

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository: <https://orca.cardiff.ac.uk/id/eprint/132822/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Nagendrababu, V., Duncan, H.F., Fouad, A.F., Kirkevang, L.L., Parashos, P., Pigg, M., Væth, M., Jayaraman, J. and Dummer, P.M.H. 2020. Preferred reporting items for observational studies in endodontics (PROBE): a development protocol. *International Endodontic Journal* 53 (9) , pp. 1199-1203. 10.1111/iej.13318

Publishers page: <http://dx.doi.org/10.1111/iej.13318>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See <http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



Preferred Reporting items for OBservational studies in Endodontics (PROBE): a development protocol

V Nagendrababu¹, HF Duncan², AF Fouad³, LL Kirkevang⁴, P Parashos⁵, M Pigg⁶, M Væth⁷, J Jayaraman⁸, PMH Dummer⁹

¹ Division of Clinical Dentistry, School of Dentistry, International Medical University, Kuala Lumpur, Malaysia, ²Division of Restorative Dentistry, Dublin Dental University Hospital, Trinity College Dublin, Dublin, Ireland, ³Division of Comprehensive Oral Health, Adams School of Dentistry, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA, ⁴Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark, ⁵Melbourne Dental School, University of Melbourne, Melbourne, Victoria, Australia, ⁶Department of Endodontics, Faculty of Odontology, Malmo University, Malmo, Sweden, ⁷Department of Public Health, Aarhus University, Aarhus, Denmark, ⁸Department of Developmental Dentistry, University of Texas Health School of Dentistry, San Antonio, TX, USA, ⁹School of Dentistry, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK.

Corresponding author

V Nagendrababu BDS, MFDS RCPS (Glasgow), MDS, PhD.
Division of Clinical Dentistry,
School of Dentistry, International Medical University
Bukit Jalil – 57000, Kuala Lumpur, Malaysia.
E mail: venkateshbabu@imu.edu.my, hivenkateshbabu@yahoo.com

Keywords: Consensus, Delphi technique, Endodontics, guideline, observational studies

Running title: Guidelines for observational studies

The authors deny any conflicts of interest related to this study.

Observational studies have a significant role in establishing the prevalence and incidence of diseases in populations, as well as determining the benefits and risks associated with health-related interventions. Observational studies principally encompass cohort, case-control, case series and cross-sectional designs. Inadequate reporting of observational studies is likely to have a negative impact on decision making in day-to-day clinical practice; however, no reporting guidelines have been published for observational studies in Endodontics. The aim of this project is to develop reporting guidelines for authors when creating manuscripts describing observational studies in the field of Endodontology in an attempt to improve the quality of publications. The new guidelines for observational studies will be named: "Preferred Reporting items for OBservational studies in Endodontics (PROBE)". A steering committee was formed by the project leaders (PD, VN) to develop the guidelines through a five-phase consensus process. The steering committee will review and adapt items from the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement and the Clinical and Laboratory Images in Publications (CLIP) principles, as well as identify new items that add value to Endodontics. The steering committee will create a PROBE Delphi Group (PDG), consisting of 30 members across the globe to review and refine the draft checklist items and flowchart. The items will be assessed by the PDG on a nine-point Likert scale for relevance and inclusion. The agreed items will then be discussed by a PROBE Face-to-Face meeting group (PFMG) made up of 20 individuals to further refine the guidelines. After receiving feedback from the PFMG, the steering committee will pilot and finalize the guidelines. The approved PROBE guidelines will be disseminated through publication in relevant journals, and be presented at national and international conferences. The PROBE checklist and flowchart will be available and downloadable from the Preferred Reporting Items for study Designs in Endodontics (PRIDE) website: www.pride-endodonticguidelines.org. [The PROBE steering committee encourages clinicians,](#) researchers, editors and peer reviewers to provide feedback on the PROBE guidelines to inform the steering group when the guidelines are updated.

