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XVII International AIDS Conference Universal ARV Scale Up: Delivering the Second Wave August 6, 2008

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CHARLES GILKS, PH.D.: This is a very big room and I would encourage you to come in a little bit closer so we do not feel too lonely up here. Okay? For those of you who are not quite sure where you are, this is Session Room 1. I think most people will know that by now and we are having a session here on Universal ARV Scale Up: Delivering the Second Wave. I will just introduce myself to you. I am one of the co-chairs and at the moment my fellow co-chair has not yet turned up, but when she does, we will allow her to introduce herself. My name is Charlie Gilks. I am from the World Health Organization where I am in charge of HIV treatment and care.

I will introduce each of the speakers as they come up and they are actually sitting in order of how they will be speaking. But before we start off, I would like to recognize Ian Weller who is sitting in the front row here, a person who is known to many of us because he is the one who has helped put this session together. So I would like to thank Ian for that. Thank you.

Okay, well without further ado, it is my enormous pleasure to introduce a very old friend and colleague, Peter. I have got a pretty dry biography of Peter which points out some of his achievements and some of his attributes. I think most people know him as the Director of the Joint Clinical Research Centre in Kampala and for the work he has done over the many years being one of the first sites and individuals in

Africa to scale up antiretroviral treatment. Peter is actually a pediatrician and he is a superb linguist as well, something he has not put down on his bio. He is also a Sunderland Football supporter for those of you who know anything about football. Okay, Peter, I have the pleasure of introducing you.

What we intend to do in this session is to allow the speakers 15 to 20 minutes to discuss their perspective on these issues looking forward to the second wave of ARV – ART scale up and then we will have 5 minutes or so, specific questions and clarification points on that individual speaker and then I hope that we will be able to have at the end some general discussions to go over and think about some of the general points that have been made that are common to the three speakers. Okay, thank you, Peter.

PETER MUGYENYI, M.D.: Thank you. Thank you, Charlie, for a very generous introduction and thank you, ladies and gentlemen, for coming to this session. I bring you greetings from Uganda and I am going to talk about the Ugandan situation. It would be very presumptuous of me to talk like I am a Ministry of Health official, but I will talk from the perspective of the organization that I work for, that is the Joint Clinical Research Centre. This organization is one of the many that are involved in the antiretroviral therapy program in Uganda. The Minister of Health is very much on the helm controlling all activities and the partners are very many and many of them doing a really wonderful job.

My organization, the Joint Clinical Research Centre was founded at the time of greatest crisis in Uganda. It was a country with the highest incidence and prevalence of HIV/AIDS way back in 1991 and this was a crisis measure which brought the Minister of Health, the university and Minister of Defense to pull their resources and to address the national crisis, having the Minister of Health in the leadership. My organization got a chance to be one of the biggest PEPFAR grantee and in fact, we are the biggest PEPFAR grantee in Uganda and our job was to scale up antiretroviral therapy and we have been doing it for the last five years. So today, I would like to share with you about some of our activities, very briefly so that you can begin to see how we stand in Uganda.

Our approach is not very much different from many other countries' approaches. We have used a series of approaches divided into sections like everybody at the beginning, we had a devastating emergency in our midst. The death toll was very high and the catastrophe was its height in Africa when we got a chance to start treating HIV/AIDS. We acted like it was an emergency and that was the appropriate thing to do and now, in the second phase, we are addressing the question of sustainability. HIV/AIDS is still with us and is going to be with us for a long time. So initially as I will demonstrate, we used the emergency measures. Infrastructure was always a constraint and we did low cost renovations and some improvisations as I will demonstrate.

One of the tools that we used in Uganda, particularly by my organization which innovated it, was a robust community mobilization program whereby it was not us that opened the centers for treatment of HIV, it was rather the communities that were empowered to do the opening and leadership in getting them initiated. We thought this was a best practice for introducing antiretroviral therapy to the community and it has worked most wonderfully. We think it has helped us in breaking stigma and in promoting community ownership of the program and above all, these occasions have been occasions for information, education and communication to the public and the feedbacks that we get from areas where we have opened numerous centers are extremely positive.

Of course in the developing countries, one of the biggest question that we face is going to a place and finding absolutely no infrastructure and yet people have got a need for antiretroviral therapy. And one such place was Mubende and this method we have used it all over and over again and it has helped us in scaling up antiretroviral therapy in our country. In such a situation, whether there is no infrastructure or not [misspelled?], we still started the program. All we do is to come with our tent, pitch it and then it is functional almost instantaneously and we start providing the treatment. It is not true that in Africa we are satisfied with this kind of infrastructures, but it is not excusable to refuse people treatment because the infrastructure does not exist. What you

need to do is start giving care and treatment while you are doing what we did and this place, this is now how it looks like in Mubende.

We have grumbled like many other countries with the question of human resource. There is critical shortage of skilled human resource in Uganda particularly to undertake advanced laboratory work and even other services like counseling and adherence work. And what we have done is to try and recruit as many staff as we could find, but these are not always available. And then another challenge is getting people to work in remote areas. And the way we have been working on this as we shall demonstrate is to try and make working in such conditions worthwhile for the staff.

The training of our people has been a very important tool to get the programs going. It would not be possible for us to get people trained and then start the programs. What we did, we started and continued to train as we went ahead and we used all kinds of methods of training while we worked. And many other countries that I have come to be associated with have been doing exactly the same thing. We have trained people in palliative care, in TB treatment, in laboratory testing, including advanced tests like viral load and CD4 and we have included also training of lay people including community volunteers to help medical care providers provide the extensive services that is necessary for countrywide antiretroviral

therapy. We have also had the generous support of some expats inside and outside our country.

