# Reproductive Health Governance: Availability and Professional Use of Misoprostol in Benin and Burkina Faso

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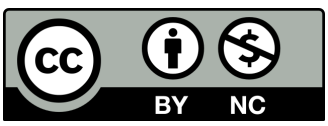

## Abstract

Misoprostol is effective not only for gastroenterology indications but also for reproductive health-related conditions and for the reduction of maternal mortality. The use of misoprostol is well documented in Latin America, where it is widely used for abortions. However, scant knowledge exists regarding its use in African contexts. In this study, we describe and analyse the conditions of the professional use of misoprostol in Benin and Burkina Faso. We ask the following questions: How accepted is misoprostol in Benin and Burkina Faso? What was the process leading to the official recognition of misoprostol in both countries? Which actors were involved in this process? How do health care workers perceive and use misoprostol in the context of care? Theoretically, we use the concepts 'social life of medicine' and 'reproductive governance' to analyse the position of misoprostol within the broader system of health policy, as well as its professional usage within the health care system. The fieldwork conducted in Benin and Burkina Faso highlights the conditions of the institutional acceptability of the drug and the logics underlying the use and non-use of misoprostol by health workers in both countries. The article highlights the social life of misoprostol by showing how the governance surrounding its use contributes to the development and cultivation of suspicions towards the drug among health care providers and institutional actors – suspicions that consequently restrict the availability of misoprostol as a medical therapeutic option.

**Keywords:** Abortion, Benin, Burkina Faso, health care providers, misoprostol, policy, suspicion

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**Conflicts of interest**

The authors declare no conflicts of interest.

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## Introduction

This article analyses the introduction and institutional and professional use and nonuse of the medicinal drug misoprostol[1] in maternity health care in Benin and Burkina Faso. The drug is used globally for various health conditions. It is a synthetic prostaglandin (a natural hormone in the human body) that was initially developed to prevent gastric ulcers. Because of the uterotonic properties of prostaglandins, misoprostol has also been used off-label for labour induction (Margulies et al. 1992), the prevention and treatment of postpartum haemorrhage (Raghavan et al. 2012), the treatment of complications associated with incomplete abortion (Ngoc et al. 2013), and medical abortions (Winikoff and Sheldon 2012). For medical abortion, misoprostol may be used either alone (Olavarrieta et al. 2012) or in combination with mifepristone (Blum et al. 2012).

In countries where abortion is illegal or where the laws are very restrictive, medical abortion, over time, has become the main method of abortion. The procedure is performed informally either by health care professionals or by women themselves, who buy the drugs at pharmacies, at markets, or on the internet. Misoprostol started being used for medical abortion purposes in the mid-1980s in countries where abortion was illegal or poorly accessible; it has gradually replaced traditional methods that endanger the life and health of women, such as the use of plants, chemicals, blunt objects, and overdoses of pharmaceutical products. Brazil has been at the forefront of women's use of misoprostol for abortion. First marketed in 1986 under the commercial name of Cytotec®, misoprostol sales have grown significantly since then (Coêlho et al. 1993). In the late 1980s, the informal use of misoprostol spread to other Latin American countries where the law restricts access to abortion (Zamberlin et al. 2012). Currently, misoprostol is also used in some Asian countries with restrictive abortive legislation, such as the Philippines, Saudi Arabia, and Bangladesh (Gipson et al.2011; Alsibiani 2014; Huda et al. 2014).

The widespread use of misoprostol has been associated with a significant decline in maternal mortality in countries with restrictive abortion laws because of the relatively safe illegal abortion that the drug allows (Harper et al. 2007; Shah and Åhman 2010). In this vein, it has been hailed as a revolution within maternal healthcare because of its role in reducing maternal mortality from postpartum haemorrhage and unsafe abortion (Potts 2006). Early on, the drug, which was being used informally and off-script, received support from international and national non-governmental organizations (NGOs), which advocated for the official use of the drug in reproductive and obstetric care. Through scientific studies, these NGOs provided information and management protocols that helped policymakers gain confidence in the potential of misoprostol to save lives (MacDonald 2021). In 2005, the World Health Organization (WHO) recognized misoprostol as a lifesaving drug by including it in the list of essential medicines. At the same time, they recognized the controversial nature of the use of misoprostol to induce abortion by recommending this usage only "where permitted under national law and where culturally acceptable" (World Health Organization 2012).

Despite the potential to prevent death from postpartum haemorrhage and unsafe abortion, misoprostol's association with clandestine abortion and the suspicion of its misuse by unauthorized providers have made it a

[1] Misoprostol is the international non-proprietary name (INN) for a pharmaceutical substance available as various brand-name drugs (such as Cytotec®, Misoclear®, and Ace Miso®) that are manufactured by different pharmaceutical companies. Cytotec® is the original misoprostol manufactured by the pharmaceutical firm Searle (later acquired by the US firm Pfizer). The medication package insert available in African countries describes indications for gastric ulcers only. Recently, Indian firms have started to produce Misoclear® and Ace Miso®, and their package inserts list indications for gynaecology-obstetrics.

marginal and suspect drug in the development of maternal and reproductive health policies (MacDonald 2021). While public health actors and advocates argue that the availability and accessibility of misoprostol is a critical component in reducing maternal deaths in sub-Saharan Africa (Fernandez et al. 2009), the widespread introduction of misoprostol into countries' health systems has been challenged by policy makers in several countries because of the drug's social history (Starrs and Winikoff 2012).

