Dr. Rachel Baggaley: I want to just give you a little overview of what we’re doing in WHO on the strategy and policy relating to self-testing. And this is a very collective effort from my colleagues in HQ, and with my regional and country colleagues, particularly Buhle here, who’s speaking after me. I’d like to start with an anecdote following on from Karen’s anecdote earlier. I can remember back in, I think it was about 1992 in Lisaraka. I had a rather nasty needle stick injury, and PEP wasn’t really available, but I thought, I really want to know, have I got HIV? And because I knew all the counselors, and I thought, I don’t really want to go to them and go through all this process. I think I’ll test myself. And at that time, you could obtain some really weird test kits, and this was a weird one that I think I got off the Internet or somewhere. And it was a salivary-based test kit that you had to filter the saliva through a sieve, and then you had to put it into various wells. There were about 25 steps. And the instructions for use were impossible to read and understand. And I completely made a botched job of this, and eventually thought, okay. And I went to the lab and I talked to one of the nice guys, and we did a little test together. But I really thought this should be the way we should have access for people, particularly healthcare workers. Many years later, when I started at WHO, I arrived, and on my desk was a piece of work that Sue and Liz had done on self-testing in healthcare workers. And they’d done a survey in, I think, four countries in Southern Africa, and found that, like me, about 40 percent of healthcare workers had already done self-tests. And I’m sure many of us in the room have done self-tests. And we wanted to do them because we wanted to know first. We wanted the power before we made our decisions about what we were going to do next. And I think now, we need to offer this power to everyone who wants to. And I think we’re really at that time to stop being so paternalistic, to allow people to, if they want to, to make that decision.

So, what have we done? I think, as we all know, WHO made a recommendation for self-testing for World AIDS Day. And we have guidelines which are in French and Spanish and Russian, and will be in other languages. And when we launched this, the WHO website went wild. It was the biggest download of any document that the website had seen for many months. And it’s great working with young and enthusiastic colleagues like Cheryl. Cheryl unfortunately is ill today, but hopefully, she will be able to join us at some stage over the next couple of days. But she led a lot of
social media type activities, and there’s a very nice YouTube video which really describes the key issues around self-testing, which is available. And so, we had a lot of Twitters and other stuff around the launch, and that was apparently highly, highly successful. More conventionally, we have a big program of disseminating our self-testing guidance and work on self-testing.

And really, WHO’s main rule is to work with ministries. So, individually discussing with Ministries of Health the potential of self-testing and how they can move forward, and a series of regional meetings. We had one the past couple of days, and we have a whole range of other regional meetings planned. And WHO is small, and so, we really rely on working with other colleagues from organizations that have much more reach and much more – greater numbers of personnel. And so, we’re working with our PEPFAR colleagues to do webinars and working with Civil Society. And it was great in our meeting over the past couple of days to have really good support from Civil Society. And as Miriam mentioned, in 2013, we had our first meeting on self-testing. And we had great representation from Civil Society from there. And it was so important at that stage to listen to Civil Society and get them on board.

And certainly yesterday, again, it’s really important to get Civil Society out there, too, so that communities understand what self-testing is and what it’s not. The fact that it isn’t a definitive diagnosis; the fact that you really do need to go and get linked for a confirmatory test and then linked into treatment if you’re positive. If you’re negative, what this means. It means that you can be pretty sure that a negative result is negative. But if you’ve had a recent exposure or if you’re an ongoing risk, to have further testing. And I think we’ve known from other new interventions like male circumcision, getting community leaders on board will be a great way of disseminating the message about self-testing.

We’re now heavily engaged in implementation guidance, and again, it came up very much in the past couple of days. A lot of great stuff is already out there, and so we need to make sure that we collect that, and we have a repository for all the SOPs and job aides that we can support self-testing for a whole variety of ways and with different communities. So, as I said, our role is really to
support countries to get on board with self-testing. And through our work and through all your work, we’re really pleased to announce that we now have 32 countries that are supporting self-testing in their national plans on self-testing. And I’m sure when we come back in 12 months’ time, that will have increased hugely. And in WHO, we have a role in reviewing these policies as they come onto our desks, and we continue to support them to make sure that self-testing’s included in a sensible and pragmatic way.

We also track research and all the other studies. Although this is focused on Africa, there are many other projects across the globe that are doing self-testing, particularly focusing on key populations. And we’re absolutely delighted to be part of the staff, phase one, phase two, and as we go on, to support other projects that UNITAID is funding under their self-testing initiative. It really is amazing that UNITAID has grasped the self-testing agenda and been so active. I don’t think we would have got such momentum and such interest from countries unless UNITAID had given that clear signal that this was a very important area, and as Robert said earlier, a game-changing intervention.

We have a website, and this is something the Cheryl initially developed. It’s not an official WHO website, which makes it much more nimble. And so, we can really upload everything very easily, from tools about self-testing, current research, anything on self-testing that we get hold of. So I urge you to look at this site and let us know if there’s anything that’s missing and you’d like us to upload. And certainly at the moment, we have information on 150 planned or ongoing projects on self-testing.

Our other kind of role is really to encourage self-tests to get prequalified. We don’t want these poor, poorly performing self-tests to be out there. There already are in numbers of pharmacies and through the Internet, completely unregulated. So, we want to encourage countries to use self-tests that are easy to use and as accurate as possible. And very, very luckily, the Global Fund and UNITAID are more expedient and faster than WHO, and we now have an oral fluid test that can be purchased through the Global Fund, and can also be purchased with U.S. aid funding through the Corps. And one other blood-based project is also available through the Global Fund for demonstration projects.
WHO will prequalify the oral fluid and test relatively soon. There are a few little steps that we need to continue to push them to do, and certainly, blood-based ones will come along the way. We’re also involved with UNITAID and others on the market landscape. And at the moment, in Geneva, at the same time as this meeting, we’re having a meeting with diagnostic manufacturers, really to encourage them to develop self-tests, particularly from those who’ve already got a prequalification for RTDs for professional use. We also have a role in supporting greater funding. And although of course UNITAID has been the star in this, we really want to press other donors to come on board and support self-testing. And the Global Fund is the obvious other big donor in this field. I’ve been very remiss here. I haven’t put the Gates Foundation, and I apologize. I was doing these slides late last night, and I don’t know how I missed the Gates Foundation. But the Gates Foundation, again, has been a big supporter of some of the formative research on self-testing, on product development, and they’re a great ally in this work.

And we also want to look at how self-testing can be integrated into other programs, particularly sexual reproductive health programs, and as a demand creation for prep and for VMMC. And we also need to look at post-market surveillance. We have a relatively large amount of experience now from self-testing, and harms have not been shown to happen, but we must be vigilant as this roles out more in a less controlled way that harms are not resulting from self-testing programs. We’re also developing a strategic framework, really to help countries think, how can they best offer self-testing across the different populations for couples and partners. And I think couples and partners is a great example, and there’s certainly been some very exciting projects showing how acceptable self-tests are to be given by partners to their partners to increase access to testing. We know men are a problem. They’re always a problem in every field that we work in.

But we also think they like a bit of new technology and something that they can do where they’re not gonna have to stand in clinics because they’re busy. They’re always working or doing stuff. So, we want to make sure that they can have self-tests available. And I’m a great lover of football, and I really want – know there’s some
great footballing projects in Kenya who do testing at the moment. And I think self-testing, getting men through these kind of activities, is a potential way for reaching these men. Key populations – we need to support key populations through a variety of ways to increase testing. As we move through the epidemic, we recognize that in every country, the proportion of new infections amongst key populations is growing, and we really need to support them to test in ways that are easy for them. Young people similarly love new things, and we know from the exciting results from the Star project that young people are going to be a great market for self-testing.

And then a whole range of approaches and considerations. And I just highlighted these potential approaches for key populations, but we can do the same for all the other populations. And then the other thing that we want to make sure is that actually, self-testing is actually doing what we want it to do. We want to make sure – and I think we have an awful lot of data on the first stage of this on preparing for self-testing. We know that it’s highly acceptable right across all sorts of communities. We do also understand that some communities will need more support than others. And again, I think some of the great work that Hannah Nails has been doing in Zambia shows that particularly as we start off, some communities are going to need a lot more support so that they can correctly do HIV tests. And willingness to pay. We’re gonna have to make these tests very, very cheap if anybody’s gonna pay them. But at WHO, we really support free access to testing. And I think this is hugely key if we’re going to reach particularly key populations and young people.

And then, we want to look at the linkage, but really to take up and reiterate Francis’s point, not to get too obsessed. Not knowing your status means that you’re not linked, full-stop. If you know your status, you may link today, you may link tomorrow, you may link in three months’ time. Whatever you do, you will link earlier if you know your HIV status than if you don’t. We also want to link to prevention. And I think it’s a bit of a demand creation activity, and we really feel this for Prep. We think that if Prep is going to be something for people who really are at high ongoing risk from HIV, coming into a service and already knowing that you’ve got a negative status, and knowing that having a negative
test, you can access these prevention interventions could really help create demand.

And I’m sure sometime during these couple of days that the data on the VMMC program that Star have shown, again, how great self-testing is creating demand for that. And then the much higher level impacts, which will be great to show. Difficult to show with much conviction, but this is our ultimate aim. So, we’re working across with the Gates Foundation, with UNITAID, with PEPFAR, with countries, really to give us a useful strategic framework so that we can make sure that self-tests are available in the most effective way, in the safest way, and having the greatest impact.

[51989_WHO-Increased testing in communities, B Ncube- 1]

Buhle Ncube: I’ll be looking at increasing testing in communities. We know that there are a number of approaches that we use in providing the HIV testing services, and these include mobile and outreach services to various sites, including for key populations; and also having services brought to our homes, where testers move between homes and provide services. The testing approach is for communities include the following. We can have an index patient or index client who is HIV, and then that one leads us to the testing of the rest family members, including children.

Door to door, mobile, and mobile for key populations specifically, workplace settings, and for schools. We know that in the 2015 guidelines, we talked about lay providers. That was one of the key recommendations that was made, that we should allow our lay providers to provide testing services and provide results to clients using rapid diagnostic tests. So, this is happening in a number of countries where there are policies or other countries, there are no policies, but the provision of services is taking place. This shows that there are a number of countries which have policies, either for allowing lay providers to do the testing, or just do the pre and post-test counseling. We need to move from just pre and post-test counseling to allowing them to provide rapid tests for clients in the rest countries, 48 countries we reviewed in this slide.

What are the considerations for success for lay provider approach? We have to choose our lay providers carefully, and provide them
with training and support, adequate remuneration. We don’t work for free. As we all know, it gives them motivation. But also, we need to have policies that cover them so that they provide good services. Test for triage is when the lay provider can do a single rapid test and provide a result to the client. But this is not a definitive test for those who are positive. These ones need to be linked to a health facility, and then we can triage and make sure that those who are positive are linked to services. I think Rachel covered that. How can we improve quality of services? We know that a number of countries have got testing policies, and WHO has recommended certain approaches, strategies, and perhaps algorithms that need to be followed.

Only 17 percent of countries were following WHO recommended guidance in testing policies. And the result of this is that we get misclassification of test results for various reasons, which Rachel touched on. These can be clerical, or user error, or cross reactivity, or if you are using a wrong testing strategy for your HIV prevalence; and poor management and supervision, where you don’t have standard operating procedures. All those can affect the quality of our services. We have recommendations in the 2016 guidelines which touch on who should be retested. We used to just say, when you are tested, you should just come back after three months. Every three months, you keep coming back.

But now we need to prioritize if you are HIV negative, are you at continued risk of HIV infection? Are you from a key population who is exposed to a high risk of HIV? Are you a pregnant woman who is breastfeeding in a high incidence setting? Do you have STI? That’s how we need to then prioritize and decide who is going to be retested. We also need to look at those who are having inconclusive results, and they need to be retested after 14 days. And as Rachel also mentioned, those who have a positive HIV diagnosis, we need to make sure that they’re really HIV positive before we start them on treatment.

There are quality system essentials, which we need to follow to assure quality of our services, and these are detailed in the guidelines. They are to do with the organization of our services, the personnel who are providing services, what equipment we are using. And the rest of the details are there, like record-keeping,
customer services, assessment of our services, and so on and so on. How about focusing our testing? We can’t just test everyone anyhow. We need to make sure that we maximize the use of our available resources, as we know the resources are not – they are not available as much as they were before. So, we need to make sure that what we have, we are using maximally.

So, we have PITC. Strategic use of that approach will depend on the epidemic. If it’s a low prevalence setting, we want to prioritize perhaps Tipi and STI or key populations. We need to decide when we should stop testing a certain group and reprioritize, depending on our resources and the epidemic. And diagnosis, what we should be aiming for, instead of retesting those who already know their test status. And we have talked about men being a population which has been left behind. We want to reach them, and we have a male circumcision program which has shown that we can actually reach men. So, we can utilize such services in legitimizing the use of lay providers who will also help us to focus our HTS.

In the past 30 years, the HIV epidemic was seen as an individual problem and program, so each one needed to know their own status and keep it to themselves. But now, want to ensure that we have our partners also tested, and encourage couple testing. The courage for couple testing is really low, 20 percent or less in the region, and we need to have strategies that ensure that couple testing is increased. On community-based approaches, these are highly acceptable, and they lead to earlier diagnosis, and they help us to reach many populations, the missing populations. But linkage to care and positivity rate, and you need – cause need to be looked at. For certain populations, as Rachel said, they are good because you can reach such key populations, as men who have sex with men. We also have index partners who are reached through this. But the positivity rate tends to be low, but it’s still worth using this approach, if you can.

Improving linkages, I think Rachel talked about it. What I really want to highlight here is when there’s home testing, we need to facilitate linkage to care because we can move our linkage to 16 percent to 76 percent just by facilitating linkage to care. I think that also covers the same. It’s the recommendation on partners and family members, and mainstreaming our HTS and existing
services. If we have HTS integrated in services, we find that there is a higher yield, and also targeting men, we’ll keep talking about that one. Key populations and marginalized populations also need to be targeted, and tailored approaches for each of these key populations is important, so that we provide nondiscriminatory services where there is supportive care for the key populations. We find also that if we use peers for outreach for key populations, we get a higher yield.

So, in summary, what are we saying about the 2015 guidelines? The core elements remain the same. The five Cs, I know some countries have a sixth C. We’ll ask them to talk about it when they present. But the five Cs have been covered on consent, confidentiality, counseling, correct test result, and connection to prevention care and treatment. The need to have better approaches to reach those who have not been diagnosed, we know we have a 90 percent target that we need to reach by 2020. So, this is why we are here, to look at how can we use self-testing, and as I said, partner notification to help us reach that goal. And then, we hope that through our increased number of strategic approaches, we’ll have a positivity rate which is high, and link our patients to services. But we need to be strategic in our approach and make sure that we have successful programs. Linkages are important, and the quality issues, I think we have covered. I think I ran out of time now, and wish to thank Neybongas Attenda.

Dr. Rachel Baggaley: We decided, although this meeting is going to really focus on the new recommendations on self-testing and partner notification, we thought we’d just give you a little recap of what’s in the consolidated guidelines. And I want you to think, as we go through and you think about the new recommendations, also think about the other modalities of testing in your country, and are there things that you need to do as well that we can help you with that you need to focus on above and beyond the new recommendations? In your back, you will have a copy of our consolidated guidelines, as well as the supplement, and as well as the policy briefs. For the Francophone colleagues, I have the two new policy books in French, so please pop in and see me if you’d like those as well.
I wanted to start with this first picture here, again, highlighting why we’re in Kenya. And it highlights one of my real passions, and that’s football. And this is a picture of testing at a football tournament. And I thought this was really fitting as a way to get men. And certainly Kenya, like many places in sub-Saharan Africa, football is a great way of reaching men. And I thought this was a rather fun and innovative way of reaching men.

So, as we all know, we’ve done fantastically on treatment. We really have. Who would have believed it five years ago that we could be really getting towards getting everybody with HIV on treatment? But as we scale up treatment, we haven’t had that great impact on reducing new infections. And so, we need to do better. We need to continue to diagnose people so that they can link not only to treatment, and eventually, when everybody’s on treatment, incidence will come down. But we also need to really focus on prevention. So, testing should be seen not only as a way of getting those with HIV onto treatment and reducing viral load, but also linking people into preventing services. And where are we with testing? I’m noticing that our slides are a bit dim, so I hope you can see.

But as Buhle and I remember from those early days, it was a struggle getting testing out there, and we really tried to drag people into testing, because there wasn’t treatment. And really, there was a huge reluctance to get tested. But as treatment became available, as PMTCT became successful, HIV was introduced routinely into a lot of clinical services, particularly into antenatal. And we witnessed a great scale-up of access to testing, particularly for women. And then there’s new community-based services. We also started to get out of the clinic into populations that weren’t going to clinics. But we’re beginning to tail off, and we really need new approaches. If we’re going to get to this first 90, if we’re really going to diagnose people out there in the communities, we need new approaches. And that’s why we hope that self-testing and partnering notification will help us on that way.

As Dr. Eggers and the Ministry of Health in Kenya noted, we still have to diagnose those 40 percent of people who remain undiagnosed. And there’s great regional variation. In Southern and Eastern Africa, we’re doing well. Not well enough. But in West
Africa and Central Africa, we really have a big struggle. And part of that is because increasingly, new infections are occurring amongst key populations. And key populations often don’t attend clinical services as regularly as general populations. They will need extra support to seek testing. And particularly outside Southern and Eastern Africa, epidemics are increasingly really focused on key populations, and it’s particularly true for the countries in West Africa that are represented here, but also in Southern and Eastern Africa. A lot of that gap is made up of people from key populations.

As has been mentioned many times, men. Men have different health-seeking behavior, and we’ve got men here, so I’m sure they will be able to speak to this. But they don’t really attend clinical settings in the way that women do. They don’t go to family planning clinics. They don’t go to antenatal. They don’t take their kids to vaccination. They don’t have these opportunities for testing. So, we need to go out and reach them. And we know even from community-based services, from door-to-door testing, that men again often aren’t there. They’re often at work. We need really to look at ways of reaching men, and hopefully, our two new methods of testing really support testing of men.

So, in our guidelines, which we produced in 2015, we made a deliberate effort to talk about HIV testing services. I think there’s been a whole nomenclature over the years from VCT to PITCT, to all sorts of different ways of describing it. But we really wanted to look at HIV testing services. Testing services in facility, community, and in self-testing. We don’t want to stop looking at community facility-based services, and we’ve done really well in antenatal testing. In most countries now, it’s offered routinely, and the vast majority of women accept. And so, we have very high diagnosis amongst antenatal women, which has led to very significant reductions in mother to child transmission, and has meant that a great number of women start immediate treatment. However, we do still struggle with offering HIV testing routinely and other clinical services in pediatric services and outpatient services, and we really need, across the region, to make sure that we don’t limit our efforts on testing in clinics to antenatal.
I’m just going to repeat this. Everyone knows it, but I’m still going to repeat it because I think sometimes when we talk about new interventions for testing, for self-testing and for partner notification. We think that maybe these don’t necessarily apply in the same way. But consent, confidentiality, counseling, correct test results, and connections are all things that must happen, whatever we do. Self-testing requires consent. And certainly, when one talks about self-testing in the community, initially, there’s a lot of concern that this could be done in a coercive way. And I think we need to understand that any form of testing must be voluntary and must involve the explicit understanding of the person that this is something that they choose to do.

And similarly, with confidentiality, people must be allowed to test and be aware that that result is theirs to share with whoever they want. That doesn’t mean to say that sharing results isn’t a good thing, and we don’t to perpetuate secrecy. But certainly, we must support people to disclose to who they want to, when they want to, and how they want to. And both self-testing and partner notification give us challenges in that field, which we will discuss later. We are, in WHO, very, very concerned about correct test results. And as we know from many settings, there have been problems with the way that testing’s been done, and we really want to minimize false positive and false negative results. And so, quality assurance is something that we have really focused on in WHO.

And we have two testing strategies, which really have been developed with a huge amount of work from our colleagues in our diagnostics team and in WHO. And if these are followed, this really gives us the best chance of minimizing false positive results. And we have one testing algorithm for above five percent – that’s our high prevalence testing strategy – and one for below five percent. And these are fully outlined, both in the test service guidelines in our policy brief. If there’s any questions about that, please let us know. And this is something that, again, we in WHO and headquarters and in the countries have really helped countries adapt their own testing strategies to fit in with these. And this is a way that has really supported a decrease, particularly in false positive results.
So, in my final slide before I hand over to Buhle, I really wanted to say what was particularly our focus in the testing service guidelines. It was really to look at ways that we could increase testing to be more strategic at testing the undiagnosed, to be more focused. As we all know, we do a lot of testing, and each year, testing goes up and up and up. And it’s a balance between a lot of easy testing – so that’s a lot of testing in an antenatal clinic, for example. Some campaign testing – it’s relatively easy to go out and do a big campaign. But you may get, from these type of approaches, a low positivity rate. And that, balanced against focus testing, focus testing to support testing of key populations, focus testing to support testing of index and family members through partner notification and other – and family testing of people with HIV – this maybe more expensive. But because the positivity rate is much higher, the test per person diagnosed with HIV can be much lower.

We also, in the guidelines, look at linkage. And this is something that testing alone without linking people with HIV to treatment and without supporting those who are negative but at high ongoing risk of HIV acquisition to prevention need to really be focused on to maximize the benefits of testing. And we give lots of examples of ways that we can support this. I think this is still something that is still very context-specific. We can’t give you a blueprint to ensure a linkage. And I think we also have to recognize, it’s not always going to be perfect. And not having perfect linkage doesn’t mean we should continue with an approach. Somebody knowing their status earlier, they may not link today. They may not link tomorrow. They may not link in the next couple of months. But knowing your status will support linkage earlier than not knowing your status.

And finally, as I said, the quality of testing, whatever that method is, is something that is very, very key. And we’ve done two things. We’ve support the quality improvement of countries in their testing to adopt the correct strategies, but we’ve also had a recommendation, which has been in WHO recommendations for many, many years, but we reiterated that because we are concerned about false positive testing, often due to errors and transcription errors and mix-up with samples, etc., not because of the following of the testing strategies. We recommend that everybody who knew
these stats on treatment should be retested to make sure that they really have HIV before starting on lifelong treatment.

[51989_WHO -Overview of key populations epidemiology and latest guidance and tools on HTS in Africa, A Vester- 3]

Annette Vester: I just would like to follow the presentation of Fabian, who really explained who key populations are and why we have defined these five groups as key populations. I would like to quickly focus on how criminalization of key populations, of the behavior of people, has an impact on HIV. And Fabian has done that very clearly. But also, on the availability and the quality of data of key populations, and of course, on their access to services and the coverage of services. I will quickly run you through some data on coverage of HIV testing key populations, some country examples from the region. And then I will outlines that we developed in 2014 and updated last year, and conclude with some considerations.

So, Fabian has explained how key populations are at risk, and I think just the scheme is just showing you an example of sex workers, but you could also use it for any other of the key populations that really, criminalization feeds into HIV risk. And in this case, because of the stigma and the violence that accompanies this – increased risk behavior, lack of access to services, and prevention services particularly, and therefore, increased risk of infection. About data, there was a very interesting systematic review published just last week in the Journal of the International AIDS Society that shows that countries where same sex behavior is illegal actually shows that there’s less behavior. So, for example, this data on MSM, men who have sex with men, where there’s really strong criminalization, you see that most of the data report a lower prevalence of this behavior; whereas where the behavior is less criminalized, you see that there’s actually – 50 percent of the studies show that the prevalence of MSM is higher than one percent. So, I hope I make this clear. But just very quickly to show this impact also on data of criminalization of key populations.

And likewise, in the same study, there was also a demonstration of how laws the criminalize same sex sexuality also have a relationship or impact on reported coverage of HIV testing. So, again, where there’s strong criminalization, two-thirds or 66
percent of studies show that there’s less than 25 percent of HIV testing coverage in this population. So, this is just to demonstrate how it also works on data and on access to services. So, quickly, here are some examples of key populations who received an HIV test and know their results here, for people who inject drugs. And you can see the various regions, and in particular, it’s basically UNAIDS data with a limited number of countries that provide this data. And again, the data have to be really considered with caution because of what I tried to explain earlier. So, testing results were pretty low, and lower than the global average.

For sex workers, you can see that actually in Africa, it’s calculated that 70 percent of sex workers know their status. But again, I think here, we need to also be careful because a lot of the data can come from programs that provide services to sex workers and may not necessarily give the national prevalence rates. So, again, data issues. For MSM, similar issue. I won’t go through it. And we also have some examples of actually the testing and treatment cascade for some key populations. Here’s an example from Togo, where you can see again that the first 90 is the real – the biggest challenge, to get sex workers tested. And once they are tested, actually, the access to treatment is not so bad. But it’s the 20 percent only that know their status. For proportion of people who inject drugs who are on treatment, you can see, depends very much on the region, and in the region we’re here, it’s less than one percent. Malawi sex workers, HIV care cascade, similar picture. I will not go into this because I think we will hear more during the remainder of the conference about this, and Mozambique, the same thing. So, I told you I was gonna skip a little bit through the data.

Here, an interesting one also on the cascade in prisons. And after this session, we actually have a few country examples, presentations, and there will also be one on prison from Uganda. But again, here I think it is again clear that the first 90 is the real roadblock, and this in part also has to do with the specific conditions in prison and the confidentiality issues, and the possibility of using lay providers. And I will move on to the actual guidelines. So, in 2014, we published guidelines where we brought together all the existing recommendations that WHO has issued with regard to HIV prevention, testing, and treatment that are relevant for key populations. And most of the general
recommendations are of course also relevant for key populations. There’s a few specific ones, and in particular, this is relevant for people who inject drugs because they need specific services. But for the rest, it’s really a matter of bringing the evidence together that – and I think the speaker earlier from – Joyce from Kenya explaining also the need to prove, at the country level, the data – to have some data that back up the recommendations that we provide is really important in this case.

So, basically, the document – in addition to the existing recommendation and a few new ones, it also addressed the structural barriers to implementing specialized programs for key populations. And I think this is probably the more important part of these guidelines, that although they are technical guidelines, they had a very strong advocacy component to it. So, here is the comprehensive package that we recommend, that consists, as you can see, of health interventions, which are pretty straightforward, but also include these structural interventions, or these enabling interventions that will help address the barriers that we have tried to summarize for you. Some data from the Nairobi modeling on the specific programs, harm reduction programs for people who inject drugs, shows basically that the more, the better the coverage and the more interventions at the same time that you provide, the better the impact is on your program.

So, this with regard to the health package, very briefly. The critical enablers that will help address the structural barriers, we defined them into four groups of areas. The first, the laws and policies, and Fabian has clearly outlined some of the issues also here in the region, but in particular, the need for countries to work towards addressing these laws and legislations, and specific ones also with regard to young key populations. For example, with regard to age of consent, and for transgender people, the recognition of a third gender that could help access to services, etc. Training also, and working with police force is really important when we’re talking about accessing services and making sure that people can actually go to programs without the fear of being arrested in front of the programs because the police knows that people with forbidden or criminalized behaviors come to these programs. Very important.

Stigma and discrimination, I think we’ve talked about it a lot. For
us, also really important is to include this into healthcare working, training, to sensitize healthcare workers to the specific needs of key populations. And really crucial, and it’s been mentioned earlier, is to work with the communities of people from key population groups, and to work towards empowering them to be part of the planning, the programming, the designing of services, and eventually working in the services. And of course, the need to work against violence to key populations. And I mentioned working with the police already. But I’ve seen I am up for time. I only have a few more minutes.

So, in addition to these guidelines, we also developed a few related documents. And for example, one document is a tool that helps countries to set targets on how to program the national response for key populations. And it’s a supplement to these guidelines. And it provides indicative targets. It provides indicators, both for the health intervention as well as for the structural interventions. And it really guides countries through the process of how to calculate what needs to be done, what needs to be programmed, and then how to measure progress. This is the framework for with the indicators. So, we have specific indicators for the structural interventions, and then the health interventions can have different indicators for both availability, for coverage, for quality, and for impact.

