

**2007 HIV/AIDS Implementers Meeting:
Trusting Your Results: Implementing Laboratory
PEPFAR, The Global Fund to Fight AIDS, Tuberculosis
and Malaria, UNAIDS, UNICEF, The World Bank, WHO, GNP+
June 18, 2007**

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MARK RAYFIELD: I'm Mark Rayfield from the Centers for Disease Control and Prevention, and I'd like to welcome all of you on behalf of the panelists tonight to session P3, "Trusting Your Results, Implementing Laboratory Quality Assurance."

As I was saying, we actually have a very full schedule tonight. It's a marathon session, and we're going to try to run it in sprinters. Our thoughts are to limit our opening comments to about five minutes apiece. We will accept some points for clarification following each of the talks, and that will give us a good 45 minutes for a roundtable discussion at the end. So if you will bear with us and support us and hold your questions to the end, I think we'll get through this fairly smoothly, all right?

I do have one piece of announcement, and that is that the buses tonight will be leaving from the Jolly [misspelled?], so we need to go to Jolly to pick up our shuttle buses back to the hotels and residency. There are buses that will take us from here to the Jolly, but then we pick up our buses to go home. Buses are located at both gates, so gate one will handle routes A, B, C and D. Gate two will handle the routes E, F and G. Thank you.

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All right, to start us tonight, we have Clement Ndongmo from the National Public Health Laboratory in Haiti. He will be speaking on "Establishing a National Laboratory Quality Assurance Program for Rapid HIV Testing." Clement?

CLEMENT NDONGMO: Thank you, and good evening, everybody. I am going to talk about establishment of a national laboratory quality assurance program for rapid HIV testing in Haiti. I am going to cover, give you a little bit of background, tell you about the steps that we took into establishing a national quality assessment scheme, then give you, share with you some of the key results, and then lessons learned and perspectives.

The ability of a laboratory to produce accurate test results, including HIV, is critical for public health. There was a need, with expanded HIV program and testing around the country for a regulatory body to determine quality of testing in Haiti. And that's why the Minister of Health, through the National Public Health Laboratory, developed a national quality assurance program. And I'm going to tell you about one of the first activities of this program, which is the establishment of a national quality assessment scheme for HIV testing. So we started, after planning and preparatory stage, we obtained [inaudible] panel, four-member [inaudible] panel, from commission source. The national workshop was

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organized for state quarters to announce and launch the program, and then panels were distributed to participating site, and then results were obtained at the National Public Health Lab, and analyzed, and then sites were visited to provide individual test results with certificate of participation, to observe local procedures and recommend corrective actions.

This is a little bit busy slide for result. Out of the 76 sites that participated, the majority returned results to the National Lab. On figure one, you see that all the 10 departments in Haiti were represented from one site to 30 sites in the Port-Au-Prince area, in the west department of this, most populated. Ninety-two-percent of the participating sites followed the national algorithm, which is a serial one, would determine as a first intention, reactive samples are confirmed by [inaudible] the individual is asked to return after three months.

On figure two, you could see - I don't know if it's very clear - that the both public and private institution achieved 60- to 70-percent efficiency. While the weak side, which is usually supported by angios and church institutions, achieved 89-percent efficiency. A total of 50 sites out of the 76 participating sites achieved 100-percent efficiency.

Comparatively during the testing, technicians and nurses, 1-

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percent of the technicians and 57-percent of nurses achieved 100-percent correct results. And overall, efficiency for the whole country was, out of 292 tests run, which is 73 sites times four samples, was 90-percent.

This was really the first national external quality assessment scheme ever conducted in Haiti. The sites were very enthusiastic. We asked for this program to extend to all our tests. Most incorrect results were due to one of the samples, which was a weak positive sample. Most sites do not have a full SOBs. The result of this first scheme of external quality assessment program, while encouraging, demonstrates the need for improvement. After site visit, immediate actions included refresher training courses, and standardized training for HIV rapid test performance.

Future plans include continuation of this activity, continuous site visit for quality assurance, and introduction of new activities, such as testing samples collected in the field or in field papers. I would like to acknowledge the institutions that contributed to this study. And I thank everybody for your attention.

[Applause]

MARK RAYFIELD: Thank you, Clement. Are there any points or clarifications needed? Would you come up to the microphone for us?

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MALE SPEAKER: Clarification, please. What is your definition of efficiency in HIV rapid testing?

CLEMENT NDONGMO: I refer to efficiency here to the ability of the site to determine correctly both negative and positive samples.

MARK RAYFIELD: Thank you. Our next speaker is Joyelle Dominique from the Institute of Human Virology. She will be speaking on "Improving Quality Assurance in Laboratories."

JOYELLE DOMINIQUE: Thank you. I'm from the AIDS Relief Consortium, and I work with Institute of Human Virology and I'm going to tell you a little bit about our approach to quality assurance with laboratories.

The objectives of our quality assurance program is quality laboratory testing and management. We want to make sure that the results that we have are able to be used by clinicians. And that they trust those results. We want responsibility and accountability by the laboratory technicians to maintain quality testing. And we want to make sure that the quality assurance program is sustainable. And two factors which can contribute to this is the cost of the QA program, and also the technology which you select.

Our approach to quality assurance is kind of three phases. Initially we put a lot of work into the first phase,

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which has been training and monitoring. And we have recently started also a lot of work in the internal quality assurance and external quality assurance, and I'm going to describe each one of these.

So for our training, we initially go to a site and spend about five to 10 days training sites on comprehensive laboratory techniques. Not only the technology that they need for the ARD care, but also laboratory management, quality assurance, good laboratory practices, laboratory organization, anything that we can put into a comprehensive laboratory training program.

And we also need to focus on retraining and continuous training. And we do that both by having laboratory specialist's work on site with the laboratory, and providing centralized laboratory trainings. And also an important component of this is the monitoring visits that occur after the initial training. We have to follow up with the laboratories to make sure there isn't enough, a need for retraining or continuous training.

Our internal quality assurance program, we started in Guyana, and this is where we're collecting the internal quality control values for the automated technology. We analyze those results by a Levee-Jennings [misspelled?] plots, and West Guard rules, and we provide feedback to the

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laboratory. Some of the challenges have been the proper documentation of the internal quality assurance, it's got quantitative values, they've done pass/fail, and also transferring analysis to the laboratory. We - our goal is to transfer this analysis so that it can be done daily in the laboratories, but that has to be changed. The laboratory has to be changed to do that. We're going to be expanding this into our other countries that we work in.

This is an example of the collection tool that we use to collect the values of internal quality control data. And it can be used either by writing, because a lot of our sites don't have computers, or by filling it in electronically and emailing it to us.