In this article, which builds on fieldwork in Cotonou, Benin and Ouagadougou, Burkina Faso between 2014 and 2016, we focus on the place of misoprostol place within the medical landscapes of the two countries. Both countries have a high rate of maternal mortality: 397 per 100,000 in Benin and 341 per 100,000 in Burkina Faso (INSD and ICF International 2012; Institut National de la Statistique et de l'Analyse Économique 2013). The cultural environments in Benin and Burkina Faso are similar, and the practice of abortion, as in many societies (Boltanski 2004), is subject to strong social disapproval in both countries. It is a very intimate experience that is shrouded in silence and not discussed in public (Rossier 2006). Abortion was, at the time of our study, legally restricted and socially condemned in both countries.[2] Since the French law of 1920 that prohibited the practice of abortion and promotion of contraceptive methods, laws have been relaxed (in 1986 in Burkina Faso and in 2003 in Benin), and abortion is now allowed in both countries, but solely to preserve the health and life of women in cases of rape, incest, and foetal malformations. For example, in Burkina Faso, the regulations that enable women to terminate a pregnancy are complicated and difficult to satisfy. Two physicians must certify that carrying the pregnancy to term would be harmful before an abortion may be performed as a therapeutic procedure. Because of the scarcity of doctors in rural regions, this is an insurmountable challenge for many women. Legal abortion cannot be provided in situations of rape or incest unless there is proof that the crime was committed. When victims face substantial stigmatization risks, these criteria seem to be particularly daunting and discouraging. Women's understanding of the legal status of abortion is also low: one-third of Burkina Faso's women do not know that abortion is permitted in certain instances (Bankole et al. 2013).

Despite discursive social disapproval and restrictive legislative frameworks, the practice of abortion is common but often concealed (Guillaume et al.2018), and studies indicate that the proportion of deaths due to abortions is substantial. A survey conducted at four hospitals in 2006 in Benin showed that 14.6% of maternal deaths were due to unsafe abortions; in Burkina Faso in the same year, the Ministry of Health estimated that this proportion reached 10% (Saizonou et al. 2006). In both countries, medical abortions are rare, whether legal or illegal. A study in Burkina Faso showed that curettage and manual vacuum aspiration[3] (MVA) (a procedure that uses a vacuum to remove uterine contents), as well as 'traditional' methods that are not supervised by biomedical professionals, are the most commonly used methods (Bankole et al. 2013). At the same time, misoprostol is legally used for incomplete treatment in both Benin and Burkina Faso and clinical studies in the two countries have shown its therapeutic efficacy in this regard (Adisso et al. 2014; Thieba et al. 2012).

In both countries, the contraceptive prevalence among women is low (regardless

[2] The law on abortion in Benin evolved several years after our field research. Abortion on demand up to 12 weeks of gestation has been allowed since October 2021 (https://www.gouv.bj/actualite/1518/encadrement-avortement-benin-parlement-adopte-modificative/).

[3] MVA was introduced in Burkina Faso in 1994 with the implementation of post-abortion care through the joint action of national obstetrician-gynaecologist organizations and international NGOs.

of marital status): 14% in Benin in 2011–2012 and 15% in Burkina in 2010 for all methods, and only 9% and 14% for 'modern' methods, respectively (Institut National de la Statistique et de l'Analyse Économique 2013; INSD and ICF International 2012). A recent qualitative study conducted in Benin (Baxerres et al. 2018a) highlighted that of 21 women interviewed who recently gave birth in Cotonou, only 9 had planned and desired pregnancies. Seven of them did not want to be pregnant and were unhappy about it. In Burkina Faso, one-third of all pregnancies were described as unintended, and one-third of these pregnancies resulted in abortion (Bankole et al. 2013).

A gap exists in the literature regarding the institutional process through which misoprostol was introduced in Burkina Faso and Benin, as well as how misoprostol is perceived and used by health professionals.[4] The aim of this article is to analyse the introduction and institutional and professional use and non-use of misoprostol in Benin and Burkina Faso and to show how the use of the drug is shaped by the different meanings attached to it. The meanings and uses, including professional uses, ascribed to medicinal drugs are shaped by social norms and political agendas (Julia Epstein 1995). The acceptance or rejection of a particular medicine is influenced by how its uses are governed by care policies, norms, and standards, and how it is perceived in society. Therefore, to appreciate the issues raised by the different uses of a medicine, institutional logics and national and global frameworks for public health policy development must be considered (Ridde and de Sardan 2012).

The article considers the anthropological perspective of the 'social life of medicine' and 'reproductive health governance' to explore the institutional and professional uses of misoprostol. The concept of the social life of medicine considers medicines as social and cultural objects that adopt different meanings in relation to different social relationships (Whyte et al. 2002). According to Whyte and colleagues (2002), the term 'social life' is a useful analytic tool to trace the path of material things as they move through different settings and are attributed different meanings. The theory allows us to follow and study medicines through different social contexts in which various actors (policymakers, care providers, sellers, and users) with diverse perceptions engage with them (Desclaux and Egrot 2015). This article highlights the social life of misoprostol by focusing on different care settings where institutional and social norms influence how healthcare providers manage the drug.

