XVII International AIDS Conference
Plenary Session, Day 4
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MALE SPEAKER: Welcome to the Thursday Plenary Session and before we start with our very interesting series of plenary talks this morning. It is my pleasure to present you the Young Investigator Awards that the IAS has been giving out any conference starting in 2001 in Oportunidades Conference in Bonasirus [misspelled?] in order to encourage young researchers and to recognize their excellence.

So, we have one for each track, and to be eligible the presenting author of an abstract must be no older than 35 years as of 3rd of August 2008. The Young Investigator Award is given to the top scoring abstracts in each of the five track categories.

So, we have in Track A, our awardee is Birgitt Dau. Birgitt Dau is a Postdoc Fellow in Infectious Disease at Stanford University in Palo Alto, California, and she completed medical school at the University of Chicago Pritzker School of Medicine, and then she has done an extensive career working in several issues, including studying the clinical outcomes in the OPTIMA cohort. She is currently studying the impact of the connection of HIV reversal [inaudible] and the impact of the biological and clinical response to antiretroviral therapy.

Birgitt's paper is staying Connection Domain Mutations Are Common in Treatment-Experienced Patients and Are Associated

with Viologic Outcomes. So, it is my pleasure to present Birgitt. [Applause]

So, for Track B, we have Dr. Alastair Teague who was born in the UK in Bristol, a city in which he graduated in 1999. Dr. Teague's primary research interest are centered around antiretroviral therapy and with particular emphasis on novel drugs and their implication of their use in the clinical setting. He has published several articles on HIV related oncology. Most recently, excelling in the Prognostic Significance of the Immune Subset Measurement in Individuals with Kaposi's Sarcoma.

So, the award for Alastair comes for a paper named Clinical Experience With Raltegravir an optimized background in highly treatment experience patients. Alastair. [Applause]

Our Awardee for Track C is Tara Beattie. A native of the United Kingdom, she completed her Bachelor of Science at the Edinburgh University in Medical Microbiology in 1998. In order to move towards in public health research, she enrolled for Masters in epidemiology at the London School of Hygiene and Tropical Medicine in 2006, she has spent her term in Karnataka State, Southern India working with Karnataka Health Promotion Trust, which is a program that is funded by the Bill and Melinda Gates Foundation.

So, the award for Tara in Track C comes for the paper, Community Mobilization: An Approach for Rapid Increases in

Condom Use and Reduction in Sexually Transmitted Infections Among Female Sex Workers in Mysore, South India. Tara. [Applause]

So, now it comes for Track D. And the Award comes for Kenneth Gimbel-Sherr who is currently the country that Director for Health Alliance International based in Maputo Mozambique and Clinical Assistant Professor with the Department of Global Health at the University of Washington in Seattle. Primary interest the focus of Mr. Gimbel-Sherr's is on identifying and testing practical solutions to support service integration into the primary health care framework as a means of improving health system efficiency, coverage and quality.

Kenneth currently lives in Maputo Mozambique with his wife Sarah and three children. The title of the abstract that won the award is Task Shifting to Mid-level Clinical Health Providers on the Quality of ART Provided By Technical Medicina and physicians in Mozambique. Kenneth. [Applause]

Okay, and the last, but not least is Richard Pearshouse who is Director of Research and Policy at the Canadian HIV/AIDS Legal Network. Previously, he has worked as legal advisor to the United Nations Special Panel for serious crimes in Dili, East Timor. Richard is a law graduate at the University of Sydney in Australia and holds a Master of Arts Degree from the International Center for Peace and Development Studies at the Universitat Jaume Castello de la Plana in Spain. And his award

comes for his paper, *Rape, Sexual Assault, Domestic Violence and HIV Promoting Women's Rights through Legislations.*

Before I give this award to Richard, I would like to underscore that as you know the award is a certificate and a check. The certificate will remain with him I assume, but he has decided to donate this check of $1,000 U.S. to a Botswana Domestic Violence Refuge. [Applause]

Now it is my privilege to introduce the Co-chairs for this morning's session. Our first co-chair, I really should not introduce him because everybody knows him, is Lars Kallings. Lars is currently serving as a U.N. Secretary General Special Envoy on HIV/AIDS for Eastern Europe.

His career in Sweden, the top of his career was serving as Professor of Clinical Microbiology at the Karolinska Institute. But probably the most relevant issue for us is that Lars Kallings is the Founding Father of the International AIDS Society. So, very welcome Lars to the session. [Applause]

Our second chair is a long-time AIDS advocate and expert on public health and is currently the Deputy Vice President of the Ford Foundation, Director of the Global HIV/AIDS Initiative of the Ford Foundation, Mr. Jacob Gayle. [Applause]

And our third co-chair is the former Director of the CDC in Kenya, current Director of the HIV Program at the World Health Organization and certainly you would agree with me that

he is one of the major experts in the world on HIV epidemiology and science, Kevin De Cock. [Applause]

Lars!

LARS KALLINGS, M.D., PH.D.: Good morning everybody. I am happy to introduce the first speaker, Anton Pozniak. He is a Consultant Physician Senior Lecturer at the Chelsea and Westminster Hospital where he is Executive Director of HIV Research. He is also an Executive Member of the European AIDS Clinical Society, and Vice Chair of the European AIDS Trial Network.

In 1996, he became a Fellow of the Royal College of Physicians. Dr. Pozniak started carrying for patients with HIV already in 1983 when AIDS was not named yet and of course, not HIV. When patients started to turn up with Pneumocystis pneumonia, and Kaposi's, another very well known symptoms. Then he went to Zimbabwe where he studied HIV and TB. He currently chairs the HIV/TB Committee of the British HIV Association and he has just been elected a member of the IAS Governing Council which particularly makes me please to announce. And he is known as a good clinician.

The title of his presentation is on *Advances on Antiretroviral Treatment*. Dr. Pozniak! [Applause]

ANTON POZNIAK, M.D.: Thank you, Mr. Chairman.

[Spanish language]

So, I am going to talk today about recent advances in treating HIV infection and what is new since the IC in 2006. I must say I found this a very difficult thing to do because as I was preparing this, it is one of the talks that really highlights the differences between resource rich and resource limited countries, and I ran out of fingers and toes to count the numbers of inequalities that you will see as I go through my talk between those two areas of the world that have drugs, and those that have none or limited number.

Now, the good message is that treatment works, as long as you got access and you take it. Patients who have successful control of HIV therapy can now live relatively normal life spans and fulfill we hope most of their dreams.

For example, dates of recently published in the *Launches* show there a 20 year old starting heart can expect to live for another 43 years on average. And a 35 year old, the Young Investigators and below can up expect 32 more years of life.

Another paper in Jadee [misspelled?] showed that the mortality rates become similar out of the general population after six years of follow-up among patients with CD4 counts had reached 500 cells. This is a very important message that if you can have access and get drugs, you can live a relatively, normal life. However, there are some inequalities in terms of drug users and women for these data.

We have continuous evolution of Heart with 25 drugs in counting all the way back from ’95 when we had a few drugs, yet some countries in the world are still way back here in terms of access to the compounds that they can have and of course, we in our units and other places in Europe, North America are way up here in terms of access to all of these compounds.

And when you look how affective antiretroviral therapy is by looking at undetected ability of our load, these recent trials you can see around about 70 to 80-percent of patients we can make undetectable in terms of their viral load and of course, the obvious benefit of that is to improve their immune system. And now even in patients who have had drugs before, were approaching that sort of level in experienced trials.

The safety and tolerability of current regimens, and most of them is excellent, and when you look at these discontinuations due to adverse events here, you can see, yet some of them are up to 10-percent, but most are below that.

