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Complete List of Authors:	Stillman, Melissa; Guttmacher Institute, Research Owolabi, Onikepe; Guttmacher Institute, Research Fatusi, Adesegun; Guttmacher Institute, Research; Academy for Health Development (AHEAD) Akinyemi, Akanni; Harvard University T H Chan School of Public Health; Obafemi Awolowo University, Demography and Social Statistics Berry, Amanda; Guttmacher Institute, Research Erinfolami, Temitope; Obafemi Awolowo University, Demography and Social Statistics; Centre for Research, Evaluation, Resources and Development (CRERD) Olagunju, Olalekan; Obafemi Awolowo University, Demography and Social Statistics; Centre for Research, Evaluation, Resources and Development (CRERD) Väisänen, Heini; University of Southampton, Social Statistics and Demography Bankole, Akinrinola; Guttmacher Institute, Research
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Title: Women's self-reported experiences using misoprostol obtained from drug sellers in Lagos State, Nigeria

Melissa Stillman, MPH[1]*
Onikepe Owolabi, PhD[1]
Adesegun O. Fatusi, PhD[1,2]
Akanni I. Akinyemi, PhD[3,4,5]
Amanda L. Berry, MPH[1]
Temitope P. Erinfolami, MSc[4,5]
Olalekan S. Olagunju, MSc[4,5]
Heini Väisänen, PhD[6]
Akinrinola Bankole, PhD[1]

1 Guttmacher Institute
125 Maiden Lane, 7th Floor
New York, NY 10038

2 Academy for Health Development (AHEAD)
Ile-Ife
Nigeria

3 Harvard T. H. Chan School of Public Health
677 Huntington Avenue
Boston, MA 02115

4 Obafemi Awolowo University
Department of Demography and Social Statistics
Ile-Ife
Osun State
220282
Nigeria

5 Centre for Research, Evaluation Resources and Development (CRERD)
Ile-Ife
Nigeria

6 University of Southampton
Department of Social Statistics and Demography
Highfield,
Southampton SO17 1BJ

* Corresponding author:
Melissa Stillman, mstillman@guttmacher.org
(212) 248-1111, ext. 2256
125 Maiden Lane, 7th Floor, New York, NY 10038

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ABSTRACT

Introduction: In settings where induced abortion is restricted, self-use of misoprostol is a critical option for women who may otherwise resort to other, unsafe, abortion methods. However, there is little evidence on the safety and effectiveness of self-managed misoprostol abortions obtained outside of formal health systems globally.

Methods: We conducted a prospective study of 394 women aged 18–49 who purchased misoprostol-containing medication from drug sellers for abortion in Lagos State, Nigeria. Data were collected through three telephone-administered interviews over one month. We assessed the quality of information provided by drug sellers; the prevalence of potential complications; and the proportion with completed abortions.

Results: About 60% of women did not know about abortion pills prior to visiting drug sellers, and 95% of women reported the experience as the first and only attempt to terminate the pregnancy. Although drug sellers provided inadequate information about the pills, 94% of women reported a complete abortion without surgical intervention about one month after taking the medication. Assuming a conservative scenario where all women lost to follow up had failed terminations, the completion rate dropped to 87%. While 86 women reported physical symptoms suggestive of complications, only six of these women reported wanting or needing health facility care and four subsequently obtained care.

Conclusion: Drug sellers are an important source of medical abortion in this setting. Despite the limitations of self-report, many women appear to have effectively self-administered misoprostol. Additional research is needed to expand the evidence on the safety and effectiveness of self-use of misoprostol for abortion in restrictive settings, and to inform approaches that support the health and well-being of people who use this method of abortion.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Data from this study are the first prospectively collected data that capture women's experiences with, and the self-reported effectiveness of, self-managed misoprostol abortion in a legally restrictive setting in Sub-Saharan Africa.
- This study utilized novel recruitment and retention approaches: drug sellers were the source of recruitment, which leveraged existing client-provider relationships; unregistered mobile phones

were distributed to participants to mitigate fears around potential loss of privacy; text messages were sent to participants periodically in between interviews, which improved engagement and likely contributed to the study's relatively high follow-up rate.

- The follow-up period for this study was one month, which is longer than that of previous studies, thus allowing more time for the medication to work and potentially resulting in a more accurate self-assessment of the medications' effectiveness.
- This study relied on women's self-report for our primary outcomes, and although we believe participants are capable of describing changes in their own bodies, it is difficult to determine the extent to which our findings will correlate with data collected under clinical experimental conditions.
- The study sites were purposively selected, and the sample could only include clients who obtained misoprostol from drug sellers willing to participate in the study and who may be different from other drug sellers in unknown ways, therefore our findings are not be generalizable to the entire population of the state and country.

INTRODUCTION

Globally, medical abortion (MA) has become an increasingly important method for women seeking to terminate a pregnancy.[1] While mifepristone followed by misoprostol is the preferred MA regimen recommended by the World Health Organization (WHO), misoprostol alone is recommended as a safe and effective alternative where mifepristone is not available.[2] WHO guidelines specify self-managed mifepristone and misoprostol as a viable approach for women to terminate pregnancies when they have access to adequate information and a trained healthcare provider.[3] However, WHO has not yet recommended self-management of misoprostol alone because of limited evidence. In contexts in which abortion is illegal or highly restricted, mifepristone is unlikely to be approved by the government, and self-managed abortion with misoprostol alone is a critical option for women who may otherwise resort to other, unsafe, methods.[1]

Nigeria has a population estimated at 200 million in 2019,[4] and induced abortion is legally permitted only to save a woman's life.[5] Despite the restrictive law, the rate of induced abortion in Nigeria was estimated at between 41.1 and 59.4 per 1,000 women of reproductive age in 2017.[6] MA drugs, particularly misoprostol, have become more widely available in Nigeria in recent years.[7–9] Nigeria has a large market of drug vendors serving informally as the first point of care for diverse health problems, and most medications can be procured without prescription.[10] However, evidence from other studies suggests that drug sellers have poor knowledge of MA drugs, commonly sell medications without packaging or instructions, and often provide inadequate or inaccurate information to women about medications, side effects, and potential complications.[11–16]

There is currently a dearth of community-based evidence on the experiences of women accessing misoprostol from drug sellers and the outcomes of self-managed abortions. Findings from a prospective study with a very small sample of women who bought misoprostol from pharmacy workers in Bangladesh indicate that 75% of women reported complete abortions after two weeks,[17] which is just below the range of expected effectiveness for misoprostol alone (78-90%).[18–21] Studies from several countries in Latin America where abortion is legally restricted suggests that even if women do not receive adequate information from drug sellers, information obtained through other means, such as hotlines, may reduce the potential risks of self-managed medical abortion.[1,22–24] The few studies in sub-Saharan Africa that attempted to assess health outcomes from use of misoprostol alone recruited women presenting for postabortion care in health facilities, and therefore do not represent all women who have used this method.[9,25] Prospective studies have the potential to provide stronger evidence but those that have attempted to explore these topics have reported challenges involving recruiting and following up women.[17,26]

To address this research gap, we designed a prospective study to explore women's experiences with misoprostol obtained from drug sellers in Lagos State, Nigeria. We investigated what dosages and information women receive when attempting to purchase misoprostol for abortion; what clinical effects

women experience, including potential complications; if and how women assess completeness; and what proportion of women have completed abortions.

METHODS

Study Setting

Data for this study were collected in six local government areas (LGAs) in Lagos State. Lagos is the most populous city in Nigeria and constitutes one of the largest markets for MA nationally. The 20 LGAs in Lagos State were stratified into more urban and less urban based on population density. From each stratum, we purposively selected three that each had at least one higher-level educational institution. We hypothesized that areas with higher-level educational institutions would have greater market for misoprostol due to the concentration of female students, a population that is likely to be at higher risk of unintended pregnancy.

Study design and data collection

Field activities were organized into two major components: 1) a drug seller study, which included a) a mapping of pharmacies and patent medicine vendors (PPMVs), herein referred to as drug sellers, and b) a screener interview to identify those selling misoprostol for any reason; and 2) a prospective study of women who purchased misoprostol, recruited by drug sellers.

Identifying drug sellers who sell misoprostol

Fieldworkers collected the names and GPS coordinates of all drug sellers in each LGA, generating the universe (N=968; Figure 1). Thereafter, they visited every shop and conducted a screening interview to generate a list of drug sellers that reported selling misoprostol for any indication. Drug sellers who reported selling misoprostol (n=340) were invited to recruit all women who purchased any misoprostol-containing medications, directly or through a proxy, for any reason over a two-month period. In total, 227 drug sellers agreed to recruit women. See Appendix A for more details on recruitment procedures.

Prospective study of women

Drug sellers recruited women who bought misoprostol, or a misoprostol-containing drug, for any reason. However, only women aged 18–49 who bought it specifically to terminate a pregnancy were eligible for inclusion. Interviewers asked questions to determine eligibility during a screener interview conducted one to two days after purchase of the medicine and eligible women were invited to participate in two additional rounds of telephone interviews over approximately one month.

A first follow-up interview was conducted five to seven days after screening to identify the medications purchased, establish if and how the woman used the medication and ask about her interaction with the drug seller at the time of purchase. A second follow-up interview was conducted three weeks later (one month after purchasing the medication) to understand women's self-reported health outcomes after taking the medication, how women assessed the completion of their abortions, support during the abortion process, and women's willingness to recommend misoprostol to friends or use it again.

Data for the drug seller screening were collected in-person by trained male fieldworkers and data from the women were collected over the telephone by female field workers trained by the study team in sensitive interviewing techniques. All data were collected using the mobile data collection application SurveyCTO on password-protected and encrypted Android tablets and stored on a secure server accessible only to the research team. Women's informed consent was obtained prior to each interview, and permission to be contacted again for the next follow-up interview was given at the end of the screener and first follow-up interviews. Women's identities were confirmed at each interview using a unique identification number, password or nickname provided at the time of recruitment. Data collection occurred between April and October 2018.

The National Health Research Ethics Committee in Nigeria and the Institutional Review Board of Guttmacher Institute approved the study.

Patient and Public Involvement

The study was supported by a Technical Advisory Group that provided input on the program of research. The advisory group, which consisted of medical doctors, local researchers and other experts in the field of sexual and reproductive health in Nigeria, provided input on the research questions, study design and tool development prior to the start of fieldwork. The advisory group provided feedback on the preliminary research findings and advice on messaging the results. The group will help plan dissemination activities, including the presentation of findings to participating drug sellers.

Study definitions (described in detail in Appendix B)

Dosage

Doses of less than 800 mcgs for misoprostol alone were classified as less than the WHO recommended dose for first trimester abortions.[2]

Route of administration

An optimal route of misoprostol administration was defined as administering it buccally, sublingually, or vaginally.[2,27] A suboptimal route was one where women were given the option to swallow the misoprostol by mouth.

Adequacy of information

We created a nine-item score for the adequacy of information covered during the drug sellers' interactions with women. We included information considered to be reasonably necessary, based on medical literature, for women to successfully self-manage abortion. We allocated each item one point if the information was provided and created the index by adding up the total number of points.

Women's experiences of warning signs of potential complications

Warning signs of complications were assessed using self-reported symptoms after taking the medication and included excessive or greater than anticipated bleeding; or a combination of greater than anticipated abdominal pain or cramping, fever and chills, or vaginal discharge that could potentially indicate an infection. Criteria used to assess these are described in Appendix B.

Analysis

We conducted descriptive analyses to summarize women's sociodemographic characteristics; the quality of information provided by drug sellers; the prevalence of potential complications; the proportion who had complete terminations without additional medical interventions; and abortion strategies women would have employed had they not used misoprostol. All analyses were conducted using Stata15.1.

RESULTS

Of the 501 women recruited by drug sellers, 446 women were eligible for the study, and 394 women (88% of all eligible women recruited) were successfully interviewed in both follow-up interviews (Figure 1). The data presented in the results are from all women who completed both interviews, including a small proportion (2%) that received mifepristone + misoprostol.

Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study

Demographic characteristics of participants

More than half of our sample (55%) were between the ages of 18 and 29, and 92% had completed senior secondary school while 38% had completed some higher education (Table 1). About three-quarters (76%) worked for someone else (non-family member) in a business, and 13% were students at the time they purchased the misoprostol. Half (50%) were married or cohabiting, and 95% purchased the drug themselves. Most respondents (83%) had taken some kind of pregnancy test prior to going to the drug seller. For 85% of women, this was their first pregnancy termination.

Table 1. Demographic characteristics of women, type of drug sellers visited and who bought the pills, proportion of women who took a pregnancy test, and previous experiences with abortion, Lagos, 2018

	Among women who completed both follow-up interviews* (n=394)		Among ever-pregnant women aged 18-49 in Lagos State† (n=1,020)	
	%	No.	%	No.
Age categories				

18 - 24	22.8	90	8.3	84
25 - 29	32.0	126	20.7	208
30 - 34	23.4	92	24.8	244
35 - 39	16.0	63	21.7	231
40 - 44	5.1	20	13.8	144
45 - 49	0.8	3	10.6	109
Median age (IQR)	28	(25-33)	34	(29-39)
Parity‡				
No children	33.5	76	4.0	44
1-2 children	37.4	85	59.5	604
3+ children	29.1	66	36.5	372
Mean (SD)	1.6	(1.5)	3.0	(1.89)
Highest Level of Education Completed				
No schooling or incomplete primary	0.8	3	7.9	81
Primary/Junior secondary school	7.4	29	28.3	289
Senior secondary school	54.1	213	42.0	420
Some higher education (or more)	37.8	149	21.8	230
Employment				
Work for someone else/non-family business	51.5	203	15.6	171
Work for own/family business	24.1	95	69.2	706
Housewife	3.8	15	NA	NA
Student	13.2	52	NA	NA
Unemployed	7.4	29	15.2	143
Relationship Status				
Currently married or cohabiting	50.0	197	88.4	894
Separated/divorced/widowed	5.1	20	7.6	81
Never married and never lived together with a man	44.9	177	4.0	45
Local Government Area of recruitment				
Lagos Mainland	17.0	67	NA	NA
Ojo	18.3	72	NA	NA
Oshodi Isolo	16.2	64	NA	NA
Epe	8.9	35	NA	NA
Ikorodu	24.4	96	NA	NA
Ibeju Lekki	15.2	60	NA	NA
Women who went to each type of drug seller				
Pharmacy	40.6	160	NA	NA
Proprietary Patent Medicine Vendor (PPMV)	59.4	234	NA	NA
Who purchased the medicine				

Medicines bought by the woman	95.2	375	NA	NA
Medicines bought by someone else	4.8	19	NA	NA
Previous attempt to end a pregnancy				
No, has not attempted to end a prior pregnancy	84.5	333	NA	NA
Yes, has previously attempted to end a prior pregnancy	15.5	61	NA	NA
% of women who took each type of pregnancy test when they suspected they were pregnant§				
Confirmation via test with a doctor	20.8	82	NA	NA
Confirmation via test at a laboratory	17.5	69	NA	NA
Self-administered urine test	54.6	215	NA	NA
No test	17.0	67	NA	NA

* Our study data
† 2013 Nigeria Demographic and Health Survey (Lagos State only)
‡ Our study data on parity are only from a subset of the sample (N=227)
§ Multiple responses were allowed
NA = Not applicable.

Abortion attempts prior to recruitment

A small proportion (5%, n=21) of the sample had made at least one other attempt to terminate the current pregnancy prior to being recruited into the study (Appendix C, Table 1). Of them, 12 had taken pills and ten ingested herbal preparations. Half the women who took pills did not know what pills they had taken, four had taken emergency contraception and two took an unspecified dose of misoprostol that was ineffective.

Medication types, determining eligibility, and dosage

Upon entering the drug store, 51% of women told the drug sellers that they needed something to end a pregnancy, and 39% said they wanted help to bring back a late menstrual period (Table 2). More than half (57%) reported that they had not known there were pills they could take to end a pregnancy prior to visiting the drug seller; 22% had heard about such pills from a friend or family member, and 7-8% found out about them online or from a health professional (not shown). One-fourth of the sample reported that they did not know what medication they purchased from the drug seller. Among those who knew what medication they purchased, a majority (93%) reported receiving just misoprostol from the drug seller, and 2% received

misoprostol in combination with mifepristone. Based on women's self-reports of the type and number of tablets purchased, we confirmed that 69% were sold less than the recommended dosage for effectiveness (<800mcg misoprostol).

Table 2. Women's experiences interacting with the drug seller, types of medications, dosages, and administration routes, Lagos, 2018

	Women who completed both follow-up interviews (n=394)	
	%	No.
How women presented themselves to the drug seller*		
Told drug seller she wanted to end a pregnancy	50.5	199
Told drug seller she wanted to purchase misoprostol or other specific brand name medicine	16.2	64
Told the drug seller she wanted to bring back a late period	39.3	155
Told drug seller something else	1.3	5
Types of medicine women reported receiving†		
Misoprostol	69.0	272
Misoprostol + Mifepristone	1.8	7
Unknown medicine‡	25.4	100
Missing	3.8	15
Dosage of medication prescribed by drugseller (n=251)§		
Less than the WHO recommended dosage (< 800 mcg misoprostol)	69.3	174
800 mcg misoprostol	26.7	67
1000-1400mcg misoprostol	2.0	5
1600mcg-2400mcg misoprostol	0.8	2
200mg mifepristone & 800mcg misprostol	1.2	3
Routes of administration of the medication prescribed by drugseller (n=228)¶		
Suboptimal route (oral misoprostol)	66.7	152
Optimal route (buccal, vaginal, or sublingual misoprostol)	32.9	75
Drug seller did not say	0.4	1

* Multiple responses were allowed

† Data on types of medicine received are not available for 15 women due to missing responses.

‡ "Unknown" means the woman did not know what medication she took, either because she was never told or because she could not remember. Although the medication was unknown to her, it still could have been misoprostol or another abortifacient.

§ The medication dosage could only be assessed among women who answered specific questions about the numbers of each type of pills they were given, and who either knew what medication(s) they were given or for whom we were able to, with reasonable confidence, parse out what medication(s) they were given based on their answers to related questions.

¶ The administration route could only be assessed among women for whom we could identify the medication(s) given. Since World Health Organization (WHO) guidelines recommend that mifepristone be administered orally and misoprostol be administered bucally, vaginally, or sublingually, any administration route instructions that diverge from these recommendations are considered suboptimal.

Instructions received from the drug sellers

Most of the sample (78%) reported that they were given some instructions about how to take the medications, and nearly all women who received instructions followed them (Table 3). Most women relied solely on drug sellers for information: 72% did not use any other source (not shown).

Table 3. Percent of women that reported drug sellers providing information about misoprostol or asking questions to assess eligibility for misoprostol prior to purchase, Lagos, 2018

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who received <u>any</u> instructions from the drug seller about how to take the medication	77.9	307
Women who took tablets according to drug sellers' instructions		
Followed instructions	75.9	299
Did not follow instructions	2.0	8
Did not receive instructions	22.1	87
Women reporting the following items were covered during the interaction with the drug seller		
Asked timing of last menstrual period	79.4	313
Asked if she took a pregnancy test	74.1	292
Informed that bleeding is an anticipated effect	66.5	262
Informed that cramping is an anticipated effect	35.3	139
Informed that severe bleeding could indicate a potential complication	12.9	51
Informed that severe and persistent abdominal pain could indicate a potential complication	3.0	12
Informed about use of pain medication	28.2	111
Informed of potential allergic reactions	7.1	28
Informed of potential contraindications	22.8	90
Number of items listed above that were covered in women's interaction with drug sellers		
No core information	9.6	38
1-3 items	42.4	167

4-6 items	45.2	178
7-8 items	2.8	11
9 items	--	--
	Mean	SD
Adequacy of information scale score (out of 9 items)	3.3	1.8

On average, women reported that drug sellers covered three of nine items we considered necessary for successfully self-management of misoprostol abortion (Table 3). A relatively high proportion reported that drug sellers attempted to assess their eligibility: 74% were asked if they had confirmed their pregnancy with a test, and 79% were asked the timing of their last menstrual period. However, fewer reported being given information about what clinical symptoms to anticipate as a normal part of the abortion process; 67% and 35% reported being told that they could expect some bleeding or cramping, respectively. Only 13% were told about severe bleeding that could indicate a potential complication.

Women's experiences of warning signs after taking the medication and subsequent care seeking

Most women did not report adverse events after taking the medication. However, 77 women (20%) reported bleeding that we classified as potentially problematic, and 15 women (4%) reported a combination of symptoms suggestive of infection (Table 4). Six women were classified as having experienced symptoms of both. Among the 86 women with potentially problematic bleeding or symptoms of infection, six reported wanting or needing medical care, and four sought care (not shown). One of the four reported receiving a blood transfusion and undergoing a surgical abortion procedure, while the rest were given painkillers, an ultrasound or blood test.

Table 4. Women's experiences of expected clinical symptoms and potential complications after using medications obtained from drug sellers, Lagos, 2018

	Among women who completed both follow-up interviews (n=394)			
	Women who experienced expected clinical symptoms		Women who experienced warning signs of potential complications	
	%	No.	%	No.
Bleeding*	84.5	333	19.5	77
Cramping/Abdominal Pain†	70.6	278	2.0	8
Headaches	8.4	33	NA	NA
Vomiting	5.3	21	NA	NA

Nausea	3.0	12	NA	NA
Diarrhea	5.1	20	NA	NA
Fever/chills‡	8.4	33	1.3	5
Foul smelling or colored vaginal discharge§	NA	NA	0.5	2
General feeling of weakness	20.3	80	NA	NA
Dizziness	2.3	9	NA	NA
None/nothing	5.6	22	NA	NA
Postabortion infection¶	NA	NA	3.8	15

* Bleeding that could indicate potential complications are categorized as bleeding that soaks through more than two regular sized pads in two hours, lasting for 12 hours after taking the medication.

† Abdominal pain and cramping that could indicate potential complications are categorized as follows:
Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
Abdominal pain at the time of the last interview (~one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

‡ Fever and chills that could indicate potential complications are categorized as follows:
Fever or chills that lasted more than 24 hours after taking the medication, or
Any fever or chills still experienced at the time of the last interview (~one month after taking the medication).

§ Foul smelling or discolored vaginal discharge that could indicate potential complications are categorized as follows:
Foul smelling or discolored (not clear or white) discharge after taking the medication, or
Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

¶ Postabortion infection was characterized as a combination of problematic abdominal pain or cramping, fever and chills, or vaginal discharge.

NA = Not applicable.

Overall, 29 women in the study (7%) reported wanting or needing medical care after taking the pills, and 24 actually sought care (not shown). Few women (25%) were given any information from drug sellers about seeking postabortion care. However, 48% of those who reported wanting or needing care also reported they had been told during their initial interaction with the drug seller that they may need to seek medical attention for potential complications, compared to 23% of those that did not report needing follow-up care. Most women who sought care were given pain medication, or underwent an ultrasound, suggesting

that they might not have presented with serious complications. One woman reported receiving a blood transfusion, and seven women were treated with a surgical abortion procedure.

Participants' assessment of abortion completeness

At the time of the second follow-up interview, around one month after taking the pills, 95% of women reported that they were no longer pregnant (Table 5). The most common way women assessed the completeness of the abortion was by the return of their menstrual period (54%). 369 women (94%) reported a complete abortion without any additional medical intervention about one month after taking the pills. Completion rates did not substantially vary according to the dosages women reported taking: 93%, of women who we confirmed received less than 800mcg of misoprostol reported complete abortions versus 97% of women who received 800mcg (Appendix C, Table 3). If we assume 50% of the women lost to follow-up had a successful termination, then 91% of all eligible women had a complete abortion, and if we assume none of them had a successful termination the rate of complete abortion drops to 87% (Appendix C, Table 4).

Table 5. Women's perceptions of pregnancy continuation and how they assessed the completeness of the abortion process, Lagos, 2018

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who reported that they were no longer pregnant at the time of the second follow up interview	95.4	376
Reasons given for believing pregnancy has ended (n=376)*		
Woman's period returned	53.7	202
Woman took a urine pregnancy test at home	33.2	125
Woman no longer has pregnancy symptoms	24.7	93
Woman took a blood pregnancy test	16.0	60
Woman passed the products of conception	13.3	50
Woman took a urine pregnancy test at a facility	5.1	19
Woman had a sonogram/ultrasound	4.0	15
Woman got cleaned at a facility/surgical intervention	1.9	7
Other	0.8	3
Women who reported a complete abortion without surgical intervention	93.7	369

* Multiple responses were allowed

Alternatives to using misoprostol and willingness to use it again or recommend it to a friend in the future

Sixty percent of women reported that they would have gone to a health facility for help had they not had access to misoprostol (not shown). Twenty-two women (6%) said they would have gone to a traditional practitioner, 17 would have drank chemicals, four would have done excessive exercise, and two reported that they would have inserted objects to self-induce abortion. About one-fourth of women (27%) said they would have done nothing.

Seventy percent of women in the study reported that they would use misoprostol again. Of those that would not, 47% said they would not terminate another pregnancy at all. Others (13-16%) thought that it would damage their health or fertility, reported that it was too painful or that they did not like the experience. Nevertheless, 85% of women reported that they would recommend misoprostol to a friend.

DISCUSSION

To our knowledge, this is the first prospective study examining the experiences and health outcomes of women obtaining misoprostol from drug sellers in sub-Saharan Africa. Around two-thirds of eligible drug sellers were willing to recruit for the study, almost all (97%) of the 501 women recruited were successfully contacted and screened by interviewers, 92% of those screened were eligible for the study, and 88% of eligible women completed the screener and both follow-up interviews. Comparing our study sample to ever-pregnant women aged 18 to 49 in Lagos State from the Demographic and Health survey,[28] we find some key differences between the two populations. Our sample was: more highly educated (92% compared with 64% had completed secondary education), younger (55% compared with 29% were between 18 and 29 years old), more often nulliparous (34% vs. 4%), more commonly worked someone else (non-family member) in a business (52% vs. 16%), and more commonly had never been married (45% vs. 4%; Table 1).

Although about 60% of our sample were not aware of medical abortion pills prior to visiting the drug seller, for nearly everyone this encounter was their first and only attempt to end their pregnancy. Most women visited the drug seller by themselves, and a majority of them appeared to have been comfortable explicitly asking drug sellers for help to induce an abortion. Most women in our study relied on their interaction with the drug sellers as their only source of information, reported trusting the information drug sellers gave them about the drugs and following their instructions for use. More than one-fourth reported that they would have had an unwanted birth had they not had access to misoprostol, suggesting they would have lost the opportunity to achieve their preferred family size or their desired timing of giving birth. Additionally, for nearly 9% of women, having access to misoprostol was essential to avoid self-inducing with highly unsafe methods such as sharp objects inserted into the vagina, drinking chemical substances or another method obtained from an herbalist or other traditional practitioner. Further, the majority of women would recommend misoprostol abortion to a friend, and, if necessary, use it in the future, suggesting high levels of satisfaction with this method of abortion. These findings suggests a relatively high level of autonomy for abortion care seeking among our sample compared to women in other studies and indicate the important role that drug sellers play as trusted sources of information and providers of medical abortion for women in Lagos state. However, the appropriateness of the drug prescriptions and the quality of information provided to women by drug sellers was poor overall as documented in other studies.[12]

Among women who completed both interviews, 94% reported complete abortion without surgical intervention. This is despite the fact that at least two-thirds appear to have received less than the first trimester recommended dose of 800mcg misoprostol and/or were told they could ingest the misoprostol orally, which is a less effective route of administration than sublingually, buccally, or vaginally.[27] The medication's high level of effectiveness despite the low doses reportedly used could be partially explained if most pregnancies were in second trimester, during which time the uterus is more sensitive to lower doses of misoprostol.[29] The perceived success of the method could also be attributed to the longer length of follow up in our study: Generally, studies assessing MA effectiveness have followed up women around two weeks or sooner after taking the medication.[17,30] Allowing for a longer follow-up period ensures that the medication has sufficient time to work in the body, and may improve its success rate.[30] Overall, even in

the most conservative outcome for women lost to follow-up, the completeness rate of self-managed abortions in our study was 87% (Appendix C, Table 4), which is within the effectiveness range for misoprostol based on recommended protocols in clinical settings (78-90%).[18–21]

WHO's task sharing guidelines recognize that women have a role in self-management of the combined mifepristone and misoprostol abortion regimen if they have accurate information and access to a healthcare provider should they want or need at any point during the process, although pharmacy-alone provision is not explicitly recommended.[3] However, no such self-management guidelines yet exist for misoprostol-only abortions, which was the regimen used by the majority of women in our study. We cannot accurately assess their weeks of gestation; however, the majority had taken a pregnancy test, were able to follow instructions, and appeared to have been able to assess the completeness of termination. Almost all women retained for the duration of the study reported complete abortion at the one-month follow-up. While most women did not report needing or wanting postabortion care, we are unable to clinically verify the proportion that actually experienced complications for which they needed medical care. The findings suggest that perceptions of needing care may be related to information, or lack thereof, they received from drug sellers about potential complications and care-seeking needs. Nearly half (48%) of those that reported needing medical care had been warned by drug sellers about complications, compared with only 23% of those who did not report needing care. However, the results show that nearly all women who reported wanting or needing care were able to access it, and most of those who sought care were monitored or given pain medications, suggesting that they presented with symptoms that were either a normal part of the abortion process or that reflected very minor complications.