Additionally, the notion of reproductive health governance is used as a framework to understand how political orientations and institutional norms related to the use of misoprostol influence the practices of healthcare providers. Reproductive health governance refers to the mechanisms through which different historical configurations of actors – such as state, religious, and international financial institutions, NGOs, and social movements – use legislative controls, economic inducements, moral injunctions, direct coercion, and ethical incitements to produce, monitor, and control reproductive behaviours and population practices (Morgan and Roberts 2012, 243). Reproductive health governance is often enacted from above – delivered in laws, policies, and state programs (El Kotni and Singer 2019). Various laws, regulations and policies seek to regulate women's reproductive lives. In this article, we highlight how the reproductive health governance in both Burkina Faso and Benin at the time of our study, through social and legal condemnation, has contributed to aggravating suspicions towards misoprostol as a drug that can potentially be used to terminate pregnancies, as well as reinforcing a view on abortion as moral deviance. Simultaneously, another form of reproductive governance promoted the use of misoprostol,

[4] Members of our research team published two articles on the popular use of misoprostol in Benin and Burkina Faso (Baxerres et al. 2018a, 2018b).

as NGOs advocate for the use and availability of misoprostol in healthcare settings for therapeutic indications recognized by law.

Through the theoretical framework of the social life of medicine and reproductive health governance, this article describes and analyses the process of officially listing misoprostol on the national essential medicines list (for specific indications) in Benin and Burkina Faso, as well as the process of importing and making the drug officially available. We also explore the perceptions underlying the use and non-use of misoprostol among healthcare workers in Benin and Burkina Faso. The article highlights how misoprostol is subjected to reproductive health governance, in which interactions and exchanges between actors with different roles and statuses define its norms of use. At the heart of complex health systems, its multiple uses incite institutional actors and health professionals to intervene to prohibit or promote it according to the professional, social, or moral values that drive them. We highlight how, at the time of our study, the effects of different forms of reproductive health governance gave misoprostol a complex social life, opening up avenues for suspicion and reservations around its use.

## Methods

We conducted fieldwork in Cotonou, the economic capital of Benin and Ouagadougou, the capital of Burkina Faso, between 2014 and 2016.[5] We collected data through a review of policy documents and in-depth interviews on abortion, post-abortion care, the distribution and professional use of misoprostol, and observations during visits to care settings.

To understand the institutional rationale for misoprostol use, we conducted in-depth interviews with high-level stakeholders working at the Ministries of Health of Benin and Burkina Faso. We conducted 14 and 15 interviews in Cotonou and Ouagadougou, respectively, with technical managers and staff of the Ministries of Health, programme directors of international and local NGOs, and directors of local organizations.

To understand the professional use of misoprostol, we conducted interviews with healthcare workers with various professional statuses: obstetrician-gynaecologists and assistant obstetrician-gynaecologists, midwives (both female and male), and nurses. These healthcare workers were working at different levels of the healthcare pyramid, as well as in both public and private healthcare facilities. We conducted this research in Ouagadougou from mid-October to mid-December 2014, with 22 interviews completed. In Cotonou, the research was carried out in September 2015 and January 2016 and included 25 participants. During visits to health centres, we scrutinized the information related to abortion care or family planning contained in posters displayed in healthcare facilities. We also observed the reactions and attitudes of our interlocutors when misoprostol was mentioned. Suspicions about misoprostol made fieldwork relationships and data collection more challenging at times.

## Inclusion of Misoprostol in the Essential Medicine Lists of Benin and Burkina Faso

The national recognition of a drug in Benin and Burkina Faso, as in any other countries, involves its inclusion in the national list of essential medicines: this registration conditions the availability of a drug within health services and specifies its permitted indications. Essential medicine lists are regularly updated, and this process involves different actors, including health care workers, Ministry of Health administrators, and representatives of national and international organizations and NGOs. The Maternal and Child Health Directorate and the Pharmaceutical Drugs Directorate are essential services for the recognition and

[5] We obtained ethical approval for this study from the Ethical Committee of Burkina Faso and Benin.

acceptance of misoprostol within the health system of the two countries.

Officially, the revision of essential medicine lists should involve a series of meetings that bring together the different actors mentioned above over several months. In Benin and Burkina Faso, according to the people we interviewed, the approval of misoprostol by the national authorities through its inclusion on the national essential medicines list was a problematic process. No consensus was initially achieved on the issue. Some actors involved in health policy development believed that including misoprostol in the essential medicines list would de facto drive healthcare workers and women to use it for voluntary abortions in contexts where this practice is disapproved of, both socially and legally; this point of view was explicitly shared by key actors within the Ministries of Health (the Maternal and Child Health Directorate and Pharmaceutical Drugs Directorate). By contrast, other stakeholders considered that the official recognition of misoprostol by national authorities would contribute to the prevention and treatment of postpartum haemorrhage and would improve post-abortion care, reducing maternal mortality; it was mainly the directors of local organizations and international NGOs who expressed this opinion. In this context, official meetings did not seem appropriate to build a consensus dialogue between national and international political actors. Therefore, more private and discreet meetings were considered necessary.

