



**Transcript of press briefing at WHO headquarters, Geneva
Dr Harvey Fineberg, Chair, IHR Review Committee**

14 April 2010

Harvey Fineberg:

Good afternoon everyone. I am Harvey Fineberg, I am the chair of the Review Committee to review the IHR and the H1N1 pandemic experience here at the World Health Organization. I am very pleased to have this opportunity to meet with you at the conclusion of the first meeting of the committee. I expect some of you, perhaps all of you, were able to sit in on portions, if not all of the deliberations over the last three days.

So I will not try to recount the experience on the assumption that you have witnessed it yourselves. If that is not a good assumption, since I can barely see over the railing to identify who is there, please let me know. Is that a bad assumption? Maybe if the others, with your forbearance then, let me just take a minute to describe what the committee's role is and what we are trying to accomplish.

The committee is made up of 29 individuals who were chosen to represent a spectrum of expertise, a variety of backgrounds and experience, a range of countries and regions of the WHO represented, balanced in gender and racial composition, all brought together for a purpose of improving the World Health Organization's, indeed the world's ability to contend with pandemics like the H1N1 in the future, and to improve the functioning of the International Health Regulations.

The International Health Regulations of 2005 called for a review in five years time, of how well they were working. So the committee was convened in part to fulfil that requirement of the International Health Regulations.

Since over the last year and a half, the experience of the H1N1 has been so important and indeed represents a kind of powerful test of the workings of the IHR, the Director-General, with the approval of the Executive Board of the World Health Assembly, elected to combine a committee's function to review both IHR in general, and the performance of the World Health Organization in H1N1.

This three-day meeting was a first effort of the committee to organize its work, to begin to identify the critical issues that would need to be looked into. The meeting had some unusual features for an expert review committee, which legally we are. One of the striking features which indeed is called for in the IHR regulations is that Member States' representatives and representatives of intergovernmental organizations and non-governmental organizations are invited to be present at the deliberations of the Review Committee. And so these last three days, we benefited and interacted from the members of the state parties who were present, who offered their views, who reacted to the deliberations and provided a very important sounding board and set of witnesses for the work of the committee. In the end, it will be the committee's task to present a report to the Director-General, and the Director-General in turn will provide her response to the report, and the two ultimately will be presented to the World Health Assembly, as called for in the IHR regulations.

Our plan is to present an interim report, essentially outlining the approach we intend to take, at the May 2010 World Health Assembly, and if the committee is able to complete its task in a timely way, the report should then, in a final form, ultimately be presented to the World Health Assembly of 2011.

The Director-General, in her charge to the committee, made clear that the committee will have free access to individuals working at the WHO, ready access to all documentation that the committee may wish to examine in relation to H1N1 or the International Health Regulations, will have a complete freedom of enquiry in terms of the areas it wishes to examine, the people it wishes to interview or to hear from, and the topics it chooses ultimately to draw conclusions upon and make recommendations about.

The committee is brought together as a group of individuals not representing any organization, not representing any state, but representing each individual's own best judgment to apply to the questions that we have been asked.

I am here because I was elected by the committee to be its chair, and I look forward in that role to working with you and the press and others in the media who will be interested and wish to follow the work of the committee and to be informed from time to time on any questions that you have in mind about what we are doing and how we are going about it.

So, with that background, let me pause and invite any questions that you may have, and I look forward to talking with you.

If you wouldn't mind, it would help me — although I have met a few of you, I have not met all of you —, and it would be a help to me if you wouldn't mind just introducing yourselves, although I presume most of you know all of the rest of you here... but I am the one who does not, so if you will bear with me and introduced yourselves, I would be grateful.

Frank Jordans, AP:

You stressed the fact that the committee members who are here as individuals, and indeed got the chance, spoke of the need for an independent and critical review, but I was wondering — if several of the members are advisors to WHO and most of them are government employees of some capacity, what stake will these people have in practice to write something that is critical and independent when they have such a close relationship with the people that they are scrutinizing?

And a quick, specific question: How many of the panel members were involved, in any way, in drawing out what is known as the pandemic phase alerts scale?

Harvey Fineberg:

I can respond quickly to the specific, and then come back to the very important general question.

