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Reporting stAndards for research in Pedlatric Dentistry (RAPID)

Jayaraman, Jayakumar; Dhar, Vineet; Donly, Kevin J.; Priya, Ekta; Innes, Nicola P. T.; Clarkson, Jan

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DR. JAYAKUMAR JAYARAMAN (Orcid ID : 0000-0003-1737-6891)
DR. VINEET DHAR (Orcid ID : 0000-0003-4175-5226)
DR. DANIELA P RAGGIO (Orcid ID : 0000-0002-0048-2068)
DR. VENKATESHBABU NAGENDRABABU (Orcid ID : 0000-0003-3783-3156)

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Reporting stAndards for research in PedIatric Dentistry (RAPID): a development protocol.

Jayakumar Jayaraman^{1*}, Vineet Dhar², Kevin J Donly³, Ekta Priya⁴, Nicola PT Innes⁵, Jan Clarkson⁶, Daniela P Raggio⁷, Noel Childers⁸, Timothy Wright⁹, Nigel King¹⁰, Venkateshbabu Nagendrababu¹¹, Mike Clarke¹².

¹Jayakumar Jayaraman,
University of Texas Health School of Dentistry,
San Antonio, Texas 78229,
United States of America
e-mail: jayakumar83@hotmail.com

²Vineet Dhar,
University of Maryland School of Dentistry,
Baltimore, Maryland 21201,
United States of America
e-mail: vdhar@umaryland.edu

³Kevin J Donly,
University of Texas Health School of Dentistry,
San Antonio, Texas 78229,
United States of America
e-mail: donly@uthscsa.edu

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⁴Ekta Priya,
International Medical University,
Bukit Jalil, Kuala Lumpur 57000,
Malaysia
e-mail: drektapriya@gmail.com

⁵Nicola PT Innes,
University of Dundee,
Dundee DD1 4HR,
United Kingdom
e-mail: n.p.innes@dundee.ac.uk

⁶Jan Clarkson,
University of Dundee,
Dundee DD1 4HR,
United Kingdom
e-mail: j.e.clarkson@dundee.ac.uk

⁷Daniela P Raggio,
Faculdade de Odontologia,
Universidade de Sao Paulo,
Sao Paulo,
Brazil
e-mail: danielar@usp.br

⁸Noel Childers,
School of Dentistry,
University of Alabama,
Birmingham, Alabama 35233,
United States of America
e-mail: nkc@uab.edu

