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**Plenary: Challenges and Solutions**  
**Kaiser Family Foundation**  
**July 24, 2012**

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**CHRISTINE KATLAMA:** Thank you. Good morning everybody. It is a pleasure and a big honor to be here for this plenary. Turning the tide against HIV, are enormous key words. We have been long enough into the fight in HIV to be altogether proud of what has been done, but not enough to be satisfied.

This morning, the plenary session will focus on challenges and solutions. Science, scientists, patients brought a lot, let's go on. Without science there cannot be durable solution to the HIV epidemics.

So now it is my very big pleasure to introduce a colleague and a friend, Professor Javier Martinez-Picado. He is an ICREA research professor at the AIDS Research Institute, IrsiCaixa, in Barcelona, in Spain. It is an institution that works to advance clinical research and translate this research into patient care. He received his PhD from the University of Barcelona where he subsequently became Associate Professor lecturing on different microbiology related subjects.

In 1996, he joined the Massachusetts General Hospital as a post doctorate fellow at at Harvard Medical School, where he engaged in AIDS research. In 2000, he obtained a position as biomedical researcher of the Spanish Health Department appointed to the Hospital, excuse me for the accent, "Germans Trias i Pujol" in Badalona.

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The research program that Javier's group is leading focus on understanding how HIV causes disease in recently infected people, exploring the best antiretroviral treatment strategies, fighting drug resistance, and collaborating on global HIV/AIDS vaccine development projects under Europe Network. Javier Martinez-Picado is now focusing his work on trying to put an agenda on putting the HIV cure and this is the program he is going to give us this morning. Please, Javier.

**DR. JAVIER MARTINEZ-PICADO:** Thank you, thank you, Christine, for this kind, very nice kind introduction.

Good morning, ladies and gentlemen, first I would like to thank the conference organizers for the great honor being invited to give this talk, but I would also like to thank the International AIDS Society and in particular, Francoise Barre-Sinoussi, for their commitment in the mission of finding a cure for HIV.

Universal access to antiretroviral therapy remains an unquestionable human right that we all must support, but at the end, we must find a cure for HIV. Through this presentation, I will try to provide you with updated information on the limitations to cure HIV. The potential strategies to achieve a cure, the core and clinical trials may appear and on-going future challenges in this field.

I think that is out of question that HIV inhibition with antiretroviral therapy has been one of the major successes

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in modern medicine. We have seen over the 25 years how newer and better drugs have improved the life of many HIV-infected people. However, despite long-term effective treatment, drugs do not cure HIV infection as evidenced by the reduction of cell-associated DNA and RNA in most patients treated with antiretroviral therapy. It is also possible to rescue [inaudible] replication competent virus from blood lymphocytes.

Persistent low level viremia measured with ultrasensitive acids can be detected in nearly all the patients on antiretroviral therapy. All this happens in blood, but it's really the tissues are an even greater source of persistent viremia, but probably the definitive proof of viral persistent antiretroviral therapy is the quick viral rebound detectable in the blood of patients that discontinue antiretroviral therapy.

Moreover, this part of treatment achieves a rapid and durable inhibition of the virus. There are many researches to pursue a definitive cure. Mortality with people with HIV infection continues to decrease as treatment improves. However, it's still higher than that of uninfected people, most likely due to higher levels of inflammation and immune-activation.

The incidents of cancer, liver disease, cardiovascular disease and bone loss is higher in treated patients compared to uninfected people, especially when CD4 t-cells count are low.

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New HIV transmissions need to be urgently reduced. For every HIV infected person who starts antiretroviral therapy, two new individuals are infected with HIV. The stigma and discrimination continues in spite of access to anti-retroviral therapy. But most importantly, HIV treatment is currently a long life commitment, implying adherence problems, potential toxicities and especially the ability to sustain each long terms goals. The most optimistic models estimate the annual cost by 2015 will be over \$22 billion USD to achieve universal access to achieve HIV prevention, treatment, care and support.

Therefore, novel time-limited treatment strategies are low in sustained viral submission absence of antiretroviral therapy should bring individual, global and economic benefits. If we want to identify strategies that will relate to an HIV cure, we need to first understand what are the different mechanisms that contribute to HIV persistence in spite of antiretroviral therapy.

First we have to face the reality of having some residual, but persistent replication below the limitation of the coronasis [misspelled?]. The second mechanism of viral persistence is latency. Understood as the person's of non-transcriptionally active viral genomes integrated in the cell DNA. Finally, there is the evidence that immune activation and inflammation do not normalize in HIV infected subjects, often it is long-term antiretroviral therapy, because of clinical

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relevance of this persistence immune dysfunction, it remains unclear.

With a receivable replication persists, during suppressive antiretroviral therapy, it's still controversial. The disbelief that HIV border in tissues and organs, including gut mucosa, genital tract, lymph nodes and central nervous system might be greater than that in peripheral [inaudible], contributing to sustain placebo replication.

Maybe as a consequence of the drug variable penetration in different tissues or to the possibility of the virus to spread from cell to cell at high multiplicity. It's also challenging to interpret the evolution of evological as well as immunological markers [inaudible] intensification with new drug families.

On the other hand, the major argument supporting the lack of residual viral replication focus in the absence of evolution in RNA and DNA feral sequences of patients on antiretroviral therapy, including the absence of drug persistent mutations, as well as the lack of quantitative changes in either HIV RNA or DNA following treatment intensification.

The second mechanism for viral persistence is latency. Memories for the cells have been described as a major reservoir for HIV. Even so, less than one cell per million with the rest of CD4 cells from patients on antiretroviral therapy are latent

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replication competent virus. Aggravated cells can get infected including new infections, but antiretroviral therapy should efficiently stop new cells from being infected, leaving to a quick clearance of circulating virus and their producing cells.

However, as more proportion of activated HIV infected CD4 t-cell good [inaudible] arresting stage, harboring integrated HIV DNA. Alternative resting CD4 t-cells can also be infected without becoming activated. The maintenance of these otherwise heterogeneous reservoir is basically, it's a slow decay due to the long half-life of t-cells. They are at capacity to proliferate and the existence of negative regulators that would limit their capacity to activate and induce the expression of integrated virus.

This [inaudible] resting memory CD4 t-cells is the best well corrected reservoir. There are other reservoirs that will require further studies including [inaudible] t-cells, tissue micro fissures, astrocytes [misspelled?], thymocytes [misspelled?], and perhaps [inaudible] stem cells.

Based on our current knowledge, one might wonder what could be the potential strategies to achieve a cure. We can envision a cure from two different perspectives. Either from eradication point of view in alignment with the sterilizing infections model in which any trace of virus or infected has to be fully eliminated from the body. The supporter to this model

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come from a very unique case of possible cure of the patient that they will discuss later on.

Alternatively we might consider the functional cure model that aims at the generation of effective host immunity to HIV that would resolve [inaudible] in the absence of therapy despite not achieving a completely eradication of HIV. The best approach to this option is a study of a limited group of patients that control viremia, either spontaneously via elite controllers or after early timely eliminated treatment, the post treatment controllers.

