EnGendeRights, Inc.
Asserting Gender Equality

Policy Brief

Access to the Life-Saving Drug Misoprostol to Prevent and Treat Postpartum Hemorrhage Can Save Filipino Women's Lives

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Access to the Life-Saving Drug Misoprostol to Prevent and Treat Postpartum Hemorrhage Can Save Filipino Women's Lives

I. THE IMPERATIVE NEED TO REGISTER AND MAKE AVAILABLE THE LIFE-SAVING DRUG MISOPROSTOL FOR PREVENTION AND TREATMENT OF POSTPARTUM HEMORRHAGE

It is imperative that misoprostol be registered and made available for prevention and treatment of postpartum hemorrhage (PPH) or bleeding after childbirth due to uterine atony or the failure of the uterus to contract after delivery.[1] Misoprostol is a safe, effective, and low-cost drug used to prevent and treat PPH.[2] Misoprostol, a prostaglandin, cause strong uterine contractions and is stable at room temperature.[3]

Misoprostol is the answer for low resource settings to prevent and treat PPH where oxytocin is not available or cannot be safely used. Although oxytocin is the gold standard to prevent and treat PPH, oxytocin may be inaccessible due to absence of health care providers trained to provide intravenous administration of oxytocin, lack of supply of oxytocin, unavailability of refrigeration or fluctuating electricity, shortage of syringes, needles, and IV oxytocin infusion and lack of resources for syringe disposal.[4] In cases where oxytocin may be available, its quality may be compromised due to non-refrigeration as in one study where 89% of the tested oxytocin ampoules failed to meet the active ingredient specifications.[5]

Women in geographically isolated and disadvantaged areas (GIDA areas), areas in the Autonomous Region of Muslim Mindanao (ARMM), areas affected by humanitarian crises, i.e., natural disasters and armed conflict, and community-based facilities are vulnerable to die due to PPH given that oxytocin used to prevent and treat PPH may not be widely available or may not be safely used. Poor, rural, and young women who may lack finances to pay for oxytocin are also vulnerable to die due to PPH especially since many public hospitals require their patients to pay for their medication.

Women from poorly-resourced areas suffer mortality and morbidity due to lack of access to uterotonic agents such as oxytocins and ergometrine and lack of skilled providers to safely administer such.

Misoprostol is the solution for these low resource areas since it has been proven safe and effective in preventing and treating PPH after delivery.[6] The low cost of misoprostol, its wide availability, stability at room temperature and ease of use make it an ideal drug to add to the package of interventions available to prevent and treat PPH in low resource settings.[7]

By providing wide access to misoprostol to specially-trained medical providers, the Philippines will lessen the mortality and morbidity due to PPH. Misoprostol will

significantly increase the number of women who receive an uterotonic following childbirth to prevent and treat excessive bleeding.

Given the proven safety, efficacy, and low cost of misoprostol for PPH prevention and treatment, it is imperative that misoprostol be included in the Philippine National Drug Formulary (PNDF) and the Food and Drug Administration (FDA) List of Registered Drug Products (hereafter "Drug Registry") for prevention of PPH and be made widely available to skilled birth attendants for the prevention and treatment of PPH.

The inclusion of misoprostol in the PNDF and the FDA Drug Registry for its PPH prevention and treatment indication will facilitate easier access to misoprostol for PPH prevention and treatment and lead to greater uterotonic coverage at all deliveries. Furthermore, the increased access to misoprostol to prevent and treat PPH would contribute to efforts to greatly lower maternal mortality and morbidity related to PPH and in meeting the country's commitment to the Sustainable Development Goals to decrease the maternal mortality ratio to two-thirds of 2010 levels under Target 3.[8]

In light of the obligation of the Philippine government to protect women's rights to equality, non-discrimination, life, and health under the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the Magna Carta of Women (Republic Act 9710), it is essential that the Department of Health (DOH) take immediate efforts to include misoprostol in the PNDF and the FDA Drug Registry and issue an administrative order approving the use of misoprostol for the prevention and treatment of PPH.

II. PPH AS THE LEADING CAUSE OF MATERNAL MORTALITY

PPH is the leading cause of maternal morbidity and mortality in low-resource settings and accounts for over a quarter of all maternal deaths worldwide.[9]

In the Philippines, about one in every five women die from PPH.[10] Maternal deaths are preventable with proper access to skilled birth attendants and active management of the third stage of labor (AMTSL).[11]

Common causes of PPH include failure of the uterus to contract adequately after birth leading to atonic PPH,[12] tears of the genital tract leading to traumatic PPH and bleeding due to retention of placental tissue.[13] PPH due to uterine atony is the most common cause of PPH and the leading cause of maternal death.[14] PPH can occur even in women without identifiable risk factors. Results show that more women without risk factors have PPH than those with risk factors.[15] Interventions should be targeted at all women during childbirth to prevent and treat PPH.

III. PREVENTION AND TREATMENT OF PPH THROUGH MISOPROSTOL

Uterotonic drugs have been recommended to reduce or stop PPH. Ergometrine, oxytocin, and prostaglandins such as misoprostol all cause the uterus to contract to prevent and/or stop excessive bleeding. Oxytocin is the currently the drug of choice for PPH prevention and treatment because it is highly effective, has an excellent safety profile, and is free from the side effects associated with ergometrine.[16] However, oxytocin is administered by injection, which requires both a skilled health provider and a clean needle.[17] Further, the active ingredient in oxytocin preparations has been shown to decrease gradually over time; and more rapidly when the drug is stored at temperatures above 30° Celsius.[18] Thus, injectable oxytocin has been limited to use in settings where appropriate cold storage facilities are available. Given the need for providers skilled in its use and appropriate storage facilities, the use of oxytocin for PPH prevention has been mostly limited to births occurring at a health facility and/or with a skilled provider.

Misoprostol, an E1 prostaglandin analog, was developed during the 1980s and was approved by the United States Food and Drug administration to be taken orally in tablet form for the prevention of gastric ulcers caused by long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) in 1988. Off-label exploration of the drug for obstetric purposes began soon after its development, and the drug has been used extensively for a number of gynecological and obstetric indications.