⁹Timothy Wright

University of North Carolina at Chapel Hill,

Chapel Hill, North Carolina 27514,

United States of America

e-mail: tim_wright@unc.edu

¹⁰Nigel King,

University of Western Australia,

Perth WA 6009,

Australia

e-mail: profnigelking@mac.com

¹¹Venkateshbabu Nagendrababu,

International Medical University,

Bukit Jalil, Kuala Lumpur 57000,

Malaysia

e-mail: venkateshbabu@imu.edu.my

¹²Mike Clarke,

Queen's University Belfast,

Belfast BT7 1NN,

United Kingdom

e-mail: m.clarke@qub.ac.uk

****Corresponding Author***

Jayakumar Jayaraman, BDS, MDS, DipFHID, MPAed Dent RCSEd, FDS RCSEd, PhD,

Department of Developmental Dentistry,

University of Texas Health School of Dentistry,

8210, Floyd Curl Drive,

San Antonio, Texas 78229,

United States of America

e-mail: jayakumar83@hotmail.com

Phone: +85251645177

Abstract

Reporting guidelines can improve the quality of reports of research findings. However, some specialities in healthcare require guidance on areas that are not captured within the existing guidelines and this is the case for Paediatric Dentistry where no such standards are available to guide the reporting of different types of study designs. The 'Reporting standards for research in Paediatric Dentistry' (RAPID) group aims to address this need by developing guidelines on reporting elements of research of particular relevance to Paediatric Dentistry. The development of RAPID guidelines will involve a five-phase process including a Delphi study, which is an explicit consensus development method designed and implemented in accordance with the Guidance on conducting and reporting Delphi studies. The guideline development process will be overseen by an Executive Group. Themes specific to areas in Paediatric Dentistry will be selected and items to be included under each theme will be identified by members of the Executive Group reviewing at least five reports of experimental and analytical study types using existing reporting guidelines. For the Delphi study, the Executive Group will identify an international multidisciplinary RAPID Delphi Group (RDG) of approximately 60 participants including academics, Paediatric Dentists, parents, and other stakeholders. Each item will be evaluated by RDG on clarity using a dichotomous scale ('well phrased' or 'needs revision') and on suitability for inclusion in the Delphi study using a 9-point Likert scale (1 = 'definitely not include' to 9 = 'definitely include'). The items will then be included in an online Delphi study of up to four rounds, with participants invited from stakeholder groups across Paediatric Dentistry. Items scored 7 or above by at least 80% of respondents will be included in the checklist and further discussed in a face-to-face Delphi consensus meeting. Following this, the Executive Group will finalize the RAPID guidelines. The guidelines will be published in peer-reviewed scientific journals and disseminated at

scientific meetings and conferences. All the outputs from this project will be made freely available on the RAPID website: www.rapid-statement.org

Keywords: Reporting, Standards, Guidelines, Delphi, Paediatric Dentistry, RAPID, Protocol

Introduction

Evidence-based practice allows clinicians and patients to make informed decisions based on the best available evidence, sound clinical expertise, plus patient values and preferences¹. To enable informed healthcare decisions, the research that contributes to the evidence based part must be reported with clear, transparent and sufficient detail to allow the reader and potential user of the information to assess the appropriateness of the research study's methodology and veracity of the findings². The repercussions of poor reporting of healthcare research are expensive, potentially serious, long-standing and pervasive, and further contribute to research waste³. Furthermore, incomplete reporting can preclude the replication of studies, harming scientific progress⁴. For instance, it has been reported that biases in low quality randomized controlled trials (RCT) show an increased estimate of benefit of 34% on the quantitative results when compared to high quality RCTs, providing misleadingly optimistic information about the effects of treatments⁵. Therefore, it is important to know if these biases exist in RCT and a lack of information due to poor reporting can make the interpretation and implementation of research findings difficult, and impair clinical decision making and policy making⁶.

Recommendation to improve the quality of reporting is to implement reporting guidelines^{3,7}. These guidelines help investigators to ensure clarity, validity and transparency in their reports. The development, promotion and implementation of reporting guidelines have

enhanced the reporting of research findings in dentistry^{8,9,10} and are available for many study designs (Table 1). There are also extensions of these guidelines for particular research designs such as for meta-analyses of Preferred Reporting Items for Systematic Reviews and Meta-Analyses - Individual Participant Data (PRISMA-IPD)¹¹, types or parts of reports, such as abstracts for RCTs¹², and other areas of healthcare such as observational studies of neonatal infection¹³. A comprehensive guide to reporting guidelines and their extensions is available on the Enhancing the QUality and Transparency Of health Research (EQUATOR) website (www.equator-network.org).

In Dentistry, although some journals have endorsed different reporting guidelines, many research reports still demonstrate low reporting quality¹⁰. This may be because the guidelines are not as well adhered to, not known or adopted as they should be. Although reporting guidelines are readily available, few journals make them clearly available to authors. Some journals include this in the authors guidelines and advise authors to upload the reporting checklist along with submission of the manuscript. A recent survey of 87 dental journals on the practice of reporting guidelines for different study designs found that less than half instruct the authors to follow the published reporting guidelines⁷. In addition, reports of studies in certain specialities in Dentistry are likely to require additional explicit information that is not captured in the existing guidelines. As noted above, in some other areas of healthcare, this has been addressed by the tailoring of existing guidelines in extensions to the main reporting guideline. For example, modified Consoliated Statements for Reporting Trials (CONSORT) statements have been developed for infertility treatments (Improving the Reporting of Clinical Trials of Infertility Treatments) (IMPRINT)¹⁴ and acupuncture (STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)¹⁵. In

Dentistry, to date, development protocols for reporting guidelines have been published for case reports¹⁶, clinical trials¹⁷ and laboratory studies¹⁸ specific to the field of Endodontics.

