Headline: Why SA needs the anti-HIV injection – for R120 a pop

Blurb: HIV researcher Linda-Gail Bekker, Yogan Pillay from the Clinton Health Access Initiative (CHAI) and activist Yvette Abrahams joined us for Bhekisisa's first Twitter Spaces event. Listen as they discuss why injectable PrEP needs to be affordable to be useful in South Africa.

- The anti-HIV injection called long-acting cabotegravir (aka CAB-LA), currently costs more than R300 000 per person for a year's supply in the United States.
- This prices the medicine out of range for many governments, including South Africa's. If nothing changes, South Africa will not have access to the injection and people will have to rely on other HIV prevention measures, like the oral pill Truvada or the vaginal ring.
- The injection could be made for as little as R300 per person, shows research conducted by CHAI. But the drug's manufacturer shows no signs of slashing the cost. "

Moderator: Joan van Dyk (Bhekisisa)

Speakers: Yvette Raphael (HIV activist), Linda-Gail Bekker (Desmond Tutu HIV Centre) and Yogan Pillay (Clinton Health Access Initiative)

Transcript

Joan van Dyk: Good evening, everyone, and welcome to Bhekisisa's first Twitter Spaces event. Thank you so much for joining us. I'm Joan van Dyk, I'm a senior journalist at Bhekisisa, and I'm going to be moderating our talk today. And what we're going to be talking about is injectable HIV prevention. The sciency-name for the medicine we're focusing on is long acting cabotegravir, which is quite a mouthful. But it's also called CAB-LA, or just CAB for short, in case you hear our speakers referring to it that way.

But basically, it's an injection that you have to take only once every two months. So not every day, like the pills that we already have in South Africa. And it significantly cuts your risk of getting infected with HIV. So people's options are really expanding. But as we know, from previous interventions like this, just having more things to choose from isn't going to be enough. There also needs to be, they need to be available in a way that works for people, and very importantly for tonight's discussion, in a cheap enough way that South Africa can actually afford to buy it for people. So that's quite a number of topics we're going to work through, but we've got an expert panel of speakers. Before I introduce them, I'll just tell you how the discussion is going to work. So after introductions, it's pretty straightforward. I'll be asking questions and follow up. But we also welcome your questions to any of the panellists.

First up, we've got Dr. Yogan Pillay, who heads up the Clinton Health Access Initiative, which is also known as CHAI, and he leads the Southern African region. Yogan also used to be the

Director General of the National Health Department's HIV and maternal health project. Then Yvette Rafael, who I'm not sure has joined us yet, but she will be with us shortly. She's an HIV activist and the director of the advocacy for prevention of HIV AIDS nonprofit. In an interview she did with Bhekisisa recently, she described herself as a 'professional protester, a sjambok feminist, and a lifelong advocate for equality. And then last but not least, we've got Linda-Gail Bekker with us. She's a scientist and a doctor, an HIV researcher, and the deputy director at the Desmond Tutu HIV Center, which is based down at UCT. My first question to kick us off with is for you, Linda-Gail, could you explain to us why is this two monthly injection such a big deal in HIV prevention? What does the science say about it?

Linda-Gail Bekker: So thanks very much Joan. The first thing to say is that we always look first to randomised controlled trials. So a randomised controlled trial has recently been finished, known as HPTN 083, in men who have sex with men, transgender woman, and other folk who have sex with men. And then a trial called 084 which was in women who have sex with men, so the one was really a global study. The other one was largely run here in eastern, southern, central, Africa, and both of these randomised control trials had a very interesting design because of course, they started after we knew oral PrEP worked. So that is a combination of tenofovir with emtricitabine which needs to be taken daily. And, you know, people, as it turns out, struggle quite a lot with the daily intervention.

So the way the study was designed was that the CAB-LA was not pitted against placebo. But against tenofovir and emtricitabine so everybody was offered PrEP, everybody got an injection - whether it was the real ingredient CAB-LA or a sham - and they got a pill, whether again, it was a real pill or a sham pill. And at the end of this, both studies, we had phenomenal results in terms of reduction of HIV acquisition, even when compared to this other active arm. So what it tells us is that people do struggle to do a daily intervention — we all struggle with daily interventions. And the beauty of this two monthly injectable is that you can have it, you know, put on board and kind of forget about your need for prevention for two months before the next injection is due.

And so within this phase three trials setting, we really did see enormous reduction in HIV, to the order that in women of 84%. We've not seen that in any other prevention trials. So we have huge hope for this as an intervention. In men, it was similar not quite as high, it does seem that men who have sex with men do actually manage the oral PrEP option. With a little more ease than women. Both are effective, we did see a reduction in incidence across the board. So definitely both work. But it does seem that the injectable has the edge in terms of adherence. So that's why it's important.