Evidence shows that health workers trained in misoprostol use can safely and effectively administer misoprostol to women in any delivery setting.[19] Thus, providing wide access to misoprostol will increase significantly the number of women who receive an uterotonic following childbirth.[20]

A. THE USE OF MISOPROSTOL TO PREVENT PPH

PPH can be prevented by active management of the third stage of labor including the immediate administration of a prophylactic uterotonic agent (preferably oxytocin), delivery of the placenta by controlled cord traction, and uterine massage.[21] The use of uterotonic agents such as injectable oxytocin and ergometrine requires skills and sterile equipment for safe administration.[22] Oxytocin may be inactivated if exposed to high ambient temperatures, thus, it needs temperature-controlled transport and storage and protection from light increasing cost of storage.[23]

The World Health Organization (WHO) recommends that active management of the third stage of labor be offered to all women delivering with skilled attendants to reduce blood loss after delivery.[24] AMTSL reduces the rate of PPH by up to 60%.[25] The WHO noted the benefits of using misoprostol for avoiding PPH and the ease of its administration in settings where other care is not available.[26]

B. THE USE OF MISOPROSTOL TO TREAT PPH

Misoprostol has been found to effectively control excessive PPH.[27] The use of misoprostol to treat women with PPH outweighs the transient side effects such as shivering and fever.[28]

IV. MEDICAL, SCIENTIFIC, AND INTERNATIONAL SUPPORT FOR USE OF MISOPROSTOL FOR PREVENTION AND TREATMENT OF PPH

A. WHO GUIDELINES

The WHO approved the inclusion of misoprostol for the prevention of PPH in the WHO 17th Model List of Essential Medicines (EML) dated March 2011 in section 22.01.00.00 under "Oxytocics"[29] where oxytocin is not available or cannot be safely used.[30] In 2015, the WHO approved misoprostol for the additional indication of treatment of PPH in the 19th WHO EML.[31]

In 2012, the WHO recommended the use of misoprostol on the Prevention and Treatment of Postpartum Hemorrhage: "Intravenous oxytocin is the recommended uterotonic drug for the treatment of PPH; however, in settings where IV oxytocin is not available, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 μg) is recommended."

As early as 2009, the WHO guidelines on emergency obstetric care already included the use of misoprostol to prevent PPH where oxytocin is not available.[32]

B. UNITED NATIONS COMMISSION ON LIFE-SAVING COMMODITIES FOR WOMEN AND CHILDREN IDENTIFIED MISOPROSTOL AS ONE OF 13 LIFE-SAVING COMMODITIES

Misoprostol has been identified as one of the 13 life-saving commodities for women and children by the United Nations Commission on Life-Saving Commodities for Women and Children (UNCoLSC or Commission).[33] These reproductive, maternal, newborn, and child health (RMNCH) commodities were identified as having great lifesaving potential by the Commission. The Commission seeks to implement the UN Secretary-General's Global Strategy for Women's and Children's Health to save lives through improved and equitable access to life-saving commodities.

Misoprostol to prevent and treat postpartum hemorrhage was identified as a key maternal health commodity where its non-inclusion in the national essential medicine list was established as a key barrier to its access.

The Life-Saving Commodities Practitioners' Network, with about 450 health experts from 83 organizations, was launched in 2016 to implement the Commission's recommendations to increase access to and use of the 13 life-saving commodities.

C. INTERNATIONAL SUPPORT OF GOVERNING BODIES

C.1. PPH PREVENTION

C.1.a. INTERNATIONAL AND NATIONAL CLINICAL GUIDELINES SUPPORTING USE OF MISOPROSTOL FOR PPH PREVENTION

Several medical bodies support the use of misoprostol for PPH prevention. International Federation of Gynecology and Obstetrics **(**FIGO),[34] Royal College of Obstetricians and Gynaecologists (RCOG) and the International Confederation of Midwives (ICM) also recommend the use of misoprostol for PPH prevention in situations in which oxytocin is not available.[35]

In the United States, misoprostol for prevention of PPH is an accepted off-label use.[36]

C.2. PPH TREATMENT

In 2012, FIGO urged national regulatory agencies and policy makers to approve misoprostol for prevention and treatment of PPH. Its guidelines on PPH provided that where there is no skilled birth attendant present, misoprostol may be the only option available to control PPH and added that research demonstrated that misoprostol significantly reduced the need for additional interventions for PPH.

FIGO and ICM issued a joint statement in 2014 on the use of "misoprostol for the treatment of postpartum haemorrhage in low resource settings" underscoring the importance misoprostol in treating PPH and recommended a single dose of 80 micrograms sublingual misprostol (Hemoprostol) to be used to treat PPH due to uterine atony.[37]

D. GLOBAL ACCEPTANCE OF MISOPROSTOL FOR PREVENTION AND TREATMENT OF PPH

Many countries have approved misoprostol for its use in preventing PPH and its global availability is increasing.[38] Several countries, including countries in Asia and Africa, have already included misoprostol for obstetric indications such as Bangladesh, Cambodia, Ethiopia, Ghana, India, Kenya, Malawi, Mali, Mozambique, Myanmar, Nepal, Nigeria, Pakistan, Senegal, Siera Leone, Somaliland, Sudan, Tanzania, Uganda, Vietnam, and Zambia.[39]

V. EVIDENCE ON STABILITY AND SAFETY OF MISOPROSTOL FOR PREVENTION AND TREATMENT OF PPH

A. EASE OF USE AND STABILITY OF MISOPROSTOL

Misoprostol is easy to use. It does not need refrigeration, has a long shelf life, is stable at high temperatures and has relatively few side effects.[40] Misoprostol is well-suited for use

in the Philippines where it can be used by a range of health providers in low-resource settings and effectively delivered at the community level.[41]

B. SIDE EFFECTS AFTER MISOPROSTOL

Women who receive misprostol during the third stage of labor are at risk for a higher temperature, shivering, nausea and vomiting. The most common side effects associated with the postpartum administration of misoprostol are shivering and pyrexia.[42] A review of the literature shows that these side effects are transient and not severe, resolving within 12 hours or less.[43] In the context of childbirth, most agree that the benefits of misoprostol as a potent uterotonic outweigh the risks of experiencing these short-lived side effects.[44]

C. MISOPROSTOL AND BREASTFEEDING

The risk to the infant is minimal with a single dose since the levels of misoprostol in breast milk are so small and decline very rapidly. When administered for PPH prevention, misoprostol has no breastfeeding contraindication.[45]

D. RANGE OF COSTS

The 2013 International Drug Price Indicator Guide published by Management Sciences for Health (MSH) was used to obtain present prices for misoprostol where the median price was USD 0.3094 per 200µg tablet of misoprostol (USD .93 per dose for prevention; USD 1.24 per dose for treatment).

