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Medical abortion can be provided safely and effectively by pharmacy workers trained within a harm reduction framework: Nepal ☆,☆☆,★,★★,☆☆☆

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Abstract

Objectives: To examine the treatment efficacy, safety and satisfaction of women using medical abortion (MA) pills provided by pharmacists following an education intervention based on a harm reduction approach.

Study design: This was an operations research study over a six-month period in 2015, using a non-inferiority design. We provided training to dispense MA pills, based on a harm reduction approach, to a group of pharmacy workers in Makwanpur district (GROUP 2). We compared selected outcomes with women who bought the pills from pharmacy workers in Chitwan district (GROUP 1), who had received similar training in 2010. The primary endpoint measured in 992 women in both districts was complete abortion within 30 days of using the pills. We assessed the efficacy of MA (self-reported complete abortion) and safety (no reported adverse event). To determine complete abortion, we asked women about passage of the products of conception, cessation of abdominal cramps, vaginal bleeding, need for manual vacuum aspiration or repeated doses of misoprostol. We used a four-point Lickert Scale to determine level of satisfaction with MA use. Pearson Chi-Square test was used to examine any differences in proportion of complete abortions between women who were served by the two groups of pharmacy workers.

Results: The difference in the rate of complete abortions between the two groups of women, 96.9% and 98.8%, was not statistically significant. The women reported no serious complications, and there was little difference in their satisfaction levels.

Conclusions: Trained pharmacy workers dispensed MA safely and effectively to the satisfaction of almost all women clients, and the positive results of training had continued several years later.

Implications: The role of pharmacy workers as providers of correct and complete information on safe and effective use of MA needs to be recognized and policies formulated to allow them to provide MA drugs for first trimester use.

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Keywords: Medical abortion provision; Pharmacy worker; Training; Safety; Effectiveness; Client satisfaction

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th Conflict of interest: All the authors declare no conflict of interest.

[★] Permissions: None were required.

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1. Introduction

Medical abortion using a combination of mifepristone and misoprostol has been shown to be widely acceptable to women in both developed and developing countries [1–4]. The World Health Organization recommends a regimen for pregnancies up to 9 weeks of 200 mg of mifepristone administered orally, followed 24–48 h later by 800 mcg of misoprostol administered vaginally, buccal or sublingually. For oral administration, the recommended dose of misoprostol is 400 mcg for gestations up to 7 weeks [5]. In recent years, evidence of the safety and effectiveness of medical abortion (MA) has resulted in the simplification of the appropriate standards and health worker skills required for its provision.

The World Health Organization published a guideline in 2015 on the range of health workers who can provide safe abortion care and manage non-life-threatening complications in the first (≤12 weeks) and second trimester (13–28 weeks) in both high- and low-resource settings [6]. The guideline does not recommend that pharmacy workers and lay health workers independently provide MA because there is currently insufficient evidence. However, when appropriately trained, these categories of health workers can, as shown through rigorous research, assess eligibility for medical abortion, administer the medication, manage the process and common side-effects independently, and assess completion of the abortion and the need for any clinic-based follow-up, for women in the first trimester of pregnancy [7–10].

In Nepal, national guidelines published by the Ministry of Health in 2009 allowed independent provision of MA by skilled birth attendants and trained auxiliary nurse-midwives (ANMs) up to 9 weeks gestation. Off-label or over-the-counter sale of MA tablets at pharmacy shops was not permitted. Despite these restrictions, various brands of registered and unregistered MA drugs are sold by pharmacy shops. Ensuring that women seeking abortion advice from pharmacy workers receive effective care remains an important challenge in Nepal.

However, trained pharmacists and pharmacy workers have successfully delivered care related to sexually transmitted infections, contraception and emergency contraception. Their success is due to their ability to facilitate rapid access to medications, supplies, information and advice, while maintaining client confidentiality [9–10].

Harm reduction is an evidence-based public health and human rights approach that prioritizes strategies to preserve health in situations where policy and practice prohibit and drive common activities underground [11]. In the context of the present study, the aim of a harm reduction strategy is to stop pharmacy workers from dispensing ineffective and unsafe medications for abortion or dispensing incorrect doses of MA pills. We hypothesized that training pharmacy workers in correct use of MA, including assessment of number of weeks of pregnancy, use of a urine pregnancy test, providing correct and complete information on regimens and effective routes of administration, and when to see a trained provider for follow-up care in case of incomplete abortion or

signs and symptoms of complications, would lead to a decline in incorrect use of MA and other ineffective drugs. Through this process women's safety would be improved and abortion-related complications would decrease.

A previous study carried out by our group, published in 2014 [12], demonstrated that pharmacy workers trained to provide MA using this harm reduction approach had increased their knowledge of recommended regimens, effective routes of administration, the recommended time gap between the two types of pill, and how to recognize a complete abortion. This, in turn, led to a decline in the incorrect provision of MA tablets and other ineffective drugs by pharmacy workers and increased referrals to safe abortion clinics when follow-up care was needed. The trained pharmacy workers reported that of 5594 women receiving MA drugs from them, only 18 women (0.03%) had had an incomplete abortion [12]. However, the study had not followed up the women themselves who had obtained MA pills from the pharmacy workers. Because an increasing number of women are getting MA from pharmacy shops, we felt it was imperative to carry out a prospective study that would follow up women clients.

The operations research reported in this paper aimed to fill this important data gap, studying the effectiveness of training of pharmacy workers who had not had training previously (Education Group 2 — hereafter GROUP 2) and also studying client compliance and satisfaction, and safety and effectiveness of MA as reported by the women. The results were then compared with those among women who had obtained MA from pharmacy workers in an adjoining district (Education Group 1 — hereafter GROUP 1), who had had similar training a few years before. The findings of this study would contribute to reforming policies aimed at expanding MA services in the private sector through trained pharmacy workers and to ensure greater safety, efficacy and acceptability of MA in Nepal.

2. Materials and methods

2.1. Study population

This was an operations research study conducted in Makwanpur and Chitwan districts using a non-inferiority design. This design was aimed to show that the effect of a new treatment is as good as, or better than that of an active comparator. We selected the two groups of pharmacy workers on the basis of geographical proximity between them (in neighboring districts). We trained the group of pharmacy workers in Makwanpur district to provide medical abortion (GROUP 2) safely and effectively. We compared the outcomes for women who obtained MA pills from them, our study participants, with the outcomes for women who had obtained MA pills from a group of pharmacy workers in Chitwan district (GROUP 1), who had received similar training a few years before. This is the first study to compare outcomes of MA use outside the healthcare system.

Makwanpur is a relatively small, hilly district (population 0.42 million) with a small urban population (25.6%). The

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