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## **XVII International AIDS Conference Plenary Session, Day 2 August 5, 2008**

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**NILS DAULAIRE:** It is my pleasure to welcome you to the plenary session, Tuesday morning. We have a very important task today, and this is to discuss prevention issues from different points of view.

As you know, prevention is one of our major issues in this conference, and we strongly feel by heart that prevention and treatment are two sides of the same coin. So, for that, we will have a really very qualified panel. I would like to ask you to turn off all your cell phones and electronic devices, and also to let you know that all our plenary presentations will be published in our journal, the *Journal of the International AIDS Society*, which is an electronic journal, and you can reach this journal just by entering the International AIDS Society web page, [www.iassociety.org](http://www.iassociety.org).

So without further delay, I would like to introduce our first chair, is Dr. Tachi Yamada. Dr. Yamada is President of the Global Health Program at the Bill and Melinda Gates Foundation. This is the acceptable time to recognize the role that the Bill and Melinda Gates Foundation have been playing in our conferences, supporting IAS, supporting our international conferences, supporting our regional conferences, as part of a large program that the Bill and Melinda Gates Foundation have been playing, supporting different initiatives regarding prevention, vaccines, the fight against TB, malaria, AIDS, etc,

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so it is really our privilege to have Dr. Tachi Yamada here as our first chair. Dr. Yamada?

**TACHI YAMADA:** Thank you very much. I am delighted to be here and to be able to introduce the first plenary speaker this morning. But first, I would like to review a little bit about the status of HIV prevention. Of course, a lot has happened in the last two years since Toronto. Two million additional people living with HIV have been placed on treatment. For that, we are truly grateful. But at the same time, we must be aware that there are five million additional people now living with HIV since Toronto.

So, clearly, we have a very important challenge, and that challenge is to work on prevention. Yesterday, there was a very extensive session on research and development in prevention. And we learned a lot about what is in the pipeline for new products, some of our successes, and, of course, some of our setbacks. The most important message from the session, however, must be that the setbacks in research for new prevention approaches are just stepping stones on the way to success.

But that is not all about development of new solutions. What we have learned is that we have many, many solutions that we know to work. There are, of course, clean needles, condoms, circumcision, prevention of mother to child transmission. We know they work. The big problem, in this case, is not

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developing new solutions, but really how to deliver them. It is about national policies. It is about financing mechanisms. It is about community action. It is about demand creation and the logistics of delivery.

There is a science to delivery and we have much to learn here. The low hanging fruit for prevention, such as the prevention of mother to child transmission, which, if fully deployed, could reduce the new incidence of HIV by 20-percent, has to be deployed. And it can only be deployed through delivery science.

On the other side of development is discovery. We need new ideas, new approaches to prevention. This is an incredible science, and for that, we are pleased to have as our speaker, Dr. Myron Cohen, who is himself a true expert on the discovery of new solutions for HIV prevention.

The topic of his lecture today will be *Prevention of the Sexual Transmission of HIV: A View from Early in the 21<sup>st</sup> Century*. Dr. Cohen is a distinguished Professor of Medicine, Microbiology, Immunology, and Public Health at the University of North Carolina. He is also the Director of the University of North Carolina Division of Infectious Diseases and Institute for Global Health in Infectious Disease. Dr. Cohen's research focuses on transmission and prevention of HIV. He has conducted landmark studies on the biology of HIV transmission. He is also a member of the Senior Leadership of the National

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Institute's of Health's Center for HIV Vaccine Immunology and HIV Prevention Trials Network. In my opinion, he is one of those rare people who can link the disciplines, bringing epidemiology and basic science closer together.

Please join me in welcoming Dr. Cohen.

**MYRON COHEN:** Thank you, Tachi, and good morning. Let me thank the organizers for inviting me to speak to you, and let me apologize in advance to the translators, I see no way that my English can be translated, it is too fast and too confusing. So if we see somebody explode in the booth where they are translating, it is my fault. I am going to use slides, which is not going to surprise anyone here, I hope.

And my purpose, I guess, will be shown in the first slide. So in my view, there are four opportunities for prevention of HIV. The first opportunity that we focused on over the last 28 years is to deal with keeping people unexposed. The second opportunity is a very special moment in time where exposure to HIV occurs, where a transmission event can occur. And I am going to focus almost entirely on sexual transmission of HIV, and especially on heterosexual transmission, since about 80-percent of the epidemic depends on that mode of transmission.

A third opportunity for transmission occurs immediately after the coital event, I will talk about that. And lastly, I will talk about what we will refer to as secondary

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transmission, trying to prevent infection from the infected person.

Now for the behavior, I am not a behavioral scientist, so I would accept certain premises as it relates to keeping the HIV negative person unexposed. Tom Coates has a wonderful article in the *Lancet* that summarizes, today's *Lancet*, this is the summer issue, that summarizes a lot of this. But I think we should accept the idea that abstinence and total monogamy in a couple who know they are zero negative are very effective, but that is a very difficult thing to achieve. And we, at this meeting, you will see a heavy emphasis on concurrency and multiple concurrent partnerships. Those obviously represent a threat that works against what would otherwise be a very effective device.

The second thing we should accept is that barrier methods work. Condoms are very effective, it is a behavioral event to choose to use a condom and use it properly. They are a reversible barrier. We know circumcision is effective, it is an irreversible barrier, but it is imperfect. We know it offers a substantial amount of protection, but not complete protection. And we know HIV prevalence has fallen in many communities, and we heard talks last night about the rapid fall of HIV in Zimbabwe. So while we are disappointed that randomized, controlled trials of prevention have not universally shown behavioral interventions that can work, we

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know that some things do work because we have seen the fall of HIV in many countries.

And lastly, and I will come back to this, we need most of the work that has been done today has been on single approaches. And there is a real emphasis in the field on combined approaches that use both behavioral and structural tools that are multi-pronged and multi-level, and they really need a chance to do their work in the coming years. But we need to face the fact that if primary prevention fails, the risk of transmission occurs. And I want to talk for a few minutes about what we have learned about HIV transmission because this sets the stage for biological prevention.

