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**39th Union World Conference on Lung Health  
Plenary Session 2: Response of Health Systems to  
MDR/XDR-TB  
October 19, 2008**

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**ANTHONY HARRIES:** Ladies and gentlemen, could we come in and get ourselves seated please? So, let us begin the Plenary Session for the day. I am Tony Harries, Senior Advisor of the Union. And with Dr. Saidi Egwaga, TB Program Director for Tanzania, it is our privilege to co-chair this session.

It is our great honor to introduce to you Ambassador Mark Dybul. Ambassador Dybul served as the United States Global AIDS coordinator, leading the implementation of President Bush's Emergency Plan For AIDS Relief or PEPFAR. PEPFAR is the largest commitment by any nation to combat a single disease in living history.

In addition to this hugely busy, important and demanding position, Ambassador Dybul oversees all U.S. government engagements in the Global Fund to fight AIDS, TB and malaria and serves as the Chair of the Global Fund Finance and Audit Committee. He is also Chair of the UNAIDS Program Coordinating Board.

Before coming to PEPFAR, Mark served on the planning task force for the emergency plan and was the lead in the Department of Health and Human Services for President Bush's International Prevention of Mother and Child HIV Initiative. Mark holds the rank of Assistant Surgeon General and Rear Admiral in the U.S. Public Health Service Commission Corps.

We're delighted that Mark has found the time out of his very busy schedule to come to Paris and address the Plenary

Session on Response of Health Systems to MDR/XDR-TB and also HIV-TB. Mark, we are greatly honored to have you hear with us today. And speaking on behalf of everybody in this room, we eagerly await your talk. Thank you very much [applause].

**MARK DYBUL, AMBASSADOR:** Thank you Tony and good afternoon everyone. I assume this is what I click on to get the slide. Yes, there we go.

Just a caveat to begin with, I am not sure how the title MDR/XDR wound up in the program. That wasn't what I was invited to speak on and while I will touch on MDR/X-TB. I think it is actually appropriate to talk about HIV-TB in that context because I think as we are all aware, we need to control HIV-TB if we are going to control MDR/XDR, and really in the context with the theme of the meeting, deal with health systems.

Before I begin, I wanted to thank a number of people who were of great help in this presentation together. From World Health Organization, our close collaborators Reuben Granage, Paul Bunn, Mario Revick-Maomi, Kevin Ducock [misspelled?], and from our own team, Dr. Caroline Ryan who really is one of the most spectacular people we have in the group. She's giving six talks here, so you will have a lot of opportunity to see her and Bill Cagen.

Most importantly, thank the people of the countries which we're privileged to serve because they're, in the end, the ones doing all the work.

To put ourselves in context as we start to talk about HIV-TB, as many of you know HIV is the largest killer of people in Sub-Saharan Africa, 2 million people per year. And of course TB is the leading cause of death among people with HIV/AIDS in Sub-Saharan Africa. TB, globally, takes the lives of 1.6 million people and malaria 1 million. So, you can see when you look at the numbers and what we're dealing with, dealing with HIV-TB is a massive global pandemic requiring immediate response.

The approach I'd like to take to this discussion is to make three basic points. First, successes and lessons learned from global TB and HIV programs are actually tremendous models for health and development in general. And we probably need to spend a little more time focusing on the extraordinary work that's been done and what we've learned from that.

Taking those lessons learned we need to move towards an understanding that we have an obligation to link HIV and TB. It is not something that's a good thing to do. It is actually a requirement, and we'll talk a little bit about that. And lastly, talk about the fact that not only is it an obligation but it is in our self-interest to link HIV and TB programs.

Let's begin with successes and begin with TB because TB programs have been implemented for a long time. I think leading into the discussion of lessons learned, we should begin with the bigger picture because the lessons we've learned and the programs that have been implemented for TB and HIV have not

just been good health programs. They have been good development programs.

And if you look at the global consensus now from the Monterey Consensus, the Paris Declaration, and, recently, the Accrar Accord, there are four fundamental principles. And these principles are at the heart of the implementation of TB and HIV programs. Country ownership, multi-sectoral engagements, all aspects of society being involved, not just governments, a result based with accountabilities, set goals, and then achieve them, and good governance.

And these themes will underline a lot of the comments I make. If I don't specifically refer back to them, I think it is important to remember that this is the context in which we're working and which success has been achieved.

Beginning with tuberculosis, this comes from the World Health Organization, in deep red or the other darkish colors are where the other new cases of TB were in 2006. And you can see heavy concentration in Africa and particularly in Sub-Saharan Africa, also Eastern Europe, India, and parts of Asia. We'll come back to the deep focus and deep number of new infections in Sub-Saharan Africa when we talk about HIV-TB.

Fortunately, there's been a response to this growing epidemic of tuberculosis. In the blue line, you can see the resource enhancement or increased contribution from external sources for tuberculosis, important to point out that countries are also contributing quite a bit on their own. And also the

number related to the increased number of sources of directly observed therapy or Stop TB countries.

Now there's no question that there's not enough money for tuberculosis right now and a lot more progress needs to be made. But I think it's important to highlight the fact that a great deal has been done, largely under the leadership of the World Health Organization, Stop TB, and others. This just puts if graphically the number of countries that have now launched directly observed therapy programs under Stop TB. As you can see, DOTS was launched when 73 countries had programs and now it's more than doubled to 155.

India's one of the great success stories through the DOTS Program, rather dramatic 900 million people covered through DOTS, more than a hundred thousand people are put on therapy now every month, rather extraordinary success. And you can see that exponential growth beginning in 1998 as DOTS came into play.

Importantly, and this gets back to country ownership and all sectors being involved. The success is widespread across different parts of the implementing community. So while the government is heavily involved, so are medical colleges, the corporate sector, private practitioners, and non-governmental organizations, all contributing to the increase in the case detection and, therefore, treatment.

Similar picture in China as programs have expanded the private clinic's traditional medics and others have been

heavily engaged bringing in the civil society community aspects of the program. And that has contributed significantly to the success linking the public health sector to the civil society community sector.

