

**International AIDS Society:
2nd IAS Conference on HIV Pathogenesis and Treatment
Forum – The Scaling-Up of Antiretroviral Therapy in
Developing Countries
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MALE VOICE: . . . and this is a forum, which mean we will have lot of discussion and we will start by two introduction talk and after each of the presenter, we will give a talk for ten minutes and after all this, all our communication, we will open the debates, and we will hope to have a very rich and very introduction -a very good debate from the floor. And the title of this session is "The Scaling-up of Antiretroviral Therapy in Developing Countries."

GIUSEPPE PANTALEO: Good morning. It's a pleasure to, to be here for, for this session and before we start, I would like to make an announcement. The community, the agent group asked me to inform everybody that tomorrow there will be a officially rally, officially demonstration to demand for more funds for the global fund and they inform that both information and the meeting points will be on Level Zero here at 10:00 AM. And we'd like to start asking Dr. Papa Salif So from the Dakar University to make this presentation about the issue, "The Scaling-up of Antiretroviral Therapy in Developing Countries". [Long Pause]

DR. PAPA SALIF SO: Thank you very much, Mr. Chairman. I would like to thank the, the scientific committee for giving me the opportunity to be one of the conveners for the forum and to give me also the fortune to visit, to visit Paris, this nice and beautiful city, as you put it [French audio]. I will during the next minutes make a summary on the update of the use of antiretroviral in countries with limited resources from pilot studies to public health

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realities, and I hope that during the debate we will have lot of contribution from the floor for the (unintelligible) this topic. We're all familiar with this figure showing at 1996 a significant reduction of the mortality and morbidity rates in HIV AIDS patients due to the impacts of the antiretroviral therapies in the developed worlds, but during this time in 1996, the man (unintelligible) to have access for antiretroviral drugs in countries with limited resources was the final (unintelligible) because of the high cost of the antiretroviral drugs during this time in developing countries. The second (unintelligible) was the lack of laboratory capacities for the evaluation of the CD4 cell count of the viral loads, and the third was a lack of - the lack of experience in the use of antiretroviral drugs in developing countries. And there is this question during these first years of using heart (misspelled?) in the North and the first question was in developing countries, is it possible to use antiretroviral drugs in the context of limited resources in terms of feasibility, in terms of effectiveness, in terms of very import-, importantly the sustainability of these antiretroviral drugs in, countries with limited resources. So the approach of 1997-1998 was first to go step by step and the first step was to contact the viral (misspelled?) study in the capital city and after evaluating the final study, making the second step will be the scaling up. So I'm not going to, to give you the different details, the different results that were obtained in the developed - in the different countries concerning the results obtained during this pilot

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study. I just want to summarize that we have learned a lot here from 1997 to 2003 actually. What we have learned is that first, it is possible to use the antiretroviral drugs in limited resource countries because of the chance the clinical efficacy and antiretroviral efficacy of the use of antiretroviral drug in limited resource countries. The adherence was good from 80 to 85 percent according to different results obtained in these African and foreign countries for our people understand how to use the drug and also the side effects can be managed. And also there is an extensive local expertise in the use of IV program (misspelled?) management in developing countries, but another thing we learned during this period was how important is the international collaboration between the North and the South helping developing countries to set up their IV program and we just want to acknowledge some of them. The INRS here in Paris, the Harvard (unintelligible) Institute (unintelligible) Access, WHO, UNSN, (unintelligible) all these institution has many developing countries to have access to the antiretroviral drug through very interesting collaboration. So where are we now? According to the UNGASS Declaration, three million patients must be on antiretroviral drugs by the year 2005, and actually currently in Africa, more national plans exist. That means three times as many as two years ago. For example, in sub-Saharan Africa 40 countries have a national HIV AIDS (unintelligible) planning including the use of the IVs. This was not a figure two years before at 1998 and the use of IV for treating the adult patients to pediatric patients for

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preventing mother to child transmission and for the positive exposure prophylactics. Where are we now? The financial resources are increasing from the global fund but we need more from the World Bank and we have also additional funding from the (unintelligible) Corporation Foundation, the Global Business Coalition and other donors. Today also lower drug prices have been achieved with significant reduction of the IV prices by the pharmaceutical companies was obtained. For example, the pre-therapy dropped from USD\$1,000 patients per month and per patient at 1998 to actually between 80 to 100 US dollars at the year 2003. So we are having more drugs with low prices in developed countries, in developing countries and also the generic manufacturers offer IV drug for developing countries. Today, also, alternative monitoring strategy was developed for the CD4 cell count evaluation. The developed method was evaluated by INRS in collaboration with some West African countries and these alternative measures come, is not expensive and these too (unintelligible) and help these African countries to make another strategy for the CD4 cell evaluation not using the (unintelligible) count. The (unintelligible) also is underway for the developing, for the evaluation. I just want to next slide to give you the update of the situation because it is my talk - what is now the situation - in terms of access to antiretroviral drugs in developing countries and you see and we are very happy because if you compare the situation at 1998 to actually 2003, the situation has dramatically turned into good way. In Uganda, actually 10,000

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patients are on HAART. In Thailand (misspelled?) 100,000 patients are on HAART and they've planned to treat 100 to -- 120 -- 120,000 patients by the year 2005. And what is very interest-, interestingly is out of new countries using drugs, that you have in Mali, '90 to '98, zero patients but actually they are treating several hundred patients on HAART. In Cameroon, 6,000 patients are actually on HAART. You also had during the opening ceremony from Dr. Marie Jos e that Burundi is actually treating 600 patients on HAART. Botswana, yesterday also we know from the plenarization (misspelled?) that they are treating something like 6,100 patients and in Benin also 600 patients. I think these numbers are very important because the situation was not the same if you compared to two years later. In Togo, also there are patients two years ago and now actually they are treating 450 patients. In Senegal actually they are treating 105 -- 1,500 patients and the goal is to reach at least 700 -- 7,000 patients by the year 2005. I think this, this number help us to know that the actually currently the situation has dramatically changes and according to the economic community of West African states, which has at least 15 or 16 West African countries the projection will be to, to put on HAART 400,000 patients by the year 2005. So if you want to make a summary of the update of the antiretroviral, the use of the antiretroviral drugs in developing countries we can say that actually the, there is not -- it's not only the classic countries using antiretroviral drugs such as Cote D'Ivoire, such as Uganda or Senegal, but actually we have a new emergence countries, which mean

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we have new countries having access to the antiretroviral drugs and we hope during the next IAS meeting all the results from all the different countries will be present, from Burkina Faso to Cameroon to Burundi to Nigeria. All these countries are actually using the antiretroviral drugs. Today also the scaling-up process is ongoing, political commitment is there, the mechanism for drug for treatment and regulatory (misspelled?) is underway and all possible entry points to the health system for access to the antiretroviral drugs are identified from the (unintelligible), from the city clinic, from the city's clinic and over from the VMCCT (misspelled?) project. All these entry points come over to our African patients to have access to the antiretroviral drug. And also the training of health care workers is under -- very in order to use, for the better use of the antiretroviral drugs in developing countries, and also the communities are mobilized in their scaling-up process. So where are we now? In the public approach, public health approach for getting many countries are now using standard first line IV's original (misspelled?) for their treatment program using two NSTI (misspelled?) with one non-NSTI (misspelled?) and the rationale for choosing this regimen was of course the low cost of the regimen, the low pew (misspelled?) counts, the side effect profile, and the availability of the regimen as a fixed dose combination. Where are we now actually in the progress of scaling-up the -- actually we have the simplified monitoring process, clinical monitoring, or minimal laboratory evaluations using the hemogram (misspelled?), the liver

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antiviral function and also the CD4 cell count evaluation using the automatic method procedure, dilated (misspelled?) and with of course is (unintelligible) something like two year status. And other countries also are proposing to use the laboratory tests only when problem presented during the IV treatment, like side effects or defective treatment failure. Where are we now actually? More African government offer (unintelligible) for the IV treatment and this strategy to subsidize treatment helps our patients to reduce their (unintelligible) participation. I just have here some example, but we have many of them, Cameroon, the maximum participation of the financial participation of the patient is actually something like 15 US dollar per month and per patient whereas there are four months for patient, in Mali, Senegal, Cote D'Ivoire, you know, people now have access to the antiretroviral drug and in many cases if they don't have a monthly salary, they don't have money, the access is free of charge. And in Brazil you will have both, you will hear later on from Paolo the unival (misspelled?) access is also ongoing. So the scaling-up of process also is ongoing in many countries in Cote D'Ivoire, the antiretroviral drugs are outside the capital city here in Abidjan you can find all the other drug in the North, in Bouake, Bondoukou, Yamoussoukro, which means the scaling-up process is really ongoing in this country. In Senegal also since 2002, we are in the process of decentralization of the IV and actually six regions out of the 11 regions have access to the antiretroviral drug, in (unintelligible) in Louga, in Thies, in the middle and in the south

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they have access to the antiretroviral drugs and we propose here in the Senegalese model the two inning (misspelled?) approach, which means a parallel system. An expert from the national, from the capital city we will only charge for one specific region helping them use the IV's in the, in their region. So I will finish by predicting the future. You know, in Africa we are using the shelf. In France we are using the shelf in order to predict the future and if you, if you lose this (unintelligible) according to the position, maybe you will be rich or maybe you will have lot of, you will have a good position during the next coming month. So we are using this to predict the future. Now what is the future for the use of IV's in limited resource countries? We hope during the next month you will have an increasing number of patients who will be on HAART. The global response is a comprehensive approach must be strengthened to reinforce the Catholic (misspelled?) effects between (unintelligible) and will be also more an international commitment which mean we need more money to fund all this access to antiretroviral drugs in developing countries, but many challenges remain and I'm happy to give the floor to my (unintelligible), Dr. Paulo Teixeira. I thank you for listening. [Applause] [Long Pause]

