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Provision of menstrual regulation with medication among pharmacies in three municipal districts of Bangladesh: a situation analysis☆

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Abstract

Objective: The objective was to assess the provision of the combination of mifepristone–misoprostol for menstrual regulation (MR) in randomly selected urban pharmacies in Bangladesh.
Study design: We conducted a cross-sectional survey among 553 pharmacy workers followed by 548 mystery client visits to the same pharmacies in 3 municipal districts during July 2014–December 2015.
Results: The survey found that 99% of pharmacy workers visited had knowledge of MR procedures but only two-thirds (67%) could state the legal time limit correctly; they mentioned misoprostol (86%) over mifepristone–misoprostol combination (78%) as a procedure of MR with medication (MRM); 36% reported knowing the recommended dosage of mifepristone–misoprostol combination; 70% reported providing information on effectiveness of the medicines; 50% reported recommending at least one follow-up visit to them; 63% reported explaining possible complications of using the medications; and 47% reported offering any post-MR contraception to their clients. In contrast, mystery client visits found that the mifepristone–misoprostol combination (69%) was suggested over misoprostol (51%) by the pharmacy workers; 54% provided the recommended dosage of mifepristone–misoprostol combination; 42% provided information on its effectiveness; 12% recommended at least one follow-up visit; 11% counseled on possible complications; and only 5% offered post-MR contraceptives to the mystery clients.
Conclusions: We found knowledge gaps regarding recommended dosage for MRM and inconsistent practice in informing women on effectiveness, follow-up visits, possible complications and provision of post-MR contraceptives among the pharmacy workers, particularly during the mystery client visits.
Implications: Pharmacy workers in Bangladesh need to be trained on legal time limits for MR services provision, on providing accurate information on disbursed medicine, and on proper referral mechanisms. A strong monitoring and regulatory system for pharmacy provision of MRM in pharmacies should be established.

Keywords: Pharmacy worker; Menstrual regulation; Mifepristone–misoprostol combination; Mystery client; Post-MR contraceptive; Bangladesh

1. Introduction

Abortion is illegal in Bangladesh, except to save a woman's life. Menstrual regulation (MR), a procedure to regulate the menstrual cycle when menstruation is absent for a short duration [1–3], was introduced into the country's national family planning program in 1979 as a strategy to reduce maternal morbidity and mortality associated with unsafe abortion [4]. A medical doctor can provide MR up to 12 weeks from the first day of the last menstrual period (LMP), and midlevel providers, such as family welfare visitors (FWVs), can provide MR up to 10 weeks from LMP [5,6]. FWVs are the cadre of service providers recruited to provide maternal and child health and family planning services by the Directorate of Family Planning under the Ministry of Health and Family Welfare. They must have 12 years of education and 18 months of in-service training prior to offering these services [7,8].

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MR services are provided free of cost at all levels of public health facilities and with fees in some nongovernmental organizations (NGOs) and private clinics using manual vacuum aspiration (MVA). In 2015, the Government of Bangladesh approved the use of mifepristone–misoprostol up to 9 weeks from LMP to be administered by service providers who have received training on MRM [9]. Although the mifepristone–misoprostol combination regimen is available at pharmacies upon prescription, it is well known that the combination pack is still not available through the government system and is not provided routinely in public sector facilities.

Women also face barriers such as unofficial fees, the legal time limit, being underage or having no children at the time of seeking MR services [10]. Moreover, the Demographic & Health Survey of 2014 showed that 55% of ever-married women were not aware of the MR program in Bangladesh [11]. Additionally, even those who are aware of MR often feel ashamed or embarrassed to access it or fear disapproval from family, community members or religious leaders, which may lead them to seek services from unskilled providers [12,13].

Alternatively, many women in low-income populations go to pharmacies as their main source of health care services where self-medication is possible due to the pharmacies' convenience, geographic accessibility and relative anonymity [14]. Pharmacies are especially attractive to people seeking care for stigmatized health needs, including STIs, family planning and abortion. People tend to expect pharmacy workers to provide good quality information and counseling for STIs or family planning methods [15,16]. However, some pharmacy workers with low levels of education and lack of formal training may sell medicines without a prescription or support from a trained health care professional, and this can lead to inaccurate advice and incorrect dispensing [14].

