

**Press Conference: Highlights from  
Late Breaker Abstracts - Part II  
XVI International AIDS Conference  
August 17, 2006**

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**MARK WAINBERG, Ph.D.:** Hello, everybody. We want to thank all the journalists for coming to this session, including Dr. Grand [misspelled?] at the back. So, we are pleased to have with us today six speakers from the late breaker abstract sessions that have taken place this afternoon. These individuals are from tracks B and C, and I'll ask each of the presenters to quickly summarize their presentation and then to agree to take questions in regard to their presentations.

So I'll first introduce Dr. Sharon Riddler, whom I had the privilege of hearing before I had to leave the later breaker session to come here. And Sharon talked about a prospective randomized Phase III trial of NRTIPI and NNRTI sparing regimens in initial therapy. Sharon.

**SHARON RIDDLER:** Thank you. We've been asked to give brief summaries, so I'll start by saying that this study was conducted by the AIDS Clinical Trials Group and was really the first study that compared the Department of Health and Human Services recommended regimens for HIV initial therapy; that is lopinavir or efavirenz with two nucleosides. So it was a direct, head to head comparison of those two regimens. Additionally, the third arm: there has been limited study of potent combinations that do not include nucleosides. And so the third arm of this study was lopinavir plus efavirenz.

The main finding of this study were that all the

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regimens actually performed very well with increases in CD4 cell count of more than 200 cells at week 96 for all three arms, as well as rates of undetectable viral load in the 80-percent range. There were differences between the regimens. The lopinavir plus two nucleoside regimen had a shorter time to virologic failure compared to the efavirenz plus two nucleoside arm, and likewise had a trend towards a more rapid time to what we determined to be regimen completion, which was switching a regimen or having virologic failure.

I think the caveats are that we have a lot of additional data. We hope to be able to explain the differences between the lopinavir and efavirenz arms. We have a lot of data on adherence, tolerability issues that we have yet to analyze. Additionally, there were some preliminary difference in resistance identified, and that being the efavirenz plus two nucleoside arm, I think as expected, people who failed that regimen were more likely to have resistance mutations identified in two classes. That does not mean that they had extensive resistance, but that there were mutations identified to drugs in two classes as compared to the other two regimens.

**MARK WAINBERG, Ph.D.:** Maybe the demonstration is dying down. Otherwise, if you just wait a moment, I'll close the door. That was just an attempt at humor.

Okay. Questions for Sharon. Yes. I think we have a microphone coming.

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**LARRY ALTMAN:** Larry Altman, *New York Times*. Are the findings from your study sufficient to change the DHSS recommendations, or do you need another study to confirm it, to have an impact on the recommendations?

**SHARON RIDDLER:** Yes. I'm not on the DHSS panel, so I'm not sure that I can answer what they will do. I guess my opinion is that they will wait, at least for us to be able to analyze additional data, perhaps, to explain better the findings that we see. I think all of the regimens are really potent, and what the study is telling us is that we really have increasing options for initial therapy and increasing opportunity to base our initial therapy on patient characteristics. My guess is that the recommendations will not immediately change, that perhaps they will change over time, depending on the results of additional boosted protease comparison studies with NNRTI based regimens.

**MARK WAINBERG, Ph.D.:** Sharon, I have a question. If you analyze for the presence in the efavirenz arm of one of the NNRTI mutations versus the presence in the Kaletra arm of just one of the PI mutations that you might expect to come up before the other PI mutations, how would that compare?

**SHARON RIDDLER:** You mean the non-major PI mutations?

**MARK WAINBERG, Ph.D.:** Yeah, but still, one of the ones that we would associate with the use of Kaletra.

**SHARON RIDDLER:** There really were no major PI

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mutations in the Kaletra arm. We've analyzed about 55-percent of the virologic failure samples—actually, a few more than that. And it's pretty equal across the arms, the proportion that were analyzed. So I don't expect that to change significantly. But there were no significant PI mutations, primary PI mutations in the Kaletra arm.

**MARK WAINBERG, Ph.D.:** You know, over a wide array in the last couple of years of studies that have used Kaletra in triple therapy and in which people have failed Kaletra, there has been really very little evidence in some cases of resistance mutations associated with the use of Kaletra. And many of us have kind of interpreted those data as suggesting, well, maybe there was non-adherence, and that's why we didn't get the resistance mutations coming up.

But I don't know about you, but I'm personally beginning to think that's a little bit simplistic. Maybe there's something else going on and it's just not obvious what the answer is.

