

**Conference: 15th Annual International AIDS Conference
Official IAS Press Briefing
July 13, 2004**

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CRAIG MCCLURE: Good morning everyone and welcome back. For those of you who haven't been here for the last couple of IAS, I'm Craig McClure, the Executive Director OF the IAS. I'd like to welcome you to today's press conference focusing on [inaudible] theme of the day scaling up access to anti-retroviral treatment. I'd like to turn the mike over to the co-chair of the conference, Dr. Utlana.

DR. JOEP LANGE: I'd like to welcome you all to this session, which is really the session on treatment of this conference, the plenary session on treatment. I'd think it's a good principle of the chair, who is visible so much already, to give the floor over to the people who likely deliver the lectures. I don't know who is the first speaker. I'm happy to comment if people have questions, but let the speaker go first.

CRAIG MCCLURE: Sure, we'll just run through a few brief summaries, we have the presenters from this morning. First of all, Dr. Kyat Ruxrungtham, the co-chair of the scientific co-chair committee.

DR. KIAT RUXRUNGTHAM: Good morning, my pleasure. I would like to spend a few minutes to summarize the highlight of the update of anti-retro therapies.

I think it's clearly that up to today we have 20 ARE [misspelled?] licensed for clinical use and there are also, many data have shown that combination anti-retro therapy really

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is life saving and quality of life improving treatment. This also been shown clearly in every continent of the globe.

One of the challenges of the deliverable of the disease, of the treatment, is also really clear at the moment that up to 70% have a viral lode undetectable up to 6 years, of 5 to 6 years, of the study.

There are many other challenges that remain. The thing is to improve a better option, to make sure the drug is more tolerable. And once theory option is now happening and become more to see. And also the long-term toxicity issue also needs to be improved. And more importantly, I think, whatever the regiment that has been proven in the clinical trial and also in the clinical practice, it really needs the adherence to the treatment by the patient. And it clearly needs to ensure that the doctor and caregiver really understand what they're doing with anti-retro therapy. I think one good thing about the treatment right now, is clearly it is a life saving therapies.

Thank you.

CRAIG MCCLURE: Thank you. I'd like to turn to Dr. Papa Salif Sow, the Director of Infectious Diseases at Dakar University in Senegal. He focused his presentation this morning on HIV TB co-infection.

MALE SPEAKER: Craig, before you do so maybe you should introduce Dr. Syrapong who is replace Dr. Wallapeer has chair of the conference. Welcome.

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CRAIG MCCLURE: Welcome

DR. PAPA SALIF SOW: Thank you. Good morning, this morning during the plenary session my talk was about the co-infection tuberculosis and HIV infection. We can summarize it, one patient with two diseases.

During the first part of my talk we tried highlight the burden of tuberculosis in the HIV patient. You know that TB is a most frequent opportunistic infection in HIV people. And actually 11 million adults are co-infected with TB and HIV, and of those 71% are living in sub-Saharan Africa and 22% here in Asia.

I also highlighted this morning that in sub-Saharan Africa up to 70% of patients which smear positive [inaudible] TB are HIV positive. We know although that HIV promotes the progression to active TB and HIV also is the most powerful known risk factor for reactive agent for tuberculosis.

There are actually two strategies to care with two diseases. The first is to decrease the burden of tuberculosis of people living with HIV and AIDS by making identification of TB case finding. Which means we have to screen people for signs and symptoms of tuberculosis and follow by diagnostic and proper treatment for all HIV positive patient in the [inaudible] center, in the [inaudible] clinic. We need to be very aggressive for identification of the tuberculosis cases finding.

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The second strategy to decrease the burden of tuberculosis of people living with HIV and AIDS is to give them isoniazid preventive therapy, which is a drug helper to all HIV positive patients when they have PPD skin test positive. If you give them, a lot of studies have demonstrated, if you give them isoniazid as prophylaxis this isoniazid will delay the onset of disease. It's now, I think, something we need to set up and to put in our different programs in our countries.

So this identification of case TB finding, is very important in order to interrupt TB transmission, it prevent mortality and also it decrease the risk of [inaudible] TB transmission and also it is an opportunity to provide TB prophylaxis to HIV positive patient. So the second thing, is also to decrease the burden of HIV in tuberculosis patients by providing HIV testing and counseling to all TB patient. Now, I think one recommendation should be that in every TB setting we have to offer the HIV testing to all TB patients, this will help us to give them [inaudible] or prophylaxis because a lot of studies have demonstrated also when you give cotymoxcil [misspelled?] or [inaudible] prophylaxis in TB patients one month after they start the anti-tuberculosis drug, this cotomoxycil [misspelled?] reduce the morbidity and the mortality of opportunistic infection. I think this might be also another reccomendation.