So, finally, just a few considerations to take into account when starting your programs or when scaling up your programs. Of course, you have to have some understanding of the epidemiology, but also of the legal and the social environment in your setting. And in order to plan, of course, although I think it will be very different to have really robust data on numbers, it is important to have a rough estimate of how big are the various key populations, and where can you best find them, and explore. And we’re also working on some more guidance on the best service delivery models. I’ll come to that later. I mentioned healthcare work training, and working and linking with community organizations. So, here are the products.

So, normative guidance, policy brief, special briefs also on specific considerations for young key populations, we developed also in collaboration with partners the target-setting guides. And this also
had the effect that partners and community organizations translated these guidelines, which are normative and maybe sometimes a little bit formal, into more implementation tools as to how to do this. So, each of the different key populations except for prisons have by now developed these implementation tools. So, there’s a sex work implementation tool, a **mismet**, a transit, and an IDUIT, injecting drug user implementation tool. And these tools really are aimed to help implement program and how to do that at country level.

I think we all know the challenges by now, and I think one of the challenges not often mentioned is also the lack of specific expertise among various stakeholders, and again, the lack of good data to really guide the response. So, what are we doing as WHO to help implement evidence-based public health policies and programs for key populations? We are offering technical support, where we continue to advocate for these programs and to mobilize commitment with governments, as well as resources to address barriers, etc. It’s very important for us to work with stakeholders, not only with other partners and implementers, but again, in particular with the community itself. And our latest work is also to improve strategic information. There will be new guidelines coming out soon on patient monitoring and case-based surveillance, which have specific chapters on key populations, including how to do a cascade analysis among key populations.

You can find all our documents on this site, the overall site. They’re in English and French. And we brought some copies, but also, I really look forward to exchanging more ideas with you all, and hope to have some meetings on the side, and to learn more in the next day-and-a-half from you. Thank you.

[51989_WH0-Overview of key populations epidemiology and latest guidance and tools on HTS in Africa, F_Ndenzank- 4]

Fabian Ndenzanko: Thank you very much. So, I’ll be taking you through the topic on key populations. I know sometimes in some of the settings, key population is quite a sensitive area. But you’ll be talking about really the epidemiology of the key pops, particularly in our African region, in our WHO African region. So, the outline of my presentation will be really on why we are really talking about key
populations when it comes to HIV prevention and programming. I will take you through some of the epidemiology in specific key pops, on sex workers, MSM, people who injected drugs, prisoners, transgender. And then I will certainly conclude.

Now, over the 15 years, we have been really investing a lot in HIV prevention. And certainly, we have not seen very significant, actually, reduction in HIV new infections. In Eastern and Southern Africa, we have done a reduction, I think, up to four percent. But in most regions over the world, HIV new infections are still really going up. Of course, we have seen good progress when it comes to HIV, reduction of HIV new infections among children. There, we have really seen significant improvement. Now, when you see that map – unfortunately, I think it’s not really clear to demonstrate the different in color. But the point I wanted to say here is that most of Eastern Europe, Central Asia, North America, North Africa, epidemic is still really going up. Even in some parts of our countries as well. So, 90 percent of new infections in these countries are really attributed to the key populations. And that contributes to close to a half of the 1.9 new infections estimated in the whole world.

So, if we are to really make significant contributions to reducing new infections, we have to invest a lot in key pops. You can see, or saw, in some of our countries where the new infections have really been contributed by the key populations. You can see, for example, in Kenya, 54 percent – this is the data that was generated from the modes of transmission by UNAIDS and CDC in 2015. But you can see really where, in most of our countries, the significant contribution of key population is to the new infections. Now, we have come up with the five groups of key populations. And I’m sure most of you, you are aware. The men who have sex with men, people in prisons and close settings, people who are injecting drugs, transgenders, and certainly, the prisoners. Of course, there are also other vulnerable groups in different settings that are being actually identified by modes of transmission, as really risky groups. And it contributes also a lot in terms of new infections.

For example, in South Africa, young girls – adolescent girls and young women and migrant workers, these are the groups that have been identified. In Kenya, for example, here fishermen and women
along Victoria, and of course the same in Uganda – Rwanda, for example, is [inaudible] [00:04:13]. So, different settings also have additional risky groups that we need really to focus on in terms of preventing new infections. Now, the key question is, why are we really talking about the key pops, despite that, yes, there is high new infections there. But also, there are additional issues in these groups. One is actually the increased hostility environment around these groups. These groups face a lot of stigma and discrimination, and also, this comes even among healthcare workers, okay?

But two, a number of countries also, these groups are also facing a lot of – the laws are not really in their favor. And you have seen cases – for example, some of you may recall a Malawian case in 2010. And of course, we have many, many of those in Cameroon, in Uganda, in Zeem, in Tanzania. So, there’s a lot of real issues, legal environment when it comes to the key populations. You can see, this is a map of our continent, but you can see, for example, four countries in Africa. If there are consensual same sex practices, the couple or the individuals involved, do they actually face capital punishment, death penalty? We have, for example, Somalia, Sudan, some parts of Nigeria. We have Mauritania. They have death penalty. And this is really not favorable when it comes to our programming. We have 57 countries in which this practice is still illegal in Africa. Of course, globally, we have 78 countries, so half of them, of countries that have illegal laws are actually on our continent. So, you can actually see a number of challenges that we still have.

Further, access to health services to these groups is also very difficult. They are vulnerable if you compare with the general populations. Of course, if we are settled, as I said, if we are to achieve fast track targets by 2020, and of course, ending the epidemic by 2030, we certainly need to invest here in targeting key populations. The risks of acquiring HIV is also very, very high. Of course, it also differs depending on which group an individual belongs to. So, in terms of prisoners, there is five times increased the risk of catching HIV than the general population. The risk increases in sex workers, which is ten times. Of course, the risk is more if somebody engages in MSM, and of course, people who injected drugs, by 24 times. And of course, in transgender, the risk is even more higher, and particularly transgender women. So, you
can see why it’s really very important that if we were to reduce the new infections, we really need to invest a lot in these groups.

Now, in sex workers in Africa, how does the situation look like? This is the data that we have collected from your ministries. This is through the global AIDS progress report, of which many of you contribute at a global level. But really, from the data we have for sex workers, you will actually note that six countries in Eastern and Southern Africa, they have HIV prevalence in this group, which is more than 50 percent, okay? And if we are to compare with the general populations, you will also see that the HIV in sex workers is actually 10 to 20 times than in general population. So, you can actually see how the HIV burden is in this group.

When it comes to the MSM, I think most of you have been to international AIDS conferences. You have visited the community villages where most of these groups really are. They showcase on issues that they are actually facing, so you’ll see MSM, sex workers, and so worth. But you also, MSM in your continent, you will also see that from also data that we collect, actually, from the same exercise. You will find that we have ten countries in our region with more than 20 percent HIV prevalence in MSM, all right? Of course, perhaps if the data – we don’t have much more information on this. Certainly, we need to strengthen our data collection and analysis and the use and so forth. But the data we have now from different ministries, this is actually what it demonstrates.

Again, in terms of comparison with the general population, still MSM have the highest proportion of HIV prevalence than certainly in the general population. Of course, we have three countries where I think there is a bit of outlier. This is the Botswana, the Swaziland, and of course, the Africa. Of course, prevalence in these three countries is also very, very high. Of course, we need to interrogate this data to see what it tells us more.

Prisoners. Perhaps some of you have visited our prison institutions, or maybe sometime you were in prison at some point. But again, really the condition in the prisons is really not conducive. There is overcrowding that is completely not acceptable. And of course also, which threatens, they have conditions of the prisoners. Now,
in Africa, we have close to 700 **Southern** prisoners every year. And the HIV prevalence in this group is significantly high as well. Prisons are overcrowded. A lot of unsafe injecting happening there. Unprotected sex also is happening. And of course, sexual violence as well. Again, programming is an issue in this group. Actually, prisoners are one of the low-hanging fruits because we know where they are. They’re just in institutions wherever, but really, programming is an issue because of stigma, discrimination, the laws. In some countries, you can’t even talk of condom distribution to prisoners. So, that is a really, really big issue.

But again, HIV prevalence, as I said, is very high – is even higher in Africa compared to other regions, actually. We have on average, 6.7 percent prevalence in the prisons, in the prisoners, compared to other regions. Again, in our sub-region, we have four countries with more than 20 percent HIV prevalence among this group. So, this is an area as well that we really need to consider for us to be able to move forward. Again, this is just a comparison between HIV prevalence, and also the general populations will actually see most of countries will have higher prevalence in prisoners than the general populations.

People who injected drugs, again, we have high prevalence again in this group. You can see more **Mauritius** is there on the top of the list, of course, followed by a number of countries as well. Again, if you compare with the general populations, still injecting drugs have certain high prevalence. In our region, we have actually only four countries that at least they have NATO exchange programs. The rest of the countries, they have really nothing. Even data is really an issue when it comes to injecting drug users. And young drug users have higher prevalence if you compare with the older ones, and certainly, that’s also cause for us to be able to desegregate our data, but also to have focused interventions when it comes to responding to HIV in this group.

Transgender. Again, this is another area that we really need to focus on in terms of our interventions. We have very limited data in our settings when it comes to really transgender groups. You can see on the global map indicating the transgender in Africa is just empty. There’s really no data. So, we really need to invest in terms of putting programs, but also on data capturing. Again, in this
group, particularly transgender women, HIV is extremely, extremely high, okay? On average, a 19 percent, but in some countries, particularly in the Middle East, but also Central Asia, HIV prevalence in these groups in transgender, particularly women, it goes up to 45, 48 percent. So, it’s really, again, a group that is neglected. We are not focusing on this group. We need to do much in terms of responding to HIV. Again, in terms of transgender, on average, you can also see really comparing the law in middle income countries, we still have HIV prevalence in this group, which is, again, very, very high.

Now, just to conclude, key populations still contributes high population of HIV new infections. The key populations have the highest HIV incidence and the prevalence than the general populations. We need to fight the stigma, discrimination, and of course, we need also to create a very supportive legal environment to be able to improve our programming. And certainly, we need to invest a lot if we are to reach our 2020 and 2030 targets. Thank you very much.

[51989_Adopting and scaling-up lay provider HIV testing in Zimbabwe, G_ Ncube-5]

Gertrude Ncube: So, the outline of my presentation, I would just prefer to show you the epidemic in Zimbabwe, the background on the lay provider, and then how we recruit the lay providers achievement in [inaudible] [00:00:16] key recommendations. And I’ll actually make a summary on the conclusion on what have been the lessons learned on using the lay provider. Maybe looking at the Zimbabwe epidemic, we are a country with a very high prevalence, which is still about 13.8. And although we have seen a significant decline in the HIV incidence, this is according to our ZIMPHIA and ZDHS report of 2015 to 2016. And looking at the prevalence as well, we see women are disproportionately affected compared to the men, with a prevalence of 16.7 for the women, and 10.5 for the men.

And then if you look at our ZIMPHIA report, in looking at our progress towards the 90-90, according to Zimbabwe Population-Based Impact Assessment, it indicated that 74 percent of living with HIV, they know their status. But if I disaggregate that 74 percent into gender, we realize that men are still – they still do not
know their status. About 62 of men were reported to know they are living with HIV, knowing their status. And disaggregating it again further into age groups, we realize in the same ZIMPHIA that our adolescents in there who are men, only about 50 percent reported to know their status. So, we still need to do a lot as it has been looked at before in the morning, that still men and our young people and our adolescents, they still do not know their status. And with that, which means we still have room for the lay providers to actually increase our attacks in testing and counseling, so that we can identify those people who need testing and counseling.

I won’t repeat this definition because it was repeated in the morning. What is a lay provider according to WHO? This is the definition of the lay provider. But what is a lay provider in the context of Zimbabwe? What we are looking at is in Zimbabwe is a lay provider who has been trained, and after training, that person is actually looking at how best we can tackle the first 90 of the 1990 fast track targets. Whether this person will be able to do the HIV testing, the rapid testing itself, and then when it comes to the second 90 as well, counseling as well services in preparation for ART, and does even the retesting before to verify the ART test’s status. And then this person is actually included as well when it comes to counseling for viral load and CD4 count for enhanced adherence counseling.

And in Zimbabwe, we’ve added the fourth 90, and I hope all this countries in this region, they know that Zimbabwe is actually spearheading the revitalization of HIV prevention. So, this same lay counselor counsels for combination – HIV lay provider counsels for combination lay prevention strategies as well, and link the clients for services, be it prevention, be it treatment and psychosocial support as well. So, why do we need this lay provider? I think, and I indicated in years, [inaudible] [00:03:33] and time, where it says this is now the time when we need the lay providers more than ever before, because as you can see, how many people we’ve reached with our HIV testing. And we are now saying by 2020, we need to have reached 90 percent. This is our last mile where we need a lot of people actually to be identified so that we put them on treatment, so that we are saying we are ending the AIDS by 2020.
We really need these skilled people to be able to assist in our HIV testing services. And the lay providers, as I have seen and as I have realized, in Zimbabwe, they are actually very good in actually improving our accesses to HIV testing services and counseling as well. And then how are the lay providers selected in our Zimbabwe context? Because in Zimbabwe, we call them primary counselors. Why we call them primary counselors? We actually looked at these people to be able one day to be absorbed within our healthcare delivery system because they are delivering services. And at one stage, we asked ourself, why should we call them lay providers? We know when you want to go into a hospital, you want to be seen by a lay doctor or a lay nurse, so they need that sense of belonging as well. So, that’s why we call them actually primary counselors.

And with that, because of our public services regulations, to say if someone is supposed to be accepted within the public service regulation, you have to have five ordinary levels. And at this house, that is the criteria which we are using to recruit them. And then these lay providers, they are locally recruited within their local health facilities, and they are recruited by the district health education executives in that. And then they are actually trained, and they are trained locally. And they form a very good link between the community and the health facility because they are actually recruited locally.

And then what is their cost structure? This cost structure for the lay providers was designed in such a way that, like I’ve already alluded to, one day we will actually absorb them within our healthcare delivery system. So, in total, they are actually trained for 24 weeks, and then we are actually looking at six weeks of theory. And then this six weeks of theory, it includes HIV rapid testing as well. And people, they will say this is a long training, but it was actually governed by the laws of our public service regulation in hiring people. And then the other weeks, 18 weeks, they are actually practical. And when I say they are practical, they will actually go back to their health facilities, where they will actually be doing counseling, being supervised by the sisters in charge and by the nurses in that health institution.

So, they have still even got a job. Their job description, which actually indicates their responsibility, their overall responsibility,
their reporting structures as well. Because I realize in other countries, you’ll find that people, they will say, “No, we don’t know who this carder is, whom they are supposed to be reporting to.” But in Zimbabwe, they report to the sister in charge of that hospital, to the sister in charge of that unit where they are actually working. And the highlights of their services, they still are indebted to the five principles of WHO, for the five Cs. But in Zimbabwe, instead of five Cs, we’ve got six Cs. The sixth C is for comfort, because we are testing women in labor and in delivery room. We are saying wherever we test them, these women should be actually in a comfortable position. So, our primary counselors, they are indebted to the five Cs of WHO, but plus one C of Zimbabwe, which is comfort. And they do the consent, the confidentiality, and the linkages to treatment and care.

And then what have been our successes? I know according to WHO, the guidelines were released in 2015, but in Zimbabwe, we started discussing about the primary counselors or the lay provider in 2005. That’s when we introduced them. Before that, we’re not doing a lot of HIV within our health institution. And when we introduce the lay providers, we actually saw actually an increase in the number of people who are tested within our healthcare delivery system. And for the five years, 2005 to 2010, these primary counselors were not allowed to do HIV rapid testing. So, with a lot of consultations and a lot of negotiations, in 2010, our lay counsel, it actually allowed the primary counselors to do rapid HIV testing. As you can see, these are the number of people whom we tested, looking at 2010 to about 2016. We tested more than two million clients a year in the health in institutions, and 80 percent of those clients were tested annually from our health institutions, and they are tested by our lay providers. And 20 percent of the clients who are tested annually, they are tested through our non-government, our organization, and then our outreach services.

So, as you can see, the workload which these primary counselors do, and looking at the number of them which we have got, by right will be actually have comfortable with having about 2000 and something lay providers within our health institution. But right now as a country, we’ve got about 1,200. And they are not only testing for voluntary testing and counseling. They test for PMTCT. As you can even see, our PMTCT testing is about – it ranges from
90 to about 99 percent. And they don’t only test for PMTCT. Already, I looked to the fact that they do counseling for adherence counseling for those who are initiated for treatment. And as you can see, our treatment coverage in Zimbabwe, we have actually – like in 2016, we managed to have about almost 1,000 people on ARV. Considering that the people are supposed to be on ARVs, about 1.3 million people living with HIV were supposed to be initiated on the ARVs.

But as you can see, with our primary counselors, our lay providers, we have actually managed to make significant progress across HIV programming. And then again, Zimbabwe is one of the countries who are piloting HIV self-testing. And we use lay providers as community-based distributor agents to provide information on HIV testing use, practical demonstrations as well. And these ones, they are selected by the community as well, and they should be able to read and write because there’s electronic data collection tools to capture for the demographic data of self-testers. And we think the community as well, we’ve got what we call community adolescent treatment supporters. We use them as well as the lay providers. But these ones, they only mobilize the communities of the adolescents for HIV testing services.

And what are our [inaudible] recommendations for lay providers? We avoid high attrition of lay providers. And I think the issue which has been alluded before, the issue of remuneration for them. We cannot just make them work without any remuneration. So, at times we find that we have got high attrition of them after training them because of remuneration. The issue of lack of recognition of these lay providers within our human resource plan for health, we still need them to be part and parcel of our healthcare delivery system. I think the issues of sustainability that were discussed in the morning as well to say, how should we sustain these lay providers? Because we are looking at most of the time, they are actually partner funded. Not funded by our governments. And then the issues of recruitment strength and quality, retraining and retention, those could be the recommendations. But actually looking at our best, we can retain them looking at even the issues of remuneration. And after training them, we find that because we depend on partner [inaudible], donor funded, we still do not have a lot of funding to
do refresher courses for them, despite the fact that there are a lot of revolving issues around HIV epidemic. The issues of testing and treating as well, these are actually the foot soldiers who will be able to advise someone after testing on the issues of testing and treating as well, and issues of enhanced adherence counseling.

But what we done as a country in Zimbabwe, we have looked at blended learning for the primary counselors. We have put a lot of modules on blended learning for our lay providers. And we are trying to overcome the issues so that they are actually keep abreast with what is happening within the HIV and the AIDS arena, especially on the new information on HIV and AIDS. So far, what have been our lessons learned?

Male Speaker 1: Gertrude, if you can think of wrapping up in the next minute? Thank you.

Gertrude Ncube: What have been our lessons learned from our lay providers? If we recruit them properly, they are well-matched to the clientele. They are actually used to the culture of that community. They are actually very good for the counselors. And if I get into a hospital, I would like to be counseled by a lay provider better than counseled by professionals because the lay providers, they are actually very good in the counseling. And with their training, they are very good. And then they still need the ongoing training, mentoring, and support, which is very key as well. The issues of quality assurance when we test of that when we need to keep the correct and accurate results. And not only quality assurance for the testing, but even quality assurance for the testing itself as well.

And then I think I don’t know how we should look at this, the adequate remuneration as well, because we cannot use them without paying them adequately. I remember at one stage, because they were not paid on time in one of our provinces, they decided to say tools down. Come month end, when people were actually consulted in their statistics, they realized that their testing rates were down. And then the highest office in that province, they actually phoned to say, “When are you going to pay the lay providers or the primary counselors? Because we cannot afford to have such kind of statistics.” It was only when they realized that these people are critical, when they’ve actually said tools down,
when they not now get the right numbers for the statistics which they wanted.

And then we are looking at how we can revisit our policies as well, where we are actually looking at they should provide the whole services of care. Because like when I say it, when we trained them before, they were not allowed to do the HIV rapid testing. But we had a lot of missed opportunities. And now with them doing the whole services, bringing the services in the supermarket approach, people are actually happy being tested by the lay providers. I would like to thank you, and I would like to acknowledge all the people mentioned in this. And like we said, we cannot do our work without the lay providers. We need to create an environment where they will actually be able to support us to achieve our first 90. Not only the first 90, but the second 90 and third 90, because this is the duty, this is the work what they do. Thank you so much.

Joyce Wamicwe: Good morning. Yeah, thank you so much for that kind introduction. And thank you to the organizers for having us here, to the participants. For those who are not from Kenya, welcome. We hope that you enjoy the Kenyan hospitality. It shouldn’t be all work and play. So, I’ll be making – it shouldn’t be all work and no play, yeah. I’ll be making our presentation on how we adopted the WHO testing strategies in Kenya. And that’s my outline. So, we know this. I don’t think I need to belabor on this, but the main essence of showing this slide is that in Kenya, we recognize testing as a key and critical entry point to not only identifying the HIV-infected persons in the population, but as a way of ensuring that for the negative, they continue being negative. So, we have that very clearly elaborated in our Kenya AIDS Strategic Framework.

Now, of course, to adopt the WHO testing guidelines, we had to adapt the guidelines. But WHO is always kind of following Kenya. So, the story will be a bit mixed up because WHO came a bit later. We started a bit earlier in 2014, late 2013. And what made us start? Obviously, the last guidelines we had had last been reviewed into ’09, 2010. And then we have very dynamic HTS and laboratory technical working groups. So, we had noticed there were several things we needed to sort out. The whole issue of linkage was still
not coming out the way we wanted. The emphasis on correct results was still a problem. And then this whole issue of quality, as much as it was in the guidelines, it needed to really be broken down. So, hence, we started the whole process of reviewing our guidelines. So, obviously, it’s a process. It had timelines, clear timelines. We thought we’d do this in one year. We ended up doing it in about two years. And it was a back and forth. And I’ll be taking us through that.

So, under the planning beat, we obviously needed to get the mandate from the technical working group. One of the things we realized a long, long time ago is you need to have the lab team on the table right from the start when it comes to HIV testing. And I think in the last few months in this country, that has still recurred in our thoughts. And it’s one of the things that we’ve learned as one of the take-home messages. And then, we developed a secretary that was just – we found a secretary that was just going to do work on the guidelines. And we had several subcommittees. We needed to involve program managers, specifically PMTCT team needed to be at the table. The care and treatment team needed to be at the table. And the legal team, because we were going to come up with crazy things like 15 years and above. Yet we know for in Kenya, an adult is 18 years and above.

So, that was the planning process. We then had a lot of consensus meetings on what would we like to see the guideline looking like based on what we had seen from the field, and what was coming out from literature. We had numerous writing workshops, but residential and unresidential, back and forth. And we had a lot of review, internal review at technical working group level, at national MOH leadership level. And around that time is when we had the WHO testing guidelines being launched, so we also had to review and see what we’re talking of, what was in the guidelines. Thank god, they had borrowed a Kenyan copy, so we were not so off. Then, we had external reviewers. And in the reviewers, we had even representation from people living with HIV. We had key population representation.

Obviously, we had the program reviewers, and again, I repeat, the legal beat. Because when you go start saying testing needs to be offered by a person who is non-lab, yet it is known to be a lab test,
you need to have a basis for that, especially if you have very strong lab boards, registration boards, like the ones we have in our country. So, we had to get all that done. And obviously, the age of consent again. Make sure that our guidelines speak to our HIV and AIDS Prevention Control Act. And then, the MOH leadership review also needed to go through this. I see a lot of us in the room who we were with at that time. And the issues of even things like algorithm brought a problem. We spent several nights discussing about why we are dropping the tiebreaker. And one of the things we noted as a country is if you have data, in country data, then it’s easy to convince leadership. But if you just come and say, “WHO said,” then the meetings can go on for quite some time. So, thank god we had a lot of proficiency testing data that could that yes, indeed, we do have incorrect results out in the field, and hence, we are able to indicate why we needed to adopt what WHO was saying.

But then, we adopted with our own special law, which I’ll be showing. And so, as part of the process, we had the launch, and then came the big animal, the dissemination. We had to have a very clear operational guideline. We noticed from last guidelines, it’s very easy to have guidelines and say targeted testing. But when you go to talk to a healthcare worker, you need to break that down. You need to say exactly what you mean by targeted testing. So, we developed operational guidelines, SOPs, and a dissemination plan, and put in how we are going to monitor what we are doing. We also realized we have to now revise every other thing, like the curriculum, the training curriculum. Thank god we were revising our mainstream HIV MNE tool, so we were able to incorporate all these retesting things in the tools.

And then, we adapt that last bar, where we’ve been now about one-and-a-half – okay, maybe one year plus three months – of having the guidelines out there. But we are clearly following up, and there’s still dissemination going on. We’ve disseminated to a majority of healthcare workers, but we still need to disseminate more. And the monitoring of the dissemination is really a mandate of the HTS and lab technical working group. We’ve realized WhatsApp is helping because we are connected to the county trainer TOTs, who update us on the issues. Like for instance, what should a healthcare worker do when they get an inconclusive
result? Those things, we think they’re easy because they’re in the guidelines, but a different kind of language is needed when you’re talking to a healthcare worker. And then, we are learning for service quality assessment to assess the uptake of the guidelines that we revised.

So, that was our dissemination plan. As I said, we’ve done a majority. We have a database. We now know who’s offering testing in our country. One of the things we realized, a lot of the persons who are offering testing under the PMTCT are actually not really trained. So, we are making plans on how we can upgrade them so that they can at least have that formal HTS training.

So, our guidelines, I know I’ve talked about them, but this is how they look. We moved from the three Cs to the five Cs. We really outlined the roles of the national and the county levels as regards the HTS policy. Given that we have devolved, health is now at the county level, issues like storage of kits is at the county level. Some counties do not even see what HTS – they wonder what we are talking about when it comes to HIV testing. Given that we have told them, we have tied this to the target of how many people they need to identify towards 1990. Then we have defined pathways that of referral very clearly. I talked about the tiebreaker issue. That was one of the things that we spent long nights really discussing should we or should we not drop. We’ve given explicit guidance on retesting for various sub-populations, put it in a table format. In our initial guidelines, the ones that we printed in 2015, we realized the way we had done it was not quite clear after we went out to train the healthcare workers. So, in the reprint, we put it in a better way.

So, one of the things we also realized, when you print, don’t print the whole bulk that you need. Because after you train is when you realize you may be speaking a language in the boardroom that’s not really understood when you go out. So, you have that opportunity to do some updating and now put it the way the frontline healthcare workers specified that they would like it to look like.

That’s the algorithm. I’ve put it there not for you to really understand. Okay, it’s like WHO, what is in WHO. But you see,
it’s pretty long. And I can tell you, even amongst us, the national HTS and lab technical working group, we took long to understand this algorithm, like what happens where, who tests where. Then we realized at some point, we had said the retesting should happen at the comprehensive care clinic, which is the place where you refer all positives. Then we realized we had left out how about the women who are identified as positive in ANC. Do you want them to start again looking for their CCC? The other thing with this algorithm, healthcare workers, especially the lay counselors, they feel like they are being tested.

Male Speaker 1: You have two minutes.

Joyce Wamicwe: Yes. So, they overtest because they’re like, somebody else is going to test after me. So, we’ve realized our commodities are running into very huge numbers. So, there’s a lot of – the retesting is now even happening like four times. So, that’s one of the things, we are trying to see how we can sort that out. So, we are telling them to relax, it’s just part of quality. Nobody’s checking whether you’re failing. But we have also now had an issue that there has been a case in Kwali where because of identify a client as positive, but later, they are identified as negative, people are being taken to court. What do we have? I mean, and yet the act, the guidelines are all saying lay counselor now should offer a test. But the lab board is saying, no, an HIV test is a lab test, you understand? So, we go back to the drawing board, okay?