**SHARON RIDDLER:** Yeah. I'm not sure. I hope that we have data to be able to address some of the questions. I certainly think that there are more—and we've not done a formal analysis—but I believe that there's more tolerability issues with lopinavir. And you can surmise that individuals who are having some tolerability problems might have less adherence. We do know that a significant proportion—and I can't quote you

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the exact proportion—of individuals who had virologic failure subsequently re-suppressed on the same regimen, which tells us that the failure was probably due to temporary discontinuation of the regimen.

So I think that we have sufficient data. We just need a little bit more time to analyze these findings.

**MARK WAINBERG, Ph.D.:** Thank you. Other questions for Sharon? If not, we'll move on to the next presentation. We'll ask Paula Munderi to speak. Paula presented an abstract from the DART analyses entitled *Survival and Causes of Death Two Years After Introduction of Antiretroviral Therapy in Africa: An Historical Cohort Comparison in Entebbe, Uganda*. Paula, over to you.

**PAULA MUNDERI:** So, what we presented was some data which I believe illustrates the impact that antiretroviral therapy can have on AIDS and AIDS-related deaths in Uganda. At one of the sites of a multi-center ARV trial, we had a clinic where we had a fair amount of data on pre-clinical health of a large cohort of patients. So what we did was take the pre-ART cohort, as we called it, that was existent in Entebbe over a certain period and compared in that group before ART was available to them the rates of death and the causes of death, compared this to the rate of death and the causes of death after two years of antiretroviral therapy.

What we showed was overall there's a reduction in

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mortality rate of 17 times, a 17-fold reduction in mortality rates, significant benefit in survival. And survival after one year on ART was 92-percent and at two years was 94-percent, compared to 55-percent without therapy and 28-percent without therapy, at one and two years, respectively.

We also looked at some of the causes of death, the diagnoses at death, which had been pretty well documented in the per-ART cohort and which of course are well documented in the ART cohort, and found that there are major reductions in rates of death due to most of the major opportunistic pathogens, as would be expected. What was important in the ART cohort was looking at the things or the conditions that are still diagnoses at death with ART. And the important causes are tuberculosis, HIV-related cancers, bacteremias. And this is probably important information as well for ART programs because these are the conditions that they should be looking at, continuing to manage with antiretroviral treatment.

The other interesting observation is that the HIV wasting syndrome, or slim disease as it used to be called in my country before therapy, has virtually disappeared as a cause of death in the ART era. That's the summary of the finding.

**MARK WAINBERG, Ph.D.:** Okay, thank you, Paula.

Questions? Terry Murray?

**TERRY MURRAY:** Why do you think the causes of death that have remained, have remained? Is that because they've got

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their genesis early, before the treatment programs began? I'm sorry. I don't remember the rest of the question, but I think I got the most part of it out.

**PAULA MUNDERI:** Is the question why some of the diagnoses have remained, like TB and bacteremias which should be treatable? Okay, let me answer this in a short way. I think, if we look at the data—and actually, most of these deaths occurred fairly early on therapy, and over half of them in the portion of patients who had really low CD4 counts. So the patients were quite ill even at the time of starting therapy. That might be a contributing factor. There may be some of them, particularly the TB—there may be a slight increase in TB with early antiretroviral therapy as an immune reconstitution syndrome. That is a possibility. But we need to probably go back and look in the data and see why the early mortality is remaining. That's in regard to TB.

In regard to the HIV cancers, I think that is just a function of health system management, because even though we are able to treat HIV effectively, we are not yet able to treat effectively HIV related cancers with effective chemotherapy. Also, they're usually quite ill and usually quite advanced. And these are mostly Kaposi's Sarcoma, lymphoma and one hepatoma. But I think that the increase in death due to malignancy means that the infectious causes of death have actually diminished in significance, and that would happen

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anywhere else.

**MARK WAINBERG, Ph.D.:** Other questions for Paula?

Paula, can you speak to rates of tuberculosis and other co-infections in the DART population?

**PAULA MUNDERI:** You mean rates in general? I don't have that data on me, Mark, no. I just have the data in the particular sub-analysis that we've done. And we had ten out of 62 deaths due to TB, four out of 62 deaths due to Cryptococcus, two cryptosporidium, and the rest were HIV-related cancers. But yes, the most common is tuberculosis.

