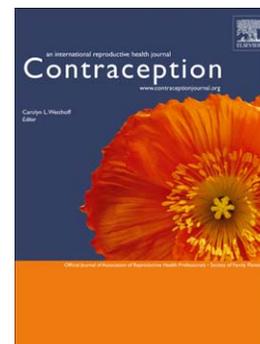# Accepted Manuscript

Feasibility of assessing the safety and effectiveness of menstrual regulation medications purchased from pharmacies in Bangladesh: a prospective cohort study

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TITLE PAGE

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Feasibility of assessing the safety and effectiveness of menstrual regulation medications purchased from pharmacies in Bangladesh: a prospective cohort study

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ORIGINAL RESEARCH ARTICLE

Abstract

Objective: To assess the feasibility of following up women who purchase mifepristone + misoprostol or misoprostol only from pharmacies in order to measure the safety and effectiveness of self-administration of menstrual regulation.

Study design: A prospective cohort study followed women purchasing mifepristone + misoprostol or misoprostol only from pharmacies in Bangladesh. Participants were recruited by pharmacy workers either in person or indirectly via the purchaser of the drugs. End users were contacted by phone two weeks after recruitment, screened and interviewed.

Results: Study recruitment rates by pharmacy workers were low (30%, 109 of 642 women informed about the study) but two week follow-up rates were high (87%). Of the 109 end users interviewed, 87 purchased mifepristone + misoprostol and 20 misoprostol only, while 2 women did not know what drugs they had purchased. Mean self-reported weeks of pregnancy was 5.7 weeks. Information provision by pharmacy workers was inadequate (40.4% received none, 8.7% received written information or pictures). 80.5% of mifepristone + misoprostol users were sold the correct regimen versus 9 out of 20 misoprostol only users. 68.8% did not report experiencing any complications (70.0% misoprostol only; 69.0% mifepristone + misoprostol users, p=1.0). 94.3% of mifepristone + misoprostol users, and 75% of misoprostol only users reported they were not pregnant at day 15 (p=0.020). However, 7.3% of all users sought additional treatment.

Conclusions: Challenges in assessing outcomes of self-managed menstrual regulation medications purchased from pharmacies must be overcome through further development of

this methodology. Interventions are urgently needed to ensure women have access to correct dosages, accurate information and necessary referrals.

Implications

This paper assesses the outcomes of women who self-manage menstrual regulation medications purchased from pharmacies. The methodology requires further development, but our study provides preliminary positive evidence on the safety and effectiveness of self-management, despite low information provision from pharmacy workers.

1. Introduction

Women seeking abortion in low- and middle-income countries (LMICs) often turn to pharmacies as they are accessible, offer anonymity, and commonly sell medical abortion (MA) pills (misoprostol or mifepristone+misoprostol) without prescription. [1] Availability of these pills in communities has revolutionised access to safer abortion and reduced morbidity and mortality from unsafe abortion in recent years. [2–4] Women can safely self-administer MA, if they have clear and accurate information to know how to take the pills safely and effectively, and when and where to seek help in case of complications or ongoing pregnancy. [5] However, pharmacy workers in LMICs lack accurate knowledge about MA, do not provide adequate information to clients [1] and commonly sell the drugs without packaging or instructions for use, particularly as misoprostol only is not indicated for MA.

There is a dearth of evidence assessing the safety and effectiveness of self-administered MA when purchased without prescription from pharmacies, according to a broad literature search and consultation with experts. [6] Such data are difficult to obtain; recruiting and following up women who self-administer drugs is challenging because pharmacies and women may be unwilling to report on a form of provision and use that is not permitted; and low client volumes hinders the identification of women who purchase and self-administer these medications. Studies that have attempted to evaluate safety have measured complications among women presenting at clinics for post-abortion care after taking pharmacy-purchased MA pills. [7,8] However, these studies suffer from substantial selection bias as samples do not include women who have complete, uncomplicated abortions without the need for follow-up care, or those who manage adverse events outside of the formal health system. One feasibility study in Mexico attempted to use pharmacy-

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distributed flyers containing a phone number to recruit women prospectively into a study intended to assess clinical outcomes, but suffered an extremely low response rate. [9]

Addressing these methodological challenges is essential in order to obtain robust evidence on the clinical outcomes of women who self-administer MA purchased from pharmacies. Such evidence can inform: WHO guidelines on health worker roles; policy makers on the safety of reducing restrictions on the availability of MA; and design and evaluation of interventions aiming to improve the availability and safety of MA in communities.

