

**South African AIDS Conference
Closing Ceremony
August 6, 2003**

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

MODERATOR: Ladies and gentlemen, if I can ask you to please put your hands together for what was an amazing set of four talks that have really captured the issues in nevirapine. Thank you very much to all speakers. (applause) It became clear to me in listening to these four speakers that there were six points in which there is no contest. There is clear agreement. The first of these is that the MTCT problem, the problem of mother to child, is a critical one that we cannot afford to sit on the sidelines and quibble about the drugs we will use whether the evidence is good enough or not. We have to save those children's lives. That is not negotiable. (applause) The second thing I heard all the speakers agreeing on is that we put our faith and our confidence in the Medicines Control Council because we want them to ensure that the medicines that they allow us to use, that they register, is of high quality, is safe and is efficacious. That is not a negotiable. (applause) We've also heard that nevirapine is widely used and is registered in many countries for the indication of mother to child transmission and we've heard that nevirapine is safe. Nobody's questioning it. It's used widely in treatment, in combination with other drugs. It's been shown to be safe in the treatment of hundreds of thousands of women. There is no question that nevirapine is safe. (applause) Nobody on this panel today questioned whether the HIVNET 012 study showed that there was a sustained beneficial effect of nevirapine, even in

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

a population that was breastfeeding. We saw the protection level of 47% early on and 41% later on. Unequivocally, the HIVNET 012 study shows that there was a beneficial effect. We also learned that AZT is an available, efficacious and safe alternative. The problem is the difficulty in implementing it, and that if we had to use an alternative such as AZT, we do not have the same options in terms of ease of administration and in terms of ease of rolling it out throughout the country. And therefore nevirapine remains our first choice. In terms of programs for nevirapine I think we've seen quite clearly, time and time again, regardless of which country we're talking about, regardless of what populations we're talking about, the transmission rate in the presence of nevirapine rollout programs are all in the range of the HIVNET 012 active ingredient arm, so that programmatically, there is supportive evidence. It's not con - it's not the evidence that we would like to see from controlled trials, but it's supporting the, the findings of the HIVNET 012 trial.

What have we disagreed on? I've laid out the six points in which we've agreed. What have we disagreed on? Fundamentally, we have disagreed on whether the findings of the HIVNET 012 trial, the finding of efficacy, is sufficiently reliable for us to proceed with registration. That is the fundamental difference that I've heard debated here. We've heard from the WHO. We've heard from the investigators. We've

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

seen the data published and they think that whatever the problems were in the study, and let's be quite frank. The study had problems. There is no perfect study. Like any other study it had problems. It had perhaps more problems than we would expect, but those problems, nobody has said and nobody has shown any evidence to suggest that those problems might overturn efficacy. What we have to do is we have to resolve that difference. We have to figure out is there something in the study that overturns that result that does not allow us to registrate. But more importantly for me, I think that South Africa without nevirapine for mother to child transmission is not an option. We have to find some way of dealing with this problem. I think Dr. Matsoso (Misspelled?) gave us some indications of a way forward and we certainly know that there are many options. But to me there are two, it seems to me, two options that need to be looked at. And Professor McIntyre (Misspelled?) laid out that we cannot solve this is if we continue to be disparate and continue to smite with one another. We have to be able to talk. We have to be able to deal with data. And we have to come together in a partnership to solve this problem.

The two options, as we've heard, the one option is to look at some kind of extension to the 90 days in order for the company to put forward some kind of study that would present an alternative set of data, perhaps some kind of combination of

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

nevirapine with some other drug, perhaps. It is not possible to do another randomized controlled trial that is placebo controlled so there cannot be another HIVNET 012 trial. No ethics committee would allow such a trial. So we have to look at some alternative for a search that we can undertake to provide that confirmatory evidence because we want to provide and we would hope the company wants to provide, and we certainly know the researchers around the table today want to provide that confirmatory evidence so that nevirapine will stay a registered drug for mother to child transmission.

The (dropout in recording) alternative is that even at the even at the end of 90 days, if nevirapine is deregistered for mother to child transmission, it remains registered for treatment. It remains a safe drug.