I do not know if any was, or how many may have been. But it illustrates, really, in a specific way, the more general point that you are raising about the backgrounds and potential sources of, let us call it, extraneous influence on the independent and objective judgment of any individual involved in an exercise such as this.

Whenever you are putting together an expert group like this, you are always trying to combine people who are unconflicted with people who are knowledgeable. That is, you want each individual to be free of conflict and also to be very knowledgeable about the subject on which they are advising.

In this regard, I think it is useful to distinguish a conflict which emanates from a financial interest which is, in terms I would use, a conflict of interest — by that, I mean that the individual might hold an interest in a company that might benefit or suffer depending on what is decided or have some other financial stake in the outcome.

As a general rule, it is, I think, good practice — and I believe it is the WHO practice, as far as I understand it — to try to eliminate those types of financial conflicts in the composition of expert

committees. When it comes to the positions of individuals, the roles they have, the appointments they may have had in the past, the views that they have previously expressed, the research they may have done, the involvements they may have had — all of these can be relevant and may be sources of what I would describe, in my terms, as bias, by which I mean not an erroneous view, distorted; I mean simply a preceding predisposition based on your experience and knowledge to think a particular way about the question. So, when you compare that to the ideal of an open-minded, unconflicted, unbiased involvement, you have to face the reality that to get the expertise that you want, you have also the possibility — indeed, I would say the usual occurrence — of people with pre-formed views or roles that were related. So the practical question now, to come to your first point, what do you do about that?

And I think the answer is two-fold:

Number 1, you want to expose and make open the biases, so that everyone on the committee as well as others know about the backgrounds, the roles, the previously expressed views, the relevant positions that may have been taken by members.

And secondly, where it may come to the committee's making determinations on matters that specifically relate to the role a member, knowing and having exposed these biases, you can take the step of recusing that member, or members, from the part of the deliberations that relate to their functions. And for us as a committee, we are actually still in the process of identifying all the possible sources of bias — this is a committee that is composed of individuals who have done a lot of things related to public health and including influenza and have, as you point out, positions in government, or had positions in government — and so we are still in the process of gathering this information about the members and our intent is to be able to review that with the committee, so that everyone on the committee is informed about those backgrounds and that we are all more sensitized as individuals to the connection between our previous positions or views and the work that the committee will undertake. So that is the two-part approach: exposure and specific-instant recusal.

Lisa Schlein, VOA:

I would like to get a sense of how the discussions went over the three-day period, whether you spoke about H1N1 in rather general terms or whether you were rather more specific in terms of the areas that you should really deal with first.

In other words, did you also give people home work, when they go home and do this? And one more thing, whether there was any kind of a separation made between the way H1N1 is occurring in developed and in developing countries because maybe the virus is the same but the effect is different.

Harvey Fineberg:

Let me give you a little more flesh on the bones of the work of the last three days, just to help on the first question.

The committee, as a whole, took advantage of the presence of the Member States to invite them early to offer their perspective on the questions that we were being asked to consider. And these presentations — which were verbally just a few minutes a piece, but can be supplemented by documents and other materials that they will send — helped to highlight a number of issues that the Members States consider important. For example, it was very important to recognize the challenge of containment as a strategy early in the epidemic. That was one of the points they raised. They raised questions about the characterization of the pandemic phases, and specifically, how the question of severity relates to the definition of phases.

They talked about the challenge of equity, which relates to your third question, and the expression of this epidemic in developing as well as in more developed countries. So that helps set the stage and identify a number of critical problems that the committee will need to deliberate on over time.

The committee then organized its work and the bulk of the days according to five areas, three of which dealt specifically with, if you will, aspects or phasing of the pandemic — the first being the preparedness phase, the pre-pandemic issues; the second being what we called in shorthand, the alert phase — that is, everything that leads up through the epidemiology analysis and decision-making to recognition of what is happening. And the third, the response phase, how you respond to the epidemic in its various stages.

A fourth group really dealt with the cross-cutting issue which is central indeed to our conversation, which is communication. And communication we understood and took to be very broad — not simply between the experts and the public, or an organization and the public, but communication at all levels: The communication from world headquarters to regional headquarters, to states; the communication to professionals and to others involved; communication and working relations with the media at all levels. So these occupied a specific portion of our time.

