

What Does Informal Access to Misoprostol in Colombia Look Like? An Exploration from Two Urban Areas

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Abstract

Abortion is legal in Colombia under a variety of circumstances, yet women still access misoprostol without a prescription through informal drug sellers. Using data gathered from two urban centers via mystery clients (N=547) and interviews with drug sellers (N=259), we examine a) the interaction with a drug seller when a young, unmarried s tries to buy misoprostol and b) drug sellers' knowledge of misoprostol (screening, information which should be imparted with a sale, dosage and routes of administration, and complications). 15% of the mystery clients were offered something to buy to bring about the termination; 84% of the drugs offered contained misoprostol. Providers said that misoprostol could be used up to a mean maximum gestational age of 6.5 weeks; 28% didn't know how to calculate gestational age. In sum, locating an informal seller of misoprostol may be difficult in Colombia and information that women get from these providers is incomplete.

Introduction

In 2006, Colombia lifted its ban on induced abortions and legalized the procedure under three circumstances: when the pregnancy threatens the life or health of the woman as certified by a doctor, when the fetus has an abnormality incompatible with life, and when a pregnancy results from an incident of rape or incest (Ceaser, 2006). The most recent study of the incidence of abortion, conducted in 2008, found that just over 400,000 induced abortions took place in Colombia in 2008, with less than 1% of these procedures being legal (Prada, Biddlecom, & Singh, 2011). This work also found that the although the use of misoprostol had increased in the country, approximately 50% of abortions performed in Colombia were induced using misoprostol in 2008 (Prada et al., 2011).

Misoprostol was in approved for medical abortion by the National Institution of Medication Surveillance (INVIMA) in 2007. For up to 10 weeks of pregnancy, Ministry of Health (MOH) guidelines for the provision of legal abortion recommends the use of misoprostol alone, or in combination with mifepristone up to 10 weeks of pregnancy. Misoprostol is available through a variety of sources, including health professionals, traditional providers, the black market, chain pharmacies and independent drug stores. Because of the role pharmacies serve in the community as a common source of health information, women may approach a pharmacy first when seeking information on pregnancy termination. Although MOH regulations require that misoprostol is sold with a prescription, INVIMA requires that a prescription only be presented, but not retained, by the seller. Anecdotal evidence suggests that these regulations are not always upheld.

Misoprostol, when used correctly, is up to 90% effective at safely ending a pregnancy up to 63 days gestation (von Hertzen et al., 2007). If the medication is used incorrectly, however, there is a higher risk of the medication not inducing an abortion, not completing the abortion, or resulting in excessive bleeding that can put the health of the woman at risk. In fact, in the 2008 study on abortion, while the rate of induced abortion remained fairly constant, the rate of treatment for complications increased - a change likely attributable to the increased use of misoprostol (Prada et al., 2011). Though misoprostol

may less likely to be used correctly when obtained through informal sources, more information is needed to understand how this medication is used when obtained through these means.

Therefore, we undertook a study to learn how women attempting to have abortions in Colombia informally access misoprostol through drug stores. In particular, the study seeks to clarify the following questions the drug sellers:

1. What proportion of drug sellers report selling misoprostol?
2. What is the drug sellers' knowledge about misoprostol?
3. What information do drug sellers report they provide to women seeking to end a pregnancy

And using mystery client data:

1. What proportion of women are offered a product containing misoprostol when they seek drugs from an informal drug seller when attempting to end a pregnancy?
2. What information do women receive from drug sellers when attempting to end a pregnancy?
3. What are drug sellers' reasons for refusal and where do they refer women?

To answer these questions, this paper utilizes data from two components of a three-country comparative study on misoprostol use for medication abortion (1) surveys capturing the mystery client interaction after mystery clients visited drug stores that potentially sell misoprostol, and (2) surveys with drug sellers who work at informal drug stores about misoprostol.

Methods

Data collection was conducted between November 2017 and May 2018 in two urban centers in Colombia, Bogotá and the Eje Cafetero which includes the metropolitan areas of Pereira, Manzanillas and Risaralda. The study was a collaboration between the Guttmacher Institute and Fundación Oriéntame. The Guttmacher Institute is a sexual and reproductive health research and policy institute based in the USA. Oriéntame is a non-profit organization in Colombia that provides sexual and reproductive health services, including comprehensive abortion care, and engages in public outreach and advocacy activities. The Comité de Ética en Investigación de la Fundación Oriéntame Colombia and the Institutional Review Board of the Guttmacher Institute approved the study.

