

COVID-19

Virtual Press conference 24 August 2020

Speaker key:

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JA Jason

MK Dr Maria Van Kerkhove

BA Dr Bruce Aylward

AV Avijit

SS Dr Soumya Swaminathan

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ES Esmir

KA Kai

CN Chen

EP Ep

EL Elaine

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DI Divia

SA Sarah

00:00:52

MH Hello, everybody. This is Margareta Harris in Geneva on this 24th August speaking to you from the Geneva WHO Headquarters and welcoming you to our global COVID-19 press conference today. Today we're going to have a focus on the ACT Accelerator so please get your questions ready on this very interesting and important subject.

As always Dr Tedros, our Director-General, will address you first. Then I will open the floor to questions. Joining Dr Tedros to answer questions today are, in the room, Dr Mariangela Simao,

our Assistant Director-General for Access to Medicines, Dr Maria Van Kerkhove, our Technical Lead for COVID-19, Dr Bruce Aylward, our Senior Advisor to the Director-General who's leading the work on the ACT Accelerator.

Joining us virtually is Dr Mike Ryan, the Executive Director for our Emergencies Programme. We hope Dr Soumya Swaminathan - yes, she has joined - Dr Soumya Swaminathan, our Chief Scientist. As always this briefing is being translated simultaneously into the six official UN languages - Arabic, Chinese, French, English, Spanish and Russian - plus Portuguese and Hindi.

But I've got some very good news for Arabic and Hindi speakers. The Zoom has been upgraded so the language button is the correct button; you simply press Arabic. However if you're not seeing it you will need to upgrade your Zoom so I'm telling you that now if you're having problems.

00:02:33

Now without further ado I will hand over to Dr Tedros. Dr Tedros, you have the floor.

TAG Thank you. Thank you, Margareta. Good morning, good afternoon and good evening. Last week I sent a letter to all member states requesting them to join the vaccine arm of the ACT Accelerator. I am pleased to announce that as of today 172 countries are now engaging with the COVAX global vaccines facility, which has both the largest and most diverse COVID-19 vaccine portfolio in the world.

At present there are nine vaccines that are part of this dynamic portfolio which is constantly being reviewed and optimised to ensure access to the best possible range of products. Even now discussions are ongoing with four more producers and a further nine vaccines are currently under evaluation for the longer term.

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The facility is the critical mechanism for joint procurement and pooling risk across multiple vaccines so that whatever vaccine is proven to be safe and effective all countries within the facility will be able to access them.

Most importantly it is the mechanism to enable a globally coordinated roll-out. This is in the interests of all countries, even those that have invested with individual manufacturers independently. We're working with vaccine manufacturers to provide all countries that join the effort timely and equitable access to all vaccines licensed and approved.

This doesn't just pool risk. It also means that prices will be kept as low as possible. New research outlines that global competition for vaccine doses could lead to price spiking exponentially in comparison to a collaborative effort such as the COVAX facility. It would also lead to a prolonged pandemic as only a small number of countries would get most of the supply.

Vaccine nationalism only helps the virus. The world has so far invested US\$12 trillion in keeping economies moving. Investing in the COVAX facility is the fastest way to end this pandemic and ensure a sustainable economic recovery.

Through the allocation framework COVAX will ensure that low, middle and high-income countries all receive the vaccine in a timely way as soon as there is supply of a safe and effective vaccine.

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The success of the COVAX facility hinges not only on countries signing up to it but also filling key funding gaps for both the research and development work and to support lower-income economies within the facility.

Our only way out of this pandemic is together. Initially when there will be limited supply it's important to provide the vaccine to those at highest risk around the world. This includes health workers as they are on the front lines in this pandemic and critical to saving lives and stabilising the overall health system.

It also includes people over 65 years old and those with certain diseases that put them at higher risk of dying from COVID-19. As supply increases the next stage of the vaccine roll-out will be expanded based on an assessment of each country's vulnerability to the virus.

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A number of vaccines are now in the final stage of clinical trials and we all hope we will have multiple successful candidates that are both safe and effective. In order to be able to secure enough doses to roll out the vaccines the next step for the partnership is for countries to make binding commitments in support of the COVAX facility.

While we're grateful for the funds already committed towards the COVAX facility more is urgently needed to continue to move the

portfolio forward. The goal of the mechanism is to deliver at least two billion doses of safe, effective vaccines by the end of 2021. As governments invest trillions into economic stimulus the COVAX facility offers a huge return on investment.

There is light at the end of the tunnel and, as I said last week, together we can do it. While investing collectively in research and development on vaccines we need to also use the tools at hand that we have now to suppress this virus.

