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Medical abortion in Ghana: A non-randomized, non-inferiority study of access through pharmacies compared with clinics☆,☆☆

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ABSTRACT

Objectives: To compare self-reported clinical outcomes following medical abortion with mifepristone and misoprostol sourced from either a pharmacy or health clinic.
Study design: We conducted a prospective, non-randomized, non-inferiority cohort study across four regions in Ghana, from high-volume pharmacies and health clinics. Participants seeking medical abortion (less than nine weeks' gestation) who met usual medical abortion eligibility criteria were recruited. Data collection included baseline surveys, follow-up phone interviews, and self-reported assessments of medical abortion outcomes. The study aimed to enroll 2000 medical abortion users (1000 from each source).
Results: Complete outcome data was available and analyzed from 1958 participants (of 2208 enrolled), with the adjusted risk difference of need for additional treatment to complete the abortion indicating non-inferiority of the pharmacy group compared to the clinic group [−2.3% (95% CI −5.3% to 0.7%)]. Both groups reported low rates of additional treatment (4.9%) and adhered similarly to the abortion regimen. Secondary outcomes showed no significant differences, with moderate acceptability in both groups (65.4% pharmacy, 52.3% facility). Adverse outcomes were rare: one ectopic pregnancy, one blood transfusion and no deaths or other major complications were reported.
Conclusions: Accessing medical abortion pills directly from pharmacies without prior consultation from a provider demonstrated non-inferior self-reported clinical outcomes compared to seeking care from health clinics. The findings align with the growing global evidence supporting the safety and effectiveness of medical abortion self-care.
Implications: This study contributes data which support future registration of over-the-counter use of medical abortion drugs up to nine weeks' gestation. Such measures could expand options for safe abortion care, especially in regions where unsafe abortion poses a substantial maternal health risk.
Trial registration: ClinicalTrials.gov (NCT03727308).

1. Introduction

Decades of research have demonstrated that the use of mifepristone and misoprostol is safe and effective for ending pregnancies in early gestation [1–4]. It has become an increasingly preferred method of abortion for reasons including privacy, perception of a more natural process, desire to manage the abortion at home, and availability in remote or rural areas lacking abortion providers [5]. Obtaining the regimen through informal routes, such as pharmacies, hotlines and websites, has become common, especially where abortion access is limited and/or during pandemic lockdowns [6,7]. Large telemedicine studies in countries such as the UK during the COVID-19 lockdown have demonstrated similar, if not superior outcomes with self-managed medical abortion, when compared with clinic-based provision [3,6–8]. Few studies, however, have been conducted where unsafe abortion persists as an important contributor to maternal mortality [9–11].

Like most countries, medical abortion pills are not yet registered over-the-counter in Ghana. Ghana's legal code from 1985 allows abortion only in a clinical setting by health professionals under

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certain conditions (rape, incest, defilement, mental or physical health) [12]. Medical abortion pills became an important method after the aforementioned legal code was enacted, explaining in part why pharmacies are not considered abortion providers, and requiring a prescription to attain the drugs. Despite the law, many covertly obtain pills without prescriptions from pharmacies [13,14]. The safety profile of mifepristone and misoprostol, meets many criteria for over-the-counter use, and data indicate women seek additional care when needed or indicated [6,7,10,15–18].

To better understand the impact of sourcing of medical abortion outside of clinics, we planned a prospective, non-randomized, non-inferiority study to evaluate whether important clinical outcomes differ among women who access a combined medical abortion regimen in early pregnancy (less than nine weeks' gestation) from a pharmacy when compared with those who access it from a health clinic.

2. Materials and methods

2.1. Trial design

We conducted a non-randomized, non-inferiority cohort study to compare clinical outcomes following medical abortion with mifepristone and misoprostol sourced from either a pharmacy or health clinic. A non-randomized design was selected due to practical and ethical considerations, while allowing a comparison of outcomes among users who select the source for abortion medicines (pharmacy or health clinic).