We know that the transmission event must depend on the infectiousness of the host and the susceptibility of the person who is not infected, and this is a biological event, and it is going to have a probability. And it will depend on how much virus is present, and I will say a bit more about that in a second, on the kind of virus that is present, and on the hereditary and other resistance factors of the host. I think it is important to emphasize that we have increasing kind of belief, or evidence, that things are not the same all over the world and at the virus in sub-Saharan Africa may be different, and that the hosts in sub-Saharan Africa are clearly different. So we have to look for more biological information about why

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transmission might be more efficient, that is the word we will use, in sub-Saharan Africa.

Now the one thing we have learned that I think is pretty clear and is shown on this slide, is that the concentration of virus and the general track will predict the probability of transmission. So this is a slide, a work from a study we did, where we actually looked at the concentration of HIV in hundreds of semen specimens, and we calculated from that using all the data available, the probability of a transmission event. What is important to note is that we can calculate it in the middle range we can calculate the probability around here. But we do not know how high the probability can go, and what is most important for us, we do not know the floor of the probability. We think that when the level in the semen or the general secretions gets low enough, transmission probably will not occur. But we need to understand that number, that is a critical number for biological prevention, and you will see why as I go forward. So the concentration of virus in the general secretions will predict the transmission probability.

We have also learned a lot about the virus that crosses, and this is really a fascinating point. The image general track, there is a swarm of virus, and that is shown here, and most of the viruses in the swarm cannot cause infection, they are defective. But some of the viruses can cause infection, and it turns out that for the most part, in

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809-percent of the people who get HIV, a single virus causes infection. And in the whole population of people who get HIV, it is never much more than two or three viral variants out of hundreds of thousands of variants. So there is a big barrier to crossing, and only the viruses that want to use macrophages cross, and that is important, there are five virus crosses. So one virus crosses and it is an R5 virus crossing in heterosexual transmission. This is what we are trying to prevent.

Now there is a lot of confusion about the probability of a transmission event. Many, many papers cite the number one in a thousand, one in 500 to one in 1,000. That is one in 500 to one in 1,000 episodes of intercourse. That is a lot of episodes of intercourse, and I do not want to get real personal for myself about it, but it is a lot of episodes of intercourse.

Now it turns out when you look carefully at the studies, and a person in our group, Kim Powers, has a paper coming out today in the *Lancet Infectious Disease*, that looks at this very carefully. And it turns out that you find this number only when you are looking, when you get rid of couples who have acutely transmitted, when STDs are rare, when you do not really count condom usage, and when anal intercourse is not practiced frequently. If you then go to a meta analysis structure, here is the one in 1,000, but when you look at a

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study where anal intercourse is practiced commonly, the number becomes much higher. When you look at the presence of sexually transmitted diseases, the number becomes much higher. When you look at uncircumcised men, the number becomes higher.

So I think it is wrong to think of transmission efficiency or the probability of a transmission that is 1 in 1,000. It is better to think of it as a dynamic risk. The risk becomes very high when the concentration of virus in the genital tract becomes high. So in the first few days of infection, there is a lot of virus in the genital tract, maybe 100 million copies of virus. So the transmission probability is not 1 in 1,000, it is probably 1 in 20, 1 in 30. Then as the virus gets lower, the probability is reduced. And these red lines are drawn to show what might transpire if this was such a low number, transmission could not occur. Then if an STD intervenes, it causes inflammation of the genital tract, and the probability will go up again.

In addition, the Eric Hunter's group has suggested that when inflammation is present, such as is caused by an STD that instead of one variant crossing, several variants will cross. So we have the inoculum, we have the inflammation, and we have the probabilities. And then as the viral burden rises in untreated people who are still sexually active, of course, and the viral burden gets higher in both the blood and the genital tract, the transmission probability will increase.

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Now what about what is called the STD paradox, or the STD debate? We have done, we in the field, have done seven trials to use interventions for STDs to prevent HIV transmission, but only one worked. And this has led to great dismay and great confusion. Are STDs unimportant? Are 40,000 papers wrong? I think not. Here is the problem. Either STDs don't amplify HIV transmission or, much more likely, the interventions we have are not adequate to suppress STD sufficiently to block HIV transmission. For an STD intervention to work, you have to treat the right STD at just the right time with just the right people, whether they are HIV negative or positive, with very effective drugs, and for the right duration of time.

This is what we are unable to do. We do not have STD vaccines like we do not have an HIV vaccine. So our strategies to use drugs have not proven successful. But that does not mean that STDs are not important, and furthermore, treating STDs has a benefit far beyond the effects of HIV prevention. My colleagues at the London School led by Sarah Hawkes wrote an editorial. I think it was Rodana Speiling [misspelled?], Sarah Hawkes and David Navy [misspelled?] wrote an editorial saying living with HIV but dying from syphilis. So we really need not to forget that the STDs have their own consequences for reproductive health.

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So let us go to our second opportunity, and let me get a drink of water. I am talking pretty fast. Let us go to our second opportunity, which is the moment of exposure. Now this is a big problem. Look at this slide. Here is exposure. This is an HIV uninfected person exposed to HIV. Within five or six days, a very short period of time, there has been a transit event where cells can become infected. And when the cells become infected, the virus integrates into the host DNA. And once the integration of that occurs, there is an irreversible infection, so we have a very, very short window of time to try and stop infection. This is a challenge of enormous proportions.

Bob Siliciano is going to talk tomorrow about the integration event and the ramp up of viremia, and it is this phase that causes and makes HIV an irreversible problem. Then a peak is reached, then a set point is reached, and I think most of the people are familiar with this.

So what now we need to focus on is the one moment in time. Can we prevent HIV infection in this moment in time? We have three opportunities. First of all, we can modify what is called innate immunity. I do not have time to talk about that, but I can tell you we do not know how to do that. Second, we can make a vaccine, and I will say a word about that. Third, we can use antiretroviral therapy. Let us talk about the latter two points.

