

# **AIDS drugs given to pregnant women block 99 percent of HIV transmission to breastfed babies**

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An international clinical trial led by researchers at the Harvard School of Public Health (HSPH) has found that AIDS-fighting antiretroviral drug combinations given to pregnant and breastfeeding women in Botswana, Africa, prevented 99% of the mothers from transmitting the human immunodeficiency virus (HIV) to their infants.

"This is the lowest rate of mother-to-child transmission recorded in a study from Africa, or among breastfeeding infants," said lead author Roger Shapiro, Associate Professor of Medicine at Harvard Medical School and Harvard School of Public Health. The mother-to-child transmission rate in the study was 1.1% when the infants were breastfed to age 6 months. "Previous interventions using shorter or less comprehensive drug treatment regimens have been unable to get rates below 5%, and without any intervention, the infection rate would be at least 25% by 6 months," said Shapiro.

The study was also the first randomized clinical trial to compare highly active antiretroviral therapy (HAART) regimens used during pregnancy or breastfeeding.

The article will appear in the June 17 edition of The [New England Journal of Medicine](#). It is accompanied by an editorial by Dr. Lynne Mofenson of the National Institutes of Health, who notes the important role for maternal HAART use during pregnancy and breastfeeding,

particularly among [women](#) who also qualify for HAART as treatment for their own health. Dr. Mofenson states, "The intervention that would have the most substantial impact on HIV-1-related maternal deaths and perinatal infections throughout the world is the initiation of lifelong antiretroviral therapy in pregnant and lactating women infected with HIV-1 who meet the treatment criteria."

Breastfeeding is normally the best way to feed an infant and is one of the most critical factors for improving child survival in developing nations. A woman infected with HIV, however, can transmit the virus to her child during breastfeeding, as well as during pregnancy, labor and delivery.

The research was part of the Mma Bana Study (meaning "mother of the baby" in Setswana) conducted in southern Botswana as a collaboration between HSPH and the Botswana government (the Botswana-Harvard AIDS Institute Partnership) to improve health for women and children. Established in 1996, the partnership is a collaborative research and training initiative between the Government of Botswana and the Harvard School of Public Health AIDS Initiative.

The use of HAART to prevent mother-to-child HIV transmission is one of the most successful public health interventions to prevent the transmission of AIDS in pregnancy. Little has been known, however, about its promise for halting HIV transmission from mother to infant through breastfeeding in areas of the world where formula feeding is neither safe nor feasible, including most of sub-Saharan Africa.

The study compared the suppression of the mother's HIV virus at delivery and throughout breastfeeding among women assigned to receive one of three treatment regimens. Overall, 730 HIV-infected pregnant women were included in the study and most started HAART early in the third trimester of pregnancy. Almost all women achieved viral

suppression by delivery, and their virus remained undetectable throughout breastfeeding. All three HAART regimens consisted of commonly used antiretroviral combinations with three active drugs. Similar results were found for all treatment groups, including 560 women who were randomized to receive either zidovudine, lamivudine, and abacavir (co-formulated as Trizivir) or zidovudine, lamivudine, lopinivir/ritonavir (Kaletra/Combivir), and 170 sicker women who qualified for treatment for their own health and received zidovudine, lamivudine, and nevirapine (Nevirapine/Combivir) provided by the Botswana government.

All HAART regimens used in the study were found to be highly effective at suppressing the HIV virus, said the authors. They also found the HAART regimens used in the study were safe and generally well-tolerated.

"Until now, HIV-infected mothers in Africa were faced with a choice between breastfeeding and a high risk of infecting their children with HIV, or using formula and risking high infant morbidity and mortality from other diseases associated with not breastfeeding. This study provides a more satisfactory solution," said senior author Max Essex, Mary Woodard Lasker Professor of Health Sciences and chair of the Harvard School of [Public Health](#) AIDS Initiative.

The rates of infection with HIV in southern Africa are 3 to 5 times higher than in the rest of sub-Saharan Africa and more than 100 times higher than in the rest of the world. This discrepancy is much greater for women and children. While about 90% of the AIDS patients in the U.S. or Europe receive effective treatment, a much smaller percentage of patients in Africa receive adequate treatment. Children who are HIV infected are much less likely to be in treatment programs, and are usually destined to die of HIV/AIDS at a young age. This makes it even more critical that effective measures are available to prevent them from

becoming infected.

The Mma Bana Study findings already have influenced WHO guidelines on the use of HAART to prevent mother-to-child HIV transmission. For the first time, WHO recently recommended that all HIV-infected mothers or their infants take antiretroviral drugs while [breastfeeding](#) to prevent HIV transmission. The Botswana government is preparing to roll out a program to provide HAART to all pregnant women with [HIV](#), said Shapiro. Other countries are considering doing the same.

The research was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. The Fogarty International Center supported several trainees involved in this study. Other Boston institutions participating in the study included Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, and Massachusetts General Hospital.

"Antiretroviral Regimens in Pregnancy and Breast-Feeding in Botswana," Roger Shapiro, Michael Hughes, Anthony Ogwu, Doug Kitch, Shahin Lockman, Claire Moffat, Joseph Makhema, Sikhulile Moyo, Ibou Thior, Kenneth McIntosh, Erik van Widenfelt, Jean Leidner, Kathleen Powis, Aida Asmelash, Esther Tumbare, Sheryl Zwierski, Usha Sharma, Edward Handelsman, Kinuthia Mburu, Oluwemimo Jayeoba, Evans Moko, Sajini Souda, Edmund Lubega, Maida Akhtar, Carolyn Wester, Wendy Snowden, Marisol Martinez-Tristani, Loeto Mazhani, Max Essex, NEJM, Vol. 362, No. 24, June 17, 2010.

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