And finally the anti-retroviral drugs, a lot of studies have demonstrated today that the anti-retroviral drugs improve the quality of life of people that have HIV and tuberculosis.

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In summary, I think we need very close collaboration between the TB program and HIV program. In each country I think we need to have a very good collaboration between the two programs. We need to reinforce, to strengthen the HIV surveillance among TB patients and also we need more financial resources for both diseases from government and through international corporation.

Thank you.

CRAIG MCCLURE: Thank you Salif. Apologies for not properly introducing Dr. Siripon Kanashana, the Inspector General of the Thai Ministry of Public Health who joined the stage. Dr. Seerapong will be available to answer questions from you all that may be directed to the Ministry of Public Health.

I'd like to turn next to Diane Havlir, Director of the University of California San Diego, Anti-Viral Research Center, University of California, to summarize her presentation this morning looking at HIV infection and other morbidities that can be addressed to further advance help.

DIANE HAVLIR: Thanks, Craig. As you just heard, tuberculosis is the most important co-infection on a global basis. In fact the early reports on AIDS in Africa reported slim disease, which is a chronic wasting illness closely associated with tuberculosis. It was originally thought that individuals in Africa and Asia would die before they developed some of the other complications of HIV disease and that turns out to be probably not true. And a couple of new things that have come out in terms of

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looking at complications are that patients in Africa and in Asia succumb to many of the opportunistic infections that we saw in the United States and Europe early in epidemic. In addition, it turns out that malaria is much more frequent and more severe in HIV infected patients, and there is a very large burden of sexually transmitted infections.

The high burden of co-infections in Africa is very important for two reasons. One, the tremendous amount of suffering that these infections incur; the blindness, the wasting, the chronic diarrhea, but also because they accelerate the natural history of HIV disease. One theory is that this is done through immune activation. In immune activation, HIV requires cellular activation in a very simplistic way, these infections can activate the cells and then HIV is induced to replicate. At higher levels HIV is transmitted easier and also we see more rapid HIV progression.

One of the questions, if that's true, if you look at siro [misspelled?] incident cohorts, so people who have siro [misspelled?] have converted it in Africa and Asia, the time to AIDS in a recent study was 7 years and this is contrast to about 10 or 11 years average progression to AIDS that was seen in the U.S. and Europe. There was also a study a few years ago of the sex workers in Kenya where the time to progression to AIDS is 4 years.

So, with this huge burden of infections as we go into the roll-up, the questions are what are the practical things we can do. Well, underscoring what Dr. Saleef [misspelled?] said, there's a very

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high burden of just general bacterial infections. When you look at hospitalized patients and mortality rates associated with these are up to 60%. So one very simple intervention is to give the antibiotic cotrimoxazole and this appears to reduce mortality and may appear to protect against malaria and pneumocystis which is seen all over the world.

Secondly, this whole predominance of co-infections presents the opportunity for HIV testing. One of the major obstacles in the scales was identifying people who are HIV infected, not just waiting until they are very, very sick. Persons presenting to sexually transmitted disease clinics, to TB clinics, to malaria clinics, they can be potentially diagnosed at this time point.

But really, the most important point of my talk is that in terms of preventing these complications, anti-retroviral therapy is the most powerful tool that we have. It's just simply not realistic that we are going to develop all of the diagnostic capabilities and the treatments for all of these complications that develop in the HIV disease. In fact, we never even develop that in the developing world because when anti-retroviral came, they were all diminished.

So, I think if I have just one take home messages from the talk, that's what it is. And that by deploying anti-retroviral therapy we will make a huge impact on the tremendous burden of suffering that's occurring from the complications of HIV disease.

CRAIG MCCLURE: Thanks, Diane. I'd like to turn now to Dr. Jim Kim, the Director of the HIV/AIDS Department at the World Health

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Organization in Geneva.

DR. JIM KIM: Thank you very much, it's perfectly appropriate to follow up Dr. Havlir's presentation with mine. My talk today focused on our so called 3 by 5 initiative, but not so much on that, but the history of - they can't hear me - the history of and the prospects for scaling up anti-retroviral therapy.

