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XVII International AIDS Conference
HIV Transmission under ART
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MALE SPEAKER: —that she is going to give us an overview, a detailed overview of the statement that the Swiss Commission on AIDS put forward a little while ago and that generated a fair bit of controversy. We will then have a panel presentation. There will be very limited five minute input statements by Myron Cohen, Nancy Padian, Kate Hankins, and Nikos Dedes. And we will follow that up hopefully with a one hour active and vivid discussion.

As you know, the field of HIV treatment and prevention is increasingly interested in the potential synergies that can emerge from using everything that we know including antiretroviral therapies to optimize our efforts to prevent further HIV infections. We in our group have taken the position that there is enough evidence out there to justify a redoubling of the effort in terms of increasing appropriate coverage with antiretroviral therapy to in other words, bring the treatment to the people in need, those that need medical guidelines for treatment, with the double goal of decreasing HIV related morbidity and mortality and the secondary goal of assisting our prevention efforts.

Soon our British government will be making an announcement of formally embracing this thinking as part of a program that we will be launching in British Columbia in the next several months. Much of the rationale in support of that

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was published by our group in the Lancet a couple of years ago and it was discussed at the Toronto conference. Subsequent to that, about a month ago in *JID* [misspelled?] we put forward some further modeling that was used using the British Columbia data. I will not expand on those details. I think that we are here to specifically review and discuss the content and implications of the Swiss statement and in order to move the agenda further, I will ask Ron Kidish [misspelled?] to step up to the podium. Ron is going to be the moderator of the session. He is the Director of Policy and Programs at The International AIDS Society in Geneva in Switzerland. He is originally from the USA and he has been living with and working in HIV and AIDS policy for the past 18 years. He has been a tremendous new addition to the International Society and I am really happy to have him moderate this session. Ron? [Applause]

RON KIDISH: Good afternoon, everyone. We knew this session was going to attract a great deal of attention, and it is nice to see a good crowd here of people from I think a variety of backgrounds. This is an issue that has generated a lot of interest around the world. To set the scene for us, the Swiss AIDS Commission study, we have Dr. Pietro Vernazza, who is the Head of Infectious Diseases in St. Gallen, Switzerland. He got his infectious disease training in Chapel Hill, North Carolina, in collaboration with Mike Cohen who is one of other

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panelists. He started his research in sexual transmission of HIV there in Chapel Hill, North Carolina, and now he is currently the President of the Swiss Commission on AIDS. Pietro, please come up here. [Applause]

PIETRO VERNAZZA, MD: Thank you, Ron for the kind introduction. I would also like to thank the International AIDS Society for giving us an opportunity, inviting us to give this seminar, and to actually share with you the basis of our statement, which was never thought as a statement that should be delivered worldwide, but that is how it went.

So, I would like, I would just like to start briefly by presenting the composition of the Swiss Commission on AIDS Related Issues. It is unique in a sense that it really includes several aspects, people from different fields and expertise, including experts in HIV medicine, but also prevention and social scientists and experts in political and legal aspects. So, you will understand that this group did not really make the statement or the basis for the statement, but the basis was actually prepared in a clinical and epidemiological expert group that is affiliated, like the diagnostic expert group, to the [inaudible].

So, why did we start this endeavor at all? Now, there were several reasons, and I will just focus on the third point here. In the past few years, actually many physicians talked to their patients and gave them some information regarding non-

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infectiousness under ART. But we had no control about the contents of those statements. In fact, I am aware of at least two public statements last year from HIV physicians, one in a German news magazine, and another on Swiss TV where individual HIV experts suggested that ART renders HIV positive individuals non-infectious. So, we wanted to influence the diffusion of this information and aim that a joint statement that was broadly supported by all the experts in the Swiss Commission.

Now, how did the clinical body assess the transmission risk? We know quite a bit about the biology of HIV transmission. For the purpose of the talk, let us suffice to say that HIV transmission is driven by two main factors, probably the most potent one being primary HIV infection and then as a secondary factor, sexually transmitted diseases that can occur during several later stages of the disease. That in each of these stages, HIV transmissibility is significantly increased while it is clearly lower in the chronic asymptomatic phase.

Now, we first started to define transmission categories, defining high risk as those risk situations that we should avoid in order to limit the epidemic, the spread of the disease. So, in this category would certainly fall primary HIV infection and STDs in the absence of ART. The next category would then be the intermediate risk, followed by a category which we termed negligible risk. We would probably all include

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condom protected sex in the absence of ART in this category. We all know that the risk is not zero, but in general, we consider condom protected sex as safe and tell our patients go ahead, no risk, since we know this risk is in the range of the risks of daily life.

So, what are the risks of daily life? Let me start with something that might be a surprise for you. Passive smoking. This is a population based study from New Zealand, and just consider you are a 60 year old man, non-smoker. Your overall mortality is about 1 percent per year. Your risk of dying increases if your household companion is a smoker by 20 percent, or in absolute terms, 1 in 600 per year will additionally die because the household companion is a smoker, because of this exposure. Just to give you a figure. There are also other activities in our daily life, and I do not know whether you recognize this young fellow, that also carry a risk.

For instance, each year approximately 200,000 Swiss alpinists are challenging snow and ice in the Swiss Alps. On average 10 of them die in an avalanche every year resulting in an average risk of death of 1 in 20,000, not speaking of all the other deadly accidents. Now, but I must tell you, this is a great source of pleasure and satisfaction. Now, when we talk about sex without condoms, some would also consider this as an

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issue of pleasure and satisfaction. However, we seem to have great difficulties to deal with this source of pleasure.

Anyway, this is not the first time that the Swiss and other commissions had to come to a statement regarding non-transmission of HIV. And I will review that data for you. More than 20 years ago we had to evaluate the risk of household contents. At the time, there were no documented cases of non-sexual transmission in households. Biological factors of transmission were poorly defined. Only few retrospective cohorts and only the four first were present in 1986, were evaluating the risk to household contents. So, less than 300 contents, all uninfected, were included in these studies. This results in an upper confidence limit of, for household contacts, of their risk of household contacts, of about 1 percent. And that was after an observation period of a little bit more than one year.

Now, nevertheless, we concluded that the risk to household contacts was minimal and our recommendation stated there is no risk to household or workplace contacts with the exclusion of sexual contacts. But in a new publication by Friedland [misspelled?] two years later even in the casual context, for casual context, there was still concern. In his introduction he wrote, "there remains a continuing concern that transmission may occur through close but non-sexual contact at home, school, workplace, and other environments." So, that

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really gave us confidence, what really gave us confidence was not the documentation of the low risk in these prospective studies. What gave us confidence was the fact that after eight years of HIV infection, we have not seen a tip of the iceberg of hidden cases of household transmission. Although I remember at least one very well documented case of non-sexual transmission from an infant to his nanny at the time.

So, ten years later, we were confronted with a very similar situation. We had to come to a public health statement regarding the risk of HIV transmission by oral sex. Again, no cohort studies to help us define the risk associated with oral sex. The problem was even more difficult since we were confronted with more than 40 documented cases where oral sex was considered the only possible risk. Lacking better data, we made the recommendation that oral sex can be considered safe. However, we wanted to exclude a specific situation where biologic arguments suggested a higher risk of transmission. Therefore, we defined oral sex as safe for sex when the positive partner does not ejaculate in the negative partner’s mouth.

Despite all these public health statements, we know exactly that the risk is not zero for virtually any situation. And significant risk estimates were published for those two practices that I have on the slide here. So, with all this in mind, we now had to come up with a risk estimate for sex

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without condom during ART. Again, the first thing to consider are published retrospective studies investigating the risk during ART. But when we looked at these studies, the numbers again were small. And if you look for these numbers [inaudible] there were no documented transmissions in viral load below 1,000. If you look at these numbers, you still add up with an upper confidence limit that is in the range of let us say passive smoking.

So, we also use then the secret formula as Mike called it, the mathematical model presented by Takra Bority [misspelled?] and others. In that model, the risk of transmission per sex act was expressed as a function of viral load in semen. We know from many experiences and also in insemination practice, that after three months of suppressed blood, blood viral load, there is no virus in seminal plasma either. And I am talking about free virus here in this model. So, we calculated the risk based on Takra Bority's formula well aware that this is an extrapolation, and confidence intervals are not known.

The Takra Bority original figure, you will see it later by Mike in the inlet [misspelled?]. Then result in this linear extra plot lot transformation and the yellow arrow here is the detection limit of the HIV ordinary detection in seminal plasma. Resulting in this again, risk that seems to be lower than 1 in 100,000. Just the use of that mathematic model.

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So, to continue, similar to the situation with household contacts, the most important basis for our estimate was the absence of documented cases of sexual transmission from an ART treated case. But what is the denominator? It must be a significant number, after 10 years of ART in many countries. Again we can only estimate. We know that at least 20 percent of the patients in the Swiss HIV cohort study that has been shown by my collaborator, Panotzzo [misspelled?], in an anonymous survey, 20 percent of patients have unprotected sex with their steady partner.