E. PROPOSED TEXT FOR THE MODEL FORMULARY FOR PREVENTION

In the Application to Include Misprostol in 2011 submitted by Gynuity Health Projects and Venture Strategies Innovations, the proposed text for the model formulary for prevention of PPH was, as follows:

> **FORMULATION (dosage form and strength)**: Oral tablet: 200 micrograms; **ATC Code**: A02BB01; **Type of List**: Complementary List.
>
> **DISEASE/INDICATION:** Prevention of postpartum hemorrhage.
>
> **RATIONALE FOR INCLUSION:** Misoprostol offers a low-cost, easy to administer means to prevent postpartum hemorrhage, one of the major contributors to maternal morbidity and mortality worldwide.
>
> **GENERAL INFORMATION:** Misoprostol is x x x used for prevention and treatment of postpartum hemorrhage, induction of labor (at smaller doses) and for evacuation of the uterus following incomplete abortion/miscarriage in many jurisdictions.
>
> **USES:** Prevention of postpartum hemorrhage (used alone).

CONTRAINDICATIONS (for use in PPH prevention): None.

DOSE: Prevention of postpartum hemorrhage, *oral administration*, **ADULT** and **ADOLESCENT** a single dose of 600 micrograms after delivery of the baby.

NOTE: In multiple births, administration of misoprostol for prevention of postpartum hemorrhage should occur *after* delivery of the last infant.

ADMINISTRATION: For prevention of postpartum hemorrhage, oral administration of three 200-microgram tablets (600 micrograms total) is recommended.

ADVERSE EFFECTS: fever and shivering.

F. PROPOSED TEXT FOR THE MODEL FORMULARY FOR TREATMENT

In the Application to Include Misprostol in 2015 submitted by Gynuity Health Projects, the proposed text for the model formulary for treatment of PPH was, as follows:

FORMULATION (dosage form and strength): Oral tablet: 200 micrograms ATC Code: A02BB01 Type of List: Core List

DISEASE/INDICATION: Treatment of postpartum hemorrhage.

RATIONALE FOR INCLUSION: Misoprostol is an effective, low-cost, easy to administer option to treat postpartum hemorrhage, one of the major contributors to maternal morbidity and mortality worldwide.

GENERAL INFORMATION: Misoprostol (600 μg) is included in the EML for prevention of PPH. It is also a complementary drug (with mifepristone) for x x x, for management of incomplete abortion/miscarriage in women with uterine size ≤ 12 weeks gestational age, and for induction of labour.

USES: Treatment of postpartum hemorrhage due to uterine atony where intravenous oxytocin is not available.

CONTRAINDICATIONS (for use in PPH treatment): Known allergy to misoprostol.

DOSE: Treatment of postpartum hemorrhage, sublingual administration (under the tongue).

ADULT and ADOLESCENT a single dose of 800 micrograms

NOTE: None

ADMINISTRATION: For treatment of postpartum hemorrhage, sublingual administration of four 200-microgram tablets (800 micrograms total) is recommended.

ADVERSE EFFECTS: shivering, fever.

VI. RATIONALE FOR INCREASED ACCESS TO MISOPROSTOL

In the Application to Include Misprostol in 2011 submitted by Gynuity Health Projects and Venture Strategies Innovations, the proposal was submitted based on evidence and considerations, described below:

1. Postpartum hemorrhage is one of the largest contributors to maternal morbidity and mortality in low resource countries and accounts for nearly one quarter of all maternal deaths worldwide.[46]

2. Misoprostol is a proven, evidence-based drug that reduces post-partum blood loss.[47]

3. Misoprostol can be safely used by providers of all levels for prevention of PPH. Evidence from randomized controlled trials shows that health workers trained in its use can safely and effectively administer misoprostol to women in any delivery setting. [48]

4. Misoprostol is a low-cost alternative to conventional uterotonics, including oxytocin and ergometrine, which require skilled administration and are not yet consistently sustainable and/or available in many low resource countries.[49]

Life-saving drugs such as misoprostol must be made available to prevent and treat PPH. The accessibility of misoprostol and the proficiency of frontline health workers to administer them whenever and wherever they are needed is wanting, hence, the urgent need for a DOH administrative order explicitly approving its use for PPH prevention and treatment.

Leading causes of maternal deaths including PPH can be mitigated by an enabling policy environment that will increase access to misoprostol and will support and empower service providers to save the lives of women during childbirth. The increased access to misoprostol supports the rights of women who are entitled to their rights to life and the highest attainable standard to health.

VII. PUBLIC HEALTH RELEVANCE

HEALTH BURDEN ON WOMEN IN THE PHILIPPINES

The Philippines has high unintended pregnancies with nearly three in ten births either unwanted or mistimed,[50] high adolescent pregnancies with one in ten adolescent women aged 15-19 years old pregnant with their first child or already mothers,[51] and high maternal mortality with 114 women aged 15-49 who die out of every 100,000 live births.[52]

In the Philippines, only 73% of the births are attended by skilled birth attendants.[53] This means that about 27% of women deliver at home and are attended by unskilled birth attendants who are unable to recognize the signs of excessive bleeding. Once the problem is recognized and the decision to take the woman to a health facility is made, emergency transportation may not be available and even if a woman arrives at a health facility in time, the facility may not have trained staff available or the necessary supplies and equipment to treat the woman.[54]

Caring for women with PPH is difficult in the Philippine setting since medication used for standard treatment requires refrigeration and injection, the specialized emergency services and personnel (for surgery, blood transfusion, and other higher-level care) are often only available in limited areas. The speed with which death from PPH occurs presents a major challenge in settings with poor communications and referral systems and short-ages of necessary drugs and equipment.[55]

The WHO identifies the clinical threshold for PPH as postpartum blood loss in excess of 500m.[56] The failure of the uterus to contract after delivery or uterine atony is the most common cause of PPH and accounts for 90% of PPH cases in most countries.[57] According to DOH, 17.2% of maternal deaths in the Philippines are caused by PPH.[58]

Due to the high rate of maternal mortality and the large proportion of these deaths attributable to PPH, effectively managing PPH in low resource settings will have a great impact on lowering maternal deaths.[59]

It is difficult to predict who will experience PPH because, of the few common risk factors known for PPH, most cannot be identified until labor has already begun, such as, prolonged and augmented labor.[60] Furthermore, PPH occurs to women without risk factors where two-thirds of women who have PPH do not have any identifiable clinical risk factors. Women are not usually referred until they develop PPH. Even trained providers often underestimate blood loss.[61] The average time to death from onset of PPH is two hours, thus, any delay in seeking health care can be deadly.[62] Prevention and treatment of PPH is extremely important especially in settings where there is limited or no access to care.[63] In the Philippines, with high maternal mortality and limited specialized emergency service, efforts should focus on preventing and treating cases of PPH.

