



REPLY TO  
ATTENTION OF

**DEPARTMENT OF THE ARMY  
SAN ANTONIO MILITARY MEDICAL CENTER  
FORT SAM HOUSTON, TEXAS 78234-6200**

**Editor of *World Journal of Hepatology*  
ESPS Manuscript NO: 29457**

**RE: Stastical Review of the Manuscript entitled: Hepatitis C eradication with sofosbuvir leads to significant metabolic changes**

Upon submission to the World Journal of Hepatology, the editors made recommendations to have the the article in question reviewed by an expert in the field of medical statistics. As a PhD Statistician at Brooks Army Medical Center this responsibility was bestowed upon me. The reviewers requested the following points be addressed: (1) Statistical methods are adequately and appropriately described when they are used to verify the results; (2) Whether the statistical techniques are suitable or correct; (3) Only homogeneous data can be averaged. Standard deviations are preferred to standard errors. The number of observations and subjects (n) is given. Losses in observations, such as drop-outs from the study, are reported; (4) Values, such as ED50, LD50 and IC50, have the 95% confidence limits calculated and have been compared by weighted probit modeling (using the functions described by Bliss and Finney); and (5) The word "significantly" is replaced by its synonyms (if it indicates extent) or the P value (if it indicates statistical significance). Upon review of the manuscript, I found some points of contention based on this criteria that needed to be addressed by the manuscript authors.

Upon review it was noted that subjects were observed both before and after treatment of HCV. Analysis of several variables was conducted comparing subjects prior to HCV treatment to the results post-treatment. The proper method for conducting such analysis would include either a paired t-test, or Freidman's Sign Rank Test. However, there was no mention of these methods used in the manuscript. Upon interviewing the authors of the manuscript, it was discovered that indeed paired t-tests were used to conduct the analysis comparing pre vs post treatment of HCV. As the statistical reviewer, I advised them to correct this in the Methods section of the manuscript.



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Again, upon review, I noted the following statement in the manuscript, "*Fisher's exact test and chi-squared test were used for statistical analysis between group comparisons of categorical data.*"

Although, this is a valid way to test categorical data, there was no categorical data analysis conducted in the manuscript. Therefore, I requested this statement be removed from the methods section.

There were 2 instances in the manuscript appeared to use the word associated with "significant", when not references or reported statistical findings. The authors were asked to correct this and remove the word from the manuscript.

Upon changes requested and implemented by the authors of this manuscript, I approve its publication in the manner as it reflects on statistical methodology and analysis.

Regards,

  
James Aden

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Revised: 07 APR 03



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