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**TITLE**

**Complications with use of misoprostol for abortion in Madagascar: between ease of access and lack of information**

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**CONFLICT OF INTEREST**

All the authors declare no conflict of interest.

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**ABSTRACT**

**Objectives:** To learn what complications some women experienced in Madagascar following use of misoprostol for abortion and what treatment they received post-misoprostol use.

**Study design:** This was a qualitative study in 2015-16 among women who had experienced complications after use of misoprostol, with or without additional methods, for abortion, what information they received before use, what dosage and regimens they used, what complications they experienced and what treatment they received post-use. We initially conducted in-depth, semi-structured interviews with 60 women who had undergone an abortion that resulted in complications. The results presented here are based on interviews with the sub-set of 19 women who had used misoprostol.

**Results:** The 19 women were aged 16-40, with an average age of 21-26 at interview and average age of 18-21 at abortion. To obtain an abortion, they sought advice from partners, friends, family members, and/or traditional practitioners and healthcare providers. Misoprostol was easily accessible through the formal and informal sectors, but the dosages and regimens the women used on the advice of others were extremely variable, did not match WHO guidelines, and were apparently ineffective, resulting in failed abortion, incomplete abortion, heavy bleeding/hemorrhage, strong pain, and/or infection. **Conclusions:** This study provides data on complications from the use of misoprostol as an abortifacient in Madagascar. Healthcare providers need training in correct misoprostol use and how to treat complications. Law and policy reform are needed to support such training and to ensure the provision of safe abortion services in the public health system.

**Implications:** Healthcare providers who provide abortion care and treatment of abortion complications need training in correct misoprostol use and treatment of complications. Women and pharmacy workers also need this information. Law and policy reform are needed to allow training and provision of safe services. Further research is needed on the extent and impact of incorrect misoprostol administration.

## 1. Introduction

In Madagascar, in 2015, the maternal mortality ratio was 353 maternal deaths per 100,000 live births, down from 778 in 1990 [1]. Abortion is illegal in Madagascar except to save the life of the woman [2]. Nonetheless, many women have abortions illegally, and some healthcare providers provide abortions illegally [3]. According to data published in 2007, in the capital Antananarivo, 20.4% of women aged 15-49 who had been pregnant had had an abortion, compared to 10.6% in rural areas [4]. In 2012, 11.8% of maternal deaths were attributed to complications of unsafe abortion [5]. In spite of legal restrictions, however, there are no prosecutions of women or healthcare professionals for abortion.

Women in Madagascar self-induce abortions, go to a *reninjaza* (traditional birth attendant with no medical qualifications [6]), or go to a healthcare provider, whether a private doctor or private clinic (doctor, midwife, nurse) [7]. The methods used to induce abortion in Madagascar [8] include traditional methods (infusions or herbal decoctions), medical methods (misoprostol, oestrogen-progestogen pills), and/or intrauterine insertion of probes or plant stems [7].

According to WHO, the most unsafe abortions can lead to complications such as: incomplete abortion, heavy bleeding/hemorrhage, infection, uterine perforation, and damage to the genital tract and internal organs. The critical signs and symptoms of complications that require immediate attention include: abnormal vaginal bleeding, abdominal pain, infection, shock (collapse of the circulatory system). In our study, we included women who reported having had complications severe enough to require treatment. The symptoms they described were mainly hemorrhage, heavy bleeding (in terms of quantity and duration: several weeks or months), and/or abdominal pain.

We conducted a study among 60 women to learn about complications women in Madagascar experience when they seek informal help to have an abortion involving misoprostol and/or other methods from traditional birth attendants and healthcare providers. For this paper, we analysed a sub-sample of 19 women who said they had used misoprostol for abortion and experienced complications. We have not been able to locate other published data on complications following the use of misoprostol for abortion in Madagascar, though we are aware of a Master's dissertation in Public Health which mentions complications following the use of misoprostol for abortion in Madagascar [7].