So, we have better and more tolerable therapy. It appears now that we have less short-term toxicities, such as diarrhea, dislipidaemia with some of the choices we can make, we have less long-term toxicities especially such as lypodistrophy. There are better formulations with pills that easy to take. There is even now a one pill, once a day for HIV, which is quite a remarkable achievement in terms of drug development coming back from the bad old days of 30 pills a

day. And also now for Ritonavir in development there is a pill whereby you do not have to keep it in the fridge anymore. Or do we have better and more tolerable therapy? There are still major access problems to the newer drugs and we really need to do this, and I will highlight one of the reasons later on.

Many patients on drugs, and I have seen posters here from all around the world, still showing people developing lypodistrophy, Neuropathy and other side effects due to some of the therapies that they have to have because they are the only ones available. However, there is several groups looking into whether reducing the dosage of these compounds might limit these toxicities. There are also new and unforeseen toxicities which may become apparent even in the tried and tested drugs that we have, such as cardiovascular, bone, kidney, liver malignancies. We have to keep surveyance.

I am now going to talk about the thorny issue of when to start. When we look at these guidelines for asymptomatic individuals, most of the guidelines in the resource rich countries say, you should start between 200 to 350, and WHO's say, anyone below 250 should have treatment. Now these guidelines are based on observational studies and experts opinion and there is no randomized evidence. However, at this meeting the new ISUSA guidelines were unfolded, and the current guidelines now say, CD4 cell count, yes Azure [misspelled?] at below 350 or approaching 350, antiviral therapy is recommended.

But now there is a new recommendation, that if you are above 350 you should think about starting patients on therapy depending on their other medical circumstances, and I am going to highlight this now. So, why should HIV infected patients be offered earlier treatment? Well, there are data that suggests that if you start patients earlier, you get better tolerability and less toxicity of the drugs. There is a better chance of making their CD4 count normal, or within the normal range. There is a low risk of them developing a resist of mutations. Of course, there is fewer OI's and deaths, but also there is this newer concept of preventing so called non-AIDS defining events.

What are these non-AIDS defining events that can lead to disease and death? And I quote Professor David Cooper, very close friend of mine. "It is the previous unrealized clinical mischief of untreated HIV infection". And this is that patients who have HIV, who are not treated, even with a high CD 4 count, have a higher risk of cardiovascular, myoplastic, hepatic and renal diseases compared with the matched HIV uninfected people or those who are on treatment.

How does this come about? Well, HIV causes as we know, continuing immune deficiency if you do nothing about it, which leads here to OI's and death. However, now we believe that HIV also causes inflammation, especially of blood vessels. It causes increased blood coagulation, and therefore it could lead

to cardiovascular disease, renal hepatic disease and through the immune deficiency and inflammation to tumors.

So, if you treat the HIV, we would hope that what would happen is you would remove the inflammation and the continued immune deficiency and you would remove the risk of both AIDS and non-AIDS complications.

So, what is the future of this, should they be treated earlier? Well, I will recommend to you that there is a randomized study plan start which is going to look at starting earlier above 500, verses another cohort starting below 350 to try and answer this question. And there is another study which is going through the process of being evaluated, looking at a similar protocol in Africa with slightly different CD 4 criteria. We need the [inaudible].

Now, the other issue about antiviral therapy, do not wait until it is too late to treat anyone. We showed several years ago that if you waited with patients who had Tuberculosis, that they actually advanced to further AIDS and some of them to death. And people are scared of starting antiviral therapy early with these, I know there are problems because of toxicity, adherence, IRIS etc. But these are certainly outweighed by not treating because of morbidity and mortality.

I just want you to look at this graph here, of two groups of patients with OI's from the United States Study

85164, starting immediately verses deferred treatment. And you can see the prognosis is much better in terms of progression to AIDS or death in those that were started within a couple of weeks of therapy, compared with those who had therapy deferred. And look at this a safety, and the incidence of IRIS was similar between the groups. We should start as quickly as we can.

But once you are on therapy, do not stop it, that is the other message and we know the SMART Study, but there is others, from Africa, the DOTS Study, and also from West Africa, Trivican. And all I want you to really look at here is the numbers in the orange. The relative risk of you getting AIDS or death whether you were in SMART in the white, or DOT in the yellow, was two and a half times if you stopped your therapy compared with if you continued on your treatment.

And also, the other thing that occurs in these patients are those non-AIDS related cardiovascular and other episodes which I have not highlighted in this slide.

Now, this is really approaching the technical side. The guidelines say that before you start any treatment you should have a resistance test. Well, it is not possible in most resource limited countries, and the reason for this is to see that before you start the treatment, do you already have resistance that have been transmitted to you. And in some countries, the rates of this are rising and others falling but

really we need to know the local situation. And actually perhaps some sort of surveyance should be going on in countries where they are antiretroviral to monitor the situation.

Even in resource rich countries if you have access to resistance tests, the problem is you may not pick up all the resist mutants on the tests, and there maybe ones in the viral collate which are very important in terms of treatment and outcome.

Now, what to start with! All the guidelines say we should start with a boosted PI or a non-nuclear side. Does it matter? Well only if you have a choice, and in most resource poor settings there is no choice, it is an NNRTI. And also PI's are only used second line. There is people who prefer an NNRTI, while I have shown a Efavirenz here. Efavirenz actually has not beaten in any clinical trial, and most of us in resource rich countries are using this drug. I realize there are issues with it in terms of side effects, and the use in pregnant women, and in the developing countries, resource poor countries, Nevirapine is often used.

Now, Efavirenz has got a problem in terms of its publicity because many people think that it does not work at high viral loads, but actually the data here shows that it works at all viral loads, and here that it works at all CD 4. All these dots are actually almost in line in terms of this strata.

So there are those people who prefer to give patients a Boosted Protease, and you can see they work very well, but less than 50 copy rate from all of these sort of Protease inhibitors in all of these studies show very good efficacy.

Now are there any trials to help us choose between a PI or an NNRTI? We saw this study presented from Mexico in the week and also the large study from the ACTG, the 5142 comparing a Efavirenz with Lopinavir, there was a third arm with both Efavirenz and Lopinavir in this, which I am not going to discuss today.

Well, if you look down the list, viral load, Efavirenz beat Lopinavir. CD 4 count, Lopinavir beat Efavirenz, although the rate of which people got to above 200 was similar. In terms of adverse events they were very similar and in terms of resistance, for those people that failed, it is not 48-percent of 253, it is for those people that failed, a lot of them had Efavirenz mutations compared with Kaletra. Actually, the jury is still out for most people in terms of the two, and many people have not changed their ideas of what to give up front.

Now, if you do prescribe these treatments, how important is resistance? Well I have shown you resistance to the boosted PI's is uncommon, but the issue is that if you go on an NNRTI regimen, and stay on it for a long period of time, you will get multiple resistant mutations and we saw a

presentation from Malawi, which showed just that at this conference.

So, a good program with supporting adherence and dealing with toxicity is really important whether in a resource rich or resource limited country. Now, I believe everyone deserves a second chance, so if they do not have biological success on a non-nuke, they should be able to have move over to a boosted PI. It is what you give those things with, and actually if the boosted PI could be given with one of the new classes of drug such as an integrate then actually if you have biological failure on one non-nuke plus two NNRTI's, you could switch immediately to the boosted PI, plus the integrate without needing a resistance test. However, access to the integrate is still not there.

