Close the Gaps: How to Counter the Retreat from HIV Treatment Scale-Up
Kaiser Family Foundation
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[START RECORDING]

[Video Played] [Applause]

MALE SPEAKER: Good evening, everyone. Thanks ever so much for coming to attend this session. There's been a slight reordering of the speakers, but the content will remain the same. The purpose of this session is to look at some of the policy and operational game changes that we feel could have an impact on HIV management in the short, medium and long term.

This session will be run in two parts: the first part will look at some of the potential game changes for bending the epidemiological curve in HIV and associates diseases; and the second part we'll look at efficiencies - ways of trying to bend the cost curve.

So the session will run in that way in two separate parts, but before we get into that agenda, we have an opening address from Carl Dieffenbach who's Director of the AIDS division the National Institute of Allergies and Infectious Diseases at the NIH.

Carl has had a distinguished career articulating urgent scientific questions and supporting key studies in a wide range of topics including, "Basic Mechanisms of HIV Disease," "New Approaches and Tools on Prevention and Therapy," and "Long-Term Consequences of HIV Disease Management." So, without further

ado, I'd like to pass over to Carl for the opening address. [Applause].

CARL DIEFFENBACH: Thank you everyone. I really appreciate the invitation that MSF gave me to speak tonight and I have a blank slate to start with, and I think that that's the best place to start because I want to take you through the vision in a visioning process. Because where we are today, and where we want to get to tomorrow does not have to necessarily grow in incremental ways.

What we need to do is link what we're doing today with the innovations of research, think strategically about the research we wish to pursue, with the long-term goal of ultimately eradicating HIV from the planet.

We need to be able to think in those terms. If we don't think in those terms as AIDS researchers, nobody else will for us. We need to own this; we need to drive forward on this.

So let's take a moment and pat ourselves on the back for where we are today. We're treating over five million people; we have people in many, many countries around the world accessing therapy. That is a really good thing.

However, the current model we have probably is not sustainable for much longer. We need evolve. We need to continue to expand access and we need a goal. We as a civil society; we as researchers; we as healthcare providers need to

endorse the goal of treating 15 million people by the year 2015. [Applause}.

With that goal - with that kind of a goal, we need to then sit down and have a serious conversation about how do we get from where we are today to 2015? We need to be able to reduce the cost of delivering drugs - antivirals - to the individual patients.

We need to be able to streamline and simplify the delivery of healthcare at the same time making it affordable for the individuals in all parts of the world, as well as continue to stress the safety for the individual patient.

Long term, we need to be able to do exactly what Mark said on the video. We need dipstick technologies; we need point-of-care diagnostics. All of these need to come together in evidence-based ways to get us to a point where we could continue to use the antivirals that we have today and that will be developed in the future. A major part of this will be trying to figure out how to dose reduce and simplify regimens, ‘cause that is another way that we can streamline and save antivirals.

From the innovation side, from the research side, we need to be able to come up with a model where starting - at some point in the future we can get to a point where we can test people and once we’re aware of their HIV infection, treat

them with highly active antiretroviral therapy, and under the cover of HAART provide them with therapeutic vaccination that we know is effective to a point where after the vaccination strategy, they stop HAART, maintain low or no viral load, are not - have such a low viral load that they are not able to transmit HIV to a partner, and then the funds that can be - that were used to treat that person can then be used to treat another individual.

So this concept of using drugs in a targeted, simplified way - getting to a point where you have the ability to give therapy in a very targeted way and then, essentially be able to monitor individuals as to whether or not the vaccine is rebounding is part of the vision.

So where we want to get to is a point where HIV is eliminated from the globe. We need to also link in prevention activities throughout this keeping in mind that there are multiple epidemics that we're dealing with simultaneously.

Here in 2010 through 2015, the advantage of being able to scale-up HAART therapy is it will have a profound impact on the TB epidemic as well. So as we move forward, we will have these abilities to impact multiple epidemics; we will get to a point where we can have an impact on the health and well-being of HIV-infected people around the world.

Long-term, though, if we do not change what we're doing, we'll be stuck in this rut of slowly increasing the number of people that are under treatment and this will be a tragedy if we don't endorse this kind of a vision. So I'll stop here. I imagine some of you would like to challenge me on some of the things I've said, so let's open this up for questions. [Applause]. Mark.

MARK: Yes, I just wanted to - on the cure - I think - this isn't on I don't think. Is it on?

CARL DIEFFENBACH: Yes, they - go.

MARK: Okay. I just wanted to get your thinking a little bit more explicitly about the different kinds of cure research that we need to undertake over the next few years. You sort of described the end point -

CARL DIEFFENBACH: Yes.

MARK: But in the meantime, there's also going to be a need to look at strategies for actually sterilizing cure, as well as functional cure, and I think it would be good to go into a little bit more detail just so people have an idea that there's quite -

CARL DIEFFENBACH: Right.

MARK: - a lot of different pathways into this.

CARL DIEFFENBACH: Thank you for the question, Mark. You're absolutely right that there are, essentially, two ways

of visualizing the cure, and I don't think they're mutually exclusive. And I actually think one leads to the other. You can conceive of a situation where there's immunity - boosted immunity within an individual that can lead to type or precise viralogic control of an HIV infection. That's similar to what we see in a group of patients called the lead controllers.

At the same time, there's the ability to directly eradicate the reservoirs - or tackle the reservoirs in some way. These two fields overlap in terms of we need to understand the reservoirs, we need to be able to pursue both, and as the Director of the division of AIDS at NIAID we will be pursuing both because I think they both need to be tracked and followed. If there are no further questions, thank you. [Applause].

MALE SPEAKER: Thanks very much. I believe that you're able to stay for much of the session, so if any questions come up, we might call on you later. Thanks very much, Carl. If I can call up the first panel, that's Mit Philips. I'll be handing over to Mit Philips who is our health policy analyst and advisor with Medecins Sans Frontia in Belgium and she will be chairing this session, so I'll hand over to her. Thank you very much.

MIT PHILIPS: Okay, so let's kick off quickly. I must say, also, I feel a bit schizophrenic because of all of the -

some of the good perspectives that we have been hearing, both from the conference and also from the experience that we have from the field; and at the same time, there is also some fear.

And I think you have seen also the reports that the MSF has brought out, "The Punishing Success," the "No Time to Quit," and you'll find in the back, also, "The Ten Consequences of AIDS Treatment Delayed, Deferred or Denied." So I hope that in this session we can reduce a bit the schizophrenia to bring the paths together.

So I'm very happy, also, that we have two excellent speakers there. What we would like to come to is saying, well, where do we go from all the data that has been presented at the conference and encouragement? Because Monday we'll have to go back into the real world and see how are we going to face this challenge and take the task up to realize promising perspectives.

So in this session, we'll talk about the possibilities to bending - to bend the epidemic curves, and also about the policy constraints and opportunities that are in front of us. For the first speaker, we have Dr. Reuben Granich. He's the HIV/TB Medical Officer at the World Health Organization in Geneva, and he has long experience in TB, treatment scale-up and, also, in HIV. He is also the author of the 2008 modeling

study that was published in the *Lancet* and sparked off both excitement and controversy.

It has fueled much of the debate at this conference, also, over the concept of antiretroviral therapy as prevention. We're very glad to have him here and with us to speak to us about the potential of HIV treatment and ART - ART in particular - to bend the curves - the epidemiology curves in the coming years.

REUBEN GRANICH: Thank you. Thanks a lot for the invitation, I really appreciate it. I'm filling in for Dr. Gottfried Hirnschall who is our new Director of the HIV/AIDS department of WHO, and I'll be delivering his talk. The other thing, I was feeling a little bit chilled, so I asked them to turn up the heat a little bit. I hope that you guys are okay with that. [Laughter]. I'm melting up here.

So I'm going to talk about the new WHO recommendations for HIV treatment. And I'm going to go fairly quickly, this is a very savvy crowd, this is day four of a long conference. You know that we're up above 5.2 million people on ART, that's an incredible accomplishment. Most of you have been involved in that and I think that's something to be very proud of. Of course, you know that there are many people that are waiting for treatment as well.

We know that treatment - the benefits are clear, I won't go into the data specifically here, but, basically, people who are put on treatment actually survive and live much longer and healthier lives.

This looks at some data that's coming out of Botswana that shows that as you - and you heard mentioned that ART has an effect on TB rates. We know that ART can reduce TB which is the number one killer of people living with HIV: anywhere from 50 to 90 percent, and you see here that as the ART coverage goes up, TB goes down. It makes sense, and we have a lot of data to support this.

This slide actually talks a little bit about our guidelines process and developing policy and WHO's a guidelines and normative agency among other things. We consider the evidence; we come out with new guidelines, and this year we've come out with new ART guidelines, an update from the 2006 guidelines.

How do we do that? Well, we have a new system at WHO, it's a guidelines review committee that looks up to the committee that makes the guidelines, and if that sounds daunting, it is. It takes a long time, but we look at the randomized clinical control trials, the observational studies.

We pull experts together: many of you were at part of this process, and then we grade the evidence according to a

formal process. We have methodologists that help us; we consider equity risk, benefits, feasibility, acceptability and these sorts of things.

I'm not going to go through the studies, but these are some of the seminal studies that informed our thinking and we need this research in order to advance the guidelines, so thank you, everybody, who supported this and the patients and the people that have made these possible.

And we know that - and this forum we're thinking about tuberculosis and we know that ART early is - early ART helps improve survival. Here's the - and I'm going fast, I'm really sorry, but most of you have probably seen these studies. This is Stearns paper in *Lancet* that talks about when to start, and we used this data. There weren't RCTs to help us, to we primarily relied on this data, among other things, to make a decision about the CD-4 criteria.

And the four guiding principles were, "Do no harm when we were doing our guidelines," "ensure access and equity," "promote quality and efficiency," and "ensure as to sustainability," so it's a complex calculus that goes into making these guidelines, but we think we got it right.

