OFFICIAL REPORT
AITHISG OIFIGEIL

COVID-19 Committee

Thursday 17 December 2020

Session 5

The Scottish Parliament
Pàrlamaid na h-Alba

Thursday 17 December 2020

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COVID-19 COMMITTEE

25th Meeting 2020, Session 5

CONVENER

*Donald Cameron (Highlands and Islands) (Con)

DEPUTY CONVENER

*Monica Lennon (Central Scotland) (Lab)

COMMITTEE MEMBERS

*Willie Coffey (Kilmarnock and Irvine Valley) (SNP)
*Maurice Corry (West Scotland) (Con)
*Annabelle Ewing (Cowdenbeath) (SNP)
*John Mason (Glasgow Shettleston) (SNP)
*Stuart McMillan (Greenock and Inverclyde) (SNP)
*Mark Ruskell (Mid Scotland and Fife) (Green)
*Beatrice Wishart (Shetland Islands) (LD)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Steve Hoare (Association of the British Pharmaceutical Industry)
Professor Jason Leitch (Scottish Government)
Professor Wei Shen Lim (Joint Committee on Vaccination and Immunisation)
Professor Andrew Pollard (Oxford Vaccine Group)
Michael Russell (Cabinet Secretary for the Constitution, Europe and External Affairs)
Dr Christian Schneider (Medicines and Healthcare products Regulatory Agency)

CLERK TO THE COMMITTEE

Sigrid Robinson

LOCATION

Virtual Meeting

Scottish Parliament

COVID-19 Committee

Thursday 17 December 2020

[The Deputy Convener opened the meeting at 09:00]

Covid-19 Vaccination Programme

The Deputy Convener (Monica Lennon): Good morning, and welcome to the 25th meeting in 2020 of the COVID-19 Committee. We have received apologies from the convener, Donald Cameron.

This morning, the committee will take evidence on the Covid-19 vaccination programme from Steve Hoare, director of quality, regulatory science and safety, Association of the British Pharmaceutical Industry; Professor Wei Shen Lim, chair, Covid-19 immunisation, Joint Committee on Vaccination and Immunisation; Professor Andrew Pollard, professor of paediatric infection and immunity, University of Oxford; and Dr Christian Schneider, Medicines and Healthcare Products Regulatory Agency. I welcome the witnesses to the meeting.

We have quite a large panel of witnesses, so we will move straight to questions. Committee members will have 10 minutes each to ask questions of the witnesses. I ask everyone to keep the questions and answers as concise as possible. If there is time for supplementary questions, I will indicate that once all members have had a chance to ask their questions.

I will ask the first question. Everyone wants to be a priority when it comes to getting a Covid vaccine. We have had a lot of discussion in Parliament about the policy around schools remaining open and whether teachers should be in the first phase of the vaccine roll-out. Do the witnesses believe that there is clinical justification for including teachers, and how practical would it be to do so, given that it is easier to find teachers all in the one place during the working week?

I will also ask a related question. We know that children under 16 are excluded from getting the vaccine at the moment. Do you have an update on the role of children in future clinical trials and the prospects of vaccinating children, particularly those with health conditions?

Professor Wei Shen Lim (Joint Committee on Vaccination and Immunisation): I will try to answer the question about the prioritisation of teachers. The current advice from the JCVI is that, for the initial wave or phase of the programme, we should prioritise protecting people who are at risk of dying from Covid-19 and protecting the national health service, which in turn saves lives.

The first phase of the programme is about trying to capture the vast majority of people who are at risk of serious and severe outcomes from Covid-19. That includes all people aged 50 and above, and people who are younger than that but who have underlying health conditions, down to the age of 16, which is the age at which there is authority to use the vaccine. That is where we stand at the moment. Teachers who are at risk from severe disease will obviously be captured in phase 1 of the programme.

The other point relates to teachers in schools who are younger than 50 but who are not at a very high risk of severe disease from Covid-19. Those teachers and other key workers across a range of occupations will be considered for vaccination, or an offer of vaccination, in the next phase of the programme.

It might be better for someone else to answer the question on including children in vaccine clinical trials.

The Deputy Convener: Dr Schneider has his hand up, so I will come to him next.

Dr Christian Schneider (Medicines and Healthcare products Regulatory Agency): Thank you. It is not unusual for there to be no children included in clinical trials for new medicines, including vaccines—unless the trial is for vaccine that is intended to be used in children, obviously. As already outlined, the vaccine is licensed for people aged 16 and above, which is based on the data on efficacy and safety.

The Deputy Convener: Professor Pollard, can you add to that, please?

Professor Andrew Pollard (Oxford Vaccine Group): Thank you. I lead the clinical trials of the Oxford vaccine. We have always planned for trials involving children because, as members will know, some subgroups of children are at a slightly higher risk than others. There is a lot of interest in that, particularly from families.

As Wei Shen Lim said, there could come a point when, once the higher-risk groups have been vaccinated, it would become appropriate to think about some of the lower-risk groups. Therefore, our trials include a plan to start evaluating the vaccine in children. In fact, we hope that that will start very early in the new year. I know from colleagues who are working on the other vaccines—the Pfizer and Johnson & Johnson vaccines, for example—that they are planning trials in children to start extremely soon, for exactly those reasons.

However, I fully support the policy decisions that Wei Shen talked about, to start with the people who are at the highest risk of disease, such as healthcare workers, and those who are at a higher risk of severe disease, particularly the elderly and adults with other health conditions.

The Deputy Convener: That is encouraging to hear. In my area, which was recently in the highest level of restrictions, children who had previously been shielding had been advised to stay at home and either be home schooled or do remote learning. I am thinking about young people with conditions such as cystic fibrosis. There was a real feeling of exclusion.

Beatrice Wishart has appeared on my screen. Do you want to add anything, Beatrice?

Beatrice Wishart (Shetland Islands) (LD): No.

The Deputy Convener: In that case, I will move on.

I have been reading that women who are—[*Inaudible*.] Can the witnesses say a bit more on that, particularly on the breastfeeding issue? There is a concern that breastfeeding rates might drop. Will there be anything in clinical trials to address the issue of uptake by women who are planning a pregnancy, pregnant or breastfeeding? It would be helpful to hear about that. Professor Pollard wants to go first.

Professor Pollard: Those groups are initially excluded from the clinical trials because, obviously, things have moved very fast this year. Quite appropriately, regulators really want to establish safety and efficacy in healthier, younger adults first, before starting to target pregnant women, given the additional concerns that there might be for them, until we have established safety data.

However, now that we have reached that point with multiple vaccines, there are plans to start evaluations of vaccination in pregnant women. That is particularly important, not just here but in many countries around the world. An important target group will be healthcare workers, among whom there are a lot of women of childbearing age. Addressing that group will be an absolute priority in 2021.

There is a second question, which is sort of related. What about women who become pregnant after they have been vaccinated? We will have quite a lot of data on that group. Although participants in clinical trials usually try to avoid becoming pregnant, inevitably, in large trials, and as is happening with all these vaccines, many women become pregnant—in this case, following vaccination.

We already have a small amount of follow-up data on those women across all the different developers of the vaccines. However, to be able to assess safety, we really need to know the outcomes of those pregnancies. We need time for that, to follow up the babies after they have been born and so on. It is not something that we can get a quick answer to, but it is absolutely a focus of the work that is going on.

With regard to the vaccines that are being considered in the UK, I do not think that there is any scientific reason to be concerned about women receiving the vaccine when breastfeeding, because the vaccine is not likely to transmit anything to the woman that would be harmful to an infant if it got to them.

Those studies have not actively been pursued so far, but the issue is certainly being considered. Wei Shen Lim may want to comment on that from a policy perspective.

Professor Lim: Thanks, Andy—I completely agree with everything that you have said, particularly on the absence of information on women who are breastfeeding that suggests any harm. What stance one takes depends on whether one is more or less permissive when interpreting that absence of information. We are trying to take an appropriate and reasonably cautious approach in terms of allowing people who are breastfeeding to receive the vaccine. The committee can be assured that, as far as we can tell, no concerns have been found so far.

The MHRA had a group that authorised the use of the vaccines in different groups of people, and it may be appropriate to ask the MHRA for its views about safety in relation to breastfeeding.

The Deputy Convener: Thank you. I have just had a message that tells me that not everyone could hear my question—there might have been an issue with connectivity. The question was about women who are pregnant, planning a pregnancy or breastfeeding and the wider safety aspects around their inclusion in the vaccination programme at this point and in future clinical trials. Does Steve Hoare want to comment on that?

Steve Hoare (Association of the British Pharmaceutical Industry): Yes. Thank you very much. Professor Pollard is quite correct that some women have become pregnant during the clinical trials. The sponsors of those clinical trials have agreed that they will follow up for at least two years after the first injection, so we should get some data. There is insufficient data to give the MHRA that confidence—I am sure that Dr Schneider would probably approve of that.

The wider question about whether pregnant women will be included in future clinical trials goes beyond the vaccine. As a trade body, the ABPI has convened a group of clinicians, academics and industry representatives to address the

question of how we can include pregnant women more in clinical trials, regardless of whether they are vaccine, medicine or therapy trials. There may be some myths that we need to break down. Part of the purpose of that group, certainly over the next year, is to start to address those myths and work out how we can include pregnant women and encourage them to come forward for clinical trials—and how we can give clinical trial investigators the confidence that pregnant women can participate.

The Deputy Convener: Thank you. The issue of confidence is important.

Dr Schneider, I come to you to wrap up on this line of questioning.

09:15

Dr Schneider: I can confirm what has been said. Basically, there is no strict contraindication; it is more of a statement that there is no or limited data for the time being on pregnancy and breastfeeding. That is why, as a precautionary principle, vaccination is not recommended. I am sure that more individual recommendations will be possible for patients who are at high risk and so on, but of course we cannot cover those scenarios in a regulatory information sheet, such as we have published. The advice stands as it is, but that is not because of a particular concern; it is because of the absence of data for the time being.

The Deputy Convener: Thank you. That is helpful.

Mark Ruskell (Mid Scotland and Fife) (Green): My question is about uptake in different groups in society. There have been concerns that uptake in the black and minority ethnic community might be lower. How are you monitoring particularly vulnerable groups, such as the BME community, who already face massive health inequalities, and older people? A lot of this comes down to confidence in the vaccine, but there may be other factors. I am interested to know how you monitor and adjust the strategy on vaccination to take account of those factors.

Professor Lim: I will start, and Andy Pollard can come in, too.

Uptake is extremely important; offering a vaccine is only the first step in the programme. The offer needs to be understood, accepted and received. Once the vaccine has been received, that is the end of the process, and—hopefully—protection starts. It is extremely important that we have a view of and monitor the whole process, including uptake by different groups.

The groups that one is perhaps most worried about include not just people from black, Asian and minority ethnic groups but groups who, for various reasons, have difficulty accessing or engaging with healthcare, such as homeless people. There are also those who live in the poorest, most deprived neighbourhoods in our society. Again, we know that those groups usually have greater difficulty in taking up vaccines. There is a range of communities in which clear monitoring, help and engagement are needed right now.

The JCVI's advice is in two halves. The first half is about the offer of the vaccine to priority groups, but the second half, which is equally important and should not be overlooked, is about implementation. We stress that implementation needs to be locally tailored and locally appropriate. That involves engagement with community leaders and opinion leaders who can influence and promote vaccine uptake in local populations. That is extremely important, so thank you for raising the point.

Professor Pollard: I can only speak from the trial perspective. An absolute priority for us and, I know, for other developers has been to make sure that testing of vaccines is done across different ethnic and cultural groups. That is definitely challenging, because it depends on the make-up of the population around the trial sites in which we work and on the willingness of different groups to participate in clinical trials. For most developers, getting good representation from the communities that we are discussing has been more difficult than we might have anticipated, despite active efforts to engage with them.

However, we have representation in the United Kingdom trials, and we have also conducted trials in other countries that have much more diverse populations, such as Brazil and South Africa. Therefore, we have good representation of people from different backgrounds across our suite of trials.