So, we are having a few issues under that algorithm. And then the whole testing to be offered to adolescents and the youth. But this one, we haven’t had problems with it. So, 15 years is acceptable. Self-testing was in the previous guidelines. What we decided with these guidelines is to operationalize it. So, we have developed operational guidelines for self-testing. We’ve decided no more pilot tests. In this country, we are going ahead with HIV self-testing because we know no matter how many times we test, there are people we just won’t get. Like men, we will never get men through the way our healthcare system was designed. It was designed for children and women. So, men, we need to look for a different way. Our current yield in 2016 was 1.7, and we are having to think through different mechanisms of increasing our yield. And then we emphasized on program integration and
included early infant diagnosis in our testing guidelines. We realized people forget babies and say that’s EID. But that’s still testing and needs to fall under HTS.

So, in summary, the revision took a lengthy process, like under two years. Consensus building and inclusion of all stakeholders right from the start was important. And then the country needed to have data that could be used to back recommendations, because even when you go to disseminate to the healthcare workers in the field, they ask you why. Why are you just following the preacher blindly? You need data. So, the more we have the data, the more we are convinced. Convinced and the more we convince. And then we have a very clear implementation and monitoring plan for operationalizing the guidelines once we launched.

So, thank you so much. Acknowledgements to the HTS and lab technical working group. Maybe they can stand. This being our country, we are allowed one minute extra. And to everyone else who has been involved in this process, and to our frontline workers and our Kenyans, who still, despite all the stories we see in the newspaper, they still seek services in our healthcare facilities. Thank you.

Nokuthula Majingo: Good morning, everyone. My presentation is on the Botswana context on the overview of the treat all strategy following the launch of the 2015 consolidated WHO guidelines. So, my presentation outline will be as follows. There is the context and the background, the modeling and custom results, the implementation, as well as HIV testing, self-testing, and the next steps.

So, in Botswana, the treat all strategy was launched in June last year. And the aim was to initiate all people living with HIV on treatment to gain epidemiological control by 2020. So, this treat all strategy meant to us that we were going to be required to identify more additional people living with HIV/AIDS at least by 2020. So, as the number of people on ART increases, the unidentified people living with HIV remaining will represent a smaller proportion of the population, and hence require more targeted and additional
HIV tests. The HIV testing strategy modeling that was developed by the country following the launch of the treat all or just prior to the launch of the treat all, it was developed from November 2015 to May 2016 to establish testing targets across 20 high-level testing strategies. Those were based on the expected reachable population size testing yields and costs.

So, this HTS modeling strategy now needed to be converted into an implementation plan. So, through this modeling strategy, the meeting, testing, and treatment, I guess, will require actions and decisions in the design of interventions and the appropriate resources to be allocated. So, amongst these interventions was to implement routine HIV testing at other health service sites, such as the TB clinics, STI service points, inpatients, and so forth. This was through the integrated modeling of health service provision. The other intervention is to implement routine HIV testing for key at risk populations in the outpatient department, specifically targeting men, children, as well as the adolescents. Among the interventions is also to increase testing coverage for sex workers, as well as MSM, and also to implement partner notifications services, as well as to roll out the HIV self-testing and scale up. This was the interventions that we modeled through our testing modeling strategy.

So, through this strategy, we identified the annual tests for the country, the yield, the patients to be identified, as well as those that need to be linked to treatment over a period of five years up to 2020. So, the modeling had identified that the number of patients to be identified will actually be declining over the years, beginning the year 2016. This will also apply to the yield that we are to achieve through these strategies. However, yes, the modeling also indicated how much we will need to achieve with the self-testing if it is to be implemented. However, the number of tests to be conducted through all these years is going to be actually higher than the tests or the yields that we will be getting to get through the implementation of this strategy, which means to get whatever you need to get, you need to actually do a lot of more tests. In relation to the modeling strategy as well, we looked at the costs that we will incur as a country as we implement the modeling strategies. We have modeled that with all that you need to do, the actual costing is going to be higher and higher with each and every single
year as we proceed. As much as you’ll be get in the few yields, you have to do that at a very high cost.

So, implementing the HTS strategy will require key operational actions along the following thematic areas. We had the thematic area on policy and coordination. The progress so far is that the HTC program assessment was conducted in 2016. The national HS guidelines were also developed in tandem with the WHO guidelines. And the HTS implementation plan is also under development, and it is currently ongoing. So, real testing algorithm was adopted by the country through our guidelines, and also started the verification of the test results adopted in both the HIV policy as well, the HIV rapid testing policy as well as the national guidelines. Thematic area service delivery at facility level. Routine HIV testing is being implemented at all service points, as I have indicated, is being integrated as part of the health service.

Testing strategies in communities were also adopted. So far, we have been implementing the following: targeted community-based testing, index partner testing, linkages across the continuum for the key populations, and as well as the home-based care. And also, in addition, we continue with our normal routine and VCT models. Program monitoring and evaluation. This is our weakest link. As a country, we have our multiple information systems, which are not interconnected, and therefore a barrier when it comes to following on the linkages.

So, here I’ll be sharing with you the outcomes of the testing strategies that have been ongoing in our communities. We have the linkages across the continuum for HIV key populations. This is data for one year, October 2015 to September 2016. This is the much we have reached. We managed to reach about 87.7 percent of the 4,810 targets that we intended to reach. We reached those key populations. We tested them. That is 63.7 percent. And out of those that we tested, we had a positivity rate of – we had 559 being tested positives. And among those, we had seven percent positivity and 21 percent for the MSM and female sex workers, respectively.

Now, with the targeted community strategies, the number of people that have been reached with HTC services and number tested by going through our APC project in Botswana. These are
the quarterly targets and achievements. And overall, we have reached 24,329. And those that have tested positive are 1,649. This is now the same project with the different modalities and their yields. The index testing has yielded as the most with 15.7 percent, followed by the 5.5, which is home testing that is targeted. And the mobile testing, because we continue doing is, is yielded as the 4.9 percent yield. And VCT yielded the least at 3.5. So, the overall yield is bringing us to 6.7 percent.

So, continuing with the community, these other testing strategies, we have, like I said, adopted the HIV testing. However, we have not yet started implementing it. It’s adopted at policy level. We are now in the process of drafting the protocol because the intention is to pilot it before it can be scaled up. So, our pilot proposal is at draft stage, so that it can inform us how we go about it. So, here is a national HIV status, cumulative from January to December 2016. This is how testing is being – the contribution to testing is faring in Botswana. Government is contributing 59 percent, and we have our NGO partners contributing the remaining part. And now, this is our quarterly performance against the first 90 as a country for the year 2016/17. We are now standing at 70.7 percent. Our baseline was at 70 percent. So, our country positivity rate is 6.2 percent.

So, the next steps is to develop and submit a protocol for the planned HIV testing operational pilot. And we are advocating for support, technical and financial and otherwise, from our development partners and other stakeholders. I think you very much for your attention. [Speaking foreign language] [00:10:56]

[51989_WHO-Overview of the new WHO guidelines on assisted HIV partner notification, R_Baggaley]

Dr. Rachel Baggaley: So, as you know, in December, we produced a supplement to our guidelines with two new recommendations, one on partner notification and one on self-testing. And everybody is very, very excited about the self-testing. But the partner notification one hasn’t really grabbed peoples’ attention. So, I hope I can grab your attention on this. And we think partner notification is really a key way that we can really start to reach people at high risk who aren’t accessing testing. And partner notification, or, as it’s sometimes known, contact tracing, has been around for many, many, many
years, and is absolutely the kind of commonplace strategy in STI care. And when I was preparing for this presentation, I just did a quick search on the Internet, and most countries have STI recommendations for partner notification. And there’s a lot of evidence out there giving the benefit of this.

And it’s normal practice, if somebody comes in with an STI, to offer them contacting their partners so that they can also be treated for STIs. Weirdly, WHO doesn’t have a recommendation on partner notification or contact tracing for STIs. However, they will be releasing one in June, so they’re being spurred on the HIV department to get their act together to address this issue. Similarly, for TB, another infectious disease, again, it’s commonplace in many countries, if you have a smear positive TB case, to go and offer screening for household contacts. And WHO’s had a recommendation on this since 2012. Oops, where am I going? Whoop, sorry about this.

So, we released this recommendation that we should now look after 30 years in the epidemic of an infectious sexually transmitted infection, that we should also offer assisted partner notification services to increase our ability to diagnose people who would benefit from treatment. And that was really building on some work that we did back in 2012. And many of you in the room, Vincent and Christina, were very much involved in this work on couples’ testing and counseling, where we recommended couples testing and counseling should be offered to partners throughout a range of services, particularly in antenatal care, and particularly for people with HIV. And what’s interesting about this recommendation is no one took any notice it. And here we are five years later, and virtually no country routinely offers partner and couples testing, even in antenatal clinics where it would be a very obvious and relatively easy thing to do. There’s only one country that really systematically does that, and that’s Rwanda. There have been many successful small projects which have shown that they’re highly acceptable and highly effective, but – and maybe you can give me this answer, but why are we still so reluctant to support partner testing?

So, the reason we had this recommendation really was to built on the obvious advantages of testing somebody with a sexually
transmitted infectious disease, offering testing for their partners and building on this recommendation, and trying to encourage this to happen more routinely in settings. And we were also spurred on by the fact that there were a few studies in Africa particularly that really showed this to be highly acceptable and highly effective in many ways. And some of the architects of these studies, and there’s Roman Peter Church, which is here, and really, we thank him for providing that evidence to support that, and also thank colleagues from West Africa, from Cameroon, who again have led the way in partner notification services.

So, partner notification has got many terms, and I think this again can be slightly confusing for people. It’s often called contact tracing. I must emphasize here that it always must be voluntary, and people who fear that they would risk any adverse offense from suggesting a partner be tested, and that partner could then get cross with them and be violent towards them, then that obviously would be something that we wouldn’t recommend.

And partner notification can be active or passive. And it can be a passive approach, where you would offer – where you’d go to a clinic, and this actually happens quite routinely in practice, that you go to a clinic. You’ve found out you’re positive, and the counselor in the post-test counseling will say, “Well, look, it’s a good idea to discuss this with your partner. I suggest your partner comes in for counseling and testing. And although that’s always been in our post-test counseling guidelines, we know that, number one, it’s not often done in a way that encourages people to bring their partners, and partners often don’t then go and do that. Other kind of passive ways are to give a leaflet and provide this to the person so that they can bring their partner in. But what we’re looking at with the assisted partner notification is something that’s more active, and really something that the person who tests positive and the person who does the post-test counseling can really together make a way to actively trace partners and really support them coming for testing and counseling.

So, there are three major types of assisted partner notification that have been described in the literature. A contract referral, where the person with HIV agrees to be in a contract with the healthcare provider. And they agree that they will tell their partners, and the
partners will then hopefully come in for HIV testing themselves. But if the partner doesn’t do that after a specified period of time, then the healthcare workers themselves will contact the partner directly. So, it’s giving that first opportunity for the partner. If that doesn’t work, then the healthcare provider will step in and help in. Provider referral, and this is something that has also proven to be very acceptable, is where the provider themself, at the agreement of the person who tests positive, again, will contact partners, either the regular partner or other partners, again, to offer them direct access to testing services.

And then there’s a kind of mélange of the duo, where a trained provider accompanies and provides support to the HIV positive partner when they disclose their state to their partners and offers testing together. And all of these have been shown to be highly acceptable, given that caveat that this is always with discussion with the person who tests positive.

So, why are we here? 30-plus years into the epidemic, and why is this so important? As I side, it’s a well-known public health method for TB, for STIs. In fact, it was also absolutely critical to the Ebola epidemic, when people went out and offered contact tracing for contacts of households with Ebola. And WHO produced guidelines on that within about 15 minutes of the epidemic, and these were readily taken up and were absolutely key to the eventual successful outcome of the Ebola. And if you’re in a partnership and your partner has HIV, you’ve got a much, much higher change of having HIV than the general population, So, you really could have that advantage to access testing and get on treatment. And then you will benefit from that treatment yourself. And if you’re negative, that also gives you that opportunity to discuss that within a relationship and remain negative within a serial discordant couple.

And we know that couples who can discuss and disclose can support each other to remain in a serial discordant couple, or to support each other to take treatment together, or support each other over PMTCT interventions. So, there are many, many benefits. I’m going to hand over to Brian, who’s going to talk about the evidence that we looked at to support this recommendation.
Brian: Thank you, Rachel. So, I’ll proceed to talk about the evidence. As you know, when WHO develops our guidance, we use the great process. And one of the core pieces of the great process is to look at the evidence. So, with regards to partner notification, there was that review of the literature and the systematic review which was done. After reviewing all the evidence, there were four RCTs. And you know that RCTs, that evidence is always taken higher than observational studies. So, there were four RCTs which directly looked at partner notification, comparing assisted versus passive partner notification. And let me use – I think I’m getting – am I getting old? My sister always says I’m getting old. My wife says I’m old. All right. I think I have to look at this screen here.

So, from the systematic review, and particularly from those four RCTs, it was clearly shown that assisted partner notification can, one, increase uptake, which you have agreed is very critical for testing. And then, but it can also result in higher proportions of positive people being diagnosed. And the most important, and we heard this morning, I think, were the colleague who highlighted it’s not just about testing, but it also can contribute to increased linkage to treatment and care among partners of those living with HIV. So, definitely, there is a very clear benefit that we can get from partner notification.

There has been a big issue that’s been coming up, the issue of harm, where the partner notification will actually result in increased harm. In the evidence review also, it was shown that actually, there is very little evidence, even though there’s a general perception that there could be harm, there’s very little evidence both from studies and from programs that have been looked at to actually show harm. So, there are a few cases of harm, but they are not serious issues of harm. But however, even though there isn’t as much evidence on harm, it’s still important that we consider the potential of harm. And that needs to be discussed with the HIV positive client.

The timing of assisted partner notification has also been shown to be important. So, two randomized control trials of those four, two of them, which were done in Malawi, showed that the different in partner rates between the passive and the assisted becomes more pronounced over time. And so, if you look at those two graphics,
the first one, the first two lines, which are closer to each other, provider and contract referral, which I think Rachel has already talked about. And then the lighter line is passive referral. So, you can see over time, the two lines are growing more apart. So, from the first week, you can see that as time goes, there is higher notification in the two groups, which are actually the provider and the contract referral, compared to passive referral. And then the other graph basically shows the same, but this is now showing passive versus active. And you see basically the same. Another RCT also showed improved outtake when you actually look at immediate partner notification versus delayed partner notification. That’s not presented on this slide.

I think Rachel has talked to the benefits, so just to highlight them. So, in addition to access to the services, adherence and retention, PMTCT, which I think Rachel has mentioned, and then the prioritization for effective prevention. And this is just an example from the Kenya – I’m half Kenyan, half Zimbabwean, and half South African. As you saw, I was in the Kenya team. So, this is from Kenya, the experience of our VCT who have been involved in doing some of the early partner notification work. And this shows an example of assisted partner notification of a young woman who engaged in transactional sex. And I won’t go into the detail about the traffic, but basically it shows the networks, and most of the clients and partners were actually trust, and most of them were actually put – accessed care and treatment.

Some of the challenges that we should expect with partner notification will obviously include those of identifying the partners. Because obviously, some groups and some people, particularly we talked a lot about the key populations early in the morning, may be quite reluctant to name their partners. And also, it depends on the dynamics between the relationships and the partners. So, identification of partners could also be a big challenge. Locating and notifying partners is another issue. And also, we had quite a lot of discussion in the morning about the laws and policies that criminalize, stigmatize, and discriminate, particularly against key populations, but also against people living with HIV. And these could easily present challenges, and they have to be addressed.
There are a number of considerations that have taken place when we think about implementing past partner notification. I think in the morning, and Rachel talked a lot about confidentiality, and ensuring their voluntariness, which are critical. Because partner notification should always be voluntary, and the notification should only be to the partner, and nobody else. And also, even particularly – and I think we heard about that in the key populations, the criminal justice law enforcement should never be informed because we know what will then happen. And also, even workers outside those who are related in taking care of the patients. So, confidentiality and voluntariness is critical. It has to be maintained if this would work.

And the choice, again emphasized in the morning and by Rachel. So, HIV positive clients should be given options on partner notification. Rachel has presented the different options. So, the clients should have an option to choose which would work best for them. And that may also be different for their different partners, depending on their relationships. And then partner notification is not a one-off thing, because it depends on where the person is. Maybe at the beginning, it may be very different, but later on, it may easier. So, it’s important that it’s actually offered regularly as the patient’s situation or person’s situation changes.

And then, with regards to the methods for contacting for partner notification, again, the preferences will vary. I think we heard about young people, about key populations, about pregnant women. So, it will differ by population. It will differ by the age and the partner type, whether it’s the direct primary partner, or it’s the partner of your partner. And there are various methods, and they are listed there. So, obviously face-to-face is one. Phone calls, text messages, emails, even video call. And that depends on the people that you’re dealing with. Young people may opt for a different method than older people like myself. And but particularly something to highlight with regards to phone call and text messaging. So, you know if you send a wrong text message to the wrong person, you can actually spread a message very quickly and inform others about the partners and what happened. So, those have to be handled quite carefully. Obviously, there are some groups who prefer them, and they do work. They’ve been shown very clearly in literature that they work, but there is a need to be
careful about ensuring anonymity and making sure the message still gets to the right person who is actually the partner.

It’s very important to also monitor partner notification. So, there is a need for documentation. We have to put in place monitoring systems and reporting systems, which would then ensure both security and confidentiality of the data, but it also ensures that the right people have access to the data and use it for programming. And those are the different indicators that have to be documented, including the number of persons who are offered assisted partner notification services, those who accept, those who are positive, etc.

So, in summary, then, the HIV obviously is an infectious STI, and there’s clear rationale, and Rachel described it quite well, for partner notification to be implemented for both individual but also public health benefit. And partner notification is an approach that actually is very effective. It has been shown to have a high positivity rate. And you know at this stage, we need to also increase the yield, of course in addition to other aspects. And then increasingly, we talked in the morning about man, my gender, and we have a major challenge with them. And it’s been shown in a number of studies that we actually can reach men and draw them into testing using past partner notification. It has to be voluntary, and particularly in situations where it’s criminalized. And we already had presentations on the number of countries where it is criminalized.

In terms of the way forward and future activities, there is obviously a need to disseminate. And Rachel highlighted that very few countries have introduced actively and are actually using partner notification. So, there will be a need for us who are here when we go home to make sure we fully disseminate these guidelines to all key people. Advocacy needs to continue so that we can catalyze the different approaches, and so that they become part of our routine HTS system. Because as long as they don’t become routine, the benefit that they can give us will not be realized. And then there are some webinars which will be coming up, which WHO is organizing with USAID, and you will be informed. And then I think you can also ask others to connect in. And then there will be a need for tour kits and implementation guidance. I think it was discussed in the morning. Just these guidelines, we know are
not usually enough.

So, there are usually a need for kits. So, kits that the implementing partners, I mean, WHO and others will help develop, but there will also be a need for implementation guidance in country on how to actually interpret. You had my colleague from Kenya talking in the morning from testing. And I think we have to do the same. And then there needs to be vigilance in monitoring on the implementation, because even though we have shown that there isn’t that much harm, we know that there’s still a risk. And also particularly, there could be a risk for misuse, which we need to track and monitor.

So, this is just to acknowledge all the colleagues who were involved, including the peer reviewers and the technical working groups and the funding agencies who funded the work. Thank you very much.

[51989_The future VCT, Dr_ Nduku Kilonzo (Director National AIDS Control Council, Kenya)]

Dr. Nduku Killonzo: As I start this presentation, I just want to kind of give a background. As I was thinking about preparing it, I know that my team kept saying, “We need your title presentation.” And I had an opportunity to look at the kinds of programs that had been laid out, as well as look at the invited guests. And I kept thinking, what is it that I can tell this team that is not already full of expats that know this area, that have looked at this area? And I wasn’t too sure. So, what I ended up doing was thinking, let me reflect back on my own experiences around HIV testing and counseling, my own thoughts and reflections around the things that worked and what didn’t work, and what it is that we need to do. And as I think about my reflections, there are a lot of people in this room that were either my trainers or enters in the HIV, in VCT testing and counseling, so I definitely have to acknowledge them, because a lot of the thoughts that I bring here come from that space. Thank you Jen and Patricia, who are here, and of course Miriam, who was my trainer.

So, let me start by giving obviously the Kenya context. Where are we? And I used 2015 data. So, this is the Kenya 2016 report. And I
used that specifically because we are just now crunching our data for many of our countries that do estimates. We’re in the estimates development process. And so, therefore, I do not have data that I can share from 2016. So, setting just the context of Kenya, we have a prevalence that’s very diverse. About a total of 1.5 million people living with HIV, but some counties that have over 15 percent HIV prevalence around the lake region. And you can see then, we have some counties that actually have less than five percent prevalence up to actually a one percent prevalence. And our key populations, though the numbers might be small in the context of the general population because Kenya has 40 million people, you can see the HIV prevalence is quite high in those three populations.

So, between 2013 and 2015 – next, please. Between 2013 and 2015, we reduced our numbers of new infections by almost 19 percent nationally. And you can see that the way in which it’s distributed across children, that’s where we had the highest infection, in eMTCT, and then across adults. And I’ll come to that in a moment, because this is significant, I think, as we talk about self-testing. The great impact in prevention – next slide – was felt in mother to child transmission And we had about 29,000 HIV positive pregnant women in the country. We had about 6,600, which translates to about an eight percent eMTCT rate, which is obviously way above the five percent, and even way above elimination. But when you look at it, we want to be on track. Are we on track in terms of we believe that that count as reduced significant. And this was occasioned by both a lot of technical will and technical options and changes. Then we had option B plus, which is no longer an issue because we have test and treat. And of course, there’s a lot of political support around eMTCT.

But when you start to actually deep dive – next – into the various counties across the country, what you find is that about seven counties achieved more than five percent target. But there were more than about 20 counties that increased. Kenya 47 counties. Let me just give the context. We have 47 counties, and that is independent governments across the country. We find that a number of them actually did record an increase in eMTCT rates. When we look across the country in terms of the new infections, we find that when you compare 2013 to 2015, which is that graph
there on your right – I hope you can see the red – you find that there were some counties that actually had a significant increase in their numbers of new infections, while there were counties that have a significant decrease. And those are the ones in green there. This is just a reflection of the total number of new infections in those counties.

Among adolescents and young people, which is a big issue, and I think as we talk about self-testing and in my reflections, I’ll be making some comments about some of the lessons we have learned about young people, and perhaps where we are not doing very well or what we are not getting right as far as being able to reach adolescents and young people is concerned. When you look at the total number of new infections, we had about 51 percent of the adult new infections, which was 71,000. That is 35,000 of them being in people age 15 to 24 years. What does that mean? Translate that into just about 100 new infections daily. Most of them were in young girls. And we have a significant population of young people living with HIV. Next.

So, coming to the 90-90-90, and some of the places we have recorded progress. You do remember that I started by saying we have 1.5 million people living with HIV as a country. Of those, by the end of 2015 in December, we had about 900,000 who were on ART. However, now we have about a million, slightly over a million, who are on ART. And although our retention has increased and viral load suppression has increased, we are still far from achieving the last two 90s.

So, where are we coming from? Does that billboard look familiar to many of us, or similar billboard across the continent? VCT is something that I think we saw a lot of branding. And I want to reflect on the lessons that we learned, because that was really was the beginning of a massive push towards HIV testing and knowledge of HIV status. And our gains so far in treatment, from a public health imperative, our gains so far in terms of human rights in the public sector really begin from the days of VCT. So, this particular slide – next slide – this particular slide is actually a slide that I picked from – I presented and made sometime perhaps around 2004/2005, just trying to explain what is VCT. And the way in which we explained it, it is aimed at people who are well
and who want to find out their HIV status. It provides a confidential test. There are no returned results. It involves pre and post-test counseling, and encourages people to come as a couple.

So, I wonder, as I reflect, and as we think about HIV self-testing, could we replace that VCT for HIV self-testing? We want people to find out their status. It is a confidential test. Perhaps, the pre and post-test is the one bullet that we will take out of that, and we encourage people to take it as a couple. Maybe not come to where we are, but we encourage people to take it as a couple. So, with that understanding, I’d like us to just make a few reflections. VCT uses rapid tests. They are accurate tests. It was individual in nature. Although we encouraged people to come as couples, a lot of the VCT, both in branding, both in the testing, both in the way we trained counselors, really talked to individual people, it talked to people who came in alone into a VCT site. Often, counselors would see people alone in VCT sites. Actually, I do remember that we did have instances where couples were separated during VCT, particularly in the pretest counseling. We did have VCT in terms of the way the algorithm, in terms of the way the counselors recorded data. As we talked about anonymity and confidentiality, one of the things I remember in my experience from Kenya was we asked peoples’ maiden names. And this is important because it’s one of the lessons that I will be reflecting on.

But as we’re asking peoples’ maiden names, people would walk into a VCT site. And I’m sure this applied across countries because I did engage in VCT in a number of the countries that are represented here. People would walk into the site and say, “My name is so-and-so.” And then when you start the record, you ask for their mother’s maiden name. Perhaps just for us to think back. It was performed by counselors versus trained lab technologists. And I remember when lay counselors, as they were referred to, began testing, there was a huge deliberation and discussion globally around whether they would give accurate results, whether they were the best people to do it, and there was even pushback. And some countries took a long time to accept that finger prick testing could be done by lay counselors.

Quality assurance included counselor supervision. There was quality control, and then there was mass media. There was
significant branding. There was investment and a lot of money trying to find out how could we get people to come for VCT? How would we need to be talking to them? What questions would we need to be asking them? What should we be answering? What are peoples’ fears and what are their motivations? Next.

So, what are the lessons we learned? I think the first one we learned is we have to start and learn as we go along. When VCT first started, it was very, very clear that at the time, ART was not widely available. And therefore, when people learned their HIV status, a lot of counseling really was about care, and even preparing them to die or preparing them in the death process, mainly because not only was there no ART, most people got their test very late into their AIDS status. So, there were fears of testing and fears of knowledge and fears of social harm. What will happen when we let people know? And I think those are the fears that we experience today when we think about self-testing. Should we? How will people react to knowing their HIV test, to knowing their HIV results? So, do we wait. given the evidence that we have so far or don’t have on social harm, or do we start and move forward?

I think sometimes the most invested are the barriers. I want us to reflect on the question of the laboratory technicians who are really invested in assuring that testing is scaled up. But there were barriers to doing it through using lay counselors. Let’s think about the issue of anonymity. When the idea of removing anonymity from VCT sites during scale-up of VCT came up, the first people to actually push back were counselors, who said, “We can’t just take peoples’ names. We can’t write peoples’ names.” So, the question around self-testing is, we are the most invested in this room. As we move forward, to what extent might we be the barriers? And that’s a question and a reflection we need to have if we think about scaling up and moving from projects, because we have been doing self-testing projects for the last ten years. Recognizing that perhaps there was no pre-qualified product, but we’ve been doing it for a very long time.

We need to trust that people will do what’s best for them when they’re motivated to. People still came for VCT even when there was no ART. There was motivation, there was sufficient information, there was knowledge. And we must actively focus on
couples. Although we talked about couples in VCT, everything about the way we designed VCT – we delivered pre-test counseling, we delivered post-test counseling; the way in which we advertised VCT. How do I tell my partner? So, I’ve already come. How do I go back and tell my partner? We already did that from the perspective that we were dealing with individuals.

