



**World Health
Organization**

**Transcript of virtual press conference with
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M. Gregory Hartl: Good afternoon, thank you for joining us here today, for this virtual press briefing, and also live here in Salle de Press III in the Palais des Nations in Geneva. We are doing it from here today because obviously we have been in the World Health Assembly here at the Palais this week, which is just finished, and at the end of this week Dr Keiji Fukuda is going to brief you on basically what has happened A(H1N1)-wise during the Assembly, more or less. Anyway, Dr Fukuda we will hand over to you in just a second to talk about A(H1N1). Thank you very much.

Dr Keiji Fukuda: Apologies, everybody for starting late. I have a little bit longer update than I normally give but we have not met for a week or so. What we have usually done in these updates on the H1N1 situation, is to go over where we are right now in terms of some of the numbers, I will give you a situation assessment and then go over a couple of issues which have come up over the past week, I think of interest to everybody and then we will just throw it open for questions as usual. As of this morning, we have 42 countries officially reporting these new H1N1 cases to WHO, and the number of officially laboratory-confirmed cases reported to WHO was 11 168 with 86 of those infected people dying.

We will continue to meet but one of the things I will point out is that as we go on into this situation, the numbers themselves will become a little bit more irrelevant. We now have countries that are moving away from counting cases individually because there are too many cases. So just to give you heads up, we will begin to de-emphasize the numbers because they will increasingly not reflect what is going on. In terms of some new information which has come out, there is a very nice article in the *WER*, the *Weekly Epidemiologic Record*, a WHO publication which summarizes the clinical information to date. This article provides an update on our understanding on the clinical symptoms and the clinical picture related to these new H1N1 cases.

The overall sense of the information is that it really supports much of the earlier impressions and ideas about this illness. Most of the cases that we are seeing continue to occur in younger people, i.e. people younger than 60 years of age. Most of the people who get infected by this virus develop a self-limited illness in which they do not need to go for hospitalization and they get better after some period of days. However, as we have noted from the very beginning, there continued to be a number of people who do develop serious illness. About half of these people - these are people who have to go to a hospital - but half of these people who are young and healthy with no underlying medical conditions and then, about half of these people are people who either have a condition like pregnancy or some

other chronic conditions, which can be illnesses such as diabetes or lung disease or some form of immunodeficiency and so on. This is in-keeping with what we have seen earlier. Among the people who have developed mild illness, again a substantial number of people - about a third of them - developed diarrhoea which is a little bit different from what we see with seasonal influenza. In the people who are getting hospitalized we do not see this occurring as often. The report - I will not go into the details -- but it also contains much more detailed information about laboratory findings in those things, which will be helpful for doctors. I think that this information will be useful for clinicians around the world.

Now, if we take a look at where we are right now in terms of the overall global picture, I think there are a couple of things that are very clear. One of them is that the situation in the global picture still continues to evolve. I know that there is much speculation in the media for example, that maybe things are over or in some countries it looks like things are going down. But really, from a global perspective and from what we are seeing, this is probably fairly early in the spread of this infection. It is clear that the global picture continues to evolve and we expect that, over the next several months, we will continue to see spread of this virus and an evolving picture of the epidemiology.

I think it is fair to say at this point that there appear to be about three different kinds of situations for countries related to this infection - three different pictures. We have one group of countries - and these are countries in North America predominantly - in which we see community transmission which is established. We have seen a widespread occurrence of the virus within these countries, we have seen a significant numbers of people with laboratory-confirmed infection. These are countries such as Mexico, the United States and Canada. Within these countries, we are now seeing an evolving picture: in some of the places, activity has been going down. This is a clear in places like Mexico City and then in other places we have seen activity go up and come down, such as New York City and then go up again. Over the past week or so, there have been renewed outbreaks in schools occurring at a much larger scale than was occurring initially when the virus entered into the city.

In another group of countries and these are some of the countries in Europe and this also includes some of the countries in Asia, such as Japan, we have kind of a mixed picture. We have some people who are infected through travel or through close contact with people who have been travelling, or we also see outbreaks occurring in institutions such as schools, and we are also beginning to see other people who are getting infected with no clear risk factors. This is another group of countries that are in a little bit of a different epidemiologic situation. However, in these countries, and we remain in very close contact with them, talking with them on a daily basis, we still do not see large scale community outbreaks, we do not see large numbers of people going to hospitals with illness consistent with this infection.