**MARK WAINBERG, Ph.D.:** Anyway, I think it's important to point out that, as Paula very elegantly demonstrated in her late breaker, that the DART program is literally saving many, many lives in Uganda at this time, and has the potential obviously to continue to save large numbers of lives. And therefore we hope that the progress will continue and the results will continue to be forthcoming over the next four or five years of follow-up. Other questions for Paula?

I'm sorry we're being a bit overwhelmed by a competing press conference that seems to be denouncing the use of ritonavir, I think, or some such thing. I think some of the demonstrations at this conference remind me of the treaty that was then to end the First World War. It was signed, but both parties were given the right to fighting until the armistice that would take place at 11 AM on November the 11<sup>th</sup> in 1918.

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and the generals on both sides, you may know, instructed their troops to keep doing battle until the exact moment that the armistice was to take effect, not because anyone had anything at all to gain but because the generals simply liked the idea of making war. That was their livelihood in life. That's what they liked to do. So from the generals' standpoint, it made perfect sense.

And I think we have a lot of demonstrators at this conference who don't understand that some of the things that they've been trying to wage war about in fact have resulted in them winning the wars. But somehow, instead of just saying, "Hey, we won. Great; we can go now and do something else," I think some people still feel that they like the idea of fighting the war. Okay. That's my aside.

And I think we'll proceed now to Leigh Peterson, who's going to talk about one of our favorite concepts of all time in regard to prevention strategies, notably a pre-exposure prophylaxis. So Leigh is going to discuss findings from a double blind randomized placebo controlled trial of tenofovir for prevention of HIV infection in women.

**LEIGH PETERSON:** Thank you. Today I presented our findings from our trial of oral tenofovir for prevention of HIV infection in West African women. The study was conducted between June 2004 and March 2006. We enrolled 936 HIV negative participants from Ghana, Cameroon and Nigeria. And our primary

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endpoints were looking at liver and kidney function as well as adverse events, and our primary efficacy endpoint was HIV infection rate.

And we found no significant differences in the laboratory abnormalities between the placebo and the tenofovir group. We also did not find any significant differences in the rates of adverse events, and we didn't find any differences in the off-product; that is, after product was discontinued in participants in Cameroon and Ghana, we did not find any differences in liver function at that time. So, this is very good news for HIV prevention.

During the study, we had eight HIV infections. Six of the participants were randomized to placebo and two were randomized to tenofovir. And while a lot of reporters have wanted to say, "Oh, this is showing 65-percent effectiveness," I need to stress today that that's not the case. These numbers were too low to give us a conclusive answer regarding effectiveness. But although the number of infections was low, we're really happy to have completed the first trial of oral tenofovir for HIV prevention.

**MARK WAINBERG, Ph.D.:** So, thank you very much for this. Questions for Leigh. Yes.

**SABIN RUSSELL:** Sabin Russell with *the San Francisco Chronicle*. I was just wondering if, based on this experience, you have a sense of how large a study would have to be, how

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many people need to be enrolled in it, to get the statistical significance and a finding, if the problem here has to do with simply not enough results. And secondly, if you could explain how you dealt with the early shut-down, how that did not in any way taint the results, the findings.

**LEIGH PETERSON:** Okay. So, the original plan for the analysis was that we would enroll 1,200 participants, and we would have a 5-percent HIV incidence in the placebo group. And this would yield approximately 30 endpoints, or HIV infections, throughout the study, and that would have been sufficient to give us a statistically significant result as to whether or not tenofovir was effective. So that answers the first question.

The early closures; there are several reasons likely to have affected the number of seroconversions that we obtained in this study; again, eight versus the projected number of 30. And one reason is lower than expected incidence. In the placebo group, we had about half of the incidence that we had expected. And also, the early closure of the Cameroon and Nigeria sites did affect this as well in that we only had six months, so we had about half the amount of follow-up time, from the Cameroon participants than we had expected. And we only had 136 participants in Nigeria enrolled. So it definitely did affect our effectiveness results.

**FEMALE SPEAKER 1:** [Off microphone] [Inaudible] sites were closed early.

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**LEIGH PETERSON:** Yes. So, in Nigeria, we closed the site after, again, 136 participants were enrolled because of operational issues, mostly with the laboratory in performing liver and kidney function testing. We were concerned about the controls and the proper documentation. We have very, very high standards using good clinical practices and the proper documentation and recording of these results, and there were some questions about how those were followed.

