

TransMedRi Workshop in Biostatistics:
Critical evaluation of statistical analysis in scientific paper

The role of statistical reviewer in
 biomedical scientific journal


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Sources


- **Petrovečki M.** The role of statistical reviewer in biomedical scientific journal. *Biochemia Medica* 2009;19(3):223-30.
 – www.biochemia-medica.com
- **Lukić IK, Marušić M.** Appointment of statistical editor and quality of statistics in a small medical journal. *Croat Med J* 2001;42:500-3.
 – www.cmj.hr

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Statistics

- scientific discipline
- scientific tool
- "mystic" procedure for data analyses
- mandatory
- required
- inevitable



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How much do we know about it?

- graduate medical study:
 - mandatory course on second year
- doctoral study:
 - mandatory course on first year
- principles?
- calculations?
- data computation?



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... and journal editors?

- only 30-60% of published papers used acceptable statistics (Altman D. *Stat Med* 1998;17:2661-74.)
- Tyson et al. (*J Pediatr* 1983;102:10-3.) reported even less than 15%

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Does it matter?

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Does it matter?




TEETERING & HOPE
acrylic on paper, 52x62 cm
by Marinka Premus

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Solution


- introducing statistical reviewer e.g. statistical editor



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Paper review process

- professional peer review
- ethics review
- statistical review (including statistical and epidemiological methodology review)



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Statistical review

- goal: to conclude if the study was properly conducted and results presented and to revealed possible errors
- from title to "the smallest" letters
- sometimes even includes original protocol of a study
- result:
 - written report containing clear and straightforward suggestions and comments highlighting issues that raise questions

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Typical statistical errors

- errors in study design
 - no randomization in controlled trials; inappropriate control group, etc.
- errors in data analysis
 - unpaired test for paired data, etc.
- errors in data presentation
 - standard error instead of standard deviation to describe data; pie charts to present distribution of continuous variables, etc.
- errors in data interpretation
 - "caused if associated" type of reasoning; interpretation of poorly done study as a well done one...




Altman D. Stat Med 1998;17:2661-74

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Decision

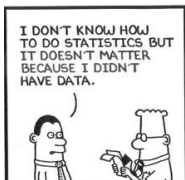
- errors in data analysis, interpretation or discussion of results - changes can be made and paper improved (usually some proposals given)
- errors in study design - paper usually rejected



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Friendly advice

- learn statistics (or find a good statistician) **before** making the final study protocol
- use the same checklist as statistical reviewers



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General comments

- properly reported statistical methodology according to the IMRaD structure
- logical and rational concept of the study and use of appropriate study design
 - case-control, cross-sectional, cohort, randomized controlled trial, etc.
- logical presentation of the study
- valid assumptions about the distributions of variables
- general statistical acceptance of the paper

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Study design

- clear aim of the study, clearly stated primary and secondary aims of the study
 - study design appropriate for the study question
- clear hypotheses (primary, secondary)
- power calculation and sample size calculation
 - ability of a study to provide an accurate description of target population
- description of treatment and control groups (in enough detail), description of treatment interventions

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Study design

- response rate for surveys
 - with a valid explanation for rates <70%
- planned duration of the study, stopping rules, explanation of the reasons for early termination of the study
- statement on authors and assistants, such as observers, raters, interviewers, and statisticians
- report of relevant data for multicenter clinical trials

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Methodology and data analysis

- description of the source of subjects and data
- clear inclusion and exclusion criteria
- explanation of the sample formation, sample size, randomization, allocation, stratification, matching, and blocking (in enough details, when appropriate)
- adequate sample size and number of variables
- data on subjects recruitments, follow up, endpoints, censoring, blinding, and interventions

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Methodology and data analysis

- clear list of variables, interpretation of uncommon variables, definition of the primary and secondary outcomes and prognostic measures
- possible confounding variables
- missing data reported and management of missing data described
- explanation of the data measured
 - presentation of units of measurement, validation of instruments and questionnaires

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Methodology and data analysis

- valid description and sufficient explanation of statistical tests
 - list of all statistical tests used in the analysis
- reasonable statistical methodology, available references for uncommon tests, explanation of unusual data loading



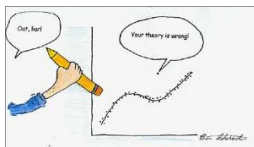
Methodology and data analysis

- appropriate statistical analysis
- appropriate use of statistical methods
- report of alpha and beta errors, level of significance
- statistical software
 - name, source, version, and operating system if uncommon



Data presentation

- clear baseline demographic and clinical characteristics
- clear data presentation, with no questions raised
- justified use of “data not presented”
- valid explanation of outliers



Data presentation

- self-explanatory tables and figures
 - explanation of statistical data, abbreviations, and symbols
- no repetition of data in tables, figures, and text
- proper use of statistical language and statistical terms (*normal, random, significant, sample, correlates, etc.*)
- appropriate and adequate statistical measures along with measures of errors and uncertainty
 - mean for data with normal distribution, median for others, standard deviation with the mean, range with the median, confidence intervals, etc.

Data presentation

- measured values expressed to the appropriate precision
 - no decimals in mean values for measurements with no decimals; exact P values - three decimals; no decimals in percentages; regression and correlation coefficients - two decimals, etc.
- statistical data presented properly, in accordance with the methods used
- transparent flow of participants through the study
- explanation of the changes in the number of subjects, if present
 - missing data, loss to follow-up, etc.


Data interpretation

- justified conclusions, data support findings and conclusions
- discussion based on the presented results
- statistical significance distinguished from clinical significance



Data interpretation

- no interpolation or extrapolation without explanation
- no generalization without proper justification
- discussion of methodological limitations of the study, bias and limits of statistical inference, and possible sources of errors



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Suggestion

- *“If you need **statistical advice** on your research problem, you should contact a statistical consultant... If you think your **research is important**, then it is also important to get good advice on the statistical design (i.e., **before** you start collecting data) and analysis.”*
- Russel Lenth, Department of Statistics and Actuarial Science, The University of Iowa, SAD
- <http://www.stat.uiowa.edu/~rlenth/Power/index.html>

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REVIEWER WANTED



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The top ten reasons to become a statistician



Deviation is considered normal.
 We feel complete and sufficient.
 We are "mean" lovers.
 Statisticians do it discretely and continuously.
 We are right 95% of the time.
 We can legally comment on someone's distribution.
 We may not be normal but we are transformable.
 We never have to say we are certain.
 We are honestly significantly different.
 No one wants our jobs.

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