

Preferred Reporting Items for Diagnostic Accuracy Studies in Endodontics (PRIDASE) guidelines: a development protocol

V Nagendrababu¹, P Abbott², HF Duncan³, AF Fouad⁴, C Kruse⁵, S Patel⁶, M Pigg⁷, DK Rechenberg⁸, PMH Dummer⁹

¹Department of Preventive and Restorative Dentistry, College of Dental Medicine, University of Sharjah, Sharjah, UAE; ²UWA Dental School, University of Western Australia, Nedlands, Australia; ³Division of Restorative Dentistry, Dublin Dental University Hospital, Trinity College Dublin, Dublin, Ireland; ⁴School of Dentistry, UAB| The University of Alabama at Birmingham, Birmingham, Alabama, USA; ⁵Section of Oral Radiology, Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark; ⁶Department of Endodontics, The Faculty of Dentistry, Oral and Craniofacial Sciences at Kings' College London, London, UK; ⁷Department of Endodontics, Faculty of Odontology, Malmö University, Malmö, Sweden; ⁸Department of Conservative and Preventive Dentistry, University of Zürich, Zürich, Switzerland; ⁹School of Dentistry, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK.

Corresponding author

V Nagendrababu BDS, MFDS RCPS (Glasgow), MDS, PhD.

Department of Preventive and Restorative Dentistry,

College of Dental Medicine,

University of Sharjah, Sharjah, UAE.

E mail: vnagendrababu@sharjah.ac.ae, hivenkateshbabu@yahoo.com

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Abstract

Diagnostic accuracy studies play an important role in informing clinical practice and patient management, by evaluating the ability of diagnostic testing and imaging to identify the presence or absence of a disease or condition. These studies compare the relative diagnostic strength of the test or device with a reference standard, therefore guiding clinical decisions on the reliability of the test, the need for further tests, and whether to monitor or treat a particular condition. Inadequate and incomplete reporting of diagnostic accuracy studies can disguise methodological deficiencies and ultimately result in study bias and the inability to translate research findings into daily clinical practice. The Preferred Reporting Items for Diagnostic Accuracy Studies in Endodontics (PRIDASE) guidelines are being developed in order to improve the accuracy, transparency, completeness and reproducibility of diagnostic accuracy studies in the specialty of Endodontology.

The aim of this paper is to report the process used to develop the PRIDASE guidelines based on a well-established consensus process. The project leaders (PD, VN) formed a steering committee of nine members (PD, VN, PA, AF, DR, SP, CK, MP, HD) to oversee and manage the project. The PRIDASE steering committee will develop the initial draft of the PRIDASE guidelines by adapting and modifying the Standards for Reporting of Diagnostic Accuracy Studies (STARD) 2015 guidelines, adding new items related specifically to the nature of Endodontics and incorporate the Clinical and Laboratory Images in Publication (CLIP) principles. The initial guidelines will consist of a series of domains and individual items and will be validated by the members of a PRIDASE Delphi Group (PDG) consisting of a minimum of 30 individuals who will evaluate independently the individual items based on two parameters: “clarity” using a dichotomous scoring (yes/no) and “suitability” for inclusion using a 9-point Likert Scale. The scores awarded by each member and any suggestions for improvement will be shared with the PDG to inform an iterative process that will result in a series of

items that are clear and suitable for inclusion in the new PRIDASE guidelines. Once the PDG has completed its work, the steering committee will create a PRIDASE Meeting Group (PMG) of 20 individuals from around the world. Members of the PDG will be eligible to be the part of PMG. The draft guidelines and flowchart approved by the PDG will then be presented for further validation and agreement by the PMG. As a result of these discussions, the PRIDASE guidelines will be finalised and then disseminated to relevant stakeholders through publications and via the Preferred Reporting Items for study Designs in Endodontology (PRIDE) website (<http://pride-endodonticguidelines.org>). Periodic updates to the PRIDASE guidelines will be made based on feedback from stakeholders and end-users.

Keywords: Diagnostic accuracy, Diagnostic efficacy, Research design, Endodontics, Reporting quality

Introduction

Diagnostic methods used during clinical examinations are designed to assist in reaching a diagnosis by identifying the likelihood of an individual having the disease or condition under investigation. The sensitivity and specificity of such tests help to guide the clinician to select the appropriate confirmatory diagnostic tests, imaging modalities, and management approaches (Kosack *et al.* 2017, Jang *et al.* 2020). Studies assessing the accuracy of diagnostic tests should ideally determine the diagnostic ability of the specific test(s) compared to a reference standard (Durkan *et al.* 2019). In other words, studies on diagnostic accuracy should evaluate the test of interest (index test) and compare it with a reference (gold) standard test within a known cohort of individuals (or samples) under carefully controlled conditions. Various output measures such as sensitivity, specificity, positive and negative predictive values, likelihood ratios, and area under the receiver operating characteristic curve (AUC/ROC) are used to determine and report the diagnostic accuracy of the index test (Bossuyt *et al.* 2015, Jang *et al.* 2020). The term diagnostic accuracy used throughout this document is often used interchangeably with the terms diagnostic efficacy or diagnostic efficiency all of which refer to the number of correctly classified diseased or healthy subjects amongst the population under investigation.

