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**XVII International AIDS Conference
Scaling up Comprehensive Prevention of Mother-to-child
Transmission Programmes: Challenges and Lessons Learned
from Adapting Global Recommendations to Country Situation
August 3, 2008**

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JIMMY KOLKER: -the issues that face countries that are implementing programs to protect children from HIV-positive mothers from getting the infection. We actually have made an enormous amount of progress in almost every country in the world. PMTCT is taking hold. We have a lot of evidence of what works. We know that this can be done. It is a complex program, but at the same time, we have mastered many of those complexities. And, it is now a routine program in many countries.

Latest statistics are that in low and middle-income countries, 33-percent of women who should be getting the prophylaxis for their newborns and going through comprehensive prevention mother-to-child transmission program are doing so. That is up remarkably from less than 10-percent only three or four years earlier.

On the other hand, it means that two-thirds of the women who need this care are not getting it.

And of course, the purpose of this session is to examine what are some of those obstacles which are hindering the even further acceleration of prevention mother-to-child transmission implementation.

We know that the flow-through of women who attend prenatal clinics, who get tested, who have counseling, who are found to be positive, who go through the regimen which is

now advanced into a regimen of drugs before birth, to the child after birth, advice and counseling on breastfeeding or alternative feeding depending on the local circumstances and the mother's situation, and then the infant diagnosis early on. These are number of steps, but again, none of them are so challenging that it has not been done even in the most resource poor and marginal settings.

So, we are eager to hear from four distinguished panelist with good experience in the field about PMTCT as well as to hear from those of you in the audience who have good experiences to add. And I repeat, please feel free to move up, there are plenty of seats in the front and I am delighted to introduce Gloria, my co-host, to start the program.

GLORIA SANGIWA: Hello, my name is Gloria Sangiwa and I work for Family Health International, looking at the issues related to counseling and testing as well as PMTCT. And I am here to co-host this session with Jimmy Kolker, which I will not go into details, but broadly speaking is to try to share the lessons that have been learned in different countries, share some experiences and, of course, have discussions with you.

Given the time constraints and as wishing to go ahead and be able to attend the opening session, I will take this opportunity to introduce our first speaker.

Our first speaker is Dr. Ying Ru Lo and she is a coordinator at WHO, a coordinator of the prevention in the health sector. Dr. Lo is an infectious disease physician from Hamburg, Germany who took up her duties with WHO in the HIV/AIDS Department as the coordinator of prevention [inaudible]. Dr. Lo has over two decades of working experience as a clinician and public health advisor in prevention, care and treatment of HIV and AIDS, working in Europe and Latin America, and 10 years with WHO in Southeast Asia. This afternoon, welcome Dr. Lo for this session. Thank you. [Applause]

YING RU LO, M.D.: Thank you very much, Gloria, and thank you very much, Jimmy, for the introduction. Before I start, I would like to thank the staff who have been preparing this satellite session, in WHO and in UNICEF, in particular Tim who is running around and Rene, Kimmy, and Cheve [misspelled?] who have been helping to organize in putting this session together.

The title of the presentation is the Emerging Evidence on Prevention of Mother-To-Child Transmission of HIV. I would like to briefly present on the progress made globally, some key issues, present a few of the new data on use of antiretroviral drugs for prevention of HIV, infant feeding transmissions, doing better with what he have now, and implications for WHO Guidelines.

Since the majority of HIV infections in children are acquired from their mothers, the global epidemiology of HIV in children reflects that of HIV in women. In 2007, 67-percent of the estimated 33 million people living with HIV worldwide were living in Sub-Saharan Africa.

Women accounted for approximately half of people living with HIV globally and 60-percent in Sub-Saharan Africa. In 2007, 1.5 million pregnant women in low and middle-income countries were living with HIV, of whom, almost 90-percent were found in just 20 countries, 19 of these 20 countries in Sub-Saharan Africa.

I would just like to remind of the four key elements for prevention of HIV infection in the infants and children which was discussed and endorsed by the UN partners and UNAIDS, at a strategic approach is leading in 2002 in margs [misspelled?].

And unless these four elements are in place, first, primary prevention of HIV in parents-to-be, prevention of unwanted pregnancies in HIV-infected women, prevention of transmission of HIV from mothers to their infants, and ultimately, appropriate treatment care and support, the number of HIV infections in children will be reduced.

And I would just like to mention one example which I showed here below. The TIA data, this is the HIV prevalence in pregnant women at first ANC visit in Thailand between 1991

to 2007 leveling off, these data were fundamental in formulating the approach of the four elements for the prevention and management of HIV infection in infants.

And Thailand has a program which has scaled up primary prevention programs for 100-percent condom program targeting sex workers and declines, they have strong family planning services, and they have introduced a very early HIV testing and counseling as an alternative care services, and successfully decreased with the introduction of antiretroviral prophylaxis and formula feeding, the number of new pediatric HIV infections, as you can see here now between 1994 down to 2007.

For pregnant women, to access any intervention for prevention of transmission requires the knowledge of their HIV status. The WHO and UNAIDS released a guidance on providing initiated HIV testing and counseling and healthcare settings in 2007. This recommends HIV testing for all pregnant women and intranatal delivery and postpartum services according to the level of the HIV epidemic.

In the global universal access report released by WHO, UNAIDS, and UNICEF in June this year, we can see that the overall proportion of pregnant women who received HIV testing increased from 10-percent in 2004, that is the yellow bar, to 18-percent in 2007, nearly two-fold increase. And we have the breakdown here by region – it is probably a little

bit difficult to see. Sub-Saharan Africa is on the very left, East and Southeast Asia, Latin America, and Eastern Europe and Central Europe on the right.

