

## Transcript of virtual press conference with Dr Marie-Paule Kieny, Director, Initiative for Vaccine Research World Health Organization

19 November 2009

**Nyka Alexander, WHO communications officer**: Good afternoon. We welcome you to WHO's weekly virtual press conference today on 19 November, 2009. My name is Nyka Alexander. With us is Dr Marie-Paule Kieny, the Director for the Initiative for Vaccine Research at WHO. She will be providing an update on pandemic vaccine. I will now pass it over to Dr Kieny who will make her introductory remarks and then will open it up for questions. Thank you.

**Dr Marie-Paule Kieny**: Good afternoon, good morning. With pandemic flu vaccine programmes well under way in a number of countries, and beginning in others, I would like to take the opportunity to update you on the overall situation, starting with vaccine availability, and then discussing safety.

Beginning with numbers, we estimate that at least 80 million doses of vaccine have been distributed and that at least 65 million doses have been administered. These are figures that we have received from 16 countries, but we think they are conservative estimates because immunization campaigns are under way now in 40 countries.

In the developing world, where WHO will distribute the donated vaccines, we expect to start shipment at the end of this month, and to continue this distribution well into 2010.

These timelines underline the importance for people everywhere to use common sense nonclinical measures to protect themselves, such as washing hands regularly, covering sneezes and coughs, and staying home when sick. As my colleague Dr Nikki Shindo discussed last week, WHO advises health providers to focus on early treatment for at-risk people with flu or anyone showing signs of serious illness.

Given this scale of vaccine administration, at least some rare adverse events could not be excluded. I will give you details in a moment, but from what we see so far, the pandemic flu vaccine has the same safety profile as the seasonal flu vaccine. The 65 million doses administered are cumulative number across countries and regions. They include different products, inactivated with or without adjuvant as well as live attenuated vaccines. No significant difference in the safety profile between different types of vaccines has been detected to date.

How has the vaccine's safety been measured? National authorities are responsible for monitoring the results of immunization campaigns in their countries. Surveillance systems are set up to record any occurrence of illness or death in people who have been vaccinated. The national authorities have been regularly sharing their findings with WHO. So far, there have been a similar number of events reported as we would see for seasonal flu vaccine. We have seen a rate of about 1 report for 10,000 doses of vaccine. Only 5 reports out of 100 reports are for a serious event. Each instance is investigated by national authorities to see if there are any connections between the vaccination and the adverse event. Since many deaths and illnesses

are expected in the general population over any given period of time from other causes, the investigations focus on finding if there is a plausible link to the vaccine. The reports are then assessed to see if the vaccine may be the cause. A small number of deaths have occurred following vaccine administration. All such deaths, reported to WHO, have been investigated by the countries. Although some investigations are still on-going, results of the completed investigations reported to WHO have ruled out that the pandemic vaccine is the cause of death.

There has been in particular a lot of concern about Guillain-Barre syndrome because of the incidences during the swine flu vaccination campaigns in 1976 in the US. To date, less than a dozen suspected cases of Guillain-Barre have been reported following vaccination. Only a few of these Guillain-Barre cases may be linked to the pandemic vaccine. Illness has been transient and patients have recovered.

What we do see is a variety of local reactions, such as pain at injection site, swelling, redness and reactions such as fever, headache, muscle pain, or fatigue. These generally resolve within one or two days. A variety of allergic reactions have also been reported.

National authorities will continue to monitor the situation closely and report their findings to WHO, and we will continue to keep you informed.

To conclude, vaccine campaigns continue worldwide. No new safety issues have been identified from reports received to date, but WHO will remain in close contact with national authorities who are monitoring for adverse events. So let me repeat, reporting so far reconfirms that the pandemic flu vaccine is as safe as seasonal flu vaccines. I would be very happy now to respond to any question you might have for me on this topic.

**Nyka Alexander:** Thank you Dr Kieny. Before we go to questions, may I remind you that an audio file of Dr Kieny's briefing will be available immediately afterwards on the WHO website and a transcript will be available later today or possibly tomorrow morning. The website is <a href="www.who.int">www.who.int</a>. To ask a question, please type 01 on your type pad to get in the queue. The first question is from Jason Gale from Bloomberg. Please go ahead.

**Jason Gale:** Good morning, good evening actually Dr Kieny. I want to ask you about demand for swine flu vaccine in the countries where it is currently available. It seems to be that some people are clamouring for it and others are spurning it. To what extent is the plethora of conspiracy theories that one reads on the internet having an effect on the perceived risk of the vaccine and what is the public health implication of that? If I can ask an associated question, which of these conspiracy theories seem to be doing the most damage?