In Cameroon, we had enrolled all 400 participants, and two months later, the Minister of Health had some questions for us regarding this study. And so, during their inquiries, they wanted to discontinue product use, although they let us continue the study, but not distribute product. So we conducted all of the assessments but did not give out product. And although we answered their questions in a timely manner, we were never allowed to restart product use, so the site was closed.

**MARK WAINBERG, Ph.D.:** Yes.

**JERRY GREEN, M.D.:** My name is Jerry Green. I'm a medical doctor and journalist in Toronto. I'd just like to ask you: what is the practicality, do you think, of convincing women to take a drug for a long period of time, practically speaking, to prevent a disease, when drugs are generally known to have some toxicity, to pay the money—you haven't mentioned the cost, what it would cost—and what is the practicality on

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that, especially when there are other non-toxic, relatively non-toxic, natural things people could take that have shown to have anti-viral activity, such as vitamin C?

**LEIGH PETERSON:** Well, the biggest issue, and what we know works, are condoms. And the problem is that not everyone is able to negotiate condom use at all times. So we need additional tools in order to help these women and men protect themselves in these particular cases where they cannot negotiate condom use. If this is found to be effective, and there is widespread use, we will always say that this needs to be used with condoms. It won't be a mono treatment.

As far as the practicality, we have not seen in this study, in HIV uninfected women, any serious side effects. And this drug has also been used in about half a million people who are HIV positive without seeing significant side effects. So it's likely to be a very, very good candidate for long term use, especially in very high risk women, where the alternative is becoming infected with HIV.

**JERRY GREEN, M.D.:** Thank you, but I didn't really ask you about condom use. But I'm asking you more about natural things like vitamin C, and dare I mention something that has been mentioned at this conference, at my risk, garlic. The Minister of Health in South Africa has mentioned garlic as an antiviral agent, and also selenium as well. There was a session on selenium on Monday at this conference, about using

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selenium as an adjunct, complimentary treatment, along with ARV. And these substances that are used as adjuncts are often, as you know, like vitamin C and selenium, can be used as preventive as well.

**LEIGH PETERSON:** Right. I think that we obviously would need to do more work in order to know if these truly are effective. And as far as I know, there haven't been clinical studies done proving effectiveness of these agents in HIV prevention.

**MARK WAINBERG, Ph.D.:** I'm sorry; can someone get him a microphone? Where did the microphone go?

**JERRY GREEN, M.D.:** I mean, you can always say we need more studies, but there is one study in the book of this conference showing selenium of use in a double blind study as efficacious. And, if you look through the literature, there's a lot on vitamin C. There's a lot more on selenium. I mean, there is evidence already.

**LEIGH PETERSON:** So, I completely agree with you. If we all agree, FDA, WHO, if we all agree that these truly are effective for preventing HIV, then they should definitely be used.

**JERRY GREEN, M.D.:** So why don't we tell HIV patients to add selenium, to add vitamin C to whatever they're doing? There's very little mention of that with AIDS patients or at this conference.

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**LEIGH PETERSON:** I think that's a bigger question. I think that's maybe a question for FDA or—it's a bigger question than—

**JERRY GREEN, M.D.:** Forgive me for asking a big question. Forgive me.

**MARK WAINBERG, Ph.D.:** Let me just add my own two cents here. In regard to what you said about the Minister of Health of South Africa articulating the need for garlic, I don't really think that we have any lessons to learn from the South African government in this field, since the President of the Republic of South Africa is a well known HIV denialist. At the recent microbicides conference that took place in that country, in Cape Town in April, we listened to several ministers of health welcome conference delegates without once mentioning HIV. I don't think that country has anything to teach us in any respect in regard to HIV therapeutics or prevention. But thank you for your well articulated points in regard to selenium and perhaps other substances as well.

Let us move on then, unless there are other questions for Leigh. Actually, I have one more question for Leigh, and that is that in Botswana, as an example, we now know that the prevention strategy has now changed from using tenofovir by itself to Truvada. And I just wonder if you could comment on what might perhaps be necessary in terms of safety data in regard to those studies, and what you know about the safety

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studies as they'll guide us to the future.

**LEIGH PETERSON:** Right. Well, the reason that they have decided to use Truvada was because the CDC had done some animal studies indicating that Truvada might have a more long term effect on HIV prevention versus tenofovir. This doesn't mean—first of all, it's animal studies, which sometimes can be applied to humans and sometimes cannot. But also, it doesn't mean that tenofovir would not be effective in humans. So we need to investigate both of these drugs and look to see the benefits.

