

STARD 2015 Checklist

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Scope: Standards for Reporting of Diagnostic Accuracy Studies.

Reference: See `source/archetypes/stard-2015.yml` for canonical link and provenance.

Instructions

- Use the boxes to confirm each reporting item.
- Add reviewer notes under each section as needed.

Title or Abstract

- ☐ **1. Identification:** 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:** Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts).

Introduction

- ☐ **3. Scientific and clinical background:** Scientific and clinical background, including the intended use and clinical role of the index test.
- ☐ **4. Study objectives and hypotheses:** Study objectives and hypotheses.

Methods

- ☐ **5. Study design:** Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study).
- ☐ **6. Participants:** Eligibility criteria.
- ☐ **7. Participants:** On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry).
- ☐ **8. Participants:** Where and when potentially eligible participants were identified (setting, location and dates).
- ☐ **9. Participants:** Whether participants formed a consecutive, random or convenience series.
- ☐ **10a. Test methods:** Index test, in sufficient detail to allow replication.
- ☐ **10b. Test methods:** Reference standard, in sufficient detail to allow replication.
- ☐ **11. Test methods:** Rationale for choosing the reference standard (if alternatives exist).

- [?] **12a. Test methods:** Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing prespecified from exploratory.
- [?] **12b. Test methods:** Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing prespecified from exploratory.
- [?] **13a. Test methods:** Whether clinical information and reference standard results were available to the performers/readers of the index test.
- [?] **13b. Test methods:** Whether clinical information and index test results were available to the assessors of the reference standard.
- [?] **14. Analysis:** Methods for estimating or comparing measures of diagnostic accuracy.
- [?] **15. Analysis:** How indeterminate index test or reference standard results were handled.
- [?] **16. Analysis:** How missing data on the index test and reference standard were handled.
- [?] **17. Analysis:** Any analyses of variability in diagnostic accuracy, distinguishing prespecified from exploratory.
- [?] **18. Analysis:** Sample size calculation.

Results

- [?] **19. Participants:** Flow of participants, using a diagram.
- [?] **20. Participants:** Baseline demographic and clinical characteristics of participants.
- [?] **21. Participants:** Distribution of severity of disease in those with the target condition; other diagnoses in participants without the target condition.
- [?] **22. Test results:** Time interval from index test to reference standard, and any treatment administered between them.
- [?] **23. Test results:** Cross tabulation of the index test results (or their distribution) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.
- [?] **24. Test results:** Any adverse events from performing the index test or the reference standard.
- [?] **25. Estimates:** Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals).
- [?] **26. Estimates:** Any analyses of variability, including subgroup analyses.
- [?] **27. Estimates:** The number of indeterminate test results or missing data and where they occurred.

Discussion

- [?] **28. Study limitations:** Study limitations, including sources of potential bias, statistical uncertainty, and generalisability.
- [?] **29. Implications for practice:** Implications for practice, including the intended use and clinical role of the index test.

Other Information

- ☐ **30. Registration number and name of registry:** Registration number and name of registry.
- ☐ **31. Where the full study protocol can be accessed:** Where the full study protocol can be accessed.
- ☐ **32. Funding:** Sources of funding and other support; role of funders.

Notes

Provenance

- Source: See sidecar metadata in `source/archetypes/stard-2015.yml`
- Version: 2015
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