**Dr Marie-Paule Kieny:** The conspiracy theories have indeed been brought to our attention. We really think that these can be damaging and indeed there are worries which are artificial worries generated by these conspiracy theories. Really what we would like to do is that we have to reiterate that the vaccines are safe, that the disease in certain people can be severe and can be the cause of death and therefore this is not the time to discuss or try to work out whatever conspiracies there may be. This is a time to work together, to produce more, to distribute more and to protect as many people as possible against this pandemic virus.

**Nyka Alexander:** Thank you. The next question is from Stephanie at Reuters in Geneva. Please go ahead Stephanie.

**Stephanie Nebehay**: I just wondered if you have any comment on a report by Novartis the other day saying that there has been a US study suggesting that half a dose of their vaccine may be enough to give people immunity and whether you have had any other data suggesting that from some other studies or drug makers. We have a second question, if you have time, on China. Thank you.

**Dr Marie-Paule Kieny:** In terms of manufacturers coming with clinical trial results showing that half a dose could be effective, these are results that we have received from other manufacturers also. Of course, this has to be taken with some caution because the numbers are still small. It may well be the case that a smaller quantity of vaccine may be protective but it is really up to the national regulators to define what is the best regimen for immunization in their countries. As for WHO, we have already made the recommendation that currently we think that one dose of a licensed vaccine is what should be used in adults at least and that in children, because of public health reasons, it may be more important to give as many children as possible the first dose as quickly as possible in countries where children are targeted. We are really relying on regulators to give us their best advice on the best dosage.

**Nyka Alexander:** Before we go on to the second question from Reuters, I want to remind those journalists on the line that you can type in 01 on your key pad if you wish to get in queue to ask a question. Please go ahead Stephanie with your second question.

**Stephanie Nebehay**: Thank you. There was a story out of Beijing this morning by medical experts suggesting that China may have had more H1 flu deaths than have been officially reported. I wondered if you were aware of these sort of reports and whether you are convinced that authorities are in fact checking and recording correctly the causes of deaths, in other words, that they are reporting accurately to WHO.

**Dr Marie-Paule Kieny:** We think that the national authorities do report accurately to WHO. As I am sure you know, to confirm that a death has been caused by H1N1 needs some confirmation and therefore we may receive it a little bit later but we are confident that the reporting that we get is what is really happening.

**Nyka Alexander**: Do we have any more questions on the line? I will give everyone one more reminder that you dial 01 if you want to get in queue. I hear there is one more question lining up. Just a moment please - sorry about the technical difficulties. I will take this moment to remind everyone that the transcript goes up on the web but first the audio goes up. So, the audio comes first and the transcript comes a little while later. We do have a question from Eliane at AP. Eliane, you are on line. Please go ahead.

Eliane Engeler: Dr Kieny said that shipment of vaccines to developing countries would start at the end of the month. Can you tell us when it will arrive in those countries and which will be the first countries getting the vaccines? I wonder if there has been any delay because a few days ago WHO said that these poor countries would receive the first doses of vaccine in late November, now it seems to be a little bit later. Then I have a second question. It seems that WHO does not have a programme to vaccinate its own staff at headquarters. What is the reason for that? Would it not make sense for WHO to vaccinate its staff to make sure that they can continue working if the outbreak gets more severe here in Geneva?

**Dr Marie-Paule Kieny:** In terms of delays in the delivery date, there has indeed been a few days' delay compared to what we thought we would do. The first delivery of vaccine will go during the first month to 35 or slightly more countries and then the same amount the next month and the third month. We expect that over the next three months we will be able to deliver vaccines to the 95 countries that are eligible to receive vaccines. For the second question, the vaccination of staff in Geneva, we are particularly fortunate in Geneva that the Swiss authorities are opening a programme of vaccination for their population and this is the case also for France, the neighbouring country, so the staff of the organization will be vaccinated through operations conducted by these two governments.

**Nyka Alexander**: Thank you. The next question is from Martin Enserink from Science Magazine. Please go ahead.

**Martin Enserink:** Thank you. I was wondering about the vaccine that will go to developing countries - who decides exactly where that goes? Is it WHO or is it the donors that actually give the vaccine? I am asking because I saw a press release saying that the US would donate almost a million vaccine doses to the Ukraine in early December. Was that their own decision or was that taken in consultation with WHO?