The next is an example of the Levee-Jennings plots that we generate, and also showing the standard deviation. And that's what we would work with a site to help them understand what's happening with their equipment.

External quality assurance is something that we would like to be able to do, but it is cost prohibitive. One way you can do this is by sampling - again, it's cost prohibitive, and then you're involving transportation and environmental exposure, which are other complications of external quality assurance. I think that the most sustainable form of external quality assurance is to form

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partnerships between the organizations to be able to purchase and distribute the external quality assurance materials.

And I just wanted to end with kind of our, not just our focus on quality assurance, because I think we need to focus on quality laboratories as a whole, and that's done by the selection of technology that you use, on-site training, development of a complete quality system for the entire laboratory, integration of laboratory services, and the knowledge transport to the local laboratorians, and that will create a sustainable laboratory.

MARK RAYFIELD: Thank you, Joyelle. Are there any points of clarification? All right, thank you. Our next speaker will be Dr. Odio June [misspelled?], and he will be presenting on "Serial versus Parallel Testing in HIV Diagnostic at Five Sites in Malawi."

DR. ODIO JUNE: I am going to share the results of an evaluation of HIV testing performance at five sites - visitor sites, to be precise - in three regions of Malawi. Now, the evolution in question was carried out to inform discussions around switching from parallel testing algorithm to serial testing algorithm in Malawi. The background to this is that Malawi's national HIV testing and counseling policy approves both serial and parallel HIV testing algorithms. But the predominant practice has been parallel testing since the HIV

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testing program was initiated over five years ago. Now, with rapid expansion of HIV testing in the country, expenses on testing commodities, particularly test kits, have gone up, and Malawi is in a situation where it has to review the testing practices and adult practices that may favor lower costs. It is against this background that the evaluation that I'm going to report on was conducted late last year. Next.

The objective of the evaluation was to determine if the final results communicated to clients tested, using a combination of two tests in parallel, would differ significantly if the same clients were tested using a serial algorithm. The second issue was to estimate the cost savings on test kits that would have been realized if the same clients were tested using serial algorithm instead of the parallel algorithm. Next.

So the framework for this evaluation is based on the key differences that we know exist between parallel testing algorithm and serial testing algorithm. Namely, use of fewer test kits and of the serial testing algorithm, and communication of test results for negative clients, that is based on a single screening test. And so that slide basically shows or summarizes the combination of tests, results of individual test kits used, that you'd get in a

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parallel testing algorithm. For example, positive test result would be based on individual positive test result for the first two tests. If the two tests do not agree, then in that situation, a tiebreaker sub-test is done. The difference in serial testing algorithm is that negative test results do not need confirmation with a second test. Next. HIV got the test results for 21,187 VCT clients in these sites over a period of six months were reviewed. All clients in these sites were tested using two tests in parallel, in this case [inaudible], and tiebreaking was done using Bioline [misspelled?], in cases where the first two were a discrepancy. For each client, results of individual rapid test performed for communicating final results were examined. And the final results were therefore compared with a theoretical situation, where the same clients would have been tested and the serial testing algorithm. So what we looked at was frequency of false negative outcomes, with [inaudible], we did the first test, and potential cost savings that would have been realized. Next.

So looking at the results then, out of the 21,187 results reviewed, only two clients would have gotten different results under the serial testing algorithm. And this, if we were to use parallel testing algorithm here, of the gold standard, we would have had a sensitivity of a

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serial testing algorithm of well between 9.6- to 100-percent.

Next.

In the area of cost, a theoretical setting where the same clients who had been tested using serial algorithm, we would have had a cost saving of between 20- and 44-percent. Just click, next. As is shown there. So that is the level of saving we could have realized if we had used serial testing instead of parallel testing at these five sites. Next.

In conclusion, a switch from parallel to serial testing is considered an intervention that would be cost saving and not compromise accuracy of test results that clients receive. But we know that it has practical implications on operational procedures, procurement, public perception and provider confidence that have to be taken into account before it's initiated. So taking those into account, Malawi proposes to undertake a phase transition from parallel to serial testing, while addressing these issues as outlined in the bullets that I am not going to read individually. Next.

So I want to thank all the people listed in this slide, and the institutions that are listed there. Thanks for listening.

[Applause]

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MARK RAYFIELD: Are there any points or clarification? Odio, I do have one, if you don't mind. Do you know the prevalence in the population you were sampling?

DR. ODIO JUNE: [inaudible - off mic]

MARK RAYFIELD: Thank you. Okay, our next speaker will be Wendy Nicodemus, she will be presenting on "Standardization of Laboratory Testing Policies as a Key Prerequisite as Operationalizing HIV Programs and Expansion." [interposing]

WENDY NICODEMUS: I'm Wendy Nicodemus. I just wanted to make one quick correction to the program. I actually work for JSI, not USAID, and we are contractors for the USAID Deliver Project. I will be presenting here on behalf of the team listed up there, and we will be talking about some of our experiences from the field with linking standardization of laboratory testing practices, to HIV/AIDS program expansion, predominantly from a supply chain management point of view.

The first point I think is something I don't need to spend a lot of time with. Everybody here knows that lab services are really critical for a comprehensive HIV/AIDS program. This includes diagnosis of HIV, STIs, TB and LIs. It also includes monitoring and detecting toxicity.

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The second point is more about the supply chain management portion of it. The management of lab supplies and, especially for expanding programs, is really complicated when there is not standardization of laboratory testing policies in the country. Now essentially, what we mean here is that the more options there are in the laboratory system for different types of testing techniques and different types of equipment, the more reagents and consumables are needed, because the reagents and consumables are unique to each testing technique and equipment. Next.

So why is it standardization important for program expansion? In addition to improving the efficiency, quality and affordability, which I'll talk about a little bit later, it also allowed for rational decision making in areas like product selection, quantification and procurement. It also enhances the management of the lab supplies in the national laboratory system by reducing the number and streamlining the actual number of products in the system. And finally, it increases the agility of the supply chain by allowing for redistribution of supplies throughout the system, which helps to avoid stock imbalances and expiries. Next, please.

So clearly on this side, we have greatly simplified the steps in standardization, but I was only given five minutes today, so I will go through it quickly. When we talk about

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standardization, I just wanted to point out it's not a matter of, from a supply chain perspective, just deciding which supplies are needed. But it requires first to address how and where the services are provided, and then the technique, equipment, and the level of the system. So the first thing that we've found to recommend is really to gather sort of the universe of what's already being done in the system. Find out what the test menus are in the country and the test techniques that are being used at different facilities. Find out if there are any standard operating procedures in the country for those laboratories, and make a list of the equipment that's used, by level.

