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SPECIAL EDITORIAL

The role of a biostatistical and epidemiologic review for a clinical journal



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Dr Vahratian is the Statistical Consultant for the International Journal of Gynecology and Obstetrics (IJGO) and an Assistant Professor in the Department of Obstetrics and Gynecology at the University of Michigan Medical School, Ann Arbor, USA. She received her bachelor's degree in statistics and women's studies from the University of Michigan, a master's degree in public health with a focus on reproductive and perinatal health from Johns Hopkins University, and a doctoral degree in maternal and child health epidemiology from the University of North Carolina. During graduate school, Dr Vahratian completed an internship at the Centers for Disease Control and Prevention and a fellowship at the National Institutes of Health. Her research area and publications focus on the health of women prior to pregnancy and its effect on pregnancy outcomes and maternal postpartum mental and physical health. In particular, she is interested in the effect of obesity and diabetes on contraceptive decision-making, pregnancy planning, and perinatal outcomes. She is committed to developing strategies to empower women to be proactive about their health during their childbearing years-pregnancy is a critical period for women and health during this period can have long-term effects on a woman's quality of life.

Although statistical consultants have a visible presence on the editorial boards of peer-reviewed obstetrics and gynecology journals, their role may be less apparent to a journal's readership. While the presence of a separate statistical review may be vexing to some authors, its purpose is to offer the editor and authors constructive feedback on the quality of the study's design, analysis plan, and findings.

As part of the IJGO's peer review process, the editor will forward a select number of manuscripts per month to me, as the statistical consultant, for a biostatistical and epidemiologic review. My evaluation will provide detailed comments not only on the methods and results sections, but also on the rationale for the study and the synthesis of the literature provided. As such, this review will take into consideration not only how the analysis was executed, but also the logic behind the design of the analysis. It is our hope that this approach will provide authors with more concrete feedback, while strengthening the science published in the Journal.

Each article that undergoes a biostatistical and epidemiologic review receives a full read-through. In the introduction, we are looking for text that sets the tone for the rest of the article. It should be brief (approximately one double-spaced page of text) and summarize what is known about the issue and what remains uncertain. A statement that clearly outlines the purpose of the study should conclude this section.

The methods section should provide sufficient detail for the reader to be able to replicate the study on their own. Key components of the methods section include a brief description of the study design (e.g. randomized controlled trial; cohort study, prospective or retrospective; case-control study; cross-sectional study), study population (e.g. inclusion and exclusion criteria, timeline, recruitment strategies), measurement of exposure and outcome, and analysis plan. The analysis plan should be presented in a logical manner based on: (1) how the analysis was performed; and (2) how the results are described in the next section. For example, descriptive statistics are usually performed first, then multivariable analyses. Provide the reader with the statistical tests used to assess statistical significance and the *P* value used as the cut-point. If a statistical package (e.g. SPSS, SAS, Stata) was used to perform these analyses, please include this information in this section.

In the results section, we are looking for an overview of the sociodemographic characteristics of the study population, followed by the results of the descriptive and multivariable analyses performed. The text should focus on key themes and findings, while corresponding tables and figures should provide more detail. Tables and figures will be reviewed for completeness, utility, and ease of interpretation. Tables should be able to stand on their own, independent of the manuscript; thus, acronyms are discouraged.

The discussion section is an opportunity to compare your results with previous studies. It is also a section to acknowledge your study's strengths and limitations. Rather than reiterating the findings of your study, this section should provide your findings in context and suggest areas for future investigation. Your concluding paragraph should focus on what can be summarized from this analysis. Be careful not to speculate beyond the scope of the study. For instance, a statistically significant association does not necessarily imply a causal relationship. Consideration must be given to other factors, such as the strength of the association, consistency in findings, temporality, and biologic plausibility before such a statement is possible [1].

Overall, we are looking for a cohesive argument from start to finish. Solid manuscripts should include: (1) a testable aim in the introduction; (2) a description of the study, its participants, and the analysis performed; (3) a summary of the results that includes detailed tables and figures where appropriate; and (4) a discussion that translates the findings to the broader literature and touches on their clinical and public health significance. In offering both general and specific comments to the authors as part of the review, we hope that this process provides our authors with a different perspective on their work and the tools to strengthen their manuscript upon resubmission.

As our readership is global in nature, we welcome manuscript submissions from all regions of the world. The translation of basic and clinical research into clinical practice is dependent not only on the strength of the evidence but also the generalizability of the study findings and practicality of the intervention under consideration. The emergence of evidence-based medicine in the early 1990s has sparked a wealth of information on manuscript preparation [2] and the scientific evaluation of the peer-reviewed literature [3–5] in both print and electronic media. Authors should peruse these resources, in addition to the Journal's *Instructions for Authors* (available online at: www.ees. elsevier.com/ijg), in advance of their submission to the Journal, to strengthen their work for publication.

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