Drug Sellers Component

We selected a convenience sample of pharmacies and drug stores (n=289) from the mystery client component. As we were interested in gaining information on the knowledge and practices of drug sellers most likely to be providing misoprostol for abortion, all sellers and pharmacies known to previously refer abortion-seeking clients to Oriéntame, as well as all sellers and pharmacies that offered misoprostol for sale during this component were included in the sample.

Interviewers were instructed to visit facilities up to two times to initiate or complete a survey. Sites that did not ultimately result in an interview were not replaced. After the interviewer introduced the study and obtained informed consent, structured interviews were conducted. Data were collected on Android tablets using the SurveyCTO data collection platform. Questionnaire topics included stocks and sales of medication abortion drugs, experience selling misoprostol, and knowledge surrounding misoprostol. Drug sellers who reported that they had never attended to clients seeking medication for terminating a pregnancy were asked what they would hypothetically do in such a situation. No financial incentives

were offered for study participation, but drug sellers did receive a tote bag and keychain as a token of gratitude. Forty pharmacies and drug stores were dropped from the sample because of stores being closed, a lack of available staff to participate in the study, or refusal of the drug store to participate.

Mystery Client Component

A sample of small, independent drug stores in four urban centers in Colombia (n=599) was selected from a comprehensive listing of informal drug stores conducted by Oriéntame in 2016. Larger pharmacies belonging to local and national chains were not included as they are more likely to be inspected by state institutions and were therefore thought to be less likely to be selling misoprostol without a prescription. The sample included equal proportions of pharmacies and drug stores known to have referred abortion-seeking clients to Oriéntame in the recent past, and drug stores that have not referred clients to Oriéntame. Facilities that referred clients were sampled at 100%, and facilities that have not referred were stratified by study area and whether they were urban or periurban, and randomly sampled at proportions equal to the distribution of the referring facilities. Sampled facilities were visited by women posing as “mystery clients,” who attempted to approach a drug store employee, request something to bring back their delayed period, and seek as much information as the drug seller was willing to provide. Mystery clients were instructed to purchase any offered medications, up to a cost of 50,000 Colombian pesos, or about US\$17.

After two unsuccessful visits, if the store was not found at the listed address, and for any duplicate listings, a sampled drug store was replaced with another facility located within the same study area and urban-area type. Because drug stores that referred to Oriéntame were sampled at 100%, only non-referring drug stores were replaced in order to maintain a balance between the number of referring and non-referring drug stores in the sample. Structured exit interviews were conducted with a trained interviewer immediately following each mystery client visit to collect data on the information and instructions drug sellers provided on misoprostol and pregnancy termination. Data were collected on Android tablets using the SurveyCTO data collection platform. Fifty-two facilities were not replaced or had incomplete interviews and were dropped from the sample.

Descriptive analyses were conducted on all completed interviews in Stata 15.0.

Results

Drug sellers practices and knowledge regarding misoprostol

Drug sellers were mainly male, on 45 years old, on average, and 58 percent had a pharmaceutical qualification of some sort: auxiliary, regent or chemist. Most of the staff who answered the questionnaire were fount counter staff. Most had worked in that pharmacy for 10 years. Five percent were trained in safe abortion, and four percent were trained in postabortion care (Table 1).

While 99 percent of providers sold emergency contraception in the last year, only 3.5 percent sold misoprostol (Table 2). Only two providers sold mifepristone in the last year and one provider reported selling a combipack in the last year. Among the providers who said that they sell drugs to help restore a woman’s period, when asked about what medications the drug seller sells, the most commonly named medications were progesterone, following estrogen and in third place was misoprostol. Seventy-four percent of drug sellers reported that they have between 0-9 clients per month with an additional 12 percent reporting that they have 10-49 clients requesting a medication to bring back their period every

month. Ninety-four percent of the clients are women; and 56 percent leave the facility with some kind of drug.