Data from Africa is very similar. In the yellow bars you see what happens when you have decentralized community approaches. In addition to the conventional approach, when you put those pieces of programs together, you significantly increase the reach and effectiveness of programs.

So, TB, while there's certainly much that remains to be done, certainly more resources are needed. A great deal of work has been done and tremendous lessons have been learned, not only for global health implementation, but for good development.

Shifting to HIV/AIDS, the global picture is currently around 33 million people infected with HIV/AIDS. You can see two-thirds of them, 22.5 million of them are in Sub-Saharan Africa and that will become very important as we talk about HIV-TB, also, central Eastern Europe with the increasing epidemic in Southeast Asia.

So where we have TB, we also have a lot of HIV. Fortunately, as with TB, there has been a tremendous response, a much larger response. Even though the graphs look the same, the dollar amount is much higher here for HIV/AIDS, currently about \$10 billion per year for HIV/AIDS. That's an increase from 2,000 of in the millions of dollars, not billions of

dollars. So you can see the exponential growth and you can see the Global Fund and PEPFAR, the President's Emergency Plan For AIDS Relief contributing.

Now, I happen to know the PEPFAR program better than anything else, so I'm going to spend some time talking about that. I think it's important to note that that is about 55-percent, or more than half of the global response to HIV. So while it's not the whole picture, it is reflective of what's going on globally. So I'll spend a little time going into detail there.

The program itself is a bi-lateral program. It focuses on 15 countries, 12 in Sub-Saharan Africa, Vietnam, Haiti, and Guiana. It's rather extraordinary these 15 countries have half the disease in the world. It's a rather remarkable statement. But it's also a multi-lateral program close working relationship with the U.N. family, particular in HIV/AIDS that the World Health Organization will talk about, but also UNAIDS, UNICEF, World Food Program, and others, and also the Global Fund. The Global Fund to fight AIDS, TB, and malaria is one of the most important global efforts to fight diseases. The United States is privileged to provide about 30-percent of all resources as the largest contributor. So this is both a multi-lateral and bi-lateral program.

And, fortunately, those dollars are achieving results, getting back to the results base of effective development and effective global health. This is what's happened with

antiretroviral therapy since 2002 now reaching 3 million people globally. And as you can see in the dark blue bar at the bottom what is driving that increase in Sub-Saharan Africa. In fact, when President Bush announced PEPFAR, there were only 50,000 people in all of Sub-Saharan Africa receiving antiretroviral therapy. Now, in Sub-Saharan Africa, we're over 2 million people on antiretroviral therapy.

This increase in therapy has actually had a benefit. As you can see, we have now seen a trailing off, a decline in the death rate, number of deaths among those adults and children globally. So we're starting to see success in real opportunity or in real benefit to people with the disease.

As I mentioned, the focus on results is a critical aspect of effective development and effective global health. Now, within the PEPFAR program, we have very specific goals to support prevention for 7 million new infections, treatment of 2 million HIV+ and care for 10 million, including orphans and vulnerable children. Therefore, our budget—and the reason I show this is because the budget is similar within the Global Fund and other large organizations. Forty-seven-percent of our budget goes for treatment, 29-percent for prevention, and 24-percent for care.

Now, that's not a prioritization. We all believe that prevention is the ultimate foundation of successful programs, treatment is more expensive, which is another reason we need to have more emphasis on prevention because by doing that, we'll

reduce the burden of treatment and care. But nonetheless, as I pointed out, globally, there's been tremendous success with over 3 million people now in the developing world receiving antiretroviral therapy.

What's happening in PEPFAR parallels what's happening globally. Through March of this year, the American people through PEPFAR supporting antiretroviral therapy for more than 1.7 million globally, 1.6 million in Sub-Saharan Africa alone. And if you look at those 15 focus countries, most of them in Sub-Saharan Africa, there's been an 1800-percent, almost 1900-percent increase in services provided. Some countries, if you see Guiana, Rwanda, Botswana, Namibia, actually achieving what is considered universal access.

Now these people on antiretroviral therapy actually the advantage is not just having people on drugs. The advantage is that they extend their lives. And through 2009, the PEPFAR program by itself and if you add them globally everyone else, will save 3.2 million life years. If you put that in context, since the United States began providing antiretroviral therapy, it's less than this number that's been achieved in the last couple of years.

And that leads to real benefit to communities and secure the future of Bristol-Myers Squibb, a good demonstration of multi-sector involvement. Over a two-year period, they saw a 50-percent reduction in HIV mortality. And importantly, they saw nearly a 50-percent reduction in hospitalization occupancy.

That builds capacity because it reduced the burden on the health system by 50-percent.

In Uganda, antiretroviral therapy with the Clinton water program and through lay healthcare workers—and we'll come back to that—reduced HIV mortality by 95-percent. It reduced non-HIV infant mortality by 81-percent. That's rather extraordinary. And the reason is probably because there was a 93-percent reduction in orphan hood. And we know if parents stay alive, kids have a three times greater chance of staying alive, regardless of the cost. And so for the first time in decades, we are seeing a turn-around in what was a disaster in public health.

These are data from Batswana. After decades of declining life expectancy, 20 to 30-percent reduction in life expectancy as HIV resources and response started to be implemented. We're seeing for the first time, an increase in life expectancy in Batswana and for the first time after significant increase in child mortality, a decline in child mortality associated with increased HIV resources and programming.

So, the HIV dollars are having an impact on global health more broadly. The community has been absolutely essential to these successes. This is just one example. Overall, there's a lot of engagement of non-government organization, but lost follow-up, something directly observed

therapy, and the TB community already knew is if you involve the community, you will actually reduce lost follow-up.

So, in this one program, it's actually the AIDS relief program through the Institute of Human Virology at the University of Maryland, by engaging the community, they went from an 18-percent lost to follow-up rate to a 3-percent lost to follow-up rate, demonstrating what we already knew from DOTS the important lessons learned.

Shifting to care, care for HIV+ people who don't yet need treatment and also for orphans and vulnerable children as a critical aspect of response to HIV/AIDS, the Global Fund also supports such programs. But the data we have are nearly 7 million people in care and 2.7 million orphans and vulnerable children through September of last year.