As governments hone their track-and-trace systems to test, isolate and care for patients and trace and quarantine their contacts everyone can play their part. If we all physically distance, clean our hands regularly, wear masks and keep informed we can collectively break the chains of transmission. Do it all; do it all now.

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Communicating challenges and solutions has and will continue to be key to ending this pandemic. More than four million people have enrolled in our training courses through the openwho.org online learning platform. WHO is partnering with the World Federation of Science Journalists to accurately communicate the intricate science as it evolves.

Through our regional offices WHO has organised webinars in multiple languages for journalists to counter misinformation and a massive open online course for journalists covering the pandemic was created through a partnership between WHO, UNESCO and the Knight Center for Journalism at the University of Texas, Austin.

More than 9,000 journalists from 162 countries enrolled. This online training was delivered in English, French, Portuguese and Spanish and will soon be available in Arabic, Chinese, Russian and Hindi. More information about these online courses is available on our website.

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We're learning new things about this virus every day and journalists are critical to helping news communicate that information to the public in a way that saves lives. We will continue to promote science, solutions and solidarity because we believe to our core that we do it best when we do it together. I thank you.

MH Thank you very much, Dr Tedros. I'll now open the floor to questions. Remember, because we have so many people online

please restrict your questions to one and remember, you can ask your questions in any of the six UN languages plus Portuguese. The first person on the list is Jason Gayle - we're going to Australia - from Bloomberg. Can you please unmute yourself and ask your question.

JA Thanks, Margaret. Apologies; my question is not directly related to COVAX. Researchers at the University of Hong Kong are reporting today a reinfection in a 33-year-old immunocompetent Hong Konger 142 days after a symptomatic infection. The subsequent infection was caused by a different virus as confirmed by genome sequencing and it was asymptomatic.

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This is the first documented case of reinfection that I'm aware of out of more than 23 million COVID-19 cases. How should we interpret this finding and what are the implications for herd immunity and for vaccination? Thanks.

MK Thanks very much for the question. I just got ahold of the press release that was provided by Hong Kong New so I had a quick look at that. From the very beginning we've been talking about when people are infected with the SARS-CoV2 virus and that our expectations are that people who are infected with this virus develop an immune response.

What we are learning about infection is that people do develop an immune response and what is not completely clear yet is how strong that immune response is and for how long that immune response lasts.

There's very good data coming out from research studies which are being conducted all over the world that are looking at this immune response for people who have had a mild infection, people who have had asymptomatic infection, people who have had severe infection and we're seeing that they do develop an immune response and most people do.

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So what we understand from the press release is that this may be an example of reinfection and if you remember, last week I was asked about this and I said that in cases like this it would be good if sequencing could be done. In a place like Hong Kong where they have very strong facilities they can do that and in fact they have done. I understand from the press release that there's a 24-nucleotide difference between the first virus and the second virus. What I think is really important is that we put this into context. As you outlined in the question yourself, there've been more than 24 million cases reported to date and we need to look at something like this on a population level.

It's very important that we document this and that in countries that can do this, if sequencing could be done, that would be very, very helpful. But we need not to jump to any conclusions to say, even if this is the first documented case of reinfection it is possible of course because with our experience with other human coronaviruses and the MERS coronavirus and the SARS-CoV1 coronavirus we know that people have an antibody response for some time but it may wane.

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What we know specifically about immune response for SARS-CoV2 is that there are a number of studies underway following the same individuals over time. These are called longitudinal studies, which follow the same individual at monthly time periods or every few months.

Remember, we're eight months into this pandemic and so these studies are still continuing. From the longitudinal studies that are underway - not all of them are published yet - we do see a strong antibody response that stays at that same level.

There are some cross-sectional surveys that have been recently published that look at the same population over time - not the same individuals but the same group of people from the same population. There was some suggestion that there may be a slight decline or waning in immunity.

Again we really need these studies to be conducted so that we really understand what this immune response looks like but I don't want people to be afraid. We need to ensure that people understand that when they are infected, even when they have a mild infection, that they do develop an immune response.

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In this particular case it's very important that we look - and I haven't read the study so I don't have the answer to this year - to see if this individual developed a neutralising antibody response, which is what will protect from the infection.

So still a lot of work underway; really good studies that are underway but it's great to see documentation and these good studies and these being shared.

MH Thank you very much, Dr Van Kerkhove. For the next question we're going to Malta, to Monique in the Malta Newsroom. Monique, could you unmute yourself and ask your question please.