The four key messages coming out of our new guidelines are "Start ART Earlier," and I think the *Lancet* paper and other thinking on this helped move us in this direction, along with,

obviously, the benefits for clinical morbidity, mortality and keeping people healthy and alive; "Use Less Toxic and More Patient-Friendly Options, and the regimens are now - we're moving away from D4T; "Improve the Management of TB, HIV and HVB/HIV Co-Infections," and I think everybody should be aware that when you're diagnosed with TB and you have HIV, we recommend that you start ART immediately, and not later than eight weeks. And so, that's a new change and that reflects the research that's come out recently. And then, "More Strategic Use of Laboratory Monitoring."

So the goal - the benefits behind the new recommendations are reducing death, disability and morbidity; costs for OI and cancer management; reducing orphanhood, these are all things that - it's kind of like talking about apple pie and motherhood, but these are things that we think that the guidelines will help us with.

And, actually, let me go back to the last point which is reducing HIV and TB - actually, it should be HIV transmission and TB, or it could be HIV and TB transmission as well. But ART does reduce TB incidents and, likely, reduces transmission of TB and then, HIV, we're fairly certain now that that's the case, that when people are on ART that there is a reduced transmission of HIV.

Here's a table that looks at the different criteria - the hazard ratios around the different - see the different CD-4 bands, and it's coming from the Stearns paper, and showing that as - of course, as your CD-4 count declines, you have a higher hazard ratio death. And so, the idea being is that we went with less than 350 as the optimum starting point.

I just want to remind us - and you've probably seen this graph a few times in this conference and elsewhere - but this is looking at the community-based effects of - as you - this is coming from Vancouver and Julio Montaner's work looking at community viral load, and HIV incidents with the idea being as you increase coverage and decrease community viral load, you decrease HIV incidents. We need far more research on this topic, but that's some evidence that ART is useful at the community-base level. There are other papers from Taiwan and some papers coming out of San Francisco as well.

And this is the Atia Meta [misspelled?] analysis and, hopefully, you've all seen this as well, which posts the other discordant couple observational studies and suggests that, really, when you suppress viral load, in discordant couples there is very little or no chance of transmission. It's a very rare event. It can happen and you would want to use other means of protection when you're on ART, but it really provides supportive evidence of the ART for prevention conclusion.

So now, the talk will switch gears a bit. We'll talk about some realities. The first reality you'll see that the tab is still open, you know that there's probably around 2.7 million new infections a year. Last year we put about 1.2 million people on ART; we're not keeping up, we need to do something different.

The other thing is that mortality in sub Saharan Africa is far higher than in Europe and North America and that disparity needs to be addressed. And that has - I think that that has a lot to do with people starting far later on ART and, of course, having access to ART.

Here is something that we're very excited about. It's the idea - is getting HIV testing out into the community and I won't go into detail in all of this, but in the lower right, you'll see a community-based campaign in Kenya which tested 40 thousand people in seven days, and then you see Obama getting tested there in Kenya as well - he's Kenyan, after all, but he tested in Kenya on the left there, and then you see home-based testing couples counseling and I think we really need to - there are some challenges there, but we really need to think about how we can bring testing to far more people.

A slide about drug pricing. I think we've made huge - and thanks to MSF and others. Many of you worked really, really hard, are still working on this keeping prices low. I

think you probably saw that paper that just came out in JAMA talking about how PEPFAR is using generic drugs and has saved hundreds of millions there.

I think we need to continue that sort of work. That being said, pricing is, you know, it's getting pretty low there, I don't know how much lower we can go, and most of the cost is actually not drug-related cost, it's all the services that go around delivering ART. And that's where we actually can probably get more efficiencies and bring more ART to people at a lesser price.

Now, what about the guidelines? Well, we've done a quick rough and dirty survey and it looks like there are a number of countries that are out there that are using the less than 350 criteria, 29 to be specific. We've got others that are considering it or have variations on the theme.

And then, there's countries that are in the process of decision making. And WHO, one of their roles is to go out and support ministries of health to adapt these new guidelines and I imagine many of you are in that - are involved in that process as well.

These are implications - and it's - I'm going fast, I'm sorry, but you've got a few things up here that we need to think about and consider. When you raise the CD-4 eligibility, then ART coverage will decrease, so politically, that's a

problem. You go from 40 percent coverage down to 15 percent coverage in some countries. So how the ministries will deal with that is an issue.

It looks like we're going backwards instead of forward. Treatment costs, it may increase, but we're looking at the cost on that and - particularly the benefits and cost effectiveness, which I think we need to do in the same breath as the inputs and the cost for ART. It has to be a more complex equation than that.

The non-drug-related costs I spoke about. Laboratories, we need wider access to better laboratory monitoring. HIV testing we spoke about. Human resources, and we're thinking of looking at this and you'll need far more people to help roll out ART, but we think that you'll get some benefits that may save you some costs there or some resources there. And then, there's a worry about waiting lists and prioritization and our focus is on getting the sickest people on treatment as early as possible.

So the next steps, we'll be working with ministries and we'll be working with our partners and stakeholders to adapt these guidelines. We need to move progressively towards adapting the recommendations and actually address the operational questions, as guidelines are only the first step

obviously. You need to prioritize resources and not compromise the ART access or exclude those most in need.

And that's the end of the talk, and I'd be happy to take any questions. [Applause].

MIT PHILIPS: Thanks, Reuben, for an excellent, very fast talk. It will give more possibility for questions, but I would like to take the questions together after Olayide speaks.

So the next speaker is Olayide Akanni and she's a journalist. She is with Journalists Against AIDS based in Nigeria, but she's also a member of the Pan African Treatment Action movement and of the African Civil Society Coalition on HIV/AIDS. So she will be setting the scene on "What is the Situation that We are Facing at Present: Some of the Opportunities, Some of the Threats." Olayide, please go ahead.

OLAYIDE AKANNI: Thanks. Good evening, everyone, and thanks to MSF for inviting me to this panel. I think that in setting the stage on threats and opportunities, the video that we just watched and the perspectives of the people who were interviewed kind of highlights some of the threats and the opportunities that I will speaking to.

So where are we now? The last speaker has alluded to some of the points, but I just also wanted to highlight some other points: the fact that there's a reduction in AIDS financing and that has been re-emphasized over and over again

in this conference; the fact that there's also a lack of sustainable, long-term, predictable financing for scaling up; the G-8's feeling on commitments, national government backtracking - you know there's a global recession. And there is still some misconception or certainty about the definition of what universal access really is on a country level, and that is going to definitely inform how they scale up.

And then, there is a clear failure of most countries to meet the universal access targets. Many countries lack ambitious targets anyway, so that, in itself, is a challenge and there's limited access to treatment and services for key populations.

Now, what are the current threats? Some of the current threats I've highlighted earlier: there's a funding gap; there's a shortage of registration of healthcare providers; there are potential consequences of AIDS treatment delays and denials; there's fatigue on the part of governments and civil society; there is centralization of prevention, treatment and care services, so people in the rural areas are not able to sufficiently access care.

Then there are the drug pricing-related issues that have been alluded to. When we scale up, definitely the cost becomes an issue. And one of the speakers in the video has also alluded to the issues of his concerns about drug pricing

and the fact that right now, the generic industry is being undermined. And then, of course, there's the big issue of criminalization and human rights violations of key populations.

What are the opportunities? We now have strong evidence that treatment as prevention works, both for people living with HIV and those who even have TB and are co-infected with HIV. There are guidelines and there's evidence which has been inspected from the BHO on the cost effectiveness of early initiation of treatment.

Even though we have a global recession and people are talking about flat lining of resources, the fact that there's financial pressure also presents an opportunity for those who innovatively about funding the skill of process, and a lot of discussions have been going on this in conference about the opportunities that exist which we can explore.

You know, there's a lot of talk about the currency transaction levy and financial transaction tax which are new, innovative mechanisms which would be an addition to the ODA that developed countries have promised.

And then, of course, there's the Global Fund, national governments, and I just want to speak briefly on national government, and the fact that even though we've missed 2010 as a target and we know that governments are not funding the process as they need to, I think this failure of us to miss the

target presents an opportunity for the ministers of health and the finance ministers to begin to talk strategically about how do we ensure that countries are locating efficient resources?

And in talking about - financial ministers are locating efficient resources - I think it also - it presents an opportunity to - for countries to negotiate with the IMF and all of these other bodies to say, look, we need to prioritize health if we're going to achieve universal access. Whatever limitations or restrictions they are putting on us, we need to be released, you know, we need to be free from this restriction so that we can be able to deliver universal access for our people.

And then, there is the opportunity of treatment simplification. A lot of people who spoke in the video talked about the fact that they want treatment simplified. If treatment is simplified, it presents a great opportunity to scale up to as many people who need it.

These I just also want to scale through briefly and the fact that we're having the MDG Summit in September presents an opportunity to discuss again with governments about the need to forecost on universal access even in the context of attainment of the MDGs by 2015. There's also a whole lot of accountability mechanisms and consultations that countries are planning; that UNAIDS is supposed to spearhead in countries to

ensure that the discussions are achieving universal access goals. A

nd I think these consultations present an opportunity for governments to come together, provide a strong evidence base to show how they're going to scale up and ensure that treatments reaches those who need them. Thank you very much and I am open to questions after. [Applause].

MIT PHILIPS: Thank you both. We're doing incredibly good in time 'cause everybody speaks very fast, so we'll have a lot of time for questions, so let me open the floor for questions, and please indicate, maybe, who you are and who you're directing the question to, please.

MONTI ZIMBALI: Hi, my name's Monti Zimbali [misspelled?], I'm an academic at Yale University in the United States. I want to direct my question to Olayide. I hope I pronounced that correctly. I think one challenge facing us is that within a country's government, not all ministries are equal, so you can find that governments' priorities are set more by the finance ministry or by the trade ministry or by the health ministry, and that the trade ministry doesn't listen to the health ministry.