So, the guidelines say that with your boosted PI, with your NNRTI you should have a nuclear side backbone, and I am going to discuss these three backbones here and have a little mention of d4T, which I know many of you using in your combinations. What drives the choice? Well for us, toxicity drives the choice then costs, availability for us is there, but for many of you it is not.

Right! Let us look at Tenofovir plus FTC verses AZT plus 3TC or d4T plus 3TC which have been in clinical trials. Six percent of people get anemia on AZT. In countries where people hemoglobin's start at 9.5 or 10 this can be an important

issue. Lipoathropy, and as I have said I have been dismayed by the number of posters and presentations here of Lipoathropy occurring in developing countries. I know we can say, we told you so if you used d4T or AZT, but actually the drugs were needed to save the lives. But perhaps now, with more drugs becoming available we could move away from the d4T, AZT paradigm in resource poor countries and move towards drugs which will not give you Lipoathropy or cause your lipids to be abnormal. With Tenofovir, there is a potential for renal toxicity, but it is relatively low, and there are sub-studies and studies within DOTS in Africa which looks at this.
Now, this conference as did Kroy [misspelled?] had a lot About Abacavir plus 3TC, now Abacavir did have a problem and that it cause hypersensitivity reactions, but by looking at the HLAB-5701 gene in patients, it they are positive we do not give them Abacavir, and if they are negative we do, and then hypersensitivity reaction seems to be a problem of the past in the resource rich world where we can do this test.

But now we have got this issue. Is Abacavir associated with a cardiovascular risk, and how good is it if you give it at a high viral load? A lot of this was initiated by the [inaudible] led by Chip in Copenhagen and Yens Lungren, and what did it say about individual drugs and cardiovascular risk? Well this is a large cohort which was started in 1999, so it is very visionary. It studied adverse events related to HIV

therapy and it has got a huge number of patients in the cohort globally.

And I just wanted to show you this. This is the risk of recent miraviroc [misspelled?] infection and use of Abacavir. And basically, if you look at the predicted risk of coronary artery disease over ten years, if you look in yellow at recent Abacavir use, you can see compared with patients who did not have the Abacavir when you get to patients were in a high cardiovascular risk category. In other words, they might have hypertension, they might be smokers, they might have abnormal lipids, and of course, male. You cannot change that very easily, they have a very high risk at doubling of the risk according to this data of developing coronary artery disease if they have had recent Abacavir use. That is very curious.

So, why should Abacavir be associated with an increase cardiovascular risk? Does it cause changes in these inflammatory coagulation markers, which I have shown you that untreated HIV cause is rising and people have measured the IL-6 and D-dimers. But however, is the effects seen in all patients irrespective of gender, race, etc? And what about the other drugs, do we have data on drugs such as Tenofovir, etc? Is the data effect confirmed in other cohort and clinical trials and there has been data here to suggest they have not, and in others perhaps.

So, what to do in the meantime, I think you should go to the late breaker session today, where there is going to be more on this, and I think it is going to be an ongoing debate. The one thing that we must not do though is not use drugs because of some problem that they might have. We have to use them within the context of that problem.

Now, what about Abacavir and the efficacy at high viral loads? ACTG-5202, has a large number patients and is basically looking at Abacavir 3TC verses Tenofovir FTC with a back bone of a PI or Efavirenz. And basically what they showed was that if you have got a viral load of a greater than 100,000 when you start on drugs, you have a significantly higher failure rate in terms of time to biological failure.

Now, this has been updated today, at the late breaker sessions and I think we should go to see the 48 week data and hopefully have some more insight as to why Abacavir might be associated with less efficacy at high viral loads.

So, there is a drug which maybe very useful and is useful in our setting which has got a question mark over it which we need to resolve rapidly. We all treat patients with three drugs, do we do that? Because, if we did, less there would be fewer drugs, less costly and less toxicity.

Now, this is a bit of color, I thought I would put this in. All the patients in yellow on this triple therapy are undetectable, so we do not need to worry about those. All the

patients in green have dropped out of the triple therapy. And all the people in this blue and red here have got viral loads, still on treatment, between above 50, in the blue 50 to 500 and in the red greater than 500. Now, here is a study of looking at patients who are only given boosted PIs.

Now, when you look, there is a yellow— the people who are undetectable; there is the green who have dropped out. You can see here that the red that are running through this is rather larger in terms of people on the monotherapy who have got viral loads greater than 50. And the question is that although this could save you money and toxicity in number of drugs, will these patients get resistance or will they continue to transmit HIV because of the level of viral load either to their unborn child or to their partner?

So, I am now coming to the last section which is new class of drugs which we have developed recently, integrase inhibitors and the one that is being licensed as raltegravir, and CCR5 antagonist, maraviroc. What is the place of new drugs in the HIV treatment-experienced patients? These are people who have had many therapies in the past and often developed multiple resistances. We must now aim for viral load undetectability in these patients because the likelihood of them reaching that is dependent of them having active drugs in the regimen and, if possible, use a new class. And actually for resource-poor countries, if you have virological failure on

your first regimen, this sort of paradigm should also fit with them that you should, again, aim for viral load undetectability with adequate therapy.

So, if you look at some of the randomized trials here, these trials had patients who had three drug experience, had a lot of resistance, had AIDS in the past, had low CD4 counts, and you look at the undetectability rates that are being sustained after 48 to 96 weeks in these people, it is approaching in some of the studies what we saw in naïve patients. The lesson is, give patients drugs that work and they will work.

So, what about the naïve patients and these new drugs? Well, there was a study of maraviroc against efavirenz in naïve patients but it did not quite match up to the efavirenz. But the problem is that you can only give a CCR5 inhibitor to patients whose virus uses this exclusively and the test to look at this, which is complex and expensive, was not, we believe, as accurate as we want to select these patients at.

Integrase, as you saw all presentation this week, has very good 96-week data but a large comparative study is now being under way in naïve patients using this drug. What about, again, not giving people nucleosides but giving boosted PI and integrase? We need the data and there is a trial planned in Europe by the NEAT Network using efavirenz, then offer FTC as a reference arm to look at some of these strategies.

Finally, public health issues and HIV treatment. There has been a huge debate here, excellent debate about the Swiss proposal that if an HIV-infected person has an undetectable viral load, could they transmit their HIV to their partner? Of course, probably not if they are in entirely monogamous relationship but actually we should not undervalue other preventative things that people have to do like use condoms, et cetera. But this debate is ongoing and I think it is of great interest to us all in terms of the interaction between treating individuals and the impact on society in a rather different way.

Now, it has been said we cannot treat our way out of the epidemic but the group from British Columbia report forward a very interesting proposal that, if you expanded HAART to everyone diagnosed with HIV below 350 cells together with prevention strategies, would that have a pronounced effect on transmission by reducing viral load to the population level? Obviously, there are lots to cover tonight. You have to find everybody, you have to have the resource for treating everybody and perhaps in certain situations, it is a very good parley to look at.

So, treatment works if you have access and you can stay on it. But today's reality is that for every new person starting treatment, two to three more are newly infected. We cannot— we are unlike a treadmill, we cannot catch up. So

prevention and treatment partnership are still crucial to fighting the epidemic. Access to a wide range of antiviral is needed to treat patients wherever they live in the world and they needed you. [Applause]

And I would like to thank many people especially my good friends Sharon Walmsley, Jürgen Rockstroh, [inaudible] for mentoring me through this talk. Thank you very much indeed. [Applause]

LARS KALLINGS, M.D., PH.D.: On behalf of us all, I want to thank you for an excellent, inspiring, and educational presentation this morning. We look forward to talking with you more.

