Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

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Gregory Hartl: Welcome to the WHO 5 o'clock virtual press briefing. Starting today, Tuesday 26 May, we will now hold these briefings once a week on Tuesdays at 5 o'clock. I would now like to hand over to Dr Keiji Fukuda.

Dr Keiji Fukuda: Thanks Gregory, again welcome everybody, thank you for coming. As usual, I will just go over a brief update and then I want to discuss one topic and we will throw it open for questions.

As of this morning, 6 o'clock in Geneva, we had 12 954 cases officially reported to WHO and these came from 46 countries. The issue that I wanted to talk about was something that we began discussing on Friday and this is about the Phase changes. Over the weekend there have been a lot of questions from some of you and still a number of issues that are of interest to people and I think it is worth talking about.

To go back, we are currently in pandemic alert Phase 5 and there has been a lot of discussion about what it is that would take us to pandemic alert Phase 6. As we talked about on Friday, one of the important things to remember about the Phases is that these were developed as planning tools to help countries in their efforts to prepare against pandemic influenza, so they came out with the *Pandemic Preparedness Guidance*. As you all know, over the last few years, we have been working with the development of these Guidelines in the shadow of avian influenza H5N1, which is a virus that has been extraordinarily lethal. This is really the background for the Phases.

The other important background that has occurred more recently is – before we had the World Health Assembly – there was a meeting in Asia, the ASEAN+3 meeting, and as part of that meeting, one of the requests from the meeting was for WHO to look at what the criteria were for going to Phase 6, and then to see whether the criteria should be adjusted. This was an official request coming out of that meeting. In addition, at the World Health Assembly there were a number of countries that also made a similar request to WHO: to take a look at the criteria and see whether they needed to be adjusted.

Again since these are tools – the Phases are tools really to help countries in their efforts to be ready for pandemic influenza – these were interventions that we took very seriously. This is one of the things that we talked about on Friday: about how we are now looking at, how we might adjust the Phases, a lot of questions about what would these adjustments be, why would we make such adjustments and so on. When we look at the current Phases – the definition for Phase 6 – right now you see it is very clear. It simply says that you have community level transmission in a country outside of the region in which we are seeing

transmission going on right now at the community level. This would mean a country outside of North America and that is basically what the current criteria calls for. But the whole A(H1N1) – or the spread of this virus – has really highlighted the fact that this is a very different situation than with H5N1, or avian influenza.

Really, two of the things that we are looking at in depth after the interventions from the countries is: what level of community spread really indicates that you have spread in the community. In addition, there are a lot of questions from countries about severity – does the impact on the country, does the impact on people make a difference in terms of going up to the Phase. These are two of the issues we are really looking at right now.

In the current situation, we can clearly see that the A(H1N1) virus is spreading. We have seen that, in Europe, it has moved to a number of countries through travellers. There has been a lot of attention paid to some of the countries such as the UK, such as Spain, and then in Asia, we have seen that there has been a lot of attention paid to outbreaks going on in Japan. Then, more recently, we have seen increasing numbers of cases reported from some of the countries in the southern hemisphere but in relatively small numbers and often associated with travellers. Then we have the situation in the United States, Canada and Mexico where we really see what established community transmission really means. We have big outbreaks in big cities, we have virus spreading through the countries, spreading through provinces and spreading through states. Somewhat of a different situation than we see in any other country right now.

The other question that has come to WHO is: "Is severity important?" Of course severity is important. The whole reason why we take action against diseases is because they harm people. If diseases are relatively mild, like colds, then we take certain kinds of precautions, if diseases are very severe, such as avian influenza or HIV, then we take another level of precautions. Clearly severity is an important concept for public health and how we deal with these issues. But it is also clear that what is severe in one country is not necessarily severe in another country. This is one of the lessons that we have learned from many outbreaks, certainly one of the lessons from influenza.

In addition, when we talk about severity, it can mean different things to different people. For example, there is definitely clinical severity. If a person gets infected, do they just develop some symptoms and then get better, or do they end up in a hospital, do they die from the infection, or do they end up on a respirator? These are important questions at the clinical level. For countries, we can see that if there are a lot of sick people getting ill at the same time, hospital systems can be overrun, cities can ground to a halt for periods of time – and we saw that with SARS in some cities.