Considering the significance of child specific growth and development status, as well as child-tailored interventions and outcomes, the need for reporting guidelines with paediatric-specific items has been acknowledged recently¹⁹. In response to this, extensions of the reporting guidelines have been developed that cover Standard Protocol Items for Randomized Trials in Children (SPIRIT-C) and Consolidated Standards of Reporting Trials in Children (CONSORT-C)²⁰, and PRISMA-Protocol for Children (PRISMA P-C) and PRISMA-Children (PRISMA-C) for systematic reviews and meta-analyses are under development¹⁹. One benefit of these extensions is that they help with the desire for research to be patient-centered and to address health problems of importance to the public, with interventions and outcomes that are considered important by patients and the healthcare providers²¹. In Paediatric research generally, specific domains that have not been accurately reported include diet history, feeding practices, behavior rating, behavior management, informed consent, dose calculations, age-specific and developmental stage-specific confounders, patient- and parent-based treatment outcomes as well as their satisfaction²². Similarly, in Paediatric Dentistry specifically, several vital information relevant to children's oral health are not being adequately reported^{23,24}. Given the changes taking place in the dentition between primary, mixed and permanent dentitions, the teeth present might be important to consider reporting on by group and yet rarely are, behavior rating, parental oral health literacy and caries risk might also be important for understanding the results of Paediatric Dentistry research. Therefore, guidance that improves the accuracy and transparency of reporting research outcomes in Paediatric Dentistry should benefit researchers, clinicians, patients and other stakeholders involved in the care and well-being of children.

To date, aside from the general guidelines on different research designs, there are no standards available to guide the reporting of studies in Paediatric Dentistry. To address this issue, the ‘Reporting stAndards for research in PedIatric Dentistry’ (RAPID) group has been formed to develop guidelines for reporting research in Paediatric Dentistry. Whilst most of the existing reporting guidelines enhance the reporting of research based on its study design, the RAPID guidelines will seek to improve reporting elements focussing on Paediatric Dentistry across a variety of study designs. These guidelines will help authors to prepare their reports and journal editors and peer reviewers to critically appraise these reports. Furthermore, if the recommendations in the RAPID guidelines are followed, this will help readers to accurately interpret and implement the findings of the published studies, thereby improving research and clinical practice in Paediatric Dentistry.

Materials and Methods

The development of the RAPID guidelines will follow a robust methodology, adhering to recommendations from the Guidance for Developers of Health Research Reporting Guidelines²⁵. This will involve a five-phase process including a Delphi study, an explicit consensus development method that will be designed and implemented in accordance with the Guidance on Conducting and REporting Delphi Studies (CREDES)²⁶. The guideline development process will be led by the project leader (JJ), co-leaders (VD, KJD) and members of the Executive Group (EP, NPTI, JC, DPR, NC, TW, NK, VN, MC) who have experience in conducting research in evidence-based dentistry.

Phase I: Initial steps

The project leader (JJ) conducted a literature search in April 2019 using the PubMed, Scopus, Web of Science and EBSCOhost databases. The search strategy “((((((guideline) OR

standards) OR checklist) OR statement)) OR reporting) AND (("paediatric dentistry") OR "paedodontics") was used to identify existing guidelines in paediatric dentistry. In addition, the leading journals in paediatric dentistry were hand searched, along with the Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network database of reporting guidelines (www.equator-network.org)²⁷. These efforts did not find any existing specific guideline for reporting research in Paediatric Dentistry, supporting the need for the development of such guidance.

