Special Article

The OHStat guidelines for reporting observational studies and clinical trials in oral health research: manuscript checklist

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ABSTRACT

Adequate and transparent reporting is necessary for critically appraising published research, yet ample evidence suggests that the design, conduct, analysis, interpretation, and reporting of oral health research could be greatly improved. Accordingly, the Task Force on Design and Analysis in Oral Health Research, statisticians and trialists from academia and industry, identified the minimum information needed to report and evaluate observational studies and clinical trials in oral health: the OHStat guidelines. Drafts were circulated to the editors of 85 oral health journals and to Task Force members and sponsors and discussed at a December 2020 workshop attended by 49 researchers. The guidelines were subsequently revised by the Task Force writing group. The guidelines draw heavily from the Consolidated Standards for Reporting Trials (CONSORT), Strengthening the Reporting of Observational Studies in Epidemiology, and CONSORT harms guidelines, and incorporate the SAMPL guidelines for reporting statistics, the CLIP principles for documenting images, and the GRADE indicating the quality of evidence. The guidelines also recommend reporting estimates in clinically meaningful units using confidence intervals, rather than relying on *P* values. In addition, OHStat introduces seven new guidelines that concern the text itself, such as checking the congruence between abstract and text, structuring the discussion, and listing conclusions to make them more specific. OHStat does not replace other reporting guidelines; it incorporates those most relevant to dental research into a single document. Manuscripts using the OHStat guidelines will provide more information specific to oral health research. (*Angle Orthod*. 2024;94:479–487.)

KEY WORDS: Dentistry; Statistical thinking; Editorial policies; Peer review; Medical writing; Research documentation; Reporting guidelines; Evidence-based dentistry

INTRODUCTION

Ample evidence suggests that oral health researchers would do well to improve the reporting of their studies. "Large proportions of articles contain errors in the application, analysis, interpretation, or reporting of statistics or in the design or conduct of research."[1] Oral health clinicians cannot critically appraise the literature without adequate and transparent reporting.

This paper is planned to be copublished in the following journals simultaneously: *Journal of Dental Research*, *Journal of the American Dental Association*, *The Angle Orthodontist*, *Journal of Oral and Maxillofacial Surgery*, and *Journal of Endodontics.* The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style. Any of those journal's citations can be used when citing this article.

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[f] Founded in 1968, the Task Force on Design and Analysis in Oral Health Research is a nonprofit, advisory organization of clinical researchers, basic scientists, biostatisticians, epidemiologists, and other quantitative scientists from universities, private research centers, government, and industry with experience in oral health research or clinical trials.

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Although oral health research is similar to clinical research in other fields, many dental studies have design characteristics that can confound analysis. For example, the unit of analysis can be a single tooth, multiple teeth, individual tooth sites, or a single patient. In longitudinal studies, teeth can be lost without disqualifying the participant from the study, and perhaps uniquely in human research, observational units may be added through the primary and permanent dentition process. Oral health studies sometimes incorporate within-person designs. Examples include split-mouth studies in which patients receive all the interventions but in different portions of the dentition or crossover studies in which patients are randomly assigned to different sequences of interventions. These and other situations common in oral health research can make design and analysis complex.

One approach to improving reporting is the use of a checklist when preparing a manuscript.[2–4] In 1996, the Consolidated Standards for Reporting Trials (CONSORT) was published,[5] and subsequent improvements, extensions, and elaborations have since proliferated. The EQUATOR Network Website lists more than 575 checklists.[6] The aim of the Task Force writing group was to unify the guidance for observational studies and clinical trials into a single tool for oral health researchers for inclusion and dissemination within the EQUATOR network.[6]

MATERIALS AND METHODS

In light of the American Statistical Association's 2016 "Statement on *P*-Values"[7] and the subsequent publication of an issue of *The American Statistician* devoted to "Moving to a World Beyond '$P < 0.05$'",[8] several journals revised their reporting standards.[9–25] At the August 2019 Editorial Board meeting of the *Journal of the American Dental Association*, board members proposed convening a working group to improve the statistical reporting guidelines of the *Journal*. To support the effort, a proposal was submitted to the Task Force on Design and Analysis in Oral Health Research, a nonprofit group composed of statisticians and trialists in the public and private sectors.[26] In November, the Task Force Board empaneled a writing group to develop a set of methodological and statistical reporting guidelines.

On December 10, 2019, the Task Force writing group began to meet online to draft new guidelines. When consensus was reached, the plan was to convene a face-to-face meeting in May 2020, but the COVID-19 pandemic made the meeting impossible. Instead, comments were solicited on draft circulated by e-mail.

