Tools for Scaling-Up Viral Load Monitoring
Webinar Transcript

Wednesday, March 22, 2017

Pia: Greetings and welcome to today's webinar on Tools for Scaling Up Viral Load Monitoring. My name is Pia Kochhar. I am the Knowledge Management Coordinator for the AIDSFree Project. Before we begin today's presentations, I'd like to quickly review the Adobe Connect environment and set a few norms for today's webinar. Today's webinar has four presentations, followed by a discussion period during which our speakers will address your questions.

Within the webinar environment, please make use of the Q&A box on the bottom-right side of your screen to share your thoughts, note your questions, or ask for help with sound during the presentation. Questions you ask are only visible to you, our presenters, and technical support. If you are experience difficulties, our technical support will respond to your question privately. We will collect your questions for our speakers and will save them for the discussion period.

It is great that we are able to connect people from so many places today, but your experience may vary based on your internet connection and computer equipment. I will briefly go over a few troubleshooting steps if you have technology challenges today. A few troubleshooting tips: If you lose connectivity or cannot hear, close the webinar. Reenter the meeting in a browser other than Google Chrome by clicking on the webinar like provided. Use the Q&A box to ask AIDSFree tech for assistance.

If the troubleshooting steps are not successful, please rest assured the webinar is being recorded, and you will receive an email with a link to the recording following today's event. Questions that don't get answered during the Q&A sessions will be compiled after the webinar, shared with presenters, and responses from presenters will be shared with participants. To get us started, I will now turn it over to our co-moderator, Alex Vrazo.

Alex: Thank you so much, Pia. I'd like to welcome and thank everyone for joining us today. My name is Alex Vrazo, HIV/AIDS Clinical Service Advisor for USAID. Today's webinar is being organized by AIDSFree, and I will be co-moderating with Sabrina Eagan, HIV/AIDS Advisor for AIDSFree.

For today's webinar, we've gathered experts in the viral load field to highlight the network approach to scale-up, and to also feature two tools that can be used by country teams in assessing readiness and building capacity for laboratory diagnostic programs. I would now like to introduce our first speaker today, Jane Feinberg of John Snow Inc., to introduce AIDSFree's Viral Load and Early Infant Diagnosis Knowledge Base. Jane, over to you.

Jane: Thank you, Alex, and good morning, everyone, or good day, or good afternoon, depending on where you are. It's great to see so many people joining from all over the world. My name is Jane Feinberg. I'm a senior technical advisor with JSI. Shirley, may I ask you to mute so that we don't have so much feedback? Thank you. Great, thanks so much.

So, I'm here today to make sure that you know about an important resource recently launched on the AIDSFree website. First, I just want to give a little background about AIDSFree. The Strengthening High-Impact Interventions for an AIDS-Free Generation Project, known in short as AIDSFree, aims to improve the quality and effectiveness of high-impact, evidence-based HIV and AIDS interventions in order to meet country-specific goals and objectives.

AIDSFree is a five-year cooperative agreement led by JSI, with partners Abt Associates, EGPAF, EnCompass, IMA World Health, The International HIV/AIDS Alliance, Jhpiego, and PATH. AIDSFree is funded and managed by USAID's Office of HIV/AIDS.

So, why did we create an AIDSFree Viral Load Early Infant Diagnosis Knowledge Base? Since 2013, viral load testing is the preferred approach to monitoring patient response to antiretroviral therapy, and WHO has, since 2008, recommended prompt initiation of ARP in infants diagnosed with HIV infection. This requires early infant diagnosis, which we refer to as EID, and as of 2010, virologic testing is recommended for diagnosis of HIV in children under 18 months.

So, both of these recommendations or preferred approaches require increased capacity to offer viral load and EID testing. Indeed, many countries have adopted these recommendations, and are in the process of building viral load and early infant diagnosis capacity. This can be challenging. So, the AIDSFree HIV Viral Load Early Infant Diagnosis Knowledge Base is a collection of resources and tools to help people—countries, you listening, program planners and managers, healthcare workers, laboratory technicians, and others—find what they need to scale up viral load and early infant diagnosis.

AIDSFree developed this database with USAID, and is continuously updating the resource. At the end of the presentation, I'll let you know how to be in touch if you want to suggest additional resources that should be added. This is a screenshot of the knowledge base on the AIDSFree website. The URL is aidsfree.usaid.gov/resources/vl-eid, and we'll be sending that URL out in a follow-up email after the webinar, and of course, it will be captured in the recording, and I'll probably read it at least one more time before I wrap up here.