As Jimmy already mentioned, tremendous progress has been made with prevention of mother-to-child transmission. The data which are regularly reported to UNICEF, and also to WHO and UNAIDS show that from the 81-percent of 109 countries reporting, they are implementing prevention of mother-to-child transmission programs. The coverage of pregnant women, what you see on the left, receiving any antiretroviral drug for the prevention of mother-to-child transmission of HIV increased from 10-percent in 2004 to 33-percent in 2007.

However, the coverage of PMTCT services varies tremendously between countries, and even within one single country. Data, on the impact of quality of services on PMTCT are, however, not systematically collected.

As of 2007, nearly 50-percent of pregnant women, as you can see here in this part of the pie chart, and the infants were still receiving only single-dose nevirapine for the prevention of mother-to-child transmission. And we all know that this regimen is less efficacious compared to current WHO recommendations to provide dual antiretroviral prophylaxis administering, a combination of AZT with single dose nevirapine or antiretroviral therapy for eligible pregnant women.

In 2006, the WHO released guidelines on use of antiretroviral drugs. I have just talked about them – this one, for treating pregnant women and preventing HIV infection on infants. These guidelines were harmonized with the set of other guidelines released in the same year on antiretroviral therapy in adults and adolescents as well as infants and children, revised WHO definitions on clinical and immunological staging and co-trimoxazole, and just this year, a few weeks ago, we released guidance on use of antiretroviral for post-exposure prophylaxis.

The use of antiretroviral therapy in pregnant women with low CD4 counts or advanced clinical disease reduces significantly, not only the risk of mother-to-child transmission of HIV, but also morbidity and deaths among mothers and improved survivals of their children.

When a pregnant woman is diagnosed with HIV infection, her clinical stage were available, her CD4 count must be assessed to determine whether she is eligible for antiretroviral treatment.

The criteria for initiating antiretroviral treatment for pregnant women are the same as for non-pregnant women with a notable exception of pregnant women who have a clinical stage III where it is recommended to start at CD4 count below 350 cells per cubic millimeter.

So, in summary, it is recommended to treat clinical stage III and IV, if CD4 testing is not available, if CD4 testing is available in WHO, clinical stage I and II, if CD4 count is less than 200, at stage III, less than 350 as I mentioned before, and at stage IV, irrespective of CD4 count.

I just would like to remind you of the recommended first-line antiretroviral treatment regimen for eligible pregnant women, the recommendation is to use two nucleosides plus one NNRTI, AZT/3TC, nevirapine twice daily antepartum, intrapartum, and postpartum; and to the baby, AZT for seven days. If the mother received less than four weeks of ART during pregnancy, one would extend the AZT administration to four weeks.

For pregnant women not eligible for ART, the recommendation currently is to provide antepartum AZT combined with single dose nevirapine intrapartum and intrapartum AZT/3TC. The AZT 3TC intrapartum serves as designed to reduce of developing resistance to nevirapine in the mother and the postpartum regimen as well with AZT 3TC for seven days; and to the infant, single dose nevirapine and AZT for seven days.

Again, if the mother received less than four weeks of ART during pregnancy, give four weeks of infant AZT.

As operation and contacts vary considerably between countries and even within a country as I mentioned before,

the guidelines gave alternatives and minimum options for ARV prophylaxis.

I mentioned a few of them here in settings that do not currently have the capacity to deliver the recommended PMTCT prophylaxis regimen or those alternative or minimum regimens. At least, they should implement single dose nevirapine.

Unfortunately, at the moment, this is still the case, and nearly 50-percent of the countries reporting to UNICEF and WHO. However, in these circumstances, the specific obstacles to delivering more effective regimen should be identified and actions taken to overcome them.

By breastfeeding, it carries significant health benefits to infants and the young children. HIV can be transmitted during breastfeeding from an HIV-infected mother to her infant. Breastfeeding accounts, as you know, for one-third to one-half of all HIV transmission from mothers to their infants.

The most appropriate infant feeding option for an HIV-infected mother depends on her individual circumstances including her health status and the local situation. The health services available and the counseling and support she is likely to receive must be considered.

The World Health Organization recommends HIV-infected women breastfeed their infants exclusively for the first six

months of life unless replacement feeding is acceptable, feasible, affordable, sustainable, and safe. We have talked about AFAs [misspelled?] for them and the infants before that time. In case those AFAs conditions are met, WHO recommends avoidance of all breastfeeding by HIV-infected women.

The ultimate goal is to promote HIV-free child survival, which includes avoiding HIV transmission through breastfeeding and minimizing risk or other morbidity and mortality.

We are facing a number of issues to work towards that goal in many resource-limited settings, being operational, and managerial issues, systems issues, socio-economic issues, and also technical issues.

On the rest of the presentation, I would like to focus on recent data on the use of antiretroviral drugs to prevent postnatal HIV transmission.

The benefits of lifelong therapy for pregnant women who need antiretroviral treatment for their own health are clear. And triple combination antiretroviral regimens are now routinely used for prevention of mother-to-child transmission irrespective of the severity of the maternal HIV disease and the non-breastfeeding context of many countries in the industrialized world.

For example, in the women and infants transmission study in the US, HIV transmission was 1.2-percent in infants

who were not breastfed and similar data reported from the European cohorts often associated also with cesarean sections.

But we are talking about the public health approach to prevention of mother-to-child transmission and we are looking at low and middle-income countries.

So in the context of countries where replacement feeding is not safe, a number of studies are looking at provision of triple combination antiretroviral regimens given as a prophylaxis to the mother starting antepartum and continue throughout the breastfeeding period regardless of CD4 count and stopping them with or shortly after cessation of exclusive breastfeeding. So, this is this part. Other studies are looking at prolonged ARV prophylaxis to the newborn. Two studies were published recently and a number of studies are still ongoing.