Joan van Dyk: And can you tell us in a country like South Africa, we have so many new HIV infections each year, who is the group that's going to benefit from this injection the most?

Linda-Gail Bekker: I would think, you know, obviously, we have to see it in the real world context. But I would imagine that the biggest bang for the buck is going to be amongst young

women and adolescent girls. The reason being that that's the population who is our biggest population that has high acquisition rate at the moment. And there are many reasons for this. But you know, we really have found that a difficult curve to turn. In other words, you know, we are still seeing daily incidence rates amongst these young women.

And so offering them something that is user controlled under their own discretion. And that is discrete, and pretty much for them like an injectable contraceptive, which of course, is the most popular way for young women to contracept today in this country, I would imagine that the population that's really gonna benefit. But obviously, we also have high acquisition rates amongst young MSM, and young women who transact sex. So those are also populations we want to be thinking about.

Joan van Dyk: Thanks so much. So my next question is for Dr. Pillay, what Linda-Gail is describing are very promising findings. But what's been a kind of unexpected twist in the story is that so far, it's being sold for what would amount to more than R300,000 to treat one person for a year. And so far, it looks like the manufacturer is not going to budge on that. And it might be too expensive for the government to buy. Can you explain to us what kind of price would make it affordable for South Africa?

Yogan Pillay: Joan, thanks very much. And thanks for the invitation to participate. And good evening to everyone on the call. So I think the first thing to say, Joan is that, you know, as Linda-Gail says, you know, providing people with choices. And this is yet another example of a prophylaxis way to prevent new infections. And you know, in a country like South Africa with over 200,000 new HIV infections a year, anything we can do to prevent these new infections should be welcomed. So there's no question about us welcoming it. And as Linda-Gail said, it's even better than the oral PrEP Truvada. But let me also say that Truvada works so let's not undermine the oral pill. It works. It works for many people, but there are people that it doesn't work for, for the points that Linda-Gail has already made.

But with 200,000 new infections a year, clearly we need to introduce other methods so that people have choices that suit their lifestyles, and that's why this is such an important and very welcome addition to our strategies prevention approaches to prevent HIV. Now, the big challenge, of course, is that these things need to be affordable, especially to low and middle income countries, including South Africa. And you know, one comparator is the oral pill. And currently the oral pill, X manufacturer — without the administration fee fees attached — costs about R60 per patient per month, per person per month. If you add the nurses time, and all of the other things, blood tests and whatnot, our paper that was published by Bhekisisa, suggests it's about R90 per person per month. So if you double that, because the injectable you only have the injection every two months, you should be, you know, around R180-R200 mark over two years. So per jab, that's kind of, if you're looking for a comparator, that's what we should, we should be paying.

And remember that, you know, government will have to provide both the oral and the injectable when it's available. So it's not as though we're replacing the oral with injectable. And, and that's

what puts added pressure on the Fiscus. And at a time when the economy, you know, is in serious trouble, both globally and in South Africa, asking government to add rather than to supplement is not an easy ask. So my CHAI colleagues have done some, some calculations and that they presented at the meeting some calculations about what it would take for generic manufacturers to produce it, and it's fairly clear from their calculations that generic manufacturers like they do with the antiretrovirals, the orals are likely to produce this at a much cheaper rate. And, you know, much cheaper even then the pill potentially over time. So we then, and I had two meetings with colleagues from ViiV, and just as background, you know, ViiV has been very good historically, about making antiretrovirals really affordable to low and middle income countries. And, you know, the most recent example is dolutegravir, you know, which is this amazing new drug that we are now prescribing to all HIV patients on first line.

So they were able to do it and, you know, licences give voluntary licenses to generic manufacturers to manufacture dolutegravir. So the key question is, you know, why aren't they able to do it with the injectable? Now, their argument has been that, you know, it's a very complex manufacturing process. They have been in discussion with some of the generic manufacturers but they have not clinched the deal yet. So that being said, then the next question is, okay, ‘so what's the price?’ What price would you offer the ViiV originated product at? Now, they aren't able to confirm a price, and the price has not been made available, transparently, as we requested. They have informed some people of what price they would offer it at, but asked people to keep it confidential.

