HOUSE OF COMMONS

International Development Committee

Oral evidence: Humanitarian crises monitoring: impact of coronavirus, HC 292

Thursday 2 July 2020

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Watch the meeting

Members present: Sarah Champion (Chair); Mr Richard Bacon; Brendan Clarke-Smith; Mrs Pauline Latham; Chris Law; Navendu Mishra; Kate Osamor; Mr Virendra Sharma.

Questions 118-139

Witnesses

I: Dr Samia Saad, Director of Resource Mobilisation, Coalition for Epidemic Preparedness Innovations; Dr Josie Golding, Epidemics Lead, Wellcome Trust (part of both CEPI and the Covid Therapeutics Accelerator (CTA) partnership); Professor David Heymann CBE, Board Member, Foundation for Innovative New Diagnostics (FIND).

Examination of witnesses

Witnesses: Dr Samia Saad, Dr Josie Golding and Professor David Heymann.

Q118 **Chair:** I would like to welcome everyone to our session on humanitarian aid and the impact that Covid-19 is having on that. We have three witnesses today. I wonder if the witnesses could start by introducing themselves and explaining a bit about your organisation, the make-up of your initiative and how close to a breakthrough you might be.

Dr Saad: I am Samia Saad from the Coalition for Epidemic Preparedness Innovations. I am director of resource mobilisation and investor relations, and partner very closely with the UK Government, which are one of the biggest investors in CEPI. It is a public-private partnership, not for profit, that sprung out of the need for a co-ordinated approach post the west Africa Ebola outbreak. It was launched in 2017 with several founding Governments as funding contributors, as well as a couple of philanthropic organisations. Since then, the number of funders has increased quite a lot. The UK joined pre-Covid, but has also given substantial funding towards the Covid vaccine effort.

The reason for CEPI being founded was that, while there were lots of different efforts towards developing vaccines or other health interventions to fight epidemics, et cetera, there was not enough investment in preparedness. For example, while there was a vaccine for Ebola, the one that ended up being successful had only gone part of the way through development and had then sat on a shelf. The tragedy is that it did eventually get developed, and it turned out to be very effective in preventing transmission and getting Ebola, but it was only made available for use a year post the peak of the crisis. That is the rationale for having set up CEPI.

The core of CEPI's mission is equitable access and leaving nobody behind. That policy and principle governs our mission and is reflected in the contracts we cut with product developers and vaccine developers. I can certainly talk about that a little bit more. I will stop there, having given you a brief overview.

Dr Golding: I am Josie Golding. I am the epidemics lead at the Wellcome Trust and my role is to co-ordinate to the various preparedness and epidemic response work across the organisation. Wellcome funds research at a global level. We have invested in academic support over the last six years, building on what Samia mentioned in the west Africa Ebola outbreak. We are a founding partner of CEPI and a funder as well. With DFID, we have supported a range of research initiatives related to epidemics. In particular, we have a large joint initiative on funding epidemic research that has been going on since 2018. It includes a lot of the Ebola work but also encompasses Covid.

Today I can also talk about the therapeutics accelerator, which is a very new initiative that was formed by the founding partners, the Gates

Foundation, Mastercard and Wellcome, with an initial pledge of $125 million at the end of April. Since then, other partners such as DFID have come on board to support this. While there has definitely been a focus on vaccine over the last few years for epidemics, there has been no co-ordination effort related to therapeutics, so this is part of what we saw as a big gap, in particular with Covid. Similar to CEPI, the main function is equitable access, particularly in low-resource settings, making sure these treatment options are available.

Q119 **Chair:** Professor Heymann, I know you have come in at very short notice. We are incredibly grateful that you did that. I wonder if I could ask you the same question. Could you tell us a bit about the institution, the make-up of your initiative and if you are getting anywhere close—or believe anybody is getting anywhere close—to a vaccine for Covid-19?

Professor Heymann: I am David Heymann and I am a professor of infectious disease and epidemiology at the London School of Hygiene and Tropical Medicine, but also a member of the board of FIND. FIND is an international organisation, non-profit, which is focused on diagnostic testing for global health. FIND has really had a strong record of success. In fact, just last week at our board meeting we reviewed the progress that FIND has made since 2003, when it was first established. It has been integral in the development of 24 new diagnostic tools; that is, tools to diagnose the cause of disease. This has been effective in providing tests to 150 lower and middle-income countries.

At the same time, FIND-supported projects have provided over 50 million tests to target markets. Those target markets are in developing countries and have been supported with 50 million tests. FIND works with over 200 partners worldwide, including academia within the UK and elsewhere, and the private sector.

In response to Covid-19, FIND is really the key organisation in diagnostic testing and the hope for developing countries, because they are the ones that need these tests and FIND is developing mechanisms to get those tests to the countries. As you know, all we now have is one test, which is useful in identifying people who have acute illness. We need different tests than this test, because this test is very costly and requires laboratory equipment that could be bypassed if there were simple tests that could diagnose infection. That is what FIND is investing in at present, diagnostic tests to identify people who have infection, as well as tests to look at the antibodies, giving a record of people who have had infection in the past.