So, what are the challenges and what are the opportunities that we need to be thinking about? And I think I just want to reflect – next slide – and to reflect on a roadmap for Kenya. And I have located a lot of the conversation around prevention, because I think, in sub-Saharan Africa, that is where our largest challenge is. And I think the opportunity offered for identification of people who need to be put on treatment is the same opportunity that self-testing offers for people who need to remain HIV negative. Kenya’s roadmap for prevention did look at how do we change our prevention? And we identified that we needed to move from national, having a sort of one size fits all approach to specific clusters by identifying who needs what service. The different populations that we needed to find are moving from just being able to provide services that were biomedical, i.e., health facility-based, and then engaging the nontraditional people in the HIV and in services.

Why do I say the nontraditional people? I think everyone who is in this room has been working and engaged in the HIV response. Everybody who is in this room has worked within perhaps testing and counseling, or ART, or other HIV services. If we are going to move VCT as a community-based option, where are the social services people, and how do we engage them? Are they in this room? I doubt. Where are the programs that reach significant masses of men? Where are the sports people who actually are able to reach men? I remember when we did a campaign around testing in 2006, I think – was it ’06 or ’07? The World Cup. And there was a campaign in Kenya on the World Cup. That was the year that recorded the highest number of men tested in Kenya in one single year, just because the testing campaign ran alongside these events that are really male-oriented. Where are they? Are they in this conversation?

So, the Achilles heel to prevention and access to treatment, I think, has been talked about a lot. So, it’s really simple. In Kenya, we had
71,000 new HIV infections in 2015, of which 35,000 were adolescents and young people. So, how do we get our HIV self-test to – first of all, who are those 35? Where are they? Those 71,000? 35,000, we know their ages. But where do we find them? What are their behaviors, so that we can try and figure out who is going to be most likely, besides just key populations and the general populations? And how do we find them, one, to get the testing to them during early or acute infection so that we put them early on treatment? Two, we reduce the potential for transmission. But three, importantly, for those that have not already acquired HIV, that they can actually use that as an intervention for prevention.

I think we need – self-testing allows us to operationalize retesting for those that are at the highest risk. We’ve talked about retesting for a very long time, and it’s become a contention. Should we be retesting? Who should we be retesting? Why should we be retesting them? It is expensive. We don’t have sufficient test kits. There’s a lot of money. We don’t have enough yields. But the reality is that there are some people that need to be able to get retested. So, how do we identify them, and what options do we give them? And I think self-testing allows us to be able to target them.

Partner notification. We talk a lot about partner notification, and I’m really glad that the WHO guidelines identified that as an issue that needs to be addressed. However, let’s consider the gender considerations of sex and sexuality. A lot of times, in many contexts, sex and sexuality is not something that even couples discuss. More often than not, I think, in many communities, even something as basic as pregnancy will not be something that a wife will tell her husband. The husband will be told by either the aunty or the sister, and that’s just the reality. And I don’t think I’m very far off from really, the larger population of where we live. But we would like that the conversation that happens is that I test, and then I test my partner. We test together with our partner. Many couples may find that very challenging.

And so, the question that I have for this team as you think about delivery options is to start to consider the context of sexual communication, especially as we think about rural areas, and how those contexts will become – we can turn them into avenues and
incentives for being able to deliver self-tests, deliver self-testing, and have partners know their HIV status. That conversation needs to move away from simply let me place a product in somebody’s hands, because the conversations around sex and sexuality are not that simple. And perhaps that is one of the lessons that we learned from VCT. Next.

So, some of the assumptions that we make, and I have taken a very specific example of Homa Bay. Homa Bay is the county in Kenya that has the most challenging HIV indicators. It has about 1.1 million people, 25 percent prevalence, two percent general population incidence rate. And in the places where you see a red, which is around the lake region or the fishing communities, you actually do have a ten percent incidence, as I presented at the HIV 4P meeting last year. It recorded in 2015 10,000 new infections, and has a significantly unacceptably high eMTCT, mother to child transmission rate. In 2014, like I said, 15 percent have never been tested. Awareness of HIV, according to DHS, was 99 percent. But when you asked the four composite questions that make prevention – knowledge, sorry – comprehensive knowledge of HIV, it was only 65 percent among adults, of course varying between men and women, and 58 percent among adolescents and young people. And condom use in this county is about 40 percent.

I want us to reflect on this because – next slide – as we talk about some of the considerations for testing and self-testing, we really need to put that in the bigger context of programs. So, one, as we have had about yield and how much we should test, should we really be having the discussion of yield in Homa Bay, or should we just try and achieve 100 percent coverage for testing? Perhaps even biannually, if possible. And how do we get self-tests to reach the people who do not have access to testing. But importantly, we’ve just seen that about a third of the population do not have comprehensive knowledge of HIV. And if they don’t, to what extent does our introduction of self-tests make the assumption that everybody knows that you cannot get HIV, HIV cannot be transmitted, for instance, through saliva, and therefore, a self-test and having a positive test does not mean that you’ll get transmission? How do we need to package that information? Because this is just general HIV knowledge, and this is DHS data. And I think this is across many countries.
When you look at levels of knowledge, awareness is 99 percent because it’s usually one question: are you aware of HIV? And the answer is usually yes, 99 percent times. However, put into tests four composite questions, and you begin to see a significant different. And therefore, what does that mean for HIV testing? So, in the context of scale up, and as we think about self-testing, why have we not scaled up some of the prevention products? Condoms, PrEP, and other of our medical products outside of treatment. I think our prevention marketing and our marketing of products, not just ARVs for treatment, must change. So, in Kenya, we have what we call for the phones. You have what you call a **Bamba** 20. A Bamba 20 is airtime. I think for Kenyans, you get what I’m saying, isn’t it? It’s airtime, and it’s a very small denomination of airtime. And that airtime is in small denominations. You can get 100, 200, 1,000, 5,000, whatever. But I’m using Bamba 20 because even my illiterate aunty in the village knows where to get a Bamba 20. Does she know where to get a condom, and will she know where to get an HIV test?

If we are looking for the men and we are looking for young people, and we are looking for partners, we must be able to do media and advertising, branding and marketing of test kits in such a way that we can actually be able to compare ourselves to something like the marketing of airtime. And I’m using that because I think it has really been significant in terms of successes for marketing. Thank you. So, I think we really must rethink the way we position the marketing of our product, which is called a self-test. And price matters. So, I know that UNITAID has talked about pricing. But a $4.00 test is not going to work. It just will not be provided. It will not be accessible. $4.00 is 400 Kenya shillings. That is a lot of money for particularly people or families who may be poor, may not be able to afford. And therefore, global negotiations for pricing must really start to rethink.

Sustained uptake. We need to leverage technology. Last year, we developed a young peoples’ program and innovation, and we say, let’s have young people drive this, in terms of just being able to reach young people, the information, but not reach – be able to reach and get some form of feedback. So, whether that was in a question, whether it was in a like, whether it was in a share, all of
those things that young people do. And when we asked young people and the target, which was based on or revolved around a football league, was three million young people reached with one-to-one information. In seven months, we had 3.8 million young people who had been reached and reacted to that information. So essentially – and this was largely through technology – few were through one-to-one reach, but a large, significant number was through technology. Can we use technology for marketing of self-tests, and can we allow people who understand people how to market in that language and in that space to market?

Many of us in this room, I think, have been left behind by that technology and that way of engaging, which is basically the social media and platforms. And although we may run successful adverts and ads at our level and for our institutions, it does not translate into one-to-one reach that people have through social marketing. And I think we perhaps need to ask, are we the best people that should be talking to each other? So, the people here, because most of us are in the health sector, work around the health sector, are we the best medium to be delivering the models of self-testing?

So, finally, let me quickly go through the opportunities. I think I’ve talked a lot about reaching men, reaching young people, rethinking whether we should be the ones reaching them, or figuring out how we get them to reach themselves through their own platforms. Our environment, obviously a regulation for kids. I won’t talk about that because I heard there’s already a panel for that. There is a lot of discussions. And for us in Kenya, we are looking at the fast track of adolescence and young people. So, finally, just as I move towards my closing thoughts, I want to talk about we must be willing to learn as we go. We must start. We can’t pilot anymore. Let’s just start. We must trust that people make decisions based for them if we motivate them. We must saturate the market. We must relinquish control of distribution models and leverage other sectors. If we don’t do that, we shall continue to provide services in the facility, and we shall be where we have always been – that couple don’t come, that men will not come, and that young people will not come.

And that we must really think about the investment in systems. Do we have forecasting and quantification system and expertise as we
think about services outside leveraging models outside of the health sector? We are very good when it comes to facility. Right now, when it comes to ART, I can tell you what we need, where we need, which facility we are [inaudible] [00:28:15]. For chemists, for community-based distribution, I’m not sure that we have those systems, or we have even though about what those look like.

And then for data collection. And data collection, I think there are three aspects of data collection that I think are important. And the first is that we must think about the way in which data is collected. A lot of our systems are based on health sector systems and health sector data collection. So, if we distribute self-tests outside of the health sector, how do we collect that data? How do we do quality assurance and quality control? Particularly quality assurance, because quality control, I think there are many established systems. How do we do quality assurance? If we say that we want social services or we want this SICOs in Kenya, what we call the savings incorporated organizations that basically are everywhere across the country, we see, and they are mainly very male-oriented. We say we want SICOs to be our distribution points. How do we get that data? And yet, our healthcare systems are not that organized around tools, around registers, the kind of facility that then we feel and are aggregated. How do we organize ourselves around those?

The other one is how do we collect that information, particularly that which comes from the set, and what indicators? I saw a list of indicators that have been suggested in the WHO guidelines. And we need to think about the extent to which those indicators, we can leverage them from some of the other sectors. So, finally, I want to just say that the knack has – Misha, next? Yes. The National Control Council, we have a hub that we call Mishareefa. Misha means life, and as you can see, that’s our logo. Life, miyareefa, is knowledge. So, it’s knowledge for life. It’s a knowledge repository where all research in Kenya. So, as you think about the research agenda, Kenya has an HIV and AIDS research agenda. Please take a look at it. It’s available on our website. It’s Kenya’s really policy document and policy guidelines on HIV research. This hub was launched in 2016. And between April and December, we have over 1,000 students that are running in the country that have been uploaded. So, it would be good to see what is already being done
across the country.

And we also host webinars in the hub. And the upcoming webinar, which is – is it next week?

Miriam: Tomorrow.

Dr. Nduku Kilonzo: Tomorrow. Thank you, tomorrow, Miriam is on self-testing. My mind is still one week away. So, it is on self-testing. Please, we ask you to register to the Misha Myareefa hub, and there will be some of the people who are here making a presentation on that webinar. Register from where you are, over your phone, you will just be able. And you can then get the schedule of all the different webinars that we host, and you can be able to engage. We would also like to offer that we can host a community of practice around self-testing, and we can then – next slide – we can then be able to provide information. And you can all deliberate and engage on an online platform as a community of practice, deliberate and discuss, share lessons, experiences, as you move towards an implementation. That is one of the things we can offer this team in terms of pushing the agenda, pushing the research, pushing the information forward.

So, with those many remarks, I wish to thank you. I think I am well within my time. And I want to thank my team for their inputs into this presentation, and for information from the different partners and colleagues that I used to make this presentation, because that’s not my slides, all of them. Thank you.

M. Honu: So, today, I’m going to share with you some insights and perspectives on HIV testing among key populations in the West African sub-region context. And the data in the presentation I’m going to make is mainly based off of the Paktvayash Project. This project is funded by USAID, implemented by FHI360. And our officers are in Ghana, but our implementing countries are in Togo and Burkina Faso. We work with key populations – female sex workers, MSM. Those are the two key populations we work with, and also priority populations, like clients of FSW. Our project is
five years. We are about rounding up the project in a few months. And over the course of the project, we’ve had 15 implementing partners and six small grants recipients. And they actually implement the project on the ground.

So, we have a comprehensive package of service which spans from prevention to treatment, care, support, psychosocial support. We have crosscutting elements like job incentives, MSM job incentives, FSW job incentives. We do case management, and we also offer family planning services. So, I’m going to attempt to explain how this comprehensive package of service, as you recall. I need to mention that I’m going to talk about the how, how it all comes together into one whole. So, I don’t have a pointer, so I’m going to do – okay – a bit of a jigsaw here. So, imagine an MSM, an 18-year-old MSM called Kofi. He lives with his uncle in Lome, the capital of Togo. So, Kofi here decides on a Saturday evening to go to a bar, have some drinks with his friends who he usually hangs out with, his MSM friends. And then he meets John. John is a peer educator. He is known in the MSM network He’s affable, easy to talk to. And he’s been trying to get Kofi to get tested for a while now.

And so, that evening over drinks, Kofi decides, okay, I’m gonna get tested. So, John gives Kofi what we call a coupon de reference, which is a reference coupon to go get tested, either in an MSM drop-in center, or go to a partner clinic that has KP-friendly staff that could treat him. So, Kofi goes to the drop-in center. He tests, gets tested. And unfortunately, he tests positive. Now, what happens is John here would link Kofi to David, who is a case manager, or what you’d call KP champion. It comes in various terms. And so, of course, Kofi will be a bit hesitant, like why do I have to meet another person? But then when he realizes that David is also an MSM and is also a person living with HIV, that inhibition goes away. And David literally hand-walks Kofi through the processes of getting linked to care and getting the treatment that he needs.

So, Kofi comes and says, well, his aunty says she wouldn’t feed him anymore because she doesn’t want to share the same plates with him. And his uncle says he doesn’t want to pay his final exam fees for him because he’s HIV positive and he’s gonna die anyway.
So, what David will do is link Kofi to our social protection services. And so, Kofi will get a nutritional package. He gets to be fed. He might even get his final exam tuition paid for him. Now, Kofi comes again and says all hell has broken loose. His uncle now knows his status, that he is MSM. And so, that even takes away from the HIV. Now his uncle is threatening to call the police to arrest him because he’s MSM. Again, David will link Kofi to legal aid under our social protection services, and that issue will be resolved.

Somewhere down the line, Kofi comes back to say that he’s finished his exam, he’s passed, and he’s found a job in another town. He’s excited for the new job, but he’s worried that when he leaves, he wouldn’t be able to access his ARVs anymore. David once again will say, “No problem. I’m gonna link you to our partner clinics nearest to you in the town that you are.” And so, Kofi can move there, and then he seamlessly gets the treatment and the ARVs that he needs. So, you realize that in describing all of this, testing is actually the triggering point to initiate all these activities, and it’s very important. I’d also like to say that John meeting Kofi in a bar is not the only way that we reach key populations.

We have two main strategies that we use, what we call the strategy advance, which is the outreach, where you’d have a mobile clinic that will go out to hot spots, which is bars or brothels or entertainment centers frequented by key population. You pack the mobile van off in a corner, usually in the nighttime, 11:30, midnight, and then the team tests people there. Or you would have another outreach where the staff will set up a table under a mango tree and rally people in the community, and then they’ll come get tested. The other strategy is the fixed strategy where you would have KP go to a clinic and get tested. And even if they go for unrelated hospital visits, they are encouraged to get tested. And in these health facilities, we have KP-trained staff that are focal persons. So, if you were referred to a public or a private clinic, you would refer to a KP-friendly staff or nurse, or somebody that would be able to navigate you through the process to reduce stigma.
Now, having said that, I know I didn’t mention this, but I just wanted to give you a visual. That’s why I put this slide in. I borrowed from FHI linkages project. And when you look at the third column, you realize that that very first 90 is very important in maintaining or increasing the cascade as it goes along. So, this is a typical cascade of the continuum of prevention, care, and treatment.

Now, this table is something I pulled from UNAIDS. I’m just trying to give you a backdrop of HIV testing in various countries, select countries in West Africa and Cameroon. If you would look at the Togo section, like right here, you will see that – just concentrate on the two blue lines. You see that for MSM, HIV testing among MSM in Togo is around 84 percent. And this is 2015 data. And you realize that it wasn’t always like this. In 2012, according to the UNAID’s website, it was only around 55 percent. So, I’d like to think that somehow, our efforts on the ground must have contributed to that. And when you look at female sex workers, the testing among female sex workers is around 74 percent. But when you are in Burkina Faso, they only have 2012 data, so I wouldn’t speak to that. I’m sure it’s different now.

But when you look at countries like Guinea and Sierra Leone, HIV testing and MSM as of 2015 was only 41 percent. And if you look at the population size estimate for MSM 20,000 and for female sex workers in Sierra Leone, you realize the enormity of the problem. And if we do not get this testing underway, we wouldn’t be able to catch the positives that we need to catch to be able to link them to the care that they need. And so, have this in the back of your minds as we go along.

And for our project, this is our contribution towards testing. This is FSW HIV testing, and I put Togo and Burkina Faso side by side. And when you look from the bottom of the graph going up, it essentially resembles a sound wave, which is fine. It’s consistent. At the beginning of the year, which is where the jobs are, we have work plan issues, signing contracts, and getting the funds out, so it slows. But then it picks up, and then it peaks off in the middle of the year, and then it goes down again. Very consistent with FSW. MSM, a totally different story altogether. When you look at the bottom side by side, Togo and Burkina Faso, it’s all over the place.
And you realize that getting to the top, it looks like there’s a bit of consistency. That is year four, and that was when we decided to actually zero in on one high yield sites, cut off non-yielding sites, and just focus on the high yield sites to get results. And so, that’s what we had.

Some of the key challenges to testing is that key populations are very hard to reach, especially MSM. And if we are able to reach even amongst the hard to reach, the most at risk in the hard to reach. And so, it’s a very interesting population. And also, they are very mobile. Key populations are very mobile. Female sex workers go to where business is, and they move from town to town [inaudible] [00:11:46]. And other challenges are, once you are able to at least reach those that you have been able to reach, there are other challenges. Some will tell you, we don’t have any money to travel all the way to where you want me to go to the DIC to get tested. The distance is too far. What if I go into the DIC and somebody sees me and goes to tell my relatives? Some will tell you, well, thank you for the information. I really don’t feel sick right now, so I’ll go when I start feeling sick.

And there’s also loss of enthusiasm after the PAs have done the sensitization. And one interesting one, which is just a perception, but I thought it was interesting to share, was that they view the outreach testing strategy not scientific enough, because a couple of them would say, well, for a disease of this magnitude, you can’t tell me you will just prick my finger, and in a few minutes, you give me a little green slip and you told me I’m HIV positive. It’s gonna have to be a bigger experience than that. But of course, when they do that, usually they have to go to the clinics to get a confirmation test done, so that takes care of that.

The recommendations that I put forward, of course the obvious one is self-testing. That’s why we are all here. And also peer testing, which is something we discussed in terms of lay providers. Last week, I was in Togo documenting high impact practices for the project as part of the closeout, and I was speaking to some case managers. And they were telling me, now when we go and do HIV sensitization, they keep telling us, well, why don’t you do it yourself? Why do I have to go all the way to a facility to get tested? Why can’t you do it, and then we can start the conversation
from there? So, that is a very important aspect that we would want to look at. Also, demand creation innovations. That’s in demand for the test. And for the Paktvayash Project, we have implemented the M Health strategy and the social media strategy. I’ll talk about it in the last few slides if I have time.

And also, there is the SNT, social network testing, a sister project that ended. Sharpa implemented social network testing and had very high yield results. And it’s something that is catching on with key populations, and I feel that if our project had time, we would have implemented that as well. But it’s something that we want to take a look at to improve testing. So, briefly –

Female Speaker 1: One minute.

M. Honu: Okay. The M Health strategy is just pushing out SMS messages to key populations, those on ART, reminding them to take their medications, reminding them to get tested every three months. And we are currently conducting a study to assess the impact of this intervention, and the preliminary results are actually quite good. The next one is social media. This is targeted solely at MSM because they are the most difficult to reach. We recruit tech-savvy MSM, and then they engage other MSM in websites that are specific for MSM social interactions, and they encourage them to get tested, and they refer them to facilities to get tested.

So, my last notes are that national testing guidelines for most West African countries preclude self-testing. And of course, these would have to be revised to be able to include all those innovations that we are coming up with. In our discourse in this room, we should also be thinking about the implications of test and treat in terms of funding and the money that is required for those people that we’ll be testing, and those that will be positive. And so, I’m happy that we are all gathered here. I feel there are a lot of gray areas with more questions than answers, and forums like this is very important in helping us move forward. Thank you.
Mahamed Majan: I’m glad to be here today. I just want to share some of our insights from South Africa and some of the experiences on HIV self-testing. The topic is entitled “Moving from product to policy to programmes,” because essentially, that’s what we’re trying to do currently in South Africa. And as you’ll see, we’re doing a little bit of everything at this point in time.

So, South Africa is in a very unique situation at the moment. The Department of Health, through the Deputy Director General, has been very explicit in where we are with self-testing. And we’ve heard this countless times today already: South Africa will only implement HIV self-testing in public health when there are WHO prequalified products available. And we are all asking WHO PQ to go as quickly as possible. We know there are processes that have to happen, but in order for us to get any sort of scale, and if we are going to deliver HIV self-testing at scale, or scale up self-testing, then we are certainly going to require WHO prequalification, not only for the oral-based product, but for any product that’s currently in the pipeline.

Whereas we have something else happening in the private sector market in South Africa, which is quite weird, actually. In December 2016, we had pharmacists in South Africa now allowed to sell HIV self-screening tests under the guidance from the South African Pharmacy Council. So, this was the only barrier that actually existed in the market. Because South Africa doesn’t have a regulatory framework, regulatory body such as the FDA or a C marking process, the MCC in South Africa doesn’t have jurisdiction over medical devices. And therefore, it’s left us with a bit of a grey zone. We have the public health on one hand, and we have the private sector strategy on the other hand, and they’re at very different places at this point in time.

Having no regulation in the market, and the Pharmacy Council now allowing HIV self-test to be sold in the market has resulted in us seeing projects enter the market, and I’ll come to that shortly. From the public health sector, this is a snippet from the Minister of Health’s presentation to an Inter-ministerial committee meeting last month. And the first point on his slide on HIV was introduction of self-screening for HIV, as the department is calling it, also called HIV self-testing. So, this shows that HIV self-testing
has been included in the national strategic plan for South Africa for the next five years. So, South Africa has to get going on it. The minister is taking this really seriously, and it got into the stage of including it in his IMC presentation. So, we certainly know that this is on the horizon.

So, in South Africa, we’ve had products that have been available informally for many years. For the last four to five years at least, you could produce products under the shelf, if you want to call it. Informally, you could procure products over the Internet, at the airport, and in various other places. And we’ve seen some of these products. Whilst we have groups such as those that presented earlier, which are really trying to optimize products and get them as usable as possible, we’re splitting hairs on wordings on instructions for use. And then on the other hand, you just have a product which is a repackaged professional product or not even professional product, that’s being put onto the market and being sold, and the instructions for use are really complicated, and nobody’s doing a thing about it. So, that’s created a lot of red flags for us. The Pharmacy Council ruling, as I said, has been a bit of a curveball thrown into the industry.

The lack of defined regulated framework, we do not have a body, but we’re hoping to have a body quite soon, because in what we call SAHPRA, the South African Health Product Regulatory Authority, the position of the Department of Health has been that we will wait for prequalified products before we can implement in public health. And that’s been one of the barriers that we need to overcome in order for us to start getting to a stage where we can start implementing and scaling up. The WHO have moved very fast and have got us the normative guidance. And that spurred us on to get the South African guidelines in place. South African guidelines are currently in draft, and hopefully concluded in the next month or so.

However, there has been a lack of evidence within the South Africa context, and not just South Africa – I think internationally, we still are striving for some data. Our issuer certainly has a lot of data, and we’ve seen a lot of it, but we have a significant gap that we don’t have enough blood-based product data available. And that’s something that we’re trying to cover in our little way. And
then WHO prequalification is something that we’ve spoken about already.

So, just touching on products, within the program, within South Africa, we’ve seen multiple products showing an interest in entering the market. Under our current program, we have not chased away any manufacturing, and are willing to assist any product that has been presented to us. So, to date, we’ve spoken to multiple manufacturers, because at the end of the day, if we are going to get scale, if we are going to demand prices be dropped, we are going to require competitiveness into the market. If we are going to create a high priority on self-testing, we’re gonna need more than one product. So, getting as many products into the pipeline for WHO prequalification is the ultimate goal. So, in this, we have a variety of both blood and oral-based products. And these products are all trying to generate the necessary data for their prequalification submissions. But whilst all of this is happening, we have this on the market in South Africa. We have these substandard products that have been allowed to be sold, and there is no policing mechanism stopping these products. As you can see, the instructions for use are not really user-friendly at all. The information on the packaging and labeling is not sufficient. And we believe that this can do more harm than good for the industry as a whole. And we’re doing our little bit to try and stop this from having. I know the Department of Health has been engaging with the Pharmacy Council to try and stop this as well.

So, the product pipeline is there, some of it good, some of it bad. And we need to make sure that we allow the good products to enter the market by ensuring that they robustly assist and supported. In terms of policy, there’s a law that needs to happen for policy to be completed. We as a South African policy technical working group merely recommend to the Department of Health what we think the guidance around self-testing should be, and hope that the Department of Health then adopts it. We’re currently busy with that process. But in order for that to happen, quite a bit needs to happen in terms of clinical-based evaluations, social science-based evaluations. And as a colleague, I knew they spoke earlier today, there are a lot of questions still to be answered in the South African
context before we can actually start implementing self-testing in South Africa.

The creation of SAHPRA is a really, really important step for us. We need some sort of gating mechanism to ensure that good products are allowed onto the market and bad products are kept out. And when that happens is anyone’s guess at this stage. The transition from the Medical and Control council to the SAHPRA is said to happen in the next year, but I have it on good authority that HIV self-tests is going to be considered a priority product and will be one of the first products that will be assessed in terms of the new medical devices regulation. The South African group has been, and as a [inaudible] [00:07:37], we will be writing to SAHPRA on what has been done on HIV self-tests, because we don’t want them to go and recreate the wheel, so to speak. And the DOH has moved on policy as well.

Just some highlights from what we have on the policy document. The development of policies and guidelines is the responsibility of the National Department of Health, but the technical working group has developed these recommendations. And under the recommendations, we have specific guidance for distributors of self-tests, guidance for implementers, guidance for manufacturers in terms of what’s the minimum requirements for their products, the minimum messaging that needs to be included on their packaging, any instructions for use, and importantly, how do we control this in terms of post-marketing surveillance, and what are the key messaging that we want the instructions to speak about?

In terms of programs, the distribution models for South Africa – and there was a slide earlier which said there’s no one size fits all approach. And we certainly agree with this. The distribution model that will be used will depend on the population targeted and based on the testing gap. What’s gonna work for adolescents might not work for young men, might not work for sex workers, might not work for MSM. So, you have to look at the specific target population that you’re looking at and design your distribution model that’s going to work with that using the various tools and approaches.
So, we’re very glad to be part of the STAR Phase Two in South Africa. We joined the EPSI consortium on the UNITAID STAR Two project that’s gonna take place. And that will be looking at integrating HIV self-testing into our national policies, developing evidence-based strategies, implementation plans, and facilitating regulatory approvals of HIV products to drive up scale. So, it’s building on the work that we’re currently doing, and the Bill and Melinda Gates Foundation budget in trying to get HIV self-tests scaled up. And we want to develop models throughout the country. We have identified key and under-tested populations in South Africa that we will target, through STAR Phase Two, young men, adolescent girls, workplaces in South Africa where you find the majority of men, big business such as mine and the transportation industry. We have a growing transgender population, especially in the Western Cape, MSM, and then index partner cases.

So, just an example of how we’re gonna go about looking at this. If we look at young men, while we’re saying one size doesn’t fit all, for young men, there will be several distribution models that might work which need to be tested. Community-based, peer referral, VMMC, sports events, which are spoken about earlier; partner delivery, and Internet-based. But then if you move to adolescent young girls, that changes, and the distribution mechanism needs to change as well. So, under the program, we’ll be designing the distribution models to fit the different populations and seeing what works and what doesn’t, so that we can inform the National Department of Health on when, after 2019, UNITAID are no longer funding a program, for example, how does the Department of Health carry on with the distribution of HIV self-tests? What mechanism works? What mechanisms don’t work? And we’re hoping that the program will answer those types of questions.