2.2. Participants

We identified sites with a high volume of medical abortion clients (both high-volume clinics and pharmacies) in four regions in Ghana: Greater Accra, Western Region, Ashanti region, and Eastern region. Identified using Ipas caseload data, clinics offered procedural abortion, and had high caseloads of medical abortion. Once we identified clinics for the study, we visited pharmacies within a two-kilometer radius. Pharmacies were eligible if they: were willing to participate in the research, had stocked or were willing to stock medical abortion combipack (co-packaged mifepristone and misoprostol; Mariprist and/or MM Combi Kit brands), were willing to sell Mariprist and/or MM Combi Kit over misoprostol alone to all women irrespective of their age, had sufficient demand for medical abortion, did not insist on a prescription and were located close to a clinic where women could be treated for complications (incomplete abortion, hemorrhage, ectopic pregnancy). Both combipacks include mifepristone 200 mg and misoprostol, four tablets of 200 mcg, as well as a package insert from the manufacturer which includes instructions on use (mifepristone 200 mg orally, followed 24–48 hours later by four tablets of misoprostol 800 mcg vaginally).

Research assistants offered study participation to those who were: at least 16 years of age, residing in Ghana, purchasing/obtaining medical abortion pills to terminate their own pregnancy, had a self-reported gestational duration of less than nine weeks, willing and able to give informed consent, and willing to be contacted with questions about the abortion. Exclusion criteria included: having an intrauterine device in place, history of an ectopic pregnancy, bleeding problems, porphyria, an allergy to medical abortion drugs, ever having had surgery on their fallopian tubes, or current or past week use of steroid medicines or blood thinners. Participants received phone credit to complete the follow-up interviews as remuneration. Participants only received counseling usually provided at the site where they purchased the combipack.

2.3. Data collection

Trained female research assistants posted to the pharmacies and clinics recruited participants for approximately eight hours a day over the duration of study recruitment; medical/pharmacy staff referred all purchasers of medical abortion to the research assistant who introduced the study, assessed eligibility, and obtained informed consent. The research assistants provided no information or counseling on use of or the process of medical abortion. Those who were eligible and consented to participate completed a baseline survey in person before leaving the recruitment site. The baseline survey was brief and collected socio-demographic and reproductive health characteristics as well as their phone number for the three follow-up phone interviews. In the first follow-up, three to seven days later, participants confirmed they had taken the pills, and those who confirmed taking at least one pill by seven days after recruitment were eligible for follow-up. If they reported not having taken a pill, they were asked if they still intended to and those who answered positively were called back three days later. If they decided not to take the pills, the research assistant thanked them for their time and no further contact took place.

Participants completed the second and third follow-up surveys via phone at 10–29 days and 30–35 days, respectively, after taking their first pill to assess abortion outcomes and experiences.

2.4. Interventions

The study evaluated whether medical abortion care in a pharmacy was non-inferior in terms of need for additional treatment to complete the abortion, to care in a health clinic. Participants sought care at their chosen medical abortion source (pharmacy or health clinic) where they received a combipack (mifepristone and misoprostol).

2.5. Outcomes

The primary outcome of the study was additional treatment to complete the abortion within 30 days of the medical abortion [19]. Assessment of the primary outcome occurred by telephone at two time points (10 days and 30 days after taking the first medical abortion pill); participants had additional treatment to complete their abortion if they self-reported additional treatment on either survey.

Secondary outcomes were the participant's confidence that the abortion was complete and whether they sought care for any health issues. In addition, we asked participants if they experienced any other problems with the abortion process. If they reported requiring a blood transfusion, hospitalization, surgery other than uterine evacuation, serious infection requiring treatment or an ectopic pregnancy (undiagnosed at the time of mifepristone), the research assistant coded their response as a serious adverse event and asked for details. Participants also answered questions on how they took the medical abortion pills: if mifepristone was taken first, if it was swallowed, if misoprostol was taken 1–2 days after mifepristone, if they took all four misoprostol pills, and if misoprostol was administered vaginally, buccally or sublingually, the use was considered to be correct. Data collected by research assistants was through self-report via telephone contact.

Finally, we assessed women's experiences through interview, including feeling prepared for the abortion process and satisfaction, as measured by asking if they would recommend the regimen to a friend who needed an abortion.