And to achieve either a functional or sterilizing cure, we have to explore strategies how treatment of immunization and intensification might help to eliminate all traces of ongoing viral replication. We now know that every treatment initiation of primary infection may limit the size of the viral reservoir.

How to purge integrated HIV DNA from the cells? How to reverse more regular signals, responsible to maintain latency? How therapeutic vaccines might contribute to enhance host control of the virus? And how gene therapy may be implemented to make cells resistant to HIV infection to specifically disrupt HIV genomes?

A number of pilot studies have already been performed to explore the roll of treatment intensification in residual viral replication. Most of them have taken advantage of more recently developed drugs, especially the inhibitor Raltegravir.

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This table leads most of the intensification studies in this field. I would like however to emphasize that they are designed significantly different in sample size, longitudinal follow-up, level of CD4 t-cell counts making comparisons them difficult. Moreover, only two of them look into tissues as specifically gut-associated lymphoid tissue, all the studies fail to show any further with action in residual plasma viremia by using ultrasensitive viral load assays and total HIV DNA remain also stable during intensification.

Only two studies show markers of new infection despite treatment. One study showed a tremendous significant increase in HIV DNA right after intensification and a significant decrease CD4, CD4 t-cell activation due to the entire follow-up.

A second study showed a decrease cell associated decrease in RNA in a particular site of the gut determined [inaudible] that this reach in lymphoid tissue and a trend reducing immune activation as well.

In the last years, we have also increased the screening of new compounds that might be helpful to reduce latently infected cells. Seven or more molecular mechanisms of latency have been proposed including insufficient levels or access of host transcriptional factors to then promote the region of HIV.

Transcriptional factors and interference of host promoter activities [inaudible] within remodeling [inaudible]

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silencing. This means you can see some of the [inaudible] having been selected in invitro [inaudible] of vital latency and reactivation.

On your left-hand side you can see those that are quickly moving towards clinical trials and I will next extend a little bit in those [inaudible].

The French scientific program, ORBAX [misspelled?] is currently sponsoring dual [inaudible] studies in Europe and North America. [Inaudible] 1 letting Europe [inaudible] combines treatment and [inaudible] with alterovir [misspelled?] and meridoc [misspelled?] in patients with successful antiretroviral therapy for at least three years.

And the use of IL-7 to explore whether [inaudible] stimulates HIV reactivation from lately infected risk themselves via the activation [inaudible] pathway.

The twin study, [Inaudible] 2, led in North America by Robert Morfair [misspelled?] adds a DNA prime, an adenovirus [inaudible] strategy to stimulate cell-ready immune responses also in subjects receiving intensified antiretroviral treatment. The primary endpoint for both studies is the reduction of total HIV DNA in peripheral bloods. Definitive data on the two studies is expected before the end of this year.

Interferon Alpha is also on the screen. Drugs based on this antiviral substance are used to treat Hepatitis C

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infection. Earlier studies on HIV-infected individuals who were not on any antiretroviral therapy showed that Interferon Alpha could reduce the level of HIV in the blood. Researchers at the NCI led by Frank Malderelli are interested in determining whether Interferon therapy will also reduce the residual low levels of HIV in patients who are already taking antiretroviral therapy.

Preliminary data in four patients suggests that despite atension [misspelled?] and reversible effect of Interferon Alpha on immune activation, there was no further decline in the levels of residual plasma viremia or total HIV DNA in blood cells.

As I said before, chromative remolion [misspelled?] is one of the potential factors involved in HIV silencing. Histone acetylation [misspelled?] and DNA methylation would induce chromatin remodeling to allow gene expression of integrated HIV, virus manufacturing, and potentially, although not completely clear yet, the clean of virus producing cells. Stone deacetylase inhibitors, also called HDAC inhibitors is a family of molecules that facilitates such conformational change on the cell chromatin.

Vorinostat is a potent HDAC inhibitor able to activate HIV from latency in vitro. This drug is licensed for cutaneous t-cell lymphoma and is in different phase two trials for other malignancies. Two studies from successfully treated subjects

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are in process in the U.S. and Australia. The U.S. study led by David Margolis is based on three single dose of Vorinostat during antiretroviral therapy, while the Australian trial led by Sharon Lewin is a continuous dose study during 14 days.

In both studies, the final endpoint is the in Vitro reactivation of latent HIV as mentioned by a cell associated HIV RNA, either in less density for the cells in blood for the American study or total CD4 cells in blood and rectum for the an Australian one.

While data for the Australian study is still pending, preliminary data for the U.S. study shows a five-fold significant increase in the expression of HIV RNA after Vorinostat administration in absence of any detectable short-term adverse events. Certainly, this is promising.

Disulfiram is also an FDA-approved drug to treat alcohol dependence. It's capacity to reactivate HIV and gene expression has been demonstrated in an in Vitro model of the latency. A joint short-term pile of clinical study led by Steve Deeks is ongoing into U.S. eyes on side trips with successful antiretroviral therapy. Disulfiram is given for 14 continuous days. Despite a transient but significant increase in low-level viremia right after the first dose of Disulfiram, there was no significant increase in the reactivation of reputation competent virus from the latent reservoir.

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A completely different strategy comes from the gene therapy field which main goal is to make patient cells resistant to HIV infection. Part of the reconviction that a cure for HIV as feasible comes from an extraordinary case report, the so-called rim patient, a 40-year-old HIV-infected man who was responding well to antiretroviral therapy developed acute myeloid leukemia. He needed complex medical interventions including chemotherapy, total body radiation and a stem cell bone marrow transplant.

Remarkably, the selected compatible donor had a very unusual deletion in their CCR5 gene, a gene that is essential to produce a key cellular receptor for HIV entry. Five years after the transplant, the patient remains off antiretroviral therapy with no viral rebound. Despite the extensive interventions to search for any trace of HIV in his body, all is still ongoing, these might be the first ever documented patients apparently cured from HIV infection.

Unfortunately, these type of interventions is so complex and risky, it would not be applicable on a large scale. This case has led to alternative interventions that take advantage of the gene therapy. The synthetic zinc finger nucleases [misspelled?] is a molecular tool engineered by the companies in Gamo [misspelled?] to [inaudible] any gene sequence. If designed to disrupt the CCR5 gene somehow

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mimicking the natural re-evolution might help to make lymphocytes refractory to HIV infection.

[Inaudible] trials in the east and west coast of the US are ongoing. Lymphocytes from cycheps [misspelled?] responding well to antiretroviral therapy are treated [inaudible] with zinc finger nucleases to disrupt the CCR5 gene, then expanded and re-infused to the patient. Modified cells show engraftment [misspelled?], proliferation and persistence [misspelled?] in blood and rectal mucosa suggesting that they have retained their functional characteristics despite the treatment.

The CD4 cell counts increase and the ratio of CD4, CD8 improve after intervention. However the number of genetically modified cells did not substantially increase. The question remains whether this system could be applicable to hematopoietic stem cell progenitors. Also if they are [inaudible] coreceptor, CXCR4, also needs to be targeted. If an [inaudible] product for this medical interaction could ever be developed.

