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Treatment as Prevention: Is it Time for Action?
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CATE HANKINS: I'd like to welcome you here on behalf of my co-chair Shawn Strub who is from the SERO Project and is the founder of POZ and is from New York. My name is Cate Hankins, I'm from the Amsterdam Instituted for Global Health and Development. Our topic is treatment as prevention, is it time for action.

We're going to hear two presenters. First of all Julio Montaner and then Ken Mayer, and then we're going to hear perspectives from two countries, from Swaziland and from Rwanda on whether it's time for action on treatment as prevention.

With no more ado let's call up Julio Montaner who needs no introduction to many of you, Former President of the International AIDS Society, from Vancouver, what else can I say? You've got more stuff here, Director of the BC Centre for Excellence in HIV/AIDS, Professor of Medicine and Head [laughter]. Julio, take it away. You're going to be talking about it is simple [applause].

JULIO MONTANER: Thank you, Cate. It is a pleasure to join you here today. It's great to be back in the U.S. and it's great to see that a movement that we started back in Toronto at the International AIDS Conference is starting to pay dividend. I was particularly thrilled with Hilary Clinton's comments today, which really makes some of this discussion twice as relevant as it was originally planned. As you know

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we've been at the IAS trying to promote thinking around how to move HIV treatment as prevention as the new approach to control both morbidity, mortality, and HIV transmission, in addition of course tuberculosis, which I'm not going to discuss specifically today.

I wanted to share with you the fact the Second International Workshop on HIV Treatment as Prevention took place in Vancouver earlier this year, and as of today we're posting the workshop's report. If you are interested you can download it completely at that site that is indicated there. You'll find that hopefully interesting and stimulating.

This is an effort supported by multiple partners, including UNAIDS, WHO, National Association of Drug Abuse, NIH, OAR, and the list goes on and on. I wanted to take this time specifically to thank the Scientific Advisory Committee, listed here for their support on putting these together.

Moving on to the specifics of my presentation. As I said, back in 2006 we felt that the evidence was compelling, that treatment was reducing HIV transmission, and although we didn't have the specific number by which the risk was diminished, we felt that the epidemiological and ecological data accumulated thus far was sufficient to make a recommendation for us to move aggressively to expand antiretroviral therapy within existing guidelines at the time, so that we can get maximal coverage for the benefit of the

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patients, but at the same time optimize the secondary prevention benefit of intervention.

At the time this generated a fair bit of controversy, but I'm happy to tell you that the expansion for antiretroviral therapy in British Columbia has led to a dramatic decrease in HIV measured by AIDS rates here, as you can see. This also has led to a mark decrease in HIV related mortality, in this slide. We use to have more than one death per day occur in British Columbia as a whole. We now rarely see anybody dying as a result of HIV or AIDS.

At the same time, pertinent to the topic that we're discussing here today. The expansion about the antiretroviral therapy seen here in the blue has brought with it a decrease in the number of HIV new diagnosis, despite a rapid increase in the number of tests that we're doing in British Columbia. As you can see on the green here, this effect has also been seen in injection drug users to emphasize then that this strategy works for all people infected with HIV, and that's an unique opportunity therefore for us to truly open the door for an AIDS free generation.

This is Pan Canadian data to show that it is not enough to have a socialized medical system and free available medications to see this effect. British Columbia is unique in Canada, in that it is the only jurisdiction showing a decline in HIV new diagnosis, as shown here. No other jurisdiction has seen these, and the prairies in particular, fortunately because to a large extent, HIV being out of control in first nation individuals, a serious neglected problem in our country is actually out of control.

First between BC and the rest of the country is that we have no copayments, no deductibles, no fees, the drugs are free, the medical services are free, the laboratory is free, and this is the only way in which we are going to be able to get full impact of these programs.

For sometime people had chosen to look at this slide and talk about vertical transmission of HIV as if it was a different set of data. Ladies and gentlemen, this is the ultimate proof that treatment as prevention can eliminate HIV, because it has already done it in the vertical transmission setting. In the most intimate relationship that you can imagine in human nature, antiretroviral therapy stops transmission from the mother to the child. It's a treatment of the mother that actually stops the transmission to the child, this is nothing more than the ultimate proof that this works.

We now have the data from the clinical trials showing that indeed, in formal prospective clinical trial, as [inaudible] has shown, you decrease transmission by 96-percent.

Where do we go from here? We need to increase testing, we need to normalize testing, we need to take the barriers away from testing. We cannot continue to accept that a quarter of the people in North America are going to be HIV infected not knowingly and we are still treating HIV testing as an exceptional encounter with the health system.

People who don't know that they are HIV infected cannot protect themselves, cannot access the services appropriately, cannot take full benefit on antiretroviral therapy, and cannot help to prevent transmission of HIV, so we need to move towards universal voluntary testing if we're going to be successful.

British Columbia announced such campaign earlier last week and we're proud to say that the pilots that we have done show that the update is actually phenomenal. People are willing to do so at a rate of 97-percent, so we're confident that offering the test is the way to go.

What else? We need to stop writing guidelines, we need to start implementing them [applause]. Since 2010 International AIDS Society U.S. has a guideline that actually calls for treatment of nearly all people infected with HIV.

In addition it's calling already since 2010 for treatment of [inaudible]. It's taken a while, but earlier this year the DHHS embraced these same principals, and I'm delighted to tell you that at this conference the DG of the WHO has actually made a formal announcement that WHO is expanding the guidelines to 350 with a treatment of [inaudible] CD4s, plus a number of other criteria, with an aim that we're going to move towards universal treatment as rapidly and as swiftly as possible. I don't know what we're discussing here [laughter]. The boss already said we're moving in the direction, let's get on with the show.

Why, because this is going to save lives, as shown by the Greenwich paper here. You see that basically the more we expand the guidelines to 350 to 500, or to test and treat, the more people we're going to save. This is in the context of South Africa for example, and yes, it's going to cost more in the short term as shown in this slide here, but the short term is very short. Notice that very quickly, we're going to be laughing all the way to the bank. we are going to generate tremendous savings, so we cannot afford not doing this.

Yes, it's true, there are a large number of valid technologies, biomedical technologies that are coming to the rescue and one day they will be ready for prime time, today they are still trying to find their niche. Let me remind you treatment as prevention is unique, because it targets people who are HIV infected, who are motivated to take the treatment for their own benefit.

The prevention benefit of treatment as prevention is free. It's a secondary freebie. We cannot afford not doing this, because by treating the people that need the treatment we get the prevention benefit at no other cost. We know how to implement this, we know where to implement this, we know who are targets are, we need to do this without any further delay.

I'm happy to tell you that Michel Sidibe embraced this notion as early as 2010, and so this commander in chief some time ago, December of last year when he said, few could have imagined that we'd be talking about the real possibility of an AIDS free generation, but that's what we're talking about. Make no mistake, we are going to win this fight. And treatment as prevention will be the cornerstone of the beginning of the end of AIDS [applause].

Let me leave you with a quote from Austin Bradford Hill. He is no lightweight. He's the person who established that established the link between smoking and lung cancer. At a time this was highly controversial and of course there was never a randomized control trial to show that smoking leads to lung cancer. He said, all scientific work is incomplete, whether it observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That's not comfort upon us, the freedom to ignore the knowledge we already have or to postpone the action that it appears to demand at a given time.

I pointed to you that the action that we need to today is to expand coverage with antiretroviral therapy to all of those in need as soon as possible. Because in doing the right thing for people infected with HIV we will have a secondary gain by stopping the spread of HIV. Thank you [applause].