This prospective cohort study aimed to assess the feasibility of following up women who self-administer misoprostol only and mifepristone+misoprostol purchased from pharmacies and to establish the clinical outcomes of women who self-administer these medications purchased from pharmacies in Bangladesh.

2. Materials and methods

2.1 Study setting

In Bangladesh, although abortion is legal only to save a woman's life, menstrual regulation (MR) services have been part of Bangladesh's family planning program since the 1970s. [10] MR is officially recognized in Bangladesh as an interim method for establishing non-pregnancy. MR services use manual vacuum aspiration up to 12 weeks after a missed period [11], or the mifepristone+misoprostol combined regimen up to nine weeks. [12] Pregnancy is not confirmed prior to administering the procedure or medications. Misoprostol is available on prescription for other indications (e.g. post-partum haemorrhage). There is little regulation of pharmacies in Bangladesh and many medications are sold over the counter

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without prescription [13], including mifepristone and misoprostol. Information provided by the Directorate General of Drug Administration shows that 32 brands of misoprostol only are registered for sale by 28 pharmaceutical companies, and 12 mifepristone only brands are registered for sale by 12 companies in Bangladesh. [14] Mifepristone and misoprostol are available packaged together, indicated for menstrual regulation, by at least eight different companies. In this study, the term 'MR medications' is used to refer to misoprostol only or mifepristone+misoprostol. The term pharmacy refers to any outlet selling medications whether or not its staff are registered or trained to do so.

2.2 Recruitment and data collection

Between November 2015 and March 2016, we conducted a prospective cohort study among women using MR medications purchased from pharmacies. We used random systematic sampling to select 110 pharmacies from a list of outlets that are supplied by a large Bangladeshi pharmaceutical company known to distribute misoprostol and the mifepristone+misoprostol combination pack in two of the country's eight administrative divisions (Dhaka and Mymensing). Field workers visited the pharmacies to explain the study and obtain informed consent. In each pharmacy, one pharmacy worker participated in the study. If more than one pharmacy worker was present, we invited the most senior to participate first. We reimbursed pharmacy workers 1,000 taka (12.70 USD) upfront for participating.

We asked pharmacy workers who agreed to take part to invite any person purchasing MR medications to participate in the study, using a script. We gave each pharmacy worker 40 information slips to distribute to women or men who purchased mifepristone+misoprostol or misoprostol only for any indication. The information slip contained a unique ID, a brief

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explanation of the study, instructions to send an SMS to the study phone line, and an explanation that callers would receive 100 taka (1.28 USD) phone credit.

Pharmacy workers instructed interested clients to SMS the study phone line immediately, and the pharmacy worker also offered to send the SMS on their behalf. Upon receiving an SMS, a trained research assistant phoned the client immediately, and asked to speak to the end user of the drug in order to check study eligibility and invite them to participate in a telephone interview two weeks later. Eligibility criteria were: women using MR medications purchased from selected pharmacies for MR by themselves or by proxy, aged 18-49 years, providing verbal informed consent, contacted before the end user took the pills, and taking MR medications for the first time in their current menstrual cycle. We excluded women who were not taking MR medications for the first time in their current menstrual cycle because we aimed to recruit women at the point of purchase, and then follow up outcomes; we would not have been able to collect adequate data on prior attempts and the woman's MR completion status at the point of making their purchase.