Shifting quickly to prevention, this is a good new story. There is no question we still have a long way to go, but if you look at the recent data from UNAIDS, we're seeing a leveling off of prevalent and new infections. If you look in the bottom panel in Sub-Saharan Africa, we are actually seeing a decline in prevalence across the continent in the last five years. That's really good news. Now we've got a long way to go. It's not acceptable to have 20 to 30-percent infection rates in some countries, but the fact that we're leveling off and declining is good news.

In the area of mother-to-child transmission, we've seen an increase in coverage from about 7-percent to 35-percent.

Now we still have a long way to go, but that type of increase in three years is rather dramatic. Within the context of PEPFAR, those are global numbers. Thus far, we've supported behavior change programs for 61 million people. We've supplied 1.9 billion condoms worldwide since PEPFAR began. As Peter Piot the head of UNAIDS has said, that's more than the rest of the world combined and supported counseling and testing for 12.7 million women leading to the estimated averted of 194,000 new infections.

Also importantly, safe blood programs are an important part of HIV prevention even though they don't contribute in Africa at least to a lot of infections. We've seen in those 15 countries that I mentioned an increase in safe units from 52-percent to 75-percent in a four-year period.

Now, I wanted to talk a little bit about country ownership because that has a lot to do with how we're going to respond to the HIV-TB epidemic, in particular MDR/X-TB by, as we had pointed out, some of the critical lessons learned from HIV and TB implementation is engaging the community. Thus far, in PEPFAR 87-percent of our partners are local organization. Eight-percent of them are non-governmental organization. And we have a way to go and that's why we're implementing some new policies and practices through partnership complex engaged further civil society and governments and to get our larger international partners to turn over a lot of their work to local organizations.

But this is how we're going to tackle the epidemic, TB, and HIV together by getting to the community level and building the communities. But we also have to build the capacity if we're going to rely on those communities because there's a lack of a lot of capacity in many places, particularly when you get to the village level and that's where we need to intervene for both HIV and TB.

In 2007, PEPFAR supported \$640 million for capacity building supporting 2,700 service sites for care and treatment, importantly, including 1,400 with significant laboratory support for CD4 cell count, blood chemistry, CBC, an increase of 42-percent in one year. The reason for that is obviously clear. The reason for that is obviously clear. We need to build laboratory capacity if we're going to tackle HIV and TB together. And we'll come back to that.

There's been a lot of work to build a health system through human workforce, which is going to be essential for HIV and TB. We work closely with WHO and UNAIDS to develop task-shifting guidelines. This is something the TB community's been doing for quite a while using the local community as we pointed out to allow non-physicians and non-healthcare professionals to be engaged to get to that village level.

Thus far we've supported training for 2.7 million encounters and we support the salaries of over 110,000 healthcare workers, many in the public sector. We also know, as we know in TB, that we have to train a new cadre of doctors and

nurses and healthcare professionals. So in each of our countries we allow \$6 million or three-percent of the total budget for pre-service training of new health professionals, doctors, nurses, pharmacists, and Masters of Public Health. So far in Namibia alone, we supported 1,000 bursaries for a new cadre of healthcare professionals.

And the United States and the United Kingdom has announced an exciting new initiative targeting Ethiopia, Kenya, Mozambique, and Zambia to increase the coverage of healthcare workers, not HIV, but healthcare workers, including for TB from one to 1,000 to 1.7 to 1,000 in a five-year period. This is something the G8 has endorsed and something we all need to focus on.

As a part of that, the next phase of PEPFAR for the next five years has a goal of 140,000 new healthcare professionals and paraprofessionals trained. That will contribute to the overall health sector.

A lot of examples from countries where we're doing innovative things to support national strategies for world retention schemes, important for HIV and TB, to bring retired people out, sometimes in a lot of countries 40 year-olds get retired. Nurses with great experience, bring them back into the workforce, supporting new cadres of healthcare workers, clinical officers in particular in South Africa and Ethiopia. Many examples of what we're all doing together, this isn't PEPFAR-specific. This is an example of what needs to be done

to build a healthcare workforce, not just for AIDS, but for HIV, TB, and everything else.

Of course, healthcare workers aren't enough. You need a place to work. So, in thirty-three facilities that we studied, 92-percent of all the new investments in infrastructure came through PEPFAR sources, buildings and renovation, lab equipment, training, and other equipment. And this building of a health infrastructure is contributing to non-HIV indicators. Family Health International did a study of 30 primary healthcare centers in Rwanda looking at non-HIV indicators and what happens with HIV resources.

And what they found is a significant increase in family planning and a natal visit, syphilis screening, other laboratory usage, that's because the HIV resources are building a healthcare capacity. It doesn't take much if you've been in the country to understand what happens. On the left was the laboratory before HIV resources. On the right was the laboratory after. You can tell the type of lab work you're going to do one or the other. And this will be very important as we talk about HIV-TB.

The same in just the waiting room. No one wants to come into the waiting on the left, but if it looks like it does on the right, everyone will come in. This is not unique to HIV. This is HIV-TB. These are many facilities that are being renovated.

Also, new building, this is a new HIV clinic that was opened in Tanzania, our co-chair's country. What this did is freed up all that space that was being taken up in the hospital, including the TB clinic to allow for better services across the health sector.

Now, one of the important pieces that we all need to work on is a health system supply chain management system. Now for the first time, through HIV resources, we have three nodal sites in Sub-Saharan Africa: east, west, and south, to provide a continuous supply chain. And there have been no stock-outs of products as a result of this. And I'm not talking about HIV. There are 120 products and commodities, including amoxil prophylaxis, including isoniazid, including TB, malaria, and other products. So we're building an infrastructure that will allow for a regular supply chain.

We're also building a monitoring and evaluation system at the site level. This is an example in Ethiopia where the Ministry of Health now knows every site in the country that's providing antiretroviral therapy in HIV services. We need to expand this to include HIV-TB.