In Benin, the Beninese Association for Social Marketing and Communication for Health/Population Services International (ABMS/PSI) [6] led lobbying activities at the Ministry of Health level in favour of the use of misoprostol. Other NGOs, such as the Benin Family Planning Association (ABPF) and IPAS[7], also participated in the discussions with the Ministry of Health, advocating for an official recognition of misoprostol as an oxytocic for reproductive health. In 2011–2012, ABMS/PSI officials contacted gynaecologists and officials of the Maternal and Child Health Directorate and presented them with a series of facts that required the government to commit to authorizing the use of misoprostol in public care facilities. These facts were as follows: 1) many abortions were performed using misoprostol, 2) misoprostol was available on the black market, and 3) fake misoprostol was sold on the black market. During the course of an interview, a Beninese clinician explained that misoprostol became available on the black market in Benin because of the strict conditions for obtaining it in private pharmacies:

> (...) in hospital settings, there were so many... restrictions... to control its use (...), misoprostol was dispensed exclusively with a prescription (...). How it has been used to induce abortions... in popular use (...) reached the Ministry of Health, and specifically the Directorate of

[6] The Beninese Association for Social Marketing and Communication for Health (ABMS), created in 1994, is a Beninese NGO and a member of the Population Services International (PSI) network. PSI is an American NGO present in 65 countries in Africa, Eastern Europe, South America, and Asia. Established in Benin in 1992, PSI aims to support the Beninese government in improving population health: http://www.abmsbj.org/index.php/qui-sommes-nous/presentation (accessed 5/9/2018).

[7] International Pregnancy Advisory Services (IPAS) is an American NGO created in 1973 that defines itself as a non-profit organization working towards improving women's ability to exercise their sexual and reproductive rights: http://www.ipas.org/ (accessed 19/09/2020). IPAS supports the promotion of manual vacuum aspiration (MVA), a technique used for post-abortion care and an alternative to curettage. IPAS is a manufacturer of MVA kits. In Benin and Burkina Faso, IPAS collaborated closely with the Ministry of Health for post-abortion care for abortions initiated using the MVA technique. However, according to the healthcare workers we interviewed, IPAS 'brutally' interrupted its activities in Benin. This action probably explains why IPAS played only a more distant role in the introduction of misoprostol in Benin. In Burkina Faso, after the introduction phase of MVA, the NGO's activities also seemed to decrease.

> Medicines, which assessed the situation, in fact they are the regulators of everything related to medical prescriptions, and they issued a memo... compelling pharmacists to dispense the drug only with a medical prescription... which specifies the doctor's address, his phone number, so from that time... it has become a little controlled (...). In addition, in fact, with the restrictions imposed by the Ministry of Health, that's when the other thing appeared, the market thing. Then, obviously, the parallel market... the black market realized that there was a strong demand for this drug, and it started to become available, because before, it was very difficult to find misoprostol, even for doctors like us, it was very difficult to get any (...) and then suddenly, when we needed it, I asked someone who said no, I can find you a box of 60, I was surprised, and actually the next day, she brought back the box of 60, which I paid for. I asked her, "But hey tell me, where did you buy that?" And from there, she explained to me that there was a parallel circuit through the black market and that it led to Nigeria... (Obstetrician-gynaecologist, Cotonou).

In Benin, discussions with the ministry officials in charge of including drugs on the essential medicines list involved the Maternal and Child Health Directorate directors and directors in charge of the department responsible for pharmaceutical drug management. The latter were very reluctant to recognize misoprostol as an essential medicine. Around the same period, a guidebook on post-abortion care and another on medical abortion were developed by obstetrician-gynaecologists from the Maternal and Child Health Directorate and with financial support from ABMS/PSI. These guidelines were used to convince actors in the department in charge of pharmaceutical drug management.

Misoprostol was listed on Benin's essential medicines list in November 2013 to treat postpartum haemorrhage and for post-abortion care. The uses of misoprostol were described in a national list of essential medicines[8] that specifies the facilities in which it can be used, indications for its use, categories of healthcare workers who can prescribe it and use it, and the conditions under which they can use it. In the Beninese essential medicines list, Cytotec® is listed (p. 56) in the Beninese essential medicines instead of misoprostol, as would normally be the case. Several other products that were mentioned by our interviewees during the research, such as Misoclear® and Ace Miso®, are not included in this list. Drugs are given trade names largely for business reasons. They are simple to remember or recognize and help differentiate the product from direct rivals who offer it under a different brand. Additionally, they enable parallel marketing channels and conceal the true nature of the product to avoid opposition (Tulkens 2006).

In Burkina Faso, negotiations with the Ministry of Health were also led by an NGO. Family Care International (FCI)[9] coordinated the lobbying for the official recognition of misoprostol in reproductive health in consultation with Marie Stopes International (MSI)[10], Ipas,

[8] *National List of Essential Medicines (Children and Adults)*, Department of Pharmacy, Medicines, and Diagnostics, Benin Ministry of Health and World Health Organization, November 2013.

[9] The American NGO Family Care International (FCI) was created in 1987. It works mainly towards the promotion of mother and child health, as well as youth health.

[10] The NGO Marie Stopes International (MSI), founded in 1976 and based in several African countries, promotes sexual and reproductive health, in particular providing counselling on contraception, vasectomy, and safe abortion in countries where these practices are legal. MSI provides services in urban and peri-urban clinics. Marketing managers and market researchers are involved in

Jhpiego[11], and the Burkinabè Association for Family Welfare (ABBEF).[12] These NGOs had several types of interactions with obstetrician-gynaecologists, as well as with the Maternal and Child Health Directorate and officials from the department in charge of pharmaceutical drug management. Again, the latter were the most reluctant for the government to recognize the use of misoprostol for reproductive healthcare, particularly for post-abortion care. For the treatment of postpartum haemorrhage and post-abortion care, misoprostol was listed on Burkina Faso's essential medicines list in December 2014.