And finally, we did want to attend particularly to the IHR as an important part of our work, the IHR — the International Health Regulations, you are all familiar with that shorthand, I trust... but the International Health Regulations as a topic in itself particularly as it relates to non-pandemic questions.

So these five, if you will, sub-groups occupied a significant portion of our effort. In addition, we had the opportunity to hear some very useful initial presentations from critical areas that we know will be of concern.

Beyond the original overview that was provided by officials of WHO and the legal structures of what we are doing and the overall experience with the pandemic, we had specific presentations on the role and workings of the emergency committee, which is the committee charged with the decision-making or recommendations to the DG about the scale and characterization of the epidemic. And we heard very useful presentations on the vaccine programme of WHO and particular reference to the H1N1 pandemic and the programme of advice on the vaccine area, with the committee that has got the acronym of SAGE. SAGE is a wonderful acronym, I think, maybe the best.

So we took all of that on board. We reflected on how we will proceed in the bulk of our work, and this is where your homework question comes in — it is not just that the staff here have to get home to do the homework, it is that we will probably never let them get home with the amount that we are asking them to do in helping us to prepare and move forward in the next phase of our work.

But in answer to your question, that is how we organized and delved into the questions in these initial three days.

(Name unclear), Kyoto News, Japan:

I actually have two questions, both related.

A lot of the discussions you had the last few days seemed quite centred on, not so much the IHR, but the pandemic preparedness plan. So I would like to know, will your committee be reviewing the pandemic preparedness plan?

And the second is, should this happen? Part of the discussions were on the questions of including severity; as I understood is mortality no more included in the definitions of a pandemic.

Now in the 1999 and 2005 pandemic preparedness plans, severity, mortality, morbidity is clearly part of the definition of a pandemic. This was removed in the 2007 and 2009 plan. So should we understand that the removal of severity was a mistake? Thank you.

Harvey Fineberg:

You should not understand that from me.

We have drawn no conclusions yet, and the committee's job will be to look at this as well as other aspects of the H1N1 management. But I would stress that what we have done in these first three days is to, in effect, tee up the problems — identify them, characterize them, develop a plan of work. But we have not tried even to draw any conclusions, much less even specific findings. So for example, the history of the definitions and the way the pandemic preparedness plans have evolved is very interesting and important input to the thinking and understanding of our committee, but we have not gotten that far as a committee as yet.

What is evident just from the discussion we have had in these few days, is that the committee will have to come to grips with this specific question of the place of severity in pandemic characterization — that is not to pre-judge what the conclusion may be, but it will certainly be on the work agenda of this committee. Thank you.

Gabriella Sotomayor, Mexican News Agency:

To learn for the future, do you think that — because there is some big advertisement here that is pharmaceutical industry... Do you think that it should be revised to their response to the pandemic.

Harvey Fineberg: The response of the pharmaceutical industry?

Gabriella: Yes.

Harvey Fineberg:

Well, it is not the purview of our committee to judge that specifically, but we are looking at the whole of the pandemic. So the behaviour and the expected contributions of all the relevant actors have to enter somehow into our reflections, because even if you were just trying to work as we have been charged to help the WHO: For the WHO to do its work, it has to be able to take account of all the relevant actors. So, in some sense, they will come to be part of our deliberations, but it is, if you said the question, is this in your charge, not explicitly. It is simply what we will have to do in order to complete the work for the WHO.

German Press Agency:

The issue of severity and the alert phases that made us uncover the outbreak was probably one of the most confusing parts. At the time, though it was raised repeatedly in April and May of last year that these were the confusing parts, and at the time no-one really listened to the questions journalists repeatedly asked that they were getting from the public. Now it is a year later, you

learn lessons for the next time — but is anyone looking into why nothing was done then, when it was obvious that the public was confused about these very things already at the beginning.

Harvey Fineberg:

I do not know the answer to that specific question of what the thinking was at that time as of now, maybe we will learn more about this — and in fact, for those of you were not at the meeting, one of the requests that I made to our journalist colleagues, if I may use that word, is to invite your help to us in understanding what the critical issues have been, also from your point of view. I asked expressly, if you could — when you are thinking of critics of the WHO, who do you call? — because we want to hear from the informed critics. And also, we need to understand better what created problems for the media, as well, to do your job? What was it that was difficult and maybe could be better understood, so that the experts of the WHO in the future can be more effective and enable the journalism community to do even better its job. So it is a genuine question that I would re-enforce in this.