PAULO TEIXEIRA: Thank you very much, Dr. Salif. I'd like first to thank the organizers who very kindly invited me to attend as the co-chair of this symposium. As an opening remark, I would like to comment in brief about the challenges for access to antiretroviral therapy in resource constraining -- constraint settings with a

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perspective of an experience from developing country that has been able until now secure important results in the fight against AIDS. As you may know, Brazil has been the first developing country to have implemented a large scale ARV distribution program. Our results have prompted the international community to regard our response as an inspiration as a reference for what they've accomplished, that want to engage in effectively combating the disease. Nevertheless, it is important to point out that evolution of the Brazilian response to HIV and AIDS was strongly influenced by its broad political and sociological context, particularly the structure and role of its public health system. This response is, response is based on a concerted early government response, a strong -- and effective participation of the civil society, a multisectional mobilization, a balanced approach between prevention and treatment, and a systematic advocacy of human rights in all strategy and actions. Actually this public health system developed throughout the last decades in Brazil, has been consolidated as free and universal under the new Constitution in 1988. It had established as a cornerstone feature for our public making -- uh, I'm sorry, our public policy making, constant dialogue with communities and civil societies, especially as a means to enhance social control over governmental policies. The construction of this successful process was not an easy task. We experienced tough times given our limited capacity to match the challenge of the epidemic. This difficulty could have made us simply shy away, however, it has been considered as a challenge to be

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overcome through new and innovative solutions. Then the implementation of our program was done progressively and the improvement and expansion of actions occurred accordingly within our needs and as the problems emerged. I remember when the first governmental, governmental AIDS program in Brazil was launched 20 years ago in the state of San Paolo when only four AIDS cases had been reported around the country. Since that time Brazil has progressively incorporated their available knowledge and technology to enhance its response. Before the availability of antiretroviral drugs the government already provided treatment and chemoprophylaxis for AIDS-related opportunistic disease. In the early 90s in order to improve quality of life, the Brazilian Ministry of Health put in place a policy of free and universal access to antiretroviral therapy and continued to provide drugs for opportunistic infections. This effort was initiated with its distribution of zidovudine capsules in 1991, double nucleoside therapy not long after and by 1996, free and universal distribution of HAART was institutionalized including protease inhibitors whose distribution began at the end of the same year. In order to provide the necessary health structure to help support this policy, a network of more than 1,000 alternative care and HIV testing services was progressively established around the world. This network is spread on a regional and administrative basis according to the complexities associated with care services and needs with the aim of improved diagnosis and monitoring of HIV infection as well as diagnosis and medical observation of opportunistic diseases.

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However, it's important to say that the first alternative HIV care was created in mid 80's, exactly in '86 based on the experience of treatment of cancer patients and was very simple in his structure as we can see in the photo in this slide. And it's important to remember that there was not a clear consensus about this kind of initiative and it has made us to start with very, very short, amount of resources as you can see in this photo. That is the first big (unintelligible) now that has been created in Brazil. Today the infrastructure of this serves is highly variable, as a network that fits the loca/regional capacities and needs. We have sites with fully developed services as these highly complex HIV AIDS reference treatment center in Sao Paolo, but even in the slum areas in the same cities who have modest services with good quality of care as shown in this slide. To adequately monitor the patients, the Ministry of Health has also established a network of viral load and CD4 lymphocyte counting laboratories. However, the initial combined antiretroviral treatment in Brazil were, were prescribed without CD4 cell count, and their monitoring was based only on clinical parameters as established in the first ARV guidelines adopted by Brazil in 1995. After that moment, the CD4 cell count and viral load tests were incorporated in clinical routine practice and the networks were progressively expanded, reaching now approximately 80 sites around the country. Adherence to treatment is also an issue, a critical issue. Since the mid 90's, we have encouraged and funded projects jointly with government institutions and civil society aimed

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at bringing together self-help groups known as adherence groups as well as putting in motion other strategies to improve patient adherence to antiretroviral and other elements associated with treatment. Among 700 community projects currently enjoying technical support from the Brazilian STD/AIDS program, 14 of them are specifically designed to improve treatment adherence by people who are living with HIV and AIDS. However, even in situations where the results such as those reported in Brazil have not been yet achieved. These problems cannot be allowed to become an artificial barrier to increase access to antiretroviral drugs. Again, this should serve as a stimulus. Experiences and strategies such as those to be presented here can present by Dr. Salif, should, should be disseminated and brought to the attention of as many as possible and the principles underlying all of them should be used to adapt to responses to the realities which exist in different countries. They can be a powerful instrument to pave the way for quick scaling-up by leveraging political support and financial resources at the national level as the experiences that will be shown by some countries as Barbados, Zambia, Malawi and India as well as also ongoing in Brazilian ARV project in some resource-poor settings have demonstrated. An additional strategy has been referred by Dr. Salif to confront this problem greatly simplifying treatment regimens by means of combining two or more antiretroviral drug -- uh, and fixes doses contained in same capsule or tablet is urgently necessary. More recently, the increased availability in generic form has increased the number of

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options for policy makers struggling to meet this - the WHO's three million target by 2005. These fixed dose combinations are simpler to adhere and -- to adhere to and can lower costs, particularly in those places with scarce human and material resources. Presently, at least six antiretrovirals available in clinical practices can be taken as a single dose per day and a further eight are under research. This pharmacological precedent opens up a substantial opportunity for a more simplified approach to antiretroviral treatment, facilitating an adherence and minimizing risk of viral resistance. However, expanding and obtaining better adherence of antiretroviral treatment in poor countries through simplification of therapeutic regimes is only one part of the process. It would be necessary also to simplify the laboratory tests aimed at determining and monitoring treatment and its adverse effects. It is necessary to urgently validate simple and clinical laboratory criteria, generic laboratory tests, and new laboratory techniques that can be carried out simply and at low cost. A good example of this issue is hemoglobin colour system that is a simple, reliable and inexpensive tool developed and validated by WHO to screen for anemia in resource-poor settings for clinical and Public Health purposes even before the AIDS era. This method requires no specialization training, costs around two cents of the dollars, American dollars per test and could be a very practical tool to monitor the use, for example of AZT, containing schemes in places where a laboratory infrastructure does not exist. These are crucial issues since some of -- some of the researchers have raised the fears

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of potential risk of multi-resistance caused by the increased use of antiretroviral therapies in developing countries. I wish to take this opportunity to remind all that there are thousands of HIV positive people living in those countries with some purchasing power that are using self-medicated antiretrovirals without standardized rules for their application where drugs are being given in sub-optimal doses and where course of treatment are interrupted due to the reduce the lack of financial resources and where even monotherapy is known to be used still. The only way forward is to promote the development of an appropriate system of access to treatment, replacing an initially anarchic system with a program organized on technically sustainable lines. It is worth recalling that Brazil, as a developing country, offers us to have seen free antiretroviral treatment and clinical laboratory monitoring for over 130,000 AIDS patients. Finally, involvement of other health professionals in the community itself will be necessary for principally in countries where the supply of health professionals is seriously lagging. To solve the latter problem, robust training and inter-sectoral integration arrangements will be needed to set up adapting them to epidemiological and socio-cultural realities of different regions involved. Last year WHO and other institutions set an ambitious target for international community to have by the end of 2005 at least three million people under ARV treatment in developing countries. As we can see in this slides, if we take into account current and future ARV delivery programs we conclude at the present

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rate we will reach no more than a third of this goal and it means that we need to establish the scaling-up process urgently. It means also that for this additional two million people will have to mobilize more funds, more capacity-building projects, and more mobilization, mobilization at country level. For that matter, I would like to conclude with a few pieces of strategic recommendation that we are presenting to the new WHO administration important to, to inform that the director, Dr. Jay W. Lee (misspelled?) has taken this role as a reference for the new administration of WHO. Obviously, no one ignores that there are elements in this strategy that fall outside of the WHO's direct control and are therefore unpredictable. However, WHO can maximize its impact by adopting a three-fold strategy focusing on technical support for design and implementation for current projects, a strong advocacy on political, technical and financial issues. To fulfill the gap, I referred to the two million HIV people. And also direct implementation of the most recent project of sustainable ARV access to confirm the feasibility of the scale-up in resource constraints. It's important to note that this demonstration projects are not to prove that the treatment is feasible and effective. It's to show that the scale-up process is also feasible and can be done on and must be done in a very short, a very short time. Before finishing, I would like to impart also in consideration a point that has been mentioned as one new patient in many countries that adopted (unintelligible) initiatives access to ARV treatment and this question relates to the payment of drugs at

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country level. I understand and there are many formations (misspelled?) considering that even if you ask for very small money, many patients in the developing countries, particularly in Africa will not be able to be involved in this program and I understand that the local community have to start, has to start immediately a discussion to consider ARV (unintelligible) as an emergency and to include ARV as tuberculosis and malaria in the group of diseases that allows free of charge access for treatment. We are living an unprecedented human catastrophe which would be properly confronted only throughout, through international mobilization of the resources. Currently, as I said, it is still concentrated in the hands of few richest countries. We need a new Marshall Plan to upgrade the response to HIV and AIDS pandemic to the world's poorest parts. Overcoming barriers against increased access to antiretroviral treatment requires political will but not only of affected countries as it is universally emphasized but also of those that have the resources to make an impact in changing the situation. We have access to a mass of technological know-how and efficient strategy has been tried and tested. The moment to begin taking action has certainly arrived. Thank you very much. [Applause]