Other potential strategies targeting HIV cure are in the cure and design including RNA-based therapies. Given the multiple mechanisms that may contribute to HIV persistence, most likely an effective intervention would require the combination of multiple strategies. The field is quickly advancing intellectual, financial and social coordination are essential in this trip.

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Over the last two years, the International AIDS Society has convened a group of international experts to develop a road map for research that works on HIV cure. The Inaugural Global Scientific Strategy that works on HIV cure was launched by Francois Barre-Sinoussi and Steve Deeks right ahead of this conference.

I would like to publicly thank both of them for their outstanding commitment and leadership. Their strategy is now published online [inaudible] immunology and identifies seven important priority areas for basic translational and clinical research and maps out a path for future research collaboration and funding opportunities.

Many are the challenges ahead of this area to ensure effective outcomes to this research. International cooperation will be critical. This includes successful cross talk between basic and clinical science, HIV and non-HIV scientists, public and industrial sectors, and the key involvement of the community, regulatory agencies and stakeholders.

Different institutions and agencies have outlined in the last years specific programs to tackle HIV cure. Financial resources specifically invested in this area without neglecting other key priorities in HIV care will be crucial to achieve the proposal. We hope the global scientific strategy towards an HIV cure will encourage others to further investment.

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The scientific and technical recommendations made by the International AIDS Society scientific working group on HIV cure include first to review basic science and to understand the [inaudible] vital and immunological mechanisms to control HIV persistence. Second, to develop new assays and experimental models to tackle vital reservoirs including tissues and cell resources in long-term antiretroviral treated individuals. Here development of animal models of latency would also be critical. And third, to investigate new therapeutic agents and immunological strategies to achieve vital remission in absence of antiretroviral therapy.

There are also other critical considerations that need to be implemented. Community engagement is essential to discuss, expectations and acceptability of proof of concept cure studies. There are ethical as well rotary issues regarding individual risks and toxicities of these interventions in [inaudible] who are otherwise doing well antiretroviral therapy.

Any successful intervention need to be safe, affordable and scalable to reach anyone who has needed. Indeed, cure and vaccine research are two inseparable priorities towards a world free of AIDS.

I would like to conclude my talk with two slides. The first one is to thank the people who helped me to put this, our presentation for you. My special acknowledge to Sharon Lewin,

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Steve Deeks, and Francois Barre-Sinoussi, but I would also like to thank all my colleagues at the International AIDS Society scientific working group on HIV cure for two years of intensive and fruitful collaboration.

The very final one is to remind you that realistically, the quest of finding a cure for HIV will require a prolonged period of investigation in many, many areas. However, this complexity should not prevent our effort. Meanwhile, continuous investment to secure universal access to prevention, treatment, care, and support should remain a top priority. Thank you very much for your attention and commitment. Thank you. [Applause]

**CHRISTINE KATLAMA:** Please welcome doctor and senator, Bill Frist. Senator Frist is both a nationally recognized as heart and lung transplant surgeons and former and U.S. senate majority leader. [Applause]

**BILL FRIST:** Dr. Nelly Mugo is a research scientist, an obstetrician/gynecologist at Kenyatta National Referral Hospital, Kenya. She has worked on two a multi-site HIV-one prevention clinical trial, as a Regional Director for the Partners in Prevention HSV/HIV transmission study, and the Site Investigator for the Partners PrEP Study sponsored through the International Clinical Research Center Department of Global Health and University of Washington. She is currently the head

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of research in programs at Kenyatta National Hospital, Kenya.  
Join me welcoming Dr. Nelly Mugo [applause].

**NELLY MUGO:** Good morning, everybody. I'd like to thank the conference organizers for giving me this opportunity to talk to you about implementation science and realizing the HIV prevention revolution.

We've heard a lot about where we are with the pandemic in these countries, and it remains a global health challenge. From 1980s to present, 30 million people have died. The current population of Kenya is 40 million. It's not a small number of people.

The current estimate is that we have 34,000,000 people living with the HIV/AIDS, and in that one year, 2.7 million were newly infected with 1.8 million deaths, close to the population of Swaziland. AIDS is still the most common cause of death in Africa, and the sixth most common globally.

Thirty years into the HIV epidemic as we have heard, new research has demonstrated that we have powerful interventions that can prevent new infections. For the very first time, we can begin to visualize a future free from HIV/AIDS as a feasible goal.

What do we need to change to deliver the HIV prevention services? We need to start thinking about the populations who are most at risk for targeted interventions. Then we will need to prioritize those interventions that work within those

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populations and deliver this in combination with high coverage for us to get high impact.

Thinking populations, I looked at data on where our new HIV infections coming from, specifically in generalized epidemics in high-pandemic areas in sub Saharan Africa. I took data from my own home country in Kenya, where married and co-habiting couples contribute 44-percent of new infections. This figure is true of other countries in the region like Swaziland, Lesotho, Uganda, and Malawi where heterosexual unions contribute the majority of new infections.

For a long time, we didn't think about other marginalized populations like men who have sex with men and injection drug users in our countries. In Kenya, from this data analysis, MSMs, sex workers, and a small proportion of injection drug users contribute a quarter of new infections. In addition to this, we know that injection drug users have higher risk of transmission at any one event, and casual heterosexual sex contributes another 20-percent in these populations.

We say that heterosexual couples are key and at highest risk of new infections, and we also know that HIV serodiscordancy is common. Across many datasets, we've learned that 50-percent of partners of HIV infected individuals are also HIV negative. The risk of transmission when couples do not know that that they're serodiscordant is up to 14-percent.

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In the absence of couple's counseling and testing, it would be very difficult to know who is at risk and who needs to be targeted for intervention. From our and studies, we've learned that serodiscordant couples' desire for children overshadows fear of infection and is often a risk driver, something that we need to think about.

Thinking about these marginalized populations, they require prioritization for intervention. HIV prevalence in these populations is high, and I take data from the sex worker project in Kenya, where 40-percent of the men who have sex with men are HIV infected and 28-percent of the sex workers. The sex worker cohort prevalence has stayed the same from the 80s. When they initiate and enrolled these people in the cohorts, only about 20-percent knew how to correctly use a condom.

I've seen many presentations in this forum looking at the issues of social and political environment for these marginalized populations that are keeping them reluctant to seek health Services. There are legal issues. For example in Kenya, sodomy is illegal, and can lead to a 14-year jail sentence. I know from our media that some of my neighboring countries have harsher sentences for men who have sex with men. They also experience social condemnation, religious intolerance, physical and sexual abuse.

We cannot have an HIV revolution without the youth. Data shows us that 42-percent of new infections occur amongst

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youth, age 15 to 24; 80-percent, 4 million youth of these infections are in sub Saharan Africa. If we targeted this population, think about what a remarkable difference we could make in a couple of years in the number of new infections.

In addition to the issue of youth is the young woman who has twice the HIV infection rates that is found in young men. I looked at data from the Kenya AIDS Indicator Survey 2007 where we found that 65-percent of new infections amongst women occurred before the age of 35. This pattern holds true, both in south and eastern African countries.

Thinking about populations, we need to prioritize our activities to be specific to the priority population, and we need to think about their vulnerabilities and address those vulnerabilities and deliver them a comprehensive package specifically designed for the population.