The second point is to really build consensus. If you're going to go through the standardization process, you need to have all of the stakeholders involved in this. I'll talk about this a little bit more later, but the key is to really have representatives from all levels of the system, helping to make the decision about what the actual standards for laboratory testing techniques will be, by level.

The third point is something that actually came up a little bit this morning at the laboratory session. And it's really that it's one thing to standardize, it's another thing to actually implement those standards. And the key is updating, disseminating, and implementing the new standards,

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probably through either a transition plan from the current standards, to the agreed upon new standards, and implementing plan. Next, please.

So we all know that there's quite a few challenges in standardization. These are just listing a few, and I know from some of our conversations this morning, there's a lot more. The first point out rapidly changing technology, basically the technologies we know are changing routinely. They are changing routinely and it's often a push for the program managers to change, they want to change to take advantage of these new changing technologies. The issue with that, and the challenge, is basically compromising the public health approach at the same time as taking advantage of the new technologies on the market. Reaching consensus on the selection of equipment was one of the major problems actually that we've had, mostly because providers have specific preferences to the equipment that they use, whether it's what they were trained on, or whether they just prefer the results from one equipment or another, changing the behavior of what they're currently doing to actually follow the new standards, can be very challenging, especially when you're talking about sort of their institutional knowledge, and their previous training. So therefore, you need to invest time and resources into actually creating this transition plan into

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the new standards. And in resource limiting settings, that can be quite challenging. Next, please.

So we're going to - I'm presenting here the results from two countries. So basically just because we feel that these results are key things that you will, that these are results that you will find from a standardization policy, or a standardization exercise, in your country. The first one for people who manage the supplies in the country is standardization can significantly reduce the actual number of products in the country, and we estimate it can be reduced by up to 90-percent. It also simplifies the training needs, basically because once the staff are trained on the new standards, moving between facilities will not require more training. In addition, it allows for some rational decision making, product selection, it enables economies of scale. Basically instead of buying smaller quantities at 3,000 supplies, you're buying larger quantities at 300 supplies, so you can get a better price on it. And it also increases the flexibility of the supply chain.

The last point, I believe, is why I was actually asked to be on this panel, but I'm not going to go into detail on it. Basically the point is if you have a standardized system, you have labs doing the same tests at

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the same level, you can have a quality assurance program.

One more slide, please. Thanks.

The recommendations, obviously it needs to be a collaborative effort, you need to have representatives from everyone in the labs, different levels, also all of the stakeholders involved in this process. Also, the national policy, you really need to enforce the new standards, and program managers need to be sure that these policies are adhered to. And then finally, the procedures should be routinely reviewed and updated, especially because of the fact that technologies are changing so regularly. So I actually have only been able to touch upon this topic, and I do have some documents in the back if you're interested. So please come and see me if you'd like one. Thanks.

MARK RAYFIELD: Do we have any questions?

MALE SPEAKER: Thank you. Wendy, my question was I wanted to ask how you dealt with the challenges of standardization. In some countries, you can find that this can be complicated by citizens. If the government is the biggest player in the market, you get citizens from alliances with companies from different places, and therefore, because the public sector is the biggest procurement sector, you end up having to look at where your citizens want to play a role in managing the health system of their country. And in some

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cases, like in Rwanda, it's called Citizen Empowerment - I think in Africa, it's called Black Empowerment - you find that there are efforts of people to see, how do you standardize it?

One of the things that we have been debating about was maybe you set out the tender guidelines in which you can be able to say, every people participated in it. But it's not an easy thing because a lot of citizens have got a lot of political win, in which they have lobby groups which are very powerful, and therefore, it can impede that. So I wanted you to share the experiences in Zambia, and tell us what you've done, how you were able to get around it. Thank you.

WENDY NICODEMUS: Just actually a quick clarification. Are you talking about the procurement process and the actual tenders, or are you actually talking about getting the agreement on the standards?

MALE SPEAKER: I'm talking about both, in which case, like for instance, if you have, let's say you have CD4 technology, you have VD, you have [inaudible], you have site flow, you have all these technologies, and you have citizens who have formed alliances with these companies, who are also looking to the government to provide them with what you need for being able to play a role in the health system. And the question is in that case, when you set out your tender

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system, it has its own political things because you can be blamed for biases, and there's a lot of questions as to how do you actually procure, because you have to distribute the procurement amongst your locals.

WENDY NICODEMUS: Sure, sure. I'm going to take a stab at that question, but I think it's something that maybe we can discuss a little further later. When it comes to, I think it comes down to the preferences of the equipment, and like I said, it's just a challenging issue, especially when people to have these kinds of alliances.

One of the challenges with standardizing on one specific equipment is that typically equipment, especially for CD4 like you mentioned, are closed systems. So once you choose one equipment, you can't do an open tender process. In Kenya, honestly, or in Kenya and Zambia, we basically went through the process of reviewing working with stakeholders, working with implementing partners, working with practitioners, to agree on those standards. It took a long time, and a lot of different people were involved in this process, it wasn't just us, obviously. And eventually the Ministry of Health came in and said this is what we're standardizing on. I'm not sure that really answers your question, but it's a start.

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MALE SPEAKER: Unfortunately, the gentleman has addressed one component of the question, but I want to raise some concerns and some specific concerns. Based on the [inaudible] investment of the lab equipment and supplies companies, how to ensure the alignment of the providers to the new standardization procedure?

WENDY NICODEMUS: I think the key there is the transition plan that I was talking about. I didn't get to spend much time on that, but there needs to be time, resources, you need to get volume from everyone in the system. One of the keys is to have a consensus building workshop in these standards, to make sure they are what everyone agrees on. Rolling out the system, it's not a small activity. It really needs to have time, training, making sure that everyone has the equipment to follow these standards. It's a very challenging topic. And you know, almost theoretical, and not as, it's important in order to have these, all of the successes that I talked about. But, and sometimes in standardization, it's just not a possibility at some facilities.

MARK RAYFIELD: Thank you. If you hold your questions to strictly clarifications, it will help. We are going to take an opportunity to assess this more widely after all the speakers have presented their opening remarks. Our

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next speaker is Ilesh Jani, out of Mozambique. He will be presenting on the "Establishment of a National External Quality Assessment Program for CD4 Lymphocyte Counting and HIV Serology." Ilesh.