Preferred Reporting items for OBservational studies in Endodontics (PROBE): a development protocol

Abstract

Observational studies have a significant role in establishing the prevalence and incidence of diseases in populations, as well as determining the benefits and risks associated with health-related interventions. Observational studies principally encompass cohort, case-control, case series and cross-sectional designs. Inadequate reporting of observational studies is likely to have a negative impact on decision making in day-to-day clinical practice; however, no reporting guidelines have been published for observational studies in Endodontics. The aim of this project is to develop reporting guidelines for authors when creating manuscripts describing observational studies in the field of Endodontology in an attempt to improve the quality of publications. The new guidelines for observational studies will be named: "Preferred Reporting items for OBservational studies in Endodontics (PROBE)". A steering committee was formed by the project leaders (PD, VN) to develop the guidelines through a five-phase consensus process. The steering committee will review and adapt items from the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement and the Clinical and Laboratory Images in Publications (CLIP) principles, as well as identify new items that add value to Endodontics. The steering committee will create a PROBE Delphi Group (PDG), consisting of 30 members across the globe to review and refine the draft checklist items and flowchart. The items will be assessed by the PDG on a nine-point Likert scale for relevance and inclusion. The agreed items will then be discussed by a PROBE Face-to-Face meeting group (PFMG) made up of 20 individuals to further refine the guidelines. After receiving feedback from the PFMG, the steering committee will pilot and finalize the guidelines. The approved PROBE guidelines will be disseminated through publication in relevant journals, and be presented at national and international conferences. The PROBE checklist and flowchart will be available and downloadable from the Preferred Reporting Items for study Designs in Endodontics

(PRIDE) website: www.pride-endodonticguidelines.org. The PROBE steering committee encourages clinicians, researchers, editors and peer reviewers to provide feedback on the PROBE guidelines to inform the steering group when the guidelines are updated.

Keywords: Consensus, Delphi technique, Endodontics, guideline, observational studies.

Introduction

Observational studies provide estimates and examine the relationship of events “in their natural settings” without intervention by the investigator (Mann 2003). They are distinct from experimental trials in which interventions are applied randomly to one or more groups of participants. In health research, observational studies include several designs such as cohort, case-control, case series and cross-sectional. The purpose of conducting observational studies is to describe outcomes that could be descriptive, analytical, or both (Gilmartin-Thomas *et al.* 2018).

In evidence-based medicine and dentistry, well-executed observational cohort or case-control studies are ranked just below the level of randomised clinical trials, with case series ranked a level further below (Forrest 2009, Murad *et al.* 2016). Observational studies differ from clinical trials as they provide critical descriptive data and information on the long-term efficacy and safety of interventions or diseases at reduced expense (Gilmartin-Thomas *et al.* 2018). In addition, observational studies can provide information on outcomes and treatments that would be unethical to test in randomized clinical trials, such as when allocation of an individual to a particular group would result in considerable risk (Coulter 2003). For example, in Endodontics, to evaluate the outcome of root canal treatment in teeth with a retained fractured instrument or after root perforation compared with root canal treatment without instrument fracture or perforation, conducting a randomized clinical trial would raise significant ethical concerns. In these scenarios, observational studies would be an appropriate study design. Results from observational studies may therefore be regarded as an indicator of how outcomes from randomized clinical trials translate into clinical practice. Observational studies can also help generate a hypothesis for a subsequent randomised clinical trial, develop research questions for future randomized clinical trials, and define clinical conditions (Song & Chung 2010). Indeed, they can provide an incentive to justify the effort and cost needed to design and run future adequately-powered randomized clinical trials. Well-designed observational studies have been shown to provide results similar to randomized controlled trials, challenging the belief that observational studies are always of lower

quality (Song & Chung 2010). However, to assess an effect of a selected exposure/intervention, it is generally accepted that observational studies are inherently lower in quality than RCTs because it is difficult to eliminate bias and control for all relevant confounding variables.