Studies have confirmed that various methodological flaws in the design of diagnostic studies can lead to bias and affect estimates of the accuracy of diagnostic tests (Lijmer *et al.* 1999, Rutjes *et al.* 2006). In a diagnostic study, there are many potential sources of bias that may lead to inaccurate observations and misguided results. The knock on effect will be a risk of inaccurate diagnosis and inappropriate management approaches. Further, incomplete and inaccurate reporting of studies on diagnostic accuracy will affect the ability of the reader to determine the risk of bias and to understand the generalisability of the findings (Bossuyt *et al.* 2003a,b).

To improve the transparency and completeness of reporting studies on diagnostic accuracy, the Standards for Reporting of Diagnostic Accuracy (STARD) guidelines

were published in 2003 with a checklist of 25 essential items (Bossuyt *et al.* 2003a). The STARD guidelines were updated in 2015 and now contain a checklist of 30 essential items contained in seven sections: title, abstract, introduction, methods, results, discussion, and additional information (Bossuyt *et al.* 2015). STARD are general guidelines applicable to all types of studies on diagnostic accuracy and they do not focus on specific issues, subjects or categories of diagnostic tests (Bossuyt *et al.* 2003a,b, 2015). Consequently, several generic and specialised reporting guidelines have been published by modifying the STARD guidelines, e.g. STARDdem and STRADAS-paraTB for reporting diagnostic accuracy studies for dementia disorders (Noel-Storr *et al.* 2014) and paratuberculosis in ruminants (Gardner *et al.* 2011), respectively.

Durkan *et al.* (2019) appraised the reporting quality diagnostic accuracy studies in Dentistry using the STARD checklist. They reported that the quality was sub-optimal with variations in reporting quality being observed between dental specialty journals. An accurate diagnosis is a prerequisite for achieving success in endodontic management and treatment, particularly considering that the success of different endodontic treatment strategies differs (Bjørndal *et al.* 2010). For example, understanding the diagnostic accuracy of pulp sensibility testing methods and methods used to detect cracks or root fractures would assist clinicians in arriving at the correct diagnosis and select the most appropriate and effective management option.

The STARD 2015 guidelines are applied mainly within human medicine (Bossuyt *et al.* 2015). However, diagnostic accuracy studies in Endodontics often require unique information that is not included within existing guidelines, for example, information related to pain assessment, radiographic imaging, biomarker investigation and pulp sensibility tests; amongst others. Hence, there is a need to develop and validate guidelines for studies on diagnostic accuracy exclusively for Endodontics. The STARD 2015 guidelines cover the majority of the important components for reporting diagnostic accuracy studies in Endodontics; however, several items, including a list of

keywords, precise documentation of intensity, duration and quality of pain, the strength of the study and implications of the work on future research are missing. In addition, Endodontology is a specialty dealing with various types of images (e.g. clinical photographs, radiographs, cone beam computed tomography), which are often assessed to monitor the outcome of treatment. STARD 2015 does not include any guidance related to imaging, which is a clear limitation for studies on reporting accuracy in Endodontics. The Clinical and Laboratory Images in Publications (CLIP) principles (Lang *et al.* 2012) were developed to guide authors in an attempt to improve the quality of how they reported on images within manuscripts. The CLIP principles provide readers with the information needed to assess the accuracy, validity, completeness and credibility of the images published in journals (Lang *et al.* 2012).

The current project aims describes a protocol for the development, validation and dissemination of the Preferred Reporting Items for Diagnostic Accuracy Studies in Endodontics (PRIDASE) guidelines. The PRIDASE guidelines will comprise a checklist and flowchart that are expected to improve the quality, accuracy, reproducibility, completeness and transparency of studies on diagnostic accuracy within Endodontics. Using the PRIDASE guidelines will allow editors of scientific journals and peer reviewers to critically appraise manuscripts submitted on diagnostic accuracy during the editorial process.

Methodology

The development of the PRIDASE guidelines follows the recommendation from the Guidance for Developers of Health Research Reporting Guidelines (Moher *et al.* 2010) and follows a similar process used to develop the Preferred Reporting Items for RANdomized Trials in Endodontics (PRIRATE) 2020 guidelines (Nagendrababu *et al.* 2020). The development and dissemination of the PRIDASE guidelines will involve five phases.