VIII. THE ENABLING POLICY ENVIRONMENT ALLOWING ACCESS TO MISOPROSTOL FOR PREVENTION AND TREATMENT OF PPH WILL MAKE PREGNANCY SAFER AND WILL REDUCE MATERNAL MORTALITY

Misoprostol, a drug previously registered in the Philippines to treat ulcers, is currently not registered for any indication including for prevention and treatment of PPH, miscarriage, and incomplete abortion leaving those residing in areas where oxytocin is not available at risk of maternal death.[64]

In 2002, the FDA issued an Advisory citing that Cytotec (brand name for misoprostol) is an unregistered product,[65] hence, its manufacture, importation, sale or distribution is a violation of the Food, Drugs, Devices and Cosmetics Act.[66] Despite the submission of EnGendeRights' request to the DOH in July 2011 to include misoprostol in the drug registry for PPH prevention, said request has not been favorably acted on until now to the detriment of Filipino women's health and lives.

Creating an enabling policy environment where there is increased access to misoprostol and empowering midwives to use misoprostol for prevention and treatment of PPH will capacitate our health system in effectively addressing emergency situations through administration of misoprostol as a life-saving drug especially in hard-to-reach areas among the 42,000 villages where lives of women are at stake in absence of doctors or referral facilities.[67] To reduce maternal mortality in the Philippines, the Philippine government must act now to mobilize the financial resources and political will to make pregnancy and motherhood safer for all Filipino women.[68]

IX. ACCESS TO MISOPROSTOL TO PREVENT AND TREAT PPH IS CONSISTENT WITH THE PHILIPPINE CONSTITUTION AND THE MAGNA CARTA OF WOMEN

Access to misoprostol to prevent PPH is consistent with the Philippine Constitution and the Magna Carta of Women. Section 5 of the Magna Carta of Women, on the State as the Primary Duty-Bearer, provides that "the State shall keep abreast with and be guided by progressive developments in human rights of women under international law and design of policies, laws, and other measures to promote the objectives of [the Magna Carta]."

The use of misoprostol for prevention and treatment of PPH is constitutional as it is reasonable and it promotes the rights of women, public health, and public interest.

The guarantee of the separation of church and state is provided under Section 6, Art. II on Declaration of Principles and State Policies of the Philippine Constitution which states that "[t]he separation of [c]hurch and [s]tate shall be inviolable." The reason for the principle of separation of church and state is to guard against the views of a dominant church from influencing the conduct of government and influencing policies to cater to a specific dominant church.[69] The separation of church and state guarantees that one will not abuse the other or that one dominant religion or belief will not be used to govern the state and its people.

It must likewise be noted that while the 1987 Constitution guarantees freedom of religion, it also guarantees the non-establishment of religion. Section 5, Article III of the Bill of Rights states: "No law shall be made respecting an establishment of religion...." This clause was included in order to ensure that the government may not coerce anyone to support or participate in religion.[70]

There is danger when the beliefs of a certain religion are enacted into law and policy. In such case, the religious beliefs and rights of others who believe in the right to provide access to life-saving drugs such as misoprostol for prevention and treatment of PPH are infringed.

The current lack of policy allowing access to misoprostol to prevent and treat PPH perpetuates the ideological framework of the religious right. The fact that the religious right may want to deny access to misoprostol since this can be used to induce abortion does not justify prohibiting its use to prevent and treat PPH for the simple reason that religious belief should not be used as basis to deny access to life-saving medication. Religious beliefs should not be used as basis for our laws and policies since doing so would aid a specific religion and violate the guarantee of non-establishment of religion and infringe on the right to freedom of religion.

The public health and welfare and human rights of Filipino women who die due to PPH should be the primary consideration in making misoprostol available for PPH prevention and treatment.

X. THE PHILIPPINE STATE OBLIGATIONS UNDER INTERNATIONAL LAW TO PROVIDE MISOPROSTOL FOR PREVENTION AND TREATMENT OF PPH

Having ratified CEDAW, the Philippines is obligated to uphold women's right to reproductive health and life, equality, non-discrimination, equal protection of the law and privacy by providing access to misoprostol to prevent and treat PPH.

The Committee on the Elimination of Discrimination against Women (CEDAW Committee), the committee tasked to monitor the Philippines' compliance with CEDAW, recommended in 2015 for the Philippines to reintroduce misoprostol to reduce maternal mortality and morbidity rates,[71] however, the government has not reintroduced misoprostol even for prevention and treatment of PPH and neither has it withdrawn the 2002 FDA Advisory citing Cytotec as an unregistered product.[72]

The right to misoprostol to prevent PPH is guaranteed by CEDAW, in particular articles 1, 2, 3, 4, 12 and 16; as well as articles 5, 10 and 11. Article 1 of CEDAW defines discrimination as:

> Any distinction, exclusion, or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment, or

> exercise by women… of human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field.[73]

Article 2 states that, "States Parties condemn discrimination against women in all its forms, agree to pursue all appropriate means without delay a policy of eliminating discrimination against women."[74]

Reproductive health is fundamental to women's health and right to equality. CEDAW commits States parties to "take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality with men and women, access to health care services."[75]

The CEDAW Committee has recognized that the denial or restriction of access to services that only women need such as misoprostol to prevent and treat PPH constitutes "discrimination against women" and directly impairs women rights to health, life, privacy and family life.[76]

Denying women's access to misoprostol to prevent and treat PPH is a clear manifestation of the State's ongoing failure to place "gender perspective at the centre of all policies and programmes affecting women's health."[77]

Article 2(d) of CEDAW specifies the obligation of States to refrain from discriminatory acts against women and employs governmental institutions to adhere to this obligation.[78]

The State is obliged to ensure that health goods and services are available[79] and "accessible to all, especially the most vulnerable or marginalized sections of the population."[80] In breach of this obligation, the health and lives of women in low resource settings are at risk due to lack of access to misoprostol to prevent and treat PPH.