You may have noticed from the screenshot that the resources in the VLEID Knowledge Base are filed either under "Viral Load," or under "Early Infant Diagnosis," and further divided into categories. The five categories are Global Guidance and Country Experiences, Laboratory Management, Logistics, Clinical Implementation, and Monitoring and Evaluation.

The AIDSFree Viral Load Early Infant Diagnosis Knowledge Base currently houses over 50 documents and tools, including recently released viral load scale-up tools developed by ASLM—the African Society for Laboratory Management—WHO, CDC, USAID, CHAI, and others, including the tools in this sample list, which are just some of the documents in the knowledge base.

These include a clinician and laboratorian training tool, guidance for developing an assessment network and referral system for viral load and infant virologic HIV diagnosis testing, a costing framework tool, an inventory and forecasting tool, an M&E framework for viral load scale-up and implementation, an HIV viral load scorecard—which I think we're going to hear more about in this webinar—and a viral load scale-up facility readiness assessment.

So, these are just some examples of materials that are available in the knowledge base. All of the documents in the knowledge base are quite new. Most of them are not more than a couple years old, with a few exceptions of documents that may be from 2009 or 2010, but that were still deemed valuable and helpful. So, to learn more and to contribute to the knowledge base, please visit the AIDSFree website. Again, that's aidsfree.usaid.gov, and to go directly to the knowledge base, /resources/vl-eid.

As I mentioned, AIDSFree is reaching out to partners and scanning for additional documents and tools to grow the information in this knowledge base. You can suggest additional documents and tools we should consider adding by contacting me. My email address is here. It's jane_feinberg@jsi.com. You can also sign up to receive updates from AIDSFree by going to the AIDSFree website, aidsfree.usa.gov/email. I hope you'll visit the AIDSFree website and have a look at the resources available. So, thanks from AIDSFree, from me at JSI—

Sabrina: Thank you very much, Jane. So, please, if you have questions for Jane, or any follow-up comments, please go ahead and add those into the Q&A box that you see on your screen. We're going to move to our next presentation, which will be presented by Shirley Lecher, and I think she'll probably correct my mispronunciation because I got her name wrong. Thank you.

Shirley: That's fine. That's what everyone says, as much as… Good morning everyone. So, I'm going to talk to you about the viral load scorecard that we have developed in collaboration with USAID, and the learning objective for the scorecard. I want to mention that the document has been undergoing continuous refinement. It has been piloted in multiple labs, and we should have a final version, which you'll be able to see on your website within the next week.

So, the learning objectives for the viral load scorecard are to demonstrate how to perform an audit using the scorecard, to assess where our laboratories are currently with viral load scale-up and their ability to meet targets that the country has set for viral loads. At the end of this brief session that I'm going to talk about, you should be able to—when you see the tool, you should be able to know how to use the tool to conduct an audit using a user's guide, following the viral load scorecard along with it.

The purpose of auditing our laboratories—we use "audit" for lack of a better term. It really isn't an assessment tool, but gives you an indication of how the lab performs at various steps, and what is needed to actually do viral load testing, and also, to make sure that those results are forwarded onward to the clinical centers so that they are utilized for patient management. The purpose of the audit is to identify areas where improvement is needed, measure improvements as gaps are addressed, develop and implement a work plan to assess the gaps, implement quality assurance elements, monitor quality progress, and maintain continuous quality improvements.

During the audit process, we ask that the laboratories complete the scorecard in advance, which helps facilitate going through the instrument in a timely manner. It does take about two hours to go through the scorecard in total. That's with verification of the documents and the processes that they have in place. During the auditing process, we provide feedback at the end, and follow up to determine compliance thereafter.

So, this is the front of what the scorecard looks like. There's a user's guide that accompanies that, and the user's guide indicates

to you how to through the scorecard efficiently. We developed the user's guide so that we would have uniform collection of the information within the scorecard. So, the scorecard itself evaluates the test site, going through individual steps from the beginning to the end. You review the viral load and antivirologic testing site records. You observe the virologic—the antivirologic test, EID, and viral load site operations, ask open-ended questions, and discover the path for the specimen from the collection to the results reporting.

There's a pre-assessment phase, identifying sites, notifying the sites, and agreeing on the audit dates, conveying the importance of the viral load and antivirologic testing checklist. You familiarize yourself with the checklist. Then, there's the assessment phase, introducing the audit team, and then discussing the purpose of the audit, conducting the assessment using the checklist, and then, the post-assessment phase, debrief with the site management on the findings and recommendations, and then, agree on a plan forward to improve areas of weakness or deficiency.