So I would like to hear ideas about how we could, maybe, empower, for instance, African health ministers to work more closely with their trade ministries to really kind of sort

of be proactive around generic expenses with the finance or foreign affairs ministries to ensure adequate development aid.

OLAYIDE AKANNI: Thank you for that question. I think it's an important one to consider in light of the fact that recently the finance ministers backtracked on - the African finance ministers backtracked on the commitment made by the African precedents in 2001. The African government is committed to allocating 15 percent to health and the finance ministers backtracked and said, no, we can't do that. That's not our reality, we're not able to commit that.

And I think that that dialogue needs to begin to happen at the country level and it's important that partners in countries help to facilitate those process, as well as, you know, ensure that there's inter-ministerial discussions, because on the one hand, the finance ministers are looking at things from a financial perspective, they probably are not prioritizing health. On the other hand, the health ministers are looking at it from a totally different perspective.

And I think, you know, it goes back to the whole discussion about the fact that, you know, health is a key development indicator and if we're going to achieve progress, if we're going to increase GDP at country level, the health and welfare of the citizens of that country and their access to treatment and care services is essential. And I think, you

know, these are discussions that even we as a civil society can begin to ensure that, you know, the dialogue happens in the country. Thank you.

MIT PHILIPS: Microphone two.

ALIA DAY: We are on microphone two. Alia Day [misspelled?]. I like - another question for you. I come from Nigeria. It was a little by [inaudible] in his introductory speech. I personally strongly believe in quantitative targets and I think when WHO invented the three by five it was a very good way to hold everybody accountable.

We have in South Africa something called NSP National Strategic Plan and we've very precise quantitative targets and certain number of achievements. And there is a priority commission civil society government to follow on a regular basis - on where we are on that plan. It didn't work always very well, but nowadays I think it works extremely well. And it allows to see how much we are progressing.

My question is do you have such thing as a national quantitative strategy plan in Nigeria, a country known to be - with not a very high coverage and a very high dependency on external donors, and do you have something like Osanek [misspelled?] where you meet regularly with government and you can see how much they achieve on their commitment?

OLAYIDE AKANNI: Thank you very much for that question. I think that one of the things that pushed - or one of the processes that pushed the quantitative target - it happened in 2006 when the then President Obasanjo had demanded that he wanted to see that 250 thousand people were placed on treatment by June 2006. Of course, that didn't happen by June 2006, but it provided the impetus for the National Agency for the Coordination of AIDS, which is the NACA, to actually work together with partners to do that.

But one of the things that that target helped to do was to help ensure that partners were working together as far as achieving treatment targets were, because before Obasanjo's announcement that he wanted a target for 250 thousand people by 2006, people were working - everybody was working in silence, you know, but because of that, there was a treatment working group that was established and all of the partners supporting treatment came together.

Recently, the government has launched a new strategy plan for 2015 because the last one expired in 2009, and there are clear targets for achievement of treatment access. Right now, the government reports that they have 350 thousand people on treatment - more than 350 thousand people on treatment, and they're actually - the National Aids Council organizes every month to provide feedback, get partners together to say, what

are we doing, what are we doing, you know, who is doing what? But definitely, one of the challenges that has been identified is there is still very limited local ownership.

We had a national conference in May and at that national conference, it was clear that only about 10 percent of funding is actually coming from the government; 90 percent of funding is still coming from [inaudible] donors, and so, it's back to our civil society and - civil society and activists to pressure our parliamentarians to, you know, to commit more resources to help because you're right, you know, we have the burden and we need to take a larger chunk of the response. And it's also about government priority and, you know, prioritization of that issue.

MIT PHILIPS: Dr. Wafaa in the back.

WAFAA EL-SADR: Yes, hi, Waffaa El-Sadr from ICAP, Colombia. Thank you very much for the presentations. I guess I think - nobody in this room will disagree with the idea of the importance of, obviously, increasing the breadth of access for our patients, but I also want us to argue at the time while we're really working towards breadth, to also work toward the depth and - particularly the issues on the quality and follow-up of patients.

And I think what has been seen in a lot of different programs is that we're increasing numbers and what ends up

happening is, of course, there's dilution of the ability to follow patients and retain them and make sure they are, you know, all the key elements that will actually enable us to achieve the individual benefits, as well as the potential community benefits in terms of prevention. So I guess my sense is, let's not forget the depth while we're seeing the breadth.

And I feel, like, at this meeting, there were - in many of the sessions, there were very interesting kernels of ideas and innovations about - and MSF had some of them - about how can we expand this breadth while achieving greater depth, and it would be interesting if MSF, or whoever it is can collate some of these ideas into really a new model of the care that we need to provide in the context of this major effort to embrace breadth. Thank you.

MIT PHILIPS: Okay, I think this is a question for Carl even though you didn't say so? Maybe you can go ahead, and then we'll group some of the questions, maybe, and then we'll go on.

CARL DIEFFENBACH: Thanks, Wafaa. That was, actually a great question because that is the tension now because we're delivering some - and I'm going to say some, because if you take some services - if you take things, something like the Three "I's" which we, you know, we've branded at WHO and Isoniazid and preventative therapy and infection control and

intensified case money, we're doing terribly on that in the facilities that we have.

So I would say that the tension is between, you know, how can we expand our services that we're giving now to actually provide access to many more people while at the same time maintaining quality?

And I think there are some programs that are working on that and the question is, you know, how far and how fast can we go to bring services closer to people? I know from seeing programs that a lot of the programs are still situated in places where patients have to travel long distances and these sorts of things.

And so, I think that is a tension and I think it's something that we'll need to work on - the WHO and others need to try and figure out and crack with the caveat being that, you know, everybody - 33 million people will need treatment and, so we're going to have - the breadth is going to have to be pretty broad and we're going to have to get far more efficient in how we deliver the services.

MIT PHILIPS: Okay. Let's state the question of Matthew and then number three - microphone number three. Sorry, it's difficult to see.

MATT CALVANAUGH: Hi, I'm Matt Calvanaugh from Health Gap. So I guess a question to Reuben. In terms of, you know,

the potential for bending epidemiological curves up there. You know, I live in Washington and one of the things we're clearly seeing is the debate in which the science that's been revealed at this conference and the economics that are being talked about at this conference, and that I think MSF has been key in highlighting, the difference not only in providing higher quality treatment, but providing it faster and to more people more quickly, and the positive benefits you get out of that is not being talked about.

And, instead, what we're hearing about far and away is a treatment mortgage as if this is, you know, buying a house, right? But, you know, I have in my bag the Zambia Partnership Framework from PEPFAR which says that they're committing to make sure that 2009 levels are maintained. That's the commitment currently put in the partnership framework for Zambia.

So I guess what would be helpful to me is to kind of hear from you a little bit about what are the messages the WHO is putting out around the potential for that game changing progress so that, you know, legislatures in the U.S., legislatures in the capital of donor countries can shift from a never-ending increasing cost paradigm to a "we can change the cost curves and the epidemiological curves" paradigm. Thanks.

REUBEN GRANICH: Thanks, right. I'll do my best to try and answer that. I mean, I think that the work that we're - the work is still in progress. We're still looking at this but the game changer, at least from my perspective, is that the fact that ART actually has a prevention benefit. And then, the next step in terms of modeling these sorts of things - it's already ongoing - is to figure out how much is that benefit, how do you quantify that, and then to put those into your projections: your projections for ART, your projections for prevalence.

Once that happens, then policymakers can - and, also, the other part of that game changer is to look at the economics and, traditionally, I call it doomsday economics where you just look at the inputs. If you increase eligibility, the costs are going to go up and it's a disaster and nobody really wants to - and it goes up in the near future because there's no prevention benefit.

So the two together, the prevention benefit and then also looking at the downstream benefits - the daleys [misspelled?] and these sorts of things that you get from providing treatment, those things actually will change our calculus and you'll be able to see, well, if you go up to less than 350 and you get very good coverage - 80, 90 percent of the community or whatever the level is - that you will see a

prevention benefit - and we're talking about combination prevention - you'll see a prevention benefit and, over time, that benefit will have an economic impact, or you'll realize the economic benefits.

So that's how we're starting to think of it. Of course, you know, these things are evolving and, you know, some of the best people working on this are thinking about that, and I think you're going to see a new economics and a new approach to target setting and these sorts of things.

MIT PHILIPS: But, Reuben, I would like to press you a bit more on that because if you want to have a high coverage, So what will be, then, the target, by when, to have the benefits of this one? Can you say something about that vision also?

REUBEN GRANICH: Well, what I can say is that we need to come together and look at the - and basically do the math and then look at the benefits. And now we've, you know, our guidelines are basically less than 350, but what we need to do now which - and I think it's a bit complex.

But what we need to do now is say, well, what is the prevention benefit for that less than 350 and at different coverage levels, and then, what will be the economic - decide on what the assumptions will be et cetera, what would be the economic benefit from that - to move to that level, 350?

And we can model higher, less than 500, and these sorts of things project those sorts of things. And then, it's a question of sitting down with ministries - I'm sorry to say, but probably ministries of finance and say, look, you know, if you stay at 200, this is what your prevalence will look like over time.

And we'll put the combination prevention in there, this is what it will look like over time, this is how much your cost will be over the next 40 years, or five years, or whatever they're perspective is; or if you go less than 350, then you'll get this benefit and this what it will look like, or, you know, if you go higher.

I just think clinically - and the guidelines are not really, probably, to go higher than less than 350, but probably in the future, that's where we'll be heading.

MIT PHILIPS: Okay. Number three then.