CATE HANKINS: Thank you, Julio. Now I'll ask Ken Mayer to come up and talk about this secondary freebie, from the point of view that it is complex, treatment as prevention. Ken?

KEN MAYER: Thank you, Cate. Thank you, Sean, and I don't know if I should thank WAFA [misspelled?] for inviting me to do this. It's always a tough act following Julio. I feel a little bit like the skunk at the garden party to be pointing out the complexities, but I think it's important. As somebody who's been involved with HIV care since the beginning of the epidemic and have lost many friends to the epidemic, I want to see treatment expanded to everybody yesterday.

Is treatment as prevention utopia? Utopia, it's a movie by Laurel and Hardy and I hope that Julio and I are not Laurel and Hardy, but the cartoon says, my vision of a peaceful utopia is better than your vision of peaceful utopia. Treatment as prevention depends on your perspective, and there are a variety of issues we have to think about as we try to roll this out.

Some of these complexities include the implementation issues, just getting the people to know that they're infecting and getting people into care, and paying for the care, and prioritizing who gets treated first. We can't be unmindful that in many of the micro epidemics around the world there continue to be health disparities, and we have to not have

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treatment as prevention roll out and exasperate some of the underlying disparities as well.

The cascade is a very popular concept these days and I think we have to address the fact that there are these cascades in different parts of the world and we have to think about where do we intervene at those places. Money is very important and support services, because it's not just giving people pills and that's the end of the story.

It's not even giving people pills and monitoring them for toxicities, there are a whole host and panoplies of other reasons why people may be at risk for transmitting HIV to others. There are reasons why people may not be adherent to medication, so it's not just take this pill and call me in the morning. Addressing concomitant issues becomes extremely important. Then we do have to think about the role of some of the newer prevention technologies, how we can use them together and get synergistic benefit if we're really trying to have a world of zero new HIV infections.

There are two other issues which can come up in the discussion that I'm not gonna touch on in any great length. When to start, which is some quarters continues to be a scientific question that some seriously think we need to address definitively, and then the roll of acute infection. If you're assuming that most of the people you know who are infected that you're treating are the prevalent infection pool,

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what about the people who have recently become infected and who might transmit HIV to others.

So just to flush out some of these issues, the majority of people living with HIV across the planet are not aware that they're HIV infected. If you look at some of these recent statistics from several heavily impacted countries in Sub-Saharan and Africa, clearly scaling up of testing has to be a fundamental piece of this equation, and this has to really happen yesterday.

If we're really going to not just be giving lip service to this concept as treatment as prevention. We still have a long way to go to reach the 15 million people by '15. It's exciting that this figure is already a little bit out of date, so that probably should invert this and it should be more than half of people of this 15 million, now that we have eight million people on treatment.

If we said that everybody who is living with HIV today should be on treatment, that means that the unmet need in terms of eight million people on treatment, with 33 million people living with HIV means that we're at about a 25-percent way in terms of implementation of the program.

The other thing we have to be real about is that we do have evidence based interventions for prevention, such as male circumcision, shown by three randomized control trials to be highly effective. It is being scaled, but to reach the kind of scalability that needs to happen, we really are only a minimal way towards that target, so again we don't want to create mantras that we can't achieve, so we have to be realistic in terms of our thinking.

Then this issue of social inequities, that there are populations that in local epidemics are not getting access to the services at the present time. One case and point are the injecting drug users in countries of former Soviet Union, Central Asia.

You can see here that although the majority of people who are HIV infected in these countries, they are a minority of individuals who are accessing antiretroviral therapy, and thinking of developing culturally tailored programs that understand the complexities of these individuals lives and create circumstances in which they can come in for care, has to be part of the hallmark when we're talking about treatment as prevention.

In the United States we have a project called the Medical Monitoring Project. These are individuals in care, and if you even look at people who are in the care system, if you are a non-Hispanic black, you're a little less likely to be prescribed antiretroviral therapy compared to others in the same setting, and a percentage of our logic suppression is far lower. Similarly compared to men who have sex with men, men who acquire HIV heterosexually in women are much less likely to be viral logically suppressed, and these are factors we have to take in account as we develop programs for treatment as prevention.

Many of you have seen this slide innumerable times. We have to accept the fact that if you take the U.S. epidemic, we may have 20-percent of people who aren't aware of their HIV infection, but if we look at the rate of viral logic suppression, that's only 28-percent. Add those two together, that 52-percent of people are falling out of the system after they've been tested, but they've not been effectively linked to care, they've not been effectively established in care, and we know ways in which we can help support that, but it does take resources.

Michael Mugavero and the College of the University of Alabama have done extensive work looking at this first year, actually making that first visit and then being engaged in care. No surprise to those of you who are involved in clinical care, poor retention in care in their studies was associated with people not taking their treatment, not being viral logically suppressed, being more likely to engage in transmission behaviors, having increased clinical events as well, and so we have this complexity.

There are approaches that have been studied. The Center for Disease Control and Prevention has an AIDS linkage study looking at case management. The Health Resource Service

Administration here in the U.S. of the training of health system navigators. If we look at the CC Artist [misspelled?] data, those individuals who were assigned to case management were much more likely to be retained in care at six months and at 12 months, but it's still not as good as we would like. 64-percent is certainly not 100-percent retention care even after one year.

When we start thinking about this several economic researchers who have been focusing on the cost of care, such as Rachele Rolinski [misspelled?] and colleagues at the CDC, Gary Marx [misspelled?] and Nicole Rapez [misspelled?] have been looking at this. This low level of relative retention is definitely abetted and that a case manager can increase linkage by 32-percent, and the cost per individual is at about $1,200 per person. This does seem to be highly cost effective, but it's key to find the resources to be able to provide this kind of linkage.

The reality which the data summarized at a recent meeting on treatment and prevention in London by Kevin Fenton of the Center for Disease Control, basically pointed out that the United States alone, there's a huge federal deficit, a five year freeze on discretionary spending, reductions in HIV prevention by local health departments with 45,000 state, local, and public health jobs lost during this recent economic meltdown.

Furloughs and people having to task shift, and many community-based organizations closed or are struggling, and this is the reality that we have to face, which is not to say that we don't want to have our goal of treatment as prevention, but we do have to face some of the realities. Some of the other realities are that the behaviors that we're talking about, taking a pill for the rest of one's life, or taking one pill a day is not necessarily simple. Some of the simple social psychology modeling, suggests that people who want to prevent progression of the disease or acquired disease have to have self efficacy.

If you have self efficacy, if you feel like you're in control of your environment, you're more likely to practice safer sex, you're more likely to be adherent to medication if you're HIV infected, but that all goes up in smoke if you're depressed, if you're anxious, if you have other mental health conditions, if there's substance abuse.

Certainly studies in many parts of the world suggest a high co-prevalence of these conditions, so one has to find the resources to use evidence based interventions to support people, so that you can treat the concomitant depression, so that you can deal with the concomitant substance use.

Then one of the last points I'd like to make is HPTN 052 which I feel privileged to have been involved as a co investigator, a very pivotal study. HPTN 052, these were individuals who entered the study as a discordant couple, yet more than 25-percent of the HIV transmission events that occurred in the study were not from the primary partner.

In other words with viral logic analysis done by Dr. Susan Eshleman and her colleagues at John Hopkins, it was clear that the virus that the uninfected partner became infected with was from another partner. We have to pay attention to the fact that even in the setting of couples, transmission outside the partnership exists. There are other individuals who may not have a primary partner who are at high risk for HIV.