I know that the same approach is taken in the trials that are under way in the United States, to ensure good diversity in the trial population. That has included extending the trials to give more time to specifically enrol the BAME communities, who did not participate as much in the first part of enrolment. The different strategies that developers use are really important to ensure good representation of the smaller populations that are sometimes harder to access in clinical research.

Mark Ruskell: Another key question is when we will know whether the vaccines are effective in preventing the transmission of the virus. When can we get clarity on that? I am not sure who to direct that question to.

The Deputy Convener: Steve Hoare has his hand up from the previous question, so we will

come to him first. If others wish to respond, waving your hand is as good way as any to let me know.

Steve Hoare: I will answer both questions from the industry perspective.

On confidence in the vaccine, the industry's duty is to listen to concerns and provide the data and assurances that are required. The ABPI has already launched the valuing vaccines campaign on social media to give some of the statistics and provide the context.

The answer to the question about transmissibility depends on some of the criteria in the clinical trials. I sit on the test and trace task force. In our most recent meeting, an NHS representative pointed out that there is an on-going study to consider post-vaccination and transmissibility, and that at least 40,000 people are involved in that. That data is being collected as we speak.

We certainly are keen to find out the vaccine's impact on transmission rates and viral loading for those who are infected. It is a wait-and-see situation, but that study is on-going.

Mark Ruskell: If the other witnesses do not want to come in on that point, I have a final question.

The Deputy Convener: Professor Pollard has raised his hand.

Professor Pollard: I will add to that. It is clear that some data will come from the trials on transmissibility and whether vaccines can interrupt that. All the vaccines on which we have data have reduced the number of cases that are polymerase chain reaction—PCR—positive in our trials, so there will be an impact on transmission. If fewer people are PCR positive in the population, there will be less disease.

The critical point is about herd immunity, which is the level at which transmission has been reduced and a number of people are protected so that the virus can no longer transmit. That is a much bigger ask than being able to show some impact on the transmission of the virus. I expect that, once a decent number of people in the population are vaccinated, we will see less transmission. That will be really important in getting back to normal.

I am concerned that we do not focus entirely on herd immunity at the moment because, in order to get close to that, we might need 80 or 90 per cent of people to be vaccinated, and that is still a long way off. It is likely that we will continue to have some vulnerable people in the population who have not been or cannot be vaccinated, and we are still in a global community, in which there will be other countries with lower rates of vaccination. The virus is extremely good at transmitting.

Herd immunity would be a fantastic goal to reach, but it is a long way off. We should focus on protecting the vulnerable and having as many people in the population vaccinated as possible for direct protection. We will also get some impact on transmission, but we will not stop the virus completely in the first few months of next year.

John Mason (Glasgow Shettleston) (SNP): On the question of how many doses there are, I see in Mr Hoare's paper that the UK has pre-ordered 357 million doses. We do not have that many people in the UK—even if we divided that number by two. Why so many doses? Does that mean that Africa and India are losing out?

Steve Hoare: That is a very good question. The doses are not all ready to land on our doorstep tomorrow; that is a portfolio of procurements that the UK Government has carried out, and they will arrive as batches are scaled up and distributed and delivered. We are seeing the first batch of the Pfizer-BioNTech vaccine; as others come through and get approval, we will see them coming online. It is about spreading our bets on various horses in the race. If other vaccines come along that would have a benefit to a particular part of the population, they would probably be distributed accordingly.

As you said, that is a large number of doses, but they will not all arrive at the same time and, if it looks like a few of the horses that we put bets on are working, I believe that there is the right to defer or divert in some of the contracts. As you know, the UK Government has already committed some money to the global COVAX facility. If we reach what we need ahead of time, some of those vaccines could be diverted to the global solutions.

John Mason: Would the contracts for the 357 million doses be legally binding?

Steve Hoare: I do not have that level of detail, but I understand that some clauses are available in order to divert, if necessary.

John Mason: Fair enough. Thank you very much.

I have a question for Professor Lim. You have already spoken to Mark Ruskell about specific groups. Your paper mentions ensuring that

"inequalities are identified and addressed in implementation."

Will you explain how that would happen? You suggest that we go through an age group. What are you suggesting about the other inequalities? Who would address them? How would they be addressed?

Professor Lim: The implementation needs to be taken on by local teams working within health authorities and public health and local community

workers. Implementation and local engagement should happen within each priority group; they are not prioritised separately. For instance, we want good vaccine uptake for all people who are more than 80 years old. If we know that certain groups within that priority group are less likely to receive information in the usual way or are more mistrustful of the usual information and the way that it is given, those groups will need more attention from local teams that understand those communities and are able to engage with them in a way that is meaningful and constructive, in order to enable those communities to have a high vaccine uptake. The prioritisation and the implementation are not two separate things—they go hand in hand.

I do not know whether that helps.

09:30

John Mason: That is very helpful. Thank you very much.

Anyone can come in on my final question. Do we have any idea about what the timescale will be to get the whole population of either Scotland or the UK vaccinated?

If no one is offering to answer that question, I will take that as meaning that we do not have any idea. Would a year be reasonable?

Professor Lim: Rather than there being silence, I will give an answer.

It is difficult to give a timescale, as it depends on vaccine supply, the ability to deploy the vaccines, and how many vaccines are available. The more vaccines that pass through regulatory approvals, the more flexible the vaccine delivery can be. The Pfizer-BioNTech vaccine has very stringent cold-chain requirements, whereas the Oxford AstraZeneca vaccine, which we hope will gain regulatory approval, has much less stringent requirements. Having more types of vaccine will enable faster deployment of the vaccines. Putting an exact timescale on that now might be a hostage to fortune, so I suspect that nobody will be willing to say that we will have achieved X percentage by a certain date.

John Mason: I think that Dr Schneider is going to give me a date.

Dr Schneider: I am afraid that I cannot give you a date, but I will build on that point.

The question is not easy to answer, because the picture is very complex. It depends on the authorisation, which is based on adequate data. The vaccines that we have been talking about, for which there are contractual agreements, are not all at the same stage of development, and we do not know whether they will succeed. Companies will have international contractual agreements, as well. We cannot always assume that the manufacturing process can be upscaled successfully and that there will be no problems with manufacturing. Therefore, it is difficult to say.

As was mentioned before, there is also the issue of people's willingness to take up the vaccines. There are a lot of factors at play. In my opinion, it is difficult to give an exact date.

John Mason: I expected that.

Professor Pollard: There have been huge efforts in the NHS to be prepared for vaccination. My sense is that, given that we have supply, the planning is extremely advanced to make sure that the doses can be put into people's arms. As has been said, there needs to be regulatory approval first, and we have only one approved vaccine at this stage. Therefore, we have to wait for other approvals to come through.

There is also the manufacturing point that Dr Schneider mentioned. There are huge efforts to make tens of millions of doses of vaccine in the first quarter of next year, but we need just one batch to fail for there to be a big shortage for a period of time. In trying to make huge numbers of doses, it is not uncommon for some of the batches to go through an institutional biosafety committee and not pass the stringent standards that are quite rightly in place.

We cannot predict the future completely, but I have a sense that huge efforts are being made to make sure that the NHS is ready to deliver, and the supply chain work that is being done by the manufacturing people—although I am not one of them—is also in good shape at the moment.

John Mason: Will Steve Hoare be brief, please?

Steve Hoare: Certainly. I echo those comments. The industry is playing its part, and we are working as fast as we can. However, we will go as slow as the science and the regulators require.

Beatrice Wishart: I am not sure who is best placed to answer this question. For how long does a vaccine remain viable when it has reached a local authority or health board area? Given the transport issues, that is of particular interest in remote and island areas, especially with regard to the Pfizer vaccine.

Steve Hoare: As the vaccine is developed, we are getting more and more stability data to give us an understanding of how long it remains viable in storage and in use. You are right to ask the question, as the Pfizer vaccine requires storage conditions that are not ideal. However, Pfizer has put in place thermal shippers to enable the vaccine to stay in the appropriate storage

conditions for as long as possible. That period of time can be extended if there are no -70° freezers around.

The industry has committed its support, wherever possible, and the supply chain is in place to deliver the vaccine to hard-to-reach communities.

Beatrice Wishart: Can you give a timescale for the storage capability?

Steve Hoare: Please bear with me for a second while I find some details about the thermal shippers. The information that I have says:

> "The shipper can maintain temperature for 10 days unopened which allows for transportation ... Once open, a vaccination center may use the ... shippers as a temporary storage solution to maintain the recommended storage conditions ... up to 30 days with re-icing every five days ... Once thawed, the vaccine vial can be stored for up to five days at refrigerated ... conditions."

That is quite an extensive bit of support.

Beatrice Wishart: I have a question about the potential wastage of vaccine during the roll-out. I understand that consignments of the Pfizer vaccine are made up of 975 doses and, within that, vials are in packs of five. If, for example, 37 people are to be vaccinated, that would require packs totalling 40 doses, which would mean three spare vials that, potentially, might be wasted. Given that there is a tier system of vaccine delivery, should some flexibility be built in for a more pragmatic approach to be taken to fully utilise the—in my example—spare three vials for another group? Should we not be trying to vaccinate as many people as we possibly can?

Dr Schneider: That is an important and valid question. The problem is that the Pfizer vaccine is a fragile construct—the messenger ribonucleic acid, or mRNA, in the lipid nanoparticles is fragile—which is why it has to be frozen at -70°. The instructions that we have given are that the authorisation is based on data that support the fact that the vaccine will be stable within the conditions that we have given. However, once it is reconstituted, it is very fragile.

The problem is that, as much as pragmatism is desirable, it could lead to a situation in which it could no longer be guaranteed that the vaccine was efficacious or safe to use. That is inherent in the nature of the product rather than in the regulations that we have in place. It is based on the science of the product.

The Deputy Convener: Steve Hoare?

Steve Hoare: I was going to direct the question to Dr Schneider. The MHRA has considered splitting the vaccine packs in order to do as Beatrice Wishart suggested.

The Deputy Convener: Both Professor Lim and Professor Pollard have their hands up. Beatrice, are you content to hear more answers?

Beatrice Wishart: Yes, I am happy to hear more.

Professor Lim: We do not want wastage, especially for these precious vaccines. The priority groupings at the moment allow for some latitude and we have advised that there should be common sense and flexibility operationally in the use of vaccines. We have not said that the priority groups are rigid and that everybody in one group has to be vaccinated because, as we know, vaccines will be offered and it might be that some groups do not want to take up the offer, in which case one has to move through the groups.

At a local level, I reassure you that at the moment the Pfizer-BioNTech vaccine is being deployed through mass vaccination sites, precisely to avoid high levels of wastage. For example, my trust has tried hard to invite people who are over 80 years of age to come for vaccination and, at the end of the day, if any vaccines are left and available, healthcare workers who are in the immediate vicinity are invited to have the vaccine. Because they are in a mass vaccination site that is a healthcare trust, they can turn up for vaccination within 10 or 15 minutes and we can make sure that no doses are wasted.

Beatrice Wishart: That makes sense.

Professor Pollard: One of the critical parts of our vaccine development has been our mission to make the vaccine not for profit and available in all corners of the world. An important part of that has been developing it so that it can run through the normal vaccine cold chain using fridge temperatures so that it can go to remote villages in Africa as well as islands in Scotland. That is an important part of how we have been thinking about the distribution.

There is a separate issue around wastage, which you brought up. One of the ways to approach mass vaccination, particularly at this time when there has been a shortage of pharmaceutical-grade glass to fill vials of vaccine, is that the manufacturing involves ten-dose vials, which comes back to the point that Professor Lim made that if you have a ten-dose vial but only five people turn up, once that vial has been opened for more than six hours it has to be thrown away, so careful logistics are required on the ground to make sure that once the vial is open those doses are not wasted. That can be particularly problematic in more remote areas, which tend to have higher wastage because it is harder to have a pool of people who can drop in at the end of the day to use the remaining doses.

Beatrice Wishart: That is very helpful. Finally, how many people would need to be vaccinated before it is safe to reduce any restrictions? Perhaps you cannot give an indication. Nobody wants to answer that one.