You asked what the breakthroughs are. There have been no major breakthroughs in vaccines or in therapeutics, but there is a diagnostic test that is useful, not only in identifying people who are sick, but in outbreak containment activities, identifying contacts who are sick and who need to be isolated as well. New Zealand and other countries, including Germany and the UK initially, have used contact tracing very well in identifying people, containing those outbreaks that occur and

preventing further transmission into the community. FIND is very well placed—and we will talk about that as we go on—through its emerging infections arm, to continue to supply diagnostic tests to developing countries. We will work closely with the ACT and other initiatives.

Q120 **Chair:** Josie, could I come back to you? You mentioned the Covid Therapeutics Accelerator. I wonder if you could speak a little more about that now.

Dr Golding: To take a step back, the treatment options that we have seen being investigated have been mostly in hospitalised patients, looking at severe cases. The therapeutics accelerator differs from that. When we talk about equitable access and having therapies and drugs available, particularly to low-resource settings, a hospitalised setting is probably not where we are going to see great breakthroughs in low-resource settings. This is looking at treatments that are preventive, treating the mild and moderate cases to prevent them from getting to severe cases. It is initially looking at repurposed drugs, similar to what we see in hospitalised cases, and looking to build evidence on that by carrying out clinical trials.

It is also focusing on very early development to make sure we have what we call a pipeline of drugs that can move up through the process, to go from early investigations into people to look at the safety. The primary objective at the moment is on repurposed drugs, so there has been focus on hydroxychloroquine, but there is also going to be a greater focus on other therapies. The biggest investments have been on hydroxychloroquine at the moment, where there is no evidence at the moment to look at non-hospitalised patients. There has been approximately $50 million invested so far.

Q121 **Chair:** We want to come on to that in a bit. Samia, did you want to come back in again?

Dr Saad: I did, because I realise I did not answer the question around how close we are to a Covid vaccine.

Chair: I thought you were avoiding it.

Dr Saad: I was not; I am not avoiding it. How close are we? The good news is that there are hundreds of projects around the world. However, there are a handful that are in clinical trials. Of that handful, six out of the nine that CEPI currently has invested in are already in clinical trials and are very exciting. One of them is quite advanced, which is a partnership between Oxford University and AstraZeneca. That is the leading one in terms of how far along towards a licensed vaccine we can get. That is promising, because the more vaccines you invest in that are robust, the bigger shots at goal you have.

In addition to the nine candidates that CEPI is investing in right now, it has an open call to see if there are other candidates and is constantly monitoring the landscape. The key for a global pandemic is that you need

an efficacious vaccine that is going to give you immunity. We still are learning a lot about the disease because it is so new. We will need billions of doses, so it needs to be really scalable. You need technologies that can scale. Speed, scale and access are the drivers around the portfolio. It is exciting that six of the nine candidates are already in clinical trials, with some of them advancing quite well. We are hopeful, but again, the science does not always do what you want it to do. We are getting good signals that we might have some doses, not billions, but 100 million doses if we are lucky, at the end of the year.

We are partnering now with Gavi and the WHO under the ACT Accelerator, an initiative in which the EU, WHO and lots of other G20 countries have come together to ask, "What can we do to accelerate?" As you know, the diagnostics partnership is led by FIND, the therapeutics by Wellcome with other partners and the vaccines initiative. It is trying to bring an end-to-end vision. Once we develop those vaccines, how do we get them equitably and fairly delivered? That initiative has been kicked off. That end-to-end view is to really accelerate, getting hopefully more than one shot at goal, because we are going to need more than one vaccine. That is the other thing to qualify; in order to scale in 2021, that is needed. It is much more promising than two months ago.

Q122 **Navendu Mishra:** I would like to echo the Chair's comments and thank you for making time for this session. To each of you, could I ask who sets out the strategy and the criteria for grants of funding? Who decides where the money goes? In addition to that, does your organisation ensure the involvement of the global south institutions in your research and development programmes, and do they have access to the funds?

Professor Heymann: I would be happy to talk about that a little bit. Let me start with your last question about developing country involvement. FACT has invested quite heavily in a project in Senegal, which will be a transfer of technology, a development of diagnostic tests from Mologic, the diagnostics manufacturer in the UK, to Senegal. There will be development and production of tests, which will then be provided to countries throughout Africa at a fair price within Africa. The whole context of FIND is to work towards tests that are effective in developing countries and can be made available.

FIND also has a role in the ACT Accelerator on the pillar of diagnostics. Diagnostic tests are a failsafe in case there is not a vaccine or in case that vaccine is available but cannot be made accessible in all countries. It is the same with the therapeutic. Diagnostic tests are there at present and can be used successfully to identify patients, get those patients isolated and treated, and at the same time examine contacts who become sick to make sure that, if they have an infection, they are isolated.

How does this work? FIND has developed a work plan on the ACT Accelerator with all the different parties involved. Funding that comes into FIND for the ACT Accelerator comes from designated contributions

from countries, and the UK has been very important in that. That funding is then spent by FIND in the way that it always spends its finances, in a controlled way that requires reporting from the sites where they are received. Today, as you may know, the ACT Accelerator has received €9.8 billion of pledges, of which unfortunately only €242 million has been earmarked for testing, just 2.5% of the total. For an intervention that is already available and must be vitally provided to countries, that is a very small amount of funding.

