Title: Development, dissemination and implementation of a reporting guideline for systematic reviews and meta-analyses of diagnostic test accuracy studies: The PRISMA-DTA initiative (Study Protocol)

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Abstract

In their 2015 report titled “Improving Diagnosis in Healthcare”, the National Academy of Medicine identified that better understanding of diagnostics is the next imperative for patient safety. Researchers can advance our understanding of diagnostic accuracy through systematic review. Systematic reviews of diagnostic accuracy synthesize data from multiple studies to provide greater insight into the ability of medical tests to detect a target condition. Clinicians and practice guideline developers commonly rely on systematic reviews as the highest level of evidence; it is crucial that their reporting is complete and informative, so that readers can assess the quality of the review. Published systematic reviews of diagnostic accuracy are often not sufficiently informative, are of heterogeneous quality and demonstrate considerable variability in approaches to fundamental methodologic steps. To improve the quality of reporting of systematic reviews, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guideline was developed. PRISMA was developed primarily to facilitate reporting reviews of healthcare interventions. Though systematic reviews of diagnostic test accuracy studies share general elements with such reviews, there are also some important differences. As such, some PRISMA items are not appropriate for reporting reviews of diagnostic test accuracy, while other crucial items are missing. We believe that an extension of PRISMA for reviews of diagnostic test accuracy studies would be a highly effective means of reducing waste in biomedical research. Our objective is to develop, disseminate and implement a guideline for reporting systematic reviews and meta-analyses of diagnostic test accuracy studies.

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Background

In their 2015 report titled "Improving Diagnosis in Healthcare", the National Academy of Medicine identified that better understanding of diagnostics is the next imperative for patient safety (1, 2). Researchers can advance our understanding of diagnostic test accuracy through systematic reviews. Systematic reviews of diagnostic test accuracy synthesize data from multiple studies to provide greater insight into the ability of medical tests to detect a target condition—this could be in the form of greater precision (e.g. narrower confidence intervals around accuracy estimates), or a better understanding of determinants of variation in test performance (e.g. patient, disease, or test characteristics) (3). The number of systematic reviews overall, and those on diagnostic test accuracy have grown rapidly over the past decade (4, 5).

Clinicians commonly rely on systematic reviews as the highest level of evidence; it is crucial that their reporting is complete and informative, so that readers can assess the quality of the review methods, and the validity and applicability of the presented findings. Evaluations have shown that published systematic reviews of diagnostic test accuracy are often not sufficiently informative, and are of heterogeneous quality (6-8); they demonstrate considerable variability in reporting of and approaches to fundamental steps such as assessing for heterogeneity, pooling data and assessment for risk of bias in the included studies (8-12).

Research waste from incomplete reporting has been identified as a major problem in biomedical research (13). To improve the quality of reporting of systematic reviews, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guideline was developed (14), consisting of a 27-item checklist and a flow diagram. The introduction of reporting guidelines has been associated with improved completeness and quality of reporting (6, 7, 15).

PRISMA was developed primarily to facilitate reporting reviews of healthcare interventions. Though systematic reviews of diagnostic test accuracy studies share general elements with such reviews, there are also some important differences. As such, some PRISMA items are not appropriate for reporting reviews of diagnostic test accuracy, while other crucial items unique to them are missing (3, 16, 17).

Several extensions of PRISMA have been developed for specific types of reviews (18-22). The development of a specific extension of PRISMA for reviews of diagnostic test accuracy studies could be a highly effective means of reducing waste in biomedical research. The need for this is supported by multiple knowledge users including the STandards for Reporting of Diagnostic accuracy studies (STARD) Group, the PRISMA group, the EQUATOR Network (including EQUATOR Canada), Cochrane (including Cochrane Canada and the Cochrane Screening and Diagnostic Test Accuracy Methods Group), several major journals who publish diagnostic test accuracy reviews (Radiology, BMJ, BMJ Open, European Radiology, Clinical Chemistry, jMRI, the Canadian Journal of Psychiatry and the CMAJ, the Public Health Agency of Canada, the Canadian Task Force on Preventive Care and the Canadian Agency for Drugs and Technologies in Health (CADTH).

