<u>Materials Design Analysis Reporting (MDAR)</u> Checklist for Authors

The MDAR framework establishes a minimum set of requirements in transparent reporting applicable to studies in the life sciences (see Statement of Task: doi:10.31222/osf.io/9sm4x.). The MDAR checklist is a tool for authors, editors and others seeking to adopt the MDAR framework for transparent reporting in manuscripts and other outputs. Please refer to the MDAR Elaboration Document for additional context for the MDAR framework.

Materials

Antibodies	Yes (indicate where provided: section/paragraph)	n/a
For commercial reagents, provide supplier name, catalogue number and RRID, if available.	Methods/paragraph 9-12.	
Cell materials	Yes (indicate where provided: section/paragraph)	n/a
Cell lines: Provide species information, strain. Provide accession number in repository OR supplier name, catalog number, clone number, OR RRID	Methods/paragraph 9.	
Primary cultures: Provide species, strain, sex of	Methods/paragraph 9.	
origin, genetic modification status.		
Experimental animals	Yes (indicate where provided: section/paragraph)	n/a
Laboratory animals: Provide species, strain, sex, age,	res (malcate where provided, section/paragraph)	n/a
genetic modification status. Provide accession		Not
number in repository OR supplier name, catalog		use
number, clone number, OR RRID		d.
Animal observed in or captured from the		n/a
field: Provide species, sex and age where		Not
possible		use
		d.
Madel and the Devide According to the		
Model organisms: Provide Accession number		n/a Not
in repository (where relevant) OR RRID		use
		d.
Plants and microbes	Yes (indicate where provided: section/paragraph)	n/a
Plants: provide species and strain, unique accession	· · · · · · · · · · · · · · · · · · ·	n/a
number if available, and source (including location		Not
for collected wild specimens)		use
for concerca wha specificity		d.
Microbes: provide species and strain, unique		n/a
accession number if available, and source		Not
		use
		d.
Human research participants	Yes (indicate where provided: section/paragraph)	n/a
Identify authority granting ethics approval (IRB or	Methods/paragraph 1.	/u
equivalent committee(s), provide reference number		
for approval.		
Provide statement confirming informed consent obtained from study participants.	Methods/paragraph 1.	
Report on age and sex for all study participants.		n/a
		Non

e.

<u>Design</u>

Study protocol	Yes (indicate where provided: section/paragraph)	n/a
For clinical trials, provide the trial registration		n/
number OR cite DOI in manuscript.		а
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Laboratory protocol	Yes (indicate where provided: section/paragraph)	n/a
Provide DOI or other citation details if detailed step-		n/
by-step protocols are available.		а
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Experimental study design (statistics details)	Yes (indicate where provided: section/paragraph)	n/a
State whether and how the following have been		
done , or if they were not carried out.		
Sample size determination		n/a
		Not
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		ble
		•
Randomisation	Methods/paragraph 1.	
Blinding		n/a
		Not
		appl
		icab
		le.
Inclusion/exclusion criteria		n/a
		Not
		appl
		icab
		le.

Sample definition and in-laboratory replication	Yes (indicate where provided: section/paragraph)	n/a
State number of times the experiment was		n/a
replicated in laboratory		Not
		appl
		icab
		le.
Define whether data describe technical or biological		n/a
replicates		Not
		appl
		icab
		le.
Ethics	Yes (indicate where provided: section/paragraph)	n/a

Studies involving human participants: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	Methods/paragraph 1.	
Studies involving experimental animals: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.		n/a Not use d.
Studies involving specimen and field samples: State if relevant permits obtained, provide details of authority approving study; if none were required, explain why.		n/a Not use d.
Dual Use Research of Concern (DURC)	Yes (indicate where provided: section/paragraph)	n/a
If study is subject to dual use research of concern, state the authority granting approval and reference number for the regulatory approval		n/a Not appl icab

le.

<u>Analysis</u>

Attrition	Yes (indicate where provided: section/paragraph)	n/a
State if sample or data point from the analysis is		n/a
excluded, and whether the criteria for exclusion were		Not
determined and specified in advance.		appl
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Statistics	Yes (indicate where provided: section/paragraph)	n/a
Describe statistical tests used and justify choice of		n/a
tests.		Not
		appl
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Data Availability	Yes (indicate where provided: section/paragraph)	n/a
State whether newly created datasets are available,		n/a
including protocols for access or restriction on		Not
access.		use
		d.
If data are publicly available, provide accession		n/a
number in repository or DOI or URL.		In
		the
		arti
		cle.
If publicly available data are reused, provide		n/a
accession number in repository or DOI or URL, where		Not
possible.		use
		d.
Code Availability	Yes (indicate where provided: section/paragraph)	n/a

Code Availability	Yes (indicate where provided: section/paragraph)	n/a
For all newly generated code and software essential		
for replicating the main findings of the study:		
State whether the code or software is available.		n/a
		Not
		use
		d.

