

**South African AIDS Conference  
Kathryn Wilfert: Nevirapine for PMTCT – Does it work?  
August 6, 2003**

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**MALE VOICE:** -- I have the honor now to introduce our third speaker, Professor Kathryn Wilfert. Professor Wilfert is the Scientific Director of the Elizabeth Glaser Pediatric AIDS Foundation. She is a pediatrician by training. Kathy is a well-respected scientist and researcher in the field of pediatric and infectious diseases and has been so for many years. I had the opportunity and the honor of talking to Kathy earlier on and I think in her illustrious research career, there has been many milestones and I think one that is of note and that I would like to bring to your attention is that together with her colleagues at Duke University, Kathy was the first to be able to employ a CT for the treatment of pediatric HIV. Her talk today is Nevirapine for PMTCT -- does it work? Welcome, Kathy.

**KATHRYN WILFERT:** -- I would like to express my thanks to the Chairman and to acknowledge the wonderful people who are speaking to you about this issue. Most of all, I would like to commend each and every one of you for your dedication, the perseverance with which you are approaching the prevention and treatment of HIV infection, and I know how much this means to you. In the course of this discussion, I would like to present the information that substantiates the efficacy and the safety of Nevirapine to prevent mother to child transmission. I would also like to share with you the information which is germane in

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Africa about the programs which have begun all over this continent to provide access to prevention of HIV infection in pregnant women. I think it is only fitting to begin by acknowledging that there are almost 132 million babies born each year. Almost 26 million of them are born in sub-Saharan Africa. Only two-thirds of their mothers have access to a single antenatal visit and about half of them are delivered by a skilled birth attendant. These are women in Malawi with their families, guardians who love and assist them in the process of delivering their babies. This is testimony to the contributions of the community and the families and the support of women who are having children, and are making choices about discerning their HIV status and if it is possible, to take an effective intervention. I know I don't need to remind all of you, but it is important to appreciate that unfortunately, where these 26 million babies are being born, 90 percent of the children in the world who acquire HIV infection live. This is an absolute crisis and it is with humility that I say when 1800 to 2000 babies a day are born with HIV infection in Africa, we in the United States, prior to the availability of antiretrovirals had the same number of infections occur in a year, so it is absolutely not our place to describe what should be done in a situation which is a crisis. It is our responsibility collectively as a community concerned about HIV, to look at the facts and each person makes their decision.

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This is an antenatal care setting, in this setting in Malowie where several hundred women are seen each day, and there are only two private spaces. Can you imagine the logistic problems of providing counseling, asking women if they want to be tested and providing them with the intervention? Without naming the facility, I will say that in the month of July, 100 percent of the women in this clinic who were counseled, made the decision to be tested. They made it for themselves. Why Nevirapine? There are some wonderful attributes to this particular medicine. It is more potent than the nucleoside reverse transcriptase inhibitors. It has a long half-life, which is a benefit when a woman needs to take a medicine in a single-dose prior to the delivery of her baby. It is absorbed rapidly after taking the medicine orally and it does cross the placenta to obtain access to the baby. This is the study, HIVNET 012. I would like to say that at no point in time have the results of this study in terms of the demonstration of efficacy, been questioned. That is with the original report peer reviewed in Lancet and with the re-review of the actual study procedures, no one has questioned the differences in infection rates between those babies and their mothers who received Nevirapine and between the babies whose mothers and they received AZT. If you look at the numbers on this slide, you will see that the infection rate at 14 to 16 weeks of age in the babies whose mothers received Nevirapine and they received Nevirapine was

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about 13 percent. This was a randomized clinical trial and the comparison arm was a comparable course of AZT. We do not know if AZT had any effect at all, but Nevirapine reduced transmission by 47 percent in the infants whose mothers received a single-dose and the babies received a single-dose. At 18 months of age, the efficacy persisted. A few babies had acquired HIV infection as a result presumably, of breast-feeding. The population studied was in Uganda, where breast-feeding was the norm and all of these infants were exposed to virus through breast-feeding. This is the 18 month infection rate and the infection free survival studies look exactly like this. The difference between the upper line, which is Nevirapine and the lower line persists for the 18 months of life of the infant. Recognizing that Nevirapine as prescribed to prevent mother to child transmission, effects the exposure to virus during labor and delivery, it is amazing that this single-dose of medicine to a mother and a single-dose to a baby, achieves such substantial reduction in infection which can be maintained despite continued exposure to virus. In this study, there were no safety concerns. The second study, which has been alluded to and has subsequently been published, subjected to the peer review process, is the SAINT study done here in South Africa. It is important to appreciate that the overall transmission rate of approximately 12.3 percent in the Nevirapine arm is essentially identical to that observed in