Prioritizing interventions that work; in 2011, we were jubilant because research provided very clear and unequivocal evidence that antiretroviral treatment and pre-exposure prophylaxis work for the prevention of sexual transmission of HIV. So in 2012, we know they work. The question is how do we deliver?

HPTN 052, I think many of us are very familiar with this data, the randomized clinical trial of immediate versus delayed antiretroviral therapy in couples. Amongst the linked transmission, only one occurred in the arm where they had

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immediate antiretroviral, and this one infection occurred very soon after HAART had been initiated. Treatment in this cohort but had a 96-percent reduction in HIV transmission.

Of interest are the 11 unlinked infections, 25-percent, which we would assume did not happen between the partnership, and that's something to keep in mind when we think about treatment as prevention. Antiretrovirals will only work when they're taken, true of many things. In HPTN, viral suppression was near universal, reflecting intensive strategies including quarterly monitoring and individual counseling, to achieve this near perfect adherence. As we move into treatment as prevention, we will have to reflect on how we can continue to achieve these very high adherence levels and suppression levels.

I will shift a little bit and go to pre-exposure prophylaxis. We have three pivotal trials' results in population groups. We have iPrEX amongst men who have sex in men, which was conducted across three continents with 2500 young men randomized to Truvada and placebo which demonstrated a protection of 44-percent.

TTF2 was in heterosexual men and women in Botswana, again, using Truvada, demonstrated a protective effect of 62-percent. Partners PrEP, which is a study I'm involved with amongst heterosexual HIV serodiscordant couples in Kenya and

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Uganda, Truvada demonstrated a protective effect of 25-percent. All this data is currently published.

PrEP, like antiretroviral therapy, works when taken. When we look at these results of blood samples where Tenofovir was detected, we can see in Partners PrEP where 81-percent of the samples had detectable drug, there was 75-percent efficacy. There's a clear dose response between the evidence of PrEP use and efficacy. If you go down, we see that in FEM PrEP, a study of young women, only 26-percent of them had demonstratable drug, and the study was stopped for futility and was not effective, did not demonstrate any effectiveness in protection.

The question is what motivates PrEP use? This perception is key, and it's a behavioral issue, just another reminder that our interventions cannot be biomedical, that we must have behavioral in impacting the epidemic. Serodiscordant couples have a known HIV infected partner. They've chosen to stay together and this helps and motivates adherence.

In FEM PrEP, it was found that 70-percent of the women did not perceive themselves at risk for HIV, and it resulted in very low adherence, and yet HIV incidents in that population was 5-percent. Risk perception is key for any strategy to be effective. As we move into these populations, we need to find out how to make people understand and perceive their risk if they're going to take up the interventions that we offer to them.

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Again on PrEP, just to keep in mind that we don't envision PrEP to be a lifelong intervention. It's something we perceive can be taken for a season. Very often, risk is in a limited period of time. When we look at data from adolescent women, they have a season of vulnerability and high prevalence is within the age of 16 to 24.

Again, serodiscordant couples from our own data, the highest risk occurred when couples wanted to conceive. Young men who have sex with men are equally vulnerable. Amongst couples, it's been noted that times of vulnerability include intimate partner violence, when people have a new partner, when there's depression, alcohol use, and perhaps we can think about conflict zones when there's a lot of abuse going on.

Last week, FDA approved a label indication for Truvada for HIV prevention. We have a really powerful tool that can be safely used by populations of vulnerable HIV negative individuals. We've worked for this and waited for it for several decades for a tool that's under the control of a negative man or a woman. Previously, everything needed to be negotiated between partners.

Just to keep in mind where we've come from in ART, when we talk about ART in Africa, and it was said that a high proportion of patients would be unlikely to adhere well unless there was intensive resource to support adherence programs. We

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know this has proven and not to be true. ART in Africa has happened, and we can do a lot more with what we know.

Just a reminder that we have many tools for HIV prevention. From 2007, we confirmed that male circumcision is very effective. Treatment of STIs; condoms, which do not cost much, are highly efficacious, and other behavioral interventions and counseling. More recently, we heard about Tenofovir gel. We've talked about PrEP and post-exposure prophylaxis and treatment as prevention. We have a large toolbox to select from and we need to use these tools in combination to make them effective.

Looking at voluntary medical Male circumcision, it was very refreshing to get these results from extended follow-up from the Rikai [misspelled?] study demonstrating a 68-percent effectiveness extended long after the randomized clinical trial ended. Similar results have been seen in Kenya and South Africa trial sites without any evidence of risk compensation.

Prioritizing what works, we finally have additional tools for a package of interventions. We haven't been here before. We need to revisit and revise how we prioritize our tools. We need to focus resources and efforts on what is proven and impactful. More challenging is to be ready to get rid of those policies and approaches that do not work.

What we need to do as a revolution and a change is to target the populations and provide them with relative packages.

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Delivering in combination and with higher coverage for impact so that we can have synergies of effective interventions and combination, interventions that reduce infectiousness like treatment as prevention, using condoms.

Interventions that reduce HIV susceptibility like male circumcision, pre-exposure prophylaxis, and when available, a vaccine, together with behavioral interventions; this would need to be delivered with high coverage for them to have high impact.

I borrowed this slide from Dr. Amin on Sunday, and I thought Cambodia had done a good job to look at the fact that HIV prevention is a team effort. The inclusion of police, media, campaigns and local authorities in targeting men who have sex with men before they come into a health care services for prevention. We cannot work alone to make this difference.

We know that testing is a gateway to prevention, and acceptability of HIV testing is high in large-scale campaigns and home-based testing. However, it's important that testing is linked to services, and we don't just accrue numbers of people tested. This will require systems for effective linkages to services.

We recognize the delivery of highly effective prevention interventions will not be without challenges. We've seen the treatment cascade from the U.S. and this is a meta-analysis from sub-Saharan data and we see out of 100-percent of

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people tested, we lose some and only 72-percent get CD4 measurements.

40-percent were found to be eligible and only 25-percent of those eligible started ART. To actually achieve treatment as prevention and have impact, we will require very high testing coverage. We will need to improve our linkage to care, so that we can achieve community virus suppression to reduce infectiousness and HIV incidents at the community level.

The other issues around treatment: the willingness to start antiretroviral. After yesterday's meeting, we heard the HIV infected people do not want to feel like they're compelled to take treatment to prevent transmission. This data from South Africa in an environment where 35-percent of the population was found to be HIV infected, 29-percent were eligible, and of them, 20-percent declined treatment.

The most common reason was that they felt well and did not see reason to commence treatment. We do not have a lot of experience treating antiretroviral in people who are asymptomatic. In my own sighting picker, we talked to HIV-positive members of discordant couples. 42-percent of men and 31-percent of HIV-infected women said they wouldn't start ART solely for the purpose of lowering the chance of infecting their partner. Part of their concerns included fear of side effects fear of stigma, peer burden and the potential for developing resistance.

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All is not lost and there've been demonstration testing in linkages to care. These results come from Mozambique in a province called Tete where patient empowerment improved retention to care and they formed support groups of patients where they supported adherence, supported clinic visits and they had very high retention of 97-percent. They only had two people lost to follow-up and two deaths. I think that was remarkable of what the community can do when they're involved in making a difference to what happens to them.