Content for the RAPID guidelines will originate from critical appraisal of relevant literature in Paediatric Dentistry using existing reporting guidelines. Principal themes in Paediatric Dentistry will be selected by the Executive Group and at least five scientific articles published in recent years (2017-2019) will be reviewed under each theme. These articles will encompass different experimental and analytical study designs, including study populations with primary, mixed and permanent dentition (Figure 1). The information gathered will be condensed and grouped under each theme to generate items that might be included in the RAPID statement. A checklist will be developed for each theme in Paediatric Dentistry.

Phase II: Pre-meeting activities

In this phase, the Executive Group will oversee a Delphi study involving a diverse group of participants in an iterative process comprising several rounds of information gathering and consensus building (Figure 2). The Executive Group will identify an international multidisciplinary RAPID Delphi Group (RDG) of approximately 60 participants based on the eligibility criteria that will include approximately 20 Academicians, twelve Paediatric Dentists, three Epidemiologists, three Clinical Trialists, three Journal Editors, three specialists in Dental Public Health, three General Dental Practitioners, three Paediatricians,

two Health Economists, two Dental Nurses, two Dental Therapists, two child patients and two carer representatives. The children's input will be obtained under the guidance of their parents or guardians.

Eligibility criteria for RDG members

Members of the RDG must satisfy the following criterion:

- *Academics* - minimum of five years as a teaching faculty in Paediatric Dentistry in a dental school.
- *Paediatric Dentists* - minimum of five years of treating children in the dental setting.
- *Epidemiologists* - minimum of five years involvement in epidemiological studies in relation to oral health in children.
- *Clinical Trialists* - minimum of five years involvement in designing and conducting clinical trials in paediatric dentistry.
- *Journal Editors* - minimum of two years as an editor or associate Editor of a dental journal.
- *Specialist in Dental Public Health* - minimum of five years involvement in school dental health programs or development of oral health policies for children.
- *General Dental Practitioners* - minimum of five years of clinical experience.
- *Paediatricians* - minimum of five years of clinical experience.
- *Health Economists* - minimum five years involvement in assessing healthcare systems and costs involved in delivering treatment and care.
- *Dental Nurses* - minimum of five years clinical experience in assisting dentists in paediatric dental settings.
- *Dental Therapists* - minimum of five years clinical experience in providing preventive and restorative dental care for children.

- *Child patients* - aged 12 to 14 years old and undergoing dental treatment or have received dental treatment in the past two years.
- *Carer representatives* - primary carer of a child patient who is undergoing dental treatment or who received dental treatment in the past two years.

The Delphi process will be conducted using an online platform. The RDG will have a balanced composition of participants, with representation from different geographical regions and socio-economic backgrounds. Potential RDG members will be invited to participate in the consensus process for developing the guidelines. If they agree, they will be sent an information booklet introducing the RAPID project, prepared by the Executive Group. This will explain the aim and process involved in the Delphi exercise.

Delphi study

This is a structured process which uses a series of surveys or questionnaires (called “rounds”) to gather information anonymously until group consensus is achieved²⁵. The first step will be informed by the items identified by the Executive Group in the first phase. These will be scored by RDG members using online forms to facilitate information gathering. The RDG members will be asked to score and comment on each item independently and confidentially.

The objective of this first step in the Delphi study will be to ensure that the items are well phrased, clear, suitable and definitive. Each item will be evaluated on its clarity using a dichotomous scale (‘well phrased’ or ‘needs revision’) and on suitability for its inclusion in the Delphi study using a 9-point Likert scale (1 = ‘definitely not include’ to 9 = ‘definitely include’). The participants will be able to add comments for each item, to provide more information on their scoring²⁸.

