Title: Development and implementation of a reporting guideline for systematic reviews and meta-analyses of diagnostic accuracy studies: The PRISMA-DTA initiative **Principal Investigators**: Matthew McInnes, David Moher, Patrick Bossuyt

Background: 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—this could be in the form of greater precision (e.g. more narrow confidence intervals around accuracy estimates), or a better understanding of determinants of test performance (e.g. patient, disease, or test characteristics) (1). The number of systematic reviews of diagnostic accuracy has grown rapidly over the past decade (2).

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, and the validity and applicability of the presented findings. Evaluations have shown that published systematic reviews of diagnostic accuracy are often not sufficiently informative, and are of heterogeneous quality (3-5); they demonstrate considerable variability in approaches to fundamental steps such as assessing for publication bias, heterogeneity, pooling data and assessment for risk of bias in the included studies (5-8).

Research waste from incomplete reporting has been identified as a major problem in biomedical research (9). To improve the quality of reporting of systematic reviews, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guideline was developed (10), 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 (3, 4, 11).

PRISMA was developed primarily to facilitate reporting reviews of healthcare interventions. Though systematic reviews of diagnostic accuracy studies share general elements with such reviews, there are also some differences. As such, some PRISMA items are not appropriate for reporting reviews of diagnostic accuracy, while other crucial items unique to them are missing (1, 12, 13).

Over the past years, several extensions of PRISMA have been developed for specific types of reviews (14-18). We believe that the development of a specific extension of PRISMA for reviews of diagnostic accuracy studies would be a highly effective means of reducing waste in biomedical research.

Objective: To develop and implement a guideline for reporting systematic reviews and metaanalyses of diagnostic accuracy studies (PRISMA-DTA).

Project leaders and strategy: PRISMA-DTA will be developed in line with previously published guidance for establishing reporting guidelines, developed by the EQUATOR network (19). A detailed protocol outlining these steps for PRISMA-DTA has been established.

The project is led by a 3 person PRISMA-DTA executive; this includes the lead author of PRISMA (DM), and the lead author of STARD (STAndards for Reporting of Diagnostic accuracy studies) (PB) (Appendix 1) (20). A 12 person advisory board complements the executive; their extensive experience in diagnostic research, systematic reviews, and reporting guideline development will contribute to the project's success (Appendix 2).

Having established that the quality of reporting of diagnostic reviews is inadequate (3-5), and surveyed the literature for potential empirical evidence of items that might lead to bias, the PRISMA-DTA team will complete a 3 round survey among a group of experts in the field of diagnostics, systematic reviews, or reporting guidelines, to assess the appropriateness of potential items to be considered for the PRISMA-DTA checklist. The experts will also be invited to nominate other items for consideration. During an in-person consensus meeting in early 2017, the PRISMA-DTA advisory board will finalize a core set of items to be included in a PRISMA-DTA checklist.

The dissemination plan will aim at publication of the checklist and an elaboration document in at least one journal; incorporation of PRISMA-DTA into training for authors of systematic reviews of diagnostic accuracy (Cochrane author training, Cochrane handbook for Reviews of Diagnostic Test Accuracy, workshops at the Cochrane Colloquium, on-line tutorial on the Cochrane Screening and Methods Page); seeking endorsement from journals that publish systematic reviews of diagnostic accuracy; presentation at conferences where potential users are likely to attend; and publication on the PRISMA and EQUATOR websites.

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)	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
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
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
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

