Reviewer's report

Title: Factors predicting mood changes in oral contraceptive pill users

Version: 2 Date: 18 August 2013

Reviewer: Jessica Bird

Reviewer's report:

Journal: Reproductive Health
Title: Factors predicting mood changes in oral contraceptive pill users

In this study, the authors conducted interviews with 500 female OCP users, using a structured questionnaire. They examined relationships between presence of reported mood change and demographic variables, as well as education and self-efficacy regarding OCP use. The authors reported finding significant associations between reported OCP-related mood change and urban living, lack of education on OCP side effects, and lower self-efficacy. This study has the potential to provide useful information regarding OCP use and the reproductive health of Iranian women. However, ability of this manuscript to contribute to the current literature is limited by written language difficulties and limited detail and lack of clarity on the participants, methods used, and results.

- Major Compulsory Revisions

1. There are a numerous grammatical and usage errors throughout the manuscript. Revisions will be important to improve the clarity, accuracy, and readability of this study. Examples include: Background, first paragraph, last sentence; Background, second paragraph, third sentence.

2. Greater detail on how women were recruited for this study should be included. How were women randomly selected to participate? Were data collected on the number of women that were offered but refused to participate? It would be helpful to know more about the family planning centres (were these located in rural or urban locations, generally what type of services do they provide).

3. Methods, questionnaire: If possible the authors should include additional demographic data, such as parity, history of mood/anxiety disorders, PMS/PMDD, and use of psychotropic medications. Previous research has highlighted history of mood disorders and PMS/PMDD as risk factors for OCP-related negative mood change. It is a limitation that the authors do not address this within the manuscript. In addition, it is quite possible that mood and/or menstrual disorders might play a causal role in low self-efficacy and lack of education about OCP side effects.

4. Methods, questionnaire: It is unclear the authors’ intent when it is stated “we asked women to name the most important side effects they experienced”. This implies that there may be been other less important side effects that women did not to name. Why not ask women to list any side effects they had experienced?
The period of time for which women were asked to report on side effects (i.e., any side effects ever, in the last month, for the current OCP used) should be included.

5. Methods, questionnaire section: Information on the scoring of the self-efficacy items should be included. Did the authors generate a total score for all six items? Total self-efficacy scores should be included in the results section. The authors do not present any information to support the reliability or validity of this item set.

6. Results, third paragraph: The focus of this paper is mood changes, yet the authors do not provide any detail on the nature of the OCP mood changes. The literature suggests that women experience both subjectively positive (mood stabilizing) and negative (depressed mood, irritability) mood changes, therefore it is important to provide further clarification.

7. Results, third paragraph: The source of the data on receipt of education about OCP side effects (i.e., the specific item) should be included. Was this an item from the self-efficacy portion of the questionnaire? Additional confusion comes from the use of “education” to refer to a participants’ level of formal education in some portions of the manuscript, and education about OCP side effects in the results section.

- Minor Essential Revisions

8. Abstract, methods: It would be more accurate to state that analyses were performed to assess the relationship between reported mood change and IVs rather than OCP use and IVs.

9. Abstract, results: Revision for clarity would be helpful here. For example, it is confusing when the authors report that education was a significant predictor of mood change, when in fact it was lack of education about OCP side effects that was significant.

10. The use of standard statistical reporting conventions should be corrected throughout (i.e., italicizing N, CI, and lowercase p for p values).

11. Abstract, conclusion: It is misleading to say that prevalence of OCP mood change in Iranian women is “relatively high”, as rate of reported mood change appears to be consistent with other studies.

12. Methods, questionnaire: For duration of OCP use, clarify whether this refers to the current OCP formulation, or numerous formulations. If possible, it would also be helpful to comment on the pill formulations used.

13. Methods, questionnaire: Consider naming all six self-efficacy items, or describing the topic areas examined.

14. Results. I am concerned about the significant finding of greater risk of mood change for urban OCP users compared to rural users given the large discrepancy in the sample sizes (425 urban vs 75 rural). I don’t feel qualified to assess the strength of this statistical approach, but it may be helpful to the reader if the authors addressed this issue.

15. Results, third paragraph. The authors do not specify whether the results they
are describing are as a result of univariate or multiple logistic regression. Further, it would be helpful for the reader if the authors would clarify the findings in a statement such as: “Women who reporting living in an urban setting, who did not receive education, and who reported lower self-efficacy, were more likely to report experience of mood change”.

16. Discussion, second paragraph. As the authors note, some research suggests that OCP-related mood change decreases after a period of adjustment. The authors may wish to comment on why they chose a period of one month of OCP use as an inclusion criteria for their study and whether this may have been a limitation to their study results.

17. Table 2. The label “cholasma (spotting)” is unclear, as spotting typically refers to bleeding between menses, similar to breakthrough bleeding. Similarly, the authors should clarify the label “bleeding”, and whether this refers to changes in menstrual bleeding or bleeding between periods. Similar to the comment on positive vs. negative mood, it should be noted that OCP users experience both increases and decreases in bleeding.

Minor Issues not for Publication (e.g., spelling, typographical errors, grammatical errors, stylistic suggestions)

18. There are several typographical errors throughout the manuscript. For example: Background, third paragraph, first sentence “The prevalence”.

Methods, design and data collection, “July2011 to June2012”.

- Discretionary Revisions

1. In the background section the authors provide data on lifetime OCP use, side effects, and discontinuation. Some of this data are from publications approximately 15 years old, and so it would be useful to include more recent references.

19. The reader may be interested in knowing how OCPs are dispensed in Iran, and whether it is common for women to receive information about OCPs.

20. This strength of this study is that it examines OCP use in Iranian women, where it does not appear that there have been previous published studies. It may be helpful for the authors to focus on adding new research on this demographic. The authors could consider comparing use and discontinuation statistics between Iranian women and women from other countries, and highlight reasons why current research may not capture the experiences of women in Iran.

21. The authors might consider including analyses examining whether differences are present for women who did and did not report experiencing OCP use side effects.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Not suitable for publication unless extensively edited
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.