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Stocking and over-the-counter sale of misoprostol for medical abortion in Ghana's community pharmacies: comparison of questionnaire and mystery client survey

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Keywords
abortifacients; abortion law; drug stocking; over-the-counter sale; sub-Saharan Africa; unsafe abortion

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Abstract

Objectives In many sub-Saharan African countries with restricted safe abortion services, community pharmacies are important sources of abortifacients. However, data on stocking and over-the-counter sale of abortifacients in community pharmacies are often limited. The main objective of this study was to compare stocking and over-the-counter sale of misoprostol at community pharmacies using questionnaire and mystery client surveys in Ghana.

Methods A cross-sectional questionnaire-based survey, complemented with a mystery client survey, was conducted at 165 randomly selected community pharmacies in Accra, Ghana. Structured questionnaires were administered to pharmacists/pharmacy workers. A mystery client survey to each of these pharmacies was also undertaken. Descriptive statistical techniques (frequencies and proportions) were used to estimate and compare stocking and over-the-counter sale of misoprostol at community pharmacies from the two data collection methods.

Key findings Some 50.3% (83) of community pharmacists/pharmacy workers reported stocking misoprostol and selling it over-the-counter for medical abortion in the questionnaire-based survey. However, in the mystery client survey, 122 (74%) pharmacists/pharmacy workers reported stocking misoprostol and actually selling it over-the-counter to the mystery clients. Thus approximately 39 (24%) more pharmacies stocked misoprostol and sold it over-the-counter even though they originally denied stocking the drug in the questionnaire survey. Also, the drug was often sold without a prescription, and many did so without asking for a confirmatory pregnancy test or gestational age.

Conclusions In contexts where access to safe abortion services is restricted, mystery client surveys, rather than conventional questionnaire-based survey techniques, may better illuminate stocking and over-the-counter sale of abortifacients at community pharmacies.

Introduction

Unsafe abortion continues to be a major public health problem in many sub-Saharan African countries, including Ghana.[1] Globally, unsafe abortion accounts for 70 000 maternal deaths yearly, of which over 99% are in low-income countries.[2] While in most high-income countries, safe and legal abortion services are fairly easy to obtain,[1] safe abortion is often a privilege of the rich in many sub-Saharan African settings with highly restrictive abortion legislations.[2] This often leaves poor people with limited sources of safe abortion.[3]

In Ghana, maternal mortality is the second cause of death among women of reproductive age, with approximately 20.8% of maternal deaths resulting from unsafe induced abortions.[4] Despite the fact that unsafe abortion

contributes substantially to maternal mortality in Ghana, abortion is largely a taboo subject in almost all public spaces.[5,6] This is partly because induced abortion is a criminal offence, regulated by Act 29, Section 58 of Ghana's Criminal Code of 1960.[5,7] This law was amended in 1985 (PNDCL 102) to allow for limited circumstances under which legal abortion might be permitted. These conditions include pregnancies that result from rape, incest, and 'defilement of a female idiot'; where there is high risk that the child would suffer serious deformity if born; and if the pregnancy threatens the physical or mental health of the woman.[5,7] This notwithstanding, integration of safe abortion care into Ghana's reproductive healthcare system has not widely occurred.[6] Consequently, access to legally safe abortion in public health institutions continues to be limited.[5]

In many low-income countries where safe abortion services are restricted, over-the-counter sale of abortifacients like misoprostol for medical abortion in community pharmacies is increasingly recognized.[8–13] Under Ghana's abortion law and Ghana Health Service's guidelines, community pharmacists are currently not listed as providers of abortion services, but may dispense abortifacients against a medical prescription. However, community pharmacies have been reported to be the first point of call for the majority of Ghanaians seeking abortion care or advice.[14] Therefore, there have been calls for community pharmacists to be included in the official list of healthcare professionals permitted by law and guidelines to provide abortion care.[15] In relation to misoprostol, Ghana's current medicines as well as pharmacy regulations make the drug a prescription only drug.[6,14] The Ghana Pharmacy Council regulations also require a pharmacist to be present anytime a pharmacy is opened. However, the regulation permits a pharmacy to be opened if other trained pharmacy workers such as pharmacy technicians, medical counter assistants, and other on-the-job-trained staff are present if it is not feasible to have a pharmacist at all times.[15]