ILESH JANI: Hi. Thank you for coming and spending your Sunday evening with us. Can I have the next slide, please? I am going to briefly tell you about the establishment of QA programs for both CD4 and serology in Mozambique. I start with the CD4 program. We established the CD4 program in 2005, in partnership with Quaze in Canada. What we do is that we send out every four months, we send out proficiency panels that are made of two specimens, one with low count and one with the normal count. These specimens are both shipped from Canada to Mozambique. And then in Mozambique, we are using services, we send out these specimens to all participating labs. In the last sendout early this year, there were 12 labs participating in these panel, which is all labs that do CD count in Mozambique. The data that I will show here very briefly, after analysis with four panels, this data summarized both in Mozambique and in Canada, [audio interruption], our analysis shows so far that 5.3-percent of institutional participations and 2.6-percent of recorded results were not acceptable as defined by NSTI, higher than

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2.0. So this is very briefly what we have done so far with the CD4 and QA. Next slide, please.

Now on the serology QA, we started it in 2006, in partnership with the Federal University of Rio de Janeiro in Brazil. We send out also proficiency panels that are, in this case, constituted by six serum specimens with mixed HIV status. These specimens are characterized and prepared by our lab in Mozambique. And we use Career Services to ship it to the various participating institutions that can be TCTs, clinical labs, blood banks, et cetera. In the last handout of this year, there were 80 institutions that were participating in these proficiency panel testing. So far, we have sent two panels, we are sending panels every six months on this one. The data is analyzing parallel in Mozambique and in Brazil.

The results that we have so far show that 22-percent of institutional participation has at least one error in testing. If you look at the number of tests that were made, then 3.8-percent of the reported tests had an error. The next slide, please.

So what I want to spend some time discussing with you is what we think are the critical processes in implementing these QA programs. First is that these programs are working so far because we have been able to establish capacity at

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national level to run these programs, and we have done this through partnership with, in one case, a Canadian institution, in another case, with a Brazilian institution. This expertise at national level is important because there is a lot of interactions that go on with the testing sites, with the programs with the Ministry of Health, and that can only be done if you have people within the country dealing with these issues. One of the big challenges has been communication with sites - many of these sites that you work with, they don't have phone lines. We're lucky that many of the people that work there have mobile phones. So again, mobile phones have played an instrumental role in communicating with these sites. We have been developing this approach, mainly based on education.

So in absence of legislation in the country that talks about certification of labs and of testing sites, people only participate in these kind of schemes because they're willing to participate and they are willing to learn. So we think that the only way to succeed is to develop an approach based on education of the people who are dealing with the testing. And the interaction with the various programs that the Ministry of Health has been also very important because whenever we want to, whenever we identify a problem, let's say in the blood bank, the only people that

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can go out and help us to interact with the technicians in the blood bank, are the people that are running the blood program. So this interaction with the vertical programs at the Minister of Health is very important. Next slide, please.

So as some of the thoughts that we have on these, on how to proceed, first this kind of QA provides what we are calling quality awareness, you know, people start being aware of quality, issues related to quality. And in QA also provides an opportunity for the introduction of more comprehensive QA programs that not only deal with HIV testing, or CD4 counting, but can start talking about other disciplines too. So it's a kind of a door to enter into the lab and start interacting with people about other activities in that lab.

The last two points - they are somehow related, but in a country like Mozambique, which is relatively speaking, a big country, we have many institutions that participate in the testing process, but the only way to approach QA is to approach, have a decentralized approach, where a regional laboratories can help the reference laboratory to run a QA program. So we have to, we are now developing an approach by which we will work with the provision laboratories, and then the provision laboratories will help us, and function more or less, as a public health lab for that process, and will help

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us to interact with the district labs, and the VCT sites, and the blood banks, in that given province. Now that poses a big challenge, because many of these places, they are understaffed, they have a heavy clinical routine, but, I mean, this is to, in our view, it's the only way forward. So we are going to concentrate on strengthening the provisional laboratories so they can work with us on more comprehensive care programs. And I think that was the last slide.

MARK RAYFIELD: Are there any immediate questions?

All right.

FEMALE SPEAKER: The QA for blood services was just for HIV, or the other, TTE?

ILESH JANI: In the last panel that we sent out, we included, we requested results also for hepatitis B surface antigen testing, so the panel were for both HIV and hepatitis B surface antigen for the blood banks.

FEMALE SPEAKER: And did you use the same panel for laboratories and blood services?

ILESH JANI: Yes. It is the same panel, and in blood services, it's the same set of specimens that work for both HIV and hepatitis B, too.

MARK RAYFIELD: All right, our next panelist is Calista Osuocha, and she will be presenting on "A Pilot Study

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on the External Quality Assurance of Retesting Modules for
the HIV Rapid Test Algorithm Performed in Nigeria."

CALLISTA ASAMOLE-OSUOCHA: Good evening, ladies and gentlemen. My name is Callista Osuocha. I will start this presentation by giving you background information on the [inaudible] projects. We have over 400,000 rapid HIV tests conducted in hundreds of cities supported by gain in six states in Nigeria. We realize the need to use QA and to establish the reliability of the test results in the testing sites. We therefore conducted two pilot studies to determine the feasibility of establishing a system procurement test program. In the first pilot, we collected 338 serum samples from 10 comprehensive sites in six states. The samples we have chosen by selecting one out of every 10 that were positive and one out of every 20 that were negative in the month of October 2006. For pilot study, we had a total of 660 serum samples from 11 comprehensive sites in the six states.

In the second pilot, we had a slightly different approach. We collected 60 serum samples, irrespective of their test results, in the month of November or December, in these sites, and the 60 sample sites we used were determined based on the CDC/WHO statistical model. And we got these samples from the states on a form giving us the lot numbers

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of the samples with the results that were at least by the sites. And the first five months, we had to retest and build up by [inaudible], and with the second pilot, the retesting was done by the state's quality of assess.

Now we had to rebuild the system because all the samples - not having to rebuild, using the EKU number that we got by using the initial EKU number, followed by a four-digit number. And after that rebuilding, we now had another form that had the EKU numbers with the corresponding site numbers, and the results generated.

Now, the testing was done using the Nigerian HIV pilot test algorithm. And this algorithm involved using [inaudible] as a tiebreaker. The results were recorded on EKU test program worksheets. The results we got was that in pilot one, out of the 338 samples, we had 336 that were not in agreement - that were in agreement, that is 9.4-percent, and two were not in agreement. In pilot two, we had 652 samples tested, and with 652 samples, they were 100-percent in agreement. Now for pilot one, we tried to investigate the two samples that were not in agreement. Next slide, please.

