



Transcript provided by the Kaiser Family Foundation¹
(Tip: Click on the binocular icon to search this document)

**Prevention and Treatment of HIV Among Drug-Using
Populations
Kaiser Family Foundation
July 23, 2010**

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

[START RECORDING]

JACQUES NORMAND: - that we've been able to get such a good attendance on the last day of the conference. A lot of people have already left, so thanks for showing. You're going to have a really exciting session. One thing I'd like to mention first is that we have copies of the report in the back of the room and also memory sticks with - we've brought the English version and the Russian version on the memory sticks, so feel free to take a copy of both, the hard copies and the memory sticks, or only the memory sticks. It's up to you.

The intent of this session - and I'm going to be very brief, because if you look at the program, it's a very tight schedule and we're going to try and stay on time, so I'm going to try to do this under five minutes to spare some minutes.

The goal of this session was to summarize the main outcomes of the meeting that we had in January earlier this year in Washington DC and provide you with an overview or some idea of what the main recommendations are, which gravitate around drug treatment as HIV prevention and also ART therapy as HIV prevention are the main themes that are coming across this report.

I'll be very brief in introducing the family. I think I'll do it all up front, that way it's going to flow better as we move along in the session, and I'm not going to do it in the order of the presentation.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

So the first - we have the honor of having Ambassador Eric Goosby. Ambassador Goosby serves as the United States Global AIDS Coordinator leading the U.S. government HIV effort. In his role as Ambassador he oversees implementation of the U.S. President's Emergency Plan for AIDS relief, as well as U.S. government engagements with the Global Fund to fight AIDS, tuberculosis and malaria.

We also have the honor of having Dr. Julio Montaner. He's full Professor of Medicine at the University of British Columbia. He's the head of the First Division of AIDS in Canada and is currently the President of the International AIDS Society. He also is the Director of the British Columbia Center for Excellence in HIV/AIDS.

In addition, we have Professor O'Brien that's Chief of Psychiatry at Philadelphia VA Medical Center and also serves as the Kenneth Apple Professor and Vice Chair of Psychiatry at the University of Pennsylvania. He's also Vice Director of the Institute of Neurological Science and Director of the Center for Studies of Addiction. He also is a member of the Institute of Medicine since the early '90's at the National Academy of Sciences.

In addition, we have the pleasure of having Dr. Nora Volkow who's the Director of the National Institute of Drug Abuse at NIH. She has received many awards over the course of her career, which I'm not going to go through, but one of them

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

is also being a member of the Institute of Medicine at the National Academy of Sciences, and much of the program at NIDA - the AIDS program at NIDA - has been changing in direction because Nora has had the ability to get us involved in all kinds of different specialty fields that did not have a big presence in the past.

Following the four speakers, we are going to be awarding NIDA IAS International Fellowships. This year we're going to be awarding five fellowships. The program started last year in Cape Town where we awarded two and this year we're awarding five of them and we're going to keep on sustaining that program for the coming year, so on that note, let me introduce the first speaker, Nora. [Applause].

NORA VOLKOW: Good morning. It's a pleasure to be here and before I start my presentation, I do want to thank Dr. Jacques Norman who directs the HIV/AIDS Program at the National Institute on Drug Abuse, and I should say he's a relentless warrior to actually bring attention to the importance of drug [inaudible] on the HIV epidemic.

I also do want to thank the International AIDS Society for giving us the opportunity to give a presentation about the science of drug self abuse and, at the same time, make you aware of this report that actually summarizes the two-day meeting which was brought upon to actually discuss where the

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

evidence was visa vie the treatment of the substance abusers that have HIV.

And this was a result of a frustration coming from the field by the lack of recognition that the substance abusers have in terms of their not being properly treated, and at the same time by not doing that, interfering with their personal outcomes, but also interfering with the ability to contain the HIV epidemic globally.

My presentation will be focused, actually, on trying to give you some summarized evidence about why we cannot ignore substance abuse if we want to actually contain the HIV epidemic; to give you the science in terms of what are the most important aspects with drugs because these are complex interactions which contribute to HIV. And at the end, I do want to bring out two of the most exciting findings as it relates to treatment.

Drug abuse - it's been recognized that drugs play - have played, from the inception, a very important role on the HIV epidemic. Indeed, there was specifically recognized visa vie injection drug use and overall, the trends have changed according to - depending on the countries - currently, the United States is approximately 10-percent of the cases and that has been controlled in a great measure because of access to its very effective medications for the treatment of injection heroin abusers.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

However, that is not the case in many areas of the world where HIV is - one of the main factors is injection drug use. Unfortunately, the contribution of drugs to the HIV epidemic is not just limited to injection drug use, but actually, it's much more widespread, and that is because drugs, by themselves, can affect behaviors of the individual.

Now what is the data that we currently have? And I'm showing you here the prevalence rates for HIV across different cities throughout the world among those that are injecting drugs, versus drug abusers that use other routes of administration.

And what is becoming increasingly evident is that the prevalence rate of substance abusers are actually, in many cities, equivalent whether they inject or they don't inject. So when we address the issue of drug self abuse, we need to expand beyond the whole concept of injection drug use.

And that other side of drugs, when they are taken by other routes of administration is even more complex than addressing just injection drug use, where what you have to address is the contaminated material. Here what you have to address are the consequences of the drugs themselves, the effect of the drugs in the brain.

Behaviorally, what do drugs do? Some of the drugs, for example, to start with, increase sexual desire, sexual arousal, and here you have data in comparison subjects who are cocaine

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

abusers who are tested after a placebo, or after injecting them with a stimulant drug, and this is their sexual desire and you can clearly see a significant increase in sexual desire just promoted by the administration of a drug.

Now that is behavioral in the way that a person will perceive it. Now what happens inside the brain? In a very simplified fashion, we've come to recognize there are two major circuits in the brain that are involved - directly linked with the actions of drugs as it relates to the effects of drug intoxication and a higher risk for contacting a sexually-transmitted disease.

One of them is the control centers in the brain here in blue purple, which are the areas of our brain that allow us to make a decision and a judgment and to be able to carry through; and the other one is the limbic brain that is actually responsible for our desires and our emotions. This is the area that gets activated with sexual arousal. So our ability when we are sexually aroused to make a judgment is dependent very much on the proper function of the frontal cortex.

Well, when people take drugs - I'm going to show you data, and it's not just illegal drugs, it's as well legal drugs, and the data that I'm showing you here is 20 normal controls who were tested under two conditions: you give them a placebo and then you give alcohol intoxication and you see inside the brain to try to see how the brain function has

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

changed during the state of intoxication. And these are actually moderate doses of alcohol. And what you can see here is the summary of the areas of the brain that differ from the state that the brain was when the individuals were sober.