Objective

To develop, disseminate and implement a guideline for reporting systematic reviews and meta-analyses of diagnostic test accuracy studies.

Methods

This project will be carried out under the working title "**P**referred **R**eporting **I**tems for **S**ystematic reviews and **M**eta-**A**nalysis of **D**iagnostic **T**est **A**ccuracy (PRISMA-DTA)". The PRISMA-DTA executive has registered its intent to proceed with this exercise with the EQUATOR network and is listed under "Reporting Guidelines Under Development" as well as on the PRISMA group web-site under "Extensions in Development" (23, 24).

PRISMA-DTA will be developed in line with previously published guidance for establishing reporting guidelines, created by the EQUATOR network (25). The main aim of PRISMA-DTA is to establish a list of essential items that should be reported in any report of a systematic review of diagnostic test accuracy studies. A secondary objective will be to establish which of these items should be included as part of abstracts of systematic reviews of diagnostic test accuracy studies.

The development of PRISMA-DTA will involve six steps: (1) establishment of the PRISMA-DTA group; (2) item generation; (3) Delphi exercise; (4) generation of a draft list of essential items; (5) live consensus meeting and finalization of list of essential items; (6) post meeting activities. The individual steps are outlined below.

Step 1. Establishment of the PRISMA-DTA group

The PRISMA-DTA group will consist of three layers:

i. *Executive committee* (n=3; Appendix 1), who will be responsible for the coordination of all the processes involved in the development, dissemination and implementation of this reporting guideline. The executive committee consists of the leading authors of the STARD reporting guidelines for diagnostic test accuracy studies (PMB), the PRISMA reporting guidelines for systematic reviews (DM), and a radiologist with 6 years of experience in developing systematic reviews of diagnostic test accuracy studies (MM) (14, 26, 27). Members of the executive will participate in the Delphi exercise.

ii. *Advisory Board* (n=14; Appendix 2), who will regularly be consulted by the executive committee to discuss general and specific issues in the development of PRISMA-DTA, will participate in the Delphi exercise, consensus meeting and will assist the executive committee in establishing the final checklist and corresponding documents. This group consists of experts in the field of reporting guidelines, and of diagnostic test accuracy studies and systematic reviews thereof.

iii. *Additional participants* (the 'PRISMA DTA Group') will assist in the identification of essential items. This group will be comprised of members that have been involved in the development of the STARD reporting guidelines for diagnostic test accuracy studies, or the PRISMA reporting guidelines for systematic reviews. This group will be supplemented with Members of the Cochrane Screening and Diagnostic Tests Methods Group as well as other experts with a specific focus on systematic reviews of diagnostic test accuracy studies and journal editors who publish a high number of DTA reviews. Members will be selected from various international organizations with interest in either diagnostic

test accuracy methods, systematic review methods, or both. Some of these additional participants will be invited to participate in the Delphi exercise.

Step 2. Item generation and pre-selection

Definition of Essential Item

Our goal is to develop a list of essential items that should be reported in all systematic reviews of diagnostic test accuracy studies. The guiding principle in doing so is to select essential items to help readers, editors and peer-reviewers to understand how the review was performed, to appraise the findings of the systematic review including risk of bias and applicability. In addition, these elements would enhance reproducibility, allow updating of systematic reviews and facilitate assessment of methodologic quality of the review.

Literature search

Searches of multiple electronic databases to identify (1) studies that have evaluated the reporting, quality, or methods of DTA reviews and (2) guidance statements on how to conduct, report, or evaluate DTA reviews. This search will be designed by an experienced information scientist from the OHRI Knowledge Synthesis Group working with the principal investigators and will employ Peer Review of the Electronic Search Strategy (PRESS) (28). Databases queried will include: MEDLINE and Embase (using the OVID platform) and the Cochrane Methodology Register (using the Wiley platform of the Cochrane Library). Hand searches of the references of potentially relevant articles will be performed, and experts in the field will be contacted. In addition, the following sources will be searched:

1) Guideline organization websites (EQUATOR, PRISMA, STARD, GIN).
2) Existing guidance for reporting systematic reviews and meta-analyses of other types of research: MOOSE (Meta-analysis of observational studies in epidemiology), PRISMA, and the PRISMA extensions for protocols, abstracts, network meta-analyses, equity reviews and individual participant data (20, 22) (18, 19, 21).