And the two samples that were not in agreement in pilot one had the original results reactive. The retest results we got were not reactive, they were retested by rapid testing, and there was three more reactive. We did the

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Western [misspelled?] blot on the two samples, the first one was indeterminate, and the second one was reactive. So because we couldn't get a conclusive result from that, we wanted to investigate by getting a hold of the patients, and then in trying to get these patients, because of the confidentiality law in rapid testing, we were unable to get these patients, to get a fresh sample and retest. We then tried to get the patient using the referral code, and we were still unable to trace them.

Now for pilot two, we had a total of 660 samples, but eight of these had insufficient quantity of sample, so we were able to test only 652. Of the whole, 652 were in agreement. Now in analyzing the samples, we saw that 37 out of the 652 samples we tested were discarded. We started back and determined, that one is reactive and the other non-reactive, even though the final results were got on retests tallied, found out the results the sites gave out. So we now tried to find out whether the discarded results were the same as what the site got originally. And in the process of trying to find that out, some issues were highlighted, like the absence of the blood for control, and we also realized that we need, for subsequent testing, we need to get information of the results of individual drug test kits, along with the final results.

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In conclusion, we realized that while the comprehensive laboratories are actually performing well, they are giving reliable and producible results, we realized that in the system even though we have to maintain confidentiality, there has to be a system of keeping records so that we can check patients in the event of quality issues like that. And we realized that the pilot program has shown that the sites are performing well.

We have actually started implementing, we've done the first phase, and we implemented by choosing four sites out of every state. We don't have that, we are still analyzing the results. Maybe sometime in the near future we will be able to share the results of the implementation. But I can share the results because this retest model is supposed to work in conjunction with the proficiency testing pilot. So we've got it at these comprehensive sites, registered with national health laboratory services in South Africa, and the center's panels in March this year, and just before we came to this meeting, the results of the proficiency testing that we did were returned to us, and all the AIDS sites had 100-percent results from the program. Thank you. I wish to acknowledge -

[Applause]

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MARK RAYFIELD: Points for clarification? Next is Ana Blanco from Health Alliance International. She will speak on the Scale-Up of Laboratory Services in Mozambique.

ANA BLANCO: Good evening. My name is Ana Blanco, I am working with Health Alliance International as a laboratory technical advisor in Mozambique. I am going to talk about the experiences of Sofala and Manica Provinces in this clean-up of laboratory services to support the HIV/AIDS care programs.

Health Alliance International, or HAI, has a long history of more than 20 years working with the [inaudible] sector in Mozambique, especially at the district and health facility level in Sofala and Manica provinces, places where the population is allowed to be 27-percent and 19-percent respectively. Mozambique is rapidly expanding HIV testing and treatment services in overall health facilities. By April 2007, in these two provinces, had 60 [inaudible] sites, 52 pntc [misspelled?] sites, and 36 regulatory sites, with approximately 10,000 persons seeking treatment. This says that this scale-up depends largely on the reliability and quality of laboratory services, qualified human resources, and essential testing such as CD4 and hematology and clinical chemistry serum, are critical, and much lower than Mozambique in meeting these requirements.

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All activities that I am going to mention were coordinated with district, financial and national health regulatory in Mozambique. In generic terms, we used an need assessment tool from [inaudible] context, in order to determine the necessities of each site, and later to provide clinical recommendations based on the needs. The upgrading of the lab infrastructure ranged from small rehabilitations to bigger rehabilitations to total reconstruction to some of the labs. The logistics for reference of samples and return of soles and transportation, were set up, and allocation of new equipment for older sites were compared to the level of complexity of each site, were both from local suppliers, and we looked for equipment that was compatible with the equipment that was already supplied by the Minister of Health. We tried to compile a kind of recommendation.

This map shows the laboratories with the capacity to perform chemistry and hematology analysis at that point in 2005. And the red square is the reference lab procedure for counting at that point. For any one period, one more lab in Manica provinces was upgraded for testing, and 17 more labs were upgraded, 10 of which were equipped. And also, we - next - strengthened the [inaudible] system. These yellow points were indeterminate, red lines were the sites without

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equipment that referred the samples to more central sites.

Next, please.

And this slide shows the huge increase on number of CD4 tested with the rapid lab, and also installation of a flow site meter in Manica province. The efficiency of city port tested increased up to six times and turn around the results, decreased from 20 to four days in Manica province, which performed CD4 test with single platform techniques. And for Sofala province, the number of turnaround of results increased from 10 to 30 days, and it's important to know that our lab is doing CD4 test, using the dual platform technique, and also a number of samples handled by Sofala's lab are much higher [inaudible] Manica province.

Main strategies to maximize human resources are the plans for a patient [inaudible] of qualified human resources. The ideal was to have at least one lab technician per laboratory with equipment, plus addition of basic staff. We also helped with trainings, in service trainings, and initially focused on CD4 testing, clinical chemistry and hematology, diagnostic for opportunistic infections, with laboratory practices, quality control and quality assurance, new equipment indication and computer use, and later during the supervision visits, we call it [inaudible].

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Follow-up was also done periodically and also evaluation of the process. Main strategies to ensure quality control were the [inaudible] laboratory standard operating procedures and a strengthening of quality assurance activity, such as user controls for each test to run, comparison of results into our laboratory in our district laboratories, and there is a - there is no nationwide systematic quality assurance program, so only the two CD4 counting labs participated in our external quality assurance program, our proficiency program, that is leaving it for the laboratory of humanology in [inaudible], which was the one that Dr. [inaudible] was just mentioned. None of these activities were performed before.

We have many ongoing challenges, continuing with expansion while guaranteeing quality, support and strengthen of lab procurement and this system, increased service training, especially for superior and medium lab technicians, guarantee with quality trainings and regularly maintaining by supply, which is currently very weak, and to find technologies to monitor patients with minimal infrastructure.

The main lessons learned: We found with this experience that leadership by lab monitors and buying all health directors were on teams sustaining availability, and finally, it is critical to ensure that lab improvement by a

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strengthening in primary health care in general, and not just to support HIV and AIDS care. Thank you.

[Applause]

MARK RAYFIELD: Thank you, Ana. Are there any questions at this point? All right. Our final panelist is Dr. Phyllis Kanki of the Harvard School of Public Health, and she will be addressing the role of Laboratory Quality Assurance Program.

PHYLLIS KANKI: Thank you. So what I'll be presenting today is a little bit of an overview of our quality assurance program in the Harvard PEPFAR Program in Nigeria. Obviously, this has been covered by many of the speakers, but the laboratory plays a critical role in diagnosing infection, looking at eligibility of our patients, looking at safety, drug toxicity, adverse events and, ultimately, treatment efficacy.

All of our laboratories go through GLP training, and we try to have policies and investigations set up as the laboratories are being developed. We want to make sure that, aside from algorithms and choice of tests, that our results are correct, that the correct results and interpretation is actually delivered all the way to the patient record in a timely manner.