In blue, you have the areas where brain glucose metabolism has gone down, and in red, you have the areas where brain glucose metabolism has gone up. The glucose metabolism is an indicator of brain function, so when glucose metabolism goes down, that means that those areas of the brain are much less active.

And what is striking is by juxtaposing the slide that I just showed you with this one is that you can see that alcohol is decreasing the activity of the pre-frontal cortex, exactly the areas of the brain that are going to be able to exert judgment and control your desire, while at the same time activating all of the limbic areas of the brain that are responsible for our ability to perceive desires and emotions.

Therefore, it should not be of any surprise that sexually risky behaviors are much higher when people are intoxicated, including in the case of alcohol. Now, unfortunately, the effects of drugs are not just effective when the person is taking them and they are intoxicated.

With repeated drug administration, the brain starts to adapt and it produces long-lasting changes that are present even when the person is no longer intoxicated, and in many

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

instances, months or years after the person has stopped taking drugs.

And I'm going to illustrate this by imaging studies that have specifically addressed changes in the brain's dopamine system. The brain dopamine system is crucial because it's what motivates our behaviors and drug self abuse exerts highly addictive effects because it activates the dopamine system. Without dopamine, we are not able to engage in any of the behaviors that are important for survival, like, sexual reproduction or feeding.

We can use imaging to actually monitor exactly the receptors that transmit the dopamine signals; at the same time, we can also measure brain function. And what has been shown across various studies by now is that across a wide variety of addictions, legal or, indeed, illegal, chronic administration of drugs leads to a reduction in the expression of the dopamine receptors that are transmitting the required motivating signals into the brain. And so, you have them here for a cocaine abuser the decreases - this is a controlled control, methamphetamine abuser control, alcoholic control, heroin-addicted individual.

And this is actually one of the first findings that led us to the recognition that drug addiction is a disease of the brain and that you can actually very specifically identify the biochemical and functional changes within the brain that

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

actually lead us to understand the disruption in behavior that you see with people that are addicted to drugs.

So here you see a decrease in dopamine D-2 receptors. What is the consequence of a decrease in dopamine D-2 receptors? Well, from animals and human studies, we now know when these receptors are down, what happens is that individual becomes much more impulsive. T

his is data from a methamphetamine abuser in which we're actually measuring the concentration of dopamine D-2 receptors as compared to normal controls here in sero. This is less than normal controls and you can see the very high levels of impulsivity.

Now why does that translate, in turn, to actually sexually risky behaviors? Impulsivity is associated with a much greater likelihood of engaging in risky behavior. So chronic drug use will further affect the ability of the brain to exert control when an individual is in an improper situation. Biologically, why is that so?

That is because when the receptors go down in this area of the brain, the striatum, metabolic activity throughout the whole pre-frontal cortex goes down, and that is, actually, the area of the brain that enables you to exert inhibition over behavior that is proponent; you want to do it, but your pre-frontal cortex says, no, do not do it. And it's equivalent to the brakes of the brain.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

So here we have a situation where - and we're not speaking injection drug use - acute intoxication interferes with your frontal cortex capacity to exert executive function and inhibitory control. Chronic drug use exacerbates that disruption such that the dysfunction persists even though the person is no longer taking the drug.

And, finally, there is a third element that contributes to the disruption on the function of these important two brain circuits when dealing with drugs and HIV. And that is what has now been recognized initially to clinical studies, that individuals with HIV had a higher frequency of extrapyramidal symptoms, which are a connotation of dopamine deficits.

And, indeed, where studies have been done to document whether there are changes in dopamine D-2 receptors or another marker of dopamine transmission, there is evidence that individuals that have HIV have a deficit in markers of dopamine brain function.

And there's now also evidence that the combination of HIV and drugs exacerbates that decrease in dopamine neurologic activity, so you have synergistic effect where the combination of two very different factors affecting the function of these neurotransmitters in the brain collide to actually disrupt it even further.

So within these circumstances, what do we do? Well, the first recognition is that we need to treat the substance

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

abuser. Ideally, of course, you want to prevent the substance abuse, but if the substance abuse is not prevented, you want to treat it, because if you don't treat it, the likelihood that that individual will engage in behaviors that will lead to a high probability of getting infected with HIV is high.

And this data is old, but it's so eloquent that I don't need, actually, to show anything more than this one which has, actually, been independently replicated by several investigators.

And this just tells you the rate of seroconversion among heroin abusers following 18 months of treatment in those that received no treatment versus those that were partially treated, or those that received continuous methadone treatment. And, again, the data speaks for itself. In 18 months, 20-percent of sero conversion, as opposed to less than three-percent sero conversion in those individuals that were continuously treated with methadone treatment.

And I think when you have data like this, I think that the evidence is overwhelming into the state this is a no brainer. We need to treat the drug abuser if we want to prevent HIV; in fact, treatment of drug abuse is prevention for HIV.

I want to end my presentation with two very interesting findings promising.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

One of them is already in humans where it has been shown results, and the other is still in animals, but both of them are very exciting. This is a study that uses for - a new medication for the treatment of heroin abusers which was developed with the understanding that, unfortunately, there are many places where there is no access to methadone or buprenorphine, to opiate substitution therapies like the criminal justice system or like several countries that do not accept these medications.

The recognition of the need of alternative treatments, so this is a medication, that rather than being an opiate agonist, it's an opiate antagonist, but it's a slow-release delivery system such that once a month the individual receives these opiate antagonist.

And this is the first clinical trial done in 250 heroin abusers, half of which, basically received the placebo, and half of which received the naltrexone slow-release formulation which is labeled vivitrol.

And this is the percent in unit urines - which at six months was 90-percent for those that received the vivitrol treatment, as opposed to 30-percent for those that received the placebo. And, again, a three-fold better outcome in the individuals that were treated with this medication.

What was also surprising and unexpected is that this medication improved the mood of the subjects and also decreased

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

the craving and the adherence rate for these individuals was close to 70-percent.

So this is a first clinical trial - we're going to be replicating this clinical trial in the United States and, again, this gives us access to a new medication that will expand our ability to be able to treat those individuals that, because of circumstances, they're not receiving proper pharmacological treatment.

And, finally, I want to also make you aware of a new development where NIDA has made one of its five priorities, which is the development of vaccines against drugs. So we currently have humans being tested, a vaccine against nicotine, a vaccine against cocaine; and in animal studies there are different laboratories, actually, already working with a heroin vaccine, again, to provide alternative medications.

And the mechanisms are, actually, quite simple. They borrow from that of any other vaccine. You inject the vaccine that is an antigen tied to your drug - in this case we speak of the heroin.

Your body will generate antibodies that will not distinguish between the drug and the antigen such that when the person injects the drugs, the antibodies will bind to the drug interfering with its entrance into the brain. So the individual can take as much heroin as he or she wants, that drug will never make it into the brain.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

And very [inaudible] data, several laboratories have shown how this approach can completely obliterate the pharmacological effects of heroin. I just want to basically end my presentation by stating drug addiction is a disease of the brain, it's a chronic disease that affects multiple areas of the brain.

