WHO-RUSH Human genome editing 1st advisory committee VPC

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Speaker Key:

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VM	Vasee Moorthy
MH	Margaret Hamburg
HE	Helen
JC	Jon Cohen
SA	Sarah
WN	William New
MB	Mary Ann Benitez

TJ Hello. Good afternoon and good evening to everyone from the World Health Organisation here in Geneva. My name is Tarik Jasarevic and I welcome you to this virtual press conference following the end of the first meeting of WHO Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Today, as we have informed you in our media advisory, we will have three speakers. We will have Dr Margaret Hamburg, who is co-chair of the WHO advisory committee. We will have Dr Vasee Moorthy, who is coordinator for research and ethics in the division of chief scientist here at WHO; and we have Dr Katherine Littler, who is senior ethics officer.

For those who follow us, I would just like to remind you that you can ask questions simply by typing zero-one on your keypad and you will be put in a queue to ask your questions. I would also like to remind you that we will have an audio file from this press conference immediately or shortly after we finish. The transcript from this press briefing will be available most likely tomorrow.

So I will start by giving the floor to Dr Vasee Moorthy, coordinator for research and ethics, division of chief scientist here at WHO to tell us more about the committee itself. Dr Moorthy?

00:01:42

VM Thank you, Tarik. Good morning, good afternoon, good evening, everyone. WHO has an overall technical strategy known as our general programme of work. We're now in our 13th general programme of work, endorsed by the World Health Assembly in May of 2018. One part of this technical strategy includes a focus on further strengthening our normative work including specifying a focus on looking at applications of emerging technologies; applications for public health around the world.

So in line with the 13th general programme of work, in December of 2018 our director-general, Dr Tedros, instructed us to establish an expert panel on governance and standards of human genome editing, both looking at germline and somatic. As the new division of the chief scientist is established or was recently announced by the director-general, this work of the human genome editing advisory committee will be a template for us for other activities in this area of applications of emerging technologies more broadly, always looking at maximising benefit and reducing risk for populations around the world.

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Because we felt it was very important that we have an inclusive process in constituting this committee, we launched an open call for applications for membership of this committee and we were inundated with very high-quality applications from people with different types of expertise working in different disciplines around the world including scientists, bioethicists, and other disciplines. As with all of our processes, we put a major focus on gender balance and geographic representation in constituting the committee.

We selected 18 members including two co-chairs. We have full transparency on membership of this committee, which is available on the WHO website, who.int/ethics. Our two co-chairs are Judge Edwin Cameron, who is a judge on the Constitutional Court of South Africa, the highest court in South Africa. We unfortunately was unable to be with us, but the other 17 members all… we're very grateful for the fact that they prioritised attendance at this committee meeting, which we have convened at short notice because we understand that this is an urgent issue and we wish to begin the process of receiving the recommendations from this committee.

The other co-chair is here with me now, Dr Margaret Hamburg, who is the foreign secretary for the US National Academy of Medicine. She's the immediate past president of the American Association for the Advancement of Science and she is a former commissioner of the US FDA. With this I'll hand over to Dr Hamburg to give us a summary of the outcomes of the first meeting of this advisory committee.

00:04:58

MH Well, thank you very much and it's a great honour to serve as co-chair of this new WHO Advisory Committee on Developing Global Standards for Standards and Oversight of Human Genome Editing. We have a very impressive group of experts from diverse backgrounds bringing a great deal of expertise and important perspectives to our work.

Over the next two years, through a series of in-person meetings and online consultations, the committee will be consulting with a wide range of stakeholders, we'll be engaging in in-depth discussions, and we are committed to providing a comprehensive governance framework that's scalable, sustainable, and appropriate for use at the international, regional, national, and local levels. We really – I think – made great progress at this first meeting to define how we would move forward to implement this important mandate and undertake this task as well as to focus on what can be done in the near term and in the longer term.