## 2. Material and methods

### 2.1. Study population

The main study was carried out between September 2015 and May 2016 in two geographical regions of Madagascar: the Analamanga Region, a mostly urban region where the capital Antananarivo is found, and the Atsimo Andrefana Region in the south, which has some of the lowest development indicators in the country and some very isolated areas. In both regions, we conducted semi-structured interviews in a rural and an urban setting.

We purposively recruited 60 women who had had an abortion and experienced complications, for a descriptive qualitative research study. In each site, to find study participants, we received the assistance of the local traditional and official authorities and the health system authorities. To identify women who had had at least one abortion that was followed by complications, we used both a screening tool among women aged 15-49 and snowball recruitment methods. First, we used a screening tool with all the women in the communities who met our criteria aged 15-49 in each of the four settings, to identify those who met the selection criteria. We also asked those women to put the interviewer in contact with others whom they believed met the same selection criteria. We stopped recruiting women in each setting when we had recruited 15 women per setting who had had at least one abortion involving complications, a total of 60 women.

The Ministry of Public Health (Madagascar) gave ethical approval for the study. An information letter was distributed to each respondent. We carried out interviews after the respondents accepted and signed a consent form. The interviews took place in the woman's home when no one else could hear them. All data have been anonymized, and pseudonyms have been used.

The national study coordinator and three female interviewers working at the Pasteur Institute of Madagascar conducted the interviews in the Malagasy language, using an interview topic guide. The co-authors developed the interview questions based on several themes: the women's socio-familial context, the relationship with health and contraception, the perception of abortion, and the women's

abortion trajectories (i.e. awareness of misoprostol, self-use or not, who they consulted, any other method used, costs, complications experienced, and care following complications). The questions were written in French and translated into Malagasy by the national study coordinator. The interviewers were trained in data collection methods and the sensitivity of the subject. The topic guide was semi-structured and open-ended in order that respondents would feel able to talk about issues of importance to them. The questions aimed to help the woman reconstruct the context of abortion (socio-familial context, partner/conjugal situation, reproductive life, perception of abortion) and the trajectory of the abortion. Questions also included how the woman discovered she was pregnant, who she informed, whether she consulted a healthcare provider about abortion, her knowledge of abortion methods, her reasons for using misoprostol, where she got the misoprostol and how many pills, her use of the misoprostol and what happened, the development of complications and what post-abortion care she received.

The interviews lasted between 45 minutes and two hours. We recorded all interviews with the written consent of the respondents. A team of two bilingual translators transcribed all the interviews in Malagasy and translated them into French. We analyzed the interviews thematically, utilizing a thematic analysis chart that was designed to identify the themes cited in each interview and to make comparisons, in order to highlight recurring issues and differences in the conversations [9]. In our sub-sample analysis for this paper, we focused on women's misoprostol abortion trajectories: how did they learn about misoprostol; how did they use misoprostol; and what were their experiences with the medication.

### **3. Results**

#### **3.1. Learning about misoprostol and obtaining the pills**

Nineteen of the 60 women had used misoprostol for abortion, sometimes also with other methods. Eighteen of the 19 spontaneously said they had used either misoprostol or Cytotec when asked what they had used. Only one did not remember the name of the medication; when we suggested "misoprostol or Cytotec" to her, she recalled that it was misoprostol. The results presented in this

paper describe the experiences reported by those 19 women. The type of complications with misoprostol that they reported included failed or incomplete abortion, prolonged bleeding, heavy bleeding/hemorrhage, serious pain, and/or infection. Among the sub-sample of 19 women, 16 women were recruited in the community in the villages/districts we targeted for the study, either by the snowball method (11 women) or by the screening method (5 women); we recruited 1 woman at the public hospital where she was hospitalized for post-abortion complications and 2 women in a private medical office through the midwife who had treated them for abortion complications.