Despite growing research on the role of community pharmacies in many low-income settings, it has been observed that due to restrictive laws on abortion in such contexts, data on stocking and over-the-counter sale of abortifacients in community pharmacies are often limited.[9,10,13,14] One particularly problematic issue is the recognition that conventional questionnaire-based surveys often do not reveal much about stocking and over-the-counter sale of abortifacients at the community level.[16] This has led to calls for complementary methodologies such as mystery client surveys.[14,16] Evidence of the use of such methods is, however, limited in Ghana.[14] This study aimed to compare misoprostol stocking and over-the-counter sale at community pharmacies using questionnaire and mystery client surveys in Ghana.

Methods

Study design

A cross-sectional quantitative study using interviewer-administered questionnaires and mystery client survey was conducted.

Setting

Empirical data collection was conducted in Accra, the capital city of Ghana. It is the most populous city in Ghana with an estimated total population of 1 665 086, comprising 51.9% females and 48.1% males.[17] Total fertility rate (TFR) is 2.2.[17] Also, general fertility rate (GFR = 63.7) and crude birth rate (CBR = 19.7) are lower than the regional and national average of 75.7 and 22.7, respectively.[17]

Study population

Community pharmacists constituted the primary population. However, in low-income settings regular absence of pharmacists in community pharmacies is widely recognized.[2,8–11] To take account of this, we included other pharmacy workers such as pharmacy technicians, medical counter assistants and other on-the-job-trained staff in cases where there was no pharmacist.

Sampling

At the time of the study, there were 771 registered retail community pharmacies in 'good standing' in the Greater Accra Region.[18] The Pharmacy Council of Ghana defines 'good standing' as pharmacies that have renewed their yearly licence and therefore are eligible to conduct business.[18] Out of the 771 registered retail community pharmacies in 'good standing', 281 (36.4%) were located in the Accra metropolitan area. These were distributed across three main residential areas in the city, namely first-, second- and third-class residential areas.[19] Generally, first-class residential areas are well planned, and have expansive and landscaped properties.[19] Generally, the richest in society live in these areas. Second-class residential areas are middle-income neighbourhoods, usually occupied by working class people.[19] Generally, these residential areas are better-planned, but often still require additional essential infrastructure and services. Third-class residential areas are generally low-income neighbourhoods. They are usually heavily populated and largely unplanned.[19]

Yamane's formula for calculating sample size from a finite population was used to estimate a sample size of

165 for the survey.[20] Using an electronic google-based random number generator programme, a random sample of 165 community pharmacies in good standing was identified.

In terms of how the selected community pharmacists or pharmacy workers were approached, letters were written to the head/administrator of each of the selected pharmacies. In each letter, the rationale and objectives of the study as well as how each facility was selected were fully explained. The head/administrator of each of the selected pharmacies was also requested to nominate the most experienced (in terms of years of practice) pharmacist or pharmacy workers at their respective facility. A research assistant delivered these introductory letters to each facility. Each facility was given one week (from the date of receipt of the letter) to decide on participation. Each facility was re-contacted via telephone or personal visit after the one-week period. Where any of the 165 pharmacies approached declined participation, further cohorts of pharmacies were approached until 165 had agreed. Following from this, we contacted each of the nominated pharmacist/pharmacy workers via phone or personal visit. Adequate information about the study was then provided to each of the nominated pharmacist/pharmacy workers, after which interview dates were arranged.

Data collection

Data were collected from May to August 2016. Two data collection methods were used, namely questionnaire survey and mystery client survey.

The question survey

Structured questionnaires were designed and administered to pharmacists/pharmacy workers in a survey (see Appendix S1). The questionnaires were pretested at 10 pharmacies not included in the actual study. The aims of the pretest were to correct ambiguity in any questions, check the reliability of the instrument, and gauge the amount of time required to complete each interview. Few questions were found to be ambiguous or irrelevant and were accordingly modified or completely removed. The reliability of the questionnaire was tested and it was found to be quite reliable (Cronbach's alpha coefficient of 0.88 was reported).