Very important for the HIV/AIDS is that it erodes our ability to exert inhibitory control and exert proper judgment, while at the same time hypersensitizing the motivational drive to take the drug.

And so when you have the hypermotivational drive to take the drug and you don't have the capacity to control it, then it becomes an automatic reflexive behavior where the individual engages in compulsive drug-taking, not because they want to take the drug, but because they have lost the ability to control that desire to stop taking the drug.

And with that, I want to thank you for your attention.
[Applause].

JACQUES NORMAND: Thank you, Nora. Our next speaker is Dr. Charles O'Brien from the University of Pennsylvania.

CHARLES O'BRIEN: Thank you very much. I would like to begin by thanking Julio Montaner and his colleagues for putting together this symposium and my colleagues at the University of Pennsylvania, David Metzger and George Woody who helped me put together this material.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

I am going to begin where Dr. Volkow left off. In fact, we have very, very good evidence that the use of drugs that produces addiction, which is actually governed in large measure by our genes.

So a lot of the people who become addicts are not really guilty of doing anything that other people don't do, experimenting with drugs occasionally, but some people, because of their genes, are very susceptible to becoming addicted.

And when they become addicted - whether it's from a drug that they have to inject or a drug that they take orally - the changes in the brain circuits that Dr. Volkow just described occur and it causes them to lose control, not only of drug-taking, but also to lose control of urges and causes them to do bad judgment things, like having unprotected sex.

So there is a strong link between the use of drugs and becoming addicted and the spread of viruses such as HIV. I'm just repeating a few of the things that Dr. Volkow said about epidemiology, I don't have to tell this group about how widespread the problem is and it is a worldwide problem, but just to give you some data about the linkage.

The odds ratio in several of these large studies for alcohol, for example, is almost double and amphetamines and injection drugs are much higher, but the point is that even oral drugs greatly increase the risk of getting seral positive or catching an infection.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

And this, of course, increases when people take the drugs by injection, and as you all know, it's worldwide and this slide shows the spread - in the darker areas in the ones that have the greatest problems, for example, Russia and the United States in North America.

Another interesting finding is that when you look at registered HIV cases, the frequency of intravenous drug users is very high in all of these countries, and the highest being Russia where it's over 80-percent, but many other countries are very high as well. So that those of you who are working with people who are infected with HIV know that the people that you see are largely involved with drugs, and this is true in numerous other countries in other parts of the world.

Now, how do we treat addiction? A lot of people don't realize how effective the treatments are, but they're more like the treatment of high blood pressure, diabetes or asthma. We don't cure it; we don't erase those circuit changes from the brain that Dr. Volkow talked about, but we change behavior and we help the person to develop new learning, new circuits.

But counseling and education and talking with patients by itself is not very effective. We do all of these things that are on this slide, but we also give them treatment for their drug addiction and the treatment for their drug addiction often involves giving them medication.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

The addiction that we know the most about is opiate addiction. We know that all the effects of heroin and other opiates go through the opiate receptor, and we also know that out-patient drug-free counseling is not effective; it's really dangerous because the people go right back to using drugs and they also spread the virus.

Therapeutic communities are very good and there are some people who have been helped and have abstained from drugs for life after going through this treatment, but they're very expensive and most patients relapse soon after they leave the therapeutic community.

So methadone has become the most effective treatment that we have for opiate addiction. It was developed in the 1960's, became widespread in the 1970's and we've gone on to develop new medications such as buprenorphine and suboxone cillin, which is a combination of buprenorphine and naloxone, and then naltrexone which Dr. Volkow just mentioned and I'll tell more about.

So we have some very good and specific treatments. Methadone is a full agonist and methadone is much more than harm reduction. Methadone is rehabilitation because I've had - and we've all had in this field - we've had some very successful patients. They're not sedated, they're able to go to school, they're able to practice law or medicine, they can behave normally while they're on methadone.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

And while some of them are able to eventually stop the methadone, many of them stay on methadone for the rest of their lives, but it doesn't interfere with normal behavior. They don't have to get injected on a regular basis; they just take it by mouth, usually once a day and they have to see the physician intermittently, sometimes once a week, sometimes as little as once a month.

Methadone works by cross tolerance so that people have their craving relief, they have no withdrawal and if they do try to cheat and take some heroin, they hardly feel it at all because of this cross tolerance.

However, some people have found that when they don't use the right dose of methadone, that a low dose is not effective, and this causes methadone failure, so those of you who are involved with methadone programs, I urge you to let your physicians - to know the literature and learn how to properly dose methadone. Properly dosed it doesn't cause sedation, but it does cause all the benefits.

And some of the evidence for that is, for example, a study that we did in Philadelphia early in the epidemic. These were people in treatment where it was stable. Out of treatment over six years, there was a great increase in HIV seral positivity and as Dr. Volkow said, there have been many other studies that have replicated this.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Suboxone cillin is relatively new medication that also works like methadone, but you can give it as infrequently as three times a week and if people try to abuse it by injecting it, the meloxin that's included with it, and generally a ratio of four to one - will prevent them from feeling high from the buprenorphine. So we find that this significantly reduces the abuse potential which is, of course, one of the problems when you're prescribing opiates, that people can divert them.

This just demonstrates in the laboratory that unblocked buprenorphine pure gives somewhat of a high - this is placebo down here - but the miloxin/buprenorphine combination is almost as low as placebo, so it shows that if people inject it, they won't get the high and this discourages abuse.

Now trexone is an opiate antagonist; it goes after the same receptors, but it doesn't activate them, but it blocks all opiates and we've been using it for years for special populations, such as physicians, pharmacists, nurses and people on parole.

Works very well, but just recently there's a new formulation called vivitrol that works as an implant once a month and this very successful study carried out in Russia was just demonstrated by Dr. Volkow and this shows that the placebo group had many more positive urines than the group that got trexone one injection each month.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

And this is showing needle sharing of people in treatment, but we also have evidence that besides a lack of positive urines, those getting the trexone also had significantly reduced craving and I think that that's really important because craving is a reflection of the changes in brain circuits; it tends to prevent people from leading useful lives, from having a job or going to school. And so we have medications now that reduce craving.

The crux of our treatments is that we reduce the risk of spreading disease by reducing things like needle sharing and risky sexual behavior. And we have numerous studies now as it's shown on this slide that shows that this is, for example, risky behavior before treatment and then it goes down during treatment; however, this is a chronic disease and this the relapse that occurs one year after stopping treatment.

What this demonstrates is that this is more like high blood pressure or diabetes; it doesn't just go away because people have been treated, but what we do is we continue the treatment and eventually they may be able to stop it, but only cautiously, and many patients have to continue treatment for the rest of their lives.

