



[Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](#)

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Findings Offer Insights into Role of Breastfeeding in Preventing Infant Death, HIV Infection in Resource Poor Countries

In many poor countries, mothers with HIV face a stark choice: to nurse their infants, and risk passing on HIV through their breast milk — or to formula feed, and deprive their infants of much of the natural immunity needed to protect against fatal diseases of early infancy. Now, two studies supported by the National Institutes of Health offer insights into preventing early death and HIV infection among breastfeeding infants of mothers with HIV in these countries.

The studies were published online in the *New England Journal of Medicine* and will appear in the publication's print edition on July 10.

One study was supported in large part by NIH, with additional funding by the Centers for Disease Control and Prevention and the United States Agency for International Development. That study found no benefit for infants born to mothers with HIV from abrupt cessation of breastfeeding after the first four months of life. In addition, this study found no difference in HIV infection rates or in death rates by age 2 among infants abruptly weaned off all breast milk at four months versus those who breast fed until later in infancy. In fact, for one group of infants, those infected with HIV, abrupt cessation of breastfeeding resulted in an increased death rate.

The other study, co-sponsored by the NIH and the Centers for Disease Control and Prevention, found that it was possible to greatly reduce the risk of HIV infection in breast-feeding infants by treating them with an extended anti-HIV regimen. The treatment consisted of the anti HIV drug nevirapine, alone or in combination with the drug zidovudine, during the first 14 weeks of life.

"In poor countries where sanitation is a problem, exclusive breastfeeding appears to confer the greatest benefits to infant health and survival, even in mothers with HIV" said Duane Alexander, M.D., director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the NIH institute that provided much of the support for the two studies. "Extended treatment with nevirapine greatly reduces the chances that infants will be infected with HIV through breast milk. The National Institutes of Health is now sponsoring additional studies to determine the most effective treatments to prevent the spread of HIV through breast milk."

In the developed world, mothers with HIV forego breastfeeding and formula feed their infants, said Lynne Mofenson, M.D., Chief of NICHD's Pediatric, Adolescent and Maternal AIDS Branch, and the project officer for the two studies. But in many poor countries, there are barriers to formula feeding. Sanitation is lacking, and clean water to mix formula is often not available. Many families have difficulty affording infant formula. They also have difficulty providing enough wood or charcoal for cooking fires to boil water needed for formula.

Formula fed infants also miss out on protective antibodies — passed on through breast milk — needed to ward off the deadly infant diseases prevalent in many parts of the world. Formula feeding, also, may carry a social stigma for mothers. The practice is often seen as a tacit acknowledgement that a woman has HIV.

"Formula feeding is a hardship in many poor countries," Dr. Mofenson said. "So the finding that it doesn't confer any apparent benefits in resource poor settings — and may even be harmful — has important implications."

The first of the two studies was conducted by Louise Kuhn, Mailman School of Public Health, Columbia University, New York, and colleagues from the Boston University School of Public Health, University of Zambia, and other institutions.

The study was conducted in Lusaka, Zambia. The researchers enrolled 958 women with HIV and their infants. The women consented to be randomly assigned to one of two groups. In the first, or intervention, group, 481 women were counseled to exclusively breastfeed their infants for four months, not offering any formula or other liquids. The women were advised to stop all breastfeeding when their infants were four months old. The women were also provided with formula and instructed in how to safely prepare it. In the second, or control, group, the women were advised to continue breastfeeding for as long as they chose to. Infants were tested for HIV at birth, and then periodically throughout the study, until they were 24 months of age.

In the intervention group, 69 percent of infants had stopped breastfeeding by 5 months of age. Children in the control group stopped breastfeeding at a range of ages, between 5 and 24 months of age. Only 7 percent of children in the control group had stopped breastfeeding by 5 months of age and 66 percent were still breastfeeding at 12 months of age.

The researchers found no significant differences in survival between the two groups. In the intervention group, 76.1 percent had survived to 24 months of age, versus 75.4 percent in the control group. Among infants who were still breastfeeding and uninfected at 4 months, there was also no significant difference in HIV-free survival by 24 months (83.9 percent in the intervention group, versus 80.7 percent in the control group.)

Breastfeeding appeared to improve survival among infants who were infected with HIV. Children in the intervention group who were infected with HIV at or before 4 months of age and still alive at 4 months of age had higher death rates by 24 months than did their counterparts in the control group (73.6 percent versus 54.8 percent). Causes of death were predominantly diarrheal and respiratory diseases, but also included malaria, malnutrition, measles, and injury.

The researchers were surprised to find that the proportion of new HIV infections between 4 and 24 months were not significantly different between the two groups despite differences in the time breastfeeding was stopped: 6.2 percent in the intervention group and 8.8 percent in controls. The researchers theorized that the chances of transmitting the virus may increase as a result of the weaning process. The breast swelling and infection (mastitis) that occurs when breastfeeding is sharply reduced may increase the likelihood that the virus will be transmitted in the few feedings that remain.

The second study, conducted in Blantyre, Malawi, was led by Taha E. Taha, of The Johns Hopkins University and Newton Kumwenda, of the University of Malawi College of Medicine. Among the study's other authors were Dr. Michael Thigpen, of the CDC, and Dr. Mofenson. In a study of 3,016 infants who did not have HIV at birth, the researchers compared two extended regimens of nevirapine (NVP) to the country's standard treatment: a single dose of NVP given to the mother during labor and to the infant at birth, with daily doses of zidovudine (ZDV) given to the infant during the first week of life.

The infants were assigned at random to one of three groups. The control group received the standard

treatment. The next group (the extended NVP group) received the standard treatment plus NVP from day 8 through the 14th week of life. The final group (the extended NVP+ZDV group) received the standard treatment plus NVP and ZDV from day 8 through 14 weeks.

When they were 9 months old, 10.6 percent of infants in the standard treatment group had acquired HIV. By comparison, 5.2 percent in the extended NVP group were infected and 6.4 percent in the extended NVP+ZDV group were infected, corresponding to a 51 percent and 40 percent decrease in HIV infection, respectively. The difference in HIV infection between the two extended treatment groups was not statistically significant.

Infants in the NVP+ZDV group were more likely than infants in the other groups to experience neutropenia, a deficiency of a certain type of an infection-fighting cell. People with neutropenia may be more susceptible to infection.

The study authors concluded that providing anti-HIV drugs to breastfeeding infants is a practical and effective way to reduce HIV infection. They noted that additional studies are needed to determine whether it was safe to provide anti-HIV drugs to infants for the duration of breastfeeding.

Dr. Mofenson said that one NIH-supported study, now in progress, was investigating whether anti HIV drugs could be safely given to breastfeeding infants for the first six months of life. Another NIH effort, now in the planning phase, will compare the effectiveness of infant nevirapine given to breastfeeding infants for the entire duration of breastfeeding, to the effectiveness of providing combination anti-HIV therapy to breastfeeding mothers.

The NICHD sponsors research on development, before and after birth; maternal, child, and family health; reproductive biology and population issues; and medical rehabilitation. For more information, visit the Institute's Web site at <http://www.nichd.nih.gov/>.

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