Guidelines for reporting the quality of clinical case reports in Endodontics: a development protocol

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Abstract

Case reports are used to communicate interesting, new or rare condition/s, innovative treatment approaches or novel techniques. Apart from informing readers, such information has the potential to contribute towards further scientific studies and the development of newer management modalities. Reporting guidelines are used to inform authors of the quality standards required to ensure their case report is accurate, complete and transparent. The aim of this project is to develop and disseminate new guidelines - Preferred Reporting Items for Case reports in Endodontics (PRICE). The primary aim is to aid authors when constructing case reports in the field of Endodontics to ensure the highest possible reporting standards are adopted. The project leaders (PD and VN) formed a steering committee comprising of six additional members. Subsequently, a four–phase consensus process will be used: 1. Pre-online consensus activities (literature search, creating PRICE guidelines), 2. Online Consensus (Delphi Process), 3. Face-to-face consensus meeting, and 4. Post-meeting activities. The steering committee will develop the PRICE guidelines by identifying relevant items (quality standards) derived from the CAse REport guidelines and Clinical and Laboratory Images in Publications principles, focussing on the content of case reports. Following this, the steering committee will identify a PRICE Delphi Group (PDG) consisting of 30 members including academicians, practitioners, and members of the public. The individual items (components) of the PRICE checklist will be evaluated by the PDG based on a 9-point Likert scale. Only items scored between 7 and 9 by 70% or more members will be included in the draft checklist. The Delphi process will be continued until a consensus is reached and a final set of items agreed by the PDG members. Following this, a PRICE Face-to-Face meeting group (PFMG) will be formed with 20 members to achieve a final consensus. The final consensus-based checklist and flow diagram will be evaluated and approved by selected members of the PDG and PFMG. The approved PRICE checklist will be published in relevant journals, and disseminated via contacts in academic institutions and national endodontic societies, as well as being presented at scientific/clinical meetings.

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Introduction

Clinical case reports form an integral component of the healthcare literature by presenting newly discovered or rare condition/s, innovative management approaches or novel techniques. These reports can provide important or additional inputs to everyday clinical practice and also convey early information on the therapeutic effects, adverse events, and costs of interventions (Nayak 2010, Riley *et al*. 2017). Furthermore, they have the potential to provide future directions for research and can contribute to the improvement of case-based learning activities.

New, rare, or unusual presentations of a disease and/or its management are the usual focus of case reports and they have the potential to become important sources of information for unique or more effective management regimens leading to improved decision-making on treatment options (Riley *et al*. 2017). Although case reports might have low specificity for decision-making in healthcare, they have high sensitivity for detecting novelty (Vandenbroucke 2001).

With the increase in the number of new journals that focus on case reports, there has been an upsurge in this category of publication (Akers 2016). A good quality case report, which contains all the relevant details and salient information is an important knowledge source in the field of health education and clinical research (Danish *et al*. 2017). Thus, the value of case reports is that they can lead to new research directions and improved patient management guidelines and hence better treatment outcomes (Cohen 2006). However, inconsistent and incomplete reporting has been one of the main problems limiting the usefulness of case reports, which can be attributed to the absence of reporting guidelines, ambiguity of existing guidelines or authors not fully adhering to available guidelines.

CAse REport (CARE) guidelines (Gagnier *et al.* 2013) were published to standardize the reporting of case reports in medicine and surgery and to ensure they were accurate, complete and transparent. CARE guidelines have been adopted by many journals and translated into several languages. The CARE checklist consists of 13 items (domains) including the title, key words, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective, and informed consent Likewise, the Clinical and Laboratory Images in Publications (CLIP) principles (Lang *et al*. 2012) were formulated as guidance for the reporting of images; to provide readers with the information needed to assess the accuracy, validity, completeness and credibility of the

interpretation and implications of images published in journals. The CLIP principles comprise six domains: subject of the image, acquisition of the image, selection of the image, modifications of the image, important details of the image itself and analysis or interpretation and the implications of the image. Adherence to the principles is expected to improve the reporting quality of images and the accuracy of the information provided.

As in other areas of healthcare, the quality of case reports in Endodontics vary in quality, and is thus subject to the risk of bias and lack of transparency. A standard guideline for reporting case reports in Endodontics will help improve their quality. It will also facilitate authors undertaking the composition of case reports. There are no published guidelines standardizing the quality of case reports in Endodontics. Thus, a set of quality guidelines is proposed, the Preferred Reporting Items for Case reports in Endodontics (PRICE) for case reports in Endodontics. The PRICE guidelines consist of a checklist and flow diagram. The PRICE checklist will be developed based on the CARE guidelines (Gagnier *et al*. 2013) and CLIP principles (Lang *et al*. 2012); it will be adapted, with items specifically for Endodontics.