Good morning to everyone, and [Spanish language]. Sometimes, when we think we are the one who is here to help others, we learned that we are actually receiving more than we are giving. As an advocate and supporter for people with disabilities, our next speaker learned that human will, can override any obstacle life provides. She has used these lessons to direct her own life and also to inspire others. This more, I see in how she has inspired me indeed and I have been the recipient of her courageous leadership and mentorship.

And, so, with great pleasure that I introduce to you, Rolake Odetoyinbo, or as we know as Rolake. Rolake is the executive director of Positive Action for Treatment Access (PATA), an NGO dedicated to the promotion of the rights and

well-being of women living with HIV and AIDS in Nigeria. She is also an activist, an advocate, a writer, trainer, public speaker, television producer, and presenter. For over 10 years, Rolake has been fighting for the rights of the marginalized and the vulnerable in societies.

It is, therefore, with extreme personal pleasure that I welcomed Rolake to the podium to discuss the greater involvement of HIV positive people in healthcare. Rolake. [Applause]

ROLAKE ODETOYINBO: Good morning, everybody. Thank you. My name is Rolake Odetoyinbo. I worked and live in Lagos, Nigeria. This presentation by myself, Alice Welbourne, and David Stevens; I could not have asked for better people. I really truly feel like a child of the village, a true community child. Thank you everybody.

My name if Rolake like I said. I live and work in Nigeria, the most populous country in Africa. Nigeria is better known as the giant of Africa. We have a population of 140 million people. We house over one-fifth of the entire African continent, a continent where most countries have very weak health systems. Our human capital and health-delivery capacity is being depleted and health is treated as a privilege rather than a right. They exist to disconnect between health system governance and the government. Maybe for some countries, this is excusable but it is not in Nigeria, the

sixth largest producer of oil in the world, a country of enough riches to provide all of us with comprehensive healthcare. Countries like mine are called resource-poor countries. However, most of the time, we are resource-mismanaged countries. We are mismanaged by our leaders. [Applause]

We are mismanaged by our leaders, many of whom are self-centered and we are also mismanaged by neocolonialists who dictate our tune under the guise of foreign aid and loans [applause] and this they do in return for our very souls. Harmful policies are allowed and imported to our country and shamelessly promoted as sponsored. Our country's resources are also mismanaged by you and I— those of us who sit down grumbling doing nothing to effectively hold them accountable. We are the ones, the late Fela Ransome Kuti called [foreign language] which mean onlookers.

Fela Kuti, the fearless human rights activist was the very first man whose AIDS-related death jumpstarted HIV interventions in Nigeria. When he died, his brother was a Minister of Health and it was the first time publicly they would announce that a public figure died of an AIDS-related illness. This year, we marked the 30th Anniversary of the Alma-Ata declaration of 1978 which was the first attempt to unify thinking about public health for all within a single policy framework.

This year also marks the 60th anniversary of the Universal Declaration of Human Rights and of WHO. These anniversaries remind us what is fundamental to our struggle to secure health and well-being for people with HIV and that the attainment of the highest possible level of health is the most important worldwide social goal. 2008 is the 14th anniversary of the declaration of the principle of greater involvement of people living with HIV and AIDS, GPA. In the response to the epidemic, it is deeply shameful that we still have so far to go in realizing the visions of this declaration.

Personally, as I mark my 10th year of survival with this virus, I invite you to come with me on a journey of what it means to be a woman living with HIV, how it feels when our healthcare systems badly let us down, how it feels to know that I as an individual and millions like me around the world have so much to offer our communities and how it feels for that offer constantly to be rejected, ignored, or even forgotten about and even for us to be stigmatized and criminalized as carriers of HIV treated as victims. Our inspiration comes from very many activists throughout history who has trouble to place the dispossessed women and the poor, all marginalized people are the center of the human rights agenda. And like us, people living with HIV to participate in the policy decisions around HIV globally and nationally is rooted in the 1948 Declaration of Human Rights and in the GPA Principle.

The term GPA was coined at the International AIDS Conference like this, the 1994 Paris Summit. Though AIDS represents a global movement that has a far longer history, the GPA statement recognizes that our contribution at all levels and in all sectors is critical to ethical and effective national response to the epidemic. GPA is important to those us living with HIV because we know that the world needs us. GPA reminds us of the need to take control of our life and health. Professor Wole Soyinka said, “The man dies in all who keep silent in the face of tyranny.” People living with HIV will not keep quiet. We will keep on talking because silence equals death. We will keep on speaking out, one for all, remembering that many people, women especially, who want to speak out about HIV cannot risk doing so for various reasons, not least protecting their bread and their children.

People living with HIV have placed a lot of importance in health systems. However, what then do we mean by health systems? The WHO world report 2000 defines health system as all organizations, people, and action whose primary interest is to promote, restore, or maintain health. Health system includes a mother caring for her sick child, private providers, behavior change programs, and safety legislations. Health systems should provide health and health equity in ways that are responsive, financially fair, and make to most efficient use of available resources. This sounds to me like health

systems, these are collective responsibility. As the WHO report indicates, this is everybody's business and that is the title of that publication.

As people living with HIV, we have learned the hard way, that our health outcome, relying only broad set of institution and systems as well as our communities and ourselves. For most of us living with HIV, none of us expected to have to learn so much so fast about things we never imagined we would need to face in life. Many of us and many of our children and family members who have seen the effects of HIV in their lives are either trained formally with caring profession including health or having formally become so-called patient experts on all aspects of HIV prevention, treatment, and care.

In patient's experts, I think, will be a better way to describe us. We are perhaps the most health and treatment literate trained body in the history of disease. To truly understand the importance of the impact we have made in the response to HIV, past, present and future, we must acknowledge the place of people with HIV in developing and fighting for the foundation now and most effective response to this epidemic. This includes the concept of safe sex, the pioneering of harm reduction, the value of peer education, progressive and inclusive policy and law beyond documented caring, the insights into treatments, the tireless work on prevention education, the creation of supportive organizations and groups often in

extremely hostile environments and the human rights campaign and sacrifices of many people living with HIV and AIDS. People with HIV have been instrumental in reshaping critical areas of HIV research from basic science to behavioral and social research.

The experience and knowledge of people living with HIV have been essential to setting a direction which is relevant, respects of right research participants and can be transferred into other interventions which will make a practical and immediate difference. Treatment activism must help us change the way in which drug trials are conducted and the approval process or the process on access to new drugs. Our involvement in this field deserves a plenary of its own. However, I am sure Gregg will tell us more about this.

In social research, our involvement helps to build the trust between researchers and holistic matters in marginalized groups helping researchers learn from their experience and insights of communities. Our involvement most certainly delivers better research outcomes and help researchers need to move to fully recognize, integrate, and value the roles we play and should take in health research.

People living with HIV have started participating in the global governance, structures of the UNAIDS, the Global Fund, and other global structures. We act in senior management and decision-making roles in addition to the critical work we

do in our communities. However, huge gap exists at the national level. We call on governments, "Please open your doors to our involvements. Doing this, you will reap the reward in thousand fold."

In terms of prevention, we have a program called Stepping Stone which I am excited to say was developed by Alice, my co-author. This is an initiative that has been created out of personal positive experience founded on the basis of care, respect, support for and inclusion of everyone with HIV in the community. And now, it is reducing gender violence on all continents of the world. Thousands of us are actively involved in prevention work, and contrary to what some people think, we are not interested in spreading this virus. However, there are specific challenges we have. There are high numbers of healthcare workers living with HIV in high-prevalence areas. As I speak, HIV is decimating the health workforce in many countries. The statistics are chilling as these lights from Uganda shows us.