One of the other reasons Truvada is being looked at is because it's not a mono-therapy. It's TDF plus FTC, and so there's a thought—again, it needs to be proven—whether or not resistance would develop as quickly in participants using this for prevention.

**MARK WAINBERG, Ph.D.:** Okay, thank you. I think we have one last question back here and then we'll move on.

**MALE SPEAKER 1:** Yeah, I'm [inaudible] from Paris, writing in two different newspapers. One is called *Protocol* and the other *Action*. I really think the title of your press conference is really—goes really quick without any danger for the people. Many people who take tenofovir note some problems that they have with tenofovir, and I am one of them. But the question is more about the safety of this product with people not infected, shouldn't be studied only two years long studies.

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And one of these studies we have about tenofovir with people not infected by AIDS, if I remember well, it's a two years long study.

And the other question is about in which population would you like to use this strategy, with a 65-percent reduction of risk if it was possible, because—it asks many questions about how we can use this product. If it's not that safe, or never, it seems very difficult to give it to the well population.

**LEIGH PETERSON:** First, we can't even say 65-percent here. It's possible that we would find later that tenofovir is 65-percent effective versus placebo. But it's also possible that we could find tenofovir is 85- or 90-percent effective. Or we could find that it's not at all effective. I completely agree. So again, this could have been seen by chance.

As far as the safety, I completely agree. The more data we have, the better. And for things that occur at very, very, very low frequency, we would need a lot of person time, of follow up, in order to detect this. And so, again, I agree that more studies should be and will be done, not only to confirm the safety results we've seen in HIV uninfected men and women, but also to confirm what we've seen in HIV positive participants.

It's also very likely—again, but we don't know—that we will have less side effects in HIV uninfected people than in

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HIV infected people. But again, more safety data is always, always good.

**MARK WAINBERG, Ph.D.:** Okay, thank you. I think we should move on. So Lynne Leonard is our next presenter. She's the author of late breaker track C on *Harm Reduction Success in the Context of Needle Exchange Programs and Safe Crack Smoking*. Lynne?

**LYNNE LEONARD, Ph.D.:** Thank you. So now, for something completely different, I presented some preliminary finding from the evaluation of a harm reduction for women and men who smoke crack. Increasing numbers of women and men are using this powerful, highly addictive stimulant, particularly among Canadian urban injection drug users, among whom between 50- and 75-percent report also smoking crack.

Most users will smoke crack using materials that are readily available. So it's very frequently metal pipes, aluminum pop cans, car antennas. Heat is conducted intensely and swiftly through the metal pipe or can as a rock of crack is smoked. And this leads to cuts, burn, blisters and open sores on the mouth, lips and gums, with the potential to facilitate HIV and hepatitis C acquisition and transmission when these blood covered smoking devices are shared, or as increasingly characterized in the literature, during blood and semen contact during receptive oral sex.

The city of Ottawa, recognizing these harms associated

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with smoking crack, and experiencing some of the highest rates of HIV and hepatitis C among injection drug users, initiated a safer crack smoking initiative in April, 2005. Through this initiative, women and men who smoke crack can now access, through the needle exchange program, safer crack smoking materials. This is a glass stem with a rubber mouthpiece which prevents any injuries to the lips, and a very stable glass screen at the end of it. Frequently, users will use steel wool, and in ingesting the drug, pieces of the steel wool will get lodged on the lips, inside the mouth and in the lungs. This costs about 40 cents. It's also distributed in a safer crack kit, such as this, which includes other materials for lip health as well as condoms and other information on safer sex and safer crack smoking.

To evaluate the positive and negative outcomes of this initiative, we worked with 550 injection drug users. We interviewed the sample at four measurement points: six months before the implementation of the initiative, and at one month, six months and 12 months following the initiative. I'm just going to highlight three findings. Uptake of the initiative was immediate, high and sustained. After one month of operation, the vast majority, 80-percent of the crack smoking [inaudible] interviewed has personally accessed the safer crack smoking initiative. And this percentage rose to 87-percent at the 12 month evaluation point. This is clear demonstration of

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the need. These resources were provided and there was immediate high and sustained uptake.

The most exciting finding, perhaps, is the impact on sharing crack smoking equipment. This is a very, very efficient way of transmitting hepatitis C in particular. We documented a modest but significant decline in the multi-person use of crack smoking equipment. But the most significant decline was documented in the frequency with which equipment was shared. Among those who reported that they had used a pipe that someone else was using or had already used, pre-implementation, 37-percent reported doing so every time. And at the 12 month evaluation point, this proportion had declined significantly to just 13-percent; so real evidence of increasing behavior change.