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Here are the strategies by which an HIV vaccine would work. This is the slide I already showed you. Exposure, ramp up viremia, set points. The higher the set point, the more contagious the person is, the more rapid the progression of disease. Here is a person who has received a vaccine that made them have a neutralizing antibody, which was present in the mucosal secretions at the time of exposure, and no infection occurred. This would be a miraculous and critical vaccine. This is what we need to do.

What we have been trying to do is an alternative strategy. We know, and I will show you a slide about this in a second, we know that cell mediated immunity is possible, and while it probably cannot prevent infection, it can lower the peak of the virus and the set point of the virus. So the person would be healthier, potentially, for a longer period of time, but in addition, if we knew how much virus was required to transmit, maybe this peak makes the person less infectious. Maybe the set point makes the person less infectious. This is where the vaccine field has been focused the last ten years.

So here is a summary. At this point in time, we know there are people with broad neutralizing antibodies, but we do not know how to make them, we do not know how to make them in the concentration of the genital tract necessary to prevent infection. This is a critical challenge that is important.

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Second, we know that in animals, that if you give an animal a cell mediated vaccine that stimulates cytotoxic lymphocytes, and this is Norm Levin's work, but there are other studies like this. Here is an unimmunized animal, and the blue are immunized animals that have lower peak and lower set point. That is exciting. That led to trials in humans, but to date, the vaccines that have been tested in humans have not done what we have seen in monkeys.

Bruce Walker and Dennis Burton wrote an unbelievably good article that I would highly recommend. Anyone interested in the vaccine should read this article. It is the clearest description of what we have done and where we are. So this is where we are in the vaccine field.

Our challenge is to make vaccines that make antibodies, to make vaccines that evoke a CTL response that does this, and we have absolutely, so I know there is frustration, I understand that. But this is not an option. Failure is not an option and stopping is not an option. We have absolutely no choice, in my opinion, but to continue to develop the science required to make an HIV vaccine no matter how long it takes. And the young people who want to go into this field, this is a great field to go in. Do not be frustrated, do not be upset, do this work, the Gay Foundation is going to pay for it, I am quite sure. I am sure Dr. Yamada is absolutely sure. See, I

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got you a round of applause. It does not matter how long it takes. Do you agree? Thank you.

So let us move on to something that we do know how to do that is almost certain to work. And I say this with great enthusiasm. Let us use antiviral agents for prevention. So the CDC investigators led by Haninge and Garcia Luhrmann, Tom Folks [misspelled?], they have done a terrific job at establishing an animal model, a Reese's Macak model, they do a rectal exposure and all the animals get infected. And then they give the animals antiviral drugs, and when they gave the animal's high dose Truvada, tenofovir and FTC to six animals, no infections were observed. This we are going to call pre-exposure prophylaxis in Macak's. These are 40 animals. These 40 animals have stimulated worldwide research in pre-exposure prophylaxis. We have daily tenofovir. We have daily tenofovir plus FTC Truvada. We have microbicides, and I will talk about it in a second, all over the world. This is a vibrant field that is going to yield answers in the next year, two years, three years, this is exciting, and it ought to work.

Now I am going to show you unpublished data from the CDC, which I think is equally exciting. I just want to show you, you will note this prep is really not completely prepped because the animals and the humans we are studying get the antivirals every day. But now, the investigator's at the CDC have done the same model, here is infected animals, now they

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give interrupted doses. They give minus 22 hours, plus two hours, and they protect the animals. So now they are giving just two pills, and those two pills are sufficient to protect these animals well. Not perfectly, but well. This is exciting; we are getting down to a strategy where a human might really benefit as we move forward. So this is a vibrant and exciting field.

Now I am going to take the liberty of getting sued or getting criticized, and the way that is going to happen is like this. Another drug that I think is really exciting is maraviroc, because of pharmacology. Maraviroc blocks the R5 receptors and 99-percent of the virus that crosses uses an R5 receptor. My colleagues Angela Cashoub and Julie DuMann [misspelled?] have done pharmacology studies in many drugs where they studied the pharmacology in the genital tract. But this is study state dosing maraviroc, here is the drug in the blood, it lasts a long time, but it concentrates in the cervical fluids and it concentrates in the cervical tissue, and it lasts a long time. So maraviroc is a potentially great drug for prep, so at the risk of getting sued, I am going to make a drug. I am going to take the trade name, Truvada, because I like that name, the generic name maraviroc, and I am going to make Truviroc. And I think I know I apologize, I have nothing to do with these companies, but I made up this name. And if

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they ever use this name, I want credit, and everybody on the panel.

Now the other issue here is the topical use of agents. This is the microbicide field; the pharmacology is really quite different. It is an incredibly vibrant field, and the field has moved from early agents that were very broad in their activity, maybe try to kill STDs and HIV and do a lot of other things, they have moved to antivirals. And these are, not all, this is not exhaustive, these are some of the drugs, some broad agents, some antivirals being used, and we are seeing combination antivirals being used. It is a very vibrant field.

The International Partnership for Microbicides, plus other agencies, are really also exploring the use of devices that could be used in the female genital tract. These are cervical rings, they can be impregnated with antivirals, and they can slowly release the antiviral, and the animal experiments in this field also strongly suggest that these agents are going to prove successful. So we have a very vibrant use of antivirals.

Let us talk about exposures occurred. No antiviral is present, no vaccine was present. Can we do anything? Yes, we can do post exposure prophylaxis. Michelle Roland has written excellent articles on this. We cannot do a clinical trial to prove this works, but we think it will work. It requires an emergent use of multiple agents for 28 days, there have been

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failures, you need to be careful about anal intercourse because it is probably a little more contagious, or more infectious, and delaying the ART is not a good idea, and one of our problems is the healthcare workers is not that familiar with this. Yesterday, one of the panelists indicated that only 30-percent of people eligible, only 30-percent of emergency rooms that he was working in actually had a prep available. So this is really important to get healthcare workers really completely on board. An article will be published from Ontario, that will show a large deficit in usage of post-exposure prophylaxis.