This problem also exists in so-called developed countries. In the United Kingdom, many staff living with HIV and employed by the National Health Service are still terrified of their colleagues and managers finding out their HIV status. At the recently concluded workshop which we held for advanced staff members in Nigeria. More than 70-percent of participants believe that healthcare providers living with HIV should be

prevented from conducting active clinical work and invasive procedures.

We need to have official recruitment of people living with HIV in health system and this is limited where it does happen. It is mainly as peer educators and counselors. These jobs are important but the lack of a proactive approach to recruiting and supporting staff in more senior position reflects and reinforces intrinsic man discrimination. In Europe, Raoul Fransen recalled the appalling way he was treated in medical school when he disclosed his HIV positive status. Things got so bad he decided to take his considerable talents into public health instead, luckily for us all.

In Africa, my dear assistant and friend, in tragedy however, chose to stay and fight for her rights to remain in school and become a nurse when she was diagnosed while still a 19-year-old student nurse. If GPA is changed to make greater investment in people living with HIV and AIDS, health workers living with HIV must be affirmed and encouraged. Opportunities must be created to help us become the very best we can be.

Until very recently, doubts about the capacity of health systems and people with HIV particularly in Africa to manage ART was common and this delayed the introduction of treatment would relate to the death of so many very people. These doubts were at best ill-conceived but, more often it was a thinly-veiled racist commentary on African people. In

accessing HIV services, many people run risks which may outweigh the benefits.

You have entrenched judgments about sex workers, men who have sex with men, transgender people, and drug users which means that quality care is simply not available. If you do not believe me, ask the woman who has been coerced into having an abortion or sterilization, ask the drug users who have been locked up and made to suffer forced detoxification and the loss of their liberty, ask men who have sex with men, and transgender people who are routinely beaten and denied access to basic services.

Health systems, however, are still struggling to integrate healthcare with other services essential to support the in people living with HIV, TB, and malaria. Sexually transmitted disease, sexual reproductive health, and mental health services need to be integrated into HIV services. HIV highlights how ineffective this vertical approach to healthcare and prevention is. We need to have programs which do not squeeze people into boxes created by management systems, prevention of mother-to-child transmission programs and not designed as reproductive health services. We are treated as machines for producing HIV negative babies. We are treated as victims of diseases, not as female beings, not as women with sexual and reproductive health and health rights. [Applause]

Unless the international physicians for health rights and the international community of women living with HIV, of all documented partner violence experienced by countless women after tested positive to HIV. It is rarely reported because violence is considered acceptable in marriage but it results in physical, sexual, and mental health problems experienced by these women, their older children and their babies. Women living HIV experience many kinds of social and economic barriers to accessing treatment and to ensuring that they are able to adhere to treatment once they get it. This is shown by ICW treatment mapping exercise funded by WHO HIV Department in three African countries.

Despite the findings from this research, WHO HIV Department has to date not reported these findings in any of its literature. Instead, it continues to publish reports simply stating that more men than women are accessing areas from public health with same status. To rub salt into our wounds, women are now being criminalized for transmitting HIV to their children as part of laws around the world, criminalizing HIV transmission in general, criminalization not only of transmission but of nondisclosure of status. Tomorrow the plenary will talk more about this criminalization of HIV infection.

Psychosocial support is desperately needed around the world. A recent study in the United States found that people

reporting HIV-related symptoms or treatment side effects were 15-percent more likely to report thoughts of suicide. We need the power to recognize that the entire AIDS response in so many affected regions especially in Africa has been built around home-based care coming from communities. Women carried the burden of care whatever the nature of the pandemic. Talk to mothers of gay men with HIV, partners of heterosexual men, hemophiliacs, and injecting drug users and you hear the same story over and over again. It is not just women who are unheard, invisible, unpaid, and desperately stressed.

Girls are the first to be pulled out of school to help their mothers cope. The first to have to use their bodies sexually to find alternative source of income, the first to be sent off to work as house servants for relatives where they are frequently exploited or married off so that there is one less mouth to feed. In spite of these difficulties, we have carried on with very limited funding.

We should sing the praises of many millions of people with HIV around the world who had to win in their own feat openly or undisclosed to make the world a better place for people all around them. Today, we salute Dr. Lydia Mungherera and her colleagues at the Mama's Club in Uganda. They are proud recipients [applause] of this year's Red Ribbon Award for their great work in providing psychosocial support for young positive mothers in Uganda. We also salute the great Dr. Jorge

Saavedra Lopez openly positive director of Mexico's National AIDS Control Center. These inspirational people have given us all so very much. [Applause]

All our initiatives and these courageous people are really struggling to keep going these glimmers of light and hope in a very dark sky. We must make these glimmers the norm, the expected. The continued involvements of people living with HIV in healthcare requires drastic step to eliminate HIV-related violence and discrimination. We have to stop violence against women. We have to stop institutional violence against sex workers, drug users, men who have sex with men, and transgender people. We owe it to human right institutions, governments and justice systems to recognize and act against the endemic violence that people living with HIV and AIDS are subjected to day after day.

For things to change, we must have some solutions. Things will not change, however, unless people with HIV are centrally involved. So, we all need to step outside of this sealed-management and system-focused boxes to develop propaganda and people-centered, not system-centered thinking to create holistic project which reflect real lives. This means understanding that a functioning health system is everybody's system. Nobody has autonomy to healthcare system. We all are and must be involved. It means listening to what can we and supporting the meaningful involvement of people with HIV to

understand how issues like law, food, or violence interconnect and how they affect health and health systems.

The WHO HIV Department has also started thinking like UNAIDS. It is beginning to commit to a meaningful civil society consultation process to recognize at last the non-biomedical dimensions to this pandemic and respond to the bringing of health system in a true holistic sense.

We need WHO to maintain the policy of keeping all data segregated by sex and age throughout healthcare systems worldwide. Dear Dr. De Cock, we plead with you. Please use the global leverage of WHO to support people living with HIV and challenge this criminalization of HIV transmission. [Applause]

We desperately need wellness centers like those run by the Swaziland Nurses Association which provides treatment, care, and support and counseling for health workers and their families. These services are essential to keeping our highly valid health workers alive. We need to increase universal access to health and eventually reverse the devastating loss to AIDS amongst all people with HIV. Let us see a new GPA. GPA like Ron McKinley has taught me, GPA that means greater investment in the lives of people with HIV and AIDS. GPA that means greater investment in the lives of those directly affected by HIV and AIDS, [applause] all partners should recognize an adequately reward the roles we play.

We should not simply be volunteers and recipients of services. We need to have our skills and hands, provide us with jobs and consult us when programs and qualities that affect our lives are being designed. Resources, however, are nonnegotiable. We need to fight to get them. Funding for HIV has come on the fierce criticism for drawing funds away from other present healthcare needs. This is not an either/or situation nor is this argument against HIV funding supported by evidence. So, let us here and now move beyond squabbles about AIDS versus TB, AIDS versus malaria, AIDS versus safe drinking water, and AIDS versus food security. We need more money for healthcare and more money for HIV, not less. [Applause] It is time to shift the balance and stop our in-house squabblings for resource control.