Other ways of proving testing and linkages has been shown by having home based testing where there's very high coverage and optic. Point of care CD4 count reduced clinic visits and cost of patients going to the clinic and community delivery of antiretroviral. This was demonstrated from work in KwaZulu-Natal.

Now thinking about ART for prevention and PrEP for HIV prevention, we find that they have similar challenges and opportunities. Both require adherence. People ask about sexual risk-taking and I think the balance to this question is to think whether risk-taking would be sufficient to undermine the prevention benefit. What is assuring is that from our own clinical trial data set, we did not observe any risk compensation and that the second edition data also does not show risk compensation.

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There's been questions about resistance. We know that people in treatment develop resistance when there's poor adherence and some of this has been seen to be rising in Africa.

In PrEP because it hasn't been taken to the community, from the clinical trial data, resistance was observed only amongst those who were commenced PrEP during acute infection and we need to weigh this against the number of infections that were averted. Who is likely to use these interventions? For ART, we know it needs to be life long, but for PrEP, we think that you only need to use PrEP during that season of vulnerability. It shouldn't be a lifelong intervention. Who will pay? These discussions have been discussed by people more able than I am and I'm reassured in this conference to have heard this important possibility of finding a way to make these interventions work.

For antiretroviral, now that we've only recently gotten the data, they've proposed demonstration projects. We see PrEP as a bridge in couples and we'll be commencing amongst discordant couples with three arms. We know that those people were eligible for ART and PrEP will be offered as a bridge for six months before full virus suppression. Amongst HIV-infected individuals who decline PrEP, who decline ART, PrEP will be offered to the negative partner; and for those not yet eligible, PrEP will be offered to the HIV-negative partner.

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Now look against implementation of prevention and the rule out of male circumcision, which shows substantial country differences. The targets was 80-percent of target populations and we have a relation between 41-percent in Kenya and 0.1-percent in other countries in uptake of this interventions. There's some lessons learned. I got this from my colleague and friend, Kawango [misspelled?], that HIV prevention plan must be community-owned at all levels from government to local community. For circumcision in Kenya, the Low Council of Elders endorse medical male circumcision.

There's a lot of public education through social media and for population impact, those that need to target so for male circumcision that was targeted in Nyanza, the lowest rates of circumcisions and highest HIV prevalence. There's a need to be flexible and creative, constantly monitoring and evaluated so the problems are caught early and interventions are built-in and there's a need to start and simply just do it.

We're reassured by results from prevention from mother to child transmission and on Sunday we heard from the mayor of the city that they haven't seen a new HIV infection from 1999 and ARVs have been what has been feasible. However, in context, we must remember that this has happened in combination of both ART as biomedical interventions and behavioral interventions like family planning and preventing infections of young women.

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So in summary, what am I saying? I'm saying we need to target populations for interventions, not taught with the interventions. We need to target the populations so we need to change course and apply the interventions that fit that population and have an appropriate intervention package for each population. I think it's clear that the interventions for men who have sex with men in Cambodia may be very different for heterosexual in Africa.

We have proven interventions which are highly effective so we must carefully select both by our medical and behavioral tools which are appropriate for each at-risk population.

For high impact, we must have high coverage and we need to link testing to services. So we need to move away from standalone HIV testing and we need to include linkages from testing to when people get intervention. The process of prevention needs to involve the communities for them to really have high impact.

In conclusion, I'd like to say that we have a real opportunity in the history of this disease to make a remarkable difference and save lives. This is not a choice, this is an obligation and we shall be judged on how we use the knowledge that we have to save lives, to save men and women from getting infected with HIV and hopefully fulfill a dream for future generations of an HIV-free life.

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I'd like to acknowledge the conference organizers for inviting me, my own home institutions, all of the investigators, advocates, sponsors, and everybody who's sticks new HIV prevention twos, the Kenya Prevention Revolution which have been thinking in this line, specifically in Nduku Kilonzo Pita Chanrocheech [misspelled?], and I'd like to thank Jared Baeten Karakalem [misspelled?] who worked with me and all of you for listening to me today. Thank you. Asanteni sana. [Applause].

**CHRISTINE KATLAMA:** Please welcome Dr. Stefano Bertozzi, a director of HIV Global Health programs at the Bill and Melinda Gates Foundation.

**DR. STEFANO BERTOZZI:** Thank you. It is my distinct pleasure to be able to introduce Dr. Bernhard Schwartländer, a long time friend and colleague. Bernhard is currently director for Evidence, Innovation and Policy at UNAIDS where he's been for the last two years. He moved to Geneva from Beijing where he was the UNAIDS country coordinator and prior to that, Bernhard was at the global fund where he was director for Performance and Evaluation and Policy and prior to that, the director of the WHO HIV Department.

I think we met when he was still director of the National AIDS program in Germany. He was trained largely in Germany, but the U.S. also claims him as a favorite son because he did part of his training at the Center for Disease Control

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and Prevention. We will now listen to him present on what does it take to turn the tide. [Applause].

**DR. BERNHARD SCHWARTLÄNDER:** Thank you, Stef. Dear friends, many of you, like many of you, I have been in the fight against AIDS for a long time. Together we have seen years of despair which after the Durban conference in 2000 turned around to become an amazing decade of progress and hope.

Thanks for civil society activism, we have seen resources grow to a point where we have turned around the pandemic. Infections are dropping in many countries, millions are getting affordable treatment and even the most affected countries, the number of people who die of AIDS have come down significantly. The signs of HIV has also made tremendous progress, so much that is instigated a new, bold vision of getting to zero.

We now dare to think of a world with zero new infections, zero discrimination and zero AIDS related deaths. We have a long way to go. We need to invest in what we know works and, as I will show you, that is possible. As much as change as we have seen in the world of AIDS, today, it is the world outside AIDS that is even changing more dramatically. My message today is simple.

In this new and complex world, all the poverty is as big a problem as ever. The days when we had a simple world of rich countries and poor ones is gone and with it we should

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abandon the concept of dependency and charity as well as habitual ways of thinking and acting. We should explore the many exciting new possibilities for collaboration, activism, financing, that this world offers.

In this environment, the forces that will make the difference a horizontal and partnership-based, the fight against AIDS must be one of shared responsibility and global solidarity, between activists and governments, among all countries, independent of their income and among men and women.

Friends, what are these dramatic changes? First, the dramatic rise in resources from official development assistance has come to an end and aid dedicated to fighting AIDS has remained flat since 2009, at least for now. So as we continue to advocate for donor funding, we need to learn how to do more with what we've got.

We need to focus on the specific conditions that facilitated HIV transmission and prioritize the interventions that make the most difference. One year ago, we proposed a strategic investment framework to do exactly this. This framework focuses on six basic programs that have been proven to work. We must invest our precious resources in them, but we must also invest in sufficient resources in programs called critical enablers to create the social and legal environment that actually enables people to take up these [inaudible] programs and stay on them. This means investing in ending

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discrimination, gender inequality and protecting vulnerable populations.