The international community is against allowing religious norms to influence public policy. In a publication of the WHO, it states that despite religious or other moral influence, "democratic governments that are accountable to their electorates and that have endorsed the Cairo Programme bear responsibility to formulate and advance laws that serve their populations' reproductive health."[81]

XI. RECOMMENDATION

Misoprostol must be made available to women to prevent and treat PPH and reduce maternal mortality and morbidity due to PPH. A policy discriminating women's access to reproductive services unnecessarily puts women's lives and health at risk. It would do well for policy makers and service providers to face the realities of Filipino women's experiences to enable them to comprehend the grave consequences of discriminatory policies against women.

The Philippines is obligated to uphold the Constitution and international human rights standards and to make the full range of reproductive health services including

misoprostol for PPH prevention and treatment accessible to women. The right of women to the full range of reproductive health services is a fundamental human right.

Policy makers and service providers have the duty to uphold women's right to health and life. The inclusion of misoprostol in the PNDF and the FDA Drug Registry for the prevention and treatment of PPH and the issuance of a DOH administrative order approving the use of misoprostol for the prevention and treatment of PPH will save lives of Filipino women giving birth.***

See:

2015 WHO Model List of Essential Medicines
http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf

***Report of the 20th WHO Expert Committee on the Selection and Use of Essential Medicines,* May 2015 (including list of members)**:
http://www.who.int/medicines/publications/essentialmedicines/Executive-Summary_EML-2015_7-May-15.pdf

[1] Application to include Misoprostol to World Health Organization EML for treatment of Postpartum Hemorrhage submitted by Gynuity Health Projects to the 20th Expert Committee on the Selection and Use of Essential Medicines of the Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, 2015 (hereafter "Application to Include Misoprostol for Treatment of PPH, 2015"), *available at* http://www.who.int/selection_medicines/committees/expert/20/applications/Misoprostol_PPH.pdf?ua=1
[2] *Id.*
[3] WHO Statement regarding the use of misoprostol for postpartum haemorrhage prevention and treatment, 2009.
[4] *Id.*
[5] *Id.*
[6]
[7] Application to Include Misprostol, January 21, 2011.
[8] The global commitment is to reduce the maternal mortality ratio to less than 70 per 100,000 births.
[9] Application to include Misoprostol to EML for prevention of Postpartum Hemorrhage submitted by various organizations and individuals to the Secretary of the 18th Expert Committee on the Selection and Use of Essential Medicines of the Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, January 21, 2011 (hereafter "Application to Include Misoprostol, 2011"); WHO Department of Making Pregnancy Safer, WHO Recommendations for the Prevention of Postpartum Haemorrhage.Geneva, 2007 (hereafter WHO Recommendations for the Prevention of PPH, 2007); The causes of maternal death include PPH, sepsis, eclampsia, unsafe abortion, and obstructed labor with PPH as the leading single direct cause of maternal mortality, accounting for a quarter of all maternal deaths worldwide cited in Gynuity and Venture Proposal for Misoprostol Inclusion 2010; Mousa H, Walkinshaw S. Major postpartum haemorrhage. Current Opinion in Obstetrics and Gynecology 2001; 13:595-603 (hereafter Mousa and Walkinshaw, 2001); The WHO found that 27.1% of all maternal deaths were due to PPH. *See* WHO Global causes of maternal death: a WHO systematic analysis, May 2014 citing 2003-2009 global, regional, and sub-regional estimates of causes of maternal death with a novel method, updating the previous WHO systematic review.
[10] According to DOH, 17.2% of maternal deaths in the Philippines are caused by PPH. *See* DOH AO No. 2010-0014, May 14, 2010.
[11] Gynuity Health Projects and Family Care International, Misoprostol for Postpartum Hemorrhage, March 2006.
[12] Uterine atony is the failure of the uterine to contract properly after childbirth.
[13] WHO Recommendations for the Prevention of PPH, 2007.
[14] *Id.*; Gynuity Health Projects and Family Care International, Misoprostol for Postpartum Hemorrhage, March 2006. (Gynuity & FCI, Misoprostol for PPH, March 2006)
[15] WHO Recommendations for the Prevention of Postpartum Haemorrhage, 2007.
[16] *Id.*
[17] Tsu VD, Shane B. New and underutilized technologies to reduce maternal mortality: call to action from a Bellagio workshop. International Journal of Gynecology & Obstetrics 2004; 85 (Supplement 1):S83-S93 (hereafter Tsu and Shane, 2004).
[18] Hogerzeil H and Walker G. Instability of (methyl)ergometrine in tropical climates: an overview. European Journal of Obstetrics & Gynecology 1996; 69: 25 – 29.
[19] Mobeen et al; Derman et al, 2006;; Høj et al, 2005; Walraven et al ,2005.
[20] Application to Include Misprostol, 2011.
[21] Proposal for the Inclusion of Misoprostol in the Who Model List of Essential Medicines submitted by Gynuity Health Projects, NY, USA and Venture Strategies Innovations, CA, USA to the 18th Expert Committee on the Selection and Use of Essential Medicines held in Geneva, 2010 (hereafter "Gynuity and Venture Proposal for Misoprostol Inclusion, 2010")
[22] WHO Recommendations for the Prevention of PPH, 2007.
[23] *Id.*
[24] *Id.*
[25] Prendiville WJ, Harding JE, Elbourne DR, Stirrat GM. The Bristol third stage trial: active versus physiological management of third stage of labour. BMJ 1988; 297: 1295-1300.