We then have a third group of countries in which most of the infections are still largely limited to people who have been travelling or in contact with travellers. So right now, in different countries, in different places of the world, we have different epidemiological situations.

And then finally, of course, there are numbers of countries that have had no infections at all, so no travellers or nobody within the population who had been infected. In terms of the Southern Hemisphere, all of you have seen that there have been more countries which have reported some infections but we still do not see large scale outbreaks occurring in communities in any of the countries in the Southern Hemisphere.

The bottom line, in this mixed picture right now, is that it emphasizes again that we are in an evolving situation, countries are in different places, but this picture will continually change over the next few to several months. We expect to see that infection will probably

continue to spread within countries and among the countries, and so I think that this is what we are thinking what will happen over the next period of time.

I think that there is a lot of speculation about what this means and I think it is very important to emphasize, as we have in the past, that when you are early in the spread of something like this around the world, you really have to keep an open mind. The picture is still evolving, we do not know what will happen later in the summer, we do not know what will happen in the fall time and as we have said on several occasions, we do not know what will happen if large outbreaks occur in some of the countries in the Southern Hemisphere.

For countries, this mixed picture has some very practical implications. And one of the implications is this: depending on the epidemiological situation where the focus of your surveillance might be, the focus of your control measures might be can differ. Again it emphasizes that in a very large world, that one size does not necessarily fit all. So in the countries with advanced spread of infection, it is now becoming very hard for them to count cases on a single basis. Some of the countries, such as the United States, are in fact moving away from large scale testing of cases and they will really be moving towards surveillance in which they are looking at: rates of illness, numbers of people appearing at doctors offices with illness with consistent with H1N1 infection, and they are really going to begin de-emphasizing, counting cases one by one.

This is a very practical issue, no country can keep up an intense amount of laboratory testing, all countries eventually run out of that capacity, but also the value of that information becomes less important. Once you know that it is there, it does make sense to move on to different kinds of surveillance. You can monitor what is going on in the country without over extending your resources. At the same time, what is important for these countries, is that when they do identify unusual occurrences - and there will probably be cases which are unusual, clinical cases, and there will probably be outbreaks, which are unusual - they still have to focus on those unusual cases and investigate them very intensively. This is how we are going to find out new patterns about this disease, this is how we are going to find out when the epidemiology is changing.

In those countries in which we see a mix of both travel-related cases and cases largely confined to institutions, such as schools, the important question then becomes: "Is the virus moving out into the community?" Again, we had mentioned that some of the countries are in this mix picture and it will be important for them to make sure that the surveillance systems are looking for that potential spread.

And then finally, for that larger group of countries, really the largest group of countries that either have no cases or have travel-related cases, the focus of surveillance is to detect whether new infections are coming into the country. I think that even in very technical matters, such as surveillance, this mix picture means that different countries are going to have to approach the situation differently. You will see that some countries will be looking at cases one way and some other countries will be looking for cases in another way, and it really is an adaptation to what is going on out there in the world, in what these countries are to be focusing on.

Over the past week in the time that we have not met, there has been a number of questions that have come up. One of these is related to vaccine, a lot of interest in where we are in the vaccine process. Just to go over some of the time frames and time expectations for this process, if we look at the development of vaccine - just the development of the vaccine as a product - by the end of this month, we are expecting and hopeful that the candidate viruses that can be sent to companies to be tested as vaccine viruses will be available. So we are hoping that these candidate viruses will be available to go to vaccine manufacturers pretty soon.

Once these vaccine manufacturers receive a candidate virus, they have to test the virus, see how it grows within their manufacturing systems. This still takes some weeks, they have to adjust and see if the growth of the virus is good, if the processing of the virus is good and so on. So this will add again some weeks of work on to that. If we put all of that together and sort of look at the kinds of work which has to be done, we are hopeful that by the end of June or beginning of July, this will be the time when commercial companies will be in the position of beginning to make H1N1 vaccine. So that is roughly the time frame that we are looking at over the next several weeks.