Actually, in our survey it was 25 percent. Much more than 300,000 patients in Europe are currently under ART. Now let us just consider 300,000 patients have been treated in Europe for at least five years. And having sex just two or three times a month. So, 30 times a year, not a month. Even if we only detect 1 percent of the cases that occur through that practice, having no documented cases so far results in an upper confidence limit of 1 in 100,000. And I used very conservative figures here. So, actually our estimate is also supported by epidemiological studies, and I am just presenting one study, a slide that I received from Burnett Herschel [misspelled?] as an example to demonstrate that the risk of transmission under ART is in the same range as with condoms in the absence of ART.

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So, and probably Nancy will also talk about this later. So, let us go back and consider biology. Same as we did with oral sex. We have to keep in mind that STDs will increase the risk of transmission. Not only that infectivity, but also the susceptibility of the non-infected partner. Another factor is timing. HIV viral load in semen may take some weeks more time to follow [inaudible] limit even if the viral load is undetectable in blood. So, it makes sense to use this information to target any communication that we might want to target to the individuals about safety under ART to the safest conditions. And that is actually what we did.

So, let us summarize again what the Swiss statement actually said. It was a statement that was delivered to Swiss physicians. And it said it is okay to talk about risk estimates. It said under optimal conditions, and I stress optimal conditions, the risk is in the range of daily life. We called it negligible. I understand that our title was misleading, and I apologize for that. I would not do that again. But still if you have read the statement, that is what was in the statement.

So, the conditions are long term, maximal suppression, more than six months, perfect adherence, regular checks with your physician, and absence of STDs. So, we also made clear that the only person who can ascertain perfect adherence and regular checks will be the steady partner and we also clarified

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that it will be the informed partner who has to decide for himself how to implement this risk assessment in his daily life. I could also very briefly mention our experience with this statement in Switzerland. A few physicians helped me to collect an anonymous survey with their patients and I have summarized that in a poster, Poster 212 tomorrow and Monday, and there are some handouts here, you can pick them up. Just briefly, it seems that people living with HIV and AIDS responded with great consent and relief to that statement and in general sexual behavior did not change in those individuals. We actually learned that many patients actually told us after we asked them and after the statement that they already had unprotected sex in the past, but they did not tell us.

So, let me summarize all these risk estimates. First of all, it is clear that these estimates have large confidence interval, and here I have started with anal sex and vaginal sex. I took this from Rachel Rohr's [misspelled?] presentation in *New England Journal of Medicine*. So, condom use is not safe, and you have the citation here again. But in a comfortable range that people can live a normal life. For oral sex, we have seen that we would discern a situation with higher risk which we would consider safe. And the other one with the ejaculation, which we considered not safe. Now, but based on the findings I have presented, we would place sex under ART in quite a safe range, but we still maintain that we would only

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consider ART as safe under special conditions, so we did a very similar, actually action as with oral sex.

So, let me end by citing the title of our media communication last January. There it said, good news, for a few prevention messages remain unchanged. Thank you. [Applause]

RON KIDISH: Thank you for the historical overview. It is interesting to see the perspective on this from a historical vantage. What we are going to do now before getting to any questions or comments for the initial presentation, is go to each of our panelists and have each of them spend five minutes on their perspective on this issue. Our first speaker will be Dr. Myron Cohen. Professor Cohen is the Director of the Institute of Global Health at the University of North Carolina in Chapel Hill, North Carolina. He is the Senior Leadership, sorry, part of the Senior Leadership Group of the NIH Center for HIV Vaccine Immunology and of the HIV Prevention Trials Network. Professor Cohen? [Applause]

MYRON COHEN, MD: Thank you. Good afternoon. This is a very patriotic symposium. So, I am a little bit anxious about contradicting Pietro’s very compelling presentation. And I kind of think I am going to set the stage with neutrality, like the Swiss flag. For this debate. And I am going to use slides, if I can figure how, how do you advance them, Pietro?

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Okay. So, the first, I am only going to show a few slides. And try and set the stage a little bit differently. And not really contradict Pietro, but present it a little bit differently. The first thing is, this is all being driven by a belief system. And the belief system is on that slide. That there is an increased risk of transmission depending on the person, the infected person. And as Pietro indicated, we have some evidence that people with acute infection are very contagious. This is based on the viral concentration recovered from both the blood and the genital secretions at the time of acute infection.

But there are only a very small number of people with acute infection. And then the risk goes down considerably. And probably the biggest group that represents risk of transmission must be people with established infection, some of whom have high viral burdens, and who do not know their status. Christoff Frazier [misspelled?] did an excellent model arguing this point in *PNAS* in 2007. There are 2.5 million people who are being treated. The question is how contagious are the 2.5 million people, and that is really the basis of this discussion and extremely important for the future as treatment marries prevention.

So, that is the belief. What is the plausibility of the belief? All of this is summarized in an article I wrote a few years ago, but there is very strong biological plausibility

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and shown in the left bars is an article by Pietro a few years go where he demonstrated that when we put people on antiviral therapy, after some period of time, we have great difficulty recovering HIV RNA in semen. There was only I think one subject out of 114 measurements in which we detected HIV RNA, and Susan Cuuven [misspelled?] did a similar study in women. So, these studies though, we do not get rid of the HIV DNA. There is breakthrough, but there is considerable suppression. So, the biological plausibility is very, very strong.

There are two retrospective clinical trials in which couples were examined retrospectively, and both suggest that when the index case, the infected person was on therapy, that the partner was at much less risk of acquiring HIV. There are two observational studies. In both observational studies, historical controls suggested that a lot of HIV transmission would be observed, but in the two observational studies, it was very, very rare for them to observe HIV transmission over a period of about 24 months. There are five or six ecological studies. These are studies of whole populations. Not modeling, but studies of the actual populations. And three of the studies suggest when the population achieves a great, when considerable ART is available to the population, that the prevalence of HIV is reduced. In two of the studies, that was not observed. But these ecological studies are susceptible I

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think to all the ecological fallacy which we can discuss later if necessary.

The problem with all of this is, we really do not know the degree of this 100,000 number that Pietro cites, I do not disrespect, but as he pointed out it is an extrapolated number. I do not personally know the actual degree of benefit from ART, we will come back to that in a second, and I certainly do not know the durability. And the durability is really an important feature of this.

Another issue here, and I realize this is probably difficult to read. At least it is for me on this screen. Another issue here is the pharmacology of the agents. And this is an advantage. The agents we are using now, which shown on this slide, is that we have characterized how much of the agent concentrates in the male and female genital tract relative to blood. And what is shown on the slide is that NRTI drugs, they often concentrate in the genital secretions. The proteus inhibitors have difficulty getting in the genital secretions.

But the issue here is very good for what Pietro's arguing. And that is if the drugs are concentrating in semen, and the drug is going to the next person with the semen. So, you are essentially bathing whatever virus is present in the drug, and you are using a microbicide. So, I think we have a big advantage in pharmacology as we try and develop this whole theme. Now the problem with the Takra Bority study, not

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problem the thing to analyze here, is that viral concentration really matters. This is a modeled study, there has only been one study of actual, one good study I will say. There are three or four studies like this, but there is one study by Tom Quinn, who is in the audience, where you have the blood plasma viral burden, and he measured the transmission probability within couples as a function of the blood plasma viral burden. Now the blood plasma viral burden only weakly correlates to the seminal plasma viral burden. That is an important issue. Nevertheless, Tom found that at a low concentration of HIV in the blood plasma burden, less than 1,500 copies, he observed no transmission events. That really agrees with Pietro's conclusions. The Takra Bority model is a model and we do not really know the upper or the lower boundaries. Every study that has been done that relates to this has all pretty much agreed with the middle boundaries. And as the copy number goes up, we think the efficiency of transmission goes up. As the copy number goes down, we think transmission is much less probable.

But I am unable to ascribe a number to it. Because I am unable to ascribe a number to it, we are doing a giant clinical study. And this is worth noting, and there is a website if you are interested in the study, it is called HPTNO52. It is a randomized controlled trial underway. And the trial has two purposes. One is to determine the very

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question that is begged by our whole meeting. That is, if we effectively treat the index case, and keep them suppressed, can we reduce transmission to the partner over many years? So, from the moment of inclusion in the study, the couple is followed for five years. That five years ought to be enough time for us to give some real numbers to this. The couples are enrolled at high CD4 count, because at low CD4 count, it would be unethical to withhold ART.

Now, when the partner has a falling CD4 count, when he gets anywhere, when he starts falling below 350, but certainly before they fall below 200, ART is then offered, and then the point is that we are also doing a when to start treatment study, since we are starting an early arm and a delayed arm, we are also going to learn whether early treatment is of benefit to the partner. So, 1,750 couples will be enrolled in the study followed for about 5 to 7 years in about nine countries. The study has about 600 couples enrolled today. It should be fully enrolled a year from December. But it will take us seven years before we have the answer to the very question that is being asked today. So, no answer will be available before 20-, I do not even want to think about it. 2016.