Here, we see data from four observational studies, DREAM Plus presenting data from Mozambique, MITRA Plus from Tanzania, AMATA in Rwanda, and the Kisumu breastfeeding study in Kenya. In all four studies, women received antepartum triple antiretroviral drugs regardless of CD4 count and continued until six months postpartum with the exceptions of the AMATA study in Rwanda where women continued until seven months postpartum. All mothers were counseled to exclusively breastfeed for six months.

All studies showed promising results with reduced HIV breastfeeding transmission rates. The data presented here excludes infants infected at birth and age four to six weeks, so that is why we have very, very low transmission rates. And these data show that very low transmission rates can be achieved in breastfeeding women under triple antiretroviral combination prophylaxis therapy and therapy by keeping the benefits of breastfeeding.

Other studies are available, I will show them in the next slide, but difficult to compare at this time such as Kesho Bora study. The final data of Kesho Bora for example, will only be available in 2009.

This slide is comparing from different studies, Kisumu breastfeeding study, Kesho Bora, and the 50/50 plus study in Abidjan 44 maternal ante partum and postpartum triple antiretroviral data by CD4 count. And they show basically in the kids in Kesho Bora that equally low transmission rates are being observed in women receiving triple antiretroviral with lower CD4 counts and higher CD4 counts.

In Kesho Bora, the cumulative risk of HIV transmission was 7.6-percent in women with a CD4 less than 200 and in women with CD4 more than 500. At this point of time, the cumulative risk was also low and there was only one

late postnatal transmission observed and that record until now in the baby apparently reportedly already weaned.

In the Abidjan study, we saw higher transmission rates and the women receiving short-course antiretroviral, but this cannot really be compared to the triple ARV part because the study was not powered to compare both arms.

And it is important to note in the Abidjan study that the infant-free survivor in the two groups were not different between infants born to women with high or low risk of HIV transmission.

We need, clearly, more data to study the additional benefit of provisional triple antiretrovirals for women with higher CD4 count for reducing HIV breastfeeding transmission.

What are the consequences of providing triple antiretroviral for mother's health? There are no data or very, very few data, basically no data, on the consequences of stopping antiretroviral therapy for pregnant women not eligible for antiretroviral therapy.

There is concern that data which were recently published in GID from the SMART study team showing that antiretroviral therapy interruptions are associated with the increased risk of opportunistic infections and deaths, and in fact, the rates of opportunistic infections and deaths were higher in patients discontinuing treatment versus those on continued treatment in periods with a CD4 count higher than

350 cells/mm³. So, we certainly need much more data on safety of triple antiretroviral therapy, and these were not pregnant women, these were adults.

Palumbi [misspelled?] presented a data and CROI on interruptions of triple prophylactic antiretroviral drugs in 220 pregnant women who stopped drugs six months postpartum with mean CD4 of around 500 cells/mm³ and about 8000 HIV RNA copies initiated after one year, clinical and immunological values were similar after drug interruption.

JIMMY KOLKER: Ying, your time is nearly up. Please wrap up.

YING RO LO, M.D.: Okay, so, I am also nearly finished.

I would just like to present two studies which were recently published from randomized control studies. This SWEN study, a modified intention to treat study conducted in Ethiopia, India, and Uganda where infants received single dose nevirapine and six weeks extended nevirapine, and a randomized control trial in Malawi where infants receive 14 weeks of extended nevirapine.

In the SWEN study, the 6 weeks extended nevirapine at six months did not show a significant benefit on prevention of HIV breastfeeding transmission, but you can see that in the PP Malawi tribe, there was around 50-percent benefit due to providing extended nevirapine.

So, there has been great success overall in reducing mother-to-child transmission in resource rich countries and to lesser extent, but also considerable in resource-limited countries.

Remaining questions with respect to antiretroviral therapy, is it safe to stop the triple combination antiretroviral prophylaxis in women who no longer needed for PMTCT and do not yet meet criteria for ARV treatment?

Secondly, what should be optimal ARV prophylaxis regimen for PMTCT that will be safest for mother and infant among women with highest CD4 counts in resource-limited settings?

Thirdly, is maternal triple ARV prophylaxis safe in terms of toxicity for mother and the infant?

Fourth, what are the implications of transmitted drug resistance for future treatment options in HIV-infected infants?

Fifth, what is the benefit of triple ARV prophylaxis for women who do not need ART compared to dual ARV and what is the benefit of continuing triple ARV prophylaxis as well as stopping it? And what are the operational feasibility and the cost.

For extended ARV in infants, is extended exposure of ARV to HIV-negative infants safe? What would be the optimum duration of administration to the infants? What are the

implications of emergence of drug resistance on prophylaxis and future treatment options and what are operational implications?

JIMMY KOLKER: Please, very quickly.

YING RU LO, M.D.: So, we should do much better with what we have, I have to stop now, I just wanted to announce that WHO is actually keeping its guidelines up-to-date and we are planning a consultation to review the new evidence for later this year by several departments in WHO. Thank you very much. [Applause]

GLORIA SANGIWA: Thank you very much Dr. Lo. In the interest of time, we would have all the presenters going through the presentation and then we will have the questions later.

At this stage, we would like to invite Dr. Max Bweupe from Zambia. Dr. Bweupe is a medical doctor with more than 12 years experience in practicing in public health sector. He was formally registered in obstetrics and gynecology at the University Teaching Hospital. He has a postgraduate diploma in public health as well as the behavior change modeling communication.