Professor Lim: I will have a go at answering the question. It is generally estimated that if a vaccine was highly effective at blocking transmission—70, 80 or 90 per cent effective—given the transmissibility of this coronavirus one might need to vaccinate up to 70 or 80 per cent of the population. That is one estimate that has been given. That is the herd immunity that Professor Pollard described earlier on. Very high levels of vaccine uptake will be required to completely stop transmission of the virus through the population.

The Deputy Convener: Professor Pollard, I will pick up on something that you said. You mentioned a shortage of pharmaceutical-grade glass. I have been aware of that issue; can you expand on that, and tell us how serious the issue is and what, to the best of your knowledge, is being done to address it?

Professor Pollard: It has been a problem globally throughout this year. More vaccines are being developed than have ever previously been made in one year, and the glass that is required to make the vials, and the filling capacity around the world, is being fully used up.

09:45

There have been huge efforts this year to ensure that supply chains for different countries and different vaccines are properly established, and I think that we are in good shape in that respect. One of the ways in which that issue has been addressed has involved the use of multidose vials. If you put 10 doses in a vial, you need less glass, and you do not need so many hours of filling capacity, whereas if you had 10 times as many vials to fill, it would take you 10 times longer.

The systems have been put in place and there has been a whole year in which to do that. One of the ways that the industry has adapted to the situation is by trying to work out the most efficient process that could be put in place.

The Deputy Convener: Thank you, that answer was helpful.

Stuart McMillan (Greenock and Inverclyde) (SNP): Are any of the witnesses aware of any testing that has taken place, or is scheduled to take place, with people who are addicted to drugs?

Professor Pollard: It is difficult to answer in a specific way the question about testing in individuals, as a population, who are addicted to drugs. What I can say is that the clinical trials, which are open to everyone, include people who take drugs and have addictions. That is a slightly different answer—they are included in the trials, but I cannot point to a specific analysis of a large number of people who are addicted to drugs.

Stuart McMillan: That is simple—thank you.

I have a question for Professor Lim. The JCVI's written submission says:

> "Care home workers are therefore considered a very high priority for vaccination."

This week, I have been contacted by multiple individuals in my constituency who work in care homes and have indicated that they will not be taking the vaccine. I am concerned about that because of the need to protect the residents of care homes as well as the individuals who work there and those in the wider community. Is there anything that could or should be done to encourage all care home workers to take the vaccination?

Professor Lim: I agree that every effort should be made to encourage care home workers to take up the offer of the vaccine. It is important for them, as individuals who are potentially exposed more frequently not only to the virus, but to vulnerable people. If there is even a small chance that the vaccine will block transmission, taking the vaccine will also help them to protect other people. There is therefore a personal benefit and a healthcare, or social care, benefit overall.

It brings us back to the advice that local leaders need to understand why care home workers might be reluctant to take the vaccine. The reasons for that may differ in Scotland in comparison with somewhere in England, for instance, and understanding those issues will be helpful in encouraging uptake.

Stuart McMillan: The vaccination programme is currently at a very early stage, so attitudes might change as more people get the vaccine, and as that is reported more widely in the local community. Nonetheless, I was concerned when I was approached by those care home workers because, as Professor Lim rightly identifies, people who stay in care homes are some of the most vulnerable in our communities.

Professor Lim: It is worth noting that the annual flu vaccination offer has also been extended to care home workers this year, and that uptake rates differ between workers in hospital or primary health care and workers in care homes. I therefore do not think that any such reluctance relates specifically to the Covid vaccine—or so it appears. It might be more about the general concept of having a vaccine in order to protect oneself and the people that one is caring for. Some work might need to be done in order to

improve uptake not just for Covid vaccines but for other vaccines that are equally important throughout the year.

Stuart McMillan: Thank you. My next question is for Dr Schneider. Did Brexit have any influence on the ability of the MHRA to grant the temporary authorisation as quickly as it did?

Dr Schneider: There was a small crack on the line, so I will repeat the question to check that I understood it correctly. Was it about the impact of leaving the EU on our temporary authorisation for the Pfizer vaccine?

Stuart McMillan: Yes; did Brexit have any influence on the ability of the MHRA to grant the temporary authorisation so quickly?

Dr Schneider: Thank you. The temporary authorisation was because of the realisation of a European law into UK law. That has enabled us to do it, as it would any other country. That will continue; such emergency situations can occur in the future, so it is enshrined in British legislation, and that will not change.

Obviously, if the European Medicines Agency authorises one of the vaccines this year, that will be directly applicable in the UK. Beyond 1 January, the MHRA has its own powers in law to issue a marketing authorisation.

Stuart McMillan: Are there any concerns about the potential impact of Brexit on the vaccine supply chain? A few moments ago, you touched on the vials, but what about other aspects?

Dr Schneider: From an authorisation perspective, I would not have any concerns, because we have the power to issue a temporary authorisation, and we will have our own powers from 1 January. We have the resource in house for doing the assessment. Obviously, there are also questions about the supply that is coming into the country, but I cannot comment on those. In so far as we are a part of it, we have ensured that everything is in place so that there are no problems from the regulation perspective.

Stuart McMillan: I have a final question, which is to any of the witnesses. When and how will we know whether the vaccine affords immunity in the longer term?

Professor Pollard: We are monitoring immunity all the time. Our trials have just reached the six-month point, and we are analysing those blood samples to see how long immunity lasts. We have some past experience with the Tamiflu vaccine, whereby we have seen the immune response last for well over a year after vaccination, but we have to take the scientific approach of doing the measurements and having a look.

Of course, no one can tell how long immunity lasts until time has gone by and, because of the nature of the pandemic, not enough time has gone by for us to answer the really important question about whether we are still going to see strong immune responses next winter, which is going to be really critical for all the vaccines and for the protection of populations. That needs following up over time.

A separate question is whether the immune responses that we see correlate with protection. We do not know that yet. Work has started among all the developers to ascertain whether the antibody levels that we are seeing in blood samples tell us that the person is protected. We can do work early in the new year to establish whether what we are seeing in the blood is a predictor of protection. If it is, we might well be able to say next winter whether we think that the population is still protected.

Stuart McMillan: At the moment, are you anticipating that the vaccine will be an annual vaccine, similar to the flu vaccine, or is it too early to say?

Professor Pollard: We do not know yet. The flu vaccine is annual because the flu viruses change every year, so we need to redesign the vaccine each year to cope with the strains that are predicted to circulate. With this coronavirus, however, we do not yet know whether any of its mutations—some of which we have heard about in the news over the past few weeks—will affect the performance of vaccines. At this stage, there is no evidence that we should be concerned about that, but it is something that we absolutely must continue to monitor.

Maurice Corry (West Scotland) (Con): Good morning. This question is for Steve Hoare. What are the implications if the national regulators reach differing conclusions on vaccines that are seeking approval?

Steve Hoare: Are you asking about a possible difference of opinion between the MHRA and national regulators for other countries?

Maurice Corry: Correct.

Steve Hoare: The industry would take the advice of the regulator in the relevant country and act accordingly.

Maurice Corry: Would Dr Schneider like to comment?

Dr Schneider: It is an important question. The MHRA is working with other regulators across the globe; we have an informal information exchange. If a situation were to transpire where one regulator came to a different conclusion from that of another, we would have to look at the details of

the different conclusion, in as much as it was applicable to the MHRA and the UK.

It really depends on the specific case. The likelihood of it happening is not high, but there is of course a possibility that it might happen. Many factors would play into it, but there are internationally recognised standards, and there have been clinical trial programmes, so I would be surprised if it did happen. As I have said, however, we are liaising with other regulators internationally.

Maurice Corry: If your organisation is confident in the safety of the vaccines when it grants approval, why have the regulations been amended to grant pharmaceutical companies immunity from civil liability?

Dr Schneider: That amendment was made because there was a provision that was unclear. To the extent that immunity—or there would be no indemnity—I am sorry: I am not a lawyer, and I am trying to find the right words. The indemnity would be waived for healthcare professionals and manufacturers, but the regulations did not explicitly mention pharmaceutical companies. The principle of equality, so to speak, was included, but the provisions do not exclude anyone from the normal liability in the case of breach of conditions or misconduct or any other items. It—[*Inaudible*.]—provisions.

Maurice Corry: I am sorry—I did not hear the last part of that.

Dr Schneider: My apologies. There was basically a gap in the provisions. They mentioned manufacturers and healthcare professionals but not pharmaceutical companies as such.

Maurice Corry: Okay—that is clear. Thank you.

Professor Pollard, are other companies likely to follow AstraZeneca's lead and produce the vaccine on a not-for-profit basis?

Professor Pollard: I do not know the answer to that. My understanding is that Johnson & Johnson is taking that approach, but I am not really involved in that world of decision making, so I cannot fully answer the question. That may be more for the industry to address.

10:00

Maurice Corry: Thank you, professor. Would Steve Hoare like to respond on that?

Steve Hoare: Many companies have committed to working on a not-for-profit basis, and the whole industry is committed to ensuring that the vaccine is made available according to an equitable and affordable process.

Maurice Corry: So, there is a possibility that that will happen. I understand from my own business background that there is a question of investment in research and development, so each case will presumably be considered individually.

Steve Hoare: Yes, and individual companies will make their own decisions. The ABPI cannot comment on that.

Willie Coffey (Kilmarnock and Irvine Valley) (SNP): Good morning. My first question is probably for Steve Hoare. Constituents ask me: how come the vaccine has arrived so quickly, and how come the clinical trials have been completed so quickly? Can you offer an assurance to the public that the whole process of getting the vaccine approved has been correct and proper and so on, and that no corners have been cut in bringing the vaccine to the market?

Steve Hoare: It has been done on the back of quite a few things, including advancements in technology. There is the fact that the genetic sequence was unveiled and shared very early in the process. There was also our previous experience with similar viruses, in addition to the unprecedented collaboration between industry and other stakeholders, such as the MHRA; we were doing things in parallel, as opposed to sequentially, as is conventional.

Ultimately, the MHRA decides whether things have been done in the most appropriate fashion, to the highest standards of quality, safety and efficacy. The industry's role is to present compelling evidence that that has been done. You can be assured that no corners have been cut.

We have learned some new ways of working. The MHRA started a process of rolling review six months ago, looking at the data as it was coming out, so it was much easier for it to take the final data and come to a decision in a short period of time. It has been a different way of working.

There are definitely some things that we can learn for future pandemics, and even some new ways of working that we can now claim as business as usual, which will have an impact on the speed of development of medicines. We will be able to get new medicines to patients even more quickly than was the case before.

Willie Coffey: That is very reassuring. It is a question that is posed quite often by constituents, so it was worth getting it on the record that everything has been done properly and no corners have been cut.

My next question is about the shielded group: those people who have underlying health conditions, no matter their age. Are they in the right place in the order of vaccination roll-out? We are correctly targeting our senior, most vulnerable citizens first, but are we giving younger people

with underlying health conditions the proper priority in the order of vaccination roll-out?

Professor Lim: Many people—particularly those with underlying health conditions—are asking that question, as you can imagine.

The unique character of Covid-19 is the very steep association of increasing age with a poor outcome, particularly the risk of dying. A lot of infections affect older people more, but coronavirus appears to hit older people particularly hard, and the association is not linear but exponential; it is like a wave that goes up very, very steeply.

When we have looked at models that consider the optimal way of delivering a vaccine to maximum benefit, in order to save the most lives, whether the outcome is to save lives or save lives measured by quality-adjusted life years—to take into account how many expected life years someone might have—in both those outcomes, we find that the optimal strategy is still to offer vaccination to older adults first. That is because of the incredibly steep association with age. That forms the basis and backbone of the recommendation and the priority groups.

We have looked and looked again at the risk of dying for the group of people who are clinically extremely vulnerable. As a group, they are at roughly the same level of risk as people who are aged around 70 or 75. That is why we have placed them alongside that group for the offer of vaccination.

Willie Coffey: That is very helpful. Dr Schneider, did you want to make a comment on that point?