The models recently have suggested the fact that as much as we want to roll out treatment to individuals who are infected, because they need treatment, as much as we want to roll out treatment to individuals, so that we can get this prevention benefit that Julio mentioned, we may be penny wise and pound foolish not to keep thinking about other evidence based interventions, including circumcision, including other kinds of combination prevention.

If we really want to achieve this tipping point of no new infections much more rapidly it's really the idea of using combination modality, so that we get a synergistic effect. This is my view of the reality that we have to deal with and intervene at multiple levels. Validational to all this work is our interventions to increase testing, that's number one.

Once people test and those who are at risk should test early and test often, just like voting in Chicago, as we say [laughter]. Testing early and testing often means if you're negative we have to train the health workforce to be able to do risk assessment, not everybody needs PrEP, but certainly there are a subset of individuals who will greatly benefit from that encounter and using antiretrovirals for protection.

Similarly for people who are infected, we have to think about linkage to care and we also have to think about ways in which we can change behaviors, even for the period of time where individuals are achieving viral logic suppression, that doesn't happen overnight as we saw it in HPTN 052.

The one transmission that did occur was an individual who was fairly recently initiated on antiretroviral therapy. Once people are in care we have to think about not only the time of initiation, but interventions to maintain ongoing adherence.

We have to continue to think about concomitant issues in people's lives, depression, substance use, relationship dynamics are important, and there still is a role to think about, the role of acute infection, in potentiating epidemics. If we get all this right we may be able to decrease HIV transmission.

I just want to thank colleagues whose slides I've been fortunate to be able to borrow for this talk. I just want to quote Oscar Wilde, "A map of the world that does not include utopia is not worth even glancing at, for it leaves out the one country in which humanity is always landing." We have to try to be utopian, but we also have to try to be pragmatic in the meantime. Thank you for your attention [applause].

SEAN STRUB: Thank you, Dr. Mayer. I think now we're going to go the Right Honorable Minister Xaba, to speak about what treatment is prevention means for your country.

BENEDICT XABA: Thank you very much, moderator. I feel a great honor that as a country we can get this opportunity also to share our ambitious dream and vision about treatment as prevention. First I would like to say that this is a project which is [inaudible] based leadership in the country, ownership, but more than that is a partnership.

We've brought in partnerships to start this project. This has been possible through the support of the [inaudible] then through CHAI, and we have many partners such as STOP AIDS NOW! We have got also support from PEPFAR and MSF, quite a number of partners are involved, but we appreciate that funding has been made possible by the [inaudible].

This really started after the International AIDS Conference in 2010 where treatment as prevention was discussed. As a country we felt that we must grab this opportunity and see what we can do. It is indeed a dream and ambitious, and it's an indeed an exciting dream.

What I can say briefly about Swaziland is the issue of HIV previous, that it is very high at 26-percent, and besides that being high we are also a small country of about 1.2 million. It's like in 1.2 million also the geographical coverage, it creates an opportunity, so we think this dream is really possible for us as a country, but we don't want to rush and start from a shaky foundation.

We felt as a country we need to have a solid foundation, so this project from the partners is built on three key. Whereby we have key one, which we will call health system strengthening. Health system strengthening is focusing on how do we [inaudible], whereby we have a project now called MaxART, that is maximizing ART for better health, as well as zero new HIV/AIDS infection.

So what we are doing with MaxART program is to ensure that we mobilize the community. We said to people to key one, not about HIV, go and test, after testing go for treatment, after starting treatment you must adhere or you must [inaudible].

So we must have a solid foundation first on key one, having a health system strengthening that we have started training nursesto initiate and we have started the rolling out. The issue of CD4 count to rural areas, [inaudible], so that is mainly on key one, [inaudible] health systems and we want to ensure that access to treatment currently to a CD4 count of 350, then people are able to access antiretroviral.

On key two, we are forecasting on social science and research, so it is very critical that we don't just arise at this program treatment as prevention, we need to involve the people living with HIV. We need to be very, very sensitive to issues of human rights, so it is very critical that we go down to the people in the social [inaudible], then we said, we look at how they are feeling, what is the view of the people living with HIV? Hands in the project, we've got partnerships of the people living with HIV in Swaziland.

Also the [inaudible], that is a network of people living with HIV in Swaziland, so that they can share with us, they are told, we don't just push it to the people. A lot of things is then on the ground, hence we have got the support of the Ambassador of Amsterdam, and we have got [inaudible] also on board, that is helping on the research, also on issues of social science. I think key two is very, very critical also.

Also in Swaziland we have got very strong strategical structures, so we must get the goals of the chief down at community level. What are they feeling? Do they support the project? It's a lot of work that has been done on [inaudible].

Then key three, which is now treatment as prevention. Key three is also based, we studied as a pilot not just to -- just that in the whole country, but we are forecasting in two

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regions whereby MSF is also working in the southern part of the region, so MSF would be coming on board. Also we have got ICARE also coming to work on the other region, so all the partners are here. Then we've got PEPFAR that has been supporting on health system strengthen, so we have got all the partners of AIDS and education and so on.

On treatment as prevention here we are looking at feasibility, how feasible it is in our section as a country, then also while looking at accessibility, what are we saying about issues of accessibility. The key issue is the issue accessibility now. Is it really acceptable, what are the people saying? We are starting it as a pilot, as a country. Then we are focusing on the [inaudible], that is [inaudible].

Now initiating people at a CD4 count of 350. We're looking at opportunity of moving the CD4 count of 550, then when we initiate treatment as prevention. I can just say that it is indeed an ambitious dream, and my colleagues have presented is it simple, is it a risk, so for Swaziland we feel, we are strategically positioned. We want to demonstrate that through research, since the evidence is there now, and as a country, that's one million people and 83 to 85-percent of our people are already on ART, so we've also done very well on our prevention of mother to child transmission. Where we have reduced is up to 4-percent of HIV transmission, so using option A and we're moving to option B plus.

You can see that the foundation, I think, is good, and [inaudible], so we strongly believe that Swaziland can be used as a model, and they say small is beautiful, so it's possible that when you use a small country like Swaziland the kingdom can then be translated to other countries, so small is beautiful, so we've got this dream and we strongly believe that we have got very strong partners, and we have got the strategic framework. And what is key in this project is that it is led by government, it is led by the Minister of Health, and there's a note of ownership, and there's a leadership that is there.

Then the partners such as MSF, STOP AIDS, ICARE, and all of them are coming here to support the project that is led by the country. So sustainability also will be assessed and issues of financing, because we need to convince the Ministers of Finance that as we move forward the issues of budget are taken care in terms of the antiretroviral drugs. Thank you very much. I hope the whole house is supporting this vision of the kingdom of Swaziland [applause].

CATE HANKINS: Let's hear from a fellow African Ministry of Health person, Anitha Asiimwe, who is the Deputy Director General of the equivalent of CDC in Rwanda. Anitha, what's your response to what you've heard from the two presenters and from the Honorable Minister in thinking of your own context in Rwanda.

ANITHA ASIIMWE: To start it off, when I looked at the theme of the session and the question at the end, is it time for treatment for prevention. For me it was time way, way back, a number of years ago it was time for us to use treatment as prevention, and I say that because I look at what we are doing back at home in Rwanda.

If I just quickly peak on prevention of mother to child, we set our target to be at less than 2-percent rate of transmission by the end of 2015. Definitely to do that among other things as we all know is the treatment, but always the big question that comes up is how are you going to reach all those women, and here we quickly look at what does it mean for one single village, how many women are we talking about in a single village.

