

WHO Virtual Press Conference Access to and Financing of Ebola Vaccines

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Speaker Key

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MK Marie-Paule Kieny

TM Tom Miles

IS Isabel Saco

YI Yutaka Ishiguro

ID Ilya Dmitryachev

HB Helen Branswell

AG Anne Gulland

JG James Gallagher

JK Jean-Pierre Kapp

GS Gabriela Sotomayor

CS Catherine Saez

AO Albert Otti

KK Kai Kupferschmidt

AP Andrew Pollack

MK Makiko Kitamura

JD Jordan Davis

VI Virginia

JC Jon Cohen

TJ My name is Tarik Jasarevic and I'm talking from WHO Headquarters here in Geneva. Welcome to all journalists who are here at WHO Headquarters and to all those who are online for the press briefing that we will host today about the meeting that WHO convened yesterday on access and financing of Ebola vaccines. Today, with us, is Dr Marie-Paule Kieny, WHO Assistant Director-General – Health Systems and Innovation. As usual, just to remind you that the audio file will be available soon after the press briefing is over and the transcript and video package will be available a little bit later. After opening remarks from Dr Kieny we will open the floor for questions. For our colleagues who are online and who would

like to ask questions, they will have to type 01 on their telephone keypad and that will place in the queue to ask their question. I will give the floor now to Dr Kieny for opening remarks.

MK Good morning, good afternoon, it's a pleasure to be with you again for this briefing on Ebola and more specifically on Ebola vaccines. Yesterday, WHO convened a meeting of high-level government representatives and these were from development partners as well as from Ebola-affected countries. In addition to these high-level government representatives there were vaccine manufacturers and funding agencies and civil society, and this was to discuss and agree on how to fast-track the testing and the deployment of promising vaccines in sufficient numbers to use in the field in 2015 to try and impact the Ebola epidemic curve.

Three important consensuses of commitments came from this meeting. First, it was well-known now to all participants that phase 1 clinical trials of the two most advanced vaccines have started and that results from these trials will be available in December 2014. Of course, these will be preliminary results. At least five more vaccines are following up closely and will be in the clinic in the first months of 2015. Without waiting for the results of the phase 1 – the clinical trials which are currently ongoing – all is put place, by all partners, to start efficacy trials in affected countries in December, as early as in December 2014. Of course, the protocols will be adapted to take into consideration safety and immunogenicity results of the phase 1 trial as they become available.

Second, the pharmaceutical companies developing these vaccines as well as the ones which are a little bit longer in the development path are committing to ramping up the production capacity to millions of doses to be available in 2015, with hundreds of thousands ready in the first half of next year. To make this a reality, regulatory authorities in countries where the vaccines are manufactured and in Africa will need to work closely with manufacturers under extremely short timelines to find ways to overcome a number of hurdles in the licensing, the regulation of these vaccines.

Third, community engagement will be key and work should be scaled up urgently in partnership between local communities, national governments, NGOs and international organisations to have this happen. WHO was called upon by all parties to coordinate efforts and ensure effective communication between the various actors.

Let me tell you just a little bit more on the vaccine trials which are currently ongoing. They have begun already in the US, as you know, in the UK and in Mali and will begin now shortly in Switzerland, Germany, Gabon and Kenya. And all these trials will test primarily safety and also dosing, which is the dose level; how much of these vaccines or these candidate vaccines should be put in one does for one person. Of course, as we accelerate in a matter of weeks a process that typically takes years, we are ensuring that safety remains a top priority with production speed and capacity a close second.

Vaccines are not a magic bullet, but when ready they may be a good part of the effort to turn the tide of this epidemic. Therefore, even today, as we engage with communities on how to treat Ebola, we will work with them and listen to how best to educate each other on how the vaccine testing and implementation can support community ownership of the Ebola response, so that effective treatments and prevention methods are embraced and shared far and wide by the most effective ambassadors, the communities themselves. I'll be very happy to answer your questions.