So now let us go to the final topic, and this is a very hot topic, treating the person to reduce their infectivity. Secondary HIV prevention; first of all, transmission occurs from those that do not know their status. Mark has published an article in the United States that suggest that 40-percent, at least, of transmission occur from people who do not know their status.

Second, couples are important. There is a misconception that if one person is infected, the other partner is infected. This is not true. Excellent door to door surveys in Uganda, and now Kenya and other countries, show that about half the couples are discordant. One partner is infected, the other partner is not infected. Nothing can be achieved until the tests are done. So the key here is HIV testing, and I think we need to unlink any controversy between the benefits of

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voluntary counseling attesting and the importance of testing to get people in a situation where we can do more for them, for their health, and for their community, and for their partner. So testing remains a very critical link, and the tests have gotten better and better, and if we could get rid of all the stigma, we would be incredibly better off, that is for sure. I think that is a given.

So we have a hierarchy or risk paradigm. We have increasing risk, we have acute infection, which is very risky, but it only lasts, we have measured the virus in the genital tract, it is high only for eight weeks. So while the people are very contagious, they are not contagious for a long period of time. We have AIDS untreated, those people are certainly likely more contagious. We have established infection, untreated with an STD, more contagious.

But here is the bulk of the species. Thirty million people infected, most do not know their status, and Kristoff Frasier argues in a wonderful paper in *PNIS* that this is where most transmission occurs. He also gets at what he thinks is the appropriate viral burden. What we are talking about is going from this group here, 2.5 million people treated who might be less contagious and making 32.5 million people treated, or 40 million people treated. Would that affect the epidemic? I know that is unreasonably optimistic, but let us look at the data of the 2.5 million and the belief system.

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So here is the belief system. When the person who goes on therapy starts their therapy, are they less contagious? First of all, there is very strong biological plausibility for this. This is one of our studies in collaboration with [inaudible], and this is semen untreated. When you treat the people, you have trouble measuring HIV in semen, and the drugs concentrate in semen. Here are women, studied by Susan Q. Uven [misspelled?], before the treatment you can see HIV in the genital tract of a female, after treatment you have trouble finding the virus and the drugs concentrate in the female genital tract. So this is very strong plausibility.

We have retrospective studies of couples that suggest when you treat one person; the partner is less likely to get infected. We have observational studies; one from Kenya, one from Rwanda, one from Uganda, where great protection was seen when the treatment occurred, and we have ecological studies, five of those in which three suggested, like Taiwan is the best example, in Taiwan, they tried to find everyone who is HIV infected, offered free therapy. They argued that they reduced the epidemic by 60-percent by treating everybody for free. So this is really exciting, and this led to what is called the Swiss Declaration, that this stuff probably is going to work.

But I have got to tell you, we do not know the degree or the durability of that benefit from ART as an HIV prevention device for a couple. So the NIH has sponsored a very large

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clinical trial. Here is the website where the trial is described. This is called HBTN052, it is underway, about 500 couples are enrolled. Couples are enrolled, the index case, the person who is HIV infected is enrolled at a high CD4 count, to be ethical, where therapy is currently not required, and they are enrolled in the trial with high CD4 cells, but the endpoint is their partner. Does giving the person their antiviral therapy over five years prevent the partner from becoming infected. When the CD4 count falls, everyone gets therapy, so you are also doing a when to start therapy study. So it is hoped that this study will show the durability of the intervention. You treat somebody for five years, and over five years, if you see no transmission, that is going to be pretty good evidence that this intervention, antiviral therapy for the infected person, is going to prevent transmission to their sexual partner. Studies are underway, we will know the answer in 2012 or 2013, so do not hold your breath for the answer, but it is a really important study, I think.

So here is where we are in the field. There are 33 trials that have been done, and of the 33 trials, the three circumcision trials worked and one STD trial worked. All the other trials failed to show at this point in time, a benefit from the intervention. But I want to remind you that RCTDs are only one measure of success for the field. If we make RCTDs the only measure of success for the field, how do we explain

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the fall of HIV in Zimbabwe, Uganda, and Thailand? We need to look beyond just RCTDs, and while I do RCTDs, it is really important.

Second, remember we are doing 15 RCTDs now to add to these 33. They are in progress; every year we are going to get another result. I almost promise, but not completely, some of these trials are going to work, and that is going to galvanize the prevention field, which will be a wonderful thing.

So what are our challenges, and I will end on a few slides on challenges. HIV prevention and public health; Malcolm Potts, our colleague originally from Family Health International, had an article in *Science*, in which I think he said the right thing. He said the resource must match the opportunities. Yesterday, we heard from a young woman talking about what the young people want to know, not about ideology, they want to know what works. And so we have an absolute obligation in the future to match the money we have with the things that we know that work.

Second, we failed to implement some ideas that worked. There is a lot of frustration that circumcision has not been rolled out faster, more broadly and there are other interventions we know work that we have not done a good job in translating from the lab, or from the bench, to the beds, to the public health community.

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And lastly, there is tremendous frustration, maybe in part because of RCTs, we focus too much on single trials. And King Holmes and Tom Coates and others have really championed highly active prevention using every tool in the tool box, all at once, right now, to try and stop the spread of HIV. It is hard to argue with this idea. They say highly active antiviral therapy is multiple agents, no one uses one agent. Why is not the prevention field using combination, multi level, multi prong agents? I strongly refer you to Tom's articles in AIDS, in the *Journal of AIDS*, as well as in the journal *Lancet*.

What is our big challenge now? We have got 22 antiretroviral agents available. We have got more than 2 million people receiving antiviral therapy. But we know there are about 2.5 to 2.7 million new infections every year. The HIV prevention field, regardless of all the hard work of all the public health field, it lags behind. It just is not at the place of the antiviral treatment field or the care field. It lags, and treatment and prevention are not married, except for mom to baby prevention.