Because we have a huge mass of community healthcare workers who help us to look out for these women. We soon learned that in a single village we are looking at less than one woman for one community healthcare worker, so meaning it's possible to look up these women.

Then looking at discordant couples and the HIV positive partner in a discordant couple. We've already made the decision that indeed we should start them on ART despite level of CD4 count, because rightly even looking at it from the cost point of view as it was presented, it's going to be way, way much cheaper if we avert the new infections much earlier on.

Then moving ahead to look at what about all the other people who are not belonging to a discordant, who are not pregnant mothers, we have decided if they have a co-infection then we are starting them on a CD4 count, a threshold of 500, for the others we are still at a 350 threshold.

In a nutshell to answer that question, for me it was way, way back. Yes, of course there are complexities, but you face the complexities. For example, testing, for sure in Rwanda, over the past five years we have seen a full fold increment in uptake of testing at household level, and that's important that people get to test early enough. We have to put in efforts to ensure that people test in time. Also we look at the aspects of adherence, because this is another huge question.

As we've always been saying, people who need ART for their health could fail to be adherent, what about those who start earlier therapy. Luckily enough again, back at home I'm looking at the last national evaluation we did for adherence, we formed that more than 92-percent of people on ART were adherent, and so we are not worried, but there's definitely a package of what we do, do to ensure that people stay on therapy. Yes, we have to look out what could be challenges, but be ready to address them instead of stay worrying, because at the end of the day it's the lives that we must protect early enough and we ensure that they stay alive for quite a long time. Thanks [applause].

SEAN STRUB: This panel I expected was going to be sort of a discussion of the pros and cons of treatment as prevention, and it's a little bit like discussing is ice cream great or is it good [laughter]. We could have had just as persuasive presentation of slides and data that would have raised a lot of questions about things like the development of resistance, and the possibility of ruining a very effective drug, three, five or seven years out with the development of resistance.

We could have had presentations on the toxicity and what it means to be giving a drug that causes irreversible kidney damage in people. We could have had a presentation on what it means to people with HIV to hear about treatment as prevention when we can't get treatment, because we need treatment [applause]. That very phrase is an insult, that phrase puts our lives, our health as secondary. It contributes to the further demonization of people with HIV, and seeing us solely through out potential to transmit a virus, as viral vectors, as potential infectors.

Dr. Montaner, in British Columbia the implementation has resulted in all sorts of concerns about ethical issues around confidentiality, course of testing, I'd like to hear the Dr.'s respond to the real controversies as prevent as prevention, not just talk about all these wonderful utopian visions. We have had an epidemic today, because we have ignored the human rights concerns, for 30 years they've been secondary.

Right now when we're talking about an end to the epidemic and all this ra-ra messaging that has been sort of slammed down the throat of everybody involved in the epidemic, and people who have had a different view have been silenced, we are again putting the human rights concerns secondary. We are creating a problem that we could avoid if we would put the human rights concerns first, which is not what has happened with the treatment as prevention discussion [applause].

CATE HANKINS: Julio?

JULIO MONTANER: It is not possible to give you a comprehensive review of our experience in ten minutes, and I would like you to know that I agree with you 100-percent. If you read the editorial I wrote in the *Lancet* last year, I entitled it, *Treatment As Prevention, A Hat Trick, Prevents Morbidity, Mortality, and Transmission*. This is not about preventing transmission, this is about securing the treatment, and I phrase it very clearly every time that I said it. It is about treating the people that need treatment, implementing the guidelines that are currently available, and driving a secondary benefit and prevention that is a side effect of doing the right thing for the people that need treatment.

I'm going to remind people here why we started this campaign. It was because my Deputy Minister of Health called me in the '05 year to tell me that they were going to put quotas on the access to treatment, because I was treating too many people and it was becoming too expensive. That's when I said to her, you are making a mistake.

The best way to slow down this epidemic is to do the right thing for the people that are infected. Let me reassure you that we have done these in a very highly ethical environment where we have been at the forefront of fighting the federal government for the most marginalized people, including taking them to the Supreme Court of Canada to keep the supervise injection site open in Vancouver, so that we can have access to low threshold facilities for people who use drugs, just to give you an example of it.

I agree with you 100-percent, we are not about coercion, we are not about mandatory anything, we are at saying that the treatment should be made available to those that want it and need it. If we do that then we'd be a secondary benefit in reducing transmission, and I use that word in specifically, because I am 100-percent with you. I don't want our approach to be taken as mandatory testing and treatment with the epidemic, that would be highly unethical, highly problematic, and counterproductive [applause].

CATE HANKINS: Anitha, could I ask you what you think the potentially uptake will be of what you're proposing, because we hear from a number of different researchers that when people are offered discordant couples for example, post HPTN 052 are offered treatment above the national guideline level, there are many couples that are not that interested. The person who's HIV positive is not interested in starting treatment, so what kind of acceptability do you think there will be in Rwanda for an offer for discordant couples?

ANITHA ASIIMWE: To start ART in the positive partner in a discordant couple will come on as an addition to a package we are already offering, because right now for the discordant couples as we follow up on cancelling on treatment, as we've been awaiting them to reach their threshold as per the previous guidelines we had. This has come in to add on to what we already had, so I think the uptake will be hard, because today the message that we share in Rwanda, we are starting the treatment earlier than we have been doing in the past.

Not only are we helping to ensure that there will be a reduction in transmission, we are also ensuring that we are starting therapy early for the one who needs it, that way the body is still strong enough, so that the person can stay and fight even much longer, if I may use that. It's a combination of not just for prevention, but also for the person who's living with HIV to start therapy early enough. Importantly it's in addition to what we've been offering, so I see the uptake being high.

CATE HANKINS: I don't know about you, Sean, but I feel some confusion a bit in the terminology, because I think we all know that treatment scale up has these secondary benefits in terms of preventing transmission, so when we're talking about treatment as prevention are we talking about scaling up to reaching everybody at 350 or below, or are we talking about opening it up, and if we do what are the issues in terms of access and equity, and are there concerns about it? What are we really talking about when we talk about treatment as prevention? Ken, do you want to respond to that?

KEN MAYER: Sure, and to get back to Sean's comments, I mean I totally support what you're saying about human rights being paramount, that nobody should feel coerced into initiating treatment, I mean I think that has to be foundational. Some of the information I shared expressed concerns about disproportionate decreases in access or decreases in engaging in the system in different populations. I mean we have to query why is that happening, so that gets back to that there are fundamental problems around the world, so I don't think we're wanting to ignore that what so ever.

Getting back to your question, Cate, I think this means different things to different people and part of why it's complex is that there probably is a threshold where everybody can agree that it would clearly be beneficial to patients. As we start getting up to higher CD4 counts clearly reasonable people can disagree on the data.

There are certainly very strong observational data now from studies like the NA Accord Study study, suggesting that there is a benefit to the individual in terms of decreases in morbid consequences of chronic viral logic inflammatory process, even when a person is asymptotic.

Others will say, well that's observational data, it's confounded and that's why there is a study underway, the Star Study to say should you really start treatment for the individual's benefit at higher CD4s, and again reasonable people disagree.

If I'm in a clinical setting I'm not gonna say to somebody, you should take these meds they're automatically going to help you, but I also think that with good medical monitoring and with a person being motivated to take medication, I think the issues of evolution of resistance, failure of first line regimens is increasingly less common if people are highly adherent to medication.