Over the past two days – very long, intense days, I might add – the committee of experts reviewed the current state of the science and the technology to ensure that all members of the committee were on the same page in terms of what the spectrum of human genome editing tools and technologies are and the state of current human genome editing research. We also received updates on pre-existing or ongoing initiatives in this area, which was very valuable because we want to build on work that has already been done. We do not want to be duplicative, but we really want to advance understanding and activities in this area.

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We really focused on how to better define the scope of our work and how to approach it, recognising that it's an urgent task, a big job, and an important one. We agreed – as I mentioned – that we would need to address near-term and long-term actions and recommendations. So coming out of this first meeting, we wanted to underscore that this is a process and we're going to be probably taking about 18 months to complete our work and that is critical – that it be done in a thoughtful, stepwise, comprehensive way – but in the meantime we also wanted to make some recommendations to WHO about some actions that could be undertaken now.

One thing that I want to underscore at the beginning is that the committee will be focusing on the spectrum of human genome editing research including both germline and somatic cell research and that the committee is absolutely committed to engaging the full range of stakeholders in these efforts and also looking at the full range of gene-editing tools. So it will be a comprehensive approach as I mentioned.

As for the recommendations that we are making coming out of this first meeting that will be part of a broader set of recommendations at the end of this important work, the committee did agree on a set of core principles that really underpin this first set of recommendations: transparency, inclusivity, and responsibility. With respect to the principle of transparency, one urgent need – we felt – was really to ask WHO to create a registry for human genome editing research such that studies being done using these

technologies would be registered with WHO in a transparent way that would be accessible to all interested parties.

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We're going to be setting up a subcommittee of our broader committee to work closely with WHO to define what this registry would look like, how it would work, and think about how we can develop it over time as well. It will have to be a dynamic, ongoing resource and activity. We think part of this is very exciting because it can also serve as a method to increase accountability of scientific researchers around the world.

For example, we are going to ask publishers – people that are involved in actually publishing the manuscripts that emerge from important research – to require that research that is published has been registered with this new entity, this proposed new registry. Similarly, we'll be asking funders of research to make registration with the WHO a requirement for funding research in this domain. So we think that this could make a very important difference and will really increase transparency around what kinds of research, what research activities are ongoing in this area.

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With respect to inclusivity, the committee requested that the director-general really work with the committee to enhance WHO's capacity to act as an information resource including through its website for both technical and lay audiences, really trying to expand what's available on the website as well as creating linkages to other websites that could have important information for interested parties. It also recognised that WHO really sits in a unique position in terms of its network and its system of regional and country offices and that materials and information could be disseminated through that network and those WHO entities, that we could expand our reach, we could engage more with audiences around the world, and that this was also an important area for WHO to begin now to make new activities go forward and to really see their role as an information resource and coordinating centre in new ways.

The committee also really sees as a fundamental principle of the work we're going to be doing in terms of global governance and oversight of human genome editing as the responsible stewardship of science and in that regard we're going to be first setting up a subcommittee of the broader committee to really delve deeply into developing a set of standards and global norms for broader discussion with the committee as we move towards the development of a strong international governance framework in this area, but I think we also felt it was important to make a statement that the committee agrees that it is irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing.

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So we felt that we made real progress in this first meeting. There's much more work to be done. I won't go into all of the other areas where we hope to move forward and make a difference, but it's an exciting – I think – first start with a lot of work to be done

and a daunting responsibility in terms of fulfilling the mandate of WHO for this committee to offer a framework for global governance and oversight of human genome editing.

TJ Thank you very much, Dr Hamburg. Thank you very much, Dr Moorthy. I just remind everyone who is online that to ask a question, please type zero-one and we can go to the first question and that's Jon Cohen from Science. Jon, can you hear me? Hello? Do we have a Jon Cohen from Science on the line? I'm just being told that we have to wait for a second, so maybe waiting to get Jon online, maybe we can just ask Dr Moorthy for example or Dr Littler, what does this mean really for WHO?