In both countries, discreet and regular discussions occurred between the different actors over nearly two years leading up to the recognition of misoprostol for specific indications in obstetrics and gynaecology, according to our informants. A community leader in Ouagadougou recalled this long and cautious advocacy process:

> It was a process of negotiation and advocacy with the authorities... through individual meetings or group meetings... uh... we also approached some people individually... at the ministry level, the secretary general was approached individually... the current minister (...). The DSF (Director of Family Health) ... gynaecologists who also supported us (...) because hey, we needed to test the waters, you see in matters of advocacy, it is really important to know one's targets well, (...), their possible reactions... their opinions on these things (...), those known and not known…, how to approach them? (...) How to present the issue or the subject so that, well, it does not upset the... the sensitivities of people, that's it! We have focused on... the health aspect, the fight against maternal and child mortality and then, here you go! People have accepted. But in any case, all those who contributed, they have always put forward the question of the fight against maternal and infant mortality. (...) It is not because there can be a misuse of the product, that we will let women die! (...) We told them that! (Community leader, Ouagadougou).

This section on how misoprostol became integrated into the list of essential medicines in Benin and Burkina Faso shows the complexity of health policies and their construction through human actions (Gilson et al. 2011). Debates concerning the recognition and acceptance of misoprostol in national public health policies show that pharmaceuticals are continually engaged in "human and nonhuman processes and practices that define their place and role in a care system" (Hardon and Sanabria 2017). To this end, the article shows how reproductive health activists, through international and local organizations and their lobbying, succeeded in finding arguments in both public health and human rights to convince the national health authorities of the two countries to accept misoprostol as a life-saving drug.

the definition of its promotion strategies. MSI representatives reported that they aimed to 'complement' government health services by positioning themselves as a 'quality' provider. MSI came to Burkina Faso in 2009.

[11] Jhpiego is an American international NGO founded in 1973 dedicated to improving the health of women and families in developing countries.

[12] The Burkinabè Association for Family Welfare (ABBEF) is a member of the International Planned Parenthood Federation (IPPF), a network of 151 associations created in 1952 to federate the fight for sexual and reproductive rights. It is a pioneer in the field of family planning in Burkina Faso. This organization provides a range of sexual and reproductive health services, including family planning, pregnancy testing, screening and testing for sexually transmitted infections, infertility prevention and treatment, cervical and breast cancer screening, and post-abortion care. In Burkina Faso, the government recognized the ABBEF as a public utility organization in 1995.

## Obtaining Marketing Authorization for Misoprostol Brands

The listings of misoprostol for the treatment of postpartum haemorrhage and post-abortion care on Benin's essential medicines list in November 2013 and on Burkina Faso's list in December 2014 have contributed to the availability of the drug in health facilities in both countries. The availability of a drug in a health system is also facilitated by marketing authorizations and is the assessment process that allows a drug to be brought into a country for use in relation to specific therapeutic indications. The authorization is finalized by the granting of a sales licence by a national drug management committee. In Benin and Burkina Faso, granting authorization is the responsibility of the department in charge of pharmaceutical drug management, which works under the supervision of the Ministry of Health. A representative of a pharmaceutical firm, a distributor, or even a firm itself can apply for authorization.

In both Benin and Burkina Faso, at the time of our study, the only marketing authorizations available (although outdated) for Cytotec® concerned gastric ulcers. For a long time, despite the evidence on the various benefits of Cytotec® in obstetrics and gynaecology, its marketing authorization only indicated its use for gastric ulcers. The need to make misoprostol available availability of misoprostol and its use in obstetrics and gynaecology required administrative arrangements for the import of the drug into Benin and Burkina Faso. For some years, international organizations imported Misoclear® and Ace Miso® through short-term import authorizations. They distributed the drugs to NGO clinics or obstetrician-gynaecologists practising in university hospitals, the latter being authorized to use misoprostol as autonomous entities also responsible for conducting research. Notably, the package inserts of these Indian brands explicitly describe indications for their use in obstetrics and gynaecology.

From the time misoprostol was listed on the national essential medicines list to when it was granted marketing authorization with indications in obstetrics and gynaecology took two years in Burkina Faso and four years in Benin. In 2016, the MSI association in Burkina Faso obtained a national marketing authorization for Misoclear®. In 2017, in Benin, PSI obtained marketing authorization for Ace Miso®, and DKT International obtained marketing authorization for MisoFem®.

Misoprostol's marketing authorization was the outcome of a carefully monitored process involving various individuals and organizations, as shown by our findings. The time it takes to gain marketing authorization for misoprostol also varies by nation, as shown by the situations in Benin and Burkina Faso. The development and registration of a medicine is a long and costly process (Russell et al. 2006), but misoprostol's role as an abortion-inducing drug undoubtedly prolonged the time it took to obtain an authorization.

## Between Miracle and 'Sin': The Professional (Non-)Use of Misoprostol

Our material shows that the terms of use of misoprostol involve three levels of restrictions. 1) There are different restrictions on therapeutic indications for accepted practices (post-abortion and postpartum haemorrhages), tolerated practices (labour induction), and prohibited practices (induced abortion not permitted by law). 2) There are restrictions based on the status and skill of the prescriber in the sense that caregivers are not authorized to use the drug of their own free will. Actions and responsibilities are delegated following a hierarchy of status from the doctor to the midwife and from the midwife to the assistant midwife. Additionally, only caregivers who have received training in the use of misoprostol are deemed 'competent' to prescribe it. 3) Finally, there are restrictions depending on the care facility, whether a hospital/district hospital or

a primary healthcare centre. For example, in Burkina Faso, a midwife not trained in the use of misoprostol can administer misoprostol to a woman at a district hospital, while the same action is officially prohibited in a primary healthcare centre. According to caregivers, the reason for these requirements is to prevent the misuse of misoprostol by 'incompetent' caregivers or to avoid 'deviant' caregivers using it for illegal abortions.