I said that progress has been slow, far slower than we would have liked, far slower than we had expected, but at the same time there are encouraging signs. There's funding in place as never before, people are getting trained and most importantly the member states of WHO, 192 member states, have all endorsed the 3 by 5 target. And we know now that after the World Health Assembly in this past year in 2004, that many countries are taken very seriously the notion of scaling up treatment to reach half of the people who need it by 2005.

Most importantly though, we have to take on the tough challenges. There are many tough challenges, including training. We believe that bringing new health workers into the work force is critical. Rather than fighting over the ones that do exist, or thinking that building medical schools or nursing schools is the answer, we feel that we simply need to bring more health workers into the fold.

We also believe that simplified high-quality public health approaches to treatment are now called for. There is an ethical issue here. And the ethical issue is that if we wait until all

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countries have the facilities that we have in the United States or Western Europe before beginning therapy, we will have many people dead. So the choice is, do we take the evidence that we have now, which is very compelling, from projects that have already been implemented in developing countries and take an attitude of learning by doing. Or continuing to study our implementation. Or do we wait until we feel that some arbitrary set of infrastructure elements are in place? Well, the World Health Organization has been clear on this subject. There is enough evidence to encourage and promote a simplified approach that preserves the quality of treatment and, most importantly, preserves lives.

In addition, we talked about moving drugs. We need to move drugs very, very quickly. I talked a little bit about the pre-qualification project that WHO has instituted. Some of you may have seen an article today in The Nation criticizing this approach. Let me just say, that the article is confused and confusing and represents a deep misunderstanding of the pre-qualification process if you'd like.

Finally we argued that partnerships and meetings and alliances have to now happen at the country level. There is a tremendous amount of energy behind scaling up treatment and in countries like Mozambique you'll find the president's initiative, President Bush's initiative, you'll find the Clinton Foundation, the Global Fund, and the World Bank, all prepared to fund treatment and yet there are only 100 physicians in all of Mozambique. We have much

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work to do but we now have to move our meetings from occurring all too frequently in capitals and centers like Geneva, and have them happening at the country level.

Three by Five, I feel is becoming something of a social movement. It's a concrete time limited goal that we have to use creatively to propel us forward.

Thank you.

CRAIG MCCLURE: Thanks, Jim. All of you know Dr. Tony Fouchi the Director for the U.S. National Institute for Allergy and Infectious Diseases.

DR. TONY FOUCHI: Thank you very much Craig. It's a pleasure to be here with you this morning. I was asked to address very briefly, in less than 5 minutes, two issues.

One is the issue of the pipeline of drugs that we are developing through the funding of the National Institute of Allergy and Infectious Diseases. Is it still a robust pipeline? The fact is, yes it is. Since we need to continue to pay attention to the [inaudible] capabilities of the virus to either escape the therapy we give through mutations and/or to develop new targets and/or to develop less toxic drugs. So very briefly at various sessions throughout this conference you are going to be hearing about a variety of old targets with new drugs and even some new targets.

Just very briefly among then entry inhibitors you know that there are drugs in Phase 1 and Phase 2 trial for both CCR5 blockers, for CXCR4 blockers, and for GP120 blockers. That's in addition to

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the drug we already have, T20 Fuision [misspelled?], which is a fusion inhibitor.

There are some new RT inhibitors, both non-nuclear side reverse transcript aids as well as nuclear side reverse transcript aids inhibitors. The NNRTI, the one that is going into Phase 3 now is Capravin [misspelled?]. There are integrates inhibitors that were just recently published in Science. The merc compound that looked very good in the monkey model. There are some protease inhibitors, particularly tamprenavir [misspelled?] which is also in phase 3 and filing with the NIH probably at the end of this years. Maturational inhibitors, sidocines [misspelled?] like Aisle 2 and Aisle 7. Other immunological strategies such as blocking activation with cyclosporin and micro phenolate and a variety of other vaccinations combinations of interruptions of therapy. So the pipeline is robust obviously in all drugs trials. There is a rate of failure that is real, so these are not going to all eventuate into drugs that we can put into our armamentarium, but hopefully at least a few will of them will alleviate some of the difficulties of people who might in fact be resistant to many of the drugs that we already have available.