MO Good afternoon. Hi, it's Monique. My question is, what is the World Health Organization's view if a vaccine is found; would it be mandatory for everyone?

BA Thank you very much for the question about vaccines and their use going forward. The question was specifically whether or not there would be a requirement for vaccination. Obviously immunisation policy and requirements are in the national domain and so those decisions would be made at the national level but clearly what we're looking for here is the greatest possible acceptance of a vaccine and that vaccine-seeking behaviour.

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So our work will really emphasise ensuring people understand the benefits of the vaccines, the safety of vaccines, the quality of vaccines and that we can encourage as much as possible the seeking of vaccines rather than mandatory requirements.

MH Thank you very much, Dr Aylward. Now we're going to move to India, to Avijit in AMN News. Avijit, can you unmute yourself and please ask your question.

AV Thank you for taking my question. We've just had the Russian vaccine announced and there's been a lot of enthusiasm amongst people all over. How effective is the vaccine and what is WHO's comment on that?

SS Do you want me to take that?

MH Dr Soumya, yes, please go ahead.

00:16:42

SS Okay. Thank you very much for that question. The first thing is that WHO of course welcomes all vaccine development programmes around the world and we're very encouraged by the fact that there are so many vaccine development programmes and over 30 candidates now in various stages of clinical development, in phase one, two or three clinical trials.

We have also put out quite early on, in May of this year, the criteria for what would be considered a safe and effective vaccine. It's called a target product profile and it describes the kind of benchmarks that we would like a vaccine to meet so a minimum of 50% efficacy in preventing infection with a lower bound of at least 30% so a vaccine that offers at least 30% protection at the population level and of course is safe.

Safety again is assessed short-term but also needs to be assessed longer-term because there are some side-effects which you only pick up later on. That is why it's so important to have these clinical trials conducted according to the standards and norms so that the data can then be examined by the experts before a decision is made on whether or not this vaccine should be licensed.

So we have started discussions now with the authorities in Russia to learn more about the vaccine candidate and we've requested the data on efficacy and safety. We understand that it's gone through some preliminary human studies and that it is about to get into a phase-three clinical trial which will really be the test of efficacy.

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So we look forward to discussing with the Russian authorities as well as seeing the data that is available so far and then having a dialogue on what the further needs should be and how further studies would need to be done. This is why we're also promoting the idea of a Solidarity vaccine trial where many different manufacturers, developers, countries can participate both as trial sites to test different vaccine candidates but also to provide the vaccine candidates into this large, global, multi-arm, adaptive clinical trial that we think will be both a cost-effective and an efficient way of testing as many candidates as possible in the shortest period of time. Thanks.

MH Thank you very much, Dr Swaminathan. We have no more comments in the room. I will now move to Christine from ABC America. Christine, please unmute yourself, go ahead and ask your question.

CH Thank you. I wanted to ask about monoclonal antibodies. Can you speak to what they are, how they can be used and limitations to getting the drug to the population at large? Because it sounds like a ground-breaking candidate therapeutic that may play an important role in helping curb the pandemic. Thank you in advance.

MH Thank you, Christine...

SS I could start, Margaret, and Mariangela might want to add.

MH Yes, I was going to say, that's for you.

SS Monoclonal antibodies are basically highly specific antibodies which act by preventing the virus from binding to the cell receptor and therefore preventing the virus from entering the human cells and causing an infection.

Monoclonal antibodies have been a fairly recent technological advance, say over the last ten to 15 years but have been used for a number of diseases, both chronic diseases, immunological disorders, cancers and there is more and more interest now in using these for infectious diseases.

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As far as COVID-19 is concerned there've been several efforts to develop monoclonal antibodies and also there are different ways of doing it. You could do it in humanised mice; you can also do it by extracting the antibodies from people who have recovered and then purifying them or it could also be done de novo in the laboratory.

So different groups, different companies have taken different approaches and at the moment there are several antibodies, monoclonals either used singly or in combination so you can also use a combination of two or three antibodies and this was something that was tested in Ebola and found to be very effective in a clinical trial done in the DRC. There were two different monoclonal antibodies that were found to be better than antiviral drugs in treating Ebola.

So at the moment we are aware of several clinical trials for the monoclonal antibodies. The NIH is sponsoring a number of these trials looking at these both for prevention of infection - so you can give it to people who have been in contact, high-risk contacts, nursing home residents, etc, to see if you can actually prevent the infection.

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It's also being tested in early disease when people are not sick, outpatients and also in those who have been hospitalised with more moderate to severe illness so it's being tested across the spectrum and it is one of the promising therapeutics on the horizon.