The first and second authors individually generated questions based on extensive literature review. Relevant questions on knowledge of Ghana's abortion laws were adapted from the Ghana demographic and health survey tool.[21] The third author then reviewed the two sets of questions and developed a composite tool. All the authors then reviewed and agreed on all the questions. In addition to collecting information on the background characteristics of respondents, the questionnaires included questions on availability of misoprostol in community pharmacies, community pharmacists' prescribing practices, reasons for community pharmacists' prescription or non-prescription of misoprostol for medical abortion, other supportive therapy or advice community pharmacists offer to clients seeking misoprostol for medical abortion and community pharmacists' general attitude towards medical abortion. Respondents were also asked questions on abortion laws, for example do you know if there is any law concerning abortion in Ghana? Questions were generally close-ended with fixed choice responses (see Appendix S1). Most questions, however, had an 'Other' option. Respondents who chose this response option were required to specify their answer in an open-ended fashion. No Likert scaled response type questions were, however, included. The questionnaires were written and administered in English.

The questionnaires were both interviewer administered (researchers asked questions and recorded responses) and self-administered (respondents read the questions and recorded their responses unsupervised). The researchers personally visited all pharmacies to administer questionnaires or distribute them for self-administration. The researchers also personally revisited all pharmacies to retrieve self-administered questionnaires.

The mystery client survey

A mystery client survey scenario was also conducted to collect data on what pharmacists or pharmacy workers actually do when approached by a client seeking abortion services.[16] This took place within two hours after the survey questionnaire was completed at each pharmacy. Two mystery client scenarios were developed (see Appendix S2). The first was for a young female unmarried student and the second a young unmarried male partner of a supposedly pregnant woman. We selected and trained eight (8) tertiary level students – four males and four females aged between 19 and 25 – to act out the scenarios. Specifically, they were trained to complain to the pharmacist/pharmacy workers about a late or missed period. They just indicated as the opening line 'please I have a problem. I hope you can help me. My menses or my girlfriend's menses has delayed this month. Do you have any drug that can help me?' The mystery client then waited to be asked about pregnancy or otherwise. This was to determine whether pharmacists/pharmacy workers attribute any delay in the menstrual cycle to pregnancy and whether they would ask the client to confirm pregnancy with a pregnancy test or even ask if the client has had unprotected sex. The mystery clients were also trained not to divulge how many weeks late the supposed pregnancy or missed period was until probed. This was also to determine whether pharmacy workers ask for

gestational age before dispensing misoprostol or any other drug for abortion. Furthermore, the mystery clients were trained not to ask for any drug in particular, but a drug for medical abortion. However, where the pharmacy worker reports back that they did not have any such drug, the mystery client then revealed that a friend told them a drug called misoprostol could help. Where misoprostol or any other drug was offered, the mystery clients were trained to check the name of the drug given, the cost and number of tablets he or she may need in all and dosing frequency. Also, where no drug was offered the mystery clients were trained to also document the reactions and recommendations of the pharmacy worker. In all the two scenarios, the mystery clients were trained to fill a short questionnaire after the encounter (see Appendix S3). The short questionnaire contained specific questions such as whether misoprostol was sold over-the-counter after the mystery client acted the scenario or whether misoprostol was sold upon specific request by the mystery clients; whether any other drug was sold to the mystery client over-the-counter; where misoprostol or any other drug was sold to the mystery client over-the-counter whether dosing instructions were given; and whether a pregnancy test was requested to confirm pregnancy. All questions were close-ended with fixed responses, mostly Yes/No to indicate whether a particular action/event happened or not. Each mystery client filled the short questionnaire in English based on information from memory after each encounter (usually within 5 min).