GIUSEPPE PANTALEO: Thank you, Paulo. Now we will have during the next coming minutes the experience from four countries from India, Zambia, Malawi and the Barbados and after the floor will be open for one hour discussion and contributions. For the first

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speaker here will be Dr. Kuzalee (misspelled?) from India and Doctor,
you have the floor. [Pause]

DOCTOR K: Thank you, chairperson. It is a pleasure to be here. What I'm going to do here is to give you information on the safety and immunological effectiveness of developing antiretroviral therapy (unintelligible) simplified fixed dose combinations amongst Indian patients. In India, still the national AIDS control programs doesn't provide antiretroviral therapy as part of this program though fortunately that is a moment (unintelligible) antiretroviral drugs and I think one of the important aspects of that program is going to be use of generic antiretroviral drugs. As we all are aware, India has taken a lead role as far as Indian companies are concerned in manufacturing of this drug generically and that has helped twofold. Improved access, accessibility and affordability of these drugs and possibly they are fixed dose combinations. Simplifying therapy has really helped in improving adherence in these patients. At the same time there has been questions about the quality of generic antiretroviral drugs, although data now increasingly shows that all the C (misspelled?) levels, chemical compositions particularly good manufacturing practices of these drugs is documented by the WHO essential drugs formally released. By equivalence (misspelled?) has also demonstrated like one of the abstracts at the last Largo meeting and safety, tolerability, and effectiveness in clinical practice of these combinations have also been documented in the previous (unintelligible) conferences. What we have done in this presentation

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here today is to give you extended follow-up data among larger number of patients trying to address this issue. For our objectives in this study is to analyze the incidence and risk factors for short-term adverse (unintelligible) to nevirapine in patients taking fixed dose combinations of (unintelligible) HAART and to assess the clinical and immunologic effectiveness of this regimen. As I mentioned before, this is an extended follow-up data we presented at the (unintelligible) two years ago. This is a prospective of the (unintelligible) study and it has been carried out in entirely in the private sector at two settings. One is the department of HIV medicine (unintelligible) where I worked. Another is the (unintelligible) clinic of Dr. Patel in (unintelligible). We have pooled data from both the centers to look at this issue. Patients paid for their own drugs and their investigations, so there was no support for these patients as far as financial concern. We followed up patients monthly clinically and we defined an immune reconstitution disorder as occurrence of an opportunistic infection within two to twelve weeks of initiation of therapy within documented increase in CD4 count in three months. The estimated CD4 count three to six monthly based on affordability of the patient's (unintelligible) and we did access better toxicity by doing routine function test at one month and as indicated based on symptoms of better toxicity. For us adverse events classified into three main groups, gastrointestinal, adverse events based on nausea, vomiting, we defined severe hepatitis as symptomatic or a symptomatic elevation

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of liver enzymes more than five times upper limit normal. We defined serious skin rash as presence of Steven Johnson syndrome or toxic (unintelligible), a presence of systemic symptoms concomitant with skin rash. And this was judged by the investigators to be definitely probably or possibility related to nevirapine. As far as the drugs we used, we used nevirapine based HAART and we had two bad bone (unintelligible) before efficacy (unintelligible). We used nevirapine in leading dose. As was mentioned before, there was fixed dose combinations of these drugs developed as efficacy (unintelligible). Even at one b.i.d. only as a very simplified dosing regimen and the cost is little expensive for, its activity reflects in the total number of patients taking (unintelligible) efficacy. There are more patients taking (unintelligible) efficacy because of cheaper availability of this regimen. (unintelligible) adherence by self-report and we defined loss of follow-up as failure to come back for follow-up more than six months. We analyzed the data for adverse events by documenting the frequency of the three major adverse events that I described previously. We tried to assess the risk factors for development of high risk events by a logistic regression model using age/gender concomitantly (unintelligible) CD4 count as predictable variables. We assessed immunologic effect-, effectiveness by doing a (unintelligible) test at 12 months and 24 months of follow-up and we assessed backbone difference, backbone nucleoside difference (unintelligible) test at one year. We assessed clinical effectiveness by documenting and calculating the incidence

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of clinical events (unintelligible) follow up and the use of descriptive statistics to find out what (unintelligible) clinical events were. And all, all analysis that I have that I'm describing here is on treatment analysis. So this is a flow of what else happened over the last two, two and a half years of starting treatment. We have 994 patients who completed at least one month of follow-up. Of these patients, 726 completed three months of follow-up and at (unintelligible) viral level, at least (unintelligible) data. For the three patients who had lost in the initial therapy to follow-up (unintelligible) discontinuation due to serious adverse reaction or death, of the patients who completed three months there is an ongoing follow-up 611 patients and we have had 115 who either were lost to follow-up or discontinued due to adverse events here predominantly (unintelligible) due to (unintelligible) and either clinical immunological progression warranting switch of antiretroviral (unintelligible) to a different regimen. This is baseline characteristics of our patients. As you see here what is important to realize is that 80% of the patients accessing antiretroviral therapy are male. There's a huge gender disparity as well as antiretroviral therapy access is concerned. At the same time, the median 3D4-cell at initiation is around 101, the 111 that is quite low, and almost 82 percent of our patients at initiation had a CD4 less than 200. When we tried to document the sequence of adverse events in nevirapine predominately operating within the first four to twelve weeks of the initiation of therapy. (Unintelligible)

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from the major group almost 16.6% of our patients developed GI disturbances but usually self-limiting or we could treat too this GI disturbances by using symptomatic treatments and there was no discontinuation of therapy because of GI disturbances. Of the skin rash, we had seven percent patients presenting to us with skin, skin rash and of which ten there was severe skin rash and nine (unintelligible) and one person died because of toxic (unintelligible), actually making it only one person of the total population that experienced this adverse events. Severe hepatitis was documented in 3.3% of patients and none of the patients died because of hepatic failures. In the (unintelligible) the risk factor for adverse events based on the logistic progression model, gender was the only factor, which was significant here associated with the development of this factor. Females had two times more risk of developing an adverse event than males, but if you see surprisingly we didn't see concomitantly (unintelligible) adverse event in neither cohort, which we really cannot explain. There is a large amount of perception that (unintelligible) concomitant (unintelligible) increases that is (unintelligible) events to either. This is immunological effectiveness of other patients on therapy. As you see here from a median CD4 mean CD4 count of 120, it increased to more than 250 by 12 months and increased to around 350 by 24 months. Then we tried to stratify based on the backbone nucleocides, we find there is not much difference between efficacy of using either (unintelligible) between these two backbone nucleocides, probably

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making us choose one of these nucleosides based on toxicity profile and cost rather than efficacy. Of course, the limitation of this is the disproportionate number of patients being on (unintelligible) rather than the AZT. When we analyzed clinical events on antiretroviral therapy including follow-up, we had 29 left occurring out of which 23 were definitely associated with the HIV infection. We had 580 person years of follow-up, making this incidence of around 5.2% per 100 person years of follow-up. Overall we had 154 different clinical events, making it around 28.1 per 100 person years of follow-up. As, it's very, very important to understand that 66.6% of these clinical events were actually (unintelligible) constitution (unintelligible). When we tried to (unintelligible) out the latest clinical events, we still find DV as the commonest opportunistic infection occurring in individual antiretroviral therapy. And this predominantly occurs within the first 12 weeks of initiation of therapy as an immune reconstitution (unintelligible). We had Herpes Zoster bacterial infections, crypto meningitis, oral candidiasis, nimosistes (misspelled?). We are seeing increasing number of patients coming to us with non-Hodgkins lymphoma probably because of a reflection of longer survival on antiretroviral therapy. As far as (unintelligible), patients who showed improved, improvement in their immunological CD4 count has reported better than 95% adherence and this was probably because of simplification of the regimen that we were providing, intensive counseling sessions, reinforcing adherence during every follow-up visit that we had and third, probably because

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patients are paying for their own medications. So many patients have told us that they take medications because they pay for it. So in final conclusion, nevirapine based on antiretroviral therapy is safe and very tolerated amongst Indian patients. The fixed dose formulation of generic antiretroviral drug shows significant and immunologic and clinical benefit. Adherence to antiretroviral therapy is good amongst these patients, maybe one of the reasons is the simplified fixed dose combination but very more important is careful clinical evaluation for TB. It is very, very important even in individuals on antiretroviral therapy because of the risk, high risk of development of human reconstitution tuberculosis. In summary, if we really want to put these two regimens in the context of a first line regimen, criteria's for first line regimen, I don't think it will fail on effectiveness, durability, cost, convenience, and adverse events definitely outweigh the benefits. There is a problem about future options not primarily because of resistance problems but probably because of the second line therapy being more costlier and unaffordable to many of our patients, even the generically manufactured. And finally, I think one of the negative points would be drug-drug interactions. The value would not become (unintelligible) concomitantly with nevirapine. WHO recommends using it, we still find there is not enough evidence to (unintelligible) and safety use of, them together. Finally, I would conclude by just mentioning to you limitations of the study. This is just an observation of cohort study, non-randomized really. We didn't do a

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routine Hepatitis B and C virus profiles in all of our patients, so we did it when patients developed hepatitis. We didn't do viral (unintelligible) beyond question of many of our patients cannot afford this. And finally we are not documented and discuss (unintelligible) related toxicity. Basically because many of these patients who develop time related toxicity are switched to the other (unintelligible), would not really effect the clinical and immunological effectiveness. And thank you for your attention.

[Applause]

GIUSEPPE PANTALEO: Thank you very much, Dr. K?

(misspelled?). Now we are moving from India to Zambia and it's my pleasure to call the Dr. Shutes to take the floor.

