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Statistical requirements for reporting nutrition research

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Editorial

Statistics involves the use of mathematical theories to design research surveys and experiments; collect, analyse and present quantitative data; and interpret the results of the analyses[1]. The profession of statistics, like nutrition, is becoming an increasingly specialized with identified domains of expertise. Advances in computing power have made previously intractable mathematical calculations possible through iterative simulation techniques and the number and diversity of statistical methods available is rapidly expanding. Diversity in statistical methods and their use in many fields of research has resulted in a range of terms being used to represent the same technique and a range of specialized software being available (often at no or little cost) to perform various analyses. At times this can make the interpretation of the statistical analysis section of a paper complicated and may leave the nutrition professional confused about what is required for publication of statistical methods.

The International Committee of Medical Journal Editors[2] state that in writing about statistical methods for publication one should “Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results”. This is also quoted in the CONSORT 2010 statement for transparent reporting of trials[3]. What then is required for the knowledgeable reader to repeat your analysis? It maybe surprising to know that it helps to refer to statistics in a number of ways and in a number of sections of the manuscript.

Introduction: Firstly it is necessary to state your primary hypothesis clearly in a way that lends to formal testing, for example “The hypothesis was that there was a significant positive correlation between fat intake and body weight” rather than “the hypothesis was there was a relationship between fat intake and body weight”. The first tells the reader exactly how the hypothesis will be tested (correlation) the second does not [4]. Secondary aims should be stated in the introduction in a similar manner.

Methods: In any form of research it is important to include details of how your sample was selected (for example a convenience sample) to allow readers to make decisions about the generalisability of your results. Details of the randomisation procedure should be included if relevant to your design.

The **data analysis** section should;

- Specify the statistical package used (for example SAS V9.2 SAS Inc Cary NC or SPSS V19.0, IBM Corporation, Somers NY) and any variations from the default procedures in general purpose packages. For example the default procedure in the linear regression menu of SPSS V19.0 is an entry model. Frequently a stepwise, forward or backward regression procedure is used and this should be indicated.
- State the alpha level used for determining statistical significance, generally this is 0.05 (or 5%) for nutrition related research. It should also be stated if adjustment is made to correct for multiple comparisons for example a Bonferroni adjustment.

- State whether tests are one or two sided. Two sided tests are the norm in the nutrition literature, the use of a one sided test will need to be justified [5].
- Specify the analyses used for both the primary and secondary aims of the study. Ensure that every procedure used in the results is mentioned in the analysis section even if further information about specific procedures is required in the results, tables or figures. If using standard statistical procedures such as t tests, analysis of variance, regression or correlation reference to a general biostatistics text will suffice. For more advanced procedures, for example mixed models, or methods not usually addressed in biostatistics texts, for example factor analysis, a method specific reference or referenced software manual should be used. The major statistical software companies produce referenced texts and manuals on the use of many of their more advanced procedures. If the statistical method is novel or requires substantial programming a peer reviewed paper reference is required and the code should be made available.
- State how assumptions made about the data will be tested, for example include any relevant tests for normality. Many tests are robust to assumptions of normality, particularly with large samples and too much focus is often given to this assumption without considering other important assumptions for example the independence of measurements and homoscedasticity (similarity of the variance).
- The use of non parametric tests for continuous data should be justified. Parametric tests are generally more powerful (at least for smaller samples [6, 7]) and their use is usually preferred. Parametric methods maybe the only option for more complicated analyses, although non parametric methodology is expanding. Data transformation should be used to improve the normality of skewed variables [8]. For decades there has been debate about the most appropriate methods (parametric or non parametric) for analysis of ranked ordinal scales which are often used in nutrition research. It is not surprising researchers, and reviewers, have difficulty deciding on an analysis. Likert scales, quality of life scales, and many questionnaires collect data using ranks from 0-10 or “strongly disagree” to “strongly agree”. Analysis of this data should be considered in the study design, often the questions addressed with this data use chi square analysis of logistic regression and the data are nominal or categorical, however if you intend to compare groups on the basis of responses to likert scales you should think about how to treat the data in the study design. Again a parametric approach is preferred however researchers using these methods should be aware of the controversy as analysis of this data may have to be defended in review. Norman provides a comprehensive review of this area [9]. A more general review of non parametric methods for nutrition research has been published by Harris et al. [10].
- Specify why the sample size was chosen and provide details on formal sample size estimations [4, 11].
- Discuss any missing data due to study dropout or non compliance and how this will be managed in the analysis [12, 13].