According to drug regulatory law in Bangladesh, no one should sell any medicine without the personal supervision of someone who has attended a training course approved by the Pharmacy Council of Bangladesh. Furthermore, the customer should receive dosing instruction and drug information before he or she leaves the pharmacy [17].

While the correct use of mifepristone–misoprostol for MR offers a safe and effective method, including in a low-resource and legally restrictive setting like Bangladesh, there are a possibility of incorrect provision of the medicines by pharmacy workers who lack training and a likelihood of ineffective use of the medications by women due to a lack of information on correct usage. Evidence from a previous study showed that some pharmacy workers in Bangladesh were providing ineffective regimens of misoprostol for MR in 2011 [18]. We designed this study to assess the provision of the mifepristone–misoprostol combination for MR by pharmacy workers in Bangladesh.

2. Materials and methods

We conducted a cross-sectional survey between July 2014 and December 2015 among pharmacies located in municipalities of three districts of Bangladesh, Dhaka, Gazipur and Sylhet districts, with a range of socioeconomic classes among the population and to include a site with low-performing reproductive health indicators (Sylhet) [11]. The study population was the pharmacy workers of randomly selected pharmacies from the three sites. We included two types of assessment among the pharmacy workers: firstly, face-to-face interviews during a rapid assessment survey and, secondly, indirect interviews through mystery client visit.

2.1. Sampling of pharmacies

First, we marked out a specific geographic boundary of 1 km in radius around the public and private health facilities in each study area. As there was no registry that listed all pharmacies, we created a listing of the 1410 pharmacies manually. Inclusion criteria for the pharmacies were as follows: (a) a fixed physical space that had medicines clearly displayed, (b) being established for at least 6 months, (c) opened regular hours each day and (d) stocked the mifepristone–misoprostol combination pack used for MR. We recorded the pharmacy names, addresses and contact numbers of the owner or pharmacy worker. Among the 1410 pharmacies listed (Dhaka: 335, Gazipur: 312, Sylhet: 763), 553 were randomly selected using a computer-generated sequence which gave 184 pharmacies each in Dhaka and Gazipur and 185 in Sylhet. This process was completed independently by a computer programmer who was not involved with the study. Unique numbers were assigned to the pharmacies for the randomization process. The selected pharmacies in each study area were then invited to participate in the survey. Eight of the pharmacies refused; we then included eight more pharmacies from the initially developed list to fulfill the required sample size.

2.2. Rapid assessment survey

We conducted a rapid assessment survey among the selected 553 pharmacies by undertaking face-to-face interviews at their working place (pharmacy) of a pharmacy worker who had at least 6 months' experience of selling medicines. Where there was more than one eligible respondent in a pharmacy, we interviewed the senior pharmacy worker because they may have been better informed/have more knowledge than others at the same site. All pharmacy workers provided informed written consent prior to interview during the survey. Eight field research assistants were trained to use a structured questionnaire to collect information on pharmacy characteristics, pharmacy workers' backgrounds, and their knowledge and practice with providing the mifepristone–misoprostol combination for MR. Questions on the two types of procedure for MR, legal time limits for MRM, dosage, route of administration, side effects and possible complications of the MR medicines, follow-up visit, referral and post-MR contraceptives were also asked. During the survey,

we interviewed the pharmacy workers at a corner of their working places. If the pharmacy workers responded to the questions incorrectly, the interviewers did not provide the correct answers.

2.3. Mystery client visit

Since survey responses do not always indicate real-life practices, the second component of the study utilized mystery client visits to the same pharmacies where the rapid assessment survey had been conducted. The mystery client visit aimed to assess the actual provision of the mifepristone–misoprostol combination by the pharmacy workers. We anticipated that the mystery client visit would minimize observer bias because this method has been successfully used in many pharmacy-based studies in other countries [19–21].

The field research assistant who interviewed a particular pharmacy worker during the survey did not visit the same pharmacy as a mystery client. Moreover, to reduce the chances of information bias and suspicion, the mystery client visits were conducted at least 15 days after the survey visit. During the survey visits, the assigned field research assistant for the mystery client visit observed the survey interview by his/her colleague at a distance from the selected pharmacy so that he/she could identify the person interviewed during the survey and have a conversation with the same person during the mystery client visit 15 days later.