So, part of the scorecard is looking directly at the records that exist at the testing site. You are to review the quality manual and policies, SOPs, any other manuals, such as safety manuals, if they have manuals, if they have one. If they don't have manuals for things, then look at SOPs that they may have. Make sure that they're complete, they're current, they're accurate, and they're reviewed annually. Usually, there's a sign-off for that process, so you look for not only seeing that they have it, but that they have been reviewed by the staff, and there's a record of that.

You look at the laboratory records as far as equipment maintenance, which is a significant challenge with many of our laboratories in sub-Saharan Africa. Daily maintenance is required, and when it's not, then that's a cause for a lot of equipment breakdown. Audit trails, incident reports, look at logs, personnel files, the internal quality control records, and proficiency testing records. You observe the site operations directly. Laboratory testing should follow written policies and procedures in the pre-analytic, analytic, and post-analytic phases. Laboratory procedures are appropriate for the testing performed.

Sometimes, the testing is ongoing while you're there. If that's the case, then you want to observe the procedure if you have the opportunity. If not, discuss the procedure from start to finish. Look for nonconformities identified, and if they're adequately investigated, and if they have been resolved and documented. Ask open-ended questions. Often, if you just ask, "Do you do this?" or "Do you do that?", the answer is often "Yes" or "90 percent of the time, I would say yes."

But, if you ask open-ended questions that allow them to explain their process, you get a more informed answer. Ask questions like "Show me how" or "Tell me about." An experienced auditor can also learn to answer multiple questions through open-ended questions with the laboratory staff.

Discover the path of the specimen. Follow a sample through the lab from collections, to registration, preparation, analyzing, result verification, reporting, printing, and post-analytic handling and storing of samples to determine the strength of the laboratory operations. As I mentioned, sometimes, you have the ability to witness that firsthand. Other times, it may be that they're not performing the procedure on the day that you go, but they can walk you through the process.

Confirm internal quality control results are recorded, that all the runs are reviewed for validation. Confirm the PT results. Evaluate the quality and efficiency of supported work areas. Talk to the clinicians if you have the opportunity. Learn the user perspective on the laboratory's performance. For reporting, the notes should be written neatly and documented. The scorecard should be properly and fully completed. This can be done on tablet form. It does not have to be done by hand. Ideally, it's done on a tablet for the ease of collecting the data and downloading.

Nonconformance forms are completed and linked to the specific requirement. Check that the accuracy of the findings are verified and a copy of the report can be given to the laboratory. Dissemination of your findings: Information is provided to the head of the laboratory, to the quality assurance officer, to the testing site personnel that are relevant to the audit, to program coordinators, to the regional and district program coordinators, to facility managers, and implementing partners.

Following the audit, you'll provide the recommendation. Ideally, you sit down and discuss any areas of deficiency, review the exit summation report, plan corrective actions jointly with the laboratory personnel, develop a plan and time frame for the corrections, and develop an official report. So, thank you.

Alex: Thank you so much, Shirley. Please continue adding your questions into the questions and answer box for our discussion session later. The next presentation is from Dianna Edgil and Jason Williams of USAID. Over to you, Jason and Dianna.

Jason: Thank you. So, we're going to take a two-presenter approach here. I'm going to basically open up and set the stage, and then Dianna will finish up the presentation and talk more about our overall network approach and overall strategy to address some of the things that we're seeing as part of the network development aspects of viral load instrument deployment, and some of the challenges that are currently coming to light as countries initiate scale-up.

I'm going to talk a little bit about some of the core components of viral load and EID scale-up, some things that we're targeting. I'll show you some numbers and instruments, a little bit on current demand and how that aligns with current instrument deployment, and then, Dianna will wrap things up and get more into some of the specifics regarding the overall network approach.

So, if you think about some of the core components—I think many folks have actually probably seen this slide, but there's four core areas for successful viral load EID scale-up. There's obviously the lab component where the instruments sit, where staff training and QA and result return methods are prioritized. Then, we have the logistics piece, which is the shop that Dianna and I work in, which is essentially around the procurement and some of the forecasting aspects of developing plans for procurement. We do have maintenance as a key piece here, also.

One of the challenges that we have in regards to the commodities component is that it's not people consuming products. These are instruments, so the maintenance issues need to be addressed as

part of ensuring continuity of service, but also to ensure that we are using the commodities effectively and efficiently. M&E is also a very big piece of what we do. It is a data-driven system, commodities as well as, obviously, the clinical lab interface, and ensuring adequate patient care in response to the viral load results that are coming out from the lab.