- TJ Thank you very much, Dr Kieny. As we usually do, we will open the floor for questions and first for questions here in the room. Just a little remark; we will be sending out a statement about the outcomes of yesterday's meeting and we apologise that we have not been able to do it in time for this press briefing. Any questions here from the room?
- TM Can you just clarify; did you say 100,000 or hundreds of thousands, please?
- MK I said hundreds of thousands.
- TJ I guess that was Reuters' question. Isabelle, please. If you just can say your name and agency.
- IS My name is Isabel Saco with the Spanish News Agency. I would like, Dr Kieny, if you could elaborate on your announcement that the efficacy trials for the vaccines could begin as early as in December; if you have chosen already the place, if there will be the three countries simultaneously and exactly if you are going to begin with the two vaccines and, if not, which will be the vaccine chosen.
- TJ Maybe we should take one more question.
- MK Yes.
- TJ Please, you had a question.
- YI It was the same question about 100,000 doses by June 2015. But are these only two vaccines which already started this testing or another two that are going to start in early 2015. Ishiguro of Yomiuri Shimbun.
- TJ Thank you, Ishiguro. And third question from Ilya, please.
- ID Ilya Dmitryachev, Russian News Agency, TASS. Maybe I understood something wrong but in the press conference this week you told us that maybe in the first months of next year there won't be a massive vaccination but there will be tens of thousands and now you are talking about a much bigger number of vaccines. What has changed in these days? Thank you.
- TJ Thank you very much, Ilya.
- MK First, the most advanced plan that was discussed during the consultation was for a trial in Liberia and plans are also in discussion about Sierra Leone and we have started to discuss also Guinea. This is not final, of course, because still there needs to be an understanding of the results that will come out in December about the safety and also the dose level but there are quite advanced plans for the time being to start in December. It may be end of December. We don't know at this point. It's quite an ambitious plan, but the idea would be to start before the end of the year and mostly likely first in Liberia.

Now, about the vaccines and the quantities. What we're talking about is the two vaccines which are the most advanced. As I said, there are five more vaccines and vaccine concepts which are following very closely; should clinical trials start in the first trimester. These will also add potentially to the quantity of vaccine available, if they are proven also to be safe and immunogenic.

About what is changing: What is changing is really changing by the week. You're right. What I have said is that by the end of the first half of the year, in 2015, if everything goes well, because there can always be hurdles, but the planning figures that we have seen would be to have access to a few hundred thousand doses. So, this could be in the order... when I said a few, it could be 200, it could be 300, and it will depend really on the pluses and minuses. You must understand that this is at the very early stages. But what is changing, really, is because there is such a mobilisation of all the communities, and also of the manufacturers, that you see that all previous plans are changing from week-to-week, and always towards greater involvement, and a greater mobilisation of all efforts to have more vaccine available more quickly.

- TJ Thank you very much. I hope the questions have been answered. Now, I will call on journalists who are online and we will take three questions in a row. First is Helen Branswell from Canadian Press. Helen, can you hear me?
- HB Yes, thanks. Before I ask my question can I ask if Dr Kieny would clarify because I think she just said several hundred thousand doses in the last quarter of 2015 but did you mean 2014?
- MK Sorry, let me clarify, because I know this is always a controversy. What I said is that before the end of the first half of 2015, which is next year, we could have available a few hundred thousand doses. This could be 200,000 it could be less, it could be more but the planning figure is around that. I am not saying and this is important I am not saying that by the end of the first half of the year these vaccines will have all been used. It will not be possible, most likely, to have these deployed so quickly, but the doses would, in all likelihood in the planning figure right now, be available for use by that time.
- HB My question would be... I have two. When you say the efficacy trial could start in December and that's a phase 3, people are going right to phase 3? Is that the GSK or is that for both? And second question, NewLink says, depending on the size of their dose, they may actually have between six and seven million doses available by the end of December. Are you suggesting you don't think that's a realistic goal?
- MK This is quite complex. Let me take this one. Helen, of course an efficacy trial is a phase 3 usually. The planning is because at the time when this phase 3 would start, the only data that we would have would be on the phase 1 trial; there is a possibility that this would be a phase 2/3, starting with enrolling a smaller number of people that would be followed more closely, and then extending immediately to a phase 3, so this might be a phase 2/3.

Now, about the vaccines, there are still discussions whether the vaccines would be involved in this trial. There is a strong willingness from everybody to have the two vaccines involved, but it may also be possible if one vaccine is ready earlier than the other that it goes first and the other one joins in. We are still in planning phases but there is certainly a willingness to test the efficacy of both products.