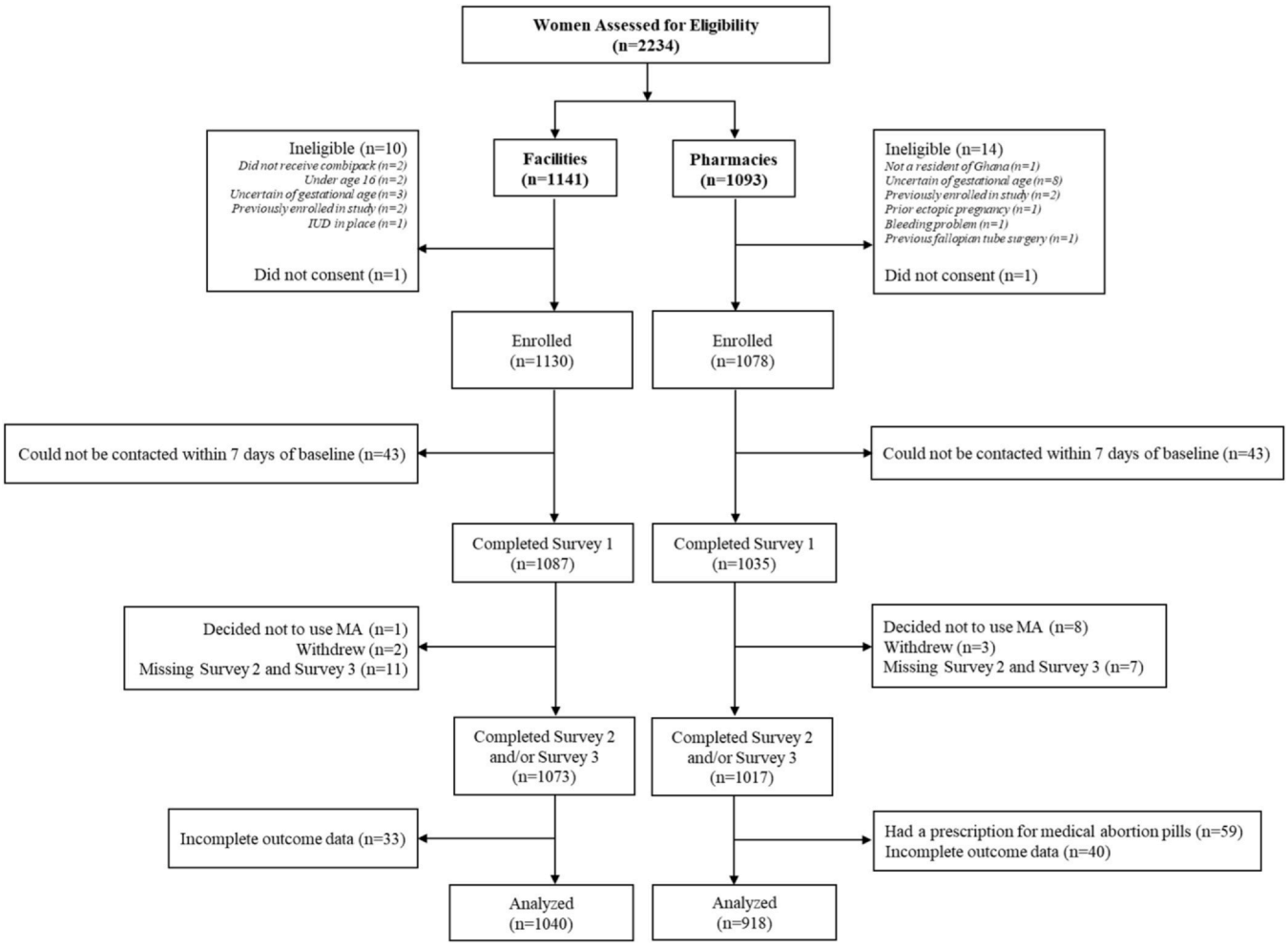

Fig. 1. Flow diagram of study participants in a non-randomized, non-inferiority study of medical abortion access through pharmacies compared with clinics in Ghana (December 2019–June 2021).