Now mom to baby prevention, instantly you saw prevention and treatment get married. The healthcare workers that do antenatal and postnatal care, they said, wow, this is a great opportunity. The prevention community said this is fantastic. Now, granted, it has not reached its full saturation, there is a lot more work to do, but it is an

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example when the treatment community marries the prevention community. We are training a huge number of healthcare workers to delivery antiviral therapy. All the foundations want to get 2.5 to 5 to 10 million people on therapy, lifesaving therapy. I would argue that the prevention field and the treatment field have been engaged for 20 years. They keep going to the altar, they never get married, okay? They have to get married today. These two fields, we cannot have all these separate fields. So the treatment field, the prevention field, and the community have to come up with a unified strategy to work together to use all the agents we have. And this is going to be so important if microbicides work and if the antiviral prep works, because the communities need to be one community by the time we get the results of those trials or we will not be able to implement what we are already doing.

So on that note, I want to show you one model and then stop, and the model is by Solomon at Stover and his colleagues. If you do treatment alone, treatment alone, you end up with more cases of HIV. You do not avert cases of HIV. But look down here. Millions of total new adult infections, and infections averted and deaths averted. Stover argues that if you combine good treatment and good prevention, you will avert 28 million cases of HIV over 20 years, roughly, or 10 years, and you will avert 10 million deaths. This is very compelling.

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So I implore the treatment community, the community, and the prevention community to get married today.

Let me stop because I am over my time anyway. Let me thank the organizers for letting me talk to you. Let me thank my collaborators over 25 years, because I have been doing this from the very beginning. I have worked a lot in developing countries, and resource countries, and let me thank all of the faculty I have worked with in Malawi, China, Madagascar, and other countries.

Let me especially thank the patients and volunteers who allowed us to learn what we have learned today without incredible efforts to collect the secretions that I discussed, we would not know any of this stuff. And let me thank the NIH, the CDC, and USAID, who also get frustrated when stuff does not work. They funded us, the community of prevention investigator's, over all these years and I really want to thank the funding agencies, and especially the Gates Foundation, who I have made a promise on their behalf to you. So thank you; thank you so much for listening. Thank you.

**FRANCOISE GIRARD:** Good morning. My name is Francoise Girard, and I am the Director of the Public Health Program at the Open Society Institute, a private foundation that funds human rights and democracy globally.

Today we will talk about a prevention approach that works, harm reduction for injecting drug users. Last week, I

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was in Kuala Lumpur in Malaysia. I had the chance to visit a needle exchange and drop-in center run by the Pink Triangle Foundation. There, injection drug users can obtain clean syringes and needles. But they can also take a shower, wash their clothes, eat a meal, and get some sleep. As a matter of fact, we were visiting at lunchtime and the place was bustling. A nurse is also there to provide basic care. And drug users are referred for medical care and for methadone therapy a few blocks away. They can even see a lawyer on site to help with their legal troubles.

There is a separate floor for women and transgender persons, where all these services are also available to them. The personnel at the center are former drug users themselves, and the environment is respectful, relaxed, and welcoming. Jimmy, one of the workers there, told us, all of us are former drug users and we are completely committed to this work. I must say I was incredibly impressed by the range and the quality of services they offer. This center is clearly state of the art.

Adeeba Kamarulzaman, who I have the pleasure to introduce this morning, is an AIDS physician in Malaysia. She told me she became involved in harm reduction because she realized early on that many of her patients in Malaysia had been infected while sharing needles to inject drugs. She was shocked by that fact, because in Australia, where she had

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practiced medicine before, very few injecting drug users contracted HIV. Adeeba decided to take action. She convened a harm reduction working group made up of academics and like minded individuals who were also concerned about the twin epidemics of drug use and HIV infection in Malaysia.

The working group was successful in its advocacy with the government, and needle exchange and methadone therapy began in Malaysia in 2005. This was achieved in spite of her country's very punitive drug laws. In addition to her clinical, academic, and research duties, Adeeba is now President of the Malaysia AIDS Council, the umbrella organization that implements community based, HIV prevention, treatment, care and support programs, such as the needle exchange center I visited.

And what I would like you to do after you hear Adeeba today, is to tell others about the example of Malaysia in this field. It shows that harm reduction is not only possible in Asia, but that it is growing fast there. Needle exchange and methadone substitution therapy are not European or American programs; they are universal programs and they save lives. Please welcome Dr. Adeeba Kamarulzaman.

**ADEEBA KAMARULZAMAN:** Buenos dias, good morning everybody. I feel incredibly honored and privileged to be here this morning to deliver this plenary. At the outset, I would

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also like to thank all those people who contributed to this morning's presentation, their generosity, ideas, and slides.

I am too short, I cannot see. Okay. Alright. As Francoise said, I started life as an AIDS physician, and I still am, and every day of my working day I am confronted with patients such as this. This is an x-ray of a 35-year old man with extensive TB who presented to me approximately three months ago, in severe respiratory failure and metabolic derangement. We were unable to do anything for him, and within two days of admission, he passed away. So this is just an example of a patient who succumbed who, because of the failure of the Malaysian government, to implement harm reduction measures 20 years ago, and this patient is just one example.

Needless to say, I think many of you in this room probably see similar patients in your daily clinical activities because at the recent estimation, there are approximately 11 million injecting drug users around the world, of whom more than 3.3 million are infected with HIV, and even more infected with hepatitis C virus. We know that outside the sub-Saharan Africa, 30% of HIV infections are due to injecting drug use and in the region I live in Asia, and in Central and in Eastern Europe, injecting drug use is the main drivers of the HIV epidemic.

The situation is even worse in prisons where the prevalence of HIV is more than 4 to 10 times the general

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community. And we know that in prisons it is like an incubator that makes transmission of HIV and other infectious diseases, particularly tuberculosis a lot worse. In the words of my colleague, Rick Alteese [misspelled?], the prison is like a semi-permeable membrane which with prisoners going in and out to the community, the HIV infection and other infections that occur within the present settings, then go out into the community and back into the prisons as the prisoners come back into the system.

As you know, drug users do not live in isolation. And this very complex diagram from Bangladesh showing the social and sexual network of injecting drug users shows how injecting drug use can quickly fuel the HIV epidemic within the HIV community and eventually into the general community.