The overall reporting quality of published observational studies has been found to be insufficient (Vandenbroucke *et al.* 2014). This has a significant impact on their clinical translation and their relevance and utility for clinical decision-making (Vandenbroucke *et al.* 2014). To improve the quality of observational studies, the STrengthening the Reporting of Observational studies in Epidemiology (STROBE) checklist was developed (Von Elm *et al.* 2008). The STROBE checklist consists of 22 items, under the following sections: title, abstract, introduction, methods, results, discussion and funding. STROBE addresses three main types of observational studies namely cohort, case control and cross-sectional studies (Von Elm *et al.* 2008). Following this, a number of complementary guidelines have been developed according to the nature of the specialties, e.g. nutritional epidemiology (Strengthening the Reporting of Observational Studies in Epidemiology Nutritional Epidemiology (STROBE-nut)) (Lachat *et al.* 2016), neonatal infection studies (Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection (STROBE-NI)) (Fitchett *et al.* 2016), and veterinary medicine (Strengthening the Reporting of Observational Studies in Epidemiology-Veterinary (STROBE-Vet)) (Sargeant *et al.* 2016).

Fardi *et al.* (2011) concluded that observational studies were one of the most common study designs among 100 top-cited articles published in Endodontology journals. Hence observational studies clearly play a significant role in Endodontology, particularly, during decision-making in clinical practice. The STROBE statement generally covers the majority of the components related to reporting of observational studies in Endodontics. However, several key items are missing in the existing guidelines such as: recommendation to include a list of keywords, guidance for a structured abstract, details of ethical approval, discussion on the strength of the study

(e.g. study design, sufficient number of participants etc.), implications of the study for future research and clinical practice, conflict of interest, quality of images and clear guidance on case series studies. A literature search failed to reveal guidelines for helping authors when reporting observational studies in Endodontics.

The aim of the current protocol is to develop reporting guidelines for observational studies in Endodontics, referred to as “Preferred Reporting items for OBservational studies in Endodontics (PROBE)”. Similar to STROBE, the PROBE guidelines will consist of a checklist and a flowchart that aim to improve the quality of reports describing observational studies (cohort, case-control, case series and cross-sectional designs). The PROBE guidelines will be developed by adapting and elaborating the STROBE statements (Von Elm *et al.* 2008) and Clinical and Laboratory Images in Publications (CLIP) principles (Lang *et al.* 2012) to Endodontics. The CLIP principles aim to increase the accuracy, validity and credibility of images (e.g. clinical images, histology images, intraoral periapical radiographs, cone beam computed tomography images) in publications. Further, these principles guide authors to report details of the images included in manuscripts: subject, acquisition, selection, any modification, important details of the image itself (e.g. resolution and magnification etc.), interpretation and implications (Lang *et al.* 2012).

Therefore, the PROBE guidelines will help:

- i) authors to improve the quality, completeness, accuracy and transparency of reporting observational studies in Endodontology,
- ii) researchers to plan, design and implement observational studies more effectively,
- iii) clinicians and patients to arrive at accurate clinical decision making and documentation of clinical encounters,
- iv) editors/reviewers of journals when they appraise manuscripts on observational studies, and
- v) clinicians and end-users who wish to understand, disseminate and integrate the results of observational research into clinical practice.

Methods

The process of developing PROBE guidelines will adhere to the recommendations based on “Guidance for Developers of Health Research Reporting Guidelines” (Moher *et al.* 2010). The development of the PROBE guidelines will follow the same methodology used to develop the Preferred Reporting Items for Case reports in Endodontics (PRICE 2020) (Nagendrababu *et al.* 2019) and similar guidelines on other study designs. This study design was approved by the Institutional Review Board on Research and Ethics of the International Medical University (IMU), Kuala Lumpur, Malaysia (No: IMU 450/2019).

Phase I: Initial steps

A thorough literature search conducted by the project leaders (PD, VN) using electronic databases with keywords such as observational studies, cohort, case-control, cohort, case-control, case series and cross-sectional designs to identify guidelines for reporting observational studies in Endodontology failed to find any published guidance. A steering committee was formed by the project leaders comprising of nine members (PD, VN, HD, AF, LK, PP, MP, MV, JJ) including the project leaders. A draft PROBE checklist and an accompanying flowchart will be developed by the steering committee. The items in the PROBE checklist will be adapted from the STROBE statement (Von Elm *et al.* 2008) and CLIP principles (Lang *et al.* 2012) to specifically suit observational studies in Endodontics.