VM So this is an important new activity for us. As I said before, we have identified that we're looking to do more in looking ahead and getting ahead of the curve as far as possible. This is an example of an area where new technologies – genetic technologies but also in other areas – are just moving so fast. So we think it's really very important for us to engage with the scientific committee and have as much visibility as possible of the status of scientific research in this area and begin to link that with different constituencies so that we can receive input from the best experts around the world in how we can have this interface between science and public health really – as the longer-term vision is – accelerate the benefits for people around the world while reducing risk because of our ability to interface with national health authorities and consider, what are the implications for countries around the world of these emerging technologies?

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TJ Thank you, Dr Moorthy. I'll just try to see if we have someone online. I will ask to Jon from Science to dial again in to get back into line. Do we have anyone who is online and having a question? So everyone who was in the queue should have been told, go back to the queue. Do we have Helen from Politico online?

HE Hi. Yes. Can you hear me?

TJ Yes, Helen. Finally it works. Can you hear as well?

HE Yes. I can. A couple of questions… I was interested to hear about the urgent need to ask WHO to create a registry for human genome editing research and for funders of research to make registration a requirement of funding. Would the intention be that this would be obligatory for all future research in human genome editing? If so, how would that be imposed? Then my second question was around the line at the end around, the committee agrees that it's irresponsible for anyone to continue with this line of research. I'm just wondering who would be… if the WHO would be monitoring that going forward. Thank you.

MH Well, this is Margaret Hamburg. I'll begin, at least. As to your first question, we think it's very important to establish this registry to get a better sense of the research that's going on around the world, greater transparency about it, and in fact greater accountability in terms of assuring that research meets standards in terms of science

and ethics. We are just beginning the discussions about what this registry would look like, how it would be implemented, and how of course it would be run over the course of time, so I think it's early days for us to answer specifics of your question, but I think it is important for all of us to have a better understanding of what research is being done and I think it will create – I think – more of a sense of responsibility of the research community in terms of what work they're doing and how they're doing it.

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It will also offer an opportunity for greater sharing of information that's emerging from research, which will likely have benefits in terms of advancing quality science. It also can have the opportunity to help those who are thinking about how to responsibly undertake research think about those activities because as this registry is created, one of the things that we also had talked about was the possibility of – over time – having it be a resource for people to be able to connect and get additional technical assistance about appropriate research. So it's an idea at the present time. It needs to be fully fleshed out and we are excited by the opportunity that it holds, but it's really the work of this subcommittee with WHO that needs to go forward to really define and make this idea real.

The second question had to do with the statement that the committee agreed at it's irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing. I think the statement speaks for itself. I think it's reflective of many other calls that have emerged from the work of national academies around the world, the UNESCO report, the recent Nature publication. So I think it reflects the state of the science and the desire to undertake responsible stewardship of important scientific technologies.

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TJ Thank you, Dr Hamburg. Again, Jon Cohen from Science, sorry for this delay. Can you hear us now?

JC I can hear you. Can you hear me?

TJ Yes. Please go ahead.

JC Thank you for taking my question. I have two quick questions. One on the registry: is it for both germline and somatic? The other question is, you don't use the word moratorium. Why not?

MH The registry would be for both germline and somatic cell editing research and the word moratorium is much in the news, but the task of this committee really is a broader charge, which is to look at how to structure a comprehensive global governance framework and the committee is going to be working on that over the next 18 months. Certainly the issue of whether a moratorium might have a role to play will be part of those discussions, but what we are really trying to do is look at the broader picture and look at how there can be a framework for responsible stewardship. I don't think that a

vague moratorium is the answer to what needs to be done. We really need to take this more comprehensive, stepwise approach and that is really the charge of this committee.

TJ Thank you very much, Dr Hamburg. If that answers your question, Jon, we will move forward to Sarah from Nature. Sarah, can you hear us?

