

**Plenary: Advancing Treatment and Universal Access-
A Report on State-of-the-Art and Progress
XVI International AIDS Conference
August 16, 2006**

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.

[START RECORDING]

DR. HELENE GAYLE: Good morning. I'm Helene Gayle, president of IAS, and I'm pleased to be with my friend and colleague, Dr. Julio Montaner, who is the IAS president-elect, who will announce the prize winners of this Young Investigators Award.

The IAS Young Investigators Award is presented to a researcher no older than 35 years of age with the highest scoring abstract in each of the conference's five scientific tracks. All abstracts submitted to the conference undergo a blind peer-reviewed process by an international review committee. This award helps us to draw attention to some of the most promising research carried out by young people working in the field of HIV/AIDS today, and for us at AIS it's a recognition of the importance of recognizing the scientists of the future who are the hope of this epidemic. So without further ado, I turn it over to Julio.

DR. JULIO MONTANER: Thank you, Helene. First things first, happy birthday, Helene. [APPLAUSE]

Now to the important matter. The first prize for Track A is for Linos Vanderburkoch [misspelled?]. [APPLAUSE] For Track B, Hassan Dios. [APPLAUSE] For Track C, Sherry Weiser. [APPLAUSE] For Track D, Gretchen Dummick [misspelled?]. [APPLAUSE] And for Track E, Savi Goos [misspelled?].

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.

[APPLAUSE]

CRAIG McCLURE: Good morning, everyone. I'm Craig McClure, the executive director of the International AIDS Society. It's my pleasure to introduce the chairs of this morning's session. Dr. Pedro Cahn from Argentina. Dr. Pedro Cahn is involved in clinical research as the director of the prestigious Huesped Foundation in Buenos Aires, which works with prevention research and direct services for people living with HIV and AIDS.

He also serves as chief of Infectious Diseases at Hospital Juan A. Fernandez. He's a member of the IS Governing Council, and is the incoming IAS president for 2006 to 2008.

Our second chair is professor Michel Kazatchkine from France. Professor Kazatchkine has spent the last 20 years fighting AIDS as a leading physician, researcher, policy maker, and diplomat. He is currently France's ambassador of HIV and AIDS and Transmissible Diseases, and has previously worked for five years as a director of the ANRS, the French National Research Center for HIV and AIDS. He is also the co-chair of the AIDS 2006 Scientific Program Committee. [APPLAUSE]

Our third chair for this session is professor Souleymane Mboup from Senegal. Professor Mboup is Professor and Chief of Bacteriology, Neurology of the Faculty Mix de Medicine de Pharmacie [misspelled?] in Dakar, Senegal. He is a founding member and chairman of the West and Central African

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.

AIDS Research Network, and also serves as the IAS regional representative for Africa. [APPLAUSE]

And our fourth chair for today's session is Dr. Mark Dybul from the United States. Ambassador Mark Dybul serves as the United States Global AIDS coordinator in the Office of the U.S. Global AIDS Office, which leads implementation of President Bush's Emergency Plan for AIDS Relief. Prior to beginning his role in the Coordinator's Office, Ambassador Dybul served on the Planning Task Force for the Emergency Plan, and he was the lead for the Department of Health and Human Services for President Bush's International Prevention of Mother and Child-to-Child HIV Initiative.

[APPLAUSE]

PEDRO CAHN, M.D.: Good morning. It is my pleasure and my privilege to introduce the first speaker, Julio Montaner, who is, as you know, the director of the B.C. Centre for Excellence in HIV/AIDS. He's also co-director of the Canadian HIV Trials Network. He also is the director of the AIDS Research Program and the Immunodeficiency Clinic at the St. Paul's Hospital in Vancouver, holding also the chair in AIDS Research at the University of British Columbia, the first initiative of its kind in Canada.

As you know, Julio Montaner has been one of the major contributors to the antiretroviral therapy field, and I think that he very well deserves to be the speaker and addressing 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.

A Report on State-of-the-Art and Progress
XVI International AIDS Conference
08/16/2006

audience today in *Re-Evaluating the Cost-Effectiveness of HAART – The Case for Expanding Treatment Access to Curb the Growth of the Epidemic*. So without further ado, I would like to bring my friend Julio to the podium.

[APPLAUSE]

JULIO MONTANER: Thank you, Pedro. It is a great pleasure to be here today to share with you what had started as a state-of-the-art antiretroviral therapy, and with further work became the new title that Pedro read for you a minute ago.

In my talk I will try to cover very briefly, and as such, with a lot of omissions that I would like to recognize up front. Recent developments in antiretroviral therapy, which include a few comments on new developments regarding when to start, how to start, some of the new thinking around how to treat experienced patients, a brief word about new drugs, and then concentrate the second half of my talk on a very important issue, which I think is rapidly becoming our major concern at the IAS and for all of us worldwide regarding access to therapy, and sustainability. And I will do that in the context of new thinking that is emerging regarding the prevention value of highly active antiretroviral therapy.

Now, let me say it now, and I'm going to say it many more times: This is not HAART instead of prevention. This is HAART to enhance prevention.

So, when to start antiretroviral therapy? I think

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.

things are starting to become a little bit more clear. There is a lot of concern out there this is the new IAS USA published this week in the *JAMA*. Scott Hammer is the first author, and this is probably a slide that has now been seen a number of times in this conference. We have increasing consensus between these guidelines and other guidelines around the world. Everybody recognizes that symptomatic HIV disease must be treated.

When we come to asymptomatic patients, individuals without low CD4s, 200 or below, should be on treatment as well, and that's illustrated here. The gray zone, if you want - less than 350 and over 200 remains the gray zone - and in that area there is an increasing feeling that, depending on the setting, depending on the circumstances, depending on viral loads, real decline of CD4s, treatment should be considered on an individual basis. At this time, treatment for CD4s greater than 350 are generally not recommended.

There is fairly good consensus between the *JAMA* Guidelines, I'm happy to tell you, and the recently released WHO Guidelines, as you can see here. Treat less than 200, consider treatment in 200 to 350, and defer treatment in greater than 350. I think that this represents a very important step forward on synergizing between these various guidelines around the world, and the consensus will hopefully help us to move this issue forward.

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.

So in sum, we treat all asymptomatic patients; we want everybody below 200 to be on treatment regardless of viral load; and over and above that we treat when individuals are ready to commit, and I cannot emphasize how important working towards that commitment. It is for us, for the patients, and for those that are supporting them.

In terms of what to start with, again things are getting a little bit more clear. There has been a lot of evolution in antiretroviral therapy development, and perhaps the single, most important breakthrough is the new fixed-dose combination tablets that we all very much appreciate. Our patients are very grateful for this development.

Not surprisingly, as a result of that, there is a general consensus that Tenofovir FTC, Abacavir 3TC and Synogalin [misspelled?] 3TC, particularly with the use of fixed-dose combinations, are the preferred cornerstone in terms of the nucleoside components of the regimens. We can only recognize two options: NNRTI-based therapy and BI-based therapy. In the NNRTIs, Efavirenz and Nevirapine are the two available options. Both are adequate, but we have to be careful.

There are caveats in terms of how to best use these drugs, and I'm not going to discuss these in any detail. Of course, in the case of Tenofovir FTC and Efavirenz, we're blessed at the moment having the one pill once a day, which

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.

again is the biggest step forward in terms of simplification in the last many years.

With regards to the PI component of the regimen, the alternatives are Lopinavir-Ritonavir boosted, Stavudine with Ritonavir boosting, Saquinavir with Ritonavir boosting, and we're very happy that there is a fair bit of data in this conference justifying the inclusion of these Ritonavir-boosted regimens as part of alternative for initial therapy, and there is a lot more throughout the conference that I'll encourage you to review in due course.

I cannot emphasize the role of adherence in antiretroviral therapy. We're all very familiar with that, and in that context it is extremely gratifying that HAART has evolved since 1996 at the Vancouver conference in a fairly dramatic fashion. These are again selected regimens, just to give you an idea where we were in 1996 in terms of pill [inaudible], three times daily dosing. We made some attempts to simplification in 1998 to 2002, but really in 2004 we were down to some regimens offering two pills once a day, and now, as I said earlier this year, the triple drug combination of Tenofovir FTC and Efavirenz has really reached what at one time it seemed a difficult goal to attain: the one pill, once daily highly active antiretroviral therapy regimen.