So what have we achieved and where are we at the moment as an organization, Joint Clinical Research Centre? This is the kind of graph that has been replicated in virtually all Sub-Saharan Africa and ours has been no exception. As our organization alone, we have been able to start close to 70,000 people on antiretroviral therapy and we follow on continuous basis in excess of 30,000 people doing complete monitoring that includes CD4 and viral loads whenever required. And we have achieved stations in all parts of the country, currently 50 of them main stations and we have got 25 outreaches. These outreaches specifically target hard to reach areas and underserved communities. In addition, we have established one Center of Excellence in each region of the country. Each color represents where each Center of Excellence serves. They serve on referred [misspelled?] basis tests like CD4s, viral load and for viral load, PCR, we also do infant diagnosis. And these are some of the pictures of some simple but highly practical structures that we have set up in each region of the country that are coordinated in Kampala at the main headquarters and are serving in various capacities. As I have said, these centers are providing CD4 and viral load which are available in each region. They do not have to come to Kampala, the capital. Secondly, we are able to do infant diagnosis, DNA PCR in each of those regional centers of excellence and we have this

validated nationally and internationally and we have [inaudible] HIV and TB resistance facilities so that where necessary, these are referred to our central laboratories.

Of course, those are not what defines a successful national program. Other aspects are equally important. I consider adherence to be a vital program for treatment success and we have established a countrywide adherence network coordinated in Kampala having a manager in each region and each center has got an adherence officer who work closely with the community and who have developed a training syllabus for community support adherence program in our centers.

We also have had another program called Treat for Life which we launched and rolled out. This is an advocacy program, a program that mobilizes our population to come for treatment at the treatment centers, provide the information and is also largely run by a volunteer force and we have produced materials in appropriate languages for the community to use in their set ups.

Perhaps of particular importance has been the establishment of working logistic systems in all the 75 places where we work. We do not run out of drugs. We do not run out of laboratory agents and we have our equipment maintained properly and regularly. This is an example which we want to be adopted nationally so that we have got a robust national program that never runs short of these essential items. You can have an excellent adherence program. You can have whatever

you like, but it will not work if drugs are not delivered to the people in a timely manner, if laboratory agents are not delivered in good condition, and you can put there are many equipment as you like, but if they are not serviced regularly, they just gather dust. So these are some of the areas where we have been concentrating our energies to work and make sure that we have got a program that can give the service that can be relied upon. In addition, we have support supervision so that people keep strengthening each other. We get centers evaluating others to make sure that they strengthen each other and keep bringing up the standards.

So we come to the second wave. PEPFAR was approved. We have been dealing with an emergency. When does the emergency end? So in the second theme in my program and I believe my country is planned to move from crisis management to quality, sustainable, and integrated program into a national health system. Certainly without improvement in general or public health sector, the services that have been established, specifically for HIV/AIDS, are ultimately futile and cannot be sustained. So it is imperative that we have a theme in our second wave of making sure that we strengthen our national health systems. How do we do it? I think what needs to be done is very well understood by most of us. Our public sector facilities need to be rehabilitated and the facilities that have been set up for HIV/AIDS through PEPFAR, through Global Funds need to be shared. Because if you are doing microbiology

testing for HIV/AIDS, for instance to diagnose opportunistic infections, there is absolutely no reason why such facilities would not be availed to other patients who may not be HIV infected, but need care. Most of those are relatives of the HIV infected patients. It is the same community, it is the same family, and therefore, we need to share out [misspelled?] these facilities

So we need also to have new structures put at all levels. This includes laboratories. In Uganda, we plan to have CD4 and viral load done at every regional hospitals and high volume district hospitals. We plan to establish desk [misspelled?] laboratory services at health centers to include HIV testing, TB and malaria diagnosis.

We cannot achieve all of these unless we address manpower needs and in the second wave, we intend to do as much as possible and we need donor support and program support to make sure that the public sector workers, because these are neglected and yet they are critical for national health service and also for HIV service, that these people are supported. If we do not support them – in Uganda we have noticed a very worrying trend of internal brain drain. We have got all kinds of programs, donor programs which are doing a good job, but they take health care providers from other programs and you get confusion. You get internal brain drain. And you also get external brain drain. We cannot have a law like some African countries who are trying to inform one of the advanced

countries that could you please refuse to have Africans coming to your country. Well, you cannot have it that way because people will find ways of beating that system. The best system is to improve work conditions in our countries so that work there becomes attractive. We can negotiate other measures like compensation because our workers who go abroad do contribute something to those developing nations and we could do that as well, but the best we need to do is to make sure that we improve our work conditions so that we can retain our workers. We need strength in training including community volunteers and lay providers, support adherence and undertake low tech [misspelled?], but high demand services. We need also as I have said to give special incentives to health care providers to work in rural areas. There are certain rural areas the incentives most health care providers need are not very difficult to provide and we can do that and that would be absolutely essential in the next wave. So we need to take away clauses from Global Fund and PEPFAR which say we cannot support workers in the public sector. Without supporting them, we cannot succeed.

We also need to establish a robust logistic system for drugs and laboratory services to all levels and we need to aim at quality and sustainable services and these would depend on good adherence, counseling and strengthening of integrated services for better outcome not only for HIV, but for TB as well.

So in conclusion, the next wave for my country must harness the available HIV expertise, logistics and facilities to strengthen the existing health system for eventual integration. Integration would be the key for the future and this will be integration into an improved national general delivery of health care services. With continued support, my country, Uganda, I have absolutely no doubt we are ready for universal ART access. Thank you, ladies and gentlemen.

[Applause]

CHARLES GILKS, PH.D.: Well, thank you very much, Peter, for that inspiring tour de force of describing how you have built up, you and your colleagues, with immense support from PEPFAR and other partners, a very impressive ART service and for the reflections that you have made on what is going to need to sustain that as we move towards universal access.

I am going to call on people if they would like to ask Peter for comments or questions or make some comments in response to his excellent presentation to come, to find a microphone, please introduce yourself first and then ask the question and try and be succinct because I can see already there are several people who want to make a contribution.

FRANCOIS JENNESKENS: Yes. My name is Francois Jenneskens [misspelled?] from the Royal Tropical Institute in Amsterdam. Thank you very much for your interesting presentation and I would be interested to get a little bit a better idea of which exact strategies you used to improve

working conditions of the health care workers and especially those ones in the public sector and if there would be a disparity between the health workers working in the PEPFAR program versus the ones working in the public sector.