2.6. Sample size

Additional treatment to complete the abortion after medical abortion use was expected to be 6% in the clinic group based on previous studies of failure rates [3,4]. We set the non-inferiority limit at a four-percentage point difference between groups. We calculated the sample size based on 80% power to confirm non-inferiority with a one-sided confidence level of 97.5%, resulting in a sample size of 1108. As the outcome may have been more similar at an individual site than across different sites due to site-level practices, we inflated the sample size to account for a design effect. Assuming an intraclass correlation of 0.01 based on preliminary findings from early data collection as well as a similar study in Cambodia [10], a cluster size of 50 which would be feasible to collect, and 20% loss to follow-up, the resulting total sample size was 1981. In total, we planned to recruit 2000 medical abortion users (1000 from pharmacies and 1000 from clinics).

2.7. Statistical methods

To assess non-inferiority, we used we Poisson generalized estimating equations (GEE) models with identity link to account for clustering by site. Both the crude and adjusted risk differences were calculated using the GEE models. We calculated the adjusted risk difference by adjusting for characteristics that were significantly different between the pharmacy and health clinic groups after accounting for site level clustering. We reported both the crude and adjusted risk differences with 95% confidence intervals. We considered pharmacy care non-inferior to a health clinic if the confidence interval did not cross the non-inferiority limit of 4%.

All other analyses, including the assessment of sociodemographic differences between groups and differences in abortion experiences used multilevel mixed effects models with random effects for site to account for site-level clustering. We considered statistical significance at $p < 0.05$, and conducted analyses using Stata/SE version 17.1 (Stata Corp).

2.8. Ethics approval

University of Ghana (ECH 034/19-20), Ghana Health Service Ethics Review Committee (012/07/19), Marie Stopes International Ethic Review Committee (025-19).

3. Results

We included 15 clinic and 24 pharmacy sites. We approached 2234 medical abortion users for participation, including 1141 who sought medical abortion care in health clinics and 1093 who sought medical abortion in pharmacies. Recruitment occurred between December 2019–June 2021. Very few potential participants were ineligible based on medical criteria (Fig. 1). We analyzed data from 1958 participants (1040 at clinics and 918 at pharmacies) who took medical abortion pills, completed at least one follow-up survey (at 10 days or 30 days), and had complete outcome data. We excluded

Table 1
Sociodemographic characteristics and reproductive history of participants by group accessing medical abortion through pharmacies compared with clinics in Ghana (December 2019–June 2021) ($n = 1958$)

	Total ($n = 1958$)		Pharmacies ($n = 918$)		Facilities ($n = 1040$)		p-value
	n	%	*n*	%	*n*	%	
Age							0.341
< 20 years	192	9.8%	86	9.4%	106	10.2%	
20-24 years	711	36.3%	310	33.8%	401	38.6%	
> 24 years	1055	53.9%	522	56.9%	533	51.3%	
Education[a]							0.623
None/Primary/Middle School	528	27.0%	312	34.0%	216	20.8%	
High School	731	37.3%	389	42.4%	342	32.9%	
College or Higher	699	35.7%	217	23.6%	482	46.3%	
Residence							0.219
City	541	27.6%	315	34.3%	226	21.7%	
Town	1341	68.5%	561	61.1%	780	75.0%	
Village/Countryside/Rural Area	76	3.9%	42	4.6%	34	3.3%	
Employment[a]							0.738
Professional/Clerical/Sales/Services	902	46.2%	437	47.6%	465	44.7%	
Manual Labor/Agriculture	423	21.6%	214	23.3%	209	20.1%	
Student	375	19.2%	154	16.8%	221	21.3%	
Not working	258	13.2%	113	12.3%	145	13.9%	
Marital status[a]							0.093
Married/Living together	557	28.4%	272	29.6%	285	27.4%	
Separated/Divorced/Widowed	50	2.6%	37	4.0%	13	1.3%	
Never married & Not living together	1351	69.0%	609	66.4%	742	71.3%	
Parity[a]							0.221
0	1136	58.0%	461	50.2%	675	64.9%	
1-2	585	29.9%	330	36.0%	255	24.5%	
3+	237	12.1%	127	13.8%	110	10.6%	
Gravidity[a]							*< 0.001*
0	838	42.8%	313	34.1%	525	50.5%	
1-2	740	37.8%	382	41.6%	358	34.4%	
3+	380	19.4%	223	24.3%	157	15.1%	
Previous induced abortion[a]							0.072
None	1377	70.3%	599	65.3%	778	74.8%	
Previous abortion using MA	419	21.4%	246	26.8%	173	16.6%	
Previous abortion using other methods	162	8.3%	73	8.0%	89	8.6%	
Gestational age in weeks[a], *mean (SD)*	*6.07 (1.42)*		*5.96 (1.50)*		*6.16 (1.34)*		0.129