Dr. Shutes: Good morning. I'd like to thank the chairs and the International AIDS Societies for giving me the opportunities to present, "What happens when a research project closes. HIV incidence, mortality and perceptions in a couple's cohort in Musaka (misspelled?) Zambia. The unscheduled six-month closure of our HIV cohort study allowed us to look at the impact as a project closure on our research participants. We believe that these findings should be considered in the planning and funding stages of future long-term research, cohort research. When research projects provide primary healthcare to study participants, mechanisms and funding should be in place when the study is finished to help transition those participants back to local standards of care. The Rolanda (misspelled?) Zambia HIV research group, under the leadership of Dr.

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Susan Allen, conducts primarily couples-based HIV research in two African capitals. This study was done in Musaka (misspelled?) Zambia in collaboration with Dr. Sinkala (misspelled?) Zulu (misspelled?) Konchaya (misspelled?) Chambla (misspelled?) and Howitz (misspelled?). Our U.S. based collaborators in this project, who are Dr. Clark, Ms. Misenger (misspelled?), and Ms. Brill (misspelled?). Our discussion would like to recognize Dr. Susan Allen from the University of Alabama at Birmingham who has recruited and followed this cohort since 1994. I would also like to thank all of our collaborators, interns, staff and research participants at the Zambia UAB HIV research project. Couples voluntary HIV counseling and testing or CVCT was established in 1994 in order to screen married couples for enrollment into perspective follow-up studies of heterosexual transmission of HIV. Between 1995 and 1998, over 10,000 couples were tested, counseled and tested for HIV together. A double rapid testing algorithm was used to facilitate same-day HIV results and over 90 percent of the couples who tested received their results the same day. Discordant couples, couples in which one partner is HIV positive and the other partner is HIV negative, were offered enrollment into the follow-up study. Enrolled couples were followed quarterly but were to report to the clinic anytime for medical treatment. Studies of this included syphilis screening, HIV screenings with the negative partner, medical exams, counseling, and individual interviews, free condoms and prescriptions filled by the study pharmacy. The Musaka district health schemes who provided for

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local after hours and emergency medical coverage. Some study subjects were referred to the hospital when necessary and followed up. As a result of funding delays the study was closed from December 1998 until mid-June of 1999. After the reopening study participants returned to study visits between June 1999 and January of 2000 and have followed data available until April of 2002. We compared the demographic data from couples that returned to the study to those couples that did not return. Incidence rates of HIV and syphilis calculated before and during the closure and mortality incidence among the originally HIV positive partners are presented. Finally, 531 returning individuals completed a questionnaire to assess the proceeds impact of the closure and to solicit deductions in case of a future project closure. Seventy-five percent of couples or 473 out of 626 couples returned to the study. Demographic variables included marital status, whether common-law or civil, years cohabitating, male and female age, number of children, male and female literacy, and income, and were similar in returned and non-returned couples. The only significant difference was that the mean monthly male income was approximately six U.S. dollars higher among those couples that returned. We were interested in the HIV incidence in the cohort without the quarterly follow-up visits that reinforced counseling and provide free condoms. Before the closure from February 1995 to December of 1998, there were 100 -- 107 smears converted, meaning that originally HIV negative partner became infected. Both the male to female transmission and the female to male transmission of HIV was

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9.1 -- 9.3 per 100 person years of follow-up. During the closure from December of 1998 until the first returns of the dates, there were 26 smears converters. The overall incidence rate was 8.6 per 100 person years of follow-up. More importantly, the HIV smears conversion rates before the closure and during the closure were not significantly different. For more information about the calculation of smear conversion rates, please see Evansville's abstract 11:30. Syphilis incidence was also compared before and during the closure. Before the closure the incidence rate for the entire cohort was 3.3 per 100 person years. During the closure, the incidence rate for cohort was 2.2 per 100 person years. The syphilis incidence rate before and during the closure were not significantly different. Mortality rates were calculated for the HIV positive spouse and are presented in this table by gender and combined for before, during and after the closure. The combined mortality as seen here in yellow nearly doubled from 6.7 before the closure to 12.4 during the closure. The decreased rate of 7.5 through April of 2002 demonstrated this finding is not a result of an HV-, HIV positive cohort. Although the change is most notable in HIV positive men, the increased mortality seen during the closure is significant for the entire cohort. Five hundred and thirty one individual questionnaire responses were used to determine the perceived impact of the project closures on the study participants. Eighty four percent of respondents reported that the closure had a negative impact on them, and of those 87% rated loss of health care as the most negative

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consequence. When asked about condom use during the project closure, 82% of respondents reported that they had enough condoms from the project or that they had found sources of free or subsidized condoms. This supports the unchanged incidence rates of HIV and syphilis and is an encouraging finding for the long-term effectiveness of the counseling and testing intervention. Many research projects provide services to study participants including healthcare, counseling and condoms. Research clinics have more resources than government clinics and the standard of care is often better. Study participants come to depend on these services, but research projects are not designed to last indefinitely. When our research project closed, most discordant couples maintained regular condom use without continuous follow-up and there were no increases in HIV or syphilis incidence. However, mortality incidence was significantly increased during the project closure compared with before and after. The majority of participants rated the loss of healthcare as the primary negative consequence of the project closure. Based on our experience, we have these recommendations for cohort research planning and funding for project closures. Recognizing the negative impact on the study participants, it is the responsibility of researchers to identify funding of potential local resources and services for participant referrals when they lose project healthcare benefits. It would be beneficial to conduct study exit counseling sessions to provide referrals to participants where possible. Our questionnaire respondents asked if there was a second district health

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insurance schemes be purchased for an additional year beyond the end of the project. This request was a reasonable suggestion to conditions back to local standard care (background voice) requires financial planning for funding to be available at the end of the study. The, the Zambia Rwanda HIV research group has several abstracts, poster abstracts that will go more into depth about our studies and these are listed on the slide. (Applause)

GUISEPPE PANTALEO: And I would like to call Dr. Durier from Medecins sans Frontieres France that will present experience on Malawi treatment of HIV disease with highly active antiretroviral therapy in, in the Shirad-Zaloo district Malawi. Please, Doctor.

DOCTOR DURIER: Good morning, ladies and gentlemen. It's a great pleasure for us to be able to present to you today the project of highly active antiretroviral therapy implemented in the Shirad-Zaloo district of Malawi in collaboration between the Ministry of Health, and population of Malawi, and Medecins sans Frontieres. As you all know, six million individuals in the developing world should be on HAART today. Instead, around only 300,000 are getting it. In this context Medecins sans Frontieres, the international non-profit AID organization is implementing models of life-saving HAART to 14 low-income countries. The Shirad-Zaloo project is one of them. Malawi, located in the southern part of the continent is among the first countries in Africa. Around 235,000 people live in the Shirad-Zaloo district. There is in Shirad-Zaloo, one district hospital, one missionary hospital and ten health centers. Healthcare is free, but

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in district hospital with 150% bed occupancy, 50% of the positions of clinical officers and nurses are vacant. In 2002, at the antenatal clinic of the district hospital, 21.7% of the women who were tested in the HIV test, were found to be HIV positive, leaving the estimation that 25,000 persons might be infected with HIV in the district, of whom 5,000 probably need HAART right now. This HIV collaborative project started with a continental information, education, and communication in the community and the voluntary counseling and testing service in the district hospital. We then opened an HIV clinic in the district hospital and the ten health centers of the district, followed an (unintelligible)-based program of prevention of mother-to-child transmissions in the district hospital. It was in August 2001 that we started to offer free highly active antiretroviral therapy at the HIV clinic of the district hospital and finally extended all services including HAART in the ten health centers and the missionary hospital early this year. Inclusion on HAART has so far been conditioned by CD4 count measurement, priority going to patients with an advanced condition. Eligibility was given to any patient with CD4 below 200, patients with AIDS and CD4 below 350, and for almost a year now children with CD4 below 15%, as well as pregnant women with CD4 below 350 are also eligible for HAART. The baseline laboratory assessment includes also (unintelligible) count and liver function test. Before starting treatment, all patients or guardians receive a minimum of two sessions of adherence counseling. Our first (unintelligible) regimen

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was initially made of ADC 3DC plus nevirapine (misspelled?), and consists now of the generic single tablet combination of the G43 and nevirapine. And, in case of treatment failure, patients would receive a second line treatment made of two new NRPI, plus (unintelligible). The follow-up consists of usually monthly visits, hemoglobin full blood counts and liver function tests are requested when clinically indicated, plus systematically every six months. Patients undergo very regular sessions of adherence counseling, control of CD4, which was initially performed every six months is now performed every 12 months. And finally, (unintelligible) no viral load was used in the patients follow-up. If we look at the essential required inputs, our first plan regimen costs to 23.5 US dollars per patient and per month. One CD4 count costs six US dollars and in terms of human resources, each HIV clinic, whether taking place daily in the district hospital, or fortnightly in each health center, requires the presence of two clinicians, one nurse, and one counselor, and it's important to precise that many clinical officers, not medical doctors, many clinical officers from MSF as well as the Ministry of Health perform the clinical work. And finally one laboratory technician is also full-time involved in this process.