Dr Schneider: It was not on that point; I wanted to make a point on the previous question of whether corners were cut. If you consider that sufficiently answered, I will not say any more.

Willie Coffey: Yes; thank you for that.

I have another question which I do not think that anyone has asked yet. If millions of people are being vaccinated, how do we manage the information technology and data management side of that? Where is the IT management of that taking place and who is doing it in order to properly record people coming to vaccination centres and being vaccinated and to make sure that they come back a few weeks or months later to do it again? I do not think that there is a role for our general practitioners' surgeries in that process at the moment, so who is managing and delivering the IT side in order to make sure that it is done correctly? I do not know who might be able to answer that question. I will try Steve Hoare.

Steve Hoare: I do not think that I can answer to that level but the manufacturers and the MHRA carry out monitoring after vaccination. There is an on-going safety monitoring process and the MHRA has its yellow card scheme; I encourage everyone, once they have had the vaccination, to download the app for their phone and use it. There is also a process of providing information to patients every time they have that vaccination, to encourage them to report any effects.

The IT side of it around who has what comes down to the NHS and local government, which make up that part of the deployment team.

Willie Coffey: Okay; that is probably a question for our next panel, so I am happy with that answer.

Annabelle Ewing (Cowdenbeath) (SNP): Good morning. My first question is for Professor Pollard. The briefing tells us that the Pfizer vaccine employs a different technology from traditional vaccines, in that the production of the viral protein is stimulated in our cells, rather than in vats of cells. Can Professor Pollard explain to me, as a layperson, what that means and what the implications are?

Secondly, there is already one clear implication, which is that people who have allergies are being advised not to take the Pfizer vaccine. What is to happen to that set of people? I imagine that their number is consequential these days. Is there a vaccine in the pipeline for them?

Professor Pollard: First, I will explain the different technologies. Many different technologies have been used, and 50 different vaccines are currently in clinical development, so there is not really time to go through them all.

The RNA vaccines, which include the Pfizer vaccine, essentially deliver a small bit of genetic code that is the code for the spike protein of coronavirus. When the vaccine is given, our cells turn that genetic code into spike protein so that our immune system can then make a response. That works very powerfully, as we have seen in the studies on the immune response to the Pfizer vaccine. The Moderna vaccine, which is one of the other ones that the UK has bought, works in exactly the same way.

Some of the other vaccines, including ours and the Johnson & Johnson vaccine, which are viral vector vaccines, do something rather similar. The delivery mechanism for the genetic code is a common cold virus, but, in the end, all those vaccines are doing the same thing: they are converting a bit of genetic code into spike protein so that the immune system can make a response to it.

There is nothing magic about it. It is a new technology, but the way in which it ends up making the immune system respond is very similar to some of the other vaccines that are in

development, as well as some of the licensed vaccines, such as the Ebola vaccines, which are licensed all across Europe.

Annabelle Ewing: I thank Professor Pollard for that answer; it is helpful to hear from the scientific experts. Perhaps my second question is even more pertinent. What about people who have allergies? When will they get the vaccine?

Professor Pollard: I have not been involved in the discussions about those cases but it might be that those individuals had an allergy to something specific in the vaccine, or they could even be allergic to something else that happens around vaccination, such as something that is in the syringes or the gloves that were used. I do not fully understand the nature of the allergy, and it is being investigated at the moment. While that is being looked into, it is a sensible precaution to pause vaccinations for that group, but that does not mean that we will not have it dealt with in the longer term or that people cannot be protected.

Annabelle Ewing: I thank Professor Pollard for that answer, which provides some reassurances.

I was pleased to hear Dr Schneider refer to the fact that the MHRA works with international bodies. However, will he assure us that that work extends to information sharing to avoid duplication, and that it is not just liaison?

Secondly, what is happening with regard to the least developed countries in the process? Perhaps Dr Schneider could share his views on that.

Dr Schneider: The information sharing is done on the basis of having a confidentiality agreement with other regulators; we have quite a number of such agreements in place. We have to explore how we can share information and also liaise with countries beyond the International Coalition of Medicines Regulatory Authorities, the US Food and Drug Administration, and the European Medicines Agency. That is a valid question and we are currently exploring it.

In response to your previous question about allergies, there were two cases of anaphylaxis, which is the highest grade of allergic reaction that someone can have. To my knowledge, any person who has a history of anaphylaxis to a vaccine, medicine or good should not receive the vaccine. If there is a history of severe or serious allergies, that should be discussed with the healthcare professional. It is not just about allergies; it is about severe allergies. However, again, we cannot exclude the fact that there has been an allergic reaction. We are looking into the mechanism and why it happened. It is not unexpected for such cases to occur when you expose many people within a short time.

I can assure the committee that we have a strong system for pharmacovigilance in the UK and that it works. We were able to act on the allergy cases and put out recommendations so that everything was kept in hand.

10:15

Annabelle Ewing: Professor Lim, is the priority approach that the JCVI adopted reflected in the approach that other countries are taking internationally? Could you perhaps confirm the position in broad-brush terms?

Professor Lim: Many other countries have adopted similar recommendations to the JCVI, which are to prioritise on age first of all and then to prioritise others who are vulnerable, to protect people from the severe effects of Covid-19.

Annabelle Ewing: That is helpful, because we get a lot of questions about priority—you have got a flavour of that this morning, Professor Lim. It is reasonable to suggest that the world is, by and large, taking that approach, which is based on clinical observation. I note that my time is just about up; I have one last question, for Mr Hoare.

I remember hearing an interview on the radio at the time that the Oxford vaccine information started to show a lot of promise. A young postgraduate student commented that she was really excited by that, because of the importance of the scientific community working together for a common good. She extrapolated that if we could maintain that momentum, we could see massive strides in, for example, vaccination against malaria. From an industry point of view, what concrete actions and reflections are now being taken forward to maintain that momentum to do something good for mankind?

Steve Hoare: It is a good question. It is exciting to have seen unprecedented levels of collaboration and co-operation between industry members, academia, the regulator and other stakeholders, as well as some real new science. We will learn a lot about new technologies and new ways of working from that collaboration. I would be surprised if we did not see knock-on effects on other diseases and approaches—not just malaria, but diseases in which antimicrobial resistance is a worry.

There could be ways of working to overcome barriers that we have come across in the past. It is absolutely right to be excited—it is an exciting time to be involved in science. I hope that one of the knock-on effects is that we see more people take an interest in science and in what we do, and that a whole new generation of students and pupils get involved in science, technology, engineering and mathematics—STEM—subjects.

Annabelle Ewing: I absolutely agree. We particularly need to see many more women in STEM. That is a really important point and must be one of the positives that we can take from the things that have happened over the past year, and will happen for a bit longer. The world will be watching and expecting more collaboration on the part of the scientific and pharmaceutical community.

My time is up. Thank you for your responses.

The Deputy Convener: Mark Ruskell has indicated that he has a supplementary question, which we can squeeze in and, I hope, get a brief answer to.

Mark Ruskell: It follows on nicely from the previous question. How does that collaboration take place on the ground and on what basis? Is it purely commercial? Are there other ways to share intellectual property and technology? In particular, is UK pharma fully bedded in to the World Health Organization's Covid technology access pool and committed to it? Discussions have been had at board level about the financial bottom line. There is a chance for real global altruism here, so how do you work with those WHO initiatives?

Steve Hoare: A lot of the UK industry is made up of global companies, and we have already made that commitment. I previously mentioned the COVAX facility that the WHO set up. I am personally involved at the international level with the International Federation of Pharmaceutical Manufacturers and Associations, our sister trade association, and we are seeing co-operation right now around not just the vaccines but general new ways of working.

We have seen the regulators do the same thing: the MHRA is prevalent at the international level as well as the ICMRA—an international coalition of regulators, in which the MHRA is also quite prevalent. It is an exciting time, as was said previously.

There is a commitment from the industry to fair, equitable and affordable access to medicines.

The Deputy Convener: There are no comments from other witnesses, so that brings our session to a close and concludes our consideration of this agenda item. I thank all the witnesses for their evidence and their time this morning. It has been helpful.

10:21

Meeting suspended.

10:36

On resuming—

Subordinate Legislation

Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) Amendment (No 5) Regulations 2020 (SSI 2020/400)

Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) Amendment (No 6) Regulations 2020 (SSI 2020/415)

Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) Amendment (No 7) Regulations 2020 (SSI 2020/427)

Health Protection (Coronavirus) (Restrictions and Requirements) (Miscellaneous Amendments) (Scotland) Regulations 2020 [Draft]

The Deputy Convener: Item 2 is evidence from the Cabinet Secretary for the Constitution, Europe and External Affairs, Michael Russell MSP, and Professor Jason Leitch, who is the national clinical director with the Scottish Government.

We will cover a lot of matters this morning, including the latest ministerial statement on Covid-19 and the two-monthly report to Parliament under the Coronavirus (Scotland) Act 2020 and the Coronavirus (Scotland) (No 2) Act 2020. The committee will also consider three made affirmative instruments and the draft regulations arising from this week's review.

I welcome the cabinet secretary to the meeting and invite him to make a brief opening statement.

The Cabinet Secretary for the Constitution, Europe and External Affairs (Michael Russell): Thank you, convener. I am sorry that there is so much for us to consider today, but I will be as brief as I can.

[*Inaudible*.]—the sixth review of the allocation of levels. That review again followed a cautious approach, especially in advance of the festive arrangements, with the majority of local authorities remaining at their current level. However, that is against the background of rises in the past week across a number of local authorities in several of the indicators that the framework uses.

Three local authorities—Aberdeen City, Aberdeenshire and East Lothian—will move from level 2 to level 3 from tomorrow. We also

confirmed, in recognition of the low incidence of Covid and as a means to combat social isolation, that we have decided to relax restrictions on in-home socialising on a number of Argyll and Bute islands. Those islands will now be able to follow the six-two rule that currently applies to many islands in level 1 areas.

However, we had concerns about an increase in case numbers in some other local authority areas, and we are continuing to keep those situations under review. We have already confirmed that there will be a review next week, but our general aim, from this week's allocation, remains that the levels should be in place until the first review point in January. However, should changes be needed during the next period, which is not our intention or wish, I have offered to make myself available to the committee, were it to decide to meet during the recess.

I turn to the three sets of regulations. The first set—the amendment (No 5) regulations—ensures that students are able to leave their current place of residence at the end of term. The amendment (No 6) regulations and the amendment (No 7) regulations make provision for the festive bubble arrangements and allow holiday accommodation to be used in level 4 areas for some specific reasons. They also make adjustments to the level allocations in 16 areas of Scotland, as set out in the First Minister's statement last week. They also allow in-home socialising to take place on certain islands, and they adjust travel restrictions to Jersey and the Republic of Ireland.

The draft amendment regulations implement the changes that were announced in the First Minister's statement on Tuesday and make a tweak to the rules regarding marriage receptions and funeral wakes in level 0 and level 1. They also adjust the Health Protection (Coronavirus) (Protection from Eviction) (Scotland) Regulations 2020. They set out that the period in which a social housing eviction order decree for rent arrears must be executed is extended by the duration of the eviction ban.

All the regulations will come into force at 6pm tomorrow.

The fourth report to the Parliament was published last week—along with a statement from myself—and covers the period to 30 November. Over and above the reporting requirements set out in the coronavirus acts, we have reported in more detail on a set of 22 statutory provisions, which we judge at this time to be of most impact and of interest to the Parliament for other reasons.

We are also reporting on a total of 60 Scottish statutory instruments with a main purpose that relates to coronavirus, as required under section 14 of the Coronavirus (Scotland) (No 2) Act 2020. We are, I hope, demonstrating that accountability is integral to our efforts to suppress the virus.

Our reports include the third report to Parliament on freedom of information, which I am happy to discuss.

Finally—I am sure that the convener will be pleased to hear that this is my final point—looking ahead to the new year, I am very mindful that only one further review of the statutory provisions is possible under the terms of the Coronavirus (Scotland) Act 2020 and that, if the act was renewed, it would expire at the end of September 2021. As I said in response to Donald Cameron in Parliament last week, I think that the appropriate time to take a view on whether any further extension is required will be when we come to the next two-monthly reporting process at the end of January.