Now to come to your point, this back and forth about severity — historically, and then how do people deal with it acutely —; it at least suggests that it is a difficult problem, because if it were a simple problem, it would have been accommodated in an easy way long before. So, what can you imagine are some of the difficulties?

Just to give a suggestion of some of the things that were not discussed in detail in our committees — so I am responding in a way just more generally, but for the sake of the question: When you think about severity, you have at least three problems.

The first is defining what you mean by severity. So, are you talking about mortality? Are you talking about morbidity, or illness? Are you talking about some combination of the numbers and the severity in meaning “severity”? What do you really mean by it? So that is the first challenge.

Second challenge is, how do you measure it? Not simply in theory — but how do you measure it practically and in real time, in a way that can be used to inform your decisions?

And third, how do you account for the variety of severity in different settings at the same time? So you may have a country experiencing a degree of severity very different to another... or within a country, you may have sub-populations experiencing degrees of severity very different to the other.

So all of these initial questions need to be very well appreciated and thought through in order to begin to answer this question — how could you combine severity and extent? It is very interesting — if I could offer a metaphor: When you are dealing with a hurricane, think of it: you

know we grade hurricanes; we grade one, two, three etc. Well, that is all about severity. The only measure that determines the hurricane grade is the top speed measured in the hurricane. It is not a measure of how big the hurricane is. The hurricane could be 200 kilometres or it could be 600 kilometres. It does not count that. It is kind of the inverse. It is only about severity; it is not about the size. Interestingly, it is very precisely measurable. You can put in the middle of the hurricane the measuring device, and you can tell, to the kilometre per hour exactly, how much speed is there. You can do it. You can track it visually.

So in the case of characterization, you have inverted what you think is important compared to the flu now, you have very precise measurement. And, by the way — we are all familiar with kilometres per hour. We know what that means. So it is got very good meaning to everyone. So I use that as just a kind of foil to illustrate the difference to certain classification schemes and the challenge, in the case of a pandemic, of applying similar thinking to try to make it meaningful and usable for the public. So this is this all going to be part of the deliberation of our committee.

Question: Just to sort of again go back to the issue of how it was handled — is this committee reviewing the regulations, or is it also reviewing how WHO staff then dealt with the regulations. This will go the level of personal responsibility.

Harvey Fineberg:

Both. It is going to deal with both the regulations — and, are they effective and are they usable —, and it is going to deal with the specific actions taken by WHO — or not taken, as the case may be — in reference to management of the pandemic.

The spirit behind this, though, I want to add, is not to point a finger at wrongdoers, or fault-finding. That is not our goal. Our goal is to identify lessons that can help the future — and that is the way we are trying to carry out our work. Thank you.

Any other questions...

French News Agency:

There were a few comments from committee members and others during the last three days relating to the nature of the virus, where it comes from. On the one hand, you might have something like Professor McKenzie who, this afternoon, mentioned that H1N1 was a “strange” virus, as he put it. On the other hand, you might contrast that with a rather, sort of affirmative statement from the World Animal Health Organization, the OIE, which the representative said that, I think, [...] they came to the final conclusion that this is not of animal origin. Does the public health community know enough about the — or let us put it this way: Are you able to look

far enough upstream into the life of this virus, and is that an issue which will be of concern to the committee?

Harvey Fineberg:

The committee is not primarily concerned with the origin of the virus, but the background of the origin of influenza as a human disease and the epidemiology of the virus are relevant to the considerations that we are going to try to take.

It is important for us try to be very clear in our thinking and understanding about the characterizations of the virus and the disease. For example, when we talk about the non-animal origin of the illness, it does not mean that the virus did not originate in human-animal interaction — almost surely it did. What is meant is that the contemporary infection of humans is caused by other humans. It is not caused by exposure now to animals. These are two very different things, both true — so that the intent of the statement that it is not animal-transmitted disease is not to characterize the origin historically. It is rather to differentiate the worry which can be falsely assigned to interface with animals or particularly with food products derived from animals, and worry that that may transmit the virus. From a scientific point of view, a pork chop is not a source of swine flu. So this is the intent on the statement about animals and viruses.

