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REPRODUCTIVE HEALTH matters

Misoprostol and the politics of abortion in Sri Lanka

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Abstract: *Misoprostol, a WHO essential medicine indicated for labour induction, management of miscarriage and post-partum haemorrhage, as well as for induced abortion and treatment of post-abortion complications, came up for registration in Sri Lanka in December 2010. The decision on registration was postponed, indefinitely. This has wide-ranging implications, as misoprostol is widely available and used, including by health professionals in Sri Lanka, without guidance or training in its use. This paper attempts to situate the failure to register misoprostol within the broader context of unsafe abortion, drawing on data from interviews with physicians and health policymakers in Sri Lanka. It demonstrates how personal opposition to abortion infiltrates policy decisions and prevents the issue of unsafe abortion being resolved. Any move to reform abortion law and policy in Sri Lanka will require a concerted effort, spearheaded by civil society. Women and communities affected by the consequences of unsafe abortion need to be involved in these efforts. Regardless of the law, women will access abortion services if they need them, and providers will provide them. Decriminalizing abortion and registering abortion medications will make provision of abortion services safer, less expensive and more equitable.*

Keywords: abortion law and policy, medical abortion, misoprostol, registration of medicines, essential medicines, Sri Lanka

Section 303 of the Penal Code of Sri Lanka, an archaic piece of legislation from 1883, permits abortion only to save a woman's life. It states, "Whoever voluntarily causes a woman with child to miscarry shall, if such miscarriage be not caused in good faith for the purpose of saving the life of the woman, be punished with imprisonment… for a term which may extend to three years, or with fine, or with both; and if the woman be quick with child, shall be punished with imprisonment …for a term which may extend to seven years, and shall also be liable to fine." It also states that "a woman who causes herself to miscarry is within the meaning of this section".[1,2]

Despite this restrictive law, clandestine abortion services have been reasonably accessible, as successive governments turned a blind eye to them, with legal action being taken occasionally against providers.[3–5] In 2007, however, abortion clinics came under attack. In a context of rising conservatism and pressure from the Catholic Church through an international anti-abortion organization with leverage at the highest levels of government, the more reputable services were shut down.[6,7] Since then, women have begun to explore medical abortion as an alternative.

Neither mifepristone nor misoprostol, the two medications that are highly effective in combination for medical abortion, are registered in Sri Lanka,[8] even for use in life-saving circumstances. Even so, both misoprostol and mifepristone are reportedly available across the country and used widely in obstetric practice.[9,10] While the unregistered status of both drugs is problematic since abortion *is* legal in life-saving circumstances, the case of misoprostol is especially so given its other important obstetric uses.

An attempt to register misoprostol was stalled at the Drug Regulatory Authority of Sri Lanka in December 2010.[11] This paper situates the failure to register misoprostol within the broader context of unsafe abortion and women's health in Sri Lanka.

Efforts to reform the abortion law

In 1995, an attempt at abortion law reform failed when the paragraph dealing with abortion was

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omitted from a series of Penal Code amendments, even before they were presented to Parliament. The opinions expressed by Members of Parliament during a parliamentary debate at the time illustrate the conservatism and misogyny pervading abortion politics in the country. For instance, one MP stated that "any attempt to legalize abortion or liberalize the existing laws on abortion… will be strongly opposed by all sections of society… [It would] affect the fundamentals of social and cultural life... Christians, Buddhists, Muslims and Hindus all believe in the supremacy of life." Other MPs voiced concern that liberalizing the law would result in an increase in promiscuity among women and false allegations of rape, and weaken the institution of the family.[2,12]

Since then, numerous efforts by the Ministry of Women's Affairs with support from the Sri Lanka Women's NGO Forum have not met with success.[13,14] The present push for change began in late 2011 when the Minister of Child Development and Women's Affairs raised the issue in Parliament.[15] A draft bill, prepared by the Law Commission in consultation with the Women's Ministry and the Ministries of Health and Justice, awaits approval before its presentation to Parliament.[16,17] This bill, if passed, will permit abortion in cases of rape, incest and congenital abnormalities on the recommendation of a panel of medical experts at a government hospital (Anonymous, personal communication, 28 August 2012). Although the Minister of Child Development and Women's Affairs has made several public statements in support of the bill, officials at the Ministry of Health have not been as vocal. Expanding the law on broader grounds has not been part of the discussion.[15–17]