Our study has many methodological challenges and limitations. The study LGAs were purposively selected, so our sample is not representative of Lagos State. We have little information on women who dropped out and are hence unable to ascertain how they are different from women who completed the entire study. Our sample only includes women who were recruited by drug sellers who admitted to selling misoprostol and then agreed to participate in recruiting women, and who may have different practices from those who did not admit to selling or agree to recruit women, which could potentially bias our results

(Appendix C, Table 5). We were able to verify the medication purchased for about three-fourths of the women. However, we hypothesize that a majority of the women in our study obtained misoprostol because this was the criterion for recruitment on which we trained drug sellers, and we do not see many differences in key indicators between the women who we were able to verify had purchased misoprostol and those who we could not verify (Appendix C, Table 2). Measures for dosage and route of administration are based on women's self-report of the number of pills they took and instructions they were given, which may be subject to recall bias and/or misinterpretation. Although these limitations are balanced by the strengths of the study, including its prospective design and woman-centered approach, our overall reliance on self-reported measures for many of our core outcomes makes it difficult to determine the extent to which our findings will correlate with clinical data and must be interpreted with caution.

CONCLUSION

Worldwide, there is a paucity of research assessing the processes by which women obtain MA (either the combined method or misoprostol alone) for self-management of abortion and prospectively documenting their outcomes. Our success with drug seller engagement and women's recruitment is high compared with previous studies.[17,26] While this success may be due in part to the urban context of Lagos and the relatively liberal environment for drug stores and medication access generally in Nigeria, our experience suggests that prospective studies on misoprostol abortion in highly restrictive legal settings with similar attributes may be feasible. While our findings may not be generalizable to the entire female population in Lagos, they do provide valuable insights into the experiences of women who self-manage their abortions using misoprostol, from their own perspectives. The majority of our sample purchased misoprostol, took the medication according to the instructions, reported that drug sellers were their main source of information during the process and appear to have been able to successfully complete their abortions with minimal complications. Recognizing the limitations of self-reported outcomes, and given evidence from clinical trials suggesting that as many as 20% of women may experience an incomplete termination using misoprostol alone, it is an important harm-reduction strategy to ensure that people who self-manage their medical abortions have adequate and correct information on warning signs of complications as well as access to postabortion care. Interventions to improve drug sellers' knowledge of best practices related to

medical abortion may be an important part of the effort to improve their quality of services and the health and well-being of their clients, especially in similar settings where drug sellers are relied on for basic medical care. However, future research should explore ways to more objectively capture data relating to the duration of pregnancy, drug dosage, and clinical outcomes in addition to documenting women's experiences using the method. It is likely that the self-use of misoprostol will remain an important option for women, especially where abortion is legally restricted. More research is needed to expand the evidence on the safety and effectiveness of self-managed misoprostol abortion in similarly restrictive contexts, and to help inform the development of approaches and mechanisms to further support women in this process and to facilitate their optimal outcomes.

CONTRIBUTORSHIP STATEMENT

OO, AB, MS, AF and AA participated in the conceptualization of the project and designed the study. AF, AA, MS, OO, AB, ALB, TE, OSO, and HV participated in project planning. MS, ALB, OO, and TE programmed the study tools into SurveyCTO for electronic data collection. AA, TE, and OSO coordinated all aspects of fielding. AA, AF, TE, and OSO conducted the piloting of the study protocol and tools. AA, TE, and OSO selected fieldworkers and organized the trainings. MS, AA, TE, OSO, AF and HV co-led fieldwork trainings. AF liaised with the Ministry of Health and relevant drug seller associations to get permission to conduct fieldwork at the local level. AF and AA convened the Technical Advisory Committee. MS, OO, TE, and ALB analyzed the data. MS, OO, ALB, TE, and OSO wrote the first draft of the article; all other authors critically reviewed the draft, and MS led the revisions. The entire team contributed to the development of study tools, participated in the conceptualization of the paper, and reviewed and approved the final version of the paper.

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DECLARATION OF INTERESTS STATEMENT

We declare no competing interests.

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DATA SHARING STATEMENT

Given the sensitive nature of the data, they are not currently publicly available. We are determining ethical clearance to make this dataset available to other researchers.

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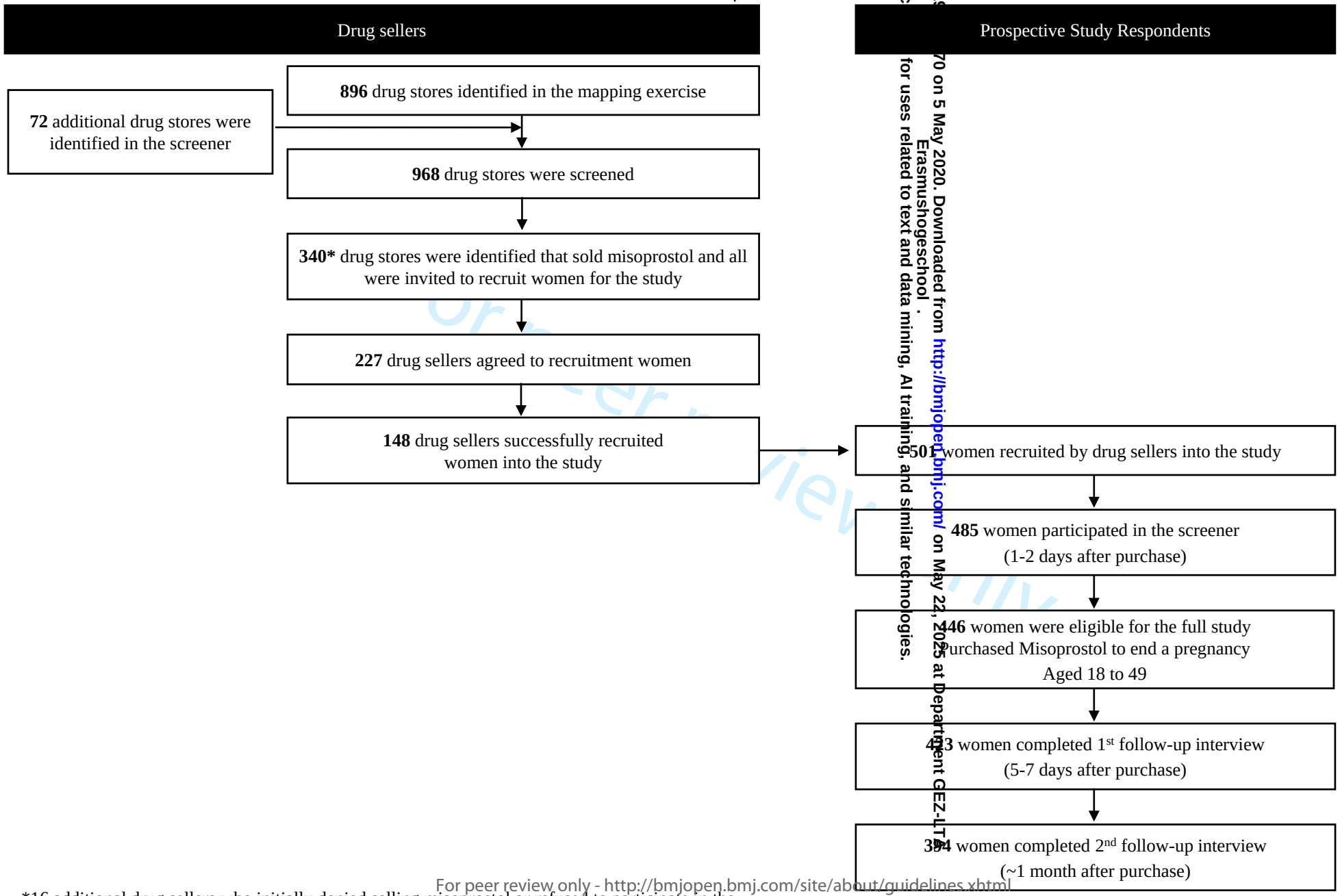
Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

Women's self-reported experiences using misoprostol obtained from drug sellers in Lagos State, Nigeria

Appendix A
Full description of recruitment and retention methodology

1. Mapping drug sellers

The mapping component was designed to enumerate the universe (sampling frame) of patent and proprietary medicine vendors (PPMVs) and registered pharmacy shops (referred to collectively as drug sellers) whom, based on advice by in-country experts, are likely the largest providers of medical abortion to women in this context. PPMVs are owner-operated drug retail outlets that were established as a category of retailer by the Ministry of Health to provide a source of medicine in communities with limited access to essential health commodities. For many people, they serve as the first point of care for a wide range of health issues. PPMV licensure does not require medical or pharmaceutical training, and regulations permit them to sell pre-packaged and over-the-counter medicines and medical products, but prohibit them from selling prescription medicines. In contrast, pharmacists must have a formal degree in pharmacy and are permitted to sell prescription medications. Official licensing of PPMVs and retail pharmacies is overseen by the Pharmacists Council of Nigeria (PCN), however there are an additional unknown number of unlicensed PPMVs in Nigeria; thus the study team conducted a mapping to generate a list of all drug sellers operating in the selected LGAs. The research team obtained a list of registered pharmacies from PCN's Lagos State office and two datasets that included a listing of all PPMVs that were operating in 16 states in 2013 (from Society of Family Health Nigeria) and all drug stores in Nigeria in 2015 (from Population Services International). These lists were used as a starting point for the sampling frame. A full mapping of PPMVs and pharmacies within the selected local government areas (LGAs) was conducted to determine the updated universe of drug sellers. All components of fieldwork (detailed in points 1-4) were conducted in two phases 1) Lagos Mainland, Ojo, and Oshodi/Isolo LGAs during April to July 2018 and 2) Epe, Ibeju-Lekki, and Ikorodu LGAs from May to October 2018.

Two supervisors and 18 fieldworkers were assigned to each LGA in the study to map all registered and unregistered drug sellers with a static point of sale (e.g., a store) whose primary business was selling medicines; clinicians or drug sellers without a shop or fixed point of sale were not included in the mapping exercise. Staff from the National Population Commission (NPopC) served as field guides and provided each field team with maps of the enumeration areas and an orientation to the LGA, including boundaries, streets and community names. LGA supervisors and NPopC staff overlaid NPopC maps with Google Maps to improve delineation of survey areas and reduce the potential for duplicated visits to drug sellers between teams in the field. Supervisors worked closely with the Field Managers to assign each fieldwork team sections of the LGA to map. Each data collection team in the field was comprised of two fieldworkers, one male and one female, to ensure their safety.

During mapping, no direct contact was made with anyone in the drug stores; the exercise was primarily to compile a list of existing stores in each LGA. GPS coordinates were collected using the data collection software *SurveyCTO Collect* along with a written description of the location to ensure field team members were able to return to the drug seller in future study components. After mapping was completed, the resulting dataset included: LGA, address, name of drug store, GPS coordinates, and a randomly generated unique ID. The Field Manager generated new project ID numbers for each drug seller in the sample, which were used to identify and link information on each drug seller throughout the study. All data were collected electronically using Android tablets. Data collected during the study were encrypted from the time of data collection, transmission to the secure server, and when downloaded to secured computers. Tablets used for data collection were password-protected and completed consent forms and surveys were uploaded to a secure server at the end of each day, which only the research team could access. The field team also carried paper copies of the instruments, in the case of power or mechanical failure.

The mapping exercise identified 896 drug stores in the selected LGAs (Appendix A, Figure 1).

2. Screening drug sellers

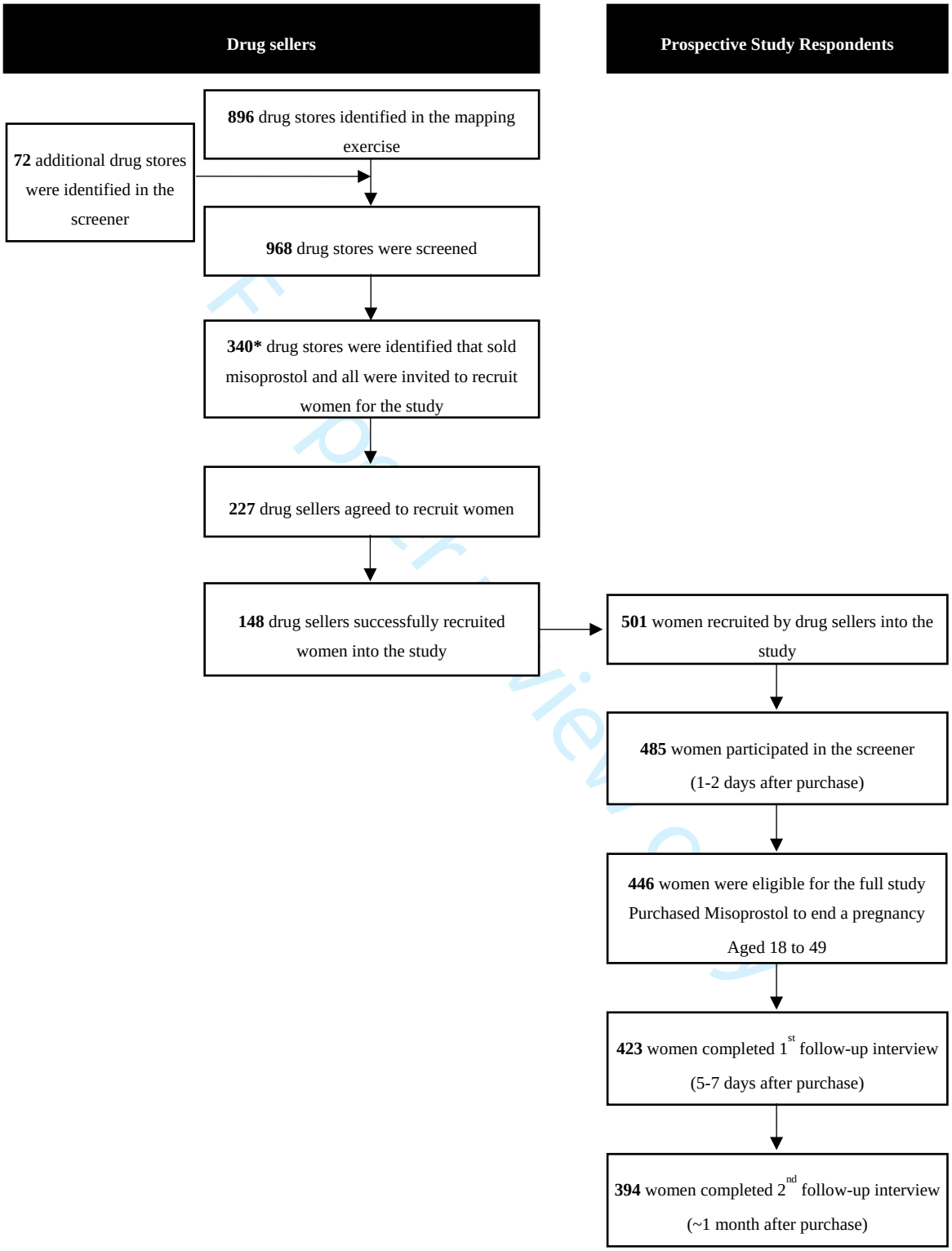
After the mapping was complete, interviewers who were not previously involved in the mapping component conducted short screening interviews of all drug sellers identified to determine whether they sold misoprostol-containing drugs. Two supervisors and approximately eight interviewers were assigned to each LGA for the drug seller screening component of the study.

Before beginning fieldwork, the research team formally notified the relevant government agencies and interacted significantly with the officials of the Pharmaceutical Services Directorate of the State Ministry of Health to secure their support and facilitate linkages with relevant stakeholders. Investigators contacted the leadership of the drug sellers associations and unions at the state as well as local levels to facilitate community entry. The study team gained approval from the following professional organizations: Association of Community Pharmacists of Nigeria (ACPN); and Lagos State Medicine Dealers Association (LSMDA). Each organization notified their membership about the study and provided letters of introduction for the study team to present to drug sellers prior to the interviews. Fieldworkers were also provided with the Lagos State Health Research Ethics Committee IRB approval letter, as well as identification cards to confirm their role on the study team to drug sellers while conducting fieldwork activities. The protocol for community entry was developed after the study team had conducted a small pilot study in another state, which revealed potential difficulties around interviewing drug sellers without the documentation of approvals at the local and national levels. These steps proved to be critical, and should be considered for other studies involving drug sellers in Nigeria.

Interviewers provided drug sellers with an introduction to the study and obtained permission from the owner or manager of each drug store to conduct the screener interview. If the owner or manager of the store was unavailable, interviewers were instructed to inquire when they could return to speak with them. If permission was granted, the interviewer explained the study to the drug seller who would be participating in the screener and obtained verbal consent for their participation. Fieldworkers were directed to interview the person working at the counter, who interacts with customers. In some cases, that person was the owner or manager, but in others it was somebody else, in which case the interviewers obtained two separate informed consents - one from the owner/manager and one from the participant. Prior to the screening component, fieldworkers were given the list of drug stores from the mapping component, but they were also instructed to document and conduct interviews in any other drug store they saw even if it was not on the list (these were stores that may have been inadvertently missed at the time of the mapping exercise). Seventy-two additional drug sellers were identified by the fieldwork teams, and included in the drug seller screening interviews. In total, 968 drug sellers were screened (Appendix A, Figure 1). Drug sellers received a token of 2,000 Naira (~USD $6) for participating in the screening interview.

The mapping and screening exercises resulted in a list of all drug sellers in the study LGAs that either reported selling misoprostol-containing drugs or did not. Initially, out of 968 drug stores in the universe, 324 drug sellers reported selling misoprostol in the screener, and 644 did not. An additional 16 drug sellers agreed to recruit women into the study, after initially refusing - one that had refused to participate in the screener interview, 13 that had denied selling misoprostol initially in the screener, and two that were approached directly to recruit by the PPMV chairmen in their LGA (Ikorodo). Therefore, the final sample of drug sellers that agreed to recruit women into the study, and whom can be presumed to sell misoprostol, was 340.

Appendix A, Figure 1. Sample of drug sellers, recruitment of women, and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

3. Recruitment of women by drug sellers

All drug sellers that reported selling misoprostol in the screener were invited to participate in recruiting women into the study. Out of 340 drug sellers that reported selling misoprostol or opted into the study, 227 (67%) agreed to participate in recruiting women, and 148 successfully recruited at least one woman (Appendix A, Figure 1). Before women's recruitment began, drug sellers who had signed up to recruit participated in a one-day training led by the study team, which covered additional background information on the study and training in ethics, maintaining confidentiality, and sensitive recruitment of clients. Drug sellers were trained on logistics for inviting any person (woman or husband/partner/proxy) purchasing misoprostol-containing drugs for any indication, to participate in the study.

Attempts to recruit women into the study were made after the drug seller had provided the drug and any routine counselling to avoid the possibility or perception that their services were contingent upon a woman's participation in the study, and to minimize any influence that study participation would have on the typical drug seller and client interaction. After delivering the normal protocol, the drug seller explained the study using a standard script provided by the study team that included a basic explanation of the study, including incentives for completing the screener interview and two follow up interviews. Drug sellers provided each woman who agreed to participate with a prepaid phone stocked with 500 Naira (approximately USD $1.50) in airtime and a pamphlet that each woman was asked to retain throughout the study. The pamphlet contained a unique participant identification number, but did not include any specific details about the nature of the study. As an additional measure to ensure women's privacy, drug sellers asked each woman to provide a nickname and a password that interviewers could use when calling them, so that they would not have to reveal their real names. The phones were provided to protect women's anonymity and alleviate any potential concerns that their identities would be linked to the study through their own personal, registered, phone numbers (which, in many cases, are linked to women's social media accounts). The idea of giving pre-registered and pre-paid phones to the study participants derived from the experience in the pilot phase of the study, whereby many women did not respond to telephone calls from the interviewers or gave the drug seller the phone number of a husband/partner or friend to contact because of the concern for anonymity.

For cases in which a buyer purchased the drug on behalf of someone else, the drug seller explained the study to the buyer and asked them to contact the potential end-user by calling her mobile phone while the buyer was still at the drug store. During the call, the drug seller briefly explained the study to the end-user and asked if she consented to be contacted by an interviewer on the research study team, who would later provide her with a more in-depth description of the study and conduct a full informed consent protocol. If the end-user was interested, the drug seller recorded the end-user's responses to the identification questions described above and gave the buyer the study pamphlet and phone to give to the end-user.

Drug sellers were instructed to document the following information in a study log book: the unique ID on the pamphlet given to each woman; the nickname and password that women provided to the drug seller for the purposes of identification to the study team; the phone number of the prepaid phone given to each woman; the purchase data; and permission to be followed up from women who agreed to participate. The nickname and password were used to verify the woman's identity in the event the woman lost the unique identification number. A combination of nickname, password, and the pamphlet unique ID information was required to verify woman's identity at each interview.

All drug sellers that volunteered to participate in recruiting women were visited by a member of the study team before recruitment began to verify the availability of a secure storage space for the log books in the facility. Drug sellers were required to store log books in locked and secure cabinets in their stores whenever the log books were not in use. Information on how the log books were stored and retrieved during fielding was also documented by interviewers during weekly site visits to collect physical copies of the log books used for recruitment. The research team initially planned to provide the drug sellers a second logbook to record data on: the total number of clients who came into the drug store requesting help terminating a pregnancy or specifically requesting misoprostol over the data collection period; clients who purchased an MA drug but did not agree to participate; clients who purchased an MA drug but were not informed about the study; whether the purchaser was the end user or not. This logbook was intended to provide the study team with some additional context and help to understand the extent to which clients were missed by the study. However, after piloting the recruitment process resulted in incomplete and inconsistent data on the number of clients seeking MA or assistance in terminating a pregnancy, and considering the additional burden this logbook would impose on drug sellers during the recruitment period, the effort was dropped. Removal of this

additional logbook from the drug seller's recruitment of women prohibited the research team from calculating participation in the study from the total population of clients approached during the fieldwork period.

Each participating drug seller received a prepaid phone and 500 Naira airtime (approximately USD $1.50) at the beginning of the recruitment period and an additional 1,500 Naira (approximately USD $4.50) after the recruitment period was completed. This amount was approved by the IRB as sufficient to reimburse them for the time they spent maintaining records on the study's behalf but not high enough to coerce drug sellers into participating.

Each interviewer for the women's component was assigned between eight and ten drug sellers. During the recruitment period, interviewers contacted each of the assigned drug sellers daily to confirm if the drug seller had recruited any women that day to input the logbook information into SurveyCTO and assess when drug sellers needed additional study materials for recruitment. At the end of the recruitment and follow-up period, interviewers for the women's component retrieved all log books from the drug seller stores and sent them in locked and secured boxes to the in-country study team's offices, to be destroyed at the completion of the study.

4. Prospective study of women

The prospective study of women included three rounds of telephone interviews with each woman, conducted by members of the study team over the course of one month. At the beginning of each call, interviewers followed a script to confirm the unique participant identification number, nickname, and security password on file to ensure the study team was speaking with the correct person. Interviewers did not provide any information about the study to anyone except the respondent, including husbands/partners or individuals who helped purchase the medicine for women.

The initial study design called for interviewers to make three attempts to contact each woman for an interview. Due to difficulties contacting respondents during early data collection, mainly non-response to phone calls from the field team, interviewers continued to call the prepaid phones for a four-week period. According to participants whom fieldworkers were later able to reach, the non-response was due to women not switching on the prepaid phones immediately after purchasing the medicine or not checking and charging the phone's battery regularly. Women working outside the home also reported leaving the study phones at home when they left the house. In total, about three percent of the women recruited into the study by drug sellers (15 women) were never successfully contacted by the study team.

For women who did participate, the average duration of the prospective study from recruitment to completion of the second follow-up interview was 37 days. Approximately 30% of women were reached on the interviewer's first attempted call across the study period; however, more than 20% of participants were called at least five times before interviewers successfully reached them for the screener and the first and second follow-up interviews with up to 16 attempted contacts required to successfully contact some respondents for interviews. While interviewers continued to call when women did not answer the phone, on average, interviewers reached women for the screener and both follow-up interviews on the second or third attempt.

Interviewers were trained to not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, women who asked for medical advice or who described symptoms that could indicate a serious problem were provided with the numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All women in the study were given this contact information after completion of the second follow-up interview, in case they had additional medical questions. Women given hotline information in the screener or first follow-up interview were asked if they had contacted the hotlines, during the first and second follow-up interviews, respectively, to account for any bias this potentially gained information may have introduced into the results. Twelve women requested further information that prompted interviewers to provide the hotline number - two at the time of the screener interview and eleven during the first follow up interview (one woman requested more information during both interviews). However, none of the study participants successfully utilized the hotline.

4.1. Screener Interview

The screener interview was intended to be conducted one to two days after women (or someone else on their behalf) purchased the medicine. However, due to difficulties reaching women, screeners were completed seven days after the purchase on average. The screener interview took approximately five to ten minutes and collected information on age, reason for planned use of medicines purchased, and a measure of literacy. The interviewer only proceeded with enrolling women into the full prospective study if the respondents could be confirmed as the same women who were recruited by the drug seller, through their unique IDs, nicknames, and passwords, and met the eligibility requirements: 18 to 49 years old at the time of the interview and intended to use the medicines purchased to end a pregnancy. Under these criteria, 446 women were eligible for inclusion (Appendix A, Figure 1). Most ineligible women were outside of the age range or planned to use the medicine for another reason (e.g., for gastric ulcers or during childbirth for postpartum haemorrhage). A few of the ineligible respondents were nurses who ran private care centers in their homes and indicated that they had bought the misoprostol from the drug sellers with the intention of selling it later.

After completion of the screener, interviewers obtained informed consent to contact eligible women for the first follow-up interview five to seven days later. Due to the challenges faced in contacting women, the length of time between the purchase of misoprostol and the screener and subsequent interviews varied for some respondents. In cases where the interviewer could not contact the respondent for the screener until five days or later following the purchase of misoprostol, interviewers conducted the screener and first follow-up interview during the same call.

The prepaid phone and airtime provided by the study team through the drug sellers upon recruitment served as the only incentive for the screener, and women were not provided with another incentive at the completion of the call. There was no significant drop out between recruitment and screening or screening and the first follow-up interview to indicate that the provision of the first incentive up-front might have had a negative impact on study retention.