So, this is the bottom line. There is every reason to believe ART, in fact the treatment acts as prevention. And there is every reason to understand the attitudes that associate with the Swiss declaration. The converse is the

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concerns. Are the breakthrough viral blips? And the answer is yes. We know that people will have viral blips both in blood and semen. They do not always agree with each other. We have to be concerned about the meaning of those viral blips. And that is in blood plasma. Likewise, there are breakthrough blips in the genital secretions. There are intermittent STDs and not all of them are symptomatic. Certainly trichomonus [misspelled?] is often asymptomatic. And so you have to be concerned about unrecognized STDs. There is ART resistance.

So, when the person on therapy starts failing therapy, they do not know the next day they are failing therapy. So, they can accumulate significant viral load before resurfacing for their next viral load measurement. Now I realize, and realizing that this is a caution, it is something to worry about since a substantial number of people acquire ART resistant virus at the time of the transmission event. And then there are ART resistant superinfections. So, all of these concerns need to be played out in this consideration.

So, in summary, I am kind of a neutral person in this. I think there is terrific biological plausibility, but I am very much in favor of the study I am already doing to try and actually add numbers to the questions. So, thank you for listening. [Applause]

RON KIDISH: Our next panelist is going to help us take a look through what are the consequences of the Swiss

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statement. I am sorry, what are the consequences of such a statement for the prevention field? Who should be informed about such specific additions that make the risk of HIV transmission very unlikely. So, we want to welcome Nancy Padian to the podium, and Nancy is currently a distinguished fellow at Research Triangle Institute in North Carolina. She is also on Pangea [misspelled?] Global AIDS Foundation at the University of North Carolina, at California, excuse me. She is an epidemiologist who has worked on heterosexual transmission of HIV since the beginning of the epidemic in San Francisco, and has worked in southern Africa as well. [Applause]

NANCY PADIAN, PH.D.: Thank you. Thanks very much. I wanted to let you know that I put together this presentation with my colleague Mary Jane Rathern [misspelled?] from UCLA who also has some interesting ideas for interventions that might be based on this, that maybe we will have time to talk about at discussion.

I also wanted to let you know that my work most recently has been on HIV prevention in women, and so I have really focused more, it was sort of difficult for me to view this without the lens of someone who works on HIV prevention in women and really looking at the susceptible partner and I think Nikos at the end will be talking a little bit more about from the perspective of the person who is infected.

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So, what are the implications for prevention? I guess some of these are issues that Mike brought up and I think there are pros and there are cons. So, one issue is that in many of the studies that some of us have done, myself included, we have been, and again, my studies have really been in heterosexual transmission, we have been disappointed with the level of adherence, with condoms. Potentially, this might be better. I mean it is something that needs to be looked at, but it is indeed possible.

One other, insofar as the prevention statement is actually to do both, and I think it is really important that that be reinforced, it is possible that this could increase adherence to both, because you are now saying you have got to do both, and maybe they would be mutually reinforcing. It also could be that you have more effective and realistic condom counseling when you really are focusing on the fact that maybe you need to have intensive condom use early and late in infection as opposed to a really high level for the rest of your life. Another benefit which is really having to do more with care than prevention is that this message out there, I think would encourage testing, and maybe entry into care. So, that would be a side benefit.

So, what are some of the possible cons? And I have to say that I know that Pietro said that in fact the prevention message does not differ, and I think that is right. But I

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think that there is potentially misconception that could result and that is really what I am dealing with. Could there be risk compensation or behavioral disinhibition? And that means if you, are people going to think that if they are ART that they need to use condoms less even though the message is to use them both? A lot of my work is on gender power inequities and how that affects women's ability to protect themselves. Could this exacerbate that? And I will come back to this later, because the uninfected partner is having to rely on what the infected partner is letting you know about how much their viral load is and again, whether it is in fact necessary for them to use condoms. Mike already brought up the issue of asymptomatic STDs. He brought up viral blips. And then the issue is real time viral load. And that is if in fact one of the markers here of you having negligible risk is having very low viral load, with what frequency do you need to establish that and as a way perhaps to verify the fact that you have good adherence. So, there are pros and there are cons.

This, which is a lovely graph that Jeff Garnett [misspelled?], he was here at this conference, I do not know if he is in this room, made in a modeling editorial actually in countering another editorial in *Lancet* and this was Jeff Garnett and his colleague looking at transmission risk over 100 acts in discordant couples and I am doing, oh, this is the pointer. So, this is couples, god, I cannot even, just copied

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that. The percentage in which heterosexual transmission occurs, quite high if they use neither. If they use treatment alone, it is quite low. If they use 100 percent condom use alone, it is quite low and pretty comparable. But if they only used 80 percent condom use and not treatment, then it would be that much higher. And so I think what this highlights is the fact that condoms are effective when they are used consistently and correctly 100 percent of the time, and how difficult that can be to maintain, and maybe this would either be a good back up, if not a good substitute.

So, finally, I am just going to end with two thoughts that I have that again are sort of the pros and the cons. I know that in the statement it says that the decision to use condoms really rests on the uninfected partner, although I think in a couple with good dynamics that would made jointly. But then I think the burden is, and I do not mean just the physician, whosever counseling, because if you read the statement, these are guidelines for someone who is counseling someone that it is okay to talk about risks, it is okay to talk about negligible transmission.

So, the risk in some ways then in the hand of the physician and how to counsel. And the control I think is more in the hands of the infected partner, because it is up to that person to communicate effectively about viral load, and again of course you have the issue of other issues like undetected

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STIs and so on. That said, however, and I think this has to be the hallmark of whatever we do to disseminate information about HIV, and that is it is our imperative to disseminate accurate information so that you can enable an informed choice. Thank you. [Applause]

RON KIDISH: It was discussed that these studies are contextually based. And so to take a look at the consequences of the Swiss statement for the rest of the world, we are going to invite Catherine Hankins, who is the Chief Scientific Advisor to the United Nations AIDS program, UNAIDS in Geneva. She began work on AIDS in 1981 as Deputy Medical Officer of Health in Calgary, Alberta, Canada. And after moving to Montreal, she was the principle investigator of the Canadian Women's HIV Study. She edits the UNAIDS blog, *HIV This Week*, and in her private life, sits on the board of Geneva's supervised injecting facility. Kate?

CATHERINE HANKINS, MD, MSC, FRCPC: I first want to thank the International AIDS Society. Should we get the first slide up or I do it myself? Good.

Okay. I first want to thank the International AIDS Society and the Swiss Commission for convening this important satellite. There is no doubt that antiretroviral drugs play a role in HIV prevention. For example, in preventing HIV transmission from mother to children, and in post-exposure prophylaxis. They are under study in a number of countries.

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Randomized controlled trials of oral and topical pre-exposure prophylaxis are underway. However, how we speak about treatment as prevention can have unintended consequences. The Swiss Commission message was interpreted to mean that condoms did not have to be used if the negative partner agreed. I want to talk about the rest of the world, and by that I mean not everything outside Switzerland. I want to talk about; I have defined it as low and middle income countries where 94 percent of all people living with HIV live today. So, I will look at the applicability of the conditions that are laid out in the statement, at the practical application of the statement, and at the public health implications.

A study published in July by the Art Link Collaboration of Idea which is the international databases to evaluate AIDS, of 17 antiretroviral therapy programs in 12 low and middle income countries revealed that the majority of patients do not have access to viral load testing. In sub-Saharan Africa about one fifth of patients have access, and in Asia only 8 percent of patients have access to viral load testing.

What about the condition of absence of sexually transmitted disease? 80 percent of people living with HIV in sub-Saharan Africa have herpes simplex virus 2 infection. A large trial is underway to see if treating and suppressing herpes and reduce HIV shedding in the genital tract and reduce HIV transmission.

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What about other chronic conditions? Malaria causes modest increases in blood plasma viral load. Does this increase genital viral load shedding?

We still have much to learn about host characteristics such as immunogenetics and viral differences such as plate [misspelled?] differences. Fekefiremia [misspelled?] is higher in sub-Saharan Africans infected with plate C HIV [misspelled?] than in US people infected with plate B. Does this translate into a higher viral load set point? Does this affect genital tract viral loads?

What about the easier transmission postulated for plate C, or the faster disease progression observed with plate D? Do these affect the correlation, or disconnect between blood plasma viral load and genital secretion viral load?

As far as the practical application of the Swiss statement for the rest of the world where viral load testing is not routinely available and when sexually transmitted infections can be common, the most obvious one is for fertility planning. For discordant couples, antiretroviral treatment to achieve undetectable viral loads in the HIV positive partner can reduce the risk of sexual transmission of HIV during conception. Where the woman is HIV negative, there may be an additional role for pre-exposure prophylaxis until pregnancy is established at which time it becomes critically important to resume condom use.