There have been other steps forward in treatment simplification that I wanted to highlight, and some of this 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.

important. For example, in terms of the practicalities of bringing in treatment to the people. As you know, Lopinavir-Ritonavir commercialized under the name of Kaletra has cold storage issues. There is now a new formulation that four heat stable tablets per day, new regimen, new formulation of Kaletra that really gets rid of that problem. Saquinavir has a more compact tablet. We can even simplify the use of Enfuvirtide using the Biojector, a needle-free, gas-powered device, so on every step of the road we continue to work very hard to make things easier for our patients.

We recognize that these treatments to be successful in the long term they have to get simpler and simpler and simpler. There have been a number of trials, and I'm not going to discuss them here today, exploring a strategy for treatment to simplify things even further.

Treatment interruption strategies, as you know, has taken a lot of attention. There is a great deal of that subject being debated at this conference. The issue remains controversial. I think it's fair to say that although it is not currently recommended, treatment interruptions as part of our clinical management strategy, this is an issue that deserves further study, and I would personally would like to see more studies, targeted studies, on this strategy to see what we can learn on how to utilize this potentially valuable approach.

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.

There has been a lot of interest regarding induction and maintenance. At one time there was a feeling that this would not be feasible, however some very interesting studies using Lopinavir-Ritonavir monotherapy have been reported. There are still small, they are tentative. I don't think that we can recommend that approach, but it is an approach that is worth pursuing further. And this, as Pedro reminds me always, emphasizes the notion that highly active antiretroviral therapy is not about three drugs, but it's about achieving sufficient potency and an adequate genetic barrier to control the spread of the virus or the repetition of the virus. So the numbers are not fixed. What we need is potency and genetic barriers. The number of drugs is ultimately negotiable.

When we come to dealing with treatment failure, things have moved quite significantly over the last few years. I summarize here some of my key thoughts in this area. I wanted to emphasize that the first thing that we need to do when dealing with treatment failure is to identify and correct the underlying cause for the failure. Pretending that the change in regimen is going to fix everything is naïve, inappropriate, and ultimately will lead to further failure.

We have seen a consensus throughout the guidelines, including the IAS-USA guidelines, where there is now a strong recommendation that with treating a failing patient or changing a regimen because of failure we should aim for a fully

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.

suppressive therapy. That is to say, the new goal, accepted goal of salvage therapy once again is a viral load of less than 50 copies. And this is not just a goal on paper. This is something that can be achieved thanks to the new drugs that industry has brought to us over the last couple of years.

We need to remember that we have to compensate for partially compromised drugs that we include as part of the optimized regimen under the regimen, and in that context that we need more research, urgent research, to better understand the residual antiviral potency of the drugs. That is to say, after the development of resistance, not all drugs are the same, and therefore, we need to have very precise measurements to address that issue, and Steve Dix [misspelled?] has done a very good job of starting to address that. We need much more data to learn how to optimize backgrounds in our patients. STIs (Supervised Treatment Interruptions) in this setting are not generally recommended, once again.

I wanted to highlight this slide from the Optima Consortium or clinical trial. This was presented by collegial friend, Dr. Joel Singer, at the last retrovirus meeting. I'm not going to go through the whole trial. I'm simply going to say that this is a trial of patients in salvage. There are two randomizations: one randomization to treatment interruption or non-treatment interruption; the second randomization to mega-HAART or mini-HAART, and that's not really what I wanted to

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.

discuss.

The point that I wanted to make is that this study has now confirmed to our satisfaction that endpoints in the study which is still ongoing were predicted based on CD4 count, changing viral load, and changing CD4 count at 24 weeks, which is extremely reassuring because this really tells us that all of the short-term studies that we have done in developing new strategies, new drugs, for treatment of experienced patients are really meaningful. Those viral loads and CD4s that we see changing at 12, 24, 36 and 48 weeks, they carry a clinical meaning, and the Optima has demonstrated that. I think it's extremely valuable information for our patients.

Moving on to some of the new drugs that have entered the clinical field in the last two years, we are very fortunate to have new potent second-generation drugs, Tipranavir being one of them, significant addition to the treatment of experienced patients when boosted with Ritonavir. Darunavir, the more recent entry into the armamentarium, again Ritonavir-boosted Darunavir has provided a very important new addition to the treatment of our experienced patients in the protease inhibitor field. These two drugs are now, I would consider, the second-generation protease inhibitors, and they are very welcome.

I'll take a moment to remind everybody - this is something that Canadian bureaucrats don't get yet - we need to

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.

treat people who are experienced with active drugs, and what that means is that we need every possible mechanism to make those drugs available to the people at the earliest possible time. As you can see here, when we use one active drug in a salvage setting, this is simply an example from the Power studies, we get one kind of response. When we use two active drugs - and in this case it's T20 and TMC114 of Dirunavir - the responses get magnified, and there is nothing magic about T20 or TMC114. This is for the purpose of illustrating. We need to combine active drugs when treating patients in salvage. To use a single active drug, more often than not, is to condemn that drug to rapid failure, and ultimately to make the situation even more difficult.

We are also blessed with a large number of drugs in the pipeline. This not always means that they're going to become available right away, but the drugs that I highlighted in the yellow are drugs that I have seen clinical data on that is encouraging, suggesting that they may be entering the clinical field, hopefully within the next year or so. The menu is growing all the time, and therefore there is hope for our patients that they could benefit from that.

On that note, however, we need to be concerned because as you well know 90-percent of the drugs are in the north of the world, while 90-percent of the patients are in the south of the world, and globally, about 10-percent of the people are

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.

having access to treatment. So we need to focus on access and sustainability, and this is a very serious challenge, and we sincerely hope that this conference will finally deliver the access that is needed worldwide.

There have been a large number of studies done in south of the world in all settings, Latin America, Asia, Africa, etc. demonstrating that antiretroviral therapies work. The treatments are blind to race, to continent. If you use these treatments and you use them properly, they will work everywhere, and in fact I highlighted this study from the ArtLink Publication [misspelled?]. Paul Brainston [misspelled?] published this recently to say that not only treatments work, but when the drugs are free to the people, they work actually much better, and significantly better, as illustrated here. [Applause]

In this paper from David Banture [misspelled?] recently published in *JAMA*, he makes a very important point as well. Adherence in the African Continent for the matter is actually probably better than it is in North America or other settings. The concerns regarding possible adherence issues in underdeveloped settings is not a valid concern not to bring the treatment to the people, so let's move on, and bring the treatment to the people as they need it.

[APPLAUSE]

Over the last year, year-and-a-half, we became

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.

increasingly concerned about issues of sustainability. Now in our midst, the deputy minister, Dr. [inaudible] at the time, a good friend of ours, motivated really our group to move in this direction. As a result of that, we came up with a hypothetical case scenario that I'm going to outline for you, which is simply a means to demonstrate the great opportunity that we're missing by not capitalizing on the prevention value of highly antiretroviral therapy, and I emphasize once again, this is not to replace our prevention effort, which needs to be reinforced even more. This is to find the synergy to our operation effort.

So the paper was published in the *Lancet*, the red [misspelled?] issue of the *Lancet*, and that's available at the conference site. I'm not going to go into this in detail. Tomorrow at the [inaudible] Symposium, I will expand on some of our plans to test these. And let me just say, we are going to move forward with the support of all of our [inaudible], the government, the community, and industry, to actually test these in the years to come in British Columbia.

The notion is as follows: We know that HAART can have an effect on transmission. Data has been derived from post-exposure prophylaxis studies, mother-to-child transmission, discriminant couples, and there is now growing ecological evidence that this is the case. Very briefly: Mother-to-child transmission where HAART is available free and promptly has led

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.

to extinction of this problem. This is a very gratifying piece of news. These programs need to be urgently expanded all over the world.

When it comes to discriminant couples, Thomas Quinn published this paper quite a while ago, and this is a very important observation, which indicates that the risk of transmission in a non-HAART setting was actually closely linked to the viral load on the indexed member of the couple; that is to say that the higher a viral load of the individual infected, his partner or her partner would have a greater risk of becoming infected. But notice that rates of infections when the viral load was less than 400 were uniformly very, very low.

This has now been confirmed separately in a number of studies. More recently Castilia [misspelled?] demonstrated a powerful effect of HAART on heterosexual transmission of HIV in Spain. For further details, I will refer you to the paper, but basically what you see is that with HAART there was very little transmission whether it was with HAART or temporarily associated with the use of HAART. Very good news in that regard.