4.2. First Follow-up Interview

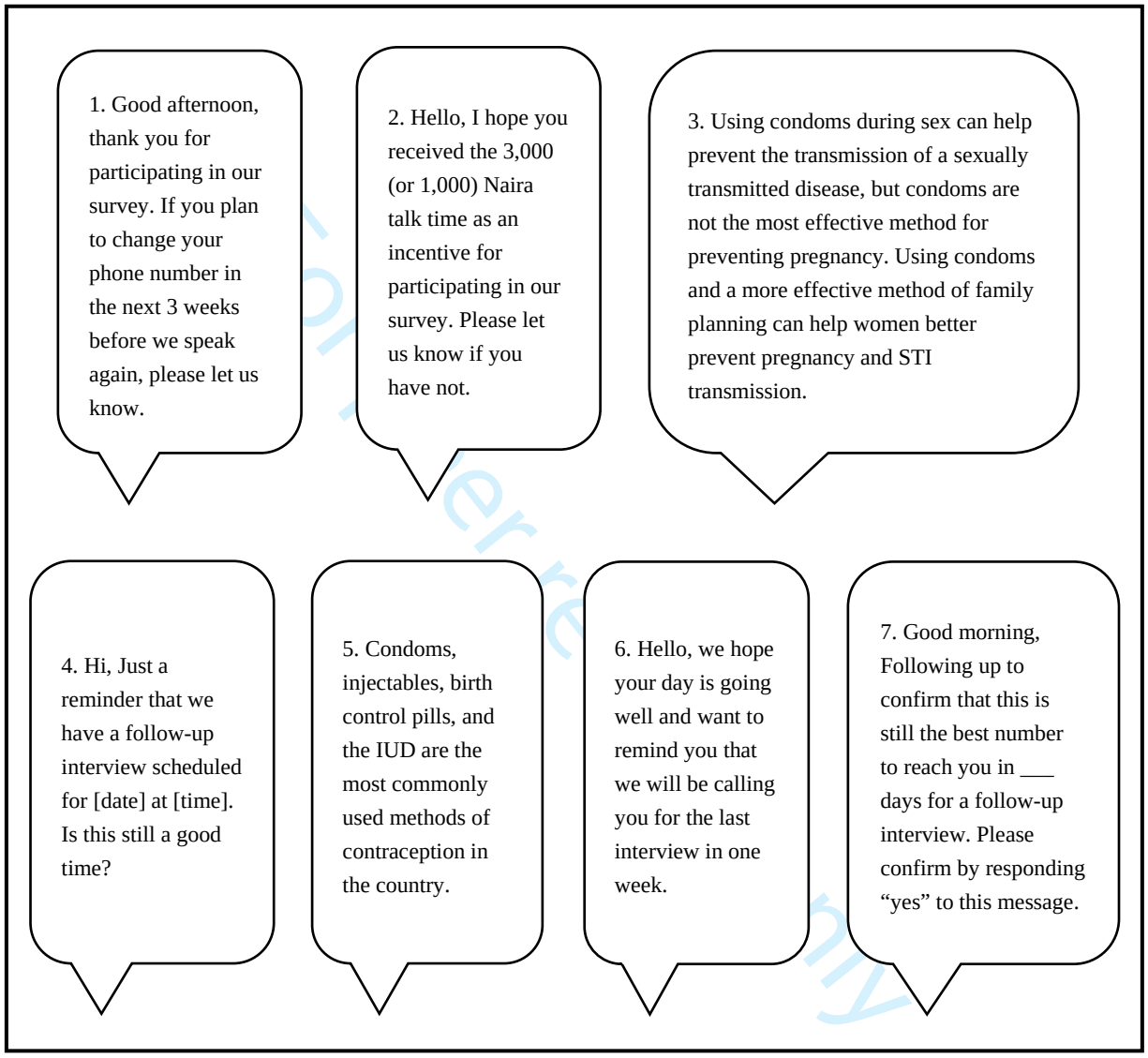
423 women - or 95% of eligible women - agreed to be followed up for another interview about a week after the screener interview (Appendix A, Figure 1). Interviewers followed the same procedure described in point 4 above to confirm women's identities prior to conducting the first follow-up interview. After confirming the person who answered the phone was the correct study participant, the interviewer reiterated the purpose of the study and obtained another verbal informed consent prior to beginning the interview. The purpose of the first follow-up interview was to determine women's decision-making processes around obtaining an abortion from a drug seller; the types of medication each woman purchased (some women purchased other abortifacients, including mifepristone alone and combi-packs of misoprostol and mifepristone); establish if the woman had used the medication; and collect information on her interaction with the drug seller, including the instructions drug sellers had given to each woman on how to take the regimen purchased.

At the end of the first follow-up interview, interviewers obtained informed consent to contact eligible women for the second follow-up interview approximately three weeks later (and approximately one month after the medication was purchased). Women who completed the first follow-up interview in the first three LGAs (Lagos Mainland, Ojo, and Ishodi/Isolo) received a 3,000 Naira (~USD $8) airtime incentive. This amount was originally considered to be enough to encourage women to participate but not so much that it would coerce women into participating. However, the incentive was reduced during the data collection in the second set of three LGAs (Epe, Ibeju-Lekki, and Ikorodu) to 1,000 Naira (~USD $3) in airtime due to budgetary constraints and confirmation by the field team that the new amount proposed then was adequate. The geographical location of the second set of LGAs made the cost of conducting the study in the areas, among others, much higher than those in the first set of LGAs particularly in terms of transportation cost and accommodation for data collectors. While the incentives for women in the second three LGAs was about a one-third of those offered to women in the first three LGAs, there was no similar difference in the completion rates: 94% of eligible women from the first three LGAs completed the first follow-up interview compared with 97% of eligible women in the second three LGAs.

In the three-week period between the first and second follow-up interviews, interviewers engaged in consistent outreach via SMS message with each participant (Appendix A, Figure 2). These messages allowed interviewers to

send reminders about the upcoming second follow-up interview and generally engage with the women. The purpose of the messages was to help retain participants in the study without sending any identifiable information or further details about the purpose of the study.

Appendix A, Figure 2. Text messages sent to respondents between the first and second follow-up interviews



4.3. Second Follow-up Interview

394 - 93% of women who completed the first follow-up interview - consented to be contacted for a second follow-up interview about 21 days later (Appendix A, Figure 1). Interviewers followed the same procedure described in point 4 above to confirm women's identities prior to conducting the second follow-up interview. After confirming they were speaking to the correct study participant, the interviewer reiterated the purpose of the study and obtained verbal informed consent prior to beginning the interview. The primary focus of the second follow-up interview was to understand women's self-reported health outcomes after taking the medication; experiences with side effects and potential complications and whether women sought further healthcare after taking the medication; how women assess the completion of their abortions; the availability of emotional or social support throughout the process; and

women's willingness to recommend medication abortion to friends or use it again in the future. Women who completed the second follow-up interview received an additional 3,000 or 1,000 Naira airtime incentive, in the first three or second three LGAs, respectively. Again, this difference in incentives was not reflected in the success rates: 94% of women who completed the first follow-up interview in the first three LGAs compared with 91% of those in the second three LGAs went on to complete the second follow-up interview.

During the programming of the study tools, a question on parity was inadvertently dropped. After exploring preliminary data, the study team agreed that interviewers should incorporate that question into all fieldwork that had not yet concluded. The team also attempted to recontact women who had already completed both follow-up interviews to ask about parity. The team successfully obtained measures of parity from 227 of the 394 respondents that completed the second follow-up interview.

Appendix B. Construction of Key Variables

The study team constructed variables to estimate the appropriateness of the dosage women received, the instructions women received on the route of administration of the pills, the adequacy of the information and instructions women received from drug sellers, and experiences with warning signs that could indicate potential complications. These measures are described below.

1. Dosage

To assess whether women purchased or were instructed to use the medication in the correct (i.e. WHO recommended) dosage, the team first determined what types of medication women were sold. This determination was based either on what was written on the manufacturer's package (if it was sold in a package and the package was still available at the time of the second interview), women's self-report of what the drug seller had told them, or their descriptions of the type of packaging and the number, color, or shape of the tablets they purchased. After determining that the medicine purchased was misoprostol, the dosage based on the number of pills purchased (assuming each misoprostol pill contains 200 mcg) was calculated. Dosages for misoprostol were categorized as less than 800 mcg (< four tablets), 800 mcgs (four tablets), 1000-1400 mcgs (five to seven tablets), and 1600-2400 mcgs (eight to 12 tablets). Nobody in the sample was given more than 12 tablets. To help in this process, the team compiled a list of misoprostol-containing drugs, including those that were registered with the government, brand names that were unregistered but found in the participating drug stores, and those that were identified by medical doctors and pharmacists on the research team. For the few women who received a combination pack of mifespristone and misoprostol, the recommended dose was defined as 200 mg mifepristone and 800mcg misoprostol, per standard packaging dosages.

2. Route of administration

According to clinical guidelines, mifepristone should be swallowed orally, and the optimal administration routes for misoprostol are vaginal, buccal (letting the pills dissolve in the cheek), or sublingual (letting the pills dissolve under the tongue). In assessing the appropriateness of the instructions given to women on how to administer the medication, any instructions that mentioned the option to ingest the misoprostol orally were considered suboptimal. The route of administration was categorized as optimal if women were told to take the misoprostol alone buccally, sublingually, or vaginally. For women who received mifepristone and misoprostol, the team categorized administration routes that included taking one mifepristone orally and misoprostol buccally, sublingually, or vaginally as optimal.

3. Core information score

Given that the safety and effectiveness of self-managed medication abortion depends, in part, on users' access to accurate information, the research team was interested in assessing the accuracy of information women received from drug sellers in the study. A score was constructedbased on the medical literature, consisting of nine items considered to be reasonably necessary, for women to successfully self-manage their abortions and assess the appropriateness of the information women received from drug sellers. Each item in the score was assigned one point, as no particular item warranted more weight than the others.

Items included:

1. Woman was asked about timing of last menstrual period
2. Woman was asked if she had taken a pregnancy test
3. Woman was told that bleeding is a side effect of the medication
4. Woman was told that cramping is a side effect of the medication
5. Woman was told that severe or prolonged bleeding could indicate a complication for which she might need to seek medical care
6. Woman was told that severe or prolonged pain could indicate a complication for which she might need to seek medical care
7. Woman was told that she could or should use pain medication
8. Woman was told anything about how to recognize a potential allergic reaction
9. Woman was told anything about potential contraindicated drugs

The data collected through this series of nine questions are limited and insufficient to provide a true measure of accuracy. For example, women may have reported that the drug seller informed them of potential drug

contraindications, but this measure does not include information about what specific contraindications were mentioned, and therefore, cannot precisely assess the accuracy of the information given. Nevertheless, the data generated could inform whether the types of information provided were within the bounds of what would be appropriate to cover and could reasonably be expected as the minimum amount of information women should receive.

4. Women's experience with potentially problematic effects of the medication

This study attempted to assess the proportion of women who experienced postabortion complications using their self-reported symptoms after using the medications purchased from the drug seller. To construct measures for estimating potentially problematic clinical effects that could indicate complications, the team created algorithms to assess excessive or greater than anticipated bleeding and signs of an infection.

Bleeding that could be symptomatic of a potential complication:

- Bleeding that soaks through more than two regular sized pads in two hours, lasting consistently for 12 hours after taking the medication.

Pain that could be symptomatic of a potential complication:

- Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
- Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
- Abdominal pain at the time of the last interview (~ one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

Fever or chills that could be symptomatic of a potential complication:

- Fever or chills that lasted more than 24 hours after taking the medication, or
- Any fever or chills still experienced at the time of the last interview.

Foul-smelling or discolored discharge that could be symptomatic of a potential complication:

- Foul smelling or discolored (not clear or white) discharge after taking the medication, or
- Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

Anyone who had a potential pain-, fever/chills-, or discharge-related complication was considered to have potentially experienced an infection complication after taking the medication. These measures likely overestimate potential complications in the sample as any self-report of a potential symptom qualifies respondents for inclusion in these estimates.

Appendix C: Supplementary Tables

Appendix C, Table 1. Women's experiences with previous attempts to end current pregnancy prior to recruitment, Lagos, 2018

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who made another attempt to end the pregnancy prior to being recruited	5.3	21
Among women who had made a prior attempt (N=21):		
Number of previous attempts to end the pregnancy		
1	81.0	17
2	14.3	3
>2	4.8	1
Women who went to each place in their last attempt		
Another pharmacy/drugstore	23.8	5
The same pharmacy/drugstore	14.3	3
Traditional practitioner	23.8	5
A friend	19.0	4
Did something at home	19.0	4
Women who used each method in their attempt(s)*		
Took some pills	57.1	12
Drank agbo/herbal preparation	47.6	10
Other	10.0	2
Pills women had taken in previous attempts (N=12)		
Misoprostol	16.7	2
Postinor (emergency contraception)	33.3	4
Don't know	50.0	6
Outcome of attempt(s)		
Nothing/light spotting	100.0	21

* Multiple responses were allowed

Appendix C, Table 2. Women's reports of receiving information about the abortion process from the drug sellers, the proportion that experienced expected clinical effects after taking the medication, and dosages received, according to whether or not we verified that they had received misoprostol, Lagos, 2018

	Women who we verified received misoprostol (n=323)		Women who we could not verify received misoprostol (n=71)		All women who completed both follow-up interviews (n=394)		P-value
	%	No.	%	No.	%	No.	
Proportion who were told about clinical effects to expect*							
Bleeding	65.3	211	71.8	51	66.5	262	0.293
Cramping/Abdominal Pain	34.7	112	38.0	27	35.3	139	0.592
Headaches	9.0	29	2.8	2	7.9	31	0.081
Vomiting	4.6	15	4.2	3	4.6	18	0.878
Nausea	1.5	5	--	--	1.3	5	0.291
Diarrhea	2.2	7	1.4	1	2.0	8	0.681
Fever/chills	3.7	12	5.6	4	4.1	16	0.458
General feeling of weakness	14.9	48	16.9	12	15.2	60	0.665
Dizziness	0.9	3	--	--	0.8	3	0.415
Proportion who reported experiencing clinical effects after taking the medication*							
Bleeding	83.3	269	90.1	64	84.5	333	0.148
Cramping/Abdominal Pain	69.7	225	74.6	53	70.6	278	0.404
Headaches	8.7	28	7.0	5	8.4	33	0.654
Vomiting	5.6	18	4.2	3	5.3	21	0.647
Nausea	3.1	10	2.8	2	3.0	12	0.901
Diarrhea	5.6	18	2.8	2	5.1	20	0.338
Fever/chills	8.7	28	7.0	5	8.4	33	0.654
Foul smelling or colored vaginal discharge	0.6	2	--	--	0.5	2	0.506
General feeling of weakness	22.3	72	11.3	8	20.3	80	0.037
Dizziness	2.5	8	1.4	1	2.3	9	0.585
Amongst women that were told about bleeding:							
Women reported bleeding	87.2	184	98.0	50	89.3	234	0.025
Amongst women that were told about cramping:							
Women reported cramping	75.0	84	70.4	19	74.1	103	0.622
Women reporting a complete abortion without surgical intervention	94.4	305	90.1	64	93.7	369	0.180
Miso dose	**n=251**		**n=0**		**n=251**		NA
<800mcg misoprostol	69.3	174	NA	NA	69.3	174	
800mcg misoprostol	26.7	67	NA	NA	26.7	67	
1000-1400mcg misoprostol	2.0	5	NA	NA	2.0	5	
1600mcg-2400mcg misoprostol	0.8	2	NA	NA	0.8	2	
200mg mifepristone & 800mcg misprostol	1.2	3	NA	NA	1.2	3	

* Multiple responses were allowed.

Appendix C, Table 3. Proportion of women reporting complete abortions without surgical intervention ~one month after taking the medication, according to the dosages received, Lagos, 2018

	Number of women that received each dosage (n=251)	Completed abortions among women who you received each dosage of medication	
		%	No.
Misoprostol dosage			
<800mcg misoprostol	174	93.1	162
800mcg misoprostol	67	97.0	65
1000-1400mcg misoprostol	5	80.0	4
1600mcg-2400mcg misoprostol	2	100.0	2
200mg mifepristone & 800mcg misprostol	3	100.0	3

Appendix C, Table 4. Estimated proportion of all women with completed abortions using different assumptions for women lost to follow up, Lagos, 2018

	Completed abortions among all women who confirmed taking the pills (n=423)	
	%	No.
Assumptions about women lost to follow up		
All women had incomplete abortions	87.2	369
25% of women had complete abortions	88.9	376
50% of women had complete abortions	90.7	384
75% of women had complete abortions	92.4	391
All women had complete abortions	94.1	398

Appendix C, Table 5. Drug store and drug seller characteristics among drug sellers that did and did not agree to recruit women Lagos, 2018

	Drug sellers who agreed to recruit women (n=224*)		Drug sellers who did not agree to recruit women (n=113)		P-value
	%	No.	%	No.	
Drug Store Characteristics					
Drug store area					0.023
Urban	96.9	217	91.2	103	
Peri-urban	3.1	7	8.8	10	
Drug store LGA					0.000
Lagos Mainland	19.6	44	14.2	16	
Ojo	18.3	41	10.6	12	
Oshido/Isolo	33.0	74	11.5	13	
Epe	4.0	9	4.4	5	
Ikorodu	17.0	38	44.2	50	
Ibeju-Lekki	8.0	18	15.0	17	
Type of drug store					0.011
Pharmacy	68.3	153	81.4	92	
Proprietary Patent Medicine Vendor (PPMV)	31.7	71	18.6	21	
Does store sell family planning products					0.758
No	1.3	3	1.8	2	
Yes	98.7	221	98.2	111	
Drug Seller Characteristics					
Drug seller Position					0.686
Owner/Senior manager	43.8	98	43.4	49	
Front counter staff - pharmacist	33.5	75	32.7	37	
Front counter staff - non-pharmacist	20.1	45	23.0	26	
Other	2.7	6	0.9	1	
Drug seller Sex					0.050
Male	61.6	138	50.4	57	
Female	38.4	86	49.6	56	
Drug seller Age					
Median (IQR)	32	(27-39)	34	(28-42)	

* Three drug sellers that recruited women did not complete the drug seller screener and are not included in this table.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8 & appendix
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8 & appendix
Bias	9	Describe any efforts to address potential sources of bias	15
Study size	10	Explain how the study size was arrived at	5,6 & appendix
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8 & appendix
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	appendix
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
(*e*) Describe any sensitivity analyses	appendix

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	appendix
		(c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	8
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-16 & Appendix
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-16 & Appendix
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	15 & Appendix
Discussion			
Key results	18	Summarise key results with reference to study objectives	17-18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-20
Generalisability	21	Discuss the generalisability (external validity) of the study results	16,19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21,22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective study in Lagos State, Nigeria

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Title: Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective study in Lagos State, Nigeria

Melissa Stillman, MPH[1]*
Onikepe Owolabi, PhD[1]
Adesegun O. Fatusi, PhD[1,2]
Akanni I. Akinyemi, PhD[3,4,5]
Amanda L. Berry, MPH[1]
Temitope P. Erinfolami, MSc[4,5]
Olalekan S. Olagunju, MSc[4,5]
Heini Väisänen, PhD[6]
Akinrinola Bankole, PhD[1]

1 Guttmacher Institute
125 Maiden Lane, 7th Floor
New York, NY 10038

2 Academy for Health Development (AHEAD)
Ile-Ife
Nigeria

3 Harvard T. H. Chan School of Public Health
677 Huntington Avenue
Boston, MA 02115

4 Obafemi Awolowo University
Department of Demography and Social Statistics
Ile-Ife
Nigeria

5 Centre for Research, Evaluation Resources and Development (CRERD)
Ile-Ife
Nigeria

6 University of Southampton
Department of Social Statistics and Demography
Highfield,
Southampton SO17 1BJ

* Corresponding author:

Melissa Stillman, mstillman@guttmacher.org

(212) 248-1111, ext. 2256
125 Maiden Lane, 7th Floor, New York, NY 10038

ABSTRACT

Introduction: In settings where induced abortion is restricted, self-use of misoprostol is a critical option for those who may otherwise resort to other, unsafe, abortion methods. However, there is little evidence on the safety and effectiveness of self-managed misoprostol abortions obtained outside of formal health systems globally.

Methods: We conducted a prospective study of 394 women aged 18–49 who purchased misoprostol-containing medication from drug sellers for abortion in Lagos State, Nigeria. Data were collected through three telephone-administered interviews over one month. We assessed the quality of information provided by drug sellers; the prevalence of potential complications; and the proportion with completed abortions.

Results: About 60% of participants did not know about abortion pills prior to visiting drug sellers, and 95% reported the experience as the first and only attempt to terminate the pregnancy. Although drug sellers provided inadequate information about the pills, 94% of the sample reported a complete abortion without surgical intervention about one month after taking the medication. Assuming a conservative scenario where all individuals lost to follow up had failed terminations, the completion rate dropped to 87%. While 86 women reported physical symptoms suggestive of complications, only six of them reported wanting or needing health facility care and four subsequently obtained care.

Conclusion: Drug sellers are an important source of medical abortion in this setting. Despite the limitations of self-report, many women appear to have effectively self-administered misoprostol. Additional research is needed to expand the evidence on the safety and effectiveness of self-use of misoprostol for abortion in restrictive settings, and to inform approaches that support the health and well-being of people who use this method of abortion.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Data from this study are the first prospectively collected data that capture people's experiences with, and the self-reported effectiveness of, self-managed misoprostol abortion in a legally restrictive setting in Sub-Saharan Africa.

- This study utilized novel recruitment and retention approaches: drug sellers were the source of recruitment, which leveraged existing client-provider relationships; unregistered mobile phones were distributed to participants to mitigate fears around potential loss of privacy; text messages were sent to participants periodically in between interviews, which improved engagement and likely contributed to the study's relatively high follow-up rate.
- The follow-up period for this study was one month, which is longer than that of previous studies, thus allowing more time for the medication to work and potentially resulting in a more accurate self-assessment of the medications' effectiveness.
- This study relied on misoprostol users' self-report for our primary outcomes, and although we believe participants are capable of describing changes in their own bodies, it is difficult to determine the extent to which our findings will correlate with data collected under clinical experimental conditions.
- The study sites were purposively selected, and the sample could only include clients who obtained misoprostol from drug sellers willing to participate in the study and who may be different from other drug sellers in unknown ways, therefore our findings are not generalizable to the entire population of the state and country.

INTRODUCTION

Globally, medical abortion (MA) has become an increasingly important method for people seeking to terminate a pregnancy.[1] While mifepristone followed by misoprostol is the preferred MA regimen recommended by the World Health Organization (WHO), misoprostol alone is recommended as a safe and effective alternative where mifepristone is not available.[2] WHO guidelines specify self-managed mifepristone and misoprostol as a viable approach for terminating pregnancies when users have access to adequate information and a trained healthcare provider.[3] However, WHO has not yet recommended self-management of misoprostol alone because of limited evidence. In contexts in which abortion is illegal or highly restricted, mifepristone is unlikely to be approved by the government, and self-managed abortion

with misoprostol alone is a critical option for individuals who may otherwise resort to other, unsafe, methods.[1]

Nigeria has a population estimated at 200 million in 2019,[4] and induced abortion is legally permitted only to save a woman's life.[5] Despite the restrictive law, the rate of induced abortion in Nigeria was estimated at between 41.1 and 59.4 per 1,000 women of reproductive age in 2017.[6] MA drugs, particularly misoprostol, have become more widely available in Nigeria in recent years.[7–9] Nigeria has a large market of drug vendors serving informally as the first point of care for diverse health problems, and most medications can be procured without prescription.[10] However, evidence from other studies suggests that drug sellers have poor knowledge of MA drugs, commonly sell medications without packaging or instructions, and often provide inadequate or inaccurate information to women about medications, side effects, and potential complications.[11–16]

There is currently a dearth of community-based evidence on people's experiences accessing misoprostol from drug sellers and the outcomes of self-managed abortions. Findings from a prospective study with a very small sample of women who bought misoprostol from pharmacy workers in Bangladesh indicate that 75% of women reported complete abortions after two weeks,[17] which is just below the range of expected effectiveness for misoprostol alone (78-90%).[18–21] Studies from several countries in Latin America where abortion is legally restricted suggest that even if adequate information is not provided by drug sellers, information obtained through other means, such as hotlines, may reduce the potential risks of self-managed medical abortion.[1,22–24] The few studies in sub-Saharan Africa that attempted to assess health outcomes from use of misoprostol alone recruited patients presenting for postabortion care in health facilities, and therefore do not represent everyone who had used this method.[9,25] Prospective studies have the potential to provide stronger evidence but those that have attempted to explore these topics have reported challenges with the recruitment and follow-up of participants.[17,26]

To address this research gap, we designed a prospective study to explore the experiences of women[a] who self-manage abortion using misoprostol obtained from drug sellers in Lagos State, Nigeria. We investigated what dosages and information women receive when attempting to purchase misoprostol for abortion; what clinical effects they experience, including potential complications; if and how they assess completeness; and what proportion of women have completed abortions.

METHODS

Study Setting

Data for this study were collected in six local government areas (LGAs) in Lagos State. Lagos is the most populous city in Nigeria and constitutes one of the largest markets for MA nationally. The 20 LGAs in Lagos State were stratified into more urban and less urban based on population density. From each stratum, we purposively selected three that each had at least one higher-level educational institution. We hypothesized that areas with higher-level educational institutions would have greater market for misoprostol due to the concentration of females aged 20 to 29 and those with a secondary education or higher, populations that have a relatively higher estimated incidence of abortion in Nigeria.[27]

Study design and data collection

Field activities were organized into two major components: 1) a drug seller study, which included a) a mapping of pharmacies and patent medicine vendors (PPMVs), herein referred to as drug sellers, and b) a screener interview to identify those selling misoprostol for any reason; and 2) a prospective study of women who purchased misoprostol, recruited by drug sellers.

[a] People of all genders are capable of becoming pregnant and having abortions. We did not include questions related to gender identity in the surveys due to concerns related to cultural sensitivity and appropriateness. For the purpose of this study, our eligibility criteria included being a woman 15-49 years old who had purchased misoprostol to terminate a pregnancy, and the word "woman" was used in the consent form as well as the interviews. Based on these criteria, in addition to assumptions made by drug sellers and the interviewers, we refer to participants as "women" in this paper.

Identifying drug sellers who sell misoprostol

Fieldworkers collected the names and Global Positioning System (GPS) coordinates of all drug sellers in each LGA, generating the universe (n=968; Figure 1). Thereafter, they visited every shop and conducted a screening interview to generate a list of drug sellers that reported selling misoprostol for any indication. Drug sellers who reported selling misoprostol (n=340) were invited to recruit all women who purchased any misoprostol-containing medications, directly or through a proxy, for any reason over a two-month period. In total, 227 drug sellers agreed to recruit women. See Appendix A for more details on recruitment procedures.

Prospective study of women

Drug sellers assisted in recruiting women who bought misoprostol, or a misoprostol-containing drug, for any reason. Drug sellers provided a general explanation of the study, and asked everyone interested in participating if they agreed to be contacted by a member of the study team. Interviewers contacted willing participants one to two days after purchase of the medicine, explained the study in detail and obtained informed consent to participate prior to conducting a telephone screener interview to determine eligibility. Only women aged 18–49 who bought misoprostol specifically to terminate a pregnancy were eligible for inclusion. Eligible women were invited to participate in two additional rounds of telephone interviews over approximately one month.

A first follow-up interview was conducted five to seven days after screening to identify the medications purchased, establish if and how the woman used the medication and ask about her interaction with the drug seller at the time of purchase. A second follow-up interview was conducted three weeks later (one month after purchasing the medication) to understand women's self-reported health outcomes after taking the medication, how women assessed the completion of their abortions, support during the abortion process, and women's willingness to recommend misoprostol to friends or use it again.

Data for the drug seller screening were collected in-person by trained male fieldworkers and data from the women were collected over the telephone by female field workers trained by the study team in sensitive interviewing techniques. All data were collected using the mobile data collection application SurveyCTO on password-protected and encrypted Android tablets and stored on a secure server accessible only to the research team. Women's informed consent was obtained prior to each interview, and permission to be contacted again for the next follow-up interview was given at the end of the screener and first follow-up interviews. Women's identities were confirmed at each interview using a unique identification number, password or nickname provided at the time of recruitment.

Interviewers did not have medical training and did not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, respondents who asked for medical advice or who described symptoms that could indicate a serious health problem were provided with the telephone numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All participants in the study were given this contact information after completion of the second follow-up interview, in case they had additional medical questions. Data collection occurred between April and October 2018.