In addition to the processes, the technical processes for making the vaccine, there are some significant other processes going on in parallel. One of the big question coming up of course is that, once you can make the H1N1 vaccine should you make it, how much should you make, should you be making seasonal vaccine and so on, should you be making both and so these are difficult questions. As we have reported in some of the earlier press briefings, WHO has a process through its strategic advisory group known as SAGE to help answer some of these questions. This group has met already once, and one of the recommendations that they made is that during this time, while the vaccine development is going on for H1N1, that seasonal vaccine production should continue. This group is the group that we will ask to help advise on some of these other difficult issues, but we will hold off on making those decisions for a little while right now because what the decisions will reflect, such as the evolution of H1N1 activity, and really a process of trying to balance, what are the risks from seasonal influenza, first is the risk from this new H1N1 infection versus the risks of H5N1 infection, the avian flu out there.

Right now these are the kinds of questions and these are the risks that have to be balanced in order to decide how much vaccine should be made, which vaccine should be made. We are not at a time where we have to make these decisions yet, but that time will come and then these are some of the things that the committee will be asked to advise on, to think about and to wrestle with.

A third parallel process related to vaccines is very close contact between WHO and other public health agencies and with the private sector, with the vaccine manufacturers out there. One of the things we are simply trying to do is that in this kind of extraordinary situation, make sure that the public sector and the private sector are very well coordinated. So that they understand what are the priorities for the public health side and we understand what are the priorities and the realities for the private sector, for the manufacturers. This is where there has really been an extensive amount of discussion and collaborative work between vaccine manufacturers and public health. Earlier in this week, for example, the Secretary-General from the UN was here to address the CEOs of many of the influenza vaccine manufacturers to reach out as partners that this is a mutual endeavour.

In addition one of the things that we have tried to really get across is that from WHO's perspective to make sure that some vaccine is made available to the developing countries is a priority for WHO and these are some of the aspects of the discussions that we are holding with these companies.

A third issue that I wanted to talk about was the discussion about Phase 6. This was a very interesting week in terms of this issue. For those of you that were covering the World Health Assembly, I think that you know that the countries raised a question to WHO as to whether there could be flexibility in terms of the movement from Phase 5 to Phase 6. To put this request and to put this whole issue in context, I want to just step back for a second to make sure that everybody understands why did this even come up as an issue and what are the issues.

If we go back and look at the entire pandemic planning, pandemic preparedness process, which has been going on for the past few years, driven by concerns about avian influenza,

these so-called pandemic Phases have been part of that planning process. This entire planning process was really initiated to help countries develop their capacities, develop their preparations as much as possible so that in the advent of a pandemic they would be better off than they would be without that process. So the pandemic Phases are really a planning tool for countries and a way to alert them that there is a situation that they need to be aware of and as a tool to make sure that they understand as we go into different Phases, there are different actions which should be considered by them and some of them which should be taken by them.

At the WHA, what the countries raised was a concern and they said that currently the criteria from going to 5 to 6 are based on geographical spread, and this is true. When you look at the criteria for Phase 5, you will see that it focuses on community transmission in two countries in one geographical region and if you look at the criteria from going to Phase 6, it focuses on community transmission in another country in another region of the world. It really reflects a sense that the virus is spreading out in the world and is becoming established in different countries. These were the criteria which were developed by the scientists advising and working with WHO over the past couple of years and in a sense they were developed to provide very clear criteria about the evolution of a potential pandemic.

But what the countries have said is that we are in a situation that is different than the spread of H5N1. In fact most of the cases that we are seeing right now are clinically mild and we are not having the kind of high death rates that we might expect if we were to see an H5N1 pandemic. Moreover, what the countries said is that we are in this mixed situation and we are concerned that if we go to Phase 6 the message to our populations will be: "You should be very afraid", whereas in fact we think that it indicates that the virus is spreading out but the level of fear should not go up and there should not be an increase in anxiety. So, in taking these comments in from countries, what we did, what we thought about and what we discussed, is that right now, when we step back and say what is most important, the most important things are that, countries are as prepared as possible. This is a single most important action and this is a single biggest help that WHO can provide to countries.