There is also severity at social level and national level, in addition to personal level. But capturing this is really a very difficult activity to do. How do you capture severity so that it is relevant for all countries, at the same time? This is a very difficult concept to capture. Nonetheless, the interventions from countries at both the ASEAN+3 meeting and the World Health Assembly were really things that should be taken into consideration. Currently what we are doing at WHO is trying to take a look at the interventions, trying to see what kinds of adjustments might be made to make sure that the definitions really meet the situation.

To do this, we will be asking a number of prominent scientists and people who really have a good perspective on the issues, to help us think this through. That is where we are right now in terms of the issues related to the pandemic Phases. I hope that it is clear. If it is not clear, please ask me any questions and I will try to clarify.

The other point that I wanted to make is that – and this is maybe the most important point of all – in all these discussions about the Phases, these are of course important questions, important issues, but the single most important question though is: "The public health actions that need to be taken, are they being taken right now?" That is more important than

any definition, that is more important than any of the discussions. And here the Director-General has been really very adamant, pushing very hard all through the response over the past four weeks or so, that those actions which have to be taken, which should be taken, are taken. I think this is one of the other really important facets. That is what allows us to have this kind of discussion at this time because we are comfortable that the countries are doing the public health actions that they need to be taking right now. With that, let me throw it open to questions.

Helen Branswell: Could you please sort of flesh out a bit the process that you are going to use to reconfigure Phase 6. You said that you are going to be asking prominent scientists. Are you drawing them together in a meeting, is there a time frame, who will be involved, how are you going to do that please?

Dr Fukuda: What we will be doing is drawing together a group of scientists and public health people. We would like to do this relatively sooner than later, hopefully within the next few weeks. What we probably try to do is to convene this group of people by video conference and by telephone, to do this electronically which will be the quickest way to do it. We will try to get a group of scientists and public health people with a wide range of opinions and views on what is the right way to approach defining this kind of Phase, in this sort of situation.

David Brown, The Washington Post: I wish if you could address the question of why there seems to be so much reluctance on going to Phase 6. It is a very clear definition. The point was made, you know, long ago that it does not measure severity. What is to be lost by saying that it is community spreading, in the community and more than one place – which is obviously is – more than one region, we are going to go to Phase 6 and it is a mild Phase 6. Why not just bite the bullet?

Dr Fukuda: The answer to that is really almost another question which is: “What is to be gained by going to another Phase?" Again when we went from Phase 3 to 4, 4 to 5, the real gains for countries by doing that in terms of focussing attention, in terms of implementing actions, in terms of bringing in resources, and really focussing everybody’s attention on what had to be done. Right now, when we look at the request: “Why cannot WHO look at going to Phase 6” coming from the countries, there are couple of concerns here. One of them is that in many of the countries they do not see H1 activity going on, and in those countries with the few cases, things are relatively mild. And so, behind that question is the sense that many countries are already doing the things that are necessary right now to address the situation. But if you go and declare Phase 6 without very clear evidence that there is a sort of change in the global situation, it can lead to extra work for countries without much gain, it can lead to some level of panic, it can lead to some level of cynicism that something is being declared but which is not usefully producing something in terms of public health benefit and gain. These are some of the considerations that countries are wrestling with and conveying that to us and these are some of the things we are wrestling with. I guess that is the answer to your question.

Mr Gregory Hart: Dr Fukuda, thank you. Can I remind those who are listening on line that if they would like a question they should dial 01 on their keypad. So the next question from on line is Martin [unintelligible], Science Magazine. Go ahead please.

Martin, Science Magazine: I am a little bit confused. I think that WHO has always made it clear that epidemic could be mild and it did not have to be a devastating one. So why was

not the whole issue of severity never integrated into an alert system? Is that just an oversight or it just did not occur to people? What was the thinking behind the system when it was designed?

Dr Fukuda: The Phases themselves as planning tools have been around for quite a long time. If you go back to the first *Pandemic Planning Guidance* which is several years ago, and the second version which I think came out in 2005, and you look at the version on the board now, you will see that they have evolved, and the way that they have evolved is that they have become in many ways simpler. The earlier versions of the pandemic preparedness Phases in fact incorporated a number of different concepts such as, the evolution of the viruses, transmission, severity, and so on. Much of the feedback, when we were going through the revision process was that the older pandemic Phases are too confusing. They have too many concepts in them, too many ideas in them and that they should be more straightforward and simpler and easier to apply. The most recent version of the pandemic Phases meet those criteria. They are much easier, they are simpler to understand, but like so many things, when you are really addressing a real situation as opposed to having discussions, what we have found is that they probably do not adequately capture all of the concerns of countries. And that is really what we are hearing now with the comments that came in over the past few days or so. That is what we now are trying to revisit and try to understand. How do we capture those things which are really important for countries at this time?