The other finding is a finding at the community level. People who smoke crack experience a myriad of challenges to their physical and mental health, and have sporadic and often delayed access to health and social service agencies. However, through the provision of these safer crack smoking resources at the needle exchange program, at the end of the 12 month evaluation period, over 4,400 contacts had been made with crack smokers. These were people who had previously had no contact with harm reduction resources.

So, from this evaluation, we've concluded that Ottawa Public Health Department's controversial decision--this was not

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an easy program to get through; still doesn't sit well with the community—but their decision to provide harm reduction resources appear to have significant impacts which were maintained in one year in reducing a practice with the potential to facilitate HIV and hepatitis C transmission. And in addition, a previously underserved population of drug users engaged with a comprehensive harm reduction program. We suggest that the results of this evaluation document the urgent utility of replicating this safer crack smoking initiative as one component of a comprehensive harm reduction strategy of other needle exchange programs.

**MARK WAINBERG, Ph.D.:** Thank you. Are there questions for Lynne? Yes.

**FRAN LOWRY:** Fran Lowry, Internal Medicine News. I missed your presentation; maybe you mentioned it there. But how did you recruit your study subjects?

**LYNNE LEONARD, Ph.D.:** These were active injection drug users. They were street recruited at various places around Ottawa. We wanted to recruit injection drug users because we wanted to see the prevalence among people who inject. We wanted to get the prevalence of crack smoking among these users. And we also wanted to make sure that we were in some way reducing social desirability responding by not making it clear that we just wanted to speak with crack users.

**MARK WAINBERG, Ph.D.:** So, Lynne, is it fair to assume

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that you think that Canada should maintain needle exchange programs in our major cities?

**LYNNE LEONARD, Ph.D.:** The evidence is very clear that that's what needs to happen, and I would suggest that the evidence here means that we also need to make sure that the harm reduction expands to other drug users, not just injection drug users.

**MARK WAINBERG, Ph.D.:** And is it safe to assume as well that you would be among those who would ask Prime Minister Harper to please maintain the safe injection site that is currently operative in Vancouver?

**LYNNE LEONARD, Ph.D.:** Mm-hmm. The evidence is compelling for its continuance.

**MARK WAINBERG, Ph.D.:** All right. Thank you very much. We'll move on to the next presentation, which is by both Leigh Anne Shafer and Alex Opio of Uganda. The presentation is on the topic *HIV Prevalence and Incidence Are No Longer Falling in Uganda: A Case for Renewed Prevention Efforts: Evidence from a Rural Population Cohort and from ANC Surveillance*. Please go ahead.

**ALEX OPIO:** Thank you very much. We are delighted to share with you this afternoon key highlights on the latest information of trends of HIV infection in Uganda. My colleague, Leigh Anne, will present to you the key points about this study, the results. And then I will conclude by giving

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you the action that the government as taken so far in the race [inaudible] to the results. This is because our policy in Uganda is evidence based, that if information occurs from studies, then we must incorporate the findings into our planning, into our monetary [inaudible] forces. So, Dr. Leigh Anne, please.

**LEIGH ANNE SHAFER:** Thank you very much, Dr. Opio. I want to state that I've written a short letter which anybody who's interested in could have at the end, describing what I'm about to say.

The presentation given earlier today was a collaborative effort between the Ministry of Health in Uganda and the Medical Research Unit Council on AIDS in Uganda. In the rural cohort, which was described in the presentation, prevalence in Uganda in the rural cohort reached a low of 5.6-percent among males and 6.9-percent among females in the year 2000. Since then, prevalence has leveled off and has even appeared to increase. By 2005, it was 6.7-percent in men and 8.9-percent in women. Incidence measures are following a similar trend.

Although the recent upward trend in HIV prevalence and incidence in this population is not yet significant, similar results were found independently in some ANC surveillance sites, anti-natal clinic surveillance sites. In other words, to produce a complete picture of recent epidemiologic trends in

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Uganda, both teams, both the Ministry of Health in Uganda and the Medical Research Council in Uganda, have independently come to similar finding. That is, the decline in HIV prevalence and incidence that occurred throughout the 1990s has stopped. It has leveled off. There are some indications that the prevalence and incidence may even be rising once again, though another year or two of data would be required in order to ascertain this with more certainty. Both the Ugandan government and the Medical Research Council on AIDS strongly believe, however, that we cannot wait before reacting to the change in epidemiologic trends. Even if the rate of new infections in Uganda is not increasing, it has at the very least leveled off since about 2000.