The Taiwan group needs to be praised for their paper in the *JID*, in 2004, where they characterized a decrease of HIV transmission after a policy of providing free access to highly active antiretroviral therapy in Taiwan. And the story goes as follows: They roll out antiretroviral therapy after 1996.

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.

They had good monitoring of HIV incidents, as shown here. This is a logarithmic scale. After 1996, in fact after 1999, they show a significant decrease in new cases – 53-percent decrease in new HIV cases – and they were smart enough to monitor syphilis incidents over the same period of time. Syphilis incidents being stable, they concluded that sexual risk behavior remained reasonably stable, and therefore they attributed these to highly active antiretroviral therapy deployment in Taiwan.

We have had the same experience. We really did not think of using the syphilis data in tandem with these, and so kudos to the Taiwan group for doing that. After that paper we looked at the same thing, and this is our data in British Columbia: Stable rates before 1996, declining rates following 1996, stable rates after 1999, and as you can see, in B.C., this is on the face of rising number of cases of syphilis. So we believe that this is a very strong ecological piece of evidence that supports added value of HAART on preventing transmission.

We have gone further and used these two to estimate what is the actual impact that this has in the terms of our cost-benefit equation. And so we term the HIV deficit in B.C. based on that slide being 400 cases averted per year. Given that the cost of medical management of one HIV infection over a lifetime is approximately \$250,000, and given that we have 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.

centralized mechanism to pay for antiretroviral therapies in B.C., that the averted lifetime treatment cost of this intervention was up to – I emphasize up to – nearly \$100 million dollars. Contrast that with the cost of treating the nearly 4,000 people that were treated that year in B.C., which is \$50 million dollars. So \$50 million dollars of cost-effective treatment to the people infected with HIV, basically doing what we had to do because they need it, and it's good for society, and it's cost-effective, saved us two dollars per dollar that we invested on HAART-mediated prevention. This is very important news and should serve as a strong motivator [APPLAUSE] for rolling out antiretroviral therapy worldwide.

I don't have full data for the United States, but in the United States we're talking about an HIV deficit using the same rationale that I put in front of you of nearly 100,000 cases, imagine the savings that this has generated in the United States of America, and everywhere else that antiretroviral therapy has been used appropriately.

Bob Hobe [misspelled?] working in our group has come up with a theoretical model, and let me say it three times – theoretical, theoretical, theoretical. I don't want anybody to take this as a recommendation. What we have done is we dreamt a dream: what would happen if we had a free, safe and completely non-toxic HIV treatment that we could give to everyone in the world? And we're putting the goal very, very

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.

high up. We don't have it, it's not realistic, it cannot be done today, but this is what would happen if we had that treatment. We need to work towards that treatment because if we continue to treat 30-percent of the people in the world, this is what's going to happen – that's HIV infections per 1,000 population – HIV prevalence will go down dramatically if this concept we apply with a safe and ethical approach. Please hear me right. I'm not asking treating people because we want to treat them. I think treatment should remain a right of the patient.

Having said that, the number of infections that could be prevented is astronomical, and the cost of treatment, it's right, with today's drugs, it would be expensive up front, but look at how it works. Today treating 30-percent we're basically going to be paying this mortgage for the rest of our lives, and the lives of the lives of the lives of our children. If we actually have this strategy at hand we could actually curtail the epidemic and even control the epidemic as long as the prevention effort could be escalated in tandem. This is an untested hypothesis, let me emphasize. There are issues of safety, toxicity, individual rights, resistance, higher epidemics, logistics, the potential erosion of prevention effort, and cost. We have answers to all of that. We need to discuss all of these. At the end of the day, this is a hypothesis, and needs to be tested, and we do have a plan to

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.

move that testing forward in British Columbia, hopefully in the years to come.

In conclusion, HAART has evolved dramatically over the last decade, HAART is cost-effective using the traditional patient-centered model, HAART decreases morbidity and mortality, and HAART is even more cost effective when it's put into effect on secondary HIV when prevention is considered. We cannot afford to ignore the prevention value of HAART, or it can bring to synergize with traditional prevention methods, and some of the newer methods that have been explored.

In my opinion, the impressive clinical impact and cost effectiveness of modern HAART provide a very powerful rationale to urgently expand HAART programs at the very least to those that need treatment on a worldwide basis. [APPLAUSE]

PEDRO CAHN, M.D.: Thank you. Thank you very much, Julio.

MICHEL KAZATCHKINE: Good morning, everyone. It's my distinct pleasure now to introduce Dr. Ruth Nduati.

[CHANTING]

Thank you. [APPLAUSE] Thank you for advocating for more health workers that was pointed out yesterday and in a number of sessions in WHO's yesterday's press conference on the treat/retain initiative.

Let me go back to introducing Dr. Ruth Nduati. She is associate professor of pediatrics, and works at the Health

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.

Sciences, University of Nairobi. Professor Nduati's professional interests include research and prevention of mother-to-child transmission of HIV, particularly through breast feeding, translation of research into standards of care, and prevention of mother-to-child transmission in pediatric care into standard care. I have known Ruth for several years. She's a generous physician, constantly caring about mothers and children, and a wonderful person. Ruth, the floor is yours.

[APPLAUSE]

RUTH NDUATI, M.B.ChB., M.M.ed., M.P.H.: Thank you, Michel, for the very generous introduction. Distinguished delegates, colleagues, and friends, I begin by thanking the organizers of this conference for giving me this opportunity to speak at this plenary on "Children and AIDS: Time to Deliver."

In my talk, I will highlight the magnitude and context of pediatric HIV, review key developments in prevention and treatment, and then discuss approaches to implementing scaled up pediatric HIV care.

Today, children aged less than 15 years make up 14-percent of all new global HIV infections, 18-percent of the HIV related deaths, and 5.6-percent of persons living with HIV, and 60-percent of the new infections and deaths in the region of East and Southern Africa.

Adult HIV deaths have resulted in an unprecedented number of orphans – 14 million at the end of 2005. In the most

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.

affected regions, illness-related absences from work in the agricultural and education sectors deny millions of children food security and regular quality education.

In Sub-Saharan Africa, the epidemic of pediatric HIV has evolved under a related existing chronic crisis of maternal child health. Sub-Saharan Africa is one of the poorest regions of the world, and continues to experience increasing poverty. Today, one-third of the 1.1 billion people living in extreme poverty live in this region. Child mortality is 29 times higher than that in developed countries, and 41-percent of the annual 10.8 million child deaths globally are in Sub-Saharan Africa, as shown in the color orange on this slide.

Related causes of death among HIV-infected and uninfected children include pneumonia, malaria, diarrhea, and neonatal deaths. Use of unsafe water and unavailability of water, lack of access to sanitation, and lack of breastfeeding critically contribute to this mortality. Measles, HIV/AIDS and malnutrition, conditions characterized by impaired immunity are frequent underlying causes of death of children in this region, and of note is that malnutrition underlies half of all the deaths among under fives.

The [inaudible] of HIV distinguishes itself by the increased cases of fatality and the imagined evidence of poor response to standard therapies. Although globally, HIV contributes only 3-percent of the overall deaths in children,

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.

it is an increasing underlying cause of death in high HIV prevalence countries.

Mother-to-child transmission of HIV accounts for 90-percent of HIV infections in children aged less than 15 years, and without intervention, 30- to 40-percent of exposed children become infected. The publication of the landmark study by Cahn and colleagues demonstrating a 67-percent reduction in mother-child transmission of HIV following prophylaxis with AZT 10 years ago marked the beginning of an era of rapid progress in prevention of mother-child transmission of HIV.

This slide shows experiences from clinical trials demonstrating increasing efficacy of ARV prophylaxis for PMTCT impressed within populations using combination therapies, and today, rates of less than 5-percent.

Significant breakthroughs have also been made in the development of PMTCT protocols that minimize evolution of resistance in the mother and the infected babies. These innovations end up in the temperature guidelines launched at this meeting.

Now, without ARV treatment, children experience a rapidly progressive course of illness. This slide is from a pooled analysis of nearly 3,500 children, including 700 infected ones from Sub-Saharan Africa. Thirty-five-percent of the infected children were dead by their first birthday, and 52-percent by their second birthday. This was compared to 5-

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.

percent and 7.5-percent one-year and three-year mortality among uninfected children. The mortality of these HIV infected children in Sub-Saharan Africa is considerably higher than the 15 percent pre-ARV infant mortality of HIV infected children in developed country settings.