So even though it is not the primary responsibility or the main focus, it is in the background. It is part of the, if you will, the gestalt of influenza that the committee has to absorb in its deliberation in order to make what we ultimately come up with meaningful and relevant to influenza in the future.

Question:

Can I take an example? For example, one health expert, quite a renowned health expert, told me before this meeting that there are now tests that tend to indicate that there were human cases, or might have been a human case or cases [...], in January. So far, the belief and most of the talk has been about March [...]. But if you put it another way, if you look at how fast the swine flu, or H1N1 pandemic, progressed in three months, from April: What was happening from the previous three months, if it had been there, and shouldn't it have been detected earlier? And that would have helped the world response subsequently as well... and would have made a huge difference.

Harvey Fineberg:

There is a big difference, just again as a general matter — this is commenting on the question, not based on anything we have discussed, because, as you know, we have not discussed that yet — but just as a general response: There is a big difference between detecting an unknown virus for

the first time in practice to going back then and knowing what you are looking for, and seeing, did it ever occur previously — were there any evidence that it had occurred previously.

Take the HIV pandemic, as a counter-example. The HIV pandemic burst on the public scene in the 1980s. That is when people became aware of HIV. With the first cases — mysterious, originally in the US — it was called Gay-related Immuno-Deficiency Syndrome. That was the first name of it. The virus itself was later identified and after that, historically, cases could be detected by means of serologic sampling and other mechanisms even decades earlier. So these are two very different propositions: detecting historically an earlier occurrence when you know what you are looking for, and being able to detect, for the first time, a new outbreak or a new condition.

Now it would be astonishing, it would be, in fact, inconceivable that the very first human case would be detected. That would be like saying that you actually felt the first rain drop that fell on Geneva. You know, that is hard. You have to be in the exactly in the right spot and it has to fall right on your nose, and then you know it is raining. But if it starts to pour, you can be pretty sure you are getting wet.

So in a similar way, what you need in a surveillance system is not this ideal that you can detect the very, very first case. But you need earlier and earlier capacity not to overlook the clinically evident cases that can reveal a new outbreak and give you the maximum time for preparation. And the two are not at all incompatible, going as early as you can and recognizing you cannot get the first.

Question:

I was wondering, sir — do you have experts in your 29 members with backgrounds in pharmaceutical production, marketing and logistics? And also if you intend to look, among your deliberations, at the change of the terminology — not to use the word swine flu — which occurred overnight; and two other agencies were involved in the decision with the WHO out of the group.

Harvey Fineberg:

On the first question, I would say that to my knowledge, there is no member of the committee with deep expertise in the manufacturing and production of vaccine. I state that with a qualification ‘to my knowledge’ because I do not want to misrepresent the backgrounds.

Having said that, it is also the case that there are many, many types of expertise that the committee will need to seek out to inform itself, but that cannot be represented in the

membership of the 29 individuals who are present. So it is an example, but it is just one. There could be quite a large number of those.

On the naming conventions: This came up, actually, in the presentations in the first phase of our meeting, and it is clearly something about the management of the alert phase that we will need to consider.

Jonathan Flynn, Reuters:

[...] Can you just say what the next steps for your committee are — the timetable for your next meeting...?

Harvey Fineberg:

The committee intends to meet again sometime during the last week of June, that is the week starting June 28 and extending to July 2. We do not know yet which three days will be best, but we expect to have a three-day meeting during those five days. So that is our next formal step.

In terms of the work plan, we are intending to continue to have a kind of conversation on the topics by the members of the committee. We have a lot of work for the secretariat to do in preparation for our deliberations at the next meeting.

And beyond that meeting, we have agreed that we will schedule at least a third meeting, tentatively set for the week of September 27. And that again, which three days of that week ending on October 1, we have not chosen, but it will be during that week. That is our current plan.

Question:

And when do you expect you should release the final report?

Harvey Fineberg:

If we are able, we would strive to have our final report out in time for the Director-General to present it formally to the World Health Assembly of May 2011.

Question:

I was just wondering if you could talk about whether the committee will address, or has already begun to address WHO's role in facilitating technology transfer and capacity building to improve access to vaccines in countries without the manufacturing capacity, including Intellectual Property flexibilities, if they are necessary.