And when we look and say: what are the actions that need to take place so that countries are as well off as they can be, in fact a number of these actions are already underway. Just to review for you quickly, I think that it is clear that all countries know that there is a new virus in the world which has the potential to cause a pandemic. I think that alert has been very successful and that is well-known. A second action taken by the countries and by WHO and a number of partners is to get information out to increase the communication. And this is well underway. There has probably been an unprecedented amount of information made available about the evolving picture, about the clinical findings, about scientific findings, than any other large scale outbreak in history.

A third action is that WHO asked countries to activate their Pandemic Preparedness Plans and overall when we look at the response to this situation compared to earlier outbreaks such as SARS, I think it is pretty clear that in fact the working on these plans and the activation of these plans has really led to remarkable level of communication and coordination among the countries. We have seen widespread sharing of viruses, we have seen immediate development work on vaccine start and so on and so these plans have been very helpful.

A fourth action that we have asked is for countries to take is appropriate control measures and again, you can see that a number of countries have done that, they have taken different actions to deal with infections going on in their country and to try to reduce that impact.

Finally there have been actions taken to increase the accessibility of important materials, such as vaccines and antiviral drugs. We have talked about this process about making vaccines available and this is underway at full scale speed. WHO has provided a number of

antivirals to many of the poorest countries in the world, the vaccine manufacturers is stepping up its productions. These are the critical actions, these are the things which really matter in this situation.

So, what we did is take these country comments under advisement for flexibility and the other thing that really struck us is that in the response to this situation, we have on a very frequent basis made a lot of course adjustments. We have come back to you and talked in earlier press conferences about how the spread of this has causes to rethink things through and that this is a different situation than the spread of a virus like H5N1. There has been a lot of work to make these course corrections.

The large lesson that we have learnt here is that the response to these kinds of situations really have to be flexible, they cannot be rigid according to pre-made plans and I think that the comments from the countries reflect their same assessment of the situation. We have to have some level of flexibility here. Taking all of this into consideration at the here and now I cannot tell you what the new criteria for Phase 6 are, but I can tell you that what we are looking for and what we will be looking for is something which are events which signify a really substantial increase in risk of harm to people

This is the sense of what Phase 6 is meant to convey and this is what we will be focussing on. This has been a very interesting request from countries, it has led to very intense discussions about what is the appropriate response to pandemic influenza at this stage and given this evolution. This really reflects where we are, right now, at this time.

But before we move down or move to questions and I close down, again I want to emphasize one point which is really important. From the outset of this whole episode with the situation, we have really emphasized that there is much that we do not understand and that much that we expect will evolve. And this is really true: we have pointed out how we are not quite sure what is going to happen in the Southern Hemisphere, we are not quite sure what is going to happen in the fall time, we do have concerns about the illness having more significant effects in those more vulnerable populations. We do know from the past that the effect of the virus can change over time and the bottom line here is that we are trying to walk a very fine line between not raising panic but also not becoming complacent and this is the fine line that I think countries have to walk, this is the fine line that public health has to walk in terms of dealing with this kind of situation.

DPA: Just two questions, just for clarifications. One on the sharing of the vaccines, we are getting some mixed messages: on the one hand the CBC is saying that they are sharing, on the other hand the American delegation to the Assembly was concerned about intellectual property issues. How is this, are you hearing anything like this, that there are some concerns over intellectual property regarding the creation of a vaccine? And you also said that it will take until end of June in order from the vaccine to go into production. How long would you then estimate it would take for this to actually roll out at a capacity that you would be happy with?

Dr Fukuda: I am not quite sure which IP issues you are referring to. With this H1N1 vaccine, there are a lot of efforts right now to develop the vaccine as quickly as possible. In terms of the candidate viruses, there are two ways in which the candidate viruses can be made. One of them is using what is called “classical reassortment” which has no ties to intellectual property issues at all. And then there is another process called “genetic reassortment technique” which is tied to intellectual property issues held by a company. But the governments themselves are making no claims on intellectual property for the vaccine and the focus of the work being done in the US, as I understand, is really to develop pilot lot of vaccine try to get some of the information that everybody is looking for right now which is information on the immunogenicity of the new H1N1 vaccines and on the safety

of this vaccines. Those studies really cannot begin until the vaccine itself is available and this is still going to have to wait for some weeks.

