



**Transcript of press briefing with
Dr Harvey Fineberg, Chair,
International Health Regulations Review Committee
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Speaker key

HF Professor Harvey Fineberg
MF Member of the floor

HF Well, thank you all and the only one who has not introduced himself is our cameraman who will remain unseen but always welcome. It's a pleasure to see you all here. As you know we have just concluded three days of meeting. This is the third meeting of the IHR Review Committee. This meeting was organised in two parts similarly to the second meeting. The first part of the meeting was plenary sessions in which we had the opportunity to interview individuals representing a variety of organizations and interested parties. I'll review that in a moment. And the second part of our meeting was what we describe as deliberative sessions. This is the part where the committee alone carries on our discussions and the development of the ideas and content organization of the report that ultimately will be released.

The plenary sessions are open to representatives of state parties, the constituents of the World Health Assembly who are invited, also UN organizations and other organizations, non governmental organizations that have a special relationship to the World Health Organization and as some of you I hope yourself took advantage but it has been our custom in the work of this committee, the plenary sessions are also open to members of the press as auditors. I don't know if any of you were able to sit in on any part of this meeting; if not that will help in what I should describe. Shall I assume we have not; that you have not heard what went on?

MF Many were covering judicial issues in the Human Rights Council.

HF Ah, so there's other events going on in Geneva even as we speak? All right, well, I will take that into account in our discussion. The plenary sessions this time included further interviews with representatives from national authorities. These are the state representatives, the national focal point, the individuals with the responsibility of communication, co-ordination from the point of view of the individual states. We heard also from representatives of industry and other organizations that are involved in response or preparedness for pandemics such as the International Air Transport Association and today or rather yesterday we heard from representatives of Sanofi Pasteur, one of the major vaccine producing companies who participated in the WHO vaccine distribution programme.

Over the course of these several meetings we've also heard from other industry representatives, from Hoffman La Roche, from Novartis, from Glaxo. We've heard from our representatives of media in Europe and particularly also from critics of the WHO including representatives of the Council of Europe, the Cochrane Collaborative, some who have been writing in criticism of one or another aspect such as the BMJ editor who spoke with us at our last meeting.

I would say though, most of the time of the plenary session, the largest single chunk of time this session was dedicated to hearing directly from the WHO secretariat. This is the group who played the key leadership responsibilities within the WHO for oversight of the management of the pandemic and indeed administration of the International Health Regulations.

I think you're all aware that our committee really has a dual charge. We're constituted under the terms of the International Health Regulations of 2005 which called for a review after five years of the performance of the International Health Regulations. We're also constituted specifically to review the performance and activities in connection with the H1N1 pandemic. Importantly this pandemic, the H1N1 pandemic was the first incidence under the implemented rules of the IHR of 2005 which went into effect legally in 2007. The first instance where there was a declared public health emergency of international concern. This is a special classification under the terms of the International Health Regulations, and it's under that authority that the World Health Organization operated to carry out its programmes and activity under H1N1 and so these two are closely enough related that it was deemed appropriate to look at both simultaneously and that in turn affects the approach that the committee is taking in preparing our report.

We have to consider both issues related to the performance of the International Health Regulations and issues related to performance and concern on the H1N1 pandemic specifically and our goal will be to cover both, to show how they're inter related and to draw lessons from each for the future. This is our overall mission; the overall mandate to our committee from the beginning has been to examine what happened for the purpose of drawing lessons for the future. What has emerged in thinking of the committee in terms of how we're organising our work thus far is really five major lines of organization and development: one is essentially setting this

context explaining the backdrop of the history of the regulations that are principles of communicable disease, where influenza as a problem fits and then specifically the 2009 outbreak.

Secondly, we're working on understanding exactly what happened in the early stage, the outbreak up through its assessment that preceded the ability to respond to it so this early phase assessment's very critical. Third, we're looking at the response and the response has many, many parts but the idea will be to understand how all these parts worked, what didn't work well, what did work well, what we can see that might be improved in the ability to respond to the epidemic.

We're going to focus more specifically on the range of functions of the IHR. If you go through the International Health Regulations themselves, it's actually a rather readable document. It's in typical legalise but it's not that lengthy. It is an international treaty. It has the force of law on all the signatories and it has, if one analyses it, a number of distinct functions, quite a part... some connected to this pandemic, some more general but understanding how they worked, how well they have served to improve preparedness capability, response capacity in countries around the world. This is an important part of our mandate so we'll be looking specifically also at the IHR. And finally and I think of special interest to this group we are going to look specifically at the issue of communication. The communication issues permeate the entire process. They arise from the very beginning. In fact they precede the beginning, the groundwork laid in communication, it's partly a matter of the processes of communication, it's largely a question of quality of communication, it's a matter of the relationships and accomplishing the goals of the communicator and achieving the desired understanding and beliefs and behaviour on the part of the audiences that are the targets of the communication. And the communication is of course a two-way street. One has to be a listener as well as a speaker for communication to be successful. And we are looking at all of these aspects of communication in connection with the total experience here so by the time we have gotten our arms around this whole problem we will have understood the context, the early stage, the response stage, the functions of the IHR and the role of communication. That's the general scope of what we're now working towards.

From a process point of view, the committee plans to extend the discussions, the deliberative discussions of this meeting in early November. Our custom really since the last meeting we have had opportunity to carry on some telephonic interactions. They've been very useful in organising our work and making some progress. Meeting in person helps a great deal. Most of the committee is actually staying along informally for another day or two here in Geneva to continue the development work. That will continue by electronic means and telephonic consultations over the next month. We'll try to gather again in person in deliberative session in early November and our goal is to have a draft that is able for us to review and try to finalise in early January and we do plan a final plenary gathering of all the countries in early January and we'll see how far we are along at that point.