We now come to the main results. First of all, the bars on this graph show you the number of patients seen month by month at the HIV clinics with the dark blue part responding to the new patients. As you can see, the activity has increased quite dramatically in two years. Just last month, in June 2003, we saw a total of 1,600

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patients and performed 2,000 consultations. This graph presents you now the movement of HAART month by month. The orange bar responds to the cumulative annulment (misspelled?) and the blue part specifies the monthly inclusion. As you can see again, our capacity of monthly inclusion has progressively increased. In the last two months, mainly because of the decentralization process of the health center, we have enrolled 100 new patients a month on HAART and up to now a total of 837 patients have started HAART, including 60 children and 50 pregnant women. The majority of the patients started on treatment are females. The median age is 34 years for adults and five years for children. Fifty percent of the patients have a baseline W2 stage 3 HIV disease, 35 percent had an AIDS-defining condition, and median baseline CD4 is 106 cells per ml in adults and 9.5 percent in children. At present, 11.7 percent of the patients started on HAART had passed away. Only 2.6 percent allow us to follow up. Only three patients have had their therapy interrupted for either non (misspelled?) or (unintelligible) compliance. And so 85.3 percent of these 837 patients are still on HAART doing good for the majority. Looking at the, an objective marker of treatment benefit, you have here average adult CD4 count change at respectively 6, 12, and 18 months of the treatment initiation. If, at 18 months, the CD4 gain is slightly lower than at 12 months, you can see that the number of patients with (unintelligible) variable is very small and overall the immunological recovery is definitely adequate. In terms of adherence to ARV, at the last visit, 94.3 percent of the patients with an

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assessment available had an adherence by peak count (misspelled?) superior to 90 percent. Regarding side effects, five percent of the patients who started an ATT counting regimen (misspelled?) experienced (unintelligible) anemia. It's actually one of the reasons why we changed AZT for D40 in our first line treatment. (Unintelligible) liver toxicity with nevirapine has been infrequent, occurring in respectively 1.1 and 0.4 percent of the patients. Although these two figures underestimate to some extent the reality, the liver toxicity events, for example, having been infected after clinical suspicion (misspelled?). These are some of the lessons we learned. We believe that these results are showing the excellent outcomes of what we can call already large scale HAART in the most underprivileged city, whose provision of quality care, eloquent patient education and free treatment. Adherence to care and education in these patients is obviously excellent. The clinical and immunological benefits are obvious too. As part of the scaling-up process, we have recently started and we plan to routinely offer HAART to patients with an advanced condition without the use of any laboratory tests, including CD4. We plan to shortly train all nurses and medical assistants of the health center to allow them to take part in the follow-up process and we're finally, very enthusiastic to know that the global fund support international health program (misspelled?) is to start shortly, and we are pleased that our experience has been (unintelligible) examined in this process. To conclude, there is no doubt that expertise as well as some key

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measures of success have been gained in this challenging field of providing HAART in resource-constrained areas. The resources needed to make this life-saving treatment available for the millions of people in need of it can simply no longer be denied. I'd like to finish with some acknowledgements. For the Ministry of Health and Population at the National AIDS Commission of Malawi. For the healthcare workers of the Chirad-Zaloo district, for all the Medecins sans Frontieres staff involved in this process, importantly for the private donors of MSF who make our work possible. And I'd like to have a particular thought for the people living with HIV and AIDS in the Chirad-Zaloo district. Thank you very much. (Applause)

GUISEPPE PANTALEO: Thank you, Dr. Durier, and the last speaker will be Dr. Adomakoh from Barbados to tell us about a project funded by West India's University in Barbados Ministry of Health, cost implications of providing (unintelligible) HAART in needling (unintelligible) in Barbados. Please. (Long Pause)

DR. ADOMAKOH: Good morning, everyone. It's a pleasure to be here today. This is the first year that a team of us have come to present internationally HIV program following the scaling-up, which has commenced the beginning of 2002. There have been many landmarks in the roads to develop an effective and potent response to the HIV epidemic in Barbados, but many would consider the most basically the most defining moment to be the declaration of political commitment and leadership to tackling this epidemic by the Prime Minister. He made this declaration at the regional conference for HIV in September

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2002. Following this commitment and in partnership with the World Bank, Barbados, Barbados followed on to fully scale up this program, which included reaccess and accelerated access to HAART. The key features of, of the HAART program were essentially the scaling-up of the laboratory testing and monitoring services and of the division of HAART, to get HAART treatment, which included counseling, social work adherence monitoring and along with a number of other services which are still in the process of being scaled up, which was the increasing of the, and accepting of this STI testing and prevention at the satellite site, voluntary testing and counseling, prevention of mother-to-child treatment, which already exists in Barbados since 1995 and is soon to be extremely effective, one of the most effective in the region. We also have scaling-up of surveillance of monitoring operational research. Before I go on to objective, Barbados is essentially a middle income country with a population of 267,000. We have an H, HIV prevalence, which has moved from 1.4 percent in '95 to just under two percent, 1.9 percent last year. The objectives of the study are to describe the resource utilization patterns by the person with HIV AIDS before and after implementation of the HAART program last year, to estimate the direct and net cost of HIV care among these patients, and also to highlight and discuss the feature resource requirements and sustainability issues with regards to procurement of HAART. The approach reused a combination of computerized data retrieval and manual data retrieval. We looked at the medical, the detailed medical records as you're looking up

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patient by patient. We also took data from our baseline study of the HIV AIDS cost and social service utilization study, a 690 item questionnaire. We looked at the clinic log books. We also observed manual financial records and materials management log books. The stages of disease severity were defined as a symptomatic HIV infection, symptomatic HIV disease without AIDS defining condition and AIDS defining conditions. We basically looked at the direct cost. We didn't, we didn't address the capital costs that were, that were used in, in infrastructural strengthening and we didn't address the overheads. We basically just looked at the costs that were influenced by the utilization patents, and were directly related to clinical care. The study population - pre-HAART before the implementation of HAART -- this is in 2001 -- we had 303 predominantly male in both cases pre-HAART and during 2002, during the implementation of the HAART program. Our ratio of HIV to AIDS in Barbados is 2.75 male to one female. And again we had the predominant presentations were AIDS defining, AIDS defining conditions, 44 percent and 50 percent of cases during the HAART era. Again, the median CD4 counts, very low. Many people presented late before HAART. Many people presented late before HAART and by the end of the HAART program, program for last year, the median CD4 cell count was 144. The median age stayed the same with the females, however, consistently for the past few years the median age of presentation has ranged from 36 to 37 years in the males and dropped last year to 32. It was observed that males were presenting slight-

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slightly um slightly younger males were presenting earlier. Again, we had a high rate, a high rate of employed both due to HAART of June last year where we only 46 percent of the males unemployed. Utilization patents -- we actually, before the HAART era we had 39 percent of registered patients who attended the clinics, 39 percent were admitted 22 percent of patients admitted last year. Lengths of stay dropped by almost five days, but what was most significant is the drop in the total in patient days stayed the same from 26 days per year per patient to 15.7 days for patients, and obviously we saw more than 50 percent dropping total hospital days spent during the year of implementation of HAART. Again, the clinic, we obviously had a, a move from inpatient to outpatient utilization. We basically saw again session go from one where we only had an informal clinic before the implement, the scaling-up of the program on implementation of HAART and when this went to full-time clinic with two HAART-based sessions, one in afternoon per, per week. This obviously almost doubled mean visits per patient, and we also saw a sixfold increase in staffing inputs. Now just to, to go over some of the key elements of the cost. We basically costed separately for each patient, the drugs di-, diagnostics um, and again we looked the total inpatient direct cost of patient and this came to on average when you looked at all the patients together, the AIDS, the asymptomatic HIV and the symptomatic HIV patients came to 6,061 US dollars, coming to a total cost of 1.3 million for the year. This is just for admissions. Again, when you separate it out, the cost of an AIDS, an AIDS patient

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per stay, per admission is 7,000 U.S. dollars. Again, this was, this was actually before the HAART era, and a number of interventions were, were deployed to help patients with AIDS but none of them were very effective and in most cases it was, death occurred. Obviously this is, this came to a cost per patient of nearly \$11,000 compared to asymptomatic patients at \$4,000. Again, we need to look at the diagnostic. The same pattern follows. We do notice that again symptomatic HIV patients, the d-, the daily cost is a lot, is less than the asymptomatic HIV patient. This is because a number of the patients who came in who were asymptomatic were female and many of them had interventions for gynecological problems, so they had surgical interventions including terminations of pregnancy. And, the, the drugs prescribed, this, this, this is just the basic drugs which do not include HAART and drugs for HAART and antiretroviral therapy and also opportunistic infections, and the same pattern applies. Now for prescribing of HAARTs, we saw informally before the HAART era approximately 13 percent of patients were on, on HAART treatment but this wasn't consistent because of the problems with provision of, of drugs. In many we saw complications, however, this increased to 42 percent of patients, which equated to 60-, 65 percent of patient-, of the estimated AIDS cases in Barbados were on HAART (unintelligible) after the implementation of the HAART program. Again, the cost difference might if it looks, it looks, it's very small and this is actually because after the implementation of the HAART program we, we, due to negotiations of our, with drug

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companies, we had a drastic fall in drug prices, so originally the cost was approximately per month \$626 and this fell dramatically due to price negotiations with each of the suppliers to 184. Outpatient cost, obviously we saw, like I say, we saw a move from inpatient to outpatient costs. We, we basically see an increase in total cost per year from 38,000 from the pre-HAART era to 46,000. Again, this is not as high as it should be and it's been mainly due to the fact that this is the first year of the program and we haven't yet got a fully implemented program, which has got the full staff and complement or, or, or even um, counseling sessions. So the cost analysis goes to show that with inpatient costs we had to move from in the pre-HAART programs of 1.3 million to 800,000, and this is a difference of 500,000. With HAART, cost of HAART we have an increase of 38,000, with OI an increase of 56,000. There was a drop in use of opportunistic infections, drugs (unintelligible) opportunistic infections. Outpatient visits costs went up by 323,000. This gave, gave us a total net incremental cost of 82,000. Again, the benefit came from this, this really minimal difference between the, the cost of HAART before and after the program started. And this re-arrived (misspelled?) then at a mere net cost of \$21,000 a month. The key findings of the study were that the baseline total cost of inpatient care for HIV patients is 1.3 million compared to 800,000 after the first year of HAART implementation. The cost of inpatient care reduced by 40 percent. Inpatient cost of care is over two times greater than that for general medical care. And the cost of

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opportunistic infection drugs outpatient level increased by 56 percent. And the cost of HAART increased by 22 percent. That's in Barbados dollars.