There are few studies in Africa where CD4 counts and viral load [inaudible] have been carried out. Consistent in studies of HIV infected children from developed country settings, low CD4 counts, high viral loads, and added failure to thrive have been associated with more rapid progression to death.

Compared to adults, HIV infected children have significantly higher viral loads which calculates into the more rapid course of illness. This slide shows the higher viral load among HIV-infected children, and especially they are higher among infants infected in the first four months of life, and may I explain the observation that the risk of death is higher among children infected before age of four months.

Mothers' clinical and vital status is a key determinant for survival of HIV exposed children. HIV-infected children have an eight- to ninefold increased risk of death compared to uninfected children. But the risk of death of both HIV infected and uninfected children is approximately halved if the mother survives. So care of the HIV-infected child must include care and treatment of their mothers and their families.

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.

[APPLAUSE]

Progress has been made in developing life-saving interventions for HIV exposed children. One of the life-saving interventions is Cotrimoxazole prophylaxis, which was shown in the under-randomized clinical trial in children to reduce the mortality by approximately 43-percent over a median period of 19 months. The benefits of Cotrimoxazole were exact across all ages, across all CD4 counts, and through all durations of follow-up.

Cotrimoxazole is a cheap drug that is widely available and on the [inaudible] essential drug lists, and yet it is scaled up widely for use in HIV-exposed children.

I think one of the greatest advances in HIV medicine has been the development of antiretroviral drugs. Antiretroviral drugs suppress HIV replication, and allow for new reconstitution, and prolong the life of HIV infected adults and children. African HIV-infected children respond well to treatment of both PI- and NRTI-based antiretroviral therapies.

This slide shows data from a study of 78 Ivorian children initiated on a PI based HAART. The overall survival on HAART was 91-percent at 12 months, and 88-percent at 18 to 24 months of follow-up. Children experienced significant increase in weight for age, a decline in the incidents of pneumonia and diarrhea following treatment. Nearly 50-percent of the children had plasma viral loads at less than 400 viral

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.

particles per [inaudible], which highlights that they respond well, but also highlights the challenge that as pediatricians we face of being able to have a large proportion of patients achieving undetectable viral loads.

Now, African children tolerate ARVs well, with only about 15-percent of them requiring change of therapy, usually from expected side effects or the need for co-treatment for tuberculosis.

Drug adherence for children is a challenge. In a study by Walmalwa and colleagues, a third of the children's care providers reported that they had missed to give treatment as required, and 19-percent had serious non-adherence that even necessitated a treatment change for two children. These adherence levels are similar to those reported in literature even studies among Thai [misspelled?] children.

Children experience difficulties with drug compliance when there's conflict between parents or where there's several adults providing care. When the HIV-infected children live in extreme poverty, in a study by Fontana and colleagues, 17 children were from families with limited resources, in fact living in households where the income was less than 50-percent of the official wage. Children depend on the goodwill of their parents and communities to access treatment and care. Even when drugs and lab tests are billed at no cost, families still have to spend money on transportation, or lose income because

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.

they have to take time off to take a sick child to hospital. Since they are not net wage earners, they often are not prioritized in expenditure of the limited family resources, a factor that may contribute to poor drug adherence. There is a need to evaluate models of promoting and supporting drug adherence for vulnerable children at the community level.

Food is essential for life, and adequate nutrition is part of the essential package for the HIV infected adults and children. Several studies have shown that malnutrition is associated with increased mortality among HIV infected individuals, and contributes to HIV disease progression independent of other HIV disease markers.

This slide of a study by Fontana and colleagues shows a five-fold increased risk of death in children with low fat-free mass. This limited data on the effect of different nutritional interventions on HIV infected children, the link between mother-child transmission of HIV and breastfeeding, as well as child survival makes feeding of the HIV exposed child really complex. The majority of HIV infected children live in poor households where they have limited access to adequate and nutritious meals, and therefore the priority intervention is to ensure household food security and to impart skills to families and care providers on how to feed the HIV-exposed child.

[inaudible] is in the process of developing a tool for supporting nutrition interventions for HIV-infected children

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.

which build on the existing tools for managing malnourished children.

Now, 25 years into the HIV epidemic, what have we achieved? Effective prevention of mother-child transmission of HIV services are offered to less than 10-percent of pregnant women worldwide, and as a result, 600,000 children continue to be infected annually.

Failure to upscale services to children is not limited to just PMTCT. Less than 10-percent of the children who have been orphaned or made vulnerable by AIDS receive public support or services. Less than one-third of women aged 15 to 24 years in Sub-Saharan Africa understand how to avoid the infection. Sadly, HIV-infected children are not accessing treatment. Essentially, there has been a failure to rapidly translate the success of clinical trials into a public health success story for the most affected populations of Sub-Saharan Africa.

How many children do we need to reach? Currently 660,000 children are in need of ARVs; 600,000 of them are in Sub-Saharan Africa. Of children needing ARVs, 270,000 are age less than 18 months, and currently four million children need Cotrimoxazole for prophylaxis.

To achieve this massive scale of prevention, treatment, and care interventions, a change of interventions are required. The concept of public health approach to intensive care has been adopted with scale-up to the lowest

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.

point of the health care system. This approach is a major departure from the model of highly specialized HIV care provided in developed countries.

A detailed discussion of the public health approach is in the current issue of *Lancet*. Several studies have demonstrated that timely immunization of ARVs in children enhances the survival and better quality of life. Initiating ARVs before five months of life is associated with significantly reduced risk of developing encephalopathy and opportunistic infections as well as a shorter time to immune reconstitution. Further, children who initiate HAART from low CD4 counts of less than 5-percent are unable to achieve immune reconstitution to 34-percent in the normal range, even after prolonged treatment with HAART.

There are similar experiences among African and Asian children, with deaths being reported among children with drug treatment of 34-percent, less than 5-percent. Shown here are data from the Ivory Coast. The [inaudible] probability of survival among children starting ARV at CD4 counts of less than five percent was only 72-percent compared to 97-percent survival for children who started treatment at a CD4 count of greater than 5-percent.

Comment [A1]: This is confusing. Maybe I misheard what the speaker is saying.

Diagnostic tools for pediatric HIV range from clinical tools to laboratory-based testing. Clinical algorithms that can be used for primary health care workers to identify

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.

children with symptomatic HIV infection have been incorporated into the MCI guidelines, but generally have low sensitivity, and identify children at extremely advanced stages of disease.

Antibody tests are useful in identifying newborns in need of ARV post-exposure prophylaxis as well as other infants in need of Cotrimoxazole prophylaxis. CD4 counts are increasingly available in resource-constrained settings, and definitely increase identification of children in need of ARV treatment.

In a study by Fassinou and colleagues 38 percent of those 78 children on ART who are asymptomatic, and treatment was initiated on the basis of a CD4 percent of less than 15 percent.

Now, virological tests such as PCR and P24 Antigen testing are a diagnostic of HIV infection, and therefore of great value to HIV exposed infants aged less than 15 months. Both are not readily available, and PCR testing requires a level of lab infrastructure that are mostly available in lab settings as illustrated in this slide.

The development of the dry blood score techniques for collection and storage of infant blood for HIV testing provides opportunities for early diagnosis of HIV. Dry blood scores can be used for PCR testing and P24 Antigen testing, the two technologies that are suitable for diagnosing children aged less than 18 months. This means that children living far away

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.

from these [inaudible] to access the technologies can now access testing.

Jean-Pierre is a [inaudible] of the [inaudible] system that has been developed in Kenya with the support of the Clinton Foundation for transporting dry blood spores to central laboratories and results back to site. To date, more than 1,000 infants have accessed testing through this system.

Technology is not the only barrier to testing. An availability of HIV testing policies for children and adolescents, shortage of staff, limited skills among health workers, health worker and parental fears of dealing with positive test results, and exclusion of children from existing services contributes the late diagnosis of children. And in some form of policy barriers found in Kenya where there is widespread [inaudible] services for adults, but because a policy of testing children in [inaudible] centers is not yet formulated, children are referred to clinical services for testing at a cost, while adults access testing at no cost.

[inaudible] strategy of upscaling preventive HIV care is active promotion of provider initiative testing. Young children frequently come into the contact with the health care system for preventive and corrective services. Routine offer of HIV testing during these visits should be incorporated into the package of services to help identify HIV exposed and infected children. Routine offer of HIV testing has been

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.

evaluated in several studies and found to be highly acceptable to parents or guardians. Providing initiative testing is still in the early stages, and is hampered by the absence of policies and shortage of staff, and therefore the majority of exposed children who access health services remain unidentified.