Now, you know that, that does not sit very well with many of us. And that's one of the reasons that Francois Venter, Fatima Hassan and I wrote this short paper, because it really harks back to, you know, the early days of antiretrovirals when low and middle income countries were told, ‘Look, you can't dispense these things because you don't have the logistics, except that when you can't afford it’. And you will recall, Joan, that the prices were very high when antiretrovirals were first available. We saw it again, in the COVID context with the vaccine. They were not made available, they were highly priced. The prices were not disclosed, as you know, the Department of Health could not disclose the prices they were paying for the COVID vaccines. And we will see the same with the new COVID meds, you know, from, for example, the Pfizer med. So, you know, we see this as a pattern from some of the manufacturers but we are rather surprised that ViiV whom I think most of us had fairly good relationship with because of the way they behaved as a pharma company, quite different from the mainstream pharma companies who are either taking their time about licensing generic manufacturers, or will not in the next few years, and have not made the price available in a very transparent way. So the likelihood of South Africa for example, affording the injectable against the price of the oral pill is unknown, and maybe unlikely.

Joan van Dyk: I want to ask a quick follow up Yogan. Why do you think you described the problem that we had with ARVs, then the patent issues with the COVID pandemic yet again, and we again had the secrecy around pricing. And now we're back to the same issue with HIV medicine. Why do you think this problem isn't going away?

Yogan Pillay: Well, it won't go away until you know, health and medicines — including vaccines — are considered a public good. So that the funding that is used to research and manufacture them are transparent. We know how much it costs, we know what the profit margins are, etc. You know, so at the moment, it's very difficult to know, when a manufacturer says, 'Well, we are going to sell this at price *x*', how they came up with that price. The second thing is that, you know, the truth is that for many of these products, public monies have been used to research and develop them. Yet the public – taxpayers money that is – the public does not benefit as much as shareholders. So you know, the medicine patent pool, for example, is one example of how to move away from the current model of researching, producing new products, new medicines, new vaccines, you know, where researchers and companies, including pharmaceutical companies, give their molecules to the MPP (Medicines Patent Pool), who can get people then to derive new products out of them, and then sell them at a much more affordable price. So we need another model.

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Joan van Dyk: I've been told that Yvette is with us and ready to speak. So for any of our listeners that might not know, Yvette's been very involved in advocacy work around the injections and engage in advocacy with this manufacturer ViiV Healthcare. And Yvette, I want to ask you, earlier this month, you and a bunch of other activists sent ViiV a letter demanding more transparency on their reasoning about the generic manufacturers that they say they can't find and their reasoning about the price. Firstly, can you tell us what kind of engagements you've had with the company? And have they given you any kind of satisfactory answers?

Yvette Rafael: Good evening, and thanks for inviting me and having me in this Space… very interesting time. And before I start with where we are, I almost want to say, 'we've told you so we said this was going to be a very expensive drug and our poorer communities, we're not going to be able to afford it'. But still, we continued with our advocacy. And that's where we are right now. Globally, this product in any poor setting will not be available, the testing algorithms are just too expensive to adhere to. Everything about this drug is almost exclusive. However, we have met with ViiV – firstly we did not only write to ViiV but we have met with ViiV as advocates to talk about some of our concerns and some of how ViiV has been engaging advocates. And we've come to an understanding, we don't want to forget the past.

ViiV is GSK, ViiV is what previously had advocates sleep outside, in Midrand outside their building in Midrand and demanding for them for their price to go down. So they have not been very nice, from my point of view as an advocate when it comes to pricing and how medicines are affordable in countries. But we've had a discussion with ViiV and our understanding with them is that they will be more transparent, even though it's going to be difficult. Pharmaceutical companies will remain pharmaceutical companies and they would want to benefit on the bodies of women who participated. I hear Yogan talk about the fiscus and money that was that that was spent for research. My very interest as an activist, is the women who've dedicated their lives and in their bodies to see this research happening. And this product might never work for them, or the generations coming after them. So that is the unfair part about research and how it stands. We've asked this question, when the study was conceptualised, will this be affordable?

Nobody could give us an answer, and that is why we are here. This product globally is not meant for poor people, and we can argue [about] that all day long. I don't know how long it's going to take for this product to become affordable at R120 a pop. But right now, where we are sitting as advocates, this is a pipe dream for the poor communities.

Joan van Dyk: I'm interested, could you expand a little bit on the transparency? What did they commit to, what did the company commit to?

Yvette Raphael: We are a group of 15 women advocates from Africa. And we've been engaging with ViiV since 2016. And one of the things that they have committed to is some of the principles that we believe in. We believe in, the ground work with regards to any HIV prevention [strategy] starts even before the product is conceptualised. Right now we see and understand the pricing issue, ut we need to ensure that some of the things that happened with the PrEP pill does not happen with the injectable as and when it becomes available and affordable for our communities. So we are talking about the testing issue that there is. We are talking to them with regards to transparency and engaging our communities with respect, and with understanding that these communities are part of the research. We're also engaging with them with regards to the processes that are the reality that needs to be followed. And we are still going to engage with ViiV with regards to that. Right now there's open label studies that are going to happen, we would like to see and engage ViiV, the funders and everybody else who's going to participate in those open label studies to make sure these open label studies are big enough for our communities to benefit.