Gynaecologists, midwives, and auxiliary midwives use misoprostol in health facilities in the public and private sectors in both Benin and Burkina Faso. However, their use follows certain regulations, according to the healthcare providers we interviewed. Gynaecologists are healthcare providers authorized to prescribe and order the use of misoprostol. In hospitals and district hospitals, midwives use misoprostol under the direction of a gynaecologist for the treatment of incomplete abortions and the management of postpartum haemorrhages. Furthermore, in Burkina Faso, hospitals and district hospitals have post-abortion care units managed entirely by midwives, who can use misoprostol without the advice of a medical doctor. Regarding primary healthcare in both countries, only midwives specially trained in the use of misoprostol are authorized to prescribe it without the advice of a doctor. Assistant midwives, who in exceptional cases use misoprostol in primary healthcare centres, do so under the supervision of a midwife trained to use this drug.

The healthcare workers interviewed (professional and assistant obstetrician-gynaecologists, nurses, female and male midwives, and assistant midwives) all emphasized the plurality of the therapeutic functions of misoprostol. Their perceptions of the drug were based on their social experiences and therapeutic incidents they had encountered during their professional careers. In these contexts, where reproductive health policies alternate between promotion, restriction, and prohibition, the uses of misoprostol by these healthcare workers in different contexts of care delivery and for different indications provide insights into the governance to which the drug is subject within society (Winikoff and Sheldon 2012).

In practice, legal abortion is very difficult to obtain for most women because of technical requirements and social context (the numbers of physicians required to offer abortion services, the need for a diagnosis to prove the need to obtain legal abortion, underreporting of rape). Additionally, some women are not informed about the legality of abortion under certain circumstances (Bankole et al. 2013). The few cases of legal abortions that we found in post-abortion care records were registered as therapeutic abortions. For example, in Burkina Faso, three cases of abortion triggered by the post-abortion care manager at a university hospital were due to a clear egg. However, according to healthcare workers in Benin and Burkina Faso, misoprostol is used by professionals as well as by women themselves for both legal and illegal abortions. In urban areas, private or clinic-based doctors or other healthcare providers, such as midwives and auxiliary midwives, often perform abortions illegally by using manual vacuum aspiration or misoprostol (Drabo 2022). In Burkina Faso, it is a common practice among some healthcare providers to divert misoprostol for illegal abortion after buying it from pharmacies or using tablets left over from other patients' treatments (Drabo 2022). In both countries, women access misoprostol unofficially through health workers and drug vendors (Baxerres et al. 2018). Despite regulatory frameworks, our fieldwork confirms that misoprostol can be purchased informally in both Benin and Burkina Faso.

The value of misoprostol for post-abortion care and medical abortions was unanimously recognized by healthcare workers; they argued that its use not only prevents intrusive manipulation of the female reproductive system, which may have side effects for women, but also reduces costs and waiting times in healthcare facilities. This recognition is evidenced by the following comments from

two gynaecologists in Benin and Burkina Faso:

> Thanks to misoprostol, women avoid intrauterine manipulations because we know that sometimes, despite the professional skills of the doctor, these manipulations can lead to complications such as uterine tears. However, with misoprostol, everything happens without any manoeuvre, without trauma, and the result in the end is perfect. (Gynaecologist, private clinic, Cotonou)

> I am in favour of that [misoprostol] because it reduces the delays in the provision of care; secondly, the woman can go to outpatient services for care, which follows very detailed recommendations. (Gynaecologist, public health centre, Ouagadougou)

Regarding the use of misoprostol for voluntary abortions (from a more liberal perspective with reference to the current legalization of abortion), healthcare workers were divided in their opinions between those in favour and those not in favour of its use. Healthcare workers who argued against the use of misoprostol to interrupt pregnancies justified their position based on religious and moral considerations. They also referred to the law that regulates abortion in their country and the potential consequences of legalizing abortion in underperforming health contexts.

> Now, I am not in favour. Let me explain. If you legalize abortion, you have to be sure that abortion centres will be available, with qualified personnel to offer the service, and this is not guaranteed. Secondly, it is important to define proper frameworks for abortion in terms of the legal age limit for abortion, the therapeutic itinerary for abortion, and its quality. Because when we see how it goes elsewhere, we do not casually conduct an abortion. This is not an ordinary act... Is it reasonable to say that we have coverage of the whole territory for that? I am not sure, so even if we legalized abortion, it would only be a façade, because in fact, women would always go for unsafe abortions because we do not have the minimum requirements such as a technical platform for all regions... (Gynaecologist, public health centre, Ouagadougou).

Healthcare workers who were in favour of using misoprostol for induced abortions emphasized the impact of unsafe abortion on the health and lives of women. They believed it better to offer voluntary abortion to a woman and then follow her up, providing her with psychological support, counselling, and contraception, rather than to let her have an illegal abortion, which could lead to complications. In contrast to some healthcare workers who considered misoprostol to be a dangerous medicine because of the risks associated with its inappropriate use and its facilitation of abortions, which are morally condemned, other healthcare workers called misoprostol a 'providential drug'.