Let me show you what we can achieve by applying this new approach. Here you can see what happens if we continue with the same investment level over the coming ten years and do the same old things that we have done so far. Exactly nothing. We can pour \$16 to \$17 billion every year without budging the number of new infections.

This on the other hand is what the strategic investment framework is likely to achieve through focus and bringing down costs. It requires certain boosts in investments for awhile, peaking at an additional \$7 billion in 2015 and then goes down gradually.

\$7 billion is a doable proposition even in this environment. In return, we will drive new infections down well over half in five years. This certainly does look like a good investment to me. And for me, the choice is clear: let us pay now and not forever.

To start with, we need to focus on doing the right things. Let me show you what a difference it makes what the country chooses to invest in. Brazil and the Russian Federation have roughly the same population size, the same GDP and they roughly invest the same amount of money in fighting AIDS, yet the results in terms of new infections are vastly different.

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Russia clearly does not get good return for its investment. Russia's refusal to grant access to evidence informed HIV prevention and treatment services to people who use drugs and other key populations not only violates human rights, it also renders its AIDS response ineffective and wastes domestic resources allocated to HIV.

Unfortunately, Russia is not alone. Many countries fund programs driven by ideology and not evidence and fail to protect key populations from the discrimination and violence that make it almost impossible for them to take up and stay on prevention and treatment; but as Brazil and other countries show, poor investments and outcomes can be avoided.

We do need to do the right things, but we also need to do the right things the right way. Colleagues and friends, something very interesting is happening. As you see on this chart on Africa, treatment numbers have continued to go up in the past years despite a stagnation in funding. A lot of very clever and dedicated people are making sure that services are delivered more efficiently and making sure that more people receive services for the same amount of money and many of you are sitting in this room today. Let us be inspired by all of those who make this happen. And there's more we can do.

We can use innovation better, find new ways of preventing resistance, simplify procedures and use low tank

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community-based solutions where possible and reduce drug prices.

We have seen significant reductions in the cost of both first and second line combinations over the past three years, but there's still room for further reduction as we have just seen last week when President Clinton announced Tenofovir based triple therapy now is available for just \$125 per person year.

Experience has told us that such reductions must come from a combination of innovation in drug design and production, activism, optimal use of flexibilities within trips as well as incentives and competition.

The management costs of AIDS programs varies significantly from under 5-percent of total cost in South America to 20-percent average in sub-Saharan Africa and around 30-percent in the Caribbean and the Middle East. There's a substantial scope for savings here. It is also clear that externally driven solutions are the costliest. Overhead goes down by 18-percent for every dollar of aid that is replaced by domestic funding.

Colleagues and friends, tax payers want to know that the money is used as efficiently as possible, but cost reductions alone cannot ensure that we will reach our ambitious treatment goals for the coming decade. We need to find additional resources. To do so, we need to think new and to

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think new, we need to understand the way the world is changing around us.

This is a map of the world of the year 2000. The red countries are those considered low income by the World Bank. This picture has shaped our worldview until today, but see what has happened and will continue to happen as we go to 2020, in just eight years from now, the number of poor countries will have declined from 73 to 20. The trend is even stronger if you look at AIDs. Look at the red section of these bars and how it changes. In 2000, when we began the fight for prevention and treatment and the creation of global fund, 70-percent of people with HIV lived in low income countries. Eight years from now it is about 13-percent.

However while many countries are getting richer, most people in them are not. Most of the world's poorest people already live in middle income countries and this trend will not abate over the coming decade. The chasm between the rich and the poor remains as wide as ever. What is changing is that the challenge of redistribution of resources is increasingly a domestic one, rather than being a matter of transfers from rich countries to poor ones.

While many rapidly growing economies have made significant efforts to reduce poverty and increase health spending, there's an acute danger that hundreds of millions of people in countries that are marginally richer will suffer as

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the countries become less eligible for foreign aid and the domestic policies and dramatic in equality disfavor the poor.

Take South Africa as just one example. This graph represents its economic growth and these bars represent the share of the country's income held by each quintile of the population. See the purple bar at the bottom? That is the share of income held by the 20-percent who are the poorest. It has not even budged despite doubling of the GDP over the past decade.

We need to go beyond thinking of the nation as the only relevant entity. What is happening within this rapidly growing economies is an more rapid urbanization and a sharper split between the poor country side and increasingly wealthy cities. With urbanization, we see an increasing share of people with HIV who live in cities.

Big cities will become the battle crown of the pandemic, but they will also be where there are the most resources available to dedicate to the fight against AIDS. In 2025, 60-percent of the global wealth will be concentrated in just 600 big cities around the globe, home to 25-percent of the world's population and 2 out of every 3 people living with HIV will live in urban areas.

There's a huge unexplored potential for all of us to approach the new breed of urban entrepreneurs and municipal authorities guess how best to fight AIDS street by street and

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quarter by quarter, but it demands a different approach since cities face very different problems and opportunities than found in the countryside.

Estimated AIDS of fee funding levels leveled off to a flat lining of international funding since 2009, however global resources were up 11-percent in 2011 because of a steady increase in domestic resources in low and middle income countries, with Brazil, South Africa, China, the Russian Federation and India leading the way. This means a remarkable turning point.

Overall, a 15-percent growth in domestic resources made up for the stagnation in the international funding. In fact, 81 countries increase domestic funding by more than 50-percent between 2006 and 2011. For the first time ever, domestic resources exceed international funding.

About half of this increase came from Africa, but still only a couple of countries in the African union are living up to the national leaders' own commitments of dedicating 15-percent of their domestic budgets to health. It is not unreasonable for people in these countries to demand that their government live up to that pledge. The lives of more than 80-percent of the people who receive AIDS treatment in Africa depend every day, every morning on whether or not a donor writes another check. That is unacceptable. Such dependency simply must end. [Applause].

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Health spending in low and middle income countries was about \$710 billion U.S. dollars in 2011. If you do nothing else than apply gross and GDP to current health budgets, this will add an additional \$670 billion dollars by 2020. If countries were to raise health budgets to 15-percent global government revenue, domestic health spending would increase to just over \$700 billion to over \$2 trillion by 2020. Surely some such increases should benefit AIDS. And while countries are faced with many challenges, remember we are just looking for \$7 billion more.

One of the important challenges in most middle income countries is to establish reliable sources of predictable governments revenue. The conventional wisdom for an efficient tax to set a lower rate at a large base. Taxation of transaction for specific products is also seen as an effective way to seal development and discourage unhealthy practices. Tobacco taxes, fuel taxes and financial transaction taxes all have been considered and in some countries introduced over the past years. In fact, 15 of the G20 countries already have some form of a financial securities transaction taxed and this is important.

When we look at new revenue, we need to realize that while imposing taxes is never easy, it is considerably more feasible to do so country by country than to organize a global agreement, even if a global agreement were desirable.

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Behind me are examples of taxes, some of which are already implemented in one or several African countries. We've extrapolated to all of sub-Saharan Africa to give you an idea of the magnitude.

While we cannot expect that all of these ideas will be implemented in the same time, each one of these approaches will generate significant resources in the fight against AIDS domestically.

