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A CHecklist for statistical Assessment of Medical Papers: The CHAMP Statement

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Despite efforts to improve the statistical quality of research articles in medical journals, serious statistical errors or deficiencies in the design, analysis, reporting and interpretation still occur, even in highly-ranked journals[1]. Flawed statistics and methodology will negatively affect the study results and could consequently impact public health and patient care[2]. Despite numerous descriptive papers on biostatistics as well as reporting guidelines including CONSORT, STROBE, STARD, REMARK and TRIPOD (and others as listed in the EQUATOR Network; www.equator-network.org) endorsed by many journals[3-7], the methodological quality of medical publications still remains low[8 9]. Editors and reviewers may not have expert knowledge of statistics, and worse, could remain unconvinced about the importance of solid methodology in medical research[10]. Thus, a systematic approach to assess the methodological or statistical aspects of a scientific paper is needed.

Introducing the CHAMP statement

Although there are some excellent guidelines on reporting statistics in medical papers[11-14], and further direction available from a small number of journals, a checklist for peer reviewers (and readers) to use to assess general statistical aspects in a research publication is lacking. In this paper, we present CHAMP, a CHecklist for statistical Assessment of Medical Papers (Table 1) which contains 30 items on general statistical aspects to assess during peer review of original papers. The checklist includes considerations in the following sections: design and conduct (items 1-6), data analysis (items 7-16), reporting and presentation (items 17-23), and interpretation (items 24-30). A complete explanation and elaboration of the 30 item checklist with glossary of statistical terms is provided (see Appendix). The items in the checklist were selected based on a previous BMJ checklist[15], literature review, and experience of the author panel in reviewing the statistical content of numerous papers submitted to a variety of medical journals. The first author produced the checklist draft, the coauthors suggested addition or removal of the items, and all authors approved the final version. Other colleagues provided extensive comments on the paper and are listed in the Acknowledgments.

CHAMP does not cover all topics of medical statistics but focuses on important and common statistical issues that may generally arise. We appreciate that each type of study or statistical model such as a randomized trial or prediction model has specific issues which may not be covered in our checklist. We also note that for some items in the checklist there may be no decisive answer, and thus assessment of the methodology of a paper may involve some subjectivity. Moreover, the issues raised in the checklist are not equally important – e.g., serious errors in design are irremediable regardless of how the data were analyzed, and problems of presentation are less important (as these can be easily fixed) than other statistical problems.

Applying CHAMP during peer-review

Using CHAMP requires some elementary knowledge of statistics, as is also needed for the authors of scientific manuscripts[16]. Further guidance on how to use the checklist can be found in the companion Explanation and Elaboration paper (see Appendix)[17]. Each item of the checklist is a reminder for the reviewer in formulating an overall assessment of the statistical analysis of the paper, and perhaps in providing clarifying comments and revision requests to the authors. Future

study of the CHAMP statement is needed to examine its utility and possibly establish a point system for rating the appropriateness of the statistical and methodological aspects of an original investigation.

In the interim, we hope CHAMP provides a useful tool in the editorial process for editors and referees for the statistical assessment of medical papers.

Design and conduct				
1.	Clear description of the goal of research, study objective(s), study design, and study population	Yes	Unclear	No
2.	Clear descriptions of outcomes, exposures/treatments and covariates, and their measurement methods	Yes	Unclear	No
3.	Validity of study design	Yes	Unclear	No
4.	Clear statement and justification of sample size	Yes	Unclear	No
5.	Clear declaration of design violations and acceptability of the design violations	Yes	Unclear	No
6.	Consistency between the paper and its previously published protocol	Yes	Unclear	No
Data analysis				
7.	Correct and complete description of statistical methods	Yes	Unclear	No
8.	Valid statistical methods used and assumptions outlined	Yes	Unclear	No
9.	Appropriate assessment of treatment effect or interaction between treatment and another covariate	Yes	Unclear	No
10.	Correct use of correlation and associational statistical testing	Yes	Unclear	No
11.	Appropriate handling of continuous predictors	Yes	Unclear	No
12.	Confidence intervals do not include impossible values	Yes	Unclear	No
13.	Appropriate comparison of baseline characteristics between the study arms in randomized trials	Yes	Unclear	No
14.	Correct assessment and adjustment of confounding	Yes	Unclear	No
15.	On-support inference i.e., no model extrapolation to the region not supported by data	Yes	Unclear	No
16.	Adequate handling of missing data	Yes	Unclear	No
Reporting and presentation				
17.	Adequate and correct description of the data	Yes	Unclear	No
18.	Descriptive results provided as occurrence measures with confidence intervals, and analytic results provided as association measures and confidence intervals along with P-values	Yes	Unclear	No
19.	Confidence intervals provided for the contrast between groups rather than for each group	Yes	Unclear	No
20.	Avoiding selective reporting of analyses and P-hacking	Yes	Unclear	No
21.	Appropriate and consistent numerical precisions for effect sizes, test statistics, and P-values, and reporting the P-values rather their range	Yes	Unclear	No
22.	Providing sufficient numerical results that could be included in a subsequent meta-analysis	Yes	Unclear	No
23.	Acceptable presentation of the figures and tables	Yes	Unclear	No
Interpretation				
24.	Interpreting the results based on association measures and 95% confidence intervals along with P-values, and correctly interpreting large P-values as indecisive results, not evidence of absence of an effect	Yes	Unclear	No
25.	Using confidence intervals rather than post-hoc power analysis for interpreting the results of studies	Yes	Unclear	No
26.	Correctly interpreting occurrence or association measures	Yes	Unclear	No

27.	Distinguishing causation from association and correlation	Yes	Unclear	No
28.	Results of pre-specified analyses are distinguished from the results of exploratory analyses in the interpretation	Yes	Unclear	No
29.	Appropriate discussion of the study methodological limitations	Yes	Unclear	No
30.	Drawing only conclusions supported by the statistical analysis and no generalization of the results to subjects outside the target population	Yes	Unclear	No

Fig 1. Checklist for Statistical Assessment of Medical Papers

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