Dr Saad: In terms of who sets the criteria, the WHO is an observer to the board of CEPI. The core priority pathogens that CEPI works on are set through something called the research and development blueprint, where scientists have been brought together from around the world to identify the potentially emerging pathogens, but also the right tools to contain and reduce transmission and deaths. The WHO is a key partner in Covid, working very closely in terms of the research agenda and what the vaccine profile needs to look like so you can deliver it in all sorts of settings, including, most importantly, in health systems settings that are weak or not as efficient. How would you deliver a vaccine, et cetera?

We also have a robust scientific advisory committee, which looks at the criteria set under the research agenda that the WHO has brought global experts together to define. How do you move from one phase of a particular vaccine project to the next? Does it maintain those attributes? Is it going to be scalable, affordable and deliverable? That is how.

The scientific advisory committee is an adviser to the board of CEPI, which has functional experts and subject matter experts, but it also has representation from the investors. For example, the UK Government have a seat at the board. Then there is an investor council, which gets exactly the same material that the scientific advisory committee is putting forward, so that there is oversight of how the investments are being made. The investor council et cetera are all under confidentiality agreements as well.

In terms of developing country involvement, the board and the investor council of CEPI all have representation that is quite global. We have representation from high-income, middle-income and low-income countries, and a civil society lens as well as a technical expert lens. The scientific advisory committee is interestingly chaired by a South African, so there are key voices in the scientific decision-making processes to ensure that, as we are doing the research, those voices of what is needed are there.

You then talked about access to funds. Funding is deployed through an open call mechanism to solicit research projects, but also manufacturing capacity. On Covid, it is really important that we manufacture the vaccines that are going to be successful, but even before they are successful there is a need to take some risks of speed and to create the manufacturing capacity to get to 2 billion doses, which is what the ACT

Accelerator vaccines pillar, COVAX, is intending to try to achieve for 2021. The manufacturing will happen all over the world, for multiple reasons: to get closer to where you need the vaccines to be deployed, but also to mitigate if things go wrong in one location versus another. There will be manufacturing capacity in different parts of the world as appropriate, and that is another way.

There are currently the beginnings of a clinical trial for one of the vaccines, which is going to start in South Africa. We are already engaging and testing some of the projects. You obviously have to have an outbreak. You still need to make sure you do your testing for later stages where there is an outbreak but, yes, that is the other way that developing countries are engaged, from both the scientific advisory side and the board and oversight side. We have Ethiopia and Mexico as investors alongside the UK and other countries, but also engaging in the research on the ground.

Navendu Mishra: Thank you. It is quite interesting to hear about representation from middle-income and lower-income countries.

Q123 **Chair:** Can I ask a follow-up question? In the news today, there were reports of protests against vaccine testing going on in South Africa. The boards they were holding up were quite clearly directed at the Gateses. Is that your testing and what are your thoughts on that?

Dr Saad: There are anti-vaccine movements around the world. The important thing is to constantly communicate that the science needs to be robust and have safety oversight. That is what we are doing, partnering with the projects being developed at the WHO, regulatory agencies, et cetera. Communities have concerns and need to be communicated to about the science in a very transparent and understandable way. That is what we continue to do: try to make sure that things are transparent and communicated as well as possible, and to engage with the concerns. Vaccine hesitancy is a broader movement than just the Covid vaccine.

Q124 **Chair:** So was it against CEPI testing?

Dr Saad: I would need to come back to you on that. You are ahead of me in reading that today.

Dr Golding: I can talk about two initiatives. First, the joint initiative is the underpinning research that Wellcome has been working and focusing on with DFID for the last two years. We launched a funding call back in February, which was linked and aligned with the WHO R&D roadmap that outlines the research priorities for Covid. It was not just Wellcome and DFID; many funders internationally aligned with what the WHO and the range of expertise across the world put forward.

We tailored our funding call to that. It was open globally. The focus for our funding call was on low and middle-income countries, so our portfolio is around £12 million pounds supporting research carried out on the

African continent and in south-east Asia. This research is critical to vaccine development and therapeutics, because it provides the knowledge we need on the risk factors and the immune response against Covid. That sort of research is absolutely essential, so we funded that.

You asked about the involvement of the global south. I hope I have made clear that that is the real requirement for our funding: where the research would be carried out. Access to funding was through an open, transparent funding call. We had—*[Inaudible]*—hundred applications and it was quite challenging to get it down to those we thought would have a great impact.

We are building on the relationships and partnerships that we have been supporting for some years now, together with DFID. Building that capacity within the countries is critically important. You also have the ability to move and enable research to happen rapidly, so it is really important in epidemics, where it is very challenging to move rapidly, to keep building on that capacity.

On the therapeutics accelerator, it is really critical to highlight the difference of this compared to something like CEPI and FIND. The therapeutics accelerator is not an entity. It is not a new company that has been established. This is really bringing together different funders, such as the Gates Foundation and the Wellcome Trust initially, that have the ability to mobilise and fund rapidly. We have come together with this partnership and it has now been expanded to those other investors. We have a clear governance structure on how we make sure we have coherence across the different funders, what our focuses are and how we will then continue to fund that research.

For example, the governance structure is set out differently depending on those funding decisions and the recommendations we want based on the funding amount. We have a funding advisory committee, which is over £10 billion decision-making, going down to a more operational level between £2 million to £10 million, and then below that is the technical working group.