The other issue that I was asked to address and probably would be better in discussion back and forth, is the issue of access and the role of the United States Government. Particularly in the form of the President's Emergency Plan for AIDS Relief, which is what we call PEPFAR, the 15 billion dollar program, which in addition to the global funds contributions, will provide treatment, care and

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prevention for 12 sub-Saharan African countries, 2 Caribbean countries and most recently Vietnam, as the 15th country. There will be 10 billion dollars of new money, the controversy that I know has been circulating around regarding whether or not generics, as they're called, will be able to be used or not. I'm sure you've heard from Ambassador Tobias [misspelled?] that the intent is of the program to get the best possible drug for the lowest possible price, including generics.

Now the issue about generics is something that I believe he may have clarified is that generics by strict definition is a drug that has been approved, at least in the United States, that is one whose patent has expired and has been approved by the FDA for use. What we're talking about on the fixed dose combination is not, strictly speaking, a generic. Though broadly it is a generic. It's a copy of a drug, which very well may be equally as good as the actual brand name drug, and some of the studies from Medson SonFrontier [misspelled?] indicate that in fact the clinical effect is real. It is the strong intention to get those drugs available for use of expenditure of PEPFAR funds with the stipulation that they pass an approval process, which I know has generated some concern and controversy. The FDA is clearly committed to putting that proposal for approval through a very, very fast track. And I know there's been criticisms about that, and I think we should give the FDA the chance to prove whether they'll be able to do it or not. The only way to prove that is to have companies that would like those drugs

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approved so they can benefit from the PEPFAR resources, is to submit the application for the approval process. And if it is the way the FDA is saying it is going to be, it should be done very expeditiously. We all hope that that's case, so that the best use of the money can be made with the lowest possible price. That is the true commitment both of the FDA and of the federal government and I'm sure there's a lot of discussion about that. But I just wanted to make that clear at least in the many discussions I have had with that, the clear intent is to get whatever drug we can that's the effective drug and the cheapest possible. There's two possible good spin offs of that. One it will drive the price down of the brand name drugs, and it might provide among the generic drugs a safe and effective drug that is considerably cheaper than others. So it might turn out ultimately to be a win-win situation.

CRAIG MCCLURE: Thanks, Tony. And now to Milly Katana the Advocacy Officer of Health Rights Action Group in Uganda, and a long time grass roots leader fighting to uphold human rights of people living with HIV and AIDS.

MILLY KATANA: Thank you very much, before I speak from the perspective of the Health Rights Action Group, I would like to convey a message from the leadership [inaudible] committee. Which has put together a track on leadership development. We think it's high time we now looked at governzing financial and human resources to be able to scale up access to treatment. We think, as leaders, both the scientific community, the donors, the civil society and governments

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in highly effected countries and countries in transition, need to get together the infrastructure as WHO qualifies over and over again to be able to deliver on the commitment to get treatment. Not only on the 3 million by 2005, but to many, many more that are living with HIV and will soon be ineligible to get medical treatment.

And another important issue around scaled up access to treatment, is the energy we all need to put in in order to sustain the treatment. HIV as we all know is a disease with a difference. It is unlike malaria where I get one weeks course and I go back to work. It's a lifelong commitment. We need to sustain the resources, the financial and human resources, we need to sustain the infrastructure and above all we need to learn to work together in a different way. It's not okay to come to meetings like this and everybody goes and follows their own agendas. From the leadership point of view, that's what we are calling up this conference and the delegates of this conference and you, the media, to help us put across.

Finally the issue of a supportive, legal, environment. Issues around trade arrangements that we enter into, issues of compulsory licensing. If we are to sustain treatment for people for 20 years, we must be able to get across the cheapest available drugs. That's all I can say for now.

CRAIG MCCLURE: Thanks so much, Milly. I'd like to turn it over to all of you know. When you ask a question please identify yourself and your affiliation.

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RICHARD INGUM: Thank you, Richard Ingum from the French News Agency, AFP. I have a question, if I may, for Dr. Kyat Ruxrungtham [misspelled?] about the problem of drug resistance, specifically in Asia. Drug prices are coming down, as you know in many Asian countries, very complex molecules are available over the counter. People can buy them freely. And yet at the same time, there's a lack of infrastructure, a lack of counseling, a lack of trained personnel to insure that drugs are going to be administered effectively. What, in your opinion is the risk that unchecked taking of anti-retrovirals of people who are able afford them but without medical supervision, could lead to an increase in the resistance for these very important drugs?

DR. KYAT RUXRUNGTHAM: Yes, I think that is a very, very important question. I think it's clearly that it's just not having drugs available but I think it's very important to insure that the infrastructure and the health care system and the care provider really understand how to do and how to do the best.