We’re busy with development of several support services as well, in conjunction with the work that’s been done globally. Mobile apps and other communication platforms such as social media and WhatsApp. Internet, we’ve developed a website specific to South Africa which will be handed to the Department of Health to control. Upscaling the call centers in South Africa to deal with HIV self-testing, and training of peer educators. So, I’d like to thank my colleagues and all the various donors and funders and consortium partners. Thanks.
Female Speaker 1: Thanks. Thank you so much.

**[51989_Interim results from the OraQuick clinical performance study in Lusaka, Dr. Alwyn Mwinga]**

Dr. Alwyn Mwinga: I’m going to sort of give you some interim results of the clinical performance study that we’ve been doing in Zambia. So, the objective basically of this study was to determine how well is a user able to use this all of self-testing kit, comparing the results that they obtained with the results of a laboratory-based testing regimen. Also, looking at the agreement between the results obtained between the user in the field with that of a professional user using the rapid diagnostic test as we have in the Zambian algorithm, as well as comparing the three. And then also, assessing the user competence in being able to perform the test using the instructions for use that are provided with the test kit, and then looking at the ability to interpret the results compared to that of a professional users. And then also looking at the stability of this test kit after it has been done, looking at the stability in the results, looking at the delayed visual reading study after about 12 months.

So, this algorithm basically shows the study, and I think it’s a bit faint. So, basically, we had two communities, an urban community as well as health facility testing, and provided the questionnaire as well as consent, and then provided the test kits to those who accepted to do the test. And in the first round of testing we did, the users were provided with the instructions for use with no other instructions, then asked to do the study. And then a research assistant readed the study and reread the results. And then blood was drawn from the participants for a rapid diagnostic test, as well as for further laboratory testing. And those who were found to be positive with the rapid diagnostic test were referred for care. Bearing in mind that the oral fluid test is more a screening test as opposed to – you still need the confirmatory test.

This slide basically shows the algorithm that we used in the lab, where if there was any discrepancies between the rapid diagnostic test and the lab test, the test was exposed to further testing using third generation test kits. So, in Zambia, we had two sites. We had a rural site, which was many community-based, and then we had
an urban site, where we had both the health facility testing as well as within the community. We had a target of 3,250. And for each site, we had two teams, two research assistants and one research nurse. In the community, these teams visited all homes in the zones, enumerated the household members and offered self-testing to the eligible household testing.

The study began in May 2016, and we had all the sites active by August. And as I said earlier, in the initial procedure, the self-test was provided with instructions, and then people were asked to actually read or follow the instructions for use. We did an interim analysis for the first 58, using both the videos – we had some videos that were done – as well as cognitive interviewing. And I think the two presentations before I think highlighted some of the issues that even we found in the analysis of the ability to take the kit and actually read the instructions. And some of these were inability to open the pouch, inability to understand even the pictorial representations of what it meant to swab the gums, as well as timing and that sort of a thing. And we looked at the results of this initial first 58, and the sensitivity and the specificity were very low.

So, we then revised the procedure and had a standardized list of instructions that the research assistant provided to the client, giving them the steps that they needed to follow in carrying out the test. So, between July 2016 and March 2017, we have had an average recruitment of just slightly over 200 participants per month. And we have just slightly over 2,000 participants at this moment in time. Looking at the distribution between the sites, we have more participants from the urban health facility, followed by the urban community, and then the rural community had the fewest number of participants. Looking at the participants that we have recruited so far based between male and female, and I think this was brought up earlier this morning as well, females have a greater representation in our sample. And interestingly enough, the rural facility, there’s very little different between the male and female distribution. But in the urban sites, the females are about two-thirds of those of the males.

We had planned to videotape at least 100 of the initial clients; however, we’ve had problems with actually getting people to
consent to the video. So, at the moment in time, we have 91 videos that are available, and we’ve found that there’s greater acceptability in the urban center than in the rural center. We have still to analyze these videos. But the initial look shows that there is some inability to understand the procedure and do it accurately, despite the instructions.

Then presenting the results of the 2,052 participants that we have up to last week, Friday, looking at the agreement between the results obtained by the user and that of the professional user with a rapid diagnostic test. And in this slide, we can see that there’s pretty high agreement between the results obtained by the user, as well as that from the rapid diagnostic test, with about 99 percent accuracy, and the sensitivity about 94 percent. And almost 100 percent with the specificity. I then present the results from the 1,080 participants from whom we have both the results of the rapid diagnostic test as well as the laboratory algorithm. This is much less than I presented in the previous slides because we have not completed all the laboratory testing. And even with this slide, we can see that there’s pretty high agreement between the client-administered read results, as well as that of the laboratory test algorithm, with the agreement almost 98 percent, and pretty high sensitivity and specificity.

We have also begun a visual stability study. So, this is a situation where the used test kits are kept at the clinic at ambient temperature, and we are beginning to do a rereading of these kits. And we have this done mainly in the urban community testing, and we plan to do this between April and June. So, we have the kits that are stored at the ambient temperature, and then we have three – they have been reread by three different people, and we have a schedule for rereading. So, each one will be read daily from day one to day seven, and then monthly. And then we enter the results into the device. This study began on 14th of March, so we don’t have many results at the moment.

So, some of the challenges we faced in actually doing the study is our rural site is pretty vast. It’s a large area with lots of distances between the homes. It’s also a farming area. So, we began our study in May/June, and July/August is probably the harvesting time, so many people were not in their homes as the research teams
went around. And then we went into the rainy season, which is also a farming period. In our urban site, we had quite a few interruptions during the election period in August, and we also had to actually reconstruct a facility to do the testing, so hence, some delays we had there.

So, in terms of where we are at the moment, we will continue the study until the end of June this year, and then hopefully soon after that, we will be able to have more definite results for the total sample site. Thank you.

Lot Nyirenda: So, I will talk about who are the key players, and look at the current assignages and interactions, the opportunities for self-testing, and then the roles and responsibilities in getting started at country level. And then we’ll look at questions for reflection, innovation to scale up. So, as I said, the focus of my presentation will be on the interaction, the relationships. And so, I speak as a social scientist. And for some technical questions to do with regulation and lab, I have colleagues, Victoria and Elliott, who will come in to tackle those.

So, this was part of the key informant interviews we did in Zambia, Zimbabwe and Malawi. But here, I’m focusing on Malawi. So, we did those interviews in Malawi, and it was a qualitative study using the framework, the policy analysis framework, looking at that policy triangle – actors, process, content and context. So, it is important to understand the actors that I involved when getting started at country level. So, the need to think widely, and as much as possible, use a snowballing method or methodology. So, the policymakers, HIV policymakers, the implementers, the lab sector, the regulators, the academia. They don’t have the Civil Society. So, all those have to be taken on board.

So, we talked to – as I said, we talked to people working in the lab sector, policymakers, and the regulatory bodies. Now, the current assignages and interactions happening currently among HIV program and reference lab in Malawi. But there is less involvement of the regulatory bodies as the pharmacies, medicines, and persons
bought actually when we started. And the pharmacies, medicines, and poisons bought, they also interact with the reference lab on some levels. So, for example, when they are doing some post-market surveillance on some products, they engage the reference lab. For instance, there were reports from the districts that some pregnancy test kits were not producing the required results, so they actually engaged them and conducted some tests where men actually were testing pregnant using those test kits.

And so, that is one of the ways how they actually corroborate. And also, the pharmacies, medicines, and poisons bought, they actually work with the policymakers like Ministry of Health. So, one of the areas where they interact, for example, is where they do drug audits. So, they actually have teams. So, they have people from the Ministry of Health, from the police, from the pharmacies, medicines, and poisons bought, and do an audit. So, for example, like this project is supported by Global Fund to see, to check drug [inaudible] [00:04:06], and check how drugs are being used. So, those are some of the arenas where interaction is already happening amongst these key constituencies. So, we should also understand that the significance of informed interactions should not be ignored.

So, usually, as we know, as human beings, decisions normally are not made when people sit here formally. But when they discuss, they chat informally over a cup of tea. And when they come to meetings like these, they consolidate what they have started. So, those informal interactions at country level, how people talk, how they meet, those are also significant. They are also significant. So, the three constituencies, the initial reference lab, the regulatory bodies, the HIV department, when we talk to them in terms of how they interact and relate, it was found that, as I said, the two, the national reference lab and the HIV department, had very close interaction, while the regulatory bodies were less involved in those interactions.

So, for example, when we talked to the reference lab, once of the respondents said that one is a statutory corporation. It’s a separate entity, so what we do is invite their members to come and join us in the technical working groups. And when we talked to the regulators, one of them said it will be key for pharmacy board to
really partner with the Ministry of Health so that whatever we put on the market is what has been prescribed to be put on the market. And the department itself, the HIV department, one colleague there said, “I think the link is quite weak. We don’t really have much interaction.” So here, they were referring to the regulatory board. Now, the challenges with the interaction is that, to summarize, the HIV program reference lab, they currently sit on the same committees – for example, in HIV testing, etc. But the pharmacy board, who is a regulator, they don’t sit there. So, at the moment, then, there is a regulatory vacuum. And the pharmacy board has no claim on that, but they’re addressing it. They are addressing that.

And then there are opportunities for self-testing regulation in Malawi. So, one key opportunity is the BEAL, the pharmacy, medicines, and poison board, BEAL, which is at the moment at committee level of Parliament. They are divided back and forth, etc., and they are hoping that maybe by the end of this year, they should have deliberated on it. And the other opportunity is the prequalification from WHO. Global Fund [inaudible] for diagnostics. So, the capacity to strengthen and support interaction between policy, reference lab, and regulators, that’s another opportunity. That’s another opportunity.

So, looking at the strategies for getting started. When we looked at how we talk to these people and interrogated our findings, we saw that there is a need to deliberately include funding for the participation of key stakeholders and working groups that focus on HIV self-testing. And what we have done is that having identified the challenges, we are working on a start to address them. So, we are bringing three constituencies together – the policy, regulatory, and lab. We are bringing them together, and we are engaging them through action planning and workshops. We started at the lab meeting, SLM meeting in Cape Town, and we are continuing here. So, we have that workshop tomorrow which will be looking at that. So, there is also a need to engage more with community health departments and civil society partners involved with HIV testing. So, the people who actually reach out to people on the ground have to be taken on board in a practical sense.

So, in terms of the roles and responsibilities of key constituencies in getting started, at policy level, there is a need to clarify the
current policy environment and research needs to inform policy and practice. And the lab have to ensure quality control, so getting informed by initiating there’s a process about the expectations. So, the issue of expectations I think is very key. And the regulatory bodies have to note capacity take-ups within the institution and regulatory framework, and clear mandates of responsibility for in vitro diagnostics. So, the researchers have to engage policymakers, regulators, and lab groups at the initial stages and retain the engagement. And the civil society is key because it has to engage the constituencies, the people they work with at different levels, engage communities and create demand.

Now, in terms of the expectations, these must be clear. But the question is, who should clarify? Who should make the expectations clear? Opportunities to facilitate scale up in Malawi, the technical working group. At the moment in Malawi, we don’t have a specific technical working group focusing on HIV self-testing. But HIV self-testing is part of the agenda of the broad HIV working group that looks at issues of ART, PMTCT, HTS, etc. So, going forward, the arrangement may be different. But at the moment, from time to time, when this technical working group meets, issues of HIV self-testing are taken on board, and presentations are made, and deliberations are made.

So, the informants said that research evidence is keenly awaited. And there’s opportunity for researchers to engage directly with policy, regulators, and reference lab. There is that opportunity. So, the process should also engage more with key stakeholders, such as community health and civil society. And health systems operations research going forward is needed to investigate the interrogation of the integration of self-testing into public health sector. So, for example, in Malawi, we’re looking at how self-testing can be delivered through surveillance assistance.

Now, to reflect on a few questions, how could we support the capacity of the pharmacy, medicines, and poisons board? Of course, one thing we are doing is the workshops that we have talked about. And how can regulation and policy development work in tandem? So, we are also addressing these in a regulatory workshop tomorrow. And what about post-market surveillance? Post-market surveillance. And how should researchers and
implementers get better engaged with policymakers and regulators? Policymakers and regulators. I acknowledge those colleagues and those organizations for their input in the process. Thank you very much for your attention.

[51989_MOH Cameroon-Implementing and scaling-up assisted partner notification in Cameroon, S Leonie]

S. Leonie: Then I will present the experience of Cameroon on implementing and scaling-up of assisted partner notification. The plan of presentation is first, the context and the national strategy for HIV detection, local experience of partners notification. And finally, we will see the challenges and we will conclude. In the context, we can say that Cameroon is one of the countries most affected by HIV in the Central and West Africa sub-region. And we have some epidemiological statistics which shows that since 2009 to 2015, the number of person living with HIV is 620,000. And for the age of 0 to 14 years old, it is 52,382. For the adults, HIV prevalence, we can say at 4.5 percent, and the ratio male to female is one to two. The pregnant woman represents 7.8 percent of the infected prevalence of adult.

When we see a key population, we can say that men who have sex with men represent 34 percent of this population. Conventional sex workers is 26 percent. Military is six percent. We have new HIV infections. Every year, it’s approximately 44,000, and the mortality from HIV is 34,000 per year. And the percentage of coverage with the treatment is 32 percent, and for PMTCT, we have 60 percent. If we consider in the context, we can see that government have strong commitment, and their alignment to the 90-90-90 global charter. The adoption of the test and treat strategy in May 2015 and ’16. Regulatory tests for routine HIV testing in health facilities. Very systematic treatment of HIV positive persons independently of the clinical stage, and CD4 tests.

The national strategy for HIV detection is four strategies. The first is fixed strategy screening. And to all entrants of health facilities, is meaning hospitals, nutrition services, [inaudible] [00:03:01], immunization, tuberculosis, everything and so on. The advanced strategy screening is fixed for the CBO, and advanced in the community screening. With mobile units that exist in our country,
the community health worker, and at home, we really don’t get to get strategy. The third strategy is family approach. This strategy is very important in our country because it is intensification of active research to zero to 19 to HIV testing in sibling and offspring of HIV positive people. The last one is the research and reporting of sexual partners, or HIV positive, pregnant women in PMCTC. And it is documentation of the partner’s HIV status and outcome in the post-natal consultation registry.

According to the guidelines, for every positive HIV tested, the provider need to obtain information on the number of sexual partners. This mean each patient’s medical records, and to bring them with agreement and support of the HIV positive partner to come and be screened. As we see in the previous presentation, it is the same situation that we have. We need to have the acceptance of the HIV positive people to call and to ask the partner to come.

The context of our study was that HIV positive people do not share information about their [inaudible] [00:04:49] status with re-infected partner. This is a study that has been done in 2010. And the finding of community-based screening is that population continue to develop at-risk behavior for infection or re-infection. And this is why we have decided to do this exercise, the strategy to propose breaking the chain of HIV transmission in the family and the community by offering HIV testing, referring people who test positive to the care structures. The places to implement strategies, it was in Nanheld district of the Litira region. Cameroon has ten regions, and it is in one of these regions between January and June 2016.

The methodology was to list sexual partners of index cases, to negotiate with the index person to get the contract of his partner, to establishing a relationship based on confidentiality, obtaining an appointment with the partner in the health facility, and pretest and screening advice. Then, between January and June 2016, 1,407 index people was identify. And we can say that A) 1,000 had 184 potential people exposed. 1,774 of exposed person have been notified. I can tell you in our context, it is very important to have this information, because it’s not really simple to have these people to come. But we were very happy about it. 1,655 mean 93 percent
tested for HIV, including approximately 900 partners and 600 children. 600 children.

Positivity rates. The partners represent 32 percent, and the children six percent. For ART treatment, it’s 93 percent of positive cases was received the treatment. Then, when we see this, the principal result, the identification of index cases and notification of partner, between January and March, April and June, as you can see here, there is a very important evolution. In blue, you have the index cases. In red, the partner identified. And in the yellow, I think it’s partner notification. Then we can say that there is an important progression during this period. This is in January to March, in April to June, you can see the progression. It’s the same situation during the screening and arraignment of partners in care. And you will see during this period, when you see the partner tests, those who was test positive in red, and partners who was coming back in the health facility. You can see the progression after a few months.

Then what are the lessons learned? The first lesson is the reluctance of contact person at the beginning. But at the end of the process, we can state the satisfaction of contact tested after acknowledge of their status and treatment of positive people. This was a personal satisfaction. And the strategy feasible in our context, not just in PMTCT, but at all gateways, is important because implementation of the strategy will make it possible to identify most potential partners exposed or infected, and to bring them into care. This is the most important that we can say here, to have people accept to be treated and to be followed by health services.

The strategy that contributes to the achievement of the first 90. We have some difficulties, sure. It is three principles. The first one is the refusal of [inaudible] people to give contacts to the process, for all the reasons that the previous presentator have done here. The threats and aggressiveness on partners and providers, the refusal of the partner contacted to present themselves in the health facilities. But we have different challenges. The first one is to define and integrate strategy for partner notification in national guidelines, and to activate notification of partner, such for partners logistical for facilities, notification integration, and so on. And one working hardest challenge is that in our country, we are putting to
make in place a multi-sectoral approach just to do that, so people don’t refuse or not be aggressive. And this is why we are working with civil or the Ministry as the Ministry of Social Affairs, the Ministry of Women, and the other ministries. And is important to do this strategy together.

In conclusion, we can say that partner notification will be a feasible and efficient strategy to break the chain of HIV transmission and improve access to treatment and [inaudible] [00:10:50] limited countries. The integration of the research strategy and active notification partners in national guidelines, the strengthening of capacity of providers in terms of reception and counseling for active notification and active search of partners, and will contribute to reduce of stigma, discrimination, to creating a climate of trust for all is very important, and to increase use of HIV testing services. [Speaking French] [00:11:23]

[51989_MoH Kenya-HIV testing among key population in Kenya, H Musyoki]

H. Musyoki: I’m here on behalf of the Ministry of Health through the National [inaudible] [00:00:08] Austere Control Program, and I’ll be giving a brief overview of our HIV testing and counseling among the key populations. This presentation will primarily cover the MSM, the injecting drug users, and the FSWs, female sex workers. And to start with, I’ll start with where our new sources of new HIV infections are coming from. And if you look at that pie chart, a third of all new HIV infections in Kenya are attributed to the key populations. You can see the 15 percent, the 14 percent, and four percent were the IDUs, FSWs, and MSMs.

Sorry. The HIV prevalence by type of KP – sorry for that typo. If you look at that table, FSWs have an HIV prevalence of 29.3 percent. If you compare that with the migrant sex workers, 23.1 percent. MSM, and this study looked in Nairobi and also in Kisimu. In Nairobi, the MSM prevalence is about 24.5 percent, but an average of 18.2 percent if you look across all the populations and their ages. Men who have sex with men who are sex workers had a higher prevalence of 27.3 percent. In Kisimu, we interviewed MSMs who were a bit younger, and the prevalence was 11 percent, actually. And those above the ages of 24 years had a prevalence of 25 percent. Injection drug users in this country overall have a
prevalence of 18.7 percent, but you will look for those who used to share needles before we had the program, because these are integrated. The behavioral survey was carried out in 2010/2011, and we did not have our needle and syringe program. The prevalence was 31 percent. And you compare that with those who were not sharing needles, which was five percent lower than what we have as the national prevalence. We have data also for the prison inmates and IBBS. That was also conducted in 2010/2011. And the inmates have a prevalence of about 19 percent for the females, and those males, it’s six percent. And the maximum prison, 16 percent versus 13 percent for male and females.

[Inaudible] [00:02:46] have also a high prevalence of HIV, and it comes up to 26.2 percent and 26.2 percent among the males, and females, 28.2 percent. The overall national prevalence is 5.6. So, if you look at that, the key populations actually are like four times more than the general population. Do we know where they are? Yes, we know where our key populations are. And the first map looks at the female sex workers and where they are. And you can see the concentrations. My extreme left is coastal region. Then there is the Nairobi area and Central, and then there is the lake region. That’s where you can see the density increasing for the key populations and the sex workers. There are the mappings for the MSMs, and this is just to show you that we know where our key populations are. And if you have to target HIV testing and counseling, you really need to know where the hot spots are. You really need to know where the key populations are. This is work that is done by the key populations themselves, and that’s a map just showing how we normally do our microplanning in this country, using our peer educators who are members of the key populations.

Now, HIV testing and counseling is basically one of the key strategies in our key populations program. And what you can see there is a guideline that we have for Kenya. And that is a guideline that really sets the standard for HIV testing this country. HIV testing and counseling is actually covered. It’s one of the very big modules in that guideline. And this guideline was revised last year, and we took into consideration the WHO guidelines.
There are principles, not only for key populations but generally, but I’ll just talk about some of them that will be looking at key populations specifically. But as a basic principle, HIV testing must always be voluntary and free from coercion. Even if you have a stigmatized group, even if you have a group that is isolated, still, their freedom still stands, and it has to be voluntary, even when you go to those outreaches, and no coercion at all. And you have to follow the five basic principles, the five Cs, which is the consent, the confidentiality. And these, you talk about outreaches. You want to know even when you do outreaches, whether you still maintain this confidentiality. Then counseling. Somebody would ask when you go for outreaches, how do you do it? When it is done, it has to be done as one of the minimum standards. Then correct results, which is very, very key. Remember, this is somebody you might meet today, and you don’t meet them tomorrow because you are on outreach, and somebody say the issues of migration. So, you have to make sure that you give the correct result and then link that person to care.

In the work of 90-90-90, I think you don’t want to lose anyone that you have tested. It is important that there is clear and robust links between the testing and HIV prevention, treatment, and care services, even though all the services may need be provided by one provider. HIV testing and services for key populations for Kenya is aligned to the current Kenya national HDS guidelines and the WHO guidelines. And if you look at that, some of the things in the breakthroughs for they key populations is that we’re able now to test people who are under 18. We used to do it, but I think it was sort of illegal because you could not record them as under 18. You just write on the registers, under 18. But now, you can say 15 to 18. So, for key populations under national guidelines for key populations recommends the quarterly HIV testing. So, as opposed to the general population, for all the key population members, we’re supposed to test them every quarter and report all the quarters. I know some partners who still report once, so we are killing the spirit of these people who have to go and look for these numbers every quarters.

So, as a prevention program, I think it is important to say that HTS cannot be the starting point for key populations. There are other issues that happen before you meet this person for the first test.
There are so many things that might have happened. And as a prevention program, I think these are things that we really need to look at.

KP has experienced several barriers to accessing HIV testing and care. Some of them are fear of a positive test result. Most of the sex workers will tell you, the first time they got tested, they were negative, they were really happy, because somebody does not imagine I’ve been having all these many sexual partners, maybe some condom bursts. Maybe that time, there was no PrEP, and I’m negative? I think it’s usually a very happy result that is usually celebrated. But there is that fear of a positive test result.

Inconvenient clinic operating hours. Remember, sex workers, most of them will work at night and they would want the clinics to be open at night because most of the day, they are sleeping. So, they want to rest during the day, just like on night duty, yeah? You want to give services, you don’t give when they are sleeping. You have to give them when they are awake at night. But you realize that most of our clinics, maybe by 9:00, they’d have closed.

Then fear that the results will not be kept confidential. And this has come up, especially when we are rolling out the self-testing, and you have to discuss the way to go about it with the outreach workers and the peer educators. So, these are the needs of key populations, making sure that the results are kept in confidence. There is fear of insensitivity, like when this person finds out I’m a sex worker, I’m now HIV positive, who will they take me? Stigma and discrimination from the healthcare providers. But of course, this is changing. But it cannot change overnight. We still do sensitizations, but we make sure that at least, we provide KP-friendly services that are able to respond to the needs of the sex workers and the other key populations.

Inability of programs to address other felt needs of the KPs. I think last week, we were in Mombasa, and most of the sex workers are telling us that we can’t get HIV testing in every facility. What is it that you’re referring the standalone sites? What is it that extra that I need? Is it family planning? Is it other SRH needs? Cancer service or cancer screening? What are you referring? What is that you’re referring that is so special and that I cannot meet in the other service delivery points? Then overemphasis of HIV testing is
becoming the first point of contact, and then they show violence against the key population. So, HTS clearly, for a prevention program, might not be the first time you’re meeting this person. You may want to meet them when you’re maybe addressing stigma and discrimination, when you’re addressing violence for these people, and then the other services.

So, given the hidden nature of the key populations, building trust and realization of their peers is very, very critical, because these are the point of contacts, and peer education is the backbone of the key populations programs. The aim of building a robust outreach program with key populations before referring HIV testing and counseling is to build trust with the community and to empower them to understand the need for regular testing. Building this relationship with key populations prior to testing will increase the uptake of HIV care and treatment services for key populations found to be HIV positive. And then developing risk reduction skills for those who are found to be negative to remain negative is very key.

Now, with the current programs, the majority of them, we are focusing on that positive person. We should always remember that there’s a negative person that we need to maintain. We have several setting in Kenya that we’re offering this HIV testing and counseling for our populations. We have the standalone HDS facilities, which are managed by agencies implementing the KP program. And they offer services besides HTS – for example, STI screening, ART. So, that’s one model, the other outreach, where you take the services to the sex worker. You go to their hot spot, and in that hot spot, it can be door-to-door. You find there are some places where you have brothels, and you can go door-to-door. So, that one is outreach, HTS. And then we have the health facility base where these key populations can now be tested where all the other people are being tested. And the facility is not specifically meant for KPs, as opposed to the standalone that is just specific for key populations.

There are new strategies that we are trying to make testing more accessible for key populations, and we are also trying to see – I think this is a popular statement, of where the yield is. So, we also try to help programs to make sure that they gain this yield, yeah?
So, we are helping programs to do that by they provide hospital data, which we analyze, and we make sure that we know how many people have been tested there, how many are remaining. And for the programs, they will only go to where the gap is. So, where you have 100 percent, you don’t need to go there. You’ll go where you have 82 percent because you still have some numbers that have not been tested. Now, if you look at that program, maybe they’re saturated. Because if you remove the number of people who are HIV positive, maybe they are reaching everyone.

So, what happens when you saturate a hot spot? What happens when you’re not able to get more numbers and your donor is asking and pushing for numbers, and you have had a very successful prevention program, and you’ve tested everyone. You have removed the positives from the number, and now you are at 80 percent. Where else can you go? So, it’s either you expand and you move from that hot spot, and you go to another and you maintain those numbers. There are some times we forget to see these, and we want to see 100 percent. But for key populations, if you test somebody, of course you have to remove them from that place where you have the people who have not been tested.

The new strategies, again, that are being tested are around self-testing, and we have a big self-testing program that is being funded by PEFA. Of course, you remember that this is part of the national policy. We just revised our guidelines, and this is part of it. And in Kenya, based on KIs 2012, 67.3 percent of all the women are willing to use an HIV self-test kit, and 70 percent overall. Key population implementation science study funded by PEFA on self-testing is in multiple KP sites and in different counties, and we are awaiting results to just see how it has worked and how we can roll out the key populations.

The other strategy is we are also looking at the biggest yield again, and we are also seeing the key populations who have been left behind. And these are the young key populations. We realize that in one of the studies that we conducted last year, the transition study showed majority of the young sex workers are actually accessing testing services. They only thing that we noticed is that they are not accessing services in the standalone clinics, but they are getting tested somewhere, yeah? Either in a normal facility just
for anonymity, but they are getting tested. But not at the drop-in centers. So, we are also trying to investigate to see why is it that they’re not coming to the standalone clinics where we actually think we have 100 percent friendly services. However, their access to other services is still limited, so you find the gap test here, but they don’t have any other services.