These efforts take place in the face of rising opposition from the Catholic Church. The Catholic Bishops' Conference expressed collective opposition to the bill, and the Archbishop of Colombo linked it to Western conspiracies involving UNFPA, other international agencies and women's rights groups.[18] The Family Planning Association of Sri Lanka (FPASL), an International Planned Parenthood Federation member, has been a persistent advocate for change.[19,20] Advocacy efforts are currently underway involving FPASL and the Sri Lanka College of Obstetricians and Gynaecologists, working together to raise awareness on the issue among policymakers (Anonymous, personal communication, 10 July 2012). But most statements in the media made recently by public figures have not been encouraging.[17,19,21]

Maternal and reproductive health in Sri Lanka

South Asian countries like India and Nepal successfully liberalized their abortion laws by framing reform as a means of population control or to reduce maternal mortality.[22,23] These reasons are unlikely to be a campaign-turner in Sri Lanka, where impressive achievements in maternal health have been attributed to the provision of free health care, well-developed health infrastructure, free education and other social welfare measures.[24] About 75% of inpatient care is provided free of charge by the public sector.[25]

Sri Lanka is doing well in maternal and reproductive health, so far as national indicators are concerned. The maternal mortality ratio, at 35 per 100,000 live births, was the lowest in South Asia in 2010.[26] According to the latest Demographic & Health Survey (2006–07), the proportion of births attended by skilled health personnel and the proportion of women delivered at a health facility were exceptionally high at 98% (excluding the war-afflicted Northern Province). Contraceptive prevalence rates for any method and for modern methods were also high, at 68% and 53%, respectively.[27] These figures are national averages, however, and some districts had far poorer indicators, for example, in 2008, the maternal mortality ratio in Mannar district in the Northern Province was 70 per 100,000 live births.[28]

With such a high level of political commitment to maternal health, it is perhaps surprising that the government has not addressed unsafe abortion urgently too.

The burden of unsafe abortion

There are no national level statistics on the incidence of induced abortion.[4] In 1998, as part of a UNFPA-sponsored project on induced abortion, 10,000 representative urban and rural households in all provinces (excluding the Northern and the Eastern provinces) were surveyed. The abortion rate was estimated to be 45 per 1,000 women of reproductive age (95% CI 38-52), higher among rural married women. Abortion rates were highest in the impoverished Uva Province. At these rates an estimated daily rate of 658 abortions per day was computed.[29] Smaller-scale studies have consistently found that the most common reasons given for seeking an abortion was to limit or space births.[3,14,30,31]

Although no data are collected on abortion-related morbidity, the Ministry of Health estimates

that about 7–16% of all hospital admissions for women are due to complications of abortion.[32] Abortion-related mortality statistics are collected through the annual maternal death review.[24] Between 2001 and 2005, unsafe abortion was the third or fourth highest cause of maternal mortality, contributing to 8–17% of maternal deaths annually.[33] By 2008, unsafe abortion, post-partum haemorrhage and cardiovascular disease vied for first place, each contributing 17 deaths each (13%) to maternal mortality that year.[34] Disaggregated mortality data by social class, ethnicity or religion are not available.

Unsafe abortion: statistics vs. lived experience

The safety of clandestine abortion services operating in Sri Lanka has not been studied. Nonetheless, it is believed that abortion-related complications are relatively low due to the availability of medically trained providers, the use of antibiotics and access to post-abortion care.[3] A 2010 study of 665 women from all parts of the island who had had an abortion, for example, found that over two-thirds said their providers were medical practitioners.[3]

While the belief that most abortions are safe might explain the lack of urgency displayed by the Ministry of Health, the lived experiences of rural and socially disadvantaged women, who are disproportionately affected by the consequences of unsafe abortion,[3,29] tell another story. Swarna's (pseudonym) story, which I witnessed personally in a hospital where I worked a few years ago, is an example.

Swarna's story

Swarna, a non-waged worker, was admitted to the intensive care unit of a provincial hospital. She had several children and could neither read nor write. Swarna had been transferred from a lower-tier hospital where she had been admitted with heavy bleeding after spontaneous abortion and was suspected to have had a reaction to blood transfusion. With a very low blood pressure, her condition was critical on admission. Swarna repeatedly denied having had an induced abortion. The obstetrician, who was familiar with this scenario, decided Swarna should undergo urgent D&E (dilatation and evacuation) to complete the abortion in spite of her denial.

Although family planning services were available in the public sector to Swarna, her social situation made her vulnerable to an unintended pregnancy. She did not take the necessary steps to avert a pregnancy when she "missed" her pills. Criminalized abortion and the fear of being reported to the police prevented Swarna from accessing post-abortion care until she was very ill, and when she did, she denied having had an abortion. After D&E, Swarna remained in intensive care for over two weeks with multiple organ failure and was lucky to survive. Many such women face the consequences of unsafe abortion daily, but are not counted because they do survive, as life-saving care is for the most part accessible in Sri Lanka. Such stories are especially relevant in Sri Lanka, in the absence of abortion-related morbidity data.