We have a goal of submitting our final report and that would have to include the translation of it as you know into the official languages of the WHO UN system and a response from the Director-General who is the direct recipient of our report. That would have to be all accomplished in advance of the meeting of the World Health Assembly in May of 2011 which is when we expect the report to be released in effect.

So that's the plan, that's the status of where we are and I'd be very happy to respond to any questions that you would like to raise. The floor is open. I think if you push the microphone. Mine doesn't have a button so I'm assuming I'm all right.

MF Yours is on all the time.

HF Mine is on all the time. All right.

MF Did you have any... are you starting to get a picture of certain elements of the response to the pandemic through this process, especially during this third meeting? Are there any particular features that come out that surprise you?

HF I would say one of the things that is, not exactly surprising but revealing, is that the principles at the WHO, the secretariat are very eager to tell their story. They are as eager to tell their story as I would say some of the critics that we have heard from have been eager to make sure we understood the nature of the shortcomings and different aspects and I think part of what's coming out from their side is two things: one is the challenge of decisions and actions under uncertainty in real time where you don't know exactly what will follow and you are facing uncertainties at every level and the press events pushing along are all going on with many things happening simultaneously so one of the key themes that's emerging from this is the force of uncertainty and the second is complexity, the complexity of what they were trying to deal with, the number of things they had to in a way invent for the first time despite all the preparations, despite all the preparedness, the nature of the discussions, for example, with the range of industry on response to the pandemic. And one interesting contrast I would say was between the preparations for managing the response with respect to antivirals as contrasted with the management of response for vaccines because in the case of antivirals the drugs could be produced. They were already available, approved, on the market. They could be distributed stationed in pre-positioning for further distribution. It was a relatively simple but still a complicated task but logistically manageable task of distribution.

In the case of vaccine, it's a totally different picture, you don't have the vaccine at the outset, you have to create the vaccine. You have to get companies to agree to participate or countries to agree to donate. There, in the end, were dozens of countries that were donating and scores of countries that were receiving. Companies had different views about what they would be willing to do and interested in doing so that was a very, very different challenge and in a way one has to

think how much of it could be prepared and how much was of necessity because of the nature of the intervention new so one of the... I would say one of the big lessons that we gathered was this sense of complexity from the WHO.

And the third point I would say, and it came through to me very, very clearly in the statement of the Director-General, which I believe is now posted already on the web and it's worth looking at I think if you want to get a feeling of the tone and a sense that she's bringing to this process but I was impressed with the willingness to listen and eagerness to hear what the committee would have to say about the assessment of what happened so that there was a reinforcement to the members of the committee who were devoting a substantial amount of time to this effort that what they produce will have an audience. I won't say that it will necessarily be adopted but it reinforced the value of the time that individuals on the committee are putting in.

So those were some of the key impressions I would say that we're particularly from the... from talking with secretariat. Other things that we got that were reinforcing again everyone from this, involved in this had come at it from their own perspective and very, very few people really had a vision of the whole, of the totality. You know, you have a certain perspective from the air transport industry which is perfectly legitimate but is different than the perspective of the state authorities, different from the perspective of the region of WHO, different from the perspective of the public health officials and similarly with industry and with the other groups that we've heard, they've each told that important side of the story and helped enrich our understanding and I think part of the job of our committee will be making a coherent whole out of all of these perspectives. Yes?

MF I was wondering if you could elaborate on the differences between what you mentioned with the antivirals and the phase with the vaccines from your interventions with industry. We understand the commercial confidentiality but what reading did you get, where did things get tangled up between the WHO and industry players in the preparation of the vaccine, the delivery, etc?

HF Well, I think the first point is that we haven't yet enumerated all of the ways that you run into trouble with this vaccine distribution. It has come up even from the beginning as a source of some criticism. For example when we heard from some donor countries, they raised the question why has our donation not been out there, what's been happening, what's taken so long? When we heard from recipient countries they were concerned in some instances that it was getting less and later than what they had desired or needed so you had on those two sides a perception and a sense of disappointment that there was not more and faster. So between the time that you have a knowledge of a vaccine getting started and the ultimate distribution there's just a myriad of things that can interfere and go wrong. We're just starting to sort that, go through all that but clearly just to indicate a few, the negotiations with the donor countries have to each be individualised and you have to, depending on where their sources are coming from, what they're

willing to pre-commit to, how firm that commitment will be and depending on what happens in the pandemic, then you have this separate negotiations which is all of the companies. They're each individual and then you have the questions of when exactly, where do you get a vaccine that hasn't been approved in the recipient country? How do you get that there? So do you have to go through all of the approval authorities when it hasn't yet been tested in those countries? How do you overcome that and then is there capability in the recipient country to administer this in a short time, you know, the whole question about implementation on the ground in the final stage so all of these can act as impediments to a successful distribution.

If you just contrast that for a moment with the story of the antivirals; drugs are very familiar. It's a pill you take once. People... every country there's distribution systems for drugs. These drugs are approved. So there's just a whole array of non-obstacles relative to the case of the vaccine so that's what we're trying to both enumerate and identify in concrete form and use to illustrate some of the challenges that were faced and then to think most critically okay, what did we learn that we could do better next time? Are we going to be in the same situation the next time, and that's the task we have. Yes?