> Misoprostol is not a dangerous thing; for me it is rather a providential drug because more than any other medicine, it has multiple uses. In addition, it applies to everything in obstetrics. So really, its contribution is huge; it has changed things a lot. Induction of labour has become an accessible thing, post-abortion care is quite simple, we can do medical abortions and we can reduce the risk of infections

> like that. (Gynaecologist, public hospital, Cotonou)

Regarding the use of misoprostol for indications other than abortion, we observed a strong consensus among healthcare workers on its use for postpartum haemorrhage and post-abortion care. Although misoprostol is effective in preventing and treating postpartum haemorrhage, certain healthcare workers believed that its use was riskier than that of oxytocin. Because misoprostol is administered mainly vaginally or rectally, it cannot be quickly discontinued in case of a dosage error, whereas oxytocin can be turned off any time because it is administered through intravenous injection.

Regarding the use of misoprostol for the induction of labour, we found differences between Burkina Faso and Benin. In Benin, a consensus was achieved regarding the value of the drug in induction. However, in Burkina Faso, the attitudes of healthcare workers ranged between tolerance to reluctance, and they believed that misoprostol should be used only if initiated, recommended, and followed up by a gynaecologist.

Professional, social, and moral references guided healthcare workers' perceptions of misoprostol. These perceptions varied from one healthcare worker to another, depending on which framework of reference they used. Beyond the locally available biomedical evidence on misoprostol (Thieba et al. 2012; Dao et al. 2009), healthcare workers conferred social properties to misoprostol, sometimes viewing it as 'dangerous' and other times as 'providential'. Healthcare workers' rhetoric concerning the professional uses of misoprostol did not only refer to its therapeutic benefits. Their rhetoric also emphasized the risks (social and medical) that the use of the drug could entail. Health workers' attitudes towards misoprostol show that the 'life' of a drug goes beyond its medical function because the meanings and uses attributed to it are variable depending on social norms and political agendas (Steven Epstein 1995). As acknowledged by Fainzang (2006), in reference to patients' attitudes towards medicines, social values play a critical role in healthcare workers' behaviours in relation to misoprostol. These attitudes contribute to and reinforce suspicions towards the drug, while at the same time it is hailed as a miracle drug.

## Suspicions Towards Misoprostol

In Benin and Burkina Faso, the misoprostol supply chain involves health workers, and drugstore vendors, and patients. As part of post-abortion care and the management of postpartum haemorrhage, health workers (gynaecologists or midwives in charge of post-abortion care services or maternity units) give patients or their relatives prescriptions to buy misoprostol. Once the drug is acquired, they return to the health centre for treatment or for instructions on how to use the tablets at home. In both countries, patients and their relatives buy misoprostol from official pharmacies or directly from certain health workers. In Benin, individuals were able to buy misoprostol from street drug vendors, which was not the case in Burkina Faso (Baxerres et al. 2018a).

The association of misoprostol with induced illegal abortions in both Benin and Burkina Faso has led to suspicions of the drug, leading to the implementation of extensive control and verification processes concerning its prescription and use. To avoid the use of misoprostol for purposes not recognized by law, in both countries, pharmacists require that a medical prescription for misoprostol bear the name of the prescriber and their telephone number so that they can contact them for verification. Caregivers described how they had to negotiate with the pharmacists and provide them with explanations to justify the prescriptions – a process evidenced by the following quote from a midwife in charge of post-abortion care services in Burkina Faso, who explained how she struggled to obtain misoprostol for post-abortion care delivery:

> I showed up with my ID card. They were too formal. I told them I was trained, I provide post-abortion care with that [misoprostol], I am a midwife. They replied that there are people who come like that to present themselves also with a card but... I told him, first, I am a Christian and what I will buy this to do. I need it only to save lives. This is how I got the drugs.

Health workers may feel compelled to use their religious affiliation or insist on the urgency of the request to justify their credibility or 'good faith' in the eyes of pharmacists, while pharmacists fear that healthcare providers use misoprostol to perform abortions. To control the usage of misoprostol, in some district hospitals in Burkina Faso and Benin, it is also recommended that when a midwife has used the drug, she records the procedure and records her name, date, and time so that the gynaecologist responsible for overseeing the delivery room can check the indications for which misoprostol has been used.

The suspicions concerning the usage of misoprostol also influence the relationship between health workers and patients. For example, it is common for some healthcare providers, both in Benin and Burkina Faso, to 'confiscate' the remaining unused tablets from women after post-abortion care or the management of postpartum haemorrhage because they fear that they may use the rest of the tablets to terminate pregnancies (Drabo 2022).

> Generally, we do not give them the rest of the medicine. We tell them, for example, after prescribing it, that we cannot let them (leave) with the rest of the product, as they can be used to cause abortion. In general, they understand… (Midwife in charge of primary healthcare in Ouagadougou, Burkina Faso)

When misoprostol is not confiscated, other practices included avoiding specifying the name of the product: "We don't tell them the name of the product; we tell them what we want to do..." Healthcare providers avoid giving detailed information (the name of the drug or the place where it can be purchased) about misoprostol to patients because they fear that this information could help the patient purchase the drug or try to access it for illegal purposes.

