

# Tackling the unacceptable: Nigeria approves misoprostol for postpartum haemorrhage

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Nigeria has 2% of the world's population, but 10% of the global burden of maternal deaths – a statistic that is described by Nigeria's president Olusegun Obasanjo as "unacceptable and must be reversed". In January 2006, Nigeria took an important step towards reversing this tragic situation when the Nigerian National Agency for Food and Drug Administration and Control approved the distribution of misoprostol for the prevention or treatment of postpartum haemorrhage (PPH). This is the first time misoprostol has been approved in any developed or developing country for this lifesaving indication.

In Nigeria, as in much of Africa, the situation of women at delivery is dire and deteriorating. It is a patriarchal society and the majority of women are illiterate. Doctors and nurses are stretched to the limit and unable to provide sufficient care in rural areas. The national Safe Motherhood Initiative, adopted in 1990, has failed. Around 40% of pregnant Nigerian women now experience pregnancy-related problems during or after pregnancy and childbirth. The national average maternal mortality ratio (MMR) is 800–900 per 100 000 live births. Many women do not reach health facilities until it is almost too late, and the MMR in hospitals is often higher than the national average. For example, at a hospital in Kano, Northern Nigeria the MMR is an astonishing 7523 per 100 000 live births. PPH accounts for a quarter of the 55 000 annual maternal deaths in Nigeria. The Nigerian Federal Ministry of Health has recognised this growing problem: "failure to factor population figures in earlier planning ... has led to the provision of inadequate facilities for the teeming and increasing population".<sup>1</sup> Between 1990 and 2003, the percentage of deliveries attended by a trained person fell from 45% to 36.3%, and the use of modern contraceptives also declined (12% to 8%). It is clear that new strategies are needed to reverse these trends and reduce maternal mortality in Nigeria.

In February 2006, a policy meeting was held in Abuja, the Nigerian capital, to discuss the next steps for using misoprostol as well as to consider other strategies for reducing maternal mortality. The 80 participants included leaders in the medical community, nurses, pharmacists and representatives of the Federal Ministry of Health. The Society of Obstetricians and Gynaecologists of Nigeria (SOGON) and several non-governmental organisations were also represented at the meeting. SOGON played a key role at the meeting, as they have made reducing the MMR a central part of their strategic focus.

It was the consensus of the meeting that misoprostol should be added to the national essential drugs list for the prevention and treatment of PPH, and that qualified health professionals should be trained in its use immediately. It was also suggested that a 25 µg misoprostol suppository should be marketed, to avoid over-dosage when obstetricians use misoprostol to induce labour.

Almost 15 000 Nigerian women die each year due to PPH; unless this trend is reversed then approximately 2 million of the 27 million women of reproductive age now alive will die from pregnancy, abortion or childbirth.<sup>2</sup> At the February policy meeting there was agreement that while access to emergency obstetric care must be improved, progress towards meeting the Millennium Development Goal of reducing maternal mortality by 75% between 1990 and 2015 would be impossible without widespread access to misoprostol.

Some participants were frustrated by the difficulty of training traditional birth attendants (TBAs), while others felt that misoprostol offered an opportunity for a renaissance in successful TBA training. Ndola Prata (an Angolan doctor at the University of California, Berkeley, CA, USA) provided compelling data from Tanzania that demonstrated how TBAs can effectively use misoprostol to treat PPH in the home.<sup>3</sup> Harshad Sanghvi (JHPIEGO, affiliated with Johns Hopkins University, Baltimore, MD, USA) reported that many thousands of Indonesian and Nepalese women are self-medicating with misoprostol immediately after delivery to prevent PPH following their successful study introducing this practice.

Those experts at the meeting with clinical experience of misoprostol have found it highly effective in both preventing and controlling PPH, especially in resource-scarce settings. They found that misoprostol's low cost, ease of use and excellent safety profile, as well as its long shelf life in tropical climates, make it an attractive alternative to ergometrine or oxytocin in some busy clinical settings. Misoprostol is also the only uterotonic appropriate for home deliveries without a skilled attendant – the setting where most births in Nigeria take place.

The approval of misoprostol in Nigeria is as a prescription drug. The policy meeting agreed that the next steps should include encouraging public health and private sector professionals to gain experience in using misoprostol. Then the potential role of less well trained providers and patients would be reviewed as more information is accumulated. To that end, operations research on the use of misoprostol after home births by TBAs in Benin City, Nigeria is underway.

The approval of misoprostol in Nigeria represents a new type of international collaboration. The drug is manufactured by the Zizhu Pharmaceutical Company in Beijing, China and is an example of south-south trade in essential medicines. Such trade is encouraged by Partners in Population and Development, the alliance of ministries of health of 21 developing countries including Nigeria and China. Research shows that women in the poorest economic quintiles in countries such as Nigeria, if they obtain any health care at all, are most likely to receive it from the private, informal sector.<sup>4</sup> Emzor Pharmaceutical Industries, a leading Nigerian generic drug manufacturer and distributor, was selected because it specialises in low-

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income markets. Although misoprostol is already marketed throughout much of the world, those countries where it has not been introduced, such as most of sub-Saharan Africa, are exactly those where most postpartum deaths are occurring.

The School of Public Health at the University of California, Berkeley provided the technical support for the registration process. Venture Strategies for Health and Development (VSHD), a California non-profit organisation that has supported the operations research and previous policy meetings in Africa,<sup>5</sup> provided financial support and, building on the Nigerian experience, is now working to facilitate the approval and distribution of misoprostol in several more countries in Africa and the Middle East. The policy meeting was co-sponsored by the International Federation of Obstetrics and Gynaecology (FIGO), the Women's Health Action and Research Center (WHARC) in Benin City, Nigeria and VSHD.

In 2003, FIGO made combating PPH globally its top priority. The Nigerian experience was reported at a July 2006 meeting in Goa, India on PPH, sponsored by the Ministry of Health and Family Welfare of the Government of India; the Jawaharlal Nehru Medical College in Belgaum, India; UNICEF (India); the Indian Council of Medical Research (ICMR); the University of Missouri-Kansas City School of Medicine (USA); the National Institute of Child Health and Human Development (NICHD, USA); USAID (India and USA);

Access to Clinical and Community Maternal, Neonatal and Women's Health Services (ACCESS); JHPIEGO (USA); the Prevention of Postpartum Hemorrhage Initiative (POPHI); the World Health Organization; and the United Nations Population Fund (UNFPA). The growing emphasis on making misoprostol available and the outcome of the Abuja and Goa meetings will feed into the next triennial meeting of FIGO to be held in Kuala Lumpur in November 2006, when FIGO will review progress and set new policies to reduce PPH deaths worldwide.

#### Statements on funding and competing interests

*Funding.* None identified.

*Competing interests.* Amy Jadesimi has established a company to hold the import licenses for needed generic drugs in Nigeria. No competing interests have been identified for Friday Okonofua.

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