He was appointed as a first program manager in Zambia at the Minister of Health in 2005 to date. He currently chairs the public health board of Zambia Medical Association and is the focal point for PMTCT in Zambia raising 14 several

consultation on PMTCT and Pediatric Care as well as chairing the National Development of Protocol and Guidelines in Zambia. This afternoon, Dr. Bweupe will present. It is already up, so go ahead.

MAXIMILLIAN BWEUPE, M.D.: Okay, yes. Thank you very much. I shall be looking at increasing access of women and children to HIV testing and counseling through the introduction of provider initiated testing and counseling into and the actual delivery and postnatal care settings, that is, experiences from Zambia.

Zambia is somewhere in the Central Africa.

[Laughter] I would like to invite you to come and visit [inaudible3]. There it is. [Laughter]

Right. I would like start by putting up this statements that according to WHO and UNAIDS, modeling for estimates of required coverage that will impact on the progression of the HIV/AIDS pandemic, we need a coverage of at least 50-percent of the target population.

My presentation summary will basically look at the epidemiology. We look at the overview, the program history in Zambia, our guiding principles, and how we justify our approaches. Then I will go through what has been achieved and the trends of where are we going as well as briefly mention some of the program constraints.

We are approximately 11 million, total population. We are in Sub-Saharan in Africa. Administratively, Zambia is divided into nine provinces which have a total of 73 districts.

We have 16-percent prevalence of HIV among pregnant women and we have about half a million births per year, actually about 468,000. Without intervention, we have been finding that our mother-to-child transmission of HIV has been about 50-percent. And some of the demographics are about 49-percent of pregnant women who deliver at home.

An overview, I mentioned that 61-percent deliveries in institutions are always conducted by skilled attendants. Ninety-three percent of pregnant women have at least one antenatal visit. In the urban areas, about 70-percent have three visits in the antenatal, minimum. In the rural areas, about 20-percent are able to access three visits.

For children, we have 90-percent BCG coverage which have presented a window of opportunity for intervention. Our postnatal attendance, again, drops very low to about 20-percent.

And together with our partners, we have been implementing a comprehensive program which means introduction of the more efficacious combination regimens, equipping the health providers with the skills needed to provide care, ensuring of our pediatric products and formulations,

expanding counseling and testing to children, and establishing a system for this year HIV DNA in the infant diagnosis as well as entrenching district level planning, using population best targets.

JIMMY KOLKER: Okay. Please remember you have just 15 minutes. I am a very strict taskmaster.

MAXIMILLIAN BWEUPE, M.D: Thank you very much for taking up 10 seconds of my time. [Laughter] Our program history is that we began implementing in about 1999 and developed lessons which we used to integrate PMTCT including MCH. From there, we developed a framework, straight frame way from which 2003 to 2006 and used a cascade model to reach every district in Zambia.

After this, in 2006, we had a major program review and we invited our IATT partners so that we could go through and see how the program was doing to rethink strategies for reaching in lesser access, how we could easily use more efficacious regimens, centralize services, and change population-based target setting, as well as innovative views and some cultural community-level initiatives and much more cardinally, introduction of provider initiative testing and counseling.

Our guiding principles are that, the Zambian government provides leadership who is courage, clarity of purpose and supports to frontline workers with unambiguous

messages to the public about where we want to go and how we shall achieve it.

All pregnant women would be tested for HIV as part of normal care, thus, normalizing HIV care. And we drive demand by appropriate communication strategies. We ensure that our logistics and support in implementing PMTCT available and not to forget, we procure technical assistance and also, of note, to lower levels whenever the need arises and we have developed the harmonized [inaudible] as well and will not forgetting that we have been very strong on leveraging of resources from internal and external sources.

Justification for our more assertive approach is that HIV and AIDS is a declared national public health priority problem with epidemic proportions with 16-percent of pregnant women who are positive and we know without interventions, 50-percent transmission risk as well as progression of the mom to AIDS.

We also know that proven interventions are available within the country and we realize that business as usual was what had taken us very far. As you know, in sub-Saharan Africa, the HIV epidemic is rather feminized and this made that we were obligated to open a second-entry point of care apart from general HIV services for women. And we also realized that there was a hesitant approach to HIV testing in

pregnancy due to there have been unclear guidance to health workers on the frontline.

The process is that testing and counseling is initiated in the antenatal, labor and delivery and professional service by a service provider and a record of all these events is kept. Because we believe that what is not written down is not done.

Babies, we initiate testing at six weeks, 12 months, and 18 months. HIV positive moms are enrolled into the pre-HAART program and are followed up.

Babies are registered as HIV-exposed and are tracked using the under-five card and register.

So, what have we been able to achieve? Running through briefly year 2004, we are able to provide services to about 74,000 pregnant women which was somewhere about one-fifth of the population in need. In year 2005, we are able to go to 94,000 out of denominator of about 500,000.

In 2007, after introducing PITC, you see that we reached from 79,000 in 2005, we are able to give care to 306,000. So, of the estimated 500,000 pregnancies annually, we are able to identify 97,000 of them as being HIV positive. We have increased coverage to our 678 sites from about 200 countrywide and we were able to test 61-percent of all pregnant women in the country and we found about 17-percent of them were HIV positive.

We were only able to give prophylaxis to 56-percent of the women that we had seen and their issues we got as well. And babies, again, only 16-percent of the babies were able to get the accepted full package of care that we have opted to use.

Then, DNA HIV PCR testing for babies, we have got 124 sites countrywide which are engaged in collier system with hubs and they transport to three central labs which do PCR for us and we were able to test last year a total of 7,664 babies and of this number, if you see the column, the lighter column is the number of babies tested and the blue column is the number of those who were finding to be HIV positive.