There are number of limitations, as you said, in terms of the limited resource and in term of the attitude of the health care provider, many of them are not keen about providing good care. I think that among those it's a number of ongoing direction, to giving more training. I think in Thailand it has created a [inaudible] society together with the Minister of Health expanding the training the program and more doctors, up to 1,000 right now, have been trained and they will learn and experience more how to prescribe and

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looking after patients taking these.

I think the resistance issue is a concern, clearly. One thing we should do, besides the training and insure that the patient really adheres to the treatment, is also we have to strongly try to get a cheap monitoring, I mean a low cost monitoring, for the viral lode and CD4 and you can hear more about this progress during this conference. The cheap testing has become more possible. Because otherwise, we are going to be faced with the late failings and setting, and you know, patients will fail with many drugs and they are hard to rescue.

The other concern is about transmission of the resistance. I think that we need all the government sector and the people that are working in the field in the research area, need to also have awareness and probably set up a resistance of viral system to looking up this issue.

CRAIG MCCLURE: Okay, Uta I think you'd like to also address.

DR. JOEP LANGE: Yes, just a few comments. I think we need to realize that the specter of drug resistance has not kept us from scaling up access to care in richer countries. That's one. Obviously we shouldn't repeat the same mistakes we made in richer countries, we have a chance to do it better in developing countries. The most important was stressed in Dr. Kyat's presentation actually, is adherence. In the end, if people have got a good regiment making sure that they take

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their drugs is the most important determinant of the therapy's success. And there are data from observed therapy studies, and one of the pilot projects was actually done by Dr. Kim's former organization, Partners in Health, in Haiti where you have community workers supporting patients taking their pills and that's had fantastic success. So I think in a way we're focusing too much on elaborate infrastructure when we could deliver therapy in a far more effective way by just involving community friends, peers, et cetera.

RICHARD INGUM: [off mike] I'd like to go back to that [inaudible] -

CRAIG MCCLURE: No, I think we have to take the next -

MALE SPEAKER: No let, him let him go back -

CRAIG MCCLURE: Okay, go ahead.

RICHARD INGUM: I was specifically talking about - what you are talking about there is these studies in which people taking medications in a controlled environment. Anyone with any knowledge of Asia will tell you that you can go to a pharmacy and you can buy your antibiotics or whatever you want and the guy will give it to you. Now is this going to happen with anti-retrovirals and what's going to happen?

DR. JOEP LANGE: It's going to happen, but again it happens, it happened in our region and we should undertake every possible action to prevent it from happening. But that doesn't mean that we should prevent people from access to the pills.

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CRAIG MCCLURE: Jim, do you have anything to add?

JIM KIM: What I would say is, from experience in both providing care in resource poor settings and also some of the best hospitals in the United States, is that I think it's an open question. The strategies that I'm familiar with in developing countries are often without access to viral lode testing and sometimes not even access to CD4 counts. We have started therapy because the choice was, start therapy or everyone dies. So we've started therapy and watched clinically. What we've tried to do is to provide treatment support, some people call it directly observed therapy and that's not really what it is. It's supporting patients socially, nutritionally and in every other way so that they can comply with a difficult regiment. What we've found that intensifying social support, which you can do in any environment, actually has led to very minimal resistance in patience over 2-3 years.

Now the other approach in the United States, which I've also watched very carefully is that we check viral lodes all the time. Knowing the viral lodes are the first indicators of the development of resistance, and then begin changing regiments based on genetic studies of resistance. Over time you see patients who have multiple regiment changes. And I would argue that it's not clear to me that that is a quality of therapy and a quality of life that's that much better from the treatment perspective from doing it the other way that we've had to do it. Which is intensive social support, really think about psycho-social support, watch them taking

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their medicines as a way of supporting them through it. I think, in fact, we have less resistance in our cohort. We haven't done a study to compare, we see less resistance in some of those cohorts that have got that intensive support than in people who have been followed very closely in laboratory monitoring. It's an open question. And once again the point I would like to make is, we don't have the answers. And as we move forward saving lives we have to try find what's the best mix between these two approaches. But what we're trying to say is that if it's a choice between letting people die or starting with this is other socially intensive method, then people should start with that approach to adherence - resistance reduction.

CRAIG MCCLURE: I'd like to just direct you all, on that issue, to the fact that there will be a World Bank supplement in the AIDS Journal launched here at this conference specifically devoted to issue of resistance coming out of a large international consultation of scientists earlier this year.

Next question please.