MARK: Yes, two suggestions. One is, Reuben, I would like ask you to go back to Geneva with a mandate from the community to re-brand the three "I's" to the four "I's" and have it be - add immediate HAART, 'cause I think one of the reasons why the three "I's" haven't work is because a lot of people thought it was just better to keep on scaling up ART and that that would be the best way to reduce TB incidents. And

so, now that the new guidelines are there, I think it gives us the opportunity to re-brand and it makes more sense actually.

MIT PHILIPS: Okay.

REUBEN GRANICH: I'd like to see and raise you. I think four "I's" has some unfortunate connotations -

MARK: Yes.

REUBEN GRANICH: - you know, there's an eyeglass store in the United States that's there, but I'd like to go with the five "I's," I think we should be pushing towards integration as well, so -

MARK: Okay. Groovy.

REUBEN GRANICH: So we'll go for five, but -

MARK: Alright.

REUBEN GRANICH: - that being said, not to be flip, but to get the three "I's" branding through WHO was - only took about ten years of my life, but, that's fine, we'll give it a shot, Mark. [Laughter].

MARK: And then, the second ambitious suggestion I want to make is that we re-frame the debate around the global health initiative - that those of us that work in the United States should re-frame the debate about the global health initiative to double the budget from a game-ending initiative that wouldn't meet any of the MDGs, which is what the current proposal is with 63 billion over six years - let's move it to

125 billion over five years and put in the health systems and the health worker training and the tax shifting and the R&D agenda that's also needed to achieve the MDGs.

I think that if the activists start demanding this from the U.S. government, and then we figure out what the rest of the global community should pitch it, we would greatly increase our chances of achieving the MDGs in sort of getting our way around this impasse that we've been in ever since Zeke Emmanuel moved into the White House. [Applause].

MIT PHILIPS: Okay. Microphone number two?

EL SORELA: Yes, El Sorela [misspelled?], Access to Medicines Initiative at Open Society Institute. I have a question to WHO. I was actually quite surprised, if not shocked to read on one of your slides that - you put it as a statement - that the cost of the treatment will go up and I think that is based on the observation that today the better first-line treatments and second and third-line treatments are, indeed, more expensive than what is currently available as a lowest price as the first line.

Now I would like to challenge that in the sense that to my knowledge, there is no technical or scientific reason why these drugs have to be more expensive, and the only reason why they're more expensive is because there are monopolies. Now, we have shown in the past that this can be changed; we have

created generic competition through various mechanisms and I think that if there is political will, we have these mechanisms available.

There is voluntary licensing, compulsory licensing, patent pools and all kinds of stuff that we can use to bring the prices down, and it would be really helpful if WHO - and, actually, others in this conference have said the same thing - and that others would challenge that and would make recommendations to reduce the prices as part of what we need to do in the future to expand and to get to universal access to treatments. [Applause].

CARL DIEFFENBACH: That's a great question. Let me back off from what I said during that slide a little bit. And I guess the point that I was trying to make is that, yes, we should not stop on trying to lower pricing for drugs, but what I'm trying to say is that the vast majority of the price, or the cost of actually delivering ART and other services, it's not the drug prices, it's everything that's wrapped up around the drugs.

And so we need to work -- we need to work on reducing that cost, and the more we can do that, the larger the gains will be, but that's, by no means, to say that we shouldn't be working on lowering prices and making sure that drug prices should come down.

And I would argue, I mean I'm not an expert in this area, but I would say that the more people we put on treatment, the economy's scale would argue that your drug pricing would come down, it would have to be that, or it should be that way if markets work right.

NATHAN: Nathan, MSF. I'd like to call on Carl if I may. My question is that this conference we've been very much fighting to support the WHO recommendations of 350 in the face of donors who are unwilling to support that for lack of funds. You mentioned, Reuben, there is not enough evidence yet for 500 but we could imagine being back in here four years' time having exactly the same debate with the donors but around a different threshold.

And so my question for Carl was to ask what his sense of that debate and those tradeoffs are and if he can imagine a way out of this paradigm of rationing access to essential medicines by degrees of sickness.

CARL DIEFFENBACH: Thank you for that question. I think it's actually an absolutely critical question that we need to embrace. I actually as I think about it, I'm a believer in access for all and currently the U.S. guidelines they treat to 500, so I think it's actually a course that we're going to come across very soon is that whether or not the start trial in the United States ends up proving feasible and

actually gets run, the evidence will continue to accumulate that the earlier you treat the better and the same arguments that you make for the economic benefit of starting a 350 will apply to 500.

The point is, is that HIV treatment reduces healthcare costs in the long term. If it's a benefit to tuberculosis to the level of 75 to 90-percent to treat at 350, it'll even be greater at 500.

So we can turn the tables on the economists and say instead of talking about the cost, talk about the long term savings because ultimately the combination of benefit to the individual of early treatment, improved economic output within communities, reduction of tuberculosis, reduction of further expansion of the HIV epidemic linked to innovation of other, whether it's a therapeutic vaccine or cure, this will become the game changer.

We need to change the conversation. Somebody said no more discussion about treatment mortgage, talk about the economic benefit because I think that that's where researchers, where the World Bank, where we need to work together to prove that there is an economic benefit to early treatment. I think that that's going to be the major game changer. Thank you [applause].

REUBEN GRANICH: I don't know if you had a chance to see Jim Kahn's [misspelled?] presentation. He's part of our informal costing group, but he had a nice presentation. I can't remember, I think it was on Tuesday or Monday and we're looking at this for South Africa. We're working with some folks down there as well and the economic benefits are huge. We were talking about hundreds of millions of dollars over a five year horizon and this is for the health sector alone.

And then you're starting to talk about break even points. Now of course, these are all dependent on assumptions of these sorts of things and that economic analysis didn't even include the macro, looking at the society of how much is a child who lives a full life, how much do they contribute. So I think that it's going to b really exciting. I think it's going to be quite easy to convince people that the economic benefits are on the plus side of expanding treatment.

OLAYIDE AKANNI: I also agree that these are the kind of discussions that the health ministers and the finance ministers should be having even at country levels, talking about what are the benefits going to be to the country and to the individual when we have to scale up treatment. Thank you.

MIT PHILIPS: I think we said already some of the questions. Also we need to have some game changes. That's what we're going to discuss in the next panel. Thanks a lot to

our speakers and thanks for the very interesting questions [applause]. I should have said that Sharonann is going to come and moderate the next panel.

SHARONANN LYNCH: Thanks Mit. Eric, I think we're going to start pretty quickly with you. Hi. Thanks for coming and joining us tonight. My name is Sharonann Lynch and I'm with MSF. I'm a HIV Policy Advisor with the Access to Essential Medicines Campaign. A comment, we held a press conference earlier and part of it was to talk about the issue that Ells [misspelled?] brought up in terms of drug pricing and also the fact that throughout this conference, we're hearing an awful lot about cost effectiveness, as Carl mentioned, and efficiencies.

But somewhere in that certainly the patients are lost and I don't see much humanity in there as well. So we would like to take the opportunity for Dr. Eric Goemaere, who has been working in South Africa and some of the other panelists to discuss some of the patient centered efficiencies.

When we talk about the cost curves, please know that in addition to the benefits that Carl spoke at, at the community level we also mean to bend the cost in terms of reducing the burden on patients, people who are on ARVs, reducing the requirements of the health system and reducing the cost of per patient per year.

Let's start with Dr. Eric Goemaere. He's the Regional Medical HIV and TB Advisor for MSF in South Africa. Then Tido will be talking later and be talking about some of the enabling policy frameworks that is needed to usher in some of the innovations.

Also on our panel is Janice Lee. Janice is a Pharmacist with the Access to Essential Medicines Campaign and will be talking about some of the future prospects of promising molecules that are in the pipeline as well as strategies to reduce the cost of current ARVs while of course maintaining quality. Eric.

ERIC GOEMAERE: Thank you Sharonann. Good evening everyone. I will not thank you myself because I'm part of it, but I will thank you all to come so late at the end of this tiring week to attend this satellite session. I'll do my best to bring provoking thoughts here about what challenge is spend.

Rueben is speaking about bending the epitomic curves and I thought well, at the local level there are other curves also that altogether would be better to bend.

It's the clinical workload curve to be more efficient and I will define that later on and this idea to distribute tasks between whoever is available among the health staff and among then the community staff, increasing the patient autonomy and adherence especially in the long term and finally reducing

the pill burden and the pill toxicity as it was alluded by different people during the interviews.

Here I have a little drawing and now it's a virtual circle that says basically what people have tried to explain here is that by increasing the coverage and lowering the CD4 threshold, inevitably you reduce the clinical time for patient need. You are loath to decentralize the primary of care and [applause] get more and more community as workers spotting good towards a patient's self management.

Of course this spending, and I'll speak to that quite a bit tonight, pending one of the conditions is to have a patient friendly regimen. It's obvious that we can only talk about this because we have now in perspective a couple of the different regimens or the kind of regimen that we aren't initially and are typically with the kind of second-line regimen that we are using still today. I don't think this would be feasible.

So I thought that the best way to illustrate this was this old dog, what to do through there is three circles in fire and the three circles in fire represent the burden for the health service, the burden for the patient first and the drug toxicity while trying to go to this beautiful circle, it's not because I live in Cape Town but I don't serve it. This perspective that you can at some point literally surf the wave

and be in front of the wave instead of being systematically on the back of the wave.

This is only possible of course if you change locally and I'll speak again local here, you must change locally the picture that you have with the patient attending the clinic. You see on the left the evolution of the baseline median CD4 count Khayelitsha.

When we started in 2001 with a median CD4 count around 40, most of the patients were brought on stretchers and were extremely sick, means all of you who have this clinical experience a lot of time to stabilize patient and to be able even to start him on the IVs with a lot of IREs to be expected afterwards and side effect.

The graphic at the bottom shows this in clinical stage terms as you can see here. In 2001, 2002 we have a 55-percent of Stage IV while I 2007 and I couldn't find more recent data, you can see the Stage II picking up and the Stage IV going down dramatically.