To fight for the poor and marginalized, to ensure that AIDS is seen as a national challenge, even in concentrated epidemic countries, to exploit opportunities for domestic funding, none of this will be achieved without a strong activist voice. I believe that the biggest challenge of the global AIDS activist movement today is to turn the focus back to the human rights and health responsibilities of governments in individual countries.

We need to strengthen national activist movements. Let me be clear. Let us not take the pressure off the world's richest countries to meet their commitments and obligations, but let us not believe that the only solution to winning the fight against AIDS lies with heckling the GA leaders.

Where we need to see the energy and activists movements in support of national movements for health and for those at the far margins of society, particularly those who are wrongly

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criminalized: men who have sex with men, transgender people, sex workers and people who use drugs. [Applause].

This is also where the development partners can be very strategic. The recent cut where traditional donors have hit NGOs, national NGOs, like the South Africa Treatment Action Campaign, the hardest. Donor funding should be channeled to activists fighting for domestic solutions holding governments responsible for their human rights obligations for all their citizens.

My advice to the global networks, provide outside pressure where useful, but more than anything else, train, support and encourage concrete rights based movements and solutions from within, country-by-country, city-by-city and province-by-province. [Applause].

Friends, I've talked at length the possibilities of increased domestic funding for HIV in low and middle income countries, however let us not forget that there will be quite a number of low and middle income countries and people that will continue to see significant amounts for the next decade and beyond. That is why we need to continue to push for global solidarity, such as evidenced by the global fund and PEPFAR as the main sources in external funding for AIDS today.

They need to get the resources to do what is needed. Let us not forget that despite the global financial crisis, there's still economic growth in OECD countries and if they did

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nothing else than to supply economic growth to wealth, to levels of ODA, of current levels of ODA, there could be another \$50 billion annually by 2020, in additions to the \$30 billion that we have today. As I had shown to you before clearly with more than 70 high income countries by 2020, we do need to think about the additional ODA by 22 OACD countries.

Let us also explore new sources of income at the global level. Many of you have dedicated much time and effort to securing a global financial transaction tax. This is one great opportunity, but let me also mention some others.

The IMF and the World Bank have argued that over time, markets and governments should price carbon tax more explicitly through taxes and other means. A tax on shipping and aviation fuel could raise more than \$64 U.S. dollars dealt annually, much of which would of course go to compensate for the damage of global warming, but also conceivably could be used for health.

Some years ago much thinking went to front-loading investments for health through bonds, etcetera. Such opportunities are far from explored. Bill Gates has mentioned the potential for investments by the many suffering wealth funds that now exist, although he did not focus on health for such investments. He also pointed out the issuing of Diaspora funds. Israel and India have already successfully experience with this and about \$4 billion could be generated funds if

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people in Diaspore would invest no more than 1-percent savings in them.

A truly innovative way of financing could be if the billions of dollars which the United States, the European Union and other countries occasionally fine pharmaceutical companies fine for competitive practices could be set aside for health assistance rather than disappear in the general coffers of these countries. A few weeks ago a single multinational company paid \$3 billion in such fines. \$3 billion could easily pay a year of drugs for all those in treatment today. I can already hear the cries of protests among financial bureaucrats, but let us ask our next speaker, Howard Koh, the deputy secretary of health and human services to put in a good word for us. [Applause].

Friends, when it comes to funding the future response to AIDS and getting to zero, I have hope. Let us not accept the notion that we cannot find the relatively humble resources to pay for the basic services that mean life for those in greatest need. The world overall is getting richer. We have to make it fairer. We will be able to deliver drugs and services more cheaply and more efficiently.

We can take the tough decisions and focus on what makes the biggest difference and stop what doesn't. With only a fraction of the new innovative funding sources that I've outlined here, we can make it. The progress so far has been

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phenomenal, in 2010, domestic funding for AIDS was larger than international funding for the first time ever. It would be exactly the wrong moment for international donors to cut back funding now that the dynamic is going the right way.

When we are finally on a path towards sustainability and quality and truly shared responsibility and true global solidarity. It is exactly ten years ago in the conference in Barcelona that I put forward the goal of reaching 3 million people with treatment by 2005, we are at 8 million today. The global AIDS movement has achieved amazing results over the past 30 years and there's no reason why it should not continue to drive change, innovation, health, human rights for all.

Friends, together we will end AIDS. Thank you.

[Applause].

**CHRISTINE KATLAMA:** Please welcome Diane Havlir, U.S. co-chair of the AIDS 2012 conference.

**DIANE HAVLIR:** Our next speaker, it's my pleasure to introduce, is Dr. Howard Koh. He is the assistant secretary of health of the United States Department of Human and Health Services. A former commissioner of Public Health of the Commonwealth of the State of Massachusetts, he has also served as a professor of medicine and associate dean at the Harvard School of Public Health. A graduate of Yale College and Medical School, he is the author of over 200 papers and the recipient of numerous awards.

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It was not until 2010 that the United State had its first national AIDS strategy introduced by President Obama. This strategic plan has shaped the public health response for our country over the last two years. So now I welcome Dr. Koh to address building on success on national strategy to save lives.

**DR. HOWARD KOH:** Dear friends and colleagues, I am so honored to join you this morning on behalf of the United States government to present the status of our commitments for an AIDS free generation. In particular, I am so pleased to review the development and implementation of the first ever comprehensive U.S. National HIV/AIDS Strategy, which addresses many of the domestic challenges already reviewed at this conference.

This strategy also incorporates lessons learned from our many domestic and global partners. It was more than 30 years ago when the first HIV cases were identified in the United States. During this critical time, I was beginning my tenure as the chief medical resident at Boston City Hospital.

I will never forget the patients we lost and the way they suffered. Since then, more than 640,000 Americans have lost their lives to AIDS and today as estimated 1.1 million people are living with HIV in the United States. 1 in 5 is unaware of his or her infection. While the U.S. incidents remained relatively stable in recent years with approximately

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50,000 new infections annually, this figure is unacceptably high.

We also know that in the United States, the burden of HIV is not shared equally by population or by region. Populations most affected include men who have sex with men of all races, in particular African American and Latino men, women of color and transgender women, people who use drugs and young people, especially young black men who have sex with men.

The region's most affected include urban areas, the Northeast and the South. None of this is acceptable. So many in our country have by providing linkages from ongoing care leads to viral suppression, but in the United States, only 1 in 4 people living with HIV currently achieves the level of viral suppression needed to preserve health and reduce the risk of HIV transmission to uninfected partners.

National strategies are critical to effective country leadership on HIV. National strategies outline a framework for responding HIV/AIDS in ways that reflect each country's unique epidemiology, disease burden and trends and they demonstrate the importance of country ownership and the need to maximize the efficiency and effectiveness of HIV/AIDS programs.

In 2009, President Obama made it a top priority of his administration to develop a comprehensive National HIV/AIDS Strategy. When drafting the plan, the White House Office of National AIDS policy consulted with people living with HIV,

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community based programs, healthcare providers, researchers, public health experts and others. The White House Office of National AIDS Policy also consulted with PEPFAR and reviewed existing HIV strategies from various countries in the global north and south.