It is really important that we have that coherence between the partners, but what is also critical, and why these two groups and the various donors are coming together, is that we build on each other's expertise. The Wellcome Trust has various investments across Asia and the African continent, which over decades has been building up clinical research capacity, particularly the trial capacity. This is where we want to be able to promote the research in the global south, to make sure research for treatment options can use those clinical trial sites.

Sarah mentioned clinical testing and testing of vaccines in countries. This is a very challenging area, where we know that vaccines in particular need to be assessed in the right populations to make sure they are actually effective. Basing it just on a European population may not be suitable; you may not end up with a vaccine that is very successful in the

population you are aiming for. We know this from other research at the Wellcome Trust. This is just as critical for testing of any vaccine treatments in the future.

Navendu Mishra: It is quite interesting to hear from all three speakers about the investment that is going in. Professor Heymann mentioned the programme in Senegal, which sounds quite exciting and I will look it up, and there is South Africa as well. Of course, as Dr Golding said, there is a lot more to be done. I am quite interested in the point you made about effectiveness in a European population compared to other parts of the world.

Q125 **Chris Law:** Dr Golding, I wanted to follow up on the Covid Therapeutics Accelerator. It is clear that almost half your funding is into research for uses of hydroxychloroquine. There are two parts to what I want to ask. Is this not the drug that President Trump famously claimed to be taking because he had heard a lot of good stories and, if it is not good, he is not going to be hurt by it, because it has been around for 40 years? Is it not the drug that the World Health Organization said cannot help Covid patients? What are the prospects for hydroxychloroquine becoming a trusted word against coronavirus after such a controversial statement?

Dr Golding: It is a very important question. These are definitely questions that we were asking internally with our partners as well. I would like to point out the differences between the use cases of hydroxychloroquine that we have seen. The WHO Solidarity trial that you referenced and the Recovery trial that has been carried out in the UK have assessed hydroxychloroquine. They have assessed it in severe patients in hospital settings.

That is different from what we want to look at when it comes to the therapeutics accelerator. Because we do not believe specialised hospital settings and critical care units are accessible to many populations around the world, that would not be our target use case. We are looking at giving hydroxychloroquine to those who have mild symptoms so we can look at the effect on that. There is a difference. The WHO has been very clear that, just because it has come out and said that, after the evidence being generated, it has not seen a benefit for the treatment of Covid in clinical settings, it should not preclude it being assessed in non-severe cases. That is one point.

We need to really think about how we assess this. Assessing any treatment in mild cases is going to be very challenging. We know this. You are not going to see the great benefit that you would see in severe cases. That requires very large clinical trials to be established. You are right that a lot of the investment to date, particularly back in April and May, focused on hydroxychloroquine, but we have to evolve and move with the times as the evidence comes out. This is something we are definitely looking at internally.

Q126 **Chris Law:** Is there any evidence at all that it is useful as a prophylaxis?

You are discussing using this on people with mild symptoms.

Dr Golding: It is looking at prophylaxis as well. There is no evidence at the moment. This is what needs to be determined. We need to determine it with a randomised controlled clinical trial so we can generate really robust evidence to say yes or no. I would not want to comment on other studies around the world that have been coming out, but yesterday the WHO held a meeting looking at and reviewing that data. It had a panel of experts discussing this. One of the really disappointing points made in the discussion was that, in the hundreds of clinical trials that had been started and logged in a global registry of clinical trials, only four major studies of four different drugs could produce any evidence of substance. It was accumulative of 20,000 people recruited across those different trials, when we know that there have been millions of cases.

That is the disappointment and that is why we need to make sure that any of the research we do is done in that robust way, so that we can capture it and make those final decisions. Either it works or we lay it to rest and move on to look at other drugs.

Q127 **Chris Law:** The therapeutics accelerator is funding only one project specifically looking at the circumstances in the global south. Are there more such studies in prospect, or is one enough in clinical terms?

Dr Golding: There are more that are being reviewed internally at the moment. They are not something that we can share externally at the moment but, yes, there are more.

Q128 **Brendan Clarke-Smith:** Good afternoon, everybody. Talking about transparency, have any of you had concerns raised about conflicts of interest arising with the granting of funds, where all the main players seem to be represented in these various alliances?

Dr Saad: Let me pick that up from the vaccines pillar, and I will let colleagues talk to the other pillars. You need to bring into the discussions experts who have manufacturing experience or pharmaceutical and vaccine development experience. The way the co-ordinating mechanism of the vaccines pillar brought that in without conflicts of interest was to get the associations to nominate candidates. There are very clear conflict of interest guidelines. For example, if there is a discussion on a candidate who is a representative nominated by the association—by the other companies—on behalf of multinational companies, they would be recused from that discussion. There are very, very clear conflict of interest clauses in terms of the discussions.

Many of the experts who have been brought to the table to make the investment decisions or give scientific advice are ex-pharma, ex-industry people. They have the expertise but they are not currently associated with a particular organisation. Having clear conflict of interest clauses for every member who sits on any of the investment or technical committees, but also trying to leverage expertise that is not tied to one entity per se, is an approach the vaccines pillar is taking.

In addition, through the board and the investor council that DFID represents the UK Government on, they get access to all the information, both what goes before the investment decisions but also the discussions that had taken place et cetera, under confidentiality, of course.