We are working on some of the standard of prevention of care, and those are the things that we're interested in. Right now, the fact is that this drug is not the magic bullet that we all thought it would be. It’s aspirational for us all to hope that this drug will be available, this drug is going to be the solution to the new infections amongst young women and girls. But the reality is, it's not going to be as soon as we think it's going to happen. It's going to be a long process. And we'd like to speak about other methods as well. Thanks.

Joan van Dyk: Linda-Gail, I wanted to ask you about some of the things that Yvette has touched on now with some of the drawbacks, or the kind of mistakes of our rollout of the oral PrEP pill. Could you describe some of the hiccups in that rollout? And how we might avoid those doing? If and when we roll out the injectables?

Linda-Gail Bekker: Yeah, thanks, Joan, lots and lots of thoughts. And, you know, in stories behind that question, but let me just begin by saying in – I suppose – in defence, I don't know if it's in defence of ViiV, but one thing they have done is they have registered with, a good number of countries that participated [HPTN] 084 [trial] and [HPTN] 083 [trial], to have regulatory approval for CAB-LA. So that is, that's good, I suppose, because one of the first steps to getting access to a new product is that the regulator in your country needs to licence it and provide a label. So you know, so I guess that is excellent and, you know, shows there's there's basis behind them wanting to move into this area and provide the the product.

I would agree with Yvette that, you know, the worry is how long it's going to take for us to actually get it into the budgets that will allow it to be used in the public sector. And that, obviously, is first and foremost in all of our minds and something we in some ways, you know, the frustration levels are high, because we really hope that this would be a very different kind of patent, and we wouldn't have to have battles and fights which Yogan alluded to. And you know, we're all getting a little old to keep having to fight these battles every time we need this kind of innovation amongst the poorest in our communities on this continent. But let me get back to oral PrEPs. I think some of the things we did, which are salient lessons. The first is when a product is considered to be too expensive, or not very accessible, or we aren't sure how to use it, we tend to ration it. So we ration it either by, you know, kind of ring fencing it to only certain populations, or we ration it in as much as we say only certain kinds of people – maybe the highest risk individuals, or people of a particular risk category can get access to the product. The minute we do that, we stigmatise the product in the eyes of, you know, the more general population. So people immediately get distrustful, and they start to say, 'what is it about this, and is this really for me, I am not in that'.

So we begin to other. 'I am not in that other category, therefore, this cannot be for me', and that immediately puts the product on, if you like, on a back foot. So, I've referred to this in many forums as offering hesitancy where, you know, we are hesitant about saying, 'let's make this available to everybody who needs it in the most generous kind of way'. Because we know when it comes to a prevention modality, when people don't obviously need it, when they don't need it today for survival, they are going to be quite circumspect about whether this is something they want to adopt into their own lifestyle. And that's the category that prevention falls into is – ideally we want to say with CAB-LA, 'here it is'. Let's offer it to everybody who might imagine they need it for their lives, and allow them to make that choice that Yogan was speaking about. The minute as I say that we either ration it, or put it into a specific category, we label that product. And we put people's sense of trust and belief in it in, you know, on spec. So I do think, you know, that probably was the single most difficult thing around oral PrEP was – and it didn't help that, the clinical trials that were run in this country didn't show the highest efficacy. So we also had to convince the health sector, that this was a good way to go. But I do think that the way we stigmatise the product, that it was only for the highest risk individuals meant that people just, you know, decided it wasn't for them. And we're not having to break through that, to say to people, 'this may well be for you, this is something you should try'. And I would really hope that we could have gone at CAB-LA in a different way. Now, obviously, if it's going to cost too much, it's immediately going to go into that ration category. We're going to say, it can only be used by certain people, under certain circumstances, because it's simply too expensive. And that's a huge, huge concern.

Joan van Dyk: I've heard you speak about the way that we should approach rolling out CAB-LA is in a way that we should rather be flooding the market with that instead of starting with smaller pilot groups. Could you give us some practical examples of what would that look like? Is there any other intervention that you think is comparable? Does that mean that it's totally available in a retail kind of set-up?