Now, we know that drug use is a chronic and relapsing disease for many years. And basically, ladies and gentlemen, the argument for or against harm reduction to prevent HIV transmission should be long over. [Applause]

Extensive, scientific evidence for the effectiveness of opiate substitution therapy and needle exchange therapy have been done over the last 20 years. Reviews after reviews, including two reviews by the Institute of Medicine in the U.S. have shown the effectiveness of harm reduction measures. Immediate action needs to be taken to slow the spread of HIV amongst injection drug users using multiple approaches, as was

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the conclusion of the review by the Institute of Medicine in 2006.

WHO and UNAIDS have also endorsed harm reduction in their policy briefs since 2005. Yet, out of the 158 countries that have injecting drug use, only 77 countries have implemented needle exchange. Even fewer countries have opiate substitution treatment with less than a million people globally receiving opiate substitution therapy.

So what is stopping us? Unfortunately, in the last few decades, criminalization of drug use and law enforcement have taken over the health issues of drug use. Governance of law enforcement over health takes over harm reduction, and moral and religious framework are leaned to prohibition. Treatment, when it is available, is often geared towards abstinence and a drug-free environment.

Conflicting policies coming from the UN Organizations often sends countries confused. The UN on AIDS [misspelled?] says that by 2005, and short wide-range prevention programs [inaudible] commodities, including condoms and sterile injecting equipment, and harm reduction if it is related to drug use. However, in Vienna, the [inaudible] on drugs say since the Vienna Convention in 1988, established stricter obligations to criminalize all aspects of cultivation and production, distribution and possession of illicit drugs. No wonder many countries are very confused.

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As you can see, the percentage of countries reporting laws, regulations and policies that present obstacles to services for injecting. As you can see, in these recent reports for UNAIDS show that especially in countries that need it most, there are many, many countries with laws that prohibit harm reduction.

Now, the presence of laws that criminalize drug use, not only prevents access to much needed harm reduction measures, but most often, also leads to outright abuse of human rights. As you can see, from this picture that I am sharing with you of a recent raid in Cambodia that led to many, even non-drug users, including children, being behind bars.

Funding for effective HIV prevention including harm reduction measures is abysmal as can again be seen from this UNAIDS report from the recent Global AIDS update. Even in countries that have embraced harm reduction, the National Drug Policy funding goes mostly towards enforcement. As you can see from the Canadian Federal National Anti-drug strategy, where funding for harm reduction is a mere 2% compared to enforcement, which takes up 70% of the National Drug Strategy.

I am moving on to treatment-opiate substitution treatment. The essential medicines list, which says that medicines that satisfy the priority of healthcare needs of the population are criteria for medicines to be included into the essential medicines list. And they are selected with due

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regard to disease prevalence, evidence on efficacy and safety and comparative cost effectiveness. They are intended to be available at all times in adequate amounts.

Methadone and Buprenorphine were listed in this list in the year 2005. However, many countries—these two drugs, which are essential components of the harm reduction program, remain illegal, or unavailable. As this recent report in the *New York Times* describes of how Russia, up until now, does not make methadone available for its severe heroin problem.

In most instances, evidence based treatment is put aside for what I call non-evidence based treatment, based on incarceration and punitive actions, as can be seen in pictures here from Malaysia, Russia, and Myanmar.

All is not bad. As Francois mentioned, there has been progress, including in my own country where upon realization that we failed to meet the millennium development goal and that it has met some review on HIV/AIDS, my government allowed for the implementation of harm reduction programs, including opiate substitution therapy and needle exchange. We now, since 2005, have more than 22,000 drug users on opiate substitution therapy, 11 needle exchange sites, including seven that are funded by the government with more than a million needles and syringes distributed up to June, 2008. More recently, we have also introduced pre-released prison Methadone programs in our prison system.

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In China, the rule out for harm reduction is also happening very fast, as only the Chinese can do, with 88 thousand on Methadone maintenance therapy, and 50,000 injecting drug users receiving needle syringe services, as of October 2007.

In the Islamic Republic of Iran, there are now 600 addiction clinics with 132 Methadone Clinics, 100,000 to 130,000 on Methadone maintenance therapy, with a very large number of prisoners receiving methadone maintenance therapy. And more recently, they have even introduced automatic vending machines offering sterile syringes and condoms.

At this point I would like to take a minute of my presentation to appeal to the Government of the Islamic Republic of Iran to release Arash and Kamiar Alaei from custody and the charges that have been brought upon them.

I have met the brothers on many occasions and had the opportunity to visit your beautiful country as a Faculty member of the HIV/TB training course for the region that they organized. It was through the inspiration that was gained by the visit to your country that the Malaysian Prison Department has implemented opiate substitution therapy in the Malaysian prison system. As a fellow Muslim I appeal to the leaders of the Islamic Republic of Iran in the name of Allah the Most Merciful and Compassionate to release these brothers immediately.

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[Applause]

If access to opiate substitution therapy and needle syringe programs is problematic, excess to anti-retroviral therapy is equally abysmal. As you can see from this review conducted by the WHO European region, where 83-percent of the HIV reported cases, for instance in Eastern Europe, 83-percent are made up of injecting drug users, only 24 of those who are injecting drug users. These kinds of statistics are seen in many, many regions of the world, including Asia.

Why is this so? I think the area to access and adherence, there are many, and as you can see here, they can be sociopolitical, social marginalization and the continued criminalization and stigma and discrimination of drug users, individual barriers including fear of side effects, psychiatric illness, homelessness, lack of trust, addiction and addiction related instability and ask the medical community equally at fault with our own perceptions and prejudice against drug users.

In an ideal world, we would like to see the integration of HIV treatment with opiate substitution therapy, tuberculosis, Hepatitis C, and mental illness. Unfortunately, these kinds of services only occur in very, very select sites around the world.

Now, I think we can all sit here and argue about the cause and against harm reduction and I would like to share with

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you that we can continue to reject harm reduction at a huge cost. For instance, in the U.S. where harm reduction is continuing to be rejected, not just in the United States, but also in countries where it supports financially through It is many, many different grants.

The number of injecting drug users who are HIV infected is around 25-percent to 33-percent in contrast in Australia, where harm reduction was adopted in the early 80's, only three percent to six percent of injecting drug users are infected with HIV.