Consultations with young key populations to understand how to use HTS as an entry point to other services and develop a comprehensive intervention package is also ongoing, and we are exploring the use of new HTS policy to reach young people, which at least has given us a leeway of 15 years.

Female Speaker 1: One minute, please.

H. Musyoki: Sure. So, we have regular monitoring testing data across the 82 programs for the key populations, and that just summarizes what we have. And you can see, when you use program data, we still have partners who are still not reaching 50 percent. So, you’d want to know why. But this, you add 29 percent because you have to remove the people who are positive. Now, if you look at this data, the regular monitoring, testing, and linkage, you still have gaps in the second 90, so we might be testing, but we are not linking those people. And if we are linking, we are not reaching all the numbers. So, we are losing some. Even if it is two people, I think it is very important and we have to reach them. We normally conduct annual surveys for behavioral outcomes, and this is the data that it shows. It shows HIV testing among key populations is still increasing. We conducted in 2014 and 2015. And for your information, the probability of testing among key populations is over 98 percent. So, any time you request a key population to be tested 100 percent, you’ll except maybe one or two because of time, but rarely they decline to be tested, so they actually want to be tested.

We also need to know where we need to take the services. From those slides you’re seeing, for those key populations who were reached by peer educators in the last three months, you can see the number there. 79 percent were reached by a peer educator. Compare with those who visited an intervention. They went to a clinic, a standalone clinic or a mainstream clinic. Again, if you were to target, then you would go to the option that is reaching
more, and you’d do more outreach so that you can use the peer educators.

There are some challenges that we are addressing. For example, to achieve 90-90-90 among key populations, we should do a good job with the first 90, and we also need to do a pre-job, just addressing issues of violence so that these people can be able to access this first service where you want to reach them. A robust PR-based outreach using microplanning and individualized tracking is also a must for the 90-90-90. However, the focus on testing as a starting point is pushing implementing agencies to compromise the pre-work before the first 90. Different targets and guidelines on the national government and funders sometimes cause confusion, and the Kenya national guidelines recommend quarterly testing, but you find that your partners just want one test per year. So, if any of you test this person ten times, they'll only report once.

The main challenge is linkage to care, and we have to address that. We also need to focus on the negative KPs so that we maintain a good prevention program. And our HIV prevention programs for key populations would have to focus on that strategy too, of keeping people negative. Now, there are emerging issues, and that’s my last slide. And I kept asking the question, is 90-90 pressurizing programs to be treatment care centers as opposed to prevention programs? For a key population, does prevention start before or after HTS? Should drop-in centers offer people-centered services or program-centered? And then, condoms still remain a cornerstone for HIV prevention among key populations, and we need to focus on prevention for key populations, and not only prevention with key populations.

The difference is, prevention with key populations is making sure that we don’t transmit HIV to the general population. But when you do key populations, then you're preventing that one sex worker who would have gotten positive today. So, we need to know the difference and use both. We do prevention with and for key populations. Thank you.

[51989_MOH Kenya-Implementing and scaling-up HIV self-testing in Kenya, S Masyuko]
S. Masyuko: So, I’ll make this presentation on behalf of our technical working group, and I have members who have participated in this. It’s been a journey. So, I’ll share a little bit around this. I think some of the challenges have already been raised from Zimbabwe and from South Africa. And those are some of the things that are actually, in a way, hindering some of the progress of implementing self-testing. So, just as a background, in terms of HIV, we have about 1.5 million Kenyans who are living with HIV. And we have about 268 of these being young people. And that’s a concern for us. We are seeing a rising epidemic among the youth. About one million are currently on treatment, and about 500,000 are yet to be put on treatment. And we think that the self-testing is a tool to reach the 90-90-90.

So, why did we choose to implement the self-testing, and where do we think it’s going to be useful? So, this is the Kenya AIDS adult cascade as of March 2016. So, this just shows some of the – about 1.4 million are people living with HIV, and currently on care, we have 902. This was a little bit behind. That was last year. But when you look at the gap in terms of those whom we need to put in care, which is your first 90, it’s 29 percent. If you look at those who need to be put on treatment, we have a gap of 23 percent. And if we look at viral suppression, then it’s 48 percent. And we really have a gap when it comes to adolescence, and also men, in that the less than – they had 43 percent ART coverage compared to 68 percent for those who are above 25 years.

When it comes to testing, we have done about 15 million tests in 2016, which a positivity rate of 1.7. And this has continued to decline over time. In 2012, it was about 9.7, but with time, this has come down to 1.7. So, you see that there is a need for targeted testing. So, we have adopted a lot of targeted testing in the country, and moving forward, the use of assisted partner services, self-testing, as well as community-testing based on populations then is becoming a useful tool.

So, in terms of the cascade that I already had shared with you, in terms of men, we had a 46 percent gap compared to the national gap of 23 percent for those who were identified to be positive, and the 45 percent gap versus a 23 percent gap for those who were put on treatment. So, you see a bigger gap for the men. And we think
that that is really one of the reasons why self-testing becomes useful. When we look at the journey of self-testing, as I said, we already had self-testing in our guidelines in 2008. But even before that, this period of time, it has taken seven to eight years to begin implementation of self-testing. And I think most countries are in that period of time, answering questions, trying to see, is this really going to work? Will we have social harm and the rest?

So, in seven years, we’ve had formative researchers on self-testing. 72 percent of respondents in the last Kenya AIDS Indicator Survey indicated that they’d be willing to use a self-test. We’ve also looked at acceptability, packaging, and social harms. And in the presentation you already saw from the WHO guidelines that really, it increased self-testing among men. It increased newly identified first time testers, and it also increased partner testing. So, there was a high uptake of self-testing as well among healthcare workers, and this was in 2005. In a cross-sectional study which was down in Aban, in rural Kenya, 91 percent of those respondents were willing to use an oral test. In a cohort study among HIV negative women 18 to 39 who presented in ANC clinics and postpartum care, we also saw a high rate of distribution of self-test kits. There were only about four women who reported IPV after self-test distribution.

And we also had 2,641 newly identified HIV partners of sex workers, about 65 percent having sought confirmatory testing within three months of follow-up. And 58 percent were reported to have linked to care. So, we think that there is still good linkage with care, even with self-testing. But this was in a research setting, so we would want to see what happened in the real world. Some of the benefits that were shown in those surveys is that it increased first time testers. There were issues about privacy, that it increased privacy, because you could do it at home. It was also convenient, and it reduced stigma. Because when somebody’s picking a test – I had to go to a chemist to buy a test, not here, but outside. But it’s really not as easy as you think to go and ask for an HIV test. So, I think it’s much better and easier when you’re doing a self-test because then, nobody needs to know what you’re doing, what you’re doing in private.
In pharmacies, they were identified as a point of distribution. But in some of the surveys, we actually found out that doing in the public facilities would also work for some populations. The wide consensus on the need for counseling in some of the studies, so we are incorporating beat of counseling in some of the – especially in the health center and in the assisted self-testing. And there was no significant harm associated with self-testing.

So, how have we moved from research to practice? So, first and foremost, in 2015, again, we included self-testing in the guidelines. And we have developed an operational manual. This operational manual guides then service providers on how to do self-testing. And this will be launched – and self-testing again is planned to be launched with PrEP. So, we are launching PrEP in the end of April, and we’ll be launching self-testing with PrEP. There is already communication that is already starting to go on around PrEP, and in the next one week or so, we’ll start having communication around self-testing. And you will find that as you communicate to the media, it’s really tricky because there are misconceptions, there are myths, and people may not truly understand. And obviously, concerns about suicides and the rest come up.

There are three self-test kits that are registered in the country by the pharmacy and poisons board, and these are what we are going to be moving forward – mainly two of them, because they also have been registered just recently. There are also lab board listings, which is ongoing. Now, this is a concern that I raise here, because – and South Africa has mentioned it – test kits can be approved by the pharmacy board, but they also need to be evaluated and approved for evaluation by the local lab boards. So, I think that needs something which – WHO needs to really support us to make sure that these things are in tandem, and we have the same quality of tests in both the private sector and in the public sector.

The other thing is resource mobilization. We’ve included self-testing though the PEPFAR grants for 2017. So, beginning 2017, we’ll have support from PEPFAR. We’ve also included in our Global Fund proposal, starting in January, we will also have support from the Global Fund. And we are also requesting for funding through the Reason Corps from the UNITAID.
In terms of this operational manual, it has several beats. We have programmatic approaches and the models that we’ll be using. We have the package of services provided under self-testing. We have commodity management. It tells us that if in the public sector, these test kits will actually go through the normal procurement system, and they will follow the same system as government. In the private sector, then we define how they will be accessed in private sector. We also have safety and infection control measure. How do they store? How do they distribute? How do they dispose of the test kits? In terms of quality assurance, we plan for post-market surveillance for the self-test kits, both in private and public sector. We usually have a post-market surveillance for most of our products, so as we are doing the national post-market surveillance, then we’ll also include self-test kits.

So, in summary, in the approaches, we are introducing both the oral and blood-based self-tests. And this will be both indirectly assisted and assisted. And there are support tools that we’ve come up with which will support the delivery of the self-tests. And I will share that a little bit later. In terms of the service delivery approaches, we have three main service delivery approaches. One is facility-based, so we’ll be distributing this in OPDs, in STI clinics and TB clinics, pharmacies and CCs wards, and the rest. And this is mainly to high-risk, not necessarily to everybody. We might have to limit it to whom we are giving to in the beginning.

For community-based, it will also be distributed at centers, VCT centers, DICs, which are the drop-in centers for key populations, and community volunteers who will also help in community distribution. In terms of other ways of distributing, we’ll distribute through pharmacies, through vending machines. The Internet is also an option, that somebody can be able to purchase online, and we are working on those modalities. There is something which we are looking at, dial a self-test. So, we have dial a condom. So, we want to introduce dial a self-test. So, somebody can be able to request and be brought for a self-test at home whenever they want to test. We have an algorithm which we are using for self-testing. And because it’s a screening test, somebody has to still go through the approved national algorithm.
But this is a concern, and I think it was discussed, because do you just go from doing a self-test to going on to starting with the first test, the second test, or do you just use it like it is right now, and it just goes directly to retesting, and you start on ART? So, self-test kits should not be used for diagnosis, and so, we are using the national protocols for that. So, some of the support and linkage tools that—

Female Speaker 1: One minute more. Just one minute.

S. Masyuko: Have been developed are the client information inserts, which details which are both in English and in Swahili. And we have community-based follow-up, which they can be able to then follow up with the people who are using the self-tests. For the key populations, there are vouchers and coupons and rebates which they can be able to claim. There is also proposed an Internet or computer-based programs. So, we’ve already developed a web-based application for the private sector, which is going to be piloted. Use of partner to deliver the test kits, which is the main strategy that we are going to be using. There is a telephone hotline for a pre or post-test testing if somebody wants that. Currently, we are putting the hotline number in the test kits, so that once – it’s going to be based at Nascop. So, this hotline, anybody who takes a test kit, they can be able to call the number. It’s a toll-free line. And they’ll also have a scanning or barcode on their test kit where they can be able to link directly to a web-based application, and they can get information and receive the video for self-testing. There’s also [inaudible] mobile SMSs, which we’ll be reminding to use people to do their test even after they have started the first test.

Some of the challenges are unanswered questions, the cost. The cost remains high, so even when you negotiate with the manufacturers, the retail price is still about seven to eight dollars. In the acceptability studies, we said one to two dollars. So, obviously, we don’t know how that is going to work out. The estimates from the manufacturer is about three to four dollars. The private sector distribution, we are planning on the private sector distribution of the self kits, there’s issues about linkages to care which we still need to answer, and loss of data. It’s really a concern for us if the majority of people who go to self-testing will
not have data on testing, positivity, the newly identified and the rest. So, we are trying to find mechanisms to be able to collect data around this. The support systems as well, and then WHO prequalification.

The kits are not available right now, so we can only use this in private sector. And some of the things which are probably making us not move forward, but we are still moving forward. I’ve also raised the issue about confirmatory testing, so I will not go through that. There is barcodes that we’ll be using and seeing how that will work, and the web-based application. And we want to monitor for adverse events such as the gender-based violence and IPV. So, we’ll be linking everybody to a call, and they will be able to give and report any incident of that. And then QC for self-testing.

In the public sector, we are going to limit – once the test kits become available, there will be limited distribution to key populations and their partners, and their partners, adolescents and youth, men and healthcare workers. That will be given priority. We are awaiting procurement for the WHO prequalification for us to continue the procurement. So, what we have planned immediately is a pilot with the private sector. So, an operational framework, or SOPs for all large and private sector has been developed. This guides them on how do we accredit how does a start to offer the self kits, how do they order, and the rest. And the [inaudible] have been drafted. The pilot is planned to simulate how self-testing will actually work in the private sector so that you start with the client, how they’re going to collect. And embedded in this is an anonymous survey where we are going to collect information on the models, the client profile of early adopters of self-testing, and then the privacy, how will we manage privacy, data, and linkage.

They have selected 16 pharmacies that will be doing in Nairobi, Mombasa and Kazoom to pilot the self-testing, and then they’ll be linked to a hotline managed by LVCT Health, because the Nascop hotline is in process. And then there will be referral sites that will be available for linkage. So, we’ll have a referral list to support that. And then following that, then we will start to roll out self-testing at a larger scale. So, the next step is a public private partnership that we want to start for self-testing, and then there is
also the pilot that will inform that larger scale-up of the launch after the launch. Then we have capacity building, which is also planned, and the launch of the self-testing at the end of April. I’ve already said that.

As we are doing this, we have incorporated implementation science research questions. So, moving forward, these are several of them. Using PrEP, so self-testing with PrEP will be some of the questions; the cost for self-testing; the use in adolescents and youth. There will be a feasibility study for the adolescents and youth with PSI starting in the next one month. So, that’s it. I just want to acknowledge the technical working group who have supported this process, WHO, CDC through PEPFAR Chai, and the rest who are working terms of private sector and delivery of this. So, that’s our brief presentation, and sorry for the hiccup in the beginning.

Male Speaker 1: Now, our thinking is based on this concept that I think has been outlined very well, and I won’t go into details about it. But we are actually calling it partner services, as far as Kenya is concerned, to encompass the fact that the goal is partner notification, but there are a lot of services that are layered onto it, including ensuring that the sex partner who has tested positive is linked to care, but also the sex partner who tests negative is also linked to HIV prevention, including PrEP. And so, that is our model that we’re using in this country. And in the study, we were very keen to actually determine the effectiveness of partner services. And I won’t spend a lot of time on this because already, Rachel and Ryan yesterday talked to us about part of the evidence that they used to make the guidelines. And this is part of the evidence demonstrating that assisted partner services is effective.

But beyond that, we also wanted to look at regional differences in terms of outcomes of partner notification. And of course, this vexing issue of intimate partner violence is something of great interest. So, we used a cluster randomized design, and basically, what we were looking at is ensuring that the package included
partner tracing and involvement, HIV testing and counseling, as well as linkage to care for the HIV positive partner. And we were doing this in 12 weeks. And we also looked at social harms as well. So, we were able to randomize 18 sites into two sites. And in those sites, we approached 1,760 HIV positive individuals. Out of that, we were able to enroll 1,119. Now, the 1,119 HIV infected individuals, which we elicited them from contact information for their sexual partners, provided for us and mentioned about 1,872 sex partners. That’s giving an average of 1.7 sex partners per HIV infected person, which was fairly high. And we were able successfully also involve these sex partners, approximately about 70 percent enrollment rate.

Now, of interest, and I think it came out yesterday, is that just similar to what we see in our HIV testing sites, the majority of the index clients were women, so we were able to sort of get women in terms of the index clients. But the majority of their sex partners were male. And so, speaking to the point we’ve heard yesterday, that partner notification is a service that is as tailored towards men and has a special focus and emphasis on men. These were our main results. I won’t go into this, but just to say that, yes, we did find that assisted partner services is effective in increasing rates of HIV testing, identifying new HIV testing people, and also linking people to care. And this is something that I mentioned before we’ve published.

But of interest is again talking to the yield, is that the HIV prevalence amongst the sex partners of HIV infected persons was 35 percent. Again, this is almost seven times the national average, again, emphasizing the point that this is one of the highly effective strategies for identifying HIV infected persons. We used this data to calculate what sort of effectiveness in terms of how many index partners, index cases you would need to reach to be able to identify one sex partner, either testing or positive. And as far as testing is concerned, you only needed just about four index cases to get to one partner who is tested for HIV. And the original differences that we noticed, and some of the difference is that in the Western part of the country, you only needed just about one index case to get you to one partner who has tested positive for HIV, compared to some of the Nairobian Central regions.
And for those who are not very familiar with Kenya, the **Yunza** region is the region with the highest pattern of HIV, highest incidence of HIV. Similarly, it’s the same story. Generally, there’s a trend of high effectiveness of partner services in rural and [inaudible] areas, and also in men. So, this could be pointing towards the fact that even when we implement partner services, we might need to target them either from a geographical perspective, or from a gender perspective, or from a population perspective.

And so, the question of intimate partner violence of course is something that’s very interesting. In our study, the prevalence of intimate partner violence amongst index clients was about 11 percent, and these were the ones that say they have experienced IPV. In our trial, though, we excluded those index clients who were deemed high risk for intimate partner violence, for obvious reasons. Now, during the trial, we had five index clients, basically women, who experienced IPV during the study. But as we mentioned, they were sort of distributed equally across the two arms, and there was basically no attribution of the study arm as far as the incidence of IPV is concerned. So, that was basically our conclusion. The rates were low, and it didn’t appear that APS or assisted partner services were harmful.

We went and then looked at those index clients who had refused to enroll into our study, and went and asked them why is it that they were not interested in enrolling in the study. And in these, I just have two quotes. We did interviews with index clients who declined enrollment, and also nine focus group discussions amongst our research assistants, and also the general population. And I’ll just give you two quotes based on what we thought. One of them was a female, age 38, who was not a spouse. And she says that, “If it was my husband,” I’m sort of talking about the relationship and the issue of notification, that, “If it was my husband and the father of my children, I would have definitely notified him or even hold his hand and come with him to the hospital. This one is different. He’s just my lover, and I don’t know where he comes from.” So, again, the issue of a relationship and how couples or partners relate has an implication as far as where partner services is concerned.
The issue of alternative methods of notification, which is in the guidelines, that we need to provide index clients with options, that also came in. And this is a 38-year-old female as well, who said that, “Let me be the one to notify him first, and when he says no and becomes difficult, then I will give you his number to talk to him. He can suspect that I’m the one who gave you his contact. Let me be the one to tell him first before you can come in when he doesn’t accept.”

We were interested also to look at economic evaluation, and this is data that we will be publishing very soon, the cost-effectiveness of partner services. And we did a scenario over ten years to see what it would give us. And in summary, we estimate that about 11 percent of population will receive APS over the ten-year-period need to be able to avert about eight percent of tallies. And in terms of the incremental cost effectiveness ratio, we assessed two models. One is basically a high level model using analysis. Another one is a task-shifting model. But in essence, both were found cost effective, particularly looking at Kenya’s GDP, which is $1,358.00. Indeed, the task-shifting model was actually lower than the Kenya GDP, but both were actually less than three times Kenya’s GDP, which is the threshold that we normally use. In terms of the budget impact, which is important mainly for global [inaudible] people actually who provide this, we did a five-year scenario, just trying to see what would be the incremental additional resources that we would require to be able to scale up partner notification in Yunza province. And just to let you know that if we took account of everyone, regardless of their CD4, we just need somewhere between two and three million additional resources in Yunza province to be able to scale up our partner services, which I think is affordable, and it’s within the overall budget – for example, if you just use [inaudible] as an example.

But moving beyond that, we do that as we are now sort of beginning to scale up the partner services in this country, there are sort of potential challenges that we have to figure out, and one of them is the scope of partner services. In the trial, of course, we just went through the primary, sort of the level one partner. But when we scale it up, should we go to partners of partners of partners of index, you know? Is that feasible? That’s a question. What would be the geographical coverage? Would we then maybe
just focus our efforts in the high [inaudible] counties or regions? The linkages with other prevention strategies, I think, is important, particularly, as I mentioned, to PrEP. In this study, we identified a large proportion of HIV negative sex partners who are at a high risk because they’ve been exposed. They may be continually exposed. How to retain them as cohorts is something that we have to figure out.

And then we have, of course, the issue of notification and the legal protection around it. We do believe that we have sufficient protection maybe in some of the guidelines that we develop or some of the laws, but there’s been debate as to whether have providers are legally well-protected to actually do notification, and whether you need a special policy change. And then of course, partner notification amongst key populations. I think it came out yesterday, the challenges in doing this, particularly among sex workers. I personally hold the view that Rachel holds, that even sex workers, for example, have many regular partners that you’re gonna be able to reach and contact. And therefore, it would be desirable to actually scale it up amongst the population.

So, the way we’ve moved now is that partner notification will be part of HIV testing services, and it’s already been integrated into the TWG. We’re working on the county-specific guidelines. PEPFAR through our COP is also part of this. It’s been included into our COP for 2017. We are currently doing a Global Fund application for 2018/2019 now, and we’ve included it there. And we do believe that we’ll have a big first implementation that will include surveillance, particularly for IPV, and eventually to be able to measure the population level impact. So, thank you, and I’m presenting this on behalf of many colleagues, including Dr. Sarah Masuko, who is here with us. Thank you.

[51989_MOH Malawi-Implementing HTS quality systems and retesting before ART initiation in Malawi, T Masina]

Tobias Masina: Good morning once again. As you have heard, I’m Tobias Masina. That is my presentation, implementing HTS quality systems and retesting before ART initiation in Malawi. That is my presentation outline. A bit of history and introduction. In Malawi, we have got approximately 17 million people. National HIV prevalence of 8.8
as of Malawi Demographic Health Survey of 2015 to 2016, slightly over one million people living with HIV. HIV testing and counseling started in 1985, using ELISA. It was a route-based testing. Through the continuous working with the lab guys, we thought that they had a lot of work to do.

So, in 2001, we piloted the use of whole blood rapid testing. It was run by an organization which was called Mali. It’s a counseling resource organization. But Ministry of Health funding that, it was a very good gesture, adopted the whole blood rapid testing in 2004. Of course, this time, it was non-lab-based, but the lab-based behind that backing the non-lab-based. Usually, what we are doing that time, we are using two tests at the same time, HIV one and two, Uni-gold and Determine. If there’s some sort of discrepancies in the results, giving two different results, the other one is giving the reactive. The other one, a reactive, we needed a tiebreaker, which was Hemastrip. So, that time, a Hemastrip was being used until there was a time we decided to remove Hemastrip, and we added SD Bio-line, HIV one and two to the algorithm so that Bio-line will be a tiebreaker.

Through that, from 2004, we had lab tech expansion. For instance, in 2002, we had 70 HTC sites. But come in 2016 December, at they did two sites. These are Ministry of Health, CHAM, and private. We also saw the increase of task-shifting from non-health areas to health surveillance assistance, which were also part of the system. But of course, they are the lowest in the incremental section. At the same time, quality assurance for HIV testing. For instance, in 2001, we are retesting five percent of our clients, so we are taking the sample that have been tested with the rapid test. We are also taking the sample for laboratory testing. In 2006, we wrote out the lab quality assurance proficiency testing and quality controls. But this time, we are using the serum. Seeing that we are using the serum rolling the serum to the whole country, it was tiresome. We thought of starting using the dry tube specimen. So, that was in 2011/2012, because the use of serum was a bit buggy.

So, our vision has been renewed with joint department the counseling four times a year. We have been doing the
evaluation of the test kits and also the algorithm 2004, 2007, 2014 and 2015. We are doing the proficiency testing twice a year since 2016. We have been piloting the lab test work improvement in selected districts from 2014, introducing the HDS. HDS are also the lay counselors. We’re just calling them HDS, but they’re HIV diagnostic assistants in 2015 [inaudible] of course backed by our partners.

Quality assurance for counseling. In 2010, counselors log book was initiated to make sure that the work of the counselor is being recorded in the log book for future references. We also trained and certified the district-based supervisors and the frequent review of tools for supervision. And these were developed and disseminated. In 2010, again, this is quality assurance for testing and counseling together. Log book rolled out, and evaluation of HIV testing services program in 2012. So, some of the key findings in the evaluation was that – found that some issues were lacking in terms of the quality. For example, I’ve talked of inconclusive clients results who are not being dealt with correctly. Even there was anonymous testing, so the linkage was a bit a problem. And at the same time, we were also having problems with the correct amount of buffer to apply only a specific test device.

So, with this review, this led to the reviewing of the training materials. And in 2013, as government, we thought of recertifying all the providers. So, we had a three times competency-based training, of which for somebody to be successful, needed to pass the theory 80 percent and above, and also must pass in proficiency testing and pass 100 percent and above.

So, as measures, we continued to review our training materials. In 2014/2015, developed what we call initial comprehensive HIV testing training for individuals. Previously, what we are doing, that HIV testing, we are doing for clients initiated counseling, or what we were calling voluntary counseling and testing, and also, they are going to training of couple, child. So, we thought that this was tiresome to the counselors, as also it was time-consuming. So, we made sure that, oh, these, we are putting one more. When somebody has gone for training as a counselor, should we cover everything? So, we have managed to revise our training guidelines
in 2016, and also supervision, we have also managed to revise it, and we are still training people using the revised guidelines.

So, coming to the retesting, before ART initiation, usually after testing, two serial positives – the first one, when they test it, test one is reactive, we go to a second test. So, if the second test is also reactive, this one is sent to the ART. So, at the ART is where they do the confirmatory testing. So, they do the two tests at the same time in progress [inaudible] [00:07:47] test. So, this one is performed by another counselor to minimize our operator’s error. So, if there’s confirmatory inconclusive, it means that somebody who came as a positive client and has come out negative. DBS sample is taken and sent to the National HIV for a swab for further testing.

So, that table is just showing us how we have been faring from 2008 quarter one. That’s the positivity ratio. You see in quarter one 2008, we are at 15 percent. But as of 2016, quarter four, we are at 4.2 percent. So, with this declining in the positivity ratio in our population, it means if you don’t do confirmatory testing, that chance that the number of false positives can increase. So, that’s why we are emphasizing that we think the declining positivity ratio in our population, we need to pull up our socks and increase the confirmatory testing.

So, that’s a brief summary. As I can take you back, I said that in 2013, you had mass retraining of all counselors. So, this data of confirmatory testing where we studied [inaudible] [00:09:17] in our national system in 2014 quarter one. So, when I’m saying the quarter one, I’m saying from January to March, and quarter two meaning from April to June. So, you can see the first dark blue color is the number of the new positives, which is on top. For the green line, which is new ART initiative, and the bottom line are the confirmatory tests done. So, from 2014, we found that the number of the positives were a bit higher, close to 34,000 in the first quarter. And the number of ART initiative, close to nearly 5,000. But the confirmatory tests then, you see that a big bottom. So, we have been struggling with the confirmatory testing, until you see the 2015 quarter three.
From 2015 quarter three, you see going to quarter four, there’s a sharp increase in the number of the confirmatory testing. To concur with my fellow speakers who have been talking over there, lay counselors, HIV diagnostic assistants, in Malawi, this is the time when back to our partners, when we introduce the HIV diagnostic assistants, also called the lay counselors. We found that previously, we had been using lab counselors, of course. But these were employed within the system of the Ministry of Health with other duties assigned too. So, it was difficult maybe to balance the regulation of the utilization that you employed as a coworker and also the HIV testing. So, for them to follow the standards and [inaudible] were big difficult.

But with the introduction of HIV diagnostic assistants, you see that there’s that jump in the performance of the confirmatory testing. You see that small sky blue bar in 2015 quarter four rising up. And as of now, the confirmatory testing is a bit high compared with the previous years. So, that is our flowchart for the ones who have come for confirmatory testing. When somebody has come for confirmatory testing, we’re expecting two results which might come. It might confirm that he or she is indeed positive, so we call that one as confirmatory positive. It makes sure that he or she is not positive either way, so that one, we call a confirmatory inconclusive, and that one will need to be sampled with the national laboratory for further testing. So, this is –

Male Speaker 1: One minute.