Data analysis

Both the questionnaires and the short mystery client questionnaire were first manually examined for completeness, then hand coded and separately entered into Microsoft Excel. To ensure data quality, the second (NTB) and third (LB) authors independently entered data from the main survey questionnaire and the mystery client data into Excel. The first author (JKG) then compared the two sets of data entries. Errors and inconsistencies that were detected were discussed and resolved before the data were then exported into Stata 15 version software for further cleaning. Cleaning of the data was done by running frequencies on each variable. All outliers were double-checked with raw data from the questionnaire, and all inconsistencies and errors were resolved. Descriptive statistical techniques (frequencies and proportions) were used to estimate and compare misoprostol stocking and over-the-counter sale at community pharmacies from the two data collection methods. Chi-square test of independence and Fisher's exact test (for observations with less than 5 cell counts) were used to assess statistical association. A 95% confidence level was set, and statistical significance held at $P < 0.05$.

Ethical approval and consent to participate

The Ethical Review Committee of the Ghana Health Service reviewed and gave ethical approval for this study (Protocol ID NO: GHS-ERC 37/12/15). Individual respondent's informed written consent was obtained before interviews were conducted. All participants were assured of anonymity, privacy and confidentiality. Participation was voluntary. As part of the consent process, respondents consented to findings from the study being published for the benefit of a wider audience.

Results

A total of 170 community pharmacies were approached in the questionnaire survey, and questionnaires were successfully completed for 165. The response rate in the questionnaire survey was thus 97% (165/170). All the 165 mystery client surveys were, however, fully completed, returned and used in the analysis.

Distribution of pharmacy workers

Table 1 gives information on the distribution of the 165 pharmacists/pharmacy workers surveyed using the questionnaires across the three categories of residential areas. The first-class residential area had the highest concentration of pharmacists (60.0%), while third-class residential areas had the lowest percentage of pharmacists (16.0%) and the highest percentage of medicine counter assistants (56.0%) and staff being on-the-job-trained (16.0%).

Table 1 Distribution of respondents by qualification and misoprostol stocking in community pharmacies by residential area (N = 165)

	Residential area, *n* (%)			
Characteristic	1st class	2nd class	3rd class	Total
Respondent's qualification				
Pharmacist	15 (60.0)	50 (43.5)	4 (16.0)	69 (41.8)
Pharmacy technician	2 (8.0)	22 (19.1)	3 (12.0)	27 (16.3)
Medicine counter assistant	7 (28.0)	38 (33.0)	14 (56.0)	59 (35.8)
On-the-job-trained	1 (4.0)	5 (4.4)	4 (16.0)	10 (6.1)
Total	25 (100.0)	115 (100.0)	25 (100.0)	165 (100.0)
Stocked misoprostol				
Yes	17 (68.0)	55 (47.8)	11 (44.0)	83 (50.3)
No	8 (32.0)	60 (52.2)	14 (56.0)	82 (49.7)
Total	25 (100.0)	115 (100)	25 (100)	165 (100)

Misoprostol stocking in community pharmacies

Table 1 shows data on stocking of misoprostol in the 165 community pharmacies surveyed using the questionnaires. A little over half 83(50.3%) of the respondents reported stocking misoprostol at their facility at the time of this study. There was, however, variability in misoprostol's stocking across the three residential areas. Generally, a decline in misoprostol's stocking was observed as one moved from first-class to third-class residential areas. However, a chi-square test of independence suggested this difference was not statistically significant ($P = 0.149$).

Over-the-counter sale of misoprostol in community pharmacies

Table 2 shows that a little over a quarter of the respondents 44 (26.7%) surveyed using the questionnaires have sold misoprostol over-the-counter for abortion in the last 6 months prior to this study. Generally, pharmacy technicians and medicine counter assistants were significantly more likely to have sold the drug over-the-counter in the last 6 months before the survey ($P < 0.01$). Table 2 also shows results on association between knowledge that there is an abortion law in Ghana and over-the-counter sale of misoprostol of abortion in the last 6 months based on data from the questionnaires. Generally, the chi-square test of association showed that over-the-counter sale of misoprostol did not differ statistically ($P = 0.197$) between respondents who knew that there was an abortion law and those who did not know or were unsure, albeit those who knew were less likely to report over-the-counter sale of misoprostol for abortion in the last 6 months.