The key findings, the number of admissions for utilization, the number of admissions decreased between the two periods by 42 percent. Total hospital days fell by 59 percent. The mean average length of stay they reduced by 29.9 percent. And we saw an increase in HAART utilization from 13 percent to 42 percent. Our target, our goal in the program is to, to, to reach 75 percent of the projected AID-, AIDS cases in Barbados by 2005. We're currently reaching an estimate of 62 to 65 percent. An overall reduction in AIDS-related events was observed, and we saw a rise in outpatient visits by 128 percent. In terms of outcomes, this has been taken from a number of studies, which we did, the rest of the team and I presented in the poster hall. We saw an overall reduction in deaths by 66 percent, a median CD4 rise of over 100 cells, and we saw 85 percent of patients achieved a greater than 95 percent adherence levels.

Despite lacking a fully functional program and experiencing teething problems, the first few outcomes are extremely positive and do speak to a high level of cost effectiveness. There has been a significant cost shift from inpatient to outpatient setting and scaling, scale-up continues and expected that the net cost against baseline will increase and so we will see a change in our cost effectiveness ratios. Basically the longer cost effectiveness will be determined by the number of patients that we attract basically

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through our voluntary counseling and testing service, which we are in the process of scaling up. And also the cost (unintelligible) outcomes of behavior change that we achieve in terms of preventing further transmission of cases and also preventing cases in the HIV, in the high risk HIV negative groups. And also once patients have been identified in the early stages through VCT (misspelled?), (unintelligible) can be assured of improved quality of life while ensuring an overall cost beneficial return. However, that really means that the, one of the government's targets is the incomes of clinical social goals, to maximize economic and social productivity of the symptomatic people living with HIV. Given the mean age, our median age of presentation in males with AIDS is 35 and our median age of presentations in females is 32. So we would hope to see their return to work amid a decreasing climate of stigma and discrimination. We hope that that participation in nati-, national volunteerism as well as projects is sustained and this is what some of the community based approaches are doing at the moment within the HAART program, working with PWA and associations and other NGOs. We also hope to see an increase in contribution in activeness in household location and community activities. Again the HAART program is implementing processes to, to develop structures and back to what programs for people with HIV AIDS. So as the continued scaling-up continues, we basically hope to see, hope to see the planned increase in HIV persons being attracted to the program, and that is going to put into, into a projected estimate. We also have to put into the

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estimate an increased staffing cost, including training for over two years and we will also then look at our projection and put in our estimate, project the number of HAART patients to go up to 75 percent of the estimated persons with AIDS. This gives us approximately a net incremental cost then of 800,000, and that is compared to and gives a net cost of patient markup 194 U.S. dollars, 388 Barbados dollars per month compared to the 21 net cost that you saw in the first year. However, we've, we've perceived despite dealing with other technical barriers to sustainability and cost effectiveness, such as starting developing an optimal, optimum staffing model scaling-up and monitoring evaluation, which we're doing in partnership with a number of international organizations, WHO, the CDCs, Caribbean HIV AIDS regional training initiative, Johns Hopkins CCT training, we have a number of partnerships and obviously the World Bank partnership in implementing the program and monitoring the program. We, the major barrier we did perceive is in price and policies basically. Despite being part of the one of the 15 countries in the (unintelligible) initiative and participating in the signing of an agreement of principles and despite the accelerated access initiative by the U.N. organizations, Barbados is really not to gain anything in terms of the cost, low cost of drugs compared to the rest of the region. We see, we're seen as the high income, higher income and a higher ratio ability to pay. Basically, in reality, because of us being a central regional hub, having purpose of intense policy and also being a communication gateway, providing

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access to migrant workers, airline staff, seafarers and also being a base for many international organizations, we actually are vulnerability and academically linked to the rest of the region particularly in light of the Caribbean single market economy, and this obviously links us (unintelligible) to the rest of the region and we need to be seen in a, a way, in a regional, in a regional perspective. So in truth, the Barbados prices are still too high for Barbados after the rest of the Caribbean. Cost effectiveness will be greater with further reduced drug costs. (Inaudible) (background talk) Finally, -- okay.

MALE VOICE: (Interposing) (inaudible) you have to finish.

DR. ADOMAKOH: Yes, last slide.

MALE VOICE: (Inaudible).

DR. ADOMAKOH: Okay. The greatest threats to our program (unintelligible) stigma and discrimination so that's all. With the removal of stigma and discrimination, the patient can be (unintelligible) in particular by (unintelligible) being kept alive just waiting to die as productive gains are minimized. Thank you. (Applause)

GUISEPPE PANTALEO: Thank you very much and we will immediately open to the floor. We have microphones on the floor to present questions to all the, the, the presenters, and remembering that these abstracts have been selected by the scientific committee among the sansufer (misspelled?) reports. Any questions please. Please. Microphone please, on the floor.

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MALE VOICE: My question's for Dr. Shutes. Regarding the program in Musaka if I understood your data correctly you said that you had a ten percent zero conversion rate while on study and while the study was closed, so essentially there was no difference. I'm curious if you know how that compares to the general population zero conversion rate and if you have an understanding why in your study a population that knew its status was receiving counseling and had access to free condoms still had a zero conversion rate of ten percent?

FEMALE VOICE: Some, some other studies that have been done, it's been estimated that the zero incidence among the discordant couples who don't know their status was about 20 percent per year, so we've, we've made a reduction of over 50 percent from that number. Even with, with counseling and free condoms, people still choose to have children and we estimate that people have at least one unprotected exposure per month.

GUISEPPE PANTALEO: We don't have an order. I'll start with microphone one through three and then we should please.

FEMALE VOICE: Hi. This is question for Sanjay and Durier together. Surprisely, the MSF project you had high involvement of women and I was just wondering whether there is any particular explanation for that and then we looked at the response to CD4's, even though both the projects have used a similar regimen and have comparable CD4 at baseline, the MSF project is 153 increase at six months, 171 increase at 12 months and 156 increases later on whereas

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Sanjay you have seen 310, 380, and 422. There's a lot of discrepancy in increasing CD4s. Maybe Sanjay, do you have any explanation why you have seen much better improvement than in MSF project even though the regimens are the same?

SANJAY: We use a fax (misspelled?) counting which is one of the gold standards for measuring CD4 count. I'm not saying that diner breeds (misspelled?) is not as sensitive specific but maybe that should be one of the reasons for seeing the higher response..

DURIER: ...and I think that the way we if I can well remember the way we presented the data, you presented the CD4 label achieved. And I presented the CD4 gained from baseline. So, there was an increase of 150, 170 place from the baseline. I didn't present the levels of CD4 which were achieved and I believe it was, it would be similar around the 300 range.

SANJAY: No, I think it that defense would still be higher. We have 250 plus 250 and plus 350, about a mean baseline.

DURIER: After 18 months in the, in the description of the project you could see that we control CD4 not every 12 months. There was a small number of, of patients with a CD4 control at 18 months. Those were many patients who had CD4 control, initial CD4 control that caught our attention and he didn't have enough chemo. CD4 increased for whatever reason, so then we controlled later on. So it might be a specific group of patients with..., in regards to fortification we a different, a different immunological recovery.

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SANJAY: Part of the agenda disparity question is concerned. There maybe two, three reasons for the gender disparity. One is females as we know have universally less access to care than males in level(unintelligible) we find less and less number of females accessing care. The second aspect maybe females are getting infected later so the indication to start antiretroviral therapy may be coming a little later, maybe less number of patients in (unintelligible) for whom antiretroviral therapy is indicated just because they got infected later. But I think major reason is access to care.

MALE VOICE: Thank you very much. Thank you, Sanjay. There are two questions for Dr. Durier and Dr. Pujari. And my name is Dr. (unintelligible) from (unintelligible)International Energy. We are managing a public health (unintelligible)charge program to, to treat with HIV and people with AIDS and to manage (unintelligible) transmission in Mozambique and our have more or less 1,000 processes in charge and our results is consistent with the delineated data with that video shown. My first question is for Dr. Pujari. What is the role from the fact that the most part of all patient didn't receive any elbow treatment before ART (misspelled?). I think there's a good chance of success for every treatment in, for our patient because (unintelligible) monotherapy (unintelligible) something like that. And the second question is for Dr. Durier (misspelled?) is that the scaling-up at the national level on this kind of program in Mozambique, in my opinion request...need the fact

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that personnel, not medical personnel to control, to, to monitor elbow treatment. What is your opinion about Malawi or Indura (misspelled?)? Thank you.

SANJAY: If I, I understood your question correctly, naïve, being naïve is an advantage. There's no doubt about it, being naïve is an advantage. But one of the factors of particularly (unintelligible) the factors of having the drugs and particularly having numerous companies manufacturing the, these drugs having competitive interest is widespread abuse of antiretroviral therapy offering. So in our practice (unintelligible) seeing increasing number of patients who may not be naïve when exposed to suboptimal regimen particularly to 2NRTIs (misspelled?) alone. So that would definitely affect and I think one of the major challenges for us in India is to manage patients who are already exposed to suboptimal regimen. It's very difficult to initiate therapy for regimen for these patients and optimize access for these patients. So I think naïve is definitely an advantage, but as the drugs increase particularly in direct practice, access to this does increase, the naiveté is going to go down, making it more difficult.

