Reviewer’s report

Title: Evaluating the utility of early laboratory monitoring of antiretroviral-induced haematological and hepatic toxicity in HIV-infected persons in Cameroon

Version: 2 Date: 30 July 2014

Reviewer: William Kwame Boakye Ansah Owiredu

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Suggested Corrections

Abstract

Background:

Line 29: delete “the”
Line 31: avoid the use of first person plurals e.g. “we”
Line 36: authors need to enumerate the “factors associated with abnormal changes…” as stated.
Line 40: consider revising the use of “rose from” and indicate with “baseline” and “two weeks follow-up” for ease of comparison.
Line 45: authors stated in Line 29 that the aim of the laboratory monitoring was necessitated by the inclusion of AZT but here (line 45) emphasis was rather placed on the use of stavudine; any possible reasons?
Lines 49 & 50: the conclusion as arrived at presents no new findings as authors stated in Lines 89-90 with valid references that “the incidence of ART-induced liver injury is low and might even be a rare occurrence after a fortnight of ART initiation”.

Introduction

Line 66: correct to read: “antiretroviral therapy does not …”
Line 67: correct to read “only prevent”
Line 77: authors should please take a look at the use of CD4 >250 cells/mm3 in relation to the sentence structure.
Line 99 – 100: with support from Lines 89-90, what will be the motivating factor to “assess if there were any pathological changes to biochemical markers”? 
Line 102: consider revising the sentence with reference to the use of “whose”

Methods

Line 110: delete “of” preceding “reference”
Line 128: correct “matrimonial status” to read “marital status”
Line 116: please consider including the exact period and duration of the study.
Line 134: define “ARV”
Line 136: correct “by the” preceding Epi-Info to read “using”
Line 140: correct “based on” to read “using”. Delete R1 GOT/ASAT up to ALAT.
Line 144: delete “based on the URIT…” up to L21.
Line 151: how did authors include “missing observations” when found to be differential among subgroups given the fact that the data has been checked for logical inconsistencies in Line 148??
Line 155: was haemoglobin level <10 g/dL chosen as the cut-off for anaemia irrespective of gender and age??
Line 163: did authors conduct tests of normality or normally was assumed? Please indicate.
Line 170: which value of “p” was considered significant in this study?

Results
Authors should consider presenting mean values “before” and “after two weeks” in a tabular format for ease of observation and clarity of the distribution among the varied groups.

Line 175: revise “who” preceding 105 (68.2%)
Line 176: authors should consider presenting results for “baseline” and “two weeks after treatment” for ease of understanding.
Line 178 – 182: are the results as presented showing “baseline” or “two weeks” follow-up??
Line 189: no mention of stavudine was made among the drugs given but stavudine was the drug implicated to cause hepatotoxicity in Line 45 of the abstract.
Line 206: what was the “baseline” and “two weeks” mean platelet results for which the decrease is quoted as $0.03 \pm 1.18 \times 10^5$ cells/µL.
Line 216: what does “chance finding” as used here relate to??
Line 217: what was the essence of correlating fasting blood sugar and ALAT?
Line 223 & 224: please rephrase the sentence “after correcting for each other”
Line 227 & 228: authors should take a re-look at the statement that “subjects who reported using and ITN were at 4.6-fold increase in odds of developing anaemia”. Is this really the outcome of model, or perhaps there was a coding error? Do author therefore recommend the continuous use of ITN’s because it predisposes users to anaemia??

Discussion
Line 232 & 233: this does not present a finding as indicated earlier in Lines 89-90 of the introduction.
Line 240: correct “regimens” to read “regimen”
Line 242: correct “cut-offs” to read “cut-off”

Line 242 – 244: the statement that sample size, laboratory reference intervals or cut-off points and the short duration of exposure to ART may explain observed differences is ambiguous and must be clearly outlined with reasons. In short all of these could have been taken into consideration before designing the study; if allowed to stand, this single statement draws credibility from the validity of the study.

Line 245: correct the word “prevalence” preceding difference.

Line 246: define LEE

Line 252: the role of stavudine in the study must be clearly outlined.

Line 252 – 253: if the assertion as presented in the sentence is true, what data on ITN did authors collect from the participants? Can peer-reviewers trust all other results as presented by authors?

Line 307: reference is continually made to univariate analysis but there is no data to show this whatsoever in the study. Could authors present the values?

Line 314 – 324: the litany of limitations stated is being presented as excuse for shortfalls in the study. Most of these limitations could have been effectively catered for and data not collected on them where there could have been problems with analysis.

Line 325: the conclusion as drawn is not solely supported by the analytical evaluations enumerated in the study. The statistical section gives a scope of analysis performed but the results and tables as presented showed very little work and all others were just given as statements.