We thoroughly trained the interviewers to ensure that they could ask pharmacy workers similar questions during the mystery client visits that they had covered in the rapid assessment survey. Selection criteria (both men and women) were as follows: (a) possessed traits (i.e., language dialect, appearance) of people residing in the area where the pharmacy was located, (b) could assume a fictitious identity with ease, (c) were detail oriented and (d) had excellent recall.

The mystery clients acted out the following scenarios in encounters with the pharmacy workers: (a) a female seeking some medicines for herself or for her female relative/friend to regulate menstruation because she/her relative/friend had missed her LMP or (b) a male seeking medicines to regulate his wife's/female relative's/friend's menstruation as she had missed her LMP.

The mystery clients' training entailed (a) overview of the criteria that were used for evaluating the outlet visited, (b) assignment of scenarios to each mystery client, (c) extensive practice/role-playing to enact assigned scenarios and (d) tips for recalling details of the encounter during a postencounter interview.

Pretesting of each mystery client scenario was conducted to assess the feasibility of their interaction with the pharmacy workers and to give standardized responses. The mystery clients approached the pharmacy workers and described their situation and also inquired about dosages, route of administration, effectiveness, possible side effects, complications, potential substitutes and cost of the medicines if they were offered the mifepristone–misoprostol combination.

Four of the interviewers waited in a suitable location outside the pharmacies, and the other four visited the pharmacies as mystery clients, and they continued the process alternately. Immediately after a mystery clients' exit, the interviewers waiting outside recorded details of the visits and information related to the mystery clients' interaction with the pharmacy workers in a standardized questionnaire.

One pharmacy was counted as one unit, and it was expected that responses would be similar from all pharmacy workers of each unit. In some cases, mystery clients purchased the medicines. This was left to their discretion as in some situations it seemed awkward or suspicious if they did not complete the transaction. In other cases, mystery clients completed the transaction by committing to return later because of not having enough money at that moment.

Data were entered through Oracle 11G, analyzed using STATA 13.0 (Stata, College Station, TX, USA) and then interpreted. The study was approved by the Institutional Review Board of icddr,b (International Centre for Diarrhoeal Disease Research, Bangladesh), and the Population Council, New York, NY, USA.

3. Results

The rapid assessment survey was administered in 553 pharmacies (184 in Dhaka, 184 in Gazipur and 185 in Sylhet), and a total of 548 mystery client visits took place in the same pharmacies (182 in Dhaka, 182 in Gazipur and 184 in Sylhet). It was not always possible for the mystery clients to interact with the same person interviewed during survey.

Survey findings showed that majority of the pharmacy workers (90%) had completed 10 years of basic education in schools and 40% of them had more than 10 years of working experience in pharmacies. About 60% of the pharmacy workers had some formal training from an authorized institution like the Medical Assistant Training School, Local Medical Assistant Foundation training center, Rural Medical Practitioner training center or Pharmacist Training Centre.

Of the survey participants (553), 545 (99%) had knowledge of the two different procedures for MR: MVA and MRM. So, the knowledge findings are presented on 545 pharmacy workers. Again, seven of them reported that no one (either women/men) usually came to them for MR services. Thus, the findings on MRM provision are shown for 538 pharmacy workers.

3.1. Knowledge of pharmacy workers

Sixty-seven percent of the participants could state the legal time limit for doing MR correctly. Regarding MRM procedure, misoprostol alone was mentioned more (86%) than mifepristone–misoprostol combination (78%) during the survey, while the mifepristone–misoprostol combination

(69%) was suggested more than misoprostol alone (51%) to the mystery clients (Fig. 1).

3.2. Practice of the pharmacy workers

Almost all (97%) of the pharmacy workers reported that they usually referred their clients to the health facilities for MR services, but only 30% of them referred the mystery clients to the health facilities to receive MR services. During the survey, NGO clinics (62%) were mentioned more than private clinics/hospitals (50%) and public hospitals (31%) as a place of referral for initial services for MR. But referral to another pharmacy (42%), followed by private clinics/hospitals (30%), NGO clinics (28%) and public hospitals (5%), was observed during the mystery client visits (Fig. 2).

Findings from both the survey and mystery client visits showed that a large majority of the pharmacy workers asked about the clients' LMP (83% vs. 87%) (Table 1).