Again, the same study that we did in Philadelphia, those without treatment had much more infections than those with treatment and there's absolutely no question to the fact

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

the risky behavior, such as needle sharing and unprotected sex are decreased while they are in treatment.

So our conclusions are that you should be optimistic about the treatment of addiction. The science is very good; we've made a lot of progress about understanding what is the fundamental problem in the brain. It's a chronic disease. We combine pharmacology and counseling and there's a great efficiency with the medications.

We find that it's affordable; it actually saves money because of the great expense of people who are not in treatment and there's tremendous data showing that the risk behaviors are decreased when people have access, not only to the HIV treatment and the retroviral therapy, but they have treatment of their underlying addiction.

This helps in many ways: it helps by reducing the risky behavior, the spreading of the infection, but also, it helps them to adhere to treatment if they're already infected. So there's a great deal of evidence to support the benefits of treatment for addiction. Thank you very much. [Applause].

JACQUES NORMAND: Thank you, Chuck. Our next speaker is Dr. Julio Montaner from the University of British Columbia.

JULIO MONTANER: Thank you, Jacques, and I would like to start by highlighting the wonderful work and the impact that NIDA is having in this field, and the perseverance and

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

leadership that Nora has shown in moving some of these issues forward.

This joint venture between NIDA and the IAS is one such an example of an opportunity to bring the evidence to the table in the home that it's going to serve to move policymakers away from the ideology-based decision making and embracing evidence-based public policy as recommended including the Vienna Declaration.

My part of the presentation relates to the use of treatment - antiretroviral therapies as prevention and it's based on work that has been very generously funded by the provincial government in British Columbia, but it was initially facilitated by a NIDA grant and a Vanguard award that I was fortunate enough to secure through NIDA.

We started this process with a paper that I had the privilege of presenting at the Toronto International AIDS conference and published in the *Lancet* in 2006, and I would like to highlight the role of my collaborators at the time: Bob Hawke, Evan Wood, Thomas Kerr, Martin Dahl, Evan Levy and Richard Harrigan, and a number of others that have joined since then and I'll name them later.

In constructing the basis for the work that I have - I will present later - in essence, we made the case at the time that if we expand access to highly active antiretroviral therapy, we would be able to curb the growth of the HIV

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

epidemic. The basis for this is fairly straightforward. Highly active antiretroviral therapy is dramatically effective at stopping HIV replication to very low levels.

Work that Thomas Quinn has done many years ago has shown that low-level viral load is rarely, if ever, associated with HIV transmission, and I remind you that the work that he's done indicated in the natural, untreated setting, that you don't have to be undetectable to have no transmission; in fact, Norwood Cuetro [misspelled?] in his study, if you read that paper carefully, it's published in the *New England Journal of Medicine*, it says that he did not see any evidence of transmission with over 1,500 copies per ml.

And so, the amount of suppression we see with antiretroviral therapy is way below the lower portal in the [inaudible] study where no transmission was found. So the paper says that if HIV levels fall to undetected lows in the blood, as well as in sexual fluids, for example, you would expect to see a sharp reduction in HIV transmission.

And before I go further, I think it's important that we repeat, and probably repeat every time that we talk about this subject, that is not about medicalize in prevention; this is about treating people who need treatment and arriving at secondary benefit in prevention, and doing so over and above strengthening traditional ways of preventing HIV, including education, changing behavior, harm reduction and now, as

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

earlier discussed, treatment of substance use, as well as embracing new studies, technologies and, possibly, vaccines if and when they become available.

But having said so, we have to recognize that these strategies have not been able, so far, to control HIV [inaudible] and, therefore, we need more if we're going to control the epidemic; if we're going to - as MSF elegantly has discussed yesterday - bend the curves and make this a statement of our position.

Now before we concern ourselves with the secondary impact of HIV treatment and prevention, in IV use in particular, I think we have a responsibility to ask the question, is this really good for them before focusing on the public health benefit.

For that reason, we were very careful to look at issues of morbidity and mortality before we looked at incidents. I'm not going to discuss this in detail, but mostly Evan Wood and Thomas Kerr in our group had done a tremendous amount of work looking at all possible aspects of the impact of treatment on morbidity, mortality, viral load, CD-4s, resistance, and so on and so forth.

I also want to highlight Viviana Deslima [misspelled?] who has been particularly involved in this work. As you can see here, this is one example: a paper we published in *JAMA* a little while ago where we showed over five years the non-

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

accidental mortality rates that we seen in IDUs and non-IDUs are basically super-imposable. I'm glad you like it.

[Laughter].

We move on next to try to explore how to assess the impact of antiretroviral therapy on HIV transmission in injection drug users. I have to tell you that we spent a lot of time trying to figure out how to do these best, because we were always thinking about the heterosexual context where this issue had been shown looking at couples, and as you can see, that doesn't work very well in an IDU setting.

I would like to give the credit particularly to Evan Wood, but also to Brandon Marshall who will be recognized later on today for this work because their team came up with the idea that we could look at this in a community setting as a community viral load approach and, truly, they coined that term for us, and this is the basis for the study that I'm going to show you next.

In this study, we looked at [inaudible], community, plasma, HIV, viral load, and incidents of HIV among injecting drug users using data collected perspective in the downtown eastside of Vancouver. Just to make it clear. Vancouver has a very small area where there is high use of intravenous drugs, a very high density of IDUs and a high frequency of HIV, approximately 30-percent in that community.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

We've been monitoring this epidemic for a number of years trying to understand it and, hopefully, as I will show you later, trying to achieve better outcomes in that environment.

So the proposal in this study was to look at the community viral load - or the average viral load in that community over time, and that's indicated on the blue line here. And as you can see, thanks to our [inaudible] efforts, we've been able to drive community viral load down in this community.

And if I show you the HIV incidents now, you see that there is a very nice story to tell: high viral load [inaudible] high incidents, and as the blue line goes down, so does the red line. And, of course, we don't eliminate HIV transmission altogether, but we have a very substantial effect in this cohort which is looking both at actual use of antiretroviral therapy, viral load and HIV incidents measured prospectively.

We ran analysis on this using Cox Proportional Regression and I just highlight for you one particular thing that is of high relevance. The plasma viral load in this analysis had a relative hausner [misspelled?] of greater than three and it was highly significant. Compare that to others things that we typically view as problematic, such as sharing needles, for example here, associated with a hausner ratio 1.45.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Let me remind you that this hausner ratio is 3.32 prolog increase in viral load. What that means is six times three is approximately 18 where looking at an untreated community of IDUs, you would be looking at the viral load being 20 full driver of HIV transmission versus needle sharing being not even a two-fold driver of transmission.

Don't get me wrong, I'm not saying that sharing needles is safe; what I'm saying is that we should be concentrating on needle sharing, but if we were able to control the viral load, the needle sharing would be relevant for Hepatitis C, but a lot less for HIV.