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What's easy to do, I think, from our experience, has been to set up a laboratory and to get the right equipment. What has not been so easy to do has been to sustain the quality and accuracy of our results.

So this just is a picture of Nigeria and many states that we're in - we're in nine tertiary Teaching Hospitals which already had significant infrastructure, and then additional 21 satellite sites. Seventeen of them are delivering ART, and about 30 are delivering PMTCT.

So this is the basic menu of the types of laboratory assays that we've put in place. Some of this has predated the PEPFAR program, but the HIV diagnostics STIs automated hematology and chemistries, CD4, CD8 by laser, viral loads, early infant diagnosis by PCR, and currently borrow subtyping and drug resistances supported separately from PEPFAR at the School of Public Health, but will be moving into the country this year.

And this just shows the different facilities in Nigeria, and the technologies that are in place, and some of those are ongoing. And then we have a shorter list or menu or laboratory assays that are done at our satellites. So just as incurred by many of the other speakers, part of the whole laboratory organization and quality assurance program is broken up through pre-analytic, analytic and post-

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analytic, and as we move through the development of building infrastructure of our laboratories, we really focus quite a bit in lab audits, anyway, at the post-analytic phase to make sure that our results are correct and that they're being delivered to the records correctly.

So we have a manual of operations, procedures. All of our sites harmonize our protocols together, and we continuously meet with all of the laboratory managers in a country, we have external quality assessment whenever possible, as well as central reference lab, which is Harvard, which provides some of the panels, and then we're encouraging cross site quality assessment. We have continuous training, usually broken by technology, and we also, particularly as we roll out to new labs, have senior labs help train our junior labs. Next slide.

So this is just a little overview of our quality assurance program, we send out to cap for our HIV and also HBV serology, in chemistries on a regular basis, and our CD4 is sent out to the UK network. Harvard provides the viral load panels, and also the panels for infant PCR, and we do that twice a year.

This just shows an example of how our sites are evaluated on a range of viral load standards. And I think this isn't something that has been covered by other speakers,

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but we feel is sort of part and parcel of quality assurance and part of lab infrastructure development, and that is making sure that the correct records, lab data, actually gets into the patient record.

So this is an example of how we will do quality improvement programs to make sure on chart pulls, the toxicity values from our laboratory are being recorded, and all of our data is electronically entered, including the laboratory, and you can see viral loads in red, big red dots, the CD4s in the blue dots, pharmacy pickups as small green on the very bottom, and then you'll see the various chemistries that we use to trigger panics. We panic on liver enzymes, creatinine, and hemoglobin, and this is a utility that automatically identifies that toxicity.

And then the last slide just shows that we also want to do, on the chart pulls, the assessment of clinical efficacy, or sorry, laboratory monitoring that supports efficacy of our treatment, and here we see the decreased viral loads and the increase of CD4s, with a switch in ART treatment. And what we're doing regularly now for each of our sites is to also chart pull on patient records, and check actually the laboratory entries from the source documents into the electronic record. Thank you very much.

[Applause]

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MARK RAYFIELD: I'd like to thank all of our panelists for their discipline, this was quite an effort to present a number of years of work in five minutes. And I think they've achieved it well, we're fairly well on time, and I'd like to open the floor for discussion at this time. Thank you.

FEMALE SPEAKER: Thank you again, panelists, for staying on time. That was really terrific. Most of you presented on program level, external quality assurance, but two of you presented Haiti and Mozambique on a national level program. And in those two national level programs, are there standardized national level SOPs and testing algorithms, to go with both the CD4 and serology, for those national external quality assurance programs?

CLEMENT NDONGMO: For Haiti, we do have a national testing laboratory for HIV serology, and I presented only on HIV serology, not CD4. We soon are planning to introduce other activities. And the SOPs, we are yet to really have national, or nationally enforced, or implemented SOPs. We're working on that.

ILESH JANI: I started with the serology, there is a national algorithm for serology testing in Mozambique, so all sites using the same algorithm. SOPs, I think, is just a bit more complicated. I mean, the SOPs for serology are part of

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the training, and we have identified the training is one of the major issues in scale-up for HIV and rapid testing in Mozambique, so unfortunately a lot of the training is being done by many of the partners in the country. There is no standardized training material that is used, so, I mean the SOPs are a big problem.

For CD4, things are better. There are SOPs in our labs and it is clear from the QA program too, that the performance on CD4 testing is much better than on serology. But one also has to say that there are 15 sites in the whole country doing CD4 testing, while for HIV serology, we probably have more than 600.

MALE SPEAKER: And thank you, all the speakers, for very nice presentations. I have two questions, or maybe a comment. In all your presentations, none of you presented or emphasized the role of site visits. Just going to the last to check, what the records keeping SOPs as actual, I think. You all were heavily involved in setting up or doing the testing, do you think this is an important aspect that we should highlight as we scale-up programs? Because in my opinion, it would become very, very difficult and challenging to be doing retesting in over seven percent of specimens, or sending out planners to 4,000 sites in the country. So I

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just want to hear from all of you, what do you think we should be doing in terms of emphasizing site visits?

The second aspect is you kind of mentioned, that one of the speakers mentioned, usually that which I like a lot, which is maximizing your resources. Do you foresee a situation where you cross train technicians, or lab experts, and go to the field and take care of at least three different tests, like CD4, serology, and smear microscopy, so that we don't need to send one personnel to go check the serology, and a representative goes out with CD4?

PHYLLIS KANKI: Hi, John. Well, I guess I should have emphasized more, we do really believe that quarterly visits, site visits, or audits, are important, and particularly as you're starting up laboratories, but even after that. And we do track the history of how each site does and check it again later on. So I do think that that's very important.

Oh, yes, and the other, the last two slides that I showed, were really how we tried to include the laboratory into a quality improvement program, which is to do chart pulls on a complete patient record, but trace back to the lab to make sure that the lab data from the source documentation, is actually getting into the patient record properly. And I think that's something that wasn't emphasized previously and

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we've actually identified a lot of different sources for error and maybe some improvements to those processes.

WENDY NICODEMUS: In our AIDS-related program, too, we also do monitoring visits. We call them monitoring visits instead of site visits, but we go back every quarter, or depending on the laboratory, if they need more intensive monitoring, to make sure that they are putting the laboratory practices, that they have quality systems.

FEMALE SPEAKER: Well, I would say that it was a very quick presentation, I probably would put an emphasize on these parts, but part of one of the main things we are approach in the upgrading of lab services and supply [inaudible] in Mozambique, where the sites visits are 20, and we perform, at the beginning of the process of intervention, we provide a lot of very frequent follow-up and training and support in site visits, and also recently, at least monthly progress, we go into the field. And every time we go to the field, we try to at least continue education and do presentation, and work with the lab technician on the things that we found the most weakest in things that they have in the lab.