PETER MUGYENYI, M.D.: I think that is precisely the point. There is a discrepancy between PEPFAR programs, they are better paid, they are better facilitated, and therefore, we are getting a movement of people from the public sector to be better paid PEPFAR and Global Fund supported jobs. This is unacceptable. The way to go about it is to get a budget of PEPFAR, not to entirely pay for the salaries of those in public sectors, but improve condition within their work places. It is already happening in my program, I did not have time to go into that, and also to sort of top up [misspelled?] some of their allowances while they give some of these services, and then of course, we do not expect our country to have all salaries of public sector workers paid by donors. We need our countries to start dedicating more budget to health care providers which can be supplemented by donors, and together, we may be able to improve the health sector conditions.

CHARLES GILKS, PH.D.: Microphone on the right, please introduce yourself.

HENRY NAGAI: Thank you. My name is Henry Nagai [misspelled?]. I work for Family Health International in Ghana. Peter, you mentioned the fact that you encourage sharing of facilities. I would like to know whether you engage the

private sector in the sharing of these facilities and how you go about that, if you do so.

PETER MUGYENYI, M.D.: Yes, sharing of facilities is fairly straightforward and we have got some examples to demonstrate. You set up laboratories like these centers of excellence. In the second wave, these kind of laboratories will be in the district and in regional hospitals. Where they are, they should not be specific and exclusively for HIV/AIDS because without additional cost, the same kind of equipment could provide services for other clinical care providers, and incidentally, this is one of the ways of improving facilities for health care providers. If a clinician can have microbiological diagnosis, if a surgeon can have electrolytes, if a woman going to deliver can have HIV HB [misspelled?] done quickly, a good hemogram done quickly, all of these are incentives and conditions that would improve general health care and it does not really need to do much. It is a deliberate program of making sure that we utilize and share out these facilities that we develop.

CHARLES GILKS, PH.D.: Thank you. We have four more people who want to ask questions. If they can try and keep the questions quick and brief and Peter can answer them briefly. And try and speak clearly. We are now competing with the rain on the roof. Thank you.

DR. RIVARI: I am Dr. Rivari [misspelled?] from India. I have two quick questions from you. I compliment you for your

insight into what the second wave is going to be, but you said your CD4 and viral load facilities are available only at regional laboratories. How do the patients who are in the periphery, how do they access these testing facilities? Number one, and number two is about the second-line drugs, since we are talking of the second wave, what is the plan for roll out of second-line drugs?

PETER MUGYENYI, M.D.: Yes, the services that have been established are accessible to anybody, any patient. They do not need to be for specific patients. They can be Ministry of Health, they can be public sector that is patients attending private clinics, they are all welcome to access these facilities that have been established. What was the second bit?

FEMALE SPEAKER: Second-line drugs.

PETER MUGYENYI, M.D.: And the second-line drugs, we are providing them as well. Fortunately, most of our patients are naïve over the last five years. The second-line drugs are going to be very, very expensive. We have to have a robust program of adherence so that we minimize the need for second-line. They are much more expensive and when first-line drugs are used very, very well, we have got fewer people progressing to need second line. Currently, fortunately, we have enough drugs for our patients who need second-line drugs.

CHARLES GILKS, PH.D.: I am afraid we have to move on to the next speaker now. Thank you. Maybe we will have time for general discussion if you could keep your questions.

PETER MUGYENYI, M.D.: Thank you. Thanks very much.
[Interposing].

CHARLES GILKS, PH.D.: [Interposing] Thank you for your questions. [Applause] Can I just check the people in the hall can hear what the speaker is saying. We are finding it quite difficult hearing from the microphones from the floor, but are you able to hear us clearly in competition with the rain? Yes? Okay, well we will try and continue and hope it stops raining.

It is my pleasure now to introduce Sam Phiri who is another old friend and colleague to give a presentation from Malawi. Sam is a Malawian clinician with a special interest in care and operations research and he has been working for seven years in the Department of Medicine at Kamuzu Central Hospital, KCH in Lilongwe. He has recently earned his Ph.D. in clinical epidemiology at London school earlier this year and he is a founding member and Executive Director of the Lighthouse Trust. And I have had the pleasure of watching his career grow as the Lighthouse Trust has grown to be one of the largest, if not the largest ART providers in Malawi. So it is a great pleasure to introduce Sam and ask him to give his paper. Thank you, Sam.

SAM PHIRI, PH.D.: Thank you. It is really a great honor to be in this session and good afternoon. One thing which I should mention that it is a great honor is that to have

Chair to chair this session as you already mentioned that have seen me growing and as one of the role models including Peter. So I think presenting after Peter is just I think a good also flow within the presentation.

I will be presenting on the national scale up of Malawi. Looking at the many of the achievements and then through the achievements, looking at what the lessons have been learned, then what are the challenges which have to be looked at as we are looking into this second wave? Now this presentation is [inaudible] because of the great leadership of the HIV/AIDS unit within the Ministry of Health and working together with the partnership within the whole country of Malawi in order to make sure that the national scale up is working on [misspelled?] in a great success.

Now, Malawi decided to look at the treatment of ART, mainly looking at the WHO clinical criteria. Malawi started to provide antiretroviral therapy in 2003 [misspelled?] with support from the Global Fund. Now in 2003, there were only 4,000 patients who were started on ART and as of December 2007, over 150,000 were started on ART and over 100,000 are alive on treatment. So this is – it was seen as like an ambitious scale up plan and everybody was looking on what the achievements are going to be because Malawi is considered as one of the countries, and it is the country, which has a lot of crisis in terms of human resource.

When the National Scale Up Program was designed, targets were set in terms of how many people should be started on ART each year. And from 2005 to 2007, what we have seen is that Malawi has been surpassing its targets as we can see that in 2007, the target was surpassed by over 30,000 patients. So this was quite a successful understanding for the people to say that we will be able to deliver the program even with a lot of challenges. Now as I mentioned already, to look at the program, it is public sector along with the private sector. And when we have looked at this, we have looked at whereby in 2006 in terms of patients alive on treatment, we just missed the target by only 20 patients. But when we look at 2007, June and December, we actually surpassed our target in terms of the number of patients alive and on treatment. This was also another achievement.