[a] Imputed to the mean for missing data. The percentage of missing data was 0.05% of the total sample (one participant) for each variable, except gestational age which was missing for 36 participants (1.8%).

Table 2
Crude and adjusted risk differences for medical abortion outcomes by group accessing medical abortion through pharmacies compared with clinics in Ghana (December 2019–June 2021) ($n = 1958$)

	Pharmacies ($n = 918$)		Facilities ($n = 1040$)		Risk difference (95% CI)	Adjusted risk difference[a] (95% CI)
	n	%	*n*	%		
Received additional treatment to complete the abortion	27	2.9%	50	4.8%	−2.1% (−5.0% to 0.9%)	−2.3% (−5.3% to 0.7%)
Felt confident the abortion was complete	767	83.6%	678	65.2%	9.5% (−1.1% to 20.2%)	9.6% (−1.1% to 20.3%)
Visited a health care professional for any other problems, outpatient or inpatient	72	7.8%	68	6.5%	1.3% (−1.2% to 3.9%)	1.3% (−1.5% to 4.1%)

[a] Adjusted for gravidity.

from analyses 59 women who presented with a prescription for combipack from the pharmacies. Though not originally an exclusion criterion for the study, the Principal Investigators determined that excluding pharmacy clients who had visited a health facility prior to obtaining combipack from the pharmacy would ensure the study comparisons were between medical abortion users who obtained care only from the site where they were recruited. See Figure 1 for a visual representation of participant flow throughout the study.

The sociodemographic characteristics and reproductive history of participants were similar by treatment group in terms of age, education, residence, employment, marital status, parity, previous abortion, and gestational age after accounting for site-level clustering. However, 605 (65.9%) of participants in the pharmacy group had at least one prior pregnancy compared to only 515 (45.9%) of participants in the clinic group ($p < 0.001$) (Table 1). Participants sought care early in pregnancy, with an average gestational age of 6.07 weeks (SD = 1.42). The medical abortion product used was comparable across groups; 1654 (84.5%) participants used Mariprist and 304 (15.5%) used MM Combi Kit (data not shown).

The rate of additional treatment to complete the abortion was 4.8% ($n = 50$) in the clinic and 2.9% ($n = 27$) in the pharmacy group for a crude risk difference of −2.1% (95% CI −5.0% to 0.9%) (Table 2). Adjusting for gravidity, the risk difference was −2.3% (95% CI −5.3% to 0.7%), indicating non-inferiority of the pharmacy compared to the clinic group.

Confidence the abortion was complete was more often reported in the pharmacy (83.6%, $n = 767$) compared with the clinic group (65.2%, $n = 678$), but the adjusted risk difference was not significant

Table 3
Medical abortion experiences by group after accessing medical abortion through pharmacies compared with clinics in Ghana (December 2019–June 2021) ($n = 1958$)