In November 2020, the Task Force writing group distributed the draft to more than 85 editors of oral health journals and to all members and sponsors of the Task Force. Subsequently, written comments were received from 12 reviewers. The December 2020 online workshop included an overview presentation (A.B.) and three detailed critiques by the past editor of *JADA*, the present editor of the *Journal of Dental Research*, and an internal Task Force reviewer. The comments and critiques were extensive. The Task Force brought in a consultant in scientific publications with experience in preparing reporting guidelines and the associated documents (T.A.L.). The goal was to incorporate the comments and critiques into two manuscripts: an overview statement that introduced the checklist (OHStat: the Oral Health Statistical reporting guidelines) and an "Explanation and Elaboration" manuscript (the "E&E paper") that gave the background of the initiative and the rationale for including each guideline. The manuscripts were then reviewed by the writing group and approved by the Task Force in September 2021 for eventual publication in the peer-reviewed literature. In 2022, the manuscripts were submitted for review and revisions made.

The Oral Health Statistical Reporting Guidelines

The OHStat checklist is recommended for reporting key aspects of most observational studies and clinical trials in oral health. The 48 guidelines were formulated for authors, reviewers, and journal editors to improve reporting of observational studies and clinical trials (both randomized and nonrandomized trials) involving human participants evaluating an oral health–related biomedical or behavioral outcome.[27] Many of the 48 OHStat guidelines are more focused or homogeneous, which increases the number of items but that make it easier to determine whether an individual guideline has been addressed. In contrast, the 25 CONSORT guidelines are more heterogeneous; they actually ask authors to respond to 53 questions. The same is true of the 22 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, which ask 33 questions.

It is strongly recommended that the checklist be used in conjunction with the E&E paper[28] because each item has important clarifications. Most of the major reporting guidelines and extensions are accompanied by E&E papers; for example, CONSORT for reporting randomized controlled trials (RCTs) generally[29] and HARMS for reporting adverse outcomes specifically,[30] STROBE for observational studies,[31] STARD for diagnostic tests,[32] PRISMA for systematic reviews,[33,34] and ARRIVE for animal studies.[35] As the foundation of the OHstat guidelines, the E&E paper has several purposes:

- It documents the need for better reporting of research in the oral health literature.
- It expands and explains each guideline and cites supporting references.
- It explains why each guideline is important.

- It calls attention to aspects unique in oral health research, such as split-mouth studies and the effect of natural changes in dentition.
- It addresses multiplicity in oral health measures or the complexity that arises from measuring multiple teeth or sites in the oral cavity.
- It makes the case for using modern multivariable and multivariate statistical methods.
- It identifies preferred practices in both research and reporting, such as why estimates and confidence intervals are increasingly being preferred to *P* values for reporting results.
- It presents several examples of good and poor research practices, including common errors.
- It calls attention to specific problems in the literature, such as image manipulation and the insufficient reporting of harms.
- It introduces new guidelines to help authors write and review their manuscripts before submittal.
- It contains additional information on preparing tables, figures, and images.
- It can serve as excellent overview and summary text of the key elements of oral health research.
- It can be a useful checklist for planning oral health research protocols.

Importantly, the guidelines identify the minimum requirements for reporting and publishing observational studies and clinical trials in oral health. Additional information may be needed to adequately report individual studies. Note that guidelines highlighted in gray with a boldface topic heading specifically apply to clinical trials but may also be applicable in observational studies (Table 1).

The checklist is intended to accompany a manuscript submitted for publication. In the right-hand column of the checklist, indicate the page number of the manuscript on which the guideline is addressed. When an item does not apply, N/A is a suitable response. In addition to helping authors and journal editors confirm that the manuscript contains the necessary information, the checklist will also help reviewers find specific information more easily.

Additional guidance for both documenting research and preparing manuscripts for publication can be found in the *AMA Manual of Style* and in *Scientific Style and Format*.

DISCUSSION

Critical appraisal and interpretation of observational studies and clinical trials in oral health will improve with better reporting of the details that support study validity. Obviously, no checklist can address all the important factors of every research design, and articles providing all the indicated information could still be substandard. The guidelines do not ensure the quality of reporting. So by all means, "Break any of the guidelines if it makes scientific sense to do so."[19] Accuracy and transparency are more important than trying to fit an unusual situation into a generic guideline.

The guidelines should not be used to evaluate the quality of oral health studies. The proportion of adequately addressed items is not a surrogate endpoint for study quality. Not all items are equally important, and reporting the required information is no guarantee of quality.