Furthermore, rigorous analysis of the rural cohort has revealed a new peak in incidence since 2000 among men in the 40 to 49 year age group. This is new and important from a public health point of view. There therefore seems to be a need to react, and without delay. And with that, I would like to turn my attention back to my co-author and collaborator, Dr. Opio.

**ALEX OPIO:** In response to the information which has just been presented, there has been a strong re-emphasis of prevention efforts by the Minister of Health directed against the transmission of HIV/AIDS, with a goal to consolidate previous successes in the control of the epidemic, and if possible to reduce HIV infection further in the country.

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Throughout the 1990s, when prevalence was falling, Uganda was hailed as the country which exemplified the positive impact of public health awareness, which can have impact on the HIV epidemic. Today, the credit of the Ugandan government and many [inaudible], over 90-percent of Uganda's people are aware of the HIV/AIDS problem, about methods of prevention, and most importantly, they currently know the methods of transmission and how to prevent it.

In light of the recent evidence of the changing epidemiologic trends, the Ministry of Health has recently launched the year 2006 as the year to intensify the ongoing prevention programs in Uganda. A policy document has been issued that lays out a roadmap of activities towards universal access to HIV prevention in Uganda for all its citizens. And the key elements of this roadmap will emphasize public education to promote risk reduction, the ABC policy to insure universal HIV consult and testing, treatment of sexually transmitted infection, prevention of mother to child transmission through administration of ARV [inaudible] to mothers. So these are some of the key highlights. Thank you for your interest in the subject.

**MARK WAINBERG, Ph.D.:** Thank you very much. Questions for either of our speakers? Yes.

**ERIKA CHECK:** Hi. I'm Erika Check with Nature. I just had two questions for each of you. Dr. Shafer, when you say

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that this trend was not significant, can you talk a little bit more about what you mean by that? Is it the number of people, or the change?

**LEIGH ANNE SHAFER:** What we mean is that the decline throughout the 1990s, with statistical analysis, there was a significant decline in prevalence and incidence. The leveling off, however, there's not been enough data in order to produce statistical significance. For that to become significant, we would need another year or two of data, which we do not believe that we should wait for until we react to these epidemiologic trends.

**ERIKA CHECK:** So even though there's been a several percentage change, that's not considered significant?

**LEIGH ANNE SHAFER:** It's not statistically significant. Among some sub-groups, there is statistical significance, but it's not strong.

**ERIKA CHECK:** Okay. And then, Dr. Opio, I guess I wanted to ask if ABC had been the policy during the time of the five years when it's been leveling off, why the Ministry of Health is now still relying on ABC to counter this trend now.

**ALEX OPIO:** We have evidence that the declining trend which was documented in Uganda in the 90s [inaudible] was based on a number of factors. Through knowledge [inaudible] and practice surveys, we were able to document that during that period there was a trend in positive sexual behavior in terms

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of young people, many more of them abstaining from sex; age of sexual debut increasing from 16 to 18 years, the median age of sexual debut. The proportion of people engaged in casual sex partners dropped during that same period. At the same time, those groups that chose to engage in multiple sexual relationships insured they used condoms during the process.

So we think that this policy is still very relevant. And that's why we are saying we need to intensify the implementation. And we think we can clearly get positive impact out of it.

**MARK WAINBERG, Ph.D.:** Yes, question at the back.

**MALE SPEAKER 1:** A question about ABC. Are you funded by PETFAR and are really free of your choice about ABC program? Can you tell us more about how much condoms are accessible in your country, because in many countries which are involved in ABC program, that's simple, you just don't find condoms or they are too expensive?

**ALEX OPIO:** Yeah, thank you. That's a very important question. Uganda is one of the countries that is benefiting from the PETFAR funding. We have had a [inaudible] report saying that maybe Uganda has been influenced by the people behind PETFAR to promote more of abstinence and faithfulness. But I'm a city official from government. I can reassure you that we have been very principled in our point of view with interacting with the PETFAR team in Uganda that they must

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support what the Ugandan government, the [inaudible] in Uganda, want to do. And in fact even President Bush's money is even being used in Uganda to promote condom use. So really it is not true that Uganda is slacking in the promotion of condom use.