What about the planning figures? I've learned also, talking to the press, talking to you, that it is better to be really realistic in what we say. I'm not saying that NewLink will not happen, but I'm giving numbers that I think in all likelihood will be there. It's already very ambitious. For the NewLink vaccines, there is much less understanding at this moment of how much vaccine would be needed to make a dose, so I prefer not to go too high on the forecasting for this vaccine.

- TJ Thank you, Dr Kieny. We will now take a question from Anne Gulland from the British Medical Journal and to be followed by James Gallagher. Anne, can you hear me?
- AG Yes. Can you hear me?
- TJ Yes.
- AG Okay, great. Thank you. I just wondered will the vaccine be tested on healthcare workers and burial workers, as you said on Wednesday or Thursday? I can't remember; so many press conferences at the moment. Also, is it possible to talk a bit more about the case in Mali? Is that something that you could talk about, Dr Kieny? Thank you.
- MK Do you want to take another one?
- TJ Yes. Let's take another one from James Gallagher if you are online, James.
- JG Hello there, it's James Gallagher from the BBC. I was trying to get to grips with what extent of a role you see vaccines taking in this outbreak. How big an impact are they likely to have, and over what timescale? I know we're saying we could have a million vaccines produced, but how quickly could you actually get them into people?
- TJ Thank you, James.
- MK I'll take these two. Certainly, healthcare workers remain one of the categories, and the frontline workers also, indeed, with burial teams one of the priorities for testing, and so these would be the targets either in one or two of the clinical trial designs that we have seen yesterday. One of them is targeting healthcare workers and the other is looking a little bit wider than that.

In Mali, what I can tell you is that this is a two-year-old child, a girl, which was presented on 21st October at a hospital in Kayes city, which is 600 kilometres from Bamako, near the Senegalese border. She was hospitalised, and she was confirmed as being positive for Ebola virus. At that very same moment, there was a team there which was working with the Mali authority on preparedness, so the team immediately started to work with the Malian authority, in order to scale up the response to this news of an infected child in Mali, and we all hope

that they will be able to control the spread of this new imported case. The child was coming from Guinea with her grandmother.

On the impact of vaccine: While we hope that the massive response which is being put in place now will have an impact on the epidemic, it is still prudent to prepare and to have as much vaccine available potentially, would they be proven to be safe and effective. Again, I would like to point out that at this point, these are candidate vaccines, they are not proven vaccines, and one of them or more or both may prove at the end not to be useable, either because they are not safe enough, or because they are not effective enough. So, let's be clear that these are still candidate vaccines. But, first, if the massive effort in response is not sufficient to really bring the epidemic under control, then vaccine would be a very important tool to use for that, and therefore, in this perspective, the scale up is going on full speed in order to prepare for this opportunity. Nevertheless, even if the epidemic would be already receding by the time we have a vaccine available, which we all hope, it is the modelling seems to indicate that the use of vaccine might still have an impact on slowing down and on completely controlling the epidemic, even in a favourable case.

- TJ Thank you very much, Dr Kieny. We will get back to the room now. We will have one question from Jean-Pierre, and then Gabriela, and then Tom, please.
- JK I have two or three questions, short ones, sorry. I would need then the names of the two vaccines you will start with, then I would like to know how big the groups will be, mainly in Liberia that's where you start and how many spots you will try to get. And the last question, sorry for that, the title of the meeting was also about the financing of the vaccine campaign; could you give us a few words on that, please? Thank you.
- TJ Thank you very much, Gabriela.
- GS Hi, thank you. Gabriela Sotomayor, Mexican News Agency. Dr Kieny, did you talk also about experimental treatment in your meeting, or other drugs to treat the patients already infected? Thank you.
- TJ Thank you.
- TM Tom Miles from Reuters. I'm also wanting to ask about the financing. I'm wondering have you got any agreement on the structure of how this will be financed and who will finance it? Are the companies involved going to be indemnified by governments, or by somebody else simply rushing to all this without perhaps having the financing, and the agreement about it's going to work in place?
- TJ Thank you, Tom.
- MK Thanks a lot. Let me take first the questions which are not about financing. Gabriela, first the meeting was only about vaccines, not at all about treatment. The names of the vaccines: one is developed by the company GlaxoSmithKline. It has the name of chimp ad3 ZEBOV which means that it's a chimpanzee adenovirus type 3 vector which is carrying the gene for the glycoprotein of the Ebola Zaire strain. It's only the glycoprotein. Again, I want to

point out that this vaccine by no means can create or induce Ebola in the vaccinees. The other vaccine is called rVSV/ZEBOV. It means recombinant VSV. So, this time it's a VSV vaccine which is carrying, again, the gene for the envelope, G envelope, of the Ebola virus. In terms of the number, we are talking about several tens of thousands, something between 20 and 30 thousands, and the focus of exactly where the vaccination will take place is still under discussion between the sponsors of the trial and the people on the ground, to see what is the best place.

