelines/stard>.