This slide is based on data from 12 district hospitals in Kenya that have recently introduced routine provider initiative testing in the MCH. In a six-month period 499 women were known to be HIV infected at the time they booked into MCH for well child clinic services. Antibody testing was offered to women with unknown status, resulting in the identification of additional 509 HIV infected women. The babies of these HIV infected women were therefore able to benefit from Cotrimoxazole prophylaxis and the mothers were linked to further care.

Now, care of the HIV infected child requires a comprehensive approach that takes into account prevention and protection of the child and provides for specific needs of the well child, sick child, terminally ill child, and children who are orphaned or living with sick parents. None of these categories are mutually exclusive, and therefore an integrated approach is critical.

This broad approach to care is captured in the [inaudible] 10 steps for the care of HIV infected and affected children and include: early infant diagnosis, preventive and

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.

promotive care, as well as psychosocial support and long-term care of the child. Although there have been significant advances in rolling out adult HIV services, children are facing a very serious service delivery gap. Lack of [inaudible] and integration between the various services is [inaudible].

This slide based on data from the Kenyan Ministry of Health where there are 280 sites providing adult [inaudible] on every site, only 76 of them provide ART to children. The consequences of this gap are that of the 76,000 people on HIV treatment in Kenya, only 4,000 are children. This type of scenario is common to many countries represented at this meeting. As a priority, children need to be able to access HIV care services at all points of contact, including the maternal child health services and inpatient services.

Training of health workers is a critical component of setting up HIV care. The generic [inaudible] training package adopted in many countries does not prepare the health worker adequately to treat children, and that is why there are many sites that only treat adults.

African pediatricians under the auspices of ANECCA developed a manual on the *Comprehensive Approach to Prevention and Treatment of HIV Exposed Children Living in Resource Constrained Settings*. A companion five-day pediatric HIV care training curriculum has been developed and is currently implemented in many countries in Africa. The production 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.

this book to date has been through funds from US AID[misspelled?]. ANCCAA hopes that the development partners will further support this process to enable timely revisions as experiences are gained in this public health approach to scaling up to pediatric HIV care.

This discussion is incomplete if the crisis of health manpower is not highlighted. Globally, we need 4.3 million doctors, nurses, midwives and other health care workers. The brain drain of qualified health personnel to developed countries is further crippling health care provision.

Sub-Saharan Africa where the epicenter of this epidemic requires 620,000 nurses to deliver effective HIV care and to cope with other emergencies. As they scale up [inaudible] HIV care, our practice needs to be informed by evidence. It is not feasible for individual sites to accrue evidence on their own, and we will need to work together to develop the knowledge base. The KIDS-ART-LINK is a collaboration between ANECCA and ISPED, and is one of the initiatives that is already implementing a clinical and operational research agenda on pediatric HIV. A [inaudible] of the activities was presented on Monday.

In conclusion, I'd like to say we have now enough resources and money to care for HIV infected and affected children. Regardless of the setting there is always something to be done for the HIV exposed and infected child. Let's go

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 Report on State-of-the-Art and Progress
XVI International AIDS Conference
08/16/2006**

forth and make a difference for the millions of children affected by HIV on this globe.

I'd like to acknowledge the contribution of my colleagues, and of particular notice, Professor Dorothy Mbori-Ngacha, and Dr. Peter Haven, the Chair of the American Academy of Pediatric Special Committee on HIV, who has regularly shared with us all the recent complications in this field of pediatric HIV. Thank you.

[APPLAUSE]

MICHEL KAZATCHKINE: Thank you, professor Ruth Nduati for this very comprehensive overview of issues related HIV/AIDS and children – our future.

It's now my pleasure to introduce Dr. Agnes Binagwaho from Rwanda. Dr. Agnes Binagwaho is the executive secretary of Rwanda's National AIDS Control Commission. She's also a member of the Expert Panel of the Country Coordinating Mechanism in Rwanda for the Global Fund, the chair of the PEPFAR Steering Committee in Rwanda. Dr. Binagwaho is a pediatrician specializing in emergency pediatrics and the treatment of HIV/AIDS in children and adults, practicing part time in Kigali.

For the next 20 minutes, Dr. Binagwaho will present the *Prevention and Universal Access: An Issue of Sustainability*.

The floor is yours.

[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.

AGNES BINAGWAHO, M.D.: Thank you. Dear colleagues and friends, it's an honor and a pleasure for me to be hear in this Plenary Session to share with you the Rwandan experience to access treatment and prevention.

I like this photo of children because it's for them that we have the moral obligation to think today of sustainability as a key factor of the battle against HIV/AIDS. As you see, I'm proud to say that Rwanda is beyond time to deliver. We are now at time for sustainability.

[APPLAUSE]

Universal access to treatment and prevention are indivisible, equal, critical, and complementary. Treating people with HIV/AIDS reduces the risk for them to transmit the HIV virus, but all people living with HIV/AIDS don't need treatment. Indications of treatment are led by biological, and critical, and clinical criteria, and in another side, being on [inaudible] doesn't mean that we don't need to promote the full package of prevention.

In Rwanda this package comprises EABC. E stands for education, and we start by E in our policy. Education is a cross-cutting issue for A, B and C. Abstinence and faithful for singles and couples, and the education teaches how to use condoms when A and B doesn't work.

Rwanda is a good example of countries concerned by these debates - universal access, prevention and

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.

sustainability. But to understand my country, we need to go back to our recent history. We lost one million people during the horrific drama of the genocide. Many highly skilled people were lost in [inaudible] to or divested. Other consequences were high numbers of orphans. Thirty-percent of children 18 years and below. One million, three hundred orphan and vulnerable children due to the genocide and HIV/AIDS. High number of our children [inaudible] head household – 34-percent of the country. Psychology cultural [inaudible] during the genocide is still there, and despite a high level of political commitment, and having left the emergency period to enter it in developing phase, Rwanda still faces problems.

Rwanda still has a high level of poverty, illiteracy, maternal and infant mortality, and low life expectancy. The numbers of doctors and nurses are too low to cover all the health problems such as malaria, acute respiratory disease, and diarrhea. The major cause of this in our country was HIV/AIDS. This is just to show you that my country is a typical African country.

The overall rates of HIV prevalence is three percent for Rwanda, with a rate of 3.6 for women and 2.8 for males, but the problem is worse in urban areas, with a prevalence of 8.2 for urban females, and 5.8 for urban males. An important point is the immunization of HIV [inaudible], meaning that women are greatly affected by the epidemic.

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.

The proportion of women is greatest in regions where heterosexual transmission is the dominant method of transition. Even in Sub-Saharan Africa, 57-percent of infected adults are women. Worse than that, 75-percent of young adults are women or girls.

If one looks at the variety of countries in Sub-Saharan Africa, the prevalence of HIV among people between 15 and 24 years old, you can see that the rate is two to three times higher among women than among the men counterparts. The reasons that such a high proportion of infected persons are women include the fact that many have all the male partners, and that may be gender inequalities who affected the use on condoms and there is impact of sexual violence. This is why prevention is crucial for women.

The situation has to be tackled, and if we talk about universal access to prevention and treatment, we need to assure that women and children are not left out, like my colleagues have just said. For that in my country we issued a law saying that if one person is found HIV-positive, all the family is treated, given care and treatment for the same condition – if you are one of 10, it's the same. This is the only way we can be sure that children we will bring to treatment and women.

The situation which led to the drama of '94 was due to ignorance, poverty, and bad leadership. The response to that, the government fight poverty, and bring education. We also go-

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 this is important – You cannot give treatment, good treatment, and quality of treatment if you don't go for the [inaudible] for giving good law and good constitution to your country. And also we went for [inaudible] this [inaudible] to bring the decision at the community level, near the community. We also ran for a wide program for reconciliation to change mentality and [inaudible] the rate of old process of [inaudible], because if we have to deal with genocide problem, with the normal justice, you know it will take us 200 years, and we don't have that time. You don't have, I don't have it.

So the fact against HIV/AIDS, as I tried to tell you, to have universal access and access to prevention needs to be done with good [inaudible] tools good technical tools. First, let us situate HIV in the context of the [inaudible]. Because we need to tackle all the AIDS goals of MDGs to assure sustainability in the fight against HIV/AIDS, all of the AIDS. If we left one out, we will not reach our goal.