Japan: Can you tell me about the situation of the recommendation for the vaccine manufacturers? When will you issue the recommendation and in what process are you in?

Dr Fukuda: Currently we are in the process of developing the candidate viruses and these are the viruses that will be made available to the companies. Once the companies receive those viruses, they must test them out in their different processes to see how well they can make vaccines out of these candidate viruses. Then, once that process is over, the companies are in the position to begin to make A(H1N1) vaccines to this new virus. This is still some weeks away and so this is probably not going to be possible until about the end of June or the beginning of July – something in that time period. At that time, that we will need to begin making recommendations to the manufacturers about influenza vaccine. But we do not want to make recommendations too early because we are on a daily basis monitoring on how the situation is evolving, and depending on the situation, this would definitely have some impact on what the recommendations would be. The recommendations themselves will be deliberated by an advisory group the so-called SAGE Group, augmented by other people and other committees helping with those deliberations. That is where are right now. I do want to point out that once vaccine is made, then there till needs to be a number of studies which will be done to quickly get a sense of how immunogenic are the vaccines and to quickly take a look at safety issues and so on.

Maria Cheng, AP: I have sort of follow up to Helen's question earlier. This consultation that you mentioned that is going to take place in the next few weeks, does that essentially mean we are going to be in a holding pattern until that happens to determine whether or not we are going to switch Phases? When we are looking at the situation around the world, as you mentioned Japan has 350 cases and if the UK and other countries in Europe start reporting you might see community transmission. So what will you do when you hit that point?

Dr Fukuda: I am not sure that I can tell you exactly, but, for example if in another countries such as Japan or somewhere in Europe or somewhere in the southern hemisphere we begin to see activities which looks very much like Mexico or the United States – very

large spread, very large outbreaks, with very large numbers of people then, you know, I think that this in and of itself could well be enough to take us up to pandemic Phase 6. But we will try to get the input in from the scientists to help us deliberate this through as quickly as we can. I cannot exactly foresee the events over the next, you know, few weeks or so.

Donald McNeil: I wanted to follow up on David Brown's question. He asked, I thought sensibly, why not bite the bullet and raise it to level 6 if it meets level 6. The response was: what is the gain, this could be the panic, this could be the cynicism, but isn't that the other danger is that if WHO changes its rules in the middle of the game, and appears to bend with the political pressure, that you create cynicism as well. If it looks like WHO will bend with the political pressure then it might do it with another public health crisis and there is a loss of confidence in WHO. There are other times when this question has been raised, for instance, when there might have been room for criticism with China doing during its silence in the early days of the SARS crisis, there might be criticism now with Indonesia for withholding viral samples. Isn't it important for WHO to maintain its credibility by sticking to its rules when it sets them?

Dr Fukuda: I think that there are clearly a number of issues in balance here, but among all of them, probably the single most important one is: "What actions can be taken, should be taken that are going to help people? What actions are going to make people safer, what actions are going to reduce the chances of harm?" When we go back and look at the current situation and also when we look at past situations that have been very difficult – and one of the most famous one was back in 1976 when we had the [unintelligible] swine flu influenza – when we go back to that event, one of the overall big lesson, perhaps the single biggest lesson from that whole episode is: "Take stock, take a look at what the reality is saying and do not put yourself in a hole and just leave yourself there". You need to take stock of actions over and over again. In this situation here, we have a situation where we have a virus spreading which is significantly different than avian influenza, significantly different than H5N1, we have a situation in which countries are saying ""We want you to take a look at these criteria because if you apply then in the wrong way, they may not help us. In fact, they may cause more difficulties."

When we look at those issues and when we look at the complexities of severity, and the complexities of defining trigger points for moving up, then it seems like it is a reasonable thing to take stock, take a look at the situation and say "really, what is the best way to proceed here." It would be possible to simply say, well, because something is written down, we need to just follow those, that is the most important principle. But really if you take the perspective that the bottom line is what is it that we are going to do which is going to be helpful for people, which is going to be helpful for countries, then I think, hopefully, it puts it more in perspective of why we are looking at this so seriously. Why we are considering what is important in moving up.

Izumi, Japanese Television: I would like to know about needs of developing countries for preparedness apart from medicines or vaccines, maybe they have special needs to be prepared.

