

Research: Microbicide to Prevent HIV Transmission During Breastfeeding

The World Health Organization estimated that there were 2.5 million children living with HIV worldwide at the end of 2009. The vast majority of these children, 2.3 million, live in sub-Saharan Africa, compared to less than 6,000 cases in North America and Western and Central Europe combined.

Recent statistics indicate that 200,000 new HIV infections occur each year in infants through breastfeeding. At the same time, malnutrition continues to be a factor in more than half of all infant and child deaths in sub-Saharan Africa, and exclusively breastfeeding an infant is a clear way to combat malnutrition. In countries where formula is accessible and affordable, where clean, safe drinking water is readily available, and where there is no stigma associated with bottle-feeding, preventing transmission of the virus is simple: do not breastfeed. However, all of these factors present challenges in resource-poor countries such as those in sub-Saharan Africa. So, HIV-positive mothers continue to run the risk of infecting their babies while trying to confer the nutrition and health benefits that exclusive breastfeeding provides.

Antiretroviral drugs can be used by the mother who is breastfeeding, but they are not without risk. Drug-resistance can develop in the patient, requiring frequent changes in the type of ARV administered. Additionally, the most common ARVs have not been tested for long-term use in infants.

Sandra Urdaneta-Hartmann, M.D., Ph.D., MBA (Drexel '09), research assistant professor in the Departments of Obstetrics & Gynecology and Microbiology & Immunology, and assistant director of research at the Institute for Women's Health and Leadership, is currently working on technology that could provide a solution. She and her research partners (see box below) are the first to report on the possible use of microbicides to treat HIV-infected breast milk.

The late Mary K. Howett, Ph.D., who was chair of the Department of Biology (Drexel University College of Arts & Sciences) until her death in 2008, was the innovator who first discovered the antimicrobial properties of sodium dodecyl sulfate (SDS), an ingredient in toothpaste and many other common consumer products. Urdaneta-Hartmann has continued that work, testing SDS in a laboratory setting and finding that it kills HIV in vitro with no significant change to the milk's nutritional value, nor in its ability to confer beneficial immunities to the infant.



Nipple shields can be modified to include disks of nonwoven material containing a microbicide to kill the HIV virus.

Image: Courtesy of JustMilk

Urdaneta-Hartmann is also exploring the use of a silicone nipple shield (a discreet device already widely in use to solve other breastfeeding difficulties) to prevent transmission of HIV through breast milk. She is seeking to modify the shield to include a disk of nonwoven material containing a microbicide such as SDS. As the breast milk passes through the shield, the virus would be killed, rendering the milk safe for the infant. Although it is already used for other purposes, SDS is not currently approved for use as an anti-HIV microbicide.

Work is also under way to use the nipple shield for delivery of the antiretroviral drug nevirapine to infants, as recommended by WHO for prophylaxis against transmission of HIV infection to infants who must be breastfed. Since nevirapine is already FDA approved, it is likely that this application will have a faster path to market, possibly three to five years.

The Bill and Melinda Gates Foundation, Family Health International, and the Mary DeWitt Pettit Fellowship (awarded by the Trust Fund of the Alumnae/i Association of WMC/MCP) have funded Urdaneta-Hartmann's research. She has a proposal currently under review for the Robert Wood Johnson Foundation Harold Amos Medical Faculty Development Program to support her research, and she and her colleagues hope to obtain funding to conduct the first clinical trials with the nipple shield device in Nigeria.

Contact: sandra.urdaneta@drexelmed.edu

Translational Research – An Interdisciplinary Effort

The goal of translational research is to take an innovation from a laboratory setting and translate it into a practical, tangible application or product to improve human health. It is the bench-to-bedside approach to biomedical research. Research of this nature is, by necessity, interdisciplinary. For example, a virologist may discover a microbicide but will need a biomedical engineer to find the delivery mechanism. They will consult a behavioral scientist to determine the feasibility and acceptability of the delivery method for the population in need, a clinician will lead a clinical trial, and an epidemiologist and a statistician will follow a patient population to test outcomes.

Additional research partners in this project represent the **Department of Microbiology & Immunology:** Fred C. Krebs, Ph.D., associate professor, and Brian Wigdahl, Ph.D., professor

and chair. **Obstetrics & Gynecology:** Michele Follen, M.D., Ph.D., professor, also associate vice dean for translational research, and director of research for the Institute for Women's Health and Leadership®; Laniece Coleman, DNP, CNM, assistant professor, also director of Drexel Nurse-Midwifery Services; Gregg Alleyne, M.D., clinical assistant professor, also chief gynecologist at the Partnership Comprehensive Care Practice. **Division of Infectious Diseases & HIV Medicine:** Erika Aaron, R.N., CRNP, MSN, director of women's services, Partnership Comprehensive Care Practice. **Drexel University School of Public Health:** Seth L. Welles, Ph.D., Sc.D., associate professor, Epidemiology & Biostatistics, and Lisa Ulmer, MSW, Sc.D., professor, Community Health & Prevention. **External collaborators:** Researchers at Family Health International, University of Cambridge, and University of Ibadan (Nigeria).