**Dr Marie-Paule Kieny.** The decision on which vaccine goes where is taken in function of the quantity of vaccine that we have from different types and of the size of the population. We try, as much as possible, to provide only one type of vaccine per country because for logistical reasons this is easier to handle. In terms of your particular case with Ukraine, the US indeed is donating vaccines to WHO and it is WHO who will orchestrate the distribution of vaccines to these 95 countries and it remains to be determined exactly which vaccine will go to Ukraine.

Nyka Alexander: Thank you. Next is Rebecca Smith, Daily Telegraph. Please go ahead.

**Rebecca Smith, Daily Telegraph**: Hi thanks taking my question. Early reports in the UK is suggesting the uptake rate among the priority groups may be fairly low. Can you tell me what would be an ideal of uptake rate that countries should be aiming for to control the outbreak?

**Dr Marie-Paule Kieny**: Well, you would hope to have the maximum uptake in the population in the target groups. So if you target pregnant women, like many countries do, we would really like to have a very high uptake more than 80% going to 100% if possible. So it is worrying indeed that certain groups don't seem to be coming up readily to be vaccinated, but we hope that the data which are being recorded by all countries and by WHO also on the safety of these vaccines will dissipate the worries that populations might have and will help them convince them that vaccine is safe and that vaccination will protect them against this disease which can be severe.

Nyka Alexander: Question from Sharon. Next we have a question from Sharon Ottawa,

**Sharon Kirkey, Canwest News:** Dr Kieny, could you go over again the adverse reaction reports? I am wondering in particular if serious reactions what the current rates are. The Chief Public Health Officer for Canada on Tuesday said that serious reactions with our adjuvented vaccine here in Canada are less than 1 per 100,000 doses. So could you go over again, just the figures?

**Dr Marie-Paule Kieny**: So the reports that we have is one report for every 10,000 doses of vaccines. So these are all reports together and can be anything from very mild to more serverw. Now, of the reports that we get, 5 out of 100 reports are for a serious event.

Nyka Alexander: Sharon do you have a follow-up on that?

**Sharon Kirkey:** Sorry could you clarify what some of the most serious events are?

**Dr Marie-Paule Kieny**: Well, of course most of these serious events is death and there has been a small number of deaths. But again a report. doesn't mean that this event is linked to the vaccine or that the vaccine is the cause. But they have been investigated so the more servere event, as I say, is death and of those we have heard around 30. Then potentially Guillain-Barre but Guillain-Barre we had a dozen of which only a few can be possibly due to the vaccination. And all have resolved without sequelae. So these are types of events that we have recorded.

**Nyka Alexander:** I have one last caller on the line. I am sorry also not very many details are .... Spanish caller. Is there is somebody on the line?

**Joseph**: There seems to be a bit of confusion in certain countries in Spain at least about whether children should or should not be vaccinated. This has come after some children have

died from influenza, from swine influenza. So I would like to ask you whether you can comment on the rationale for or against vaccinating children.

**Dr Marie-Paule Kieny**: Well, there is absolutely no reason not to vaccinate children. Now as we have discussed many times countries' national authorities have different strategies as to the use of the pandemic vaccines. And really they need to see what they target first, if they what they want to target first high risk groups, pregnant women or if they want to try to have an impact on spread of the pandemic and then target children first. It is really specific strategy which is adapted to each of the national situation but there is no reason not to vaccinate children. The vaccination is safe, and is safe also in children.

**Nyka Alexander:** We have a question, I believe it is the last from Blaise Lempen, ATS, in Geneva, please go ahead.

**Blaise Lempen, ATS**: Yes, thank you. Do we need to be vaccinated also against seasonal influenza and it is safe to do it simultaneously?

**Dr Marie-Paule Kieny** So this question has been reviewed also recently by the Strategic Advisory Group of Experts, the highest level advisory body on immunization at WHO and they have looked at the pros and cons of simultaneous administration and they have recommended that seasonal vaccine and pandemic vaccine can be administered together. The only case when this is not the case which should not be done, and these are really very rare cases, is when both the seasonal and pandemic are live attenuated types where they should not be co-administered. Apart from that the recommendation of WHO on seasonal vaccination haven't changed and the groups who are priotized for seasonal vaccination should continue to be vaccinated.

**Nyka Alexander:** Thank you very much. That was our last call and I would like to thank everyone today for listening into the Virtual Press Conference from the WHO headquarters with Dr Mary-Paule Kieny, the Director for the Initiative for Vaccine Research. Thank you Dr Kieny, thank you to the journalists on the line. We remind you once more that audio file will be posted on the website: <a href="www.who.int">www.who.int</a> and the transcript later this evening or tomorrow morning. The next virtual press briefing will be next Thursday. Thank you to everyone and have a good day.