If people are not ready to start the medication then it makes no sense, because I agree with you, we do not want people to blow through their options and their medication, that makes no sense what so ever. It's not the individuals who start Tenofovir cannot develop nephrotoxicity, it's not that there

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are not side effects with even some of the newer medications, but they are less frequent, and they're particularly less frequent when people are carefully monitored.

But part of the complexity to my mind is to do that well you can't just do this in a public health algorithm, it's not take these pills and we'll see you in a few months. It does involve laboratory testing, it involves conversations, it involves people being engaged in their care, and being followed up, so none of those things are simple.

I think at each country, each jurisdiction has to look at their epidemic and understand who is infected, who do they think is infected that doesn't know that they're infected. First of all how do they engage those individuals and then how do they start the conversation. Public health people have the challenge of figuring out what dollars they can count on and what can they hope to leverage over the next few years, so think about where is the calculus of where do we make that threshold, of when do we make recommendations to initiate treatment.

The reality of how it's already playing out in the United States which I can speak to certainly more so than elsewhere, is that first of all the lab work, we're hearing CD4 cells don't matter, places aren't even doing them anymore. If you're positive you're on treatment, it doesn't matter what your CD4 cells are. We have the health departments in New York and San Francisco now recommending treatment for everyone who is positive, even though it is absolutely an open question whether that treatment will deliver a net benefit to people with higher than 500 CD4 cells. It very well may harm and shorten the lives of many of those people above 500, and that is an open question.

To be going out and recommending this treatment to people without them being fully informed, you're very careful to reference voluntary treatment and that's nice to say that, the way it's playing out, it's not voluntary, it's not informed consent when people aren't being told fully about the health ramifications of taking treatment when it hasn't been demonstrated to deliver a net benefit to that patient. They are not being told about the legal liability, Canada like the United States is a leader in criminalization.

In my own criminalization work I've observed that people who get tested in a routine setting, because they're pregnant or going in the military service, far more likely to end up in a criminalization prosecution, because they are not as prepared to handle disclosure issues. It isn't informed if people are not given full information or they're given misleading information, or information is omitted, and that is what is happening all over the United States.

JULIO MONTANER: I would like to counter. I don't deny anything you said, but I will counter that the situation in the

United States today is unacceptable, and I hate to come here to tell you [applause] that this is unacceptable, but the situation in the USA is not acceptable in that less than 30-percent of the people infected with HIV are undetected in this country and there are people lining up to take treatment that want to take treatment, that need it for their own survival.

I think that what we need to do is agree that 100-percent of the people that have a medical indication, now listen carefully because I said medical indication, using whatever guidelines you want to embrace should have urgent access to those treatments if they so wish.

By doing that you will have at least 50-percent of the people infected with HIV on treatment and that by itself will carry a benefit in terms of preventing this disease, that's all I'm saying. The reason why I think phrasing it that way is important is because my policy makers understanding allowed us to float HIV programs to the top of the healthcare, because the return on investment is so beneficial that I'm not giving resources to support people into testing, to support them into accessing care, to support them in to accessing treatment, because they understand that it's valuable for them.

I am not asking people not to go ahead and treat when they are neither prepared, not willing, not eligible. What I'm saying is it is unacceptable that today we have people that are

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eligible, willing, and eager to take treatment and they cannot access it [applause].

CATE HANKINS: We have about five minutes before we're going to open it to you and the audience to pose questions and make statements, but before we do I just wanted to ask the Right Honorable Mr. Xaba just to clarify, so Swaziland is moving to treatment availability at 350 throughout the country, as I understood it, using this partnership support and with country ownership, and then you will do a pilot for people that are higher than 350, can you just clarify that?

BENEDICT XABA: Thank you very much. First I would like to just to add to that, we are not changing anything, but we are building on what we have been doing as a country. Counseling will remain a foundation and core, as we move to treatment as prevention. Also in Swaziland the involvement of people living with HIV, we have studied it using [inaudible] in our facilities who are doing the counseling and issues of adherence, so same thing as we move to treatment as prevention.

People should not be coerced, and fortunate also in Swaziland we don't have people waiting to get treatment, we don't have a waiting list. Everybody who wants treatment gets the treatment, but we have people in our assumption who don't know their HIV status, and these are the people who are supposed to be taking [inaudible], but they don't know their status, that's why we have got a foundation of community

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mobilization, who are encouraging people to go for voluntary testing and they know their HIV status.

Coming to the pilot, we felt that we cannot just let it take just a blanket problem. It is critical that we start with the regions, like we've got four regions in the country. We'll be starting with two of our regions, mainly with the region where MSF is already working and we have already rolled out to almost all the clinics in rural areas, as well as the issue of TB. The co-infection of TB in Swaziland is very high, about 84-percent of the people who are HIV positive. They are co-infected also with TB, so it is critical that we do this pilot, and also we are going to have a strong monitoring and evaluation of this project as we continue.

Also we have looked at issues of sustainability, how are we going to sustain and capacity building within the ministry, hence the University of Amsterdam is involved.

Already we have got [inaudible] and so on. Ownership is critical. The people of Swaziland should understand what is meant -- what do they understand treatment as prevention is and the people who are really affected, the people living with HIV, fully involved, hence we have got 1,000 people [inaudible] living with HIV involved in this program. We think that we need to have [inaudible] and we need to have a strong foundation, so that's how we view it in Swaziland.

CATE HANKINS: Sean, any comment before we throw it open. Okay, so let's throw it open to the mics. We'd ask you not to take a long time at the mic in posing your question or making your comment. Please identify who you are, where you're from, and if you want to address a specific panel member you are free to do so.

RON HATTIS: My name is Ron Hattis, I'm President of Beyond AIDS, an American National organization to improve public health response to HIV prevention and I'd like to play the diplomat. I think everybody was right [laughter]. Treatment as prevention is a simple idea which will be complex to implement into national strategy.

The only bone I have to pick is with Sean Strub, because I think some of your criticisms about toxicity and resistance are more relevant to pre exposure prophylaxis than they are to selecting drugs that are not too toxic for the individual, a full range of therapy that will be good for the patient, and have the side effect of helping us reduce the epidemic.

Perhaps some people are not aware that on March 29th, the American National Institutes of Health reduced guidelines that now permit all HIV patients to be treated. It's not that CD4 count is irrelevant, but it's beneficial to all patients to consider treatment, but to take it voluntarily.

Now what I have done is I have produced what may be a synthesis of how to introduce this simple idea as the cornerstone of AIDS prevention strategies for all of the countries. I have a limited number of hard copies, but it's posted for all of you to read at beyondaids.org and go to News and Views and you'll see it on our blog. Also under beyondaids.org, under Archives, we look for a articles and go to the very bottom of the list, because I think I was the first person to promote treatment as prevention in 1996, and if anybody here wrote it off and presented it before then I'd like to add it to the history that's in this document.

CATE HANKINS: Thank you. Thank you very much. Thank you. A second one from this mic and then we'll move to the back mics. We won't forget you.

JONATHAN COHEN: Hi, Jonathan Cohen with the Open Society Foundations and the UNAIDS Reference Group on HIV and Human Rights. I want to make a plea for greatest collaboration between scientists and human rights activists on the human rights issues involved in treatment as prevention [applause], just as it was collaboration between scientists and human rights activists that brought a scale up of treatment in the first place.

Obviously issues of mandatory testing and treatment are always going to be thorny and controversial, but to me the fundamental human rights question when it comes to treatment as prevention is as follows. Of the two-thirds of people with HIV in the U.S. who are not virally suppressed, who are these people and why are they not virally suppressed? Are they criminalized? Are they immigrants? Do they have mental health issues? Are they in prison? Are they homeless? Are they in violent marriages? Who are these people?