The viral load EID cycle—we've split it up into four key areas. Again, these are all systems. Think about the sample collection component. The network that we look at here—we have two different types of sample plans. We have DBS, which is predominantly a priority for the EID, but now, as we move into Abbott platforms in the field, it's a core sample type also for viral load. Sample referral is a big obstacle that we're looking at also.

We see that some of the tools that Dianna will speak to in a few minutes will help us map lab networks and identify ways to optimize those pieces of the sample referral network. We have the result return forms, and then we have the actual use of the results as part of clinical care. As we think about the number of machines that are actually deployed within countries, we see significant shifts over the past six months.

Here is a graphic representation of some of the larger countries. If we look at the blue bars, we're seeing instrument counts provided directly from the manufacturers in May, and as we move into the beginning of this year, we can see the beginning of some significant growth in some of the core areas. It's interesting that some of the numbers have actually gone down, and this is because of instrument replacements, changing to higher-volume machines, as well as getting further clarity from the countries in regards to which machines are used as part of the MIH HIV-related programs.

I think one of the things that we're learning very quickly here is that as we model and try to optimize the lab's network, it becomes very difficult for any one group of individuals to actually understand how many machines are actually within a particular country, since we have so many players and stakeholders that are contributing to the overall network.

Here, we're just looking at the instrument capacity, based on current instrument counts for just the Abbott and Roche platforms, and aligning that with the actual viral load and EID demands from 2016. You can see that some countries obviously do have significant access capacity in relation to the actual patients that are currently on treatment. Those that actually have more capacity than demand—obviously, there's some issues there, but when we do see demand increasing capacity, I just want to point out the fact that a lot of these countries are actually in a process of scaling up, and this would be basically their target for 100 percent coverage based on the 2016 demand.

This next slide is illustrating some of the GeneXpert instrument module procurements, as well as cartridges. A lot of folks are interested in GeneXpert, as well as the **[inaudible] [00:25:53]** for EID. This is the global, but if we actually do touch on just Africa, we're looking at around 13,000 modules for Africa and about 15.5 million tests with the project since 2010 for just the continent of Africa. So, I'm going to stop there and hand it to Dianna. Dianna will talk more about how we're actually addressing some of the network-related issues.

Dianna: I think that perhaps what is obvious from the data and the two graphics that Jason showed is that while in the past, we have been thinking about laboratories as individual structures that have people and equipment inside of them, sometimes that have a very specific **[inaudible]** done on funding, that are very specific to a certain implementing partner or a region within a country, what we're advocating for, based on the fact that there are so many pieces of equipment that come from a particular manufacturer, all of which are supporting the public health network and the healthcare system within an individual country.

Because of the need to rely on the underlying systems that Jason pointed out—such as your sample referral network, your supply chain system, your waste management system—that we should be treating our laboratory network as a network rather than as a series of individual laboratories with individual needs. This is specifically in the case of our conversation with manufacturers.

Right now, what we're seeing is that individual machines based on whether or not those machines or the individual within the laboratory has a good relationship with the manufacturer or in-country distributor, and often based on the in-country distributor, some machines are receiving better support than others. Some machines—based on the donor funding source—are receiving a better price per test than others. Some machines are not covered under a service maintenance warranty, whereas a machine in a building next door is covered under a service maintenance warranty.

So, what we're advocating for at this point is for us all to come to some understanding of what it means for us to have a laboratory network—how many machines exist within our network, what the capacity is for those machines, what the throughput is for those machines, whether they are over- or underutilized, what the commodity's needs are going to be for those machines, and to do so essentially as one team, agnostic of implementing partner, agnostic of funding source, agnostic of anything but their role in supporting your healthcare system.

So, in order to do that, what we first need is a baseline mapping of your system. We are definitely advocating for that in any way, shape, or form, but we do have a tool that can help, and I'll be presenting a bit on that tool in just a bit.

From the baseline mapping, from an understanding of what your sample referral network should look like, from an understanding of what your supply chain should look like, and from an understanding ultimately of what your commodity's needs are going to be, you can then have a more fruitful discussion with manufacturers about what should be one per-test cost that is all inclusive of your service and maintenance, of your connectivity solutions, of training for your staff over time, of any additional technology support that you might need—and we've just pulled out barcoding, sample processing, and workflow analyses as some that manufacturers might also support—and of enhanced commodity management strategies like vendor-managed inventory, where instead of having your laboratory staff having to

keep tabs on stock needs, the manufacturer would also be keeping tabs on those stock needs and would be informing you when you start to run low on a specific reagent.