Dr Golding: For both the joint initiative and Wellcome's part in the grant-making for the therapeutics accelerator, we have a very robust grant-making process, which is particularly focused on conflict of interest. Similar to what Samia had talked about, we seek external advice on whether something is appropriate or is reaching its objectives and aims, and on the way the research is carried out. We use that process. It has been continuously evolving over the years, but it is very robust. That is our primary way of controlling conflicts of interest. To ensure that we get a range of people applying for funding as well, we have an open mechanism on the therapeutics accelerator for people to submit their expressions of interest, and we follow up.

This is not specific to the therapeutics accelerator, but for epidemics in general, in building the clinical capacity I talked about before, we know where centres of excellence exist around the world, particularly in the global south. That is a good starting point, to ensure that we are building on that and the ability to carry out robust research.

Professor Heymann: FIND has always been very transparent in its conflict of interest work. That includes involving the board, of which I am a member and which encompasses people from different continents around the world, and its donors council. Particularly with the accelerator, there is a need to work with industry to understand what is going on and stimulate the development of new tests, but at the same time to make sure there is access to these tests. In order to do this properly under the accelerator, there has been a registry established, which is used by all members of the accelerator, which clearly state what they are doing and what their role is. This is made transparent to everyone, so that there are no questions that there could be even a perceived conflict of interest.

FIND has always treated this very cautiously, because of the need to work so closely with the diagnostics industry and ensure access at the same time. We will continue to work in that transparent way in the accelerator with this added register, which will be open to everyone.

Q129 **Brendan Clarke-Smith:** Following on from that, what arrangements are there for those working within the various funding pools to be transparent about their roles and responsibilities elsewhere in the medical research and development system?

Professor Heymann: Could you clarify that a little? I am not sure I understood the question.

Brendan Clarke-Smith: It is on the different funding pools that are available and the people who work within them. In terms of people being transparent with their roles and responsibilities within the whole research

and development system, do you think there are opportunities there for transparency or do you think that is a wider problem?

Professor Heymann: There certainly are. Groups have required that board members, me included, have to sign a conflict of interest statement identifying their conflicts of interest at the start. That is a transparent system, which is available to everyone. At the same time, when research projects are established with the industry, there are agreements with industry in that agreement that make it clear that industry must provide some type of fair price for the diagnostics it is developing and, if it should exit from that, that the intellectual property comes to the FIND organisation.

By being transparent both in conflict of interest and in intellectual property, it is a way of making sure that things move ahead without even a perceived conflict of interest. The board is conscious of that and the accelerator is conscious of that. They are doing everything they can to make the funder's pool as transparent as can be.

Dr Saad: Similarly, the CEPI board and, indeed, the research and development and manufacturing investment committee under the vaccines pillar have a conflict of interest declaration before coming in. That is checked every time there is a meeting and decision on investment. That is there; it is transparent for everybody to see. If there are any conflicts, there is a way to manage them and recuse people from any discussions or decision-making. That is the main approach. As Dr Golding indicated, using an open call to solicit the research makes it an even playing ground. Having an open call soliciting research in a transparent way, trying to create a level playing field, is another way to prevent the cherry-picking of projects.

Dr Golding: What I would say is in alignment with what has been discussed. For the joint initiative, which is focused more on funders, where Wellcome and DFID come together and make the final decision on that, the recommendations have come from an external peer review group, which has met and made those decisions. They have all had to declare their conflicts of interest before their engagement on that panel, as well as any other written peer review comments. That is the robust system I talked about earlier. That is similarly applied in the therapeutics accelerator to those funding advisory groups, the different tiered groups, to identify who is conflicted within the funders, philanthropic organisations and other donors.

Chair: I am afraid we are only halfway through the questions, but we only have 15 minutes left. Could I ask you either to be brief in your answers or to just support what the other person said and move it on?

Q130 **Mrs Latham:** The first half of my question was very similar to Brendan's, so I am going to miss that out. Given that there is a lot of money being thrown at this problem very quickly, I hope that the standards and efficacy of all these things in R&D actually work. Money has been thrown

there very quickly because of the pandemic and the urgency, so those standards need to be kept. A lot of media reports have talked about the efficacy of the coronavirus antibody test and the claims made by the manufacturers. How can you guarantee that nothing like that will occur in relation to the products of your various initiatives?

Professor Heymann: I will start with diagnostics. Right now, we have a good test to determine whether someone is infected and that is the PCR. We need other tests in that area that can tell whether somebody is infected and can be used closer to the patient, as a point of care diagnostic. For antibody tests, many, many tests have been put on the market. These have been validated by the companies where they have been made, an internal evaluation, and then licensed by regulatory agencies. That does not mean they are sensitive and specific enough to be used in daily life. FIND has been taking new diagnostic tests for serology when they become available and testing them on a broad panel of bloods—of sera—to make sure they do not pick up other coronavirus antibodies, for example, that they pick up the coronavirus antibody, that they are sensitive enough to do that, and that they are specific enough to give a good diagnosis.

These tests are under study at present. This involves collecting a panel of bloods from around the world, which have been provided by many of the FIND offices, and FIND does have offices in developing countries. Those are then used to see whether these tests are valid. At present, there is no test that has really been recommended as valid to go ahead and be used as a serological test by the World Health Organisation, based on the studies being done by FIND. FIND has done many tests from—*[Inaudible]*—and is now doing tests from Europe and other parts of the world.