This is actually being done at the village level through an innovative public/private partnership called phones for health. It's a U.S. government investment that has now spread and we take no ownership over it. In fact, the government and people of Rwanda lead the effort. We just provided the resources. It's partnership with Baxiva, GSM

[misspelled?], which is providing mobile phone companies who'll provide the airtime for free. They are using handheld devices at the point of delivery for reporting. For the first time Ministries know what's going on in the villages and it's national in scope. While it was begun for HIV, Rwanda's now expanded it for TB and malaria. And we're moving now out to nine countries, excellent example of how you can use health infrastructure to incrementally build from one program to another.

This is an example from malaria but one I think we need to do for neglected tropical diseases and tuberculosis as well. In Zambia, working with the President's Malaria Initiative, more than 500,000 bed nets were silvered in six weeks before the rainy season. The reason they were able to do it is because we had supported an infrastructure of home-based care and delivery to 350,000 homes.

So, within six weeks, if they're going out once a week for HIV/AIDS care, they can carry a bed net with them. Importantly, they can also do neglected tropical diseases. They can also start developing TB programs in a similar way through DOTS programs where people are visited in their homes. We can begin to build out HIV/AIDS programs and that's what we need to do.

And that moves us to the next piece we want to talk about, which is the obligation to link these huge successes in global health, TB programs, and HIV programs together. Now, as

I mentioned before, this is not just a good thing to do. It is an obligation. It is an obligation because TB and HIV are inextricably linked, at least in Sub-Saharan Africa and contributing to the MDR/XDR-TB problem we are having. We also know how to respond and we're going to see some extraordinary data from a number of countries. And because we know how to do it and know there's a problem, we have to do it and we have an obligation to do it.

This is an example of HIV prevalence in TB cases. Getting back to the map you saw before, you can see in the dark colors now the heavy concentration of HIV-TB in Sub-Saharan Africa. And this shows more graphically what's going on. Unfortunately when I transferred the slides, you've lost some data. But what you see are in established market economies in the upper left. And in other parts of Asia and countries where we don't have a heavy link of HIV-TB, we've actually seen declines in TB cases.

But if you look in Sub-Saharan Africa, which is the lower left, especially where there's a lot of HIV, we've seen a marked increase in TB cases, same in the former Soviet Union in the upper right panel. So as we're seeing an increase in the TB epidemic, we can link it directly in Sub-Saharan Africa to HIV-TB. Now why is this happening? I think most everyone in the room knows TB is the leading cause of death among people living with HIV/AIDS and is one of the most opportunistic infections.

The reason for this occurring makes a fair amount of sense because people with HIV are more susceptible to TB because their immune system is weakened. And people with tuberculosis, unfortunately, also have weakened immune systems and so we believe are more susceptible to HIV as well. So there's a vicious cycle with the two epidemics feeding off of each other.

This has come home to roost, to some degree, as we talk about XDR and MDR-TB. As many of you know, MDR and XDR is not a new phenomenon. It has existed for 20 years in many places. And you can see the 35 countries where it exists. What's concerning are those three dots which would actually now be four or five dots because just in the last month, Namibia's reported cases of XDR-TB. What we're seeing is a new epidemic of XDR/MDR-TB, closely associated with HIV/AIDS.

There was a survey done in KwaZulu-Natal, in South Africa, looking at 119 TB patients with antiretroviral therapy. There were 14 deaths. Ten of them had MDR-TB, and six of the 10 of them were resistant to first and second-line drugs. Because of that, a more in-depth analysis was done and what was found was rather frightening and was the cause of a lot of public discussion. And that is of the 542 cases evaluated, 53, or 10-percent of all the cases had XDR-TB and 24-percent of them had MDR-TB.

When you look at the XDR-TB cases, they studied 44 of them to see whether or not the patients had HIV. All 44 of the

people evaluated for HIV XDR-TB had HIV. And 52 or 53 of them died. So you can see this close nexus between XDR-TB and HIV. And that is of great concern looking forward.

Now, why is this happening? Well, this slide, which Caroline Ryan created, talks about a perfect storm, which is rather unfortunate. We have an introduction of second-line TB drugs in low and middle-income countries, sub-optimal TB control practices, high HIV prevalence and high TB burden. Put all that together and we're going to have a big problem.

So how do we respond? Well, the most effective response is to effectively combat tuberculosis through DOTS and reducing MDR-TB and other innovative approaches and TB infection control. The best thing to do is prevent new infections of tuberculosis, but then we also need to respond to those people who have tuberculosis. In the end, MDR and XDR-TB is not a de novo phenomenon. It's a symptom of a failed tuberculosis response. So the more effective TB response we have, the more effectively we'll respond to XDR-TB

Similarly, if we can effectively combat HIV, prevention, care, and treatment will decrease the number of people who have HIV and therefore are more susceptible to TB. And if we treat people with HIV, we'll have a more effective response, which I'll show in a moment. And then of course we need to link the programs together.

These data come from a very impressive study on the impact of just antiretroviral therapy on new tuberculosis

cases. People with antiretroviral therapy generally have increased CD4 cell counts, a more competent immune response, and therefore are better able to handle opportunistic infections. And what we saw in this evaluation by LAN et al. [misspelled?] is a more than 60-percent reduction in the cases of new tuberculosis among HIV+ people when antiretroviral therapy's introduced. So simply by introducing effective antiretroviral therapy, we can begin to combat tuberculosis. And of course if we prevent HIV infections, we can also combat tuberculosis.

But we need to do more than that. This slide comes from Mario Raviglione at Stop TB. And it just shows how we combine the national TB program and the national AIDS program schematically, well, more than schematically, to actually work together to begin to implement from the national to the intermediate to district level, and importantly to the primary care service level and the integral engagement of the community.

Getting back to what we talked about, if we don't engage civil society and the community, we cannot effectively respond. As part of this response, the World Health Organization has launched the three I's, increased case detection, isoniazid preventive treatment, and infection control. I would also add in there CPT, or cotrimoxazol preventive therapy, which is important in multiple areas for tuberculosis, but also for HIV.