I think the issue that you mentioned is very important, which is the possibility of scaling this and really making it accessible to people around the world because it is a complex product to make. These facilities do not exist in all parts of the world.

It could also be expensive of course depending on what technology is used and therefore we're looking very closely and also talking to many partners to see how technology transfer could be accomplished and how once these are found to be safe and effective, just like vaccines, you also want them to have broader access.

But it is a challenge because technologically it is going to be difficult but it can be done and it will be useful in the long run to build this capacity in countries around the world because monoclonal antibodies are likely to be therapy for other infectious diseases as well and so this is a platform technology and we urgently need technology transfer to happen. Mariangela might want to add something to this.

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MS Thank you, Soumya. Just to highlight, affordability is likely to be an issue because of capacity of production. Nowadays the monoclonal antibodies that are already on the market for other diseases are extremely expensive so they are among the high-cost drugs so this is a concern.

First we have to have one or two monoclonal antibodies that prove to be safe and efficacious and we need to scale up capacity. To that let me say that through the ACT A, the therapeutics pillar, we have been working already not the landscaping and the possibilities to scale up capacity for some of these candidates which are proving to be more potentially effective and safe.

The other issue that will come to light if we do have one of these drugs available for COVID will be the flexibilities around the use of biosimilars. We will potentially scale up the availability of the product in the world so there are a lot of issues. It's very good, welcome news that potentially we have a good - more than one monoclonal antibody.

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The other side is, we need to make sure they will be affordable and we will be able to scale them up. Thank you.

MH Thank you very much. No more. Oh, there is one more intervention, I think, Dr Aylward.

BA I think we've covered the main points on this but an interesting part of the question was about how they would be used and one of the discussions we've had over the last couple of weeks - and the Director-General has emphasised this - is that while vaccines are going to be an extremely important part of what we use in the fight against COVID there will also be some limitations and one we're concerned about is how well these vaccines, like others, will work in populations like the elderly and others.

This is where sometimes an intervention like the monoclonal antibodies can be very important because potentially this may work in populations where a vaccine or others wouldn't. That comes back to that point we've made over the last couple of weeks and again the Director-General emphasised today.

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The ACT Accelerator is really all about looking at that comprehensive, integrated portfolio. We need diagnostics, we need therapeutics, we need vaccines and the comments and questions just now about monoclonal antibodies really emphasise that.

One last point I would make is that - again you asked about the limitations - there are such challenges in proving that monoclonal antibodies actually work. The design of these trials is complicated because of the endpoints in them, especially when you're looking to prevent a disease or change the course of what is usually a mild disease.

Then the production ones we talked about and then even the challenges of using them and making sure they're in the right places at the right times so again one more, as you said, promising part of the armamentarium against this disease but like all of them, none are silver bullets but together hopefully the combination will work like one.

MH Thank you very much, Dr Aylward, Dr Simao and Dr Swaminathan. For the next question we're going to Bosnia, to Esmir from N1TV. Esmir, can you unmute yourself and ask your question.

00:27:21

ES Hi, can you hear me?

MH Very well. Please go ahead.

ES My question is, do you know how many countries from the western Balkans have already joined COVAX? Also in light of this some instances [?] here in the western Balkans are considering purchasing vaccines from Russia at the moment. Would you recommend them to go ahead and purchase vaccine from Russia or to wait until we have a vaccine accessible through COVAX? Thank you.

MH Thank you. I think this is a question for Dr Aylward.

BA Thank you very much for the question. As the Director-General mentioned, I think, last week and again this morning, we've had 80 countries - just over - countries and economies express an interest to join the COVAX facility. These would be self-financing countries, in addition to the 92 countries that would receive financial assistance through the COVAX facility for a total of over 170.

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This number represents countries from every single region and area of the world. As many of the conversations are ongoing about the terms of the facility as well as negotiations around those, not all countries want that their names be publicised so for that reason as the negotiations are ongoing we won't be able to talk about specific countries other than some that have said that we could use their names to promote the facility, the importance of it and the confidence in it.

But we prefer that what's available on the GAVI websites and our own gives you an update on who's joined at this point and have made their names public.

Sorry; also on the point about joining COVAX I want to be clear. It was a bit of a milestone yesterday as the terms of agreement went out to all potentially, what we call fully-self-financing countries for the COVAX facility and those are the terms now that lay out whether or not you're joining through what we call the confirmed doses way or through option doses and to make an indication, confirm your intent by 31st August. So that was an important milestone that went out just yesterday.