LAMAR LONS: Lamar Lons, radio one, the Netherlands. I have a question for Dr. Kim. You told us something about 3 by 5. Would you recognize is a possibility of negative side effects of promises that do not substantiate?

DR. JIM KIM: People have said that 3 by 5 could be very damaging because it creates demand. Now my personal experience living in many poor countries, working in many poor countries and also interacting with many groups of people with HIV/AIDS. I don't

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think we've created any demand, I think the demand has been there and is there, as you can see at this meeting.

What would be the negative side effects of saying WHO has to commit itself to the 3 by 5 target and then failing? I think one of the negative side effects is that because I've been behind it, I could get fired. [laughter] But that's nothing compared to the difference that it has made inside the WHO to get things moving. Things that took 2 years, we can turn around and say, "I'm sorry we don't have a 2 years to do that, we only have a few months." And it's created some discomfort within WHO and I have to say that I'm not the most popular person in WHO, but without it we wouldn't have been able to move our bureaucracy as quickly as it's moving right now.

What we're also seeing is that countries when they pledge themselves to a target, often take it very seriously. Because they know they come back to the World Health Assembly the next year and have to report on their progress.

So I think that there are potential negative side effects, but mostly for bureaucrats like me, and I'll still be able to eat, I'll probably be able to find a job somewhere. So I'm not saying, my point is, it wasn't a promise that sort of, I'm going to look at myself and say, "Well can I keep it or not?" It's a creative use of time and we invite everyone to use time as creatively as we're trying to at WHO.

CRAIG MCCLURE: Okay, Laurie.

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07/11/04

LAURIE: We're on, we're on Bob

CRAIG MCCLURE: Introduce yourself -

LAURIE: Posted today on the Internet the general accounting office has released their analysis of what's wrong with the President's Emergency Plan for AIDS Relief, PEPFAR. The GAO report is based on field interviews at 28 field sites with HHS employees, USAD employees, et cetera. The report says that in 25 out of 28 site the primary impediment of success to PEPFAR is U.S. policy constraints and lists policies related to ARV use, to primacy of abstinence programming, difficulties in purchasing needle access for drug abusers and so on. I wonder if Tony and well you're the only victim on the panel that's from the United States government, so Tony, I wonder if you care to respond?

DR TONY FOUCHI: I'd really like to the see the report. We go through this a lot, you court a reporter. I really would like to see the report before I can make any comment on it.

I'm not sure what point you're making. The PEPFAR program has just dispersed its funds now, with the approval from February, they now have hundreds of millions of dollars dispersed out in the field. And through at least the first round are starting to get now thousands of people on therapy. I'm sure that it's not perfect and I'm sure that there are some constraints on it, but before I can comment about a GAO report that says all of the things that are wrong with it, why don't we just give it a chance to see how it's working? But I'd happy to discuss that with you later. But, I have not seen

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that report.

CRAIG MCCLURE: Okay, Mark.

MARK HARRINGTON: Thanks, I'm Mark Harrington, Treatment Action Group, I have a sort of omnibus research question for Drs. Fouchi, Kim, Salif Sow and Kyat which relates to, I think it relates to accountability and results in the scale up efforts. The U.S. thanks to activists in part and thanks to leadership like Dr. Fouchi, has a 3 billion a year budget for AIDS research. I think it's the flagship for the global effort and I think it's the U.S has a unique responsibility to make research results that are relevant for developing countries. Yet, much smaller agencies like the ANRS in France have been doing studies for over five years that are done in partnership with countries like Senegal and researchers there, that have come up with results that have pushed forward results in our standard of care, like in the use of Chlortrymoxical [misspelled?] or the use generics in Cameroon. The U.S. has been spending millions on setting up these sort of Cadillac research units at international program sites around the world and yet zero trials have opened with zero patients in the pediatric or adult AIDS clinical trials group. Of studies that were designed in a true partnership with and relevant for those resource poor settings. So my challenge and question for both you and the three others, is what is the NIH's strategy for doing an operational research agenda in true partnership with the countries with leadership by country researchers with results relevant to those countries? And how is that going to interact with

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the WHO three by five program? And particularly what are the perspectives from Senegal and Thailand about how NIH and WHO could do a better job of coordinating to get operational research questions answered? So for example, we need to know if Nevarpin [misspelled?] can be used with Rivapacin [misspelled?] for TB/HIV? That's one question that's been burning on the agenda for several years now and nobody's doing a PK study or safety study to find out.