FEMALE SPEAKER: In Nigeria, we actually realize the importance of on site monitoring visits, and for the retesting and the proficiency testing, we do it in such a way

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that we do those ones three times in a year. But for the onsite monitoring visit, because we realized the importance of following closely, these sites are monitoring their performance and emphasizes relearning. We have stuff in every state of the nation, and we have a way we have worked out on site monitoring, so that each site gets visits on a monthly basis, so we actually put more emphasis on onsite monitoring visits, but it was not highlighted in the presentation because this is actually tilted towards the richest model. But we have such plans in our program.

MALE SPEAKER: Okay, I did mention in my presentation that actually all the sites participated in the scheme, were visited so that someone besides that score 100-percent on that panel, when we went visiting them, actually they did not meet our requirements of follow SOPs. So we really recognized the importance of site visit, not just sending samples and getting results. In terms of maximizing the human resources, and standardizing, having integrated site visit, I think we actually use the HIV technical assistance to have technical lab passing out to go and stay for an extended period of time to accompany the sites into providing them the systems.

MALE SPEAKER: I think one cannot underestimate the importance of site visits, but having said that, if one

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considers sending QA panels expensive, it's even more expensive to go out to each site and visit them. it's a tremendous effort to go and visit sites, so I think at least in our setting in Mozambique, the only way a program of site visits and local technical assistance, is if we can decentralize the QA program, and not run the QA program from one national reference lab, but try to work with all regional labs that are involved in the program. And it think that way we can both have a program of site visits, and at the same time, maximize the use of human resources.

FEMALE SPEAKER: Sorry, I'd also like to mention that we have an onsite monitoring checklist that we use for onsite visits, and we have tried to work out a situation where we have quality of assess in the states, they work along with our sites to do this onsite monitoring, because we are looking at a situation of sustainability as time goes along. So it's actually a major part of our QA program.

MARK RAYFIELD: Is that everyone? If we could have Ezekiel [misspelled?], and then Douglas [misspelled?].

MALE SPEAKER: I want to thank all the speakers for good presentation. And in line with what John had said, in line with our own experience of the action projects of the Institute of Virology in Nigeria, we are presently observing these sites. And one of the observations that we find during

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regular, frequent site visits, is transcriptional error. And that's why it is very important that site visits should be a regular component, and to ensure the effectiveness of a quality, monitoring, or improvement program, with a now sufficient regular quality assurance officer, and have a dedicated site quality assurance that is nominated by the site, that take and monitor the [inaudible] of the quality assurance program at the site level.

Now my question goes to my friend from Malawi. The change in authority, is it prevention being driven, or cost driven? And is your change, or planned change, in line with the World Health Organization strategy of testing? Now the other question goes to Joyelle. Perhaps you need to elaborate what you mean by internal quality assurance program. Is it the same as internal quality control or not? And if it's the same, how do you prevent the sending out of a wrong result when the results generated, it's out of range? To my friend from Mozambique, I'm quite interested in learning from you, your experience in CD4 quality assurance program, or a standard quality assurance program, the metal of your shipment to sites, and what are the challenges that you encounter in terms of variations in results from various sites? Thank you.

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FEMALE SPEAKER: Our internal quality assurance program, is a large component of it, is the internal quality control, but I think it also brings in the aspect that this is not one approach to quality assurance, it combines all the training that you put into the program and all the monitoring visits, and ensuring that the laboratories, you work side by side with the laboratories, to make sure that they are increasing their level of quality assurance. And one of the factors of that is the quality control.

MALE SPEAKER: Regarding the proposed shift or switch of retesting algorithm, from parallel to serial testing in Malawi, first it is in line with the WHO testing strategy, second is, it is more a cost consideration, but based on prevalence, I think Malawi qualifies to be in the category of that implement serial testing, it's long overdue, actually.

MALE SPEAKER: I think with the CD4 QA, the major challenge has been to have permanent communication with the labs to participate in the QA so, for example, the people in the lab, they need to know that the specimen is coming, and this communication is not always easy, and I mentioned in my presentation, for example, labs don't have phones, so one has to rely a lot of mobile phone communication with the people that actually do the testing to let them know that the specimens are coming.

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And the other one, the other challenge is that these specimens, they are temperature sensitive, so you want to get the specimens to the labs in a time frame that is reasonable, so the only way to do that, in our setting at least, is to use screening services, so we approach screening services to have the specimens delivered. And in our case, it has been a lot of an education process to the career services too, because they are not, at least in Mozambique, they were not used to transport specimens that are very temperature sensitive, and that need to get to the labs quickly. So it has been a learning process for us, and also for the career services, and for the participating labs, too. Now, I would say that in this year and a half to two years of experience, results have not been bad, considering all the challenges that we face in implementing the program, so so far we have had one participation that had an error that was considered to be significant.

It is true also that most of the labs are using single platform testing, but there are a few labs that use double platform, and the single error that we had, in fact, was from a lab that used single platform testing.

JACK JORDAN [misspelled?]: You thanked us for being here. I want to thank you for being here on a Sunday night, I'm Jack Jordan from University of Washington I-Tech in

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Ethiopia, and I appreciate any perspectives that you have about retention of trained laboratory personnel and how much of a challenge, and if you've been able to surmount those challenges regardless of your own country. Thank you.

WENDY NICODEMUS: I think retention of staff is a problem in all of our programs, and I think what we try to do is come up with things we think are motivators to keep the laboratory staff involved in the whole process of basically building this ARV program in the clinic, because a lot of times laboratories feel very disassociated from the program. So we try to hold training sessions, and also really encouraging networks between laboratories so that they can have us support some between their laboratories. And we also really advocate for communication between the senior clinical officers and the hospital directors and laboratory management, to make sure that they are communicating their needs, and what their staff needs.

FEMALE SPEAKER: Retention of staff is also a problem we have had in our program, but most once they are trained we have discovered that maybe something will happen in the government system, and they are transferred out. So what we have tried to do is to train as many people as possible, so that it is not restricted to a particular person, so that

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even when one is being transferred out, we will have a way of getting them back up to supplement.

FEMALE SPEAKER: Although I don't work with national programs, I just wanted to share one thing that I saw in a country that I visited, a way that they had actually addressed staff retention and some of the staff that I had been working on, was to give them incentives. In that case, it was actually to help them buy cars, and they were able to get cars for inexpensive price for a long through the government, as long as they stayed working with the government. As soon as they decided to leave and move on, then they had to basically repay the loans. But it was an interesting approach, I'm not sure how appropriate it is for developing countries, but it was a developing country that I saw that in.