The National Health Research Ethics Committee in Nigeria and the Institutional Review Board of Guttmacher Institute approved the study.

Patient and Public Involvement

The study was supported by a Technical Advisory Group that provided input on the program of research. The advisory group, which consisted of medical doctors, local researchers and other experts in the field of sexual and reproductive health in Nigeria, provided input on the research questions, study design and tool development prior to the start of fieldwork. The advisory group provided feedback on the preliminary research findings and advice on messaging the results. The group will help plan dissemination activities, including the presentation of findings to participating drug sellers and other stakeholders.

Study definitions (described in detail in Appendix B)

Dosage

Doses of less than 800 mcgs for misoprostol alone were classified as less than the WHO recommended dose for first trimester abortions.[2]

Route of administration

An optimal route of misoprostol administration was defined as administering it buccally, sublingually, or vaginally.[2,28] A suboptimal route was one where women were given the option to swallow the misoprostol by mouth.

Adequacy of information

We created a nine-item score for the adequacy of information covered during the drug sellers' interactions with women. We included information considered to be reasonably necessary, based on medical literature, for women to successfully self-manage abortion. We allocated each item one point if the information was provided and created the index by adding up the total number of points.

Warning signs of potential complications

Warning signs of complications were assessed using self-reported symptoms after taking the medication and included excessive or greater than anticipated bleeding; or a combination of greater than anticipated abdominal pain or cramping, fever and chills, or vaginal discharge that could potentially indicate an infection. Criteria used to assess these are described in Appendix B.

Analysis

We conducted descriptive analyses to summarize women's sociodemographic characteristics; the quality of information provided by drug sellers; the prevalence of potential complications; the proportion who had

complete terminations without additional medical interventions; and abortion strategies women would have employed had they not used misoprostol. All analyses were conducted using Stata15.1.

RESULTS

Of the 501 women recruited by drug sellers, 485 women (97%) were successfully contacted and screened by interviewers,446 women were eligible for the study (92% of those screened), and 394 women (88% of all eligible women recruited) were successfully interviewed in both follow-up interviews (Figure 1). The data presented in the results are from the 394 women who completed both interviews, including a small proportion (2%) that received mifepristone + misoprostol.

Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study

Demographic characteristics of participants

Among our final sample, more than half (55%) were between the ages of 18 and 29, and 92% had completed senior secondary school while 38% had completed some higher education (Table 1). About three-quarters (76%) worked for a family- or non-family-owned business, and 13% were students at the time they purchased the misoprostol. Half (50%) were married or cohabiting, and 95% purchased the drug themselves. Most respondents (83%) had taken some kind of pregnancy test prior to going to the drug seller. For 85% of participants, this was their first pregnancy termination. Compared to the overall population of reproductive aged women in Lagos State who had ever experienced a pregnancy,[29] our sample was: more educated, younger, more often nulliparous, more likely to be working for someone else (non-family member) in a business, and more likely to have never been married (Appendix C, Table 1).

Table 1. Demographic characteristics of women, type of drug sellers visited and who bought the pills, proportion of women who took a pregnancy test, and previous experiences with abortion

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Age categories		

18 - 24	22.8	90
25 - 29	32.0	126
30 - 34	23.4	92
35 - 39	16.0	63
40 - 44	5.1	20
45 - 49	0.8	3
Median age (IQR)	28	(25-33)
Parity‡		
No children	33.5	76
1-2 children	37.4	85
3+ children	29.1	66
Mean (SD)	1.6	(1.5)
Highest Level of Education Completed		
No schooling or incomplete primary	0.8	3
Primary/Junior secondary school	7.4	29
Senior secondary school	54.1	213
Some higher education (or more)	37.8	149
Employment		
Work for someone else/non-family business	51.5	203
Work for own/family business	24.1	95
Housewife	3.8	15
Student	13.2	52
Unemployed	7.4	29
Relationship Status		
Currently married or cohabiting	50.0	197
Separated/divorced/widowed	5.1	20
Never married and never lived together with a man	44.9	177
Local Government Area of recruitment		
Lagos Mainland	17.0	67
Ojo	18.3	72
Oshodi Isolo	16.2	64
Epe	8.9	35
Ikorodu	24.4	96
Ibeju Lekki	15.2	60
Women who went to each type of drug seller		
Pharmacy	40.6	160
Proprietary Patent Medicine Vendor (PPMV)	59.4	234
Who purchased the medicine		
Medicines bought by the woman	95.2	375
Medicines bought by someone else	4.8	19
Previous attempt to end a pregnancy		
No, has not attempted to end a prior pregnancy	84.5	333

Yes, has previously attempted to end a prior pregnancy	15.5	61
% of women who took each type of pregnancy test when they suspected they were pregnant§		
Confirmation via test with a doctor	20.8	82
Confirmation via test at a laboratory	17.5	69
Self-administered urine test	54.6	215
No test	17.0	67

‡ Data on parity were only from a subset of the sample (n=227).
§ Multiple responses were allowed.

Abortion attempts prior to recruitment

A small proportion (5%, n=21) of the sample had made at least one other attempt to terminate the current pregnancy prior to being recruited into the study (Appendix C, Table 2). Of them, 12 had taken pills and ten ingested herbal preparations. Six women who took pills did not know what pills they had taken, four had taken emergency contraception and two took an unspecified dose of misoprostol that was reported as ineffective.

Medication types, determining eligibility, and dosage

Upon entering the drug store, 51% of women told the drug sellers that they needed something to end a pregnancy, and 39% said they wanted help to bring back a late menstrual period (Table 2). More than half (57%) reported that they had not known there were pills they could take to end a pregnancy prior to visiting the drug seller; 22% had heard about such pills from a friend or family member, and 7-8% found out about them online (n=33) or from a health professional (n=28) (not shown). One-fourth of the sample (25%) reported that they did not know what medication they purchased from the drug seller. Among those who knew what medication they purchased, a majority (93%, n=272) reported receiving just misoprostol from the drug seller, and 2% (n=7) received misoprostol in combination with mifepristone. Based on women's self-reports of the type and number of tablets purchased, we confirmed that 44% were sold less than the recommended dosage for effectiveness (<800mcg misoprostol), 20% received a dosage within the range of effectiveness, and we were unable to assess the dosage for an additional 37% of the sample.

Table 2. Women's experiences interacting with the drug seller, types of medications, dosages, and administration routes

	Women who completed both follow-up interviews (n=394)	
	%	No.
How women presented themselves to the drug seller*		
Told drug seller she wanted to end a pregnancy	50.5	199
Told drug seller she wanted to purchase misoprostol or other specific brand name medicine	16.2	64
Told the drug seller she wanted to bring back a late period	39.3	155
Told drug seller something else	1.3	5
Types of medicine women reported receiving†		
Misoprostol	69.0	272
Misoprostol + Mifepristone	1.8	7
Unknown medicine‡	25.4	100
Missing	3.8	15
Dosage of medication prescribed by drug seller§		
Less than the WHO recommended dosage (< 800 mcg misoprostol)	43.7	172
800 mcg misoprostol	17.0	67
1000-1400mcg misoprostol	1.3	5
1600mcg-2400mcg misoprostol	0.5	2
200mg mifepristone & 800mcg misoprostol	0.8	3
Not assessed	36.8	145
Routes of administration of the medication prescribed by drug seller¶		
Suboptimal route (oral misoprostol)	38.6	152
Optimal route (buccal, vaginal, or sublingual misoprostol)	19.0	75
Drug seller did not say	0.3	1
Not assessed	42.1	166

* Multiple responses were allowed

† Data on types of medicine received are not available for 15 women due to missing responses.

‡ "Unknown" means the woman did not know what medication she took, either because she was never told or because she could not remember. Although the medication was unknown to her, it still could have been misoprostol or another abortifacient.

§ The medication dosage could only be assessed among women who answered specific questions about the numbers of each type of pills they were given, and who either knew what medication(s) they were given or for whom we were able to, with reasonable confidence, parse out what medication(s) they were given based on their answers to related questions.

¶ The administration route could only be assessed among women for whom we could identify the medication(s) given. Since World Health Organization (WHO) guidelines recommend that mifepristone be administered orally and misoprostol be administered bucally, vaginally, or sublingually, any administration route instructions that diverge from these recommendations are considered suboptimal.

Instructions received from the drug sellers

Most of the sample (78%) reported that they were given some instructions about how to take the medications, and nearly all women who received instructions followed them (Table 3). Most women relied solely on drug sellers for information: 72% did not use any other source (not shown).

Table 3. Percent of women that reported drug sellers providing information about misoprostol or asking questions to assess eligibility for misoprostol prior to purchase

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who received any instructions from the drug seller about how to take the medication	77.9	307
Women who took tablets according to drug sellers' instructions		
Followed instructions	75.9	299
Did not follow instructions	2.0	8
Did not receive instructions	22.1	87
Women reporting the following items were covered during the interaction with the drug seller		
Asked timing of last menstrual period	79.4	313
Asked if she took a pregnancy test	74.1	292
Informed that bleeding is an anticipated effect	66.5	262
Informed that cramping is an anticipated effect	35.3	139
Informed that severe bleeding could indicate a potential complication	12.9	51
Informed that severe and persistent abdominal pain could indicate a potential complication	3.0	12
Informed about use of pain medication	28.2	111
Informed of potential allergic reactions	7.1	28
Informed of potential contraindications	22.8	90
Number of items listed above that were covered in women's interaction with drug sellers		
No core information	9.6	38
1-3 items	42.4	167
4-6 items	45.2	178
7-8 items	2.8	11
9 items	--	--
	Mean	SD

Adequacy of information scale score (out of 9 items)	3.3	1.8

On average, women reported that drug sellers covered three of nine items we considered necessary for successful self-management of abortion using misoprostol (Table 3). A relatively high proportion reported that drug sellers attempted to assess their eligibility: 74% were asked if they had confirmed their pregnancy with a test, and 79% were asked the timing of their last menstrual period. However, fewer reported being given information about what clinical symptoms to anticipate as a normal part of the abortion process; 67% and 35% reported being told that they could expect some bleeding or cramping, respectively. Only 51 women (13%) were told about severe bleeding that could indicate a potential complication.

Women's experiences of warning signs after taking the medication and subsequent care seeking

Most women did not report adverse events after taking the medication. However, 77 women (20%) reported bleeding that we classified as potentially problematic, and 15 women (4%) reported a combination of symptoms suggestive of infection (Table 4). Six women were classified as having experienced symptoms of both. Among the 86 women with potentially problematic bleeding or symptoms of infection, 7% (n=6) reported wanting or needing medical care, and 5% (n=4) sought care (not shown). One of the four reported receiving a blood transfusion and undergoing a surgical abortion procedure, while the rest were given painkillers, an ultrasound or blood test.

Table 4. Women's experiences of potential complications after using medications obtained from drug sellers

	Among women who completed both follow-up interviews (n=394)	
	Women who experienced warning signs of potential complications	
	%	No.
Bleeding*	19.5	77
Cramping/Abdominal Pain†	2.0	8
Fever/chills‡	1.3	5
Foul smelling or colored vaginal discharge§	0.5	2
Postabortion infection¶	3.8	15

* Bleeding that could indicate potential complications is categorized as bleeding that soaks through more than two regular sized pads in two hours, lasting for 12 hours after taking the medication.

† Abdominal pain and cramping that could indicate potential complications are categorized as follows:

Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
Abdominal pain at the time of the last interview (~one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

‡ Fever and chills that could indicate potential complications are categorized as follows:
Fever or chills that lasted more than 24 hours after taking the medication, or
Any fever or chills still experienced at the time of the last interview (~one month after taking the medication).

§ Foul smelling or discolored vaginal discharge that could indicate potential complications are categorized as follows:
Foul smelling or discolored (not clear or white) discharge after taking the medication, or
Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

¶ Postabortion infection was characterized as a combination of problematic abdominal pain or cramping, fever and chills, or vaginal discharge.

Overall, 29 women in the study (7%) reported wanting or needing medical care after taking the pills, and 24 (6%) actually sought care (not shown). Few women (25%, n=97) were given any information from drug sellers about seeking postabortion care. However, 48% (n=14) of those who reported wanting or needing care also reported they had been told during their initial interaction with the drug seller that they may need to seek medical attention for potential complications, compared to 23% (n=84) of those that did not report needing follow-up care. Most women who sought care were given pain medication, or underwent an ultrasound, suggesting that they might not have presented with serious complications. One woman reported receiving a blood transfusion, and seven women were treated with a surgical abortion procedure.

Participants' assessment of abortion completeness

At the time of the second follow-up interview, around one month after taking the pills, 95% of women reported that they were no longer pregnant (Table 5). The most common way women assessed the completeness of the abortion was by the return of their menstrual period (54%). 369 women (94%) reported a complete abortion without any additional medical intervention about one month after taking the pills. Completion rates did not substantially vary according to the dosages women reported taking: 93% (n=160) of women who we confirmed received less than 800mcg of misoprostol reported complete abortions versus 97% (n=65) of women who received 800mcg (Appendix C, Table 4). If we assume 50% of the women lost to follow-up had a successful termination, then 91% of all 423 eligible women had a complete abortion, and if we assume none of them had a successful termination the rate of complete abortion drops to 87% (Appendix C, Table 5).

Table 5. Women's perceptions of pregnancy continuation and how they assessed the completeness of the abortion process

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who reported that they were no longer pregnant at the time of the second follow up interview	95.4	376
Reasons given for believing pregnancy has ended (n=376)*		
Woman's period returned	53.7	202
Woman took a urine pregnancy test at home	33.2	125
Woman no longer has pregnancy symptoms	24.7	93
Woman took a blood pregnancy test	16.0	60
Woman passed the products of conception	13.3	50
Woman took a urine pregnancy test at a facility	5.1	19
Woman had a sonogram/ultrasound	4.0	15
Woman got cleaned at a facility/surgical intervention	1.9	7
Other	0.8	3
Women who reported a complete abortion without surgical intervention	93.7	369

* Multiple responses were allowed

Alternatives to using misoprostol and willingness to use it again or recommend it to a friend in the future

Sixty percent of women reported that they would have gone to a health facility for help had they not had access to misoprostol (not shown). Twenty-two women (6%) said they would have gone to a traditional practitioner, 17 would have drank chemicals, four would have done excessive exercise, and two reported that they would have inserted objects to self-induce abortion. About one-fourth of women (27%, n=105)) said they would have done nothing.

Seventy percent of women in the study reported that they would use misoprostol again. Of those that would not, 47% (n=56) said they would not terminate another pregnancy at all. Others (13-16%) thought that it would damage their health or fertility, reported that it was too painful or that they did not like the experience. Nevertheless, 85% of participants reported that they would recommend misoprostol to a friend.

DISCUSSION

To our knowledge, this is the first prospective study examining the experiences and health outcomes of women obtaining misoprostol from drug sellers in sub-Saharan Africa. Around two-thirds of eligible drug sellers were willing to recruit for the study, and 88% of eligible women completed the screener and both follow-up interviews.

Although about 60% of our sample were not aware of medical abortion pills prior to visiting the drug seller, for nearly everyone this encounter was their first and only attempt to end their pregnancy. Most women visited the drug seller by themselves, and a majority of them appeared to have been comfortable explicitly asking drug sellers for help to induce an abortion. Most women in our study relied on their interaction with the drug sellers as their only source of information, reported trusting the information drug sellers gave them about the drugs and following their instructions for use. More than one-fourth reported that they would have had an unwanted birth had they not had access to misoprostol, suggesting they would have lost the opportunity to achieve their preferred family size or their desired timing of giving birth. Additionally, for nearly 9% of women, having access to misoprostol was essential to avoid self-induction with highly unsafe methods such as sharp objects inserted into the vagina, drinking chemical substances or another method obtained from an herbalist or other traditional practitioner. Further, the majority of women reported that they would recommend misoprostol abortion to a friend, and, if necessary, use it in the future, suggesting high levels of satisfaction with this method of abortion. These findings suggest a relatively high level of autonomy for abortion care seeking among our sample compared to other studies and indicate the important role that drug sellers play as trusted sources of information and providers of medical abortion in Lagos state. However, the appropriateness of the drug prescriptions and the quality of information provided to women by drug sellers was poor overall, as documented in other studies.[12]

Among women who completed both interviews, 94% reported complete abortion without surgical intervention. We were unable to assess the dosage received and instructions given on routes of administration for 37% and 42% of the sample, respectively. Among those who we could assess, at least

two-thirds appeared to have received less than the first trimester recommended dose of 800mcg misoprostol and/or were told they could ingest the misoprostol orally, which is a less effective route of administration than sublingually, buccally, or vaginally.[28] The medication's high level of effectiveness despite the low doses reportedly used could be partially explained if most pregnancies were in second trimester, during which time the uterus is more sensitive to lower doses of misoprostol.[30] The perceived success of the method could also be attributed to the longer length of follow up in our study: Generally, studies assessing MA effectiveness have followed up women around two weeks or sooner after taking the medication.[17,31] Allowing for a longer follow-up period ensured that the medication had sufficient time to work in the body, and may have improved its success rate.[31] Overall, even in the most conservative outcome for women lost to follow-up, the completeness rate of self-managed abortions in our study was 87% (Appendix C, Table 5), which is within the effectiveness range for misoprostol based on recommended protocols in clinical settings (78-90%).[18–21]

WHO's task sharing guidelines recognize that women have a role in self-management of the combined mifepristone and misoprostol abortion regimen if they have accurate information and access to a healthcare provider should they want or need at any point during the process, although pharmacy-alone provision is not explicitly recommended.[3] However, no such self-management guidelines yet exist for misoprostol-only abortions, which was the regimen used by the majority of our study sample. We could not accurately assess their weeks of gestation; however, the majority of the sample had taken a pregnancy test, were able to follow instructions, and, similar to findings from other studies,[32] appeared to have been able to assess the completeness of termination. Almost all women retained for the duration of the study reported complete abortion at the one-month follow-up. While most women did not report needing or wanting postabortion care, we were unable to clinically verify the proportion that actually experienced complications. The findings suggest that perceptions of needing care may be related to information, or lack thereof, they received from drug sellers about potential complications and care-seeking needs. Nearly half (48%) of those that reported needing medical care had been warned by drug sellers about complications, compared with only 23% of those who did not report needing care. However, the results show that nearly all women who reported wanting or needing care were able to access it, and most of those who sought care were

monitored or given pain medications, suggesting that they presented with symptoms that were either a normal part of the abortion process or that reflected very minor complications.

Our study had many methodological challenges and limitations. The study LGAs were purposively selected, so our sample was not representative of Lagos State. We had little information on women who dropped out and were hence unable to ascertain how they differed from women who completed the entire study. Our sample only included women who were recruited by drug sellers who admitted to selling misoprostol and then agreed to participate in recruiting women, and who may have had different practices from those who did not admit to selling or agree to recruit women, which could have potentially biased our results (Appendix C, Table 6). We were able to verify the medication purchased for about three-fourths of the women. However, we hypothesized that a majority of the women in our study obtained misoprostol because this was the criterion for recruitment on which we trained drug sellers, and we did not see many differences in key indicators between the women who we were able to verify had purchased misoprostol and those who we could not verify (Appendix C, Table 3). Measures for dosage and route of administration were based on women's self-report of the number of pills they took and instructions they were given, which may have been subject to recall bias and/or misinterpretation. These limitations were, in part, balanced by the strengths of the study, including its prospective design and its focus on women's direct experiences rather than relying on third party reporting. However, our overall reliance on self-reported measures for many of our core outcomes makes it difficult to determine the extent to which our findings will correlate with clinical data and must be interpreted with caution.

CONCLUSION

Worldwide, there is a paucity of research assessing the processes by which women obtain MA (either the combined method or misoprostol alone) for self-management of abortion and prospectively documenting their outcomes. Our success with drug seller engagement and women's recruitment is high compared with previous studies.[17,26] While this success may be due in part to the urban context of Lagos and the relatively liberal environment for drug stores and medication access generally in Nigeria, our experience suggests that prospective studies on misoprostol abortion in highly restrictive legal settings with similar

attributes may be feasible. While our findings may not be generalizable to the entire female population in Lagos, they do provide valuable insights into the experiences of women who self-manage their abortions using misoprostol, from their own perspectives. The majority of our sample purchased misoprostol, took the medication according to the instructions, reported that drug sellers were their main source of information during the process and appear to have been able to successfully complete their abortions with minimal complications. Recognizing the limitations of self-reported outcomes, and given evidence from clinical trials suggesting that as many as 20% of women may experience an incomplete termination using misoprostol alone, it is an important harm-reduction strategy to ensure that people who self-manage their medical abortions have adequate and correct information on warning signs of complications as well as access to postabortion care. Interventions to improve drug sellers' knowledge of best practices related to medical abortion may be an important part of the effort to improve their quality of services and the health and well-being of their clients, especially in similar settings where drug sellers are relied on for basic medical care. However, future research should explore ways to more objectively capture data relating to the duration of pregnancy, drug dosage, and clinical outcomes in addition to documenting individuals' experiences using the method. It is likely that the self-use of misoprostol will remain an important option for people, especially where abortion is legally restricted. More research is needed to expand the evidence on the safety and effectiveness of self-managed misoprostol abortion in similarly restrictive contexts, and to help inform the development of approaches and mechanisms to facilitate optimal outcomes for those using this method.

CONTRIBUTORSHIP STATEMENT

OO, AB, MS, AF and AA participated in the conceptualization of the project and designed the study. AF, AA, MS, OO, AB, ALB, TE, OSO, and HV participated in project planning. MS, ALB, OO, and TE programmed the study tools into SurveyCTO for electronic data collection. AA, TE, and OSO coordinated all aspects of fielding. AA, AF, TE, and OSO conducted the piloting of the study protocol and tools. AA, TE, and OSO selected fieldworkers and organized the trainings. MS, AA, TE, OSO, AF and HV co-led fieldwork trainings. AF liaised with the Ministry of Health and relevant drug seller associations to get

permission to conduct fieldwork at the local level. AF and AA convened the Technical Advisory Committee. MS, OO, TE, and ALB analyzed the data. MS, OO, ALB, TE, and OSO wrote the first draft of the article; all other authors critically reviewed the draft, and MS led the revisions. The entire team contributed to the development of study tools, participated in the conceptualization of the paper, and reviewed and approved the final version of the paper.

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DECLARATION OF INTERESTS STATEMENT

We declare no competing interests.

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data interpretation, or writing of the report. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication.

DATA SHARING STATEMENT

Given the sensitive nature of the data, they are not currently publicly available. We are determining ethical clearance to make this dataset available to other researchers.

LICENSE STATEMENT

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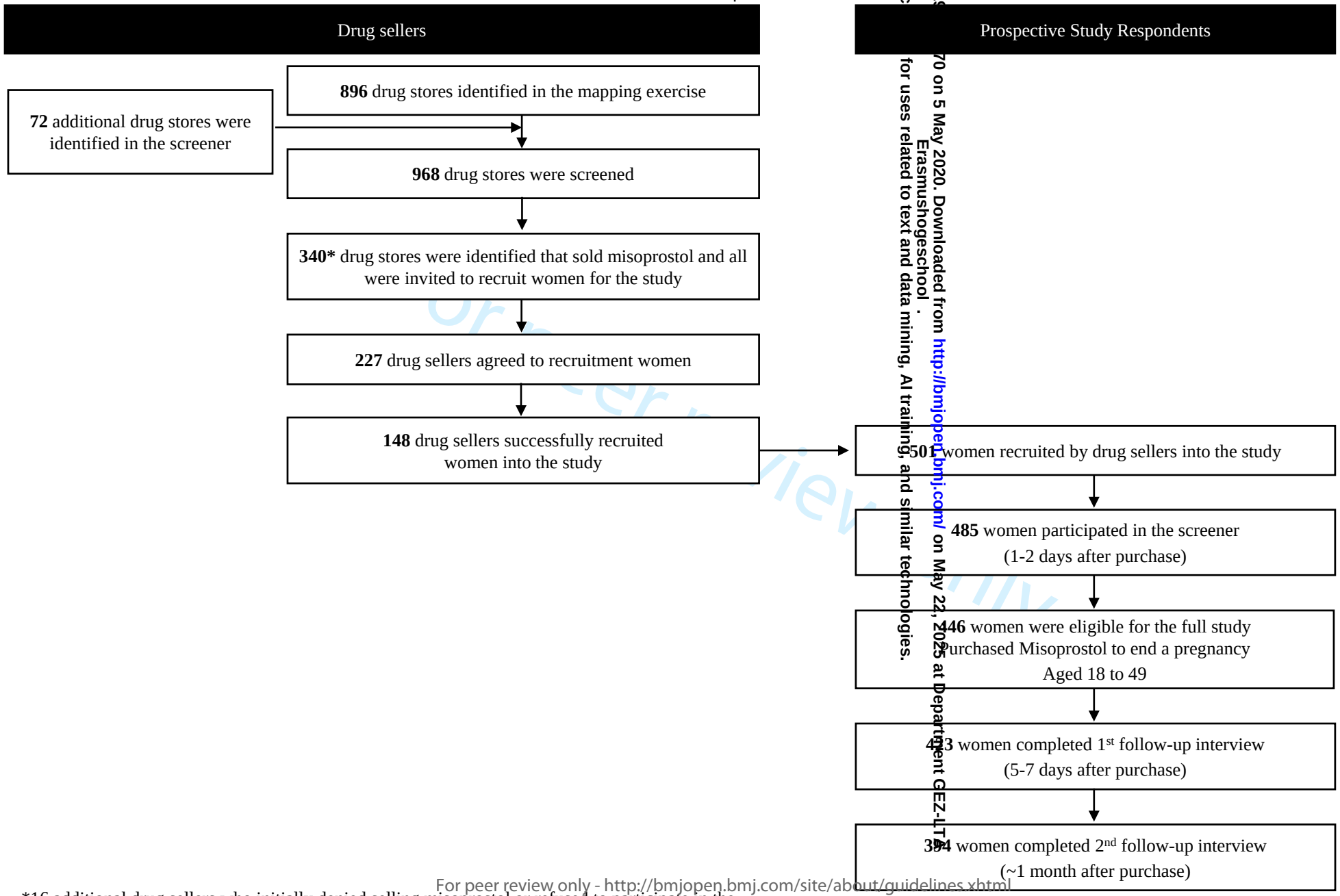
Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective study in Lagos State, Nigeria

Appendix A
Full description of recruitment and retention methodology

1. Mapping drug sellers

The mapping component was designed to enumerate the universe (sampling frame) of patent and proprietary medicine vendors (PPMVs) and registered pharmacy shops (referred to collectively as drug sellers) whom, based on advice by in-country experts, are likely the largest providers of medical abortion to women in this context. PPMVs are owner-operated drug retail outlets that were established as a category of retailer by the Ministry of Health to provide a source of medicine in communities with limited access to essential health commodities. For many people, they serve as the first point of care for a wide range of health issues. PPMV licensure does not require medical or pharmaceutical training, and regulations permit them to sell pre-packaged and over-the-counter medicines and medical products, but prohibit them from selling prescription medicines. In contrast, pharmacists must have a formal degree in pharmacy and are permitted to sell prescription medications. Official licensing of PPMVs and retail pharmacies is overseen by the Pharmacists Council of Nigeria (PCN), however there are an additional unknown number of unlicensed PPMVs in Nigeria; thus the study team conducted a mapping to generate a list of all drug sellers operating in the selected LGAs. The research team obtained a list of registered pharmacies from PCN's Lagos State office and two datasets that included a listing of all PPMVs that were operating in 16 states in 2013 (from Society of Family Health Nigeria) and all drug stores in Nigeria in 2015 (from Population Services International). These lists were used as a starting point for the sampling frame. A full mapping of PPMVs and pharmacies within the selected local government areas (LGAs) was conducted to determine the updated universe of drug sellers. All components of fieldwork (detailed in points 1-4) were conducted in two phases 1) Lagos Mainland, Ojo, and Oshodi/Isolo LGAs during April to July 2018 and 2) Epe, Ibeju-Lekki, and Ikorodu LGAs from May to October 2018.