Fortunately, we have seen some progress. You see a nice graph showing a significant increase in HIV testing for TB patients because if you don't identify the patients you can't do much. But unfortunately while the graphs show a nice slope, we're still on that 12-percent coverage. We've seen an increase in treatment for HIV+ people with tuberculosis in terms of antiretroviral therapy, which as we just talked about, will help decrease the burden of tuberculosis by simply decreasing new cases. Unfortunately, while the slope looks good again, we're still only at 41-percent coverage.

This slide is particularly disturbing looking because those just show increases in programs where you actually have a pool for your denominator of the TB patients you identified. This showed the patients screened for TB, diagnosed for TB, and started on IPT. And in the small percent—it's less than one-percent of the top were screened tuberculosis and started on ITB—is the total percent of estimated TB patients in the country that are covered. So while those slopes look very good, we're less than one-percent coverage in the countries in terms of people estimated to have tuberculosis. So we have a long way to go and we need to work together.

Now, one of the problems we've been having is there's a lot of debate—and I actually believe it's not a healthy debate—on which model to pursue. Do you have a program where HIV refers to TB program and TB refers to HIV? Do you have partial integration of the programs? Do you have one-stop service

sites where you do HIV-TB in the same site? There are some countries doing each. Mozambique and Tanzania are doing the first approach. Kenya is using the last approach. Zambia is doing the middle approach, as is Rwanda and Tanzania.

As is often the case, we're getting spun up in a lot of meetings about what is the right approach. The right approach is the most effective approach and the right approach is what the countries pursue. So we should pursue what will be effective and get on with implementing and stop talking about the theory of what we ought to do. That's my only editorializing for the day.

Some of the lessons learned from these programs so far is routine screen for tuberculosis is essential. I can't do voluntary testing that we need, what is effectively opt-out testing, and that we need to begin cotrimoxizol, isoniazid treatment therapy before antiretroviral therapy begins.

One of our biggest problems is clinicians treating TB-HIV are not aware of the HIV infection, the resurgence of HIV, when TB begins treatment. There's a lot of misunderstanding in the community about the interaction between HIV-TB. And we also need some studies. While we have had some success, there are still a number of unanswered questions and we can get to some of those in the questions-and-answers session.

Importantly, TB infection control is not something that's focused on very much in countries. I hope that we're never going to catch up, just like we can never treat our way

out of the HIV epidemic, we can't treat our way out of TB or HIV-TB. We've got to prevent new infections.

The United States is trying to respond, as is the global community. Again, I know our program better. So I'll talk a little bit about that. We've increased our contribution to direct HIV activities from about \$18 million three years ago to what will be \$160 million this year, a huge increase still probably could be better. And so far, we've supported care for 367,000 HIV-TB co-infected persons.

Some success is being seen. And through an initiative where PEPFAR is collaborating with the World Health Organization, we targeted three countries to work together under that model where we combined the national TB and national HIV programs and see what we could do. And the results over a couple of years are extraordinary.

In Rwanda, more than 88-percent of TB patients are now tested for HIV. That's almost a doubling. Sixty-one-percent of co-infected patients are receiving cotrimoxizol preventive therapy. Thirty-six-percent of TB patients who are HIV+ have access to antiretroviral therapy. These are more than doublings over a three-year period. And compare these numbers to the abysmal numbers I showed you a little bit earlier.

In Kenya, there was an increase from 41-percent to 84-percent in the uptake of HIV testing among TB patients. An increase of Cotrim uptake from 39 to 90-percent, and ART uptake

from 19 to 28-percent. In Ethiopia, Cotrim and antiretroviral therapy for co-infected patients is rolling out.

Now one of the reasons these programs have been a success is because we're working collaboratively and internationally. The World Health Organization and Gates Foundation has funded and brought together more than 20 countries to have lessons learned from these programs, look at these numbers, see what's working, and try to increase them.

Let me show you some of the more exciting data from Rwanda. This is an increase in cotrimoxizol and antiretroviral therapy and testing in a three-year period. They went from 48-percent to 89-percent tested. HIV+ people were identified. Going down is actually a good thing because that means you're testing more people. You are not concentrating the pool.

And importantly, the patients on cotrimoxizol preventive therapy, which is good for HIV but also TB and spread of TB, went from 8-percent to 61-percent in the number of people receiving antiretroviral therapy. This is a matter of four years. This is what can be done when we work together.

Importantly, task-shifting was employed in Rwanda, bringing in the community so that it's not just physicians and a physician-based approach. And what we saw was a massive decrease in green of the time physicians had available for other services by engaging the community. And what happened when we involved the local community. You actually increase the capacity of the health sector when you engage the

community. Those physicians can now deal with more severe cases.

As I mentioned, the Global Fund's an important part of all this and the United States is privileged to provide about 30-percent of resources, which means 30-percent of every TB and TB-HIV grant comes as part of PEPFAR. So far, the Global Fund has committed \$1.4 billion to tuberculosis. Again, we've got a ways to go, but that's pretty impressive. You also support the Stop TB partnership, both for advocacy and also technical support so countries can get through the green-light committee faster.

I want to talk briefly about laboratory strengthening because this is a critical piece of where we need to go. If you don't have laboratories, you can't diagnose tuberculosis and you certainly can't begin to understand you MDR/XDR-TB problems.

I'm not going to go through all these specific topics. I just want to emphasize that in six countries, we are working together to strengthen the lab capacity. And part of that is expanding rapid surveys of XDR-TB epidemiological investigations to identify the extent of drug resistance, using renovated wards to get people out of the community so they're not coughing on each other and spreading the infection, working with WHO on new guidance linking infection control to larger occupational health, and training a new cadre to focus on HIV-TB.

We're also expanding the monitoring and evaluation of TB and HIV, and therefore XDR-TB, with WHO and UNAIDS. And again, I'll go back to that phones for help initiative. If we can get hand-held devices in to the village level, we can not only identify HIV-TB, we can identify early on when we're starting to see something unusual, like patients dying with HIV-TB and focus rapidly on a rapid response to possible XDR-TB.

Finally, on infection control, infection control, as I mentioned, has been a problem throughout the continent and it's unfortunately not something people focus on early. Without effective infection control, all the other things we do are not going to work. And so what's happening now is a new approach to try to ventilate and properly deal with health facilities, but also train people so that the healthcare workforce can solve problems.