One of the things which we have to look at when we are looking at delivering ART is that in terms of the challenges of the stock-outs or [misspelled?] one-third of our therapy and also to look at drugs for opportunistic infections. When the program was set as of December 2007, no facility had a stock-out of the first line regimen looking at the initiation and also the continuation. One of the things which we saw, 12 facilities had a complete stock of cotrimoxazole prophylactic therapy, CPT, Vincristine and morphine which are drugs to be used for the opportunistic infections, for example KS, and also for the prophylaxis for opportunistic infections. The target

was about 40, but there were about 12 facilities which are for complete stock. However, when we looked at facilities providing CPT of the package, the target was about 20, but as of that time 113 facilities were providing and this I am going to talk about later on when we look at challenges.

The new initiatives which have been put forward after learning from the first wave are that all patients looking at the lessons which have been learned internationally and also locally was that we were giving d4t, 30 and 40, but then it was decided that we should be able to provide d4t 30, stavudine 30 for all the patients regardless of their weight because there is actually less toxicity with the same efficacy and also as a program, it is easier for focusing the procurement and also looking at the expense.

One other thing we have been discussing task shifting is that instead of only physicians to start treatment on ART, we have now nurses who are initiating ART on top of the following up of the visits as they were doing starting from the program. And in order to monitor the program quite well, it was actually put forward to make sure that the public and private sector monitoring and evaluation is aligned so that we should be able to have a good grasp of the successful program within the country.

But as we are talking that patients now ever started over 150,000, the question is how do we manage these patients?

In sites whereby you have over 5,000, over 8,000 and using the

paper record system. So one other new initiative is look at the electronic data system which was [inaudible] in the northern [misspelled?] and the central region to make sure that all the [inaudible] sites should be able to use electronic data system in the monitoring.

Now I will just briefly look at the national data, looking in the public sector, in terms of the number of patients and also the outcomes. In terms of access, as of 2007 December, in the public sector, over 140,000 were started and a great proportion of them, 61 percent were women and about 8 percent were children. In terms of as I mentioned already that initiation of ART was based on clinical criteria, 65 percent of the patients were in Stage 3 and one thing which I need to mention over here is that we had about few patients who were started as clinical criteria being as TB because 70 percent of TB patients in Malawi are HIV positive. And TB is an eligibility for ART initiation. And having 14-percent being started because they are on TB treatment is a small proportion and also in terms of the number of patients started on ART amongst the PMTCT moms. So this is another area which I will address later on when we are looking about the future.

In terms of survival, we look at number of patients who are alive and on treatment and we still had about two-thirds of the patients being alive and on treatment and you can see that we have about 12-percent mortality and a default rate of 10-percent and those who have stopped treatment were less than 1-

percent. And then there are people who transfer from one center to the other were around 10-percent.

Now let me just look at the patients, the 12-percent who died. Just consistent to other countries, about 65-percent of the patients have died in the first three months. So the mortality is higher in the first three months and this is attributed to the late [misspelled?] health-seeking behavior within Malawi and this, as I mentioned already, is consistent with the data which has presented here and also which has been published.

Just quickly to mention that in terms of we do clinical monitoring, now 96-percent of the patients are still on first-line regimen and those who are on second-line are still less than 1-percent and this [inaudible] is because we look at the clinical monitoring in order to ascertain failure or in order to ascertain on who goes on second-line regimen.

Now after looking at that, as you can see that starting from 4,000 patients in 2003 to over 150,000 patients in 2007, now we are looking at what are the challenges which we have experienced throughout this program. Then as I am looking at the challenges I will be able to be looking at also what are the possible solutions which we have looked at. We have already mentioned that there were few patients who were started on ART and what has happened now in the country because previously only specialized centers were providing treatment for children. So pediatric care was actually realized and

recognized to be done on the other specialized center.

However, we actually decided to make sure that as a country, we should roll out pediatric care to all sites which are providing ART. So that we should increase the access of care of children to ART.

And one other component is to make sure that the diagnosis – we should be able to increase the uptake of care by the early infant diagnosis using PCR in most of the sites. The idea is to fall in line even with the WHO recommendation to make sure that these are put on treatment.

One other thing which I mentioned already, a challenge is few pregnant women who are put on ART and these are challenges in terms of how they are referred from the antenatal clinic to go the ART because of being probably different buildings or different sites. So one other solution to that is to make sure that in our effort, as we look into the future and currently, is to make sure that we improve the linkage between the PMTCT sites like the antenatal clinic and the ART sites to make sure that there is a physical linkage and also in terms of planning, there should be actually great linkage. And some of these for example one of the initiatives is the Martin Preuss Centre which is actually a center which the Lighthouse operates in collaboration with the Lilongwe district head office. This is actually purposefully built to link up patients from the PMTCT to the ART.

Another component as a challenge and as a solution to the PMTCT is to make sure that when we talk about CD4 count as the priority we would make sure that the pregnant moms would be able to access the CD4 count because the setting would increase actually the number of patients who would access treatment basing on this. From my experience from the Martin Preuss Centre, we saw that there was an additional 21-percent actually of patients who actually were not eligible according to the clinical criteria from the PMTCT, but they were eligible because of the CD4.

I mentioned already also coming to TB. There is an issue of TB and HIV co-infection and few patients from the TB are accessing ART. The set up in Malawi is that most of the sites which are providing TB treatment are manned by the people who are in the public health field, so while the ART is managed actually by the clinicians and nurses.

Now if you want to make sure that you harness the two, it means that when someone has a TB, when they are being treated for TB, then they should be able to move to the ART clinic and patients are lost in between. One of the solutions is to make sure that we have all the TB sites and the ART sites as should be aligned to make sure that they are providing the integrated management. And as I mentioned already about the Martin Preuss Centre is one of the purposefully built center in order to link up also TB and ART. And as a country, we are actually making sure that we are discussing put some efforts to

make sure that all sites which are providing TB should also be able to be providing antiretroviral therapy.