Our government must ask the Global Fund to fund grants to address massive healthcare workers shortages that are undermining all our efforts. This includes funding for recurrent costs like salaries, for efforts to reduce stigmatizing behavior by healthcare workers, money for treatment literacy, and yes, money for health technology currently available only in the rich nations. Universal access must mean universal standards. The quality of care I get should never be determined by the part of the world where I live. Universal standard is what we want. [Applause]

There is clear need to place the expansion of health education and services at the center of national economic planning if we are to seek countries truly able to respond to HIV and AIDS. This cannot be achieved unless governments are allowed to invest in health without the restrictions imposed by the International Monetary Fund (IMF). Because of IMF, so many of our countries are unable to employ health workers because they have restrictions and this is having a huge toll and a huge burden in our systems. [Applause]

Finally, to people living with HIV all over the world, through our own personal journeys of pain, grief, and the realization of our mortality, we do indeed have a rare gift to share with this world, a greater insight into the true meaning of live and death. We have toiled to make a difference around HIV in our communities. However, most of the time, our efforts are trivialized and we often feel patronized by other stakeholders. Those of us who are living with HIV and have come to terms with that diagnosis, those of us especially who are decided to dedicate our lives with this cause of activism the long journey we all have taken in our lives to get where we are today in terms of our own ability to survive the traumas of our diagnosis and daily fight for our rights to existence. Each and every one of you who live and breathe HIV is a leader, people with other health conditions look up to us for inspiration.

The world recognizes our leadership and we know that very soon everyone will celebrate and respect the roles we have played at this time in human history. People living with HIV never, ever forget you are a leader. Do not give up, when life knocks you flat on your face get on your knees. Stand to your feet, hold your head high, and keep on going. Thank you very much. Gracias. [Applause]

ROLAKE ODETOYINBO: I am supposed to introduce Greg, but I should start by thanking Rolake. Thanks. [Spanish language] I bring you greetings from the World Health Organization and its staff who serve in 193 countries around the globe including the 80 or so who are attending this meeting. In the 34 years that I have been privileged to be a doctor the most extraordinary experience unquestionably has been witnessing the emergence and the spread of the AIDS epidemic in all its heterogeneity. The second most extraordinary experience is to see the introduction of antiretroviral therapy, its almost miraculous effect on the brutal manifestations of HIV disease and later its global scale up.

The advances in treatment that have resulted in 3 million people worldwide being maintained on therapy at end 2007, the science of antiretroviral therapy, the clinical trials, the clinical applications, and the extension of all of that to people who are poor would not have happened without the

pressure from AIDS activists and civil society groups. It simply would not have happened. And, another product of the epidemic humbling and sometimes challenging to a physician like myself has been the emergence of a cadre of activists, many living with HIV, whose self taught knowledge of technical issues combined with frontline experience gives them the right to a seat at any scientific table. And, they remind us that rights are not always granted, but often must be taken.

This experience of AIDS activists and treatment access well as experience in AIDS always does, already has, unquestionably influences other spheres of medicine and health, which actually may be one of the greatest legacies of AIDS activism because universal access is not about HIV alone. It is about viewing attainment of the health related millennium development goals including those in child and maternal health as a global public good. But, we are here to talk about unfinished business of HIV and therefore yes the still greater expectations that we have of activists in civil society.

And, let me mention just three immediate challenges where activism is better placed in any other force to change norms and increase our chance of achieving universal access. First is repeatedly emphasized at this meeting. We must forge a strong indivisible coalition between prevention and treatment, strong and indivisible, including positive prevention, which WHO views as a holistic continuum that

ensures people living with HIV maintain their own physical health through preventive care interventions, such as access to safe water, malaria bed nets, isoniazid preventive therapy, and other interventions that they benefit from sexual and reproductive health, and family planning as basic rights. And, that therefore they will be better placed and better able to also prevent transmission of HIV to others. This is urgent everywhere, but especially in the unbelievably severe co-epidemics of HIV and tuberculosis in Southern Africa.

Second, activism and civil society must reintroduce urgency and energy for prevention of HIV amongst men who have sex with men who live their lives sometimes proudly, sometimes furtively, not just in San Francisco or Amsterdam, but also in small places in every country on every continent. Places so small that you will not find them on any map of the world. Do not ask me why it has taken 27 years for us to recognize that? [Applause] Activism must emphasize from today that the epidemic of HIV in men who have sex with men is a global epidemic requiring urgent attention.

Third, as Peter [misspelled?] emphasized yesterday, we must do better with HIV testing. Universal access will remain a cruel hoax without increased knowledge of serous status. If only 20 percent of persons living with HIV in low and middle income countries know their HIV status. We need activism and civil society to change attitudes around HIV testing. HIV will

declare itself either through a test result or through the unforgiving natural history of HIV itself. We have to choose.

The coalition between public health and civil society can overcome any remaining distrust and barriers around this issue. WHO supports voluntarism and consent opposes coercion fights stigma and discrimination is evidence based and rights based. But, once and for all together let us abandon tolerance of preventable death from AIDS. Let us never pretend that it should be a human right to die of AIDS.

That is provocative, which brings me to our speaker. Gregg Gonsalves has been living with HIV for many years. He began his career as an AIDS activist, as a treatment activist in 1990 to 1991 with Gay Men's Health Crisis in New York City, ACT Up, and the Treatment Action Group, three groups who have had such a profound effect on this epidemic. In an act of solidarity in 2006 he moved to South Africa where he coordinates a program to educate communities on AIDS and TB treatment, how to advocate for rights to health care administered by the AIDS and Rights Alliance for Southern Africa based in Cape Town. It is the only regional network on human rights in AIDS in Southern Africa and promotes a rights based response to the epidemic to advocacy training and capacity building.

I am pleased, very pleased to introduce Gregg, whom I consider a friend, but I am especially pleased to call a colleague. [Applause]

GREGG GONSALVES: Buenos dias. Do you remember where you were eight years ago? I remember it distinctly. In the summer of 2000, I was in Durbin, South Africa for the first and so far the only International AIDS Conference held on African soil. You know, there are many unkind things said about these events, but those few days in South Africa changed the lives of millions of people forever. I still get shivers when I remember the challenge directed at us by Edwin Cameron, a Justice of the South African Supreme Court of Appeal, and an openly HIV positive gay man. He said those of us who live affluent lives well attended by medical care and treatment should not ask how German's or white South Africans could tolerate living in proximity to moral evil. We do it ourselves today in proximity to the impending illness and death of many millions of people with AIDS.

As Edwin was appealing to the delegates conscious' thousands of ordinary men and women from the treatment action campaign were outside marching on the conference center demanding access to AIDS treatment. Their message was simple. We are sick and there are drugs that can make us well. We are dying and we want to live. Edwin's challenge and the marchers' demands could have gone unheeded. There were plenty of

naysayers telling us that AIDS treatment was not cost effective in the developing world and that we should only focus on HIV prevention. They said that antiretroviral therapy should wait until we had more robust health systems to manage such a complex intervention. They said such things even though they knew the wait could be decades long and that tens of millions of untreated HIV positive people would likely die over those years.

Luckily the cry for access to AIDS treatment was answered shortly thereafter by a few brave leaders in the public health community spurred on by activists and challenged by activists and people with AIDS around the world, they took on the conventional wisdom and launched, most notably, the Three by Five Initiative, the Global Fund to fight AIDS, tuberculosis, and malaria, and the president's emergency plan for AIDS relief. Such initiatives have now made AIDS treatment and many other services available to 3 million people, millions of people in poor and developing countries would be dead today without it.

The scale up of antiretroviral therapy is the most ambitious public health undertaking of our lifetimes. Make no doubt about it, we are making history together; activists, scientists, policy makers, doctors and nurses, government and public health officials, and ordinary men and women in communities around the world. AIDS has radically shifted the

trajectory of global health. Instead of settling for the bare minimum of services for people with HIV, advocates for the disease have made the case that no one should die from a treatable illness simply because they are poor. Until recently, the idea of health for all, the core promise of the Alma-Ata Declaration signed by the World Health Organization member states 30 years was, as my colleague Paul Former [misspelled?] has said, "the bud of international ridicule and international health circles."