So in conclusion, HIV and TB, it's an understatement to say they're associated. These are epidemics fueling each other in Sub-Saharan Africa, and especially with the emergence of XDR-TB, what we know is we are failing despite our good responses and good HIV-TB responses or XDR-TB would not be emerging.

Progress is being made but we're still a long way to go. And we need antiretroviral therapy, CPT, and the three Is. And most importantly we need greater collaboration between the TB and HIV communities in that schematic from Mario that I

showed. The HIV community, I think, needs to take much greater responsibility and role in the TB-HIV effort and that's why I'm so pleased to be here.

I'm going to end with this slide because not only is this a massive human catastrophe with millions of people dying and with a risk of a spread of a pandemic that will kill everyone and therefore we're obligated to act. It's in our self-interest to act. With the increased financial challenges in the world, resources for developmental issues are going to become harder and harder to come by.

If we can't link HIV and TB, two things that are so close and connected, how are we going to link health interventions with education and economic development and clean water? We're not going to be able to if we can't do it on HIV-TB. And if we can't come together in responses to our challenges to our health and development, if we can't show greater effectiveness, if we can't show that we're working together on a response, we are not going to be able to get resources.

And so it's in our self-interest, but I hope that's not why we do it. I hope the reason that we do it is because we're obligated to because where people are suffering and dying, it is our job to intervene to support the countries and to save their lives. And with that, I'll be happy to take any questions [applause].

**ANTHONY HARRIES:** Thank you very much, Ambassador Mark Dybul, for that moving presentation and for reminding us once again that we need to work together as a team to move forward to provide services for the people, patients who need it. We have thirty minutes. We'll both take questions please. The microphone are available one, two, three. Questions? While we are waiting for people to come to microphone, let me just ask a question. Thank you very much, Mark, for a great inspiring talk.

When PEPFAR started—I'm focusing on antiretroviral treatment—it had a target of 2 million people being placed on treatment. And I think at the time that was absolutely appropriate because there were so few people. I think there's now a concern about retention of treatment and whether in fact that should be quite a key target that we aim for. It's no good just putting people on if actually at the end of the day only 50-percent have actually retained our treatment.

**MARK DYBUL, AMBASSADOR:** I think that's an excellent point Tony, and one that I know you're very familiar with Malawi. We're seeing 15 to 30-percent, in general, lost to follow-up in clinics. Now, I think it's important to note too that that doesn't mean people are fudging numbers. When we report people in treatment, it's the number of people currently in treatment so people aren't counting people who were in and then are out.

But still it's a huge issue. It actually gets to the point of a new generation of how we evaluate things moving from outputs to outcomes. And one of them has got to be quality of services including lost to follow-up. And, so, Caroline Ryan, actually, and some folks in our office are focused on this next generation of indicators.

But, most importantly, we're working as a global community on that next generation of indicators with World Health Organization, UNAIDS, the Global Fund, the World Bank, and others. So, we absolutely need to be focused on and evaluate that. Actually systems are being built to look at some other qualities. It's one of the advantages because we're actually putting in, for the first time, quality assessments and follow-ups.

It also points to the essential need of civil society in communities. The data over and over and over again show that if all you're using is the public health infrastructure or the medical infrastructure you are going to lose people. You have got to link the community for the follow-up when they leave the center.

We need to be innovative. People are using handheld devices and cell phones to remind people to take their drugs to follow people when they don't come back to the clinic. And that's why it was so impressive to see some of those data. I showed you the data from one of the programs across nine countries on lost to follow-up went from 18-percent to three-

percent with community engagement. We see that over and over and over again. Some of it's been published.

So, we do need to focus on better indicators that focus on outcomes not only for this but for everything. And then we also need to make sure we're engaging the community and the health sectors talking with these fully engaged with civil society. But we're not going to solve the problem is. We'll just know what the problem is and won't do anything to solve it.

**ANTHONY HARRIES:** Thank you. I think we have, I'll start with Diana, Peter, and Steeny [misspelled?].

**MARK DYBUL, AMBASSADOR:** You can tell it's a close community when moderator knows the names of all the - [laughter].

**DIANA WEIL:** Well, at least we have new person on the podium next to us. I'm Diana Weil from the WHO's Stop TB department and obviously our collaboration with PEPFAR is incredibly important and growing and very exciting to us today and we hope that the future is bright on that front. I have a question related to what do you think you're learning in the AIDS community on drug resistant surveillance and where you're going with antiretroviral resistance and what we can learn from TB and how that links to laboratory strengthening some of the other things we're doing adherence, support, and things to insure that resistance doesn't become an overwhelming problem in HIV as well.

**MARK DYBUL, AMBASSADOR:** Yes, it's a critical point and MDR-TB and multi-drug resistant HIV are expected outcomes of the programs because we know that a certain percent of people will develop resistance. You won't get any resistance if no one's treated. So actually it's a sign of success that you're starting to get some of these problems.

But it's also a sign of failure. And that gets back to what needs to be done, not only to monitor and evaluate because the laboratory and understanding there's a problem is only part of the issue. You've got to solve it and that means you have to have programming behind the evaluation. We are seeing gross under-estimates of the amount of resistance. And the reason for that is we don't have a lot of resistance to it. We probably won't have clinical resistance testing for HIV for 10 years. It's just too difficult to establish. What we have is clinical monitoring for resistance and then sentinel surveillance to try to give us a sense of what the problem is. Right now in our clinical programs we're seeing three-percent resistant per year. There's no way it's only three-percent. We're assuming it's 10 to 15-percent.

The other problem with HIV, as in TB, is when you're doing clinical monitoring. By the time you pick up someone who's resistant, their CD4 cell count dropped or their clinically ill and they've lost pretty much every drug in your regimen unlike here in Paris or in the United States where we'll pick it up early and be able to switch drugs out.