3) Existing guidance for reporting diagnostic test accuracy studies: STARD 2015 and STARD for Abstracts (27).
4) Existing guidance for assessing the methodological quality of systematic reviews and meta-analyses: AMSTAR (A Measurement Tool to Assess Systematic Reviews), ROBIS (Risk of Bias in Systematic Reviews) and MECIR (Methodologic Expectations of Cochrane Intervention Reviews) (29-31).
5) The Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (32).

The members of the executive will review these information sources and include any potential items relevant to DTA systematic review reporting and use these to establish a long-list of items to consider for PRISMA-DTA.

Pre-selection of items that are potentially essential

The executive committee will assess each item on the long-list for its potential relevance to systematic reviews of diagnostic test accuracy studies. Each member of the executive will independently evaluate the long-list of items; they will each score potential items from 1 to 5. Items that are assessed as definitely not relevant by all three members of the executive (a score of 1) will be removed. Items identified as potentially relevant (a score of 2 or higher) will be kept to create a list of items for evaluation in the Delphi exercise.

Step 3: Delphi exercise

A three-round Delphi exercise will be conducted using established guidance for healthcare applications (33, 34). The survey process is an adaptation of a previously described methods by Philips *et al.* and used to develop the GREET reporting guideline (and others) (35). The aim of this process is to achieve consensus on essential items that should make up PRISMA-DTA.

The Delphi process will be facilitated by a research associate with experience in the Delphi process and in guideline development. The executive committee, advisory board, and some of the additional participants will take part in the Delphi process. For each survey round, participants will be invited by email (with 1 reminder 1 week prior to survey closure) and they will have 3 weeks to complete each survey (via Survey Monkey

©). All participants will be invited for each round of the survey regardless of whether they completed the previous round.

During each round of the survey, potential essential items will be proposed, and participants will be asked to rank which items are considered essential to report in a systematic review of diagnostic test accuracy studies on a 1-5 Likert scale (1 being not essential; 5 being essential).

Likert scores will be categorized as follows: 1-2 = low score (item should not be part of PRISMA-DTA), 3 = moderate (item should be discussed), 4-5 = high score (item should be part of PRISMA-DTA). Two separate questions will be posed during the likert process: 1) should the item be included in full text of the reports of systematic reviews? 2) should the item should be reported in the abstract? For an item to meet 'consensus', more than 66% of the Delphi respondents will need to rate an item within one of these three categories; this threshold is based on that used for other guidelines, such as STARD for abstracts (23).

During the first round of the Delphi survey, all items identified during Step 2 (as described above) will be proposed. Participants will also be asked to suggest any additional items that are potentially relevant to report in systematic reviews of diagnostic test accuracy studies as well. The second round of the survey will include any items that did not reach consensus in the first round, and any new items suggested by respondents (any items suggested by at least 1 respondent will be included) in the first round. As with the second round, the third round will involve items that did not reach consensus in the first or second round.

Following the three rounds, the mode (most frequent) score for each item will be tabulated. Items will be categorized as follows:

Mode Score (all rounds)	Consensus Reached?	
	No	Yes
Low (1-2)	Do not include	
Moderate (3)	Discuss at meeting	
High (4-5)	Discuss at meeting	Include in PRISMA-DTA

Step 4: Generation of a draft list of essential items

Based on the results from the Delphi survey, two lists of items will be created: one list consisting of items for which consensus was reached that they should be included in PRISMA-DTA; and one list consisting of items that will need to be discussed during the meeting.

Step 5: Live consensus meeting and finalization of list of essential items

A two-day consensus meeting will be organized by the members of the executive committee, who have considerable experience in developing reporting guidelines and are, therefore, familiar with the administrative and scientific processes required to prepare for the consensus meeting. All members of the executive committee and advisory board will be invited to participate in this meeting.