So what is the way forward? Obviously, we need to stop arguing about the merits of harm reduction and just do it. We need to expend coverage which is not a major priority for many countries. We need to raise funding for health measures at the same level as law enforcement. We need to harmonize public security and health policies and lastly we need to integrate prevention and treatment services and of course, we need to do all this based on science, public health and human rights.

Now ladies and gentlemen, while we sit here and argue, and while we sit here and collect statistics of drug users becoming infected with HIV and hepatitis C, I would like to share with you something that I think brings home to all of us that drug users are like you and me. They are somebody's son, somebody's brother, somebody's daughter. This is a documentary

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that was done by the BBC more than 15 years ago, but the messages that it brings, I think is relevant until today.

The video does not want to work, but what it shows is the anguish of this mother over her son's drug addiction. [Video played]. Thank you ladies and gentlemen. [Applause].

**NILS DAULAIRE:** Good morning, I am Nils Daulaire, president of Global Health Council, and I am here to introduce this years Jonathan Mann memorial lecturer. As you heard earlier, highly active, HIV prevention has as one of its pillars social justice in human right. Jonathan Mann was a pioneer and a towering figure in this field. He mobilized global attention and action against AIDS and the council is very proud to have been the sponsor of the Jonathan Mann memorial lecture at every international AIDS conference, starting in Durban in 2000.

Jonathan Mann was a practitioner and a scholar. He started his work with AIDS in the early days of HIV/AIDS in Kinshasa, Zaire in the early 1980s and became the founding director of the World Health Organization's global program on AIDS in 1986. After his work with the United Nations, he moved on to become the Professor of Health and Human Rights at Harvard University, where he stayed through much of the 1990s.

Jonathan was among the first to expound the intellectual framework linking health and human rights, using as his warrant, his years as a public health practitioner and

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strategist, and as his text, the universal declaration of human rights. He said that respect for human rights and human dignity was built on a scaffolding of words, but that actions were the essential building blocks for a just and healthy world no justice, no health. No health, no justice.

As a friend and teacher to many of us here today, he irrevocably changed the paths that we chose and our lives. Jonathan's own life ended abruptly 10 years ago, along with that of his wife, Mary Lou Clemmens, in an airplane crash off the coast of Canada. We carry forward his legacy with this lecture series.

Our Jonathan Mann memorial lecturer today is indeed a true practitioner of this legacy, a man of principal and actions, Dr. Jorge Saavedra is a physician and a public health specialist as was Jonathan Mann. Dr. Saavedra founded the first ambulatory HIV clinic in Mexico, La Clinical Condessa, here in Mexico City, and for the past five years, he has been the head of the National HIV/AIDS program in Mexico, Sinsida.

In this role, he launched Mexico's universal access to ARB policy, and has led government-wide anti-machismo and anti-homophobia programs, as well as appointed the first transgender woman to an official position with the Mexican government.

For the past two years, Dr. Saavedra has also served on the board of the Global Fund to fight AIDS, TB and Malaria,

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representing Latin America and the Caribbean region. In this role, he and other members have developed the sexual minority's decision point.

Dr. Saavedra will speak to us today on the topic of sex between men.

**DR. JORGE SAAVEDRA:** Well, finally a plenary dedicated to sex between men. I think I do not need the extra platform here, but I will really be happy if I can have one of those big condoms besides me. We always use them in the National Conference on AIDS, and they are always with us, so if that is possible, great.

Good morning ladies and Gentlemen, friends and colleagues. On behalf of myself and co-authors doctors Jose Antony Sicilo [misspelled?] and Chris Berg [misspelled?], I would like to thank the organizing committee for the honor of presenting the Jonathan Mann memorial lecture. Thank you.

I am going to talk to you today about the global epidemic on MSM, and discuss the epidemiology of this increasingly recognized epidemic, the human rights issues that are so important for MSM and their communities, and the responses that are so ardently needed.

First let me start with a few definitions. MSM is a construct which tries to capture behavior in that tight entity. Sexual orientation includes homosexual, bisexual and heterosexual. MSM is a category that includes gay and non-gay

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identified men, bisexual situational sex between men, prisons, schools, militaries, male sex workers and some trans-gender persons. MSM includes a wide variety of traditional and local terms worldwide.

Now let us discuss the epidemiology of HIV among MSMs. At the individual level, there are a number of known risks of HIV infection among MSM. This includes unprotected anal intercourse and the greatest risk is with receptive ones, a high frequency of male partners, also a high number of lifetime male partners, injection drug use. These are dual risk MSM and IDU, and we see this where IDU and MSM overlap, non injection drugs especially methamphetamines, which likely increase sexual risk and in the case of the USA, blood African-American ethnicity is associated with much higher odds of being HIV infected.

Overall, the US epidemic remains spread among MSM who account for some two-thirds of US infections. Here, U.S. CDC data on MSM by race and ethnicity and we can see the highest rate, by far, are among black MSMs.

What about the rest of the world? This 2008 data shows new infections among MSM in Europe. The trends are generally either stable or increasing, meaning HIV among MSM is not over in Europe, but if we compare MSM shown here in red. And the rates of HIV among the general adult population

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of [inaudible], shown here in yellow. In the case of Europe, we see that MSM are at much greater risk for HIV infections.

We see the same in the Ukraine. We see the same in South East Asia. In my own region, Latin America, where we see much higher rates among MSM in Mexico, Peru and Argentina shown here as an example. On this pattern it is emerging also in an enormous population of China and India. And even in Africa, where general population rates have been the highest, the MSM populations are among the most hidden and stigmatized worldwide.

This analysis from Berol Eral [misspelled?], shows the adjusted ratios for MSM compared to reproductive age adults by region and by prevalence. In Latin America, MSM were 33 times more likely to have HIV infections. In Asia, more than 18 times and in Africa, 3.8 times as likely. These odds are statically robust.

How are governments or building systems doing in assessing this epidemic? This data from UNAIDS, show inclusion of MSM in National Surveillance Systems. Red means no MSM are included, and we can see how few regions actually include MSM. Overall, only 31-percent of countries reported on MSM.