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So in the coming weeks we'll have a sense of how many actually have confirmed intent to join because again the question to me was how many have joined and at this point we're in that expression of interest with confirmation of intent by 31st August.

In terms of the second question about WHO recommendations re specific vaccines I think Dr Swaminathan already answered that question and WHO recommends vaccines through its P [or pre] qualification or emergency use licensing process which a vaccine would have to go through before we would, as an organisation, recommend it for purchase.

MH Thank you very much, Dr Aylward. For the next question we go to Kai Kupferschmidt from Science. Kai, can you unmute yourself and ask your question.

KA Thanks a lot. I was going to ask how many countries have signed up but I guess we've covered that with COVAX. Let me ask something else. You're pitching COVAX as a possibility to do both; countries that are doing their bilateral agreements might still sign up to COVAX.

But don't those still interfere with each other? Basically if you want to equitably distribute the vaccine globally then all the vaccine that countries are hoovering up with their bilateral agreements is outside of that scope. Right? So how do you see the connection between these two different mechanisms?

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MH That's also for Dr Aylward.

BA Thanks, Kai. In terms of how many countries have signed up you're absolutely right but the number again is over 170 countries now engaged in conversations and that represents over 70% of the world's population so a huge number.

Per your second question, this is so important to ensuring that vaccine gets out to all countries at the same time in a managed order so that we reduce risk around the world as rapidly as possible and then get the world's societies open again, health systems safe and economies open as well.

On the question about, do the new changes in the design of the COVAX facility affect the ability to equitably allocate the vaccine, actually it makes it much better because whether or not countries have signed bilateral deals or as individual countries or groups of countries the important thing is how that vaccine is used and the order in which that vaccine is used.

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What we're looking for - and the Director-General emphasised it last week and again today - is the more countries that join forces with the COVAX facility the more they can work together in a co-

ordinated manner to ensure that we roll these vaccines out at the same time and equitably across countries, not just because this is the right thing to do.

But what we've learned over the last few months is this is absolutely essential; no country can emerge from this crisis along and what we need is to get our health systems safe and protected first and foremost because that and the severe disease it manages is what is having the knock-on effect with the changes in societal behaviours we've had to promote as well as of course the economic impact.

So what we've learned really in a nutshell is that the critical thing is to ensure that some vaccine gets to all countries as early as possible and the design changes in COVAX where we can have the participation of all countries now provide an even stronger mechanism through which we can co-ordinate that roll-out so that all countries benefit and most importantly the entire world comes out of this crisis as rapidly as possible.

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MH Thank you, Dr Aylward. Now we will go to Chen from China Daily. Chen, could you please unmute yourself and ask your question.

CN Hi. Beijing made headlines just a few days ago about lifting the mandatory mask-wearing restrictions and actually in a lot of Chinese cities they've already done that. I'm actually based in Brussels, Belgium and Brussels has been added by the German Foreign Ministry just two days ago to the quarantine list and more and more by other countries too.

According to WHO's experts' views, what makes a difference? Considering that the whole population of Belgium is only half of Beijing's population but over a larger area, what policy measures make a difference? Thank you.

MK Thanks for the question. I will begin. Yes, I think what we're seeing is that a number of countries are taking a risk-based approach to the interventions that need to be used and applying them where and when necessary. You mentioned Beijing lifting one of their tools that they are using, in this example the use of masks.

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Masks are one of the tools that can be used in the control of this pandemic, controlling the transmission of the SARS-CoV2 virus. Then you mentioned another country. I think what we are seeing

is that what countries are doing is with the surveillance that is taking place where they are actively looking for cases, where they're using public health measures such as isolation and clinical care for cases, contact tracing and quarantining of contacts of known cases, the use of masks where appropriate, physical distancing, good information countries are collecting data.

What they're doing is they're using that data to help advise them on what needs to be done next. Can some of these measures be lifted or do some of these measures be implemented again? Countries are at different stages of the pandemic and so while many countries are seeing success in suppressing transmission, breaking chains of transmission they're able to lift some of these measures.

In other countries where measures have been lifted and they're seeing a resurgence in some areas - and we've seen in a number of countries that there are clusters of cases that are happening where people are coming together and congregating - some of these measures need to be implemented more strongly again.

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So we need to expect this, all countries need to expect this and we need to continue to use the tools that we have right now, which include active case finding, contact tracing, the use of masks, physical distancing, respiratory etiquette, hand hygiene and then applying measures where and when necessary.

We're very hopeful that countries will not have to impose nationwide measures but could impose perhaps some smaller, more geographically-bound, time-limited interventions where they are most needed to get through any resurgence in cases.