The first one, eradicate poverty and hunger. It's necessary for sick people to take their medicine. The second one, achieve universal primary education is a strong prerequisite for education. We all know the link between education and prevention. The third one, promote gender equality and, for a woman, it's crucial because they are the most affected.

The fourth goal of MDGs, reduce child mortality,

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.

crucial also, because HIV is a major contributor to child mortality. The fifth one, improve medical health. To provide good [inaudible] services we need to have a good antenatal care and good delivery services. The sixth one, halt HIV/AIDS, tuberculosis and malaria needs no comment.

The seventh one, assure [inaudible] health sustainability is also a concern. You should talk and think about this today because we have to think about disposal of millions of condoms we have already used, and the billions I want the people to use today, tomorrow, and the years coming to prevent HIV/AIDS. This is [inaudible], this is [inaudible]. We have to think about our [inaudible].

The eighth goal is partnership. We need that. We need you to all together overcome this epidemic. Dear colleagues, HIV has brought a unique situation never faced before by the world, and we have to adapt ourselves, and continuously find new ways to face the challenges with flexibility. No person has the solution. We have to work all together under the national leadership. Therefore, to create a favorable environment of success, the [inaudible] principles are absolutely necessary to reinforce the national institution which are the spine of our countries. But on the other hand, we all need to be sure that the national institutions are working and serving the communities adequately with result-oriented programs and good monitoring.

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.

The key instruments of the success of the fight against HIV/AIDS in my country is the National AIDS Control Commission who has the governments to draw strategies, policies, to plan and coordinate, monitor and evaluate all activities in the field of HIV/AIDS, also to sensitize the population at all levels, and to mobilize resources.

There are three sectors in the fight against HIV/AIDS, and we have to base on them for the success of sustainability. There is a public sector, and I'm part of that sector. There is a private sector, and the [inaudible] sector, and the third one is the community sector. We have created mechanisms to engage and coordinate all sectors under new leadership in the sectors themselves. We call them umbrellas. Those umbrellas help us to coordinate the fight in their sectors. The majority of them are [inaudible] in society's organizations, and they concern youth, women, and [inaudible], people living with HIV/AIDS, [inaudible], media, and also a new one we have just created for handicapped people, because people who can't hear cannot hear our messages. People who have no vision cannot see our - so we need to create specific tools for them. This also is an issue of sustainability.

The way we process has allowed us to bring in the fight of people at the grassroot level to increase the knowledge and the civil society as this specific role, and without them we cannot [inaudible] of the treatment, we cannot [inaudible] 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.

the prevention, and what we do has no sustainability.

Some coordinations brings economies of scale, simplify and harmonize planning and reporting. We have one plan sheet for all the partners, and one reporting sheet for all the partners, and it helps us to see what we do, where we stand, and what we have to plan. This allows to understand the real costs, and to determine the cost efficiency, and is very useful for the compilation of intervention models. We made this improve our policy and protocol using the same [inaudible] serving the largest number of needed people, and also to improve the quality of services. It's a necessary step on the way of sustainability harmonization.

We have a strategy of a systematic national ownership. On the left, you can see all our partners. We have [inaudible], we have global fund to go for the three diseases, we have Royal Bank for the [inaudible] project, we have [inaudible], UN family, Clinton Foundation, [inaudible], and in the other hand, all partners' funds allocation is decided in committees where the civil society is represented, but chaired by a random official, either the [inaudible] Secretary in the Ministry of Health, Heather, the executive secretary of National AIDS Control Commission.

Our national institutions are responsible for normative process, standard protocol, and [inaudible], but these on performance [inaudible] basis. We are not allowed to delay,

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 we signed for that. In our side, we are accountable to communities, and at district level the mayors – that means the local government – have signed a memorandum of understanding with the president of the [inaudible] for [inaudible] in that district. And they have also signed a memorandum of understanding with the National AIDS Control Committee on results for [inaudible] and IV delivery. That means, by that way we get the support of the local government, and they are totally implicated and financially responsible of what happened in their district. It's also a way to give the decision to the districts, and to create good [inaudible] for sustainability.

Integration in the sector in a comprehensive manner it is also necessary to provide [inaudible] and prevention. We cannot go to communities and only treat HIV if we don't tackle the other problems of the communities. That means we have reached the three ones, but as you see down we go for three ones for the big three. That means the three big diseases for the same communities for the same health workers with the same partners, because the partners who help us in those areas are the same. So we go for the three ones, for the three bigs, integration in the sector, and in the [inaudible].

This is to show you that the true decisions are taking away the threat at district levels. At national level, our role is just to see if they follow the national policy, and if there is money available. Another key issue of sustainability

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.

for IVs [misspelled?] and prevention is to put our work in the continental and regional framework, and in that area, Rwanda has played a big role with linking with original and continental organizations like the first [inaudible] organization to fight HIV/AIDS, like the Pan African News Association to fight against HIV/AIDS, and the great lake initiative to fight HIV/AIDS. But we linked also with others, and this is crucial because we are a little country, and there are many countries outside, and HIV has no borders. If we [inaudible] together we can lower the price and serve more people.

This is to show you our achievement with this process. We came from one site in '99 for PMTCT, and we have reached now, in July 2006, 221 sites. For IVs, this is the contribution of all stakeholders. We came from 800 people in 2002, and we have now 25,500 people on IVs, we have reached the 3 by 5, but I have to tell you that two partners who were helping us in that are ending their project in the end of the year. I want to pay you attention, because 10 years from now, not far from here in Vancouver, the fight was bring access to the Third World. Now the fight should be sustainability for the Third World.

[APPLAUSE]

This is to show you the general increase in services in VCT, PMTCT and IVs. Rwanda plans to give universal access to

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.

treatment and prevention, and we have a long way to go for that, but we are fighting hard for that. We don't have to forget that to give IVs, we need to be able to do VCP first and PMTCT. That means having labs, and to have labs, what is important for prevention strategies, we really need, first of all, to give basic care to the place where we are going to give IVs. That means giving basic care not to HIV/AIDS facilities, because we don't have HIV/AIDS facilities. We have health facilities. That means giving basic care to people affected or not affected by HIV/AIDS. And this is very important, and you should support this idea, because if you don't do so, there is no sustainability in giving treatment for people affected by HIV/AIDS, and there is no [APPLAUSE] and there is no sustainability in prevention. That means integrating the ordinary health system is a prerequisite for providing IVs in a safety manner, and in respect of the needs of the entire community.

We hope that sustainability in the area of prevention will come in a couple of years through microbicide and through vaccine, which we have here, and fortunately that all our dear scientists are working hard, but it's not easy, and they [inaudible] a couple of [inaudible]. That means during that time people were in IVs need to remain on IVs, and need to have the assurance to remain on IVs, and we need to have the assurance that we can put other people who need, because there

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.

are still millions of people dying day after day because they don't have access to current treatment.

That means also that the scientists have a long way to go. They need our support. They need funds to do so, so we all have to stand and be behind them for vaccine, because vaccine will be the only way women can have access to prevention in a full manner, because when you have vaccine, you don't have to make a risk [inaudible] when you are not capable to do so. And this was a theme all along this conference. We know that many women have no capacity to negotiate because of economic problems, because of education, or they don't know. If there are vaccines, they will be protected, so let's all fight for the world to have a vaccine.

The health sector's sustainability means no [inaudible] program, and for doing so, we have integrated. I have already saved TB, HIV, STI, malaria, and the common diseases, and also we try to link it with income generating activities for people to be able to pay one day when the project will [inaudible].

We also go for performance-based approach to keep nurses and doctors in remote areas, and we reinforce education of the communities for them to use services. As I told you, we have 221 health centers giving PMTCT. Sixty-eight percent of women who attend those services get the services, but we serve only 28-percent of women needed, because 80-percent of women deliver at home. That means to give universal access to

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.

services we need to promote and to strengthen health system, the overall health system. If not, we don't reach people who are needed with the best program.

And we also go for what we call [inaudible], a community based health insurance so that people for who we give access to treatment for more than our [inaudible], for more than \$100 a year, then die for \$5 because the family cannot treat diarrhea or common pneumonia.

We also manage to pay those insurance and minimum complementary package for almost 800,000 poor people and orphans, 70,000 children, and 100,000 people living with HIV/AIDS. We do training for health staff at whole level. This is also absolutely necessary for sustainability, giving knowledge and capacity to give good services, and also it keeps the health centers so that they can deliver good services.