There is the option of using the drug off label. We have many instances in this country where we use drugs off label. In other words, there is no registered use for this, but there are options about using these drugs off label. In fact, the classic example we have right now in antiretrovirals is the off label use in terms of policy in the use of antiretrovirals for the prevention of transmission of HIV in the case of rape. That is a policy or program to provide antiretrovirals in the cases of sexual assault and it is an off label use. So there is the option of off label use.

So we have many options ahead of us. Let me just ask

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003

6

all of you to once again thank our speakers and to thank the chairpersons for chairing such an exciting session, but for us, most importantly, an informative session so that we can now engage in this discussion knowing what the facts are. Thank you very much. (applause)

Before I hand over to Professor Coovadia, I'd like to call on Professor Bunnell (Misspelled?) to join me at the front here. Many of you have seen a letter that has been circulating in the course of this conference. A group of, uh, people who are actively involved in mother to child programs from throughout the world, and you've heard many of them come from the Culture Action Fight have been collecting signatures on that letter. I'd like to call upon three healthcare workers who are actively involved in mother to child transmission programs using nevirapine to come forward and to hand over this letter. It has 800 signatures from people from over 50 countries. These are mainly researchers and programmatic, individuals involved in programmatic implementation of nevirapine, to Professor Bunnell (Misspelled?) who has kindly agreed to accept it on behalf of the MCC. Could I please call you to the stage? (applause) The letter contains 800 signatures and is - I'm not going to read out the letter because you've seen it around. It, it just basically highlights the concerns of the community about the need to resolve the issues around nevirapine and recommending that we do so in some kind of

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003

7

partnership together. Thank you very much. (applause)

And now I would like to call of Professor Coovadia, who will take over the proceedings for what is the closing ceremony, which we hope will take about 45 minutes so we will probably close slightly after the scheduled closing time of 2:30. Any handover to Professor Coovadia. (applause)

PROFESSOR JERRY COOVADIA: Thank you. You want a few minutes break? You going to stand up there? No. My word, you're a, victims of punishment. Okay. Now this is the last in the closing session, so please bear with us and we have three very important speakers and three very important individuals so I'm not going to waste time. The first speaker is Dr. Zwili Keys (Misspelled?) who is the Emissary for Health in KwaZulu-Natal. He's been an eminent fighter for freedom and for the improvement of health services in this province and probably fits over as the final person responsible for one of the largest nevirapine programs on the African continent. Zwili. (applause)

DR. ZWILI MKHIZE: Thanks, Jerry, Chairperson of the conference, the organizing committee, honored guests and delegates. I want to start by making an apology for, on behalf of Minister Manto Tshabala Msimang who is the representative of government at this level and has been taken by an urgent trip overseas and only arrived this morning. I then (unintelligible) here to represent the Minister, the Embassies,

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003

8

my colleagues, the government at all levels.

Chairperson and colleagues (pause) chairperson, today our national conference on HIV/AIDS comes to an end. In the opinion of government, the past few days constituted an intensive session of the direction of different stakeholders from different parts of our country who are conversed in (unintelligible) of solutions for the spread of HIV and the impact of AIDS in our county. Despite any possible suggestions to the contrary, we believe this conference was a resounding success. As one of the major sponsors of the conference, government, on its part, has ultimately worked for the success of this historic conference. It has been a (unintelligible) from the start. Government sought to contribute in the provision of an appropriate forum for government officials, scientists, clinicians, researchers and government and local organizations, community activists and from the private sector to openly exchange views. This conference has succeeded in doing just that. It has offered, it has also offered an environment that encourage the creation of the culture of an open debate that will assist us in the future when dealing with the complex issues, complex issues surrounding our approach to HIV and AIDS. We are convinced that the presentations were well balanced, (unintelligible) where research findings have been presented shedding more light in the very complex subjects of HIV and AIDS. Presentations have also demonstrated that a

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003

9

lot of work has been done in the public and the private sectors, as well as nongovernment organizations. As the report further demonstrated, the variety of government approaches to the challenge of HIV spread and the impact of AIDS. This direction has been based on the recognition on the, of the different roles we all have to play in this partnership. From the report tabled in the different sessions, delegates will all agree that government approach to HIV and AIDS prevention, clinical management and care is based on sound scientific research. To that extent, we wish to express our gratitude to our guests from the different parts of the world for sharing their scientific work with South Africans, helping to guide our joint response. Their (unintelligible) and experience has ensured that our country's on par with the rest of the scientific world in terms of the latest available data.