Now in terms how long will it take for the vaccine to be made available. Once a decision is made about how much vaccine can be made, one of the things we still do not understand right now is how much antigen you need in these vaccines in order for them to be immunogenic. We do not know whether it is the same that was done with the avian flu vaccines whether it would be closer to seasonal vaccines. So there are still some fundamental things that are not known until the trials can be started up.

John Cohen, Science Magazine: I think there is still a great deal of confusion about Phase 6. Are you saying that you are redefining Phase 6 to include severity? And let me put a fine point on it, if I might. Are you saying that if this were H5N1 at this moment, that the level of spread would lead you to declare Phase 6?

Dr Fukuda: I think that the fairest way to say this, because it is not clear to me, that severity is the only thing which would be considered in looking at what makes up Phase 6. I think that the larger concept is: what kinds of signals would be needed to tell you that the risk for people has really significantly gone up. This could be a change in the clinical severity. That could be a big impact. It could be other kinds of signals, such as what is the effect on countries in the Southern Hemisphere and so on, on a population level as opposed to a the clinical level for individuals. This is not decided yet but I would say that it is really an adjustment on our current concept of what is needed to go to Phase 6.

In terms of your other question about if this were H5N1 would we be at Phase 6, I think that even if it were H5N1, we would still be looking for clear evidence of widespread community outbreaks going on in countries in multiple regions. So this is still a situation that we have not seen yet. We know that there have been these outbreaks in schools, we know that there are some cases in which it is hard to find epidemiological links, but we have not seen the large scale kinds of outbreaks that we have seen in places such as Mexico and the United States and Canada. But I think that in many ways the distinction about going from Phase 5 to Phase 6 is important but really what is the most important, what is the real issue underneath here is, what is it that countries need to be doing now to be best prepared for what may come down the road and here we feel that many of the actions which should be taken are underway in many of the countries.

John Zaracostis: In follow-up to my colleague's question, you mention the possibility of vaccine production of H1N1 at the end of June or July. Would that be trial production or commercial level, because what about the human trials and the efficacy issues. Can you fast track them, we have heard that it takes 4-6 months before this process is done. Have you been able to short-circuit all that?

Dr Fukuda: At the end of this month - you know we talked about how the candidate viruses would become available and then it will take some time for the vaccine manufacturers to work with the viruses themselves. There are still some questions which are needed - to know what dosage level of the antigen, what is the potency level that would be needed to make an immunogenic vaccine and certainly safety will be very high on everybody's concerns. So there will need to be fast-tracking of some of these kinds of studies that will have to go on. These are some of the things which need to take place. At the same time, it may be possible to push ahead with some of the production of the vaccine. But it is certainly before you begin injecting people with vaccine, you want to know about some of these kinds of data and they will still have to be collected. They are not available right now.

Maria Cheng, AP: I have a couple of questions about Phase 6. Can you just clarify in light of these requests you have been getting from countries and the need for flexibility, is WHO right now re-writing its criteria for moving from Phase 5 to 6? And secondly, since we all know that influenza is so unpredictable, why were the old criteria so tied to H5N1, if all the experts knew it was possible there could be another strain that could cause a pandemic which would not be as deadly.

Dr Fukuda: I think that having finished the WHA today, we do have to sit down and think about the criteria. I think that the writing down of them is probably the easiest of the things to do. It is really to sit down and assess what sorts of indicators are needed to really go to Phase 6 in this kind of situation. In terms of the criteria themselves, I do not think that it is quite accurate that they were just tied to H5. But what really was the thinking during the process with the advisers was with the earlier versions of the criteria - the earlier versions really had a lot of things mixed into the criteria. They were quite confusing for people and difficult to interpret. A great deal of effort was put into making the criteria as clear and as understandable as possible, in a way that could be acted upon and measured as easily as possible. What has become clear is that it is not just the spread of the virus which is considered important by countries who really have to act upon the Phase changes, it is really the impact on the populations. It is this input that has to be taken in and considered in terms of the Phase 5 to Phase 6 change.