As you probably have understood from that last slide, this is definitely going to need to be coordinated amongst donors, amongst all stakeholders in-country with the full support and leadership of administrative health, with all of the IPs on board. Otherwise, we find that there is still uncoordinated procurements, that machines continue to arrive in-country, and that manufacturers, in fact, can use that uncoordinated conversation and procurement to continue to expand the system in a way that may not make sense in the context of the entire network.

We also are advocating for the development of supply funds. Based on that network, we feel that data is important to an ongoing understanding of your system, and that reagent rental and bundling of services is something that will be ultimately supportive of manufacturer investment in your system.

So, as you're moving through your decision to expand your capacity, if you feel that that is necessary, once you've done your mapping of your network, additional equipment should be placed by manufacturers, and they should own and invest in your system rather than you setting aside the initial investment for that piece of equipment and then being stuck with a piece of equipment that either isn't supported by the manufacturer or, in a few years, becomes obsolete, and you then need to further invest in the system. So, we're definitely advocating for rental or leasing options.

We're also advocating for the development of and adherence to criteria for placement of additional machines, and one of the ways in which you can do this is to go through that mapping exercise, and to then come up with agreed-upon criteria for the appropriate placement of additional platforms based on their throughput, and based on whether they are conventional, near to point-of-care, or point-of-care, and what you see your needs as being in-country.

And then, of course, as I've just indicated, the integration of POC platforms into current networks is necessary. In the past with POC, what we've seen is that they have not been integrated effectively into a network. I'll move on to the next slide to talk about that a little bit more. We're all interested in point-of-care, and I think there may be a very optimistic assumption that some of the point-of-care technologies are going to fix the issues that we're seeing in-country with our current conventional laboratory network.

What we saw with CD4 point-of-care platforms was that this wasn't necessarily the case, that those pieces of equipment sometimes were utilized appropriately when sold appropriately, but WHO had released an article earlier in the—maybe later in 2016—indicating that up to 40 percent of instruments weren't even installed in countries, and we also—through our supply-chain systems—have seen that a large number of those machines were placed at points within the system where those patients were already being covered by conventional technologies.

And so, when you look at the number of additional CD4 tests being performed in an individual country, you actually don't see very much of an increased based on the addition of point-of-care equipment. Now, what that indicates to us is that in fact, we are taking tests away from the conventional network and putting them through point-of-care, rather than augmenting the system in any way and increasing access to patients, which is not ideal, and not what we had intended.

So, for point-of-care for molecular diagnostics, we now have two machines that have been approved by WHO pre-qualification for diagnostics programs, for use in antivirologic testing, and those are the Alere Q and the GeneXpert machines. They are machines that are at two different stages. The Alere Q is totally new technology, whereas the GeneXpert exists, and most countries have many of these machines that are already in use for TB programs.

What hasn't been worked out for these machines—specifically for HIV-related molecular diagnostics—is where they are most appropriately placed. So, we're advocating for a network approach

that includes the development of criteria for point-of-care so that when you are expanding your network, as you think through your access issues in remote regions, as you think through what a network looks like—especially in the case of—unlike conventional platforms—the possibility of having hundreds of these point-of-care machines in-country—you are, as well, having that conversation with manufacturers about their support for the network.

When it comes to conventional platforms, if you've got five or ten, it's a relatively easier situation for a manufacturer to know where all of those machines are and to provide some level of support for them. When you have hundreds of machines, and it's not really clear where they are, and they're somewhat more mobile than a conventional platform, we all start to lose control of our system. And so, up front, having that conversation with manufacturers is going to be critical.

So, these are the next sets—the next two slides, rather—are the tools that can help you to come to a better understanding of what your network looks like and how your network can evolve over time. So, the first is the LabEQIP tool, and the LabEQIP tool is a network mapping and optimization tool. Essentially, for LabEQIP, you can use it as a straight mapping tool where you take in coordinates of all of the elements of your healthcare system facilities, if you have a temporal referral network already designed, your hub-and-spoke, as well as your laboratories, and from there, you can determine what your footprint looks like, how many machines you have…

You can input specific assumptions around the quality of the laboratory itself, based on your proficiency testing data if you are a part of a proficiency-testing program in-country. You can put in any information that you have about utilization of those pieces of equipment. If, from your supply chain network, you have any information about the amount of product that has been bought for those machines or delivered to those sites over time, you can also look through the efficiency of each of those laboratories.

So, if you've got consumption data and you've also got your service statistics, the difference between the two of them can tell you whether or not you're wasting quite a bit of those consumables or reagents that go into your site. It can allow you to input information about human resources capacity, as well as information about equipment downtime. So, from all of those pieces of information, then, you can have a relatively good understanding of how functional your current network is.

