

# Comment on “Is It Safe to Provide Abortion Pills Over The Counter? A Study on Outcome Following Self-Medication with Abortion Pills”

LAURA J. FRYE<sup>1</sup>, BEVERLY WINIKOFF<sup>2</sup>**Keywords:** Abortion, Safety, Mifepristone

Dear Editor,

We read with interest the article “Is it safe to Provide Abortion Pills over the Counter? A Study on Outcome Following Self-Medication with Abortion Pills” by Dr. K. Nivedita and Dr. Fatima Shanthini [1] and we agree that studying the implications of self-administration of abortion pills is a worthy research aim. However, the evidence presented does not support the authors’ conclusion that “unsupervised medical abortion can lead to increased maternal morbidity and mortality”.

The authors analysed the case sheets of 40 hospitalized women who reported self-administration of abortion pills, but this analysis lacks a meaningful denominator. Safety and efficacy cannot be known without quantifying the number of women in the catchment area who self-administered abortion pills and had complete and uncomplicated procedures and never sought follow up care. In fact, the data presented could indicate a very low failure and complication rate, depending on the denominator. By collecting data from only those women who present at the facility, the study introduces selection bias and will not be representative of the experiences of the wider population of women who self-administer abortion pills.

Tellingly, there were no deaths or hysterectomies in the series reported and 17.5% of the women analysed required either no treatment of simply additional misoprostol. This indicates that even those women who ended up in the hospital did not suffer major morbidity.

The author’s assertion of an increase in maternal morbidity and mortality is unjustified as there is no baseline from which to calculate such an increase. In fact, it is plausible and perhaps likely that the expanded availability of abortion pills over the counter reduces maternal morbidity and mortality by offering a safer alternative than invasive or violent methods.

The study also suffers from a number of ascertainment issues that make the results difficult to interpret. The authors rely upon women’s self-report of administering “abortion pills” without any validation of what specific pills, doses, and regimens were used. There is also no systematic collection of other remedies attempted. Therefore, the complications seen cannot be directly attributed to the use of mifepristone and misoprostol obtained at pharmacies.

The available data are insufficient to make any conclusions regarding the societal and policy implications of the availability of abortion pills in pharmacies. We cannot rely on this study to inform our understanding of the safety of abortion medications for self-use in India or elsewhere.

Sincerely,

Laura J. Frye, MPH

Beverly Winikoff, MD

**REFERENCE**

- [1] Nivedita K and Shanthini F. Is It Safe to Provide Abortion Pills over the Counter? A Study on Outcome Following Self-Medication with Abortion Pills. *J Clin Diagn Res.* 2015;9(1):1-4.

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**FINANCIAL OR OTHER COMPETING INTERESTS:** None.Date of Submission: **Apr 02, 2015**Date of Peer Review: **Jun 01, 2015**Date of Acceptance: **Jun 03, 2015**Date of Publishing: **Aug 01, 2015****REPLY TO THE COMMENTS**

In response to the comments given by Dr. Laura J Frye and Dr. Beverly Winikoff, we would like to emphasise the following points.

As mentioned in the article, the limitation of our study is that it is a retrospective observational study carried out in a small sample in a Medical College Hospital and not done at a community level. It is note worthy that in the Indian scenario it would be impossible to get data on self administration of pills at community level as the sale of mifepristone is not monitored by any system and none of our women will admit to the fact that they have consumed pills as they want to maintain secrecy as many consider MTP as illegal.

Only due to minor or major complications they would report to the hospital and in the absence of any complication they will not disclose the fact that they have consumed abortion pills.

This study took into consideration, the use of mifepristone and misoprostol only and its consequences. Even though there was no maternal mortality in our study, a similar study had shown maternal mortality and also major surgical intervention in the form of laparotomy for ruptured ectopic after self administration of abortion pills [1]. Moreover the incidence of anaemia is very high in India and hence even normal blood loss expected with abortion pills could turn fatal.

Unlike, western women our rural women are mostly uneducated and even if educated may not be capable of reading and understanding the literature accompanying the drug. So they consume the MTP pills without being aware of the contraindications, time period until which it can be used and also what to expect following the consumption of pills. It is also worthwhile to note that these women have obtained the drug without any prescription and so have not received any counselling.

Even though we are well aware of the safety profile of these drugs, due to our social conditions we would still like to emphasize that MTP pills should be dispensed by qualified personnel with proper counselling and unregulated and un supervised use of these drugs should be curtailed to avoid major complications.

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## REFERENCE

- [1] Rajal VT, Kruti JD, Parul TS. Self medication of abortion pill: Women's health in Jeopardy. *NHLJMS*, 2014; Vol 3:26-31.