I emphasise that it absolutely remains the Government's intention to have these exceptional provisions in place for no longer than is necessary. Equally, however, it is essential that we continue to have the tools that we need to deal with the consequences of the Covid pandemic. As we have seen this week, that is a difficult balancing act, and we will all need to think carefully about what we should do in the run-up to the expiry of the provisions at the end of March. Of course, Parliament will have the final say on any extension.

I hope that all that was helpful, if a little lengthy.

The Deputy Convener: Before we turn to questions, I remind members that there is a lot to cover today and that we have approximately eight minutes each for questions and answers. It would therefore be really helpful if we could all be as concise as possible. As with the previous item of business, if there is time for supplementary questions, I will try to take them at the end. Members should indicate in the chat function if they have a supplementary question.

The cabinet secretary touched on the two-monthly reports, the latest of which we are considering this morning. The end of the next reporting period will be close to the expiry date for coronavirus acts. Reflecting on the use of the powers over the past two months and their on-going necessity, will the cabinet secretary say a little bit more about the plans that Government is currently making for extending the acts beyond 31 March 2021?

Given the significance of the next extension period covering a dissolution or pre-election recess period, will the Government ensure that Parliament has 40 days to consider an extension of the legislation, if an extension is, indeed, requested by the Scottish Government?

Michael Russell: It is certainly my hope that we can stick to all the regulations that we have in place in relation to consideration. I have made it crystal clear that Parliament will have the final say, which is absolutely the correct approach. We will have to balance the situation as it exists at the time with our expectation of what will take place.

On the positive side, the roll-out of the vaccine is taking place, which the committee has just taken evidence on. That is an important step and will be helpful. On the downside, we are in a more difficult position this Christmas than many of us had hoped to be, even three months ago. We have to be mindful of the fact that many of the things in the regulations are needed and will remain needed.

I would like to have a full and open discussion about the issue. The committee might want to have an evidence session in which we discuss that, and only that, to look at the details. A good time to do so would be the end of January.

Of course, we cannot pick and choose from the legislation. We can switch provisions off, but we cannot put new things into it or make things permanent, which is good. Therefore, we have a series of decisions to make. As you said, at the end of March, we will go into an election period, for which we are making special arrangements in other legislation, so we will need to be mindful of what we can and cannot do. I hope that we can approach that together as parliamentarians and find a way forward.

10:45

The Deputy Convener: That is helpful. Thank you.

You mentioned the roll-out of the vaccine, on which we had a very useful session earlier. Does the Scottish Government have any concerns about the potential impact of Brexit on the vaccine supply chain? Can you give us an update on the discussions that are taking place between the Scottish and UK Governments in that regard?

Michael Russell: I answered a question on that from Pauline McNeill in the chamber yesterday. We are all concerned about the situation, but there is a strong determination by all the Governments of these islands to prioritise the delivery of the vaccine. You will have seen press coverage of the arrangements that are being made to directly ship it by air, if necessary, by military aircraft into various airports. It will be a category 1 product and prioritised in that way.

It will not be a surprise to anybody on the committee that there are strong tensions between the Governments of these islands on a range of issues. However, on the roll-out of the vaccine, as on many issues, there has been a strong attempt to work closely together and to benefit from one another's experience, knowledge and determination. Therefore, I am as confident as I can be, as is the Cabinet Secretary for Health and Sport, that the vaccine roll-out will continue according to plan, as indeed it must.

The Deputy Convener: Thank you, cabinet secretary. We move on to questions from members.

Mark Ruskell: I will ask Professor Leitch about the situation in Edinburgh. The figures over the past week completely vindicate the Government's position that Edinburgh needed to stay at level 3 and not drop to level 2. What do you see as the wider trends in our larger conurbations? A few areas have moved from level 4 to level 3, but the indicators then appear quite sticky. What is influencing that? Is it shopping? Is it relaxation of restrictions? What should we be mindful of?

Professor Jason Leitch (Scottish Government): Hello again, everybody, and thank you for having me.

You asked an excellent question—it is one that the world is finding tricky. Every mainstream country, if I can put it that way, that has developed a levels structure—I am thinking of the Republic of Ireland, France and Germany, or even Australia—is struggling with exactly where that balance sits, and the balance appears to be different in urban and rural areas, as we discussed last week. The balance also seems to be different depending on where an area is when it comes into and leaves a level.

We have created a slightly artificial argument about the range of data at which an area should enter and leave a level, but the reality is more dynamic than that. Should we wait until an area is near the bottom of level 2 before it gets into level 2? Should it not move out of level 2 until it is sustainably in level 1? That is the kind of thing that we are learning.

We have been doing this for only a few weeks. Over the next few weeks, the plan is not only to have reviews, as we have had, but to review the processes and the nature of those reviews. Should we add other elements of data? Should we add something about the dynamic nature of the data, rather than having a fixed point. People are obviously attached to having fixed points—for example, if an area gets under 100, it becomes level X. Of course, however, it is not as simple as that, because a local authority the size of Edinburgh, with X hundred thousand residents, does not behave as simply as that. We will try and refine that with advice for the decision makers, who will choose whether to take that advice.

The second part of the question about what drives the stickiness is very difficult to answer. As

you and I have discussed many times, I do not think that it is driven by one thing.

As we move down through our levels or the English tiers—whatever you want to call them—we bring people together. There is no question but that, when we bring people together, particularly when prevalence is still at a relatively high level, the virus accelerates. All the global curves show that prevalence goes up quickly and comes down slowly. The incubation period means that reducing the prevalence of the virus happens slowly, but that it is easy to get exponential growth—we see from the R number that one person can infect many others. That is what this horrid virus does. I wish it were not like that, but that is the nature of the infectious agent.

The protection levels are a relatively blunt tool—we have discussed that many times. Level 3 reduces interaction more than in level 2, and level 2 reduces interaction more than at level 1. The levels try to tackle all the elements: hospitality, retail, gyms—wherever people come together. The balance will not be completely correct, but it is our best attempt and we are getting better at it.

Mark Ruskell: I turn to the modelling of the Christmas relaxation rules that have been brought to the committee in the amendment (No 6) regulations. I am still trying to understand what modelling has been done. The other day, Chris Whitty said that there has been a lot of modelling of the impact of different numbers of people mixing in different settings. I do not see that evidence being brought to the committee, nor do I see any assessment of the four harms.

What evidence, risk assessment or modelling has been used to look at the impact of the Christmas relaxation regulations?

Michael Russell: Jason Leitch should address that, but part of it is evidential and based on past experience. We have seen what happens when people get together, when the virus can spread between them. Some of it is axiomatic: we have stopped people gathering in one another's homes because we know that that is a factor; ergo, if people gather in one another's homes, even in limited numbers and in bubbles, that will have an effect.

Jason Leitch will want to say more about the detail, and about the science and the experience behind it, but the regulations are based on nine months' experience of the virus. That is not a long time, but that is the experience that we based the regulations on.

Professor Leitch: The blunt answer to Mr Ruskell's question is that it is difficult to model. There are two UK-wide scientific pandemic insight groups—SPI-B, which is the group for behavioural science, and SPI-M, which is the modelling committee—that feed into SAGE, the scientific advisory group for emergencies, and we have equivalents that feed into our scientific advisory group.

Chris Whitty is right to say that there is a lot of modelling. The modelling that the Scottish Government publishes every week is an attempt to look at bed usage and the impact on intensive care units, for example.

It is tricky to model what will happen over the five-day Christmas period. We know from polling that between 50 and 60 per cent of people say that they will not do anything that is different from what is permitted in the regulations for the level that their area is in, and that 25 per cent are pretty convinced that we should let people do as they please.

It is difficult to work out the present prevalence in each area. Mixing in a house in Orkney will be different if a lot of Londoners arrive; it will not be so bad if no Londoners arrive. It is difficult to make the presumptions that feed into the modelling black box. We have tried to do that as best we can. Fundamentally, the more that people mix, the higher the prevalence; the less that people mix, the lower the prevalence. I do not have to tell you that—everybody knows it.

It is difficult to be accurate. As the First Minister said again yesterday, and as you have heard the leaders of the four nations say, a judgment was made that it is better to have some relaxation and some advice, rather than none.

Annabelle Ewing: I want to pick up—[*Inaudible*.]—some weeks ago. Professor Leith can add his comments if he wishes.

We are looking at Christmas, but Hogmanay will come along soon after. I suppose that the message will be, "Don't do Hogmanay." I recall that specific guidance was issued for Halloween, for example. What is the Scottish Government planning for Hogmanay? Even in Scotland, a lot of stuff happens outdoors but, equally, the kind of stuff that happens outdoors is probably not the kind of stuff that the Government would encourage.

Michael Russell: Do not do Hogmanay—that is the advice. Obviously, people are permitted to meet outdoors, and they might wish to meet outdoors at midnight, but they should not, in any sense, do that if they do not feel that they should. If people meet outdoors, the rules where they live, including social distancing rules, have to be applied to the letter.

There is no relaxation at Hogmanay. We are being clear in saying to people that they should meet at Christmas only if they feel that they have to do that because of the other harms. Yesterday,

the First Minister was clear about how restrained the contact should be. Please try to avoid staying in other people's houses. Do not feel that you have to meet up. Keep the numbers even lower than are permitted.

There is no relaxation of the requirements where people live at Hogmanay—no ifs, no buts. As you said, people can mix outdoors, but the numbers should be very limited. If people feel that they should not do that, and if there is any risk at all—there will be risk—they should be very careful about the decisions that they make.

There is a great element of common sense to this. The vaccine is becoming available. We are in the midst of a very difficult period. The relaxation at Christmas was much discussed and debated—even then, new guidance indicates how limited the relaxation should be.

There are no arrangements for Hogmanay—no ifs, no buts. The rules pertaining to that time are what should be followed. This morning, many members will have seen the BBC's reporting on parties. The vast majority of people are observing the rules, but the people who are not are putting themselves and others at serious risk, including risk of death. They need to be reminded of that constantly. Legal sanctions are available, and they are applied.

Annabelle Ewing: That is very clear: do not do Hogmanay.

My next question is for Professor Leitch, but if the cabinet secretary wishes to comment, too, that would be welcome. What is the current thinking on how long the roll-out of the flu vaccine should be pursued? We hope that further supplies of the Pfizer vaccine and other duly approved vaccines will arrive. At what point should we switch resource, if that would be beneficial with respect to potential harms?

Professor Leitch: Let me add a sentence or two to Mr Russell's answer on Hogmanay. I underline his very clear advice. Hogmanay is not cancelled, but gatherings at Hogmanay are cancelled. People should still celebrate. We did not cancel mothers day, Easter or Halloween. We cannot cancel wonderful, systematic annual events such as Eid, Hanukkah and Christmas, but they are different this year. Hogmanay will be very different. Our challenge was that, given the potential increase in prevalence as a result of the Christmas relaxation, adding another relaxation six or seven days later could have resulted in that positivity being spread further around. That is why our strong advice was that there should not be the same relaxation for Hogmanay.

You make an excellent point about flu and Covid vaccines. The first good news is that, on 17 December, the number of flu cases remains unseasonably low. That is excellent news, but it is not entirely unexpected. The southern hemisphere had a good flu season, and we are all washing our hands, keeping distant and cleaning our surfaces, which will help with other infectious diseases. Flu is not not here, but the number of cases is quite low.

As we always say, the flu vaccination continues through the winter. It is therefore not too late to get your flu vaccine. Although a lot of the flu vaccination has been done and it tails off into December and January, you should still get it if you are invited to go or if you have been invited to go but have not yet gone, because it will still protect you into February and March when flu could still be around and could cause you serious harm, particularly if you are in a senior group.