And this is a graph showing the trends of children on antiretroviral therapy. It is a gradual rise, but we think we are going to accelerate now and so far, we are putting everything in placed.

Results: We have seen an added advantage that facility deliveries in Zambia have increased from 47-percent to 61-percent in the past five years and we tend to believe there must be a quite contribution although we are providing PMTCT services.

We know that 50-percent of women needing HAART now have been initiated on it. This is 59-percent of men. So, this is again a reflection of that. We are adding more

emphasis on the pregnant women and the results are showing that we are attending to the women much more to the men.

Population-based coverage of HIV pregnant women, of all eligible women, 14-percent accessed care in 2005, 25-percent in '06 and 59-percent as [inaudible] December '07.

And in selected areas, we found that a transmission of MTCT has been reduced from an initial 50-percent to between 9 to 11-percent.

Let me ask then to inform you that 25-percent of our women are using the more efficacious combination regimens of AZT 3TC and NVP. The other 75 by year end '07 had still been using NVP and once tried on and reverse this by year end of this.

We have seen a decrease in dropout of clients from the program due to SAMBA testing and giving of results with reflex CD4 testing done on the same day as well.

A summary of the key tools we are using, the mother has ANC card which has provision for HIV status delivered register documenting HIV status and interventions given, postnatal record of delivery interventions to optimize delivery as well as a feeding option initiated. Revised under [inaudible] registered documenting feeding practice as well as tracing interventions given to baby including infant-treating choice co-trimoxazole initiation, and a PCR testing and ARV prophylaxis is given.

We are streamlining the treatment package for health workers and community workers and put very clear protocols, guidelines, and job aids and with the introduction of mentoring of service providers which we have realized is a very key part of interventions.

Lessons learned and [inaudible] forwards. This strategy, PITCT, it has increased acceptability with HIV testing by mothers both of PMTCT as well as for children. The role out has been very well accepted. It is feasible and desirable and it is possibly imperative.

It has made strengthened linkages among programs, MNCH, malaria, HIV, AIDS intrusion for synergy as well as geographic or equatorial services. We still feel that mentoring of offering healthcare workers in pediatric HIV care services is needed. And then monitoring on the implementation of pediatric HIV care services and skill out of plans is a major priority and the way forward.

Some of the program constraints as in the most of the Third World, it is human resource deficits both in numbers and capabilities and then a lack of predictable sustained financing with inadequate infrastructures especially in the rural areas and we have to work hard at community labor [inaudible].

Our logistic system still needs to be lubricated as we still have pockets of stroke outs and things like that and

then we still have insufficient systems for care of the HIV-exposed child and we do not have sufficient male partner involvement.

Up to 2010, we want to build on lessons learned and maintain successful approaches, improve them both within from the in-country lessons and from the global arena.

We want to entrench PITCT countrywide and in all points of service delivery. We plan to reach 61-percent of eligible HIV-positive pregnant women by December '08 and 80-percent by 2010 and we are on track and we plan to reach 50-percent of infectious children by 2010.

I would like to acknowledge all PMTCT and pediatric HIV champions who are operating in Zambia and who are supporting us externally. Thank you. [Applause]

JIMMY KOLKER: Thank you, Dr. Bweupe for almost keeping time. The next speaker is Marthe Mukaminega, who is a pediatrician, also has a Masters of Public Health from the Institute of Tropical Medicine in Rwanda.

She has worked in the HIV field since 1999 and has now with the Elizabeth Glaser Pediatric AIDS Foundation in Rwanda as Technical Director. She will present the PMTCT Program in Rwanda on behalf of Elévanie Nyankesha who could not be here.

MARTHE MUKAMINEGA, M.D.: Okay, thank you so much. I would like to apologize for my little English, but I am going to transmit the message.

The PMTCT Program in Rwanda - I am going to present the national background first and after that, the national HIV response, the strategy, some key result, lessons learned and the challenges and the way forward.

Talking about the background, I would like to highlight that Rwanda is a very small country with around 9 million. The population is 9 million. What I would like to highlight to is that the access to clean water is still really a big problem.

Talking about some maternal and child health indicators, I would like to share with you that the fertility rate is really high. The other thing is that we still have a lot to do in delivery in health facility because according to our last DHS, we have 5-percent to 6-percent of pregnant women, only that portion is delivering at the health facility. If I talked about HIV prevalence in Rwanda, I would like to show you that 5-percent is the HIV prevalence in pregnant women.

What was the National HIV Response in Rwanda?
Starting in 1987, we had a National AIDS Control Program and in 1999, the first PMTCT site has been opened. In 2001, we had the National AIDS Commission instead of National AIDS

Control Program and at this time, we had also the treatment and the research on AIDS center which is really working closely with clinician and to make PMTCT really applicable.

This slide show you some milestones and I would like to highlight that since 2005, Rwanda has introduced the more efficacious ARV regimen of PMTCT. What is the package given to the mother and the infant? To the pregnant woman, routine counseling and testing is given not only to the mother, to the pregnant woman, but also to her partner.

The laboratory investigation is also done. The routine pregnant medication is given. For example, malaria prevention and anemia prevention.

I will be talking about the ARV prophylaxis. The package includes also safe practices, delivery, infant feeding counseling and support, family planning services and psychosocial and adherence support.

To the exposed infant, post-exposure prophylaxis is given. The CTX and the monitoring of growth and the symptom of early HIV infection are also monitored. The early infant diagnosis through DNA PCR and serology is also done.

This is the clinical and the biological criteria for HAART initiation in HIV pregnant women and I would like to take a minute and talk about the ARV prophylaxis guidelines in PMTCT Program in Rwanda. We have four scenarios.