Linda-Gail Bekker: I think when we know that something is beneficial, we know it works, and we really believe it will make an impact – then we do. So take antiretrovirals, for example, we have really gone out and made those available to the people who live with HIV. Now that we've come around to recognise this as no longer something you save till people are very sick and about to die. We realise this is a life saving intervention, that, you know, we should even offer to people on the day that they test positive. That's a very different take. And I think it's meant that we've been able to get treatment up to 5-million people in this country now accessing treatment. We really need a very similar approach to HIV prevention, we're a country that has the highest burden of HIV per capita in the world. That means prevention to my opinion, is an emergency – as Yogan said so beautifully.

It is something that should be urgently on the top of the priority. That means if we have something that works, we should be going out and marketing it and making sure that anybody and everybody that could benefit from it has access to it. And access means you do not put any kind of barrier in the way of it whether it be financial, logistical, structural, even, you know, sometimes it's healthcare attitude, we have to remove all of those barriers and make it absolutely available. I've described, PrEP should be like fast food. And that would be my description of how we've rolled out something on this continent. It has been fast food, whether it's hamburgers, fried chicken, we have rolled that out with incredible ability and capability. And in a way, we need to think about fast PrEP, in the same kind of context. It should be available at many points, many ways. And choice – like fast food – is very important, because people are more likely to adopt something to the use and their need, if it's something they really feel they can incorporate into their lifestyle. And you know, people can say this is kind of a luxury – it is not a luxury in this country. We have an HIV burden that is such that it should be a top health priority. And something we should really be looking to, to get to as many people as possible.

Joan van Dyk: Thank you so much. I'm going to go over to a question from the audience. And I just want to encourage everyone again, so ask your questions to the panellists. Just #BhekisisaSpaces. This question I think might be best answered by Yvette. And the question is, what was the initial agreement when the study was done in South Africa if the participants and the communities aren't going to benefit. Are they're not going to benefit as planned?

Yvette Raphael: I think that's where I say the advocacy has to play a part in. So as we move into open label studies, we need to make sure that first of all, the participants who participated in the trials have access – post trial access. And secondly, is to make sure that the participants and the communities around them get the same standard of care of packages. So package as the trial participants, that is actually what open label studies should be doing. So our advocacy had started long before, and we hope and understand that ViiV understands that, and going forward policymakers, researchers, and everybody involved in trials understand that that is what is expected from them. The least that we can do right now is to make sure that those who participated in the trials have access to this drug as we are rolling out open label studies.

Joan van Dyk: Thank you. Yogan, my next question is for you. We know as well that the South African medicines regulator has received an application from the manufacturer we're talking

about – ViiV, and to register the injection for use in South Africa. And they applied sometime last year. That means that they must think that they have a market here and they must be gearing up to make it available. Do you think that will translate in you know, that they might give into pressure on their prices?

Yogan Pillay: Yeah, that's a curious thing. Linda-Gail did mention that one of the positives is that ViiV has sent in the dossier to a couple of countries, including South Africa. They did submit their dossier to Sahpra in December. So you would, expect then that if they took the trouble to send the dossier in for registration with zero the possibility of it being registered, that they have a sense of what the markets looking at. And that's the curious thing. I mean, they registered their product with no idea of what the market is going to look like, because we don't know what the price is. You know, so one of the things that ChAI does is market shaping, right? So we look at what the market looks like, what's the ability of whoever is paying for it to pay for it? At what levels of threshold against what volume of the product? And what we've also been able to do with the number of products in the last 20 years is work with, these large philanthropies. Whether it's the Gates Foundation or others, to provide some upfront budgets in order to in a sense sub vent the costs. So if you put up the money upfront, the manufacturer is more likely to produce the product because there's anticipation then that the product will be used, and as the numbers of the volumes go up, the prices will come down.

So volume guarantees by, for example, people like the Gates Foundation have been used in the past to get manufacturers to manufacture products and the volume guarantees then kick in, and the manufacturer then doesn't lose any money. And we you know, we use that in South Africa, for example, with a number of philanthropies with GeneXpert, you know, the technology to diagnose TB. So, you know, that's also possible. So I'm not aware of any initiatives that are looking at getting philanthropies or PEPFAR or the US government or Global Fund, to engage with ViiV on volume guarantees, for example – because that might be another way of decreasing the prices to at least the country. But somebody else is paying the difference between what the country can afford and what the manufacturer is charging.

