Reviewer’s report

Title: The Effectiveness and Cost-Effectiveness of Three versus Six-monthly Dispensing of Antiretroviral Treatment (ART) for Stable HIV Patients in Community ART Refill Groups in Zimbabwe: Study Protocol for a Pragmatic Cluster Randomized Trial

Version: 0 Date: 28 Nov 2017

Reviewer: Richard Holubkov

Reviewer’s report:

This is an extremely well-written and interesting study protocol. The cluster-randomized non-inferiority design is an interesting one and appears appropriate for this setting. I have only some minor comments/requests for the protocol.

Title. Add the ART acronym in parenthesis after the word "Treatment" in the title. You may also want to modify "Stable Patients" to "Stable HIV Patients" in the title, though this is optional.

Abstract, line 78. Suggest outcome be stated here as "..proportion of participants alive and retained in care..." Also suggest adding the sample size (1,920 per arm) to the abstract to give abstract readers an idea of the "magnitude" of the trial.

Methods, line 184. I would recommend changing the language "three-monthly" and "six-monthly" to something like "at three month intervals" and "at six month intervals", for clarity.

Line 201. Consider specifying the non-inferiority margin of 3.25% here.

Line 232. Perhaps clarify the "no facility or ART collection for >90 days" primary outcome here. For example, if a patient does not come in in-person for the 12 month visit (but has not transferred to another clinic), what would be acceptable to be considered retained in care for the 12-month outcome? Would they then have to come in, in person, within the next 90 days for a "late" annual visit?

Line 245. I would mention again, as is stated in the Abstract, that each CARG consists of approximately 6-12 patients.

Table 1: change "Weigh" to "Weight"

Line 316: the intracluster correlation of 0.01 is per institution (not per CARG), correct? Might there be higher ICC's at institutions assigned to CARGs?

Line 330: All of the patients within a CARG do not need to enroll in the trial, is this correct? Also, can/will patients still be in CARGs, if they are at centers participating in the control arm? If so, please clarify (if needed) how CARGs would function at the control sites compared to the 3MC and 6MC centers.
Line 402: how is the subset of participants participating in the cost study selected?

Line 554: "Suppression" is misspelled.

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