We have heard that statistic at least three times today, including twice in the plenary. Ken, Julio, who are they and why are they not virally suppressed, and how can human rights analysis and action, and advocacy, and pressure help us change that statistic? Thanks [applause].

KEN MAYER: Jon, thank you. Thank you for your very important point. We don't have one homogeneous epidemic in the U.S. and in most countries there isn't. It's multiple micro epidemics, there are multiple different drivers, so to answer John's question, we know that some of those individuals indeed are homeless.

We know that some of those individuals indeed have issues related to mental health, substance use, relate to economic deprivation, and these are all factors that clearly make it harder for people to engage in care, harder for people to feel that there's a beneficent healthcare system, particularly in this country where we have very segmented healthcare, at least up until now, hopefully that will change with the Affordable Care Act.

We also don't want to assume that just because somebody is not engaging in care and is not viral logically suppressed, that they fit into all those buckets. The answer is definitely that a human rights frame has to be paramount for all these discussions, but the actual solutions to trying to increase that percentage of people who are viral logically suppressed to enter the care system means, developing a variety of nuanced approaches all of which require resources, which again is why this is an important conversation, but why treatment as prevention, treatment as treatment is a complex issue.

JULIO MONTANER: Let me add to that. It is through the careful understanding of who are those that are not accessing the system, that we have been able to generate new programs to facilitate access to it and that applies to IDUs thanks to the NIDA support that we have got, the commercial sex trade workers, first nation individuals, other minorities, those who are particularly vulnerable and you’re perfectly right.

You need to map your epidemic and know who they are because the more you succeed, the more difficult it becomes to find those individuals who are farther and farther removed for accessing healthcare for all of these reasons that you pointed out, all of the systemic varies that exist in our environment between some countries and others, but the basic recipe is the same. I fully agree with you.

SEAN STRUB: Why don’t we take the person in the back microphone here? No, that’s you!

MICHAEL KALISMAN: Hi, I’m Mike Kalisman from the University of Connecticut and you know, adherence is often far suboptimal and incidence of other STIs remains high in a lot of populations with HIV. Both of these concerns will really undermine the hope of treatment as prevention, so my concern is that treatment as prevention is really being distilled down to the simple idea of giving people pills.

When you look at 052, for examples, the standard of care that people got in 052, that were suppressed was quite high, if you ask the investigators, read the paper, look at the protocol, people who were not adherent were hounded down and told to take their pills, people were screened every six months for STI and treated. I don’t know of those kinds of standards being included in new treatment guidelines, but I think that we have to think about treatment as prevention as being the full package of the 052 protocol to hit 96-percent suppression.

Dr. Montaner, my question to you is, do you see the whole package as simple, or because surely you can’t just believe that just giving pills is treatment as prevention?

JULIO MONTANER: No, you’re absolutely right. What we’re talking about is that the notion of preventing HIV transmission within the notion of treatment of prevention is simple in as much as what we’re doing is what we’re supposed to

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doing to begin with, which is to offer people optimal treatment infected with HIV and have a medical indication to be treated, to be supported and the access to the treatment is to be facilitated.

The problem is not that the notion is not simple. The problem is that we need to move the standard of care to what the standard of care should be and not what the standard of care is, which currently is pathetic. [Applause].

SEAN STRUB: We’re going to rotate through the mics here.

RONALD BASSEAU: Hello, my name is Ronald Basseau [misspelled?], I live with HIV and work in a French NGO, which is called AIDE [misspelled?]. AIDE is presenting 70 cities in France and every time we made interventions, every time we make group to allow people to express what they need, there is a common consensus is that actually presently with actual present treatment, people live with very well with that treatment.

They have very much progress for treatment and medical aspects, but on the stigmatization and discrimination aspects, there are, I think, very few progress and the people when we ask them what could be useful in their life to increase their quality of life is that they want everybody to know that HIV-positive people, who is already infected was an undetectable viral load and no STIs and virtually no risk to pass the viru.

Because I see this as a very powerful tool to present the stigmatization because HIV-negative are afraid to have sex with an HIV-positive people because they are afraid to become HIV-positive and a lot of HIV-positive people don't want have sex with an HIV-negative people because they don't know that treatment as prevention is an effective tool.

Even if they use condom, a lot of HIV-positive people prevent them to have sexuality, so we see the people now in our action see really the treatment as prevention as a very powerful tool to decrease the stigmatization. One problem is in the international conference is that we only speak from public health perspective, but we never put on the front of the scene the very strong individual benefit of treatment as prevention. Thank you.

JULIO MONTANER: A patient of mine, and more recently a friend, Nick Constales [misspelled?], reminded me that treatment as prevention has done more for his quality of life than anything was done before because it normalizes his sexual life.

RONALD BASSEAU: Exactly. What we see also is that the people who will meet in our action says that they have been to rebirth in their life. The 96 year with arrival, the advent of multiple therapies, which allowed people to live and not to die, the 2008 revolution with the Swiss statement that allowed people to live like everyone, like HIV-negative people.

SEAN STRUB: Thank you. Yes.

JORGE SALVERA: Thank you. Jorge Salvera [misspelled?]. AIDS Healthcare from [inaudible] Mexico. When we see that 34 million are living with HIV globally and only 8 million are getting treatment, do we really think that the reason why 26 million people living with HIV are not getting treatment is because we are trying to protect them from a potential human right violation? Isn’t the opposite the most common? I really think so. Denial for treatment, no access to treatment, stock-outs. Those are the most common human rights violation, not the opposite. [Applause].

Only this approach comes from a point of view from our very wealthy rich country who has covered all the ART needs, which is clearly not the United States, but I really think that the opposite is the main concern from human rights activists, the concern about not accessing treatment for people living with HIV. The opposite is a rare case, where sometimes it needs good to address them, but the opposite is the most common and we should focus on that. Thank you. [Applause].

KEN MAYER: The human rights abuses of which you speak of are hardly unique to the United States, that’s for sure. It’s coercive sterilization. There’s criminalization and scores of countries. There’s all sorts of issues. I just want to make that clear.

SEAN STRUB: Yes, back here.

JENS LUNDGREN: Hi, Jens Lundgren [misspelled?] from the University of Copenhagen. I have two points, really, the first point is that I agree with the panel that we have been using HIV treatment as prevention for quite a number of years, since many people is on treatment, is enjoying that secondary benefits, so I think we all agree on that, so in some sense, the question posed on this symposium is likely rhetorical.

My second point was really to address the discussion benefit to the HIV-positive person with high CD4 count and Keith, you mentioned one observation study in support of benefits to that person. I would want to draw you attention that there is three other observation.

That is they did not confirm that in NA Cortisol on balance and also think I would like to emphasize that there is an ongoing randomized trials since the general uncertainty in the field that we do not know whether there is innate harm to an HIV positive person with a high CD4 count, but being placed on treatment early on in the course of this infection, and therefore the question that we really need to address is the risk benefit ratio to treating people with HIV and early infection which is why we need a randomized trial.

A randomized trial is ongoing, we have been randomizing eight patients today, Monday, so clearly, there is clinical poise among the 230 clinics in 31 countries to actually address this question, so I think we need to really put pause on being too rhetorical around the benefits for the individual until we have further more solid evidence. Thank you.

JULIO MONTANER: I simply would say that none of the four medical studies that you’re referring to show a signal that there is net harm, so when you phrase that statement, I would agree with you that the magnitude of the benefit has not been fully established. It may be that the benefit is very small, point that is negligible, mortality end point, but harm? I am not aware that we have a signal.