11:00

The difference with the Covid vaccine just now is that we do not have hundreds of thousands of doses and it is a relatively niche market. We have people doing Covid vaccination specifically in hospitals and care homes; we are not yet doing it in GP practices or in mass vaccination centres. However, we will do that, and that is when we will begin to think about the workforce—we are planning for exactly that. As flu vaccination falls away, we will be able to replace it with Covid vaccination.

The Pfizer vaccine is not really suitable for GP practices just now, because there are 975 doses, so you need to find 975 people to vaccinate and you need to do that fast. That works if you have a big centre, but not if you have a small centre. However, once we get all the regulations, we are hopeful that the AstraZeneca one will be able to be in GP practices and dental surgeries and all over the country much faster. However, it is all dependent on supply.

Annabelle Ewing: I thank Professor Leitch for that. I did not note the time that I started, but I suspect that that might be my time up, so I will stop there.

The Deputy Convener: I will be happy to return to Annabelle if we have more time at the end.

Willie Coffey: I will start off, if I may, with my usual question about Ayrshire, which is probably for Professor Leitch. We noticed that test positivity rates for East Ayrshire and South Ayrshire have dropped below the Scottish average, which is very welcome. However, North Ayrshire seems to have exceed it by quite a bit between 4 and 11 December. Are we worried at all about Ayrshire, or parts of Ayrshire, or about the spiking that we see between 4 and 11 December?

Professor Leitch: Yes, we are. Over Sunday and Monday, the Deputy First Minister and Ms Campbell had a series of local authority calls supported by clinical advisers, including me. Most of them were conversations about areas that were moving up or down—you could make up that list yourself; there were about 11 of them. We spoke to Edinburgh, as you would expect, and to Midlothian and East Lothian. However, we also had a number of watch-list local authorities, one of which was North Ayrshire. We therefore had a call with it on exactly that point.

We were not at the stage of thinking that we wanted it to go up a level; it was just a conversation to say to both the political leaders and the local authority officials, including the chief executive, that we see the numbers and that we know that they see them as well, and to ask whether there is anything that we could do. That could be about local messaging or about sending environmental health out around the clubs—whatever it has to be. It was about getting reassurance from the local authority that not only are we giving it all the support that it requires but it is doing everything that it can.

As we learn in local authorities around the country, we are able to share best practice. The Convention of Scottish Local Authorities is able to help us with that and with what it means in North Ayrshire.

The fundamental answer to Willie Coffey's question is that yes, we do see a rise, particularly in North Ayrshire, which is translating into both prevalence and positivity. We are keeping a very close eye on those numbers. We should remember that the secret here is that, whatever level you are in, it is about interaction. If something is allowed, it does not mean that you should do it; it means that you should think very carefully before you do it and be safe when you do so. Mr Coffey is right and is clearly paying attention.

Willie Coffey: Thank you for that. As you know, North Ayrshire residents use Crosshouse hospital in Kilmarnock, which is in East Ayrshire. There is a bit of a concern that, although parts of the county were split into different tiers, they are still mixing and mingling pretty much, particularly in coming to Crosshouse hospital. Are you keeping an eye on that to see whether there is any further impact?

Professor Leitch: Yes. Hospital or healthcare-type infections are pretty much following community prevalence. If Covid is in the community, it is almost impossible to keep it out of institutions, whether they are call centres, hospitals, prisons or police cells. We try hard to keep it out of them by building protective barriers around them but, in reality, community prevalence often leads to outbreaks of some description in institutions.

We know that it is still safe to access healthcare if you need it. We have green and red pathways and so on, so people should not avoid healthcare. We have also hugely increased the number of videoconference appointments that people can access from their home or workplace. That has been a huge revolution across the health service that I think we will hold on to in the future, because it is much more convenient for people and saves them travelling.

People should not be scared of Crosshouse hospital, but they should be careful when they go there. They should take face coverings, they should wash their hands, they should use hand sanitiser when they go back to their car and so on.

Willie Coffey: I want to ask a question that I do not think is been asked so far in this process. It is about the IT and data management of the vaccine roll-out programme. Who is doing that? Who is communicating with people? Who is recording that someone has been for a vaccine, if it is not the GP surgery's data management services?

Professor Leitch: Fortunately—actually, by design—the director in charge of vaccination is Caroline Lamb, who was the finance director, and then chief executive, of NHS Education for Scotland. She entered the Government a number of months ago to run digital services in health and social care. At the emergence of Covid, she was redirected to testing, and she has now been redirected to vaccination. Her heart, would you believe, is in digital. Along with the vaccination roll-out, she has been involved in a parallel workstream of apps, data management and everything else that you would expect.

Relatively recently, I met her team, which is based in NHS Education for Scotland and has designed the vaccination data collection processes that will be embedded in the NHS. Those processes are really good—I was very impressed. It is the same group—with different individuals—who designed the Protect Scotland app and have handled a lot of the testing data for us.

There is a dashboard—that is confidential, of course—that monitors who is being vaccinated, when they will need their appointment for the second dose and whether those people are care home residents, health and social care workers and so on. We are grateful for the fact that we have community health index numbers, which means that the health service has a long history of individual identification numbers for every person in Scotland. Not every country has that, and it is hugely valuable at points such as the one that we are at now, when we need to have a register of who has had a certain intervention and when they have had it. Those numbers allow us to

incorporate that information into this digital exercise.

The digital approach is one of our key workstreams, and it is working well. There will be blips, as there have been in the past 24 hours around Protect Scotland. Of course that will happen—the digital side is not perfect, but it is good.

Willie Coffey: That is encouraging.

My last query is probably for the cabinet secretary. Last week, I met the directors of Kilmarnock Football Club. Like others, they are asking about what a road map for getting football supporters—and other sports fans—back into stadiums might look like. They were not asking for dates and other specifics; they were simply asking whether we are working on what a potential road map might look like. Are we doing any work on that at the moment? Can we give them any assurance that we are thinking about that?

Michael Russell: The system of levels that is in place indicates the route map whereby restrictions are eased all the way down to a position of near normality. That is the route map that is in existence. Sports clubs should be assured that there is a way forward.

Secondly, as can be seen from the work that Joe FitzPatrick has done on support for football, a great deal of work is going on to ensure that there is support for clubs and spectators, so that we can move towards some form of normality. In every sector, ministers will be involved with every part of their portfolio to see whether they can fully understand what things will look like and how they will be laid out. I am sure that Joe FitzPatrick can reassure football clubs of that and I encourage you to engage with him.

Beatrice Wishart: According to the National Audit Office this week, NHS England and NHS Improvement are planning on the assumption that they will vaccinate up to 25 million people with two doses throughout 2021; do you have the figures for Scotland?

Michael Russell: Professor Leitch is the right person to answer that question.

Professor Leitch: We have tried not to set targets for very good reasons—we simply do not know enough about vaccine supply. We are encouraged by the early stages and the relationship with the companies and how that is working on a four-country level. The procurement is good and we have invested correctly in the vaccines that seem to be coming.

We have said publicly that we want to vaccinate 4.5 million people, which would take roughly 9 million doses, but we do not, and cannot, know where those 9 million doses will come from yet. We are hopeful that the AstraZeneca vaccine will be a big bulk of that, because at a four-country level we have invested in 100 million doses of that vaccine, but that needs regulation approval and approval to distribute and it needs to be manufactured in huge numbers. It also needs to go to, for example, Belgium, Senegal and Austria. We need to be careful not to set unrealistic targets, but we are aiming in 2021 to vaccinate 4.5 million people twice.

Beatrice Wishart: I understand that it is not wise to set unrealistic targets. I will ask about vaccinating priority groups. The JCVI recommends vaccinating all individuals aged 16 to 64 with underlying health conditions that put them at a higher risk of serious disease and mortality; that group would be the sixth priority after all those aged 65 years and over. How will it be decided who those people are and what priority they will be given?

Professor Leitch: Nine groups were announced by the JCVI. We have to be slightly careful here, because that is the existing JCVI advice, which is based on what we know now about vaccines, so do not be entirely surprised if the JCVI changes its advice over time, as you would expect it to do for the measles or yellow fever vaccines. For now, with what we know about vaccination, immunity and risk from Covid, it has listed nine groups with a tenth group at the bottom, which is everybody left under 50.

Everybody who was previously shielding—what we now call the clinically extremely vulnerable group—will be vaccinated with the over-70s. Once the over-65s group has been vaccinated, on the risk-of-death graph—it is a horrible name, but that it what we use—we move down to the over-60s and to that group we add the high-risk group, which is basically those who get the flu vaccine. That is roughly how we do that, although there may be some nuance around the edges of that based on Covid risk rather than flu risk. However, we do not need to do that group tomorrow; that will be some months ahead, and we will know more about the disease and the nature of the vaccine by then. In rough terms, those who get the flu vaccine who are 16 and above will get the vaccine with the over-60s. The idea is that their general risk is about the same as the over-60s' risk; that is not completely accurate—of course it is not—but in rough terms that is where they fit into the scheme. I am drawing a graph like the one in the paper that decided this—it shows very high risk for the over-80s, which falls as your age falls, and you add in disease as you go up the graph.

Beatrice Wishart: That is helpful for people who have had the flu vaccine; they will have a pretty good idea of where they might fall in that list. My final question is to ask whether there is an

update on recent figures of the number of people who have been fined for breaching travel restrictions, bearing in mind the importance of adhering to travel restrictions, especially in light of what the cabinet secretary said about Hogmanay?

11:15

Michael Russell: I have no detail on the travel restrictions part of that question. However, I can give you the update on the policing figures to 9 December, which are important overall.

Between 27 March and 9 December, 6,126 fixed-penalty notices were issued. The figure for those who dispersed when informed is 67,262; the number who dispersed, but only when instructed, is 18,819; and the figure for those who were dispersed using reasonable force is 636. There were 6,126 fixed-penalty notices issued, and 486 people were arrested. A subset of that will be those who received notices about travel, and it would be an operational matter for Police Scotland to break those figures down even further.

As we can see, not only is the four Es approach the underpinning guidance, it is also useful, because it shows that people are capable of being persuaded and informed, and that only at the very end will enforcement be needed.

Beatrice Wishart: Those are helpful answers. Thank you.

John Mason: Professor Leitch, you said that we need 9 million doses of the vaccine. However, we heard during our previous committee meeting that the UK is ordering five doses per person, so it looks like we could have 25 million doses available. Will you comment on why the UK is ordering so much and whether doing so puts poorer countries at a disadvantage?

Professor Leitch: That is an excellent, well-made point, Mr Mason. The reason why we have, in effect, put our chips on different manufacturers is that we do not know which one will get there first or how many doses it will have. Initially, until we know what the virus does in the longer term—whether it will come back, whether we will have to keep vaccinating people over time, et cetera—we will need the first set of vaccines. Every country in the world needs that.

Let us imagine a world in which we got 2 million doses of Moderna's vaccine, 2 million doses of AstraZeneca's and a million of Pfizer's. That would allow us to vaccinate half of our population. The vaccine procurement committee decided not to put all the chips on one vaccine because it could fail at any point—during manufacturing, regulation or trials. That is why there is a broad approach to procurement. In reality, we will probably not get 25 million doses. We will probably get somewhere between the 9 million and 25 million doses that we require.

In response to your other point, I have been very concerned about vaccine hoarding in western Europe and developed countries, but I am reassured by the World Health Organization's engagement on that issue. It is doing a specific piece of work on global vaccination. It has sought donor countries, and my understanding is that the UK was the biggest donor to the fund. The UK will in effect buy doses of the vaccine at cost price from the main drug companies, and the WHO will then deal with supply, distribution and all the other, related things that we would expect to be required.

Pfizer and AstraZeneca have both said publicly that they will make extra portions of the vaccine available at cost price through that WHO procurement and provide it to the likes of Yemen, Ethiopia and Senegal, which simply would not be able to do what we have done, so I am reassured.

As I said at a previous meeting of the committee, Dr Tedros Adhanom Ghebreyesus, who is the director general of the WHO, said a few weeks ago when he launched the programme that we should vaccinate some people in all countries before we vaccinate all people in some countries. He is correct. This is a global problem, not a Scottish one. It is of course a Scottish problem, but it is much bigger than us.