MH Thank you very much, Dr Van Kerkhove. The next question comes from Estonia, from Ep Ehan from Estonia public broadcasting. Ep, could you unmute yourself and go ahead and ask your question.

EP Hello. Thank you very much for the possibility. I would like to ask again about reopening the schools and transmission of the virus among children. You have said many times that there are a lot of things we don't know but maybe you could explain once more what we do know and what is your opinion at the moment. What would be your recommendation number one for schools?

00:38:20

MK Thank you very much for the question. Indeed we have a lot of questions about schools, especially in the northern hemisphere as many schools are starting to consider reopening for the school year. There are several things that we are learning about this virus. Every day we are learning something new about this virus thanks to the incredible work by public health professionals, front-line workers, researchers all over the world so a special thank you to everyone conducting high-quality research.

With regard to schools we know that schools operate in communities, they don't operate in isolation so the big thing that we look for is what does transmission look like in the community where those schools operate. That's first and foremost to really understand; we need to bring transmission under control in the communities where the schools operate.

As it relates to SARS-CoV2 infection among children there're three things that we are looking at and we're working with a technical advisory group that we have pulled together to help advise us, we're working with UNICEF, we're working with UNESCO, we're working with a number of partners to consolidate our understanding about this disease in children; first of all what type of disease is caused in children.

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Luckily the vast majority of children who are infected with the SARS-CoV2 virus appear to have mild disease or asymptomatic infection and that's good news. But there are young children, there are children that can develop severe disease and there are children who have died from infection.

The second thing that we look at is the amount of infection that is actually happening among children and this is difficult to measure because most children have mild disease or asymptomatic infection and so they're not picked up normally with current surveillance systems.

So we have seroepidemiology studies that are conducted that look at if a child had been infected and this is measured through antibodies. There are a number of studies underway and so the data is still preliminary and we're looking at studies that look at all the population.

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What we see from some of the preliminary results of the seroepidemiology studies is that there is some difference in the

infection rate among the youngest children versus older children, teenagers so we do need to distinguish children by age group.

The third thing that we look at is transmission among children and again most schools, many schools were closed in the beginning of this pandemic. Not all countries closed their schools but many did and so many of the children were removed from the school system and brought home.

We know from household transmission studies that children can be infected and we know that adults can infect children and we also know that children can infect adults although that appears to happen less frequently.

But again if we look at transmission we need to break children down by age group and there appears to be less transmission among the youngest kids versus kids who are in their teenage years.

So this data is preliminary but the bottom line is that children can be infected. Most children have mild disease although some children can have serious disease and some children can die. Children can transmit the virus although there are differences in transmission rates depending on the age with the youngest children transmitting less.

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These are studies that are ongoing. If there's transmission that's happening in a community it can enter into the school systems so what we really need to focus on is bringing transmission down in the school system.

We have outlined guidance on how schools can reopen safely. Everyone agrees how important it is that schools are operating safely and we've outlined how that can be done in terms of physical distancing and hand hygiene stations, respiratory etiquette, the potential use of masks by either the workers or the children themselves.

So there are a number of considerations of how the schools can be opened but again we really need to focus on reducing transmission in the community first.

MH Thank you very much, Dr Van Kerkhove. The next question comes from Elaine from Health Policy Watch. Elaine, can you unmute yourself and go ahead and ask your question.

00:42:32

EL Hi, thank you for taking my question. We saw last night the announcement by the US FDA for emergency use authorisation of blood plasma from convalescent patients. I was wondering if you could explain what's the difference between that treatment and one of monoclonal antibodies, which I presume might be a bit more precise or particular but if you could explain the two and perhaps give us a little thinking about how useful the blood plasma treatment may portend to be. There is a bit of a debate going on over that, as you may know, in the States. Thank you.

SS I can start. Can you hear me?

MK We can hear you.

SS Thank you. Convalescent plasma therapy is actually something that's been used for over 100 years for various infectious diseases and it's been effective in some and not so effective in others. As far as COVID is concerned, again this was one of the early therapies that began to be used.

Essentially what it involves is collecting plasma from people who've recovered from COVID and then using it to transfuse into someone who's ill. Generally it's been used in severely ill patients who've been hospitalised.

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There are a number of clinical trials going on around the world looking at convalescent plasma compared to standard of care and only a few of them have reported out on results and the results are not conclusive. I should say that the trials have been relatively small and the results in some cases point to some benefit but not have been conclusive.

We've been tracking this and we do ongoing meta-analyses and systematic review to see where the evidence is shifting and pointing. At the moment it's still very low-quality evidence so we recommend that convalescent plasma is still an experimental therapy, it should continue to be validated in well-designed, randomised clinical trials.