The women had consulted close contacts, whether a family member or a close friend, a healthcare professional or a traditional birth attendant who provided abortions, in order to seek advice about abortion methods. Some of the women confided first in their husband or boyfriend before going, with his approval, to a healthcare professional (doctor, nurse, midwife) or a traditional birth attendant. One woman went directly to a traditional birth attendant. The younger women mostly sought advice from a female friend or an elder sister, who told them about misoprostol and sometimes even bought the pills for them. Four of the youngest girls and students confided in a family member (mostly their mother), who made the decision what approach to follow. Sometimes, several family members (mother, grandmother, sister, uncle) were involved in the decision and in deciding on the process to follow (finding the medication, paying for it, or accompanying the young woman to a healthcare professional). Their choice of whom to approach appeared to be influenced by issues around concealment, as with Mbola who wished to keep her pregnancy and abortion secret from her parents:

*"Who did you approach when you decided to abort?"*

*"First of all my friends, because I did not dare to tell my parents, so it was my friends, it was to my friends that I said what was happening to me, it is they who told me to do this. One friend told me: 'This - misoprostol - can expel it.'" (Mbola, age 22)*

One of the advantages of misoprostol use, especially from the point of view expressed by some of the young women, was that it did not necessarily require the participation of a third person, which enabled the abortion to remain secret from their families.

All 19 women had heard of misoprostol through “word of mouth” from friends, sisters or partners, including its abortifacient effects and where it could be purchased. Some mentioned Cytotec, others a generic brand. They said it was easy to find, even in remote areas. The majority purchased the misoprostol on the informal drug market – at a drug depot (in rural areas) or from a vendor operating in the informal drug market (in urban areas). The others got it from a healthcare provider or traditional birth attendant, or purchased it from a pharmacy, with or without a prescription. The price of generic misoprostol per packet of ten pills ranged from 5,000–15,000 Ar per packet (\$1.60 to \$4.80). For Cytotec®, prices ranged from 18,000–40,000 Ar per packet (\$5.70 to \$12.70). (In Madagascar, the official minimum wage was just under \$42 per month in 2016.) Some women had obtained the pills from others, and were unaware of costs:

*"And how much did this Cytotec cost?"*

*"I don't know, it wasn't me who bought it. We sent our servant there and my mother gave her the money so I do not really know." (Lovatina, age 22)*

### **3.2. Using misoprostol**

Most of the women said they were only able to give an estimate of how many weeks pregnant they were at the time of misoprostol use. A small number had used misoprostol as soon as they noticed they had delayed menses. The estimates of the others varied from 2 to 2.5 months pregnant, to about 3 months pregnant, about 4 months pregnant, and 5 months pregnant, but almost all were below 12 weeks.

Their use of misoprostol was also haphazard. Ten of the women had used misoprostol in varying dosages following a consultation with a midwife or doctor; seven had self-administered the pills in amounts they decided upon themselves; and two had used the pills following a consultation with a traditional birth attendant. Most of the seven women who self-medicated took the pills orally. They took between 8 and 20 tablets, spaced out at different intervals – half an hour, an hour, two hours, 12 hours. Only two women who self-administered the misoprostol used vaginal administration. Of those

two, one woman used 10 Cytotec pills in total, administering two tablets vaginally every 3 hours. The other inserted one misoprostol tablet vaginally and took nine tablets orally every 30 minutes.

When the misoprostol was prescribed by a healthcare provider, the administration and number of tablets were just as varied as with self-use. Some prescribed oral use only (for example, taking anything from 7 to 12 tablets one by one at hourly intervals). One midwife in a health center prescribed four pills, one every evening. Others prescribed combined vaginal and oral administration – for example, inserting between one and four tablets vaginally and then taking between 2 and 10 tablets orally, one by one, at hourly intervals. One traditional birth attendant prescribed one tablet of misoprostol every 12 hours for two days to one woman. Some health professionals also used another method along with the misoprostol (for example, a probe or an oxytocin injection), or prescribed misoprostol preceding a curettage. One woman described some kind of simultaneous surgical intervention:

*"The doctor made me lie down on a bed. First, he introduced I don't know, a round thing. It seemed to me that it turned like a spring does, when he inserted it in the passage. Afterwards, he introduced the probe, and he left the probe in. And he said, "You're going home, but you're going to come back here tomorrow." He gave me Cytotec, Cytotec, small tablets, he gave me some. He said: "Here are the Cytotec tablets, when it's seven o'clock sharp, you'll swallow two and you'll introduce two in the vagina. When it's eight o'clock, you'll do the same thing. When it's nine o'clock, you'll do the same. Then at ten o'clock, it's the last time. " (Soafy, age 17)*