The Executive Group will use the feedback from the RDG to refine the Delphi study, the first full round of which will then be opened for input from groups across Paediatric Dentistry. All responses will be anonymized. This first full round will seek opinions on the suitability of each item for inclusion in the reporting guidelines and will also use the 9-point Likert scale (1 = 'definitely not include' to 9 = 'definitely include'). Respondents will also be given an opportunity to suggest additional items. The responses will be used to prepare a second round of the Delphi study, which will include additional items suggested during round 1. Items scored as 3 or lower by at least 80% of respondents in round 1 will be removed for round 2 and the results of the first round will be summarized and provided to the participants as part of the second round. This will include descriptive statistics for the percentage distribution, median and inter-quartile range of the item scores, graphical representation outlining responses and scores, and collective anonymized comments from participants on each item. Reporting median and inter-quartile range for the scores for each item adds robustness because it is independent of the impact of any outliers and less sensitive to skew in the distribution of responses. These data will provide respondents with some indication of the extent of consensus or non-consensus achieved in the first round²⁹. The Delphi study will continue for up to four rounds or until there are no changes between rounds on the items that achieve this level of support. Consensus for possible inclusion of an item in the RAPID guidelines and its eligibility for discussion in the face-to-face meeting (explained below in Phase III) will be defined as the item having scored 7 or above by at least 80% of respondents in the final round.

Phase III: Face-to-face consensus meeting

When this initial agreement has been achieved in the Delphi study, or after four rounds have been completed, the Executive Group will organize a face-to-face consensus meeting to

discuss the items to be included in the final RAPID statement. Members of the RDG will be invited to attend this meeting and it will be organized far enough in advance to maximize participation. The aim is to have approximately 20 participants including five Academicians, four Paediatric Dentists, one Epidemiologist, one Clinical Trialist, one Journal Editor, one specialist in Dental Public Health, one General Dental Practitioner, one Paediatrician, one Health Economist, one Dental Nurse, one Dental Therapist, one carer representative, and one student undertaking postgraduate studies or residency program in Paediatric Dentistry. If fewer than 20 members of the RDG are able to join the face-to-face meeting, other participants who meet the RDG eligibility criteria shown above may be sought. Attendees will receive the meeting agenda, meeting participant list, results of Delphi rounds, draft RAPID statement and papers highlighting the reporting quality in Paediatric Dentistry research, two weeks before the meeting.

Two chairpersons independent of the Executive Group will chair the meeting. The meeting will begin with the introduction of the participants indicating the relevance of their particular experience and the purpose of the meeting. The project leader (JJ) and co-leaders (VD, KD) will then present the rationale for the RAPID guidelines, results of the Delphi study, including a diagram showing the flow of participants through the Delphi study and the included items. Thereafter, a detailed discussion will take place on the information content of the RAPID statement and its supporting evidence. The aim of this will be to agree on the items to include and, although it is anticipated that the views of the participants will converge, there may be instances when voting on some issues may be necessary. In such cases, the decision of a majority of participants will be accepted. Following the selection of the items to include in the RAPID statement, an elaboration and explanation of these items will be discussed to finalize the guidelines. Finally, publication strategy, plans for

disseminating the guidelines, strategies for maximizing adherence to the RAPID guidelines and journal endorsement will be discussed. The meeting will be recorded using audio and video media and comprehensive minutes will be taken for future reference.

Phase IV: Post-meeting activities

The Executive Group will use the inputs from the face-to-face consensus meeting to finalize the RAPID guidelines using concise, unambiguous and comprehensive wording. The guidelines will be supported by an Explanation and Elaboration (E&E) document, with each item supplemented with at least one example of good reporting identified or prepared by the executive group. The drafts for these reports will be shared with the members of face-to-face consensus meeting for their comments. The RAPID statement will be pilot tested among five academicians and five paediatric dentists, before the final RAPID statement is prepared and submitted to a peer-reviewed, open access journal. The guidelines will also be disseminated at national and international events, such as scientific meetings and conferences.