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My third and final point is about the public health implications of the Swiss statement. A modeling exercise that Nancy's just mentioned published in the *Lancet* last week reported that the risk of HIV transmission is not zero in heterosexual partnerships and can be high among men who have sex with men. If the message is misinterpreted to equate treatment with prevention and risk compensation based on the perception that risk is now minimized occurs, with declining condom use there could be substantial increases in HIV incidents.

In conclusion, using treatment as prevention as has been suggested by the Swiss Federal Commission has limited applicability for the vast majority of people living with HIV worldwide. At the population level, this strategy can do more harm than good. However, if treatment is combined with correct and consistent condom use, there is potential for real synergy as can be seen here in the figure that Nancy mentioned. Rather than stopping condom use with treatment, we need to be stepping it up around the world along with exploring non-penetrative sex for mutual pleasure. Thank you. [Applause]

RON KIDISH: There has also been much community response to the statement, and here to look at the consequences of this statement for the community we are going to invite Nikos Dedes who is the former Chair or the European AIDS Treatment Group and currently Chair of the EATG Policy Working

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Group. He is also Co-Chair of the European Union Civil Society Forum on HIV and AIDS, Co-Chair of the EMEA Patients and Consumers Working Party, and he has been involved in AIDS activism in Europe since 1997. Nikos? [Applause]

NIKOS DEDES: Thank you. I would like to thank the organizers for the invitation. I was asked to provide some comments on the Swiss presentation, both as a person living with HIV, but also as a community activist involved in national, European, and international policy. As you know, the Swiss statement created a controversy which was mirrored in the divided opinions of the community. The community still has not resolved and has not reached a consensus. And therefore, what I will be presenting are the current thinking, my personal current thinking based on the reading that I did around community based articles.

So, in my presentation, I will have three parts. First about the impact that the Swiss article and the debate around the article can have on people who live with HIV, about policy makers, and then there are some other statements that I will make.

For me, a simple translation of the existing data is that there is logarithmic reduction of the risk of transmission that parallels the logarithmic reduction of viral load. In other words, all risks of transmission regardless of their relative difference are reduced accordingly on treatment. The

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most important I think impact for people living with HIV is that the realization that we will no longer consider ourselves to be a life long threat to others, and to our partners. When I was diagnosed and had the relation, discordant relation, I always had the fear that a condom might break, and that my partner would be infected. And if one interprets the data of how likely this is when you are on a successful treatment, then you know that this is no longer the case.

It is also important that the discussion around this will help regain the right to uninhibited experience of intimacy and sexual pleasure, for all couples. And yes, we can have children. With the algorithms that were presented, it becomes clear that even discordant couples with the help of treatment and pre-exposure prophylaxis throughout the world can have children, and I mean throughout the world because sperm washing and assisted reproduction is not widely available.

And finally, these messages if they are communicated extensively, they can help reduce the stigma and discrimination towards people living with HIV. They will not be the vectors of disease or the index cases ready to transmit the virus.

So, it is our joint moral obligation to communicate in a clear and understandable way what the data says to all. To the people living with HIV who do not perhaps recognize what are all the consequences of these data. And of course to the general public and to the policymakers.

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Coming to the policy and the public health, I think the article has been criticized that actually it may be applicable on an individual level, but it is not very useful for public health. I believe the contrary. I think that it helps tell us where transmission takes place and where it does not. And this clarity is necessary if we want to design interventions, and I have noted there that it is clear that it is most likely to happen in circumversion [misspelled?] where STIs are present and to people who are undiagnosed.

The other point that comes very clear from the data is that treatment equals prevention. There is a mutually dependent continuum of prevention, testing, treatment, care, and [inaudible] legal protection. This has been identified; I think it also came quite clearly in Toronto. Treatment can be part of the prevention strategy, and it has to be utilized as such.

It also contributes to the traditional prevention because it will force us to come up with more subtle and more effective safe sex messages. It is no more a taboo to discuss existing practices, unsafe sex practices between couples has been the norm rather than the exception, and the fact that doctors were not willing to listen did not help patients share that. There is, it also refocuses the attention to the responsibility for the protection of the undiagnosed people who, so these will become also a priority for HIV prevention.

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And it refocuses on the importance of sexual health. STIs are treatable and preventable and they should be monitored both for people living with HIV, but also for the high risk groups.

And here I have some positive outcomes, as I believe could come out from a generalized discussion on the Swiss article. It helps alleviate the burden of being HIV positive. It contributes to disclosure to friends and partners. It contributes to safe sex negotiation. People on treatment and their partners are motivated to increase adherence. It highlights the need to create affordable diagnostics for the developing world. People reluctant to initiate treatment are also given another motivation to do so. It also helps maintain a relationship of trust between HIV communicators, both doctors and community people, and their audience, by not being deceptive or suppressing relevant information.

Apparently people are aware of this data and they receive very conflicting message from their doctors. And from the community. No more ludicrous and terrorizing warnings about superinfection towards positive couples on treatment. Better understanding for legislators and prosecutors of the inability of the law or prosecution to contribute to prevention. It also helps define the real intentional and deliberate exposure for transmission versus fear of disclosure. And it has highlighted the number of unanswered research

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questions and created an intense and present demand for the answers.

It has a vital importance in increasing awareness of sero conversion symptoms to both doctors and members of the high risk groups; because we know that it is very likely that transmission is taking place there. No more nightmares for condom breaks for discordant couples. And increased intimacy and sexual pleasure will also contribute to more fulfilling and thus, longer lasting couple life and make perhaps extramarital sex less desirable. [Applause]

So, in conclusion, I think that the Swiss National AIDS Committee, whether they fully realize it or not made a call for evidence based and data driven communications, policy, and programs. Thank you. [Applause]

RON KIDISH: So, we have a panel of very diverse expertise and opinions, and what we want to do now is have a very rich discussion. What I think we could do is there are two microphones. If we could maybe start, take three or four questions. Come up to one of either of the microphones. Please introduce yourself and the organization you are from, and if we could urge people to please keep their questions brief and maybe start off letting us know whether you are asking a question or making a statement. And if you are asking a question, we can check with that in a minute, and if you are asking a question, please let us know who you would like to

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direct the question toward or if it is a general question for all panelists. And we are asked to see if there is a way of getting more light in the room. From up on the podium it is hard to see the audience.

The AV people will check on that. But first—

GEORGE MARCUS: Okay, my name is George Marcus [misspelled?]. I am from Germany. I am working at the Robert Koch Institute [misspelled?] in Berlin. And this is more a general statement, not a specific question. In Germany we made the experience after the publication of the Swiss statement that there is some, well; some expectation from the community that we adopt a similar statement in Germany and what we see is that the pressure to adopt a similar statement comes mostly from the MSM community. Not from heterosexual people who are infected with HIV.

So, what do people understand if they hear the message from the Swiss statement, whose first desire is not to get a child in a sero-discordant relationship? Who are not monogamous. And who come from a community, HIV positive, MSM have in recent years experienced in Europe and in North America, well, a rise of co-epidemics of other sexually transmitted infections. We have STI incidences in HIV positive MSM of bacterial STIs in the range of 30 to 50 percent per year. That is very high incidences of STI, of bacterial STI co-infections. So, what, again what, how do people understand

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this message and how will, and how do they want to act on these messages? If you look at HIV sero-discordant couples in MSM, then we can see from studies we did that the HIV positive partner in such a sero-discordant couple has higher STI incidence than the HIV negative partner in such a sero-discordant couple. Which is related to another strategy that has evolved in recent years in HIV positive, mainly in HIV positive MSM, which is sero-sorting. So, not taking condoms if they think their partner has the same sero status.

RON KIDISH: Okay.

GEORGE MARCUS: Which is a strategy—

RON KIDISH: If I could, you have a lot of issues for the panel to look at so let us stop there. There is another question.

Do we have other questions from the audience?

RON BARREM: My name is Ron Barrem from the United States from Columbia University. I think there is a little confusion on the panel actually, because the statement by Nancy Padian and the statement that I thought I understood as coming from the Swiss statement were completely different. My understanding was that the Swiss statement did not say that couples should continue to use condoms and be on therapy, but rather that the option was available where a discussion had taken place about whether to use condoms or not. That is a very, very different statement. I think we have to clear about

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what the Swiss statement was saying. The other thing about potential risks with viral blips, et cetera, there is no such thing as risk free existence. And the question is if there is the potential for a viral blip and if there is the potential for a viral blip in conjunction with an STI, I am not talking about Africa now. Then the question is how often will these occur and on a population basis, what risk is created? That it seems to me is the question. Not whether there is zero risk. Pregnancies are not zero risk. Having penicillin is not zero risk. So, I think the idea of trying to place the level of risk in the context of what in research we described as negligible risks, is precisely the way to go.

RON KIDISH: Thank you. And one last question?