DURIER: Regarding the implication of the community for non-medical staff in the follow up of patient on the IV, actually I think that's one of the necessary direction to, to take an actually (unintelligible) the process of decentralization (unintelligible) levels, that's one of the things that we are going to do so the medical staff from the health center will be more involved

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in the medical follow-up of the patients but the community itself will be also very involved in support of (unintelligible) with, with the patients with, with whom they live, with whom they live.

GIUSEPPE PANTALEO: Okay. I'll try to, to, to be, to use better our time. I'll take two or three questions and then your response. Please take notes. Please microphone three.

MALE VOICE: Rensaw (misspelled?) Sheer (misspelled?) from Chicago. Also for Dr. Durier. In, in Malawi did you experience a migration of people towards the region for the purpose of accessing antiretroviral therapy since there are so few sites. I think yours is one of the few offering antiretroviral therapy in Malawi so, and how did you handle that (unintelligible)?

GIUSEPPE PANTALEO: Thank you very much. Microphone four.

MALE VOICE: I, I'd like to thank all the speakers for their presentations. My question is to the gentleman who is from India. Did you report on any experience on peripheral neuropathy in (unintelligible) patients. And to Dr. Durier did you collect any quality of life, life data particularly data around people being able to get back to work ?

GIUSEPPE PANTALEO: One more question. Microphone five, please.

FEMALE VOICE: Yes, Janice Fikes (misspelled?) from the United States. I wanted to get back to the first question on women, why there was a difference and why there was a difference in CD4 count, and I'm thinking perhaps that the Indian population was so

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selective that they could afford to pay so they had better nutrition, better other indicators of health. Perhaps maybe that's why the CD4 counts went higher and as far as the gender equity bit goes. Also because the Indian cohort paid and women are less valued and then came forward for treatment and not the women, whereas in the MFS project it was free and open to everybody.

GIUSEPPE PANTALEO: Okay. Please, Dr. Pujari and then Adomakoh.

SANJAY: As far as peripheral neuropathy is concerned, it is quite common. We didn't report an NRTI toxicity in the study because it did not really have an impact on the effectiveness because as soon as we diagnose NRTI toxicity, we switch over the patient 40(unintelligible) regimen or vice versa.

DURIER: Maybe the, the quickest answer about the question of life, we are not recalling specifically this outcome, although there is obviously patients who return back to their, to their activity, to farming activities or to activities in, in town. And I didn't present to the weight gain of patients because in the (unintelligible), the monitoring of this parameter was, was not (unintelligible), but in a smaller, in a small number of patients the, the median gain of the treatment initiation is, uh, is, is dramatic. For example, with people who have BMI below body mass index below 17 at baseline, they gain 11 kilo at six months of treatment. But again it's for a small proportion of patients. Regarding the population coming from other parts of the country,

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there is in Malawi, two governmental programs in the two major cities, Lantia and Lilongwe represent the (unintelligible) program has not started so at present the treatment that's been charged for the patient and its significantly high. We are very near from Lantia, just 30 minutes away, by small boats from Lantia and obviously we have more and more patients coming from the capitol and seeking care and access to free treatment. It becomes an increasing problem. In response to these were giving access to treatment for these people and the way we link with, with our (unintelligible) is to request, do it in a, in a proper manner for definitely people would be sent by another clinic, we would request a clinical details of the patient and treatment he gets. And also we link, we try to link with the global fund representative in the country to know exactly what would be the detail of the plan and when we would start and help to find, to make this possible a bit quicker. I think that's one of the, the only option that we have in (unintelligible).

GIUSEPPE PANTALEO: Thank you very much. Microphone six, please.

MALE VOICE: Thank you. I'm Dr. Pouli (misspelled?) from (unintelligible) Cameroon. My concern is about the adherence. Everybody here have a, a rate of 80 to 90, even more of presentation variance I know that this is a very difficult process involving not only counseling, regimen costs, side effects, but all those things, involving also cultural and social obstacles. We in the mutual cycle, we have a social psychological, working on the field and

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everywhere and we have a 98 percent of adherence but I know that is a very difficult process. I would like to know how the, the other teams reach their strategies of implement to have their rate of adherence. A (unintelligible) link to this question is a, the, the drug resistance (unintelligible) seems to me to, to increase (unintelligible) this (unintelligible) this problem in the following presentation. I know that it is very important issue which is going on. Would like to have your opinion on this question. Thank you.

GIUSEPPE PANTALEO: (Inaudible) (off mic) Microphone seven, please.

BETH MILLER: Beth Miller from Centers for Disease Control, Global AIDS Program. I have a question for Dr. Pujari and wanted to hear more about how the patients who are going to be put on antiretroviral therapy are screened for active tuberculosis and if TB disease is ruled out, I was wondering if you would consider preventive therapy, given your extremely high rates of TB?

GIUSEPPE PANTALEO: Thank you very much. I'll ask again to microphone seven, the gentleman while he was there for some time to present his question. Yes, please.

MALE VOICE: Thank you. I have a question for -- my name is Riesen (misspelled?). I'm from the Netherlands. I've got a question for Dr. Durier and in your presentation you gave us some background information on, on Chiradzulu to the hospital. You showed us that there is a great shortage of staff. I believe Chiradzulu hospital does not, does not have a doctor and there's 50 percent

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vacancies for the clinical officers and nurses. I would like to know how the hunting of your project is going to affect the regular work of Chiradzulu? And my second question is during the period of your project within 2001 and 2003, there are two episodes of famine in Malawi and I wondered whether you have any death count information of how many people died of starvation during the time of your project?

GIUSEPPE PANTALEO: Okay, please, one more question.

Microphone eight.

MALE VOICE: Michael Sung (misspelled?) from the United States. I have a question for Dr. Pujari. Given the low incidence of liver problems that you found, do you think that testing at one month for a liver function test was perhaps too frequent. And then question for Dr. Durier. On the other hand, do you think that since you maybe underestimated the problems of liver disease in your cohort that perhaps you didn't measure LFTs frequently enough and whether you would, you know, would have changed this testing?

GIUSEPPE PANTALEO: Dr. Durier, please.

DR. DURIER: Right. There are many questions so I believe the first one was on, on adherence and you specifically interested to know what is the support to adherence that we give for patients. Was, was that right?

MALE VOICE: Yes.

DR. DURIER: Um, as, as I said, patients undergo very regular sessions of adherence counseling and in practice (unintelligible) treatment, patients receive two sessions of

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adherence counseling through counselor goes in depth around the question of whichever disease needs treatment, what's implied for the long-term and so on. And then after treatment is scheduled, after two months each time the patient with their clinician you will see a counselor in the initial phase of treatment where maybe they can decide (unintelligible) has to be reinforced particularly. And then as the treatment advance the issues of resistance become different but the support with a special consultation becomes a bit less frequent every three, every three months in average. About the resistance in, in, in the (unintelligible) project of (unintelligible) South Africa 90 percent of the patients had undetectable viral load if they're working man during (unintelligible) for treatment blood counts and 90 percent of the patients had undetectable viral load, so (unintelligible) was not undertaken in the study yet but we're planning to do a cross section of study correct (misspelled?) and putting correction endurance (unintelligible) and viral loads, and if viral loads are detectable in some of the in, in, in a subset of patients we go from (unintelligible) safety so we'll have adequate figures to present in (unintelligible) project. But based on the experience from South Africa, we're pretty optimistic that a (unintelligible) is a major issue. About the hunger crisis in Malawi, nationwide indeed there was some, there was some malnutrition and there was, there was a lot of response from different organizations for this hunger, hunger crisis situation and considered nationwide some of it was a bit

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exaggerated and some of it was a bit made over, over reported from the media. For example, intradoo (misspelled?) we did an in-depth analysis of the nutritional status of patients (unintelligible) and we found that the proportion of malnutrition was way under catastrophic levels that were, that were presented.

(Inaudible) (microphone echo)

MALE VOICE: On the issue of rolling out active tuberculosis (unintelligible) and I think even you understand it's a very shaky situation and predominantly do it by doing clinical evaluation and doing routine x-ray prior to therapy but that really doesn't rule out because the majority of these patients with lower CD4 counts who tend to have more extra pulmonary forms of tuberculosis and that may be one of the reasons why we see (unintelligible) reconstitution disorders because of the tuberculosis once we are in therapy because we know that some clinical infection is not being really taken care of. (Unintelligible) issue may be prophylaxis with INH would be considered but it's still not recommended in our country because lack of (unintelligible) country, because of a lack of indicators to initiate (unintelligible) prophylaxis like PPD would not really be used in that setups. This point of time, rather than screening out patients with, for intensifying screening as far as ruling out the tuberculosis, I would probably look for a monitoring more frequently for (unintelligible) factors for tuberculosis in these patients.

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GIUSEPPE PANTALEO: Thank you very much. The gentleman of for microphone four, he's for a long time. Please start and then we'll come to, to you. Please, microphone four.

MALE VOICE: My name is Richard South (misspelled?) from Glaxo SmithKline Community Partnerships and my question is for Dr. Durea (misspelled?). And I was wondering whether do you have any data or any perceptions of whether the availability of antiretroviral treatments had an impact on stigma and discrimination in the community and whether levels of stigma and discrimination were reduced? And also whether, you know, just people presenting for HIV testing more frequently.

GIUSEPPE PANTALEO: Okay, please, microphone one.