Moving further, we have already also noted that it is a high area of death rate amongst ART patients and as I mentioned the reason being because of the late health-seeking behavior. One of the things which we have to put in is to make sure that we should roll out the provision of CPT into all ART sites because previously as it was already mentioned in another session that we have not been doing pre-ART clinics because of the bearing [misspelled?] of the number of patients who come to the clinic. But we want to make sure that all the patients who are eligible starting from Stage 2 should be put on CPT which is going to actually improve their life. And also where CD4 count is available, then it should be able to be done which would actually like increase the number of patients to be started on ART.

The other component which is like a challenge is the high numbers of patients who are lost to follow-up. And over 10-percent being lost to follow-up, now the question is how do we make sure that these patients are coming back? And what we have to put in is to put in supportive active default tracing which we will be able to follow up these patients. In some of the studies which have been done in Malawi, we found out that about 50-percent of the patients who are recorded as lost to follow-up have actually died. And some of them are alive on treatment, but have moved to another center without a transfer.

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So when you are able to trace them, we would be able to ascertain if these actually are components. And so we should be able as a country to put up support for the default at tracing within this program.

And as I am moving actually to close is that skilled human resources are too few in Malawi and I do not need to emphasize more on that. So the issues of task shifting have been discussed in most sessions within here and the nurses as I mentioned already are able to initiate on top of also the follow-up of the patients. And also one of the things we have done is to make sure that the health care workers are treated on ART to make sure that they remain within the system and provide the service. One other thing which we have to mention is to make sure there are better conditions within the service to make sure that these health care workers are retrained within the system. And this is going to be critical for the second wave.

And finally, as I am looking at the number of patients exponentially increasing in all sites, the issue is there are other strategies on top of task shifting which are supposed to be used, one of which is being decentralization and we have seen a presentation for example this afternoon by [inaudible] district in Malawi with MSF to look at how effective it is to go further beyond the specialized centers to go to the health centers. And also to look at the role of the community in

terms of how they would be able to assist in treatment adherence.

So with actually these challenges and solutions what I can conclude is that the national scale up of ART is feasible in a developing country like Malawi at the same time it has challenges which are going to be available throughout the delivery, but the partnership of the Ministry of Health with other partners is critical also to make sure that you can actually work out the strategies together in order to make sure that you deliver in the second wave.

So in closing let me actually thank the head of the HIV Unit Dr. Kelita Kamoto, Professor Tony Harris and Mr. Simon Makombe for providing the leadership in the HIV/AIDS Department of the Ministry of Health to make sure that this program should be a success. And on top of that, for being open enough to other partners to make sure that they should work together. And funding for the program is from the Global Fund and [inaudible] Partners and the recipient of the Global Fund is the National AIDS Commission and also as I said for the collection of the drugs and collection of data is through with other stakeholders. And I should also thank the Fogarty International Center [inaudible] for actually bringing me over to Mexico to be able to present several accurate presentation. Thank you very much. [Applause]

CHARLES GILKS, PH.D.: Thank you, Sam, for a great and inspiring presentation to outline how one of the poorest

countries in the world with one of the most severe generalized epidemics has managed to produce some outstanding results. If people could come to the microphone and introduce themselves. I am just going to take Chairman's prerogative here and just make one very brief comment. Malawi does have some excellent and unusual data and one of the points with the 100,000 people or just under 100,000 people alive and on ART at the end of 2007 is to note that 2-percent of those are when they registered for ART call themselves health care workers. So there are 2,000 health care workers alive and on ART at the end of 2007 who would either had been too sick and incapacitated to work or already would be dead. So I think that is a very important contribution that ART and treatment services are making to the human resource is in health crisis in many parts of Africa. Okay, so over to Ronnie.

RONNIE ZACARIAH: Yup. Ronnie Zachariah [misspelled?] [inaudible], Brussels. Thanks, Sam, for an excellent presentation. I was just wondering, could you tell us if there are any national plans or strategies to increase the number of qualified health staff to cope with the second wave? Thank you.

SAM PHIRI, PH.D.: Okay, first thank you, Ronnie. Actually it is great to see you actually in this session after a long time without coming to Malawi.

There is indeed a plan whereby there is human resource strategy which is looking at to retain people who are in the

country and also to actually attract actually more people to go into training and also to make sure there should be a program whereby some other people who moved out from the public sector should be able to come back, so there is a clear national human resources strategy which looks out to make sure that we should have a lot of people to come back into the service and deliver the service including the ART.

CHARLES GILKS, PH.D.: Microphone on the right.

JAHED ISLAM: Hi. My name is Jahed Islam [misspelled?], International HIV Alliance, Ukraine. My question is you have made a very nice presentation and a very impressive scale up. Just to highlight maybe one or two main driver of this success if you could just point out, which was your main driver of the success? Like one or two examples, task shifting or something else what you consider the main - your driver of this success.

SAM PHIRI, PH.D.: Good, that is an excellent question. In terms of the driver of success, to begin with is that when we decided that we should be able to start the roll out, one, we decided to make it simple so one first [misspelled?] regimen for all the sites in the country and using the like public health approach. And the other one was also to look at the Ministry trying to embrace all the partners within the country from the inception of the design of the program throughout to make sure that we should share. For example, colleagues like MSF, Dignitas, The Lighthouse complex [misspelled?] and also

the other partners within the country. So these are the driving forces of making sure that the success is there.

BUKENI: Yes, thank you so much, Mr. Phiri, for your wonderful presentation. My name is Bukeni [misspelled?]. I am from New York State [misspelled?], but originally from the Congo. I used to work in the DRC demobilizing [misspelled?] child soldiers, among them girls. In 2004, I demobilized a girl who was 21 years old and she learned that she was HIV positive in 2006. I paid for her to have the HIV test. She just passed away on June 27, less than two months from now. Now as we are talking about delivering the second wave, that girl died. Since she learned she was HIV positive, she never got any ART. I tried my best, but I could not find any. That was in [inaudible]. My question – actually I have two questions. The first one is, that is just one example among millions, hundred others in Africa, and many other countries, so the questions, are do you think we can achieve a universal action since in some part of the world, people are still paying \$3 to get HIV test. And the second one, what do you think would these people who were left out in this first wave, do you think they will be included in the second wave? Thank you.

