

Parents Raising Children: Premature Babies

Bill Number:

Hearing Date: May 13, 2004, 10:00 am

Location: SD-430

Witness:

Duane Alexander, MD

National Institute of Child Health and Human Development, NIH

Director

Testimony

Good morning. I am Duane Alexander, Director of the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH). I am pleased to be here to talk about the critical health challenge of prematurity.

Last year, during our celebration of the 40th anniversary of the Institute, we had an opportunity to take stock of our efforts to advance research in the fields that fall within our mission. Infant mortality is a major index of a nation's health, yet the infant mortality rate in the United States remains far higher than it should be, given the advantages we have compared to many countries with lower rates. We were gratified to realize that since the founding of NICHD, infant mortality rates in the United States have dropped more than 70 percent (to an all-time low of 6.8 per 1,000 live births in 2001), with much of this decline resulting from NICHD-sponsored research on care of low birth weight infants, Sudden Infant Death Syndrome, and other factors. For example, resulting from the research efforts of NICHD and other Institutes, survival rates for very premature infants with respiratory distress syndrome have gone from five percent in the 1960s to 95 percent today, due to advances in respirator technologies and the availability of replacement lung surfactant.

Sadly, even with these important accomplishments, we are still far from solving the problem of prematurity. Preterm birth (before 37 weeks of gestation) poses great risks to the infant. At least one in eight infants -- about 476,000 -- is born prematurely in the United States each year. Over the last twenty years, preterm birth in this country has actually increased by 21 percent. Preterm birth is the leading cause of death among African-American infants, contributing substantially to racial and ethnic health disparities in infant mortality, and is one of the top causes of all neonatal and infant deaths. In addition, preterm babies are more likely to have long-term health problems, such as a higher incidence of developmental disabilities. Premature delivery accounts for one of five children born with mental retardation, one of three who have some visual impairment, and almost half of those babies with cerebral palsy. Over the longer term, for the baby, for reasons we cannot explain, preterm birth carries with it an increased risk for cardiovascular disease and diabetes as an adult. For the mother, not only is preterm labor a leading cause of hospitalization of women, but she faces a greatly increased risk of delivering prematurely in the future.

Few other medical challenges fall so squarely within the mission of the NICHD, which is "to assure that every individual is born healthy and wanted, that women suffer no adverse

consequences from the reproductive process, and that all children have the opportunity to fulfill their potential for a healthy and productive life unhampered by disease or disability.” We are focusing on prematurity using every mechanism at our disposal, including investigator-initiated grant applications from scientists across the country, our own requests for grant proposals in specific areas, conferences and workshops, and most of all, our multi-center networks – the Maternal-Fetal Medicine Units, which deliver about 120,000 babies each year, and the Neonatal Network, which cares for about 60,000 babies every year. As you can see, the numbers of pregnant women and infants we are able to care for at these hospitals, staffed by some of the leading clinician-researchers in the field working collaboratively, gives us an opportunity to quickly and thoroughly test new preterm delivery prevention and management strategies.

Until recently, most previously tested strategies to prevent preterm birth in high-risk women failed to produce effective, reliable results because too few patients were studied and conditions were not well controlled. The Maternal-Fetal Medicine Network was established to overcome these problems. In one of the few concrete breakthroughs on this tremendously difficult front, published in the *New England Journal of Medicine* in 2003, we reported that our scientists who participate in the MFMU network had demonstrated that weekly injections of 17-hydroxy-progesterone, can reduce preterm birth by one-third among women at increased risk of preterm delivery because they had previously had a preterm delivery. Not only were the women treated with progesterone 30 percent more likely to carry their babies to term, their infants also had a much lower rate of life-threatening complications. The 463 women involved in the study were considered to be at high risk for preterm birth because they each had previously spontaneously delivered a baby early, at an average of about 31 weeks. As in many clinical trials, some of the women enrolled received the hormone being tested (the progesterone), while some received a placebo injection. The reduction in preterm birth – for African American women as well as non-African American women -- was so dramatic that the scientists halted the study early to make the results available to practitioners. Shortly thereafter, a committee of the American College of Obstetricians and Gynecologists notified its members of the success of this trial, recommending that women who had had a previous preterm delivery be considered for treatment with progesterone.

Let me talk for a moment about preventing preterm labor, one of the best ways to reduce the numbers of preterm births. Over the years, we have supported a range of studies to examine the effectiveness of various preventive measures for preterm labor, and this research has revealed some surprises. For instance, studies have shown that bed rest, which until very recently was the most common preventive approach, was not effective in preventing preterm labor or in delaying preterm birth. In some cases, bed rest may have actually made the situation worse. One possible explanation for these findings may be that active pregnant women are better able to expand their blood volume, which is necessary for a successful, full-term pregnancy. Other studies have examined the effectiveness of different drugs in suppressing uterine contractions early in preterm labor, although no effective treatment has yet been identified. Yet another Maternal-Fetal

Medicine Network trial demonstrated that Home Uterine Activity Monitoring, an expensive, highly touted regimen claimed to reduce preterm delivery, was completely ineffective for this purpose, thereby saving money and wasted effort by ending this useless practice.

Many NICHD-supported studies have been trying to answer the basic question of why women with no known risks experience preterm labor. During the course of these studies, researchers noted a relationship between bacterial vaginosis and preterm labor. In 1999, NICHD completed a large study that recruited pregnant women who had asymptomatic bacterial vaginosis to explore this possible association and results of treatment for it. Although the study found no difference in preterm labor between women who received an antibiotic and women who received the placebo, the research provided important clues about other possible treatments. It also stopped the growing practice of treating women who have asymptomatic bacterial vaginosis with antibiotics unnecessarily. Scientists at other institutes are looking for other clues to the cause of preterm labor. For example, the National Institute of Environmental Health Sciences is supporting research on whether exposure to certain environmental contaminants during pregnancy relates to preterm birth.

In addition, NICHD's newest intramural branch, the Perinatology Research Branch, is devoted to the study of premature birth and its consequences. Among other developments, the Branch has provided evidence that many premature newborns were critically ill prior to birth due to intrauterine infection, and is exploring the role of premature delivery in order to help these babies receive earlier treatment in order to survive.

We were able to rule out bacterial vaginosis as a direct cause of prematurity, and building on the progress we have made, we will conduct more research on understanding the causes of this condition, how we can prevent and treat prematurity in pregnant women, and further work on how best to manage or treat newborns who have been born prematurely.

Thank you for the opportunity to discuss NICHD's research on prematurity and for your interest in this important topic. I am happy to answer any questions you may have.