Now, financing, indeed, I didn't talk finance right now – I guessed that there would be questions – but there was a lot of discussion at the end of the meeting also about financing. There has been commitment from a number of entities about financing this operation, and financing also the deployment of the vaccine because, as you know, it's not only to have a vaccine which is a product, but you need also to be able to deploy it. I remind you also that you might have heard that for the time being, these vaccines need to be kept in very cold temperature, at -80 degrees, so it means that these are really specific freezers that need to be used to store these vaccines. So, there's a lot of investment in the logistics to be made, and also a lot of investment into community mobilisation, into working with healthcare workers on the deployment of these doses for the clinical trials.

There has been commitment made by MSF. MSF pledged, if necessary, to create a fund. There were also a number of traditional donor countries who pledged to finance vaccines. The World Bank was interested also and, of course GAVI is looking at how they can play a role in response to Ebola. You know that GAVI is the main financer of vaccines for developing countries and they are working on a proposal that they would put to their board – the board is meeting in December – on a strategy that GAVI could take to help vaccine introduction and vaccine deployment for the Ebola epidemic.

There was a question about liability. Indeed, as you know, these vaccines are being developed very quickly, and by the time they may come to use, there will certainly not be as much known in terms of their safety as would be normally for vaccines that are introduced for paediatric populations, for example. Indeed, usually vaccines are trialled on many thousands of people before they are used in affected populations. In order to deal with this problem there was a proposal also from the UK initially to create a fund that would be able to have resources that could indemnify any people who would have had an unfortunate adverse event following immunisation.

TM May I follow-up?

TJ Yes, Tom. Please.

TM Sorry. Just wondered if you could be more specific about these commitments. You told us last week – I think it was last week or this week – that this is likely to cost in the hundreds of millions of dollars, so what proportion of that is covered by these commitments? Would you say 10% or 100%, or are there blank cheques available? And I think you also promised to tell us about the Russian vaccine before, so I'm wondering what more you can say about that. Thanks.

MK We haven't talked about figures for the time being, but there is a broad understanding that money will not be an issue with these Ebola vaccines. It may be a mixture of several mechanisms: GAVI may be one, then the governments, especially the ones who are helping specific countries. The UK, for example, is especially assisting Sierra Leone. So, there will be direct assistance to the countries. I haven't seen the money, nor did we discuss precise figures, but the general understanding is that this will not be a hurdle to the deployment of vaccines.

The Russian vaccine. There was also a Russian representative at the meeting yesterday and he told us a bit more about the vaccines which are being developed in Russia. As you may have seen in the press, they are developing three vaccines: one vaccine which is based on adenovirus, so it's the same type of principle as the one which is developed by GlaxoSmithKline, and also by Johnson & Johnson, by the way. There is another one which is developed by Vector in Novosibirsk, which is based on a lentiviral vector. And there is a third one which is developed in St Petersburg, which is based on a naturally attenuated strain of influenza virus. We understand that one or possibly more of these vaccines could go into clinical trials very shortly.