(hereafter Prendiville et al, 1998).
[26] WHO Recommendations for the Prevention of Postpartum Haemorrhage, 2007.
[27] Application to Include Misoprostol for Treatment of PPH, 2015.
[28] *Id.*
[29] WHO 17th Model List of Essential Medicines (EML) dated March 2011 (hereafter WHO 17th EML), a*vailable at:* http://www.whoint/medicines/publications/essentialmedicines; WHO cites that essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. The Model List is a guide for the development of national and institutional essential medicine lists. For the past 30 years the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity. Essential medicines are one of the most cost-effective elements in modern health care and their potential health impact is remarkable.
The concept of essential medicines is forward-looking. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs.
Lists of Essential Medicines also guide the procurement and supply of medicines in the public sector. Many international organizations, including UNICEF, UNHCR and UNFPA as well as nongovernmental organizations and international non-profit supply agencies, have adopted the essential medicines concept and base their medicine supply system mainly on the Model List.
[30] WHO 17th EML.
[31] 19th WHO Model List of Essential Medicines (April 2015), sec. 22.1, 38 *available at* http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf. Misoprostol is a life-saving drug that has been included in the 2015 19th Essential Medicines List (EML) of the World Health Organisation for the prevention and treatment of post-partum haemorrhage (PPH), management of incomplete abortion and miscarriage, induction of labor, and medical abortion; Misoprostol, a prostaglandin, can be used for other lifesaving purposes such as therapeutic abortion in cases of missed abortion, intrauterine fetal death, and severe eclampsia, and cervical ripening prior to obstetrical/gynecological procedures such as therapeutic curettage and insertion of intrauterine devices. See WHO Expert Opinion on Abortifacients citing Blanchard et al, 2002 and Weeks et al, 2005.
[32] Monitoring emergency obstetric care: a handbook (2009), World Health Organization, United Nations Population Fund, UNICEF, Mailman School of Public Health. Averting Maternal Death and Disability.
[33] United Nations Commission on Life-Saving Commodities for Women and Children, Commissioners' Report, September 2012.
[34] FIGO is the only organization that brings together professional societies of obstetricians and gynecologists on a global basis. Currently, it has member societies in 124 countries or territories.
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[36] United States Pharmacopeia Misoprostol for Prevention of Postpartum Hemorrhage: An Evidence-based Review (2001), http://www.usp.org/pdf/EN/dqi/misoprostolReport.pdf. The United States Pharmacopeia lists misoprostol for prevention of PPH as accepted off-label use.
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[40] Gynuity Health Projects and Family Care International, Misoprostol for Postpartum Hemorrhage, March 2006.
[41] *Id.*

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[44] Derman et al. 2006); Durocher, J, J Bynum, W Leon, G Barrera, and B Winikoff. "High fever following postpartum administration of sublingual misoprostol." British Journal of Obstetrics and Gynecology, 2010. BJOG 2010; DOI: 10.1111/j.1471-0528.2010.02564.x (hereafter Durocher et al, 2010).
[45] Alfirevic et al, 2007.
[46] Gynuity and Venture Proposal for Misoprostol Inclusion, 2010.
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] 2013 National Demographic and Health Survey [NDHS 2013].
[51] This also translates to 57 per 1000 women aged 15-19 who are already mothers or are pregnant with their first child (NDHS 2013); birth rate is 59 per 1000 women aged 15-19 under the UNFPA 2015 State of the World Population.
[52] WHO, UNICEF, UNFPA, World Bank Group, and United Nations Population Division Maternal Mortality Estimation Inter-Agency Group, Maternal mortality in 1990-2015.
[53] UNFPA, 2015 STATE OF THE WORLD POPULATION.
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[58] DOH AO No. 2010-0014, May 14, 2010.
[59] Gynuity and Venture Proposal for Misoprostol Inclusion 2010.
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Moss N, Kodkany BS, Derman RJ. Factors associated with acute postpartum hemorrhage in low-risk women delivering in rural India. International Journal of Gynecology & Obstetrics 2008; 101(1):94-99 (hereafter Geller et al. 2008); having a large baby is also a risk factor for PPH.
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Health Technical Briefs. United States Agency for International Development (USAID). Last updated 21 February 2008, *available at* http://www.maqweb.org/techbriefs/tb48posthem.shtml (hereafter USAID 2008).

[64] Oxytocin needs refrigeration while misoprostol does not need refrigeration.

[65] The FDA then known as the Bureau of Food and Drugs (BFAD) issued the Advisory BFAD 2002-02 (12 August 2002) *available at* http://www.fda.gov.ph/attachments/article/38928/FA%20200202%20Cytotec.pdf [accessed 1 June 2016]. The Advisory has not been withdrawn and is still effective.

[66] Republic of the Philippines Act No. 3720 (The Food, Drug, and Cosmetic Act) as amended by the Republic of Philippines Act No. 9711 (Food and Drug Administration (FDA) Act of 2009) (http://www.lawphil.net/statutes/repacts/ra2009/ra_9711_2009.html) The law provides for imprisonment of one to ten years, fines of up to 500,000 pesos, or both. (Sec. 12)

[67] DOH AO No. 2010-0014, May 14, 2010.

[68] Gynuity Health Projects and Family Care International, Postpartum Hemorrhage: A challenge for safe Motherhood, 2006.

[69] *See* Board of Education v. Everson, 330 U.S. 1, 15-16 (1946) where the Court stated that "[n]either a State nor the Federal Government can set up a church…[or] pass laws which aid one religion, aid all religions, or prefer one religion over another…Neither…, openly or secretly, participate in the affairs of any religious organizations or groups and vice versa. In the words of Jefferson, the clause against establishment of religion by law was intended to erect 'a wall of separation between Church and State.'"

[70] *See Lee v. Weisman,* 505 U.S. 577, 587 (1992). In *Lee*, the U.S. Supreme Court invalidated the performance of a nonsectarian prayer by clergy at a public school's graduation ceremony; *see also Santa Fe*, 530 U.S. at 310-312 where the court invalidated student-initiated and student-led prayers at football games because they coerce students to participate in religious observances; In *Kerr v. Farrey*, 95 F.3d 472 (7th Cir. 1996), the Seventh Circuit followed *Lee* in striking down prison programs where inmates' sentences were affected by participation in substance abuse programs that stressed religion. It was held that the program runs "afoul of the prohibition against the state's favoring religion in general over non-religion."; *see* Center for Reproductive Rights (CRR), Petition for Certiorari in the U.S. Supreme Court case of *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Envtl. Control*).

[71] Committee on the Elimination of Discrimination against Women (CEDAW Committee) findings on its inquiry on Manila EO 003 and E0 030 finding the Philippines accountable for grave and systematic violations of women's rights under the CEDAW Convention and recommended to reintroduce misoprostol to reduce maternal mortality and morbidity rates, *available at* http://tbinternet.ohchr.org/Treaties/CEDAW/Shared%20Documents/PHL/CEDAW_C_OP-8_PHL_1_7679_E.pdf

[72] BFAD Advisory 2002-02 (12 August 2002).

[73] Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), *adopted* Dec. 18, 1979, G.A. Res. 34/180, U.N. GAOR, 34th Sess., Supp. No. 46, art. 10(h), U.N. Doc. A/34/46 (1979), 1249 U.N.T.S. 13 (*entered into force Sept. 3, 1981*) [hereinafter, CEDAW], Art. 1.