MF Two questions: the first is your...from what I understand you're going to look at the... part of what you're going to look at is going to involve whether the response was appropriate at an epidemiological level but when you're examining this will you also look at the whether it was reasonable at an economic level? I think a lot of people would want to know how much do the public and private sector spend on for this pandemic. There's no reliable study out there yet. How much vaccines are rotting away in warehouses, etc so will you be looking at whether the economic response was appropriate or not? And the second question is regarding the methodology by which you will reach your conclusions: you speak of several stories from different agents which tend to reinforce themselves. Shall we assume that you will be discarding the outliers from this great narrative? How will the report take into account that maybe some individuals have an entirely different story to tell?

HF Well, let me take the two questions: I think it's beyond the capacity and scope of this review to conduct an original in-depth economic analysis. This is not something that we're going to be in a position to do but I am aware of several that are underway including some in Europe, some in the Americas and perhaps more and what we will try to do is to take advantage of the analytic work that is being done and use that as part of our assessment and understanding but to take the larger point, certainly a judgement about the wisdom, the correctness of the judgement that was made or judgements really that were made have to have an economic element so I accept the premise very, very well, just that if you, as you ask the question will we have an original and complete assessment of the cost, the answer is not by our committee. We'll try to take advantage of what others will do.

Now on the other point that you raise, the committee has a responsibility to make its own judgement about the merit and validity of the information we hear from all sources and it's not just what we have gained of course in the testimony. We have an immense amount of documentation that we have accessible to us, available to us. We have of course the entire literature and what may be referred to as the fugitive literature, the stories along the way. We have a history of the media coverage for example that is available to us. So the committee will be deliberating based on the information it has gleaned from our testimony plus the documentation and other sources of information that are available to us. It's hard to know generically what we will accept and/or reject and I think it's entirely imaginable that a committee would reject what is a mainstream view and accept an outlier view or reject the outlier view and accept a mainstream view. That's the judgement that we have to elicit from the committee's honest assessment and I wouldn't want to say which is going to be ultimately the committee's choice. And of course there are many, many varieties of position on some of the key issues. Yes, please? I will work our way around if I may.

MF [Unclear] there was a discussion on the definition of the pandemic, if there are [unclear]?

HF Yes, we covered this point in our discussion with the secretariat and we also understand ourselves, very, very firmly that this is a critical element of our review. There's a debate about what is the proper definition, what elements should go into the definition. There is debate about the definition actually employed at different points in time and how and in what ways the WHO conveyed information about working definitions, if not legal definitions. There are questions about the implications of the definition for action and the connection between if you will the assessment of a pandemic or potential pandemic, the risk assessment part and the management or response to the pandemic, the so-called risk management part so how are those connected, how should they be connected?

So the committee is very firmly focussed on this question as a part of what it is attending to. So the issue of definition is very important and as you know from even from our past discussions, those of you who were present in the last discussion, the question at a basic level of severity as well as spread is an important component of that question of definition but that's not the only part that we have to examine. Yes, please? I'll just work... go around and please push the microphone button, thank you.

MF So I wanted to ask whether following up on definition issue has your committee been able to find a definition? When you talk about the definition are you referring to a text, written, published that one can cite, quote and if we all quoted it it would be the same and unchanging or are you referring to a general concept because there is no definition? Can you kind of explain, please?

HF What I would say between the definition and no definition is rather many definitions. There are multiple ways people have elected to define and describe what they mean by a pandemic and I would say that part of the difficulty is that the small duplicity has led to confusion and at least induced very different understandings of what the meaning of the field reality is today and so I think that what we are going to try to accomplish is to explain what was both in the minds and on the paper or in the electronic form at different times, how these had implications for thinking and action at different times and what the recommendations would be for the future in terms at the minimum of clarity, consistency and practicality which are attributes you would like to have in a definition.

Now finally I would add that when you begin to look at the responses to, or potential responses to a pandemic it also may come to be seen that you want different definitions for different purposes, that is you want to understand different aspects of the field reality for different types of decisions or actions that you may want to take and that is also something the committee will have to consider so I would pose the characteristic a little differently than none or one, I would say many right now. Yes, please?

MF You've heard from a great number of people already in groups and so on: have you heard from the right mix of actors and are there... is everyone being heard that wants to be heard?

HF From the outset we have made very open invitations to any individuals, groups or others to please convey to us their advice, their papers, their comments, their suggestions and so we have received from a number of professional and non-professional sources input to the work of the committee. We have had papers shared by writers of those papers. We've had presentations sent to us. We have had references to other work that people think have a bearing. We have received from some of the state parties very interesting and thoughtful assessments not only of their own situation but of their relationship to WHO and the role of the WHO. We've had an opportunity in the course of these three meetings thus far to hear from a good range of representation, from the public and private sectors, from government, non-government sectors, from the global to the local. We've heard from industry representatives. We've heard from professional associations of different kinds.

I would be very eager to make sure that we can definitively answer that question yes and indeed I would say that if we have omitted an explicit invitation from any group that any of you feels would be informative I would actually appreciate knowing it because there's still time but we have been very insistent from the outset that we want the best advice that we can get. We feel we have an obligation to try to absorb the best thinking that's out there and if we have the benefit of that we think it's likely to improve our final product so that's working hard toward that goal, thank you.

