HOUSE OF COMMONS

Science and Technology Committee

Oral evidence: Commercial Genomics, HC 140

Wednesday 17 June 2020

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Watch the meeting

Members present: Greg Clark (Chair); Aaron Bell; Dawn Butler; Katherine Fletcher; Andrew Griffith; Mark Logan; Carol Monaghan; Graham Stringer.

Questions 1 - 112

Witnesses

I: Dr Tara Clancy, Council Member, Nuffield Council on Bioethics.

II: Graeme Tunbridge, Director of Devices, Medicines and Healthcare products Regulatory Agency.

III: Lord Bethell, Parliamentary Under-Secretary of State (Minister for Innovation), Department of Health and Social Care; Professor Sir Mark Caulfield, Chief Scientist, Genomics England; and Graeme Tunbridge, Director of Devices, Medicines and Healthcare products Regulatory Agency

Examination of witness

Witness: Dr Tara Clancy.

Q1 **Chair:** Today, the Committee is continuing an inquiry initiated by its predecessor in the previous Parliament on commercial genomic services. We are going to hear from a range of witnesses, concluding with Lord Bethell, Minister for Innovation in the Department of Health and Social Care. As Lord Bethell is also Minister for testing, track and trace, the Committee may have some questions for him to help us with our other inquiry into the scientific aspects of the handling of Covid-19.

I am delighted to welcome our first witness, Dr Tara Clancy, a council member of the Nuffield Council on Bioethics. Thank you very much indeed, Dr Clancy, for joining us today.

Why should the Government regulate people's access to commercially provided tests of their own genome?

Dr Clancy: Rather than thinking about it in that way—nobody is answering the question that should have been asked—we think it might be better to consider the environment within which testing could be offered ethically. Going back to 2010, the Nuffield Council and the UK's Human Genetics Commission set out principles. That was about direct consumer testing.

The Council highlighted that: individuals should be able to pursue their own interests; private information should be safeguarded; the state should act to reduce harm; public resources should be used fairy and efficiently; and social solidarity—sharing risks and working together to protect the vulnerable—should inform public policy.

We think it is about establishing conditions to ensure people are able to make their own choices and are aware of what they are getting and what will happen to their data, at the same time minimising adverse consequences for others and the NHS.

Q2 **Chair:** Help us with what those adverse consequences might be. A person's genome is unique to themselves; it is theirs. If they contract with someone to analyse it, why should this be any business of public policymakers? Tell us about the concerns that you and your Council have.

Dr Clancy: For one thing, we share much more of our genomes than are particular to each of us as individuals. Genomic information is often considered to belong to a family as much as to an individual. That is one arm of the problem. Another is to ensure that people know what they are getting, what it could mean and that it is reliable.

Q3 **Andrew Griffith:** Continuing the Chair's theme, as a Science and Technology Committee we are very keen that policy is evidence based. Your report singled out children as a particular area for strengthened regulation. What evidence is there of harm to support that

recommendation?

Dr Clancy: A lot of the evidence about harm is probably more anecdotal than published. Testing in childhood is normally limited to conditions for which there are immediate medical benefits, based on professional guidance in the UK, Europe and internationally. It would be good to understand more about the benefits and harms; and the recently announced plan to sequence the genomes of 20,000 healthy newborn babies is likely to provide some valuable insight into that.

The harms we would be concerned about are false positive results, uncertain results, overtreatment and perhaps the impacts on the period of bonding between parents and children in the newborn period and the parent-child relationship in childhood.

We are keen to ensure that as children develop capacity they can make decisions for themselves in the future.

Q4 **Andrew Griffith:** These sound like hypotheses of harm as opposed to evidence of harm. To what extent do you weigh up the risk of regulation stifling and suppressing the benefits of genomics by coming down too hard early in the development of a new and, I think we all agree, exciting field of medical testing?

Dr Clancy: It is indeed going to be that, hopefully. I think that is a separate question from thinking about what the harms might be to do with children and preserving their right to make decisions in the future. If we consider the environment within which testing could be offered ethically, that does not mean looking to restrict what decisions people make on their own behalf.

Q5 **Andrew Griffith:** But is there specific evidence of harm that you can share with the Committee today?

Dr Clancy: About problems that have happened?

Andrew Griffith: Yes.

Dr Clancy: There is evidence of women having had risk-reducing breast surgery on the basis of an inaccurate result, for example. There are complications about the interpretation of results by some commercial laboratories.

Q6 **Chair:** If there is a requirement to regulate, there need to be some tangible problems to address. Reading various submissions to this inquiry, a number seem to suggest certain things. One is the quality of the analysis. How can you make sure that competitors are attaining a high quality and whether you get reliable results? Another is that some of the results might have quite life-changing implications, and the question is whether counselling should be indicated around that. One of the points about children is whether their parents, on their behalf, as it were, should discover things about their long-term prospects without them being able to make an informed decision. Are these not the areas that were of

concern?

Dr Clancy: Yes. I might have misunderstood the previous question, which seemed to be more about the technical side of things.