- TJ Thank you very much, Dr Kieny. Now, we will turn again to journalists online. I will call first on Catherine from IPW, Intellectual Property Watch. Catherine.
- CS Yes, good afternoon. Most of my questions have been answered. It was about funding. The remaining question that I have is, "Did pharmaceutical companies commit to any special licensing schemes or just commit to affordable prices for the vaccines when they are ready?"
- TJ Thank you very much Catherine. I will now ask Albert Otti from DPA. Albert.
- AO Yes, hello. Thanks. Albert Otti, German Press Agency, DPA. I have a question just to make sure that I understood correctly: So, effectively you're bringing the efficacy trials from the previously planned start date in January, forward by one month to December? That's my first question. And the second question is: you hope to have hundreds of thousands of doses ready by the end of the first half of next year. Does that mean that mass vaccination will not start before that time?
- TJ Thank you very much, Albert. And the third question is Kai Kupferschmidt. Kai.
- KK Thank you very much. I have two short questions, I if may. First of all, obviously, at the moment, the clinical trials are planned for Sierra Leone and Liberia and I've heard a few times that Guinea doesn't have the infrastructure, maybe, to do one, but I do wonder, since all of these countries have a legitimate interest to be part of this, is there any way of involving Guinea? Are there any plans? And the other thing is filling capacity seems to become a major issue because these need to be done under BSL-2 conditions, so obviously the companies have asked to relax the regulatory process that would normally be part of this. Does the WHO have any opinion? Should the vaccine be allowed to be filled at BSL-1 facilities, for instance?
- TJ Thank you very much, Kai. Dr Kieny.

MK Okay, so what about commitment of the vaccine manufacturers. Of course, there's commitment for affordable prices; that's quite clear. In terms of licences, this has not been discussed so far, but as you know one of the reasons these vaccines were never developed is there is no market, so it's difficult to envisage that you would have quite a number of manufacturers wanting to produce Ebola vaccines, so what will be needed when this outbreak is put to rest is most likely then to create a stockpile, possibly more than one stockpile, to have vaccine which will be available to treat any new outbreak that will come. This may not be millions of doses because, of course, when you start and you are able to intervene in an outbreak which is a nascent outbreak, then the size of what you need to do is much less, so for the time being there hasn't been discussion of licences, as much as I know.

Yes, it is true that we are talking about now starting in December and not January. This shows again how everything is really pushed forward and the massive effort which is undertaken by everybody to make this happen. I said that there would not be mass vaccination before June. I can say that I haven't seen a plan for mass vaccination before June now, but does it mean that I will not come and say there are plans? I don't know. I think it really depends on the epidemic curve and as I said, also, if we see that fortunately because of a massive deployment of response teams now, this is something which brings the epidemic under control, then the urgency for mass vaccination will be less than if we have more difficulty. The reality, I think, will adapt to the facts, but certainly people in need in the affected countries or at least certain groups will have access to vaccines before the middle of the year, most likely.

Now, Kai, about Guinea, you're absolutely right. Guinea is less talked about for vaccine trials for the time being. One of the reasons may be also that there seems to be less intense transmission, general transmission in Guinea right now than in the other two countries, so this is why there is more focus on Liberia and Sierra Leone, but we have been discussing also in the margins of the meeting yesterday, of a partnership for Guinea, and we are currently investigating what would make sense in terms of the evidence that needs to be built and then can be addressed in Guinea. So, certainly, something will be also happening in Guinea, but I cannot at this time really tell you what type, or what will be tested exactly in Guinea.

You are right, also – I see that some of you have become specialists of vaccine production – that one of the main bottlenecks is filling capacity. What does this mean, so that everybody understands? According to the type or product or vaccine that you are working with, you need to work under certain types of containment. If you have a vaccine which is a protein simply, like a hepatitis B vaccine which is just a protein, this is not infectious and you can work with it under what is called BSL-3 [sic]. Now, if you have something which is very... not for a vaccine, but a virus which is quite dangerous like HIV, you need to work under what is called BSL-3, where you have a negative pressure – it's more contained. For something like these vaccines – which are attenuated, but they are still viruses – the use under which they are worked under is called BSL-2. So, it's in between something which is well-controlled but not that much contained, and what is used for HIV virus, which is very well contained. It's in the middle.

It's quite expensive, and for these facilities to be able to do the vialling - to put all the vaccine in vials – there are not that many. And if suddenly these vaccines are produced in hundreds of thousands, and in millions, then this takes a lot of places for vialling. So, the question to the regulators is whether, in view of the urgency and in view of the fact that these two vaccines are attenuated but still viruses, is it possible to do this vialling under BSL-1 conditions instead of keeping them under BSL-2? WHO has no opinion on that. What we will do is that the Director-General has committed to bring together the regulators in the producing countries, and also in Africa, to work together on how to reduce bottlenecks. This discussion among regulators will happen, but I cannot tell you yet what the decision will be.