John Mason: I appreciate that answer, which was helpful. I will move on to a different subject. Recently, we had mass testing in certain areas, one of which was Dalmarnock, which is in my constituency. Can you tell us what we have learned from mass testing? Based on what I saw in the figures, there were not huge numbers of positive results.

Professor Leitch: It has been an interesting exercise. You will remember that, when we launched it, we discussed with the committee the fact that we had decided to do things slightly different from other parts of the world and not go for whole-population, mass testing in a city or region. We decided to go to particularly high-prevalence areas, which we chose from the public health dashboard that everyone can see: Dalmarnock, Pollokshields, Clackmannanshire and a couple of areas in Ayrshire.

That has proven to be a useful approach, particularly for the Clackmannanshire outbreak. The numbers there look high because we found quite a lot of asymptomatic cases. We also found some cases in Dalmarnock and Pollokshields. You are absolutely correct to say that there were not enormous numbers. However, tackling every positive case interrupts a chain of transmission, which is a good thing.

That is one of the reasons why we have been able to drive down the level 4 rating. Another is that we have been able to offer testing to specific, targeted areas of the population, particularly in areas where testing is easily accessible, local communication is good and local authority and community leaders can help us with it.

I do not particularly like the phrase "mass testing", because it does not really describe the process. "Targeted testing" is better. Our approach in the areas that I have mentioned has been a good example of how we can use such testing. I think that we will continue to do that, particularly with polymerase chain reaction testing, which is our most reliable form of test. It is one of the reasons why we have seen Glasgow's numbers fall pretty well over the past few weeks. It is not the only reason, though—there are others, which relate to people's behaviour.

John Mason: Were you happy with the number of people who came forward for testing?

Professor Leitch: I will always want there to be more. I would like to queue them all up in a big line and test them all. I would have to look up our most recent percentage, because I cannot remember it, but I recall that, compared with figures for the global city testing that has been done, it was much higher.

Please forgive the shorthand, but that approach also reached some of the harder-to-reach groups that we had been worried about. Those are people who are sometimes difficult to get to for various reasons, which might be factors in their lives or things to do with the design of our services, such as where people have to travel to in order to reach testing sites.

We tried to carry out testing as locally as we could. Community leaders in places such as mosques, churches and community centres and local authority politicians gave us a lot of help with communication. It was an encouraging set of circumstances, which brought us benefits. However, I would still rather have more people come forward—of course I would.

John Mason: My third and final area of questioning is on the testing of students that is being carried out before they go home for Christmas. Has there been good uptake of that? How has it been going?

Professor Leitch: The uptake has been excellent. The big, headline news is that it has picked up very few positive cases. We know that lateral flow testing is not as sensitive as PCR testing, but that is not to say that it is not sensitive at all: it detects about 64 per cent of positive cases. The fact that we have found some positive cases but not many would suggest that the student population has been following the guidance and the rules, and that things are going well among students.

That gives us some assurance, although not 100 per cent, that when they go home they will be safer than they would otherwise have been. We will have broken the chains of transmission in those who tested positive with lateral flow, by retesting them with PCR and self-isolating them and their households. That is another layer of protection.

We will do the same lateral flow testing on the staggered re-entry of students after Christmas. We hope that one test can be carried out nearer their home and another when they get back to university. We are discussing and negotiating that with the student body and the institutions.

Maurice Corry: Good morning, gentlemen. I want to go back to the question of the submarine base at Faslane, which is near to my heart and in my area. There seems to be good news there in that the number of cases has gone down from 96 to 37. That clearly shows that the strategy for industrial sites is working. Would Professor Leitch like to comment on that?

Professor Leitch: As you can imagine, that has been a complex outbreak. There is a lot of hierarchical leadership there, which includes the local director of public health and the Scottish Government, but also Ministry of Defence representatives, who are the local leaders inside the base.

The outbreak has been dealt with very well. Those who tested positive were isolated. Of course, it is a slightly different environment because of the nature of that workplace. However, that is also true of a chicken processing plant, a call centre or a hospital. We adapted our instructions and guidance to the local environment. Fortunately, the last time that I got a report, nobody was seriously unwell, which is the most important thing. It is a relatively young and fit cohort, but that does not keep them entirely safe.

The crucial thing for Mr Corry's constituents is that we have not seen onward community transmission of a meaningful size. The leadership managed to control the environment in the workplace and supported those who tested positive to self-isolate. The multiworker element of the environment has been well handled by UK and Scottish Government liaison, as well as by the local director of public health.

Maurice Corry: That is interesting and it is good to hear. My concern and that of my constituents is about onward transmission, particularly when a parent who is serving at or working in the base comes home, and their kids go to local schools. From what you say, however, that transmission has not followed through.

Professor Leitch: I am touching wood, although that will not get us out of trouble. So far, that appears to be the case. If we look at the published graph for Argyll and Bute, it is clear from the numbers that something happened—statistically, we call it a special cause. We know that that was a workplace outbreak, but the numbers have come down again. It appears that, as things stand, community transmission has not happened, because of self-isolation, household isolation and strong support for that isolation.

If we can enable people to self-isolate, that makes it easier. Whether it is through food parcels, phoning people up to ask how they are or peer group pressure to keep everybody isolating, that support appears to have worked well in that environment, as it did in the outbreak at the Coupar Angus chicken processing plant. That was a fairly severe workplace outbreak, but there was little community transmission from it.

Michael Russell: The outbreak at Faslane also illustrates some of the issues that arise in the local authority context. Faslane is not in my constituency, but it is in the Argyll and Bute local authority area. This week, that context has led to us being able to have a slight relaxation for certain island groups that are distant, although still in the local authority area, but also to have important discussions about what happens in diverse or large local authority areas, and ones that include extreme rurality as well as urban or semi-urban areas. Big issues are raised by that and, as Professor Leitch indicated, they need to be discussed in the context of fine tuning the system.

Maurice Corry: Thank you for that comment, cabinet secretary. You pre-empted what was going to be my next question, which was on that.

Professor Leitch, I would like to drill down a little more on the issue of the Faslane base. Were the 96 cases predominantly among the younger members of that site—the non-marrieds with no families?

Professor Leitch: I do not have that level of granularity, but I have confidence that the local incident management team has it and makes judgments accordingly. If someone has a positive result, the whole household isolates, so if one of the workers in that workplace tested positive and they have school-age children, those kids will have isolated with them. That appears to have worked, because we have not seen onward transmission from schools, shops or wherever else those individuals go.

Maurice Corry: I thank you for that on behalf of our area. That is very good and I am glad to see that positive outcome.

I have a final question for the cabinet secretary, but Professor Leitch should jump in and comment as well, if he wants to. What further consideration should be given to the issue of students having to pay for unoccupied accommodation over the winter break?

Michael Russell: It is a good question. We tackled that in one of the two pieces of coronavirus legislation, but it has recurred as an issue. If it is not covered in that legislation, which was designed to meet that situation, we need to do two things. The first is for members to raise individual cases, because it would be wrong if demands were still being made for money from people who are not there. The second thing is to consider whether there is anything that we can do in legislative or regulatory terms, as we have done in preventing evictions, to deal with the problem.

I have seen no evidence from individuals of the situation that you describe. If other members have seen such evidence, they should raise it with Richard Lochhead and Kevin Stewart, as the relevant ministers. I am sure that they will want to talk to me about whether we need to do something more in regulatory terms. We should certainly be doing our best to ensure that students are not disadvantaged at this time. What they are having to go through is hard enough.

11:30

Maurice Corry: Is there a plan in your file, as it were, in case the issue becomes more prevalent?

Michael Russell: The plan in my file is always that, if something is required urgently, it will happen. If members are raising the issue with the relevant ministers, I am more than willing to consider what we can do with it.

Stuart McMillan: My first question is for Professor Leitch. Earlier, Willie Coffey raised a point about North Ayrshire. Looking at the daily dashboard figures, it is clear that the figures in that area have gone up. Does that pose a risk to Inverclyde? We are in tier 2 and North Ayrshire is in tier 3. If North Ayrshire was to go up to tier 4, would it mean that Inverclyde might go up to tier 3 in order to restrict movement in the area?

Professor Leitch: That would not be the principal reason. Mr Russell might want to comment on the balanced nature of the conversations in Cabinet on such issues.

Previously in this committee, we have talked about how those decisions are made. I will deal quickly with how the advice is given. We start at local authority level, but that is not where we finish. We cannot finish there, because there are not barbed-wire fences around the borders of council areas. The reality is that we start with the numbers inside the geographical unit—that is how

we have decided to measure the prevalence of the virus—and we work up from there.

The local public health lead says what the position in Inverclyde is, and we then have to think about issues such as the fact that the intensive care unit provision for Inverclyde is partly in Inverclyde and partly in Glasgow city, so we must consider what that means for our plans. We have to think about where people go to work, shop and access hospitality, and where the care homes are that people from Inverclyde visit. That takes us up a layer and makes things a little more inexact, and that leads us to the conversations about borders that you have just described.

South Lanarkshire is a rural area—the extreme south is very much so—but it is well connected to Glasgow city and other parts of the country. We have to take that into account in our advice. Subsequently, in the Cabinet, there are conversations about how such factors are taken into account in relation to travel regulations. If an area is surrounded by a group of areas that are in tier 3, is it possible to make that a tier 1 area? If so, how will we advise the people there to behave?

There is not a direct relationship between North Ayrshire's number and Inverclyde's number, but they are not completely disconnected. There has to be a conversation about that somewhere in the process. I have described what happens at the advice level, and Mr Russell might want to talk about what happens at the Cabinet level.

Michael Russell: There is always a question about boundaries. Many years ago, I was a member of the Arbuthnott commission on voting systems and boundaries. In Scotland, boundaries are about natural populations. Sometimes, those boundaries cut across natural populations and how people live and move from one place to another. In this case, as Jason Leitch indicated, there is the added complication of what we might call an island effect—I am not talking about islands in relation to reducing the regulations; I mean areas that are islands among areas of higher incidence and prevalence.

Discussions around those issues are complex and difficult. As Jason Leitch says, there is not an automatic assumption that, if one area is in tier 3, another area must also be in tier 3. The question is: where does the population naturally look to? As an elected member, you will know that local authority wards are sometimes extremely unwieldy, that they do not address people's movements from one place to another and that they can bring together people who have no natural affinity. Therefore, the knowledge that exists in the Cabinet about the various areas of Scotland and how people move to work, shop and socialise comes into play. However, as I said, there is no automatic assumption that one area being in tier 3 will mean that a neighbouring area will also be in tier 3.

There is also recognition of the boundary effect. There will be bleeding across boundaries simply because of where people live. Some local authority boundaries run across communities. It is a sensitive and complex area that needs a lot of thinking.

People might ask why we use local authority areas. We have to use something, and using local authority areas is better than using health board boundaries, because they are even less logical in that sense. We think about the matter a lot.

Professor Leitch: I should perhaps start my answer to Mr McMillan with a single sentence to say that Inverclyde's numbers are encouraging—and remain encouraging—but fragile, as is the case in the rest of the country. At level 2, Inverclyde has managed to maintain a relatively slow but sustained reduction. The situation is stable. The numbers are not plummeting, but nor are they rising. Whatever is going on with travel and everything else among the people of Inverclyde, things are going relatively well there compared with the situation in other parts of the country.

Stuart McMillan: My next question is about the vaccine. It will not be mandatory for anyone to have the vaccine, but a couple of individuals who work in the care home sector contacted my office this week to indicate that they are not prepared to take the vaccine. Those in care homes are the first group of individuals to get the vaccine. It would probably be an issue for the human resources department if staff were not prepared to take the vaccine, because they could be putting at risk care home residents as well as others. Is there anything that Professor Leitch or the cabinet secretary can say to encourage anyone who works in a care home—whether it is in Inverclyde or across Scotland—to take the vaccine?