Emtiaz Diab: I want to ask about the number in the beginning and another question. You said there is 11168 cases and I think when quoted ten days ago, I asked the question, how many days the case infected to dies, I had been told in 6 days. That does mean those cases will die in 6 days? And I have another question about the pilgrim. Soon a big occasion in the Islamic world. Millions of people will go to the Saudi Arabia and that is a big danger. So are you thinking about that? We know that WHO negotiate at the moment with Saudi Arabia about this event and I would like to know your opinion about the danger of this amount of people who will be travelling.

Dr Fukuda: In terms of the first question, I want to emphasise that it is a small number of people that die from this infection. The vast majority of people develop in illness in which they will recover without needing to go to the hospital. Among those people who do develop a fatal illness, they generally end up going to the hospital in about a week or so, give and take some number of days. But the length of illness actually I do not think I can give you an average length of illness before people pass away. I don't know. Nikki is that available? The average length of illness before fatality?

Nikki Shindo: We only have data from hospitalized cases and that ranges from 1 day to 22 days. One of the cases was prolonged because of the ventilator support up to 30 to 40 days.

Dr Fukuda: So quite a wide range of days from the time that a person becomes infected to when they might die. And this again can depend on the kinds of complication that they develop. They do not necessarily die very quickly. Some of them may die quickly but others may die after some weeks after being in a hospital. In terms of your question about the Hajj, we are in discussions with the authorities in Saudi Arabia and there is recognition that the Hajj represents quite a unique event in which a very large number of people come together. This is under discussion with the authorities as to what steps might be taken to help reduce the chance of infection in that situation. I think that these discussions will continue over the next several weeks.

Diab: But what is your opinion as a specialist? As an expert?

Dr Fukuda: I think, it is a unique event. It is something that the health authorities in Saudi Arabia are very focussed on both this virus as well as the number of other infections in terms of how to protect the pilgrims who are coming to the Hajj. It is a difficult situation to think through and how to protect people in this kind of situation. But again we are under discussions with them about it.

Helen Branswell: I am going to ask two, if you don't mind. You mentioned the fact what is important at this point is that countries take the measure they need to be prepared. But I believe that some pandemic plans will have, or some pandemic vaccines contractors, will have rights on them that only taken when a pandemic is called. So if you do not move to 6 will countries and will vaccine makers make this vaccine in the scale that you are hoping they will make. That is my first question and my second question is, you said you were looking for widespread now, community spread of the disease. Some European countries including, I believe, the United Kingdom are using an algorithm or a testing protocol that specifically tell doctors not to test people if they do not have epidemiological link to a country where the disease is spreading like in Mexico and the United States or a confirmed or a probable case. With an algorithm like that you are never going to catch community spread. Is that appropriate at this point?

Dr Fukuda: In terms of the question about contracts, one of the lessons about the plans developed both by countries but also by WHO is that many of these plans were developed without any recent experience about pandemics. One of the key concept is that we have learned that we need to be flexible in their application. Certainly vaccine production can go ahead, whether there are contracts in place or not contracts in place, and I don't have significant concerns about that, I think it is really the evolving picture of the disease and decisions and recommendations made by the Advisory Groups to WHO and also to other national authorities which will really drive the vaccine process. I am not worried about the contracts in terms of slowing down vaccine production, but I think it is an important lesson to everybody in developing the plans they do need to be flexible.

In terms of the question about algorithms and finding cases, it is clear that what you are looking for at the beginning of an outbreak is different than you might be looking for later on the outbreak. In Europe much of the attention was spent on initially finding travel-related cases and so when you look at case definitions and so on being used by countries, it really reflect that emphasis. And more recently, number of questions have come up "Is that appropriate?" and what we have seen in these countries is that they are also greatly broadening the case definition so they are not restricted just to finding infections among travellers or close contacts. But another point that is important to make is that no matter what kind of case definitions you have out there, if you have large numbers of people who are getting sick, they will show up in hospitals and you will have these people being noticed at the same time. In a certain way it is probably a testament that if there are cases out there that are being missed, a lot of them are fairly mild cases and are not showing up in hospitals and are not showing up in physicians' offices. It's good - it's certainly the right time for the surveillance efforts to broaden out and to detect what may be going on in communities but I also think if they were significant numbers of severely ill people, these would be detected in hospitals with or without any case definitions - it wouldn't be dependent on that.