00:23:38

SA Yes. I can hear you. Yes. I was wondering if you could explain a little bit more about the kind of position that you're thinking at this point the WHO could take, whether it's going to be more of an enforcement mechanism that they could take or whether it's going to be passive information-sharing. Then I was also wondering if you were discussing the possibility of having some sort of hotline or way that people could report if they find genome editing happening in a way that might not be considered ethical.

MH We are at the very beginning of our work as a committee and we're really looking at a broad range of issues. We used this first meeting – as I said – to make sure that we were really all up to speed in terms of the state of the science and existing and ongoing activities in this area and then to begin to focus in on what a global governance framework might look like including beginning to identify the relevant issues, the range of specific mechanisms that could be used to address them, and also how to make sure that we involve the widest range of stakeholders and recognise the different contexts in which a global governance framework would have to actually be implemented both at the local, national, regional, and international but also countries that look very different and have very different national laws and regulations and different capacities, etc.

So it's a daunting task, but it's the beginning of a process and we really don't know all of the strategies that might be used, but certainly WHO is uniquely situated as an international health organisation with broad membership and a commitment and tradition of providing normative standards and guidance in critical areas and we want to build on that capacity and tradition as we move our work forward.

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TJ Thank you very much, Dr Hamburg. We will now move to William from Health Policy Watch. William, can you hear us?

WN Yes. Can you hear me?

TJ Yes, William. Please go ahead.

WN It's William New at Health Policy Watch in Geneva and I'm sitting in New York. The question I had was largely answered by the previous answer, but I might as well take another angle on it and that was maybe just to ask a procedural question about the goal. Is it expected to be ultimately… I know it's early and you just went through this, but was there an anticipation by some that there might ultimately be a binding

arrangement among WHO members? Could that be one of the possible goals on the horizon?

Then through this process – you said 18 months – what would be the path from here to there in terms of meetings and involvement of the various players including the private sector? Then finally I just wanted to go back to what you just indicated. Was there a large amount of variation among the members of the committee within the two-day meeting in terms of maybe definitions or goals or objectives for the committee, possibly by region or development level and these types of things?

TJ Thank you.

00:27:44

VM So this is a technical consultation process which is explicitly within the scope of the 13th general programme of work, so working with the committee to define the parameters of the consultation process will be engaging – as has been described in a wide variety of methods – to seek input from different constituencies from around the world including whatever we can do to be as inclusive as possible as we go forward. The outcome of this… this is an advisory committee of WHO, so the outcome is recommendations to the director-general and the steps after that will be for the director-general to decide how he chooses to take this forward.

In terms of the committee, maybe I can follow on to say that everything that Dr Hamburg has stated was agreed by the committee in its entirety and we have rich discourse between the different members of the committee. One of the reasons we put such a big emphasis on geographic representation is that it's very important to take into account the perspectives from different cultural and societal perspectives from around the world. So we had African representation, representation from the Eastern Mediterranean office, from Latin America, from Southeast Asia, from the Western Pacific, and everybody agreed, but importantly – taking into account all of these different perspectives – it was still possible to come to agreement on these elements.

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MH And with respect to your question about how we're going to get our work done, we do anticipate that there'll be at least three more in-person meetings. There will also be opportunities for phone teleconferences. We'll be creating several subcommittees of our group that will meet in parallel to the broader committee. We also plan to use online consultations to enrich our work where we will pose questions to the broader group of stakeholders and seek information back to help us gather additional information and fill in gaps and extend our ability to engage. So we will be working hard as members of this committee, but I would say that it was really robust, rich conversation and a great deal of consensus around critical issues and concerns including of course the recommendations that we are making coming out of this first meeting.

TJ Thank you.

WN Can I just ask if the recommendations or the principles that you've referred to are available? Because I haven't seen them in the press release yet. Or will be available?