MF I apologise if you answered these before I got here. Two questions: the first is that one thing I keep hearing from you today and then also it was in Dr Jen's opening statement was thank goodness this was a mild pandemic because we just didn't get the vaccines where they needed to go in time and I'm wondering if, as the committee is reviewing what happened, if you're centering in on any sort of plan for making the vaccine distribution and implementation process go faster and in particular I'm curious, there's elsewhere in the WHO negotiations on going for a pandemic preparedness framework and one of the things being discussed is a material transfer agreement that would be standard for the transfer of vaccine and virus related materials so would that speed the process or would that not. And then the second question is one of the things that critics of the process have been complaining about for a long time is this sort of mysteriousness around the members of the Emergency Committee who declared the pandemic and if now they were released on the 10th of August, you have the names; I wonder if that has changed any of the discussions within the IHR Review, has there been anything brought to light you think is important?

HF On the first question one of the very interesting parallel activities is a group that is a working group of the World Health Assembly that is looking at the question of virus exchange and benefits, the sharing of information and of bio material and the benefits that ought to follow from that and what is the correct balance of advantage and reward for those parts of the world where the virus may appear and those parts of the world where the vaccines and other drugs may be produced. Sometimes those are similar and sometimes those are dissimilar.

In most pandemics they have been different and it's most of the influenza pandemics have arisen in densely populated, relatively poor countries, not in this particular instance but that could well occur again and then the issue will come up, well, if you provide the virus material as a nation what is the proper positioning that you have in relation to the vaccines that will be produced because that virus has been available?

Now this working group has been deliberating for many months, more than a year on this and I believe they are... they may be coming towards some conclusions on their work. They are very eager to take advantage of the thinking of our committee as we are eager to know what their thinking is and we had at the second meeting actually a presentation from the co-chairs of that committee which was very helpful so I think that on this issue there is a lot of parallel activity going forward and there will be more than just our committee's report that will have to deal with these questions. Now...

MF But you haven't come up with anything that you think [inaudible] yet?

HF Well, I wouldn't say that we have come up with anything that is a solution yet. I would say we have not come up yet with a recommended solution. That we have not done yet to be clear. But let me answer the second part of your question and then I'll come on... I think the

second part of your question was on the Emergency Committee and the names that are revealed and has that affected our thinking. We of course knew that the Emergency Committee was confidential until such time as it was revealed and the question of the advisability of that in the future is clearly one of the issues that our committee is going to have an opinion about so we are fully engaged with that.

There are pros and cons that have been articulated. The fundamental pro in favour of confidentiality is the idea of protecting the members of that committee from undue influence from either national or commercial sources and it's not just influenza cases, I mean you have to think back to the SARS case and the intensity of national interests around SARS and concerns about what it would mean for different countries economically and otherwise so there's an argument on that side and then the argument on the side of revealing the names is about transparency and assuring a public that individuals who've played a part in recommending these actions indeed are doing so without influence by commercial or other sources so that's... that is a... that is definitely one of the issues we have to come to grips with and draw our own conclusions and recommendations so we're very much aware of that.

MF But this time around have you drawn any conclusions?

HF You mean about this particular committee?

MF Because you now know the names, you did not the last time?

HF We haven't as a group yet looked at the individuals to answer the question: was this group well constituted if that's what you mean, was it fairly constituted, was it correctly constituted: we have not yet done that. Yes?

MF I'm back. Sorry. Come back to your deliberations with member states and in particular their assessment on their relationship with the WHO. I presume some of these interventions were also from the focal points. What were the lessons, what did you learn that could improve things in the future? Where did the member states sharpen the pencil on the secretariat and where do they think the secretariat was up in the job?

HF Yes, thank you for the point especially the distinction between member states and national focal points. They're both nationally based but we've heard from both. We've heard from ministries more broadly and we've certainly interviewed and met with and heard from a number of the national focal points. The national focal points are the individuals designated in each country with the responsibility for liaison and action with respect to the International Health Regulations. That's their role. And most of what we have heard from the national focal points who have testified, we heard from a number also at this meeting, by and large has reinforced the value of having the ready channel of communication and the clear designation of responsibility.

We have not heard, to the best of my knowledge, from any national focal point or responsible individual who has offered a negative assessment of the value of that designation and role.

Now we have heard about suggestions for improvement. We have heard about ways that communication could be improved for example. We have heard about from some questioning whether the legal authority given to the WHO is sufficient to deal with some let us say deviations from recommended policy. I'll give you the prime example that has come up is the early assessment at the WHO that border closing would have no role in significantly altering the course of the epidemic. Nevertheless a number of countries took action to close or to limit entry in their countries and of course some spoke very candidly to us. We heard from a couple who said, well, you know, in a country you have a political need to demonstrate to your public that you are doing something about this threat and so it may be that the thermometers measuring temperature at a distance at an airport have no value from the point of view of the literal control of the epidemic but they may have a lot of value of reassurance to a public that is comforted to see, well, at least the authorities are doing something so we had this discussion. It was very informative, very candid and I think very helpful to us.

MF What about the member states?

HF The member states, yes. I would say...

MF The policy level.

HF The policy level: one of the kinds of points that some member states raised had to do with this again the question of donation and receipt of the... of vaccine. That was an issue, that was a source of at least criticism from some of the member states that we heard. Some framed it more as questions they wanted us to look into, others more as a criticism. Some of the member states found certain negotiations more tedious than they would have liked, more difficult communication than they would have felt was ideal so that was another type of comment that we've heard from member states.

One of the things that I would say though as an overall comment from the majority of the member states and particularly the countries that you would say have received assistance from the regional or central offices of WHO, most of their assessments by and large have been positive. There's the problems of the lateness of the vaccine but by and large we're not hearing a lot of sharp criticism from those quarters. The most critical views that we have heard I would say have come more from the developed parts of the world, particularly from Europe, at least overall that is what I would say so far.

MF Criticisms?

HF Of criticisms, yes, mainly.