Misoprostol and medical abortion

Misoprostol has been included in the WHO Essential Medicines List (EML) since 2005. In 2005, it was included for labour induction where appropriate facilities are available, and in combination with mifepristone for medical abortion "where permitted under national law and where culturally acceptable".[35] The qualifying statement included in relation to medical abortion reflects the controversial nature of abortion and the politics at play. In 2009, incomplete abortion was added to the list of indications, and in 2011, post-partum haemorrhage where oxytocin is not available or cannot be used safely.[36,37]

Misoprostol was initially developed for treatment of stomach ulcers and has been approved for this purpose in over 80 countries,[38] although not in Sri Lanka. Due to its widespread availability and low cost, women self-medicate with misoprostol in resource-constrained settings, especially where abortion laws are restrictive.[39]

The availability of abortion medications in Sri Lanka has been publicized in several local newspapers.[9,10,40] While misoprostol is reportedly cheaper and easier to access than mifepristone, the cost of both drugs is inflated because abortion is criminalized.[9,10] In a statement issued to a local newspaper in October 2010, the Director of the Drug Regulatory Authority expressed the need to address unregistered use of abortion medications.[9]

Why registration of misoprostol was stalled in 2010

Drug regulation is codified in the Cosmetics, Drugs and Devices Act,[41] which provides a legislative

framework for registration, manufacture, import, transport, sale, labelling, advertising and distribution of medicines. Registration is controlled by the Drug Regulatory Authority at the Ministry of Health. Registration decisions are made by a Drugs Evaluation Sub-Committee comprising clinical pharmacologists, physicians and representatives of professional medical bodies. Applications for registration submitted by pharmaceutical companies are reviewed and technically evaluated by the Sub-Committee. Their decision is forwarded to a Technical Advisory Committee, which advises the Minister of Health and makes the final decision, which also involves a range of policymakers, and representation from the pharmaceutical industry. There is no provision for the participation of advocacy groups or a mechanism for the public to appeal decisions made by the Committee.[41–43]

In January 2011, as part of a larger qualitative study of the barriers to addressing unsafe abortion in Sri Lanka for my Master's thesis,[11] I interviewed ten key informants in Sri Lanka who were engaged in the field of women's health, either as members of professional or policy-making bodies or as providers of women's health care, about why registration of misoprostol was stalled in 2010. Four of them were members of bodies that had a direct influence on the registration decision. Anonymity has been maintained here due to the sensitive nature of the topic and ethical review board requirements. The participants were identified by snowball sampling. Data were collected by semi-structured interview and analyzed using qualitative descriptive methodology.[44]

In 2010, the Drug Regulatory Authority received an application from a pharmaceutical company to register misoprostol. Unable to reach consensus, the Drugs Evaluation Sub-Committee decided to seek the opinion of the Sri Lanka College of Obstetricians and Gynaecologists (SLCOG). From the perspective of the Regulatory Authority, they needed to register misoprostol as it was already prescribed "liberally" by obstetrician-gynaecologists, general practitioners and pharmacists across the country. This situation was unique: physicians were using supplies obtained from representatives of pharmaceutical companies or issuing prescriptions for misoprostol to be purchased from pharmacies. Pharmacies were stocked with supplies smuggled "in suitcases" into Sri Lanka from India and other neighbouring countries. It was no surprise that the College supported registration, although they recommended restricting its availability to government hospitals.

In reviewing the application after the SLCOG recommendation was submitted, the Drugs Evaluation Sub-Committee was, once again, unable to reach consensus, due to strong opposition from some members, including those who represented SLCOG. Concerns raised were the possible side effects and complications of "inappropriate use". Anecdotal accounts of two women who allegedly died due to misoprostol following labour induction were alluded to by a powerful member, who opposed registration. The potential for widespread use of misoprostol for medical abortion was not even discussed. But many of the health policymakers interviewed were convinced that this is what actually influenced the decision. The Sub-Committee eventually agreed to keep the decision pending and it remains pending at this writing (Anonymous, personal communication, 5 October 2012).

Implications of non-registration

Although women in Sri Lanka do not have *legal* access to misoprostol, a restrictive abortion law alone has not served as an effective barrier to its use for obstetric and other indications. Given that the law permits abortion to save a woman's life, both misoprostol and mifepristone could in fact be registered for legal terminations.