We conducted follow-up telephone interviews with the woman who took the pills 15 days after they took the first pill. Women who gave verbal consent during this call were interviewed using a structured questionnaire, which covered: information received from the pharmacy, MR regimen used, MR outcomes, side effects and complications. We developed questionnaires in English, which were then translated into Bengali, reviewed, revised and back-translated. Pregnancy was assessed through self-report because women were interviewed by phone and provision of pregnancy tests may have affected behaviours relating to self-administration. To identify the regimen used, participants were asked the brand of drug provided, the number of pills provided and the number of pills taken. Women

were not asked whether they had confirmed the pregnancy through a pregnancy test, but gestational age was estimated through women's self-report of weeks of pregnancy at the time of pill-taking. Women who reported needing medical help during the interview were referred to the Marie Stopes Bangladesh call centre for advice or onward clinical referral.

2.3 Sample size

We calculated a sample size of 432 misoprostol only clients and 400 combination pack clients (i) to measure a 15% difference in regimen effectiveness between misoprostol only (75%) and combination mifepristone+misoprostol (90%); and (ii) to compare the effectiveness of combination MR medications provided with and without prescription (which was estimated at 50%). The sample size calculation for misoprostol only clients was increased to 550 to account for clients who used misoprostol for other indications, estimated at 23% (unpublished data). The planned sample size was further increased to 825 misoprostol only and 600 combination MR clients to account for 33% expected loss to follow-up. The intended sample size was designed to have 80% power with α of .05. An average of 12 MR clients per month was expected per pharmacy (unpublished data). Allowing for 50% refusal among MR clients and 30% refusal among pharmacies, we estimated we would need to approach 110 pharmacies to complete recruitment within 3 months. Pharmacy workers were instructed to keep a tally sheet of all clients purchasing MR medications in order to estimate response rates.

2.4 Analysis

We double-entered data into Epi Data (version 2.0.3.15), exported data into SPSS (version 18) and conducted descriptive analysis. We compared outcomes between misoprostol only users and mifepristone+misoprostol users. We intended to compare outcomes between

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women who did and did not have a prescription for the combined regimen, but the number of participants with a prescription was too small for this analysis to be conducted. Comparisons between groups were made using chi-squared tests, or Fisher's Exact Test when the sample size was less than 5 per cell.

2.5 Ethics

We obtained ethical approval from the Bangladesh Medical Research Council and the Marie Stopes International Ethical Review Committee.

3. Results

Figure 1 details recruitment processes and loss to follow-up. Of 110 pharmacies approached, 76 agreed to take part (69%). Almost a third of clients during the study period were not informed about the study by the pharmacy worker (31%). Of the 642 pharmacy clients who were informed about the study by a pharmacy worker, the response rate was 30%. Clients were recruited from 22 of the 76 pharmacies. Among those pharmacies that recruited clients, the total number of respondents ranged from 1 to 18 per pharmacy, with a mean of 5 (median: 4) respondents recruited per pharmacy over the 3-month study period. The follow-up rate was 87%, among whom 109 respondents were eligible for a complete interview.

Respondent characteristics are displayed in Table 1. Respondent characteristics were not significantly different between those who purchased the drugs themselves and those who purchased drugs through a proxy purchaser (data not shown). The majority of women had used mifepristone+misoprostol (79.8%) versus 18.3% who used misoprostol only. Two

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respondents did not know what drug they had purchased. Only two respondents had a prescription and three did not state whether they had a prescription (all mifepristone+misoprostol purchasers).

The mean self-reported weeks of pregnancy of the clients at the time of taking the pills was 5.7 weeks (SD 1.8) (Table 1), and ranged from 2 to 12 weeks. Most women (89.9%) did not have their eligibility for taking the medication assessed by the pharmacy worker (criteria included: pain in lower abdomen, IUD inserted, severe asthma, long-term treatment for a medical condition, heart disease, bleeding problems) (Table 2). In an open-ended question about the information received from the pharmacy worker, women reported receiving very little information about the MR medications; 40.4% reported receiving no information. Few (8.4%) received written information or pictures on how to take the drugs. However, 97.2% stated that they administered the drugs as advised by the pharmacy staff. Most women (80.4%) reported that they were not informed of any warning signs and 50.5% were not told what to do in the event of complications.