The first one is when a pregnant woman has to take ART because she is eligible for ART. Those kind of woman, we have AZT 3TC and the nevirapine in antepartum period and after delivery, she will continue with the treatment.

The second scenario is the women who are not yet eligible for ART. She receives AZT starting at 28 weeks and during delivery, she will be receiving single dose of nevirapine and after delivery, AZT 3TC for seven days.

The third scenario is the pregnant women tested after four weeks, she will have triple therapy and after delivery, she will have AZT 3TC for seven days.

The last category as the pregnant woman is seen in delivery room or the pregnant woman, who has a husband, HIV-infected.

Of all four scenarios, the infant will be receiving single dose of nevirapine, single dose, and AZT serum for four weeks. We had to implement those complex regimens.

In Rwanda, we had three types of site. The first one is a site with ART and the PMTCT services. The second is a kind of site which is giving under the PMTCT services and we have also some site with or PMTCT services without ART.

What have been done is to place a training of trainer gender, after that to train the healthcare providers and to put in place doctor's team to a city or center to insert ART for HIV-infected pregnant and to develop anemone tool for

that. Some research as you could see, in 1999, we had only one site giving PMTCT services. Now, by May 2008, we have 308 sites giving PMTCT services.

This slide is showing to you that on counseling and testing we still increase women who are having counseling and testing. This is an example to show you that among pregnant women, CD4 count is being done and this is a research for the first and the second term of 2008.

I would like to share with you that in Rwanda, the nevirapine single dose is decreasing and the nevirapine plus AZT is slowly increasing among HIV-infected pregnant women.

Talking about health facility deliveries among HIV-infected women, if we try to compare with the all women, I could show you that, in red, we have delivery among all women and in yellow, health facility delivery among HIV-infected women, we still have more HIV-infected women delivering at health facility if you compare with all women. And we believe that we are getting those results because of counseling.

I would like here to share with you the coverage of ARV prophylaxis among HIV-exposed infant. In 2005, we had 58-percent of expected children for ART. We had only 58-percent receiving ARV prophylaxis. But now, if we look at data from January to May 2008, we are giving up to 87-percent

of exposed expected children, we are giving to them ARV prophylaxis.

I would like to say that ARV prophylaxis includes both nevirapine single dose plus AZT. Talking about infant feeding practice at birth among HIV-infected mother, I would like to show that most of the mothers are breastfeeding.

Now, moving on the lesson learned, I would like to say that the coordination done by Ministry of Health and the PMTCT Technique Working Group has done a lot in coordination. We have the support of Rwanda politician. The decentralization of CD4 count system from National delivery to district delivery, the organization of services to make CD4 count a reality and the development of jobs and provision of monitoring tools has make shifting to more efficacious ARV regimen possible.

JIMMY KOLKER: Dr. Mukaminega, one minute please.

MARTHE MUKAMINEGA, M.D: Okay. Let us go the challenges. We still have challenges in sufficient number of laboratory performing CD4 count, means of transport. I am talking about transport of samples for CD4 count and indeed, delay of result because if we had to transport samples from a site to another, it takes time to get the results. I would like also to talk about this scaling up of DNA PCR to make early infant diagnosis for the mother HIV transmission during

the breastfeeding and the fact that in Rwanda, ART prescription, up to now, is done by only doctors.

Way forward, lastly, is integrating the monitoring of more efficacious regimen within the National Electronic Health Information System to strengthen the capacity of laboratory for CD4 testing, clinical monitoring to support scaling up of more efficacious regimen, scaling up our infant diagnosis, we have mother-to-mother approach to strengthen [inaudible] support and adherence to program and lastly, we need food. Thank you so much. [Applause]

JIMMY KOLKER: Thank you very much, Dr. Mukaminega. The next speaker is Professor Linhong Wang, who works at the Chinese National Center for Women and Children's Health. She has been working for many years in the area of women's and children's health and more recently, on PMTCT. Professor Wang is also the head of the National Technical Expert team on PMTCT in China.

WANG LIN HONG, PH.D.: Mr. Chairman, good afternoon everyone. I am very glad to have a chance to share the experience of PMTCT and the sexual and reproductive health surveys from China.

So, this is my presentation profile. First, I would like to introduce some background data in China. By the end of 2008, it is estimated that 700,000 are now HIV-positive. Among them, about 30-percent were women, but the calculated

total of the reported HIV-positive was more than 200,000 including 62,000 AIDS case and the 22,000 recorded deaths.

For the transmission way, the proportion of the sexual transmission increased from only 30-percent among the calculated reported case before 2007 increase to 41-percent among the reported case in 2007.

So, the sexual transmission is now the main mode in China. Another thing is the mother-to-child transmission. The proportion is increased very quickly from 0.1-percent in 1998 to 1.6-percent in 2007.

This is the [inaudible] of the MCH, so you can see that. On the natal coverage is the 89-percent, hospital deliveries 91-percent. [Inaudible] birth dependent at birth is 98. In whole China, maternal mortality ratio is to 36 and the infant mortality ratio is 15-percent.

For the PMTCT, the Chinese government report various focused on the HIV and AIDS prevention and control include PMTCT. The many positive policy were made such as the 4 Free and 1 Care policy. So you can see one of the four free, the free counseling test and the treatment for HIV-positive pregnant women and their newborn baby.

And also we have National AIDS Regulation. The PMTCT is the important part of them. Then we have service of the policy were made by the promoted and improved PMTCT work, so there are some policy and the document from the government.