Further, while the risks associated with using misoprostol inappropriately for labour induction are real,[45] it can also be argued that maintaining its unregistered status encourages inappropriate use through lack of guidance. Guidelines released by WHO in 2011 recommend misoprostol for labour induction at term when labour is prolonged, except in women with previous caesarean sections.[46] If misoprostol were registered, health care providers would be trained to use it safely and complications would be rare. Such training is especially needed in Sri Lanka, a country that has one of the highest rates of labour induction in the world (35.5%).[46] Furthermore, the value of misoprostol in the management of spontaneous abortion, as evidenced by clinical studies undertaken in government hospitals in Sri Lanka,[47] cannot be dismissed.

In 2011, WHO expanded its list of indications for misoprostol to include provision of misoprostol for prevention of post-partum haemorrhage where oxytocin is not available or cannot be used safely.[37] All but two health policymakers I interviewed

believed there was no place for misoprostol in the management of post-partum bleeding in Sri Lanka, as oxytocin is widely available, including in peripherally located hospitals. However, the two other interviewees argued that misoprostol may well be useful for rural women whose first point of contact with the health system is a lower-tier facility where oxytocin is not available or cannot be used safely.

Self-medication with misoprostol for inducing abortion is less than ideal, especially where accurate information on dosage and side effects is not available and where there are barriers to accessing post-abortion care. While resistance to registering misoprostol may have been grounded in fears of women having access to a drug that could terminate pregnancy, the fact is that they already do. What they may not have is timely access to post-abortion care. They may also be reluctant to access these services for fear of being reported to law enforcement authorities, especially because police raids of abortion clinics are increasingly publicized in the media, even though women accessing these services are rarely indicted.[48,49]

Importantly, due to its unregistered status, misoprostol cannot be provided free of charge in the public sector, like most other medications, financed by the Ministry of Health. On the other hand, physicians and others are free to charge high fees for misoprostol, subjecting women to financial exploitation within a largely unregulated private sector.[50]

The Ministry of Health and the medical establishment wield the power in health policymaking in Sri Lanka. The public have little or no access to information on how or why policy decisions are made. It is unlikely that registration of misoprostol would even have become an issue had the Drug Regulatory Authority and the Sri Lanka College of Obstetricians and Gynaecologists – both powerful bodies – not wished to register the drug for different reasons. Questions relating to misoprostol's efficacy as a drug became irrelevant as the decision was eventually based on social values held by a few powerful members of the Drugs Evaluation Sub-Committee.

The failure to address unsafe abortion

It would seem that the Ministry of Health is unwilling to address unsafe abortion in any meaningful way. Instead, its strategy remains resolutely focused on preventing unintended pregnancies and providing post-abortion care.[33] Under these circumstances, one would expect a dynamic family planning programme and accessible sexual and reproductive health education and services. One would also anticipate the provision of effective post-abortion care that is sensitive to women's needs. However, there is no evidence for any of these. For instance, contraceptive services provided through the public sector continue to target married women.[24] There is no state-sponsored comprehensive sexual and reproductive health education programme for adolescents.[4] The Population and Reproductive Health Policy of 1998, the most recent policy on reproductive health, does not include provision for post-abortion care.[4] The National Strategic Plan on Maternal and Newborn Health (2012–2016) does not provide any guidance on how to address unsafe abortion.[34] There is no evidence of national-level research efforts that seek to fill the gaps in knowledge on unsafe abortion; current prevalence and complication rates are not known. And now, the Ministry of Health remains silent in response to the current initiative for legal reform.

This initiative focuses on expanding the abortion law to permit abortion under very specific circumstances, that is, where women are perceived to be "innocent" or "victims" of violence. Such a strategy will hopefully be advantageous in keeping diverse groups and actors on board, and would take us a step forward. But it must also be acknowledged that the evidence shows most abortions are sought to limit family size, which means that unsafe abortions will continue to take place, particularly among poorer women in rural Sri Lanka, who are most at risk.[3,29] Maintaining the status quo means this inequitable situation will continue.

Little support is available for advocacy to decriminalize abortion in Sri Lanka. The International Conference on Population and Development (ICPD) Programme of Action (1994), which was endorsed by Sri Lanka, incorporated a human rights perspective on population issues, including reproductive and sexual health. Although considered a watershed for reproductive rights, it did not address abortion in any helpful way for countries like Sri Lanka. It focused on the prevention of unintended pregnancies and provision of post-abortion care; and although it says unsafe abortion is a serious public health problem, it states only that safe abortion services should be provided in countries where abortion is *not against the law*.[51] This leaves women in countries like Sri Lanka, where abortion laws are very restrictive, to suffer their fate unaided.