The problem may have been made long ago by others, but we will keep it. In fact, we are the heirs of Alma-Ata, of the struggle for primary comprehensive healthcare, a campaign that was launched 30 years ago. Each treatment can be the catalyst, is the catalyst, for building comprehensive primary care for poor people all over the world. Indeed, AIDS treatment— [Applause] Indeed, AIDS treatment can only be sustained over the long term if we succeed in this task. Although the goal is ambitious and the conventional wisdom will always tell us to settle for far less, we have already done the impossible.

Where are we today? You have heard already from Alex Katino [misspelled?] earlier this week that there are now three million people alive today on antiretroviral therapy, despite the warnings that saving their lives was unwise, unsustainable, and was contrary to expert opinion on how health and development should work, but we saved lives.

Here are the data on city core counts and a large cohort of patients on ARVs in low and middle-income countries, and mortality data from the largest ARV trial in Africa, compared with an untreated cohort. Now, how did we do this? How did we sustain and build upon our success? First, we set targets. We did not meet the Three by Five goals on time, it took us two additional years to reach 3 million people on antiretroviral treatment, but the lesson to learn on Three by Five is not that we should not be so ambitious, instead it is that setting a goal and striving towards it is the only way to make significant progress towards that destination. [Applause]

Unfortunately, the current campaign for universal access was built without global targets because UNAIDS, Gifid [misspelled?], and the US government refuse to accept them. I was at those meetings, I heard them speak. At the same time, the definition of universal access is so now irresponsibly vague. Just take a look at the latest UNAIDS report which contains more twists and turns than an Olympic gymnast to avoid any concrete commitments. The decision not to include global targets and to step back from specificity is a political one taken by organizations and agencies that are political to a large, if not complete degree, but that is really a poor and pathetic excuse, and one with potentially devastating public health consequences. Unless we have clear targets with clear timelines, we will never reach our goal of universal access.

[Applause] Approximately 10 million people need antiretroviral therapy today, perhaps we can reach that goal by the next time we gather in Vienna in 2010, but let us not leave Mexico City without attaching a firm deadline nonetheless, and let us not set the goal so far into the future that it becomes essentially meaningless.

Second, scaling up antiretroviral therapy in resource poor settings would not had happened if it had not been done in richer nations. The scale of the problem and the paucity of resources meant that a new way of providing healthcare needed to be developed, now known as the public health approach. The public health approach depends on standardizing ARV regimens, thus simplifying formulas and lowering procurement costs through bulk purchasing, simplifying algorithms on when to start, substitute, and switch and stop regimens. It involves standardizing monitoring of the response to treatment, management of toxicities and drug to drug interactions, and population level monitoring of drug resistance.

In addition, the public health approach requires decentralizing delivery of care, task shifting ensuring that services are free at the point of care, strengthening procurement and supply management, and tracking ongoing progress.

Finally, the public health approach – these antiretroviral treatment is a matter of chronic disease

management to be treated in the context of primary care. Please remember that last point.

Despite our success, coverage of antiretroviral therapy in low and middle-income countries is still at 31-percent of need. The lives of millions of people depend on whether we can expand the reach of these programs. Furthermore, for 3 million on ARVs now, their continued survival depends on long-term management of their HIV disease which means we must strengthen primary care systems to manage AIDS as a chronic illness. It is going to take sustained commitments from donors, countries, healthcare workers, communities themselves, all of us, to make this happen. And it is going to take political will. But remember, we have accomplished the impossible in the last 10 years. We can succeed again, but our future is precarious. The technical challenges are formidable and the political ones are brutal.

Let us start with the technical challenges. We have a lack of human resources. There are plenty of presentations at this conference about a shortage of healthcare workers, but while we think of long-term solutions for increasing the supply of trained professionals on ART, we need to invest in task shifting now to deal with this crisis. We cannot rely on position driven models for providing antiretroviral therapy. There are simply too few doctors to go around. This means that nurses, clinical officers, community health workers, and even

non-clinical staff, need to take on activities that they have never been asked to or allowed to do, such as allowing nurses to provide and prescribe antiretroviral therapy. We need to move beyond the resistance of governments and professional societies, stop talking about this, and make this really happen. [Applause]

However, task shifting within the health sector ignores the greatest resource available, communities themselves. Now, what does this mean? Arasa [misspelled?] treatment action campaign and our partners have been working in southern Africa to educate and mobilize communities around their own health, to map services and communities, work in clinics, and act as watchdogs for provision of services. We advocate for what communities need and communicate this to district and national health officials. This is not just about expanding home based care which narrowly cast communities' roles in health, but about bolder attempts to turn communities themselves into the first line of primary care providers, as Ernest Darko [misspelled?] has said. We need to enable patients, with the help of their families and communities, to take more control of their own disease and its management. This is a critical tenant of chronic care delivery for problems like diabetes or hypertension, and it can be done for HIV if we get away from the need to have an expert specialist at every turn.

Now, though the human resource needs are acute in low and middle-income countries, there is also a shortage of leadership and management skills that is hampering the efficiency of programs and slowing the rollout and scale up of antiretroviral therapy. Those working on scale up of antiretroviral therapy have little training in basic skills like planning, budgeting, strategy development, problem solving, running a meeting effectively, creating a work plan, organizational and project structuring design, managing teams, and monitoring evaluation. These things are not very sexy, let us face it. They sound rather bureaucratic. But in reality, they are vital to the core goal of helping as many people get access to treatment in the most sufficient sustainable way. We need to invest in building these skills now in the health sector, while addressing the large inequities and access to education in low and middle-income countries which have created these problems in the first place.

In addition to the shortage of human resources, the physical infrastructure of health cannot cope with the expansion of services required. Clinics are overcrowded with patients with AIDS, with TB, and many health needs. Pharmacy shelves are sagging under the weight of AIDS drugs; laboratories are ill-equipped for even the most basic services, let alone more complex technologies like CD forward counts [misspelled?] and viral load. We need to renovate existing

structures and build new buildings for AIDS and general primary care into the future. Now, this is not about vanity projects, those littering buildings you see in many capitals to house national AIDS commissions, international NGOs, or as monuments to new partnerships between academic institutions in the north and the south. These are basic structures; health posts, health centers, hospitals, hospices, laboratories. [Applause]

You know, at least once a week I get an e-mail about an AIDS or TB drug stock out somewhere around the world. The lack of secure and reliable drug supplies is the Achilles heel of ARV programs, risking drug resistance, and undermining our success in AIDS treatment. Central medical stores in many countries just cannot simply handle this task. We need to be honest about this and contract out this effort of if necessary. This is where the sterile debates about horizontal versus vertical approaches to health are over simplistic. We have simply just got to do what works in the short term, and get the drugs to people, while simultaneously trying to address the longer term challenges, the supply chain management, and the health sector. This is not rocket science, but we cannot hold decisions about supply chain management hostage to theoretical debates and political dogma. [Applause]

Now, we need regular and reliable national data on ARV scale-up, not estimates, but real numbers. This means the capacity of countries and donors and healthcare workers to

collect, compile, and evaluate the data that these skills need to be enhanced. There needs to be standardized registration, recording and reporting procedures allowing for quarterly cohort analyses or treatment outcomes, particularly survival; whether people are alive or dead at all sites. These data need to be reported to WHO and back to the sites on a regular basis. This kind of program monitoring needs to be integrated into and highlighted in the public health approach and endorsed by WHO, and we need to keep things simple. Government attempts to develop simple and uniform monitoring systems are all too often undermined by a multitude of donor requirements, while these requirements in themselves are frequently difficult to collect using a paper based system, and this is spawning an industry where untested technology solutions are offered as a panacea to ease reporting requirements.

