Author's response to reviews

Title: Comparison of two doses and two routes of administration of misoprostol after pre-treatment with mifepristone for early pregnancy termination

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To: Reproductive Health Editorial Team

Re: MS: 1056185954180286

Thank you to the reviewers for their comments. We have included the suggested changes in the protocol:

Item

2.2 Last line, the reference to footnote is deleted

3.1.1 The first sentence amended as suggested

3.4.1 First paragraph, last line: amended as suggested: 24 (+/- 2) hours

3.4.3(b) Mola corrected to molar; risk factor corrected to risk factors

3.4.4 Typo corrected: At each ..

3.4.10 The first sentence deleted as suggested.

3.4.12 The first sentence corrected as suggested: To establish the non-inferiority (one-sided equivalence) of the 0.4 mg misoprostol (sublingual or vaginal) regimen compared to the 0.8 mg with respect to efficacy, we require the upper limit of the one-sided 95% confidence interval (or the two-sided 95% confidence interval) for a difference in complete abortion rates (that of 0.8 mg minus that of 0.4 mg) to be within a margin of equivalence of 3%.

Why did we choose sublingual route?

Sublingual route seems to be very effective and acceptable according to the results from pilot studies we had at the time when we wrote the protocol. We also carried out a comparative study of vaginal and sublingual misoprostol when used alone for abortion (Lancet 2007;369:1938-46). Buccal route seems to be used only in the USA.
Diary card: women record daily the information on bleeding/spotting and any symptoms/adverse events they may have until the end of the study.

With kind regards,

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