	Total ($n = 1958$)		Pharmacies ($n = 918$)		Facilities ($n = 1040$)		*p*-value
	n	%	*n*	%	*n*	%	
Type of additional treatment to complete the abortion[a]							
More MA pills	24	31.2%	12	44.4%	12	24.0%	0.101
Manual vacuum aspiration (MVA)	48	62.3%	13	48.2%	35	70.0%	0.117
Traditional method or homemade concoction	3	3.9%	2	7.4%	1	2.0%	0.274
Other	3	3.9%	0	0%	3	6.0%	0.996
Timing of additional treatment to complete the abortion[b]							0.879
Within 7 days of taking mifepristone	38	49.4%	14	51.8%	24	48.0%	
More than 7 days after taking mifepristone	39	50.6%	13	48.2%	26	52.0%	
Reason for seeking additional treatment to complete the abortion[b]							0.246
Concerns about bleeding	14	18.2%	3	11.1%	11	22.0%	
Thought she was still pregnant	63	81.8%	24	88.9%	39	78.0%	
Used the medical abortion package insert							*< 0.0001*
Yes	414	21.1%	362	39.4%	52	5.0%	
No or Don't know	1544	78.9%	556	60.6%	988	95.0%	
Took medical abortion pills correctly							0.686
Yes	1712	87.4%	796	86.7%	916	88.1%	
No or Don't know	246	12.6%	122	13.3%	124	11.9%	
Felt prepared for what happened after taking the medical abortion pills							*0.006*
Yes	1668	85.2%	753	82.1%	915	88.0%	
No or Don't know	289	14.8%	164	17.9%	125	12.0%	
Experienced but not expected[c]							
Heavier bleeding	79	4.0%	45	4.9%	34	3.3%	0.066
Longer bleeding	51	2.6%	35	3.8%	16	1.5%	0.197
More pain	142	7.3%	73	8.0%	69	6.6%	0.250
More nausea	23	1.2%	16	1.7%	7	0.7%	*0.035*
More vomiting	53	2.7%	38	4.1%	15	1.4%	0.078
Higher or longer fever	24	1.2%	10	1.1%	14	1.3%	0.870
More diarrhea	50	2.6%	34	3.7%	16	1.5%	0.462
Saw clots/tissue	59	3.0%	34	3.7%	25	2.4%	0.133
Minimal/No bleeding	10	0.5%	8	0.9%	2	0.2%	0.144
Vaginal discharge	9	0.5%	3	0.3%	6	0.6%	0.420
Would recommend medical abortion pills to a friend							0.260
Yes	1139	58.5%	599	65.4%	540	52.3%	
No	29	1.5%	11	1.2%	18	1.8%	
Wouldn't recommend any type of abortion	189	9.7%	104	11.4%	85	8.2%	
Wouldn't recommend a specific abortion method	418	21.5%	178	19.4%	240	23.2%	
Don't know	174	8.9%	24	2.6%	150	14.5%	

[a] Among women who reported additional treatment to complete the abortion ($n = 77$). Percentages sum to more than 100% because participants could report multiple types of treatment.
[b] Among women who reported additional treatment to complete the abortion ($n = 77$).
[c] Among women who reported they did not feel prepared for what happened after taking the medical abortion pills ($n = 293$). Percentages sum to more than 100% because participants could report multiple symptoms.

(aRD 9.6%, 95% CI −1.1% to 20.3%) (Table 2). Similarly, visiting a healthcare professional for other problems was not significantly different between groups (aRD 1.3%, 95% CI −1.5% to 4.1%).

The type of additional treatment received to complete the abortion among those who required it ($n = 77$) was similar across groups; most received MVA (62.3%, $n = 48$), followed by additional misoprostol (31.2%, $n = 24$), a traditional method (3.9%, $n = 3$), or something else (3.9%, $n = 3$) (Table 3). Of those who received additional care to complete the abortion or for complications, seven were hospitalized for additional treatment; five from the pharmacy and two from the clinic group ($p = 0.107$) (data not shown). Two had no bleeding and underwent uterine aspiration, four were treated for severe pain or severe bleeding with aspiration procedures, and one was hospitalized for malaria. One received a blood transfusion, and one received antibiotics (data not shown). One ectopic pregnancy was diagnosed and treated, after the participant in the pharmacy group experienced no bleeding following the medical abortion pills. There were no deaths, or other major complications.

There were some differences between experiences with medical abortion across the two groups (Table 3). Groups took the abortion regimen similarly; 796 (86.7%) took pills correctly in pharmacy compared with 916 (88.1%) in the clinic group ($p = 0.686$). More people read the combipack product insert information in the pharmacy (39.4%, $n = 362$) compared with the clinic group (5.0%, $n = 52$) ($p < 0.0001$). Fewer participants in the pharmacy group felt prepared for the abortion process (82.1%, $n = 753$) as compared to the clinic group (88.0%, $n = 915$; $p = 0.006$). Among those feeling unprepared, the only significant difference was in nausea (1.7%, $n = 16$ in the pharmacy, compared to 0.7%, $n = 7$ in the clinic group; $p = 0.035$). Acceptability, measured by whether the participant would recommend her abortion process to a friend, was equivalent across groups after accounting for site-level clustering, at 599 (65.4%) in the pharmacy and 540 (52.3%) in the clinic group ($p = 0.260$).