MALE SPEAKER: Okay, hello. I have a question for the Nigerian project. Transcription errors are very common and are a major cause of wrong results. Okay, I said, do any of the levels in Nigeria have an intervention system?

PHYLLIS KANKI: Yes, so all of our laboratory data is entered into computer, but as you can imagine, some of the source data which comes out of computers, or there's probably other assays where you have intermediate and electronic records, and then you also have some handwritten registers,

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so one of the issues that we try to deal with in terms of developing this quality improvement plan, is that we trace all transcription from the source document for each of the assays. And we do that on a regular basis as part of the quality improvement, so say if you go into the site and you do a random chart pull of 100 clinical records, in addition to the clinical records, you will also trace back all of the CD4 chemistry hematology, all the way back to the source, to check for things like transcription errors.

And we did this recently at a site about a month ago, and we found a little bit below 5-percent of a transcription error. That error actually didn't make any difference in terms of what, in essence, was logged copy of ours, but I'm just saying that we did identify transcription errors, which isn't surprising.

FEMALE SPEAKER: Quality program in a laboratory is to improve the efficiency and accuracy in the laboratory. What I want to know is what do you do when you detect some problem, what is the step you take to resolve that problems, and especially when after you have give recommendation, and the problem continues to be the same in the laboratory?

FEMALE SPEAKER: Well, one of the things that this programs are supposed to pick out is staff competency, and then retraining. In our project, we just started this

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retesting program, and in some of the cases, we have looked into, like the issue of lack of records for kids control and things like that. We try to send out groups to those sites and ask them to give accurate information. And as time goes on, depending on what we pick, we have lots of strategies of fully correcting the errors at this site. So far, we have not had a case because we have not really implemented fully of where we have tried to address the issues and [inaudible], but maybe when that time comes, we will be able to address it. Thank you.

CLEMENT NDONGMO: I think the same thing applies to Haiti, where we just had the QA activity. So what we plan to do is to continue with this activity after giving recommendations. Actually I did not mention that we had the second QA scheme already, about two weeks ago, so we will be able to see how the site performance compares with the first scheme. And, of course, the training, we did training and I mentioned that also, that when we saw the most deficiencies of people not using the standard operating procedures, that we did training just to improve their skills.

FEMALE SPEAKER: Thank you. I am just wondering how you address the issues of internal quality control. Many of you mentioned external quality control. Personally, I think external quality control is wonderful, but I'm wondering if

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you have problems with people doing internal quality control on a regular basis, and if you do, or if you don't, how do you reconcile the cost of an external quality control program versus internal quality control? And especially for CD4 counting, which is fairly difficult in hematology.

CLEMENT NDONGMO: In Haiti, actually in the forum that followed the panel, we did ask questions about whether they use internal controls, and, of course, the response weren't very consistent. But when we went to the field for a site visit, we found some sites that were not using the controls, so we had to address that in our refresher training courses. Some of them did not - I don't know whether they do not realize the importance of internal quality control, so we had to have a refresher course to stress on the importance of that. So we hope that with the next session they will be more responsive as to whether they use, and the site visit will also tell us whether they are consistently doing that.

FEMALE SPEAKER: In our program, we actually look at a lot of infrasystem quality control in our trainings. So those sites, the sites that have been trained to do controls on a regular basis, and we actually check the records when we go to on site visits, we check the worksheets, and usually we have developed a system of record keeping for internal quality control, where they leave an account for the number

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of test kits that used as controls, and what they have used for the actual tests, and we often see reported to us on the data, a monthly summary of the monthly visits, and that cuts across for CD4 chemistry and everything, but it is built into the training, and from our assessment, our sites are actually complying in internal quality control measures. Thank you.

PHYLLIS KANKI: I'll just make a brief point. I think that most of the assays that we're using in the HIV system have internal controls with them. I do think that because of the cost of external quality assurance, that the concept of setting up protocols in four labs that are close by each other, that you can do the split sample cross site quality control. I think that's a nice alternative, and certainly we're thinking about that for some of our smaller satellite labs, that we wouldn't be, instead of registering them with say one of the international quality groups, we would probably do cross site, or have our main labs generate the panels and do it that way.

MALE SPEAKER: My question is on the cost and sustainability and capacity of building on those providers doing the external quality control. I was wondering that most of the presenters were saying they are using actually providers outside the continent, out to Canada, Brazil, U.S. Why are you, particularly in the case of Mozambique, I found

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it quite interesting, just next door in South Africa, you have basically the national laboratory service, as a WHO center, providing external quality control regionally in Africa. Why are you sending your samples to Brazil or to Canada?

ILESH JANI: I think there was some misunderstanding. But for serology, in fact, we prepare our own panel. The panel is prepared in Mozambique. So we are not importing proficiency panels, not even from South Africa, for serology. For CD4, it's different, it's a commercial preparation, I mean CD4 is a very challenging system. It's extremely difficult to use fresh specimens to send out, so what is working out now, at this all examples that I know, they are commercial, long term, stabilized specimens, for CD4. and these are commercially available. I think all sources that I know are in the U.S., in fact.

So there is no way, there is no other source for specimens with CD4 for QA. But for serology, I think you are right. These specimens can be prepared nationally, and in fact, it's not expensive. What we do is that we go out to the neighbor that is the blood bank, and we get plasma specimens that have been rejected, and we use these plasma specimens to prepare our proficiency panels. We need to

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characterize them, and allocate them to send, and in all the system in Mozambique.

CLEMENT NDONGMO: In Haiti, we use a commercial panel because the national lab is pretty new, and we haven't built good capacity to do our own panel preparation, but we plan to do that as soon as we have a good, solid lab capacity.

PHYLLIS KANKI: In Nigeria, I think the choices that we made were based primarily because we also have been working where they are doing an NIH funded clinical trial, so we are using the same groups. We didn't think that there was a large difference in cost, but we really went with Canada and UK, UK had some advantages for us in terms of transportation into Nigeria, because that's a very, there's a ready route, and, as I said, several of our site laboratories are anticipating being involved in clinical trials for ARV, so we thought it was important to have the internationally recognized external quality assurance group.

MARK RAYFIELD: Are there any further questions? Well, I'd like to thank everybody for staying with us, it's late, we appreciate your participation. Just one final reminder on the housekeeping: Buses to the hotels and residency will be leaving from the Jolly site. There are two gates. Gate one will be routes A, B, C and D. Gate two will be routes E, F and G.

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