This is to show you that income generating activities is absolutely necessary, and for doing so we use the civil society's signed memorandum of understanding with them so that they can bring the knowledge and organize communities. This is also absolutely crucial for sustainability. The knowledge of the community has to be upgraded. Education has to be bring. I think I'm going too short.

I'm just going to talk about constraints, and this is very important. The constraints, the biggest one is that the fight against HIV/AIDS is largely externally financed. We

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.

solved partially the problem making the fund country driven and in country community driven, but we use also a sector wide approach, and then within the center a [inaudible] team, and now we receive integration in our national program.

But many interventions remain underfunded. And hunger—no partner agreed to fund nutrition part. They are very few—the nutrition part of the treatment. We know that nutrition is essential for people who are taking tablets. You cannot take tablets solo when your stomach is empty. We have also the balance between the [inaudible] addressing the human resource gap and services according the true purity of the country. It is a ethnic problem.

I want to bring here these slides, because we need to assess part of our partners, like FO. FO is in Africa for years and years and years, and I wonder why, if our people in the rural area are not clever enough to understand or to be taught how to be self-sustainable, and to have food security. I think they need to review the way, and to be more results oriented.

[APPLAUSE]

Another challenge is integration into the [inaudible], and for us to develop a sustainable plan, but we have started with a short-term commitment of our partners. So partners have to start to be family oriented. They need to be results oriented. It's like if you take a friend to cross a river who

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.

doesn't know how to swim and you tell them, "I'm finished."
You tell them, "I take you for five minutes, and if you don't
reach the other side of the river you left your hand." Thank
you.

[APPLAUSE]

MARK DYBUL, M.D.: Thank you, Agnes, for that excellent
presentation, and for doing what you always do so well: take
general theories and teach us what they mean for implementation
on the ground.

It's my distinct pleasure to introduce our last
speaker, Dr. Kevin De Cock. Kevin is the director of the World
Health Organization's Department of HIV/AIDS, a post to which
he was appointed after serving six years as the director of the
U.S. Centers for Disease Control and Prevention in Kenya. In
that capacity, I've come to know Kevin quite well. He's a man
of great intelligence and commitment, and we are all very
fortunate to have him at the helm of WHO's HIV/AIDS effort.

Dr. De Cock is an infectious disease specialist, with
expertise in HIV/AIDS, tuberculosis, liver disease and tropical
diseases such as yellow fever and viral hemorrhagic fevers.
Kevin, we look forward to your presentation.

[APPLAUSE]

KEVIN DE COCK, M.D.: Thank you, Mark, for that kind
introduction, and thank you to the organizers for the honor of
speaking here and for recognizing the World Health

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.

Organization.

Colleagues and friends, as I reflect on this world so radically different from 25 years ago, I'm struck by the inevitability of change if science and public health are to maximally impact on the HIV pandemic, and universal access is to mean something tangible.

Much has changed in the world since AIDS was identified in 1981, since we learned about combination therapy in Vancouver 10 years ago, and if the benefits of antiretroviral treatment are to spread and be sustained more across many areas of our response to AIDS will need to change.

The World Health Organization, one of the co-sponsoring agencies of UNAIDS is the agency that sets non-standards and policy for global health. Experience with antiretroviral scale-up has taught that a strong health sector is essential for a comprehensive response to HIV, and universal access will require that the health sector play a central role, one far stronger than that sector that was eroded by Africa's impoverishment over the past two decades, or by misinterpretation that a multi-sectorial response to HIV meant medicine and public health were less important.

In this presentation, I will review global treatment scale-up, discuss the role of the health sector in working towards universal access, and conclude with comments, comments of hope, but also realism.

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.

I wish to acknowledge Dr. Lee Jong-Wook, Director General of the World Health Organization who died unexpectedly in May this year. His death reminds us that life is fragile; take nothing for granted; seize the moment. Aided by loyal supporters such as Dr. Chim Kim [misspelled?], he led 3 x 5, the WHO/UNAIDS call to action in late 2003, to place three million persons in low and middle income countries on antiretroviral therapy by the end of 2005. The saving of several hundred thousand lives in the two-year period of 3 x 5, the lessons learned, the partnerships created, are a credit to his memory. But also to all those programs and all those individuals from diverse backgrounds, including many in this room, who can say with pride, "I contributed to the beginning of treatment scale-up."

Of the global total of 38.6 million persons living with HIV, approximately 6.8 million in low and middle-income countries currently require antiretroviral therapy. WHO estimates that by end of June 2006 some 1.65 million persons in need were accessing ART for an overall coverage of 24 percent. Coverage by region ranged from 5-percent in North Africa and the Middle East to 13-percent in Eastern Europe, to 75-percent in the Caribbean and Latin America.

In the most challenging environments of Sub-Saharan Africa, over a million people are now on treatment, a 10-fold increase since December 2003, and Africans now represent 63-

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.

percent of all treatment recipients in low and middle-income countries. In Asia, a more than threefold increase in treatment uptake has occurred. At least 20 low- and middle-income countries in the Americas, Asia and Africa are treating over 50-percent of their citizens in need.

Equity of access can be viewed in different ways. This slide shows numbers of persons in need receiving and not receiving treatment by region. Although a majority of people on therapy are African, and Sub-Saharan Africa has the second-highest coverage after Latin America and the Caribbean, Sub-Saharan Africa still accounts for 70-percent of the world's unmet treatment need.

It is a credit to programs that women have accessed treatment at high rates. In this slide, the horizontal bars depict the percentage of treatment recipients in selected countries who are women, and the vertical red bar is the estimated percentage of all HIV infections in those countries that are in women. In most settings, including in Africa, the proportion of ART recipients who are women corresponds closely to the proportion infected, and in some settings exceeds that proportion. More qualitative data are required on gender and other aspects of access, such as quality of care and support, including coherence.

As we heard from Dr. Nduati, an estimated 800,000 children below the age of 15 require antiretroviral therapy,

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.

again the vast majority in Africa. Information on treatment access in children is scarce, but children account for at least 14 percent of AIDS deaths, but for well under 10-percent of all recipients of ART in low and middle income countries. And despite the great strides in research on the prevention of mother-to-child transmission, which was an early focus of donor interest, less than 10-percent of HIV-infected pregnant women in low- and middle-income countries current benefit from antiretroviral prophylaxis.

There is inequity of treatment for drug users. In Eastern Europe and Central Asia injecting drug users, a majority of them men, account for over 70-percent of HIV infected persons (in blue) and of treatment need. However, only about a quarter of treatment recipients (in red) are drug injectors, and it is likely no coincidence that regions and countries where treatment coverage is lowest and scale-up has been most modest are the same ones where injecting drug use accounts for most HIV infections.

To assess equity better we will require more extensive data relating to time, place and persons, the essentials of descriptive epidemiology. Rapidity of scale-up, its geographic distribution including in relation to type of epidemic, and urban versus rural coverage, and populations served, such as drug users, sex workers, specific occupational groups and refugees.

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.

In the meantime, urgent priorities are strengthening mother-to-child transmission prevention and improving access to antiretroviral therapy for children, especially in Africa, and for injecting drug users everywhere.

Treatment scale-up has been funded through resources that were unimaginable five years ago, through the U.S. President's Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank, other bilateral donors, and pharmaceutical companies through contributions such as the Accelerating Access Initiative.

The best price scenario of around \$130 U.S. per person per year for a first-line generic antiretroviral drug regimen is an achievement, but it's one that's not available everywhere. The cost of first-line regimens in middle income countries remains a barrier to access, as does the price of second-line regimens, pediatric formulations and diagnostics in nearly all countries.

Additional obstacles include the slow pace of registration of medicines in some countries, the imposition of tariffs and taxes on drugs and diagnostics by some recipient governments, and limited use of flexibilities afforded by the TRIPS Agreement.

The best data on treatment outcome come from special studies. The ART-LINK and ART Cohort collaboration mentioned earlier examines survival in over 27,000 patients from

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.

developing and industrialized country settings. CD4 response and viral suppression were similar in both environments.

Overall mortality at one year was 6.4-percent in low income settings, approximately 3.5 times higher than the 1.8-percent one-year mortality in high-income settings as shown by these hazard ratios – the hazard for mortality in low income versus high income.

Mortality was 4.3 times higher in low-income settings in the first month, but fell to a ratio of 1.5 during months 7 to 12, not shown on this slide. Importantly, this high mortality in the first month for low income settings was still 40- to 60-percent lower than that in historical untreated cohorts.