When asked differently, i.e. about medication to help terminate a pregnancy, only six providers said that they sold drugs for this purpose. All said they sold misoprostol-containing medication, one reported selling oxytocin and one reported selling Ergometrine (Table 2). Eighty-four percent of drug sellers said they have 0-9 clients per month. Drug sellers specified that 85 percent of clients requesting medication to terminate a pregnancy are women, and that 54 percent of clients requesting medication to terminate a pregnancy receive something. Among the 182 drug stores that have attended to clients seeking misoprostol or another drug to restore her period or terminate a pregnancy, 44 percent said that they refused to sell her anything but provided her information, 36 percent said that they refused to sell to the client and don't provide any information. Sixteen percent reported that they refer clients to Oriéntame, and only four providers said they sell medications with a prescription while another four said that they sell without a prescription (Table 2).

Twenty-six percent stated that the date of the last menstrual period should be queried before selling misoprostol. Twenty percent believed they should ask if a woman had taken a pregnancy test, 17 percent said that they should ask about the woman's gestation age, seven percent said they should ask whether has a prescription, and three percent felt they needed to ask about the woman's age (Table 3). Nine percent said they did not need to ask anything before selling misoprostol.

The most important information drug sellers said they needed to provide was the dosage: 21 percent identified this response. 19 percent spoke about the importance of telling women what to expect after taking the pills and an equal proportion named the potential warning signs of complications. 17 percent said that they need to inform women on how to take the pills (Table 3). Their source of information was most often Oriéntame (52 percent); 15 percent said they were drawing on their clinical knowledge, and another 15 percent reported using the pharmaceutical manual of Colombia. When asked how they calculate gestational age, the largest number of drug sellers (28 percent) said that they don't know how, an additional 23 percent said that they did a mental calculation, while another 12 percent reported using LMP (Table 3).

The mean maximum gestational age for medication abortion reported by the respondents was 6.5 weeks (Table 3). Twenty-six percent could accurately cite the correct dosage for a first trimester abortion, while six percent could report the correct dosage for a second trimester abortion. Most recommended oral (62 percent) administration while 55 percent also recommended vaginal administration. Thirty-one percent reported that they don't know the routes of administration. The complications which require immediate attention which were known to the drug sellers were heavy vaginal bleeding (80 percent), severe abdominal pain (35 percent), high fever (16 percent) and severe vomiting (12 percent). Shivering, severe diarrhea, and continued pregnancy symptoms were named less than five percent of the time (Table 3).

Results of Mystery Client interactions

There were slightly more males than females in the sample of the drug sellers who the mystery clients interacted with. Half of the drug sellers were perceived to be 41 years or older and were perceived to be an employee working at the drug store and not the owner (Table 4). Thirty-five percent had their drug store registration certificate visible, indicating that they were a registered pharmacy. In the

remaining cases, we can't be sure if they were registered and didn't have the certificate displayed or if they weren't registered.

All mystery clients were able to have an interaction with a drug seller. The most common outcome of those interactions was that the drug seller refused to sell the woman something to bring back her period—this was the outcome in 69 percent of the interactions. In 16 percent of the interactions, the drug seller offered to sell the client a drug to bring back her period (Table 4). In an additional 15 percent of the interactions, drug sellers refused to sell the drug, but provided information to the client.

The majority of the drugs that the clients were offered were misoprostol-containing medications. Eighty percent were offered misoprostol alone, and an additional 13 percent were offered misoprostol and something else. Sixteen percent were offered a non-abortifacient (Table 4). The demeanor of the drug seller during the mystery client interaction was generally helpful, neutral or friendly.

During the course of the interaction, mystery clients were most commonly asked how many weeks/months pregnant she was—this question was posed in 80% of the interactions. In 74 percent of the interactions, mystery clients were asked if they had taken a pregnancy test. In 20 percent of the interactions, mystery clients were asked when her last menstrual period was (Table 5). And in 10 percent of the interactions, mystery clients were asked how old they were. Only one was asked whether she currently had an IUD, a contraindication to using misoprostol.

Thirty-two percent of drug sellers attempted to estimate the client's gestational age. Among that 32 percent, most of the drug sellers tried to do it mentally while 19 percent used a calendar (Table 5). Among those who were offered a medication for purchase, only six mystery clients were asked if they had a prescription and only one of those six was asked to show a prescription (Table 5).

