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More clarity needed for contraceptive mobile app Pearl Index calculations

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We reviewed the novel evaluation by Scherwitzl et al. [1], “Perfect-use and typical-use Pearl Index of a contraceptive mobile app” at our Family Planning Division journal club. We recognized a few issues that limit the understanding of efficacy and our ability to compare the outcomes to currently available contraceptives. The app investigated in this study uses a proprietary algorithm that augments menstrual cycle calendar input with basal body temperature and optional urine luteinizing hormone tests to predict potentially fertile days and prompt the user to avoid unprotected intercourse. The authors aimed to calculate perfect-use and typical-use Pearl indices from end-user app input among 22,785 women. Although not exactly reported, approximately 10,500 women used the app for a full year based on the author’s reported 12-month discontinuation rate of 54%.

The investigators report typical-use and perfect-use Pearl Indices of 6.8 pregnancies per 100 women-years (95% CI 7.8-8.9) and 1.0 pregnancy per 100 woman-years (95% CI 0.5–1.5), respectively. Although the investigators acknowledged limitations in available baseline characteristics due to their use of unstructured end-user data, we would have expected at least a secondary analysis that takes into account known approval agency requirements for Phase 3 efficacy studies. Most notably, such limitations include restricting the efficacy evaluable population to women 35 years and under at the time of enrollment and enrollment of women with regular menstrual cycles.

Based on the average age of 29.2 ± 5.0 years, approximately 15% of the population would be excluded from efficacy evaluation based on age criteria alone. The app and corresponding website (<https://www.naturalcycles.com/en/faqs>) inform women with irregular cycles that the method “will still be effective, but you might experience more red [potentially fertile] days.” Thus, we can only assume that women with irregular cycles are included in the calculations. The authors should provide failure rate outcomes that remove women more than 35 years old and those with irregular cycles. It is likely that

the actual number of women and cycles available to provide data only for women 35 years and under with regular cycles will further limit the accuracy of the findings, demonstrating the need for larger, more focused trials before making any formal conclusions.

Lastly, the authors report that users recorded intercourse in only 32% of cycles and that 47% of the cycles with pregnancies included no reported intercourse. Phase 3 efficacy studies require documentation of intercourse at least once per cycle for that cycle to be included in efficacy calculations (unless a pregnancy occurs in which case the cycle will be included regardless). We acknowledge that it is highly likely that app users had intercourse commonly that they did not register. The authors comment that the lack of information on intercourse from most users is a challenge for a perfect-use efficacy calculation. However, we believe this missing data limits an accurate calculation of typical-use efficacy as well. Future studies will need accurate documentation of intercourse to provide adequate data for comparison to other methods.

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[1] Scherwitzl EB, Lundberg O, Kopp Kallner H, Gemzell Danielsson K, Trussel J, Scherwitzl R. Perfect-use and typical-use Pearl Index of a contraceptive mobile app. *Contraception*. 2017;96: 420-5.