Twelve of the 538 pharmacy workers surveyed did not provide any advice on MR services except referral. Among the remaining pharmacy workers, more suggested MVA (96%) at a health facility than MRM (89%). With mystery clients, pharmacy workers suggested MRM more often (80%) than MVA at facility (60%) (Table 2). In the survey, few pharmacy workers reported correctly a recommended dosage[1] of mifepristone–misoprostol combination compared to that for the mystery clients (36% vs. 54%) (Table 2). The pharmacy workers suggested both oral and buccal or sublingual routes during the survey (92%) and mystery client visits (96%) to administer mifepristone–misoprostol combination (Table 2).

Nearly three-quarters (70%) of the pharmacy workers reported providing information on indications of effectiveness of using mifepristone–misoprostol combination to their customers, and only 42% provided the information to the mystery clients (Table 3). Both survey and mystery client visits revealed that all pharmacy workers mentioned "bleeding" as the first indication of effectiveness of mifepristone–misoprostol combination regimen (Table 3). Half of the pharmacies (50%) reported that they asked those clients who took medicines for MR from them to make at least one follow-up visit with them 2 weeks after using the medicines; only 12% of the pharmacy workers suggested a follow-up visit with them to the mystery clients (Table 3). Regarding counseling on side effects of the medicines used for MR, headache/vertigo (70% vs. 68%), nausea/vomiting (66% vs. 55%) and fever/chills (32% vs. 41%) were commonly reported during survey and mystery client visits, respectively (Table 3).

About two-thirds (63%) of the pharmacy workers surveyed reported counseling on complications of using mifepristone–misoprostol combination, but 11% did so to

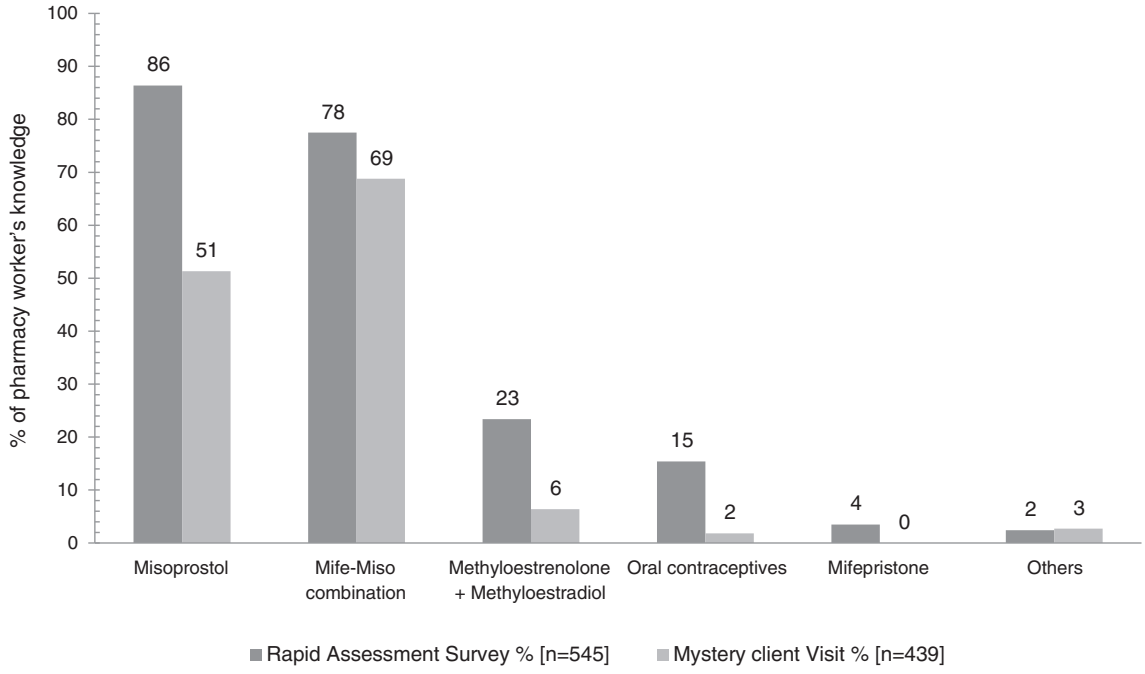

Fig. 1. Knowledge of the pharmacy workers on procedure of induction of MR with medications (rapid assessment survey vs. mystery client visits).