And then, the LabEQIP software also includes an optimization algorithm. That algorithm allows you, then, to include additional assumptions about what your sample referral network might look like based on what you know about the operation of individual laboratories, and it can help you to redesign your network, or to design a backup network, or any other number of different dynamic options where you would be managing your laboratory network over time.

If you have a laboratory, for example, that has a piece of equipment that has been utilized at 40 percent, and then you see that you are increasing your utilization, and suddenly, you are now at 80 percent with that particular platform, you can then start to understand whether or not you need to place an additional piece of equipment in that laboratory or you need another laboratory to help you with your network over time.

So, the LabEQIP tool is useful for understanding your network. The next tool is the ForLab tool, which many people have experience with. It's been used in, I think, 23 countries in Africa at this point, and the forecasting tool—based on your laboratory network—can help you to understand your commodity needs over time. Both of these tools are linked on the ASLM website, and are also linked through the AIDSFree web resource, and if you have any questions about the use of those tools, you can always come to Jason and myself.

I think our email information is at the end of this presentation, but I can't remember. So, we'll see in just a second. Some of the takeaways here are that we are definitely advocating for a network approach; planning and procurement must be coordinated

amongst the donors; reagent rental is the way to go as you develop your—

Sabrina: Thanks very much, Dianna and Jason. For those of you who were listening, please continue to add your questions for Dianna and Jason into the Q&A box on your screen. Our next presentation is from Ritu Pati, who is from the CDC, so I will turn it over to you. Thank you.

Ritu: Thank you. So, I'm happy to spend a few minutes this morning talking about Project ECHO. ECHO stands for Extension for Community Healthcare Outcomes, and it is a model of evidence-based distance learning and mentorship that was developed at the University of New Mexico to improve access to care for complex health problems for underserved populations.

There are some key elements of the ECHO model, and that includes the use of hub-and-spoke network. So, what that means is that there's a hub of subject matter experts that connect with spoke sites, where participants are located at the spoke sites at distant locations from the hub. And, the hub and spokes connect via video conferencing. And so, the picture you see on the right side of the screen is a snapshot of what the video conferencing screen would look like, where this is the gallery view, and you can see all of the participants at the spoke sites, as well as individual subject matter experts and a hub of subject matter experts.

ECHO is also a case-based learning platform, so the typical ECHO session is structured to begin with about 15 to 20 minutes of a didactic presented by a subject matter expert, and then, it's followed by case presentations from participants at the spoke sites. Finally, ECHO really focuses on the management of chronic diseases.

So, the ECHO program was started by the University of New Mexico in 2006, and for those of you who may not be familiar with New Mexico, it is a large state in the United States, and very rural, and the ECHO program was started to help connect the subject matter experts for hepatitis C with providers in the rural areas of New Mexico because patients were traveling a very long distance

to get their hepatitis C treatment from the experts, and what ECHO did was allow those experts to connect with the local providers so that the patients could be managed closer to their home.

But, one point I want to make, which is important, is that ECHO is not telemedicine, which is a model where a subject matter expert is overseeing or managing the care of a patient from afar. Rather, what ECHO is—ECHO promotes increasing the capacity of the providers to manage the patients themselves. So, in that sense, it's considered a mechanism of de-monopolizing medical knowledge and really building the skills of the local providers to manage patients themselves.

So, what do you really need to start an ECHO program? Some of the key essentials are the support and leadership of stakeholders. So, in the countries that we've supported with ECHO programs, the ministries of health, as well as the key education and training institutions, are some of the stakeholders, and you really need a basic internet infrastructure and connectivity.

The ECHO program thus far has been using the ZOOM platform, which is a crowd-based platform, very easy to use, user-friendly, and can even be downloaded as an app on a mobile device. When we're thinking about where to implement ECHO, we also look for implementing partners in countries whose scope of work includes clinical mentorship so that ECHO could fall under one of those activities. And then, another important thing is to have a partnership with Project ECHO at the University of New Mexico, because they are really the global experts on this model, and their input can really elevate the quality of the ECHO program.

So, in this current PEPFAR era of promoting treatment for all HIV-positive patients and increasing rapidly the number of patients on ART, it's essential that we find ways of training healthcare workers—more and more healthcare workers—and keeping up their clinical skills in a cost-efficient and sustainable way. And so, our division at the CDC identified ECHO as one key intervention to consider to help support PEPFAR in this goal of achieving epidemic control.