Two supervisors and 18 fieldworkers were assigned to each LGA in the study to map all registered and unregistered drug sellers with a static point of sale (e.g., a store) whose primary business was selling medicines; clinicians or drug sellers without a shop or fixed point of sale were not included in the mapping exercise. Staff from the National Population Commission (NPopC) served as field guides and provided each field team with maps of the enumeration areas and an orientation to the LGA, including boundaries, streets and community names. LGA supervisors and NPopC staff overlaid NPopC maps with Google Maps to improve delineation of survey areas and reduce the potential for duplicated visits to drug sellers between teams in the field. Supervisors worked closely with the Field Managers to assign each fieldwork team sections of the LGA to map. Each data collection team in the field was comprised of two fieldworkers, one male and one female, to ensure their safety.

During mapping, no direct contact was made with anyone in the drug stores; the exercise was primarily to compile a list of existing stores in each LGA. GPS coordinates were collected using the data collection software *SurveyCTO Collect* along with a written description of the location to ensure field team members were able to return to the drug seller in future study components. After mapping was completed, the resulting dataset included: LGA, address, name of drug store, GPS coordinates, and a randomly generated unique ID. The Field Manager generated new project ID numbers for each drug seller in the sample, which were used to identify and link information on each drug seller throughout the study. All data were collected electronically using Android tablets. Data collected during the study were encrypted from the time of data collection, transmission to the secure server, and when downloaded to secured computers. Tablets used for data collection were password-protected and completed consent forms and surveys were uploaded to a secure server at the end of each day, which only the research team could access. The field team also carried paper copies of the instruments, in the case of power or mechanical failure.

The mapping exercise identified 896 drug stores in the selected LGAs (Appendix A, Figure 1).

2. Screening drug sellers

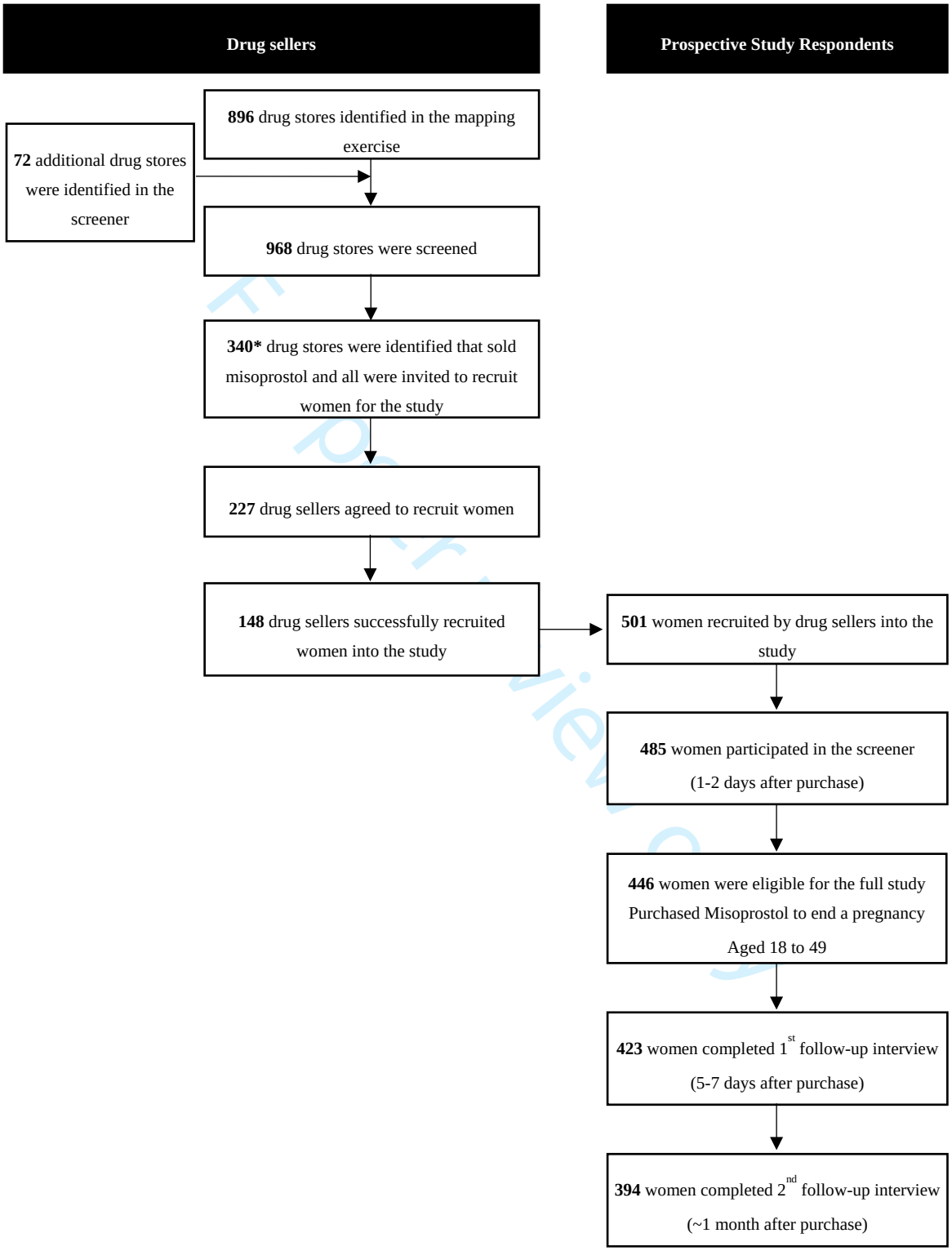
After the mapping was complete, interviewers who were not previously involved in the mapping component conducted short screening interviews of all drug sellers identified to determine whether they sold misoprostol-containing drugs. Two supervisors and approximately eight interviewers were assigned to each LGA for the drug seller screening component of the study.

Before beginning fieldwork, the research team formally notified the relevant government agencies and interacted significantly with the officials of the Pharmaceutical Services Directorate of the State Ministry of Health to secure their support and facilitate linkages with relevant stakeholders. Investigators contacted the leadership of the drug sellers associations and unions at the state as well as local levels to facilitate community entry. The study team gained approval from the following professional organizations: Association of Community Pharmacists of Nigeria (ACPN); and Lagos State Medicine Dealers Association (LSMDA). Each organization notified their membership about the study and provided letters of introduction for the study team to present to drug sellers prior to the interviews. Fieldworkers were also provided with the Lagos State Health Research Ethics Committee IRB approval letter, as well as identification cards to confirm their role on the study team to drug sellers while conducting fieldwork activities. The protocol for community entry was developed after the study team had conducted a small pilot study in another state, which revealed potential difficulties around interviewing drug sellers without the documentation of approvals at the local and national levels. These steps proved to be critical, and should be considered for other studies involving drug sellers in Nigeria.

Interviewers provided drug sellers with an introduction to the study and obtained permission from the owner or manager of each drug store to conduct the screener interview. If the owner or manager of the store was unavailable, interviewers were instructed to inquire when they could return to speak with them. If permission was granted, the interviewer explained the study to the drug seller who would be participating in the screener and obtained verbal consent for their participation. Fieldworkers were directed to interview the person working at the counter, who interacts with customers. In some cases, that person was the owner or manager, but in others it was somebody else, in which case the interviewers obtained two separate informed consents - one from the owner/manager and one from the participant. Prior to the screening component, fieldworkers were given the list of drug stores from the mapping component, but they were also instructed to document and conduct interviews in any other drug store they saw even if it was not on the list (these were stores that may have been inadvertently missed at the time of the mapping exercise). Seventy-two additional drug sellers were identified by the fieldwork teams, and included in the drug seller screening interviews. In total, 968 drug sellers were screened (Appendix A, Figure 1). Drug sellers received a token of 2,000 Naira (~USD $6) for participating in the screening interview.

The mapping and screening exercises resulted in a list of all drug sellers in the study LGAs that either reported selling misoprostol-containing drugs or did not. Initially, out of 968 drug stores in the universe, 324 drug sellers reported selling misoprostol in the screener, and 644 did not. An additional 16 drug sellers agreed to recruit women into the study, after initially refusing - one that had refused to participate in the screener interview, 13 that had denied selling misoprostol initially in the screener, and two that were approached directly to recruit by the PPMV chairmen in their LGA (Ikorodo). Therefore, the final sample of drug sellers that agreed to recruit women into the study, and whom can be presumed to sell misoprostol, was 340.

Appendix A, Figure 1. Sample of drug sellers, recruitment of women, and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

3. Recruitment of women by drug sellers

All drug sellers that reported selling misoprostol in the screener were invited to participate in recruiting women into the study. Out of 340 drug sellers that reported selling misoprostol or opted into the study, 227 (67%) agreed to participate in recruiting women, and 148 successfully recruited at least one woman (Appendix A, Figure 1). Before women's recruitment began, drug sellers who had signed up to recruit participated in a one-day training led by the study team, which covered additional background information on the study and training in ethics, maintaining confidentiality, and sensitive recruitment of clients. Drug sellers were trained on logistics for inviting any person (woman or husband/partner/proxy) purchasing misoprostol-containing drugs for any indication, to participate in the study.

Attempts to recruit women into the study were made after the drug seller had provided the drug and any routine counselling to avoid the possibility or perception that their services were contingent upon a woman's participation in the study, and to minimize any influence that study participation would have on the typical drug seller and client interaction. After delivering the normal protocol, the drug seller explained the study using a standard script provided by the study team that included a basic explanation of the study, including incentives for completing the screener interview and two follow up interviews. Anyone interested in participating was asked to verbally agree to be contacted by a member of the study team one to two days after the purchase. Drug sellers provided each woman who agreed to participate with a prepaid phone stocked with 500 Naira (approximately USD $1.50) in airtime and a pamphlet to retain throughout the study. The pamphlet contained a unique participant identification number, but did not include any specific details about the nature of the study. As an additional measure to ensure women's privacy, drug sellers asked each woman to provide a nickname and a password that interviewers could use when calling them, so that they would not have to reveal their real names or personal information to the drug seller during recruitment. The phones were provided to protect women's anonymity and alleviate any potential concerns that their identities would be linked to the study through their own personal, registered, phone numbers (which, in many cases, are linked to women's social media accounts). The idea of giving pre-registered and pre-paid phones to the study participants derived from the experience in the pilot phase of the study, whereby many women did not respond to telephone calls from the interviewers or gave the drug seller the phone number of a husband/partner or friend to contact because of the concern for anonymity.

For cases in which a buyer purchased the drug on behalf of someone else, the drug seller explained the study to the buyer and asked them to contact the potential end-user by calling her mobile phone while the buyer was still at the drug store. During the call, the drug seller briefly explained the study to the end-user and asked if she agreed to be contacted by an interviewer on the research study team, who would later provide her with a more in-depth description of the study and conduct a full informed consent protocol. If the end-user was interested, the drug seller recorded the end-user's responses to the identification questions described above and gave the buyer the study pamphlet and phone to give to the end-user.

Drug sellers were instructed to document the following information in a study log book: the unique ID on the pamphlet given to each woman; the nickname and password that women provided to the drug seller for the purposes of identification to the study team; the phone number of the prepaid phone given to each woman; the purchase data; and permission to be followed up from women who agreed to participate. All potential participants verbally agreed to this information being recorded in the log book and shared with the study team. The nickname and password were used to verify the woman's identity in the event the woman lost the unique identification number. A combination of nickname, password, and the pamphlet unique ID information was required to verify woman's identity at each interview. Drug sellers did not record potential respondents names or any other identifying information, such as individuals' phone numbers, email addressess, or physical addressess.

All drug sellers that volunteered to participate in recruiting women were visited by a member of the study team before recruitment began to verify the availability of a secure storage space for the log books in the facility. Drug sellers were required to store log books in locked and secure cabinets in their stores whenever the log books were not in use. Information on how the log books were stored and retrieved during fielding was also documented by interviewers during weekly site visits to collect physical copies of the log books used for recruitment. The research team initially planned to provide the drug sellers a second logbook to record data on: the total number of clients who came into the drug store requesting help terminating a pregnancy or specifically requesting misoprostol over the data collection

period; clients who purchased an MA drug but did not agree to participate; clients who purchased an MA drug but were not informed about the study; whether the purchaser was the end user or not. This logbook was intended to provide the study team with some additional context and help to understand the extent to which clients were missed by the study. However, after piloting the recruitment process resulted in incomplete and inconsistent data on the number of clients seeking MA or assistance in terminating a pregnancy, and considering the additional burden this logbook would impose on drug sellers during the recruitment period, the effort was dropped. Removal of this additional logbook from the drug seller's recruitment of women prohibited the research team from calculating participation in the study from the total population of clients approached during the fieldwork period.

Each participating drug seller received a prepaid phone and 500 Naira airtime (approximately USD $1.50) at the beginning of the recruitment period and an additional 1,500 Naira (approximately USD $4.50) after the recruitment period was completed. This amount was approved by the IRB as sufficient to reimburse them for the time they spent maintaining records on the study's behalf but not high enough to coerce drug sellers into participating.

Each interviewer for the women's component was assigned between eight and ten drug sellers. During the recruitment period, interviewers contacted each of the assigned drug sellers daily to confirm if the drug seller had recruited any women that day to input the logbook information into SurveyCTO and assess when drug sellers needed additional study materials for recruitment. At the end of the recruitment and follow-up period, interviewers for the women's component retrieved all log books from the drug seller stores and sent them in locked and secured boxes to the in-country study team's offices, to be destroyed at the completion of the study.

4. Prospective study of women

The prospective study of women included three rounds of telephone interviews with each woman, conducted by members of the study team over the course of one month. At the beginning of each call, interviewers followed a script to confirm the unique participant identification number, nickname, and security password on file to ensure the study team was speaking with the correct person. Once this was established, interviewers obtained verbal consent to participate in each interview. Interviewers did not provide any information about the study to anyone except the respondent, including husbands/partners or individuals who helped purchase the medicine for women.

The initial study design called for interviewers to make three attempts to contact each woman for an interview. Due to difficulties contacting respondents during early data collection, mainly non-response to phone calls from the field team, interviewers continued to call the prepaid phones for a four-week period. According to participants whom fieldworkers were later able to reach, the non-response was due to women not switching on the prepaid phones immediately after purchasing the medicine or not checking and charging the phone's battery regularly. Women working outside the home also reported leaving the study phones at home when they left the house. In total, about three percent of the women recruited into the study by drug sellers (15 women) were never successfully contacted by the study team.

For women who did participate, the average duration of the prospective study from recruitment to completion of the second follow-up interview was 37 days. Approximately 30% of women were reached on the interviewer's first attempted call across the study period; however, more than 20% of participants were called at least five times before interviewers successfully reached them for the screener and the first and second follow-up interviews with up to 16 attempted contacts required to successfully contact some respondents for interviews. While interviewers continued to call when women did not answer the phone, on average, interviewers reached women for the screener and both follow-up interviews on the second or third attempt.

Interviewers were trained to not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, women who asked for medical advice or who described symptoms that could indicate a serious problem were provided with the numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All women in the study were given this contact information after completion of the second follow-up interview, in case they had additional medical questions. Women given hotline information in the screener or first follow-up interview were asked if they had contacted the hotlines, during the first and second follow-up interviews, respectively, to account for any bias this potentially gained information may have introduced into the

results. Twelve women requested further information that prompted interviewers to provide the hotline number - two at the time of the screener interview and eleven during the first follow up interview (one woman requested more information during both interviews). However, none of the study participants successfully utilized the hotline.

4.1. Screener Interview

The screener interview was intended to be conducted one to two days after women (or someone else on their behalf) purchased the medicine. However, due to difficulties reaching women, screeners were completed seven days after the purchase on average. The screener interview took approximately five to ten minutes and collected information on age, reason for planned use of medicines purchased, and a measure of literacy. The interviewer only proceeded with enrolling women into the full prospective study if the respondents could be confirmed as the same women who were recruited by the drug seller, through their unique IDs, nicknames, and passwords, and met the eligibility requirements: 18 to 49 years old at the time of the interview and intended to use the medicines purchased to end a pregnancy. Under these criteria, 446 women were eligible for inclusion (Appendix A, Figure 1). Most ineligible women were outside of the age range or planned to use the medicine for another reason (e.g., for gastric ulcers or during childbirth for postpartum haemorrhage). A few of the ineligible respondents were nurses who ran private care centers in their homes and indicated that they had bought the misoprostol from the drug sellers with the intention of selling it later.

After completion of the screener, interviewers obtained informed consent to contact eligible women for the first follow-up interview five to seven days later. Due to the challenges faced in contacting women, the length of time between the purchase of misoprostol and the screener and subsequent interviews varied for some respondents. In cases where the interviewer could not contact the respondent for the screener until five days or later following the purchase of misoprostol, interviewers conducted the screener and first follow-up interview during the same call.

The prepaid phone and airtime provided by the study team through the drug sellers upon recruitment served as the only incentive for the screener, and women were not provided with another incentive at the completion of the call. There was no significant drop out between recruitment and screening or screening and the first follow-up interview to indicate that the provision of the first incentive up-front might have had a negative impact on study retention.

4.2. First Follow-up Interview

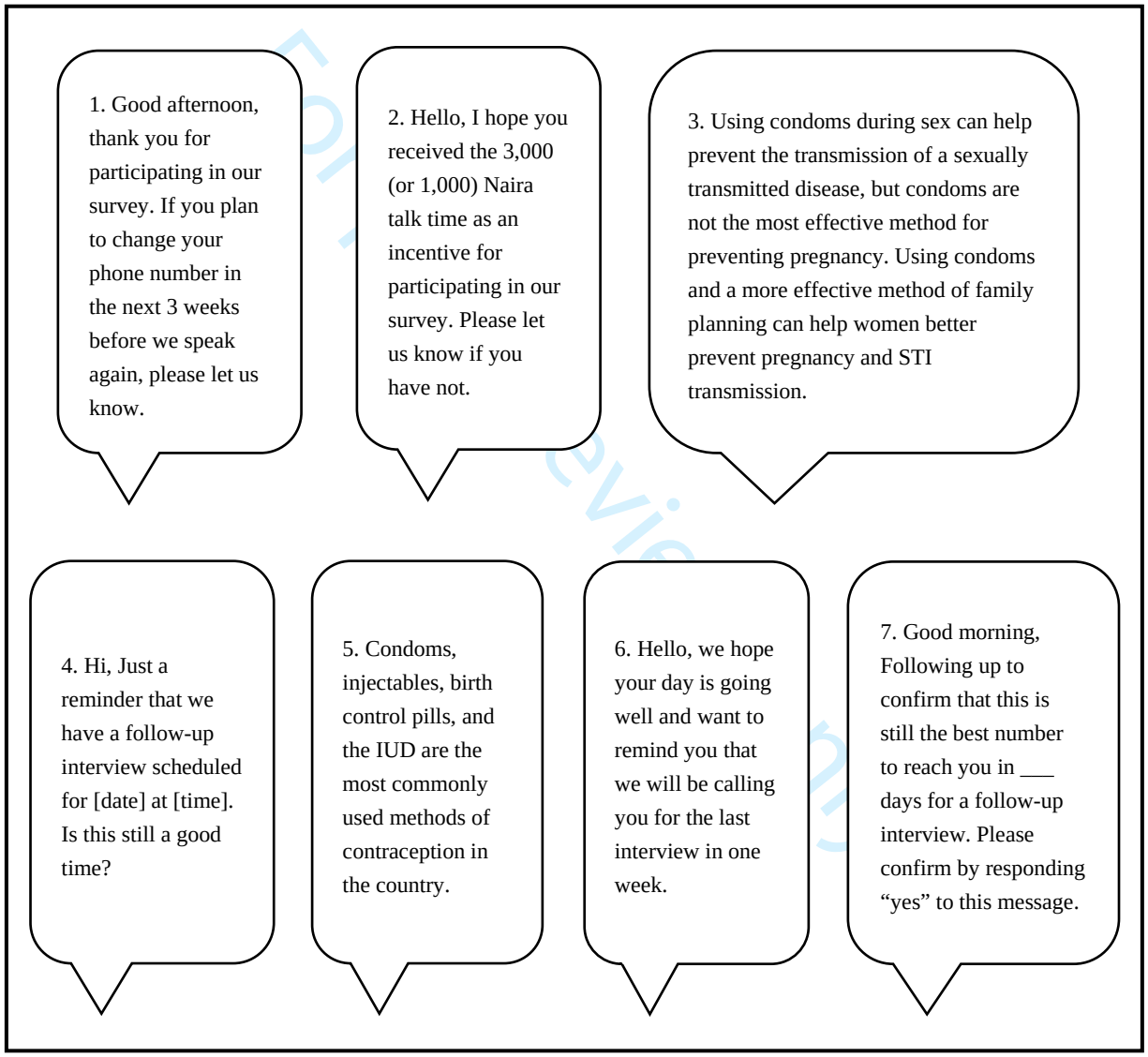
423 women - or 95% of eligible women - agreed to be followed up for another interview about a week after the screener interview (Appendix A, Figure 1). Interviewers followed the same procedure described in point 4 above to confirm women's identities prior to conducting the first follow-up interview. After confirming the person who answered the phone was the correct study participant, the interviewer reiterated the purpose of the study and obtained another verbal informed consent prior to beginning the interview. The purpose of the first follow-up interview was to determine women's decision-making processes around obtaining an abortion from a drug seller; the types of medication each woman purchased (some women purchased other abortifacients, including mifepristone alone and combi-packs of misoprostol and mifepristone); establish if the woman had used the medication; and collect information on her interaction with the drug seller, including the instructions drug sellers had given to each woman on how to take the regimen purchased.

At the end of the first follow-up interview, interviewers obtained informed consent to contact eligible women for the second follow-up interview approximately three weeks later (and approximately one month after the medication was purchased). Women who completed the first follow-up interview in the first three LGAs (Lagos Mainland, Ojo, and Ishodi/Isolo) received a 3,000 Naira (~USD $8) airtime incentive. This amount was originally considered to be enough to encourage women to participate but not so much that it would coerce women into participating. However, the incentive was reduced during the data collection in the second set of three LGAs (Epe, Ibeju-Lekki, and Ikorodu) to 1,000 Naira (~USD $3) in airtime due to budgetary constraints and confirmation by the field team that the new amount proposed then was adequate. The geographical location of the second set of LGAs made the cost of conducting the study in the areas, among others, much higher than those in the first set of LGAs particularly in terms of transportation cost and accommodation for data collectors. While the incentives for women in the second three

LGAs was about a one-third of those offered to women in the first three LGAs, there was no similar difference in the completion rates: 94% of eligible women from the first three LGAs completed the first follow-up interview compared with 97% of eligible women in the second three LGAs.

In the three-week period between the first and second follow-up interviews, interviewers engaged in consistent outreach via SMS message with each participant (Appendix A, Figure 2). These messages allowed interviewers to send reminders about the upcoming second follow-up interview and generally engage with the women. The purpose of the messages was to help retain participants in the study without sending any identifiable information or further details about the purpose of the study.

Appendix A, Figure 2. Text messages sent to respondents between the first and second follow-up interviews



4.3. Second Follow-up Interview

394 - 93% of women who completed the first follow-up interview - consented to be contacted for a second follow-up interview about 21 days later (Appendix A, Figure 1). Interviewers followed the same procedure described in

point 4 above to confirm women's identities prior to conducting the second follow-up interview. After confirming they were speaking to the correct study participant, the interviewer reiterated the purpose of the study and obtained verbal informed consent prior to beginning the interview. The primary focus of the second follow-up interview was to understand women's self-reported health outcomes after taking the medication; experiences with side effects and potential complications and whether women sought further healthcare after taking the medication; how women assess the completion of their abortions; the availability of emotional or social support throughout the process; and women's willingness to recommend medication abortion to friends or use it again in the future. Women who completed the second follow-up interview received an additional 3,000 or 1,000 Naira airtime incentive, in the first three or second three LGAs, respectively. Again, this difference in incentives was not reflected in the success rates: 94% of women who completed the first follow-up interview in the first three LGAs compared with 91% of those in the second three LGAs went on to complete the second follow-up interview.

During the programming of the study tools, a question on parity was inadvertently dropped. After exploring preliminary data, the study team agreed that interviewers should incorporate that question into all fieldwork that had not yet concluded. The team also attempted to recontact women who had already completed both follow-up interviews to ask about parity. The team successfully obtained measures of parity from 227 of the 394 respondents that completed the second follow-up interview.

Appendix B. Construction of Key Variables

The study team constructed variables to estimate the appropriateness of the dosage women received, the instructions women received on the route of administration of the pills, the adequacy of the information and instructions women received from drug sellers, and experiences with warning signs that could indicate potential complications. These measures are described below.

1. Dosage

To assess whether women purchased or were instructed to use the medication in the correct (i.e. WHO recommended) dosage, the team first determined what types of medication women were sold. This determination was based either on what was written on the manufacturer's package (if it was sold in a package and the package was still available at the time of the second interview), women's self-report of what the drug seller had told them, or their descriptions of the type of packaging and the number, color, or shape of the tablets they purchased. After determining that the medicine purchased was misoprostol, the dosage based on the number of pills purchased (assuming each misoprostol pill contains 200 mcg) was calculated. Dosages for misoprostol were categorized as less than 800 mcg (< four tablets), 800 mcgs (four tablets), 1000-1400 mcgs (five to seven tablets), and 1600-2400 mcgs (eight to 12 tablets). Nobody in the sample was given more than 12 tablets. To help in this process, the team compiled a list of misoprostol-containing drugs, including those that were registered with the government, brand names that were unregistered but found in the participating drug stores, and those that were identified by medical doctors and pharmacists on the research team. For the few women who received a combination pack of mifespristone and misoprostol, the recommended dose was defined as 200 mg mifepristone and 800mcg misoprostol, per standard packaging dosages.

2. Route of administration

According to clinical guidelines, mifepristone should be swallowed orally, and the optimal administration routes for misoprostol are vaginal, buccal (letting the pills dissolve in the cheek), or sublingual (letting the pills dissolve under the tongue). In assessing the appropriateness of the instructions given to women on how to administer the medication, any instructions that mentioned the option to ingest the misoprostol orally were considered suboptimal. The route of administration was categorized as optimal if women were told to take the misoprostol alone buccally, sublingually, or vaginally. For women who received mifepristone and misoprostol, the team categorized administration routes that included taking one mifepristone orally and misoprostol buccally, sublingually, or vaginally as optimal.

3. Core information score

Given that the safety and effectiveness of self-managed medication abortion depends, in part, on users' access to accurate information, the research team was interested in assessing the accuracy of information women received from drug sellers in the study. A score was constructedbased on the medical literature, consisting of nine items considered to be reasonably necessary, for women to successfully self-manage their abortions and assess the appropriateness of the information women received from drug sellers. Each item in the score was assigned one point, as no particular item warranted more weight than the others.

Items included:

1. Woman was asked about timing of last menstrual period
2. Woman was asked if she had taken a pregnancy test
3. Woman was told that bleeding is a side effect of the medication
4. Woman was told that cramping is a side effect of the medication
5. Woman was told that severe or prolonged bleeding could indicate a complication for which she might need to seek medical care
6. Woman was told that severe or prolonged pain could indicate a complication for which she might need to seek medical care
7. Woman was told that she could or should use pain medication
8. Woman was told anything about how to recognize a potential allergic reaction
9. Woman was told anything about potential contraindicated drugs

The data collected through this series of nine questions are limited and insufficient to provide a true measure of accuracy. For example, women may have reported that the drug seller informed them of potential drug

contraindications, but this measure does not include information about what specific contraindications were mentioned, and therefore, cannot precisely assess the accuracy of the information given. Nevertheless, the data generated could inform whether the types of information provided were within the bounds of what would be appropriate to cover and could reasonably be expected as the minimum amount of information women should receive.

4. Women's experience with potentially problematic effects of the medication

This study attempted to assess the proportion of women who experienced postabortion complications using their self-reported symptoms after using the medications purchased from the drug seller. To construct measures for estimating potentially problematic clinical effects that could indicate complications, the team created algorithms to assess excessive or greater than anticipated bleeding and signs of an infection.