DR. TONY FOUCHI: Mark, your point is extremely well taken and I know we've discussed this before but let me just summarize where we hope to be within the next year to year and a half. And that is that with the recompetition with the broad clinical trial network that we have that asks and answers research questions we really want to see if we can get that linked up to the actual treatment program that is not a research program. So, if you look at the pure research that we have been asking, have been in settings in which we haven't been able to get the kinds of answers that you're asking for, which are critical answers now when you want things globally. Because treatment was not available. Now that treatment is and will be even more available with the programs that you mentioned, not only our program but international programs, one of the major features of the research agenda will be, and will be judged on that, is just that what kind of relevant questions are you asking that have to do with the broad global issues that you're asking about. So it's an extraordinarily important question. And I hope we're going to get there, I'm certainly pushing for us to get there,

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to use research money to be able to answer the operational questions that you're asking as opposed to taking treatment money - there was some confusion early on about taking some of the 15 billion dollar over 5 year money and doing research with it - I don't think that that's a good idea so long as you do operational research with your research money. And that's where I hope that we will be by the 06 deadline. Thanks for the question, it's a great question.

CRAIG MCCLURE: Salif, can you comment from the Senegalese perspective?

DR. PAPA SALIF SOW: Yes, I think it is very important for this scaling up of access to the anti-retroviral drugs to have to a very close collaboration with many partners. Like you mentioned we have in Senegal, collaboration with INRS helping with us to scaling up the access to anti-retroviral drugs. And we just finished last year, a study showing the effects of once a day regiment using two NFDI and one non-NFDI so people have just to take the pills one or two hours before going to bed, so it was very helpful.

At the other side also we have nice collaboration with firm access using [inaudible] with [inaudible] trying to treat many African people not in Senegal, but also in the Uganda, in Nairobi, and also the first one -

MALE SPEAKER: Leecodivar [misspelled?].

DR. PAPA SALIF SOW: Leecodivar [misspelled?], where we are treating also people having access to that. And also

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international collaboration with United States, we are receiving money from the NIH, trying to help our women living with HIV and AIDS to avoid the appearance of cervical dysplasia, which you know, is an opportunity infection in women. Because of this collaboration with the University of Washington in Seattle, the cervical dysplasia screening free of charge for all HIV positive women. And now I think things are moving, not only in Senegal, but in many African countries they are trying to boost the access for having anti-retroviral drugs to our people there. They are living better and our hope now is to use it in all countries, because the needs are very, very important. Not only the drugs but the health infrastructure. You need also human resources, medical doctors to be trained, nurses, midwives. So I think it's a very good challenge and I think we are in the right way to achieve this goal.

CRAIG MCCLURE: Kyat perhaps you could comment on the operational research agenda in the context of scaling. . .

DR. KIAT RUXRUNGTHAM: Yeah, I think I very much agree in terms of operational trial research needs to be done implemented and unfortunately even through the global fund, that's not really the case. That's also one of the things we'd love to see that global fund including this trial research to be able to in parallel with providing good care and getting out the good question, to further improve the care. So I think that's very important, I agree with you.

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CRAIG MCCLURE: Jim, I think you had something to add.

DR. JIM KIM: At WHO the basic issue for us, is that we get questions all the time. Since we are most closely in touch with ministries of health, we get direct questions like: What do we do next? When do we change regimens? Should we base it on clinical measures? Do we have to have CD4 counts and viral loads? These questions come at us all the time.

But even simpler questions come at us, like: Has anyone else had success dealing with this kind of problem in this kind of setting? So for us the so-called operational research agenda has to be much broader. In some instances it's simply what we're now calling knowledge management. Are the insights that we have developed in one place available to all the other sites that are trying to do research? Simply sharing of information, which has been done extremely well in first world health care settings, can be extremely useful. The classic notion of operational research is that you start a study, you collect data, you analyze it for awhile and then you send it out for review and you publish it 3,4,5, 10 years later. That's not going to be helpful in this particular context and that is the classic research model. We're now talking about WHO about something we're calling real time interactive operational research, that looks a lot more like the quality improvement approaches that have been very successful not only in industry, but in the U.S. health care

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systems. And we're actually working with people who are trying to do this. In other words, can you know within a week or two whether something seems to be promising? And in this context where it's - we improve our methods or people die, we feel that we have to now begin to implement this kind of approach.

Knowledge management, real time operational research, that also lead to the kind of long term studies that are the traditional notion of operational research. We need to answer those bigger questions as well. We have tons of questions, we think we have a good idea about how to proceed, we just don't have a penny to push this forward.