Furthermore, suspicions around the use of the drug have created a lack of trust that tends to influence professional and therapeutic relationships, which are often tinged with pejorative representations and stereotypes. Some gynaecologists accuse midwives of often diverting misoprostol for illegal abortions. In turn, some midwives in charge of post-abortion care also accuse auxiliary midwives of performing unlawful abortions, arguing that their access to misoprostol will strengthen their illegal activities. Some caregivers, who suspected their colleagues of providing illegal abortions, confided that they sometimes used misoprostol without the knowledge of certain colleagues they did not trust because they feared that knowledge about the drug would lead them down the wrong path:

> I personally do not use it because here we have more assistant midwives than midwives. Therefore, I do not use it to have more precautions because you are going to use it and someone else will see it and he will decide to use it and misuse it. (Midwife in charge of a primary healthcare centre in Ouagadougou, Burkina Faso)

Similarly, during our research at one primary healthcare centre in Ouagadougou, a midwife did not want us to interview the auxiliary midwives because she feared that

this would make them discover misoprostol and its ability to perform abortions. The close association of misoprostol with the tabooed topic of abortions has led to research on the topic becoming taboo as well, with suspicions potentially being directed towards researchers and the intentions behind their research. During our data collection at a healthcare centre that belongs to Catholic groups in Burkina Faso, just mentioning misoprostol during the presentation of our research caused reluctance in our interlocutor, who was one of the officials of this centre. He politely set up another meeting for us to follow up on our request. During the second meeting, the secretary of the health facility let us know that our request to speak with healthcare workers had been rejected because the centre did not perform abortions. This example demonstrates how the term misoprostol quickly conjures up images of induced and illicit abortions and raises suspicions about those who use or speak about the drug.

The social force of misoprostol is illustrated by the drug's ability to influence the experience and course of professional and therapeutic relationships. Beyond its therapeutic effects, misoprostol, given its capacity to terminate pregnancy and the close association of its name with illegal abortions, influences several relationships: the relationship between different caregivers, between caregiver and patient, and between researchers and research participants.

## Conclusion: Issues Raised by the Official Recognition and Professional Use of Misoprostol

The social life of misoprostol extends beyond its medical characteristics to include how different actors consider the drug socially, based on their perspectives and multifaceted interests. Gosden and Marshall (1999) stated that one can determine the social life of things by examining how meaning and values are accumulated and transformed during interactions between people and things. Similar to our results, other processes of recognition of misoprostol also highlight how medical professionals, patients, governmental institutions, and NGOs negotiate the appropriateness of a reproductive health technology to perform a certain job (Suh 2015). As also demonstrated by studies recently performed in Senegal by MacDonald (2021) and Suh (2021), our findings underline how the work of international NGOs has been instrumental not only in the approval processes of misoprostol, but also in shaping the social life of misoprostol by producing persuasive scientific evidence of its efficacy, safety, and advantages. Simultaneously, our ethnography shows how the drug approval processes were not simply about medical value; rather, suspicion about how potential users would use the drug in the future formed an intrinsic part of these processes. In the end, the introduction of misoprostol in the two countries raised more sociocultural issues than health issues, and in relation to abortion the health perspective was subjected to severe scrutiny from a social perspective.

As confirmed by other studies, suspicions towards misoprostol emanate from fears among key actors, such as policy makers and health care providers, of being unable to 'control' the use of the drug. These suspicions towards the use of misoprostol in turn often lead to authoritative practices through which healthcare providers decide who is authorized by society and regulatory bodies to make clinical decisions and who is entrusted with the knowledge and use of biomedical devices and drugs (MacDonald 2021). Both regulations and suspicions concerning the use of misoprostol emerge as part of a reproductive governance. The suspicion and mistrust towards misoprostol in care settings in Benin and Burkina Faso are based on ideas of morality and fear of legal consequences rather than on the therapeutic effectiveness of the drug. Our ethnography, similar to the findings by MacDonald (2021), shows that some healthcare providers would like to use misoprostol; however, they avoid

usage fearing damage to their professional reputation and legal repercussions if they are suspected of using it illegally. This indicates that the increased bureaucratization of care and authoritative practices are likely to discourage healthcare workers from using this lifesaving drug (MacDonald 2021), while less restrictive abortion laws in countries such as Benin and Burkina Faso could breathe new life into misoprostol. The probable effect of changes in laws on the professional uses of misoprostol merits further investigation.

The governance of misoprostol usage in Benin and Burkina Faso demonstrates how different actors or organizations interact, interpret, and position themselves in relation to the use of the drug, which is promoted, tolerated, accepted, or contested depending on healthcare standards and decision makers' religious and moral considerations. While reproductive health governance contributes to making available a drug which is essential for women's survival, it also contributes to limited access to the same life-saving drug.

The use of misoprostol in Benin and Burkina Faso highlights the effects of the ambiguous medical and legal status (legal for some therapeutic indications and illegal for others) of the drug in countries with restrictive legislation on abortions (Zordo 2016). In addition to its potential to save lives, misoprostol has a social life that evolves depending on legal and social norms, which limits the access of misoprostol to poor women in countries where abortion laws remain restrictive. These women's bargaining power is too weak to allow them to circumvent the law to access relatively safe abortions (Zordo 2016; Drabo 2019), which puts them in a very vulnerable position in which they might be forced to resort to unsafe abortions (Suh 2021), and/or be exposed to sexual abuse and violence when trying to access cheap illegal abortion services from men (Drabo 2019).

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