TJ Well, I think that recommendations, William, are already in a press release. Maybe we didn't spell out directly these principles that co-chair was speaking about, but information and recommendations are there.

MH I think the press release does mention that we agreed on several core principles that underpin our current recommendations. That doesn't mean that we won't define additional principles going forward, but we did… as we talked, several core principles emerged where we felt that there were action steps that could be realistically undertaken in the near term and we felt that there was no reason to wait until the end of the 18-month process to try to initiate those activities, but it is a work in progress and really the final report will be – I think – the culmination of a great deal of effort and perhaps a series of recommendations that will emerge following our next in-person meeting.

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VM Just to add, we will be developing a meeting report which… after the process of clearing the meeting report with all the members of the committee, we will be making this publicly available, which might be a useful reference, together with the background documents that were prepared for this meeting.

TJ Go ahead, William.

WN Yes. I just wondered, will there be a report of the committee at this point to the WHA or is this too soon?

VM No. There's no plan for this to be reported to WHA at this time.

TJ Thank you, William. Just re-reading the press release, we did in the third paragraph mention core principles of transparency, inclusivity, and responsibility in the work of the committee. If we have people with more questions, please type zero-one on your keypad. We move to South China Morning Post. Do we have anyone online?

00:33:16

MB Yes. This is Mary Ann Benitez.

TJ Hello. Can you hear us? Please go ahead if you hear us.

MB I'd like to ask you… one of the members of the expert committee is from China and I was wondering whether she has discussed with you what happened to the two genetic babies that came out of the work by He Jiankui, the scientist from Shenzhen. Also, following up on what the other reporter – I think from Politico – said, why did the committee discuss about any moratorium at this time instead of waiting 18 months down the line? Do we know whether also the two genetic babies that were produced using CRISPR… how are they doing? Thank you.

MH Well, we were very grateful for the participation of our colleague from China on our committee and she added to our discussion across all of the areas of work that we addressed. Certainly the episode in China was of great concern to all the members of the committee and we did have the opportunity to hear from our Chinese colleague about some of the new legislation in China and what it hopes to address with respect to human germline genome editing, but as I said earlier, the work of this committee is not to investigate cases that have occurred but to really try to create a global governance framework and proposal for responsible stewardship and oversight of human genome editing more broadly.

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That is really where we focused our time and effort and that is the mandate of this committee and its work. We did feel at this moment in time that it was important to reiterate what many scientific organisations and other groups looking at human genome editing have said, which is that we agree that it's irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing and that certainly includes the recent case in China.

TJ Thank you very much. We have time for one more question and it's Sarah from Nature with a follow-up. Sarah, please go ahead.

SA Yes. I was wondering if you could say anything else about… you mentioned that it's not your job to investigate cases that have occurred, but is that something that's on the table for a recommendation to WHO to establish some sort of investigative or enforcement body? I know it's early days, but is that something that's on the table?

MH Well, I think it is very important for us as we think about how to formulate a meaningful and sustainable global governance framework for this set of issues to look at where governance and self-regulation and other approaches has been working and where it has not been working. So in that context, the experience in China is very important to examine. We think it's important to try to gather additional information about scientific research and experience that maybe hasn't gotten quite the same media attention but can inform our decision-making and I'm not talking about necessarily research that mirrors exactly what happened in China across the whole spectrum, but clearly we need to learn more and we need to use that additional information-gathering to inform our work as we move forward towards our recommendations for global governance.

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TJ Thank you very much, Dr Hamburg. Well, at this point I think we don't have any more questions and I think we explained the work of the committee in the last two days. We will certainly have opportunity in the future to speak again with tonight's guest. Just to remind everyone, the audio file from this press briefing will be available in the coming hour and also we will have a transcript most likely tomorrow. Thank you very much for dialling in, thank you for your questions, and thanks to our guests. I wish to everyone a nice day or nice evening. Thank you.

MH Thank you.