Phase V: Post-publication activities

To increase the uptake of the RAPID guidelines, various strategies will be used to engage relevant stakeholder groups bearing in mind that the RAPID guidelines are intended to help Paediatric Dentists, General Dental Practitioners, patients, parents or caregivers, researchers, academics and other stakeholders. Feedback from the stakeholders will be welcomed and dealt with by the executive group. The RAPID guidelines and the supporting documents will be made freely available from a dedicated website (www.rapid-statement.org) and the EQUATOR Network will be approached to include it in their resources. The executive group will also seek endorsement for the guideline from relevant groups such as the American Academy of Paediatric Dentistry (AAPD), the British Society for Paediatric Dentistry

(BSPD), the Cochrane Oral Health Group (COHG), the European Association for Paediatric Dentistry (EAPD), the International Association of Paediatric Dentistry (IAPD), European Organization for Caries Research (ORCA), the International Association for Dental Research Paediatric Research Network (IADR-PRN), guideline development groups including the United States Public Health Service (USPHS), National Institute for Clinical Excellence (NICE), the Scottish Intercollegiate Guideline Network (SIGN) and the Scottish Dental Clinical Effectiveness Programme (SDCEP), journal editors, trial registries and major funding bodies such as the National Institute for Health (NIH), UK National Institute for Health Research (NIHR), and Health Technology Assessment (HTA). To maximize reach and usability, the RAPID guidelines will be translated into various languages. Efforts will be taken to introduce the RAPID guidelines into the curriculum in research methodology modules of postgraduate students and residency programs in Paediatric Dentistry to promote good reporting quality. Feedback from stakeholders, the emerging literature and advances in paediatric dental treatment and care will inform reviews of the RAPID guidelines and future updates, should these be necessary. The Executive Group will be responsible for maintaining the RAPID website and for periodic consideration of the need to update the guidelines.

Why this paper is important to Paediatric Dentists

- ‘Reporting stAndards for research in PedIatric Dentistry’ (RAPID) group aims to develop guidelines to improve reporting elements focusing on Paediatric Dentistry across a variety of study designs. This study protocol describes the process in which the reporting standards will be established.

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Legends

Table legends

Table 1. Study types and their reporting statements.

Figure legends

Figure 1. Themes for item generation for the RAPID checklist.

Figure 2. A methodological flowchart for developing the RAPID guidelines.

Table 1. Study types and their reporting statements.

No.	Author	Year	Study types	Reporting statements	Website link
1	Gagnier et al ³⁰	2014	Case reports	CAse REport Guidelines (CARE)	www.care-statement.org
2	Kilkenny et al ³¹	2010	Animal studies	Animal Research: Reporting of <i>In Vivo</i> Experiments (ARRIVE)	www.nc3rs.org.uk/arrive-guidelines
3	Von Elm et al ³²	2007	Case-control studies	STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)	www.strobe-statement.org
4	Von Elm et al ³²	2007	Cohort studies	STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)	www.strobe-statement.org
5	Von Elm et al ³²	2007	Cross-sectional studies	STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)	www.strobe-statement.org
6	Schulz et al ³³	2010	Trials	CONSOLidated standards for Reporting Trials (CONSORT)	www.consort-statement.org
7	Bossuyt et al ³⁴	2015	Diagnostic/Prognostic studies	STAndards for Reporting Diagnostic accuracy (STARD)	Refer to www.equator-network.org
8	O'brien et al ³⁵	2014	Qualitative research	Standards for Reporting Qualitative Research (SRQR)	Refer to www.equator-network.org
9	Calvert et al ³⁶	2018	Trials protocol	Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)	www.spirit-statement.org
10	Brouwers et al ³⁷	2016	Clinical practice guidelines	The Appraisal of Guidelines for REsearch and Evaluation (AGREE)	www.agreetrust.org
11	Moher et al ³⁸	2009	Systematic reviews & Meta-analysis	Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)	www.prisma-statement.org