Limitations

The OHStat guidelines do not cover all study designs. Examples of unaddressed designs include systematic reviews and meta-analyses,[34] the performance characteristics of diagnostic tests,[36] equivalence or noninferiority studies,[37] and comparative effectiveness studies using large databases.[38]

CONCLUSIONS

- Evidence-based dentistry is literature-based dentistry.[39] Clinicians, authors, reviewers, and editors should take the time to learn how to accurately report and assess the validity, relevance, and implications of the published literature. The Cochrane Center is the premier site for systematic reviews in health care.[40] Sites such as the ADA Center for Evidence-Based Dentistry[41] and the University of Dundee Centre for Evidence-Based Dentistry[42] make it easy to find clinical guidelines. Such guidelines are based directly on the existing evidence and on the ability to appraise that evidence through the process of critical appraisal.
- Ultimately, patient care is improved when valid and useful research is planned, executed, communicated to practitioners, and widely implemented. Therefore, it is also expected that the OHStat guidelines will serve as a template for updating and informing improvement in oral health research reporting.

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Author Contributions

A.M. Best, T.A. Lang, J.C. Gunsolley, and E. Ioannidou contributed to conception, design, drafted, and critically revised the manuscript; B.L. Greenberg contributed to conception and design and critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of the work.

Disclaimer

This article was written and approved by the writing group authors, who take sole responsibility for the final content. The views expressed do not represent the policies, views, or opinions of the authors' institutions.

Table 1. The OHStat Checklist for Reporting Oral Health Research[a]

No.	Section/Topic	Guideline	Page
Identifying information			
1	Title	Space permitting, identify the research design in the title.	
2	Abstract	Provide a structured abstract, as specified by the journal.	
3	Consistency	Confirm that all information in the abstract is identical to that in the article, especially the conclusions.	
INTRODUCTION: WHY DID YOU START?			
4	Problem	Describe the background, nature, scope, and importance of the problem addressed by the research.	
5	Objectives	State the specific research objectives, including any prespecified hypotheses, in terms of a clinically important outcome measure or measures.	
METHODS: WHAT DID YOU DO?			
6	Design	Describe the overall study design and any variant (e.g., split-mouth, crossover, equivalence) and planned subgroup analyses.	
7	**Approach**	In a therapeutic clinical trial, say whether the study was intended to assess the intervention under ideal and controlled circumstances (an explanatory trial assessing efficacy) or under real-world conditions (a pragmatic trial assessing effectiveness).	
8	**Registration**	If the study is registered, name the registry and give the registration number. State whether the trial was registered before the first patient was enrolled and whether the statistical analysis plan was determined before the data were analyzed.	
9	Ethics	Name the institutional review board that approved the study and give the study identification number. If the study was exempt from review, so state. State whether written informed consent was obtained from participants. Identify any competing interests of the authors and their employers.	
10	Funding	Indicate who funded the study and any role the funder had in planning the study, providing products or technical support during the study, analyzing the data, or publishing the results. Identify any competing interests of the funders.	
11	Setting	Indicate the setting(s) and location(s) of the study.	
12	Eligibility	Describe the population of interest. Give the criteria for eligibility.	
13	Recruitment	Tell how participants were recruited or identified. If done, describe any group assignment, stratification, or matching.	

Table 1. Continued

14	Interventions	Describe the interventions or experimental conditions—including control conditions—and the protocol under which they were delivered.	
15	Variables	Clearly identify the primary outcome variable (the primary response variable), important secondary outcomes, and explanatory variables (exposures, risk factors; interventions; confounders). State the duration of follow-up, if any.	
16	Unit of observation	Name the unit of observation or analysis (e.g., tooth, region of mouth, patient). Justify the use of partial-mouth studies.	
17	Clinical importance	Where possible, but especially in clinical trials, report the minimum clinically important difference for the primary outcome.	
18	**Assignment**	In randomized trials, tell how the random allocation schedule was created, concealed, and implemented. Tell how patients were assigned to groups.	
19	**Blinding**	In clinical trials, indicate who was blinded to what information and how blinding was implemented. If applicable, indicate whether the control intervention could be distinguished from the experimental intervention.	
20	Data collection	Tell how data were collected throughout the study. If patients or information were excluded during the study, describe how the exclusions were identified and the reasons for exclusion.	
21	Measurement	Describe any steps taken to improve the quality and accuracy of measurements. For judgments, describe the adjudicators' qualifications, as well as what they knew about the participant before making their judgment, and report the degree of agreement for their judgments.	
22	Threats to validity	Describe any procedures used to minimize error, confounding, and bias.	
Statistical Methods			
23	Sample size	Explain how the sample size was determined; specify the minimum clinically meaningful difference in the primary outcome variable (effect size) and other values used in a power calculation.	
24	Analytic approach	Identify the key statistical methods used to analyze the data.	
25	Primary analysis	Explain how differences or changes in the primary outcome were analyzed; how associations were estimated.	
26	**Analysis populations**	In randomized trials, indicate whether the analysis was by intention to treat, per protocol, or both. Describe exactly who was included in each analysis.	