We are similarly proud of our South African world-renowned researchers, all the experience and research expertise are represented in the world, are respected in the world over. We're also proud of the various nongovernmental organizations, NGOs and other partners, and in particular women, who have participated in this conference. We are convinced that a combination of these experiences will inspire our young researchers to follow their lead. We have taken note of the various findings that have been tabled in the conference and we will take this data to form the basis of our policy formulation

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

and strengthen government response to the epidemic. As I (unintelligible) the conference delegates, our policy makers and managers from different spheres of government all in implementing these proposals and share with their colleagues all the knowledge they have received.

There was not enough time to showcase most, most of all, the work done in the provinces. We acknowledge the different levels of capacity for different provinces, some variation in financial resources, different population numbers and different levels of poverty may lead to unfair comparisons across provinces. Within all, within the time available, it would not impossible to provide the commentary on all or any of the issues that arose during the conference. A few of them, however, do require clarification.

First, it is important to clarify to the conf - to conference the matter of the Global Fund against AIDS, TB, and malaria. Government has been concerned about the delay in the finalization of the award. The speculation in the media that the cause of the delay was due to government reluctance in distributing these funds is misinformed. The real causes of the delay were not political, but rather technical processes which required certain specifics to be clarified in the, in relat, in respect of the details of the, of the disbursement of the funds, their accounting procedure and et cetera. This being the first amount of funds to be received means that the

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

rigorous processes will not be repeated in the subsequent applications and the delays will be reduced. The weekend newspapers incorrectly reported last week that there was a risk that these funds would be lost. (unintelligible), the Minister of, for Health, Manto Tshabala-Msimang, and the province of KwaZulu-Natal are confident that these funds will be safely delivered as approved. We are all, we are certain that in all the necessary signature, that all the necessary signatures to conclude the agreement will be finalized by the end of this week. A formal statement will be released by the relevant offices in due time.

The second matter concerns the debate on the possible deregistration on, of nevirapine for the purposes of prevention of mother to child transmission. We have noted the debate on this matter and it has been a very interesting and very, uh, I think very important debate. We do not wish to prejudge the issue. We are concerned about the claims of political interference. Of course, there is no places for such accusations. The Minister and government understand clearly that the Medicine Control Council is an independent body. The matter of registration or deregistration will be left in the hand of the Medicine Control Council. We are, however, a government concerned, very concerned, that the positive benefit of our vital nevirapine program in the prevention of mother to child transmission should not be undermined. The safety of

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

those children whose mothers were, were HIV positive during pregnancy, which the nevirapine PMTCT program offered must not be compromised. We share the cries of women, such as were presented earlier and more eloquently today, the frustration of parents, especially mothers, and reject the consequences of destruction of this program. And I think some of the slides that you have seen will indicate to what extent we, we will be concerned about any reversal of such a program. The Department will therefore explore all possibilities of available alternatives to save these children and limit the reversal of the, of all the gains of the PMTCT program. We owe this to our children. We owe it to our mothers. And we owe it to South Africa.

On the other hand, it should also be true that on the broad, many issues there's a general agreement on the approach to the HIV and AIDS epidemic among delegates in the government. Where there are any significant differences, those reflect to the weaknesses and (unintelligible) failure of coordination. The main area of sharp debate is the matter of the widespread provision of antiretroviral therapy, which as resulted in a robust public discourse. From the government's point of view, the matter of antiretrovirals does not constitute an area of disagreement. It needs to be placed on record as the matter of antiretrovirals is not an ideological issue. A cabinet statement of the 17th of April, 2002, clearly established the

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

program to rollout the PMTCT program and use, the use, the use of nevirapine as well as the utilization of antiretroviral treatment for post-exposure prophylaxis, particularly in dealing with survivors of sexual assault. The debate today may only be to the, the extent to which progress has been recorded in these programs.