Phase I: Creation of the steering group and draft guidelines

A rigorous literature search conducted by the project leaders identified that no comprehensive guidelines are available to guide authors when reporting diagnostic accuracy studies in Endodontics. The project leaders (PD, VN) created a steering committee (PD, VN, PA, AF, DR, SP, CK, MP, HD) of nine experts across the world. The members of the steering committee will create the first draft PRIDASE guidelines using a combination of the STARD 2015 guidelines (Bossuyt *et al.* 2015) and CLIP principles (Lang *et al.* 2012), which will be adapted and enhanced for Endodontics.

Phase II: PRIDASE Delphi group

The PRIDASE Delphi Group (PDG) will consist of 30 experts from across the world including 22 academics or researchers and four clinician-Endodontists. The members of the PDG will fulfil at least one of the following criteria for eligibility: i) be an author of minimum one scientific article on diagnostic accuracy in Endodontics; ii) be an author of at least one reporting guidelines for *in vitro* / *in vivo* research; iii) have at least ten years of clinical or academic experience. In addition, the PDG group will also include two general dentists and two representatives of the public. The PDG group will be invited to participate in an explicit consensus development process. The role of PDG and the process involved in the Delphi survey will be sent individually to the members of the PDG.

A series of sequential online surveys will be conducted among the PDG to reach consensus on which items from the draft guidelines should be included based on their clarity and suitability. The PDG members, independently and confidentially, will be asked to evaluate the items in the surveys based on the following criteria:

- clarity of each item – dichotomous score (yes/no);
- suitability of each item for inclusion in the guidelines – 9-point Likert scale (1 = 'definitely not include' to 9 = 'definitely include').

Confidential and anonymous comments provided by the members on the individual items will be used to inform the development of the checklist. Items with a score of 7-

9 by more than 70% and items with a score of 1-3 by less than 30% of PDG members will be included in the guidelines. The items with a score of 1-3 by more than 70% and items with a score of 7-9 by less than 30% of PDG members will be excluded. Each round of the Delphi survey will allow corrections/modifications to be made on the items in readiness for subsequent rounds. This iterative Delphi process will be continued until a final set of clear and suitable items are developed for the guidelines (Nagendrababu *et al.* 2020). The PDG members will receive a summary of the results and any revised items following each round.

Phase III: PRIDASE meeting

Following the Delphi process, the list of items forming the guidelines will be presented to a face-to-face or online meeting of experts for further discussion and validation. The PRIDASE Meeting Group (PMG) will consist of two chairpersons and 18 members selected by the steering committee using the same eligibility criteria as PDG members. Members of the PDG will be eligible for the PMG. In addition, the PMG will include two Endodontic postgraduate students to allow the perspective of those in training to be considered. The date and time of the PMG meeting will be communicated to the confirmed members. The draft items of the PRIDASE guidelines (checklist and flowchart), Delphi process report and meeting agenda will be provided to the members at least ten days before the meeting.

The project leads (VN, PD) will present the meeting agenda/objectives and Delphi process report to the PMG. The rationale for the items in the checklist and flowchart will be discussed to clarify and resolve any issues. The dissemination plans of the PRIDASE guidelines, endorsement by various relevant journals and plans to improve adherence by the scientific community will also be discussed. The meeting notes will be recorded for future reference.

Phase IV: Piloting and creating the final PRIDASE guidelines

The PRIDASE guidelines will be finalized by the steering committee based on the outcome of the Delphi process and feedback from the PMG meeting. The guidelines

will be piloted by several authors during the development of manuscripts. An explanation and elaboration document will be prepared by the steering committee with suitable examples of good reporting for each item to guide researchers, reviewers and journal editors in order to provide a better understanding of the PRIDASE guidelines. Before publication, the steering committee will send the explanation and elaboration document to six individuals from the PDG and PMG for their comments. The final document will serve as a 'user manual'.

Phase V: Dissemination of the PRIDASE guidelines

The PRIDASE guidelines will be published in an international peer-reviewed journal and presented at various scientific meetings by the steering committee. The editors of relevant journals will be approached by the steering committee in the hope they will consider adopting the PRIDASE guidelines. A freely accessible dedicated website (Preferred Reporting Items for study Designs in Endodontology (PRIDE) - <http://pride-endodonticguidelines.org>) will be used to archive the guidelines and associated publications for effective dissemination and feedback from stakeholders. The guidelines will be translated to several languages for the benefit of users. The PRIDASE guidelines will be updated regularly to maintain their relevance in light of changes to good practice.

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