So we need to be awfully careful here. We could be back in 20 years where we were five years ago because our drugs won't be effective anymore. So it's a combination of surveillance and building the lab capacity. It's probably going to have to be sentinel surveillance for a while. And I think we can learn a lot from each other by building these nodal clinics which we're working on together to build clinics that can do multi-drug resistant HIV and TB together and extremely drug resistant TB and also to built that laboratory capacity on, at the moment, a national level. It would be good if we could get to regional level, but there are a lot of complexities with that. And then we want to have the programs to fix it.

**ANTHONY HARRIES:** Thank you. Peter?

**MALE SPEAKER:** Thanks, Tony, and thank Mark for a whirlwind tour of what's going on with the U.S. government's support and the broad TB-HIV agenda. I just wanted to ask your thoughts and ask what PEPFAR is doing to emphasize that community engagement that you started to discuss with Tony with regard to adherence follow-up. We know for tuberculosis control that there are very large numbers of tuberculosis patients out there in communities who have minimal interaction with the health system.

So for instance we just conducted surveys as part of the [inaudible] that show that as many as 50-percent of the people who are identified as TB suspects in the community

haven't been to the health center with us. Unless we engage in case finding both for tuberculosis and for HIV beyond where Mario Raviglione's diagram starts, which is at, sort of, a primary healthcare level.

Unless we get well beyond that actually and don't look just in communities to find cases and start people on communities to find cases and start people on treatment both for HIV and for TB, I think we'll lose an awful of opportunity for interrupting transmission. I just wondered where PEPFAR was going with that step.

**MARK DYBUL:** Well, first of all, I think you're exactly right. And I would point out that Mario's slide didn't end with primary healthcare and beneath that it had community involvement for the same reason. We've got to get to the communities. There are two parts to the solution really. One is to get the health system further out to the village level. And a couple of countries are working really hard on that, Mozambique, Ethiopia, Zambia. So part of the problem is to rebuild that health infrastructure to get it to the village level to get it to the community level.

But it's still not far enough down and that's where you get to the community workers to get into. And it's not just having someone present. Community workers and civil society tend to have more credibility and reach and are able to get into the home. Eighty-percent of our partners are non-governmental organizations. And the vast majority of them are

community-based organization. And so what we're trying to do is to get them into the community level.

And a great example is that malaria example I showed where there are 350,000 households reached on a weekly basis by a community worker that was doing HIV pallet of care or orphan care. So that's how we could deliver the bed nets. We need to be doing the same with tuberculosis and HIV-TB. And both for care, but also for monitoring and that's the advantage of those handheld devices.

If those people are going out into the homes and seeing are you coughing, are you losing weight? You can feed those systems back in. So it's a combination of extending the health system, linking it to the community and then having the evaluation systems go deeply down.

Now, there are a lot of promising starts, but that's all they are. They're promising starts. This is hard work. And funding of these organizations is very complicated. We're trying to set up new systems of umbrella organizations who can manage the managerial pieces and accounting pieces so that the organizations can do their work. And to be honest, I don't think we've gotten to the point where a lot of governments, including our own, is comfortable getting to that level. And it's going to be a hard slug but we've got to do it.

So it's a problem. People are working on it. I think the more HIV and TB is linked and we take advantage of the infrastructure that's been built for each to add on to, the

better off we're going to be, but it's going to take a lot of time. But I think you're absolutely right. But it is important that Mario's slide did talk about the community. That's why I emphasized the community in each of those Stop TB programs and the HIV programs. But we have a long way to go. It's not a success story yet. It's a good start.

**ANTHONY HARRIES:** Thank you. Steeny?

**MALE SPEAKER 2:** Thank you very much for your very detailed and elaborate presentation. And thanks to PEPFAR for the work that they have managed to assist countries to achieve; however, the achievements that have been made is actually because of available resources to the countries that need them. And these resources, some of them are in Global Fund. Is there something that Global Fund can learn from PEPFAR systems especially because if you look at the TB world, there's very little money that is distributed from Global Fund to the countries which need these monies? Perhaps because of some strange reason is it that countries do not have the capacity to write Global Fund proposals the way Global Fund wants these proposals submitted?

**MARK DYBUL, AMBASSADOR:** Thank you for the question. As I mentioned, we believe that Global Fund is one of the more important institutions in not only health, but development. And it's very much driven by country ownership. So the country coordinating mechanism comes forward with the proposals. As I mentioned, the Global Fund has about \$1.4 billion dedicated to

TB right now. It doesn't mean it's all dispersed, but the grants have been committed.

I think we can all learn from each other and it has to do with how you put pieces together. What we fundamentally need to be doing, and again we have a long way to go but I think we've made a lot of progress is to put all of the external folks together in support of a national strategy. In general, a national strategy is not going to work. So you need a national TB strategy, a national HIV strategy, a national education strategy, and you've got to have national strategies but then each piece can come in and support.

And Rwanda does this beautifully and so do a number of other countries, but we've got to get further along in that to get back to those principles of country ownership. So I think the most important thing to do is to work at that country level, particularly the CCMS to build the programs that are needed because in the end, the Global Fund only funds what comes from the country's needed funding.

And thank you for your words on PEPFAR. I just say it's the American people that we should thank. It's an emanation of that. But it's a great privilege for us. We believe this an extraordinary opportunity for there to be a partnership between people and that's an extraordinarily important thing. It increases respect and concern for each other both ways where people understand the American people better and we understand others better. It brings people

together. And if we can do that, then I have a lot of hope and believe firmly we can solve not only TB-HIV, but a lot of other issues. So thank you for that.

**ANTHONY HARRIES:** In the interest of time, I think we should take at least one, two, three questions. I know I missed you. Let me come back to you. Let us just take three questions at the roll and then, of course, Ambassador Mark will be able to respond.

**RENEE WOODSON:** Renee Ridzon from the Gates Foundation, than you all for your talk. Ambassador Dybul, I was wondering if you could just give us some of your thoughts about how PEPFAR is approaching the very challenging job of integrating national AIDS programs and national TB programs. I know PEPFAR is rather country specific in how they approach or let the countries decide how they approach the treatment issues. But are there any overarching policies or thoughts that you have about PEPFAR in overcoming this challenge?