Phase II: Pre-meeting activities

A PROBE Delphi Group (PDG) will comprise individuals who satisfy at least one of the following criteria:

1. Have published at least one observational study in Endodontology;

2. Have published a manual, handbook or method guidelines related to observational studies in Endodontology;
3. Have published any reporting guidelines for *in vitro/ in vivo* research;
4. Have a minimum 15 years of clinical or academic experience.

The PDG members will be selected across the globe based on recommendations from the steering committee. A total 30 PDG members will be identified comprising 22 faculty members or researchers in the field of Endodontology, four specialists in Endodontics, two general dentists and two patient representatives.

An invitation will be sent by the PROBE project leaders (VN, PD) to all potential members to participate in the Delphi process. After receiving their confirmation to participate, a Delphi document prepared by the steering committee will be shared with each member of the PDG. The online Delphi process is an interactive approach (Jones & Hunter 1995) that contains sequential surveys undertaken by the PDG members to gain consensus on the checklist items and flowchart. Each member of the PDG will share their response independently on each of the items of the PROBE checklist and the flowchart. To ensure that the comments are provided without undue influence, all the responses will be anonymized and the identity of the PDG member will be masked. For each item, the PDG members will be asked to provide their opinion on whether the individual item is clear ('yes' or 'no') as well as suitability of the item to be included in the checklist using a 9-point Likert rating scale (1 = 'definitely not include' to 9 = 'definitely include'). To better understand and analyze their responses, the PDG members will be asked to give their opinion in the form of free text for each item (Maher *et al.* 2015). Based on this response, the PROBE checklist will be assessed for inclusion with or without modification. For inclusion, each item must score between 7 and 9 by $\geq 70\%$ of members and between 1 and 3 by $\leq 30\%$ of members. Similar to the above, items will be excluded from the PROBE checklist if $\geq 70\%$ PDG members score an item between 1 and 3, and $\leq 30\%$ members score between 7 and 9. The items scored between 4 and 6 will be revised by the steering committee considering the feedback received by the PDG and added to the

next round of the Delphi exercise. This process will be continued until a consensus is reached on all the items and the PDG members agree on the final set of checklist items (Agha *et al.* 2017).

The revised PROBE checklist will be then discussed in a Face-to- Face meeting. The Steering Committee will identify the following for the Face-to-Face meeting:

1. Venue, date and time to conduct the meeting;
2. Two chairpersons to lead the meeting;
3. Names of those participating in the meeting.

The members of the PROBE Face-to-Face meeting group (PFMG) will be identified by the steering committee and consist of 20 members (2 chairpersons and 18 members). In addition, two endodontic postgraduate students/residents in Endodontics will be invited to the meeting to provide their comments on the checklist items. The eligibility criteria for the PFMG will be same as the PDG with individuals being eligible to be a member of both. The PROBE project leaders will send an invitation to the 20 members and two postgraduate students/residents selected for the meeting through email to be part of the PFMG. After confirming their willingness, the PFMG will be notified about the venue, date and time of the Face-to-Face meeting. The project leaders will share the PROBE checklist, the overall results of the Delphi process, the list of members and agenda of the meeting to the PFMG a minimum of ten days before the proposed date of the Face-to-Face meeting.

Phase III: Face-to-Face meeting

The project leaders (PD and VN) will present the following information to the PFMG at Face-to-Face consensus meeting:

1. Results of the Delphi process resulting from the PDG members;
2. Rationale for inclusion of items in the PROBE checklist;
3. Rationale for content and format of the flowchart.

A discussion will be conducted on the suitability of the individual items in the PROBE checklist and flowchart.

Phase IV: Post-meeting activities

The PROBE guidelines will be finalized based on the feedback received during the Face-to-Face meeting. The guidelines will then be piloted by several authors during the development of a manuscript using the PROBE guidelines. Following this, the steering committee will develop an Explanation and Elaboration document to accompany the PROBE guidelines and send to six members (three from PDG and three from PFMG) for final approval. The finalized PROBE guidelines will be disseminated through publications in peer-reviewed scientific journals and the findings presented at regional, national and international scientific meetings.