Harvey Fineberg:

The presentation that we had today on vaccine programme at WHO touched upon these questions, and the committee in its posing of questions afterwards did include a desire for more information on the issues of capacity and on the pre-qualification questions. So we expect we will be investigating those along with our other topics in the coming months.

Question:

Out of curiosity, I am wondering how you will approach what appears to be this very broad topic — it what may have landed you into this committee exercise to begin with — as to whether the pandemic has been hyped. Around the world, I have been reading reports which are beginning to scapegoat the media for having hyped it; I read something else about medical workers, health workers refusing to be vaccinated, and they should know better — maybe.

So have you been dealing with this, and broadly speaking — how do you approach this, or is this something that magically comes together after you have done, put together all the elements of your investigation?

Harvey Fineberg:

On this question of scapegoating the media — after all, turnabout is fairplay. So you have to expect you are going to be the subject of accusation in the same way. It is feeding the hen that bites you, is it the opposite? So yes, you just have to expect that it is part of the territory that comes with being responsible journalists and even more so if you are an irresponsible journalist, but that is the just the way the world is.

Now we are very mindful that a number of criticisms have been levelled at the WHO and, more generally, about the management of this pandemic, and we want to give a hearing to those. We want to take account of those. We want to consider those, and indeed today, I also asked our journalist colleagues if you would be willing to share with me, you know the answer to the question — when you are looking for a critic, who do you call —, which was really a way of asking, who do you feel is informed and critical about the process? Because we would like to hear from them. We would like to understand what their criticisms are, and the basis for them. We want to be able to take that into account. We want to face up to those. We are not here to either defend or to prosecute the WHO. That is not our job. We are here to find out as best as we can and in as truthful a way as we can: What are lessons that we can learn?

And finally, we will take one more question.

Question:

Since we are in the early stages of this whole process, I will come back to your question of the composition and the purpose of the committee, since there really aren't that many questions that we can ask at this stage about the content of your deliberations; you have only just started. I still find it difficult to understand how this committee can be described as external committee given the relationships between the members and WHO and governments. I mean, no US Senate hearing or British parliamentary committee hearing would operate in this way. They would have people like the members in as witnesses, but there would have to be a line drawn between those with any interest because they worked on the whole process that is being scrutinized, and the people who are doing the scrutiny.

Harvey Fineberg:

I will offer my take on it, but again, I am one of the appointees — I am not the appointer, so I can only give you my view about it.

I believe that when the term 'external' is used in describing this committee, or this type of committee, essentially what it means is, non-employees. It means people who are not employed or in the payment of the WHO.

Now it does not mean utterly disconnected. It did not rule out anyone who has consulted for or helped advise either governments or WHO and — so, that was the distinction that I think would apply just to the definition of that word.

If you said, well, how can it be truly independent in judgment because it has had these previous connections — if that was the thrust, then I would return to my discussion of bias. We have to recognize that every one of us brings predispositions based on our experience, our knowledge base, positions we hold or have held, and we are trying to deal with those by exposing and by recusing in specific instances. Whether that is an adequate response to the demands of independence of thought is perhaps a judgement I would acknowledge. It is not an absolutely clear-cut case. I think the reality is, if you are trying to get that combination of expertise and freedom from conflict in a financial sense, you deal with that by acknowledging, exposing, and appropriately recusing, in specific circumstances, the members. At least, that is the implicit strategy behind this selection. That is as much as I can say.

Question:

I will give an example to ask the question.

Mexico was the most concerned country. And there was a ceremony here that the Minister of Health came and donated the eggs to the world to do the vaccine. So after that, Mexico asked to the pharmaceuticals, to the laboratories, to have the vaccine. And the industry said, we cannot give you any because there are countries that have pre-ordered the vaccines, and we cannot give it to you.

A lot of countries are throwing away vaccines. A lot of countries do not have it! This should not be happening in the future, in another emergency.

Harvey Fineberg:

You could have been speaking on behalf of some of the presentations from the Member States in your comments, because these questions of equity, fairness — these were raised. And I do not know how we are going to ultimately come forward with fresh ideas on how to improve on this, but I can assure you that the committee will do its best to look at the question.

With that perhaps, I would thank you all for your interest and willingness to be here today, and I look forward from time to time to be able to respond to your questions as we go forward.

So thank you all.