The reason to pursue the ECHO model to do this is because ECHO is accessible and cost-efficient. It really offers a means of providing clinical mentorship and continuing professional education credits to healthcare workers while they remain at their posts, and therefore reducing the costs related to travel and limiting their time away from seeing patients. ECHO also fosters the development of peer networks and communities of practice, which has been shown to reduce provider isolation and improve provider satisfaction. It's a very flexible model. It offers the opportunity to address numerous programmatic priorities, including operational issues, clinical issues, laboratory issues, and we'll see some examples of that.

So, with this in mind, our division helped support the launch of the first ECHO program—HIV ECHO—in Africa, in the country of Namibia, in November of 2015. So, these are some pictures from the launch in Namibia, and the picture on the bottom right is a picture of the hub of experts at Windhoek, the capital of Namibia. This hub was seated at the Ministry of Health. And then, the pictures on the top-right corner as well as the bottom-left corner are pictures of two spoke sites in Namibia, and what we can see here is when a participant from the spoke is speaking, their picture gets enlarged on the screen so that other participants can view them more clearly.

Here's a map of Namibia, and at the center, you see Windhoek, which is where the hub of the ECHO program was, and then, you see the ten spoke sites that are located throughout the country. So, during the course of the pilot year for this program, actually, an additional ten sites joined the ECHO sessions, so it was clear that this program was catching on, and that it was very well-perceived, and that participants liked it and were gaining a lot from it. There were an average of 72 participants in the ECHO sessions per week, and as we can see, there was a significant number of training hours that were earned.

This was actually a motivational factor for Namibia to launch this program because its providers were indicating that it was a challenge for them to meet their minimal training requirements.

The HIV ECHO program in Namibia really focused on the clinical management of patients with HIV, so the sample of topics that were addressed during the ECHO sessions is shown there on the slide.

This past year, in 2016, the CDC International Laboratory branch also launched a lab-based ECHO, which focused on rapid testing. So, the ECHO programs were launched in Tanzania and Uganda, and really, the aim was to train sites and train laboratory technicians to be certified in rapid testing. So, what you can see here on these maps is that there was one hub in each of the countries, and that they were connected to five to six spokes, which were different laboratory sites. The program really allowed for the labs throughout the country to share best learning practices and have ongoing learning and mentorship through the ECHO program.

So, how might ECHO support viral load scale-up efforts? These are just a few potential approaches that can be taken to use ECHO. None of these have actually been implemented yet, but one potential approach is to use ECHO to set up a global community of learning and practice among different countries.

So, in this approach, the different countries would actually be serving as the spoke sites, and a country would present a case that would describe a viral load implementation challenge, and it would seek help from the group of countries and subject matter experts on how to address that challenge. Some of the outcomes from this would be being able to list the next steps and recommendations for how that country would address that challenge.

Another potential approach is to use ECHO at the individual country level. So, this first example is more of the traditional model of using ECHO for the management of virologic failure in patients. So, in this approach, case presentations would be from providers or adherence counselors to seek help with managing patients with non-suppressed viral load, and the outcomes would be measures of clinical improvements in patients that were discussed during the case presentations.

Another example at the country level could be developing an ECHO program that focuses on viral load quality improvement. So, in this approach, case presentations would be from multidisciplinary team members, and they would be working together to try to optimize the capacity, efficiency, and quality of routine virologic viral load monitoring. So, the cases that might be presented would, for example, be a prolonged turnaround time for the return of viral load results. And, the outcomes of such a model would include measuring whether work processes and systematic improvements were actually happening as a result of these ECHO sessions.

So, in this last slide, I've included the contact information for myself, as well as my coworkers at CDC, who have been intimately involved in launching ECHO programs in various countries, and also have included the website for the University of New Mexico, and the picture is of Dr. Sanjeev Arora, who is the founder of Project ECHO at the University of New Mexico, and his passion for this model is contagious. So, I would say—I would highly encourage anybody who's interested in ECHO—

Sabrina: Thank you so much, Ritu, for the excellent presentation. We will now take some time for discussion. Please type questions for our presenters into your Q&A box in the webinar screen, and we will try to get to as many questions in the time that we have remaining. So, I will ask our presenters the first question that has come up. So, the first question is from **Tembo Aaron**, and the question is: Here in Zambia—Luapula Province of Zambia—it's really challenging to refer viral load specimens to MANSA while maintaining cold-chain. What suggestions are there to improve this situation? I'd like to suggest that either Dianna or Jason help by answering that question. Thank you.