There are a few challenges with convalescent plasma as opposed to monoclonal antibodies, which we talked about earlier. Monoclonal antibodies, because they're developed in a manufacturing set-up under GNP; you know exactly the titre of antibodies and the dose that need to be given.

Whereas convalescent plasma; one of the challenges is each individual may have different titres of neutralising antibodies after recovery and it's very difficult to really test that and standardise that and so it's not one standardised therapy because blood is being drawn from different patients and then being transfused so that's one of the challenges.

There's also limited capacity for plasma [unclear] where you have to separate the plasma from the cells in the blood. Not all countries and not all hospitals have that kind of facility and also there's a lack of donors so there isn't enough to go around.

But I think the most important question really is about its efficacy and safety being proven in randomised trials and I hope that we will get that evidence in the coming weeks. Of course countries can do emergency use listing if they feel that the benefits outweigh the risks and they want to provide it but that's usually done while awaiting the more definitive evidence which is yet to come. Thanks. Mariangela might want to add.

MH Dr Aylward, go ahead. He has something to add.

00:46:48

BA I just think one other point that we'd make with regard to convalescent therapy is, as with all therapies, there can be risks and so that's another thing that one has to consider. In the case of convalescent plasma therapies there are a number of side-effects from relatively mild chills and fevers that can be associated with it to more severe lung-related injuries, even circulatory overload.

So for that reason, as Soumya outlined, the clinical trial results are extremely important to know that we've got a clear, demonstrated benefit so that we can weigh both of these in considering the final recommendations.

MH Thank you very much, Dr Swaminathan and Dr Aylward. The next question comes from Oriol from El Pais in Spain. Oriol, please unmute yourself and ask the question.

TR Hello, good afternoon. I hope everyone can hear me. I wanted to ask; last Friday the Spanish Ministry of Self [?] said that in the coming hours they were going to run out of stocks of remdesivir because of the increase of cases in Spain. They also said that they were going to try to bring units from research programmes so that they could treat patients in hospitals.

00:48:15

As you're aware, this was a controversial subject at the time when the United States announced that they were buying nearly all of the stocks until September. It was then said that there was a guaranteed supply for all countries throughout the summer until we could go back to the normal stock levels.

Then we heard that there could be a new delivery this week but my question is... We were told it wouldn't happen but it has happened. Another country, not a small one, the fifth in Europe has found itself without a pharmaceutical product which may be limited, doesn't reduce mortality but it can assist.

But I wanted to ask if this is not just a very dangerous precedent for what's awaiting us in the next months, not only in terms of vaccines but also in medicines that could be effective and have a significant effect in reducing mortality and when we look at unilateral trade operations that could endanger people in other parts of the world. Thank you.

MS Thank you for the question. I heard it in Spanish so I hope I'll be able to respond. I think you raise a super-important question which is when you have one provider only of a medicine and this risks the production globally.

00:50:04

We do have a particular situation with the remdesivir because of the commitment in one country to buy the stocks of the originator but we also have the bilateral agreements that the company, the originator made with the generic producers but this has not yet led to mass production elsewhere.

As you said, remdesivir is one example; it's the limited use for certain patients, severe patients and it has been shown only to reduce hospitalisation and not reduce mortality yet. But it's one of the reasons why WHO is working so hard with the partners to make sure that whatever technology's out there there is an increased capacity to address the market needs when they come out. Thank you very much for raising the issue.

MH Thank you very much, Dr Simao, for that answer. We will now go to India to Divia from Economic Times in India. Divia, please unmute yourself and ask your question.

00:51:16

DI Hi. I just wanted to check if there is any update on the Solidarity trial for the drugs. I have another question for Maria. Has there been any update on the sero study from India? They

were supposed to present to WHO a few weeks back. Thank you very much.

SS I can start with the Solidarity trial. I'm hearing echo. Is it okay?

MH It's settling down. Yes, I think you can go ahead.

The status as of last week was that we had 24 countries that were actively enrolling in the Solidarity therapeutics trial at about 400 hospitals and over 9,000 patients enrolled. As you know, we have discontinued two arms of the Solidarity trial, the lopinavir/ritonavir and the hydroxychloroquine arms. This was based on interim analysis which showed a lack of efficacy so these arms were dropped for futility.

The two arms that are continuing at the moment are remdesivir and Interferon beta. We're currently actively engaged with manufacturers discussing for inclusion for the next stage of this trial, looking for anti-inflammatory drugs that can be used in hospitalised, moderate to severely ill patients but also at monoclonal antibodies that could also be used for treatment, as we were discussing earlier.