MANUEL BADIGAY: Manuel Badigay [misspelled?], Switzerland. Actually as a disclosure, I was in a subclinical commission also regarding these guidelines. Just a very short statement and then a question. First I would like to say that these guidelines are really an excellent instrument for physicians to have really very good thought about this situation.

So, my question to all non-Swiss panelists is, is there a movement now to do guidelines, at least I say now for the Western world, as there are treatment guidelines for developing countries and developed countries, they may differ, but to have a comprehensive guideline which take into account some very

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good thoughts of this excellent symposium. I congratulate the organizers. Because I think the time is right. I see that there is not a real great contradiction what is said. There are very good caveats we discuss with patients and nevertheless I think it would be very useful not to just say the guidelines are not optimal or this and that, but that we go on a way even if data is lacking as we did before in all fields of medicine where evidence is not complete, to have comprehensive worldwide guidelines. I think the time would be right. [Applause]

RON KIDISH: Thank you. So, we have a number of key questions for the panel. The first was the example from Germany where there was pressure within Germany not to make a statement from in this case the MSM community for among other reasons, fear of STI epidemic or other co-infections. There was a question of how the message has been received in Switzerland in terms of the statement. What has been the response? There is a question about the movement in other countries from our last questioner here. Will this have an impact in other countries to follow suit or continue further study? And then a question specific to the Swiss statement, what did it say about condoms, relative to transmission, and questions about viral blips and risk levels. So, let us start from this end of the panel and see who else wants to respond to these many questions.

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NIKOS DEDES: Thank you. I take the liberty to start. One thing that I would like to make sure that these should not be questions and answers. It is not that we have the answers. I think there is a big group of experts in the room and I would just enjoy if we could discuss these issues. So, for the German experience, I do not really know what the problem is, but one thing I can tell you from the experience in Switzerland after the statement, I think we have never talked so much about STDs after this statement. So, I think what the statement really made is to stress the importance of STDs. And it is my big hope that patients and partners would actually understand the importance and implement that and take this into their daily life. So, there are many other collateral affects that we have not expected, actually. But, so I would not be too much concerned. I mean, I have many other issues, but I have talked.

NANCY PADIAN, PH.D.: Yeah, I would just like to make a comment about the communications issue here. There is no doubt that physicians worldwide who are dealing with patients who have undetectable viral loads and no STDs and are in committed monogamous relationships need to be equipped to counsel them, both about conception risks and about HIV transmission risks. But when one holds a press conference, we live in a very global world. That message goes out worldwide. Now I have heard a lot of anecdotes about the effects of the statement. I will

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just mention two. One from Geneva where the organization working with sex workers in Geneva said they were having trouble explaining on the ground the meaning of the statement. That sex workers who were HIV positive and on treatment interpreted it to mean that they did not have to use condoms and therefore could make more money. The other was from the head of a national AIDS commission who said, I asked what happened in your country. How did you deal with the statement? And he said we suppressed it. We did not, journalists contacted us and we said we have no comment. This has no relevance for our population. So, I think we have to be very careful to be very sure about what we are saying and to whom it applies, because there are many negative, unintended, but negative consequences. [Applause]

MYRON COHEN, MD: Well, I would just add a few points. One point is that of course the Takra Bority study that was shown by several different speakers was focused on heterosexual vaginal intercourse. So, the probability number that was ascribed does not relate to receptive anal intercourse. Receptive anal intercourse is much more efficient. The discussion of whether ART has the power to suppress receptive anal intercourse, we do not understand that transmission very well, it is just worth keeping in mind based on our German colleague's statement. I am a little concerned, Kate Hankins indicated one of her big concerns, I am going to criticize

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another panelist, take that liberty, one of her big concerns was a technical concern, and that is having the ability in a country outside the developed countries, or less research constrained countries of measuring minimal viral load for example. I think that is a technical problem, but there is a lot of work going on and a lot of, within a couple of years, I suspect there will be tests that are cheaper and more widely available.

So, I think that it would not be a reason not to pursue this line of reasoning, that technical limitation. I think that would be a soluble problem. Third, I am a little concerned. I am much more confident that the population level benefits, again I am going to argue with Kate a little, I think the population level benefits of more testing, people knowing their status, using more antivirals, that we will see reduced prevalence. And I know Julio plans on doing a study in British Columbia that I really think is worth just mentioning because your hypothesis is population level hypothesis, not a per couple hypothesis, and I am going to turn the microphone over to you and force you to mention what you are interested in, in a second. And lastly in terms of the US guidelines. The US guidelines or policy statements would come from the US Center for Disease Control and Prevention. They are having a panel meeting in October. I do not know the full scope of what will be discussed, but it certainly is related to the benefits of

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ART as they relate to prevention, but I do not know that they will get into this issue. So, we will see, but they are having a meeting. Julio?

JULIO MONTANER, MD, FRCPC, FCCP: He does not think much to force me to talk about this issue, so I will gladly accept. A few years ago we were struggling with some of these same issues. And we took the position that while we are not 100 percent confident at the individual level, how well this works, and you can tell the real controversy around it, it is a lot easier to understand that at a populational level if we lower the population viral load through the use of antiretroviral therapy, we could act as an added secondary layer of protection and therefore see decreases in HIV transmission.

I do not want to take too long to explain where that comes from, but at the end of the day, we use populational data to model these and the data is quite compelling in the sense that we expect the direction of the effect of wider coverage of antiretroviral therapy in the population to be associated with decrease in transmission. And there is a unique window of opportunity to do this because with the newer guidelines that greatly expand the number of people who meet a medication indication for antiretroviral therapy, and with a greater willingness of our bureaucrats and the politicians to really drive an effort to expand antiretroviral therapy, we think we

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are in a position to make a demonstration project out of this.

I must confess that on a private level, when we have been able or asked to counsel individuals specifically on issues of procreation or for a variety of particular reasons, even before the Swiss guidelines were out, we had taken a similar position. That there may be a risk. The risk would be relatively small and probably acceptable within the risk that you as an individual have demonstrated comfort since you are already engaged in a serious discordant couple whereas you pointed out earlier, condoms do break and accidents do occur and so on and so forth. So, I think that with I have completely clean on this issue.

BERNARD HIRSCHEL, MD: I have just one thought to add to the German colleague’s statement about very elevated levels of STIs in German gays. Well that must mean that they are not using condoms, does it not? And that is a problem. Because I have heard it said that doing the same thing twice and expecting a different result is the essence of what is stupid. And if the result of 20 years of condom promotion in Germany is that we have a very high incidence of sexually transmitted infections, then maybe it is time to look for other means of prevention. I would add that the same is true of some studies from Africa where infection rates in programs with condom promotion are shockingly high. And suggests that condoms have not been used in spite of the promotion. [Applause]

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RON KIDISH: Just because he was not introduced, he is also going to be summarizing this session, who just spoke was Dr. Bernard Hirschel, who is a self described dinosaur of the HIV/AIDS world. He is currently the Director of the HIV/AIDs unit at Geneva University Hospital in Geneva, Switzerland. I am sorry. Nikos?

NIKOS DEDES: Well, what I wanted to say both about the statement from the German colleague and from the Swiss physician is that indeed this highlights the need to agree on how we communicate what the data show. And we have to agree on specific counseling guidelines for doctors or other communicators towards HIV positive people. I wanted to make a comment about some of the caveats that I see in many slides and are mentioned many times. I wonder way Bernard does not trust them.

For example, these so called blips. Blips in therapy means that you have a detectable viral load of 80, or 150, or 200, but you cannot call a blip something which is 2,000. And for all the data that has been published there is no transmittal which has occurred when viral load is less than 1,500. Therefore, it is very probable that these blips are completely irrelevant for the increased risk of transmission. The other point I wanted to make is about the acceptable risk. It was mentioned by Ron Behr [misspelled?] that we live in a life where we have to accept risk. I would like to remind the

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audience that young people today if they are heterosexual, they pay no attention to condoms, and even if they engage in gay practices, they also do not pay any attention to the use of condoms, one of the reasons being that HIV is no longer perceived as a terminal disease.

So, the perception of risk even if one gets infected, has decreased very much. But what we are discussing here is not this type of behavior, but we are discussing whether it is an acceptable risk to have unprotected sex with someone who is on treatment which is actually a lower risk than having sex with a condom with someone of unknown status or who is HIV positive. And for the prevention messages and for the prevention interventions, it is vital that we understand that the people who do not know their HIV status are actually contributing to HIV infection much more than people who have diagnosed their HIV status. [Applause]

CATHERINE HANKINS, MD, MSC, FRCPC: Quickly, just because my name was brought up I feel like I have to say something. But it really just gets back to the issue about communication. Honestly Ron, I do not understand what you thought that I, that was a misunderstanding. But it is, just to reinforce what everyone is saying, this is a tool that could be, insofar as I understand it, and I do not want speak for you guys, but this is a tool for people who are counseling to use to counsel people about potential risk and that is in fact

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again, it is up to the negative partner, whether jointly or individually, whether they want to use condoms, knowing that. And I just think, and if I screwed that up in my presentation, then I apologize.