Hedayat Abdel Nabi, Kuwait News Agency: Can I go back to your comment on the impact on the population which is affecting to move to Phase 6. Would the impact include for example high death rates, inability of hospitals to cope with the numbers, insufficient medical supplies, no availability of the vaccine, would all these compounded together

would be factors affecting the population to move to Phase 6 regardless of the geographical spread?

Dr Fukuda: I think that these are some of the kinds of things that would look at for sure. To give you a good example, if the virus moves into the Southern Hemisphere and causes significant outbreaks in places such as Africa or South America and we see patterns which are different from what we are seeing in North America and that it appears clear that there is either a much more severe effect or there is a change in how the virus is behaving, these are the kinds of things which would signal that there is an increased risk for people getting harmed. And this is the kind of picture that we would be looking for, the kind of information that we would be looking for, and the kind of signal that countries would be expecting WHO to provide. That something is changing and that you really need to increase your state of alertness, your state of preparations, even to a higher level than it is now. I think it's a little bit early to give you exact words about what they might be, but I think that gives you the sense of what it is that would really be looked for to drive a message out that there is a significant increase in risk.

Takuya Arai, Kyodo News: I have two questions if I may. I understand that you decided to redefine the criteria from Phase 5 to Phase 6 after listening to the many countries' requests. On the other hand, I think you gave us a kind of impression that you changed the rule of the game in the middle of the game itself. Don't you think it does undermine the credibility of WHO's past decision? My second question is about the new criteria you are starting to consider. I think you don't have much time to do that. In what time line do you create the new criteria for Phase 6?

Dr Fukuda: First, we have to look and go back and say again "What is the intent of all of this?" Earlier on when I was talking - what is the value of these Phases, why are they even developed, why are they in place? Again, the big picture is that these kinds of tools are really there to help countries to prepare themselves, to provide alert, to get ready, to have some guidance that there is a time to take actions and then what sorts of actions should be taken. The criteria themselves developed under the guidance of a very large number of scientists from a very large number of countries over a significant period of time, led to the development of quite good criteria which are quite clear, but there is nothing like reality to really tell you whether something is working or not.

The purpose of WHO and the reason for WHO to exist is really to help people be protected. That is the bottom line and so rigidly adhering to something which is not proving to be useful in fact would not be very helpful to anybody. What we are trying to do here is to not change the rules but really to adapt to what is the situation, to really ask ourselves what is going to be most helpful for countries. I think the guidance provided by the countries in the WHA was extremely useful, very timely, and so we have taken that under advisement.

In terms of the timeline, I cannot give you an exact timeline. You know this is something which is obviously caught everybody's attention including our attention and we will think this through and we will try to get this right.

Gabriela Sotomayor, Notimex: It is just a clarification in this context could you define severity? Is it the dead people in the hospital?

Dr Fukuda: One of the interesting things about the discussions related to Phases had exactly to do with that issue: "What does severity mean?" Many people assume that severity simply mean how many people die versus people who are infected. When you talk about pandemic, people usually focus on: this many people die, this percentage of people die among the people who are infected and so on. In fact, I think that there are a lot of

different aspects to criteria. That is one of them. How often people develop severe illness or how often people develop die from an infection. But there are other aspects. From earlier pandemic examples, we know that younger people are often affected at much higher rates than they normally would be from seasonal influenza. Besides that in some groups, such as pregnant women, back in 1980 pregnant women were about the highest risk groups who were dying from the pandemic influenza. It highlighted that there are certain groups that were at risk. Some times with other influenza infections we have seen that children develop unusual complications.

All of these things will certainly go into an assessment of what is severity. You know if you see certain groups of people who are disproportionately developing something quite serious then this would be important. But also on the level of populations, we know, what is the impact on the population itself. There are very large groups of people out there if you take many people who are malnourished, many people who have HIV infections, this is having a particular impact in the whole population on that group of people. Are things causing hospital and medical systems could not be able to function - these are different kinds of aspects of severity. It really depends on how you look at it. But I think all of these things go into to the ideas of severity.