Tobias Masina: Data which is just showing the train of the confirmatory positives and the confirmatory inconclusives are starting from quarter one 2014. So, we found that in 2014, we are just starting – we had about seven percent who we had found to be confirmatory inconclusive, and 93 percent, we have confirmatory positive. But come to 2016, quarter four, 99 percent are being found to be confirmatory positive, and one percent confirmatory inconclusive. Those are some of the successes. The increase in performance of the confirmatory tests, revision of the guidelines, supportive supervision at all levels.

Still, we have some challenges – for example, space for offering HIV testing. Most of the hospitals were built in the years when
there was no HIV. So, as of now, HIV is also coming with a lot of programs. We are talking of ART or talking of HIV testing and what you have used. So, it’s too [inaudible] [00:13:07] the space is a problem. Refreshers for 2016 guidelines has not reached a counselor, and still there are some focus where confirmatory test is not being done. Those are some of the recommendations. I thank you for you are listening. Thank you very much. [Speaking foreign language] [00:13:28] Thank you.

[51989_MOH Mozambique-Implementing assisted partner notification in Monzambique, G_Amane]

G. Amane: So, this is the outline of the presentation. I would like to start saying that in Mozambique, we have start to notify partner years ago in the PMTCT clinics because the providers in those service, they always training to say to the persons that they have to bring their partners to test. So, in the 2014, the Ministry of Health sent a real orientation to offer ART to discordant partners. So, on that way, we started to reinforce to the providers to bring or to offer counseling and testing to the partners.

In 2015, we finalized and begin to implement new HTC guidelines. In these HTC guidelines, we have some priorities to find people who are living with HIV. And one of these priorities is to do the index case testing. So, with index case testing, we can see – I hope you can see – the prevalence with the index testing implementation in the community and in the health facility. So, because of that, we can find that there is a high prevalence when we test partners of people who are living with HIV. So, we begin to reinforce those strategies.

Our expectation is to test at least one of the index case person, and to find a high prevalence, of course, because we are testing people, sexual partners of people living with HIV, and to test everyone. Because now in Mozambique, until we finalize the HTC guidelines, we were testing everyone in the community in their facility. So now, we are focused on to find people who are living with HIV. So, we hope that we’ll find a high prevalence with those contacts.
As I said at the beginning, we are working with many strategies to find those partners. But now, we take two models, one in the community, another one in their facility. In the community, we work with JHPIEGO model, and then our facility with ITECH model, which are different but the real main objective of this is to find those partners. Of course, other partners are working hard to emphasize those strategies. That’s why on HTC new package trainer, we have a module about index case testing, so the providers are trained to offer counseling and testing for the sexual partners.

These are the programmatic results from JHPIEGO. The principal thing we find here is that with index case, we test the partner and the children of the index case. So, we found that just one percent of children from index case were found positive. But we can see that the prevalence of partners were 27 percent. We didn’t find all the partner of index case. But this low number, we can see that the prevalence of HIV are very high.

So, with ITECH, we conduct a study in the health facility in two phases. First, we did a passively patient one initiative. And the second phase, we tried to find those partners with a counselor’s assistance. We worked with the lay counselors and peer educators to help the patients or the index case to disclose their results and invite their partners to counseling and testing. The results with the index case in the health facility, we can see that when we put the lay counselors and peer educators and the providers, when they spend much time with the patient and they reinforce the importance to disclose the diagnosis, and to bring their partners to the test, we can see that we increase the notification of partners, and we increase the testing of those partners.

So now, we have invite ITECH to implement these strategies into our facility for provinces nationally. And we’re beginning to implement the strategy in those provinces, in all province of Mozambique. And we’ll train all HTC implementing partners to help the providers in those facilities to notify and test the sexual partners. And this is the assisted partner notification training module. We can see that in these training modules, we have gender-based violence. Because during the study, we found that many patients were not able to reveal their diagnosis because they
were [inaudible] [00:08:00] of violence. So, in this package of training, we include the gender-based violence for the lay counselors and providers know that they don’t have to force someone to disclose their result, or when they find some sign of violence, they have to refer for the gender-based violence clinics in the health facility.

So, we’ll try to implement the new guidelines of notification partner. And we learn that we have to train our providers to train our peer educators and counselors to spend more time of this strategy. Because until now, they only invite and say, “Bring your husband or bring your woman to test.” It’s not easy for anyone to disclose diagnosis without any assistance. Thank you. Okay. These are our lessons learned. And finalizing, I would say obrigado.

Female Speaker 1: Thank you.

L Dube: My name is Lensa Dube. I come from Swaziland. I’ll be taking you through key population and sensitization training for healthcare workers in Swaziland. My presentation outline is as follows. We’ll be looking at the background, key population in Swaziland, comprehensive integrated service package, HTS, HIV can treatment for KPs, training for healthcare workers and KPs, ongoing operational challenges, and recommendations.

This is the background. Swaziland, as we know, as a generalized HIV epidemic, and currently, we are at 26 percent prevalence HIV amongst adults 18 to 49. HIV risk is not evenly distributed through the population. Focus is on different population groups. The key population program in Swaziland started in 2008. And it started by the national key population and vulnerable people focal person, and the MOH is currently leading the program. And as the program started in the Ministry of Health, two complementary studies were conducted because this was a new program. It has never been there before. We did about three studies – the quantitative study to evaluate HIV prevalence among KPs in Swaziland, and we also looked at comparative qualitative study between Swaziland and the Dominican Republic to explore the needs of KPs living with HIV
in Swaziland. And then there’s also another one that has been done recently by Sada, the Sada cross-border study on sex workers and long distance truck drivers.

The key populations that we have in Swaziland, we have the men who have sex with men, which is the MSM; the transgender, sex workers, prisoners, people who inject drugs, and vulnerable groups. Some of the vulnerable groups that we have, we have the mobile population, the cane cutters – in Swaziland, we grow a lot of sugar cane. Then we find that we have got a lot of cane cutters who move from their homes and stay in a particular place when it’s that season. And then construction workers, factory workers, transport operators, long distance truck drivers, young women 15 to 24 years, people living with disability, uniformed forces, and we are looking at the police and the correctional services as well as the military.

These are the estimated number of KPs in Swaziland according to the groups. The circles that I have in red, if you look at them, map of Swaziland, these are the hot spots that we have in the country. We’ve got the Mbabane/Manzini corridor, where we have got a total of about 1,709 MSM 15 to 49 years. And then female sex workers, 2,562. And this is one of the busiest areas around town. And then we’ve got an area called Pig’s Peak, the upper north, where we’ve got 341 MSM and 796 sex workers. Nhlangano, 363 and 498 sex workers, and then Lamumisa, we’ve got no data for MSM because those ones are very, very hard to reach, and we’ve got 186 female sex workers.

And then other estimates of vulnerable groups that we have. Currently, inmates, we are having 3,062, and our prison capacity as we speak is around 3,000, meaning it just surpassed the capacity. And sometimes, we experience quite a lot of overcrowding when it comes to the inmates. And then we’ve got transport operators, which are 15,055, and then the IDUs.

The HIV prevalence for the subgroups. For sex workers, we’re at 69.7 percent. And then MSM, 17.1 percent; prisoners, 33.8; factory workers, 50 percent; cane cutters were at 33.4; and then long distance truck drivers, 26 percent. The comprehensive HIV management guidelines that we in the country that were developed
in 2015 are nondiscriminatory, meaning all the services that are supposed to be given to the KPs, we do not discriminate KPs in Swaziland. They’re supposed to get all the services like any other person in the country. And you can see the picture below there, a man is ready to buy. And you can see that he’s actually smiling to the client, meaning they’re about to buy right now.

And then frequency of HTS for KPs. In our guidelines, it is mentioned that our KPs, they should test in every eight weeks, because we understand that they are one of the high-risk groups, and they are frequently exposed. And then key populations, under Test and Start, they are ready to start CD4, regardless of CD4 count. The country has really launched Test and Start last year, October. And our KPs are one of the groups that are prioritized. However, the challenges that we are facing, the KPs report feeling stigmatized or discriminated in the community and in the healthcare facilities, meaning we do have those cases in the community and the facilities. And violence is a common experience in both the female sex workers and MSMs, as populations are criminalized and constantly fear being caught, because in Swaziland, it is still illegal.

And then to address these challenges, there is a legal environment assessment that has been done. It reviewed all relevant laws, regulations, policies, and practices relating to HIV and AIDS. Looking at the impact on HIV transmission, whether they protect rights and permanent access to services or create barriers to access. Engagement of law enforcement to also protect sex workers. In the country, I think we have done well by engaging the law when we deal with such issues. We have engaged the high profile officers in the police, in the military, and in the correctional services, and they have been sensitized in all levels. And we have successfully got their buy-in, meaning in all our programs and the KPs who work with them.

This is one of the pictures that we have in the correctional services, where we’re seeing one of the high-ranking officials there working together where we were doing Test and Start among the prisons. And then if you look at this slide, we are looking at the healthcare workers’ thoughts on KPs before sensitization. Before we started sensitizing, there were a lot of those that were going among
healthcare workers. The ones in red were the ones that were quite negative, where some of the healthcare workers were saying the KPs, they are demon-possessed. May find that even if they go to the facilities, you find that if a KP is coming to a facility, they’ll think that person is possessed by a demon, and there’ll be a bible by their site. Probably they can quote some verses to that particular person.

And then they are not living a normal life. That’s what others are saying. They are thinking they’re under a spell. They engage in ungodly behavior, and they are being used by the devil. Key populations are already infected with HIV, and they want to spread it. So, these are some of the thoughts. But we had some positive thoughts whereby others were saying key populations are part of our society, and a unique group. Others, they were saying they are human beings just like everyone. So, these are the general thoughts that we had just before we did the sensitization. And then, responding to that, there was a training of healthcare workers to improve access to health for the KPs. We were training the healthcare workers. So, a training manual, the one by the side, was developed in August 2016 to improve access to comprehensive healthcare services for KPs. It was tailor-made and defined per group, and it was mainly targeting the IDUs, sex workers, and MSMs.

Comprehensive package that includes prevention, treatment, care, and support, and psychosocial support services were part of the package. The training manual developed was a response from the Ministry of Health and partners to ensure that KPs have a right to health, and their right to health is not compromised by poor access, fear to access, or lack of service specific to them. IDUs, sex workers, and PWs and transgender were represented in the development of the manual.

And under biomedical interventions, if you look at the package, we are having HIV testing services, the STI screening, TB screening and treatment, HIV care and treatment, condoms, the condom compatible lubricant, sexual and reproductive health services, PrEP, PrEP and post-exposure prophylaxis, voluntary medical male circumcision cancer screening, and OST for PWDs. Of course, if you look at the last bullet, we do have it in the package.
But as a country, we are not offering it for now. And then under behavioral, we have peer education and outreach, sexual health screening, risk reduction counseling, referral for drug and alcohol abuse, promotion of utilization of HIV, STI, and TB screening, and treatment.

And then other additional optimal interventions that as a country we’re still discussing, we are looking at PrEP. And right now, there’ll be a pilot program scheduled to start in May 2017 for KPs in the general population. And of course, we are prioritizing the KPs. And then hepatitis B screening and vaccination, HPV screening and vaccination, periodic presumptive treatment for STIs among sex workers.

Female Speaker 1: Two minutes, please.

L. Dube: Training progress. When we are doing our trainings, at first we had expert trainers having been trained outside of the country, and they are trained by the COC. Initially, the one that was from Netherlands, they were the one facilitating the training. And then a pool of trainers were trained from there. And then out of that one, we had five days’ training for healthcare workers. And these trainings are ongoing. And then we have KPs to share their experiences and their needs with the healthcare workers. And then healthcare workers, they have to complete evaluation forms at the end of each training so that we get feedback from them. And then ongoing feedback is received from KPs. On the way, they are treated in the facilities.

And then this is the outline of the manual that we have developed. And then the healthcare workers that are in direct contact with KPs are prioritized in our trainings, and then referral to those facilities where they need to be referred to are also sensitized. So, as we speak, we have sensitized over 287 facilities, and we have trained 1,674 KPs healthcare workers. And then with our evaluation process, we have a form that is usually completed by our healthcare workers, so that we understand if maybe they have changed their thoughts, or maybe the treatment that they give to the KPs.
And then I would like also to share some of the comparison of findings from behavioral surveillance for 2011 versus 2015. This is the one that we attribute to the sensitization that has happened. Sex workers that felt afraid to seek health service, in 2011, there were 44 percent, but in 2015, we are in 24 percent. And we are looking at doing another one just to evaluate where we are. And then MSMs were at 55 percent, those who were afraid to seek healthcare services, and right now at 26 percent. And then HIV testing among MSMs. We were at 55; we are not at 87. And then for sex workers, we were at 74. We’re now at 96 percent.

And then some of the progressive ongoing operational issues that we have as a country is the legal issues on KPs, which are still ongoing, and they are still under discussion. And then female sex workers usually focus on business other than their health. Like if you can see, the female sex workers population is very mobile, moving where they feel they can get clients, agent going up to some area – there’s an area called Pig’s Peak where we grow a lot of taha, not to say are marketing the product before I see people coming to Swaziland. But just to mention that once it is harvesting time, you find that the key pops will be moving to that area because there’ll be a lot of clients that are having money there. And then MSM, of course, they’re hard to reach. And then peer outreaches of healthcare workers towards KPs, they are still there. And lack of mentoring and ongoing supervision to the healthcare workers, and resources available are limited to sex workers and MSMs. And we’ve got no biomedical for the PWDs.

Female Speaker 1: Okay, all right. Thank you.

L. Dube: So, these are some of my recommendations. I’ll just rush through. We want to ensure provider competency in addressing the health-related needs of MSMs and sex workers in the country, and changing social norms and acceptance towards sexual minorities among youth at earlier ages. And then strengthening of safe spaces for female sex workers, MSMs, and their families; offering HIV and SRA services, and scale up access to an education of condom-compatible lubricant; and scale up context-specific KP service to optimize the continuum of HIV care and treatment among key populations. Thank you.
Gertrude Ncube: Thank you so much for the opportunity which I have been given to try and discuss about the implementation and scaling up of HIV self-testing in Zimbabwe. As you might be aware, I think I presented this yesterday, where I’m looking at where are we in Zimbabwe in connection with the first 90. As you know, all of us, we have to contribute to the three 90s, the fast track targets for 2020, and we need to add AIDS by 2030. So, if you look at the Zimbabwe Demographic Health Survey for 2015, it actually indicated that males between 15 to 49 years, 62 percent reported that they’ve actually been tested for HIV. And for females, it was about 87 percent, they reported that they’ve been tested for HIV, and they know their status. But if you look at the overall, I think there is really more to be done so that we are able to reach our first 90.

Looking again at the Zimbabwe Population Impact HIV Assessment, which was done again last year, looking at our progress towards the first 90, the second 90, and the third 90. We’re at 74 percent as a country on the first 90, identifying those who are positive, and then we are at 87 percent to those who are actually on treatment. In viral suppression, we are at 86 percent. But disaggregating the data into different age groups, we have realized that when we look at our different age groups, we still to do more on the 15 to 24 years old. Only half of them, they reported that they know their status, and we still need to do – if you look at the women between the ages of 15 to 24 years, 42 percent reported that they are aware of their status, and then for men, only 26 percent between the ages of 15 to 24 in that given year, they actually reported that they knew their status.

So, again, to say what is it that we should do to actually achieve the first 90, as I have already alluded to, Zimbabwe is one of the countries which is piloting the STAR project, which is piloting HIV self-testing. [Inaudible] [00:02:23] was done by Andrew Philips and Valentina. They actually said, if we maintain our testing rates, which are already high in Zimbabwe – but if we put it as business as usual, we will never reach the first 90 by 2020. But if there is additional testing services, like if we are looking at
introduction of targeted community-based HIV testing, HIV self-testing, especially to young people, as we had already in our KP, our young people, we are not testing many of them, and even our men, not many of them are being tested. Even our key populations, our female sex workers, not many of them. But if you additionally put that mathematical modeling indicated that by 2019, as a country, we will actually be able to reach the first 90. But if we don’t have those additional strategies for HIV testing, like self-testing, we will never reach the first 90. And as you can see, it’s actually the last year to have gone this far, but without putting other innovative strategies, we will never reach the first 90.

So, what have we done in Zimbabwe? Like I have already said, we are piloting the STAR project, and with that, two years ago as a country, we actually started to have technical working groups discussing on self-testing how we should roll it out in the pilot manner. So, we actually looked at how best it can be distributed. We looked at community best distributors. And four percent of our awards in the country, they were the ones which were selected to actually distribute self-testing. And within that community-based distribution, we even looked at our new STAR centers. Our new STAR centers are actually supported by PSI, ways our nongovernmental organization providing HIV testing in the country. And we looked at that. We can still do self-testing within the new STAR centers.

And then the second distribution, which people are talking about right now this morning, what we are saying for partner tracing as well, we have discussed as a country that we have to introduce HIV self-testing for partner tracing as well. And even for our VMMC clients, as you know, one of the barriers when you look at VMMC for men to come for VMMC, because they have never this position, they are afraid of an HIV test. So, then we say, how about if we introduce HIV self-testing for our men? And we have actually seen the results, that it has actually paid dividends when we introduce self-testing within our VMMC centers. And we have got distribution points within our sex worker program. We have got a national sex worker program where we have actually introduced HIV self-testings with it.
And then within our community-based distributors, what do they do? They do house-to-house distribution of self-test kits, and we are distributing to the 16 years and above. And this is in accordance to our national HIV testing consent for those who are supposed to be consenting for testing. So, it’s 16 years and above. These distributors, they just don’t distribute the test kits, but they provide again information on the use of the test kits. They even do a bit of pretest information given to the communities who are actually saying they need the HIV self-test kits. They collect the data. I know there is a lot which you need to look at when you look at the monitoring and evaluation of HIV self-test kits. But these are community-based distributors who are trained for three days before they start their way. They actually enter their data electronically because they need to enter demographic data as well.

Then, because it’s a research study, these self-test kits, the self-testers, they are actually advised to return their test kits to a logged dropbox, which can be found at a health facility or at a local business center. And then because it’s still a research, there’s late read of these test kits to estimate the positivity rate. So, what we have seen is self-testers, they actually tend to use the test kits, and the return rate is about 68 to 70 percent for the areas where we’ve actually distributed these test kits. And these community-based distributors, they inform the people that if they test positive, they need to go to the nearest health facility or maybe go to a nearest testing center within that area. And then those who test positive, they go to a health facility and they are tested again, and then to confirm the positive result.

So far, our community-based distributors in those 44 wards, they’ve distributed about 80,000 self-test kits. And first, we thought maybe people were not going to take these self-test kits, but we were actually surprised when like we give them a period to say maybe by six weeks, you should have distributed so many self-test kits. But in one district, we realized that where we were distributing these self-test kits, in less than four weeks, all the test kits have actually been distributed. Yet they were supposed to distribute them within six weeks. And then we have realized on the evaluation of the data which you get 23 percent first time testers, which means they are actually the young men and the young men who are not coming for testers who are actually coming. And 44
percent of them are actually men. And then 43 percent are from the age group 16 to 24 years old.

And then again, when the distributor is distributing the HIV self-test kits, some people say, okay, I’ve understood, because they even show a demonstration video, which I will show it to you later on. They actually say, ah, okay, I’ve realized to what I’m supposed to be doing. I don’t need your assistance. So, in Zimbabwe, we’ve actually realized that 73 percent of the self-testers test on their own. They are not assisted by the community-based distributors.

And these are some of the results from the pilot study, where as you can see, 16 to 24 years old, they are actually accepting the HIV self-test kits. More men are actually coming. And then if you look at the positivity rate, those who test positive and those who test negative, the positivity rate actually mimics whatever is the positivity rate within the country, even with self-testing. And then the integration of services. Like we have said, maybe first year we’re using the community-based distributors. But now, within the second year, we are saying let’s integrate the HIV self-testing within facility-based in Zimbabwe. We have already seen the NGOs within their facilities, they have already actually integrated. And we are looking at a point where even within public health institutions, we will actually be integrating self-testings.

And so, these are the results for those when you get into a facility base, you are actually asked whether you want to test yourself or you want to be tested by a provider. Most people, they will be tested by providers. And if you look at what is happening, maybe those who are tested by providers, because maybe they will already be sort of ill. Then they really say, ah, no, let me tested. They are afraid of actually testing themselves. But there are even those who are actually saying, I will take the self-testing, and maybe there are those who are worried well before they take the HIV self-testing. But what we can even see from these results, we have seen a percentage of more men actually getting the HIV self-test kits, even if they come to those institutions.

I’ve already talked our VMMC models that we are actually distributing HIV self-testing kits, and we are using our mobilizers. And we have realized that when we introduced this starting in
November last year, our males, they are actually testing themselves, and then they are [inaudible] [00:10:35] after testing and they found that they are negative, they actually go for the voluntary medical male circumcision.

And then what are the plans for Zimbabwe on the HIV self-testing? The Ministry of Health is actually leading, is actually the ones who are looking at the technical working group involving everyone in HIV self-testing. And in December 2016, we actually launched the WHO normative guidance on HIV self-testing. And our STAR project is still with us until 2019, and we are planning for implementation and securing the resources. And within our dreams, I hope most of our countries here, they are actually dreams project countries. And within our dreams as well for our adolescent girls and young women and men as well, we’ve actually introduced HIV self-testing. Plans are underway to scale up HIV self-testing beyond the STAR project, and we have just submitted our Global Fund proposal. We have included self-testing kits within our Global Fund, and although it was only above allocation, we are hoping that we will get something so that we scale up the self-testing.

In summary, HIV testing is reaching population groups, especially men and youth. The yield actually can be achieved for us to reach the undiagnosed. And if integrated within our health institutions, we are actually looking at increasing efficiencies of services. And Ministry of Health, they have actually taken HIV self-testing as part of their policy, and there’s actually a policy which has been circulated to all the health institutions. I will play you a short video. I don’t know how many minutes I’m left with, but this video is two minutes, how to use HIV self-testing.

Male Speaker 1: Hello. This is a video that shows how to test yourself for HIV using OraQuick. This test uses a sample collected from swabbing your gums, and has been shown to be effective and safe. This video is a step-by-step process, and follows the instructions provided with the test kit. If you are HIV positive and on Aravese, this test can sometimes give a false negative result. Do not use if you are HIV positive and are on Aravese. You can ring the toll free number, 08080117, if you have questions about the test procedure.
or if you would like to discuss your result. Do not eat or drink for 15 minutes before you self-test.

To do the test, you will need a private space, good lighting, a flat surface, and something to tell the time. Take out the instructions, test kit packet, and stand from the box. Your test kit packet has two pouches. First, open the pouch containing the small plastic bottle. The bottle contains liquid. Open the bottle by flipping open the cap. Carefully slide the open bottle into the hole in the stand, taking care not to spill the liquid in the bottle. Now, open the other pouch and take out the test device. Do not touch the flat pad when removing the test device. Use the handle instead.

The same pouch will contain a desiccant packet. Throw this away, as it is not needed for the test. Holding the handle, use the flat pad to swab your upper and lower gum one time around each gum. Immediately place the flat pad into the open bottle until it touches the bottom of the bottle and note the time. Leave the test device in the bottle for 20 minutes. It’s now time to interpret your results. Make sure to read your results in an area with good lighting. If you see two red lines, it means the test is HIV positive, even if one of the lines is faint. If the test is positive, it means you may have HIV and you need to do a second test to confirm this result.

Visit your nearest HIV testing center or health facility as soon as possible for confirmatory testing. If you see one line, it means the test is HIV negative. Seek regular testing if you are exposed to HIV. If you are HIV negative, you should continue to be careful to protect yourself against HIV. Minimize your number of sexual partners. Use condoms, and consider male circumcision. If you do not see any lines, then the test did not work properly. Visit your nearest HIV testing center or health facility to test again. You have come to the end of the testing process. Please place the used testing pad in the envelope supplied to you, and drop it in the collection box with your CBDA, or at the nearest outreach. Put the rest of the kit contents in the outer packet and dispose in a bin or toilet.

Gertrude Ncube: Okay, that’s the end of the video which we actually use when our community-based distributors are talking about self-testing. And before that, we actually developed videos, both in our local languages, and there’s actually [inaudible] literacy
materials which we developed. And we actually sensitized even our communities before we had our community-based distributors, and we sensitized our local leadership so they were aware of this HIV self-testing and all that. I would like to thank you for you listening, and as you know, I think self-testing is the way to go. One of these days when you will sit in that room and being counseled for a lot of time, and then you are told to come for two weeks for your results, you have died so many times before your deaths before those results. But now, you can get the results in 20 minutes. Thank you.

T. Chidarikire: I think first it’s important to just note upfront that South Africa public sector is not yet rolling out HIV self-testing. While we actually support it in terms of policies, but the public sector is not yet rolling out. In the private sector, however, there is some self-test kits that are actually available. So, I’ll go into deeper details with regards to both sectors. This is the current situation as of 2015 in South Africa. Epidemiology. An estimated seven million people who are living with HIV in South Africa. Our population is about 52 million, and prevalence is sitting at 19.2 percent. And adults on antiretrovirals is about 48 percent. And we have 380,000 new infections just under one percent incidence.

So, where are we with regards to the first 90, or rather, 90-90-90 in general? This year, slides support – actually the first slides that I showed you – and we see that if we are looking at the first 90, with 100 percent of people that are estimated to be living with HIV, 74 percent actually know their status. And I’ll focus mainly on the first 90. However, just a few seconds just to say 52 percent are on treatment. And out of the 52 percent on treatment, 32 percent have taken viral loads, and 26 percent is virally suppressed.

Current approach to the first 90. South Africa revised their HTS policy, the national HTS policy, in 2016 in alignment to the 2015 WHO guidelines for HTS. And it embraces the full range of services, including the five Cs, as well as task-shifting, which actually was approved by the minister in 2010 when we first pulled out our HTS policy. Now, all our lay personnel are trained, and lay
counselors are able to conduct rapid testing in public health facilities and in communities. Quality assurance is also quite emphasized, especially for the delivery of correct results. And while we revised out HTS policy for 2016, we also revised our testing algorithm and validated them for correct diagnosis.

We have ongoing training and mentoring to support quality assurance. We have actually rolled out IQC in all public health facilities, and we are rolling out in community testing. We have also started rolling out proficiency testing, and we are still in the process of rolling out RTQI to ensure quality of testing. We have introduced targeting in terms of testing to increase yield or to maximize yield. And while you may be aware that South Africa tests about 10 million people a year, we also, just like Zimbabwe, if it’s business as usual, we may not necessarily be able to reach those that actually need to be reached to get to the first 90. So, we have introduced targeted testing in terms of population and regions. And we’re using data to inform that.

Our testing modalities for HTS, we still use facility-based client initiated counseling and testing. We are also using provider initiated counseling and testing. And when it comes to community-based, we still use our standalones, we use our mobile, particularly to reach those hard to reach communities. We do testing in the workplace, especially when we talk about those that do not really go to facilities. We’re talking about the farm workers, the miners, construction workers, who are not necessarily able to go to facilities for different reasons. And again, we do a lot of mobile testing in public in higher institutions, and we have introduced home-based testing.