[1] *Recommended dosage and routes of administration of mifepristone-misoprostol combination regimen for induction of MR Day 1: Single oral dose of one tablet of mifepristone (200 mg) under the supervision of a qualified medical professional in a clinic, medical office or hospital. Day 2: Single buccal or sublingual dose of four 200-mcg misoprostol tablets (total 800 mcg) 24 h after taking the mifepristone tablet. Misoprostol tablets can be administered by the patient herself (two tablets on each side of cheek & gum or under tongue). She has to wait for 30 min and then swallow the remaining part of the tablets with water* [9]*. Day 14: Follow-up visit*

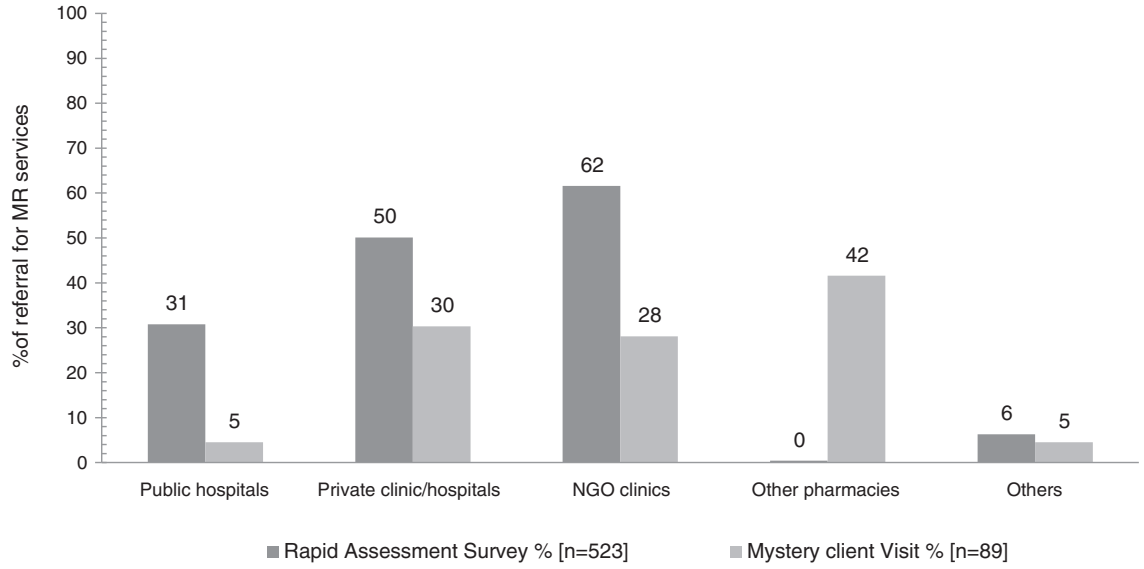

Fig. 2. Places of referral of clients by the pharmacy workers for receiving initial services for MR (rapid assessment survey vs. mystery client visits).

the mystery clients (Table 4). Excessive bleeding (97% and 92%) and severe abdominal pain (34% and 29%) were commonly reported as possible complications of using the medicines during survey and mystery client visits, respectively (Table 4).

For management of complications, 44% of the pharmacy workers reported that they referred the clients to private clinics/hospitals, followed by NGO clinics (36%), public hospitals (26%) or another pharmacy (15%), while the responses regarding complications management were reversed during the mystery client visits (Table 4). Though 47% of the pharmacy workers reported offering any post-MR contraceptives during the survey, only 5% offered post-MR contraceptives to the mystery clients (Table 4).

During the survey, the cost of the mifepristone–misoprostol combination varied from 60 to 300 BDT (equivalent to US$0.70–$3.70) depending on which brand was offered, and the cost was found to be higher (110–500 BDT, equivalent to US$1.30–$6.00) during the mystery client visits.

Table 1
Information on LMP and referral for MR services by pharmacy workers (rapid assessment survey vs. mystery client visits)

Characteristics	Rapid assessment survey, *n* (%)	Mystery client visit, *n* (%)	p value[a]
Asked client about LMP	*n*=538 (%)	*n*=548 (%)	
Yes	448 (83)	478 (87)	
No	90 (17)	13 (70)	.07
Referred client for MR Services	*n*=538 (%)	*n*=302 (%)	
Yes	523 (97)	89 (29)	
No	15 (3)	213 (71)	<.01

[a] p value is calculated from Fisher's Exact Test.