RON KIDISH: Get more comments and questions from the audience. Please stand up behind the microphones. Okay.

ORLANDO HUDEL: My name is Orlando Hudel [misspelled?] and I run an organization that is called HIV Africa. I do work in Africa. It is interesting to see that the entire panel is white. What I would like to beg you and plead with you is when you speak always make clear which population you are speaking about. In Cameroon where I work, two thirds of positive people are female, and the population, I have never ever seen a couple where one person is positive and the other person is negative. The infection occurs immediately in couples. And I want someone here on the panel to answer the question, have you ever calculated a percentage of people that you are actually talking about? We have 42 million people that are HIV/AIDS positive. You are talking about 2.5 million on treatment, and from those 2.5 million, actually it is only a very small part that are the ones that have no STDs, no other infections, that are monogamous, and I can go on and on. So, you are speaking of a population of what? 0.001 percent? [Applause]

NIKOS DEDES: Just to make a brief comment here. I think you are perfectly right and I would like to repeat what

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we said in our media letter. Good news for a few individuals. And I think I could not agree more with what we said.

RON KIDISH: Okay. We will take you sir.

GREG BROWN: I am Greg Brown [misspelled?] from the Australian Federation of AIDS Organization. I also work in a school of public health. And my main question is that, is realistically what we are looking for is being able to open up the kind of discussions that we would like to have between, within community, with doctors and so forth, so that it is actually clear, it is honest, and it is up front, and we can actually start talking realistically about risk and things that have been happening for some time now.

My concern is that we know the data, in Australia a lot of the concern and the reluctance and so forth around the statement, one of the major issues has been the studies have been predominantly within heterosexual context, and have not engaged, it is not a lot of data apparently around risks of anal intercourse. What I would like to know, and I am happy with anyone else is what are we then doing about that? Because it concerns me often that we tend to sometimes go down the path that if we do not know the answer, therefore we cannot go there. Or if there is not the evidence, that means we do not go there. What I would like to be knowing is if this is already happening, which we know it is, in couples in relationships, what do we know about how this translates within

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anal sex. And if we do not have all the answers, how are we going to get them?

EDWIN BERNARD: Edwin Bernard [misspelled?] from the UK. I would like to ask about the other part of the statement which was driven by the draconian HIV exposure laws, both public health and criminal laws in Switzerland. And I wonder whether there might actually be unintended negative consequences by your suggesting that the positive partner needs to disclose to the negative partner and the negative partner needs to make the decision about whether condoms are used during unprotected sex. Because HIV exposure laws are actually disclosure laws. They are HIV exposure laws that happen in jurisdictions all around the would, particularly many states in the US and all over Canada. They actually force disclosure when an HIV positive person has unprotected sex. And people have been prosecuted and are in prison for this one incidence of unprotected sex without any transmission, just exposure.

So, no actual harm. And I wonder whether your statement actually reinforces some of these HIV exposure laws by recommending that the HIV positive person discloses that they are on treatment, discloses they have an undetectable viral load. It means that the HIV negative person has to make the choice. Because good public health education suggests that the responsibility is equal. It lies with both the HIV positive and the HIV negative person. [Applause]

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Thank you.

RON KIDISH: I am going to ask our moderators to please take notes, I mean our panelists to take notes of issues or questions you want to respond to and take a couple of more statements or comments from the audience.

HUNTER GUISE: Yes. My name Hunter Guise [misspelled?], and I am from HV Demark, and we have in fact, okay. My name is Hunter Guise and I am from HV Denmark. And we have in fact one of the countries in the world which has exposure conversation in relation with HIV. And my question is very similar to the question before, but more specific. Because you have talked about condom use and kind of put up a measurement for that and also for people that are on treatment, and I would like to just have a clear answer, would you consider condom breakage as the same being on treatment? Because in Denmark if you have a condom breakage, the law in Denmark does not apply any more. So, would you say that treatment would do the same in our case of our law? Thank you.

RON KIDISH: Okay.

MALE SPEAKER: Could you repeat the question? It was not quite—

MALE SPEAKER: Condom breakage?

RON KIDISH: Are you saying that condom breakage is criminalized? Was that what you were trying to say?

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HUNTER GUISE: No. No, with condom breakage, it is, when, then the law does not apply any more in Denmark. When you can prove that you have condom breakage. So, if you, then the law does not apply any more, and the exposure law. But what I am saying is that the equivalent of condom breakage, is that the same risk as being on treatment? Does that clarify, or?

RON KIDISH: Essentially, he is saying if you use a condom, but it breaks, you are not liable, and so what is the relative of this statement to others. From a legal perspective.

RON KIDISH: Sir? Have you spoken already? Okay. Go ahead. Well— I would like to give the chance to folks who have not asked a question yet if you do not mind. Please at the back?

NICK RASMUSSEN: I am afraid this will just take a little bit longer. It is not really a question. It is a statement because I suppose that you also wanted to hear about the organizations of PLHIVs. Not only the statement of Nikos Dedes, I think what you will experience now is life comment to only Marcus' [misspelled?] statement, as well as support for at least the last statement in Nikos' very fine presentation. It is called the Mexico Manifesto which has been a paper running around for the last several weeks under nondisclosure until today. The Mexico Manifesto is a call for action by people who

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live with HIV and AIDS. It has until now been subscribed by a considerable number of organizations, PLHIV organizations in Europe, as well as some individuals in the US. And I do not know whether my Brazilian friends are here and therefore decided to sign as well.

RON KIDISH: Sir, could you tell us what the Manifesto says?

NICK RASMUSSEN: What is the benefit of it? It is meant to support the ECOF [misspelled?] statement. This statement by the Swiss Commission. We PLHIVs really clearly welcome this statement and we also draw some conclusions in the sense of requests that we wish to address to all actors and key players in the field of HIV as well as to the media, and finally this could help improve some stigmatization and discrimination and criminalization defects that we are still suffering from. I did not want to tell it, but I am the member of LIFE, the Swiss National Organization, a member of the Board.

My name is Nick Rasmussen [misspelled?], and I would like Michelle Meyer [misspelled?] who is the initial author of this Manifesto just to give you the six key sentences of this Manifesto. She is actually the President of LIFE, and I did not want to tell it, she is also my partner, and here are our two young girls. We are one of these sero-discordant partnerships or different what we like to say, who really

engage for this statement. So, if I could give the word to Michelle, now.

RON KIDISH: Sir, if we could, before going into that, I think you have physical copies of the Manifesto and perhaps give us the electronic link. There are many other issues to discuss and I think we want to congratulate you for your action, but continue with our discussion around a variety of issues, if that is okay.

Okay, could we have one more comment from the—

ELIZABETH CUZANNI: Yes. My name is Elizabeth Cuzanni [misspelled?]. I think that we, to get back to this issue of risk. Everyone takes risks. We decide what risks we take in the light of the best available information that we have. Strategic positioning, that was not something that came from public health professionals. It was something that came from a community that was trying to minimize its risk and maximize its pleasure in sexual relations as best they could in front of the data they had. And the same thing with sero-sorting.

Now, sero-sorting actually is working quite well for people who are HIV positive bare backing among people who are both positive. It is not working so well for people who are HIV negative. Why? Because if you are on gaydar or gay.com three times a week or four times a week looking to bare back with another HIV negative partner, you are quite likely to find a partner who is undiagnosed, newly infected, very highly

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infectious, and therefore you put yourself at great risk. So, in fact this statement is of enormous use to people who do make sophisticated decisions about the risks that they take every day of their lives, and this just gives them an extra piece of information, which is oh, gosh, if I am going to bare back, maybe I should do it with someone positive on treatment, rather than someone who says they are negative. [Applause]

RON KIDISH: I wanted to just, before we take more comments from the floor, ask our panel to make any responses to some of the many issues that were brought up. Hopefully you were taking notes. Some of the key issues were around criminalization and legalization issues, what were some of the outcomes about anal sex, how was this taken into context? And who was targeted by the statement was the first comment that we had from the floor. So, all of the other issues that were brought up, does anyone want to make some comments?

Kate?

CATHERINE HANKINS, MD, MSC, FRCPC: Yeah, just two comments. One is that I agree with Nikos that if this puts the spotlight on undiagnosed people and encourages knowledge of HIV status then this is a positive consequence of all of this. And I would just like to clarify for the woman that is working in Cameroon, I actually have in front of me data from DHS from five countries including Cameroon, and basically two thirds of infected couples are discordant couples, two thirds of them.

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In 30 to 40 percent of them it is the woman that is the HIV positive person.

So, I think there is an assumption among people that if one person is positive then the other one must be as well. And we need to be really encouraging sero-discord, well non-diagnosed couples to come forward and be tested and if they are sero-discordant, there are things that we offer and part of it is treatment. Part of it might be male circumcision. Certainly prevention of mother to child transmission. It creates the possibility for prevention and for treatment.