[74] CEDAW, Art 2.

[75] Id., Article 12(1).

[76] CEDAW General Recommendation No. 24, 20th session, 1999, 12 para. 31 (b), (c).

[77] CEDAW Comm., *Gen. Rec. 24, supra* note 133, para. 31(a).

[78] REBECCA COOK, ED., HUMAN RIGHTS OF WOMEN: NATIONAL AND INTERNATIONAL PERSPECTIVES 245 (1994).

[79] CESCR, *Gen. Comment 14*, *supra* note 34, para. 12.

[80] CESCR, *Gen. Comment 14*, *supra* note 34, para. 12 (b).

[81] REBECCA J. COOK & BERNARD M. DICKENS, CONSIDERATIONS FOR FORMULATING REPRODUCTIVE HEALTH LAWS 8, World Health Organization, 2nd Ed. (2000).

About the Author

Clara Rita "Claire" Padilla is the founder and executive director of EnGendeRights. She is a widely published feminist lawyer and human rights activist.

She has worked in the Philippines and in New York. In New York, she worked as an International Visiting Legal Fellow at the Center for Reproductive Rights from July 2002 through July 2003.

She holds a Juris Doctor degree from the Ateneo de Manila University and has been practicing law for over 23 years working in the fields of gender, gender-based violence, sexual and reproductive health and rights, and sexual orientation, gender identity and expression (SOGIE).

She has extensive experience in training, litigation, research, writing, and policy advocacy. After graduating from law school, she has dedicated her life in changing laws, policies, and practices that are discriminatory against women. As an advocate on reproductive rights, she has been quoted in various articles including the New York Times (Oct. 26, 2009).

She drafted the very first version of the Reproductive Health Care bill in 2001 when it first carried the name "Reproductive Health Care Law". She has also proposed language for draft bills and ordinances that have been passed into law including the Anti-Sexual Harassment Act; the Expanded Anti-Trafficking Law or RA 10364; the Quezon City Gender-Fair City prohibiting discrimination based on SOGIE and providing affirmative acts passed in 2014; the ordinance creating the Quezon City Protection Center for victim-survivors of gender-based violence and abuse passed in 2012; the first comprehensive anti-discrimination bill prohibiting ethnic, racial or religious profiling to prohibit discrimination based on ethnicity, race, religion or belief, sex, gender, sexual orientation, gender identity, language, disability, or other status which was adopted on third reading by the Senate in December 2011, among others. She was also one of the drafters of the DOH AO 2016-0041 on Prevention and Management of Abortion Complications.

She has won several Supreme Court en banc cases including the 2010 landmark case of Ang Ladlad vs. COMELEC (G.R. No. 190582) where she and several other lawyers won their petition for certiorari with the Supreme Court granting the accreditation of the lesbian, gay, bisexual, and transgender (LGBT) party-list organization that was originally denied accreditation by the Commission on Elections (COMELEC). She was the lead counsel and drafter of the Comment-In-Intervention and Memorandum of the intervenors Catholics for RH et al in support of the Reproductive Health Law (RH Law) wherein their contribution was crucial in winning the constitutionality of the RH Law in an en banc decision of the Supreme Court. Another Supreme Court en banc case she won was the landmark case of Pioneer Texturizing Corporation vs. National Labor Relations Commission and Lourdes de Jesus. In the Pioneer case, she successfully argued that illegally dismissed employees should be automatically reinstated at work or in the payroll without need of a writ of execution with the Supreme Court overturning its previous doctrine laid down in Maranaw vs. NLRC.

She spearheaded the submission of the request for inquiry on Manila EO 003 (Series of 2000) to the CEDAW Committee which was a collaborative effort of the Philippine-based Task Force CEDAW Inquiry, the New York-based Center for Reproductive Rights, and the Malaysia-based International Women's Rights Action Watch-Asia Pacific (IWRAW-AP) where the Philippines was found to have committed reproductive rights violations. She has made oral interventions before the CEDAW Committee in New York (2006) and in Geneva (2016) and before the Human Rights Council in Geneva (2008).

She advocated for the adoption of the Optional Protocol to the International Covenant on Economic Social Cultural Rights (OP ICESCR) in Geneva which was finally adopted in December 2008. She represented the Women's Caucus on the ASEAN Human Rights Body that advocated for a strong promotion and protection mechanism in the ASEAN Intergovernmental Commission on Human Rights (AICHR) that was eventually launched in October 2009. She was part of the OutRight Action International (OutRight) Advocacy Week team that met with UN officials and diplomats of various embassies in New York (2016).

She has been conducting trainings in different parts of the Philippines and around the world such as on the Optional Protocol to CEDAW for Cambodian government officials and UN Country Team in Cambodia (Cambodia, 2011, sponsored by UN Women), NGO-GO dialogues on CEDAW at an ASEAN High-Level Consultation Meeting (Vientiane, Lao PDR, 2008, sponsored by UN Women) and NGOs (East London, South Africa, 2012; Bogor, Indonesia, 2012; Kuala Lumpur, Malaysia, 2008, sponsored by the International Service for Human Rights (ISHR), Forum-Asia, and IWRAW-AP; Jakarta, Indonesia, 2007; on the Human Rights Committee Gender Discrimination Cases (Nepal, 2007); on sexual orientation, gender identity, and expression (SOGIE) (APCRSH, Hyderabad, India, 2007). She has represented Asia in several international panel discussions, *inter alia*, the problem of criminalization of sexual rights (Women Deliver Conference, Copenhagen, Denmark, 2016, panel sponsored by Amnesty International) and at a side event during the Commission on the Status of Women on economic, social, and cultural rights and the Beijing Declaration (New York, 2015, panel sponsored by ESCR-Net). She was also a panelist on domestic and family violence based on SOGIE at the ILGA World Conference (Bangkok, 2016, panel sponsored by OutRight). She has been a guest presenter for meetings of international legal experts (New York, 2005; Nairobi, Kenya, 2001 where the other participants/presenters included Navanethem Pillay, then President of the International Criminal Tribunal for Rwanda and former High Commissioner for Human Rights and Professor Catharine MacKinnon, sponsored by Equality Now). She has also acted as a speaker in the two AICHR ASEAN Maternal Health Conferences (2011, 2014) and participated in various international conferences and meetings on reproductive rights (e.g., Global Roundtable ICPD 10th Anniversary, London, 2004; International Consortium on Emergency Contraception (ICEC), New York, 2002) and global trainings of trainers on the Optional Protocol to CEDAW, *inter alia*, sponsored by IWRAW-AP (Warsaw, Poland, 2008).