Among women who were refused, 69 percent of the drug sellers said they don't sell the drugs to help a woman bring back her period. Six percent told the mystery client that a prescription is required to purchase the drug, another six percent said that they don't know what to sell for that purpose. Four percent refused because they said that they disagree with abortion, and an additional two percent said that the drug was not in stock (Table 5). Women were most commonly referred to Oriéntame (63 percent) but this is also a bias inherent in our sample as our sample was selected from a listing of pharmacies that had been exposed to Oriéntame already. Another 17 percent of mystery client interactions included referral to another pharmacy, and seven percent of interactions included referral to a health facility. Nine mystery client interactions included referral to a private doctor/nurse/midwife (Table 5).

Among the drug sellers who offered to sell the mystery client a drug or offered them information, forty-seven percent told the woman to take more than the basic dose of pills, the basic dose being four 200mcg pills taken over the course of a single day. Forty-five percent told the woman to take the basic dose, and eight percent of drug sellers told women to take less than the basic dose (Table 6). Almost all women (87 percent) were told that they may bleed for a few days, 55 percent were told that they may expect to have cramping for a few days, and 14 percent were told that bleeding is normal (Table 6). 10 mystery client interactions included the drug seller telling the woman that if she experiences heavy bleeding, she should seek care for potential complications and two women were told to seek care if they experienced severe pain (data not shown). Most who were told to seek care if they experienced potential complications were told to seek care in a hospital (data not shown).

Drug sellers were much more likely to give information to mystery clients about follow-up. Fifty-five percent were told to confirm that the abortion was complete. The most common way women were told to confirm was through a pregnancy test (45 percent of women who were either offered the drug or information were advised to do this). Twenty-four percent of drug sellers told women to confirm the termination of the pregnancy through the expelled fetus and an additional 19 percent of women were told to confirm the pregnancy was complete through the return of their menstruation (Table 6). Only two women were advised to get an ultrasound. Very few drug sellers specified where women should seek follow-up care: five mystery client interactions included the advice to seek care from the same drug seller to confirm they are no longer pregnant and only one mystery client interaction included the advice to go to a healthcare center or clinic (Table 6).

References

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Table 1. Drug Seller and Store Characteristics, Colombia Misoprostol Study, 2017-2018

		% (n=258)	
Sex			
	Male	60.1	(155)
	Female	39.9	(103)
Age in Years			
	Mean	-	44.7
	SD	-	14.9
	Min	-	18
	Max	-	85
Health-related qualification			
	Any health related qualification	84.9	(219)
	Pharmaceutical qualification (auxiliary, regent, chemist)	57.8	(149)
	Nursing qualification	3.9	(10)
	Other qualification	23.3	(60)
Position			
	Owner	32.9	(85)
	Manager	42.2	(109)
	Supervisor	0.4	(1)
	Front counter staff	71.7	(185)
Years worked at store			
	Mean	-	10.0
	SD	-	10.5
	Min	-	0.01
	Max	-	54
Any staff trained in			
	Safe abortion	5.0	(13)
	Post abortion care	3.9	(10)

Table 2. Drug Store Medication Stocks, Sales, and Client Encounters, Colombia Misoprostol Study, 2017-2018

	% (n)		Mean	SD
By Medication Type				
Emergency Contraception				
Available in last year	98.8	(255)		
Sold in last year	98.8	(255)		
Number of units sold in the last month	-	-	16.0	17.75
Misoprostol				
Available in last year	3.9	(10)		
Sold in last year	3.5	(9)		
Number of units sold in the last month	-	-	8.6	9.35
Number of brands stocked	-	-	1.1	0.57
Mifepristone				
Available in last year	1.2	(3)		
Sold in last year	0.8	(2)		
Number of units sold in the last month	-	-	2.5	2.12
Combipack				
Available in last year	0.8	(2)		
Sold in last year	0.4	(1)		
Number of units sold in the last month	-	-	4.0	-
By Medication Purpose				
Offer medications to help restore period	12.4	(32)		
Top medications				
Misoprostol-containing medication	15.6	(5)		
Estrogen	18.8	(6)		
Progesterone	31.3	(10)		
# of women that request per month			5.1	17.9
0-9 clients	73.6	(190)		
10-49 clients	12.4	(32)		
50-99 clients	0.4	(1)		
100+ clients	0.4	(1)		
Refuse to answer	13.2	(34)		
% of clients requesting medication to restore period that are women			93.6%	17.6%
% of clients requesting medication to restore period that receive something			56.2%	44.3%
Offer medications to help terminate pregnancy	2.3	(6)		
Misoprostol-containing medication	100	(6)		
Oxytocin	16.7	(1)		
Ergometrine	16.7	(1)		