00:52:59

So in the next couple of weeks we will be ready to announce what the next stage of the Solidarity therapeutics trial will be looking at and we will also have the data from the ongoing study ready for dissemination.

But we've seen incredible co-operation with Solidarity. We've had a number of countries waiting to start enrolling and hopefully they will now join when we start the next phase of the study but currently this is the second-largest clinical trial in the world, coming close to 10,000 patients, and also the largest trial looking at remdesivir with 3,000 patients randomised to remdesivir.

So hopefully we will have a definitive answer on the impact of remdesivir both on mortality and on clinical progression. Over.

MH Thank you. Maria will answer the second part of the question.

MK Thanks, yes. As you mentioned there are a number of serosurveys, seroepidemiology studies that are ongoing across the world and there are a number that are currently being conducted in India so there are some preliminary results that have come back looking at different antibody levels in different

cities across the country, some of them finding quite high levels of seropositivity.

00:54:26

What we're trying to get a better understanding on from all of the seroepi studies that are occurring globally are the tests that are being used. The different antibody tests measure different parts of the antibody response. Some of do what is called IGM or IGG and some are looking at neutralising antibodies.

Then there's a whole separate type of study that's looking at a cellular response. In India we're working to better understand which ones have looked at neutralising antibodies because these are quite important for us to understand the possible protection and how long that protection will last.

But we work very closely with our regional office in CRO [?] and our country office in India and in fact a number of other additional studies will be conducted in India as part of what we call the Unity studies, which is using a standardised approach of conducting these types of investigations so that we can compare them across a large number of countries.

00:55:21

But in India, in the preliminary results we've seen so far in some areas that have been hardest-hit, that have had high incidence levels, they've seen a higher measurement of those antibodies.

MH Thank you. I'm just double-checking whether Dr Mike Ryan wanted to add anything. No. The next question goes to Sarah Wheaton from Politico. Sara, could you unmute yourself and please go ahead.

Sarah, could you unmute yourself and ask your question?

We're not hearing you, Sarah. I'm really sorry. Can we hear you now? I think...

SA Are you able to hear me now?

MH Yes, loud and clear.

SA Sorry about that. About COVAX; you've asked for the confirmations of intent by August 31st. Is that a drop-dead deadline or if countries decide in December or March of 21, oh, yes, we probably should participate in this, is that still a possibility? Thank you very much.

00:56:46

MH It's one for Dr Aylward, I think, again.

BA Sure, and Soumya may want to come in on this. There're a couple of deadlines that are coming up that are important. 31st August is for the confirmation of intent and then we'll have the financial commitment or rather - sorry - expression of intent by 31st August - sorry, Sarah, to be really clear - and then the confirmation of intent is what happens on 18th September; then by 9th October to have the initial payments in place so those are the target dates that we're working toward.

Always - and you'll understand this - there are challenges for countries in terms of sometimes legislative process, sometimes financial processes, etc, so we work with countries on a case-by-case basis to try and ensure that we can work with them toward those deadlines.

We're still considering what would be the mechanism for countries that subsequently decide that they may wish to join. Soumya, you may want to speak to that issue if you have further information.

00:57:59

SS I think in the next couple of weeks there're going to be a lot of discussions between countries both in groups as well as individually with the Secretariat of the COVAX facility discussing what the different options are.

I think, as Bruce mentioned earlier, it's much more flexible now and countries that have their own bilateral deals also have the opportunity to participate in the COVAX facility by having a number of different options and there are also options for countries to make either committed commitments to purchasing a certain number of doses or keeping their options... by investing a little bit up-front for retaining the right to purchase vaccines at a later date.

We also expect to see a large number of vaccine candidates ultimately entering into this facility starting with at least a couple in the early part of 2021. But investing in the facility now is going to give that long-term view both of flexibility in terms of volumes but also in terms of having a variety of different vaccines that countries could choose from to suit their own situation and their own populations. Over.

00:59:29

MH Thank you very much, Dr Swaminathan. With that I will close this press briefing because we've come up to the hour. I

apologise to all of you in the queue with many questions. Please send your questions to mediaenquiries@who.int and we'll make sure we answer your questions or you can hold them for the next press briefing.

We will also provide the audio file and, as always, the text of the Director-General's remarks. Now I will hand over to Dr Tedros for his final remark.

TAG Thank you, Margareta, and thank you all for joining today. See you in our next presser. Thank you. Have a nice day.

01:00:31