- TJ Thank you very much, Dr Kieny. I'm calling now on Andrew Pollack from New York Times to be followed by Makiko from Bloomberg. Andrew.
- AP Yes, thanks very much. Just a couple of questions:. US officials seem fairly definitive in what trials might happen a trial comparing the two vaccines and a control in Liberia, and a stepped wedge design in Sierra Leone, I think, starting with the GSK vaccine. Is that not set in stone yet? You haven't really described what specific trials might be done. The other quick question I had is if all goes well, what's the earliest you think we'd have data, either showing the efficacy or showing that the vaccines are not efficacious?
- TJ Thank you, Andrew. Makiko, Bloomberg.
- MK Yes, hello. Just a few questions. Can you please clarify whether these trials will be placebo-controlled? And then the second question on stockpiling; has there been any specific discussions that WHO is having with specific governments about how much stockpiling they would be considering? Thank you.
- TJ Thank you very much. Dr Kieny, would you like to take those?

MK Yes. Of course, Andrew, you're right. The US has presented a clinical trial design. The Liberia trial that I mentioned, would be the first one, and I said that it would be both vaccines if they are ready at the same time. Indeed, this is a randomised controlled trial. And the other one which was discussed, but less in depth, was a stepped wedge design in Sierra Leone. These are still plans, although there have been quite a lot of details already worked out potentially for the Liberia trial. These will be discussed further to see whether some modulation should be put in some of the designs of these trials. This is why I think unless they have been completely locked in, and the design accepted by the authority on the ground and the trial started, I think it's preferable not to enter too much into the details because this is still a work in progress.

When would the data be available? Well, it's difficult again to say when but for planning purposes everything is put in place to have initial data about efficacy by the end of the first trimester, or the beginning of the next one, so around April see something that everybody says is likely to have results. But, again, a line for production capacity can be more and can be less. I'm saying possibly, for planning purposes, April; it can be slightly before, it can be slightly after that.

Placebo: here again the idea is that the trial in Liberia would be against placebo. Most of the voices that we hear are saying that for a vaccine trial, in view of added speed that such a design, would have in terms of demonstrating definite efficacy that this would be the preferred design, and this is also what came out of the consultation that we had in end of September this year. Of course, the volunteers would be given another vaccine so that they have some benefit for those who do not receive Ebola vaccine, and all the volunteers would be followed-up very, very closely, in order for them to be able to be brought to treatment as soon as possible.

On the stockpile, thanks Makiko for your question, because nobody at this point of time is talking about stockpiling now. Let's be reasonable. Now, every vaccine which is available will be used if it is found to be effective, and everybody is targeting West Africa, so there's no doubt about that. When we discuss stockpiling, we're discussing stockpiling for vaccine in a new outbreak that will certainly happen one of these days, one of these years, so this will happen after this epidemic is brought under control. How much would be needed? I think nobody has really started to discuss this because it's very early and everybody is focused on the response to the epidemic.

- TJ Thank you very much, Dr Kieny. Let's go maybe for the last round here in the room. We have a question, gentleman, sorry, I'm not familiar with the name, and then Ilya.
- JD Jordan Davis with Radio Télévision Suisse. Madame Kieny, are you saying that there are going to be health workers in Liberia who will be receiving a placebo during these trials?
- TJ Thank you, Jordan. Ilya.
- ID You said that there won't be mass vaccination before June. It may mean that after June there will be a mass vaccination. So, that means maybe you are optimistic about how the clinical tests are going, just only the fact that you are planning such things. And if I may ask you, before these vaccines are ready, before the mid of next year, how many people could be treated by therapy of blood, if you have some estimations of this, while the vaccines are not ready yet.
- TJ Thank you. And last question from the room. Gabriela, please.
- GS Yes, just a clarification. According to your colleagues there is going to be 10,000 new cases each week in December, so, with that scenario in mind, how many vaccines will you need to contain the epidemic in the three countries, just to have an idea?
- TJ Thank you very much, Gabriela.
- MK The population, the targets in Liberia, are not only healthcare workers but certainly the idea in a randomised controlled trial would to give to a part of the volunteers a vaccine which is not an Ebola vaccine. It's not an inert placebo it's not a question of that but, indeed, some of the volunteers will not get... the idea is that some of them will not get the Ebola candidate vaccines. This has been deemed as being the best way of having a response on whether the vaccines will be effective, or not, and therefore this will be the best for the

whole community to know whether the vaccines work, or not, or whether they can be used on a larger scale. Of course, this would be following informed consent and doing the best for everybody.