JENS LUNDGREN: I need to respond to that because these observations are not designed to assess any harm that we are concerned about, which is antiviral toxicity outcomes which usually is non-fatal and as the consequence of the observational studies that has been assessed by the question is not capturing those types of events, so they cannot address the and give the picture about harm, so they can only provide a what I would claim to be an insufficient picture understanding on the potential of benefit although they are not consistent and we really need to emphasize that they are not consistent in their finding and several of them, the most recently published, did not claim any benefit at all and they are not able to assess the harm of non-fatal toxicity. Thank you.

SEAN STRUB: And one can only believe that they say there’s no net harm if you believe that the drugs are benign, which I don’t believe that they are.

JULIO MONTANER: Again, we have not discussed here the distant three proposal that is one of the extremes of the treatment as prevention scape. My proposal was to treat who have a medical indication of treatment based on current guidelines. I’m simply trying to correct Jens, which alluded to the harm has been part of the concern.

I simply said that if he says, they don’t show evidence of harm for the speculations we have studied. Jens’s own study previously have shown that chronic viral replication that’s associated with inflammatory processes that are devastating to the individual and therefore, there’s a significant amount of physiological data to support the current DHA recommendations that I did not write, but there are out in the public domain, suggesting that people should be offered treatment, not mandated to take treatment at any CD4s and I think that given this data, the evidence, that is a very defensible recommendation. [Applause].

SEAN STRUB: And that recommendation is based on expert opinion, not on clinical data.

JULIO MONTANER: The expert opinion is based on a variety studies including epidemiology studies, official pathology studies, drug cessation, therapy studies where they have been able to show that upon stopping treatment you actually get rebounds inflammatory activity and upon starting treatment, you shut down those inflammatory processes.

So there is a large body of evidence that points in that direction and what the experts have indicted is that in the evidence of definitive data about the magnitude of the effect, the patient and the doctor should have the benefit of having the discussion of the appropriate therapy as opposed to taking the patronizing view that we shall not offer the treatment until the ultimate bit of evidence is available.

Because there is no evidence at this time that starting treatment a year or two or three or four earlier will have a negative overall impact when, indeed, people who have HIV are going to need the treatment regardless within the foreseeable future and are going to need treatment for five to six to seven decades, so we are having a big argument about less than 10-percent of the time that these people are going to get treatment. That’s a very important point that we should all –

SEAN STRUB: Except the important point is the violation of patient autonomy. I don’t know –

JULIO MONTANER: You’re putting actually saying that I told you –

SEAN STRUB: No, no. I understand what you’re saying, but I’m talking about how it is then being translated and how it’s being –

JULIO MONTANER: But the fact that it’s been misimplemented doesn’t mean that the principle is wrong or the guidance is wrong. What we need to do is 540 implementation to be done and as it should be with respect to the human rights and with respect to the individual. [Applause]. Not stop the strategy, but actually ensure that we do it right.

KEN MAYER: But I think the crux of the issue really is the clinical encounter and I don't believe in acting loco parentus when I talk to a patient. I feel the onus is upon me to give them the information, let them make the best informed decision so I don't go into this ideological zealotry, but there are some people that say, what can I do now? If there's any likelihood that having untreated infection's going to hurt me in the long run, I'd rather move forward and I think there's evidence to support that.

There's some people who say, I really don't want to take these pills until the last possible moment, I've heard bad things about them. I'm not going to say, you're stupid, you're wrong, don't take these lessons. At the individual level, it's a much more nuanced conversation than we're having in the course of a large hall discussion.

More people are hearing what you're saying and not in radical disagreement about raising all the issues with the patients to be honest with them.

SEAN STRUB: Would the doctors then support the a written informed consent form that advised people of, say, for in routine testing for the risks of criminalization or that it was a more objective document for people outside of the guideline and people with high CD4 cells that detailed the known risks and benefits?

JULIO MONTANER: I have no difficulty with that. I have absolutely no difficulty with that. As I said, the past majority of North Americans here today in this city and in this country who need treatment are not on treatment and those are people that are outside of the courthouse that justice is having a clinical trial. Those are people that have less than 500 CD4. They have no options. That's a human rights violation that we need to fix. Above 500, they really fall apart and it's really not the focus of this discussion. It shouldn't be. [Applause].

CATE HANKINS: I think we have time for just a couple more comments. Do you want to comment, Anita?

ANITA ASIIWE: I tend to think that healthcare providers contribute quite a lot to stigmatization of HIV. Why are thinking about consent for HIV? But we don't do consent for malaria, where we are coming from? It's all supposition, so I think healthcare providers are knowingly or unknowingly, I tend to think it's more unknowingly, do a lot of stigmatization around HIV. You have to be very careful. Let's handle it as a disease condition just like others. [Applause].

PYLES TEE: My name is Pyles Tee [misspelled?] and I am from Cameroon. My question is orated to Ken. When the moderator asked a question to you, with those who have CD4

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counts superior to 350, what are you meant that they could all be placed on treatment, you can’t modify your very strong point which you made following your study in British Columbia, which showed treatment as prevention is very effective in all case including the prevention of mother to child transmission. You didn’t make that distinction that if the woman were pregnant or breast-feeding; it may be this could be an exception.

Now would your answers be the same? Because you seem to place it more on human rights than on the medical evidence that you give, so I wonder if your answer would still be the same that the country or the individual could decide and not as the person on treatment at this point. So I want you to at least make a distinction between the person who is actually breast-feeding or is pregnant and whose CD4 is superior to 350. Should it still be optional? If it’s optional, what about the rights of that unborn child or the baby who is still breast-feeding?

KEN MAYER: You’re giving a very important specific example and I think what also I’m trying to say is that when it comes to clinical situation, you have to deal with the specifics of the clinical situation. So I don’t know that we’re really prepared to say today that these are the indications that the different settings.

What is incumbent is to have the providers sufficiently knowledgeable to be able to inform that woman about her ongoing risk of transmission to the infant and that’s part of a conversation that needs to be held in a non-judgmental way, the idea is not to make the woman feel guilty, but inform her on what are her health consequences for that specific health situation, so again, as much as we’d like to make blanket pronouncements, I don’t think that’s how clinical care is performed.

What I think is important for us is to advocate for the resources so that clinicians and patients have the opportunities to have these conversations and that people can make more informed decisions based on the best evidence that currently exists.

LUIZ BRIGE: Luiz Brige [misspelled?] from Brazil. I try to solidify a new paradigm, like treatment for prevention but with the discussion coming back to Durban and access is what we really need to focus, especially to treat the third world, the developing world within the developed countries. So treatment prevention maybe could come as a secondary goal or a secondary byproduct, but do you really need to focus in a different direction when you should refocus on what we raised in Durban and we didn’t accomplish yet?

Maybe if we focus on that and again cooperation subproject because you came and you brought this the guidelines, let’s do it, let’s solidify, let’s treat, which is not like being treated, so this is the goal, this is the target. I don't think we need to open a new frontier and if it's still many issues. What the chair brought, I think it's true, human rights, maybe, I wasn't aware of that.

I've been to British Columbia by a cop, four Brazilians in a car. They treat us too well, better than my grandmother. You cannot compare, there are issues of rights and issues of stigma in this British Columbia to Brazil or other places, I think this a real important issue and you have to that in mind. Maybe focus here on treatment access. Let's implement, let's expand. That's the major issue.