SAM PHIRI, PH.D.: Thank you. That is an incredible question. It is actually a general question and actually what I can answer is on the basis that it is great to have Charlie here from WHO and other partners around, but what I can say is that there is always a starting point and I have lots and lots

of stories which I can give before 2000 in Malawi and before 2004 in Malawi whereby patients had to contribute or there was not even – the drugs were not even available in the country. So my actual instinct is that there is always a starting point and some countries like Malawi and others have started and it is actually all the donors and partners who are available should be able actually to buy into and work with the governments. Also governments have to put in their own initiative on what they can contribute in order to deliver the second wave. So from my perspective of Malawi is that there is only a starting point. You could start and move forward as long as there is a government commitment, then you would be able to attract other supporters. When you have a successful program then actually other things will be falling into place in terms of supporting. So that is I think one thing which I can mention of it.

CHARLES GILKS, PH.D.: I will allow one more question, Dr. Rawari [misspelled?], nice and short please.

DR RAWARI: Thank you. Thank you, Mr. Phiri, very excellent presentation and analysis of data. We have something similar in India where 190,000 patients have been initiated on ART and 155,000 have continued. My comment was about the second-line regimen. You said less than 1-percent patients are requiring second line. I think in four years roll out that is an excellent thing because we have a failure rate of around 2.8-percent. The question, second, was about the deaths, you

said 65-percent of deaths in first three months. Have you analyzed it further in terms what are the reason, was it a low baseline CD4 count, late entry, or toxicity and not treating the [inaudible] because your regimen does not have provision for treating tuberculosis, you not mention you only one regimen [inaudible]. What could be the possible reasons for this early deaths, 65-percent deaths in three months?

SAM PHIRI, PH.D.: I think that what I can say that to begin with your first question is that as I already said that we actually ascertain failure using our clinical criteria. So of course because we do not do viral loads so if we are able – we will do clinical criteria and also immunology work [misspelled?] for only some of the patients who are able to have a CD4 count. So that is another reason. If we are doing like virology [misspelled?], actually this actually could go beyond actually less than 1-percent.

In terms of your second question which is the looking at what are the causes of death, I can talk about on like a subset of the patients which we look at. We cannot be able to say much on – we have not analyzed more on what are the main causes. However, the main causes which we have observed for example in our Lighthouse perspective which is one of the largest centers is that it is really undiagnosed TB is one of the causes. So the undiagnosed opportunistic infections and these patients are coming in late already as they are starting

– once we are stabilizing them, some of them actually are dying at this time.

DR RAWARI: Thank you.

CHARLES GILKS, PH.D.: Thank you very much, Sam.

[Applause]

SAM PHIRI, PH.D.: Thank you.

CHARLES GILKS, PH.D.: Okay, now we move on to our third speaker who is from the Ukraine and obviously a very different HIV epidemic. I have not had the pleasure to meet Andriy Klepikov before so I do not know what football team he supports. He will tell me later. But Dr. Klepikov is the Executive Director of the International HIV/AIDS Alliance in Ukraine which is the largest HIV/AIDS-focused organization in the country and in fact one of the largest in the Eurasian region. He has had managing portfolio of the two Global Fund AIDS programs in Ukraine. He is also a Chief of Party of the five-year project scaler of national response to HIV/AIDS through information and services with a delightful acronym of SUNRISE which is funded by USAID. In the past, he has worked as a Senior Program Manager International Health Studies in the New School for Social Research in New York. And he has currently participated at the Business Education Program International Masters in Practicing Management out of McGill. Okay, thank you.

DR. ANDRIY KLEPIKOV: I would like to thank the organizers for the opportunity to present the progress we made

in Ukraine over the last couple of years and to thank all the colleagues with whom I am working with on this program.

That is correct that situation in Ukraine is quite different from the situation in Malawi and Uganda. At the same time, this is the most problematic situation among all European countries. The prevalence rate is 1.63-percent among adult population, the highest in the region. Estimated number of HIV positive people is 440,000 people. At the same time, official statistics says a lower figure. It is over 130,000 officially registered HIV cases in Ukraine. In Ukraine, we have concentrated epidemic fueled by injecting drug use. At the same time, epidemic is slowly getting generalized, but most of the heterosexually attributed infections lean to drug use. So to affiliate it with drug users, so its sexual partners of injecting drug users.

If you look on the map of Ukraine, you may see that its diverse situation among different regions, but in South and Eastern part of Ukraine, this is the most problematic situation.

All these problems we are trying to address. With the help of international assistance, major response is provided through the fund and from the Global Fund to fight AIDS, tuberculosis and malaria. Ukraine was awarded two grants with overall budget over \$250 million. We have very unique situation because initially Round 1 grant was provided to the government mainly focusing on ARV treatment. At the same time,

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government failed to implement the program due to the problem in procurement and managing the grant. So at the beginning of 2004, it was a really crisis situation for the country. We nearly faced the situation of losing opportunity to change the situation in the country.

And starting from March 2004, NGO, nongovernmental organization HIV/AIDS Alliance was appointed as the steward of the grant to save the situation. So it was extremely challenging task for us actually to pick up a failed grant, failed program from the government, program focusing on ARV treatment and aimed to change the situation in the country.

Today, I am really happy and proud to say that due to the grant funding, we managed in broader partnership to achieve the major ARV scale up in the region.

137. What do you think this figure is about? It is about the patient on ARV by the time we started the grant by early 2004. With several hundred thousand of HIV infected people, only 137 patients just four years ago had access to governmentally-funded ARV treatment. Situation has looked differently today. So almost – actually over 9,000 people are on ARV today and mainly due to the support of the Global Fund grant, so over 63-percent, you see the right [misspelled?] column, it is the number of patients funded by the Global Fund.

We also influenced growing share of the governmentally funded patients through advocacy and lobbying for allocation bigger financial resources. If describe our partnership and

approach, as I mentioned it was extremely challenging task for NGO to manage nationally wide ARV treatment program roll out with no success previous background, so starting from scratch. Partnership was extremely important, so we agreed to partner with Ukrainian AIDS Center, its major governmental infrastructure for the treatment provision as well as having umbrella agreement with the Ministry of Health and our main partner [inaudible] NGOs is All-Ukrainian Network of People Living with HIV/AIDS.