Table 2 Over-the-counter sale of misoprostol by qualification and knowledge of abortion law ($N = 165$)

	Sold misoprostol over-the-counter for abortion in last 6 months, *n* (%)			
Characteristic	No	Yes	Total	*P*-value
Respondent's qualification				
Pharmacist	52 (75.4)	17 (24.6)	69 (100.0)	0.001
Pharmacy technician	17 (63.0)	10 (37.0)	27 (100.0)	
Medicine counter assistant	44 (74.6)	15 (25.4)	59 (100.0)	
On-the-job-trained	8 (80.0)	2 (20.0)	10 (100.0)	
Total	121 (73.3)	44 (26.7)	165 (100.0)	
Knows there is a law on abortion				
No	21 (63.6)	12 (36.4)	33 (100)	0.197
Yes	74 (78.7)	20 (21.3)	94 (100)	
Not sure	26 (68.4)	12 (31.6)	38 (100)	
Total	121 (73.3)	44 (26.7)	165 (100.0)	

Responses to mystery clients

From the mystery client survey, pharmacists and pharmacy workers responded to the mystery clients' request for misoprostol in four ways. These were those who said they stocked misoprostol at their facility and sold it over-the-counter to the client in direct response to the mystery client scenario 122 (74%); those who said they did not stock misoprostol and did not ask the client any questions 15 (9%); those who said they did not stock misoprostol and referred the client to the hospital 23 (14%); and those who said they did not stock misoprostol and tried to help by selling another drug over-the-counter 5 (3%). The results from the mystery client survey suggest that in approximately 39 (24%) more community pharmacies, misoprostol was stocked and was sold over-the-counter to the mystery client even though in the questionnaire survey, respondents from those same pharmacies said they did not stock the drug.

Further analysis was conducted on the specific responses of the 122 (74%) respondents who reported in the mystery client survey that they stocked misoprostol at their facility and sold the drug over-the-counter to the mystery client. These responses were categorized into 'sold misoprostol spontaneously' over-the-counter, and 'sold misoprostol upon request'. The relationships between how the drug was sold to the mystery client, and whether pregnancy test was requested and whether gestational age asked about, were then investigated. Results are shown in Table 3. In total, 95 (77.9%) of the 122 respondents who sold misoprostol over-the-counter to the mystery clients did so spontaneously, while the remaining 27 (22.1%) did so after the mystery client specifically requested for the drug. Among respondents who sold the drug spontaneously, only five of them asked for pregnancy test while only 19 (20%) asked for gestational age. The difference was statistically significant ($P < 0.01$). Among respondents who sold the drug upon request, a minority 11 (41.6%) did not ask for pregnancy test. However, majority 17(60.3%) of them did ask for gestational age. The difference here was also statistically significant ($P < 0.01$).

Discussion

Results from this study showed that many community pharmacists/pharmacy workers tended to under report stocking and over-the-counter sale of misoprostol for medical abortion in the survey questionnaire compared to mystery client surveys. The study has a number of strengths. In addition to being one of the few studies to assess stocking and over-the-counter sale of misoprostol in community pharmacies in Ghana, the complementary design (using both questionnaires and mystery client surveys) helped to triangulate and better illuminate the

Table 3 Distribution of pharmacy worker's response to mystery client (n = 122).

	Asked for pregnancy test, *n* (%)			Asked for gestational age, *n* (%)		
Misoprostol sold over-the-counter	No	Yes	*P*-value	No	Yes	*P*-value
Spontaneously	90 (94.7)	5 (5.3)	0.001	76 (80.0)	19 (20.0)	0.001
Upon request	16 (59.3)	11 (40.7)		10 (37.0)	17 (63.0)	

stocking and over-the-counter sale of misoprostol in community pharmacies. We believe important lessons could be learned from our study design and results to inform practice and future research. These strengths notwithstanding, our study has some limitations. First, the questionnaire relied on respondents to recall events that may have taken place several months back. Similarly, the mystery clients filled the short questions five minutes after their encounters with pharmacists/pharmacy workers. In both of these cases, the possibility of recall bias is acknowledged. Second, while we ensured that the mystery client survey took place within two hours after the survey questionnaire was completed at each pharmacy, it is possible that the pharmacist or pharmacy worker who answered the questionnaire may not have been the same personnel who attended to the mystery client. This could potentially create discrepancies in the responses.