Bleeding that could be symptomatic of a potential complication:

- Bleeding that soaks through more than two regular sized pads in two hours, lasting consistently for 12 hours after taking the medication.

Pain that could be symptomatic of a potential complication:

- Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
- Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
- Abdominal pain at the time of the last interview (~ one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

Fever or chills that could be symptomatic of a potential complication:

- Fever or chills that lasted more than 24 hours after taking the medication, or
- Any fever or chills still experienced at the time of the last interview.

Foul-smelling or discolored discharge that could be symptomatic of a potential complication:

- Foul smelling or discolored (not clear or white) discharge after taking the medication, or
- Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

Anyone who had a potential pain-, fever/chills-, or discharge-related complication was considered to have potentially experienced an infection complication after taking the medication. These measures likely overestimate potential complications in the sample as any self-report of a potential symptom qualifies respondents for inclusion in these estimates.

Appendix C: Supplementary Tables

Appendix C, Table 1. Demographic characteristics of the study sample and the overall population of ever-pregnant 15-49 year old females in Lagos State

	Among women who completed both follow-up interviews* (n=394)		Among ever-pregnant women aged 18-49 in Lagos State† (n=1,020)	
	%	No.	%	No.
Age categories				
18 - 24	22.8	90	8.3	84
25 - 29	32.0	126	20.7	208
30 - 34	23.4	92	24.8	244
35 - 39	16.0	63	21.7	231
40 - 44	5.1	20	13.8	144
45 - 49	0.8	3	10.6	109
Median age (IQR)	28	(25-33)	34	(29-39)
Parity‡				
No children	33.5	76	4.0	44
1-2 children	37.4	85	59.5	604
3+ children	29.1	66	36.5	372
Mean (SD)	1.6	(1.5)	3.0	(1.89)
Highest Level of Education Completed				
No schooling or incomplete primary	0.8	3	7.9	81
Primary/Junior secondary school	7.4	29	28.3	289
Senior secondary school	54.1	213	42.0	420
Some higher education (or more)	37.8	149	21.8	230
Employment				
Work for someone else/non-family business	51.5	203	15.6	171
Work for own/family business	24.1	95	69.2	706
Housewife	3.8	15	NA	NA
Student	13.2	52	NA	NA
Unemployed	7.4	29	15.2	143
Relationship Status				
Currently married or cohabiting	50.0	197	88.4	894
Separated/divorced/widowed	5.1	20	7.6	81
Never married and never lived together with a man	44.9	177	4.0	45

* Our study data
† 2013 Nigeria Demographic and Health Survey (Lagos State only)
‡ Our study data on parity are only from a subset of the sample (n=227)

Demographic characteristics of the study sample compared with the DHS sample

Our study sample was purposively selected and therefore we cannot assume that it was representative of the population of Lagos. To better contextualize our findings, we compared the sociodemographic characteristics of our sample to those of the Demographic and Health Survey sample (limiting the data to ever-pregnant 18-49 year-old females living in Lagos State). We found that our sample was: more highly educated (92% compared with 64% had completed secondary education), younger (55% compared with 29% were between 18 and 29 years old), more often nulliparous (34% vs. 4%), more commonly worked someone else (non-family member) in a business (52% vs. 16%), and more commonly had never been married (45% vs. 4%; Appendix C, Table 1).

Appendix C, Table 2. Women's experiences with previous attempts to end current pregnancy prior to recruitment

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who made another attempt to end the pregnancy prior to being recruited	5.3	21
Among women who had made a prior attempt (N=21):		
Number of previous attempts to end the pregnancy		
1	81.0	17
2	14.3	3
>2	4.8	1
Women who went to each place in their last attempt		
Another pharmacy/drugstore	23.8	5
The same pharmacy/drugstore	14.3	3
Traditional practitioner	23.8	5
A friend	19.0	4
Did something at home	19.0	4
Women who used each method in their attempt(s)*		
Took some pills	57.1	12
Drank agbo/herbal preparation	47.6	10
Other	10.0	2
Pills women had taken in previous attempts (N=12)		
Misoprostol	16.7	2
Postinor (emergency contraception)	33.3	4
Don't know	50.0	6
Outcome of attempt(s)		
Nothing/light spotting	100.0	21

* Multiple responses were allowed

Appendix C, Table 3. Women's reports of information received from the drug seller, clinical symptoms experienced after taking the medication, and dosages given, according to whether or not we verified that they had received misoprostol

	Women who we verified received misoprostol (n=323)		Women who we could not verify received misoprostol (n=71)		All women who completed both follow-up interviews (n=394)		P-value
	%	No.	%	No.	%	No.	
Proportion who were told about clinical effects to expect*							
Bleeding	65.3	211	71.8	51	66.5	262	0.293
Cramping/Abdominal Pain	34.7	112	38.0	27	35.3	139	0.592
Headaches	9.0	29	2.8	2	7.9	31	0.081
Vomiting	4.6	15	4.2	3	4.6	18	0.878
Nausea	1.5	5	--	--	1.3	5	0.291
Diarrhea	2.2	7	1.4	1	2.0	8	0.681
Fever/chills	3.7	12	5.6	4	4.1	16	0.458
General feeling of weakness	14.9	48	16.9	12	15.2	60	0.665
Dizziness	0.9	3	--	--	0.8	3	0.415
Proportion who reported experiencing clinical effects after taking the medication*							
Bleeding	83.3	269	90.1	64	84.5	333	0.148
Cramping/Abdominal Pain	69.7	225	74.6	53	70.6	278	0.404
Headaches	8.7	28	7.0	5	8.4	33	0.654
Vomiting	5.6	18	4.2	3	5.3	21	0.647
Nausea	3.1	10	2.8	2	3.0	12	0.901
Diarrhea	5.6	18	2.8	2	5.1	20	0.338
Fever/chills	8.7	28	7.0	5	8.4	33	0.654
Foul smelling or colored vaginal discharge	0.6	2	--	--	0.5	2	0.506
General feeling of weakness	22.3	72	11.3	8	20.3	80	0.037
Dizziness	2.5	8	1.4	1	2.3	9	0.585
Amongst women that were told about bleeding:							
Women reported bleeding	87.2	184	98.0	50	89.3	234	0.025
Amongst women that were told about cramping:							
Women reported cramping	75.0	84	70.4	19	74.1	103	0.622
Women reporting a complete abortion without surgical intervention	94.4	305	90.1	64	93.7	369	0.180
Miso dose	**n=249**		**n=0**		**n=249**		NA
<800mcg misoprostol	69.1	172	NA	NA	69.1	172	
800mcg misoprostol	26.9	67	NA	NA	26.9	67	
1000-1400mcg misoprostol	2.0	5	NA	NA	2.0	5	
1600mcg-2400mcg misoprostol	0.8	2	NA	NA	0.8	2	
200mg mifepristone & 800mcg misprostol	1.2	3	NA	NA	1.2	3	

* Multiple responses were allowed.

Appendix C, Table 4. Proportion of women reporting complete abortions without surgical intervention ~one month after taking the medication, according to the dosages received

	Number of women that received each dosage (n=249)	Completed abortions among women who you received each dosage of medication	
		%	No.
Misoprostol dosage			
<800mcg misoprostol	172	93.0	160
800mcg misoprostol	67	97.0	65
1000-1400mcg misoprostol	5	80.0	4
1600mcg-2400mcg misoprostol	2	100.0	2
200mg mifepristone & 800mcg misprostol	3	100.0	3

Appendix C, Table 5. Estimated proportion of all women with completed abortions using different assumptions for women lost to follow up

	Completed abortions among all women who confirmed taking the pills (n=423)	
	%	No.
Assumptions about women lost to follow up		
All women had incomplete abortions	87.2	369
25% of women had complete abortions	88.9	376
50% of women had complete abortions	90.7	384
75% of women had complete abortions	92.4	391
All women had complete abortions	94.1	398

Appendix C, Table 6. Drug store and drug seller characteristics among drug sellers that did and did not agree to recruit women

	Drug sellers who agreed to recruit women (n=224*)		Drug sellers who did not agree to recruit women (n=113)		P-value
	%	No.	%	No.	
Drug Store Characteristics					
Drug store area					0.023
Urban	96.9	217	91.2	103	
Peri-urban	3.1	7	8.8	10	
Drug store LGA					0.000
Lagos Mainland	19.6	44	14.2	16	
Ojo	18.3	41	10.6	12	
Oshido/Isolo	33.0	74	11.5	13	
Epe	4.0	9	4.4	5	
Ikorodu	17.0	38	44.2	50	
Ibeju-Lekki	8.0	18	15.0	17	
Type of drug store					0.011
Pharmacy	68.3	153	81.4	92	
Proprietary Patent Medicine Vendor (PPMV)	31.7	71	18.6	21	
Does store sell family planning products					0.758
No	1.3	3	1.8	2	
Yes	98.7	221	98.2	111	
Drug Seller Characteristics					
Drug seller Position					0.686
Owner/Senior manager	43.8	98	43.4	49	
Front counter staff - pharmacist	33.5	75	32.7	37	
Front counter staff - non-pharmacist	20.1	45	23.0	26	
Other	2.7	6	0.9	1	
Drug seller Sex					0.050
Male	61.6	138	50.4	57	
Female	38.4	86	49.6	56	
Drug seller Age					
Median (IQR)	32	(27-39)	34	(28-42)	

* Three drug sellers that recruited women did not complete the drug seller screener and are not included in this table.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8 & appendix
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8 & appendix
Bias	9	Describe any efforts to address potential sources of bias	15
Study size	10	Explain how the study size was arrived at	5,6 & appendix
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8 & appendix
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	appendix
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
(*e*) Describe any sensitivity analyses	appendix

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	appendix
		(c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	8
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-16 & Appendix
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-16 & Appendix
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	15 & Appendix
Discussion			
Key results	18	Summarise key results with reference to study objectives	17-18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-20
Generalisability	21	Discuss the generalisability (external validity) of the study results	16,19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21,22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Title: Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective cohort study in Lagos State, Nigeria

Melissa Stillman, MPH[1]*
Onikepe Owolabi, PhD[1]
Adesegun O. Fatusi, PhD[1,2]
Akanni I. Akinyemi, PhD[3,4,5]
Amanda L. Berry, MPH[1]
Temitope P. Erinfolami, MSc[4,5]
Olalekan S. Olagunju, MSc[4,5]
Heini Väisänen, PhD[6]
Akinrinola Bankole, PhD[1]

1 Guttmacher Institute
125 Maiden Lane, 7th Floor
New York, NY 10038

2 Academy for Health Development (AHEAD)
Ile-Ife
Nigeria

3 Harvard T. H. Chan School of Public Health
677 Huntington Avenue
Boston, MA 02115

4 Obafemi Awolowo University
Department of Demography and Social Statistics
Ile-Ife
Nigeria

5 Centre for Research, Evaluation Resources and Development (CRERD)
Ile-Ife
Nigeria

6 University of Southampton
Department of Social Statistics and Demography
Highfield,
Southampton SO17 1BJ

* Corresponding author:

Melissa Stillman, mstillman@guttmacher.org

(212) 248-1111, ext. 2256
125 Maiden Lane, 7th Floor, New York, NY 10038

ABSTRACT

Objectives: This study aimed to assess the safety and effectiveness of self-managed misoprostol abortions obtained outside of the formal health system in Lagos State, Nigeria.

Design: This was a prospective cohort study among women using misoprostol-containing medications purchased from drug sellers. Three telephone-administered surveys were conducted over one month.

Setting: Data were collected in 2018 in six local government areas (LGAs) in Lagos State.

Participants: Drug sellers attempted to recruit all women who purchased misoprostol-containing medication. To remain in the study, participants had to be female and aged 18–49, and had to have purchased the medication for the purpose of abortion. Of 501 women initially recruited, 446 were eligible for the full study, and 394 completed all three surveys.

Primary and secondary outcome measures: Using self-reported measures, we assessed the quality of information provided by drug sellers; the prevalence of potential complications; and the proportion with completed abortions.

Results: Although drug sellers provided inadequate information about the pills, 94% of the sample reported a complete abortion without surgical intervention about one month after taking the medication. Assuming a conservative scenario where all individuals lost to follow up had failed terminations, the completion rate dropped to 87%. While 86 women reported physical symptoms suggestive of complications, only six of them reported wanting or needing health facility care and four subsequently obtained care.

Conclusions: Drug sellers are an important source of medical abortion in this setting. Despite the limitations of self-report, many women appear to have effectively self-administered misoprostol. Additional research is needed to expand the evidence on the safety and effectiveness of self-use of misoprostol for abortion in restrictive settings, and to inform approaches that support the health and well-being of people who use this method of abortion.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Data from this study are the first prospectively collected data that capture people's experiences with, and the self-reported effectiveness of, self-managed misoprostol abortion in a legally restrictive setting in Sub-Saharan Africa.
- This study utilized novel recruitment and retention approaches: drug sellers were the source of recruitment, which leveraged existing client-provider relationships; unregistered mobile phones were distributed to participants to mitigate fears around potential loss of privacy; text messages were sent to participants periodically in between interviews, which improved engagement and likely contributed to the study's relatively high follow-up rate.
- The follow-up period for this study was one month, which is longer than that of previous studies, thus allowing more time for the medication to work and potentially resulting in a more accurate self-assessment of the medications' effectiveness.
- This study relied on misoprostol users' self-report for our primary outcomes, and although we believe participants are capable of describing changes in their own bodies, it is difficult to determine the extent to which our findings will correlate with data collected under clinical experimental conditions.
- The study sites were purposively selected, and the sample could only include clients who obtained misoprostol from drug sellers willing to participate in the study and who may be different from other drug sellers in unknown ways, therefore our findings are not generalizable to the entire population of the state and country.

INTRODUCTION

Globally, medical abortion (MA) has become an increasingly important method for people seeking to terminate a pregnancy.[1] While mifepristone followed by misoprostol is the preferred MA regimen recommended by the World Health Organization (WHO), misoprostol alone is recommended as a safe and effective alternative where mifepristone is not available.[2] WHO guidelines specify self-managed mifepristone and misoprostol as a viable approach for terminating pregnancies when users have access to adequate information and a trained healthcare provider.[3] However, WHO has not yet recommended self-

management of misoprostol alone because of limited evidence. In contexts in which abortion is illegal or highly restricted, mifepristone is unlikely to be approved by the government, and self-managed abortion with misoprostol alone is a critical option for individuals who may otherwise resort to other, unsafe, methods.[1]

Nigeria has a population estimated at 200 million in 2019,[4] and induced abortion is legally permitted only to save a woman's life.[5] Despite the restrictive law, the rate of induced abortion in Nigeria was estimated at between 41.1 and 59.4 per 1,000 women of reproductive age in 2017.[6] MA drugs, particularly misoprostol, have become more widely available in Nigeria in recent years.[7–9] Nigeria has a large market of drug vendors serving informally as the first point of care for diverse health problems, and most medications can be procured without prescription.[10] However, evidence from other studies suggests that drug sellers have poor knowledge of MA drugs, commonly sell medications without packaging or instructions, and often provide inadequate or inaccurate information to women about medications, side effects, and potential complications.[11–16]

There is currently a dearth of community-based evidence on people's experiences accessing misoprostol from drug sellers and the outcomes of self-managed abortions. Findings from a prospective cohort study with a very small sample of women who bought misoprostol from pharmacy workers in Bangladesh indicate that 75% of women reported complete abortions after two weeks,[17] which is just below the range of expected effectiveness for misoprostol alone (78-90%).[18–21] Studies from several countries in Latin America where abortion is legally restricted suggest that even if adequate information is not provided by drug sellers, information obtained through other means, such as hotlines, may reduce the potential risks of self-managed medical abortion.[1,22–24] The few studies in sub-Saharan Africa that attempted to assess health outcomes from use of misoprostol alone recruited patients presenting for postabortion care in health facilities, and therefore do not represent everyone who had used this method.[9,25] Prospective studies have the potential to provide stronger evidence but those that have attempted to explore these topics have reported challenges with the recruitment and follow-up of participants.[17,26]

To address this research gap, we designed a prospective study to explore the experiences of women[a] who self-manage abortion using misoprostol obtained from drug sellers in Lagos State, Nigeria. We investigated what dosages and information women receive when attempting to purchase misoprostol for abortion; what clinical effects they experience, including potential complications; if and how they assess completeness; and what proportion of women have completed abortions.

METHODS

Study Setting

Data for this study were collected in six local government areas (LGAs) in Lagos State. Lagos is the most populous city in Nigeria and constitutes one of the largest markets for MA nationally. The 20 LGAs in Lagos State were stratified into more urban and less urban based on population density. From each stratum, we purposively selected three that each had at least one higher-level educational institution. We hypothesized that areas with higher-level educational institutions would have greater market for misoprostol due to the concentration of females aged 20 to 29 and those with a secondary education or higher, populations that have a relatively higher estimated incidence of abortion in Nigeria.[27]

Study design and data collection

Field activities were organized into two major components: 1) a drug seller study, which included a) a mapping of pharmacies and patent medicine vendors (PPMVs), herein referred to as drug sellers, and b) a screener interview to identify those selling misoprostol for any reason; and 2) a prospective cohort study of women who purchased misoprostol, recruited by drug sellers.

[a] People of all genders are capable of becoming pregnant and having abortions. We did not include questions related to gender identity in the surveys due to concerns related to cultural sensitivity and appropriateness. For the purpose of this study, our eligibility criteria included being a woman 15-49 years old who had purchased misoprostol to terminate a pregnancy, and the word "woman" was used in the consent form as well as the surveys. Based on these criteria, in addition to assumptions made by drug sellers and the interviewers, we refer to participants as "women" in this paper.

Identifying drug sellers who sell misoprostol

Fieldworkers collected the names and Global Positioning System (GPS) coordinates of all drug sellers in each LGA, generating the universe (n=968; Figure 1). Thereafter, they visited every shop and conducted a screening interview to generate a list of drug sellers that reported selling misoprostol for any indication. Drug sellers who reported selling misoprostol (n=340) were invited to recruit all women who purchased any misoprostol-containing medications, directly or through a proxy, for any reason over a two-month period. In total, 227 drug sellers agreed to recruit women. See Appendix A for more details on recruitment procedures.

Prospective cohort study of women

Drug sellers assisted in recruiting women who bought misoprostol, or a misoprostol-containing drug, for any reason. Drug sellers provided a general explanation of the study, and asked everyone interested in participating if they agreed to be contacted by a member of the study team. Interviewers contacted willing participants one to two days after purchase of the medicine, explained the study in detail and obtained informed consent to participate prior to conducting a telephone screener to determine eligibility. Only women aged 18–49 who bought misoprostol specifically to terminate a pregnancy were eligible for inclusion. Eligible women were invited to participate in two additional rounds of surveys using structured questionnaires administered by telephone over approximately one month.

A first follow-up interview was conducted five to seven days after screening to identify the medications purchased, establish if and how the woman used the medication and ask about her interaction with the drug seller at the time of purchase. A second follow-up interview was conducted three weeks later (one month after purchasing the medication) to understand women's self-reported health outcomes after taking the medication, how women assessed the completion of their abortions, support during the abortion process, and women's willingness to recommend misoprostol to friends or use it again.

Data for the drug seller screening were collected in-person by trained male fieldworkers and data from the women were collected over the telephone by female field workers trained by the study team in sensitive interviewing techniques. All data were collected using the mobile data collection application SurveyCTO on password-protected and encrypted Android tablets and stored on a secure server accessible only to the research team. Women's informed consent was obtained prior to each interview, and permission to be contacted again for the next follow-up interview was given at the end of the screener and first follow-up interviews. Women's identities were confirmed at each interview using a unique identification number, password or nickname provided at the time of recruitment.

Interviewers did not have medical training and did not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, respondents who asked for medical advice or who described symptoms that could indicate a serious health problem were provided with the telephone numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All participants in the study were given this contact information after completion of the second follow-up interview, in case they had additional medical questions. Data collection occurred between April and October 2018. A description of the study and the study tools are on OSF (Open Science Framework), and are accessible at https://osf.io/3akjx/?view_only=960f46d756fd4bb189499e1fe5ae54a5.

The National Health Research Ethics Committee in Nigeria and the Institutional Review Board of Guttmacher Institute approved the study.

Patient and Public Involvement

The study was supported by a Technical Advisory Group that provided input on the program of research. The advisory group, which consisted of medical doctors, local researchers and other experts in the field of sexual and reproductive health in Nigeria, provided input on the research questions, study design and tool development prior to the start of fieldwork. The advisory group provided feedback on the preliminary

research findings and advice on messaging the results. The group will help plan dissemination activities, including the presentation of findings to participating drug sellers and other stakeholders.

Study definitions (described in detail in Appendix B)

Dosage

Doses of less than 800 mcgs for misoprostol alone were classified as less than the WHO recommended dose for first trimester abortions.[2]

Route of administration

An optimal route of misoprostol administration was defined as administering it buccally, sublingually, or vaginally.[2,28] A suboptimal route was one where women were given the option to swallow the misoprostol by mouth.

Adequacy of information

We created a nine-item score for the adequacy of information covered during the drug sellers' interactions with women. We included information considered to be reasonably necessary, based on medical literature, for women to successfully self-manage abortion. We allocated each item one point if the information was provided and created the index by adding up the total number of points.

Warning signs of potential complications

Warning signs of complications were assessed using self-reported symptoms after taking the medication and included excessive or greater than anticipated bleeding; or a combination of greater than anticipated abdominal pain or cramping, fever and chills, or vaginal discharge that could potentially indicate an infection. Criteria used to assess these are described in Appendix B.

Analysis

We conducted descriptive analyses to summarize women's sociodemographic characteristics; the quality of information provided by drug sellers; the prevalence of potential complications; the proportion who had complete terminations without additional medical interventions; and abortion strategies women would have employed had they not used misoprostol. All analyses were conducted using Stata15.1.

RESULTS

Of the 501 women recruited by drug sellers, 485 women (97%) were successfully contacted and screened by interviewers,446 women were eligible for the study (92% of those screened), and 394 women (88% of all eligible women recruited) were successfully interviewed in both follow-up interviews (Figure 1). The data presented in the results are from the 394 women who completed both interviews, including a small proportion (2%) that received mifepristone + misoprostol.

Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study

Demographic characteristics of participants

Among our final sample, more than half (55%) were between the ages of 18 and 29, and 92% had completed senior secondary school while 38% had completed some higher education (Table 1). About three-quarters (76%) worked for a family- or non-family-owned business, and 13% were students at the time they purchased the misoprostol. Half (50%) were married or cohabiting, and 95% purchased the drug themselves. Most respondents (83%) had taken some kind of pregnancy test prior to going to the drug seller. For 85% of participants, this was their first pregnancy termination.

Table 1. Demographic characteristics of women, type of drug sellers visited and who bought the pills, proportion of women who took a pregnancy test, and previous experiences with abortion

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Age categories		
18 - 24	22.8	90

25 - 29	32.0	126
30 - 34	23.4	92
35 - 39	16.0	63
40 - 44	5.1	20
45 - 49	0.8	3
Median age (IQR)	28	(25-33)
Parity‡		
No children	33.5	76
1-2 children	37.4	85
3+ children	29.1	66
Mean (SD)	1.6	(1.5)
Highest Level of Education Completed		
No schooling or incomplete primary	0.8	3
Primary/Junior secondary school	7.4	29
Senior secondary school	54.1	213
Some higher education (or more)	37.8	149
Employment		
Work for someone else/non-family business	51.5	203
Work for own/family business	24.1	95
Housewife	3.8	15
Student	13.2	52
Unemployed	7.4	29
Relationship Status		
Currently married or cohabiting	50.0	197
Separated/divorced/widowed	5.1	20
Never married and never lived together with a man	44.9	177
Local Government Area of recruitment		
Lagos Mainland	17.0	67
Ojo	18.3	72
Oshodi Isolo	16.2	64
Epe	8.9	35
Ikorodu	24.4	96
Ibeju Lekki	15.2	60
Women who went to each type of drug seller		
Pharmacy	40.6	160
Proprietary Patent Medicine Vendor (PPMV)	59.4	234
Who purchased the medicine		
Medicines bought by the woman	95.2	375
Medicines bought by someone else	4.8	19
Previous attempt to end a pregnancy		
No, has not attempted to end a prior pregnancy	84.5	333
Yes, has previously attempted to end a prior pregnancy	15.5	61

% of women who took each type of pregnancy test when they suspected they were pregnant§		
Confirmation via test with a doctor	20.8	82
Confirmation via test at a laboratory	17.5	69
Self-administered urine test	54.6	215
No test	17.0	67

‡ Data on parity were only from a subset of the sample (n=227).
§ Multiple responses were allowed.

Abortion attempts prior to recruitment

A small proportion (5%, n=21) of the sample had made at least one other attempt to terminate the current pregnancy prior to being recruited into the study (Appendix C, Table 1). Of them, 12 had taken pills and ten ingested herbal preparations. Six women who took pills did not know what pills they had taken, four had taken emergency contraception and two took an unspecified dose of misoprostol that was reported as ineffective.

Medication types, determining eligibility, and dosage

Upon entering the drug store, 51% of women told the drug sellers that they needed something to end a pregnancy, and 39% said they wanted help to bring back a late menstrual period (Table 2). More than half (57%) reported that they had not known there were pills they could take to end a pregnancy prior to visiting the drug seller; 22% had heard about such pills from a friend or family member, and 7-8% found out about them online (n=33) or from a health professional (n=28) (not shown). One-fourth of the sample (25%) reported that they did not know what medication they purchased from the drug seller. Among those who knew what medication they purchased, a majority (97%, n=272) reported receiving just misoprostol from the drug seller, and 3% (n=7) received misoprostol in combination with mifepristone. Based on women's self-reports of the type and number of tablets purchased, we confirmed that 44% were sold less than the recommended dosage for effectiveness (<800mcg misoprostol), 20% received a dosage within the range of effectiveness, and we were unable to assess the dosage for an additional 37% of the sample.

Table 2. Women's experiences interacting with the drug seller, types of medications, dosages, and administration routes

	Women who completed both follow-up interviews (n=394)	
	%	No.
How women presented themselves to the drug seller*		
Told drug seller she wanted to end a pregnancy	50.5	199
Told drug seller she wanted to purchase misoprostol or other specific brand name medicine	16.2	64
Told the drug seller she wanted to bring back a late period	39.3	155
Told drug seller something else	1.3	5
Types of medicine women reported receiving†		
Misoprostol	69.0	272
Misoprostol + Mifepristone	1.8	7
Unknown medicine‡	25.4	100
Missing	3.8	15
Dosage of medication prescribed by drug seller§		
Less than the WHO recommended dosage (< 800 mcg misoprostol)	43.7	172
800 mcg misoprostol	17.0	67
1000-1400mcg misoprostol	1.3	5
1600mcg-2400mcg misoprostol	0.5	2
200mg mifepristone & 800mcg misoprostol	0.8	3
Not assessed	36.8	145
Routes of administration of the medication prescribed by drug seller¶		
Suboptimal route (oral misoprostol)	38.6	152
Optimal route (buccal, vaginal, or sublingual misoprostol)	19.0	75
Drug seller did not say	0.3	1
Not assessed	42.1	166

* Multiple responses were allowed

† Data on types of medicine received are not available for 15 women due to missing responses.

‡ "Unknown" means the woman did not know what medication she took, either because she was never told or because she could not remember. Although the medication was unknown to her, it still could have been misoprostol or another abortifacient.

§ The medication dosage could only be assessed among women who answered specific questions about the numbers of each type of pills they were given, and who either knew what medication(s) they were given or for whom we were able to, with reasonable confidence, parse out what medication(s) they were given based on their answers to related questions.

¶ The administration route could only be assessed among women for whom we could identify the medication(s) given. Since World Health Organization (WHO) guidelines recommend that mifepristone be administered orally and misoprostol be administered bucally, vaginally, or sublingually, any administration route instructions that diverge from these recommendations are considered suboptimal.

Instructions received from the drug sellers

Most of the sample (78%) reported that they were given some instructions about how to take the medications, and nearly all women who received instructions followed them (Table 3). Most women relied solely on drug sellers for information: 72% did not use any other source (not shown).