Women who used the combination mifepristone+misoprostol regimen reported purchasing brands that are sold as a combination pack of 200mcg mifepristone and 800 mcg misoprostol. Among women who purchased the mifepristone+misoprostol regimen without prescription (n=87), 80.5% were sold five pills, the correct number for the WHO approved mifepristone+misoprostol regimen (Table 2). 69% took the correct regimen (200mcg mifepristone followed by 800mcg misoprostol after a 24-hour interval) [15] (data not shown).

Among the 20 women who purchased misoprostol only, four were sold less than 800mcg, 5 were sold 800mcg, 7 were sold between 800mcg-2400mcg, and 4 were sold 2400mcg. The

recommended misoprostol only regimen for MR up to 12 weeks is an initial dose of 800mcg of misoprostol, with subsequent doses of 800 mcg administered as needed. [15] Nine women were therefore sold a correct dosage of the drug (800mcg or 2400 mcg), but additional purchases may have been required for those who purchased less than 2400mcg (Table 2).

Among all participants, expected self-reported common side effects were cramping (79.4%); feeling very unwell with nausea, vomiting or abdominal pain (39.3%); and fever (19.6%). Self-reported potential complications were rarer, with 68.8% not experiencing any complications described in Table 3. The most common self-reported potential complications were heavy, prolonged bleeding (12.7%); or minimal or no bleeding (10.8%). The only side effect or complication that differed between misoprostol only and mifepristone+misoprostol users was minimal or no bleeding (22.7% vs 5.8%, p=0.021), possibly reflecting under-dosing and ongoing pregnancy. Eight (7.5%) women had sought additional treatment; of these, five reported they received an injection or tablet, one reported receiving a blood transfusion, and two received other unspecified treatment (data not shown). The source of treatment was a pharmacy for five of the women and a general practitioner for two of the women (data not shown).

At day 15, 89.9% of participants reported they were not pregnant. This was higher among mifepristone+misoprostol users (n=82 (94.3%)) than misoprostol only users (n=15 (75.0%)) (p=0.020). However, some participants were experiencing symptoms on day 15 that suggested the need for medical attention, including fever (13.8%), heavy bleeding (10.1%) and bad cramping or pain (4.6%) (no difference between drug types).

4. Discussion

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This study assessed the feasibility of following up women self-administering misoprostol or mifepristone+misoprostol purchased from pharmacies in Bangladesh to examine their clinical outcomes.

4.1 Feasibility of the study methodology for following up women who self-administer MR medications purchased from pharmacies

This study has highlighted methodological challenges for conducting research on pharmacy-provision of MR medications. Using pharmacy workers to recruit clients into the study did not yield the planned sample size. Pharmacies did not inform all MR clients about the study, which may have been because the recruiting pharmacy worker was not present or was too busy to inform clients. We recruited most respondents from a small number of pharmacies, and those pharmacies that were better able to recruit clients may systematically differ from pharmacies with low to no recruitment, with regard to the information they provided to clients. Therefore the experiences of our respondents may not be representative of all pharmacy clients. In future research, staggered payment to pharmacy workers for study participation and regular monitoring may improve study engagement, and including all pharmacy workers at each outlet may help to reduce the number of clients not informed about the study. Collecting detailed data on the characteristics of pharmacies that are included in similar studies in the future would also enable better understanding of how pharmacy characteristics might influence information provision and women's experiences.

According to the pharmacy workers, purchasers were reluctant to participate in the research. This contrasts with our previous experience interviewing MR clients in clinics, which may be because pharmacies are intended to be a faster, anonymous option or because clinics are viewed as more trustworthy than pharmacies. Response rates in this

study were low (30%), and those who agreed to participate likely differed from those who did not, which may have affected our estimates of information provision, regimen taken and reporting of outcomes. Future research needs to ensure that recruitment processes are non-threatening and convenient. Recruitment rates could be increased by placement of research assistants in pharmacies, investing in recruitment from a much larger sample of pharmacies, or selection of pharmacies known to have higher client volumes.

Participant follow-up was more successful than recruitment (87%). However, the study's reliance on self-report means that estimates of side effects, complications and completion may not be aligned with clinical definitions. Measures to assist self-report of outcomes would strengthen further studies attempting to distinguish between complications and side effects and to assess completion. In future studies, longer follow-up times may also help to verify self-report of MR completion. Similarly, since pregnancy tests were not used to verify pregnancy status, we cannot be certain that women were pregnant before they took the medications. In future studies, women should be asked how they knew they were or were not pregnant, to assist with verification of self-reported pregnancy status and self-reported completion rates.