Currently, all 27 regions are enrolled into ARV treatment and we were basing on detailed assessment of all the regions done in partnership with WHO and other partners including nongovernmental sector. Because we are NGO, so we were strictly following the guidelines and actually helped to adopt WHO guidelines on treatment and diagnostics, [inaudible] and TB diagnostics and STI guidelines as well.

Our model was based on multidisciplinary teams which includes social worker from NGO, medical doctor and nurse. As it was mentioned by my colleagues, human resource factor was very important, so we trained with the support of the WHO established knowledge cap [misspelled?] of 450 professionals.

From this chart you may see HIV treatment coverage. Its huge step forward was made over the last four years from 3-percent of coverage according to the need to 35-percent of coverage. 35 is still a low figure, but at the same time the right column shows estimated number of patients need the

treatment, but you know that it is very important to treat not an estimated percent, but the real person, so it is also a challenge to involve bigger numbers of marginalized groups, drug users, into the treatment programs. You may see the major progress made in comparison with 2004, 2005. I would like to draw your attention to the percentage of patients still alive after 12 months, after the initiation of treatment, so it is 89.9-percent by now and percentage of unsupervised discontinuation of treatment is 5.7-percent which exceeds our target.

This diagram I am especially proud of. Epidemic is growing everywhere, almost everywhere, so we almost everywhere see the diagrams going up and up which means more and more problems. In 2007, there was a turning point in number of HIV, a number sort [misspelled?] of AIDS cases registered in Ukraine. So this figure dropped from 4,723 patients to 4,573 patients. So it is relatively small figure, 150 patients, but at the same time we saved life of these people and HIV did not turn into the AIDS for them. At the same time we see stabilizing of AIDS mortality rate. It is still growing, but we see the slow down of this growth which also may be attributed to the ARV treatment mainly scaled up by the Global Fund support. I would like to say that in some regions when ARV treatment was initiated earlier and the appropriate scale, we already see the drop out in mortality rate, so we really hope that this tendency will be nationwide.

We also proud by the changes which are very important for our country, several of them I would like to list. Setting up implementation standards. It is very important that we are managing the program in appropriate way because we will be not managing this for ages, government will and should pick up this commitment in regard to the treatment of all patients, so one example is price reduction. When the grant was suspended, government procured some of the drugs with the price exceeding our price in 27 times. It is huge difference. It is like buying a piece of bread for \$100, so it is harder to imagine this difference. At the same time, year by year, prices are getting normalized and today almost, there is no big differences between prices government pays and Alliance pays for ARV drugs which is very, very positive tendency and guarantee for further sustainability.

Another very important change civil society organization brought is in plans and policy environments. Sometimes it is very difficult to change a policy for the government officials. For the NGO it is more easy to be critical about higher price, about nontransparent mechanics, about lack of funding from the national sources, so we even manage to reach the presidential level addressing these issues, not only addressing, but basically influencing some positive changes.

Crucial innovations, the most important is introduction of substitution treatment was initially was buprenorphine and

[inaudible] with methadone. It is very, very important for the country when according to the WHO estimation, 60,000 drug users required this treatment, substitution treatment. Another innovations, ARV treatment in prisons, rapid tests are so important addition to the ARV treatment provision.

Ensuring sustainability by strengthening national capacities and systems, as I mentioned we did not build a parallel system. We invested all resources even channel it through NGOs into the strengthening governmental system for the long-term support. We advocating for the setting appropriate targets for the government for the future five-year national strategy.

So key lessons from managing big national scale ARV treatment focused programs that NGOs are able to do this, are able not only to be involved, be in charge of the small part, but basically do it with the government, sharing ownership, jointly sorting out problems and sharing the responsibility for our future steps.

Addressing challenges, they are very important for us, nearest one is actually handing over all patients treated with Global Fund, grant fund to the government and it should happen really soon from October 2008, so we really aim to guarantee this to ensure governmental funding and proper procurement and even logistics in time.

Another challenge is decentralization of treatment, especially having in mind so ambitious treatment scale up plan.

It is very important to go beyond specialized infrastructure of the AIDS centers. We have some good pilots in several regions particularly in [inaudible] where treatment is also provided through the system of general medical service provision. So it is very important to do further decentralization of treatment provision and train medical professional, ensure appropriate planning, logistics and treatment monitoring mechanisms.

Another very, very big issue for us is integrating services for patients with HIV, TB and drug dependency, including establishment of special centers for comprehensive service provision for these patients. TB remains one of the biggest, if not the biggest issue associated with HIV/AIDS in Ukraine and it is not appropriately addressed yet.

Ensuring cost effective mechanics for the governmental procurement and adherence quality standards are very important tasks for us for the next months as well as in a long-term prospective.

Eliminating policy barriers for scaling up methadone by substitution, maintenance [misspelled?] and treatment remains a key task because epidemic is still fueled by injecting drug use and majority of adult HIV infected people, almost 70-percent are injecting drug users, so access for substitution therapy for majority of them means access to ARV treatment as well.

Further plans are very ambitious. In our new five-year strategy, government set very ambitious universal access ARV target as 80,000 patients by the end of 2013. To achieve these

very ambitious targets, all the issues listed before should be realized. Otherwise, it will remain unachieved. So, thank you so much and we will win the battle. No pasaran. [Applause]

CHARLES GILKS, PH.D.: Thank you very much for that equally inspiring presentation outlining the immense challenges that we are faced in Ukraine, particularly with the Global Fund, but how they have been overcome and how you are now looking forward with the lessons of that towards universal access.

We have time for a few speakers or comments from the floor if people would like to find a microphone. Please introduce yourself and try and keep the questions short. Thank you. Okay, over here, the first question.

WIZAL MUSTAFA: Thank you. My name is Wizal Mustafa [misspelled?] from Health Alliance International, might be confused by the organization, Sudan. I remain a bit skeptic when it comes to countries with lower HIV prevalence, probably Malawi I think it was at what, 12-percent and at Ukraine is 1.6-percent. How far should decentralization go and especially with an epidemic that is fueled by IV use? So that is – could you comment on that?