The routes of administration and the number of tablets the women used were equally incorrect no matter where they got the advice or the pills from. Not one of the women used a dosage or regimen that came close to those advised in the WHO *Clinical Practice Handbook for Safe Abortion*, 2014 [10]. Their misoprostol use reflected both their uncertainty about how to use it and a leap of faith that it would work, as the following quote illustrates:

*"My friend said there is a medicine that can be taken. I did not know at that time what it was: 'There is a medicine you can take. Why not buy that, look for it and take it.' My husband was not my husband at*

*the time, but he was my boyfriend. We had to make quite an effort, first to look for this medicine, and then to borrow money from several different people to be able to buy it."*

*"What is this medicine that you took?"*

*"Hmm, hmm ..., its name was Cytotec, I did not even know what the instructions were for using it but that was what we looked for."*

*"When you had the Cytotec, how did you use it?"*

*"As I have said, all we knew was to take the necessary steps to get this medicine and take it. They were little pills. We decided I would take some pills every two hours. We did not know how much I should take altogether. But first I took four, then three more and then two more until the package was empty." (Tantely, age 40)*

### **3.3 The women's abortion outcomes**

The 19 women experienced the following complications: heavy bleeding, which some of the women described as hemorrhage (18 women), accompanied or not by strong pains, no fetal expulsion (7) or incomplete abortion (12), and infection in two women. Heavy bleeding is a normal part of an abortion with misoprostol, but most of these women did not know what to expect during the process, some of them might have interpreted heavy bleeding as a complication. All the women reported that they received treatment from a healthcare professional for their complications, whether in a private clinic (9), a public health center (2), or a public hospital (8). The most immediately obvious complication was prolonged and heavy bleeding, as the following recollection illustrates graphically:

*"Blood was flowing, blood was flowing, blood was flowing. By day five, day six, it had increased instead of stopping gradually. It had increased, it had increased, it had increased. Let's say that for about a month, I continued bleeding and in the end, I had an intense hemorrhage and suddenly I was hospitalized and cleaning [curettage] was inevitable. The reason for the bleeding was that there was something left inside me. (...)"*

*"Did you know in advance that abortion could have complications?"*

*"No, I did not know at all." (Lina, age 28)*

Although many women had wanted to conceal their abortions from their families, the women turned to their partners and/or family first when they experienced worrying complications (e.g pain and abundant bleeding). The partner or family member(s) were the ones who made the decision to take the woman to a healthcare provider, and they paid for the costs involved.

In addition to the price of the misoprostol, the fees of the professionals who the women consulted for treatment of complications varied from 40,000–170,000 Ar (\$12.41 to \$52.73)<sup>1</sup> depending on the position of the consulted professional, the methods and/or treatment provided, and the length of the pregnancy. One of the women interviewed had had three abortions with the same midwife. She paid 60,000 Ar (\$18.61) for the first one (3<sup>rd</sup> month of pregnancy), 40,000 Ar (\$12.41) for the second (2<sup>nd</sup> month of pregnancy) and 20,000 Ar (\$6.20) for the third (1<sup>st</sup> month of pregnancy). The amounts paid to traditional birth attendants were much lower – 1,200–2,000 Ar (\$0.37–0.62).

When they attended for complications, once again, the women were uncertain about what kind of treatment they received. In one case, the woman knew only that the medication was to stop the bleeding. Those who did know the names of at least some of the treatments they received mentioned curettage, the use of a probe, antibiotics, pain killers, and blood transfusion.

One woman, Stella, who was three months' pregnant when she used misoprostol, went to a neighbor, who was a nurse, for help. He prescribed 7 tablets of Cytotec (one tablet to be taken every 30 minutes orally). After taking the Cytotec, she said she had severe bleeding for a week. She went back to him and "he treated her". She paid him 20,000 Ar (\$6.20) for the Cytotec and gave him 10,000 Ar (\$3.10) as a gift as well. Indeed, several of the women gave gifts of money to the health professionals whom they knew personally who treated them.