4.2 Safety and effectiveness of MR medications purchased from pharmacies

There is a dearth of prospective research assessing the process and outcomes of pharmacy-purchased, self-managed MR medications. The study implementation itself illustrates the factors hindering communication of adequate information to users when MR medications are purchased from pharmacies: they lacked space for privacy; pharmacy workers were too busy or unavailable; and drugs were sometimes purchased by friends or family members.

Women's ability to distinguish side effects from complications or to self-assess completion without adequate information may also hinder care-seeking after self-administration.

Our study found that pharmacy workers did not adequately screen clients for eligibility before selling the medications, or provide adequate information about warning signs and complications. These findings are in line with previous studies of pharmacy practice for MR in Bangladesh. [16] Despite this, 97% of participants stated they had taken the drugs as advised by pharmacy workers, suggesting that although very little advice was provided, women felt that they had been given some direction on how to use the pills. Most women who were sold mifepristone+misoprostol took the correct regimen, and 94.3% of users reported the medications were effective at two weeks. A lower proportion of misoprostol only users were given an adequate quantity of the drugs, and effectiveness at two weeks was lower (75%), although small numbers in this group mean estimates should be treated with caution. The estimated completion rates in our study are within the range of expected effectiveness of clinic-provision of mifepristone+misoprostol (95-98%) [15] and just below the range for misoprostol only (78-90%). [17–19] Lower than required doses of misoprostol may have been used as a result of misoprostol not being indicated for MR, because instructions are not included in packaging. It could also reflect purchasers' inability to pay for a high enough quantity of the drugs upfront. The continued use of misoprostol only following the registration of mifepristone+misoprostol in 2013 may be due to cost, poor knowledge of the new regimen among purchasers or pharmacy workers, or lack of availability of mifepristone+misoprostol, and should be studied further. Increasing availability of high quality combination regimen products is important for reducing complications from incomplete abortion. [15]

Further work is also needed to develop and test interventions to improve the quality of pharmacy provision of MR medications. While training can be effective in increasing knowledge, turnover of staff and low availability of trained persons in pharmacies can limit the sustainability and scalability of such interventions. Support mechanisms for both pharmacy workers and for women directly are needed to ensure users have adequate information for safe self-management; this may include pharmacy worker training or individual detailing visits, written and pictorial instructions for self-management in product packaging, tools to support self-assessment of completion, and hotline support for women and pharmacy workers with phone numbers printed on product packaging.

5. Conclusions

Understanding the experiences and outcomes of women who purchase MR medications from pharmacies is critical, given the increasing scale of this practice. This feasibility study offers important lessons on appropriate methodologies to recruit and follow up pharmacy users, and to collect data on the outcomes in women who purchase MR medications from pharmacies. Further development of this methodology is needed, particularly in countries where misoprostol is commonly used alone as inadequate quantities of the drugs appeared to be commonly sold. The study has also shown that increasing access to accurate information and referrals in case of complications, as well as access to correct quantities of these drugs (in particular mifepristone+misoprostol) is required to reduce potential harms for women caused by incorrect dosing and administration. Measures to support safe self-management might include registration of the combination regimen (where not yet available), pharmacy worker training, hotline/call centre support, informational materials in product packaging, and user tools to assess eligibility and completion.

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Author contributions

KR, SN and SD conceived the methodology for the study. FT, KF, SD and KR applied for ethical approvals for the study. FT and SD managed implementation of the study. KF conducted data analysis. KF, FT, RS and KC co-wrote the manuscript. All authors reviewed and contributed to the manuscript.