Michael Russell: We have to take an inclusive and open approach that is based on evidence and information. As politicians and community leaders, we should show by example that we regard the vaccination programme as extremely important and that the risks that are being talked about do not exist in the way that some people view them. We should definitely try to persuade people to take the vaccine. Therefore, I do not think that we are at the stage at which we should be talking about HR issues. We should be talking about how we reach out by leading by example, by persuasion and by providing information. We should say that the vaccine is desirable, safe and important, and that we should move in that direction.

I would be reluctant to enter into a speculative discussion about HR issues and other such issues, because I hope that they will not become issues of importance. The issues of importance are about saving lives. The vaccines are a remarkable testament to the hard work, ingenuity, inventiveness and dedication of those who have worked on them. Nobody is being asked to do things that are dangerous; they are being asked to do things that will, in the end, result in a good outcome.

Jason Leitch might want to say more. I certainly think that it is a matter of persuasion and discussion at the moment. I do not think that we should speculate on other matters.

Professor Leitch: I agree. Forgive me if I have the numbers slightly wrong, but I saw data yesterday that suggest that 27 million people across the United Kingdom are not hesitant in any way. They will rush towards the vaccine when they are offered it. Another 27 million people are hesitant but are not anti-vax. They are not suggesting that vaccines are a bad thing, but they want more information. They want to know that the vaccine is safe and that the regulator has done all the right things. They might want to hear from clinical advisers and—forgive me, folks—not always from politicians that it is safe to have the vaccine.

We have not started our mass information campaign, which will include TV adverts and door drops. We do not think that it is the right point to do that, because we are not providing mass vaccination yet. There will be a UK-wide campaign and a Scottish campaign. There will be a door drop to provide every household with information on vaccination. We will use clinical advisers and some famous faces to help with the campaign. I am hopeful that that will get through to most of the people who are hesitant.

To be completely honest, I am not sure that there is much that I can do to communicate with people at the extreme edge, who think that we are microchipping the vaccine so that we can follow people around the country. There are things that we can do for the hesitant group. We can explain the science, the regulations and the process that the vaccine has been through. I hope that that will be enough for your constituents and for everybody else, particularly for those who might put others in care homes at risk.

Stuart McMillan: My final question is about domestic abuse during the five-day festive period from 23 to 27 December. Reports indicate that there has been a 7 per cent increase in the number of domestic abuse incidents over the past year. The Scottish Government has undertaken two-monthly reporting of those figures. Has that helped to shape the thinking about the festive period and beyond? Will it inform the provision of additional resources or assistance to help to deal with domestic abuse incidents?

Michael Russell: The figures are distressing, but they are important in how we shape policy. I indicated in my response to questions on the report last week that the police have taken a number of initiatives and will continue to do so. Regrettably, holiday periods can bring additional difficulties. I am sure that the police are aware of that and are taking forward strategies that will help.

The Deputy Convener: I would like some clarity on an issue that has emerged in the media today. Professor Leitch might be best placed to answer this. How does the six-week rule relate to the rules about self-isolation? *T*he Scottish Government has confirmed to *The Ferret* that there has been

"no change to national guidance"

and that there is no six-week exemption. However, NHS Greater Glasgow and Clyde has told councils that people who have been identified as having been in contact with Covid-19 do not have to self-isolate if they have been infected with Covid in the previous six weeks.

It would be helpful to know why the advice in the NHS Greater Glasgow and Clyde area is different from that in the rest of Scotland.

Professor Leitch: We will take that away and respond in writing. That would be the most sensible approach, as I have not seen the article in *The Ferret*.

If an intensive care doctor tests positive and self-isolates, there is no point in retesting that doctor for about 90 days, because people can shed inactive and non-infectious genetic material of the virus. There is no risk to anybody, but that doctor would still test positive if they were retested and we would lose that intensive care doctor from work for a much longer period.

We have often talked about testing. The test cannot distinguish between the live virus and its remnants. We know that a person who has had a positive test and self-isolates, particularly if they have had symptoms and have recovered, will not be shedding the live virus a month later. That is not biologically plausible. There are some occasions when the 90-day point is true, but I am not sure whether it is true on this occasion. I am not aware of a change in the guidance about contact tracing and whether people should isolate, and I would probably be in that loop.

I will get back to you in writing on the specifics of that, if that is all right with Mr Russell.

Michael Russell: That is fine; it is the right thing to do.

The Deputy Convener: I appreciate that offer.

Annabelle Ewing: I have a question about something that came up at a meeting with elected representatives and NHS Fife last Friday. I am getting inquiries from over-80s who are not in care homes and who need reassurance that they are on the vaccination list. There might be a communication issue. Until I reassured them, members of one family had spent 24 hours worrying about whether a grandmother or elderly aunt in her nineties would be left behind. I was able to reassure them, but it is a shame that they had any worries. Could we reflect on the way that that group of people is being communicated with? They may not use social media every day.

11:45

Michael Russell: I will ask Jason Leitch to comment on that in a minute, but I saw material on this last week, and it was very clear—and I hope that it is being widely distributed. People are not to worry if they have not been contacted yet. We are at the start of the programme, and they will be contacted. Jason has made it clear that a very careful and rigorous programme is under way.

I take the point that we do not want anybody to worry about the issue. There is an assurance that they will be contacted, and that they have not been and will not be forgotten. If we can reassure people further on that, we should do so. Perhaps Jason Leitch can confirm that nobody will be forgotten, and that everybody will be included.

We are at the start of a programme, and it has started well. The figures for the percentage of the population covered so far are higher than those elsewhere. However, the programme has a long way to go.

Professor Leitch: It is an excellent question. I should say that one of the people who is probably watching this meeting will be my mother, and she has a very special birthday today that puts her in the relevant category. I should wish her many happy returns.

Michael Russell: Happy birthday!

Annabelle Ewing: Happy birthday!

Professor Leitch: She, too, is asking when they will come for her and hoping that she will not be forgotten. I reassure her and your constituents, Ms Ewing, that we know who all the over-80s are and we will get to them just as soon as we have a vaccine that we can take to people or that can be made available at a place to which they can come.

We will of course not be able to do everybody on the same day. This is perhaps not right, but I think that there are 280,000 over-80s, or just over 300,000. The simple equation is that that is more than we have vaccine, but we hope that we will get that level of vaccine in January. That will allow us to reach that group.

People will be split into two groups: those who can travel to the vaccine and, slightly more complicatedly, those we will have to take the vaccine to. That is a little bit more tricky, but we will get to them. To reassure people further, the system will not be foolproof, so there will be mechanisms by which people who feel that they have been forgotten will be able to reach out to us to ask whether they have fallen through the net or there has been a mistake. That is what we do with the flu vaccine, and it is what we will do with the Covid vaccine.

I am not naive enough to think that this will be a completely smooth process. Of course there will be challenges with people's addresses, phone numbers or names, but we will get to them. We know who they all are, because everybody has a CHI number and a GP. We can therefore get to that register of people, including my mum and your constituents.

Annabelle Ewing: Thank you, and happy birthday to Professor Leitch's mother—enjoy your day.

The Deputy Convener: I think that this is the COVID-19 Committee's first birthday shout-out—happy birthday!

Mark Ruskell: A lot of parents are still writing to me. They are feeling cautious and do not want to send their children to school on Monday, Tuesday and Wednesday next week. Are they right?

Michael Russell: No. We have said repeatedly at the committee that we are doing everything that we can to preserve normal schooling, and that is what we should continue to do. I hope that we are all of one mind on that. The advice that John Swinney has operated on is public health advice, and he has been very clear about it.

The Deputy Convener: That concludes our evidence session under item 2. I thank the cabinet secretary and Professor Leitch for their evidence.

We move to item 3, which is consideration of the motions on the subordinate legislation on which we have just taken evidence under the previous agenda item.

Does the cabinet secretary wish to make any further remarks on the Scottish statutory instruments before we deal with the motions?

Michael Russell: No, thank you.

The Deputy Convener: Are members content for motions S5M-23534, S5M-23603 and S5M-23683 to be moved en bloc? Any member who is

not content with that approach should type N in the chat box.

I see that Mark Ruskell is not content with that. In the interests of time, I ask Mark to indicate what his objection relates to.

Mark Ruskell: It relates to SSI 2020/415—the amendment (No 6) regulations.

The Deputy Convener: Thank you.

As the cabinet secretary does not wish to make any further remarks, I invite him to move motion S5M-23534.

Motion moved,

That the COVID-19 Committee recommends that the Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) (Scotland) Amendment (No 5) Regulations 2020 (SSI 2020/400) be approved.—[*Michael Russell*]

Motion agreed to.

The Deputy Convener: I invite the cabinet secretary to move motion S5M-23603.

Motion moved,

That the COVID-19 Committee recommends that the Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) (Scotland) Amendment (No 6) Regulations 2020 (SSI 2020/415) be approved.—[*Michael Russell*]

The Deputy Convener: Mark Ruskell wishes to speak in the debate on the motion.

Mark Ruskell: I find it difficult to ignore the chorus of concern that we have heard from the medical community over the past few weeks about the regulations and the potential for a surge of cases as a result. I welcome the Scottish Government's cautious overlay of additional guidance yesterday, but I am still concerned that we have had a lack of clear modelling and a lack of clear evidence presented to the committee to back up the change in the regulations. That leaves me in an uncomfortable position. At the same time, I realise that we sit here on 17 December and that time is running out before Christmas.

I would like to hear from the Scottish Government that, if cases go up in the days to come, the regulations will be reconsidered, even at the last minute. I am concerned about the messages that we are getting from the medical community on the potential for a surge in cases in Scotland. As I said, that leaves me in a very uncomfortable position in respect of voting to approve the regulations today.

Michael Russell: I understand the concerns that Mr Ruskell expresses. Concerns clearly exist—he has heard from Professor Leitch, for example, about how difficult the modelling is.

The four countries have worked hard to try to come to an understanding on the matter. We would have been criticised if we had not done so, and we have been criticised for having done so, so we are in an unfortunate set of circumstances. We clearly want to ensure that everybody is as safe as possible, and we have therefore put in place for next week an additional review—which we had said might not take place—to look at the figures.

All that I can say to Mr Ruskell is that we look, and will continue to look, at the figures daily. The Cabinet will have the opportunity to review the figures again on Tuesday, and of course the Cabinet can be called into session at any time. We have to balance that against the—[*Inaudible*.]—to take advantage of the Christmas relaxation in the most limited way possible. I stress yet again that it should be limited; the guidance in that regard is much stronger.

I understand Mr Ruskell's reservations, but we have to accept that we are currently in a situation in which a Christmas relaxation will take place. We are asking people to be very restrained and careful, and we will of course continue to look at the figures. I do not want to create panic, uncertainty or fear in people's minds, so we will act responsibly and carefully, alongside the other Administrations.

The Deputy Convener: The question is, that motion S5M-23603 be agreed to. If any member disagrees, they should type N in the chat bar now.

Members are not agreed, so there will be a division.

For

Willie Coffey (Kilmarnock and Irvine Valley) (SNP)
Maurice Corry (West Scotland) (Con)
Annabelle Ewing (Cowdenbeath) (SNP)
Monica Lennon (Central Scotland) (Lab)
John Mason (Glasgow Shettleston) (SNP)
Stuart McMillan (Greenock and Inverclyde) (SNP)

Abstentions

Mark Ruskell (Mid Scotland and Fife) (Green)

The Deputy Convener: The result of the division is: For 6, Against 0, Abstentions 1.

Motion agreed to,

That the COVID-19 Committee recommends that the Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) (Scotland) Amendment (No 6) Regulations 2020 (SSI 2020/415) be approved.

The Deputy Convener: I invite the cabinet secretary to move motion S5M-23683.

Motion moved,

That the COVID-19 Committee recommends that the Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) (Scotland) Amendment (No 7) Regulations 2020 (SSI 2020/427) be approved.—[*Michael Russell*]

Motion agreed to.

The Deputy Convener: In the coming days, the committee will publish a report to the Parliament, setting out our decisions on the statutory instruments that have been considered at this meeting.

I thank the cabinet secretary and the national clinical director for their attendance and time this morning. We had quite a lot to get through, so I thank committee members for their patience.

Meeting closed at 12:01.

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