So that doesn't help on the transparency, it doesn't help on you know super profits. All it does is help through philanthropy to get the prices as low as possible for the country. That's one option that I think we could try. But really, you know, we have to get ViiV to be more transparent on the pricing, we have to get ViiV to be more serious about engaging with generics. And we have to get generics to come to the table as well. Now I, not to be unfair to ViiV, you know, because it's not very transparent, which generic companies they are engaging with, and what the promise or the potential is for generic manufacturers. You see, that's the thing. If medicines are a public good, these things should all be transparent. So that as Yvette says, the people on which well, this vaccine has been trialled, can benefit from it. Because, I think it's quite unethical actually, and as Linda-Gail said, most of the participants in these trials – well a significant numbers of participants in both trials – were from low and middle income countries, both in Latin America, and here. Some of them were in the north, but the bulk were in the south. I think it's quite unethical to try out these things, show they work in low and middle income countries on the backs of – as Yvette said, poor women, and vulnerable women, and of course, other other

population groups – and then not make it available to them. So there's an ethical issue as well as an affordability issue, as well as a transparency issue, etc. And these are not just with this particular application of this particular antiviral, it's a general problem with medicines and you see it with the cancer drugs, you know, it's another example of cancer drugs are super expensive. And, as I think we all know, the non-communicable diseases in low and middle income countries are rocketing. You know, we have a bigger problem now, and soon we'll have the biggest problem with non-communicable diseases – diabetes, hypertension, cardiovascular diseases and cancers. And, the cost of those medicines are also beyond the reach of many low and middle income countries. So we've you know, we've got to take a stand, it can't just be for this injectable, we now need to go to a new model of developing these public goods, so that they are affordable to the people who need it most. Over.

Joan van Dyk: So we've heard about the value of the injection and the kind of scientific innovation behind it. And people might be wondering, well, if it is so amazing, shouldn't the company be rewarded for that? But we do know a little bit about how these prices are put together and that they're not always that they can be in faith. Could you – Yogan – and tell us a little bit about that.

Yogan Pillay: So my colleagues at CHAI have been looking at this product and looking at you know what it would cost if generic manufacturers produce it. Clearly, generic manufacturers can't produce it tomorrow, right? So I mean, let's let's accept that. They need to tool up in order to produce it. But let's say they are able to tool up and the calculation is that they can manufacture it for about 1000 times less than what the manufacturer is currently selling it in the US. You know, in the US it costs as you said Joan, over R300,000 per person, per year. And I'm not sure even in the US how many people can afford it at this price, but clearly, they have been able to find the market in the US. But clearly at those prices, we can't afford it here. Colleagues at Hero, [unintelligible] and others have recently some did some modelling and they have a pre-print, which they are hoping to publish in The Lancet that showed at a cost effectiveness level CAB-LA cannot cost more than twice what the oral pill currently costs. You know, which we put web-nursing and testing and then the drug itself at R90 per person per month.

So, you know, so they've done some work on it as well, comparing the injectable to the oral. That said, of course, as Linda-Gail said, you know, the injectable has quite a few benefits over the oral pill. So, you know, we have to take the benefits also into account. And because we don't know, even if we have tiered pricing, which is typical of what pharmaceutical companies do, right, they offer a very high price to the North. And they use the profits of the North to, at least to some extent, subsidise the South. And within South Africa, they do the same between the public and the private sector. Of course, the public sector's volumes also kind of make a difference to the fact that the public sector gets drugs that is a different price compared to the private sector. So the tiered pricing occurs at both those levels – the North and the South – as well as within a country between the private and the public sector. We don't know yet. I certainly don't know if they're offering – once it's registered – if they're going to be offering to the private sector, what the cost in the private sector is going to be. The smaller numbers, they're clearly and clearly we're more worried about the public sector cost. But we don't know that either. So the issue of

transparency, I think, is really important. And the the issue about the ethics of it, I think is equally important. Over.

Joan van Dyk: Yvette, in your talks with the manufacturer ViiV, as anything become more clear, when we're talking about finding a generic manufacturer. Have they explained what is so difficult to make, and what their processes have been at all?
Yvette Raphael: Yes, thank you so much. What the manufacturer is is defending itself, and that is ViiV. [They're saying] is that 'this is a difficult process, it won't be easy for us to do, it's going to take long, it won't be as fast as we think it's going to be'. That's their process. Me as a woman, as an activist, my issue is to make sure – and to the people that I say I represent – get prevention methods in the basket of prevention. So what this clearly for me, as an advocate says is that we are going to wait for CAB-LA longer than we thought we would, what do we have available? And how can we fix that? And how can we ensure we don't make the same mistakes again? Like I said, South Africa just approved the ring, can we use that ring until we sort this price thing out? We know it's impossible. Like this is the top tier, this is the top tier of ARVs of HIV prevention. It's not going to become cheap tomorrow. Even if we stand on our heads, it's not going to become available. What we hear from ViiV is that it's difficult to do. So we had a meeting yesterday with medicines patent pool, and what they are saying is the same, it's not going to be less than four years. So what are we going to do? My big issue is what's going to happen between now and in four years, not only with CAB-LA, but with HIV prevention? And like some of my colleagues on the call said, is that so many infections happen that we cannot play around, we realise CAB-LA is not the answer. We need to start working with what we have. The ring was approved, we messed up with PrEP, but we can still save it. We can still ensure that PrEP is available. What we need to make sure, is to ensure we fix this, we make sure that PrEP is available for every single young person who needs it. And that we don't wait for young people to ask about PrEP, we get political leadership behind some of the HIV prevention methods that we currently have available. I'd like to continue the discussion about CAB-LA. But that discussion is not going to help where we are as a country with the highest HIV infections for young people. Over.