The **results** section should start with a description of your study sample. A combination of tables, figures and text should be used to present your findings. This makes the information more appealing to readers. Key variables, such as those relating to the primary and secondary hypotheses should be described using appropriate summary statistics.

- For normally distributed data the mean and standard deviation (SD) or confidence interval describe the variability in the study sample. Standard errors of the mean are used only in inference where you wish to compare your sample mean to a population mean and this is rarely the case in nutrition studies. The standard error of the mean is calculated as the $\frac{\sigma}{\sqrt{n}}$, where σ is the sample SD and n is the sample size, and as such is always smaller than the SD. It often "looks better" and is often used for this reason particularly in figures. The two are often confused [14] and it is important that whichever is used is clearly labeled.
- Skewed data should be presented as a median and interquartile range. Dietary intake data is often skewed to the right. If data is transformed the raw medians and IQR prior to transformation are generally presented in the descriptive statistics to assist with interpretation.
- Proportions should be used for categorical data, again a measure of variability (confidence interval) should be included when inference is made.
- Be careful when working with variables that have a large number of zero values for example values for alcohol intake. Assumptions of conventional tests are not always met by these variables and consideration to their analysis (for example non parametric testing or treating them as categorical variables) should be given. The distributional assumptions of these variables are understudied in the nutrition literature. For example a case could perhaps be made for alcohol intake that there are two distributions, those who drink and those who do not. It would be wise for those working with these "zero inflated" variables to seek statistical advice.
- Report the exact *p*value rather than a range eg $p<0.05$ or "Not significant"(NS). Not significant can be misleading in small sample sizes where the power to detect an effect maybe limited and an exact *p* value may indicate a potential effect if a larger sample were studied (this is an example of type 2 error [15]). There are times when a *p* value > 0.05 is of interest for further exploration, for example it is suggested that all variables in a univariate logistic regression with a $p<0.25$ be considered for a multivariate model [16]. *P* values should be regarded as a continuum from 0-1 rather than just significant or not significant [17]. Fisher when first suggesting this value (0.05) did not intend for it to be used as an arbitrary cut-off [11].
- Each analysis should provide clear details on the number of subjects included and whether subjects have been excluded due to drop out, non compliance, survey non completion or have been excluded because of implausible or outlying values.

If publishing a study assessing the validity and/or reliability of a dietary intake method be sure to understand the definitions and types of validity and reliability [18] and be familiar with the literature on the methods for statistical analysis for comparing agreement between two clinical methods [19]. Studies developing new dietary assessment tools are common and have been widely published in nutrition journals. Standards for these trials are increasing, for example a systematic review has recently been published examining the validity of dietary assessment methods compared with doubly labeled water data for energy [20]. Individual dietary assessment tool validation studies must be designed carefully to ensure an adequate power, particularly if relative validity with another tool such as a food record is used. Studies validating dietary assessment instruments for micronutrients should consider the use of a biomarker and analyse the results using the method of triads [21].

It is an exciting time in statistical methodology. The development of the free comprehensive user driven software package 'R'[22] has made statistical analysis available free of charge to all and this, in addition with the computing advances, has led the explosion of new methods and variations on old methods. The increased computing power has also led to renewed interest in the Bayesian "philosophy" [23] of statistics and the increased use of these methods in publications. 'R' is still not considered user friendly and has yet to gain full acceptance in some fields of science as the programs are written by users, and in some cases can lack scientific documentation and may contain errors. Authors using 'R' should fully reference the source code used or if the code has been specifically written for their analysis should provide the code on request.

Despite these advances, many studies in nutrition research can be answered by simple designs with straight forward analyses. The "parsimony principle" [24] is the term used in statistics to advocate that when several different models or analysis strategies are available, all of which will answer the research question, the simplest is preferred.

References on guidelines for statistics for publication aimed at the non statistician include Altman et al [25] and Greenhalgh [26].

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2 International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. (|Also available from: www.icmje.org, accessed 27th May 2011).
3 Item 3-12a - Statistical methods used to compare groups for primary and secondary outcomes. (|Also available from: www.consort-statement.org, accessed 27th May 2011).
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