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another country and in another study. The transmission rate is substantively lower than in women who receive no treatment or no prophylaxis. AZT/3TC administered together as two drugs for the same time interval is comparable to Nevirapine. No one is denying that. Administering two medicines is a touch more difficult than administering a single medicine and it may indeed increase the costs. Because of these data and because of our conviction in the Elizabeth Glaser Pediatric AIDS Foundation, we were fortunate to secure funding from the Gates Foundation and more recently, from USAID. All of these monies were to support implementation projects around the globe. The places featured on this map are the countries in which these programs are located. There are 12 countries in sub-Saharan Africa and I would like to share some of the experience which has been had with these programs with you. What does the call to action or prevention of mother to child transmission program do? It provides resources to investigators or to health-care providers who wish to initiate a program. The people in the in country or in the health-care facility, elect how they will do this. They elect what drug or drugs they will use. They elect what the procedures will be that they will follow. We try to provide technical support. We try to assist in evaluation and monitoring of these projects, but these are projects to which everyone acknowledges that the local leadership are responsible for seeing that they are successful, and they are. Every

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component that you might wish for, they may not all be in place in all programs but the community sensitization, the training of staff, the provision of counseling, the accurate ability to test and the access to a standard package of antenatal care are all included. Infant feeding counseling is provided and according to the ability of the sites, the diagnosis of HIV infection in the infants. I would like to say one word about infant feeding and that is it is also locally determined by policies in country and guidelines developed in country. Essentially, all of the countries in which these programs exist have elected to support exclusive breast-feeding because that is the safest means to get nutrition and provide that to children. I'd like to share with you a few photographs, community sensitization programs. This one happens to be in Zimbabwe. These are brave people who have been through the program, who are educating their communities about Nevirapine and it certainly is no secret what they are saying. If we look now collectively at the women who have had access to an intervention to prevent mother to child transmission, these programs have been available to 416,000 women throughout Africa. Over 350,000 of these women received counseling and 275,000 women elected to be tested. As Prudence said, these are individual decisions. The women are deciding for themselves. This is approximately 80 percent of the women. The women have obtained their results. That is about 90

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percent of those who are actually tested, and 45,000 HIV positive women have been identified and 28,000 have received Nevirapine. These happen to be women who were delighted to see people who are interested in providing Nevirapine. They and their infants have all participated in the prevention of mother to child transmission program in Vermbenda (misspelled?) Zimbabwe. The women who are coming to these clinics, although the bars are small, number more than 20,000 in each country. So that when you think back to my original numbers, 131 million deliveries, 26 million of which are in sub-Saharan Africa, you'll see that collectively, we have a long ways to go and we can't afford to pause and we can't afford to step back from this as they move with their programs but they are committed to provide access to every woman seeking antenatal care. More women who are enjoying their babies, their healthy babies I might add, how many women are actually tested? It is often said that it's hard to have people agreed to be tested. I've said that the women make up their minds for themselves and they do. Across the board, approximately 80 percent of those who are counseled, as high as 100 percent may agreed to be tested. We've learned some things about opt in versus opt out approaches. The more routine this is in antenatal care, the more likely it is that people perceive it correctly and women take advantage of the opportunity to learn their status. And I would like to point out that this is, the end results of this

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will be healthy babies, more healthy babies. But it also provides the steppingstone for access to treatment. If you provide the ability to counsel, you provide the ability to do the testing, you are opening the door to be able to provide treatment in a knowledgeable fashion. If we look at how many women are infected throughout Africa, I repeat this because it is so important, it is a crisis. In South Africa in the sites in which we have provided support, more than 30 percent of the women are HIV-infected. In other countries like Zambia and Zimbabwe, it is almost that high and each of these countries is electing to move ahead as fast as possible with their programs. The community education attracts children, which is a good thing. It also attracts partners, i.e. men and other elders in the community to learn about the process. Now the problem and here comes the feasibility of Nevirapine; we would like 100 percent of the women who are diagnosed as positive to receive Nevirapine. Some places don't give the medicine to mothers to take home with them; they only provide it if they come back to maternity. That's a problem because many women don't get to come back to have their babies in a health-care facility. It's also, I think, extremely important to appreciate how this highlights the difficulty of delivering and intervention. These are women who've been counseled, tested and know their status and it is still a little difficult to get the medication to all of the women who understand that they are positive.

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That difficulty is multiplied if there are two drugs. It is multiplied if it's weeks of drugs. That's not to say that we don't all aspire to that, but you have to start someplace where the interventions can be delivered in the simplest fashion and build as rapidly as possible. This is Cameroon, where the entire Northwest province has more than 80 facilities providing Nevirapine to pregnant women. Cumulatively, these are the data, as I displayed them to you in the very first slide that I showed. It's the 416,000 women and the incremental growth of these programs throughout sub-Saharan Africa. There is incremental growth in the provision of Nevirapine also and we are the first to recognize that we would like to do even better, and this reports the progress in South Africa, which is quite excellent. These are the programs that the Pediatric AIDS Foundation supports and do not encompass all of the other programs. Hereto, there is some difficulty actually providing the drug to the women who test positive and providing the drug to their babies. So, I would like to say to all of you to keep up the hard work. Fathers can be included also, although clearly, we've been talking predominately about women. It is terribly important that the community support and family support be obtained and be continued because this is really hard work. This is what we are all aiming for, healthy babies, these from the Congo and I thank you so much for your attention and would like to say one more word of tribute to the people

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who have done all of this work in all of these countries; it is they who should be standing here and not me. Thank you.

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