PEPFAR has long prioritized supporting countries as they develop and implement the national strategies, maximizing the efficiency and effectiveness of our programs is a shared area of emphasis of PEPFAR and domestic HIV efforts. The following year, 2010 when President Obama unveiled the National HIV/AIDS Strategy, he noted, and I quote, "The actions we take now will build upon a legacy of global leadership, national commitment and sustained efforts on the part of Americans from all parts of the country and all walks of life to end the HIV epidemic in the United States and around the world."

[Applause].

This process of community dialogue continues today. The White House recently completed a series of these community dialogues across the nation where ideas for implementation at the local level were discussed with key stakeholders. To date the National Strategy has reinvigorated our efforts and reenergized our communities under one unifying set of goals and in one short period of time, we have demonstrated progress of the national strategy's three key goals.

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In particular, each of the goals is guided by strong science and solid evidence of what works best. We have the benefit of the world's leading scientists and researchers at the National Institute of Health. They and other researchers across the U.S. They and other researchers around the world have contributed of many of the scientific breakthroughs that provide us with the knowledge and tools to end AIDS.

The National Strategy's first goal is to reduce new HIV infections because after all, this is a preventable disease. By the year 2015, we seek to lower the number of new infections by 25-percent. We plan to do this by reducing the HIV transmission rate and increasing the percentage of people living with HIV who know their zero status; to reach these targets as well as support similar global efforts to reduce HIV incidents, NIH continues to invest in cutting edge prevention research related to vaccines and microbicides.

We are so pleased to see greater emphasis on the use of treatment as prevention. Also, last week's approval of Truvada by the U.S. Food and Drug Administration marks a milestone for pre-exposure prophylaxis, adds another tool to our efforts to reduce incidents.

As part of the National Strategy, all Department of Health and Human Services Agencies are charged with realigning federal dollars to concentrate on both geographic areas and populations with the greatest need. To that end, the Centers

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for Disease Control and Prevention launched high impact prevention strategies in the most heavily infected populations and is promoting its recommendation that every adolescent and adult get test for HIV at least once in his or her lifetime and that those at increased risk get tested at least once per year.

For example, the Centers for Disease Control and Prevention has released a new social marketing campaign called Testing Makes Us Stronger. That was designed for and in consultation with African American gay and bisexual men, the fastest growing demographic in the United State for HIV infection.

Meanwhile the Department's Health Resources and Services Administration's National Network of 8100 publicly funded health community centers has scaled up testing for low income people leading to a 13-percent increase in persons tested last year alone. [Applause].

In communities are implementing more creative strategies. Here in the nation's capital, the District of Columbia's Department of Health makes HIV testing available at the Department of Motor Vehicles for customers waiting in line for a driver's license or other services at the Motor Vehicle so customers at motor services can get a free HIV test. [Applause].

Up to 35 people are taking advantage of this resource every day. We need to continue to build on this effort and

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others to reach people in non-traditional settings. The second goal of the national Strategy is to increase access to care and improve health outcomes to people living with HIV since fewer than 50-percent are retained in consistent care.

Currently the Health Resources and Services Administration's Ryan White HIV/AIDS program, a federal funded program that provides services to low income people, and are publicly funded community health centers are working together to expand nationwide access to care for people living with HIV.

In addition, the new healthcare law signed by President Obama two years ago is crucial for HIV/AIDS and implementing the National HIV/AIDS Strategy. [Applause].

Thanks to the Affordable Care Act, we are putting into place common sense rules that prevent insurance companies from locking people with HIV/AIDS out of the market by capping their care or by refusing to sell or renew policies because of their preexisting condition. Specifically the preexisting condition ban will apply to all Americans on January 1<sup>st</sup>, 2014 and is already in effect for children.

The Affordable Care Act will also soon expand access to preventative services including making HIV screening available for women at no cost. In 2014, it will extend coverage to millions more Americans that will result in a dramatic expansion of coverage to people living with HIV.

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Recently the Secretary of Health and Human Services, Kathleen Sebelius, announced two important actions relevant to the National Strategy's second goal.

First, the Secretary announced nearly \$80 million in new grant awards that will expand care to an additional 14,000 low income living with HIV/AIDSs and, based on estimates provided by state administrators, will eliminate any waiting list for AIDS drug treatment. Also, Secretary Sebelius announced that the Department is working in partnership with the MAC AIDS Fund to pilot a program that will use mobile phone texting to provide important tips and reminders about disease management to people living with HIV.

The third goal of the National Strategy is to stress HIV health related health disparities in our nation. Complex social and economic factors, including poverty, stigma and the lack of access to care limit opportunities for prevention and treatment. To better address many of these social deterrents of health, we've expanded our efforts to work across programs administered by our colleagues at other federal agencies such as the Department of Housing and Urban Development, Labor, Justice and Veteran's Affairs.

We have also engaged leading national organizations to support populations hardest by HIV. For example, the Centers for Disease Control and Preventions Act Against AIDS Leadership Initiative, represents a partnership of leading national

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African American and Latino organizations. It is designed to increase prevention efforts through outreach communication and mobilization.

In the United States, women and girls account for 23-percent of all new HIV diagnoses. Among women the epidemic disproportionately affects women of color, particularly black women; and tragically, gender-based violence often goes hand-in-hand with disease. Women and girls are all too frequently victimized by intimate partner, violence and sexual assault. This not only increases risk for HIV, it also blocks women and girls from seeking prevention options and treatment. This is unacceptable. [Applause].

So in an effort to address gender disparities, the White House recently established an interagency working group of an intersection of HIV/AIDS violence against women and girls and gender related health disparities. This group is working to share best practices, to facilitate research and foster opportunities for partnerships.

Finally we know that stigma drives discrimination and disparities. As a result, too many Americans avoid learning their HIV status, disclosing their status or accessing medical care. To overcome stigma, our efforts include a new Centers Disease Control and Prevention Campaign called Let's Stop HIV Together, which features people living with HIV standing with their family and friends and calling on all Americans to join

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the fight against the disease. This national communications effort will not only address stigma associated with the infection, but also complacency about the epidemic. We must prevent the next generation from suffering the burdens we have witnessed in the past.

In conclusion, we are making important progress in the first two years of the National HIV/AIDS Strategy, but much more lies ahead. We can succeed by making our international public health community even stronger. Over the years the United States has been part of that effort to build that community along with so many domestic and global partners and in particular, PEPFAR has coordinated the power of us working together to plan, coordinate and collaborate to save lives.

As we go forward, let us reflect on the past, and accelerate our efforts to fight against the HIV/AIDS for the future. Here in the United States, we believe the National HIV/AIDS Strategy can bring us closer to a vision of a society where new infections are rare and everyone receives the care that they need and deserve. You can follow our efforts to implement the strategy on [www.AIDS.gov](http://www.AIDS.gov).

My hope is that together, we can seize this moment of opportunity and channel its momentum toward achieving our goal of an AIDS-free generation. Thank you very much. [Applause].

**CHRISTINE KATLAMA:** On behalf of my co-chairs this morning, on behalf of you, I would like to thank all the

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speakers this morning who give us perspective to end the HIV.  
So now you have a break and there will be another session on  
the clinical studies in this room. [Music].

[END RECORDING]

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