The recommendations to Sri Lanka on unsafe abortion by UN treaty bodies have also been limited. In 2010, the Committee on Economic, Social and Cultural Rights expressed its concern about maternal mortality from unsafe abortion in Sri Lanka and urged the State to take action and consider reforming the law in relation to rape, incest and congenital abnormalities.[52] The CEDAW Committee also expressed concern about the restrictive abortion law and maternal mortality from unsafe abortion in Sri Lanka both in 2002 and 2011, in their concluding observations. In 2002, the Committee recommended that "abortion be permitted in cases of rape, incest and congenital abnormalities",[53] and in 2011 it recommended "[reviewing] the laws relating to abortion with a view to removing punitive provisions imposed on women who undergo abortion, [and] providing them with access to quality services for the management of complications arising from unsafe abortion".[54] While these recommendations lend support to the current initiative of the Women's Ministry, they did not recommend *providing* safe abortion services in law or practice.

Moving forward

Any move to reform abortion law and policy in Sri Lanka will require a concerted effort, spearheaded by civil society. Clearly, the support of the Ministries of Health and Women's Affairs, human rights groups, health and legal professional bodies and non-governmental organizations are all crucial, as well as supportive members of Parliament. Right now, the extent of this support is unfortunately small. A critical mass of support that cannot easily be crushed by anti-abortion elements has yet to be developed. The debate needs to become broad-based and involve women and communities facing the consequences of unsafe abortion. Health policy-makers and health care providers must be held accountable, not just with respect to unsafe abortion but more broadly for the provision of accessible and equitable health services. Lastly, *ad hoc* policy decisions that ignore existing evidence, like that on the registration of misoprostol, need to be challenged.

The situation in Sri Lanka only confirms what is already known: women will have abortions if they need them, whether they are legal and safe or not, and abortion providers, including physicians, will continue to provide these services. Decriminalizing abortion and registering mifepristone and misoprostol in Sri Lanka will make provision of abortion services safer, less expensive and more equitable.

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Résumé

Le misoprostol, médicament essentiel de l'OMS indiqué pour le déclenchement du travail, la prise en charge des fausses-couches et des hémorragies du post-partum, ainsi que pour l'interruption de grossesse et le traitement des complications de l'avortement, aurait dû être enregistré à Sri Lanka en décembre 2010. La décision sur son enregistrement a été reportée, indéfiniment, ce qui a de vastes conséquences car le misoprostol est disponible et utilisé largement, notamment par les professionnels de la santé à Sri Lanka, sans conseils ni formation à son utilisation. Cet article tente de placer le non-enregistrement du misoprostol dans le contexte plus

Resumen

Misoprostol, uno de los medicamentos esenciales de la OMS indicado para inducción del parto, manejo de pérdidas del embarazo y hemorragia posparto, así como para aborto inducido y tratamiento de las complicaciones postaborto, fue considerado para ser registrado en Sri Lanka en diciembre de 2010. La decisión fue aplazada por tiempo indefinido. Esto tiene implicaciones de gran alcance, ya que en Sri Lanka el misoprostol está disponible y es utilizado extensamente, incluso por profesionales de la salud, sin orientación o capacitación en su uso. Este artículo, basado en datos de entrevistas con profesionales médicos y formuladores de políticas

large de l'avortement à risque, se fondant sur des données recueillies lors d'entretiens avec des médecins et des décideurs à Sri Lanka. Il démontre comment l'opposition personnelle à l'avortement influence les décisions politiques et empêche de résoudre le problème de l'avortement à risque. Toute mesure pour réformer la loi et la politique sur l'avortement exigera un effort concerté, dirigé par la société civile. Les femmes et les communautés touchées par les conséquences de l'avortement à risque doivent être associées à ces activités. Quelle que soit la loi, si elles en ont besoin, les femmes auront accès aux services d'avortement et les prestataires les leur fourniront. En dépénalisant l'avortement et en enregistrant les médicaments, on rendra les services d'avortement plus sûrs, moins onéreux et plus équitables.

de salud en Sri Lanka, intenta situar el no registrar el misoprostol en el contexto más amplio de aborto inseguro. Se demuestra cómo la oposición personal al aborto infiltra en las decisiones de políticas e impide que se resuelva el problema de aborto. Todo intento de reformar la ley y políticas referentes al aborto en Sri Lanka requerirá un esfuerzo concertado, encabezado por la sociedad civil. Las mujeres y comunidades afectadas por las consecuencias del aborto inseguro deben participar en estos esfuerzos. Independientemente de la ley, las mujeres obtendrán servicios de aborto si los necesitan y los prestadores de servicios se los proporcionarán. Si se despenaliza el aborto y se registran los medicamentos para inducir el aborto, la prestación de servicios de aborto será más segura, menos costosa y más equitativa.