RON KIDISH: Anyone else? Does anyone have any comments about the criminalization issue that was brought up?

NIKOS DEDES: Maybe a short comment about the criminalization issue. I think the ECOF statement was not addressing couples that do not disclose HIV information. So, I could not see how the statement could address those couples. The legal issue that we have in Switzerland is that you are liable even if you disclose your information to your partner and if you have sex with your partner without condom, you are actually liable of trying to transmit an infectious disease. And we wanted to stop at least that point. So, I could not see the other problem.

One thing, I am very happy with the information that Kate Hankins just corrected from Africa. I was very surprised to hear those figures. And one thing that I also would like to

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correct which you said, we did actually not make, need a conference. That was not our aim. We never did that. We actually wanted to respond to minor conferences that have taken place already. And that is one thing that you also mentioned. The physicians, you think it is okay, physicians talk to their patients. Our point was that we do not know what they talk to them, and what we have realized now, they have not talked about STDs and adherence as we do it now. So, I think the statement stresses these important parts that will also answer the concerns that Mike had with resistance. I do not see a single patient who develops resistance if he is six months suppressed and remains with perfect adherence. That just does not exist.

RON KIDISH: Other comments from the panel? Okay, from the floor? Yes, sir?

MALE SPEAKER: Okay, so I would really welcome it if we could use the first statement on reduced infectiousness under antiretroviral therapy if we adopt it to populations like MSM, if we can use it to refocus the attention on the problem of the STI co-epidemics that have evolved in these populations. If that would be the outcome, I would welcome that very much. So, far, I think, the health care systems in countries with MSM epidemics have been very inefficient to address the STI problems in the MSM communities. So, in HIV positive men who get antiretroviral therapy, so who should see a health care provider at least four times per year, in Germany they have

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just a slightly minor STI incidence than HIV positive people who do not see a health care provider. So, much about the efficiency of the health care systems to address the STI epidemics in MSM communities.

RON KIDISH: Thank you. Sir?

ADRIAN COMACHO: Hi, my name is Adrian Comacho [misspelled?]. I am an ADID fellow here in Mexico. Just a brief question. How is the Swiss government planning on doing an evaluation on the outcome of this statement, positive or negative, and should we be waiting for another statement?

RON KIDISH: Okay. Go ahead, sir.

JIM PICKETT: Thank you for a great panel. My name is Jim Pickett. I am the Chair of the International Rectal Microbicide Advocates. And I have not heard a lot of discussion about new prevention technologies, vaginal microbicides, rectal microbicides, prep, and I am wondering how this I think fabulous statement and very important statement might be a way to help us push forward in the need for more technologies to protect ourselves that go beyond condoms and speak to things like pleasure and enjoyment of sex and that could be for anybody but perhaps the gentlemen who spoke on behalf of the community.

RON KIDISH: Any other comments from the floor? Please?

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MICHELLE MEYER: My name is Michelle Meyer from Switzerland. I just wanted to say about communication, I think it is time to accept a maturity of individuals and society so I am wondering why we are asking what should be communicated and what not. And then I want just to say that the Manifesto you can find on bbblhive.gh [misspelled?]. So, you can see who has signed the manifest.

RON KIDISH: Just to, to repeat that would be www.lhive.org, was it? .ch excuse me. Dot-c-h.

CIPRI MARTINEZ: Cipri Martinez [misspelled?] from Australia. I just wanted to firstly say thank you to Switzerland. [Applause]

I applaud you, I applaud you, I applaud you. You are magnificent, courageous, and I will stand by you 100 percent all the way. I would also like to ask some clarifying questions as well. Could you please clarify us how this statement, the implications that this statement has for male to male sex, because a lot of the studies were around heterosexual sex. And also in the direction of how do we get research on clarifying these questions. So, there are the two things I would like the panel to maybe make some comments on.

RON KIDISH: Good. One more question.

DAVID GELDEN: Hi, I am David Gelden [misspelled?] from New York City. Actually my question is a follow up to his question. It is also a clarifying question. There has been a

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lot of discussion about the role of STDs and whether that obviates the protective effect of treatment. Do we really know that, that people who are suppressed due to treatment then become unsuppressed, at least in your genital fluids, if they have an STD? Have there been studies, or have I missed them somehow that detail that?

NIKOS DEDES: Maybe there are so many questions I would like to start with the last one. That is the one I could remember. I would like to make this very clear. We did not say that an STD under complete suppressed treatment actually increases the risk of transmission. This is something we do not know. There is only one study I know from Birmingham, UK where they looked at urethritis and they found two out of 20 patients under ART had a slightly increased viral load in semen during the urethritis episode. And otherwise it was always suppressed. But we did not say those individuals are more infectious. We said if we are uncertain, if there is a confidence interval, if we are close to the place where we would not be so confident, we would decide that those would be the individuals where we would be more careful. So, we did not say it is more infectious, but we just made it our concerns. I think that is an important difference.

RON KIDISH: There is a question about evaluation. Would you look at, speak to that?

NIKOS DEDES: Yeah, one thing, we are not the Swiss government. We may make suggestions to the Swiss government. We as a commission are not in a status that we develop evaluations, but I have realized that not only in Switzerland but also in other countries now this statement has stimulated a lot of research questions and people are starting to address them. But I think we are not the right group to address that.

RON KIDISH: Other comments from the panel?

MYRON COHEN, MD: There was a question about the broader use of antivirals as preventive agents. And I think that is probably one of the most prolific and important topics going on right now. The meeting next door is about antiviral for pre-exposure prophylaxis. There is at least ten different topical microbicide trials that are involving different single or combination antiviral agents.

So, this whole idea of antiviral therapy for prevention, we are focusing now on the infected person, but the package is post exposure prophylaxis, pre-exposure prophylaxis, and it is a field that has not realized its potential, because there is so much, I do not want to call it commitment, there was so much belief that we would make a vaccine that was going to solve this problem that perhaps the energy that is now being realized in the ART field is kind of surging. And because we can modify drugs, and because some of the newer drugs have very unusual and positive properties for prevention, it seems

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inevitable to me that the topic that one of the gentlemen asked, it is going to get broader and broader, and broader. I think it is also inevitable that we are going to see success, and those successes are going to have to be measured and become part of public health policy, so I think that was a very good question.

RON KIDISH: Dr. Cohen, someone asked about homosexual transmission, and the study that you are doing, would that include-?

MALE SPEAKER: Let me clarify something. I think it is incredibly wrong to look at anal intercourse as limited to MSMs. Every single, this is wrong. This is about a sex act that is common among heterosexuals as well. I think a recent study came out from Africa. Kate might know the exact number. I think it was something like 12 to 14 percent of South African mature couples were actually engaging in heterosexual anal intercourse, so it is about the act, not about the selection of partner. And so that is my number one overriding concern. That we not just focus on MSMs. Now, recognizing though that obviously, recognizing all the obvious, that this is a behavior that is not well studied. It is a difficult behavior to study. We do not understand the transmission events, the probabilities that occur in that, and we do not understand a lot about ART in that setting. So, this is going to require more research. I would be wrong to say more than that.

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RON KIDISH: Okay. Anyone else?

PIETRO VERNAZZA, MD: I want to say hi to my fellow treatment activist from the prevention field. Indeed the EATG and the community of course, we support very much the use of new preventive technologies and they will play, perhaps they will be the only solution for the next years. That was one of my statements from the public health impact of the guidelines. Actually prevention is treatment in the sense that within the comprehensive package that, with the ways that treatment can be used as Myron mentioned. I also wanted to say something about what George Marcus has said about indeed this statement and what it says in there should be used. We should turn this information into positive outcomes, and STIs are not regularly screened in HIV units, which is given the data, is criminal. I said that these are preventable and treatable. So, screening should be one of the priorities for, strategies for people who are followed in clinics. [Applause]

MYRON COHEN, MD: I probably, for the sake of full kind of discussion, I have to add something. And this is complicated. And there is one additional paper that you did not cite by Nago, N-A-G-O, who is of the ANRS. One problem we have is that HSV2 is very ubiquitous. It is a lifelong disease. It has been very popular in the HIV STD overlap field because the shedding of HSV occurs quite silently and some of the investigators believe that HSV2 shedding while subclinical

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drives HIV shedding as well. What Nago showed in his paper was, this was very recent, that even people on ART unless they also received acyclovir had an increased shedding.

Now, whether that shedding, now these were females, women. Whether that amount of virus is enough to cause a transmission of that is totally unknown. There would be no way to get into that. And I want to separate those two issues. But it is also true that a substantial number of people around the world also have HSV2 infections which are chronic, asymptomatic, of very little clinical consequence to the average person, but it really has to weigh into the whole discussion. So, when you talk about screening, it would be very difficult to deal with HSV2 in all candor.