MF On the topic of criticism, I guess when I think about criticism, you know, criticism's expected for any governmental agency: whenever EPA is considering regulations there's criticism or there's criticism to pass regulations, there's criticism for FDA for approving drugs, there's criticism for not approving drugs. Is there anything different about the criticism this time and, you know, what do you make of the criticism and some, I'm just referring to the recent speech in Hong Kong, Michael Osterholm, he sees the criticism as part of an anti-science movement so what do you and the committee feel? Has that been discussed and how's it best to interpret the criticism? Your mention of Osterholm reminds me we also heard from Osterholm actually as one of the witnesses. I didn't mention it. We had... this was in a group of... among experts let's say but now...

MF [Inaudible.]

HF No, he's an American actually. The name is not... I think it's actually... is Osterholm Swedish, Danish? Perhaps Danish but he's Scandinavian I think more but in any case he's American and he's based in Minnesota so that Minnesota is... we have a lot of Norwegian immigrants in Minnesota so I have no idea if that has anything to do with it but in any case, to come to your real question, we are interested in all criticism as a committee and not be, not with the judgement is it similar or different to other criticism; we're interested in one key question: how does this criticism help us to do better in the future. And I will say that even ultimately where the committee may as a group come to say we don't agree with that criticism, the fact of a criticism that is widely shared or widely spoken is itself a message about the process. And so you have to take criticism seriously at least at that level and then you have to make a judgement about the substance of the criticism and the legitimacy of it and in all cases we're looking at those questions with the pure intent of what do we learn that could be more successful in the future. That's our laser focus as we look at all of the criticisms so we're not making judgements is it the usual stuff or exceptional stuff; is it outrageous or is it logical; we're asking how does it bear on a greater success of coping with the next emergency pandemic and that's the question the committee is asking. Yes, you want to follow up on that?

MF Yes, one of my... my understanding of some of the nature of the criticism is that there is fundamental research and some of the science is not sound and these... that assertion is something that goes back to before the pandemic, before April 2009 and so how is the committee addressing the fundamental scientific issues that are raised by those criticism?

HF Give me an example because there's people who say flu doesn't exist, really and so what you mean?

MF What have you heard?

HF Well, within the people we've heard from [overtalking].

MF And [unclear] I think [inaudible].

HF We did hear from all three of those actually and so they're quite different in the nature of their criticisms. I would say starting with the Cochrane collaborative ideas, they are much more critical of the science undergirding the effectiveness of interventions, period, interventions, whether it's antiviral or even vaccine, and at a public health level as distinct from individual level so that's the nature of that criticism.

I would say that when you look at the whole array of let us just call it expert view on efficacy, that that's an outlier view, that is not a mainstream position. However, it's a position that is firmly held and grounded in an interpretation of a body of evidence that is highly selected and highly refined and this gets into the whole philosophy of the Cochrane approach which is legitimate but in my mind limited so that's what we heard on that level.

The criticism from the BMJ, from the editors and what they wrote was really I would say largely focussed on the question of transparency. That was the fundamental thrust that again relating to the earlier question, that the Emergency Committee's secretiveness is contrary to the public interest and urging that that be reconsidered.

From the Council of Europe was hardly that but more fundamental about the, I will say the suggestion more than the accusation, the suggestion that there was corruption of the decision-making and advising due to commercial interest and so that was... that's quite a range of criticism, each I would say distinct, bringing a different vantage point to us and we have to take it all, and are taking it all on board. You're asking what do we make of it as yet? I'm sorry.

MF The question is for Tom Jefferson if there's only Jefferson out of those three, there are concerns that the science is, that is being employed is not correct assumptions and so the scientific assertion of disagreement so is, within the scope, I heard your opinion about that science but within the scope of the committee and its review and its report is that going to be something you're going to address or is this going to not address the scientific questions?

HF I can't answer that yet. That is to say it's up to the committee to decide to what degree we will deal with that specific aspect of the question. I would say though that it is... it represents an outlier of the scientific view and it's not a widely held position that that is the extreme position which is to say fundamentally don't use antivirals and don't use vaccine. The implication is because you haven't proved that they work by randomised control trials. That's the argument and there're many randomised control trials and writers of randomised control trials of vaccines that would take different view of their results so as I said it's a view that is grounded in a selected

body of evidence that has merit to a degree in my opinion but is an outlier of the scientific view so will the committee in depth deal with that question? Probably, you know, it's a little bit of a distraction from our main responsibility because, you know, it would take us into... if I were writing it myself, you know, or if we were writing it we would make it an appendix, you know.

MF Like you did in your book?

HF For example, I mean besides... that would be the way, you know, you might want to deal with that but I wouldn't put that in the mainstream of the story. I think it would not be the main line of what we're trying to develop as an argument to prepare better for the future. How are we doing on time? Is it okay? Can we keep going? Okay, great. We'll start back... why don't we start back around in case anyone has a final question, to go round once more.

MF Considering [unclear] what happened for [unclear] lessons for the future, will this review answer the question on whether WHO's response to the pandemic was appropriate or not? That's my first question. And considering the WHO's responsible, rightly or wrongly, to the pandemic which thankfully was pretty mild, do you as a public health professional feel that the public has lost trust with the WHO's judgement on these significant issues?