JULIO MONTANER: You're absolutely right. The reason why I stay in Canada was because the cops were very nice to me. The point that I'm making is that in my opinion treatment as prevention is the best thing that ever happened to universal access because us understanding the secondary preventative benefit of doing the right thing as originally proposed by universal access, we elevated the value or the proposition so that hopefully the leaders of the world are going to be more willing to impress so that we more deliver on it.

So at the end of the day, while technically it's true, in my case, I view it as a gimmick to ultimately deliver what we promised what we were going to deliver to begin with. Since the guideline cover Durban today, all we're doing is saying, let's update the universal access pledge to 2012, as opposed to what it used to be, which is no longer valid.

CATE HANKINS: [Inaudible] and then we'll come back to this mic.

PEDRO KAHN: Pedro Kahn [misspelled?] [inaudible]I come from Buenos Aires, Argentina. What I said yesterday, as a member of two guidelines panels, the [inaudible] panel and the ISUSA government panels, I feel the need to reassure everybody that we are protecting the basic human rights by promoting treatment. We are promoting the basic human right, first to keep people alive and second to help people living with HIV to have as healthy as possible their lives.

Let me tell you, we are discussing it's all about the patients. It doesn't' matter. Do we agree that 500 CD4 is an accepted threshold? Almost for every value, even in double and triple from 350, it's almost possible, we will see the new guidelines going also to 500, okay, but also above 500, we have B-plus, we have pregnant women who should be get the treatment. We have people with TB.

We have people co-infected with HPV and HCV. We have people more than, whatever, 50 or 60 years old and people with high countable [inaudible] real diseases risk, etcetera. They are all eligible for their one benefit and there is certainly a proportion of patients that doesn't comply with any of these conditions. How long does it take until these people come down to 500 CD4s? Are we talking about three years?

Are we talking about five years? Are we talking about seven years? In a treatment, it's supposed to be for the lifetime. A lifetime for it, people living with HIV, thanks to antiretroviral therapy, it's not 52 years for a person that acquires HIV at the age of 25, so we are discussing that in a small nutshell. Let's leave it to the people that are doing the studies to tell us if we need to treat or not a person with 700 CD4s, it doesn't comply with any of the conditions.

On top, I forgot having viral load above 100,000 copies and the study will tell us about that. Meanwhile, treat everybody. That we agree. It's a 350 in what country treat everybody below 350. Is it 500? Treat everybody and obviously do it with the concept of the patient respecting the human rights but again, the basic human rights to be exercised is to be alive and healthy. [Applause].

PAUL BELLMAN: Dr. Paul Bellman [misspelled?] from New York City. I take care of many, many HIV-infected people and have for many years. So many things I could say in response to this wonderful session, but what comes to mind, just in the moment is to really thank Dr. Montaner for his incredible passion and knowledge and leadership on this vital issue.

The complexities are there, they've been beautifully addressed by the panel members, but if there's one thing to me that accounts for the cascade effect or this diminishment

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effect, it’s the lack of leadership at a public health level in this country.

I would welcome you to come to New York and lead in this endeavor. I’d like to say one or two more specific points or questions.

I’ve always been bothered by this idea that treatment as prevention is 96-percent effective. It’s not 96-percent effective, it may or may not be this or that; my question to you is why not work as hard as hell to define a stake for an HIV-positive individual where we can say, that specific individual is non-infectious today because everything in my mind in the literature, whether it be the analysis of semen, whether it be the epidemiology, whether it be what I see in my very large practice indicates to me that there is such a stake

The gentleman from France indicated with incredible boon it’s been for HIV-positive individuals to finally start to get out from under the stigma of feeling that they’re infectious, a danger to others and for together, a danger to them. That stigma, that fear, that shame, even within the public health community is what’s driving, in my mind, a good part of the new infections.

So why not really get to that place and saying, I insist on a test so that I know whether or not I’m infectious and if I’m not, it is something that’s a milestone in that individual’s life and a milestone in this epidemic.

JULIO MONTANER: Thank you for your comments. It's a long question, a long answer, but I would say that for practical purposes, the Swiss Declaration is the answer that you're looking for.

PAUL BELLMAN: But the CDC won't say that. Why not?

JULIO MONTANER: You asked me, so you know? [Laughter] I'm going to tell [inaudible] to say that. I'm going to present data at this conference that is going to show that the 96-percent actually is a 100-percent if you discount the first few weeks of the persons who started treatment. In my opinion that validates the Swiss Declaration. [Applause].

CATE HANKINS: I'm afraid – I'll let you speak and then I'll close. Well, then, sorry –

AVA AVALOS: Thank you. My name is Dr. Ava Avalos [misspelled?]. I serve as the clinical advisor at the Primary HIV Prevention and Care at the Botswana Ministry of Health. I wanted to speak to a couple more complexities. One is if I'm not mistaken, I know 52 over 80-percent that did zero convert were from sub-Saharan Africa.

This talks to the complexity of what a couple constitutes in our setting and also the complexity of sexuality in general. Also, at least in Botswana, we're already beginning to see some problems with supply CHAI and the availability in the long term as we're trying to scale up to 350.

Finally I have the privilege of living in Botswana for the past 11 years, but when I touch down now in the United States and I've seen the plicate climate of this country, I am scared. I'm scared because if somebody that looks like me right now in the state of Arizona can be picked up and held in prison without even probable cause, our reproductive rights as women, abortion, our rights for sexual reproductive health right now are on the table and it's extremely scary.

We need to politicize ourselves and yes, I absolutely support treatment as prevention and increasing access, but we really have to politicize ourselves very carefully right now in the context, with the outcome of the November election is incredibly important to all of us right now and we have to really be careful as we move forward that we're really taking the context of our treatment situations into account. Thank you.

SEAN STRUB: Thank you to all the panelist. Thank you for enduring my – well, we said we're cutting it off. We're at our time, I apologize. We were supposed to top at six, but thank you to the panelists. Thank you for enduring my passion as well. The one thing I do want to say that I want people to understand and Dr. Bellman referenced it. What we need is leadership. We need leadership and we need leadership from the scientists, we need leadership from the public health community, and we need political leadership.

The situation in the United States in terms of stigma is getting vastly worse. Vastly worse. Fear of casual contagion has slowly declined over the years. Stigma in terms of marginalization. Stigma in terms of pre-judgment? It’s much worse. Much more difficult for a young gay to come out being positive today than it was in my era when I came out to a loving AIDS community that was going to support and help and empower me to become an activist and an irritant at times.

Until we get the leadership to address the stigma and this is not about buying more ads on the sides of buses or billboards, it’s about eliminating the criminalization statutes. It’s about empowering and supporting networks and clinical HIV which have all gone away in the U.S. There’s no funding for that.

Just in the last few years, we have documented more than 1,000 circumstances where people with HIV have been charged under HIV specific criminal statutes because they have HIV. More than 1,000. We’re releasing data tomorrow showing that 2200 people in the U.S. survey with HIV, more than 25-percent of them knew people who specifically declined to get tested because of fear of criminalization.

This is a serious. It’s not that we can’t find the people who are positive. They don’t want to be tested. They are afraid of being tested. WE don’t offer anonymous testing any longer in any significant way. So these are the things if we brought these things back, we would get more people tested and more people in care and you have the stature. People listen to you. This is for real.

You just said you would support a disclosure statement for testing to identify. These are really important things for you to say that that has meaning. I would just urge you to really accept and help lead in that area and that’s how we’ll together realize what we’re all trying to accomplish. Thank you. [Applause].

[END RECORDING]