DR. ANDRIY KLEPIKOV: Yes, thank you for this question. We already facing difficulties, infrastructural difficulties because in the country we have only 35 AIDS centers, so further scale up is very difficult to continue just within the existing infrastructure. At the same time as I mentioned TB remains a

major issue, narcological clinics or drug treatment facilities again dealing with a number of HIV patients, so it is still infrastructural challenge for us to accommodate all the services in specialized institutions. So we are planning to continue treatment of course through the AIDS center so at least this is governmental structure, but at the same time to introduce ARV treatment or to create special centers for treatment of patients with these three problems, HIV, TB and drug use.

From the other side, pilots we conducted in one of the regions demonstrated its success. So some even general medical facilities after the appropriate training of the human resources are able to maintain quality treatment and monitoring of the patients. Another reason for this is easy access. Ukraine is relatively big, geographically big country, size of France, so it is easy access for the patients if treatment will be decentralized.

FRANCOIS JENNESKENS: My name is Francois Jenneskens from the Royal Tropical Institute in Amsterdam. I would like to understand a little bit better the population that you have in treatment now. What is the proportion of IV use as compared to general population? It seems that your scale up is a little bit slower than we see in the African countries, but on the other hand your adherence seems to be, and your people that you still have on treatment, much higher, while if you have an IVU population, I would think that it would be a very difficult

population to keep on treatment. So I would like a little bit more explanation on which specifics you have done and whether this is because you are an NGO that you have a better entry to reaching these hard to reach populations and if it is a good strategy to hand over the IVU population as well to the government or only your other population? It is a bit long question, but – [Laughter]

DR. ANDRIY KLEPIKOV: Yes, I will start with coverage. The situation is appalling as I mentioned that according to the governmentally registered system only 131,000 cases of HIV were registered and more than 30,000 of people positive [inaudible] already, so in reality medical system dealing with not estimated number of patients, but with real patients registered in the medical system and if you take this figure which is about 80,000 HIV positive people who stay alive, so more than 10-percent are on treatment which is a reasonable proportion. So in terms of the coverage, it is more or less reasonable in this situation.

In regard to the reaching the drug user population, it is still the problem and according to the code of all HIV positive people are registered, majority of people in treatment received HIV through injecting drug use so it is still the biggest group on ARV treatment. At the same time we understand that most of the hidden population, most of the populations who are not registered in AIDS center are injecting drug users so our recent interventions demonstrated that availability of

substitution treatment with methadone is actually gives access for injecting positive drug users to be on treatment as well so that is why we consider this linkage as crucially important for further scale up of AVR treatment in Ukraine.

CHARLES GILKS, PH.D.: Okay, thank you. Next question?

JAHED ISLAM: My name is Jahed Islam, International HIV Alliance, Ukraine. Actually, this is not a question, just two comments. First comment is follow up on what Andriy is saying about retaining 89-percent of patients on treatment it is because of NGOs together with the AIDS center has been working in the field, so therefore, they had number of collaboration between the NGOs and the health care institution. Due to that, they could follow up the patients together with the NGOs. So that is why it is the high number of retention rate in the treatment. And second one is about the previous question on – I just forgot, sorry. Anyway, thank you.

CHARLES GILKS, PH.D.: Final contribution or comment or question.

NAOKO ISHKAWA: Actually, this is a comment and a general comment for all the speakers. My name is Naoko Ishkawa [misspelled?] from International Medical Center of Japan and we are working in Zambia to bring the ART service down to health center through JICA project and I try to make the comment that the questions that we really need to answer now is are we really ready for the second wave of scale up? Because now the PITC is launched, we are expecting more and more people who

needs ARV and but actually, the existing ART site such as the central hospital, regional hospital, or district hospital is already overwhelmed and they cannot really accommodate more patients. So I think it is a time to bring the service to the health centers, but this is very challenging. And also, I think that some of our colleagues said that strengthening the public sector, the health system is very, very important. So the question and I just think that we need to ask as a donor, is that are we really strengthening the public sector of that country? Are we really supporting their government system, health system, or not? And just I try to give example of the other project in Zambia. We make the one team of the physicians or nurse or sometime the lab technician which we call that ART support team who goes to the selected health center like every two weeks and then they help the health center staff to provide care and treatment and then so after the health care centers, they start to be able to learn the [inaudible] by themselves. We withdraw and we move to another health centers, but also we found that this is quite challenging. So, as a conclusion, what I want to point out is that the second wave of scaling up is really tough one and we really need to be ready for it. Thank you very much.

CHARLES GILKS, PH.D.: Thank you for that intervention.

I would just point out that if we look at the global figures for treatment scale up, in the year 2006, there were about 800,000 people who newly started ART. In 2007, we saw just

under a million, 980,000 people newly starting ART. So globally there is no evidence that there is a slowing down of the numbers of people entering treatment programs and indeed the pace of entering programs appears to be continuing to accelerate. So I think it is a concern that we will not be able to sustain and deliver on the second wave, but we do not have any figure, any evidence of that at the global level.

I would like to thank all our three speakers. First of all a round of applause to Andriy. [Applause] And then I would like to wrap up this session and again thank you again for suggesting it and making it happen.

We have heard from three absolutely excellent and really quite inspiring presentations representing three very different ways in which scale up has been achieved in countries and some very interesting discussions of what the issues are for looking towards universal access. The first from Peter was from PEPFAR funded program that he is involved with in Uganda that really drove the national Ugandan ART program forward. The second from Malawi, [inaudible] Global Fund Program, which had the government as the principal recipient. And then the third from a different epidemic entirely from the generalized epidemic in Africa from the Ukraine which had a global fund resourced program, but it was managed by an NGO rather than government.

I think you will all be able to reflect on some of the similarities of the challenges that have been discussed and

presented and I would like to thank everybody in the audience for the points, comments, and questions that they have made. And also that we need to reflect on some of the specific challenges that are quite context specific either to the country, or the type of the epidemic that they have or indeed some of the funding mechanisms and the challenges that they have, present themselves. So, if we could all thank once again the speakers and I would also like to thank the audience for this excellent session. [Applause]

[END RECORDING]