HF Okay. On the first question we'd have to be much more precise about exactly what aspect of response we're talking about. There were innumerable responses and implementation of those responses and there were certainly flaws in those responses but if you target a particular decision and implementation of it and you'd say what was right about it; what was wrong about it, what do we learn from it, that's the way we're going to be thinking about this. We're not coming at the question from the beginning with a question of just making a judgement for its own sake, we're not here to praise or to decry what happened. We are going to make judgements about critical aspects and if out of that there's a let's call summary judgement that one would want to draw whether the committee wants to draw it or a reader wants to draw it from our assessment, that will be accomplished at the end but that's not our principle purpose. Our purpose again is to look at each of these elements and see what could we do better.

MF If I could follow up on that, will the committee examine whether the decision by Dr Chan to declare the H1N1 virus a pandemic was appropriate or not?

HF Yes. That I can answer yes, I do and the second question was remind me again, trust, do I worry about trust. I worry about trust every day. I, as an individual who spent a fair portion of time in public health, as a teacher and as a researcher and someone who was concerned about public health I feel that every day what we do in public health, in communication either strengthens or weakens the public trust. It doesn't stay the same. It either gets stronger or it gets weaker and there are a lot of forces to weaken public trust in public authority of all kinds, not just public health authorities. So public health is embedded in attitudes of public toward

authorities, toward government, toward experts and if you look at the least, where I'm most familiar with, the US public opinion polls over decades, in general public trust has been diminishing in virtually every profession may I say including journalists so all of us who are involved in relating to the public ought to be worried every day about this and I am. Yes?

MF Two questions: the first one is more controversial to just referring back to something you just, you mentioned [inaudible] a national source, a government source and I'd like to turn it around slightly and take an international look at it and ask the question is whether you would be discussing [inaudible] and the question is does the WHO have a political view to demonstrate [inaudible] but in fact more general terms. I was wondering if that's an issue to take down?

HF Unrelated to our examination I would say it certainly does. WHO depends on the political support of the World Health Assembly in the first instance for its mandate. It depends on donor countries to get its financial support. It depends on demonstrating repeatedly that that money is well invested and used wisely so undoubtedly the WHO as an organization has a powerful interest in documenting and demonstrating that it is doing well.

MF And do you think that is something that the committee should take up to see whether or not influence on the decisions related to the [inaudible]?

HF Well, one of the beauties of an independent committee is we don't particularly care whether it helps or hurts the WHO as an organization, that is it's not our mandate or concern or worry. I would say that if I were separately advising the Director-General I would say that the best hope you have of maintaining a political confidence, public trust is to do the job the best way possible so I think there's a nice convergence in fact of interest of the WHO doing well by doing good. That is it will retain its support if it simply does a very good job and I actually don't think in the long term there's any alternative. There's no sleight of hand or means that the WHO could mobilise other than doing its job. It would persuade anyone that is worth supporting. I'm sorry, the second question about the state...

MF No, the second question was [inaudible] national political [unclear] but it's whether or not WHO... now the second question is something else. It's more simple. I was just wondering what are the gaps, what's missing from what you've been hearing so far either in terms of the committee either in [unclear] divide it into two, either in terms of their being gaps in what you have heard and would like to explore if you feel there are gaps and secondly what's outstanding on your agenda?

HF Yes, well, I would say on the question of gaps, if you look at these lines of work that I outlined earlier, in the detail there are many, many gaps. In fact we've been working hard with access to let's call them informers. These are experts or individuals in positions of knowledge or responsibility who can help fill our gap so we have at the detailed level multiple gaps. In terms

of the overall assessment, where we have been really just beginning our effort is in examining an extensive library of material which includes some that are public materials but available to WHO, some that are internal WHO documentation of what they were doing at different times, the minutes of meetings and such including of the Emergency Committee for example and then some confidential materials which have been made available for examination which includes such things as the agreements with the vaccine manufacturers so where we have a lot of work to do in this next phase is immersing ourselves in that body of information to make sure we've got our arms around it. You want to direct me on that? Yes, please.

MF Yes, on this very question, have you examined any of this material especially the commercial confidential agreements between WHO and companies and also the donated materials given by companies and if you saw any delays for errors in judgement or logistical problems by the secretariat or by industry or was it a combination of both? We've heard... some of us have heard for instance that some industry groups had vaccines available from WHO but logistics was the problem at the WHO.

HF Yes, you know, this gets also to this point I was making earlier that, you know, if you talk to different groups you hear their version of the story but it is true for example, WHO didn't necessarily have all the money it needed just to ship the vaccine. How do you get it from the donor to the recipient? You had to get carriers to take it for free. No, well, how do you pay for that shipping? So, you know, that was... that sort of you think, well, gosh you would wake up in the morning, you'd know you have to pay for the shipping but then where do you get that money and in the middle of doing a hundred other things and what if no one thought about that, what if there was an assumption that the donor was going to ship it of course but what if the donor said no, here it is on the dock; take it or leave it. You know, we'll be glad to have it available and you just come get it so that was... this was one area of shocking you might say, you know, lack of full communication and preparedness so that's part of the story of this.

Now getting to your specific point on the... we haven't in depth gone into the agreement but my suspicion, and it's just a suspicion now is we'll have learned more about these problems not from the content of the final letters but from understanding a little of the process that led up to them, from looking at some of these other logistical matters and from questions of practicality. Those are more likely I think to reveal lessons about doing it better in the future but we are going to look at these...

MF Am I allowed a follow-up?

HF Yes, sure.

MF We were hearing from WHO officials, especially in the vaccine area; we were told vaccines would be available X period and then there was a delay and a delay and a delay. So

was there a communications breakdown between WHO and key vaccine suppliers? Were the industry people misleading WHO or were the... was it an internal problem?