Dr Golding: This is essential to make sure that the data being generated through this funded research is robust. It is being generated in a system; it is not a standalone occurrence. Within that, you have various thematic working groups within the WHO focused on Covid and that would include the diagnostics, therapeutics and vaccines. There is a lot of guidance being developed there, with the involvement of regulatory authorities such as the EMA and FDA, which is essential when it comes to designing the clinical trials in the first place, to make sure that the data being generated is suitable and will be on the pathway to licences.

That is really important to talk about. It is definitely a requirement that we want those discussions to happen earlier on, particularly with the study design. On one of the studies funded through the therapeutics accelerator, there was engagement with the WHO on the study design, to make sure that it was not benefiting just what we were investing in, but also the global community and other groups they may wish to invest in.

For all of these various studies, what is established is a data safety monitoring board. That is looking at the data that is coming out quite regularly, to assess it, analyse it and determine whether to continue with

the study. A study will not be continued if it is not showing that benefit, but of course we need that expertise at the international level, with statisticians, et cetera, who can provide that level of oversight and linkages with the WHO where feasible, so it is absolutely critical for us.

The way Wellcome funds means that, although we state that we are committed to funding a project, the research needs to be carried out for the funding to be disbursed, so we are monitoring all the grants for Covid very closely and having those regular discussions with the researchers.

Finally, between the funders for the therapeutics accelerator, we have a commitment for the data-sharing principles that we set out at a global level through our data sharing statement. Again, we are working together across the various projects being funded to ensure that this data, when appropriate, can be released so others can benefit from it as well.

Q131 **Mrs Latham:** Dr Saad, you mentioned AstraZeneca's vaccine right at the beginning. Could I ask what you think about their decision to start using it as a potential vaccine before they know whether it actually works? Do you think this is just wanting to be the first to the market and a gamble? Do you think it is extreme philanthropy or a bit of both?

Dr Saad: Just to qualify, nobody can use a vaccine without some sort of licence. It will at least need to have some emergency use licence given by the WHO or a regulatory authority. It needs some sort of licence. As Dr Golding and Professor Heymann set out, the speed comes from different aspects. For example, there were already platform vaccine technologies being used, at least in the CEPI portfolio, to look at other priority pathogens, such as MERS, Lassa fever, et cetera. With our partners, we were able to pivot quickly to use those same technology platforms but with the sequence for the coronavirus. Some of the speed comes from there.

We stage-gate the research: the research has to hit certain safety parameters, such as for the immune response, so those are not compromised. Those are still in place, with regulatory oversight and partnering with the WHO. You set certain criteria that you will not fund the next tranche of that project before you are satisfied that the safety signal looks right and the stability looks right. It is a reassurance that those processes are robust and stay in line.

The speed comes from another different aspect, at least in the vaccines side. Sometimes investments that you would do sequentially have to now be done upfront. Sometimes they are at risk, because we need all three tools, to be honest, to really make a dent in the pandemic over the next 12 months. For the vaccines in particular, you often wait to start doing scale-up manufacturing until you have the licensed vaccine, but we cannot do that right now. We need to make some investments at risk in order to hit the ground running when one of the vaccines gives really good scientific efficiency signals in terms of an immune response.

But the regulatory processes are still there; they are still robust. As Dr Golding said, there is a real sense of solidarity in terms of scientists sharing data and CEPI, like other organisations, investing in cross-cutting platforms, enabling science platforms and data sharing platforms, so that scientists all benefit from the knowledge we are gaining. That helps everybody speed up some of the processes, but regulatory and safety oversight remains paramount.

Q132 **Mr Bacon:** May I join others in thanking the witnesses for taking the time to come this afternoon? I would like to address this question in the first instance to Dr Saad, although I would be interested to hear from the others, because your job title includes investor relations and you referred to investment many times. It is in the nature of an investment that it is to produce a return. While the return for the public weal and for Governments in many cases will be a healthy world, there are obviously financial implications as well. The world's drug companies have been very good at making very large profits, very often through the process of doing their basic research funded by publicly funded institutions, controlling access to the clinical trials evidence base so that the claims of the efficacy of their drugs cannot be easily contradicted, and spending a lot of money on marketing.

In relation to the contracts you have cut, as you put it, with these various organisations doing research, what protection is there for the public purse and for the taxpayer-funded institutions in terms of intellectual property, both for the vaccines and for any other kinds of intellectual property that may emerge? We are all familiar with that: sometimes basic research produces huge potential financial gains in areas that were not originally expected. Is that a consideration that has been at the forefront of your minds?

Dr Saad: In the short term, nobody is going to make any money out of any of these tools, really. In terms of the IP and how we manage it, the focus is on equitable access. There are very stringent global access conditions in the contract. For example, if a company or an entity developing vaccines decides at some point to step away from it, we have step-in rights so we can take that project with the IP and move it forward, should that be necessary.

