Reviewer's report

Title: Immediate vs. Delayed Insertion of Intrauterine Contraception after Second Trimester Abortion: Protocol and Rationale for a Randomized Controlled Trial

Version: 3 Date: 13 May 2011

Reviewer: Keith Wheatley

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1. The sample size calculations are correct (my program gives 348 and 372) assuming that 2-sided alpha of 0.05 had been used, though it could be argued that a continuity correction should have been used which would increase each by about 50. The 366 is, of course, too precise since a number of assumptions and estimates have gone into the calculation, so “about 370” would be better.

2. The treatment effects anticipated are very large and, even if theoretically justified, may not be found in practice leading to smaller, but still clinically worthwhile, effects being missed.

3. If there is no rationale for believing that the two devices will differ in the likelihood of early insertion being beneficial (I didn’t see one), the trial could have been designed on the basis of the overall population, with a subgroup analysis to test for any interaction between device type and early/late insertion. This would have lead to a (much?) smaller sample size or the possibility of detecting smaller effect sizes (see point 2) with the same sample size.

4. The exclusion criteria (page 7) list some post randomisation exclusions, yet the analysis section (page 11) says that ITT analysis will be used. The latter is correct and no patient should be excluded from the trial post randomisation (unless they withdraw their consent) – see also next point.

5. If a chi-square test is to be used for analysis, how will patients who are lost to follow-up prior to one year be treated – e.g. will they be assumed not to have had a pregnancy if they hadn’t had one prior to loss? Wouldn’t a time-to-event analysis be better, thereby allowing patients who are lost to follow-up to be censored at the time of loss (while still checking for any differential loss between the arms)?