In terms of mass vaccination, I have not said that there would not be mass vaccination before June. I have said that we have not seen plans for mass vaccination before June. If, again, if the vaccine – and there are multiple ifs – if the vaccine is proven effective and if the epidemic curve is justifying the fact to do mass vaccine, and if the vaccine is available in enough quantity, then there might be mass vaccination, but again, this is with three conditions: that it is safe and effective, that the epidemic curve justifies that something like that should be done, and the third, that there would be enough doses available. So, there are a lot of provisos, but definitely I have not said that by no means will this happen. We don't know.

Now, blood, how much? I don't know. This is starting to be put in place. There is actually the material for serum, also for plasma purification, and preparation of serum of volunteers is also being put in place. Preparation of serum is something which is likely to be more... something that can be put at a higher scale than just blood transfusion, because blood transfusion is one person to one person, whereas serum you can take multiple people and you pool it and then you have a resource that you can use on multiple people also. Blood transfusion is something which is happening right now. What is also ongoing is to collect as much evidence in order to be able to judge whether this is effective or not, because for the time being, we still don't know whether it works or not. There is only anecdotal evidence that this works and not solid enough scientifically, so this is likely to remain at a relatively small scale. In the plasma and serum, how much will be available and how many people will be treated? We don't know for the time being, but what I started to say is that the equipment to do this is starting to move to affected countries and will likely reach Liberia at the first instance, and then also, there are advanced plans also for Guinea for the time being.

TJ Thank you very much, Dr Kieny. Ah, yes, there was question. Gabriela, on the number of vaccines.

MK How many vaccines in terms of doses, or in terms of quantity?

GS Quantity.

MK Will be available but I...

GS No. How many do you think you need to contain the [overtalking]?

MK Ah, sorry, yes. Well, it's not difficult to say but it's not decided yet what would be the most effective target for vaccination because you can have different approaches, and according to the number of doses that you need you can go to healthcare workers – that's a done deal – but then what is the next target? Do you go for pregnant women? Do you go for children? Do you go for adults? Do you go for general population? And each of these targets would have a different number of doses of vaccine which are needed. So, right now, there are efforts to do modelling on the epidemiology and the epidemic curve to see for each of the populations that you could target, what is the maximum impact in terms of public health.

Until the moment where the targets are clearly defined, then it will not be possible to say how many doses would be needed in order to reach these targets.

- TJ Thank you very much. We will take the last round of questions from journalists online before we close this press briefing. I'm calling first to Georgina from medical press. Georgina, French medical press, can you hear me?
- VI Okay. Virginia. Yes, I can hear you. Are those trials, are they going to be phase 2-3 trials with three arms; two arms comparing the two vaccines and one placebo arm?
- TJ Thank you very much, Virginia and sorry for not having your name correctly. Second question Jon Cohen from Science.
- JC Are there any plans to do vaccine studies in Guinea and if not, why not?
- TJ Thank you, Jon. I think this has been talked about. And lastly, there is a follow-up from Helen. Helen.
- HB My question was asked but I couldn't figure out how to get out of the queue. I apologise.
- TJ Okay, thank you very much. Dr Kieny.
- MK The plans are most advanced for the Liberia trial and the Liberia trial is meant to be three arms with the two vaccines and a control vaccine. So, this is if the two vaccines are ready in time at the same time, as I said. The plans are a little bit less advanced for Sierra Leone; it may be two or three arms, and the planning, as much as I know, would not have a control arm but again this is still to be defined. In Guinea, there are no firm plans about exactly what in Guinea, but also you must understand that I think running a second trial which is exactly the same design in Guinea, doesn't add much. It adds politically to do something in Guinea, but we are discussing with the Guineans and with a lot of partners what question would be best answered by an additional trial in Guinea and how we would do this. But, certainly, there will be a trial in Guinea, simply we are not clear yet of exactly what we will research in this particular trial, and therefore, which will be the target in terms of the vaccines and the population in Guinea.
- TJ Thank you very much, Dr Kieny. I see no other questions here in the room and no questions online, so this closes down our press briefing. We will send you the audio file shortly as well as transcript and video package a little bit later. We also expect our regular situation, our roadmap update tonight with updated figures and I hope you will receive it all on time. Thank you very much. Have a nice weekend.