For PMTCT - also the financial support for PMTCT increased every year including food and garment financial support include a free HIV test and counseling. This is provided for the all pregnant women in the program area and the ARV infant formula and the follow-up surveys and some financial assistance for the hospital delivery in the rural area are freely provided for HIV-infected pregnant women.

For the PMTCT surveys, we combine that the PITC and the VCT, also the [inaudible] test and the counseling are encouraged. Strengthen the MCX surveys for the HIV-infected pregnant women follow-up and hospital delivery, safe delivery, assistance.

The effect is combined ARV treatment both for the infected pregnant women and their infant, and also included the quality of their ARV treatment. Also, we encourage and support the formula feeding for the infant. Strengthen the charter healthcare for the children prone to HIV-positive pregnant women and also provide a care, support and the referral surveys.

For the achievements, more pregnant women and their children received the PMTCT surveys. The data were from the 271 national program counties from September of 2003 to the end of last year. Total [inaudible] of the pregnancy women have received NAC surveys. Among them, 82-percent concealed for HIV and that 79-percent got tested.

For the HIV-positive pregnant women and their infant, 74-percent of the women get the ARV treatment and then 83 infants got the ARV medicine, and 88-percent of the infant got the formula feeding.

Here, the last year we got the achievement for the mother-to-child transmission rate is estimated to be reduced by 60-percent.

Another achievement here is the coverage increasing each year is getting up quickly. So for the national PMTCT program was initiated from the one pile-out county from the 2001. The program areas were increased each year since most of them are in the relative high prevalence. So far, national PMTCT program has covered 333 counties all over the country and the PMTCT program closed the [inaudible] based national HIV and AIDS promotion and the National MCH surveys and different health work.

For the PMTCT and the sexual and reproductive health surveys are being linked. So we integrated HIV prevention, education and HIV-PMTCT surveys into the national sexual and the reproductive health program, and others, it provide perinatal family planning and HIV-PMTCT surveys including the condom promotion by the health and the family planning sectors.

Also, service of the technical guidelines such as global elimination of the congenital syphilis and the vaginal

operation framework for linking HIV-STI service-base reproductive health, adolescence, maternal, and the new-born and the child health surveys by WHO were translated into Chinese and also we already developed some relevant guidelines such as the prevention and the treatment, the guideline for congenital syphilis in China and we developed a national plan for the prevention and the transmission for congenital syphilis in China.

Also, the operational linkage proposal has been developed in 30,000 to 5,000 women and to their partners toward a [inaudible] to be covered.

Although we have get much achievements, but for the challenge because China is very big, population is large, so for the size of the China, PMTCT coverage is still low, and also we still have the [inaudible] liberating among health and the non-health sectors. And also the [inaudible] to provide quality in sex surveys.

For the follow-up, we still very [inaudible] infected women and their children, also the early infant diagnosis available is very few size, only for the some of the research area and that we [inaudible] have the continuous probation of the ARV tailored for the infant and the small children.

Another thing here to know, enabling policy directive, also that evidence that there will be work still have to be general [inaudible]. Also, [inaudible] funding

and the human resource [inaudible] stigma and discrimination. Another thing is the poor involvement of the NGO and private sectors.

For the next step, we will assess the feasibility of the operationalizing the PMTCT and the sexual and reproductive health surveys and also finalized the linkage framework for the China based on the pile out experience.

And also increased the coverage that should read of the 100 more counties per year in the next two years is supported by UN and the UNIGASS got many support from UNICEF, UN and WHO, and also strengthen the prosperity to ground the effective program like PMTCT surveys, mechanism and the multi-sectoral cooperation and the responsibility and training and also improve the quality of the PMTCT surveys.

So this year, the steady progress has been sped up, based to the quickly increasing financial support by both the central and the local government in the live based target set by the UNIGASS and Universal Access Declaration of the Commitment. So, thanks for your attention. [Applause]

JIMMY KOLKER: Thank you, Professor Wang. Our final speaker is Ilcia Rebeca Garcia Morales who is a psychologist and holds a Masters in Educational Administration. She is on the faculty of the University of Francisco Marroquín and also is the national coordinator, the STD, HIV, AIDS Counseling National Program on AIDS on Guatemala. Mrs. Garcia Morales.

ILCIA REBECA GARCIA MORALES: [Speaking in a foreign language] [Applause]

GLORIA SANGIWA: At this state, we would like to thank all of our presenters who did a marvelous job and who have tried to keep in time. They have looked at different things and I will do a quick summary.

Dr. Lo gave us a very brief description of what are the guidelines from WHO and globally. Dr. Max Bweupe gave us information on how things are evolving in Zambia and in all these sessions—in his session, he looked at the effect on introducing the provider-initiated counseling and testing and how that has led to not only seeing evidence of reduction in the infection from mother-to-child transmission, but also seen an improvement in health facility deliveries in Zambia setting.

In the Rwanda setting, we learned that they are doing extremely well in terms of improving the coverage on ARV that is feasible to introduce the WHO recommended three-tiered approach.

They are noting a significant reduction in the use of the single-dose nevirapine and gradual increase on dual therapy, but they are also noting that the HIV-positive women are actually having higher rate of delivery to both the facility levels, although there are some challenges including issues of lab and how to transport their samples.

Professor Linhong from China gave an example of how in within a long prevalence setting that integrating PMTCT with other related activities like sexual reproductive health and improving policy is a way moving forward and how that has led to improved coverage and reduction in PMTCT, although they are meeting some challenges and also planning to succeed more.

Then last presenter from Guatemala talked about the experience on how that with introducing PMTCT and the goal of increasing success rate, talked about the challenges related to infant feeding options in that setting, specially taking into account of the issues of poverty and safe water, and all the efforts they have done in terms of looking for innovative and creative way of addressing the issues that provide effective and safe infant feeding option as according AFAs.