She has been a speaker in several trainings for the Commission on Human Rights (CHR) staff on CEDAW Committee jurisprudence (September and December 2015; 2016) and

continuing challenges on reproductive health (2017 co-sponsored by the Asia Pacific Forum and the CHR).

She was a speaker on sexual and reproductive health and rights for the 11th IBP National Convention in Cagayan de Oro (2007) with about 1200 lawyers, prosecutors, and judges. She was a speaker for the IBP Eastern Visayas with more than 700 lawyers and judges (2006) on the "Anti-Violence Against Women and Their Children Act of 2004" and "Gender Issues in Legal Ethics".

She facilitated discussions on gender equality and CEDAW for the justices of the Philippine courts and trainings on sexual harassment for members of the committee on decorum and investigation of the Philippine judiciary in 2008 (a project under the European Commission).

She also drafted the following:

- A comparative study of gender-based violence (GBV) and HIV/AIDS legislation in ASEAN member countries and a model legislation addressing the link between GBV and HIV/AIDS, Philippine Commission on Women, 2009;
- Country Analysis of the AIDS, Gender and Age Situation and Response in the Philippines, Gertrudes Libang, Gladys Malayang, and Clara Rita Padilla, 2010 (co-written), available at http://www.unicef.org/philippines/Engenderights_Final(1).pdf;
- A Review of the Beijing Platform for Action Accountability Mechanisms, APWLD, November 2014
- Outcome Report and Background Paper, Asia Pacific Roundtable: International and Regional Standard setting to Eliminate Violence against Women, Bali, Indonesia, APWLD, 2013
- 2016 Universal Periodic Review submission of the Sexuality Rights Network
- Review of The Forum et al. consortium project entitled, "Sustained National and Local Advocacy for Reproductive Health in the Philippines" funded by the Bill and Melinda Gates Foundation (October through December 2016)

EnGendeRights publications include:

- Access to Safe and Legal Abortion and Post-Abortion Care Can Save Filipino Women's Lives (Policy Paper & Fact Sheets 2016)
- What You Should Know When Assisting Rape Survivors (2015)
- What You Should Know When Assisting Violence against Women Survivors (2015)
- The Constitutionality of a Reproductive Health Care Law (2012)
- Ensuring Adolescent Right to Reproductive Health through an RH Law (2012)
- Reasons Why We Need the RH Law (2010)
- Primer on the Inquiry Procedure under the OP CEDAW (2010)
- Advancing Reproductive Rights Using the Inquiry Procedure of the OP CEDAW and the UN Special Procedures: The Philippine Experience (2010)
- Stop VAW & Stop Rape flyers, BPO & Temporary and Permanent Protection Order flyers (2010)
- Engendering Women's Rights: A Paralegal Manual" on gender-based violence (2007)

EnGendeRights press releases and position papers include:

- EnGendeRights Calls for the Repeal of the Prostitution Law Penalizing Women in Prostitution (March 2012);
- Proposal to Include Misoprostol on the Philippine National Drug Formulary and the FDA Drug Registry for Postpartum Hemorrhage Prevention (July 2011)
- Calls to junk congressional bills restricting access to contraceptives and increasing penalties on abortion (May 2011, December 2006)
- Upholding Women's Right to Levonorgestrel as Emergency Contraceptive Pill submitted to the Bureau of Food and Drugs (BFAD) (March 2007);
- Marital Infidelity does Not Have a Place in Our Penal Laws (November 2007)
- The right to education of an adolescent who induced abortion (2007)

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About EnGendeRights

EnGendeRights has done groundbreaking work in raising Filipino women's concerns to the international level especially the United Nations mechanisms.

Shadow Report to the Committee on the Elimination of Discrimination against Women (CEDAW Committee) and Oral Statements

- August 2006 for the 36th Session done in collaboration with the Center for Reproductive Rights (CRR), Reproductive Rights Resource Group, Philippines (3RG-Phils.), and Health Development and Initiatives Institute (HDII). EnGendeRights executive director Clara Rita Padilla orally presented highlights of the Shadow Report during the CEDAW-NGO dialogue in New York. Recommendations included access to the full range contraceptive methods, access to safe and legal abortion, sexuality education for adolescents, skills and education for women in prostitution, legalization of divorce and repeal of discriminatory Muslim Code provisions.

- June 2016 for the 64th Session:
  - EnGendeRights & OutRight International submission (representing a total of 34 organizations) on Lesbian, Bisexual, Transgender Rights
  - EnGendeRights individual submission on VAW, Marriage, and Family Relations
    - Clara Rita Padilla made an oral statement before the CEDAW Committee in Geneva

Request for Inquiry to the CEDAW Committee

- EnGendeRights as part of the Task Force CEDAW Inquiry together with CRR and the International Women's Rights Action Watch, Asia Pacific (IWRAW-AP) submitted a Request for Inquiry under the Optional Protocol to CEDAW in 2008 requesting the CEDAW experts to investigate grave and systematic reproductive rights violations resulting from contraceptive restrictions under Manila City EO 003 implemented since 2000. CEDAW experts Pramila Patten and Violeta Neubauer conducted the on-site investigation in November 2012 investigating, *inter alia*, national and local government officials including heads of hospitals and clinics, representatives of the DOH, DILG, Manila City. It was the 2nd inquiry conducted by the CEDAW Committee throughout the whole world.
- In May 2015, the CEDAW Committee released its report on its inquiry (CEDAW/C/OP.8/PHL/1, paras 49 to 52) finding the government accountable for grave and systematic reproductive rights violations and recommended, *inter alia*, to the Philippines to:
  - provide women access to quality post-abortion care in all public health facilities including by reintroducing misoprostol to reduce maternal mortality and morbidity rates
  - ensure that women experiencing abortion-related complications are not reported to law enforcement authorities, threatened with arrest, or subjected to physical or verbal abuse, discrimination, stigma, delays in access to or denial of care
  - amend articles 256 to 259 of the Revised Penal Code to "legalize abortion in cases of rape, incest, threats to the life and/or health of the mother, or serious malformation of the foetus and decriminalize all other cases where women undergo abortion, as well as adopt necessary procedural rules to guarantee effective access to legal abortion."