MALE VOICE: Thank you very much. Rick Berzon (misspelled?), United States. First of all, thank you all very much for your information and your data. Some of it came across very quickly and I was wondering in particular, Dr. Salif So, if, if any of these data may be available at handouts at some point during the conference so that we can more thoroughly review some of the numbers. I have a question for Dr. Durea (misspelled?). We heard at a conference last night a talk on expanding access to treatment in the developing world, that there are times when NGO's have difficulty training individuals to provide care because registration is done through the government and sometimes the government bureaucracy is a, is a bit slow and, and so there's an impediment there and I was wondering if you had experienced any of those sorts of difficulties

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as you train up your staff to provide direct care. And then I also wanted to know from Dr. Adomakoh from Barbados, your adherence numbers were really quite good and I was wondering how you measured adherence in your research.

GIUSEPPE PANTALEO: Thank you very much, ah, one more question maybe. Microphone two, please.

MALE VOICE: (Unintelligible) Atlanta (misspelled?) U.S., and two quick questions. One is another TB-related question for Dr. Pujari. It has to do with the immune reconstitution syndromes you mentioned, which are obviously quite significant in your experience. These, in fact, misdiagnoses of TB as you just suggested in your answer a few minutes ago or were they in fact patients who had been diagnosed that were on therapy and I wondered if you could tell us a little bit more about your handling of these reconstitution syndromes. And then a quick question for Dr. Durier. And I think it's, it's wonderful you're able to use Dynabeads (misspelled?) test as an example of a low technology CD4 test. I wonder if you could tell us about your methodee (mispronounced), method of quality assurance for using that to make sure you're getting accurate results.

GIUSEPPE PANTALEO: Dr. Pujari to start.

DR. PUJARI: The question about immunity constitution (unintelligible) is we often wonder whether we have been not ruling it out before initiating antiretroviral therapy but (unintelligible) risk, we had another (unintelligible) list is starting at the very

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low CD4 count, less than 50 is a definite risk factor for the development of immune reconstitution disorder, not just TB but (unintelligible) disorders (unintelligible). As far as management is concerned obviously we can't stop antiretroviral therapy so we continue with antiretroviral therapy and add (unintelligible) for these patients and manage them. As I mentioned in my presentation, concomitantly using both these drugs delivered seems to have not really increased the incidence of adverse events in the logistic regression model.

GIUSEPPE PANTALEO: Dr. Durier, please.

DR. DURIER: For the increase access (rapid speech)voluntary access has been quite dramatic in the past two years but mainly in the past two months of the past last year and one of the explanations for (unintelligible) availability of the (untreatment. We cannot ascertain this by anybody or anything (unintelligible) the patient (unintelligible) that it's part of the explanation. We have also patients who come earlier stage, earlier stage of the HIV disease to other HIV (unintelligible), and again we have a lot of patients now who come from (unintelligible) for example and who heard about the availability of the other treatment (unintelligible). So indeed disclosure trying to low the HIV death sentence is probably is improved by the availability of the (unintelligible). For the training the, the country has a plan of treating 25, between 25,000 and 50,000 people with HIV by five years from now with support of the Global Fund, and obviously the training

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is an enormous part of this plan and we, we have good links, very good links with the, with the Ministry of Health and actually we are even one site that will be helping in training other practitioners in other district before they implement the, this plan. So I think that the possibility to do adequate training is definitely there and the Ministry definitely is satisfied to have, to have an on-site (unintelligible) where they can be qualified to teach. The dynabeads quality control with a faxcount (misspelled?) machine in, in (unintelligible) and the median difference between the CD4 results obtained with dynabead system and the faxcount (misspelled?) (unintelligible) is very small. It, it, it's not significant.

GIUSEPPE PANTALEO: Thank you very much. Dr. Adomako (misspelled?).

DR. ADOMAKOH: Yes, thank you. First of all, just to refer you to LB41 (misspelled?), which is a poster detailing the study undertaken by the physicians at, at the unit, the ladymead (misspelled?) reference unit. Also to highlight that we did have, we do have a (unintelligible) for adherence program in Barbados and it's, it's, it's gone on from the goodwill and volunteers before the program was scaled up, and now what the program does its adherence counseling and monitoring is undertaken by the P-staff (misspelled?), the nurses, the physicians and the pharmacists for all patients and that's how the study was undertaken as well. Question is for issues from three points, starting points. Again so the community support and the support within the clinic is quite strong and that has, that

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has really transferred from the goodwill (unintelligible), but you could get the details from LB41

GIUSEPPE PANTALEO: Thank you very much. I'll take the three last questions. Microphone three then four and then two please.

FEMALE VOICE: Hi. This is Walfa (misspelled?) Alsider (misspelled?). I'm from the NTCT (misspelled?) Class Initiative at Columbia University. I have a couple of questions, quick questions for Dr. Durea (misspelled?) and then a comment to Dr. Gilajee (misspelled?). You indicated that you are also enrolling pregnant women in your program and certainly NTCT Class were also focusing on their enrolling women during anti-(misspelled?) natal care so I'm wondering about your experience to date on pregnant women on, in your program and whether those were on ARVs (misspelled?) are then, what do you do about the PNTC regimen around the event of their delivery? Another question for actually anyone on the panel is that we felt from the beginning that it was very important to have a component of the program for the healthcare workers who themselves have HIV infection and whether you offer the benefits of these programs for your healthcare workers. And, of course, that raises other issues around confidentiality and so on. And then a comment I guess for Dr. Gilajee (misspelled?) is just to temper your conclusions about people who pay are more likely to be adherent, I think there are data from several countries that demonstrate that actually having to pay out of

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pocket has been noted to be one of the main causes of non-adherence, especially in situations where employment is unstable. That's all.

GIUSEPPE PANTALEO: Thank you very much.

MALE VOICE: (Unintelligible). My question is for Dr. Durier. Could you concerns (misspelled?) your first line regimens you referred to women and infants who previously received (unintelligible).

GIUSEPPE PANTALEO: Thank you very much. Microphone two.

MALE VOICE: (Unintelligible). We, we are at the turning point for ARV availability, however, we don't speak about regulation models for the widespread use of ARV and in my personal experience in country in Central Africa, we see a lot of irrational prescription and the wasting of generic drugs because of under-clarification and I would say organization of the use of those drugs (unintelligible), do you think it would be the time especially for international, international organization to put the (unintelligible) also about formalize and harmonize and generalize regulation models and training modules, like for example (unintelligible)?

GIUSEPPE PANTALEO: Thank you very much. Dr. Durier. Who has question for Dr. Durier?

DR. DURIER: The first question was for pregnant women (unintelligible), what do we do after delivery? Basically we cut off at 350 at the level of CD4 under which pregnant women would receive half and there was one advantage with this kind of is under 350, the mother's health is the (unintelligible) issue so at all treatment.

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Let's put it this way. Treatment would be of evident benefit in this, in this woman. So we decided that pregnant women would start (unintelligible) below 350 and that case we never stopped half and, and one of the reasons also is that it's been clear whether or not when we decide a pregnant woman would wean at six months and stop replacement, replacement feeding with, with other food. It's really unclear whether or not they will completely stop the breast feeding. So we thought that if women would carry on with breast feeding from time to time with infant it wouldn't be any risk of viral rebound because the women would still be on the same high activity antiretroviral treatment. And for pregnant women who, yea, for pregnant women who have received nevirapine before, we would have advantage to put them on this (unintelligible)

(unintelligible) as well as in both newborns from, from in pregnant women who got the nevirapine (unintelligible). Although I believe there is some control issue but around this, this uptake and I don't think that it's 100 percent certain that initiating a regimen with nevirapine would be, would be significantly less effective than another one. But still it presents, we, we offer (unintelligible) for those (unintelligible) patients.

GIUSEPPE PANTALEO: (Inaudible)

DR. SALIF SOW: Yea, I just want to raise a question about training. I think training is very important and must be the first step, which need to be put on the country before the (unintelligible) provider drug because if you don't have very good medical doctor who

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can prescribe and (unintelligible) the patient, you will lose all the (unintelligible). That's why actually we have the African clinician network and we will try to help other different African countries for training of the healthcare workers. And the second issue is about the healthcare workers who are HIV positive, not because of (unintelligible) but because of their private lives. In lot of experiences in particular in Senegal, they have access free (unintelligible) to the antiretroviral drug so they're treating free of charge (unintelligible) HIV positive.

GIUSEPPE PANTALEO: Thank you very much. We are going to, to close the, the session and I have to thank to all the presenters who have had so many (unintelligible) but I understand that the, the context is different than two years ago. We are talking about results and how to scale-up, how to go on. We are talking about (unintelligible) and it has been very important to see more demonstration about, about cost effectiveness of, of ARV treatment, disability, adherence and so on. I would like to, to members note that this project of, of presentation of Dr. Shoots (misspelled?) is very important for us to have mind all the time what we are going to do at the end of the research projects and I understand that you have to take this in consideration at the very beginning of, of the projects. I'd like just to say in the name of (unintelligible) that it's clear for us considering all this experiences and this concern that we have some very concrete things to, to, to (unintelligible) very briefly, and one is to (unintelligible) network to monitor HIV

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resistance immediately and we understand have cleared that resistance is concern (unintelligible) but this is not an argument to prevent initiatives to treatment and will be permitted to in monitoring and given the, the, the, the information necessary for this (unintelligible). And about the commitment and the, the concentration of efforts (unintelligible) to offer more support, technical support in particularly try using all the present experience to establish some global guidelines based guidelines (unintelligible) to facilitate this stellar process and trying to prevent (unintelligible) treatments for, based upon a consequence of resistance of nodes (misspelled?). I would like to thank all of presenters and, Dr. Salif, I'd like you to close this.

DR. PAPA SALIF SOW: Thank you very much.

(Unintelligible), I would like also to thank other speakers and all the participants for their questions and contribution and I think we can close now the session. I thank you very much.

[END OF RECORDING]