**ANTHONY HARRIES:** Okay.

**MALE SPEAKER 3:** Thank you, Mark. First of all, let me extend a welcome to the inner sanctum of the tuberculosis community. The question I have is I wanted to give you an opportunity to say more about operational research which is going to be very much a part of the newly enacted authorization. In tuberculosis, after so many years of a dry spell, we're sitting on new compounds that look very promising.

We're sitting on new diagnostics as well as I just saw some

results yesterday of an eight-year trial in Darussalam with Dartmouth University. So it's some promising results of a BCG kind of vaccine.

So given that reality, we're just chomping at the bit to scale up our capacity to do the problematically relevant research that will make such labor-intensive efforts easier on this community because what we now have is very different which is sustained over the years that it's required. So, I wanted to give you an opportunity in that context to say some more about what PEPFAR, too, will be doing on behalf of operational research.

**MALE SPEAKER 4:** [Inaudible] You already mentioned that as we go along there will be more and more patients that will be drug resistance and lead a second-line generation and in terms of antiretrovirals. And we already see that this means a huge cost increase as these drugs are more expensive. And we are unlikely to see the same kind of generic competition as we have before given that there's much more patent protection in some of the generic producing countries. So what are you going to do to make sure that as we go along your funding were not eaten up more and more by increasing drug cost but will be there to keep as many as possible patients on treatment? Thank you.

**ANTHONY HARRIES:** Thank you. Ambassador, can I take the last two since they have been standing for the last 10 minutes?

**ALASDAIR REID:** [Inaudible] and thanks Mark, particularly for your leadership at PEPFAR to making sure that TB is integrated with global HIV response. My name's Alasdair Reid, I'm the HIV-TB advisor at UNAIDS. And I'd just like to hear how you would answer to the increasingly vocal critics that say that single disease organizations like UNAIDS that perhaps their time is up and that we should move away from disease-specific funding and enter more health system-wide investment. Thanks very much.

**JANE CARTER:** Jane Carter from the USAID-AMPATH partnership in El Diret [misspelled?] Kenya. This is actually just an invitation. Tomorrow afternoon it's the last session, the last two lectures and the USAID-AMPATH partnership is going to be talking about our home-based counseling and testing, really the attempt to carry its integrated prevention messages door-to-door as a model.

**ANTHONY HARRIES:** Thank you. Ambassador Mark Dybul?

**MARK DYBUL, AMBASSADOR:** Thank you. And I should point out that our biggest implementing agents are USAID and the CDC. And so we had comments from each of them and they're doing a great job. It's the PEPFAR-AMPATH partnership that was just mentioned about that USAID has implemented. Let me try to run through each of them. Some of them are related.

In terms of integrating and what we're trying to do, we've actually made money available for TB that hasn't been used, for HIV-TB that the countries haven't stepped forward to

use, which has told us that there's not enough integration on the ground. And I don't think we have enough expertise on the ground related to TB. So we're trying to provide more guidance and to work more to get the expertise on the ground so that people can come forward with proposals.

It's related to the Global Fund question too. If there's not the expertise and thought on the ground, you're never going to have a Global Fund proposal either. So we're open to anyone's thoughts on how to do it because honestly it's been a little frustrating when we have money available and people don't come forward with proposals, which is somewhat related to operations research.

Ken, what you talked about is not something we're ever going to do. We don't do evaluations of new diagnostics and new drugs. That's NIH, CDC, and others' work. We implement. So if products are shown to be effective then we will use them. But what we do need to do is what we're calling public health evaluations, which is how did you improve your programs? What big questions can we ask in a six-month to one-year period that will change the way we do things? And we have a system in place now to do that in a more coherent way. We've got a ways to go, but we're trying to do that. And that engaged and there actually is a new approach to monitor an evaluation for tuberculosis is we're going to pursue.

But the drugs and diagnostics isn't something that we're ever going to get engaged in. That's not operations

research. That's new product evaluation. But when they've got to the point where they've been approved for years, we can put them into use and then there can be operational questions around how to use them.

But we can't do anything until they get to that point, which is somewhat related to the products. Our policy has always been that we will supply products at the lowest cost as long as they are high quality. So about 70-percent of all our antiretrovirals right now are generic products, 90-percent of them through our supply chain management systems. And where we're not using generics, it's generally because they're either more expensive than the innovative products or they're not available in some pediatric and second-line version.

So we will continue that policy going forward and aggressively pursuing because we think as long as the drug is safe and effective and usable in that country, we should be using the lowest cost product, regardless of what it is. We actually have a public/private partnership working on this topic and Caroline actually has mentioned and I think it's a good idea. We did actually support and pursued and our approval process was the first to approve the pediatric three-in-one combination. Something Caroline has mentioned is maybe we ought to start looking in that partnership at tuberculosis as well, combination of tuberculosis products. It's very much a high priority for us.

In terms of how we deal with vertical/horizontal, actually, I think there's been a big shift because it's such a silly debate. And the more we talk about those types of things, the more we're going to lose work. I mean we're in a tough economic situation. The more we talk about things as if they're competing against each other, and what I consider to be silly is we're all going to lose out.

Disease-specific programs build health systems. And I just showed an awful lot of that. Health systems that didn't exist before are being created in a way that has never been seen at the village level and that is leading to an improvement in non-HIV and non-TB care.

What we need to do more of is see how we connect the dots and develop. How do you incrementally add on to an HIV or TB program? Other aspects, malaria and neglected tropical disease education, clean water, economic development, but that requires us to all break down an awful lot of bureaucratic walls. It's not an issue of vertical/horizontal theoretically. It's often a bureaucratic issue of siloed groups that don't want to talk to each other or find it very difficult to talk to each other.

So I don't think it's an issue of disease-specific funding or anything. To be honest, it's a disease of bureaucracies that we can't put these things together. And that's our responsibility. And that gets back to the last slide, which is it is in our self-interest as well as our

obligation to start putting these programs together. And we've passed these debates which are lovely in capitols but don't do much on the ground.

**ANTHONY HARRIES:** Thank you very much for that last and lively response. I want to thank everybody for the lively discussion and Ambassador Mark Dybul for being with us today enlightening on TB-HIV for operation. Thank you very much [applause].

[END RECORDING]