Right. So, HIV self-testing has been identified to have potential benefits to assist the country to reach that first 90. It has the potential impact to increase the access and acceptability for those that are under-tested and those test-averse populations. And we’re talking about serial discordance customers, men, adolescents, female sex workers, MSMs, people who inject drugs, and so on. And again, as we said, HIV self-testing has that potential approach to scale up HTS in general to assist us in closing that gap of testing in South Africa, particularly for the populations already tested.
And in terms of our profile of the product that we will be using, again, we are looking for high quality manufacturing products. I think Sheryl made a good presentation in terms of that. We need them to be appropriate for an untrained and nonprofessional lay person, acceptable analytical performance in the lab, quality assurance, and high sensitivity. I think it’s important to note that because it is a screening test, not necessarily providing definitive diagnosis. And for those communities that may not necessarily be high in terms of education, we need them to have pictures so that they’re able to follow the instruction leaflet. Fewer steps, it needs to be simple. It needs to be easily interpreted. First time to results, it needs to be stable, because we know that some of our community members or testers, they want to actually see that stability without it changing over a short period of time. And again, we are also recommending that it should include referrals.

And we also have a national HIV and AIDS help line, which is what we are hoping to use for those clients that may need assistance in terms of pre or post-test counseling, or how to use the test-kit, in addition to the public health facilities. So, in terms of how we are going to approach implementation, it will really depend on the target populations. However, we have testing really run on the backbone of public health facilities, hospitals, and now again in the public sector, as I said, pharmacies are now selling HIV test kits. Workplace programs are also another approach that we may use, and special services within the public health facilities. And this will be considered for both assisted and unassisted testing.

In terms of the policy environment, we are guided by WHO internationally, the HTS guidelines of 2015, as well as the self-testing guidelines. Nationally, we have actually captured self-testing in our HTS, the national revised HTS policy in our consolidated treatment guidelines. We’re working with the South African Clinician Society on finalizing the guideline for implementation, as well as in our national strategic plan. This is the framework that was actually launched in 2012; however, we may be aware that we’ll be launching our new NSP for 2017 to 2022 on the 31st, and self-testing is captured there as well. I’ve really talked to this.
So, in terms of addressing policy, addressing implementation, as well as addressing regulatory, it’s very important that we have a regulatory body to actually manage what is already happening in the country at the moment. In 2015, the South African Pharmacy Council actually approved the selling of self-test kits over the counter in pharmacies. This resulted in an influx of different test kits into the market that are unregulated, and that we may not necessarily be able to validate the quality assurance. And then in 2016, following several discussions, again, the council published a notice for public opinion to actually now talk to the minimum standards for the selling of the test kits. So, at least this provides some kind of guidance in terms of the how. And the department and other sectors have actually made inputs to these, and hopefully to be published, because the deadline was now in the end of March, so we’ll see how this continues.

And while we are not necessarily rolling out in the public sector, we have ongoing demonstration projects throughout the country to inform eventual implementation. And these cover feasibility, acceptability, feasibility, how we target different populations, distribution, and waste disposable, etc. And as a department of health, we’ve been working with WRHI, with WHO, our country office, the South African Clinician Society, the National Institute for Communicable Diseases, which is our reference lab, and it assists us with the quality assurance recommendations in the lab. So again, we are waiting patiently for prequalification, WHO, and this will inform implementation in the public sector. And I said, there are already different kits available on the market.

Again, we are hoping, and we are already trying to engage the South African health product regulatory authority, SAHPRA, as well as the South African Pharmacy Council to assist us in working together to try and regulate what is in the country at the moment, and what will come in at a later stage, because lack of regulation has led to different test kits that are now found in South Africa. Some are even branded. We see that we have branded ones. These you find mostly at the airport. But as we said, this can lead to those challenges where we are unable to ensure the regulation as well as the quality of the kits. As I’ve said, we have demonstration projects, and these are informed by these kind of questions: Who should we access? Should we roll out to everyone? Should we
target? And as we know, we have planned to do targeted implementation. Priority groups, adolescents, young people, age of consent. Our age of consent in the country is 12 years at the moment. Should we use the same for self-testing as well? How and where should we distribute, as well as the cost? In public sector, obviously, it will be free, but how will the private sector subsidize to ensure that people are able to use?

And these are just some findings for studies that have been done that acceptability and feasibility is relatively high for HIV self-testing. This, again, studies on usability, on acceptability, specificity, as well as, again, acceptability in different population groups, particularly in key populations. We see the MSM, truck drivers, sex workers, and young girls. WRHI is working with the STAR program, again, that is working towards conducting usability and assessments to fast track implementation in the country, and they are mostly used to working on usability projects. We have another team in Cape Town, Desmond Tutu Foundation, Linda Gale Becker and et. al, who are working on self-testing in young people, adolescents.

And South Africa is also planning to participate in the phase two of the PSI UNITAID project, and that will also give us guidance in terms of how to move forward in terms of HIV self-testing. And in terms of what’s coming, conclusion and way forward, we are fast tracking finalization of the minimum standards to regulate currently available test kits, working with the South African Pharmacy Council, and with SAHPRA. We are trying to finalize implementation with our WRHI, the Clinician Society, as well as our country office and ICT. And we are finalizing the demo projects, waiting to get the results of those, awaiting prequalification from WHO, and again, ongoing implementation in terms of targeting the population that need to be targeted with regards to self-testing.

And finally, I would like to acknowledge everyone who was involved in the presentation and in self-testing in South Africa. Thank you.
Dr. Euphima Sibanda: So, this is work that we did before the STAR project began, and it was led by Dr. Zumbadenge, who is here. He was the principal investigator of the study. We implemented it between Pesha and PSA Zimbabwe. And we conducted the study among individuals who had come to the PSI Static Center at New Africa House in Harari. We had come to seek HIV testing. PSI also offers outreach services in different locations outside Harari, including rural areas, so we also conducted this study among the clients who came to the outreach testing facilities. And lastly, we also conducted the study among female sex workers who had come to seek HIV testing services at that National Sisters Program that is situated in Harari.

The study had four aims, starting from developing the instructional materials that I’ll talk about, and then looking at acceptability of self-testing when you give people the offer of self-testing versus provider delivery testing, and some qualitative components. But for this presentation this afternoon, I will talk about the work that we did in terms of optimization of instructions in the general population, and also among female sex workers. So, firstly, aim one, which was conducted at the New Africa House site, the Static site in Harari, and also the rural outreach site in an area called Shamva in Mashulin in Central Province. What we aimed to do was to develop instructional materials that people could understand and use to accurately self-test to produce accurate results when they self-tested themselves.

And in aim one, we were dealing with the general population at the new static centers. And in aim four, we are doing the same procedures of seeing whether people could understand the instructions and test themselves accurately. And this was among female sex workers. So, what methods did we employ? Some of the methods are similar to what Malawi did. It was an iterative process, where we started with a first draft of instructions, and then we changed it according to feedback that we got from participants in terms of what was clear and what wasn’t clear. So, first of all, we conducted cognitive interviews among participants at the Static site in Harari, where a social scientist sat with a participant and went point by point on the instructions to asking the participant to recall or to tell them what they understood each step of the
instruction meant to them. And then after the participant has given this information, they would be asked to actually perform the test while the social scientist was observing and could notice what were problems areas that the participant was facing.

When we came to a point where we were happy that we’re not getting new information on how to improve the instructions from cognitive interviews, we then went on to a process we called supervised self-testing, where a person that has come for testing was given these self-test instructions and left to self-test alone in a private room, and to actually record the results of the self-test. They would then give a finger stick blood sample for confirmatory testing, and would compare the accuracy of the test by looking at the recorded self-test result. And that test that is given by the healthcare worker in confirmatory testing. I should say that with this supervised testing, this was unsupported testing. The participant didn’t get any prior instructions or any guidance on how they were supposed to do the test. They were just given instructions and left to self-test themselves.

And for willing participants, we asked to put a video recorder during the process when they were self-testing themselves so that we could observe and see any challenges that they had when they were doing the self-test. So, going on to more about cognitive interviews, we did eight of them at the Harari Static site. And this was mainly – for the Harari, we were reviewing the first draft of instructions to see how people understood our initial draft of instructions. And then in the Shamva district, which was our rural facility for the outreach, we reviewed a major overhaul of instructions, which I’ll come to in a moment. But just to say, initially, we did eight cognitive interviews, and then we moved on to supervised testing at the Harari site.

So, some of the insights from our cognitive interviews are similar to what Moses presented for Malawi. And the first one I’m going to talk about is the fact that just giving special instructions alone is inadequate. We had initially had a situation where we said open the bottom pouch first, open the top pouch second. But this depended on how the participant was holding the pouch, so it was confusing for participants because they wouldn’t know which one was bottom or top because it depended on how they’re holding it. So,
we had to change our instructions to make that clearer. And we noticed that there were challenges with inadequate labeling as well, where it needed to be very clear how participants were going to open the pouches. We had some situations where we had to actually put arrows to make it clear which incisions participants were to use for opening the pouches.

We also had challenges with the stand. The picture there, the [inaudible] [00:05:53] is the kind of stand that we’re using during cognitive interviews. And we found that participants didn’t always recognize it as a stand because it looked liked it was an integral part of the packaging. So, people sometimes didn’t find it, and they had problems understanding where they were supposed to put the container. Then we also had challenges with translations, and symbols were also a challenge, where this symbol that we thought was a do not eat symbol was interpreted differently, with some thinking that it was a plate that was on a stove, a cup that was on a stove, sorry.

So, going on to after we had finalized our instructions from cognitive interviews among participants at the Harari site, we then went to supervise self-testing still at the Harari site. And this was done among 172 participants between August 2014 to ’15. And most of them, 86 percent, agreed to be videoed, so we had some insights from the videos as well. And we selected some of them according to the checklist of the videos that we could review. And from participants in Harari, when we look at the accuracy, looking at the final iteration that we used in Harari, among the final 52 participants, we found that 93 percent of them got an accurate result when we were comparing the self-test with the confirmatory test result. And we were satisfied in general with the sensitivity and specificity information figures that we got. And so, we took out this version of instructions for testing among participants in the rural community.

And what we found among the first 29 participants we recorded was that the results could not be replicated. People in the rural areas had challenges producing accurate results. 31 percent initially were not able to determine their results, and there were a lot of inaccuracies that we saw as well. So, we looked at the videos to try to understand what challenges people were facing, because
from the interviews, we were not able to get more information. And what we saw from the interviews was that all participants read the instructions, and we could tell by looking at videos that those of lower literacy struggled in terms of going through the instructions.

And when he looked at the possible reasons for unsure or invalid results, we found that people had challenges with the desiccant, where in some cases, people would pour the desiccant crystals into the developer solution, and we had some who drank the developer solution or even ate the desiccant, which were some of the problems that we saw. And there were some spills of the developer fluid when someone could not find the stand where they could put the container. And then I won’t go through the specific – all the examples that are there. But best on this information that we got from the videos. We made decisions on how best we can optimize accuracy. One of the main things that we did was to make sure that we take account of the lower literacy that we saw in the rural areas. And this meant that we were supposed to have as little text as possible to facilitate understanding and have more pictorial instructions.

So, you will see at the top of the slide, that was one of our earlier versions where we had a lot of text and very few pictures. But we did a complete overhaul of instructions at this point to have as little text as possible and many more pictures. So, it is at that point when we had this overhaul that we did an additional cognitive interviews with the participants in Shamva district to see if they could understand the new pictures and the little text that we had introduced. And we found that after this overhaul, there was marked improvement in accuracy in Shamva district, where 90 percent of participants got accurate results. But we still worried about the false positive results that we were getting. And we felt at that stage that we really needed to do something to enhance understanding of instructions, especially interpretation of results.

So, we came up with the idea to augment instructions by a video which we developed in conjunction with Ministry of Health, as Gertrude was saying earlier, so that we could ensure that it covered all the important information that Ministry of Health wanted to cover. And this video is short. It’s about three minutes long. And
it’s so small that it can be shared via phones using WhatsApp. And after this video, we found that participants were happier and they could understand the instructional materials better. So, our final package of instructions is a package which has both the written instructions, which are mainly pictorial, which go together with the instructional video.

And we found that our accuracy figures were acceptable. And at this point, we couldn’t identify additional information that could be changed to improve the accuracy of the self-test. So, we then took this package of services of the written instructions and the video to female sex workers, and we were very happy to find that the female sex workers were clever, and they produced very accurate results. When we are looking at sensitivity and specificity, they had the best accuracy tests for all the participants that we had looked at.

So, in summary, as has been shown also by Moses, in development of instructional materials, it’s important to have an iterative process so that you address any areas where people don’t understand. You could have cognitive interviews, as we did, and supervised self-testing would be good as well so that you can see peoples’ ability to produce accurate tests. And having a video during supervised self-testing is important because you might then catch some of the difficulties that people face which they may not report to you. We also, in retrospect, thought that it would have been more efficient if we had started with the least literate population. If we had started with the rural population, then we had a good package that we could take to more literate participants, it would have taken us a shorter time in terms of optimization of instructions.

I have already talked about the importance of making sure that you have as little text as possible, and that the instructional video is really an important component of these instructions. I will end by thanking our study participants and the Ministry of Health, and also acknowledge our funders:

[51989_Uganda Prison service-HIV testing in prisons in Uganda, J_ Kisambu]
J. Kisambu: I make a presentation from Uganda prisons. I think it’s the only one from prison, so it had better keep up. I’m going to make this the ten minutes also, which I’ll be done, don’t worry. I’ll go through a few headings. Introduction, some considerations that you make while making programs for the prisons, HTS strategies that we have done in the prisons, the linkage to care, monitoring, treatment, quality assurance, challenges, and way forward.

Well, just like in most areas, the prisons have been largely neglected, and most diseases, especially HIV and TB, are disproportionately high as compared to national figures. As you can see in Uganda, among the prisoners, HIV prevalence is about 15 percent, and among our staff of the prison service, it’s about 12 percent, as compared to the national average of 7.3 percent. And unfortunately, a total of 45 out of 249 prisons are the only ones that can actually carry out HTS services, which is very unfortunate and part of the reasons why most people don’t know and they continue to engage in sexual relations and transmissions. The ART is only accessed at ten facilities. These are the accredited facilities within the prisons.

And other considerations, the Uganda prisoners population is very mobile, just like, I think, all other prisons. People are moving between the prison and the community most of the time. And the annual turnover is 100,000 prisoners per year that have gone through the prison, from going to prison back to the community. And on average, you have a population of about 50,000 at any one time in the prison. And most of these movements are unscheduled. For example, people go to court and they get bail, and they don’t come back. So, if you are doing a program with them, then it’s cut short suddenly. Sometimes, it’s movement between prisons. People are transferred between prisons for various reasons. Part of them are political, others are [inaudible] security. So, there’s no appointment. They are sudden. A vehicle comes and picks a number of prisoners, and some of those are your clients. Sorry.

And then the other consideration to make is the security, that a prison is a security institution. And because it’s a security institution, it’s very different for the community best healthcare services to access a prison and provide care. That means that for it to provide care to prisoners and staff, you need to have the care
introduced inside the prison. Now, what are some of the [inaudible] strategies that we have undertaken in Uganda? We’ve on entry medical screening for staff and prisoners. Staff are recruited from the general community. They undergo a screening before their training starts. And unfortunately, in Uganda, if you are found with a TB or HIV right now, you will be stopped from undergoing the training because you may not be able to go through and complete the training. You may develop complications along the way, so you are asked to leave.

And for prisoners, as they come in, they are taken through a medical screening the next day, because most of the time, on the first day, they come in late after 5:00, and then they have to go through all of this procedure of entering into the prison. So, there’s no time. It’s night by the time they are through with that. So, very early the next day, we take them through a medical screening. And this involves HIV testing. And this is done on – it’s not forced. It’s voluntary. We counsel them and we offer the service. And mostly, almost 100 percent of them take up the testing because you see, most of the time, they are first offenders. They are unstable. They are scared. They don’t know what happened to them. Unfortunately, we take advantage of the situation and give them a test.

We also offer a routine HTC, including PITC, just like the normal ones, as we work with the Ministry of Health. We conduct HTC outreach activities to various prisons that do not have the capacity – they don’t have the infrastructure, they don’t have the health workers to do the service themselves. And this is the major hindering factor. So, we call out outreaches to major prisons that have more than 500 prisoners as inmates. Then we also call out by annual medical screening, mass screening, twice a year. And this one is almost – I didn’t say it is, I’m saying almost compulsory, because everybody has to come together and they have to get counseled. They have to accept, because to them, the risks of having any one of them being a positive or refusing to take the test, and therefore refusing the treatment, is a danger for everyone. So, we work with them to make sure that even among themselves, they get each other to come and take the test.
And obviously, after the testing, we have the linkage to care. We have two types of linkages. We have one for prisoners and one for staff. So, the one for prisoners, we have the referral from outreach points to accredited facilities. As we go to the outreaches, we have some prisoners tested and they’re positive. We refer them to one of the ten ART centers to continue treatment. And sometimes, we take them to nearby community-based facilities where they are tested. And when they are found positive, then they are referred and taken to the treatment centers.

We have referral from the prison to prison following the transfers. This was quite a bit of a hitch because as I said, most of the time, the prisoners are transferred without appointment, meaning that they will not go – they will not get a referral. So, when they go to the next point, they are retested and recounted, and probably start all over again, if they’re lucky. And there’s time lost, and there’s resistance on all of – some and other problems. So, we have generated a referral strategy to make sure that wherever you are taken, we can know whether you’ve been on treatment or not, and which treatment, so that we can continue on treatment.

And then there’s a referral to public healthcare facilities on this from prison. This was also another one. You see, prisoners are fearful when they’re discharged. You don’t want to go with an assigned person. You see you guys have been in prison, and then they start accessing care from your facility. It’s not possible. They hide. So, we have come up with another strategy to make sure that as they leave prison, they are already linked to recommended best healthcare that will take them up after prison. And for staff, we refer them depending on where they’ve been posted. If they are posted at a facility with care, a prison facility with care, one of the ten, then we integrate them that care. If they are referred to a facility which does not have care, then we refer them the nearest community-based service for them to be cared for. This depends on transfer and on retirement.

And then modality for treatment. We normally use regional hubs. We have established regional hubs. We have 16 regions in the country where they have put laboratories that can provide a lot of services, including
monitoring. And we do viraldi and Genexpat, and for MDRMTB. We also use VHTs, village health teams, to provide community tracing for referral. And we have introduced a group [inaudible] system on [inaudible]. That’s what we use. It’s Internet-based, so wherever you go, we can access your data if you have the access codes. I punch in your name and your prison number, then all of your file will come to me, so I can continue on treatment. And we can do this anywhere wherever we are. And then, we’re also implementing loads to ensure that everybody takes their treatment when they’re supposed to.

On supplies, we are getting supplies from the Ministry of Health. There are no problems there. Labs are monitored by the regional hubs and the national public health laboratories to ensure quality. And then service centers are supervised by CDC. We get funding from CDC. So, on a quarterly basis, CDC comes to see what we are doing and offers quality control. And also, the regions have a quality control team that got onto the [inaudible]. Demanding quarterly post supervision visits to give technical support. You have a method of quarterly facility regional and counterpart performance reports in the DHS too, which we meet and review and evaluate. We also do studies to evaluate our performance. We have so far done one where we got this performance. We are in the process of doing another one to evaluate the further linkage structure using the [inaudible].

The major challenges are poor infrastructure, understaffing, and lack of equipment. This cuts across the board, but it’s more [inaudible] in the prison environment. We have inadequate supplies. Sometimes we run out of testing kits because of the big numbers, especially when we do mass HIV screening, by annual. And then we have the attitude of prisoners getting services from uniformed VHTs. The VHTs are uniformed because those are the ones that we can maintain within the system. But this guy’s been holding a gun at your back. Now he turns around and says, “I want to take your HIV test.” You may have second thoughts.

We have legal barriers, as we have already seen, on MSM. And we think that task shifting’s a good strategy to go forward using VHTs and community people to conduct the testing. We need to improve the infrastructure. We need to strengthen the monitoring aspect,
and we need to improve the supply chain management. Thank you very much.

[51989_When perfect isn't possible, Dr_ Eliott Cowan]

Dr. Elliott Cowan: The objectives of this talk are to describe the evolution of thinking that led to the approval of the US FDA’s approval of the first over the counter home use rapid HIV test, otherwise known as an HIV self-test. I had the privilege while I was at the FDA to be leading the group that was responsible for the approval of this test and been working on that since 2005, and so I feel partially responsible for what’s going on here. Also to appreciate the flexibility that can or should actually be exercised to meet critical public health needs.

So, let me just start with some commentary on regulation, assessing the HIV self-test. And assessment involves looking at two thing: quality and performance. The purpose of looking at quality is for consistency. The bottom line here is that if you can’t trust the test, you can’t trust the testing. That’s a basic pillar, and there’s about five talks that go through that. I’m not gonna talk about it anymore. I am gonna talk about performance. And the question here or the issue is that are regulators usually looking to see that the test is performing at the highest level as possible? But I put a question mark on that, and you’ll see why in just a few minutes. Another important point to mention here is the reality is that no test is 100 percent sensitive and 100 percent specific. If a manufacturer comes to you with such a claim, you should have a lot of questions about that. It simply doesn’t exist.

What you are looking for is that the benefits outweigh the risks. And that’s going to be the theme that I’m going to carry through this talk. So, let me go through what the FDA did as far as the approval of an HIV self-test. And I just want to mention that Alwin’s data is remarkably similar to what was seen in the US, and I’m actually very encouraged and – I don’t know, not frightened, but it’s spooky the way that the numbers are similar. So, let me set this up by telling you why an HIV self-test was considered for the US. So, the number of Americans newly diagnosed with HIV infection is about 50,000. The number of HIV-infected people in the US is 1.2 million. And the number of people who are infected with HIV and don’t know it is about one in five. So, about 20
percent of people in the US, at the time of the consideration of this, didn’t know that they were infected with HIV. That’s a serious public health issue.

So, the test, of course, I’m going to be talking about is the OraQuick in-home HIV test system. This is exactly the same test—well, pretty much the same test that is being used here. Notice that the packaging is slightly different. Of course, the instructions are different. But the actual device is the same, other than the fact that they are manufactured in two different places. So, the expected performance of the professional use test—and by the way, the self-test is also exactly the same as the professional use test. Traditionally, FDA has expected sensitivity and specificity to be at least 98 percent as the lower bound of the 95 percent confidence interval. For a self-test, an advisory committee recommended that sensitivity and specificity be dropped—acceptable sensitivity and specificity—be dropped to at least 95 percent, rather than 98 percent, as a lower bound of the 95 percent confidence interval. Why? Because there was an expected decrease in performance in the hands of nonprofessionals.

So, the traditional way of dealing with this as a regulator is that if you’re gonna look at test performance and then determine if that performance is good enough to say that this test is safe and effective. It’s a straight line. Let me show you some results. So, here’s the professional test performance for the OraQuick test. What I’m showing you here is specificity and sensitivity, and the second column over is performance of the professional use test, and the last column is what the expectation is—again, 98 percent as a lower bound of the 95 percent confidence interval. You can see that the specificity of the professional use test was 99.6 at that lower bound, and the sensitivity was 98.4. It just made it. Again, for professional use.

Here are the data from the testing that was done in support of the home test. And what you can see is that the specificity is phenomenal. It was supposed to be at least 95 percent. It was actually 99.9 percent in the clinical studies that were done to support this approval. However, when we look at the sensitivity, the expectation, again, 95 percent, it turned out that the lower bound was 86.64 percent. Again, the number is remarkably similar.
to what Alwin was talking about, which means that this may be the maximum capability of this test for use with oral fluid. That’s for another study. So, the question here is, what is a regulatory agency to do with data like this? Two choices. One is, the obvious one is, hello Oral Sure, go back and redesign your test, because you’re just not good enough. It has to be at least 95 percent at that lower bound. So, instead of looking at the straight line, what FDA actually decided to do was to take a different route, and that was to say, okay, what are we getting for performance like this? And we would get to that through a risk analysis, which looks at the public and individual health implications, and then make a decision on safety and effectiveness based on what that lower sensitivity will give you. And that’s what I’m gonna show you right now.

So, FDA generated a risk model, and the inputs into that model were the estimated test results for the number of people who would be tested annually who wouldn’t otherwise be tested in that first year of use. And looking at true positive results and false negative results, as well as true negative results and false positive results, the output from the model would be the estimated net transmissions, which would be averted in the first year of use. The impact of switching from professional testing to self-testing, recognizing that if the self-test were available, people would use it instead of going to get professional testing, and the public health implications and individual health implications for a test that would perform at that level.

So, let’s talk first about the projected outcomes of testing in that first year. Here are the numbers based on the model. 42,000 true positives would be expected from those people who wouldn’t ordinarily be tested. 7,000 false negatives would result. There would be 2.7 million people who had true negative results, and 3,600 false positives. To put other numbers on this, there would be a ratio of six true positives for newly identified people for every false negative result; versus a professional use test, which would yield 62 previously unidentified infections for each false negative result, a difference of about tenfold. On the specificity side, it’s really not even worth talking about because the specificity is so high. In fact, the specificity appeared to be even better than professional use.
Next piece here is the projected net transmissions averted. And what I’m showing you here is there would be about 4,000 to 4,500 transmissions that would be averted as a result of using a test that had a sensitivity at that particular level. And it’s important to note here that what I’m showing you here on the y-axis is the percent of people who are switching from professional use testing to home use testing. And this is just a projection – anywhere from 10 percent people switching to home testing to 100 percent people switching. And even if you have everybody switching to home testing, there would only be about 300 fewer transmissions averted if the current users of professional tests switch to the home tests. Okay.

So, the summary of the assessment is that on the basis of this risk model, the FDA projected a net public health benefit to the OraQuick in-home HIV test, and that would be in the form of a net increase in the number of HIV infections newly identified in the first year, and the number of transmissions that would be averted in that first year. Keep in mind, this is a value judgment. There are no hard and fast ways to say whether something is acceptable or not acceptable. But this is what the advisory committee had recommended, that there was enough of a public health benefit to actually approve the test that was performing at that level. At the same time, you have to admit that there is a certain amount of risk. And that would be in the form of increased numbers of false negative results.

So, what FDA did was, as it usually does, is say there is risk, and to try to mitigate it. How was that done? It was through a series of messaging. I want to point out here that the graphics you’re gonna see are graphics that I inserted that did not go into the package insert. So, the first message is that a positive result doesn’t necessarily mean that you’re infected. You have to follow it up with supplemental testing. Second message is, a negative result doesn’t necessarily mean you’re not infected. And because especially if your exposure has been within the previous three months, which is the window period for this test. Next message is, retesting is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection. And finally, a negative result doesn’t mean it’s safe to engage in risk behavior for HIV infection.
So, earlier there were some questions around imperfect tests and how you actually communicate with people. It’s very, very important that people who are using an HIV self-test know what the limitations of that test are. What this does is a couple of things. It empowers people to test themselves, but at the same time, it tells people who are using the test that they too have a certain level of responsibility, and that they have to understand that this test is not going to be effective within the window period, for example. And people need to pay very close attention to the messages that communicate the risk.

So, where do we take this in terms of STAR? Does the modeling that was done at the FDA apply to STAR? Well, the technique does, yes. But the numbers don’t necessarily transfer, because the assumptions that are being made that go into the inputs to the model and the outputs of the model are likely very different. But the concept here, I think is the same. Let’s see. I just said that. The challenges that remain are where do you draw the line between acceptable and not acceptable? I mentioned earlier that there are no hard and fast rules for the number of false negatives that you’re willing to accept. It is a value judgment, and that takes an extensive discussion. And then some conclusions need to be made on the value of this test, because if you admit that there are people who will simply not be tested unless they have a self-test, that needs to be taken into account.

Monitoring is also necessary to determine if the right choices were made. And let me just finish here with some concluding messages. Be flexible to meet a defined public health need. Be rational in your decision-making. Considering the benefits and the risks can actually take you in some directions you really didn’t expect. And sometimes, what’s expected is actually a good thing. Finally, be willing to accept risks, but also at the same time, acknowledge them and mitigate them as much as possible. Thank you very much.

[End of Audio]

Duration: 394 minutes