This only can be achieved and it's another way to express what a lot of us have tried to express this week, can be only achieved this sort of transition, it has to happen as soon as possible and require an early aggressive approach in what you called, as far as I remember in the last conference I

was listening to you, this emergency phase before we can transit to a chronic phase.

To go further into the detail about distributing cost which is called in other words the shifting or the sharing as some people prefer, actually the first thing to do and it took us apparently there's still a confusion existing on the entity of consultation. What is a consultation made of?

There is a certain amount of clinical screening, psychosocial support and drug refill. Actually with time, you see there is a color code there to say that the clinical screening is going down dramatically while the psychosocial support is relatively going up with the long term adherence issues that are requiring ongoing adherence while drug refill is more or less the same.

But confusion and that's where you see DHL, not that I want to do some publicity for them, but some friends told me that in England if you are under the NHS on antiretroviral actually the clinical consultation has nothing to do with the pill refill because simply DHL comes to bring you on a monthly basis your ARVs at home. We cannot afford DHL in most of the side where we are, so I will explain later on what we do to try to create an alternative to DHL.

In terms of the shifting, the fact that a nurse can do the job and actually very rapidly has been I think established

and it's beyond critics because there's a lot evidence. They started with a retrospective observational study done my colleague in Lesotho showing in terms of outcome they were actually equivalent in terms of mortality but better in terms of retainment and care once you decentralize in nurse based clinics. This has been also proven in Uganda and most recently by this famous RCTC trial that shows beyond doubt that there is no inferiority when nurses are doing so.

Again a word of caution, if you have managed to provoke what I call this epidemic transition, in other words when patients are not coming always at Stage IV. Now I looked a little bit, rather [inaudible] looked at what would the situation look in a place like Khayelitsha where I have been working for the last 10 years and a simple model.

I reassure you Reuben, no competition here. It's a very simple model for the situation in Khayelitsha 2009. We are as you can see more or less 70,000 patients and among them 58,000 none on ARV and 12,000 on ARTs new, that's your famous step, new infection estimate more or less at 4,000 new infections per year while we manage in 2009 it's a little bit more now manage to start at 4,000 on ARTs during that same year.

Well the problem is that, so we tried to look at 2019, 10 years down, what it would look like from an epidemic

perspective and actually while we believe that incidence is slightly reduced so maybe, and this is a very conservative of course figure, 3,000 new infections per year.

Well actually we would still have the same reservoir probably of people waiting for treatment but, and I want you to focus on that, the biggest problem is that we would have at least 52,000 people on ARVs in 10 years' time and I'll just make this point, to expect the fact that there's no way in the clinics, physically there is no space to accommodate 52,000.

So the day we discovered this, thanks to my colleague there in Khayelitsha we started to think about other systems and the system we came with is this so called adherence club. It's supposed to be, it's not yet, it's supposed to be decentralizing the community instead the principal of a club is that instead of doctor or nurse appointment, it's 20 to 30 patients are allocated to one club and they are managed by a counselor or expert patient circles and there's a principal of peer supported, this global support instead of individual consultation, everything happens in group.

For the patient, it means a huge difference because instead of waiting for one full day in the clinic to be seen by potentially a nurse for 10 minutes while of course it's only for stable patients, while they can only do it for only two hours and instead of having monthly refills they will receive

two to three months refills. We don't have unfortunately the outcome yet. We are busy collecting the outcome of this, but needless to say in quantitative focus group interview both with the nurses and with the patients it was a very popular initiative.

Looking at Thyolo in Malawi there is another idea that came out. They are decentralizing to the health center over there but they thought maybe this is not good enough. So they started an outreach initiative where one nurse accompanied by two to three community workers who are going to do advanced health posts to basically deliver minimum package of HIV services, check on adherence and of course main function assure that patients are resupplied with ARVs.

And third but certainly not least an experience that was done in Tete, Mozambique, Northern Mozambique and presented here in this conference in a poster where actually it goes one step further at a community level this is purely driven by expert patient.

It's a sort of support group with ART provision. They elect a representative to go to collect ARVs at the nearest health center and this one brings back the pills for the group of a maximum of six patients. In terms of outcome, it's a relatively fresh initiative started June 8th so it has only 18 months and unfortunately we don't have the outcome and precise

time for when the patient have been stated early and started later but you see among these 1,253 patients excellent results in terms of remaining care and with extremely loss to follow up rate.

Let me now address briefly a totally different subject about bending the curves and it's the third one. It's the issue of drug toxicity and cost. In MSF there is a large group working together with the Clinton group on dose optimization and we did a triple objective of course is to reduce patient toxicity in the future, reduce pill burden but also reduce the cost.

Everybody knows in this room about what was done about D4T reducing from 40 to 30 milligram, but actually there are many other drugs today that could potentially, and this was a discovery from being reduced in the dosage and it was explained to me that it's due to the fact that [applause] that dosage is usually fixed in phase 2 trial and not reviewed afterwards for different reasons so that usually drugs are overdose.

I think Andrew Hill from the Liverpool University central in his research he's been working on this for the last 10 years. Just to illustrate what it did for D4T and these are figures that are coming from the referral ID unit that we have in Cape Town where we are sending all of our patients thanks to Charlotte Schultz there, you see this curve here where we had

up to four persons of severe hyperlactatemia due to D4T in 2005 while it was decided to reduce D4T to 30 milligrams and immediately you see that the number of patients in exactly the same condition started to diminish.

Thanks to drug reduction but also this little machine called Accutrend that allowed every service provider to measure lactate as a point of care because the question remains and that's what I've borrowed the 20 milligram based on disagreements still whether D4T 20 milligram is an option but I will not enter into that one.

Apparently they are as I mentioned while discovered in AZT is actually still commercial as a 250 milligram in Europe and nobody knows exactly why the dosage has been increased to 300 but they are testing to reduce the dosage to 200 million bd cut 3DC by half, cut efavirenz in this I think in terms of toxicity might have launched impact cut efavirenz from 600 milligrams to 400 milligrams and the same for Lopinavir.

Most of those, they are in cold trials. Results are expected probably by beginning 2011 and these studies are fronted by the Bill and Melinda Gates Foundation and the University of South Wales. Let me now just finish on those two slides.

Looking at the long term and long term therapeutic strategy and there comes the question in terms of treatment

paradigm should we have a different treatment paradigm for high prevalence, low resource country compared to the one existing in high resource countries and of course this is still, we spoke about it with Carl earlier in the week and this is still open for a lot of discussion but we are for the moment in a paradigm of sequential regimen, one flowing and the other requiring a lot of money between there and the question is should we not go for a new paradigm based on induction and maintenance.

So it would look something like that with a very aggressive induction regimen. Of course robust and aggressive to reduce the viral load initially and then a long term fully toxic regimen and a switch not to requiring much monitoring. Of course it will require some drugs very important for induction but for the maintenance phase probably a PI based regimen with safe and minimal side effects as much as possible and RTIs sparing to avoid long term [inaudible] mitochondrial effect.

There are some promising new drugs out there. While it's difficult to beat nowadays this three-in-one, Tenofovir, 3DC efavirenz that seems to be coming in. I have put this little blister next to it because I think it's a unique opportunity as we have one pill once a day.

Why not to put it in a blister with days to remind patients about taking their pills? New promising drugs Rilpivirine apparently a very long half life it's in Phase III and Tibotec I heard they're studying it in injectable formulation maybe for PrEP. Elvucitabine an NRTI in Phase II. This pro drug of TDF that seems to be much more potent than TDF and could be administered once a week.

And to finish with this we switch what Tido has to say. Point of care tests. I will not elaborate too much here and to remind everyone how much it was a revolution seven, eight years ago to move from this ELIZA [misspelled?] where you have to send a blood sample to a lab and wait for the result and with sometimes a very long turnaround time to this rapid test and of course what we are all looking for is to simplify this fantastic machine into viral load dipstick for which a prototype is already circulating. Thank you for your attention [applause].

SHARONANN LYNCH: Thanks Eric. Now we're going to hear from Janice Lee. Janice is going to be going through some of the drugs that are currently in the pipeline and again strategies on optimizing the drugs we already have.

JANICE LEE: So I'm asked to speak about the antiretroviral drug pricing so I'm going to show you the prices there has been in the past, what we are seeing at present and

the future pricing. So what did we learn from all this antiretroviral since we started to have access to antiretroviral? This graph shows basic Stavudine, Lamivudine, Nevirapine which is the most widely used combination in the WHO which has helped access too hard.

In the beginning before the treatments started in the working countries, the drug cost as high as $10,000 U.S. per patient per year and look what happened today. This year the drug is dropping to $67 per patient per year and there is a 99-percent decrease in the originator, and not fix those combination but individual drugs and 76-percent decrease in the generic three-in-one fix those 30 milligram Stavudine combination.

And what about the prices of improved first line? So we stop talking about Stavudine now, what we are interested now is the future, what we are going to use will be mainly [inaudible] base or Tenofovir base. So if you use an NNRTI, which is Nevirapine, the cost is much lower but it's very similar between zedowodine [misspelled?] and Tenofovir because these two single molecules they cost about the same.

If you move to use efavirenz, NNRTI, which is more patient friendly in terms of TB interaction, the cost of a regimen tenofovir containing regimen is $176 per patient per year but sad to say that these drug prices are only available

for countries where there are no IT access barriers so price for middle income country for example from the originator drug still costs at $1,033 and this is only limited to a list of middle income countries.

What about the prices as we go from first line to second line to third line regimens? Here we see the lowest first line regimen with AZT, 3DC, Nevapirine is $137 per patient per year and as we move to second line the cost tripled to $465 per patient per year with atazanavir, ritonavir, which now is recommended by WHO as one of the PIs to be used in second line.