# that request per month		3.0	4.4
0-9 clients	84.1 (217)		
10-49 clients	7.4 (19)		
Refuse to answer	8.5 (22)		
% of clients requesting medication to terminate pregnancy that are women		85.3%	26.3%
% of clients requesting medication to terminate pregnancy that receive something		54.2%	45.9%
Drug stores that have attended to clients seeking misoprostol or other drug to restore period or terminate a pregnancy (n=182)			
information	35.7 (65)		
Sell medications with prescription	2.2 (4)		
Sell medications without prescription	2.2 (4)		
Refuse to sell, but provide info	44.0 (80)		
Refuse to sell, but refer to Orientame	15.9 (29)		

Table 3. Drug Seller's Knowledge and Attitudes on Misoprostol, Colombia Misoprostol Study, 2017-2018

	% of drug sellers (n)	
Questions that should be asked before selling misoprostol (n=258)		
Date of LMP	26.0	(67)
If taken pregnancy test	20.2	(52)
Gestational age	16.7	(43)
Family planning use	10.9	(28)
Prescription	7.0	(18)
Age	3.0	(8)
Nothing	9.3	(24)
Information that should be given (n=258)		
Dosage	20.9	(54)
When to take tablets	9.3	(24)
How to take tablets	17.4	(45)
What to expect after taking tablets (side effects)	18.6	(48)
To go to hospital upon bleeding	0.0	(0)
Potential warning signs of complications	18.6	(48)
Postabortion family planning advice	0.4	(1)
When to seek medical attention	4.3	(11)
Where to seek medical attention	3.5	(9)
Other ways to terminate pregnancy	0.4	(1)
How to avoid unintended pregnancy in the future	0.8	(2)
Advise to continue with pregnancy	0.8	(2)
No information	11.2	(29)
Don't know	12.0	(31)
Source of information given (n=87)		
Clinical Knowledge	14.9	(13)
Other Employees	1.2	(1)
Internet	14.9	(13)
Pharmaceutical Compendium	4.6	(4)
Drug Inserts	2.3	(2)
Training Chartss	4.6	(4)
Orientame	51.7	(45)
How to calculate gestational age (n=257)		
Using LMP	12.1	(31)
Pregnancy test	10.1	(26)
Mental calculation	22.6	(58)
Calendar wheel	0.4	(1)
Other	26.5	(68)
Don't know	28.4	(73)
Maximum gestational age for medication abortion (n=121)		
Mean numer of weeks (SD)	6.5	(3.53)

Dosage			
	Report knowing dose for 1st trimester abortion	26.4	(68)
	4 pills, once a day for one day	19.1	(13)
	2 pills, twice a day for one day	16.2	(11)
	3 pills, twice a day for one day	8.8	(6)
	3 pills, once a day for one day	1.5	(1)
	4 pills, twice a day for one day	8.8	(6)
	2 pills, once a day for one day	5.9	(4)
	6 pills, once a day for one day	4.4	(3)
	4 pills, twice a day for one day	2.9	(2)
	4 pills, three times a day for one day	1.5	(1)
	4 pills, four times a day for one day	2.9	(2)
	4 pills, twice a day for 2 days	1.5	(1)
	2 pills, twice a day for 2 days	1.5	(1)
	12 pills, twice a day for three days	1.5	(1)
	Report knowing dose for 2nd trimester abortion	5.8	(15)
	Route of administration for misoprostol (n=258)		
	Oral	61.6	(159)
	Buccal	0.0	(0)
	Sublingual	1.6	(4)
	Vaginal	55.4	(143)
	Rectal	0.0	(0)
	Don't know	30.6	(79)
	Complications that require immediate attention (n=258)		
	Heavy vaginal bleeding	79.8	(206)
	Severe abdominal pain	34.9	(90)
	High fever	16.3	(42)
	Severe vomiting	12.4	(32)
	Shivering	4.3	(11)
	Severe diarrhea	2.3	(6)
	Continued pregnancy symptoms	1.2	(3)