Table 3. Percent of women that reported drug sellers providing information about misoprostol or asking questions to assess eligibility for misoprostol prior to purchase

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who received any instructions from the drug seller about how to take the medication	77.9	307
Women who took tablets according to drug sellers' instructions		
Followed instructions	75.9	299
Did not follow instructions	2.0	8
Did not receive instructions	22.1	87
Women reporting the following items were covered during the interaction with the drug seller		
Asked timing of last menstrual period	79.4	313
Asked if she took a pregnancy test	74.1	292
Informed that bleeding is an anticipated effect	66.5	262
Informed that cramping is an anticipated effect	35.3	139
Informed that severe bleeding could indicate a potential complication	12.9	51
Informed that severe and persistent abdominal pain could indicate a potential complication	3.0	12
Informed about use of pain medication	28.2	111
Informed of potential allergic reactions	7.1	28
Informed of potential contraindications	22.8	90
Number of items listed above that were covered in women's interaction with drug sellers		
No core information	9.6	38
1-3 items	42.4	167
4-6 items	45.2	178
7-8 items	2.8	11
9 items	--	--
	Mean	SD

Adequacy of information scale score (out of 9 items)	3.3	1.8

On average, women reported that drug sellers covered three of nine items we considered necessary for successful self-management of abortion using misoprostol (Table 3). A relatively high proportion reported that drug sellers attempted to assess their eligibility: 74% were asked if they had confirmed their pregnancy with a test, and 79% were asked the timing of their last menstrual period. However, fewer reported being given information about what clinical symptoms to anticipate as a normal part of the abortion process; 67% and 35% reported being told that they could expect some bleeding or cramping, respectively. Only 51 women (13%) were told about severe bleeding that could indicate a potential complication.

Women's experiences of warning signs after taking the medication and subsequent care seeking

Most women did not report adverse events after taking the medication. However, 77 women (20%) reported bleeding that we classified as potentially problematic, and 15 women (4%) reported a combination of symptoms suggestive of infection (Table 4). Six women were classified as having experienced symptoms of both. Among the 86 women with potentially problematic bleeding or symptoms of infection, 7% (n=6) reported wanting or needing medical care, and 5% (n=4) sought care (not shown). One of the four reported receiving a blood transfusion and undergoing a surgical abortion procedure, while the rest were given painkillers, an ultrasound or blood test.

Table 4. Women's experiences of potential complications after using medications obtained from drug sellers

	Among women who completed both follow-up interviews (n=394)	
	Women who experienced warning signs of potential complications	
	%	No.
Bleeding*	19.5	77
Cramping/Abdominal Pain†	2.0	8
Fever/chills‡	1.3	5
Foul smelling or colored vaginal discharge§	0.5	2
Postabortion infection¶	3.8	15

* Bleeding that could indicate potential complications is categorized as bleeding that soaks through more than two regular sized pads in two hours, lasting for 12 hours after taking the medication.

† Abdominal pain and cramping that could indicate potential complications are categorized as follows:

Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
Abdominal pain at the time of the last interview (~one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

‡ Fever and chills that could indicate potential complications are categorized as follows:
Fever or chills that lasted more than 24 hours after taking the medication, or
Any fever or chills still experienced at the time of the last interview (~one month after taking the medication).

§ Foul smelling or discolored vaginal discharge that could indicate potential complications are categorized as follows:
Foul smelling or discolored (not clear or white) discharge after taking the medication, or
Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

¶ Postabortion infection was characterized as a combination of problematic abdominal pain or cramping, fever and chills, or vaginal discharge.

Overall, 29 women in the study (7%) reported wanting or needing medical care after taking the pills, and 24 (6%) actually sought care (not shown). Few women (25%, n=97) were given any information from drug sellers about seeking postabortion care. However, 48% (n=14) of those who reported wanting or needing care also reported they had been told during their initial interaction with the drug seller that they may need to seek medical attention for potential complications, compared to 23% (n=84) of those that did not report needing follow-up care. Most women who sought care were given pain medication, or underwent an ultrasound, suggesting that they might not have presented with serious complications. One woman reported receiving a blood transfusion, and seven women were treated with a surgical abortion procedure.

Participants' assessment of abortion completeness

At the time of the second follow-up interview, around one month after taking the pills, 95% of women reported that they were no longer pregnant (Table 5). The most common way women assessed the completeness of the abortion was by the return of their menstrual period (54%). 369 women (94%) reported a complete abortion without any additional medical intervention about one month after taking the pills. Completion rates did not substantially vary according to the dosages women reported taking: 93% (n=160) of women who we confirmed received less than 800mcg of misoprostol reported complete abortions versus 97% (n=65) of women who received 800mcg (Appendix C, Table 3). If we assume 50% of the women lost to follow-up had a successful termination, then 91% of all 423 eligible women had a complete abortion, and if we assume none of them had a successful termination the rate of complete abortion drops to 87% (Appendix C, Table 4).

Table 5. Women's perceptions of pregnancy continuation and how they assessed the completeness of the abortion process

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who reported that they were no longer pregnant at the time of the second follow up interview	95.4	376
Reasons given for believing pregnancy has ended (n=376)*		
Woman's period returned	53.7	202
Woman took a urine pregnancy test at home	33.2	125
Woman no longer has pregnancy symptoms	24.7	93
Woman took a blood pregnancy test	16.0	60
Woman passed the products of conception	13.3	50
Woman took a urine pregnancy test at a facility	5.1	19
Woman had a sonogram/ultrasound	4.0	15
Woman got cleaned at a facility/surgical intervention	1.9	7
Other	0.8	3
Women who reported a complete abortion without surgical intervention	93.7	369

* Multiple responses were allowed

Alternatives to using misoprostol and willingness to use it again or recommend it to a friend in the future

Sixty percent of women reported that they would have gone to a health facility for help had they not had access to misoprostol (not shown). Twenty-two women (6%) said they would have gone to a traditional practitioner, 17 would have drank chemicals, four would have done excessive exercise, and two reported that they would have inserted objects to self-induce abortion. About one-fourth of women (27%, n=105)) said they would have done nothing.

Seventy percent of women in the study reported that they would use misoprostol again. Of those that would not, 47% (n=56) said they would not terminate another pregnancy at all. Others (13-16%) thought that it would damage their health or fertility, reported that it was too painful or that they did not like the experience. Nevertheless, 85% of participants reported that they would recommend misoprostol to a friend.

DISCUSSION

To our knowledge, this is the first prospective study examining the experiences and health outcomes of women obtaining misoprostol from drug sellers in sub-Saharan Africa. Around two-thirds of eligible drug sellers were willing to recruit for the study, and 88% of eligible women completed the screener and both follow-up interviews.

Although about 60% of our sample were not aware of medical abortion pills prior to visiting the drug seller, for nearly everyone this encounter was their first and only attempt to end their pregnancy. Most women visited the drug seller by themselves, and a majority of them appeared to have been comfortable explicitly asking drug sellers for help to induce an abortion. Most women in our study relied on their interaction with the drug sellers as their only source of information, reported trusting the information drug sellers gave them about the drugs and following their instructions for use. More than one-fourth reported that they would have had an unwanted birth had they not had access to misoprostol, suggesting they would have lost the opportunity to achieve their preferred family size or their desired timing of giving birth. Additionally, for nearly 9% of women, having access to misoprostol was essential to avoid self-induction with highly unsafe methods such as sharp objects inserted into the vagina, drinking chemical substances or another method obtained from an herbalist or other traditional practitioner. Further, the majority of women reported that they would recommend misoprostol abortion to a friend, and, if necessary, use it in the future, suggesting high levels of satisfaction with this method of abortion. These findings suggest a relatively high level of autonomy for abortion care seeking among our sample compared to other studies and indicate the important role that drug sellers play as trusted sources of information and providers of medical abortion in Lagos state. However, the appropriateness of the drug prescriptions and the quality of information provided to women by drug sellers was poor overall, as documented in other studies.[12]

Among women who completed both interviews, 94% reported complete abortion without surgical intervention. This finding is consistent with findings from other studies that assessed the effectiveness of self-managed misoprostol only abortion.[29,30] We were unable to assess the dosage received and

instructions given on routes of administration for 37% and 42% of the sample, respectively. Among those who we could assess, at least two-thirds appeared to have received less than the first trimester recommended dose of 800mcg misoprostol and/or were told they could ingest the misoprostol orally, which is a less effective route of administration than sublingually, buccally, or vaginally.[28] The medication's high level of effectiveness despite the low doses reportedly used could be partially explained if most pregnancies were in second trimester, during which time the uterus is more sensitive to lower doses of misoprostol.[31] The perceived success of the method could also be attributed to the longer length of follow up in our study: Generally, studies assessing MA effectiveness have followed up women around two weeks or sooner after taking the medication.[17,32] Allowing for a longer follow-up period ensured that the medication had sufficient time to work in the body, and may have improved its success rate.[32] Overall, even in the most conservative outcome for women lost to follow-up, the completeness rate of self-managed abortions in our study was 87% (Appendix C, Table 4), which is within the effectiveness range for misoprostol based on recommended protocols in clinical settings (78-90%).[18–21]

WHO's task sharing guidelines recognize that women have a role in self-management of the combined mifepristone and misoprostol abortion regimen if they have accurate information and access to a healthcare provider should they want or need at any point during the process, although pharmacy-alone provision is not explicitly recommended.[3] However, no such self-management guidelines yet exist for misoprostol-only abortions, which was the regimen used by the majority of our study sample. We could not accurately assess their weeks of gestation; however, the majority of the sample had taken a pregnancy test, were able to follow instructions, and, similar to findings from other studies,[33] appeared to have been able to assess the completeness of termination. Almost all women retained for the duration of the study reported complete abortion at the one-month follow-up. While most women did not report needing or wanting postabortion care, we were unable to clinically verify the proportion that actually experienced complications. The findings suggest that perceptions of needing care may be related to information, or lack thereof, they received from drug sellers about potential complications and care-seeking needs. Nearly half (48%) of those that reported needing medical care had been warned by drug sellers about complications, compared with only 23% of those who did not report needing care. However, the results show that nearly all women

who reported wanting or needing care were able to access it, and most of those who sought care were monitored or given pain medications, suggesting that they presented with symptoms that were either a normal part of the abortion process or that reflected very minor complications.

Our study had many methodological challenges and limitations. The study LGAs were purposively selected, so our sample was not representative of Lagos State. We had little information on women who dropped out and were hence unable to ascertain how they differed from women who completed the entire study. Our sample only included women who were recruited by drug sellers who admitted to selling misoprostol and then agreed to participate in recruiting women, and who may have had different practices from those who did not admit to selling or agree to recruit women, which could have potentially biased our results (Appendix C, Table 5). We were able to verify the medication purchased for about three-fourths of the women. However, we hypothesized that a majority of the women in our study obtained misoprostol because this was the criterion for recruitment on which we trained drug sellers, and we did not see many differences in key indicators between the women who we were able to verify had purchased misoprostol and those who we could not verify (Appendix C, Table 2). Measures for dosage and route of administration were based on women's self-report of the number of pills they took and instructions they were given, which may have been subject to recall bias and/or misinterpretation. These limitations were, in part, balanced by the strengths of the study, including its prospective design and its focus on women's direct experiences rather than relying on third party reporting. However, our overall reliance on self-reported measures for many of our core outcomes makes it difficult to determine the extent to which our findings will correlate with clinical data and must be interpreted with caution.

CONCLUSION

Worldwide, there is a paucity of research assessing the processes by which women obtain MA (either the combined method or misoprostol alone) for self-management of abortion and prospectively documenting their outcomes. Our success with drug seller engagement and women's recruitment is high compared with previous studies.[17,26] While this success may be due in part to the urban context of Lagos and the relatively liberal environment for drug stores and medication access generally in Nigeria, our experience

suggests that prospective studies on misoprostol abortion in highly restrictive legal settings with similar attributes may be feasible. While our findings may not be generalizable to the entire female population in Lagos, they do provide valuable insights into the experiences of women who self-manage their abortions using misoprostol, from their own perspectives. The majority of our sample purchased misoprostol, took the medication according to the instructions, reported that drug sellers were their main source of information during the process and appear to have been able to successfully complete their abortions with minimal complications. Recognizing the limitations of self-reported outcomes, and given evidence from clinical trials suggesting that as many as 20% of women may experience an incomplete termination using misoprostol alone, it is an important harm-reduction strategy to ensure that people who self-manage their medical abortions have adequate and correct information on warning signs of complications as well as access to postabortion care. Interventions to improve drug sellers' knowledge of best practices related to medical abortion may be an important part of the effort to improve their quality of services and the health and well-being of their clients, especially in similar settings where drug sellers are relied on for basic medical care. However, future research should explore ways to more objectively capture data relating to the duration of pregnancy, drug dosage, and clinical outcomes in addition to documenting individuals' experiences using the method. It is likely that the self-use of misoprostol will remain an important option for people, especially where abortion is legally restricted. More research is needed to expand the evidence on the safety and effectiveness of self-managed misoprostol abortion in similarly restrictive contexts, and to help inform the development of approaches and mechanisms to facilitate optimal outcomes for those using this method.

CONTRIBUTORSHIP STATEMENT

OO, AB, MS, AF and AA participated in the conceptualization of the project and designed the study. AF, AA, MS, OO, AB, ALB, TE, OSO, and HV participated in project planning. MS, ALB, OO, and TE programmed the study tools into SurveyCTO for electronic data collection. AA, TE, and OSO coordinated all aspects of fielding. AA, AF, TE, and OSO conducted the piloting of the study protocol and tools. AA, TE, and OSO selected fieldworkers and organized the trainings. MS, AA, TE, OSO, AF and HV co-led

fieldwork trainings. AF liaised with the Ministry of Health and relevant drug seller associations to get permission to conduct fieldwork at the local level. AF and AA convened the Technical Advisory Committee. MS, OO, TE, and ALB analyzed the data. MS, OO, ALB, TE, and OSO wrote the first draft of the article; all other authors critically reviewed the draft, and MS led the revisions. The entire team contributed to the development of study tools, participated in the conceptualization of the paper, and reviewed and approved the final version of the paper.

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DECLARATION OF INTERESTS STATEMENT

We declare no competing interests.

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data interpretation, or writing of the report. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication.

DATA SHARING STATEMENT

Given the sensitive nature of the data, they are not currently publicly available. We are determining ethical clearance to make this dataset available to other researchers.

LICENSE STATEMENT

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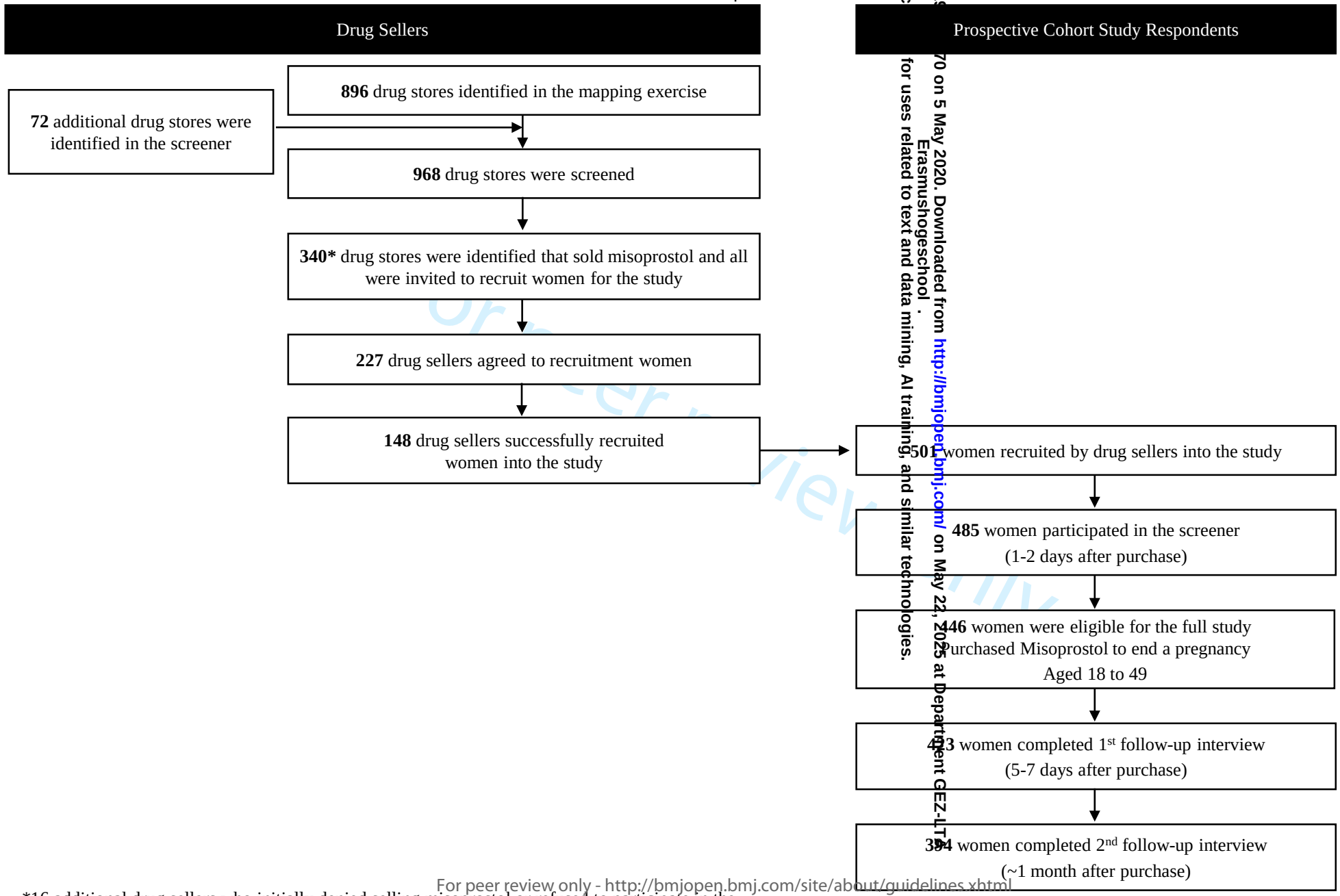
Figure 1. Sample of drug sellers, recruitment of women and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective cohort study in Lagos State, Nigeria

Appendix A
Full description of recruitment and retention methodology

1. Mapping drug sellers

The mapping component was designed to enumerate the universe (sampling frame) of patent and proprietary medicine vendors (PPMVs) and registered pharmacy shops (referred to collectively as drug sellers) whom, based on advice by in-country experts, are likely the largest providers of medical abortion to women in this context. PPMVs are owner-operated drug retail outlets that were established as a category of retailer by the Ministry of Health to provide a source of medicine in communities with limited access to essential health commodities. For many people, they serve as the first point of care for a wide range of health issues. PPMV licensure does not require medical or pharmaceutical training, and regulations permit them to sell pre-packaged and over-the-counter medicines and medical products, but prohibit them from selling prescription medicines. In contrast, pharmacists must have a formal degree in pharmacy and are permitted to sell prescription medications. Official licensing of PPMVs and retail pharmacies is overseen by the Pharmacists Council of Nigeria (PCN), however there are an additional unknown number of unlicensed PPMVs in Nigeria; thus the study team conducted a mapping to generate a list of all drug sellers operating in the selected LGAs. The research team obtained a list of registered pharmacies from PCN's Lagos State office and two datasets that included a listing of all PPMVs that were operating in 16 states in 2013 (from Society of Family Health Nigeria) and all drug stores in Nigeria in 2015 (from Population Services International). These lists were used as a starting point for the sampling frame. A full mapping of PPMVs and pharmacies within the selected local government areas (LGAs) was conducted to determine the updated universe of drug sellers. All components of fieldwork (detailed in points 1-4) were conducted in two phases 1) Lagos Mainland, Ojo, and Oshodi/Isolo LGAs during April to July 2018 and 2) Epe, Ibeju-Lekki, and Ikorodu LGAs from May to October 2018.

Two supervisors and 18 fieldworkers were assigned to each LGA in the study to map all registered and unregistered drug sellers with a static point of sale (e.g., a store) whose primary business was selling medicines; clinicians or drug sellers without a shop or fixed point of sale were not included in the mapping exercise. Staff from the National Population Commission (NPopC) served as field guides and provided each field team with maps of the enumeration areas and an orientation to the LGA, including boundaries, streets and community names. LGA supervisors and NPopC staff overlaid NPopC maps with Google Maps to improve delineation of survey areas and reduce the potential for duplicated visits to drug sellers between teams in the field. Supervisors worked closely with the Field Managers to assign each fieldwork team sections of the LGA to map. Each data collection team in the field was comprised of two fieldworkers, one male and one female, to ensure their safety.

During mapping, no direct contact was made with anyone in the drug stores; the exercise was primarily to compile a list of existing stores in each LGA. GPS coordinates were collected using the data collection software *SurveyCTO Collect* along with a written description of the location to ensure field team members were able to return to the drug seller in future study components. After mapping was completed, the resulting dataset included: LGA, address, name of drug store, GPS coordinates, and a randomly generated unique ID. The Field Manager generated new project ID numbers for each drug seller in the sample, which were used to identify and link information on each drug seller throughout the study. All data were collected electronically using Android tablets. Data collected during the study were encrypted from the time of data collection, transmission to the secure server, and when downloaded to secured computers. Tablets used for data collection were password-protected and completed consent forms and surveys were uploaded to a secure server at the end of each day, which only the research team could access. The field team also carried paper copies of the instruments, in the case of power or mechanical failure.

The mapping exercise identified 896 drug stores in the selected LGAs (Appendix A, Figure 1).

2. Screening drug sellers

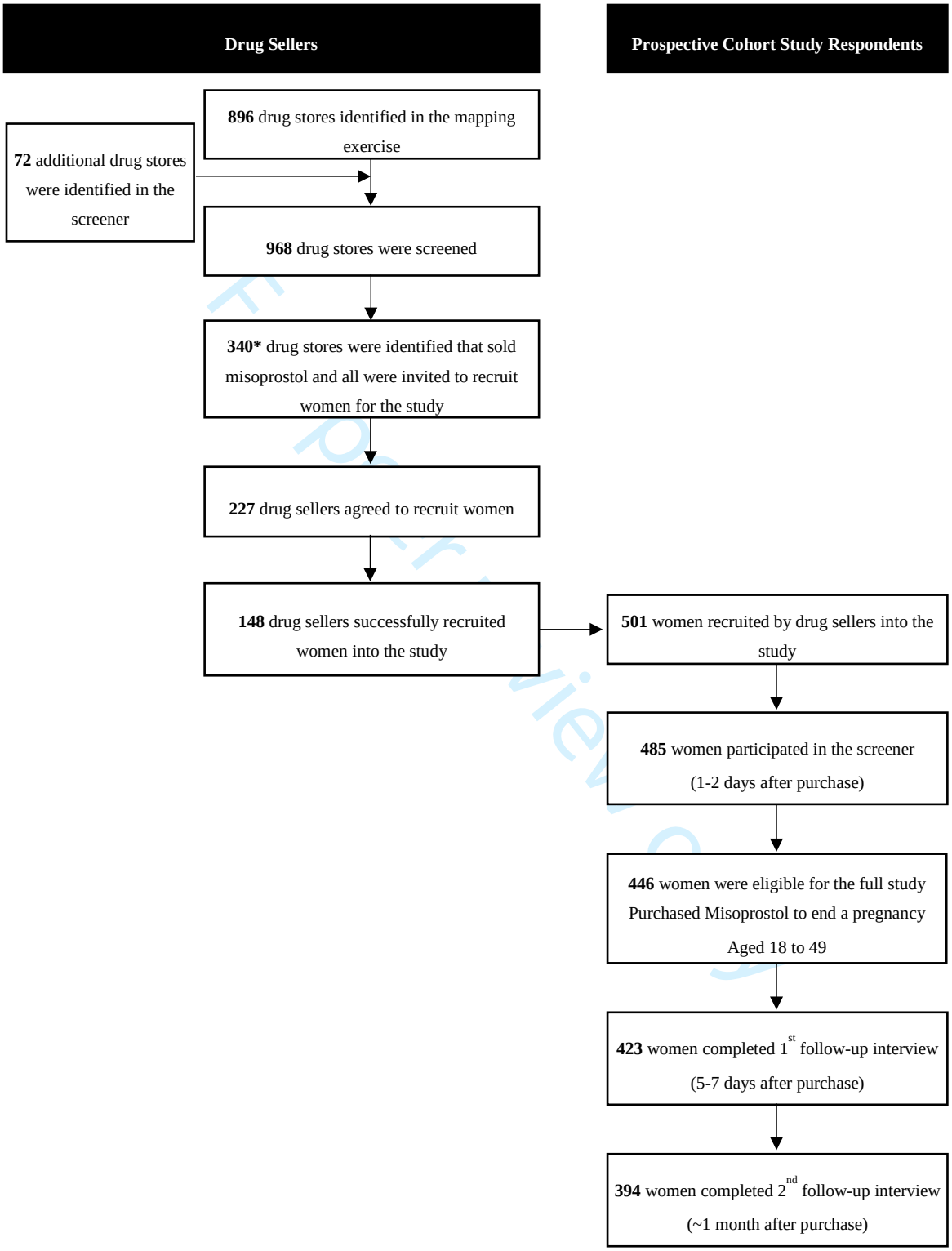
After the mapping was complete, interviewers who were not previously involved in the mapping component conducted short screening interviews of all drug sellers identified to determine whether they sold misoprostol-containing drugs. Two supervisors and approximately eight interviewers were assigned to each LGA for the drug seller screening component of the study.

Before beginning fieldwork, the research team formally notified the relevant government agencies and interacted significantly with the officials of the Pharmaceutical Services Directorate of the State Ministry of Health to secure their support and facilitate linkages with relevant stakeholders. Investigators contacted the leadership of the drug sellers associations and unions at the state as well as local levels to facilitate community entry. The study team gained approval from the following professional organizations: Association of Community Pharmacists of Nigeria (ACPN); and Lagos State Medicine Dealers Association (LSMDA). Each organization notified their membership about the study and provided letters of introduction for the study team to present to drug sellers prior to the interviews. Fieldworkers were also provided with the Lagos State Health Research Ethics Committee IRB approval letter, as well as identification cards to confirm their role on the study team to drug sellers while conducting fieldwork activities. The protocol for community entry was developed after the study team had conducted a small pilot study in another state, which revealed potential difficulties around interviewing drug sellers without the documentation of approvals at the local and national levels. These steps proved to be critical, and should be considered for other studies involving drug sellers in Nigeria.

Interviewers provided drug sellers with an introduction to the study and obtained permission from the owner or manager of each drug store to conduct the screener interview. If the owner or manager of the store was unavailable, interviewers were instructed to inquire when they could return to speak with them. If permission was granted, the interviewer explained the study to the drug seller who would be participating in the screener and obtained verbal consent for their participation. Fieldworkers were directed to interview the person working at the counter, who interacts with customers. In some cases, that person was the owner or manager, but in others it was somebody else, in which case the interviewers obtained two separate informed consents - one from the owner/manager and one from the participant. Prior to the screening component, fieldworkers were given the list of drug stores from the mapping component, but they were also instructed to document and conduct interviews in any other drug store they saw even if it was not on the list (these were stores that may have been inadvertently missed at the time of the mapping exercise). Seventy-two additional drug sellers were identified by the fieldwork teams, and included in the drug seller screening interviews. In total, 968 drug sellers were screened (Appendix A, Figure 1). Drug sellers received a token of 2,000 Naira (~USD $6) for participating in the screening interview.

The mapping and screening exercises resulted in a list of all drug sellers in the study LGAs that either reported selling misoprostol-containing drugs or did not. Initially, out of 968 drug stores in the universe, 324 drug sellers reported selling misoprostol in the screener, and 644 did not. An additional 16 drug sellers agreed to recruit women into the study, after initially refusing - one that had refused to participate in the screener interview, 13 that had denied selling misoprostol initially in the screener, and two that were approached directly to recruit by the PPMV chairmen in their LGA (Ikorodo). Therefore, the final sample of drug sellers that agreed to recruit women into the study, and whom can be presumed to sell misoprostol, was 340.