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Table 1: Characteristics of respondents (n=109)

	n (%)	
Age		
Under 20	13	(11.9)
21-25	37	(33.9)
26-30	35	(32.1)
Over 30	24	(22.0)
Education		
None or incomplete primary	18	(16.5)
Primary complete	16	(14.7)
Secondary incomplete	48	(44.0)
Secondary complete or higher	27	(24.8)
Employment status		
Housewife	81	(74.3)
Employed	19	(17.5)
Student	8	(7.3)
Unemployed	1	(0.9)
Marital status		
Married	107	(98.2)
Number of living children		
0	13	(11.9)
1	36	(33.0)
2	36	(33.0)
3+	24	(22.1)
Who purchased the pills		
End user	55	(50.5)
Husband	44	(40.4)
Other relative, friend or neighbour	10	(9.2)
Prescription status		
No prescription	104	(95.4)
Had a prescription	2	(1.8)
No response	3	(2.8)
Type of medication purchased		
Misoprostol only	20	(18.3)
Mifepristone + misoprostol	87	(79.8)
Not known	2	(1.8)
Mean weeks of pregnancy	5.7 weeks (Range: 2-12 weeks)	

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Table 2: Information provision and dosages sold by pharmacy workers (n=109)

	n (%)	
Information provided by pharmacy worker		
None	44	(40.4)
Information on warning signs *		
None	86	(80.4)
What to do in case of danger signs/complications*		
Not told what to do	52	(50.5)
Eligibility criteria checked		
No eligibility criteria checked	98	(89.9)
Written information or pictures provided showing how to take pills	9	(8.4)
Was the regimen taken advised by the pharmacy worker?		
Yes	106	(97.2)
No	1	(0.9)
Don't know	2	(1.8)
Mifepristone-misoprostol dosage sold by pharmacy worker (n=82)		
Combination mifepristone+misoprostol pack including 5 pills	70	(80.5)
Misoprostol only dosage sold by pharmacy worker (n=20)		
Under 800mcg	4	(20.0)
800 mcg	5	(25.0)
1000 mcg	2	(10.0)
1200 mcg	5	(25.0)
2400 mcg	4	(20.0)

*Open-ended multi-response question

Table 3. Experience and outcomes of women using pharmacy-purchased MR, by drug regimen

	All users (n=109)	Misoprostol only users (n=20)	Mifepristone-misoprostol users (n=87)	
	n (%)	n (%)	n (%)	p-value
Experience of side effects in the 15 days since taking the first pill				
Fever	21 (19.6)	2 (10.0)	18 (20.7)	0.351
Feeling very unwell – nausea, vomiting, abdominal pain	42 (39.3)	8 (40.0)	33 (37.9)	1
Cramping	85 (79.4)	17 (85.0)	66 (75.9)	0.557
Experience of potential complications in the 15 days since taking the first pill				
None	75 (68.8)	14 (70.0)	60 (69.0)	1
Minimal or no bleeding**	**11 (10.0)**	**5 (22.7)**	**5 (5.8)**	**0.021**
Heavy, prolonged bleeding that made you feel faint or lasted beyond 4-6 hours of last tablet	14 (12.7)	2 (9.1)	12 (14.0)	1
Low blood pressure	2 (1.8)	0 (0.0)	2 (2.3)	1
Foul smelling vaginal discharge	1 (0.9)	1 (4.5)	0 (0.0)	0.19
Severe low abdominal pain that persisted or spread and was not reduced by pain medicines	6 (5.5)	0 (0.0)	6 (7.0)	0.59
Shoulder pain along with severe pain in your abdomen	1 (0.9)	0 (0.0)	1 (1.2)	1
Effectiveness of MR (self-reported)				
Thinks she is no longer pregnant**	**98 (89.9)**	**15 (75.0)**	**82 (94.3)**	**0.020**
Continuing side effects at day 15				
Experiencing heavy bleeding	11 (10.1)	1 (5.0)	8 (9.2)	1
Fever	15 (13.8)	3 (15.0)	11 (12.6)	0.73
Bad cramping or pain	5 (4.6)	0 (0.0)	4 (4.6)	1
Additional treatment sought				
Woman sought additional treatment after taking the tablets	8 (7.3)	0 (0.0)	7 (8.0)	0.341

**Comparison between misoprostol only and mifepristone-misoprostol users is significant (p<0.05) using Fisher's Exact Test

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