And then as we move from second line to a possible third line therapy which this last year in 2009 it's already mentioned in the [inaudible] guideline as [inaudible] though we do not know what would be the combination. A possible combination could be ratograve [misspelled?], darunave [misspelled?] boostered with atravoline [misspelled?] and that cost $3,204 per patient per year and this is seven times a cost of second line and more than 23 times the cost of the cheapest and proved first lines.

Why is it so expensive? It's because they are all originator drugs, there's no competition and basically there's no production in India because all these drugs are already

patented in India. So you can get all this information in our yearly publication of "Untangling the Web".

We started the publication in 2001 because there was a lack of transparent ARVs pricing and reliable information. It's used a lot as lobby advocacy to quotes in publication. It's also price comparison. There's patent informations and access issues and it is one of the most comprehensive pricing information available on originator ARV drugs.

We have distributed 1,000 copies already and also there have been no hard copy available but don't worry, we are available online and if you are not very green, you can click a button and print out the whole copy. So in my next presentation, I'm going to show you some of the cost projections of antiretrovirals, projections in 2014 which very grateful has been provided by the Clinton Health Access Initiative.

When I was working as a pharmacist used to have patients coming to me asking me why the drugs are so expensive and my naïve answer to them is that it's because the companies they need to recuperate on R&D and so they need to charge more on the drugs.

But as I joined the Access campaign I realized that there's a lot of other issues involved in the drug pricing so what you're going to see next would be, I will put a disclaimer

because I don't want to be sued by the companies, these prices are estimations of products which is commoditized in generic market base on costing models where APIs constitute 70-percent of the cost of the drug.

As we know there's published paper Brazilian study showed that 55 to 99-percent of the direct manufacturing cost of the drug is represented by the active pharmaceutical ingredient of the drug and this cost estimate of some of the pipeline drugs that you're going to see is based on triple FDC and not indicative of a single product price. They do not address access related issues other than the long term cost in the competitive market.

Also the pipeline drugs that you're going to see shown here are for the interest of the price comparison and more data of course is needed to determine the safety and efficacy. So I want to show you the first slide of the drug group NRTIs. As you can see here that in 2014 with generic competition, with economic scales, these are the prices you're going to see per patient per year and in the pipeline there is a drug in Phase II which has cost from $6 to $12 per patient per year and this drug is still in Phase II.

Moving on to NNRTI, in 2014 you may see the price of Nevapirine and pharmas decrease to wherever is shown here and still perhaps in the pipeline we should look at Tibotec's

Rilpivirine which is still in Phase II studies and there seems to be a very competitive price here at $7 to $15 per patient per year.

And here I grouped the proteus inhibitors and the integrase inhibitors. I just want to say that the Elvitegravir and GS9350 cobicistat is not marketed. They are in Phase III studies by Gilead and the Raltegravir and Deronavir [misspelled?] pricing here are pricing estimates using conservative long term estimates on generic API costs representing pricing in a commoditized generic market.

So what's interesting is that when you look at all these drugs it seems like elvitiwir [misspelled?] we just need some boosting and it's been developed by Gilead with a booster, its own booster, cobicistat, and the drug will cost $120 to $200. But if we boost it with retonavir, for example it can cost $90 to $130 per patient per year and this is one third the price of Raltegfavir.

And everybody talked about those optimization and there are lots of people working on those optimization and there are not funded by pharmaceutical companies. If it really turns out to have data showing that these drugs can be dose optimized, let's look at the savings per drug.

If you multiply these savings by the number of people whom we are going to put on treatment in the future, five million now, 15 million in 2015, am I correct Sharonann?

SHARONANN LYNCH: Yes, please.

JANICE LEE: So it's a lot of savings. Let's look at some of the price if we dose optimize our drugs and we use some of the pipeline drugs that are relatively cheap, what will we arrive to? We can see on top the current regimen price of first line, second line and third line and then we dose optimize our current first lines with tenofovir and 3DC 150 and efavirenz 400 it reduced to $121.

If we use AZT reduced dose Lamivudine reduced dose and Lamivudine reduced dose and efavirenz dose we come to $116. And if we use AZT reduced dose, Lamivudine dose and atazanovir [misspelled?] booster reduced dose, it's $300 and all these are cheaper than the current price at the moment.

Some of the newer drugs are also being studied or going to study for dose optimization and this could really translate into very attractive drop pricing for us to start thinking about what is the best regimen for our patients, not in terms of cost, in terms of which drug is the best to use in which line and which line we want to use them.

Then looking further below, using some of the ARVs in pipeline, not to say we are advocating cheap drugs to be used.

Of course more data have to be seen but bear in mind that this could turn out to be some of the game changers that we're talking about in this satellite.

In an ideal world, we would like to have the dose of our drugs optimized so that patients have less side effects. We would like to see generic competition even if there's one generic who's producing it, and there's no competition, it doesn't work, so we need competition.

We want to live in a world where there's no intellectual property access barriers. Of course, initiatives such as intellectual property license or patent pool should be used much more. And not to forget that some of these drugs, the process chemistry has resulted in some of the very sharp price decrease that we see over the last two years.

Just to cite an example, they found new process syntheses for efavirenz and now the price is reduced by 30-percent in over a year, and that translates to a triple combination of generic TDFTTC efavirenz, which is much more affordable.

So, is there more to costs? Well, I think so, because as we're talking about costs, we also hear from the video, when we started the satellite, that people are talking about less drug toxicity; people want to see less drug toxicity. And I

think cost effectiveness study is useful to measure the health benefits gain when you use a better regiment.

And I just want to highlight there is analysis of patients started on Tenofovir regimen in Lesotho, which is going to be presented tomorrow at the [inaudible] session from 11:00 to 12:30, session room four, which we'll find out about how much we would like to see the drugs price reduced in order to have all the health benefits gained.

And thank you, and lastly, I would like to acknowledge the people who have contributed to this presentation. [Applause]

SHARONANN LYNCH: Thank you. We're a little bit pressed for time, so we're just going to go straight to Tido, and then take your questions. And then remember Dr. Peter Mugyenyi is going to be giving closing remarks and partly a bit of reaction to some of the new information that we're providing on this panel. Thanks. Tido.

TIDO VON SHCHOEN-ANGERER: Thank you. I will not give a presentation, but I want to start a – continuing the conversation about the game changers, and I think one area that we started to talk about is what I would call the radicalization of the ART tools and the deliveries.

The second I would say is the new ways to manage intellectual property, those of aggressive use, of trips

flexibilities, and an effective patent pool. And thirdly, financial transaction tax, tax and trade.

So on the first one, I think a lot of this has been mentioned here already, and I probably will continue some of the discussion in terms of the importance of the treatment for prevention really as the game changer, and some of the aspects that Eric has explained in terms of the more patient-friendly delivery that we think we can achieve in the next few years with tool optimization and the way we deliver care.

But I just want to also really re-emphasize the importance of point-of-care diagnostics, and Mark made that point in this video. And I would be leaving here with the conference with at least I think some better hope on where we are with CD4 now.

We have at least two that are really in and are going to be going to field testing, that are getting us closer to an affordable point-of-care testing; one is the CD4 initiative, that has worked with Zyomyx, and that's a little unit where the capulet blood is filled, it is spun in a manually-driven kind of centrifuge, then you twist it, and you spin it once more, and then you can read the result.

And it seems the whole thing takes about six minutes; their target price is $2 per test, and the actual kind of

centrifuge there is probably also very cheap, and it's manual, it has no electricity.

The other one that I really found very intriguing here is the ductory [misspelled?], which is also – it's a portable unit, it's battery-driven, and it works a little bit like our old tape players when we were small, and it's this cartridge that is next to it where you directly, after the finger prick, the blood is delivered into it.

And that also takes less than 10 minutes; the target price I think is $6 for this cartridge. The unit itself, I think it's probably going about $300. So I think – I mean they have to go into real field validation, but I think we're getting those point-of-care CD4 firmly really on the horizon. I think viral load is absolutely essential. There are several projects, but it's seems there's still much more delay, and I think this really has to become a major priority because it's so essential.

Now the second game changer here is new ways to manage intellectual property. And the reason I'm saying that is drug costs continue to be very important, and our MSF data are a bit different than what Reuben said, I think about 20-percent. I think we're much more around 50-percent, depending a bit on the project, and of course we see this cost explosion on the horizon.

So I think the real game changers here and that have been talked about at the conference; one is the medicines patent pool that is now being established.

And the critical thing is to make that work, and it's really – the onus is on the companies to provide the licenses at the right terms that this patent pool is going to work, but it's an additional tool to what we need to see as a much more really aggressive and widely use of the flexibilities that exist in the international trade agreement, including strict patent ability criteria, patent opposition like they are practiced in India, use of compartalizes [misspelled?] and others.

Thirdly, some of the threats that are out there in terms of free trade agreements or anti-counterfeit legislations and agreement that are really harming access to medicines, these have to be stopped in order to really secure the generic competition that we know is more efficient in terms of reducing prices and tier pricing.

I think we will see very widely promoted I think, in the coming months, tier pricing, differential pricing is the same thing, promoted as the solution, and I think we have to be cautious. And also the kind of dose optimization, the production costs that Janice referred to, you can only realize them if you have generic competition.

Now lastly, and is the big game changer I think will be the additional funding for health, tax and trade. A pre-condition, before we get into a financial transaction tax is still that the global fund is going to be replenished later this fall with more than $20 billion.

You know the $20 billion does not include the full implementation of the WHO recommendations, but as a real major opportunity for additional resources, the financial transaction tax that can really raise the additional resources needed, what we could say to bail out the health-related millennium development goals.

And one type of tax within that is the currency transaction tax, which can be started between any two currencies at any time. So this is something that can be really kick-started right away, even if you do not have immediately a global agreement, and it's politically and technically feasible, you know this is discussed at high political level, without necessarily saying this money should go to health, and I think this is something we have to fight for.