4. Discussion

This study found that pharmacy workers widely suggested mifepristone–misoprostol combination to those who

Table 2
Differences in responses of the pharmacy workers regarding MRM service provision

Characteristics	Rapid assessment survey, *n* (%)	Mystery client visit, *n* (%)	p value[c]
Procedure suggested for MR[a]	*n*=526 (%)	*n*=548 (%)	
MVA with syringe at health facility	504 (96)	329 (60)	<.01
MRM at home/facility	471 (89)	439 (80)	<.01
Medicines offered to the clients for MR services[a]	*n*=380 (%)	*n*=213 (%)	
Misoprostol	137 (36)	7 (3)	<.01
Mifepristone	15 (4)	0 (0)	<.01
Mifepristone–misoprostol combination	344 (90)	213 (100)	<.01
Other drugs	22 (6)	2 (1)	<.01
Mife–miso combination provided	*n*=349 (%)	*n*=213 (%)	
Following recommended dosage[b]	126 (36)	114 (53)	
Did not follow recommended dosage	95 (27)	44 (21)	
Following provider's prescription	128 (37)	55 (26)	<.01
Suggested route of administration of mifepristone–misoprostol combination	*n*=221 (%)	*n*=158 (%)	
Oral only	17 (8)	6 (4)	
Oral and buccal/sublingual	204 (92)	152 (96)	.13

[a] Multiple responses.
[b] Recommended dosage: day 1: mifepristone 200 mg, single dose (orally); day 2: misoprostol 200 mcg, 4 tablets (total 800 mcg) (buccally/sublingually/vaginally); day 14: follow-up.
[c] p value is calculated from Fisher's Exact Test.

Table 3
Differences in responses of the pharmacy workers indicating effectiveness and side effects of mifepristone–misoprostol combination for MR

Characteristics	Rapid assessment survey, *n* (%)	Mystery client visit, *n* (%)	p value[b]
Informed about effectiveness of mife–miso	*n*=349 (%)	*n*=213 (%)	
Yes	245 (70)	90 (42)	
No	104 (30)	123 (58)	<.01
Indications of effectiveness of mife–miso[a]	*n*=245 (%)	*n*=90 (%)	
Bleeding	245 (100)	90 (100)	.99
Abdominal cramp	114 (46)	25 (28)	<.01
Counseled on side effects of mife–miso[a]	*n*=187 (%)	*n*=22 (%)	
Diarrhea	13 (7)	2 (9)	.66
Nausea/vomiting	123 (66)	12 (55)	.34
Fever/chills	59 (31)	9 (41)	.47
Headache/vertigo	131 (70)	15 (68)	.81
Informed about follow-up visit	*n*=349 (%)	*n*=213 (%)	
Yes	175 (50)	25 (12)	
No	174 (50)	188 (88)	<.01

[a] Multiple responses.
[b] p value is calculated from Fisher's Exact Test.

Table 4
Differences in counseling on complications of medicine use by pharmacy workers (rapid assessment survey vs. mystery client visits)

Characteristics	Rapid assessment survey, *n* (%)	Mystery client visit, *n* (%)	p value[b]
Counseled on Complications of mifepristone–misoprostol[a]	*n*=349 (%)	*n*=213 (%)	
Yes	221 (63)	24 (11)	
No	128 (37)	189 (89)	<.01
Complications of using mifepristone–misoprostol[a]	*n*=221 (%)	*n*=24 (%)	
Excessive bleeding	214 (97)	22 (92)	.21
Severe abdominal pain	76 (34)	7 (29)	.65
Infection (fever >1 day)	13 (6)	0 (0)	.62
Where to go in case of complication	*n*=221 (%)	*n*=24 (%)	
Referral	219 (99)	23 (96)	
No referral	2 (1)	1 (4)	.26
Places of referral for complication management[a]	*n*=219 (%)	*n*=23 (%)	
Government hospital	57 (26)	4 (17)	.45
Private clinic/hospital	97 (44)	5 (22)	.04
NGO clinic	79 (36)	4 (17)	.10
Another pharmacy	32 (15)	7 (30)	.06
Counseled on post-MR contraceptives	*n*=349 (%)	*n*=213 (%)	
Yes	165 (47)	11 (5)	
No	184 (53)	202 (95)	<.01