Similar to previous studies in Bangladesh[10] and in Southeast Asia,[22] our results showed that as high as 24% of community pharmacists/pharmacy workers who denied stocking misoprostol in the survey questionnaire actually sold it over-the-counter to the mystery client either spontaneously or upon request during the mystery client survey. We think this discrepancy could be explained by the restrictive nature of Ghana's abortion law, and the fact that community pharmacists are currently not listed in both Ghana's abortion law and Ghana Health Service's guidelines as providers of abortion services.[23] Therefore, fear of legal prosecution or sanctions could deter pharmacy workers from disclosing stocking or over-the-counter sale of misoprostol in their facilities. This probably explains why respondents in our survey who knew about Ghana's abortion law were less likely to report ever selling misoprostol over-the-counter for medical abortion compared to those who did not know.

Results from the mystery client survey also showed that pharmacists/pharmacy workers seldom confirmed pregnancy and gestational age of the pregnancy before offering an abortifacient. This is very concerning because although misoprostol can be given alone or in combination with other abortifacients for safe medical abortion, the dose given is dependent on gestational age, with the dose reducing as the pregnancy advances. Lower doses may lead to incomplete abortions, which could be complicated by bleeding and infection, while large doses in advanced pregnancies could also result in uterine rupture. Therefore, the lack of reference to gestational age could result in inaccurate dosage, and this could contribute to mortality and morbidity related to abortion. These results are to be expected; however, because many pharmacists/pharmacy workers may have had insufficient training in the use of misoprostol as an abortifacient partly because they are not supposed to undertake abortions as per Ghana's abortion law. Insufficient training is more likely to be a factor given that only 41.8% of the community pharmacies surveyed had pharmacists at the time of the study.

Taken together, the results from this study suggest that in contexts where abortion services are restricted, complementary research methodologies such as survey questionnaires and mystery client surveys have the potential to better reveal actual stocking and over-the-counter sale of misoprostol and other related abortifacients in community pharmacies. The inconsistencies observed in the report, and behaviour of respondents in this study suggests that abuse and harm in the use of misoprostol could easily arise. This would suggest a need for legislative reforms, first to completely legalize and provide safe abortion services in all public health facilities; and second, to legally recognize and include pharmacists/pharmacy workers as key providers of safe abortion services. This is particularly critical because without this legislative reform, regulatory authorities cannot train and monitor community pharmacists on prescription of misoprostol for medical abortion. However, if these legislative reforms are implemented, training could be offered through both regular curriculum and on-the-job training on appropriate prescription and dispensing of abortifacients like misoprostol. This training should include rapid test to confirm pregnancy first, how to determine the gestational age of pregnancy by use of appropriate charts, the WHO recommended dose of misoprostol for abortion, and counselling on post-abortion contraception to prevent repeated episodes of abortion.

Conclusion

This study has shown that in contexts where access to safe abortion services is restricted by law, a combination of complementary research methodologies such as conventional questionnaire-based survey techniques and mystery client surveys has a potential to better reveal stocking and over-the-counter sale of abortifacients such as misoprostol in community pharmacies. This clearly has implications

for future abortion-related research at the community level in contexts with restrictive abortion regimes. Finally, as misoprostol is stocked widely in community pharmacies in Ghana, Ghana's abortion law needs to be reformed not only to make safe abortion legally available but also to include community pharmacists and other pharmacy workers as safe abortion service providers.

Declarations

Conflict interests

The authors declare no conflict interests.

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Authors' Contribution

All authors have contributed equally to this work. NTB conceived the study. NTB and JKG contributed to the study design. NTB collected the data, entered and performed data analysis with LB. JKG and LB interpreted the data. NTB and JKG drafted the manuscript. All authors read and contributed to the revision. All authors also read and approved the final draft of the manuscript for submission for publication.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Study questionnaire.

Appendix S2. Mystery client's scenarios.

Appendix S3. Mystery client short questionnaire.