In terms of whether there is a commercial value or a potential to make profit, all our contracts similarly have profit-sharing conditions. In case the vaccine developed with CEPI funds is commercialised and makes a profit, we are applying some principles. A share in commercial benefits shall be proportionate to the values the CEPI investment brought to the vaccine, so that is really important, with no share in commercial benefits from sales to LMICs, protecting the pricing components in low and middle-income countries so that they are affordable. Those global access agreements absolutely apply in those settings so, if the commercial benefits happen, they need to be outside of the low-income communities that cannot pay.

Q133 **Mr Bacon:** That is understood. I understand that there is not likely to be any profit for anybody soon. I think I understand you correctly, but just confirm this. If there are big commercial benefits at some point in the future, those commercial benefits would be obtained from richer countries that can afford to pay more. The funders of the research, including CEPI and others, which in some cases have been using public funds, would get their share of those benefits financially.

Dr Saad: Yes. It varies contract by contract, but that is the principle. It then gets plugged back into the mission of developing vaccines for disadvantaged populations or where we think there are going to be outbreaks, et cetera.

Q134 **Mr Bacon:** That is very clear, thank you. You will be familiar with the work of the AllTrials campaign, people like Sir Iain Chalmers, Professor Carl Heneghan, Ben Goldacre and others. I know that progress has been made, but we are still nowhere near having full exposure, full access and full registration and reporting for all clinical trials for all uses. For these funded pieces of research, are you taking a different approach that insists on full clinical trials, registration and reporting from the outset?

Dr Saad: Because I do not do the negotiations myself with the manufacturers, I can come back. The key is that those terms are in there where there is an importance in data sharing. I cannot tell you whether we require everybody to sign up to that database.

Mr Bacon: If you could come back on that it would be helpful.

Dr Saad: I will.

Q135 **Mr Bacon:** Whether it turns out to be important or not, the whole point about the AllTrials campaign is that many pharmaceutical companies over many, many decades have controlled access to the full evidence base in order to make the drugs that they are developing look as if they have much greater efficacy than they actually do. They then spend a great deal of money marketing them when they have, in some cases, not much effect and, in some cases, no effect at all. The National Health Service spent £420 million on Tamiflu. It was useful for cold and cold-like symptoms, but had no use whatsoever—and this was proven to be the case—in terms of pandemic flu, yet the public purse spent over £400 million on it.

Having full access to and registration of all the evidence, all the trials, and knowledge that they exist, in all domains—because many multinational companies will report research they are doing in one country, say the United States or Canada, but not research they are doing in Switzerland, or the other way round—all the time, is actually the whole point, isn't it?

Dr Saad: I agree with you. In our contracts, global data sharing is part of what we do. I cannot immediately answer whether we require specifically that each project is registered on the clinical trials register, but I will come back to you.

Mr Bacon: It would be very helpful.

Professor Heymann: I said a little bit about IP previously. It is the same arrangement that is being used by CEPI. There has to be an agreement with the company receiving funds for development to say that they will give a public sector price that will permit FIND, which also has an arm on access, to make these products available in countries. There is a requirement on that. If the company exits from the product, the intellectual property then belongs to FIND. The reason that FIND has recently decided to set up a donor council, which will include all the donors that are providing funding to its programmes, is that they will then be able to have oversight on this and make any corrections they wish to make going forward.

Q136 **Kate Osamor:** Thank you to the witnesses for coming along for this grilling. I want to follow on from what Richard was speaking about around profit and pharmaceutical companies. I want to focus now on health inequality. Coronavirus has exacerbated that and exposed that people with underlying health issues are more likely to contract coronavirus and die from it. We have received a lot of information, evidence from NGOs and civil society organisations, focused on the need for commitments, guarantees and concrete arrangements to ensure global accessibility to vaccines, treatments and tests arising from, obviously, public money. Can you tell the Committee what guarantees are in place to ensure that products for coronavirus produced with the assistance of public money will be made available to those who need them, irrespective of personal or national income?

Professor Heymann: FIND has just been setting up a new access initiative and alliance, which, working with the Global Fund and others, will be able to procure and shape the market in developing countries, and make sure these goods are then delivered through proven mechanisms, such as within the Global Fund, where Peter Sands, who is heading the fund, has set up mechanisms that get goods to the countries, including in some instances diagnostic tests. Using that model, FIND will continue to increase its accessibility and access, because it is clearly understood that developing countries, like our own countries, have many people with comorbidities, and those people are at greatest risk of serious illness and death.

FIND is grateful to the partnerships that are developing around this. Investment in these diagnostic tests is really the only tool we have at present that can help us contain outbreaks, keep that reproductive number low and keep the viral transmission suppressed. These tests will be useful when and if vaccines and other therapeutics come on board.

Dr Saad: With respect to vaccines, as part of the global access facility under the ACT vaccines pillar, the core mission of CEPI and Gavi is to have appropriate vaccines available to populations when and where they are needed, regardless of ability to pay, with nobody being left behind. The challenge in ensuring access to a vaccine during a pandemic is

fundamentally different to an epidemic, which is more localised, because demand is everywhere. At the same time, the other big challenge is that the supply of any successful vaccine is likely to be insufficient to cover the entirety of the 7 billion-plus global population for several years. The premise here is that, as long as there is a case of the virus anywhere in the world, everyone is at risk. It is in everybody's interest that the vaccine is made accessible based on need.