[a] Multiple responses.
[b] p value is calculated from Fisher's Exact Test.

sought a means of self-induction of MR. However, pharmacy workers had significant knowledge gaps in terms of the recommended dosage and regimen, route of administration, adverse effects and referral for complications, and the extent to which they offered post-MR contraceptives. Though many of the pharmacy workers had mentioned some institutional training for their current work, quality of training may be an issue. There were three different settings where this study took place, and the pharmacy workers' education and training backgrounds were diverse.

Additionally, this study showed that a considerable number of pharmacy workers were unable to provide correct, consistent advice for MRM. It can be assumed that a significant number of women who avail MRM from pharmacies may use it incorrectly or too late in pregnancy. Though MR is free in public facilities, pharmacy workers are unaware of the best practices for MR provision and referral for management of complications. Sometimes, the pharmacy workers referred their clients to another pharmacy rather than a public health facility.

Pharmacy waiting times are usually short, and services including information and direct sales of medicines often cost less than those of other health care providers [14]. However, mystery client interviews revealed that pharmacy workers often capitalize on the situation of the clients by asking for a higher price than regular as most women buy these medicines during a critical situation.

The study has some limitations: although mystery client visits were recorded immediately after exiting the pharmacy, recall bias or misreporting was possible. Also, there may have been better counseling by pharmacy workers if they had any possible suspicion since the mystery client visit scenarios were not diverse enough. Our intention was to have the same respondent, particularly the senior pharmacy worker who was interviewed during the survey, be the pharmacy worker serving the mystery clients, but it was not always possible for the mystery clients to interact with the same person interviewed during survey. We did not discuss ectopic pregnancy with the pharmacy workers during the survey and with the mystery clients, which was another limitation of the study because ectopic pregnancy may remain undiagnosed with potentially serious consequences in women who have taken MRM without earlier confirmation of intrauterine pregnancy [24]. Additionally, the background and practices of pharmacy workers in this study may not reflect the background and practices of pharmacy workers in other areas of the country.

A gap between knowledge and practice in MRM provision has commonly been identified in other studies [18,22]. In this study, improvement in knowledge and practice was observed compared to a study conducted in a similar setting in 2011 that had observed knowledge and practice of pharmacy workers about misoprostol only for MR [18], though this time, we did not collect information on practice provision of misoprostol alone. One NGO (Marie Stopes Bangladesh) is providing training on the harm reduction approach to improve access to MRM with the

aim of increasing the capacity of informal practitioners, particularly pharmacy workers in Bangladesh [23]. Since that program's timeline overlapped that of the current study, it is likely that our results reflect an increase in the knowledge and improvement in the practice of MRM among pharmacy workers in Bangladesh.

Nevertheless, remarkable differences between the reported and the actual practices of the pharmacy workers on referral to health facilities for MR services were observed in the current study. Actual practices are likely to more accurately represent the advice that women customarily obtain. Particularly of concern are the differences in information provided about effectiveness of the mifepristone–misoprostol combination, a possible follow-up visit and counseling on post-MR contraceptives. Although short-term contraceptive methods such as oral hormonal contraception and condoms are available without prescription, pharmacy workers did not offer these.

Pharmacies often serve as the first platform where women go to access MR options, and the mifepristone–misoprostol combination regimen for MR has the potential to offer a safe and effective method in low-resource and restrictive settings. This study has shown that pharmacy workers need to be trained on the legal time limit for MR services provision, on providing accurate information on disbursed medicines, and on proper referral mechanisms. In a health system where pharmacies and/or pharmacy workers play a key role, a referral linkage strategy between pharmacy workers and public hospitals should be in place to facilitate the continuity of care which is important for family planning services. Because government is the regulatory body for providing licenses to the pharmacies, a strong monitoring and regulation system should be established by the government to oversee MRM service provision by the pharmacy workers. Results from this study can be used as a baseline to inform researchers and policymakers who seek to evaluate the impact of future interventions for pharmacy workers on provision of MRM. Further research can be conducted to better understand how the informal sector can be engaged to improve MRM services for poor and disadvantaged women.

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