Joan van Dyk: Linda-Gail, I'd like to come back to you and touch on what Yvette just mentioning about until we get affordable access to CAB-LA, how do we improve our current PrEP rollout? And I know your organisation has these Tutu trucks, and all these different ways that you're trying to get PrEP to people? Do you think there's anything we can learn from that? How do you think we could improve what we've got at the moment?

Linda-Gail Bekker: Yeah, so Joan, you know, I want to say perhaps just lead off on the one concept that Yogan and Yvette both have alluded to is, you know totally agree that ViiV and the manufacturer should be rewarded for, you know, coming up with a great product. There is also of course, the economies of scale. So if indeed, this becomes a global, almost household product, and goes to vast numbers, there is also that to consider and so there is this tension between making it so expensive, that it is something only available to the few versus something that is affordable and available to everyone. And, you know, that is the sweet spot that I guess

you really want to engage generics on. And of course, we need those generics to come to the table. So I couldn't agree more to what Yogan saying, is that has been the answer for the antiretroviral program. We now have some of the cheapest drugs in the world. And it's been a hard fight. But that's a model, you know, and there's the model to be looked at, as to how we can do this better. And, you know, I absolutely share Yogan, Francois, and Fatima's exhaustion around this, because we had to fight that battle for a really long time, and we're at a good place now in in some ways. And one would hope, therefore, that that model could become something that, hepatitis C, and other cancer drugs etc, that we could follow a similar kind of pathway, and not have to go down the road of needing to fight all the way to get to where we need to be.

Having said that, what can we be doing in the interim? I do agree with Yvette, we have to work with what we've got. And I'm delighted that, National [health department] is already engaging around the vaginal ring. Obviously, it's only available for women, it is a product that is inserted into the vagina, but it also has less frequent use capability. So we asked women to insert it monthly. The idea is, you know, insert and forget for the month, and come back for your new ring at the end of the month. So that, certainly for those individuals who really struggled to do something daily, that becomes an option. But in the meantime, let's do what we can with oral PrEP, which luckily is is affordable, and make sure that we get that to every square inch of this country. So again, really happy to see that government has now increased their numbers of clinics, numbers of districts that have access to PrEP. I want to give, I'm afraid that I'm going to give one big sort of blockage. Notice here that we do still require PrEP to be given out by nurses who fall under this accreditation of NIMART training. Now this came into play at the time that we're rolling out antiretrovirals. NIMART requirements for nurses to give out PrEP is a barrier. And as I mentioned before, we really want to try and remove all of these barriers.

In Thailand, where they really do innovate in the most extraordinary ways, we've seen very effective methods were peer individuals – so people who look like the individuals who use the PrEP – ordinary people are actually giving out the PrEP very effectively and very safely. You know, can we adopt those lessons to say, at the very least, we should let nurses in general, be trained to give out PrEP. And we might even think about task shifting beyond nurses, which I think would be an extraordinary removal of a barrier. You've already alluded that we need to move out of conventional health facilities and into community spaces. Because again, as I've already mentioned, people don't perceive themselves to be sick, in order to utilise prevention, they want to utilise prevention in their everyday lives. And therefore, if we can bring the PrEP to them, that can be very effective. And again, here, we've shown the value of Uber PrEP, couriered PrEP, PrEP pickups from, you know, ATMs, from other community based venues. Today, if you need contraception, in Switzerland, you can go to a vendor on the train station platform, and alongside your chocolate that you can get out of the vendor, you can get your contraception, that is almost where we need to go with our PrEP in this country. And I think we have the capability to innovate, we've got to work, move the policy and the legal issues aside, deal with them, and get the PrEP to the people. And I think, then maybe we'll find obviously, we still have to overcome the daily component. But again, we can help people do this. And so this is my passion, that we really do bring differentiated service delivery, and innovation to the space. And again, the late Joep Lange who unfortunately, he was killed in [flight] MH17, he said,

‘we've managed to get Coca Cola to every single part of the African continent, we should be able to get antiretrovirals there as well. And that certainly applies to PrEP.