PIETRO VERNAZZA, MD: Yes, but, so in answer to that, there was also this question of what kind of research do we need. And indeed the presence of STIs does not necessarily result in increased risk of HIV transmission. And the other very important research question is is there a threshold under which transmission does not occur? Whether we need enough of an inoculum in order to have transmission, therefore, even this shedding that you are describing probably would be irrelevant.

RON KIDISH: Okay. But let us take maybe three more comments, and then we are going to have a summation of the session. So, please, go ahead.

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NICK PARTRIDGE: Nick Partridge from Terrence Higgins Trust [misspelled?] in the UK. I do want a clarification if I may. I recognize that the statement is good news for a few people. Can I just be clear that those, anyone who enjoys anal sex are not part of those few people that have good news in this statement? Because that was the suggestion I was getting from you, Mike. That actually irrespective of sexuality, what this risk statement says excludes people who enjoy anal sex.

MYRON COHEN, MD: That is not a true statement.

RON KIDISH: Well, because the question about anal sex is being sort of dodged. It has been asked four times now. So, can we be clear about how the statement goes for sero-discordant couples who enjoy anal sex? Just to help me understand it.

PIETRO VERNAZZA, MD: I would just like to make very clear that we did not discern anal sex, vaginal sex, whatever sex. The reason why is that the most important source of our confidence was the fact that after ten years of ART we do not see these cases regardless of the mode of sexual contact. So, all the other biological arguments help to explain it, but the evidence is the same situation as with household context as I explained in 1986.

RON KIDISH: Okay, thank you. Does that clarify?

Yes, please go ahead.

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PIETRO VERNAZZA, MD: Well, I think one way perhaps to understand this is if you start with the risk of mother to child transmission which is from 20 to 40 percent, the introduction of one pill or two pill combination actually makes transmission very, very unlikely. When you compare that to sexual risk of transmission, which is much lower than the, and I am talking now about anal risk, which is much higher than vaginal, but still, it does not begin to compare with mother to child transmission. If you then have the same impact of the antiretrovirals, it goes to say that the risk is infinitesimal. So, what the Swiss have been describing is that it is irrelevant, and that is why in my presentation I said that the reduction of risk is logarithmic and parallels the logarithmic reduction of viral load.

RON KIDISH: Thank you. Okay. Two more comments. Yes?

ARI FRITELU: Yes, thank you. I am Ari Fritelu [misspelled?] from [inaudible] in France. And I share your concern, Kate on provisional [inaudible] and viral load test access is, the variability of viral load tests is very weak. But it remains for me that we need to improve access to viral load and that is it. I have a very naïve question, and please be indigent with me if you think it is a stupid question, but how come it was possible last year to promote circumcision in many high prevalence countries even if the efficiency of

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circumcision is lower if I remember well, is just 60 percent from woman to man, it is lower than the efficiency of prevention of HIV transmission with treatment. So, I do not understand why UNAIDS and WHO are so shy now compared to what you did last year on circumcision. Thank you. [Applause]

RON KIDISH: Next comment. Yes?

FEMALE SPEAKER: I think that listening and talking about this statement makes me realize how much this statement is about privilege and the privilege in access to medical care and doctors and regular treatment and intervention. And I think that it comes with a responsibility and acknowledgement that there is always a trickle down effect. And having worked as a provider in both the States and in what is considered the global south, I do not see that in a couple of years that there is going to be a change and there is going to be a lot more viral load testing, and there is going to be the possibility of access to medical care in a way that makes this statement relevant to a lot of places. So, or, I guess what I am asking is what are the next steps and what is happening to make this statement true for everyone who is infected with HIV and how is that becoming a global statement and in a real and practical way?

RON KIDISH: Thank you.

FEMALE SPEAKER: Do we have time for another comment?

RON KIDISH: Yes, please go.

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SUSANNE ATI: My name Susanne Ati [misspelled?]. I am working with the Institute of Social and Preventive Medicine in University of Barin [misspelled?] Switzerland. So, we were looking at-

RON KIDISH: Could you speak to the microphone, please?

SUSANNE ATI: Oh, excuse me. My name is Susanne Ati. I am from Houston, Texas working with the Institute of Social and Preventive Medicine in Barin, Switzerland. And we are also looking at the evidence regarding transmissibility of HIV according to use of ART, viral load, and STIs, and so far we have found in a review of the literature that the lowest transmitting viral load has been 362 copies per milliliter. And if you would like to know more, I am actually presenting on Thursday at 5:15 in Session Room 11 on this exact topic. So, I hope it is of interest to everyone who can help in the discussion.

RON KIDISH: Thank you. A couple of, Kate did you want to respond?

CATHERINE HANKINS, MD, MSC, FRCPC: Yeah. I will just respond. We are not shy. Do not worry about that. What we want to do is make sure that the messages are well contextualized. Anything that increases the choices for people, the options for people for HIV prevention is important. More people are getting infected each year than are being placed, than all of the ones that are on treatment. So far.

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So, we have got a real negative balance here. I think it is important to get the message across that this is for a select few people, and yes we need to increase viral load testing in countries. We need to decrease the number of people with undiagnosed infection, because that is where the bulk of infections are occurring. And we need to look at options and combinations, so that is why male circumcision, three randomized control trials and now further Phase IV trials showing very good results in the community, that is really strong evidence. We are not saying now circumcision replaces everything else. Everything has to be additive and synergistic with what we have.

RON KIDISH: Thank you. And now I would like to ask Dr. Hirschel to come and give us a summation of the session.

BERNARD HIRSCHEL, MD: Okay. I have typed these during the session, so please bear with me with typos and problems with the page layout and all that. Okay.

How do I move this forward? I just press the button? Oh, the green button. Alright. Let us go.

Alright. I am not a member of the federal commission. I am guilty by association. I have for a long time been a fan of Julio's, particularly since his talk at the Toronto conference. What we need is new methods for prevention. Vaccines are pie in the sky. Microbicides have not worked so far. We have circumcision that is partly affective. And we do have

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treatment. And we need treatment for prevention. Pietro Vernazza explained to you what the Swiss statement is. It is directed at physicians. It is of help in counseling. It evaluates the relative risks of sex on ART without condoms versus sex, off ART, with condoms. And it is very tightly qualified: on ART for at least six months, consistently undetectable viral load, no STDs, and perfect adherence. The Swiss statement does not advise against condoms and does not condone unsafe sex.

Behind the Swiss statement is the general idea that all risks are created equal and that there is a problem if equal risks are unequally treated. Because how can one permit sex with condoms in an untreated patient, while proscribing sex without condoms in a treated patient, when the latter is equally or less risky than the former? I have not yet found an answer to this question.

Myron Cohen pointed out the great biological plausibility of the protective effect of HAART, and that certainty is very difficult to come by. Events are rare and there are many confounding influences such as pharmacology of ARVs. His pioneering study of discordant couples will give us some of the numbers we need, but will take a long time.

Nancy Padian looked at the Swiss statement from the women's standpoint. She finds pros and cons, states that

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compliance with condoms is disappointing. And points out the issues related to power and gender.

Nikos Dedes presents the standpoint of the people living with HIV and AIDS. I quote him here. "The conscience of being infectious is a heavy burden to carry, and lifting it off is taking a load off our HIV positive people. There are other issues, regaining the right to uninhibited intimacy, procreation, and the fact that I very strongly believe myself, that being less infectious will reduce stigma and discrimination."

Catherine Hankins points out that first world views are not necessarily applicable in developing countries where most HIV infected patients have no access to viral load testing and to diagnosis of STDs. It is therefore doubly difficult to be quote-unquote be sure about the absence [inaudible] of risk in less developed countries. The Swiss statement will find its first application in pregnancy planning, perhaps complimented by pre-exposure prophylaxis, but has little applicability to other situations where condom promotion in combination with treatment and circumcision must remain the rule.

Okay, after this, let me hazard into the difficult field of politics and philosophy. What do we do when we as a panel make recommendations? Well, we have to cope with what I would call the asymmetry of risk. To say that something is dangerous while in reality it is not has no consequences for

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the politician or the panel member who says so. The opposite however, to say that something is not dangerous and then something bad happens, is at times career ending.

And therefore there is a natural tendency of panels and commissions to first and foremost protect themselves. One way of protecting themselves is to ask for more evidence. But the time it takes to obtain perfect evidence has a great cost. Remember that for circumcision, between good circumstantial evidence, that it worked, and the acceptance through a randomized controlled trial, 17 years elapsed.

And here is an additional consideration: no offense meant to my attractive fellow panelists, but there is one thing for sure: at every new world AIDS conference, they are two years older. Their sex lives are largely behind them. And the age difference between panel members, and the sexually active to whom they mostly address their recommendations, has increased by another two years. So, I think we should take heed from the largely irrelevant recommendations put out by that venerable institution, the Catholic Church, and make a second Swiss statement. Let us not be AIDS cardinals. Thank you. [Applause]

RON KIDISH: Thank you all for your rich discussion and comments. Thank you to an excellent panel that I am sure will be very thought provoking throughout the coming week of the conference. Please enjoy the conference. Bye.

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