Phase V: Post-publication activities

The PROBE guidelines will be sent to journals publishing articles in Endodontology for endorsement with the aim of improving the quality of manuscripts reporting observational studies. The PROBE checklist and flowchart will be downloadable from Preferred Reporting Items for study Designs in Endodontics (PRIDE) website: www.pride-endodonticguidelines.org. Authors and researchers will be able to provide their feedback on the PROBE guidelines via the PRIDE website (contact@pride-endodonticguidelines.org). The PROBE steering committee will periodically update the guidelines, as the need arises.

Funding

This work was supported by the International Medical University, Kuala Lumpur, Malaysia under Grant no: IMU 450/2019

References

- Agha RA, Borrelli MR, Vella-Baldacchino M, Thavayogan R, Orgill DP; STROCCS Group (2017) The STROCCS statement: Strengthening the Reporting of Cohort Studies in Surgery. *International Journal of Surgery* **46**, 198-202.
- Coulter ID (2003) Observational studies and evidence-based practice: Can't live with them, can't live without them. *Journal of Evidence Based Dental Practice* **3**, 1-4.
- Fardi A, Kodonas K, Gogos C, Economides N (2011) Top-cited articles in endodontic journals. *Journal of Endodontics* **37**, 1183-90.
- Fitchett EJA, Seale AC, Vergnano S *et al.* (2016) Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection (STROBE-NI): an extension of the STROBE statement for neonatal infection research. *Lancet Infectious Diseases* **16**, e202-e213.
- Forrest JL (2009) Introduction to the basics of evidence-based dentistry: concepts and skills. *Journal of Evidence-Based Dental Practice* **9**, 108-12.
- Gilmartin-Thomas JF, Liew D, Hopper I (2018) Observational studies and their utility for practice. *Australian Prescriber* **41**, 82-5.
- Jones J, Hunter D (1995) Consensus methods for medical and health services research. *BMJ*. **311**, 376-80.
- Lachat C, Hawwash D, Ocké MC *et al.* (2016) Strengthening the Reporting of Observational Studies in Epidemiology - nutritional epidemiology (STROBE-nut): An extension of the STROBE statement. *Nutrition Bulletin* **41**, 240-51.
- Lang TA, Talerico C, Siontis GCM (2012) Documenting clinical and laboratory images in publications: the CLIP principles. *Chest* **141**, 1626-32.
- Maher TM, Whyte MK, Hoyles RK *et al.* (2015) Development of a consensus statement for the definition, diagnosis, and treatment of acute exacerbations of idiopathic pulmonary fibrosis using the Delphi technique. *Advances in Therapy* **32**, 929-43.

Mann CJ (2003) Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emergency Medicine Journal* **20**, 54-60.

Moher D, Schulz KF, Simera I, Altman DG (2010) Guidance for developers of health research reporting guidelines. *PLoS Medicine* **16**, e1000217.

Murad MH, Asi N, Alsawas M, Alahdab F (2016) New evidence pyramid. *Evidence-Based Medicine* **21**, 125-7.

Nagendrababu V, Chong BS, McCabe P *et al.* (2019) Guidelines for reporting the quality of clinical case reports in Endodontics: a development protocol. *International Endodontic Journal* **52**, 775-8.

Sargeant JM, O'Connor AM, Dohoo IR *et al.* (2016) Methods and Processes of Developing the Strengthening the Reporting of Observational Studies in Epidemiology-Veterinary (STROBE-Vet) Statement. *Journal of Food Protection* **79**, 2211-9.

Song JW, Chung KC (2010) Observational studies: cohort and case-control studies. *Plastic and Reconstructive Surgery* **126**, 2234.

Vandenbroucke JP, von Elm E, Altman DG *et al.* (2014) Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *International Journal of Surgery* **12**, 1500-24.

Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative (2008) The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Journal of Clinical Epidemiology* **61**, 344-9.