Secondly, in terms of figures, we are really having incremental figures in the condom use in Uganda. As I talk now, our yearly estimation is close to 120 million, and that came from about 60 million about two years. So in fact it has doubled. So really, the notion that we are not using much condom is not correct.

But I also wasn't to make a point that we also do recognize that there are different groups that promote the reduction of HIV transmission in Uganda. We have the religious groups. So we find it extremely difficult to force the religious community to promote condom use because their area of strength is the promotion of abstinence and faithfulness. So we say, take on the area of your [inaudible] advantage.

**MARK WAINBERG, Ph.D.:** Yes, a question in front.

**MALE SPEAKER 2:** Two questions: I'm wondering what has been done to evaluate the potential sources for this increasing infection rate. Are you looking at issues as have been seen in the West, for instance, among gay men regarding what some people call prevention fatigue? And secondly, I was wondering if you could tease out a little bit more this increase that you

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sited, particularly in the 40 to 49 year old age cohort, and what you think the significance of it might be.

**LEIGH ANNE SHAFER:** Yeah, thank you very much. In terms of the prevention fatigue, there is a concern that what's called normalization, people are becoming used to it in their everyday lives. This is an issue that the Ministry of Health is taking on board. It is the reason they're going to try to step up policies for prevention.

In terms of the older men and the increase in incidence among those men, yes, looking at changes in sexual behavior over time, one thing we saw is that since about 2000, every year since 2000, there's been an increase, at least in the rural population cohort, in the percentage of men aged 40 and above who have claimed to have had two or more casual partners in the last month. That percentage has increased since the year 2000. So there are some other sexual behavior indicators that we looked at, such as condom use, which doesn't appear to have changed very much. In young men, age 16, the percentage of 16 year olds who have ever had sex has increased a bit since 2000 as well. But that doesn't address the older men issue, but certainly it addresses overall rise in incidence.

**ALEX OPIO:** Maybe I can add that we have also been working in order to identify what we think the drivers of the current level of epidemic. In addition to what my colleague has just said is that we have also found out that a great

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proportion of adults have a coinfection with herpes simplex virus type II; in fact, close to 50-percent. And because of the close link between the sexually transmitted infection and HIV infection, we think this is a very strong factor.

Secondly, we have also seen that there's a high level of HIV discordance among couples where at least one partner is HIV positive. Fifty-eight-percent of them have HIV discordance. And that's why the issue of condom use must be promoted, even within marriage.

So really, there are a number of things which we are doing. And you may wish to get onto the Minister of Health website, [www.health.go.ug](http://www.health.go.ug), and you'll find a survey report which is very comprehensive, and you'll get a lot more information. [www.health.go.ug](http://www.health.go.ug). On the front page you'll get the report.

**MARK WAINBERG, Ph.D.:** We're running out of time, so I would ask the questions to be brief and the answers to be brief. Yes, please.

**FEMALE SPEAKER 2:** Yes, thank you very much. I'm concerned about the increase in HIV rate in Uganda, and I'm just wondering whether it has something to do with the increasing number of people that may be surviving and on ART, because you know that prevalence is always related to incidence and duration. And so, if duration had been stable, and people are now on drugs, duration will increase, and that may have a

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feedback effect on the incidence of the disease. I don't know if you've looked at this problem.

**LEIGH ANNE SHAFER:** Absolutely. You are correct. ART did not become readily available in Uganda until the last two years, since the beginning of 2004. In the rural cohort, the Medical Research Council cohort, they began offering ART to qualified people beginning of January, 2004. And the Ministry of Health started a mass rollout of ART in the middle of 2004. So I believe that the epidemiologic trends that we've seen, which started in 1999/2000, are not related to increased survival because of ART.

**ALEX OPIO:** In addition to that, related to ART, we're also saying that is there complacency, people misinterpreting that may be ARV leads to a cure. So we are saying while we want as many AIDS patients to access ARV drugs, they must also know that it is not a cure. It improves on life. So when you have a partner, you must use condoms.

**MALE SPEAKER 3:** I've got a quick question for Lynne Leonard. In your presentation, you noted that you had done some HIV testing and you didn't report any HIV data. So if I was right, if I understood it correctly, you had done some saliva tests. Do you have results?

**LYNNE LEONARD, Ph.D.:** We don't have those available at this time.

**MARK WAINBERG, Ph.D.:** Okay. I think we have to end

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this press conference. I want to thank all at the podium and I also want to thank the audience for having asked a wonderful array of questions. Thanks to all.

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