The main objective of this meeting will be to reach consensus on items for which no consensus was reached during the Delphi survey, to come to a final list of essential items to report in systematic reviews of diagnostic test accuracy studies (and their abstracts). In addition, for the items that have reached consensus prior to the meeting, discussions regarding precise wording/ phrasing of items will be initiated.

Additional aims of this meeting include to review the PRISMA flow diagram to determine if any revisions are necessary, discuss an outline of the main manuscripts (checklist and elaboration-explanation document), plan publication dissemination and implementation strategy, and discuss development of training material.

Step 6: Post meeting activities

Following the consensus meeting, the Executive Committee will lead the following activities:

Checklist Pilot

Members of the executive and advisory board will apply the checklist to diagnostic test accuracy systematic reviews in order to identify any practical challenges with any of the items and to inform writing of the statement, explanation and elaboration. The piloting phase will include testing by graduate students in the University of Ottawa who are

enrolled in the Systematic Reviews course (of both Cochrane and non-Cochrane reviews). After this pilot exercise, the executive will refine the checklist with input from the advisory board.

Develop the Statement

Members of the executive will lead the writing of the guidance statement. This will be circulated to the advisory board members for input prior to submission for publication.

Develop the Explanation and Elaboration Document

Members of the executive will lead the writing of the explanation and elaboration. This document will serve as a 'user's guide' for the checklist with an item by item explanation provided. This will be circulated to the advisory board members for input prior to submission for publication.

Publication strategy

The executive will target multiple simultaneous publications in journals who publish diagnostic test accuracy reviews. Several major journals who publish diagnostic test accuracy reviews have endorsed the need for PRISMA-DTA, will consider publication of the statement and explanation/ elaboration, and provide guidance regarding use of PRISMA-DTA in their instructions for authors.

Baseline Assessment

The executive will lead a study whose aim is to provide a baseline assessment of completeness of reporting of diagnostic test accuracy reviews (as measured by the PRISMA-DTA checklist) in order to track change over time. This will involve assessment of ~100-150 recently published DTA systematic reviews and evaluating their adherence to the PRISMA-DTA Checklist. These would be separate from the reviews used in the pilot exercise.

Dissemination

The Executive and Advisory Board will lead further dissemination and implementation strategy that will include:

- Presentation at major imaging, laboratory medicine, clinical microbiology, pathology, evidence-based medicine, epidemiology, bio-statistical and systematic review conferences
- Presentation at editorial and peer- review forums (e.g. the International Congress of Peer Review and Biomedical Publication)
- Dissemination of PRISMA-DTA via the EQUATOR, PRISMA, and Cochrane Screening and Diagnostic Tests Methods Group web sites

Implementation

The Executive and Advisory Board will lead activities aimed at user training and encouraging uptake of PRISMA-DTA. Table 1 outlines stakeholders and beneficiaries. Implementation strategies to reach out to stakeholders will include:

- Workshops at conferences such as the Cochrane Colloquium.
- Incorporation of PRISMA-DTA into the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy.
- Incorporation of PRISMA-DTA into Cochrane Author Training.
- Contacting journal editors to encourage endorsement and implementation of PRISMA-DTA.
- Development of a PRISMA-DTA on-line tutorial to complement Cochrane Screening and Diagnostic Tests Methods Group web-based author training resources.

Table 1: Proposed stakeholders, implementation strategy and potential benefits.

Stakeholder	Action	Benefits
Review Authors	Use PRISMA-DTA during protocol design and manuscript preparation	Improved quality and completeness of protocols and manuscripts
Journal Editors	Encourage use of PRISMA-DTA via instructions for authors Offer PRISMA-DTA as a template for submission of DTA reviews	Better understanding of journal requirements for authors Improved transparency and reproducibility of DTA reviews
Peer- Reviewers	Use PRISMA-DTA as a template to gauge completeness of reporting	More efficient reviewing regarding missing critical reporting items
Policymakers	Advocate adherence to PRISMA-DTA for authors and funders of DTA reviews	Higher quality, more complete reviews to inform decision making
Practice Guideline developers	Use PRISMA-DTA for guidance regarding completeness of reporting of DTA reviews when considering inclusion into guidelines	Improved ability to compare reviews and their relative quality
Educators	Use PRISMA-DTA as a training tool	Simplified teaching of DTA reviews
Students	Use PRISMA-DTA for coursework on or design and reporting of PRISMA-DTA reviews	Ease of understanding of required DTA review content
Funding agencies	Promote PRISMA-DTA as a template for proposals for DTA review grant applications	Improved quality of submission More efficient peer review process