HF I'll speculate a little bit here, because we don't... we haven't nailed this down completely, but I believe that part of the difficulty was too definitive a communication about availability dates in the face of a lot of uncertainty around production and all of the things that you need to do between having the seed virus and having the actual vaccine in a immunisable form. How potent is it going to be? How effective? One dose, two dose? How much will you need? How much will the virus grow? How much antigen will you get produced in the eggs and so on. So you've got a lot of uncertainties. So it's speed... amount that would caution you against excessive definitiveness of the date when something is going to be available. So, you know, it's a little bit like when you say to someone; I'll be there at seven sharp and you're there at 7:03, you've disappointed them. But if you say; you know, I'll get there around seven and you're there by 7:10, that's fine, that's around seven. So it is partly communication and expectations of what is determined.

Now having said that, there also were some other delays that we need to look into and understand. But it was... It's partly how it was framed and partly how it was executed, I think, that are both subject to improvement. Another question. Yes? Sure.

MF Actually I have four right now.

HF Four! Oh my gosh.

MF They are quite small.

MF This is a press conference.

MF I don't know how they work.

HF It's good, it's good, we'll go as far as we can.

MF So one is a quick one, a yes or no I think.

HF Okay.

MF So will the criticism you heard of the three people... will those become public documents? The second one is; what is your understanding of the phase six definition, what impact did it have recently and there's debate about this between nature and BMJ [?], one suggesting that it didn't have an impact at all? Sort of like a foregone conclusion and others saying it had an impact. And I was wondering if your committee has also been thinking about

what impact the US declaration of a National Public Health emergency has on WHO's decision making, because it proceeded chronologically if my understanding is correct. And the last one is to get a sense... I'm trying to understand what's already going on in your committee's work; so how much time do you spend on this and other people and do you have people in your staff, like for example, like the Institute of Medicine, who work on this, prepare documents like briefings. What's the manpower and time going into all this? I'm happy to repeat if...

HF Do them one at a time if you wouldn't mind.

MF So will the criticism that you heard in the second meeting...

HF Will be public.

MF Become public document?

[CORRECTION TO THE FOLLOWING SECTION: transcripts or audio files of interviews done in plenary sessions of the IHR Review Committee are not posted on the WHO web site. Plenary sessions were open to public observers but WHO noted that interviews would not be transcribed for public dissemination at the outset of the sessions. Other documentation related to the committee are available on the web site at www.who.int .]

HF As far as I know, it's already public. We're just to say... I don't think we heard anything from any of the three specific critics that you've named, who told us anything they haven't written and said publically many times. So we were... we did not receive what I would call unique criticism from them, if that's... So that's already public.

MF But as a story you'd want... I mean they made a statement on a certain day and you want to be able to look at what they said, how they framed their open statements and things like that, but...

MF It's online.

HF I think it may already be. Is it already available? I think it is. I think everything is on. Anything that was in our plenary sessions is available. Okay so that... The short answer is yes.

MF They are already public documents.

HF The answer is already.

MF That's the answer.

HF Yes, okay. Second question was...?

MF The BMJ [unclear] debate over whether phase six...?

HF Oh yes, did phase six matter? You know part of the difference depends on... You mean does it matter to what the course of the epidemic is, or does it matter to responses that were taken? And you know there's certainly... there were certain arrangements such as advanced purchase agreements that had built into them triggers that depended on the definition of a... or the declaration of a pandemic. So there were certain things that were triggered. Now would those things have...? Well then the argument is; well it might have been there as an agreement, but that was going to happen anyway. I mean that purchase would have gone forward regardless. I mean the United States, just to give you one example that I'm very familiar with, United States wasn't waiting for WHO to declare a global pandemic before it was doing everything it could to mobilise the vaccine. So I think that you could see where this argument is going back and forth. The committee I think has to come... Where the committee has to judge isn't you know, nature versus BMJ; that's not our problem. Our concern is; what can we say about the way epidemics are characterised in the future, that...? And what implication should it have for risk management as opposed to risk assessment, that would help clarify and avoid inappropriate or misunderstood reaction. So that's where we're going to focus. Now the third question?

MF Well it's... you mentioned somewhere, the US Declaration.

HF The US Declaration; I don't think... You know again you have to remember this; the pandemic was going on in different degrees in different parts of the world. And so certain countries who were early affected naturally had an earlier policy response than other countries which had not yet been affected or were just beginning to be affected. So I wouldn't say that as a declaration, as a policy question it had a direct influence. What it did is, of course mobilise a lot of action within the United States, that's totally different. But I don't... I wouldn't say that I see a basis on which it had, in that policy arena, an action or effect in WHO. And on your last question, which I do remember, because it was reminding me how much time we're spending on this; the committee is putting a great deal of time into this and indeed I would say for many, if not all members of the committee it's taking up more time than they might have understood at the very outset of accepting the obligation. We have a support staff based here in Geneva, who are dedicated to our work on the committee and have been very helpful to us. And in answer to your specific question, that's the staff on which I rely for this project. So it's not an Institute of Medicine activity. I'm here as an individual and working on this in the capacity as an individual

MF So that's supporting WHO staff?

HF They are based at WHO, but dedicated to us.

MF But they are WHO staff.

HF They are employed by WHO, yes.

MF Don't you think you need to have an arm's length relationship with them?

HF With that staff? Well they're not staff who were involved in the...

MF But they still work for WHO.

HF They still work for WHO, that is true. I think that, you know, we're very aware of that, but this is going to be the committee's report, that I can assure you. As I think every member of this committee, working on every element of this, would assure you. Well, if there are no further questions, thank you all very much for being here. One more? One more, all right.