Appendix A, Figure 1. Sample of drug sellers, recruitment of women, and retention throughout the study



*16 additional drug sellers who initially denied selling misoprostol or refused to participate in the screener later agreed to recruit women.

3. Recruitment of women by drug sellers

All drug sellers that reported selling misoprostol in the screener were invited to participate in recruiting women into the study. Out of 340 drug sellers that reported selling misoprostol or opted into the study, 227 (67%) agreed to participate in recruiting women, and 148 successfully recruited at least one woman (Appendix A, Figure 1). Before women's recruitment began, drug sellers who had signed up to recruit participated in a one-day training led by the study team, which covered additional background information on the study and training in ethics, maintaining confidentiality, and sensitive recruitment of clients. Drug sellers were trained on logistics for inviting any person (woman or husband/partner/proxy) purchasing misoprostol-containing drugs for any indication, to participate in the study.

Attempts to recruit women into the study were made after the drug seller had provided the drug and any routine counselling to avoid the possibility or perception that their services were contingent upon a woman's participation in the study, and to minimize any influence that study participation would have on the typical drug seller and client interaction. After delivering the normal protocol, the drug seller explained the study using a standard script provided by the study team that included a basic explanation of the study, including incentives for completing the screener interview and two follow up interviews. Anyone interested in participating was asked to verbally agree to be contacted by a member of the study team one to two days after the purchase. Drug sellers provided each woman who agreed to participate with a prepaid phone stocked with 500 Naira (approximately USD $1.50) in airtime and a pamphlet to retain throughout the study. The pamphlet contained a unique participant identification number, but did not include any specific details about the nature of the study. As an additional measure to ensure women's privacy, drug sellers asked each woman to provide a nickname and a password that interviewers could use when calling them, so that they would not have to reveal their real names or personal information to the drug seller during recruitment. The phones were provided to protect women's anonymity and alleviate any potential concerns that their identities would be linked to the study through their own personal, registered, phone numbers (which, in many cases, are linked to women's social media accounts). The idea of giving pre-registered and pre-paid phones to the study participants derived from the experience in the pilot phase of the study, whereby many women did not respond to telephone calls from the interviewers or gave the drug seller the phone number of a husband/partner or friend to contact because of the concern for anonymity.

For cases in which a buyer purchased the drug on behalf of someone else, the drug seller explained the study to the buyer and asked them to contact the potential end-user by calling her mobile phone while the buyer was still at the drug store. During the call, the drug seller briefly explained the study to the end-user and asked if she agreed to be contacted by an interviewer on the research study team, who would later provide her with a more in-depth description of the study and conduct a full informed consent protocol. If the end-user was interested, the drug seller recorded the end-user's responses to the identification questions described above and gave the buyer the study pamphlet and phone to give to the end-user.

Drug sellers were instructed to document the following information in a study log book: the unique ID on the pamphlet given to each woman; the nickname and password that women provided to the drug seller for the purposes of identification to the study team; the phone number of the prepaid phone given to each woman; the purchase data; and permission to be followed up from women who agreed to participate. All potential participants verbally agreed to this information being recorded in the log book and shared with the study team. The nickname and password were used to verify the woman's identity in the event the woman lost the unique identification number. A combination of nickname, password, and the pamphlet unique ID information was required to verify woman's identity at each interview. Drug sellers did not record potential respondents names or any other identifying information, such as individuals' phone numbers, email addressess, or physical addressess.

All drug sellers that volunteered to participate in recruiting women were visited by a member of the study team before recruitment began to verify the availability of a secure storage space for the log books in the facility. Drug sellers were required to store log books in locked and secure cabinets in their stores whenever the log books were not in use. Information on how the log books were stored and retrieved during fielding was also documented by interviewers during weekly site visits to collect physical copies of the log books used for recruitment. The research team initially planned to provide the drug sellers a second logbook to record data on: the total number of clients who came into the drug store requesting help terminating a pregnancy or specifically requesting misoprostol over the data collection

period; clients who purchased an MA drug but did not agree to participate; clients who purchased an MA drug but were not informed about the study; whether the purchaser was the end user or not. This logbook was intended to provide the study team with some additional context and help to understand the extent to which clients were missed by the study. However, after piloting the recruitment process resulted in incomplete and inconsistent data on the number of clients seeking MA or assistance in terminating a pregnancy, and considering the additional burden this logbook would impose on drug sellers during the recruitment period, the effort was dropped. Removal of this additional logbook from the drug seller's recruitment of women prohibited the research team from calculating participation in the study from the total population of clients approached during the fieldwork period.

Each participating drug seller received a prepaid phone and 500 Naira airtime (approximately USD $1.50) at the beginning of the recruitment period and an additional 1,500 Naira (approximately USD $4.50) after the recruitment period was completed. This amount was approved by the IRB as sufficient to reimburse them for the time they spent maintaining records on the study's behalf but not high enough to coerce drug sellers into participating.

Each interviewer for the women's component was assigned between eight and ten drug sellers. During the recruitment period, interviewers contacted each of the assigned drug sellers daily to confirm if the drug seller had recruited any women that day to input the logbook information into SurveyCTO and assess when drug sellers needed additional study materials for recruitment. At the end of the recruitment and follow-up period, interviewers for the women's component retrieved all log books from the drug seller stores and sent them in locked and secured boxes to the in-country study team's offices, to be destroyed at the completion of the study.

4. Prospective cohort study of women

The prospective study of women included three rounds of surveys, using structured questionnaires with each woman, conducted over telephone by members of the study team over the course of one month. At the beginning of each call, interviewers followed a script to confirm the unique participant identification number, nickname, and security password on file to ensure the study team was speaking with the correct person. Once this was established, interviewers obtained verbal consent to participate in each interview. Interviewers did not provide any information about the study to anyone except the respondent, including husbands/partners or individuals who helped purchase the medicine for women.

The initial study design called for interviewers to make three attempts to contact each woman for an interview. Due to difficulties contacting respondents during early data collection, mainly non-response to phone calls from the field team, interviewers continued to call the prepaid phones for a four-week period. According to participants whom fieldworkers were later able to reach, the non-response was due to women not switching on the prepaid phones immediately after purchasing the medicine or not checking and charging the phone's battery regularly. Women working outside the home also reported leaving the study phones at home when they left the house. In total, about three percent of the women recruited into the study by drug sellers (15 women) were never successfully contacted by the study team.

For women who did participate, the average duration of the prospective study from recruitment to completion of the second follow-up interview was 37 days. Approximately 30% of women were reached on the interviewer's first attempted call across the study period; however, more than 20% of participants were called at least five times before interviewers successfully reached them for the screener and the first and second follow-up interviews with up to 16 attempted contacts required to successfully contact some respondents for interviews. While interviewers continued to call when women did not answer the phone, on average, interviewers reached women for the screener and both follow-up interviews on the second or third attempt.

Interviewers were trained to not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, women who asked for medical advice or who described symptoms that could indicate a serious problem were provided with the numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All women in the study were given this contact information after completion of the second follow-up interview, in case they had additional medical questions. Women given hotline information in the screener or first follow-up interview were asked if they had contacted the hotlines, during the first and second follow-up

interviews, respectively, to account for any bias this potentially gained information may have introduced into the results. Twelve women requested further information that prompted interviewers to provide the hotline number - two at the time of the screener interview and eleven during the first follow up interview (one woman requested more information during both interviews). However, none of the study participants successfully utilized the hotline.

4.1. Screener Interview

The screener interview was intended to be conducted one to two days after women (or someone else on their behalf) purchased the medicine. However, due to difficulties reaching women, screeners were completed seven days after the purchase on average. The screener interview took approximately five to ten minutes and collected information on age, reason for planned use of medicines purchased, and a measure of literacy. The interviewer only proceeded with enrolling women into the full prospective study if the respondents could be confirmed as the same women who were recruited by the drug seller, through their unique IDs, nicknames, and passwords, and met the eligibility requirements: 18 to 49 years old at the time of the interview and intended to use the medicines purchased to end a pregnancy. Under these criteria, 446 women were eligible for inclusion (Appendix A, Figure 1). Most ineligible women were outside of the age range or planned to use the medicine for another reason (e.g., for gastric ulcers or during childbirth for postpartum haemorrhage). A few of the ineligible respondents were nurses who ran private care centers in their homes and indicated that they had bought the misoprostol from the drug sellers with the intention of selling it later.

After completion of the screener, interviewers obtained informed consent to contact eligible women for the first follow-up interview five to seven days later. Due to the challenges faced in contacting women, the length of time between the purchase of misoprostol and the screener and subsequent interviews varied for some respondents. In cases where the interviewer could not contact the respondent for the screener until five days or later following the purchase of misoprostol, interviewers conducted the screener and first follow-up interview during the same call.

The prepaid phone and airtime provided by the study team through the drug sellers upon recruitment served as the only incentive for the screener, and women were not provided with another incentive at the completion of the call. There was no significant drop out between recruitment and screening or screening and the first follow-up interview to indicate that the provision of the first incentive up-front might have had a negative impact on study retention.

4.2. First Follow-up Interview

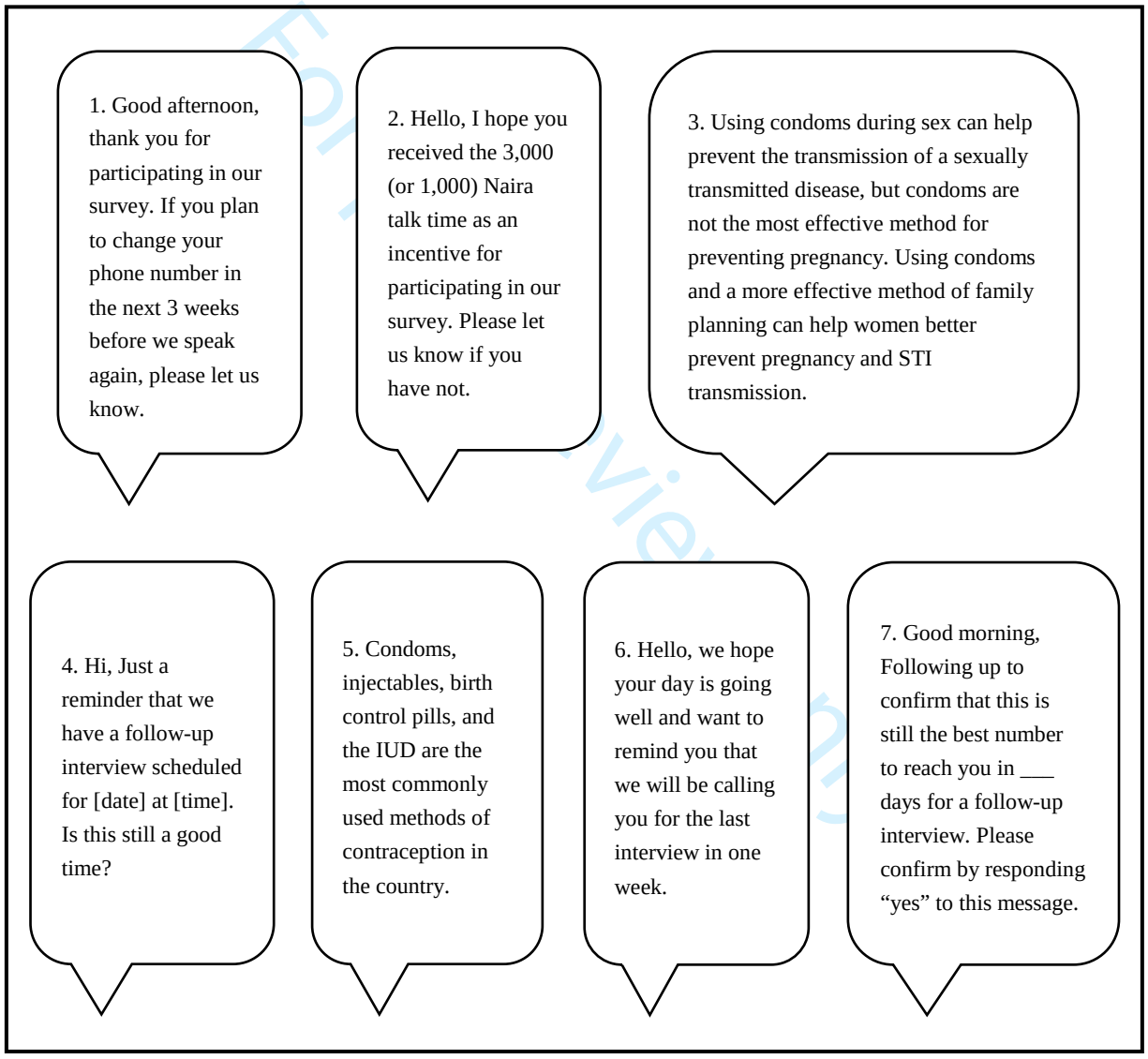
423 women - or 95% of eligible women - agreed to be followed up for another interview about a week after the screener interview (Appendix A, Figure 1). Interviewers followed the same procedure described in point 4 above to confirm women's identities prior to conducting the first follow-up interview. After confirming the person who answered the phone was the correct study participant, the interviewer reiterated the purpose of the study and obtained another verbal informed consent prior to beginning the interview. The purpose of the first follow-up interview was to determine women's decision-making processes around obtaining an abortion from a drug seller; the types of medication each woman purchased (some women purchased other abortifacients, including mifepristone alone and combi-packs of misoprostol and mifepristone); establish if the woman had used the medication; and collect information on her interaction with the drug seller, including the instructions drug sellers had given to each woman on how to take the regimen purchased.

At the end of the first follow-up interview, interviewers obtained informed consent to contact eligible women for the second follow-up interview approximately three weeks later (and approximately one month after the medication was purchased). Women who completed the first follow-up interview in the first three LGAs (Lagos Mainland, Ojo, and Ishodi/Isolo) received a 3,000 Naira (~USD $8) airtime incentive. This amount was originally considered to be enough to encourage women to participate but not so much that it would coerce women into participating. However, the incentive was reduced during the data collection in the second set of three LGAs (Epe, Ibeju-Lekki, and Ikorodu) to 1,000 Naira (~USD $3) in airtime due to budgetary constraints and confirmation by the field team that the new amount proposed then was adequate. The geographical location of the second set of LGAs made the cost of conducting the study in the areas, among others, much higher than those in the first set of LGAs particularly in terms

of transportation cost and accommodation for data collectors. While the incentives for women in the second three LGAs was about a one-third of those offered to women in the first three LGAs, there was no similar difference in the completion rates: 94% of eligible women from the first three LGAs completed the first follow-up interview compared with 97% of eligible women in the second three LGAs.

In the three-week period between the first and second follow-up interviews, interviewers engaged in consistent outreach via SMS message with each participant (Appendix A, Figure 2). These messages allowed interviewers to send reminders about the upcoming second follow-up interview and generally engage with the women. The purpose of the messages was to help retain participants in the study without sending any identifiable information or further details about the purpose of the study.

Appendix A, Figure 2. Text messages sent to respondents between the first and second follow-up interviews



4.3. Second Follow-up Interview

394 - 93% of women who completed the first follow-up interview - consented to be contacted for a second follow-up interview about 21 days later (Appendix A, Figure 1). Interviewers followed the same procedure described in point 4 above to confirm women's identities prior to conducting the second follow-up interview. After confirming they were speaking to the correct study participant, the interviewer reiterated the purpose of the study and obtained verbal informed consent prior to beginning the interview. The primary focus of the second follow-up interview was to understand women's self-reported health outcomes after taking the medication; experiences with side effects and potential complications and whether women sought further healthcare after taking the medication; how women assess the completion of their abortions; the availability of emotional or social support throughout the process; and women's willingness to recommend medication abortion to friends or use it again in the future. Women who completed the second follow-up interview received an additional 3,000 or 1,000 Naira airtime incentive, in the first three or second three LGAs, respectively. Again, this difference in incentives was not reflected in the success rates: 94% of women who completed the first follow-up interview in the first three LGAs compared with 91% of those in the second three LGAs went on to complete the second follow-up interview.

During the programming of the study tools, a question on parity was inadvertently dropped. After exploring preliminary data, the study team agreed that interviewers should incorporate that question into all fieldwork that had not yet concluded. The team also attempted to recontact women who had already completed both follow-up interviews to ask about parity. The team successfully obtained measures of parity from 227 of the 394 respondents that completed the second follow-up interview.

Appendix B. Construction of Key Variables

The study team constructed variables to estimate the appropriateness of the dosage women received, the instructions women received on the route of administration of the pills, the adequacy of the information and instructions women received from drug sellers, and experiences with warning signs that could indicate potential complications. These measures are described below.

1. Dosage

To assess whether women purchased or were instructed to use the medication in the correct (i.e. WHO recommended) dosage, the team first determined what types of medication women were sold. This determination was based either on what was written on the manufacturer's package (if it was sold in a package and the package was still available at the time of the second interview), women's self-report of what the drug seller had told them, or their descriptions of the type of packaging and the number, color, or shape of the tablets they purchased. After determining that the medicine purchased was misoprostol, the dosage based on the number of pills purchased (assuming each misoprostol pill contains 200 mcg) was calculated. Dosages for misoprostol were categorized as less than 800 mcg (< four tablets), 800 mcgs (four tablets), 1000-1400 mcgs (five to seven tablets), and 1600-2400 mcgs (eight to 12 tablets). Nobody in the sample was given more than 12 tablets. To help in this process, the team compiled a list of misoprostol-containing drugs, including those that were registered with the government, brand names that were unregistered but found in the participating drug stores, and those that were identified by medical doctors and pharmacists on the research team. For the few women who received a combination pack of mifespristone and misoprostol, the recommended dose was defined as 200 mg mifepristone and 800mcg misoprostol, per standard packaging dosages.

2. Route of administration

According to clinical guidelines, mifepristone should be swallowed orally, and the optimal administration routes for misoprostol are vaginal, buccal (letting the pills dissolve in the cheek), or sublingual (letting the pills dissolve under the tongue). In assessing the appropriateness of the instructions given to women on how to administer the medication, any instructions that mentioned the option to ingest the misoprostol orally were considered suboptimal. The route of administration was categorized as optimal if women were told to take the misoprostol alone buccally, sublingually, or vaginally. For women who received mifepristone and misoprostol, the team categorized administration routes that included taking one mifepristone orally and misoprostol buccally, sublingually, or vaginally as optimal.

3. Core information score

Given that the safety and effectiveness of self-managed medication abortion depends, in part, on users' access to accurate information, the research team was interested in assessing the accuracy of information women received from drug sellers in the study. A score was constructedbased on the medical literature, consisting of nine items considered to be reasonably necessary, for women to successfully self-manage their abortions and assess the appropriateness of the information women received from drug sellers. Each item in the score was assigned one point, as no particular item warranted more weight than the others.

Items included:

1. Woman was asked about timing of last menstrual period
2. Woman was asked if she had taken a pregnancy test
3. Woman was told that bleeding is a side effect of the medication
4. Woman was told that cramping is a side effect of the medication
5. Woman was told that severe or prolonged bleeding could indicate a complication for which she might need to seek medical care
6. Woman was told that severe or prolonged pain could indicate a complication for which she might need to seek medical care
7. Woman was told that she could or should use pain medication
8. Woman was told anything about how to recognize a potential allergic reaction
9. Woman was told anything about potential contraindicated drugs

The data collected through this series of nine questions are limited and insufficient to provide a true measure of accuracy. For example, women may have reported that the drug seller informed them of potential drug contraindications, but this measure does not include information about what specific contraindications were mentioned, and therefore, cannot precisely assess the accuracy of the information given. Nevertheless, the data generated could inform whether the types of information provided were within the bounds of what would be appropriate to cover and could reasonably be expected as the minimum amount of information women should receive.

4. Women's experience with potentially problematic effects of the medication

This study attempted to assess the proportion of women who experienced postabortion complications using their self-reported symptoms after using the medications purchased from the drug seller. To construct measures for estimating potentially problematic clinical effects that could indicate complications, the team created algorithms to assess excessive or greater than anticipated bleeding and signs of an infection.

Bleeding that could be symptomatic of a potential complication:

- Bleeding that soaks through more than two regular sized pads in two hours, lasting consistently for 12 hours after taking the medication.

Pain that could be symptomatic of a potential complication:

- Abdominal pain self-reported as greater than five on a one to 10 pain scale that lasted more than 24 hours after taking the medication and was not alleviated by taking pain medication, or
- Abdominal pain self-reported as greater than five on a one to 10 pain scale that occurs with nausea and (vomiting or diarrhea) that lasted more than 24 hours after taking the medication, or
- Abdominal pain at the time of the last interview (~ one month after taking the medication), that was rated qualitatively by women as being "moderate" or "severe" or greater than five on the one to 10 pain scale and that had either lasted more than six days, or had not improved over time.

Fever or chills that could be symptomatic of a potential complication:

- Fever or chills that lasted more than 24 hours after taking the medication, or
- Any fever or chills still experienced at the time of the last interview.

Foul-smelling or discolored discharge that could be symptomatic of a potential complication:

- Foul smelling or discolored (not clear or white) discharge after taking the medication, or
- Foul smelling or discolored discharge at the time of the last interview that had either lasted for more than six days or had not improved over time.

Anyone who had a potential pain-, fever/chills-, or discharge-related complication was considered to have potentially experienced an infection complication after taking the medication. These measures likely overestimate potential complications in the sample as any self-report of a potential symptom qualifies respondents for inclusion in these estimates.

Appendix C: Supplementary Tables

Appendix C, Table 1. Women's experiences with previous attempts to end current pregnancy prior to recruitment

	Among women who completed both follow-up interviews (n=394)	
	%	No.
Women who made another attempt to end the pregnancy prior to being recruited	5.3	21
Among women who had made a prior attempt (N=21):		
Number of previous attempts to end the pregnancy		
1	81.0	17
2	14.3	3
>2	4.8	1
Women who went to each place in their last attempt		
Another pharmacy/drugstore	23.8	5
The same pharmacy/drugstore	14.3	3
Traditional practitioner	23.8	5
A friend	19.0	4
Did something at home	19.0	4
Women who used each method in their attempt(s)*		
Took some pills	57.1	12
Drank agbo/herbal preparation	47.6	10
Other	10.0	2
Pills women had taken in previous attempts (N=12)		
Misoprostol	16.7	2
Postinor (emergency contraception)	33.3	4
Don't know	50.0	6
Outcome of attempt(s)		
Nothing/light spotting	100.0	21

* Multiple responses were allowed

Appendix C, Table 2. Women's reports of information received from the drug seller, clinical symptoms experienced after taking the medication, and dosages given, according to whether or not we verified that they had received misoprostol

	Women who we verified received misoprostol (n=323)		Women who we could not verify received misoprostol (n=71)		All women who completed both follow-up interviews (n=394)		P-value
	%	No.	%	No.	%	No.	
Proportion who were told about clinical effects to expect*							
Bleeding	65.3	211	71.8	51	66.5	262	0.293
Cramping/Abdominal Pain	34.7	112	38.0	27	35.3	139	0.592
Headaches	9.0	29	2.8	2	7.9	31	0.081
Vomiting	4.6	15	4.2	3	4.6	18	0.878
Nausea	1.5	5	--	--	1.3	5	0.291
Diarrhea	2.2	7	1.4	1	2.0	8	0.681
Fever/chills	3.7	12	5.6	4	4.1	16	0.458
General feeling of weakness	14.9	48	16.9	12	15.2	60	0.665
Dizziness	0.9	3	--	--	0.8	3	0.415
Proportion who reported experiencing clinical effects after taking the medication*							
Bleeding	83.3	269	90.1	64	84.5	333	0.148
Cramping/Abdominal Pain	69.7	225	74.6	53	70.6	278	0.404
Headaches	8.7	28	7.0	5	8.4	33	0.654
Vomiting	5.6	18	4.2	3	5.3	21	0.647
Nausea	3.1	10	2.8	2	3.0	12	0.901
Diarrhea	5.6	18	2.8	2	5.1	20	0.338
Fever/chills	8.7	28	7.0	5	8.4	33	0.654
Foul smelling or colored vaginal discharge	0.6	2	--	--	0.5	2	0.506
General feeling of weakness	22.3	72	11.3	8	20.3	80	0.037
Dizziness	2.5	8	1.4	1	2.3	9	0.585
Amongst women that were told about bleeding:							
Women reported bleeding	87.2	184	98.0	50	89.3	234	0.025
Amongst women that were told about cramping:							
Women reported cramping	75.0	84	70.4	19	74.1	103	0.622
Women reporting a complete abortion without surgical intervention	94.4	305	90.1	64	93.7	369	0.180
Miso dose	**n=249**		**n=0**		**n=249**		NA
<800mcg misoprostol	69.1	172	NA	NA	69.1	172	
800mcg misoprostol	26.9	67	NA	NA	26.9	67	
1000-1400mcg misoprostol	2.0	5	NA	NA	2.0	5	
1600mcg-2400mcg misoprostol	0.8	2	NA	NA	0.8	2	
200mg mifepristone & 800mcg misprostol	1.2	3	NA	NA	1.2	3	

* Multiple responses were allowed.

Appendix C, Table 3. Proportion of women reporting complete abortions without surgical intervention ~one month after taking the medication, according to the dosages received

	Number of women that received each dosage (n=249)	Completed abortions among women who you received each dosage of medication	
		%	No.
Misoprostol dosage			
<800mcg misoprostol	172	93.0	160
800mcg misoprostol	67	97.0	65
1000-1400mcg misoprostol	5	80.0	4
1600mcg-2400mcg misoprostol	2	100.0	2
200mg mifepristone & 800mcg misprostol	3	100.0	3

Appendix C, Table 4. Estimated proportion of all women with completed abortions using different assumptions for women lost to follow up

	Completed abortions among all women who confirmed taking the pills (n=423)	
	%	No.
Assumptions about women lost to follow up		
All women had incomplete abortions	87.2	369
25% of women had complete abortions	88.9	376
50% of women had complete abortions	90.7	384
75% of women had complete abortions	92.4	391
All women had complete abortions	94.1	398

Appendix C, Table 5. Drug store and drug seller characteristics among drug sellers that did and did not agree to recruit women

	Drug sellers who agreed to recruit women (n=224*)		Drug sellers who did not agree to recruit women (n=113)		P-value
	%	No.	%	No.	
Drug Store Characteristics					
Drug store area					0.023
Urban	96.9	217	91.2	103	
Peri-urban	3.1	7	8.8	10	
Drug store LGA					0.000
Lagos Mainland	19.6	44	14.2	16	
Ojo	18.3	41	10.6	12	
Oshido/Isolo	33.0	74	11.5	13	
Epe	4.0	9	4.4	5	
Ikorodu	17.0	38	44.2	50	
Ibeju-Lekki	8.0	18	15.0	17	
Type of drug store					0.011
Pharmacy	68.3	153	81.4	92	
Proprietary Patent Medicine Vendor (PPMV)	31.7	71	18.6	21	
Does store sell family planning products					0.758
No	1.3	3	1.8	2	
Yes	98.7	221	98.2	111	
Drug Seller Characteristics					
Drug seller Position					0.686
Owner/Senior manager	43.8	98	43.4	49	
Front counter staff - pharmacist	33.5	75	32.7	37	
Front counter staff - non-pharmacist	20.1	45	23.0	26	
Other	2.7	6	0.9	1	
Drug seller Sex					0.050
Male	61.6	138	50.4	57	
Female	38.4	86	49.6	56	
Drug seller Age					
Median (IQR)	32	(27-39)	34	(28-42)	

* Three drug sellers that recruited women did not complete the drug seller screener and are not included in this table.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8 & appendix
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8 & appendix
Bias	9	Describe any efforts to address potential sources of bias	15
Study size	10	Explain how the study size was arrived at	5,6 & appendix
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8 & appendix
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	appendix
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
(*e*) Describe any sensitivity analyses	appendix

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	appendix
		(c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	8
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-16 & Appendix
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-16 & Appendix
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	15 & Appendix
Discussion			
Key results	18	Summarise key results with reference to study objectives	17-18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-20
Generalisability	21	Discuss the generalisability (external validity) of the study results	16,19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21,22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.