4. Discussion

Accessing medical abortion pills directly from a pharmacy without first having seen a health care provider in Ghana resulted in comparable self-reported clinical outcomes of safety, effectiveness and acceptability when compared with those seeking care through a clinic for pregnancies less than nine weeks' gestation. These data add to the growing literature demonstrating the safe and effective use of medical abortion pills independent of a clinic visit, and crucially expands these settings to settings where unsafe abortion is a substantial contributor to maternal mortality [6, 7, 10, 18].

As in a similar-designed study in Cambodia, we found overall low additional treatment rates to complete the abortion, with no differences between those who received care from a provider or

directly purchased medical abortion drugs [10]. A consistent finding across these studies is the early gestational duration of pregnancies among participants (generally less than six weeks). An advantage of abortion medicines' availability from pharmacies is that it may increase accessibility and decrease some logistical access barriers. Demographic differences between groups, particularly in reproductive history, is also consistent with findings in Cambodia, indicating that those with less experience with pregnancy and abortion may be more likely to choose care with more support, such as through a clinical provider [10].

We noted some differences between the current study and the prior one conducted in Cambodia; overall we found more similarities between the pharmacy and clinic groups in terms of acceptability in Ghana, whereas in Cambodia, acceptability was higher amongst the facility group [10]. Confidence in completing the abortion among the pharmacy group was lower than the clinic group in Cambodia, whereas in Ghana the confidence was highest among the pharmacy group. Although those seeking care from a pharmacy in both settings had more experience with pregnancy and abortion, which might translate to greater confidence in confirming abortion completion, only in Ghana was that confidence manifest. This finding may be related to the interaction with the pharmacy worker, counseling or offers of follow-up provided, which may also contribute to greater acceptability with self-care in Ghana, or to other factors which we did not measure. Extra care-seeking and requiring additional treatment were reassuringly low in both settings, and in Ghana, are similar to existing data from systematic reviews of clinical trials [3, 4, 20].

There are limitations to this study: importantly, all outcomes were by self-report and unconfirmed by medical records, mandated pregnancy testing or provider reports. We attempted to address this to an extent by choosing an objective primary outcome (additional treatment). The study design also has limits: we recognized that people seeking abortions from different sources may have differing characteristics, and thus intentionally clustered study sites to ensure the surrounding environment, including presence of dispensing pharmacies and clinics which provided abortion and care for complications, were similar between groups. Further limitations may be the generalizability of findings to people purchasing medical abortion beyond nine weeks' gestation and in settings geographically far from clinic support for treatment of complications.

Moving forward, research should examine similar use of misoprostol-alone regimens in low-middle income countries, more thoroughly examine the support needed as gestational duration increases and how to facilitate choice of care pathways to best meet abortion-seekers' needs. Future studies could also assess provision through more informal routes such as drug sellers, who undergo less training than pharmacists. In parallel, registration of over-the-counter combipacks could accelerate the normalization of such use, improve user comprehension and the role of different cadres of providers during the abortion process.

Data on the safety and efficacy of medical abortion sourced outside of clinics through various models of care (telemedicine, accompaniment, hotline-support and over-the-counter like settings) is mounting. Indeed, the World Health Organization's latest guidance on abortion care from 2022 endorse the safety legitimacy of abortion self-care as a strategy to promote choice and increase accessibility to services [20]. As medical abortion self-care in our studies result in similar clinical outcomes as those received through a clinic visit with a provider, expanding policies and registration of over-the-counter use should be prioritized.

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Author contributions

Samuel K. Antobam: Validation. **Jamie L. Menzel:** Data management. **Caesar Agula:** Data curation. **Ayga A. Bawah:** Supervision. **Erin E. Pearson:** Formal analysis. **Elisabeth Eckersberger:** Project administration. **Patrick O. Asuming:** Project administration. **Nathalie Kapp:** Writing – original draft, Conceptualization.

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