If code is publicly available, provide accession	n/a
number in repository, or DOI or URL.	Not
	use
	d.

Reporting

Adherence to community standards	Yes (indicate where provided: section/paragraph)	n/a
MDAR framework recommends adoption of discipline-specific guidelines, established and endorsed through community initiatives. Journals have their own policy about requiring specific guidelines and recommendations to complement MDAR.		
State if relevant guidelines (eg., ICMJE, MIBBI, ARRIVE) have been followed, and whether a checklist (eg., CONSORT, PRISMA, ARRIVE) is provided with the manuscript.	ICMJE guidelines were followed, as the journal follows ICMJE recommendations for publication. STARD reporting checklist is also provided with the manuscript.	

Article information: https://dx.doi.org/10.21037/jtd-22-343

STARD 2015

Section & Topic	ltem No	Item	Reported on Page Number/ Line Number	Reported on Section/ Paragraph
TITLE OR AE	BSTRAC	T		
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	Page 1, line 2-4	Title page/Paragraph 1
ABSTRACT				
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Page 2, line27-49	Abstract/Paragraph 1
INTRODUCT	ION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	Page 3, line 54-75	Introduction/Paragraph1.
	4	Study objectives and hypotheses	Page 4,line 76-88	Introduction/Paragraph
METHODS				·
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Page 4, line 93-94	Methods/Paragraph 1
Participants	6	Eligibility criteria	Page 4,line 93-94	Methods/Paragraph 1
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Page 4, line 93-94	Methods / Paragraph 1
	8	Where and when potentially eligible participants were identified (setting, location and dates)	Page 4, line 93-94	Methods/Paragraph 1
	9	Whether participants formed a consecutive, random or convenience series	Page 4, line 93-94	Methods / Paragraph 1
Test	10a	Index test, in sufficient detail to allow replication	Page 4-8, line 99-181	Methods/Paragraph 2-13
methods	10b	Reference standard, in sufficient detail to allow replication	NA, Not used.	NA, Not used.
	11	Rationale for choosing the reference standard (if alternatives exist)	NA, Not used.	NA, Not used.
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	NA, Not used.	NA, Not used.
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	NA, Not used.	NA, Not used.
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	NA, Not used.	NA, Not used.
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	NA, Not used.	NA, Not used.

Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	Page 6, line 129-133	Methods/Paragraph 7
	15	How indeterminate index test or reference standard results were handled	NA, Not used.	NA, Not used.
	16	How missing data on the index test and reference standard were handled	NA, Not used.	NA, Not used.
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	Page 6, line 129-133	Methods/Paragraph 7
	18	Intended sample size and how it was determined	Page 4, line 93-94	Methods/Paragraph 1
RESULTS			·	
Participants	19	Flow of participants, using a diagram	NA, Not used.	NA, Not used.
	20	Baseline demographic and clinical characteristics of participants	NA, Not used.	NA, Not used.
	21a	Distribution of severity of disease in those with the target condition	NA, Not used.	NA, Not used.
	21b	Distribution of alternative diagnoses in those without the target condition	Page10, line 226-228	Results/Paragraph6
	22	Time interval and any clinical interventions between index test and reference standard	NA, Not used.	NA, Not used.
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Page 8-11, line 183-255	Results/Paragraph 1-8
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Page10, line 226-228	Results/Paragraph 6
	25	Any adverse events from performing the index test or the reference standard	NA, Not used.	NA, Not used.
DISCUSSION	N			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Page 14, I ine 322-325	Discussion/Paragraph6
	27	Implications for practice, including the intended use and clinical role of the index test	Page 11-14, line 257-339	Discussion/Paragraph 1
OTHER INFO	ORMATI	ON		
	28	Registration number and name of registry	NA, original research	NA, or iginal research
	29	Where the full study protocol can be accessed	NA	NA
	30	Sources of funding and other support; role of funders	None	None
	I		1	l

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 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.

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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.