At this stage, I would like to open—let Jim Kolker help us to open this session for discussion.

JIMMY KOLKER: This group does not need much help. I see a lot of experts in the audience. But in the interest of getting to the opening ceremony, we can limit to three very, very short questions or comments.

So, are there three people in the back? Yes. Just line up three of you at the microphone, then we will cut it off. So, first come, first served.

FEMALE SPEAKER: It is just a question to Dr. Lo from WHO. There is quite an international attention now to the use of triple HAART for women not yet eligible for HAART. So let us say triple HAART just as prophylaxis. There will be a suggestion in the new WHO guidelines late 2008 to move towards use of triple HAART for prophylaxis and if yes, would it still a nevirapine-based regimen with all the complications for women with more than 250 CD4, and if no, should the [inaudible] based and [inaudible]? Thanks.

MALE SPEAKER: My question is addressed to the speakers of Rwanda. You have demonstrated a very-high achievement in terms of coverage, also demonstrating effect on the health system.

I suppose that Rwanda has received a lot of resource to do that. I wonder at this stage, if you could give us more information about the integration of your PMTCT programs [inaudible]. What are the challenges you are facing as a management level, as well as operational level in terms of human resource because I guess, at 97-percent coverage, I think the question now is to find out how this is going to be integrated. So what are the issues the lesson learned in that sector at both levels? Thank you.

RAMPA DIJU: Hello. Good afternoon. My name is Rampa Diyu [misspelled?]. I am a pediatric resident [inaudible] on New Delhi, India. My question is directed

towards Dr. Ying Ru Lo. I wanted to know you said [inaudible] for the mother for prophylaxis and you did say that it worked but did not give a single drug or anything.

I wanted ask should not we continue this free drug regimen to all the mothers taking special case and view of a child who is going to be born. And secondly, ma'am, you said you saw three or four studies where the breastfeeding transition rate as highest was 1.1.

I was wondering if suppose if doing the exposed breastfeeding, it is fine, but in [inaudible] exclusive for six months. In some set, it does occur, and then the mother starts feeding breast milk again. I was wondering if we start again, how much is the transmission rate? Thank you.

JIMMY KOLKER: Okay. Who wants to talk about the reaction to the question of woman on heart routinely?

WANG LIN HONG, PH.D.: The WHO guidelines process review will look systematically at all available and also upcoming data from clinical trials from observational studies, but we will also review data from program implementation.

So, we will gather a number of researchers, program, planners, and implementers to review all the available evidence and decide whether further data are required to make decisions, what are the best and feasible recommendations for WHO guidelines in low and mid-income countries.

We will not be done with one consultation, that is for sure because we will also look at—we have to model cost, we have to look at feasibility, we have a grading approach in WHO where we grade all the available evidence.

JIMMY KOLKER: Can I also use this opportunity for advertisement or commercial for a session tomorrow at 6:30, called Keeping the Promise about unite for children, united against AIDS, which the Colombia University presenter, I think has done some good studies about the effect of viral load on transmission and recommendations for heart, so that, please, join us at one of the session rooms tomorrow at 6:30 for that. On the integration of services in management in Rwanda.

MARTHE MUKAMINEGA, M.D.: Thank you for the question. The integration is still a big issue in Rwanda, but we have started to work on this integration. Saying about PMTCT, at national level, it is under TRAC which is Treatment and the Research on AIDS Center. And the maternal and child health department is not under TRAC. This is a kind of lack of integration but activities and the PMTCT are now being done and the maternal and child health department at health facility level.

What I am saying is that for example, counseling and testing, immunizations, follow-up of HIV-exposed children are

now being done at health facility level into maternal and child health department.

What I am saying is that we have to do something on integration, but we are starting to work on. Thank you.

JIMMY KOLKER: If I understood the third question, it was to Ying about the breastfeeding and one other topic. Did you get that?

YING RU LO, M.D.: I can answer that after this session?

JIMMY KOLKER: I am sorry. Speak in the microphone right.

YING RU LO, M.D.: I would suggest to the colleague of India that we discuss that after at the end of the session.

JIMMY KOLKER: This does give us the right to one more question very quickly.

PETER DRUBECK: Hi. Thanks for the presentations. This is Peter Drubeck [misspelled?] from Harvard Medical School on Partners in Health in Rwanda.

I think one of the biggest hindrances to progress in PMTCT care has been the absence of really good metrics for monitoring and evaluation of programs.

PMTCT coverage is just a weak process indicator that can have ten-fold variation on efficacy within it and that is often all that we have to evaluate different programs for

different countries and I am wondering if Dr. Lo or anyone else can provide some guidance or feedback on thoughts about more robust indicators for monitoring and evaluation of PMTCT that is taken into consideration not only transmission but possibly also the survival of the child down the road.

Thanks.

YING RU LO, M.D.: WHO, UNICEF and other development partners, we are looking on an indicator framework for PMTCT and I hope that is about to be published within the next few weeks or months.

JIMMY KOLKER: Thanks. I know that the presentations were very high-quality and very good country examples with indeed a lot of statistics from which we can draw some conclusions about both the successes and challenges of scaling up.

So I want to again thank the presenters, but also the good news is that during this week, there are going to be quite a few other sessions about PMTCT and about the integration of services. So, it is good that this is on the agenda and I think this was an excellent substantive start to that discussion during the week.

So, thanks to the sponsors. FHI, UNFPA, WHO, and on behalf of UNICEF as well, we are very pleased that we were able to put this on the agenda and bring more attention to these important questions.

So, a big round of applause to the excellent
presenters. [Applause]

[END RECORDING]