Table 1. Continued

27	**Stopping rules**	In clinical trials, describe any interim analyses or stopping rules and indicate who could stop the trial.	
28	Data preparation	Identify any data-cleaning procedures used to modify raw data before analysis (e.g., missing data, loss to follow-up, transformations, creating or combining categories, outliers). Clearly distinguish between prespecified modifications and those arising during analysis.	
29	Modeling	Report the results of any multivariable modeling, including interaction terms. Consider how to best report the models in tables.	
30	Correlated data	Tell how correlated data (e.g., nonindependent or paired) were treated in the analysis. More than one outcome measurement from the same participant (e.g., multiple teeth or across time) usually must be explicitly modeled in the analyses.	
31	Ancillary analyses	Describe any ancillary analyses (e.g., sensitivity analyses, data imputation, assessing assumptions of the analysis, interaction analysis, confounding).	
32	Post hoc analyses	Identify any post hoc or exploratory analyses, including unplanned subgroup analyses, and identify them as such.	
33	Hypothesis testing	If *P* values are reported, identify what is being compared, as well as the statistical test used for the comparison, and report the calculated *P* value (e.g., *P*=0.063, not *P*>0.05 or NS).	
RESULTS: WHAT DID YOU FIND?			
34	Participants	Report the number of participants included and excluded at each stage of sample selection, group assignment, at key times during the study (including those lost to follow-up), and the number analyzed in each group and subgroup (consider summarizing this information in a flow diagram).	
35	Study data	Describe the sample; report baseline demographic and clinical characteristics, including measures of variability, for each group.	
36	Study periods	Define and give the inclusive dates or defining events of any distinct study periods (e.g., recruitment, data collection, outcome assessments, follow-up). Consider presenting this information in a timeline.	
37	Results	Report the results of the outcome variables for each group; provide a measure of precision (95% confidence intervals) for each comparison, focusing on the primary outcome. Distinguish within-group differences from between-group differences.	
38	Deviations	Report any changes in the protocol during the study.	

Table 1. Continued

39	**Harms**	In clinical trials, describe any adverse events or harms, including whether or not they might have been caused by the intervention.	
40	Modeling	Report the results of any multivariable modeling, including interaction terms. Consider how to best report the models in tables.	
41	Exploratory analyses	Report the results of any exploratory analyses (e.g., subgroups, interactions, sensitivity analyses) separate from the primary outcome results.	
DISCUSSION: WHAT DOES IT MEAN?			
42	Summary	Summarize the study and the main results.	
43	Interpretation	Interpret the results cautiously and suggest an explanation for them. Separate the interpretation of the prespecified outcome analysis from post hoc analyses.	
44	Integration	Compare the results with what else is known about the problem; attempt to integrate the study findings with those in the literature.	
45	Generalization	Discuss the generalizability of the results (their external validity).	
46	Implications	If reasonable, comment on the applications or implications of the results on health care delivery.	
47	Limitations	Describe likely sources, direction, magnitude of error, confounding, and bias that were not controlled for in the study design or analysis. Do not cite the standard limitations of the study design.	
Conclusions			
48	Conclusions	List the conclusions in terms of a clinically important outcome measure. Do not restate the results; give their implications.	

[a] The completed checklist should be included with the submitted manuscript. The presence of a page number indicates that the guideline has been met as well as where it is addressed in the manuscript. We strongly recommend that the checklist be used in conjunction with the Explanation and Elaboration document, which clarifies each item.

Task Force Writing Group

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Reviews

Substantial written critiques were also provided by M. Glick, former *JADA* Editor; N.S. Jakubovics, *JDR* Editor; W.M. Thomson, *Community Dentistry and Oral Epidemiology* Editor; B.S. Michalowicz, University of Minnesota; L.N. Borrell, *Community Dentistry and Oral Epidemiology* Associate Editor and City University New York; J.M. Grender and J. DiGennaro, Procter and Gamble; M.J. Hayat, Georgia State University; R. Brignardello-Petersen, McMaster University; P.B. Imrey, Cleveland Clinic and Case Western Reserve University; D. Wu, University of North Carolina; P.G. Robinson and T. Walsh, *Community Dental Health Journal;* and K. Divaris, University of North Carolina. Five anonymous reviewers also submitted comments and suggestions. We gratefully acknowledge their contributions; the final manuscript does not necessarily reflect either their views or the official policy of the organizations they represent.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: All authors have completed the ICMJE unified competing interest form, a copy of which is available from the corresponding author.

In order to encourage dissemination of the OHStat Statement, this article and the checklist is freely available on http://taskforceondesign.org/. This article has been simultaneously copublished in the *Journal of Dental Research*, the *Journal of the American Dental Association*, *The Angle Orthodontist*, the *Journal of Oral and Maxillofacial Surgery*, and the *Journal of Endodontics.* The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style. Any of those journal's citations can be used when citing this article.

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