Editorial Commentary

To reveal or to conceal: Appropriate statistical analysis is a moral obligation for authors in modern medicine

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Research is an integral part of science, and the strength of clinical or basic research vests in robust statistical analysis of data for the practice of evidence-based medicine. Though statistics, historically and at present, is still a tool in gambling, it is an integral part of research methodology and involves the collection, organisation, and analysis of data as a sample of the entire population. This allows for a robust study design to reach a logical conclusion. This is often neglected during the planning stage of a study and is applied after data is collected. It allows us to choose the right sample size and apply statistical findings in order to reduce bias and errors arising from the research process.

The researcher puts forth a hypothesis and can use simple methods to present data like mean and distribution or interpret it—using the available statistical methods, especially variance—as patterns or trends to arrive at the proper conclusion. This can involve simple graphs and tables for a descriptive analysis, especially when data are skewed from normal, inferential analysis to represent the entire population when the sample size is limited, or other methods depending on the need and purpose of the study [Figure 1].

Ali and Bhaskar,[1] in their article, emphasised the importance of knowing the basic concepts of statistical methods which would help one to publish valid and reliable results. Failure of such knowledge can lead to faulty conclusions, induce errors, and undermine the significance of the article. To quote the authors: 'Bad statistics may lead to bad research, and bad research may lead to unethical practice.' Lang and Altman[2] set forth the Statistical Analyses and Methods in Published Literature (SAMPL) guidelines.

Farrokh Habibzadeh,[3] the former president of the World Association of Medical Editors, states that precision should be a norm for reporting numbers. Standard error of the mean (SEM), as an index of data dispersion, should not be used in a manuscript while reporting. Normally and non-normally distributed data are to be described using mean (standard deviation [SD]) and median (interquartile range [IQR]) with 95% confidence interval (CI), which is essentially a measure of precision to represent main outcome variables. *P*-value is simply an estimate for rejecting the null hypothesis when it is actually true.

An inappropriate practice, referred to as '*P* hacking' involves comparing a large number of variables and reporting them as 'statistically significant' even though it is not the primary objective of the study.[4] This should be strongly desisted by authors.

Figure 1: Types of statistical research methods (https://www.enago.com/academy/statistics-in-research-data-analysis)

Literature surveys show that statistical analyses often do not convey important information involving credibility issues as there is little transparency and an inability to reproduce the same results. The basis of statistical analysis, either through the Bayesian or the frequentist approach, is that data are represented with a mathematical model and this reflects the data used.[5]

Which approach would be better in current times is debatable. Bayesian analysis is based on the science of probability and seems to be substituting or replacing the frequentist approaches based on the *P*-value. It integrates knowledge from fresh trials with pre-existing knowledge, thereby reducing uncertainty and changing management strategies.[6]

Bayesian models begin with a prior probability distribution for all the parameters. This includes both the likelihood function (which expresses the probability of data given the parameter values) and the prior probability distribution (which is an expression of the probability of the parameter values) before taking the new data into consideration. New data is incorporated into the analysis, and the probability distribution is shifted towards parameter values that are relatively consistent with the data. 'Posterior distribution' is the term used for the credibility across parameter values which are re-allocated.

With different approaches and results, authors can flexibly approach data rather than following a single method. Results from either method may not always lead to the same conclusions. Data with a frequentist approach may suggest that a logical way may be to use methods that reduce random error to prove the null hypothesis. Using posterior probability, results may suggest that relative to the various hypotheses, one is most likely followed by the others and the last is most unlikely. Both approaches point to the need for data being more robust.[7]

The prior distribution is influenced by earlier research, which can affect the posterior distribution. This can sometimes depend strongly on the choice of the prior distribution, because of which, the researcher needs to justify the choice of priors as also explicitly explain the prior distribution on the parameters.

Statistics benefits from transparency, an acknowledgement of the uncertainty of the analysis, and it being open to other or alternate interpretations of data. Wagenmakers *et al*.[8] propounded that to inculcate these into practice, seven tenets of statistical procedures should be incorporated into manuscripts, namely, (1) visualising data by using charts/plots/diagrams; (2) quantifying inferential uncertainty like using confidence intervals; (3) assessing data pre-processing choices using different ways of grouping subjects by age/sex/race, etc.; (4) reporting multiple models using alternate statistical tests; (5) involving multiple analysts by having different statisticians analyse the same data; (6) interpreting results modestly by acknowledging probable limitations; and finally by (7) sharing data and code so that others can draw their conclusions too.

Statistical methods and practices continue to evolve, and statistical analysis must be used by authors to report critical data appropriately, especially in relation to clinical relevance. Many software packages are available which are free for use.

Authors should, ideally, seek the advice of a statistician when planning a study and present the study design in the manuscript, addressing it as the type (randomised/non-randomised/observational, etc.), prospective or retrospective, blinded or non-blinded, etc. They should mention the sample size and how it was calculated, with emphasis on sampling errors (a Type I error is a false positive conclusion where the risk of committing this error is the significance level (alpha or α) usually set at 0.05 or 5%, while a Type II error is a false negative conclusion. Type II error rate is designated beta (β), wherein a study may not have enough statistical power, i.e. the extent where a test can correctly detect a real effect when there is one. An 80% power level or higher is generally considered acceptable.) with

P-value and its significance level. The various tests for statistical significance used to analyse the data and how it data is presented (chart, pie/bar diagrams, confidence intervals, interquartile ranges, etc.) are to be highlighted. A CONSORT diagram is to be submitted, along with approval from the ethical committee or institutional review board and registration with the Clinical Trials Registry of India.

As raw data are unavailable for editors and reviewers, and with post-publication review becoming relevant, editorial staff, when doubtful of results, should request the authors for raw data to enable re-analysis so that mistakes can be identified and corrected or manuscripts even be retracted. This requirement should be included in instructions to authors who are interested in publishing their work and data in peer-reviewed journals.

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