We decided to look - I decided to eliminate the cost effectiveness analysis for [inaudible] of time, but I'm going to share with you the more recent data that we have been able to put together. In this case, I want to thank Viviana Deslima, Warren Debarrios, Beta Epva [misspelled?], Evan Wood, Thomas Kerr, Kate Shannon, Richard Harrigan, Buck Holt, Patricia Daly and Barry Kendall for their support of this fairly comprehensive study.

This paper was published in the *Lancet* on Sunday this week and, again, this was funded by the provincial government, the [inaudible] Research and NIDA. The idea here was to look at the true populational level; what is the association between use of HAART, expansion of HAART coverage, that is - community viral load and new diagnosis of HIV in the community.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Now there are a few features of this study that are quite unique. The first one is that this is not a random sample; this is not a clinic-based sample, this is a true relationally-based study. The limits of this study are the borders of the province of British Columbia in Canada.

The second thing is that we have a socialized medical system, a single payer, and, therefore, there is free access to antiretroviral therapy and medical monitoring. And let me emphasize that when where I move free access, that means that there are no co-payments, there are no deductibles, there is no this, no that, it's 100-percent free no matter who you are and no matter whether you have an income or not.

There is also central data captured and a single source for all monitoring and laboratory, so CD-4s, viral loads, they all come to our center and so we know exactly who is monitoring what and how and what are the outcomes. And resistance is also measured at a single center which is ours, so we have a very tight control over all of these variables. We also monitor the outcomes and counsel the patients on a long-term basis.

In addition, in partnering with the BCCDC, the Center for Disease Control, we gain access to epidemiological data, surveillance data for STIs and for Hepatitis C. And, finally, let me emphasize that this study has a retrospective phase, but the final half of this study consists of prospectively collaborated data.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

We had incorporated International AIDS Society USA guidelines in British Columbia, starting in the 1996 international conference, where you see here is, as a consequence of that, the increase in the use of treatment therapy.

Originally, the small blip that you see at the beginning of the plot, that pertains to the Incas Trial [misspelled?] that proved that treatment therapy with NNRTIs was valuable, but you can see here, after the trial, in the summer of 1996 predominantly, the increase in the number of people taking HAART, this is a typo, this should be 1999.

As from 1999 a steady state, this is at a time where there was a sort of a tension between the people starting treatment and people availing themselves of treatment interruptions.

In January 2004, the International AIDS Society - before even this Marks study - recommended against treatment interruptions and, therefore, you see a net increase on the number of patients on treatment, and then, as the guidelines were liberalizing progressively over time, you see Phase Three where there were more and more patients going to treatment.

Around this time is when we negotiated with the government,- authorization for us to expand liberally antiretroviral drug therapy because we were able to convince them with existing retrospective data, and that this was going

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

to lead to better outcomes for the patients, but also, better public health outcomes.

Before I show you the actual results of that study, I want to quote briefly the study from the Vick Engrail [misspelled?] and Richard Harrigan in our group, which basically addresses the concern that some people have had that expansion of antiretroviral therapy is invariably - will be invariably associated with increased resistance. This study shows for you on the bottom part the number of patients, or the proportion of patients achieving viral loads less than 50-percent - there are 50 copies per ml percent.

You see that this has gone from the 60 range to the - nearly a 90-percent range between 1996 and 2010; and, on the other hand, you see at the same time a very dramatic drop in resistance rates. This is incidents of resistance in the province of British Columbia all together. And what you see is a 90-percent decrease in the resistance because this is a semi logarithmic scale.

The acquired resistance has fallen steadily as a result of better treatments, better adherence and better outcome related to the program. So let's go to the main results of the study. You see here, that in the first phase of the study we saw an increase in the number of people taking antiretroviral therapy which is associated with a decreasing new diagnosis. It is not represented here, but you can take my word for it.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Prior to this, the number of new diagnosis was actually quite stable.

On the second phase of the study, we reached a steady state on the use of antiretroviral therapy and you see a steady state on the number of new diagnosis. As we purposely move to expand antiretroviral therapy, you see that we did the same thing; we saw the same trends and HIV diagnosis also fell.

Interestingly, because we were monitoring IDUs all along, we were seeing no changes until we developed aggressive outreach initiatives to actually engage them in care specifically. You see that when we did that in 2007, in collaboration with Vancouver Coastal Health Authority, you saw a 50-percent decrease in new diagnosis among IDUs.

In fact, it's interesting to know that wherever we targeted the epicenter of the epidemic, the decrease was seen throughout the province among IDUs, and that's because there's a lot traffic of IDUs through that particular area of the province.

Bob Hawke did the slide for us showing what would have been if things would have remained stable, so you can either chose to follow that line all along, or each one of the phases. So in each phase, you can see that expansion of antiretroviral therapy led to a significant decrease in the first phase of new diagnosis. When the treatment use was stable, there was no

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

change; when we expanded the treatment, again, there was a significant change as you can see here.

CD-4 counts change over time, guidelines change and preferences change. What this shows is the early days of antiretroviral therapy where we were very liberal in the use of treatment, then the conservative phase where treatment was less aggressively used and then, the most recent phase where you see a significant liberalization of the treatment program.

And then, to make the connection of these events, we had the ability to look at the plasma viral load for non-IDUs in this case and IDUs in this case and you can see how the frequency use plots demonstrate that the expansion of the epidemic in non-IDUs continues to be predominantly among the undetectables, if you want, and only recently, we have got a dramatic impact in that regard in IDUs as you can see here.

I show you this slide to give you a sense of how much work we have in front of us if we're going to optimize the contribution that antiretroviral therapy can help to decrease in transmission. And so, in other words, we have an opportunity - this is sort of the low-hanging fruit - the opportunity to work with these people to drive out viral loads undetectable.

But I remind you that there is a hidden bar here of the 25-percent of individuals that at all times have been driving the epidemic as well who have not yet been diagnosed - every

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

year - with HIV, and so, the initiative that we have crafted moving forward is called "Seek and Treat."

In other words, we are aiming to seek individuals in the community so to engage them in appropriate testing, eventually appropriate antiretroviral therapy and if we can do so in a supportive environment, we believe that these curves will continue to improve.

I wanted to give you the sense that we're finding less HIV in an environment where we are testing more, as you can see here, and in an environment where other conditions of hepatitis C, syphilis, gonorrhea and chlamydia actually are not going down; they remain either high or they're going up indicating that risky behaviors in our environment, unfortunately, are not going away.

Let me just show you one aspect of the cost effectiveness of this work. This is the paper that we published in NAIDS a couple of weeks ago looking at the incremental benefit in millions of Canadian dollars, which is as good as American dollars these days, over 30 years.