I think that what Dr. Lang has done in Farm Access and what Dr. Kyzocki [misspelled?] and others at ANRS is a wonderful model. But in addition to those models, and I know that they are open to them, we have speed things up even more in terms of how we share information. And my understanding, actually, is that the global fund is looking at trying to provide funding for this kind of work underwriting the monitoring and evaluation framework. Because in many ways, it's sort of what it is, so we encourage other funders, too, to look at these innovative ways of improving our work as we go, because frankly I think that is our only choice.

CRAIG MCCLURE: Thank you Jim. Siripon, I think you wanted to add something.

SIRIPON: Yes, I would just like to add for Thailand,

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Thailand cares. Actually we did have to care to try to increase the access to the treatment for the AIDS patient, even before the 3 by 5 target comes out. And during those time it did run like operational type of implementation. And now it is already a national program. We have scaled up our public health system, trying to have the capacity building infrastructure so that we can deliver the standard of care at each level. And also we have the referral system when it is more complicated, the primary care unit then they can be referred to the secondary care and tertiary care. So now in Thailand we are receiving the funding from Global Fund that helps implement the national program. But actually it is probably about 20% from Global Fund, but 80% of the money is from the government of Thailand. And to make it more sustained in the long-term we were thinking about the co-payment from the patients themselves, so that they can be more access to more people that needed them. Because they're going to live longer and they're going to need more medicine and many more people will need the medicine. So we're thinking about another system that makes the treatment sustained and quality services that deliver all of the people of Thailand. Thanks.

CRAIG MCCLURE: Thanks. We'll take one more quick question and then we have to be out of here for the Richard Gere press conference begin. Or you might want to stay.

[laughter]

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STEVE FARAGONA: Steve Faragona with Voice of America, with a question for Dr. Longe and Dr. Fouchi. Dr. Fouchi you are one of the few representatives from the U.S. Government here and wondering what impact you think that's having on the conference when one of the leaders of the field is so under-represented? And Dr. Longe we are a few days into the conference, how has it been going and have absences been noticed?

CRAIG MCCLURE: Do you want to start Tony?

DR. TONY FOUCHI: I'm sorry, I hear part of the question. I'm one of the few?

STEVE FARAGON: Yes, one of the few from the U.S. Government -

DR. TONY FOUCHI: Right.

STEVE FARAGON: - that's here. And I'm wondering how you think that's affecting the discussion of science and policy and funding here at the conference.

DR. TONY FOUCHI: I'm not so sure it's going to have any impact on funding, because the funding will take place independent of the conferences. It's a peer reviewed issues that we always do. Certainly there are scientists who submitted abstracts here who in reality would have been here had the been a larger quoted number that are not presenting there work. I think that's unfortunate but that's the policy as it stands right now. Hopefully we'll make the best of it.

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With the money, the decision was made that the money would be spent better by just funding research. Again, I know that this is a big controversial issue and there's not much else I can say about it.

CRAIG MCCLURE: Second part of the question was to you.
[inaudible]

DR. LONGE: Which?

CRAIG MCCLURE: As co-chair of the conference what is your impression related to the reduced number of U.S. Government's funded scientists participation.

DR LONGE: Obviously some presentations had to be withdrawn. I don't think that the impact of the outcome on the conference is enormous but I think it is a real pity that we don't have more people from CDC, NAH and other institutions who are actually doing the work in the field to have them here. We need the U.S., the U.S. is the biggest player, as Mark Harrington said, the U.S. is the only country in this world that puts sufficient money into HIV/AIDS research. It's a real pity. We want the U.S. to present. At the same the time we need to realize that some of the things that happen at this conference are totally counter-productive, the shouting down of Secretary Thompson in Barcelona has done a lot of harm. What just happened in HOLA, where Hank McKenna who is the CEO of the largest pharma company in the world, is willing to stand on the podium and have a dialogue with people, was shouted down and

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insulted. I think that's not helping. I think we need to be realistic. We want the U.S. back but we need to work hard to get them back. Thank you.

CRAIG MCCLURE: Can I just say on that note that the IAS has released a freedom of expression statement last week. We feel at the IAS very strongly that all the voices need to be heard at this conference and that includes speakers as well as activists and other delegates.

We're going to have to close the press conference now, but thank you all for coming we'll see you all tomorrow at 11:00 again. Thank you.

[END RECORDING]