And there are some key dates now in September, with the MBG in New York, and then the G20 in Korea, where I think all of us have to really highlight this as much as we can, and as

Joseph did here so eloquently on this picture. Thank you.

[Applause]

SHARONANN LYNCH: Peter, would you mind speaking first, providing your remarks? I'm sorry, I said – I told you I was going to give you some minutes to collect your thoughts, but some bossy lady over there won't let that happen. So these are just a few of the future prospects, and what we've been calling possible game changers that could radically simplify ART, and also facilitate scale-up.

So my purpose was to try to impress Dr. Peter Mugyenyi; he's the director of the Joint Clinical Research Center in Uganda, and as many people know, a defender of people living with HIV, and a long-time activist and AIDS doctor working in Uganda. Thanks Peter.

PETER MUGYENYI: Thank you, and thanks very much for staying for this very important meeting, and really having had what I consider one of the conference's most important points made here, and seeing some of your people whom I know personally involved in this is very, very touching. I really don't know how I can summarize this; it has been a very good session. But perhaps I could just say a few things.

I could start perhaps by talking about the long term. If we don't have a purpose, and a target which we are aiming to achieve, we are not going to get there. Carol put it quite

plainly; we are in this business so as to have a world free of HIV/AIDS. That's what we are, and this is the target, and this is what we should be working towards. There are minimal draws that we have seen, but one of the most discouraging things that I have seen recently are movements that take us back to the 1990's.

In 1990's, we are being told by [inaudible] the economists that AIDS treatment was just impossible, that it will cost too much, and the world would not have the resources. Two days ago, I got the shock of my life. An economist said the world was awash with money in 2003, and that that's why PEPFAR became possible; a contradiction in the terms. So really, we have to remain very, very focused.

There have been talk about treatment strategies, and we have learned a lot since some money became available over the last 10 years. HIV treatment, AIDS treatment has been scaled up to a level that was not so possible. It is now being hindered by lack of funds, by not real lack of funds as such; by really commitment fading to continue to tackle this.

We have seen the benefit of HAARTS, I don't want to go through it again. And me, who works on a day-to-day with a big population of HIV patients, and who you see the carnage, and have seen how it has worked out, I know from first-hand experience what has changed. Among the people we treat, we see

less HIV – I mean less TB. We see less malaria. We see less of the opportunistic infection. These, if you calculated them and put them in the equation, I don't know what sort of savings we would be coming up with.

Now, looking back to Dublin conference and other early AIDS conference, the theme was on drugs costs, and failure to access treatment on account of the cost. One of the most pleasing things I'm seeing are young people who are joining in the HIV/AIDS mission, to get rid of it from the world. But most of them are too young to know what was happening in 1990. But what I would like to say to them, please look at the history, and do what is written at the back of our tee shirt. Don't stand back.

I like to go to people who have said we want to maintain the 2008 numbers; we want to maintain 2008 numbers. Actually what is happening, if I may tell you a personal story, is that as we scaled up treatment, we got a commitment from donors, especially PEPFAR. A lot of people came forward to be tested, and we have two groups of people whom we have.

One group is totally ignored, increasingly ignored; I'm very worried about that group. That is the group that came forward for testing, that we found HIV positive, that we put in a program called CARE. Some of them have been with us for

eight years. They come to us regularly, we counsel them about prevention, and some of them are helping us with the program.

What is really very disappointing is that every six months, from the education we have given them, they follow their progress, they have passed; they have kept their promise. We have not kept ours. Ours was simple. The message was on cards and posters. It was clear.

We told these people and promised to them, when you are in CARE, we will look after you, give you preventive treatment when it is needed, but when time comes for you needing treatment, it will be provided to you. These people are forgotten. What we are hearing, we are keeping our promise. Be sure that nobody already started on treatment will fail to continue his treatment. This is not good enough. I called this formula a recipe for curse.

This is what is happening. Who are those people who are in CARE? HIV/AIDS is a disease that affects anyone, and it comes in families. In certain instances, it might be the wife, let's take it for example, who hit 200 CD4, the old criteria, and she went on treatment. The husband, six years later, two years also, whatever, reaches 200.

And I want you to imagine, this is not something theoretical; this is something that is now happening in my clinic every day. We are telling them we have reached not 350.

I saw a list of countries who are having their 350 criteria for starting. It's on paper, ladies and gentlemen.

We are treating less than 50-percent. Imagine now the husband has come, and you say now we cannot give you treatment; we don't have it, after eight, six, five or four years of follow up, and we tell them we don't have it.

So finally, I'll go to the economists, not to the magazine, but to the economists. *The Economist*, the magazine, described Africa as the hopeless continent at one time. This is not true. The innovations that have come out of Africa over the last eight years in success became increased unbelievable. Thank you for outlining some of them.

We have seen how Malawi has come up with cost-effective strategies that reduce costs, which in the end lead to increasing the number of people accessing treatment. Mozambique, my own program, we had a strategy in my own program. For every dollar, we did the work of two, and it has so far worked. So these cost-effective strategies will need to continue. But the bottom line, ladies and gentlemen, more funds are needed; otherwise, we'll not go over that curve.

I end with the economists. These people are really great people. They help us to plan. What I would like them to do, as part of our progress, we the scientists are trying to find ways in which we can treat HIV/AIDS, would like our

economists to move from being doomsday economists, as it was described, to being people who cut out to research that define the way we can cost-effectively treat HIV/AIDS.

Yesterday and two days ago, I asked a question. If we cannot afford universal access, are we going to afford the carnage? So ladies and gentlemen, I want us to leave on a highly optimistic note. As we walk out of this door, this is a momentous time.

This momentous time has brought us new scientific evidence. This new scientific evidence is very exciting to me. We are seeing descriptions of drugs that can be more affordable, but we need to continue to press for intellectual property, to have a fairer way of making money by pharmaceutical companies without killing people.

I wrote a book and stated, “it is not true that the world is so dumb that the only way pharmaceutical companies can make money is by doing it over the bodies of the poor.” I don’t think we are that dumb.

The pharmaceutical companies have shown they can lead the way, and we must work with them to know that their future as a company is to invest in humanity and to know that it will pay in the long term for a disease that we hope we could eliminate in a generation, and create other opportunities.

I think I'll stop there. Thank you for giving me an opportunity [applause] to share. [Applause].

SHARONANN LYNCH: Thank you. If anyone has any comments or questions, we'll take those, but I would just like to say thank you to all the panelists, and in addition we were hoping to start to inform some of the debates that have been occurring, not just in this conference, but as Matthew said, back in capitals, where unfortunately we hear that some governments are deciding upon the pace of the response to AIDS, not just in terms of speed, but also what interventions and who gets the interventions, and when.

And we know that the signs from this building is certainly that speed is linked to survival. So it's not a static environment; there's dynamism in the field, and not certainly just in price, but other strategies to improve quality. Mark?

MARK: Yes Peter, thanks for that great talk. I wanted to ask you whether Eric Goosby actually followed up with you when we are on stage together talking about the stock out situation in Kampala, and I told you that Eric had told me that were no PEPFAR stock outs, and you said that wasn't true, and then Eric said oh, let's talk later.

So I wanted to ask you, A, are there any PEPFAR stock outs; B, did Eric follow up; and C, what should we do together

to prevent stock outs in this disastrous era that we're in right now?

SHARONANN LYNCH: Tony?

TONY: Yes, thank you very much for the great presentations. It's a comment and a question in fact to the panel. If I go back to Malawi – I'm ex-Malawi – 2004, when we started scaling up anti-retroviral treatment, we decided on a very simple public health approach, and we decided we would not link ourselves to CD4 counts, because we couldn't do it. And wow, were we criticized.

We were criticized from within the country, and we were criticized from without the country, and basically we were criticized for providing second-class care. Now, six years later, we're at 2010, we've made good progress, but we're still linked to a CD4 count, which has gone from 200 to 350.

And two nights ago, I was at a late-breaker symposium where the ministries of health of Kenya, Zimbabwe, Malawi were debating how they would react to the new WHO guidelines, particularly for pregnant women. And Kenya and Zimbabwe said no, we think these are very good guidelines; we're going to buy lots of CD4 machines, albeit perhaps point-of-care machines, and we're going to make sure we test everybody and see who's eligible or not.

Now of course, the pot of money is limited. If you spend a lot of money on your CD4 machines, it means you've got less money for drugs. Malawi said national policy, we've been thinking about this, we're going to test people, and if those pregnant women are found to be HIV-positive, we are going to treat them with anti-retroviral treatment, and we're not going to worry about a CD4 count because our whole system is weak, laboratory infrastructure, et cetera.

Now the response was quite interesting; there were sort of murmurs of this is alright; sympathetic murmurs of approval, and you heard a little bit that maybe it was a second-class, that no CD4 counts versus second-class care.

Now, if there's one thing I've learned in the four days of this conference, it's that if you get HIV, it is bad for you from day one. If I find I'm HIV positive today, I want to start ART today; I don't want to wait for two years. So I just wonder isn't it time to de-link ourselves from CD4 counts? That's what I put to you. I mean it's alright to use it to monitoring, but do we really need a CD4 count to tell us should we start treatment or not?

FEMALE SPEAKER 1: Yes, it's also on the new – the application of the new guidelines because I understand those are the – there is this great opportunity now where the WHO

teams are going to discuss with countries how are we going to make this work.

And I have just a bit of a fear, because I hear a lot the word adaptation to the context. And we know what it means often in practice. You will adapt, and it never is going to be higher than what the guideline says, just like Tony says what we would like to do.

So I wanted to also take the opportunity with the WHO people to being here, to see what they foresee exactly in terms of discussing about application of the guidelines; not only about the guidelines in isolated way, but also to bring some of these changing factors.

Can we discuss, can we do business differently, and not only – and maybe do more task shifting and so on. So to widen it up, so that we can make sure also that this dichotomy between health system and health worker's costs and drug costs are being put together in something that makes sense for the people.