If you were to increase coverage from 50-percent of people with medical eligibility of HAART to 75-percent of those eligible for HAART, this curve here shows the patient's center's return on the investment, and because your life, my life, and anybody's life has a limited economic impact, this

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

curve, necessarily will plateau after time - after a certain period of time.

But when you add the particle benefit in terms of decreasing HIV transmission, the beauty of this is that it makes our investment grow exponentially over time and this will never grow any more and this will continue to grow forever, because what we're doing is we're stopping the chain of transmission generation after generation after generation.

I think the conclusion is obvious and for the interest of time, I'm just going to leave it at that, but I wanted to highlight that for this to be successful, we need to marry Nora's talk with Chuck's talk with my talk doing everything we can so that there is behavior intervention, drug addiction treatment and HIV treatment in an environment where there's the human rights of individuals, so that we can engage in appropriate care on a long-term basis.

And I'm happy to tell you that Michel Sidibe announced at this conference that treatment as prevention has now become the cornerstone of Treatment 2.0 which makes me personally very happy, but it also opens the door for us to do the right thing. And Michel, himself, has signed off on to a paper in the *Lancet* calling for what he calls, "treatment therapy for IDUs" meaning opiate substitution, needle exchange of HAART, which I think is quite appropriate as well.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

And I close with an editorial piece that Nora and I wrote in the *JAMA* earlier this year, basically making the point that sooner or later, people have to figure out that we're not going to be able to solve the HIV epidemic if we don't address the need of the injection drug users, and if you want an example of that, you have to go to eastern Europe to see how where the worst in injection epidemics is now rapidly becoming a mixed epidemic and that is quite unfortunate. Thank you. [Applause].

JACQUES NORMAND: Thank you, thank you, Julio. Our next speaker is Ambassador Eric Goosby. We're doing pretty good on time so I think we're going to be able to take about five minutes of Q&A after Eric's talk before we go to the awards.

ERIC GOOSBY: I want to thank all of you for coming today, my colleagues and friends on the panel. I also want to thank Dr. Richard Needle for the preparation of this presentation, as well as the thinking and orchestration of our USG efforts in the office of the Worldwide Coordinator.

We're going to look at the background from PEPFAR's perspective, the burden of disease. This is service coverage from injection drug users globally focusing on the countries in which PEPFAR works, and plans to increase access, expand coverage, reduce disease burden and, then, the challenges that we face.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

PEPFAR launched in 2003 - has a number of partners USAID, Center for Disease Control, the Peace Corps, the Department of Defense, Department Labor, it really is the whole of USG that has converged on our effort to make these programs work in countries, in partnership with our partner countries.

It builds on the first phase - as we move into PEPFAR II - establishing country ownership as a focal piece and continuing to support countries with both generalized and concentrated epidemics to scale up treatment to more than four million, prevention more than 12 million, and care more than 12 million.

We now are including a focus on HIV prevention that will intensify our efforts to focus prevention care and treatment in countries with concentrated epidemics and populations that have not been effectively identified, entered or retained in care: persons who inject drugs, men who have sex with men and female sex workers.

Injection drug users in countries where PEPFAR works, we've seen this already today. Out of the 16 million injection drug users on the planet, estimate 5.3 million injection drug users are living in the countries where we work with PEPFAR. Concentrated - this epidemic as we've seen already in Russia, Ukraine, central Asia and China.

The gender distribution of injection drug use is of special interest focusing on the number of males to females.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

We have - in much of our work - found a perception on part of our colleagues in country, but men dominate.

They clearly do dominate, but women are playing a central role in the actual use of injection drug use and need to be targeted and brought into care in a different way, estimating 800 thousand HIV-positive injection drug users in countries where PEPFAR is focused, the leading driver of HIV/AIDS in Asia and eastern Europe as we've pointed out.

HIV cases are attributable to injection drug use going from the percent across from Russia, Ukraine, Georgia, across India - it's not on here, but China has a 38.5-percent, Indonesia 42.2-percent. There's still 4.5 million injection drug users who are HIV negative in countries with PEPFAR programs, and this is something that we want to address. The ability access services, needle exchange, drug treatment and antiretroviral therapy is dismally low.

Our access to core interventions needs to be intensified; specific access points, conduits to access and retention strategies need to be highlighted and linkages to medical care and social services need to be ensured.

Needle exchange programs coverage in countries with our PEPFAR programs, 5.3 million injection drug users. Those who do access, 44 million needles, or just over 80 needles per injector per year choose too low an access point to the number

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

of needles and syringes that would have the impact that we're seeking.

Drug treatment, 3.2 million opiate users in these countries, only four-percent are on drug treatment as the table showed, recently have begun in Tajikistan and Cambodia. Drug treatment, Tanzania in July/August will begin a program of drug treatment as well, and this is a photograph of the first individual in Cambodia to receive methadone, and this was on the day that it opened it.

A coordination between PEPFAR, the White House and the Office of National Drug Control policy, National AIDS policy was part of our challenge to create in a dialogue process that allowed for alignment: the Obama Administration's National Drug Control policy strategy, comprehensive approach, based on balancing a public health and a public safety model. The main goals are to curtail illicit drug use and to reduce the consequences of drug use including those imposed by HIV and AIDS.

The goal to support the prevention of more than 12 million new infections based on evidence-based combinations of HIV prevention including the structural and policy changes to create supporting and enabling environments, bio-medical and behavioral.

PEPFAR, in a strategy to move toward an injection drug-using focus, provides a comprehensive package of evidence-based

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

interventions; creates enabling environments and a human rights-based approach to prevention for injection users; it secures commodities to reduce the risk of HIV transmission; it coordinates an efficient international response; links to international indicators.

Evans and Space Comprehensive Package of Interventions [misspelled?], the document is being passed out at the back of the room for you to take home with you. The three areas that are from a U.S. perspective engaging in needle and syringe programs, medication-assisted therapy and other drug dependent treatments, and the antielectroviral therapy for ART with injection drug use in addition to the other seven interventions.

PEPFAR programs should seek to create safe spaces for injection drug users to access services and ensure that the services are based on equity, non discrimination, voluntariness and collaboration in involvement of effective populations; combat stigma, discrimination and not increase the risk for violence or incarceration.

PEPFAR will formulize, strengthen and coordinate our responses with key multi-lateral and bilateral organizations. With multi-lateral and bilateral partners, we will provide critical and country technical support, bring significant resources for prevention, build political will to bring civil society into the process.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Improving health outcomes from injection drug users is a shared responsibility. The challenges ahead are many. We know that this has been a long road and one in which many of you in this room have played a critical role. We hope to join and partner - intensify a partnership with you in this effort. Hope to move to a rapid scale-up of services to increase our capacity of healthcare systems strengthening; ensure the programs are available, accessible, high quality, sustainable, achieve high coverage, monitored and evaluated, and impact the epidemic.