References

- 1. McInnes MD, Bossuyt PM. Pitfalls of Systematic Reviews and Meta-Analyses in Imaging Research. Radiology. 2015;277(1):13-21. doi: 10.1148/radiol.2015142779. PubMed PMID: 26402491.
- 2. McGrath T, McInnes M, Korevaar D, Bossuyt P. Diagnostic accuracy metaanalyses in imaging journals: analysis of pooling techniques and their impact on summary estimates of diagnostic accuracy. University of Ottawa Medical Student Research Symposium; Ottawa, Ontario, Canada.2015.
- 3. Tunis AS, McInnes MD, Hanna R, Esmail K. Association of study quality with completeness of reporting: have completeness of reporting and quality of systematic reviews and meta-analyses in major radiology journals changed since publication of the PRISMA statement? Radiology. 2013;269(2):413-26. doi: 10.1148/radiol.13130273. PubMed PMID: 23824992.
- 4. Willis BH, Quigley M. The assessment of the quality of reporting of meta-analyses in diagnostic research: a systematic review. BMC Med Res Methodol. 2011;11:163. doi: 10.1186/1471-2288-11-163. PubMed PMID: 22151233; PubMed Central PMCID: PMCPMC3258221.
- 5. Willis BH, Quigley M. Uptake of newer methodological developments and the deployment of meta-analysis in diagnostic test research: a systematic review. BMC Med Res Methodol. 2011;11:27. doi: 10.1186/1471-2288-11-27. PubMed PMID: 21401947; PubMed Central PMCID: PMCPMC3065444.
- 6. Naaktgeboren CA, van Enst WA, Ochodo EA, de Groot JA, Hooft L, Leeflang MM, et al. Systematic overview finds variation in approaches to investigating and reporting on sources of heterogeneity in systematic reviews of diagnostic studies. J Clin Epidemiol. 2014;67(11):1200-9. doi: 10.1016/j.jclinepi.2014.05.018. PubMed PMID: 25063558.
- 7. Ochodo EA, van Enst WA, Naaktgeboren CA, de Groot JA, Hooft L, Moons KG, et al. Incorporating quality assessments of primary studies in the conclusions of diagnostic accuracy reviews: a cross-sectional study. BMC Med Res Methodol. 2014;14:33. doi: 10.1186/1471-2288-14-33. PubMed PMID: 24588874; PubMed Central PMCID: PMCPMC3942773.
- 8. van Enst WA, Ochodo E, Scholten RJ, Hooft L, Leeflang MM. Investigation of publication bias in meta-analyses of diagnostic test accuracy: a meta-epidemiological study. BMC Med Res Methodol. 2014;14:70. doi: 10.1186/1471-2288-14-70. PubMed PMID: 24884381; PubMed Central PMCID: PMCPMC4035673.
- 9. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. Lancet. 2014;383(9913):267-76. doi: 10.1016/S0140-6736(13)62228-X. PubMed PMID: 24411647.
- 10. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol. 2009;62(10):1006-12. doi: 10.1016/j.jclinepi.2009.06.005. PubMed PMID: 19631508.
- 11. Plint AC, Moher D, Morrison A, Schulz K, Altman DG, Hill C, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. Med J Aust. 2006;185(5):263-7. PubMed PMID: 16948622.

- 12. Macaskill P GC, Deeks JJ, Harbord RM, Takwoingi Y. Chapter 10: Analysing and Presenting Results. In: Deeks JJ, Bossuyt PM, Gatsonis C (editors), Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy The Cochrane Collaboration; 2010.
- 13. Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med. 2011;155(8):529-36. doi: 10.7326/0003-4819-155-8-201110180-00009. PubMed PMID: 22007046.
- 14. Beller EM, Glasziou PP, Altman DG, Hopewell S, Bastian H, Chalmers I, et al. PRISMA for Abstracts: reporting systematic reviews in journal and conference abstracts. PLoS Med. 2013;10(4):e1001419. doi: 10.1371/journal.pmed.1001419. PubMed PMID: 23585737; PubMed Central PMCID: PMCPMC3621753.
- 15. Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015;349:g7647. PubMed PMID: 25555855.
- 16. Stewart LA, Clarke M, Rovers M, Riley RD, Simmonds M, Stewart G, et al. Preferred Reporting Items for Systematic Review and Meta-Analyses of individual participant data: the PRISMA-IPD Statement. JAMA. 2015;313(16):1657-65. doi: 10.1001/jama.2015.3656. PubMed PMID: 25919529.
- 17. Welch V, Petticrew M, Tugwell P, Moher D, O'Neill J, Waters E, et al. PRISMA-Equity 2012 extension: reporting guidelines for systematic reviews with a focus on health equity. PLoS Med. 2012;9(10):e1001333. doi: 10.1371/journal.pmed.1001333. PubMed PMID: 23222917; PubMed Central PMCID: PMCPMC3484052.
- 18. Hutton B, Salanti G, Caldwell DM, Chaimani A, Schmid CH, Cameron C, et al. The PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of health care interventions: checklist and explanations. Ann Intern Med. 2015;162(11):777-84. doi: 10.7326/M14-2385. PubMed PMID: 26030634.
- 19. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med. 2010;7(2):e1000217. doi: 10.1371/journal.pmed.1000217. PubMed PMID: 20169112; PubMed Central PMCID: PMCPMC2821895.
- 20. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, et al. STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies. Radiology. 2015:151516. doi: 10.1148/radiol.2015151516. PubMed PMID: 26509226.