Dr Fukuda: In most respects the needs of developing countries are exactly the same as they are for developed countries. In these kinds of situation what countries need and what they want is the ability to monitor what is going on in their countries: "Do we have the infection in that country, what is the level of the level of activity, are people getting more sick or things getting better?" So I think that these are basic capacities and to be able to do that, you know, you need laboratory capacities, you need epidemiologists, you need the

training for those kinds of things, you need to have the ability to develop and apply control measures that are really appropriate for this situation. And many things like good communication skills and then in addition access to a variety of materials, such as vaccines and antivirals. In this respect, basically all countries are the same, all countries need the same things and they want the same things. What distinguishes the developing countries is that they often have fewer resources to get those and they have less of an ability to get access. Here, WHO and many partners in the developed countries have a big role to try to play in meeting some of those gaps in the developing countries. But there are a lot of basic capacities that all countries need, including the developing countries.

Question: This capacity building must take a long time and it must be very difficult. And people can get sick, they don't go to hospitals. Maybe they have much severe symptoms when they get to the hospitals. Maybe at the level of hospitals, they can have, I don't know something specific for these people?

Dr Fukuda: Yes, capacity building is really a very, very long-term activity. And it is not something that you can do in a few years. But on the other hand, this kind of activity has been going on for a long time. If you look at some areas which did not have laboratories in the past for influenza, there are now many more laboratories in the world that can diagnose influenza viruses. There has been a lot of experience over the last few years in terms of pandemic preparedness planning and this has been a huge help, both in the developing world as well as in the developed world. We see communications are much better, we see that countries immediately understand some of the issues about control measures, such as social distancing, isolation of patients. There has been a lot of discussion in planning – which is part of basic capacity building – which has gone on and which has been really very helpful. I think we are much better off now than we would have been if this had happened, five years ago or ten years ago. Nonetheless, certainly things like medical services in poor countries could be strengthened, they could be helped and these are clear gaps and we need to keep working on them.

Richard Knox, NPR: Thinking ahead, not too far, but over the summer and early fall as the vaccine production machinery cranks up and presumably will go forward to good significant degree and if we still have a lot of ambiguity about what the virus is doing and might do, I am wondering what you are planning to spell out in advance some of the criteria by which you would decide whether to deploy vaccine or not in the northern hemisphere fall, or whether you – especially in light of this past difficulty with phasing – would tentatively leave that as an ad hoc question

Dr Fukuda: No, it will not be left as an ad hoc question. What to do about vaccine production is clearly a critical component for responding to something like the current A(H1N1) situation. And particularly if things turn more severe rather in the southern hemisphere or in the fall time, but it is going to be a very difficult and complicated discussion if the situation remains as it does at the time when decisions have to be made. The way WHO typically works on this sort of situation, is that we do collect together or have advisory committee, SAGE committee is the group which usually advises WHO on immunization practices. In this instance we have augmented that group with additional members from other committees because the issues are particularly difficult. What we will do is to pose these questions to the committee and the committee will deliberate them and they will be asked to provide advice to the Director-General. This is how we will address this questions.

Jon Cohen, Science magazine: Leaving aside the Phase question, is it appropriate for the media to refer to this as a pandemic, and if it is not, what is your definition of the word "pandemic"?

Dr Fukuda: An easy way to think about pandemic – and actually a way I have some times described in the past – is to say: a pandemic is a global outbreak. Then you might ask yourself: "What is a global outbreak"? Global outbreak means that we see both spread of the agent – and in this case we see this new A(H1N1) virus to most parts of the world – and then we see disease activities in addition to the spread of the virus. Right now, it would be fair to say that we have an evolving situation in which a new influenza virus is clearly spreading, but it has not reached all parts of the world and it has not established community activity in all parts of the world. It is quite possible that it will continue to spread and it will establish itself in many other countries and multiple regions, at which time it will be fair to call it a pandemic at that point. But right now, we are really in the early part of the evolution of the spread of this virus and we will see where it goes.

Steve, USA Today: I want to ask about surveillance in Latin American countries. What sorts of mechanisms are in place and how confident are you that we have a clear picture of what is happening down there?