This is the drug control commission slide that went out earlier this year, the Drug Control Commission in Tanzania. I want to just mention Amani Wisani [misspelled?] Yurvan Evo [misspelled?], and around USG, Irene Bench, who really played a critical role in putting this together. It's an exciting project in Tanzania that is now addressing the needs of injection drug users with a drug treatment capability.

There's a mismatch between the current burden of disease among injection drug users and the coverage rates. PEPFAR is working with partner governments and civil society to address this imbalance. We hope that the guidance that has been created supports country-driven interventions that are evidence-based and human rights-based and reach populations who are at most risk.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

PEPFAR seeks to ensure that country-owned and led programs and interventions are developed and implemented with respect for the human rights of the injection drug user and the strategies that are made to identify and retain these individuals in care over the natural history of their disease, taking into effect that the, indeed, high rates of recidivism require that we have a strategy to stay connected to that individual during recurrence of active drug use. Thank you very much. [Applause].

JACQUES NORMAND: Thank you, Eric. We have about five to 10 minutes for Q&A, so if there's any questions?

DAVID MILLER: Good morning. David Miller with the National Association of People with AIDS in Washington DC, and I'm from the United People's Republic of the Bronx, which is now the epicenter of the epidemic in all North America. And I was really excited to see the question of immune therapies for - as an opiate substitution for IVDUs.

My question's for Eric and for Julio, AMP, hearing some persistence from HIV positive IVDUs on OST is becoming more difficult. Several immune-based therapies and maturing Phase 2-B therapeutic vaccines shown at a special session here sponsored by NAPWA and the Aids Institute, demonstrate control of longitudinal community plasma HIV RNA concentrations amongst HIV positive IVDUs, we well as demonstrating suppression of the pathogenesis and proliferation of resistant profiles of

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

minority sub-species. And this has been shown in poster sessions, as well as special sessions.

But the fundamental sirens regarding the organized systematic harassment of HIV positive, IVDUs on HAART by law enforcement authorities, including in the United States, because of gentrification programs is making AMP impossible, and is making the conference statement, the Vienna Declaration, stink of hypocrisy because we're not address [Applause] the implementation of new therapies that would address IVDUs with HIV on OST.

So my question, Julio and Eric, will you both come - either sit with me and Mike Bloomberg and try to convince him to get his cops to stop killing my patients, or will you go on record and support research for therapeutic interventions that are emerging, like therapeutic vaccines and IVTs that may address the unique issues that IVDUs with HIV have in seeking treatment.

JULIO MONTANER: I am not aware of the posters that you're referring to, but I'd be happy to have a look at the data, and if the data is as compelling as you have referred, you are making a very compelling case. Now, separate from that, I think we have called for the decriminalization of drug use. I'm not really available to go to every city in the world to do this work, but we're bringing the conference to

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Washington for one very good reason and you just highlighted one of the possible outcomes of that conference. So my -

DAVID MILLER: My patients won't make it for two years; I'll send you a plane ticket.

JULIO MONTANER: Sure - [Applause].

DAVID MILLER: It will be coach.

JULIO MONTANER: I'm sorry.

ERIC GOOSBY: I would just echo Julio's comments about really being interested in looking at that data as well. I think that it is critical that we really address your concern around not supporting or creating a safe space for injection drug users to access both needle exchange and drug treatment programs, as well as medical care and services without feeling that they're jeopardizing themselves to incarceration. So that would be -

DAVID MILLER: You need to go on record to support therapeutic interventions. [Interposing]

JACQUES NORMAND: We need to proceed to other people, there's only a few minutes left for Q&A, thank you. First mic, thank you.

ANDRE KLEPIC: Andre Klepic [misspelled?] of International HIV/AIDS Alliance Ukraine. In our country we have drug user-driven epidemic and due to successful prevention measures covering 55-percent of IDUs and MAT [misspelled?] we achieved good impact on this epidemic.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

At the same time, the message of this conference "Test and Treat," is seen as very controversial in our region because risk, we anticipate that it may decrease the government's attention, if not eliminate at all MAT, and needle and syringes exchange program.

So I'm very glad that technical guide for UNAIDS, UNADC and WHO was mentioned, and ART is part of the successful prevention interventions amongst the nine for IDUs.

My question is to Eric and to Julio. Would it remain, these technical guides, sorry this nine intervention including ART, as the main package for preventing an epidemic among IDUs, or new attention to treatment means revision of this guidelines.

ERIC GOOSBY: You know, the effective treatment requires both. Individuals who are burdened with addiction to opiates are constantly in an internal dialogue around staying clean and then falling back into active drug use. It really is the natural history of that addiction.

Recognizing that as the natural history of the disease and responding to it with strategies that accommodate both behaviors to as not to lose the patient from care in either drug treatment, when they move into active disease, needle exchange programs and strategies to reduce transmission of both HIV and hepatitis C in particular, is the correct and needed

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

approach. It's a dual approach. Both should be available continuously.

JACQUES NORMAND: Mic number three.

JULIO MONTANER: Sorry. He alluded to me as well. I want to echo Eric's words 100-percent, and I said it several times in my presentation. There is no successful intervention for HIV that does not include a comprehensive package for people who use drugs; that's non-negotiable. And you can quote all of us saying exactly the same thing. There's a paper in *Lancet* signed by a number of people including Michel Sidibe and Michel Kazatchkine that makes the case of triple therapy for IDUs, including opiate substitution, harm reduction including needle exchange, and HAART as number one.

Number two: you used the word "Test and Treat." I did not. And this is not an omission on my part; it's very deliberate, and let me just explain to you why. The notion of "Test and Treat" is a hypothetical notion that needs to be tested in a research setting. "Test and Treat" means that you go out, you test and offer treatment to everybody, assuming that this is good for the individual and good for society, but it has not been proven.

I believe that one day we will have the proof, but this is not what I'm talking about. I'm talking about maximizing and optimizing coverage and more people who got a medical

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

indication for treatment will want to be treated and not want to be forced to be treated.

In doing so [Applause], we have shown that you can have a very dramatic impact on the survival of patients and on the epidemic, and I believe that this is exactly what Michel - in fact, I know that this is exactly what Michel Shevivia is talking about in Treatment 2.0, so rest assured that we are very clear that we're not going for "test and treat," but rather, the "seek and treat" approach that I'm talking about.

JACQUES NORMAND: Mic number three.

CARAMINA BESWARSE: Yes, I'm Caramina Beswarse [misspelled?] from the School of Public Health at the University of Puerto Rico; we're second in the U.S. in HIV incidents related to injecting drugs with contaminated equipment, second only to Washington, and we compare with the countries that you have presented here today. Being from a public health environment, I'm very intrigued about vaccination and my question is directed to Dr. Volkow.