To maximize benefits, WHO's public health approach places emphasis on initiating therapy for patients with Stage 3 and 4 disease rather than requiring CD4-based decision making. Let me say that around this conference, three new WHO guidelines for treatment in adults and adolescents, the new guidelines for treatment in children, and revised guidelines for PMCTC have all been released and are available.

If CD4 testing is available, all persons with counts below 200 should be treated, and therapy should be considered for those with counts below 350. Experience now gives us a broader perspective. In most developing country programs the majority of patients have late stage disease. In the ART-LINK

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.

Study approximately half had a CD4 count below 100 when initiating therapy. Almost three-quarters of deaths were in people whose initial count was less than 100, and over 80 percent of mortality occurred in the first four months. Many people, therefore, are receiving therapy too late to get the full benefit that ART can offer.

The ART-LINK also found a 75-percent lower mortality, as Julio mentioned, in treatment programs offering free access, and a meta-analysis of published literature associated free provision of ART with increased probability of sustained viral suppressions. And other studies have associated requirement to pay with non-adherence, which is a major risk factor for drug resistance.

WHO and its partners in the HIV RESNET Program are monitoring drug resistance in populations on treatment, and implementing surveillance for the transmission of drug-resistant mutants. Areas in green on this map indicate countries participating in such resistance surveys from we hope first data will be available later this year.

A special effort is required to ensure coordination between HIV/AIDS and tuberculosis programs, especially in Africa, to ensure that TB does not become the Achilles heel of ART scale-up. Patients on ART remain vulnerable to tuberculosis, as indicated by elevated incidents and recurrence rates, and in patients initiating ART distinguishing between

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.

incident tuberculosis, unrecognized prevalent TB, and immune reconstitution inflammatory syndrome is challenging, as are the complexities of drug interactions. But TB prevention and treatment must become a central component of AIDS care.

From this review, five clear priorities emerge if we are to reduce HIV/AIDS mortality in low and middle income countries. First, to scale up HIV testing so that persons with HIV infection, including TB patients are diagnosed earlier. Second, to ensure that all patients diagnosed as HIV-positive benefit from a minimum package of care that includes TB screening and treatment or preventive therapy, Cotrimoxazole prophylaxis, and other simple interventions, including in places where ART is not yet available.

Third, to ensure that all those with Stage 3 and 4 disease receive ART as early as possible since they are at the greatest risk of dying. Fourth, expanding laboratory capacity for CD4 testing, allowing earlier initiation of therapy on immunologic criteria; and fifth, to define HIV/AIDS treatment as a global public good, requiring the abolition of user fees at the point of care.

[APPLAUSE]

These are not just priorities, but they are requirements if we are not to squander what this precious commodity of ART can offer.

Let us now turn to the dream of the universal access.

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.

In June of this year member states of the United Nations expanded the commitment by leaders of the G8 in 2005 by pledging to come as close as possible to universal access to prevention, treatment and care for all who need it by 2010. By legitimizing the aspiration and right of anyone irrespective of geography, status, or wealth, not to die from HIV, 3 x 5 helped lay foundations for this promise by the G8 and the world community. Public health agencies, like UNAIDS and WHO must now help countries translate this political target into health goals at country level.

So what should now be the focus of our efforts? Under the multi-sectorial coordination of UNAIDS, WHO has defined five strategic directions for its own work and for the health sector's contribution to universal access, and these are: expanding HIV testing and counseling, maximizing prevention; increasing access to treatment and care, strengthening health systems, and investing in strategic information. And for the health sector, the five directions represent the pillars of universal access.

Prevention and care are inextricably linked. With treatment reducing mortality, with HIV incidents unchanged, the prevalent pool of HIV and AIDS will continue to increase, as shown here by the red line for the United States. It is HIV incidents that will write the final history of HIV treatment, determining whether we will approach universal access with

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.

vigor and hope or be trapped in an ever-widening treatment gap as the prevalent pool of persons with HIV escapes beyond any feasible treatment target.

We cannot treat our way out of this epidemic. Debate around prevention has been frequently contentious, sometimes divisive. Our best recourse is to listen to science, epidemiology, and the communities most affected. One key area underserved to date is the provision of prevention services for people living with HIV now diagnosed in the millions through treatment scale-up.

Hope has been reaffirmed at this conference by discussion of emerging prevention technologies, such as male circumcision, microbicides, treatment for HSV2, and pre-exposure prophylaxis, and WHO looks forward to the partnerships that will be required for the future's translation of this science into policy and program.

Universal access will require health system strengthening to become as high a political priority as ART access itself did some years ago. A major lesson from 3 x 5 was that the biggest obstacle to treatment scale-up is the frailty of health systems.

We should not be distracted by theoretical arguments pitting horizontal health system strengthening against more vertical HIV treatment and prevention scale-up, both are necessary and can be mutually reinforcing.

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.

The term "strategic information" encompasses epidemiology and surveillance, monitoring and evaluation, and operational research. To ensure accountability and assess progress, WHO, with partners, will report annually on the health sector's work towards universal access, assessing availability, coverage, and impact of the delivery of health sector interventions, and the first report should be delivered late this year. And this subject will be discussed in more detail by my colleague, Dr. Chase Borma [misspelled?], Track E, Room 12, at 17:05 tomorrow. Strategic information should evaluate and guide our efforts, learning from the past to shape the future.

The final issue, if I may have five more minutes, is HIV testing and counseling. While calling for urgent expansion of different models of testing, WHO and UNAIDS retain their commitment to basic standards in all contexts: respect of human rights, consent and non-coercion, confidentiality, counseling and information, and policy and legal frameworks to prevent discrimination.

That fact that 21 years after the HIV test was introduced, only about 10-percent of infected persons worldwide know their status is an indictment of our commitment to public health and to affected communities whose most basic rights: life and health, are compromised by the unforgiving natural history of undiagnosed, untreated HIV infection. And as 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.

data indicate, too often treatment delayed is treatment denied.

Encouragingly increased uptake of client-initiated VCT has occurred in many settings, including through innovations such as mobile services, and new approaches include family VCT, as here in Uganda, and the universal Know Your Status Campaign in Lesotho.

But much discussion here is around the additional specific, much narrower issue, the different approach of provider initiative testing and counseling in health care settings. Health care settings where people go seeking diagnosis, treatment, and care, when ill or in need of specific medical services. Botswana introduced its well-known policy in early 2004 of HIV testing all patients at medical visits unless they explicitly opted out. And Kenya published these guidelines in 2004 advising that HIV testing be performed in clinical settings in the same way other tests are conducted, with simplified pre-test information, emphasis on post-test counseling for HIV infected persons, and informed consent defined as the right to decline.

In this changing environment of universal access, the key question is how to assure maximal access to HIV treatment, prevention, and care. And WHO and UNAIDS continue to consult on this issue, and will issue guidance later this year, as always, guidance that has to be tailored to local circumstances.

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.

Provider initiated testing should be viewed in the context of plans for scale-up, and patients must be provided with the opportunity to decline with essential information to receive their test results, and to be linked to appropriate services. Testing linked to punitive action, such as imprisonment of infected drug injectors, is a violation of human rights. [Applause] At the same time the status quo of preventable, undiagnosed endstage immunodeficiency as the typical first indicator of HIV infection is incompatible with universal access, or with WHO's accountability for setting standards in global health, and this discussion is about health.

In closing, I think the many colleagues who have directly or indirectly contributed to this talk. The unusual opportunities that are before us inspire tremendous hope. Funding and political support have never been as high. Structural issues previously ignored such human resources and health systems now feature in the discourse recognized by activists as well at this conference by a former president and the richest man in the world.

At the same time, we should remember that from those to whom much is given, and that's us, much shall be expected. Our biggest failure would be to have limited impact despite increased funding, and to have AIDS become accepted as a normal part of life, sidelined by other global priorities that will

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 Report on State-of-the-Art and Progress
XVI International AIDS Conference
08/16/2006

inevitably emerge in coming years: infectious disease,
security issues, the environment.

The slogan of this conference is "Time to Deliver." My aspiration is that by working towards universal access we might deliver at least in health on the slogan of that earlier conference in Vancouver 10 years ago, when we first heard of protease inhibitors, combination therapy and viral load, time to deliver, time to deliver, one world, one hope. Thank you.

[APPLAUSE]

PEDRO CAHN, M.D.: Thank you, Kevin, for this inspirational speech, and we that we come to the close of this Plenary Session. We thank the speakers and the audience for being with us.

[END RECORDING]

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.