Joan van Dyk: Thank you so much. I see we don't have any other questions from the audience. So to end, as of this evening, I’m just going to ask all the speakers to kind of give us the thought that you hope everyone's going to kind of remember about HIV prevention, injections. And Yvette will you start us off?

Yvette Raphael: It's interesting that we are moving forward, that we are here, that innovation is there. It's happening – it’s exciting. But we must remember the most important people in this are the women, are the people, are the participants of trials, are the women who are carrying the highest burden of HIV new infections in this country. And we should make sure that they have HIV prevention that suits their needs. And all of these are going to be important, they're going to be women who are rich and can afford the injectable. If it's affordable, and it's available, if it's there, let them have it. And the women would choose to take a pill for 30 days to prevent themselves from getting HIV, we also should not forget the fact that there's a female condom, which is also scarce, like chicken teeth, it's nowhere to be found. It's available. It works. But you cannot find it everywhere. When we speak about condoms in this country. We speak about male condoms, it's time we think out of the box and think about the women, the people who are the most affected and get the most new infections in this country. And there's adolescent young women and girls, and we make sure that HIV prevention is in their hands! Thank you so much.

Joan van Dyk: Oh, sorry, I'm sorry, I was muted. Sorry about that. Dr. Pillay, your final thoughts.

Yogan Pillay: Joan, thanks very much. I just want to make two points. The first is that we shouldn't let up on the pressure on ViiV. Because this is a novel product, it's innovative – which both Linda-Gail and Yvette called for. So we have an innovative new product and novel product, we need to get it to the last mile. And in order to do that, we've got to put pressure on ViiV unfortunately, until as Yvette said, we can get generic manufacturers in place. We should also put pressure on those that can fund it, philanthropies, PEPFAR etc. To do these volume guarantees because you know, if they do the volume guarantees in Sub Saharan Africa or even in southern and eastern Africa, the volumes will be quite large, potentially. So that might be something practical that we can try. But the last point I want to make is that you know, clearly prevention is hard. We've got what we think of magic bullets, but as it turns out, they're not magic bullets. So prevention generally is hard. Because our model is wrong in health, our model is, we will treat you when you are sick. Now we want to actually keep people well, we have not got in this country, sadly, and I was part of the problem when I was in the department, we do not have a wellness program. That means anything. If we focus, if we flip it and focus on wellness rather than on illness, you know, we'll be able to get more people to take care of themselves and take the opportunity, whether it's oral PrEP, or the injectable PrEP, or a contraceptives, you know, or whatever, that would help prevent disease, and keep people well. So we need a wellness model. And I think we need to, you know, as advocates, also advocate for wellness, and not only for products that will be helpful to people when they are ill. So I think we need a new model for helping the country. Thanks, Joan.

Yvette Raphael: Woohoo, Yogan!

Joan van Dyk: Thank you so much. Linda-Gail, do you have a final thoughts as we end, our off our first Space?

Linda-Gail Bekker: There's a high five there, that we're all shouting so couldn't agree more. But let me say, Joan, that whilst we have been on this very interesting Twitter Space, young women in this country have acquired HIV. This is an urgent, unrelenting problem that has been with us for more than 20 years. We have, you know, a moral and ethical… I can't even describe how important it is that we move to seeing this as something that we all need to work on, tirelessly, day and night to solve. Those individuals, those young women, not only will their lives change, because they will be labelled as living with HIV, but they will have to take treatment for the rest of their lives. So there is a financial reason to urgently find a solution to the problem that we have in this country, because our treatment pool is the largest and it will continue to increase in size if we do not start to turn off the tap.

So you know, I couldn't agree more with Yogan, that we need to keep the pressure on the manufacturer, on the generics and on particular potential funders. But this needs to be a whole society approach. The last two years have taught us what political will, money and investment can do together with science. We have got the science on our side. Now we've done the clinical trials, I absolutely agree with Yvette, it's immoral – and Yogan – that we have done these trials in this country, we now need to follow up with the delivery and the delivery is that we all need to come behind making sure that this product is available as soon as possible. And I believe that these mountains can be moved. I've seen it in the last two years. We're not only one but many products have been rolled across the world in the matter of months. We can do this. We've got to get behind this, believe that it needs to happen and deliver for the people who, as Yvette says, put their lives on the line to deliver this fantastic innovation. And let's start to see the end of HIV in this country.

Joan van Dyk: Thank you so much. And thank you to all our speakers. That concludes our first Bhekisisa Twitter Spaces event. Thank you so much for joining us. And enjoy the rest of your evening and good night.

This Twitter Space was facilitated by the Bhekisisa Centre for Health Journalism. Sign up for the newsletter.