MF Did you get...? When you say you got responses from policy makers, did you get responses from Ministers of Health to get an insight on how cabinets dealt with the Pandemic at the national level and how was the response? Because if there was one missing link, very few heads of Government or State took a proactive stance on this issue.

HF Yes, we did hear... Some of our witnesses happened to be Ministers of Health, but not of what you would say the major critics or donor countries. But most... To the best of my recollection, as I think back on the input we have received, it's not been from a particular individual, whether minister or other, it's been a delegation submission of the delegations here at the assembly. That's to the best of my recollection. So as I remember looking at the...

MF But these submissions draw on... drew examples of how it was held at the cabinet level. For instance, when Dr Chan on June 11th said; pandemic, did you get any insight on how it was dealt at the cabinet level in various governments...?

HF No.

MF Given that the Ministries of Health are not necessarily the heavyweights in cabinet.

HF No, we're not getting at that. Keep in mind, we're... An assessment of what happened at a national level is way beyond our scope. We...

MF But that's very important.

HF It is important, but it's not something that we're in a position to examine systematically around the world - what effect did this have? Now if you mean by this; what did it mean for the

country response overall, when the WHO made certain declarations? That is relevant to us, but we're not getting it out of these submissions.

MF It could be helpful though.

HF It could be - it could be. Very good. Another question?

MF I'm sorry.

HF All right, number five.

MF It's on this whole Ministries of Health and early on, in May 2009 the Ministries of Health, not the majority... I didn't take a count, but I know the UK, China, Japan, these are the main probably... they were very critical of the possibility that WHO would declare a phase six. So are you tapping into that criticism and concern from those ministers or those... whoever the delegates were, to the World Health Assembly in May last year, to understand why that mattered to them?

HF I would say we haven't specifically pursued that, but actually I would welcome your guidance on what you know about who was reacting at that early period because we could still enquire about that.

MF It was a plenary session in the [unclear], where most of the Ministers spoke on the record in a three hour session.

HF Yes, but I don't remember from... I... At that session we heard from many, but I don't remember China or the UK specifically.

MF UK spoke.

HF Did they speak?

MF Oh yes, he was very critical of the definition.

HF Yes, a lot of the people then... But he was critical on the question of severity, as I recall.

MF Exactly.

HF Yes, so it wasn't this issue. I'd like to understand what was the positions taken at that stage and I think your point of why; it's a very good question. Were they concerned about the triggers, were they concerned about public anxiety or rumours. What were they worried about?

That's a... I think it would be helpful to know and it might be different in the different countries. I should look back. I don't think that China did speak though, at that meeting.

MF I think they did.

HF China also spoke?

MF Minister of Health.

MF The ones I recall immediately are UK sort of led.

MF A lot of countries jumped in - Spain.

MF Japan.

HF Yes, in May?

MF Japan I remember being one of the other countries.

HF Yes. Well you know it's a very relevant point and I think it would help me if you could identify with specificity which ones that you know had issued some sort of public statement at that stage. I would be appreciative.

MF He has a question as well.

HF Sure you have one.

MF Looking at the whole pandemic just through the phases, there was no phase one, there was no phase two. On April 27th it was phase three, on April 29th it was phase five, so it in effect had skipped a phase, and then went phase six, but there was no post-peak. There wasn't really post peak, so basically half of the phases, you know, this beautiful [unclear] pandemic [unclear] plan was ignored by the WHO. Half the phases weren't [unclear].

MF You're a little off there; there was a four.

MF Yes, it was on... But it was on the 03rd in the morning, on the 27th in the morning was the three... on the 27th at night it was the four. It's now on the 29th it was a...[unclear]

MF It was three because they were already in phase three.

MF So just as a lay... as a non... I'm not a medical... I'm not a doctor; I'm not a medical professional, but if I just look at the application of the tool you have and how it's applied, the tool is completely useless...

HF Well let's take a medical analog for a moment. If you're just measuring temperature, you know you can have a normal temperature in the morning and you can have a fever by night. And the question isn't how swiftly did they go from one phase to the next or did they skip a phase? To me the question is, first, are the definitions logical and helpful and optimal and then, did the criteria actually get met and when and with what basis. And if it turned out that the temperature just became evident in the course of that day, that's the way it is. So you know, I think the mere fact that it was jumping or skipping or condensed, that isn't per se a criticism, it's only if that mismatches to the reality.

MF Every phase comes with a certain policy response both at the WHO level and at the national level and these phases exist to, you know, give some kind of coherence to national government, especially those organising resources. So this tool which was basically to simplify... to give government sort of a plan in the case of an actual pandemic, was ignored.

HF Yes, that virus didn't cooperate, did it? I mean that's basically the problem there. You know, you have to deal with nature as it is, and the reality. And then you learn from each experience, as we're trying to and you figure out, can we adjust those in a more effective way. But I think again it's... You can criticise the logic, which is valid, you can criticise the completeness, which is a valid question, you could criticise the application and say; did they have the right evidence at the right time? But the mere fact that you move quickly or slowly, to me is not a criticism.

MF In your interventions, did you hear anything, or from anyone that most people had been prepared for years on the H5N1?

HF Oh yes.

MF Which has a higher fatality rate and that the mindset was prepared for something horrific.

HF Absolutely, this is... I would say that one of the other, I think very evident lessons from an array of the testimony is that a lot of this thinking and planning was actually predicated on a mindset grounded in H5N1 and that is... that's undeniable and it's actually quite important. So I think it's actually a very, very relevant point. It did set the framing of how people thought about flu and the virus didn't cooperate again. A different one happened to come up. Anyway, thank you all very much.