The primary objective of CEPI's access commitment is to contribute to the economic and social benefit of developing countries by securing that equitable access, making sure they are not left behind and they get their fair doses of the vaccine at the same time as everybody else. As part of building up this global access facility for Covid vaccines with Gavi, we have tried to ensure that there are vaccines for low and middle-income countries at the same time as for everybody else, and there is not a monopoly just by those that can pay. The premise is that you cannot just solve for one high-income country's population; that will not solve the global pandemic problem. It is important that everybody that needs a vaccine gets it, so all the work that we are doing is based on the premise of not leaving anybody behind.

Kate Osamor: As we all know, Gavi and Global Fund are proven partners, so you are on the right track. Thank you for your work.

Q137 **Mr Sharma:** I know we are running over time. Is the capacity of healthcare systems to cope with the distribution of any vaccine in poorer countries or conflict zones a matter for CEPI and the other partnerships, as much as the development and protection of that medicine?

Dr Saad: CEPI's mandate is really the R&D, getting research project vaccines developed and manufactured, and then there is a handover to those who know how to deliver. We partner with Gavi, especially in creating an advance purchase commitment mechanism for low and middle-income countries, and in the health system strengthening work that Gavi does in countries, building on the childhood vaccines packages. How do you build on that to deliver a pandemic vaccine? All the tools are going to need partners on the ground among the multilateral organisations—whether it is Global Fund, UNITAID, UNICEF or Gavi—that have expertise in delivering tools in settings where supply chains are not as robust as everywhere else.

It will be a mammoth task, because we are trying to get hundreds of millions in one country delivered, depending on the population and the priority populations within a country. The delivery challenges are going to be tough, but CEPI has systems and partnerships in place, not least with Gavi and UNICEF, to work to deliver vaccines in settings where supply chains are not necessarily as robust as other places.

Professor Heymann: The answer to developing country diagnostic testing is making point-of-care diagnostic tests, diagnostic tests that can be used as close to the patient as possible, which are simple in format,

like a pregnancy test that anybody can do, especially the village workers and the people in the laboratories in the regional, district and local hospitals or health facilities. Those are not yet available, so one of the aims of FIND, in the accelerator and in general, is to stimulate and encourage the development of point-of-care diagnostic tests that can be used closer to the patient.

In the meantime, for the Covid-19 pandemic there are no point-of-care diagnostics available, so FIND is working with the WHO and especially with regional organisations, such as the Africa CDC in Addis Ababa and other groups, to make sure that the necessary training is there for the complicated tests we have today, which require infrastructure and equipment, and that that equipment is made available to countries, while waiting for more appropriate equipment and diagnostic tests that can be used. FIND is coming at it from both sides: research and development on diagnostics closer to the patient, at the same time as training and access to the goods that are necessary to do the testing with the tests we have now.

Q138 **Mrs Latham:** Could you tell me if you have seen any difference in communications or anything else since the announcement of the merger of DFID and the FCO, and how that might have impacted on your organisations? I would also like to say that there are some of these so-called pregnancy-type tests available that are very efficacious and should be looked at more strongly. I have one in my constituency called SureScreen, which is over 99% accurate, but nobody seems to be using it, although they are selling it all over the world.

Professor Heymann: The UK is one of FIND's biggest contributors, as you know, through DFID. FIND has been working closely and will continue to work closely with DFID, no matter where DFID eventually ends up and how things work out. We will work with DFID. In fact, I was just on the phone with the Permanent Secretary two days ago discussing various issues, some of which were about diagnostic tests. We will continue close relationships through FIND and are grateful for the support the UK Government give to the core activities of FIND.

Dr Golding: We have a very close relationship with DFID over the years, built on the various different research programmes. Since the announcement of the merger, I will not say it has not affected the communication between the two organisations. I can only imagine the uncertainty that the merger at this stage brings, when there is so little information. Thinking more long term, what does that mean? I think we are all eager to know and understand that.

Q139 **Mrs Latham:** Do you feel that there will be sufficient scrutiny once it becomes absorbed into the Foreign and Commonwealth Office and it is just the Foreign Affairs Committee looking at it, not us?

Dr Saad: It is a good question. There should always be as much scrutiny as possible. The leadership role that the UK Government have shown in

their aid policy is really important, not least dedicating a certain amount of DFID's budget to R&D for epidemic and pandemic research investments. It is paying dividends now. It is really important that that continues wherever DFID ends up living, with that principle of investments where markets fail. We do not want populations to be left behind. It must, and we hope will, continue in the same vein.

To date it has not affected our communication. In terms of scrutiny that people are getting good value for money, we all want funding to be disbursed efficiently, transparently and with the robust science underlying it, in service of populations in need that would not get the vaccines, diagnostics or therapeutics for Covid or any other infectious disease if we did not have Governments like the UK Government and DFID supporting the efforts.

Chair: Thank you to our panellists from CEPI, the Wellcome Trust and FIND. It has been an incredibly interesting session. You have given us a lot to think about, looking at research and development of diagnostics and vaccines around Covid-19. There are clear issues coming out over testing, liability, procurement, distribution and then the equitable delivery of whatever results from the research you are supporting. I would like to end with the comment that a number of you kept using: until everybody is safe, no one is safe, which is why in a pandemic it is so important that we all work together internationally. Thank you again for your part in that, and your organisations for the sterling work you are doing.