Need for PRICE guidelines

The PRICE guidelines will help authors to compose accurate, transparent and high-quality case reports in Endodontics that will benefit all relevant stakeholders, including patients. Furthermore, the PRICE guidelines will provide a checklist for editors and referees of scientific journals to critically appraise the quality of case reports during the review process. Therefore, the aim of this project is to formulate a protocol to develop and disseminate the PRICE guidelines for reporting the quality of clinical case reports in Endodontics using a consensus process.

Methods

The development of the new PRICE guidelines will follow the Guidance for Developers of Health Research Reporting Guidelines (Moher *et al*. 2010).

Phase I: Premeeting activities (developing the PRICE checklist)

Following a literature search, the project leaders (PD, VN) identified the need for developing guidelines for reporting case reports in the field of Endodontics. The project leaders formed a steering committee comprising of eight members (PD, VN, BC, PM, PS, SJ, JJ, EP). The steering committee will facilitate the development of the PRICE checklist and a flow chart. The specific items within the PRICE checklist will be generated by combining the items from the CARE guidelines (Gagnier *et al*. 2013) and CLIP principles (Lang *et al*. 2012). These items will be adapted specifically for Endodontics. The items focus on the quality of the information provided in the case report, and the quality of the images used to complement the text; in addition, a flow chart will be developed.

Phase II a: Online consensus (Delphi process)

A PRICE Delphi Group (PDG) will be established consisting of individuals who fulfil at least one of the following criteria:

i) published at least one case report related to Endodontics;
ii) published a manual, handbook, or method guidelines related to case reports in Endodontics;
iii) published any reporting guidelines for *in vitro* / *in vivo* research;
iv) a minimum 15 years of clinical experience in dentistry.

The steering committee will identify potential PDG members internationally. The PDG will consists of 30 members comprising of 22 academicians or researchers, four Endodontists, two general dentists and two patient representatives.

The PRICE project leaders (VN, PD) will invite potential members via email to ascertain their willingness to be part of the PDG and to participate in the Delphi process. After confirming their agreement to participate, a Delphi document will be shared with each member of the PDG. An iterative approach will be employed using sequential surveys that will be undertaken by the PDG members to gain consensus. Members will share independently their views on each of the items of the PRICE checklist and flow chart. The responses will be anonymized, to ensure comments are provided without undue pressure or influence. For each item, all the members will be asked to give their opinion on whether the individual item is clear (‘yes’ or ‘no’) and whether the item should be included using a 9-point rating Likert scale (1 = ‘definitely not include’ to 9 = ‘definitely include’). Later, members will be allowed to give their opinion, in the form of free text,

which will help to clarify the meaning of the item (Maher *et al* 2015). The PRICE checklist will be assessed to decide whether the items should be included, with or without modification. Items for inclusion must score between 7 and 9 by ≥70% of members and between 1 to 3 by ≤30% of members. Similarly, items will be excluded from the PRICE checklist if ≥ 70% PDG members score an item between 1 and 3, and ≤ 30% members score between 7 and 9. The results of these opinions on each item will be shared with PDG members. This will include: the percentage of the group members that agreed the item is clear, has a median rating for inclusion, percentage of the group who rate the item as 'definitely include', and combined comments. If an item requires modification, members will be asked to re-rate the revised version. The Delphi process will be continued until a consensus is reached and a final set of items is agreed by the PDG members (Agha *et al*. 2017).

Phase II b: Premeeting activities

Once the PRICE checklist and flow chart has been finalized by the PDG, it will be discussed in a face-to-face consensus meeting. The Steering Committee will identify the following:

i. venue, date and time to conduct face-to-face consensus meeting;
ii. two chairpersons;
iii. participating members.

The steering committee will identify the PRICE Face-to-Face meeting group (PFMG), consisting of 20 members (18 members and two chairpersons). Two postgraduate dental students (Endodontics) will be invited to the meeting to share their views. The PRICE project leaders will contact the 20 members via email to ascertain their willingness to be part of the PFMG and contribute. After confirming their agreement to participate, the PFMG will be informed of the venue, date and time of the face-to-face meeting. The project leaders will share the PRICE checklist, results of the Delphi process, members list and meeting agenda to the PFMG at least 10 days before the face-to-face consensus meeting.

Phase III: Face-to-face consensus meeting

On the day of face-to-face consensus meeting the project leaders (PD and VN) will present the following:

i. results of the Delphi process;

ii. rationale for including the items in the PRICE checklist;

iii. rationale for including the flow chart to PFMG.

The individual items in the PRICE list will then be discussed.

Phase IV: Postmeeting activities

Based on the comments from the face-to-face consensus meeting, the PRICE guidelines will be finalized. The steering committee will prepare an Explanation and Elaboration document to accompany the PRICE guidelines and send to 10 members via email (five from PDG and five from PFMG) for final approval. Later it will be sent to selected journals for acceptance, publication and endorsement.

Dissemination plans

The PRICE guidelines will be disseminated by publications in peer-reviewed journals as well as presented at national and international scientific meetings. Ultimately, when a journal endorses and applies the PRICE guideline, it will lead to improvement in the quality of the case reports published.

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