Lastly, it is important to note that the women expressed astonishment in the interviews that they had experienced method failure and complications with misoprostol, which demonstrates not only how much confidence they had in the efficacy of misoprostol to cause an abortion, but also how little they

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<sup>1</sup> At the time of the study, US\$ 1 = 3,224 Ariary.

and the healthcare providers they consulted actually knew about how to use misoprostol safely and effectively. This is perhaps not surprising given the failure of the state or the health system to take any responsibility for abortion. Yet the women painted a picture of the healthcare professionals who advised and treated them as showing great willingness to help them when they were in trouble, both before their attempted abortion and when they consulted them with complications.

#### 4. Discussion

The findings reported in this paper are limited by being a purposive study of complications associated with misoprostol. We did not seek to study and therefore are not able to comment on successful use of misoprostol in Madagascar, nor on the prevalence of incorrect use. Nevertheless, it is reasonable to assume that a significant number of women may be accessing misoprostol without adequate knowledge and information. Important lessons can therefore be drawn from this study.

Self-medication is common for many reasons in Madagascar (not least because it costs less than a medical consultation and also empowers the individual), but with abortion it is primarily because of the illegality of abortion [11–13]. Knowledge of the use of misoprostol for abortion has spread to all world regions since the 1990s [14–16], and this includes Madagascar. In this study, women had learned about the abortifacient properties of misoprostol, and this indicates some level of popular knowledge of the ‘abortion pill’. The women’s accounts suggest that this knowledge is circulating mainly by word of mouth through social networks and via healthcare providers, including its abortifacient effects and where it can be purchased. Misoprostol was easy to find for the women we interviewed, with or without a prescription, even in remote areas, through both formal and informal drug distribution points. And even though the experiences of the 19 women in this study turned out to be far from straightforward, misoprostol was still seen as being easy to use, including with self-administration.

Importantly, however, our results strongly suggest a widespread lack of information regarding the correct use of misoprostol for abortion in Madagascar, among both women and healthcare professionals, as well as among traditional birth attendants. We found important differences in the advice women received on how many pills to take/use, as well as the frequency of use and routes of administration. None of the 19 women received correct advice. The gestational age of the

pregnancies for which misoprostol was used also varied and ranged from a few weeks to five months, but almost all were below 12 weeks. Moreover, there was no awareness that in the second trimester, the dosage and regimens should change. Instead, we found women with incomplete abortions and serious complications, particularly heavy bleeding and in a few cases, infection, due almost entirely to the lack of this very knowledge.

The health care professionals and traditional birth attendants who attended women who came to them with complications demonstrated their willingness to provide help when it was needed. But the practice of abortion and the treatment of post-abortion complications can also be lucrative in a context where most people are low paid and where there is no institutional oversight. The range of charges paid, as described by the 19 women, was very wide, and the types of treatment provided were not always of the best or recommended.

## **5. Conclusions**

In conclusion, the results of this study highlight the need to disseminate information to both healthcare providers and to women regarding the safe and effective use of misoprostol at different stages of pregnancy, and when clinic use should replace home use. Information on the risks associated with incorrect and ineffective use should also be widely communicated to healthcare providers and women, as well as information on what is best to do in the event of complications.

The wide range of doses reported, none of which matched WHO guidelines, is a key finding in this study. Use of misoprostol without information on correct use may not be as unsafe as traditional and invasive methods of abortion, but the women we interviewed were still experiencing serious complications and required urgent treatment post-abortion. The objective of this qualitative study was not to measure the prevalence of the problems we uncovered, but we hope this study will lead to larger studies that are able to do so.

Healthcare providers whom women consult for abortion care and for treatment of abortion complications need training in correct misoprostol use and how to treat post-abortion complications.

Law and policy reform are also needed to support such training and to ensure the provision of safe abortion services in the public health system.

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