Dr Fukuda: Surveillance in Latin America and in the southern hemisphere, like it is in the northern hemisphere, is variable from country to country. So some countries have greater capacities, and others have fewer resources or do not have a good surveillance, but in general, we have enough good surveillance in enough countries and that if it is moving into a region, it will get detected. There are a number of surveillance systems that look at ill people going to hospitals, there are a number of good laboratories that can test specimens from these people and the bottom line is that, even in areas in which you do not have really good surveillance, when you start having large number of people becoming quite sick and going to hospitals, that gets noticed, independent of formal surveillance systems or not. The global awareness of the spread of this virus is pretty good. Countries are looking for it in their countries, and I am pretty confident that if the virus is moving out in a number of countries in the southern hemisphere that we will be able to pick it up.

Betty, The Wall Street Journal: Am wondering if the early tests all pan out well and things were going ahead. If you can provide something like a time-table, when do you think WHO and advisory committees will meet, when do you think some of these decisions will be made and when a vaccine likely will be ready given that it takes some time to produce?

Dr Fukuda: Just to go over the timeline that I mentioned a little while ago, we are now in the process of the most basic development of the vaccine, which is the development of the candidate virus and getting the candidate viruses and reagents to the vaccine manufacturer for them to test them out and to see whether they can develop vaccines out of the available candidate viruses. That group of activities will take us up probably through the end of June, beginning of July. That is the projected timeframe right now, and it is at that point that the companies will be in a position to begin developing vaccine. There will need to be still testing of the vaccine for immunogenicity, looking at safety and those sorts of issues, but from that point onwards it can go into production. Giving some indications from WHO in terms of A(H1N1) production will be important some time during the summer. Right now, I cannot be much more precise than that. We are in pretty close contact with the companies, trying to look at where they are, as well as being in close contact with our Collaborating Centres and the regulatory agencies to figure out where everybody is. And at some point we will need to reconvene the SAGE committee. They have already been convened once, they

have provided one set of recommendations which are being acted upon now, but then they will have to be reconvened to help provide additional recommendations.

Helen Branswell: If you could explain something to us more clearly because I think there is a lot of confusion and I certainly share it. You are talking about the Phases as a tool and about how they are designed to be helpful to countries and how, actions are taken accordingly. But at the end of that scale, there is an event and there is a pandemic. Most of us are seeing that as a biological entity not a tool, not something that can be redefined. I am hoping that you could explain to us how you feel comfortable putting off the declaration of a pandemic at this point.

Dr Fukuda: If you look at the tools in the context in which they are provided in the overall *Pandemic Preparedness Guidance*, they do not stand alone. Where they are, they stand as a framework for countries to look at, in which there are a number of associated and recommended actions for countries to consider. When we look at the pandemic Phases, in a sense, what they do is to provide some sense of the spread of the virus, but they are clearly not an epidemiological description. If we were purely looking at the epidemiological description of the spread of these viruses, we could go over country by country and say where the spread is. They are also a tool that helps countries organize their thinking in terms of what sort of actions might be contemplated or might be acted upon at a certain point, and they also provide a certain kind of alert.

If you go from Phase 3 to Phase 4 to Phase 5 to Phase 6, it certainly conveys to countries that it is important for them to look at their plans, important for them to dust off certain actions and take certain actions. These are all public health tools, they are way of communicating with countries in a somewhat organized way about what their level of concern is, what their level of action should be. It is not primarily an epidemiological description. It is maybe a little bit confusing for people, but the intent of the Phases – and the Phases could have been worded in a number of different ways – they are plastic in that regard, they were really developed so that they could provide guidance to countries. If you are talking about natural laws, natural physical laws you cannot word them in too many ways, otherwise they are no longer a law, but these kind of things such as pandemic Phases are intended to help countries That is the fundamental issue that we are wrestling right now: how do we configure these tools so that it is most helpful for countries to deal with this current situation, and hopefully this will lessen some of the confusion.

Gabriella Sotomayor, Notimex: If the outbreak in other countries remains mild, but if the situation continues to evolve in North America or if it turns more severe for any reason, will WHO raise any kind of special alert for that particular zone, something like that?

Dr Fukuda: Right now, WHO has no specific plan to raise an alert for one region or another. The Phases, for example, are really intended to give alert to all countries around the world, a global alert about recommended actions and assessment of where we are. But clearly if the disease were to become significantly worse in one of the affected country, this is the information that we would get out to other countries as quickly as we could. This would clearly have implications for them about how they might think about what they should be doing in their countries. This is a little bit independent of Phases or alerts, but it would be critical information, and yes, we would definitely get it out to all countries as quickly as we could.