Dianna: This is Dianna. I'm not sure if Zambia has considered converting to or transitioning some regions to dry blood spots. I know that cold-chain can be an issue for plasma across the **[inaudible] [00:53:46]** If you really are struggling and you have Abbott platforms, which actually are approved for use with DBS, or Roche platforms, which would require an in-country evaluation, but for which CDC does

have some evidence of potential use, the conversion to DBS is probably your best bet as of right now.

We can talk through some of the issues offline that would help you to find balance the blend of your sample network, that you might want to improve cold-chain capacity for, and where you would make or how you would make the decision about which length of your cold chain are maybe too—

Sabrina: Thank you, Dianna. The next question is from **Falagoon Kehende**, and I think it's also for Jason and Dianna. Based on the slide for viral load capacity and demand for Nigeria, it showed that demand is below capacity. Experience in the region where I work, however, in **Zanu** State, is that the demand is higher than capacity, so that the only processing laboratory in the state has given quotas to IPs on the number of VL samples that can be logged in a week. Perhaps this is due to imbalance in the distribution of viral load machines to match regional demand. Dianna and Jason, I don't know if you have some thoughts to share on this.

Jason: Yes. So, this is Jason. What we're representing in that graph, that basically is the aggregated national numbers, so actually, if you did disaggregate it by regions or provinces, you would actually see some uneven distribution. Some may be way under utilization, and others may be above.

I do know that Nigeria has about 26 or 23 labs, so excluding viral load, I do know at this point in time, they are actually looking to compress that diagnostic circle into about 11 or 12 labs, and over the next month or two, I actually will be helping them using LabEQIP and other optimization software to look at how, potentially, we can optimize the existing use of those machines and potentially consolidate, compress, and move some machines around based on the demand and instrument capacity.

So, it is challenging. I do see, when you actually look at the aggregate, it does distort what is actually happening. We know that problems within the districts of Nigeria may be a completely different story, so, when we actually aggregated the average across, it distorts the picture. Hopefully, that helps.

Sabrina: Thank you much, Jason. The next question comes from **Kego**. Kego asks, "What are the requirements to partner with ECHO?" I want to assign that question to Ritu.

Ritu: Hi. Actually—I think the question is referring to how to partner with Project ECHO at the University of New Mexico, and actually, it's quite simple. It's really—what they want is to document that there is a partnership in order to exchange information with each other. So, University of New Mexico really keeps a resource for materials that are used for training throughout the world. So, by assigning a partnership with UNM, basically, a country's program has access to their resources, and UNM is also then able to provide technical assistance and also share the resources from that country with others.

So, it's essentially an assigned agreement. There's no financial obligation. University of New Mexico does offer ECHO trainings, which is about two to three days, in Albuquerque, and that training is also at no cost. The only cost that comes to participants is what's required for their travel.

Sabrina: Okay, thank you very much, Ritu. This is the last question that we'll have time for today. It's from **Eric LoCarria**. "What strategies can be put in place to ensure quality of test results for the POC? Do we have EQA programs?" So, this question will be for Dianna, and I'm sure Jason will probably jump in as well.

Dianna: So, there is quite a lot of guidance, and there are tools that are being put together with regard to EQA for POC platforms. I think that UNICEF is actually leading the development of a toolkit right now, and USAID and CDC and Global Fund, CHAI, and EGPAF are all part of the development of that toolkit. My understanding is that the toolkit itself will be released in May of this year.

So, what I would do is to keep tabs on the AIDSFree website, because as soon as that toolkit is released, we'll start to link to the rest of the tools that include an EQA tool that can help you with the development of that EQA strategy. I don't know that one exists currently for the EID cartridge for GeneXpert, although there is—for the GeneXpert TV cartridge, there does exist a program. So, I

would expect that that one would look very similar for Alere Q because it's such a new technology. That one may be a little bit longer in coming, but as I said, keep looking to the AIDSFree website and to ASLM and those other resources, because there will be a toolkit that does address EQA.

Sabrina: Okay. Thanks very much. So, we are out of time, and we won't be able to answer any more questions in this presentation, but we will try and get them answered by the experts afterwards. We'd like to first thank all of the participants for your time, and certainly, we'd like to thank our presenters for sharing their expertise. In the next couple of days, you'll be receiving an email with a link to the recording today, as well as the presentation.

I can see some of you are already filling out the poll about how well we did today with the webinar, and that's really helpful for us. We'll use the feedback to improve future webinars. Please also be sure to go to the AIDSFree Viral Load Early Infant Diagnosis Knowledge Base, and sign up on the website to receive updates on the knowledge base. Thanks very much to everybody who joined us today. We appreciate your participation.

[End of Audio]

Duration: 63 minutes