Table 4. Characteristics of the drug sellers that the mystery clients interacted with and visit outcomes, Colombia Misoprostol Study, 2017-2018

	%	(n)
Sex		
Male	53.4	(292)
Female	46.6	(255)
Estimated Age		
Less than 20	0.9	(5)
20-30	19.9	(109)
31-40	29.4	(161)
41 or older	49.7	(272)
Perceived position of drug seller		
Owner	10.4	(182)
Sales person	56.3	(308)
Unclear	33.3	(57)
Drug Store Registration Certificate visible	34.9	(191)
Outcome of mystery client interaction		
Refusal	68.9	(377)
Refusal, but gave some information	15.4	(84)
Offered the mystery client something for purchase	15.7	(86)
Medication mystery client was offered for purchase	15.7	(86)
Misoprostol alone	70.9	(61)
Misoprostol + another medication	12.8	(11)
Non-abortifacient	16.3	(14)
Demeanor of drug seller during mystery client interaction		
Helpful	36.6	(200)
Neutral	33.5	(183)
Friendly	24.7	(135)
Interested in selling MC something	17.0	(93)
Unfriendly	10.2	(56)
Hostile	7.7	(42)
Bothered	6.9	(38)
Threatening	2.0	(11)

Table 5. Interaction with drug sellers: Questions asked by drug sellers, Colombia Misoprostol Study, 2017-2018

	% (n)	
Percentage of mystery clients who were asked the following questions during their interaction with the drug seller:		
How many weeks/months pregnant she is	80.1	(342)
If she had taken a pregnancy test	73.5	(314)
When was her last menstrual period	19.9	(85)
What her age is	10.3	(44)
Where she lives	6.1	(26)
If she has a boyfriend	6.3	(27)
How many children she has	5.2	(22)
If she currently had an IUD	0.2	(1)
Percentage of mystery clients offered a medication for purchase or information that had sellers attempt to determine their gestational age	31.7	(54)
Assessed by calculating mentally	81.5	(44)
Assessed using a calendar	18.5	(10)
Among mystery clients offered a medication for purchase		
Asked if they had a prescription	3.5	(6)
Asked to show a prescription	16.7	(1)
Reasons for refusal		
Doesn't sell drugs	69.1	(322)
Prescription is required	6	(28)
Doesn't know what to sell for this purpose	5.8	(27)
Disagrees with abortion	3.9	(18)
Not in stock	2.4	(11)
Client is young	1.5	(7)
Drug is expensive	0.6	(3)
Seller busy, asked MC to leave	0	(0)
Asked MC to come back later	0.2	(1)
Seller didn't know MC	0.2	(1)
No reason given	4.0	(19)
Among sellers that did not offer medication for purchase, percent referred to elsewhere (n=461)		
Orientame	63.1	(152)
Another pharmacy	16.6	(40)
Health facility	7.1	(17)
Private doctor/nurse/midwife	3.7	(9)

* Sellers may have calculated gestational age in multiple ways

Table 6. Information given to mystery clients by drug sellers who offered a medication or information, Colombia Misoprostol Study, 2017-2018

	% (n)	
Misoprostol dosage information (n=78)		
Higher than basic dose	47.4	(37)
Basic dose*	44.8	(35)
Lower than basic dose	7.7	(6)
Percentage of mystery clients given information about potential side effects (n=115):		
They may bleed for a few days	87.0	(100)
They may expect to have cramping for a few days	54.8	(63)
Bleeding is normal	13.9	(16)
To seek help immediately if they started bleeding	7.8	(9)
Were told they may expect to have diarrhea	3.5	(4)
They may expect to have mild shivering or fever	1.7	(2)
Percentage of mystery clients given information about follow-up (n=115)		
Drug seller told women to confirm termination of pregnancy via the following method(s):	54.8	(63)
Pregnancy test	44.4	(28)
Expelled fetus	23.8	(15)
Return of menstruation	19.0	(12)
Ultrasound scan	3.2	(2)
Told to seek follow-up care at the following locations:		
Same drug seller	4.3	(5)
Healthcare center or clinic	0.9	(1)

* A basic dose refers to four 200mcg pills of misoprostol taken over the course of a single day