Every time we do prevalence studies are conducted among MSM, we are served the same, consistent result. The best way of denying this reality is by not looking at these

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results, not doing any research at all on this population or simply, by not believing in scientific evidence.

Now, let us turn to those factors that influence risk and vulnerability for MSM. These include human rights violations, criminalization of sexual orientation, stigma and discrimination and homophobia.

The 2008 UNAIDS report states that long-term success in responding to the epidemic will require sustained progress in reducing human rights violations associated with it, including gender and equality, stigma and discrimination.

US AID has put it this way criminalization and homophobia limit MSM access to HIV prevention, information, commodities, treatment and care. UNAIDS has said, faced with legal or social sanction, MSM are excluded, or exclude themselves from sexual help and welfare.

How this works in the real world? In and how police have beaten peer OUTREACH workers for carrying condoms. Indian sodomy laws are an active barrier to HIV prevention. The National AIDS Control Organization argued that no credits a public health risk, so long as the gay community is forced to go underground, it limits the access to them, and makes it difficult to reach them. This is [inaudible].

In Russia, political leaders have used violence to stop Gay Rights protests. And as reported by the New York

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*Times*, the Mayor of Moscow, in June last year, called gay demonstration as Satanic acts.

Now Uganda, three LGBT activists were arrested and charged in Uganda during the HIV Implementer's Conference meeting, when peacefully, demonstrating for access to HIV services for MSM. I am sorry to have to tell you that just two weeks ago, on July 25th, the Uganda police arrested and tortured one of the three, the only man.

International Lesbian And Gay Organization, ILGO, maintains a web site, with a map of the status of rights and protections world wide. Here you can find your country. Eighty-six countries in the world criminalize sex between consenting adult men. More than half of the African countries, some of them report some of the highest HIV prevalence rate of the world, 10 states have death penalties for homosexual relations between consenting adults; Pakistan, Saudi Arabia, Iran, Nigeria and Sudan.

Here is a story shared with me by an HIV positive MSM in Senegal. I am HIV positive here in my country, to be gay is against the law. The ones who are like myself, we cannot say it openly. In order to socialize or meet other gay people, we need to go to clandestine places. These places are frequently closed by the police. Therefore, every three months, we need to look for the new one. When we go out of the clandestine, gay bar, most of us will separate and take

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different roads to our own homes in order to return to normal life with our wives and kids. The only possible way to have a socially acceptable life here in Senegal is to get married and have children.

Combination of eradication of all forms of discrimination against women, perhaps we can learn a lot from the women's movement. Nobody should be forced to marry against their will, and people should have the right to choose who to marry. Should this also apply to men? To gay men perhaps? [Applause]

First international march against stigma, discrimination and homophobia and here are some good news. The conference began with the Gross First International March against Homophobia [misspelled?]. In advance of the march, we alerted the activists and government of Panama, that we will highlight Panama as the only Latin American country still criminalizing homosexuality. The law was changed by executive order two days before the march. [Applause]

Human rights arguments for MSM inclusion. International convention on civil and political rights, ICCPR, signed in 1966 of which all African states are signatories grant this right without distinctions of any kind such as race, color, sex, language, religion, political or other opinion, national or social region, property burden or other status. In 1994, the Human Rights Committee held that

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sexual orientation was a status protected under ICCPR from discrimination with reference to sex, including sexual orientation. Now let us go to the response.

This is a map of UNAIDS data for 38 countries, which reported on MSM organization's participation in National AIDS Programs through abuse. The red are countries reporting no participation. Here we see the proportion of men reached with prevention services by whether countries had or did not have protection for MSM from discrimination. These are data on reported expenditures in MSM. Government owned expenditures in blue, international donors in purple, government expenditures are highest in MSM supported countries and lowest in homophobic ones, as defined by ILGO. I am pleased to see that the one five blue bar is Mexico, but overall, the funding commitments are unacceptably low.

Here again, is the [inaudible] country reports data; targeted prevention to MSM, sex workers and IDU is a tiny proportion of the commitment despite [inaudible]. This figure compares the needs versus the expenditures on MSM. Some three million spent, some 30 million needed. The MSM response is underfunded 10 to 1. These are the countries reporting data. Most do not even report on MSM. In terms of services received, the numbers are also terribly low. Even if we could find services as shown here, by having been given

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at least one condom and being told where an MSM could get an HIV test.

What is needed for our response for MSM? Both individual and structural level actions including a minimum package of services, education, behavioral intervention, peer outreach, condom promotion and social marketing, lubricants, HVI/BCT, SDI diagnosis and treatment, syphilis, ARB treatment, care and support, addressing homophobia, MSM friendly services, in health services, addressing the social structure determinants which are the criminalization, change of norms, addressing stigma, discrimination, and homophobia, and of course human rights.

Here are AIDS Program expenditures for Mexico, and what I am proud to be able to show is that we have increased spending overall from 2001 to 2005 and we have also expanded funding for MSM specific programs in Mexico in these last three years.

Finally, some conclusions and recommendations: HIV continues to disproportionately affect MSM worldwide. It is crucial from civilian charged that prevention and treatment and are for MSM still limit the global response to HIV. We have failed to bring down incidence in MSM because some exceptions we have not tried. Mexico's [inaudible] weakens so he could try.

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To improve the human rights and health for MSM comprehensive as long as the efforts are needed. Advocacy and activism, more and better data, funding to meet the needs and bring successful experiences to scale.

Here are some of my acknowledgements: UNAIDS, Secretary [inaudible], Johns Hopkins, [inaudible] listed here as well to prevent my [inaudible] Carlos Garcia, Carlos Cassidy and Lee Triaca [misspelled?]. And, finally, yes, I am married, so I would like to thank my husband for his patience during all these weeks previous to the conference. [Applause] Yes, Mexico, I said husband. I did not make any language mistake. We got married where it is legal, almost four years ago. And of course, condoms and testing are part of our lives. Thank you very much.

[END RECORDING]

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