SHARONANN LYNCH: Great. Thanks. Would you like to start –

PETER MUGYENYI: Yes, Mark, thank you for that question. It was very interesting. Eric said that there are no stock out. Actually, what is happening in Uganda is this;

that the patients already on treatment, those already on treatment are continuing to get their drug supplies.

But as I said there, this is not good enough, so I raised this issue with Eric, asking, rather explaining that no new patients – and remember these are the majority – are not being put on treatment. His answer was that we can expect that action. He acknowledged that, and said we can expect some action to be taken.

Well, we will take him on his word, but it is not just that. I don't expect quick action on that, because it is long overdue. I would urge you, the founders, PEPFAR to know that in the – not actually in the long term, in the near future, if they can continue the program of putting people in need, those in care on treatment, these are PEPFAR patients, already supported in care.

If we can fulfill the promise we made to them, that they would get on treatment, it would be a good start. So I'm still hoping that a conversation on this issue can continue, but as we stand, this is a very critical question. We are having people still being turned away because they are new patients. Old ones are continuing to get treatment.

SHARONANN LYNCH: Eric, can I ask you to respond in terms of utilizing CD4 tests? And then Gottfried, I was hoping you could -- thank you for coming -- you could take Mit's

question, but also Tony's, in terms of treatment as prevention, and why we didn't hear much in terms of official communication at this conference from WHO on some of the previous reports and articles.

ERIC GOEMAERE: Yes, Tony, on the use of CD4, there's no doubt that you have marked the entire world personally by driving Malawi towards simplification. It was your brand name, and you have hit the headline.

And I've had a lot of discussion in different therapeutical missions in South Africa, where they're not easily impressed, the South Africans, by the surrounding countries, but they were very impressed by Malawi, I can tell you. And you have constricted the paradigm of public health within a program that initially was meant for specialists and individual care.

So it's a difficult question, and the thinking is evolving. We still believe that – let's put it like that – it was a lot of discussion, what did we learn from this HIV vertical program, and one of the things we learned probably from history is that building in innovation and political will is certainly something that can make things evolve rapidly.

And that's why today I can see we shift more towards viral load than CD4, and some people say well maybe CD4 only for baseline, but not for monitoring, and more viral load. But

definitely, first one size will not fit all, and some programs will be much more simple than others.

And secondly, and that's why I presented this new treatment paradigm, we need to think in the future about systematic regimen with intensive maintenance phase with no monitoring at all. I agree with you; and some countries will take it because it's as simple as that; they have no access to decent lab, and it will be a permanent barrier, and other countries will keep probably a western paradigm.

So on the MSF side, I'm very glad we keep pushing on innovation because well we learned some lesson from the TB treatment paradigm and the dots, and I don't want to fall into that trap.

SHARONANN LYNCH: Are you sure? Yes, he's sure. Gottfried, could I ask you to come up, actually up here. Well Dr. Gottfried Hirnschall is the new director of the WHO HIV Department, and Gottfried, I wonder if – I know you weren't here for the whole session, but you know certainly there have been calls for a couple of things.

One is clear target, and carl specifically called for a scale-up target of 15 million people by 2015. There have been calls for a robust research agenda. Obviously there needs to be an enabling policy framework that would usher in some of the technical innovations that we're hearing about. I know -

GOTTFRIED HIRNSCHALL: If it goes beyond three, I need a pen.

SHARONANN LYNCH: Well let's start with those three, but also a general observation, because I had attended the UNAIDS Town Hall Meeting, which in the U.S. it was much like a big infomercial here at the AIDS Conference. I felt like we were all cheering on the very sharp knives or products that UNAIDS was selling.

And yet, WHO was not up on that dais, and yet it's been WHO that has been providing a lot of the data and some of the support for showing that ARV's scaled up, including that higher CD4 threshold can help to bend more of the epidemiological curves. And we've seen at least in terms of outside of this conference, to bend some more of the cost curves, both that we've been talking about, and on the long-term perspective. Can you speak to those four issues?

GOTTFRIED HIRNSCHALL: Okay. First of all, good evening, and sorry that I wasn't with you the whole evening. It was originally my intention, but then I had another engagement that I couldn't get out of. And thanks Reuben for chipping in with the presentation. And thanks for putting this panel together and having the session. And thanks Peter for those very encouraging words.

A couple of things I would like to mention, even maybe in addition to your requests. First of all, the target. We very clearly will need a treatment target. There's no doubt. We need to have something quantifiable, measurable towards which we will work.

When we discussed – and thanks [inaudible] and your colleagues for your visit at WHO to visit with our DG when we discussed whether we should put a treatment target forward 15 by 15 now, or whether we should rather put this into context. I think we all agreed that it would be not useful to put an isolated treatment target forward, such as three by five. I think we have moved on to have an initiative driven by one target, but we will need a set of targets.

For us, the opportunity to do this and the process to do this is the following: number one, as I'm sure you're aware of, countries are now invited to review their progress towards Universe Lexis, Universe Lexis consultation at the country are taking place.

Number two, we are now, based on the information that we receive from countries, putting forward and putting together all the information from countries, and we will launch the Universe Lexis report around the MBG Summit.

The third process that is very important for us in WHO, and I believe will be also important more broadly is the development of a new strategy towards 2015.

2010, the Universe Lexis year, we had a strategy until 2010 through now, we are working towards a strategy of 2015, and obviously scale up will be the central theme, and Universe Lexis will be the sustained commitment that we would like to – that we will propose in that strategy.

In that context, based on consultations with countries, we would very much want to put forward obviously also a treatment target. 15 by 15 seems to be a logical thing to think about in terms of the numbers, but we have put together a target setting group that works in the context of the strategy development that will come up with proposals, and we hope to have a set of targets ready by October, okay.

But again, we don't want to sit in Geneva or Washington, or wherever that is, dream up targets that are not based on realities and haven't been done based on a consultative process with countries and other stakeholders, with governments and other stakeholders.

So that's the process to which we would like to have a set of targets that will not be just about treatment and prevention; we would also like to measure issues on effective linkatures on maternal care, how a scaled up response would

have a benefit on child health and child care, on system strengthening, and other aspects. So we really want to look at this in a more comprehensive manner.

The second issue is resources. I think a central theme in this conference, an anxiety that we all share. Will there be enough resources, but I think the question is – and that's a bit the way we would like to change the conversation – it's not just about costs, it's about the need for investments.

And investing in what is obviously very important, and we are now – and Reuben and the team in treatment is doing some more work on costing to really look also at cost savings to justify the investments better, because in this conference, it was all about costs.

Yes, there costs, but I think we need to be more strategic also in saying by having up-front investments, by now changing the eligibility threshold, we are actually making very clever, very strategic investments in keeping people healthier, alive, and reducing the number of transmissions.

So we really have to put our arguments collectively together much better; we need to get away from this polarization that I see a little bit, well this one is treatment; the other one is treatment for prevention. We're talking about the same thing.

We are talking about scaling up access to medicines, and we need to be much more strategic and also quantify better on what this up-front investment is that we need to make, and what the gains are in terms of health outcomes, but also in terms of costs benefits. And we need to put the information together, and I would like to convey to you, based on commitment of WHO to formulate this better than we have been able up to now even, even though we have some cost triggers, but I think we still have some gaps. We recognize this, and we need to fill those gaps very quickly to be in a better position.

On the issue of – and I'm sorry, but you need to cut me off if I'm getting too long – on the last issue of why is it 350 and why are we not now saying well, maybe everybody who gets a diagnosis should immediately start, as this is starting to happen in some parts of the world. Those guidelines that have just come out have, as I think Reuben would have explained, undergone a fairly rigorous process at looking at the current evidence. WHO, in terms of developing new guidelines, has changed a couple of years the process through which new balance can be developed, and really has a very rigorous evidence review process. Based on that, and based on the findings that we had, 350 seemed to be, and seems to be, the best thing to say at the moment, based on the evidence, the

firm evidence that we have. We will very soon have to look again. There's so much happening, it's such a rapidly evolving field of new knowledge, it's a very dynamic thing.

So I anticipate that we need to start now looking on discordant [couple issues very, very quickly. It's coming up, the study that we're all very happy about that we saw obviously.

And we will need another revision of the guidelines; but for the time being, we would really like to work with countries – to come back to another question – to see okay, what adaptation can we work, would make sense in a given setting, pushing as much as possible for the 350 threshold. Obviously, we want to have the best standard of care implemented in all parts of the world.

In an ideal situation, we do not want to get back and retrieve to double standards in this world, we can't afford this, and we can't allow this to happen; that's very clear. But, we will have to be more – do better in terms of looking at the best ways of getting there.

The service delivery aspects, obviously we need to continue to drive down – make a strong argument for driving down the costs in getting cheaper and better and simpler diagnostics, et cetera.

I think that all needs to happen, and the forum, we hear about treatment 2.0, it's nothing but a forum to look to those things in a partnership context. Certainly UNAIDS is there, we will play a strong role, rest be assured, in this.

We just met also with Gates this afternoon; there's interest there. We met with Julio Montaner; I asked, they're very much pushing for this. We talked to Michelle; this is certainly one of the take-home messages, to now go back home – we've created the platform 2.0, now we need to go back and say what exactly is it, how can we fill some of those blank spots in the conversation, and how can we collectively move forward in it. Thanks. [Applause]

SHARONANN LYNCH: Thank you. So just a final word. If you don't mind me, I'm going to quote Dr. Mugyenyi at a previous panel, because in the hope that the science becomes implemented and becomes policy, because as Dr. Mugyenyi said, there is not one science for the rich, and one science for the poor; there is only one science.

So thank you very much, and the discussion will continue at the MSF Beach. Okay, so the discussion will continue at the MSF Beach, Danube Canal, close to the subway, Ul Schwedenplatz with food, drinks and music. Thank you, thank you.

[END RECORDING]