Glossary

Executive Committee

The principal investigators Matthew McInnes, David Moher and Patrick Bossuyt.

Advisory Board

Experts with knowledge in the field of diagnostic test accuracy studies, systematic reviews and reporting guidelines (or any combination of these).

Research team

The combination of the Executive Committee and Advisory Board.

Delphi participants

Participants in the Delphi survey. These consist of the Executive Committee, the Advisory Board, and additional participants (STARD Group, PRISMA Group and additional participants with relevant expertise).

Checklist

A one-page document listing the essential items that should be reported in all diagnostic test accuracy reviews. It constitutes the core of the reporting guideline.

Statement

A document that provides the rationale for the initiative of developing this reporting guideline.

Explanation and Elaboration (E&E)

A document that provides explanations and examples of reporting for each item in the checklist.

Reporting guideline

The combination of the checklist, statement and E&E material

Appendix 1: PRISMA DTA Executive

Name	Expertise	Affiliation(s)	Country of Origin
Matthew McInnes	DTA Reviews, Methods and User (Imaging)	Ottawa Hospital Research Institute University of Ottawa	Canada
David Moher	Reporting guideline development (PRISMA), implementation	Ottawa Hospital Research Institute University of Ottawa PRISMA Group	Canada
Patrick Bossuyt	DTA and DTA Review methods, Guideline Development (STARD)	AMC Amsterdam STARD Group	Netherlands

Appendix 2: PRISMA DTA Advisory Board

Name	Expertise	Affiliation(s)	Country of Origin
Jeremie Cohen	DTA Methods and User (Pediatrics)	French Institute of Health and Medical Research STARD Group	France
Jon Deeks	DTA Review Methods (Statistics)	University of Birmingham Cochrane Methods Group	UK
Constantine Gatsonis	DTA Review Methods (Statistics)	Brown University STARD Group	US
Lotty Hooft	DTA Review Methods, Guideline Development (STARD)	UMC Utrecht Cochrane Netherlands STARD Group	Netherlands
Chris Hyde	DTA Review Methods	University of Exeter	UK
Daniel Korevaar	DTA Review Methods & User (Internal Medicine)	AMC Amsterdam STARD Group	Netherlands
Mariska Leeflang	DTA Review Methods, Guideline Development (STARD)	AMC Amsterdam STARD Cochrane Methods Group	Netherlands
Petra Macaskill	DTA Review Methods (Statistics)	University of Sydney Cochrane Methods Group	Australia
Hans Reitsma	DTA Review Methods, Guideline Development (STARD, PRISMA-IPD)	UMC Utrecht Cochrane Netherlands Cochrane Methods Group STARD Group	Netherlands
Rachel Rodin	Knowledge User (Policy)	Public Health Agency of Canada	Canada
Anne Rutjes	DTA Review Methods (Risk of Bias)	University of Bern Università G. D'Annunzio Cochrane Methods Group	Italy/ Switzerland
Yemisi Takwongi	DTA Review Methods (Statistics)	University of Birmingham Cochrane Methods Group	UK
Brett Thombs	DTA Reviews, Methods and User (Psychology)	McGill University Canadian Task Force for Preventive Care	Canada
Laura Weeks	Knowledge User (Health Technology Assessment)	Canadian Agency for Drugs and Technology in Health	Canada
Penny Whiting	DTA Review Methods (Risk of Bias)	University of Bristol Cochrane Methods Group	UK
Brian Willis	DTA Review Methods (Applicability) & User (Primary Care)	University of Birmingham Cochrane Methods Group	UK

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