Government has opposed the implementation of the comprehensive (unintelligible) HIV and AIDS in a phased manner. Action has been taken to deal with the vast question of the high cost of drugs. Government continues all efforts to secure affordable (unintelligible) and dialog with the pharmaceutical industry. Another (unintelligible) initiative within the Department of Health and Trade and Industry will ultimately secure the availability of generic drugs both in the public and private sector, including antiretroviral treatment. A present committee has been appointed and it will hold its first meeting at the end of, or by, before the end of August. This committee will be (unintelligible) with the matter of reducing drug prices and will advise the Minister on the desirability of parallel importation and compulsory licensing. Already generic, some generic antiretroviral drugs are being manufactured in South Africa. In September, last year's cabinet, too, assigned a joint health team of the Department of Health and Treasury to determine the cost implication of widespread utilization of antiretroviral treatment. The

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

cabinet is currently considering the report that has been submitted. The cabinet has to consider the most valid and appropriate response to deal with the situation created by this epidemic. That is out of 45 million citizens, the 40 million HIV negative citizens must be kept negative for as long as possible. And (unintelligible) 5 million who are HIV positive must be kept as healthy and delay their progression towards full-blown AIDS for as long as it is possible. The key intervention here would, here would help support a new system through the variety of intervention, including nutritional support, proper, and proper treatment of opportunity infections. There are about 500,000 who may have progressed to full-blown AIDS in whom the value of antiretroviral treatment, properly administered and supported, is beyond any question. Such treatment, such treatment must be provided through a sustainable program, supported by adequate financial and human resources to support life, a life-long program. Setting the joint task team was already an acknowledgment of this need. The tremendous investment the government has made on the health services has placed the country on a stronger position to embark on this program. That includes, for example, the development of the PMTCT, the (unintelligible) for exposure prophylaxis, the employment of lay counselors, the use of (unintelligible), et cetera, all which have been set up, as well as the programs of socioeconomic development. Cabinet is

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

therefore (unintelligible) with a document of needed, have process which requires refining, clarification and the search for available sou, resou, sources of funding. And there are choices to be carefully made and, and also to made available, to - for resources to made, necessary resources to be made available.

We have noted the contents and the frustration that have (dropout in tape) and the express about this process. But we wish to assure you that we all have gone beyond the point of whether, but rather when antiretrovirals will be available, bearing in mind the need of a sustainability, and the need for progressively building the capacity of the public health system. Already too much work has been done in this regard for us to despair. The work and preparations necessary to reach finality on this matter must never be underestimated. We are seriously concerned about the rising mortality as a result of HIV and AIDS in this country. One more death is one too many. We appeal for the stakeholders represented within this conference and outside this building to join hands with government in mounting an effective, comprehensive response to decisively deal with this, the number one challenge and enemy that our country ever faced. This conference has provided us with a possibility for a fresh start in redefining the basis of our partnership and a new commitment to fight, side by side, to defeat the spread of HIV infection and the impact of AIDS in

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003

16

our country, a commitment to support each other and participate in joint or related programs to move it as a popular response to strengthen prevention, treatment and care. In acknowledging the success of this conference we wish to propose that consequences becomes a regular feature of our therapeutic intervention and concentration. In that regard we shall be approaching the organizers of the conference to seek a commitment extending in this regard. We (unintelligible) that the delegates here present will be so gracious as to support our humble desire to ensure that government programs are regularly guided and (unintelligible) are shaped and influenced by the collective wisdom of such participants that this conference has managed to muster at one time under one roof.
(applause)

Lastly, may we express our gratitude to the organizers of the conference. We are pleased to note that their acquired valuable professional experience in this possible attack. When they organized the 15th International AIDS Conference in the year 2000, fortunately and coincidentally, it was also in this same place. They represented South Africa magnificant, magnificently. (applause) To the guests and delegates, it is time to take action. We have been inspired by the information and the knowledge we have received. Let us go back and work. We wish you a safe journey home. Thank you very much.
(applause)

¹ kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

South African AIDS Conference
Closing Ceremony
August 6, 2003
[END OF RECORDING]

17