We all know that vaccines can have, you know, secondary effects as well. I would like to know, in using a vaccine against drugs, how do you anticipate that they might affect the medical use of both opiates and stimulants, for example, for pain relief and surgical procedures? And also, pleasure, which is a valued state of affect in human beings. Who would be

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

eligible and what would be the outcomes that would be followed in vaccine trials? Thank you.

NORA VOLKOW: Yah, and all of those, of course, are very important questions, and I wish I had very precise answers, but because this is a completely transformative way for us to address the treatment of substance abuse, we want to have to be doing clinical trials to answer some of those questions.

However, from the data that we currently have, we can state, for example, that yes, indeed, a side effect - a limitation of the heroin vaccine will, indeed, be the fact that if you do require an opiate analgesic, this opiate analgesic will - while it is not similar to heroin from a pharmacological structure, it will have no negative effect. So it will limit access to medications that are similar from a pharmacological structure to heroin itself, otherwise it has no side effects.

The big investment of resources when you take these treatments clinically is to document that they are safe to the individual. There are Phase One and Phase Two trials already done, both for the nicotine and the cocaine vaccine. So as of now, the data has shown to not produce any medical adverse effects.

Unfortunately, with the heroin vaccine, we're further behind, but I would [inaudible] that if the data in the animals is as strong in humans, and we're using similar antigens as

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

those that have been used, for example, for the nicotine vaccine, these vaccines will be safe.

Now who will be accessible to them is an important question, we'll need to understand it better. At this point, we are promoting the use of these vaccines for individuals that are interested in going into treatment, because one of the problems that happens is that people go to a rehabilitation and within one year, 70-percent of them will relapse. Giving them these vaccines will interfere with that relapse.

Whether in the future, for example, as one develops better vaccines, one could use them to even prevent some of these drugs use; it's something to be determined by the technology advance.

And, finally, your question, which is also a very important one. If I'm vaccinated against heroin, will I start to take cocaine, will I start to take methamphetamine? And, again, that is something that is likely to be the case, but in that situation - because individuals that want to take drugs will go from to the other - we may have to utilize more than one vaccine.

JACQUES NORMAND: Thank you. I'm sorry, we're running out of time, so the speakers will be available after this session, so - I'm really sorry. [Applause].

Okay, now we're going to proceed to presenting the awards to the five awardees, and like I mentioned earlier, this

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

fellowship started a year ago and we are increasing the number of awards.

We have information on the thumb drive [misspelled?] regarding these awards, so if you would like to get that information to apply, it's on the IAS page as well, the web page at IAS.

FEMALE SPEAKER: And again, good morning, and I do, again, want to thank Dr. Jacques Normand and Lynn Direano [misspelled?] from NIDA because they have been instrumental in making these awards possible. Now, why are we generating this award; and again, these award is in collaboration with the International AIDS Society. And the concept is ultimately we can change practices by providing good knowledge, and in order to generate and accelerate the knowledge, we want to make it as diverse as possible.

And recognizing the gap that exists in terms of opportunities for scientists in countries that do not have the economical resources as those of countries like Europe or the United States, we generated specifically this fellowship to provide the opportunity for researchers that come from countries that do not have sufficient resources to go and work with investigators in the area of HIV and drugs to provide that background mentorship and then, hopefully, when they return to their countries to maintain that collaboration.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

So it's a pleasure for me to recognize our five awardees today and we're going to be making the presentations of each one of them. Julio?

JULIO MONTANER: The first award is for Elena Dukhoulinova of Russia who studied genetic diversions of transmitted HIV strains among newly and recently-infected injection drug users of St. Petersburg, Russia, under the guidance of Arronal Ivan Sonstrum [misspelled?], Professor of the Center for AIDS Research of the University of North Carolina in Chapel Hill.

She obtained her Ph.D. in biochemistry from the St. Petersburg State University in 2010 while working at the laboratory for molecular biology in the project of region specific HIV vaccine development. Elena? [Applause].

FEMALE SPEAKER: It's a pleasure for me to give the second award, and the second award is to Dr. Jonathan Claud Ipser of South Africa for work on the Executive Function of Frontal [inaudible] Deficits in HIV and Methamphetamine under the guidance of Dr. Igor Grant, Professor and Executive Vice Chair of the Department of Psychiatry at the University of California in San Diego. [Applause].

JOHN MONTANER: The next awardee is Shusen Liu of China, who has prepared an oration of AIDS and HIV transmission risks among urine-testing positive patients, Metal Magnus Treatment Clinics in China under the guidance of both Dr. Su Mo

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Yu [misspelled?], Director of China's National Center for AIDS and STD Control and Intervention. He recently received his Ph.D. in epidemiology from the University of California in Los Angeles through a scholarship provided by UCLA for its International AIDS Research and Training Program. [Applause].

FEMALE SPEAKER: The fourth award goes to Brandon Marshall of Canada who will examine structure of vulnerabilities to injection drug use and HIV infection and who marginalized young people using complex system modeling and social epidemiology under the guidance of Sandra Gallea [misspelled?], Anna Cheskee Skellman and Maury Charles, Gellman Professor and Chair, Mailman School of Public Health, Columbia University.

Brandon Marshall is completing his Ph.D. in epidemiology at the School of Population and Public Health at the University of British Columbia in Vancouver, Canada.

Mr. Marshall currently works as an analytic coordinator in the Urban Health Research Initiative at the British Columbia Center for Excellence in HIV/AIDS. [Applause].

JULIO MONTANER: The next awardee is Adhi Nurhidayat of Indonesia who will study risk behaviors and psychiatric symptoms of HIV-infected drug users at three hospitals in Jakarta, Indonesia, under the guidelines of Dr. David Metzger, Associate Professor of Psychiatry at the Penn Center for AIDS Research.

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

Adhi Nurhidayat is the Director of Addiction and AIDS Research Center in Indonesia. He also works as a psychiatrist at Independence Hospital SKO in Jakarta. He obtained his doctorate from the University of Indonesia and completed it with a master's in public health from Coterie University, the Netherlands, with a thesis entitled, "Heroin Harm Reduction in Indonesia." [Applause].

There will be a further round for these awards in 2011. Fellowship applications for the next round will be accepted at the IAS website starting December 8, 2010, and until February 10, 2011. The applicants must have an appropriate mentor who holds an established post for the duration of the fellowship and has a track record in research and training in HIV and drug use.

There will be two types of awards, and to be perfectly honest with you, I think that the best thing I can do to expedite the proceedings is refer you to the website where you can see all of the information. We look forward to having another very rich competition next year and to continue this effort in years to come.

I want to thank Nora, in particular, for her vision, passion and dedication to these kinds of initiatives and starting to engage people working in various areas of disciplines into the field of HIV and drug addiction. She

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

sucked me into it and quite successfully so and I thank her for it. Thank you. [Applause].

JACQUES NORMAND: Thank you. That brings the session to a close. If you have any questions, some of the panelists will be remaining for a few minutes.

[END RECORDING]

¹ The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.