The public health approach to ART demands we use simplified and standardized regiments. Right now, the backbone of ART programs around the world depends on D4T based regimens, mostly because of cost; the medium cost is about 91 US dollars per patient per year in 2007. However, the toxicities assorted with D4T including painful peripheral neuropathy and lithoatrophy [misspelled?], neither of which are likely to be reversible, make it highly problematic. Yet, this simple change has significant cost implications because the most common used to replace D4T, Tenofovir, is much, much more

expensive. Tenofovir alone is slightly under 200 dollars per patient per year from generic suppliers. Therefore, in South Africa, making a switch from D4T to Tenofovir for instance, and making that cost-neutral for the South African government would mean bringing the price down to 74 dollars per patient per year, according to a recent study by Sidney Rosen [misspelled?] and others at Boston University. But the cost of switching regimen, indeed making any change in ART programs, has other hurtles as well. Staff need to be trained, there are procurement issues, with Tenofovir there are real renal toxicity risks, do we do creatinine screening at baseline, and if so, what are the implications for this? Not just in terms of cost, but in the complexity it adds to scale up.

There are other problems with other drugs. Nevirapine's interactions with Rifampicin make it a suboptimal choice in settings of high TB prevalence. Switching from Nevirapine to Efavirenz for instance would make ART more costly for programs. In addition, since Efavirenz is [inaudible] indicated in pregnant women, moving away from the therapy would perhaps mean having two different regimens for men and women, increasing the complexity of drug supply and management for programs. Challenges like these are straining the need to depend on simplified standardized regimens over the long term.

Other pressures are moving us away from a public health approach. For instance, there is compelling evidence that

earlier initiation of ART at 350 CD4 sales is superior to long established guidelines recommending that individuals begin treatment when their CD4 counts are below 200 cells. However, it should be pointed out that much of this new data is from cohort studies, not randomized controlled trials, and from resource rich countries rather than resource poor settings. Raising the threshold for starting therapy may be clinically beneficial for some patients, but its wider impact on health services may end up weakening ARV programs by creating longer cues in already saturated natural programs using relatively temporary facilities where even now the sickest patients have troubles accessing medicines.

Lifting the threshold for initiating ARVs at 350 CD4 cells without assessing the effectiveness, indeed the feasibility of this intervention at the population level in low and middle-income countries, may end up doing more harm than good. The question of when to start antiretroviral therapy has vexed the field for years now. It is time to do a study to answer this question in resource poor settings. And we cannot forget perhaps the most basic obstacle. Patients do not come forward for care until they are very sick. We are going to have to do a whole lot better at getting people to know their status and getting them into care before earlier initiation of therapy becomes more than just a theoretical concern.

Even when we do have data on changing treatment guidelines from randomized control studies in resource poor settings, as we have heard from the shared study, how to provide universal access to ARVs for infants before 12 weeks of age, has some significant hurtles from lack of access to diagnostics, to pediatric formulations, to health care workers trained in how to treat young children. Perhaps the best way to deal with the complexities of treating pediatric HIV infection is to ensure that infants are not infected in the first place by making sure that all pregnant women get the treatment and care they need. [Applause]

Finally, there is a great deal of pressure to institute virological monitoring and treatment programs, but this often comes from researches and some activists even in the north, who seen any detectable viral load as an anathema. However, you look at a recent study in *The Lancet* by Andrew Phillips for patients on first on regimented Stavudine, Lamivudine, and Nevirapine. The benefit of viral load or CD4 count monitoring over clinical monitoring alone are just modest. The conclusion is not to delay access to treatment while waiting for new diagnostics. Before rushing to make treatment programs more complex, most costly, we need to weigh the evidence on both the clinical benefits and risk for patients, but also on the feasibility, on the operational risks and benefits for programs.

As we look into the future, with millions of people on ARVs, we are going to need to manage the long-term complications of not only ARV therapy itself, but also the other [inaudible] that are now going to strike us, people living with HIV and we live longer and healthier lives. This brings us back to the question of comprehensive primary care. Scale-up of antiretroviral therapy in low and middle-income countries has been a miracle for millions of people who are alive today because of these drugs. Technical challenges can be overcome, but the political challenges ahead are toxic. This means that all of us in this room, in fact all of us who believe not just in the struggle for AIDS treatment, but for health for all, for comprehensive healthcare, need to make a commitment today to become activists in any way you can.

Right now we are seeing a backlash against AIDS that is being led by some very senior figures in the health and development community. You have likely heard their three-pronged mantra. Put simply, it goes like this: the threat of AIDS has been exaggerated, AIDS gets too much money, and AIDS is destroying health systems. These people want to take us backwards. Their vision is essentially destructive, their hopes for the future incredibly small. They are saying we must be satisfied with doing less for less, that we should provide a few basic interventions in the health sector because doing any more will create unsustainable entitlements to health for the

poor. Their words and attitudes threaten to hobble, if not kill our efforts to scale up ART and to strengthen primary care for low and middle-income countries. They are public health minimalists promoting Malthusianism for the masses while they sit at home with easy access to the highest level of care for themselves and their families. [Applause]

These naysayers are wrong in so many other ways. First, they make the naïve assumption that funding for AIDS can be quickly and easily shifted to fund their utterly vague notions of the horizontal. Activists for primary care have been advocating for more funding for years, but until the movement for AIDS treatment, we did not have the billions to make a real run at health for all. It has been 30 years. They also completely missed the point of AIDS treatment; it is fundamentally a health systems function. If you ask the most competent health ministers in the world today, they will tell you that all health systems need both focus and breadth. Without continuing sustained focus on AIDS treatment, many millions of the poorest and most marginalized people in the world will die, period. And without breadth, not only will AIDS treatment be incomplete, but we will miss the greatest opportunity in history to build functioning health systems in some of the poorest countries in the world. [Applause]

Let me say this very, very clearly. Stop the inane sterile arguments about AIDS funding versus health system

strengthening. The real task is to bring everyone together, and by everyone I do not just mean all of us working in health, but systems engineers, architects, management and operation specialists, and other unusual suspects whose expertise and insights we need and which will be invaluable.

Let us move forward together. Scaling up antiretroviral therapy depends on a new movement to provide comprehensive healthcare in low and middle-income countries to all who need it. The systems that will sustain ART provision and make it a chronic manageable illness are the same ones that will ensure health for all, that will allow us to address sexual and reproductive health, maternal and child health, the management of other infectious disease and chronic conditions, to provide care for marginalized populations including substance use, treatment, and harm reduction. We have got a chance to fulfill the dream of Alma-Ata from 30 years ago, not by going backwards to old debates about horizontal and vertical initiatives, but by building on the innovations, the successes, the vitality of people working with AIDS for a better future for all of us. This is just the beginning of all our work together, it is time to get busy. [Applause]

A great number of people helped me with this talk, you can see it is barely readable, but it would not have been done without them, this is a truly collaborative effort, and we invite you tonight to come to session room 3 to continue this

conversation because we need all of your help. So, we are going to have a town meeting tonight in session room 3 to talk about the future of ARV scale up and we hope you will join us.

And finally, two of our colleagues are in jail right now in Iran, some of whom were supposed to report at this conference, and I hope you will talk to Sarah at Physicians for Human Rights to make sure these men are not killed for doing the work that they need to do to keep people free of HIV and TB in Iran. [Applause]

[END RECORDING]