We would probably all agree that having adequate information provision, consents and interpretation of results is critical in protecting consumers. We know that, in the UK at least, the right of children to exercise autonomy is recognised separately from parents' wishes and preferences.

Q7 **Aaron Bell:** Dr Clancy, thank you for your time today and the evidence your Council gave to our predecessor Committee.

May I ask a few questions about privacy and consent and where you see the risks at the moment?

Do you think the broad consent frameworks that have been set out by commercial genomic providers are sufficient for the testing they are undertaking?

Dr Clancy: There are certainly concerns about broad consent. One of the major advantages of broad consent is that it reduces the need, in the context of a commercial company or research project, for example, to re-contact people for further consents. In turn, that reduces the burden on individuals, but it treats consent as a one-off process and tests might be done or data shared in a way that individuals would not have agreed to or may object to.

An alternative is dynamic consent, which is more of an ongoing interactive process. That has the potential to enhance confidence, but at the same time ongoing requests to re-consent might be burdensome.

A Nuffield Council report on the use of health data recommended that what you really need are good governance systems to meet people's reasonable expectations about how their data will be used. We feel commercial companies need to prove they are trustworthy. Doubtless they want to act and be seen to act responsibly.

One of the difficult things—this is not peculiar to commercial genomics at all—is that terms and conditions of services can be hard to understand, and few people will look at them in detail.

It is really about thinking of good governance systems rather than getting tied up and thinking, "Is broad consent or is dynamic consent definitely the way forward?"

Q8 **Aaron Bell:** Given we all want good governance, if we put good governance in place do you think that a method of broad consent could still be applicable? I think we can all see that not having that burden and allowing the data, whether it is de-identified or however it works, to be used in research is a huge benefit from what we are going to get out of genomics.

Dr Clancy: I think there are limits to broad consent in that things may be done that people would not have agreed to. Most people can understand that at the start of a research project, for example, you do not know what questions might be uncovered in the future, but there would still be cases where people might end up finding that tests had been done and their data used in a way that they would not have agreed to.

Something more like revisiting consent would be preferable. It is also different in the context of commercial genomic testing from what it would be in research projects, because those projects have separate governance and oversight anyway.

Q9 **Aaron Bell:** This links into what I was going to ask about privacy. The Council wrote in its submission that "there are circumstances in which it may be acceptable to challenge normal expectations of privacy," and you have said that an ethically appropriate use of data should respect core moral standards rather than simply aiming to satisfy the requirements of the law.

In terms of what people expect from privacy rather than consent, could you expand upon that?

Dr Clancy: In part, there has been a pretty big case about it recently. I do not know whether you are thinking about disclosure of information to other people.

Q10 **Aaron Bell:** You set out some ethical principles about how data would be used and the principle of respect for persons. I am trying to clarify where you think the law does not go far enough, if you are suggesting there need to be some revisions to the law.

Dr Clancy: I am not sure I can answer that, sorry.

Q11 **Aaron Bell:** I want to pick up on something you said in your initial answer to the Chair about the implication for relatives of what comes out of a test, which I think you are right to raise. Do you think the High Court ruling in ABC *v.* St George's in February of this year provided satisfactory clarity, or do you think more is required?

Dr Clancy: Speaking as an NHS professional, I think it has provided clarity. For a long time we have had a professional obligation to balance the rights and interests of patients and public interests in preserving confidentiality. This case was about genetics and relatives. If we disclose the information, we might be able to reduce or prevent harm.

The case established that we have a legal duty as well as a professional obligation to do that, at least when we have a relationship with the other person—the relative. I think it has made the situation of professionals safer in a sense.

But in genetics we work very hard to encourage and support people to share information with their families, and we know most people do that.

When they do not it is usually because of lack of contact, or they might be estranged, or they are worried that sharing the information will do more harm than good. I think it is an example that will apply in the commercial sector as well where both pre and post-test counselling support is important.

Q12 **Aaron Bell:** You mentioned the commercial sector. I can see it has been beneficial to the NHS, particularly in cases where you are dealing with both members of a family. Where does the duty fall on a commercial provider? Does it fall on the provider to fulfil that duty, or is it about them telling their client or customer that they have a potential duty to inform?

Dr Clancy: Depending on what someone is having a test for, I guess it would be highlighting before the test that the result could reveal information that would be important to other people in the family as well as the person asking for the test, and, depending on what the result is, it might be appropriate they should be urged to share the information. Clearly, the commercial companies are not going to be in a position to know who the relatives are to take on that role of disclosure.

Q13 **Carol Monaghan:** Correct me if I am wrong, but it seems there is a bit of an issue. When people sign up to companies such as 23andMe, which has given evidence to our predecessor Committee, there is often a long list of things they agree to and they simply tick the box without properly reading it. We have become used to this because consent agreements are so wordy that it is easier just to tick consent and move on.

Do we need to revisit the way in which individuals are giving their consent to companies such as 23andMe?

Dr Clancy: The short answer is yes. I referred earlier to how terms and conditions can be hard to understand and are quite lengthy. I would be surprised if any of us in this hearing today had not ticked the box without necessarily going through the terms, not just genomic testing, to be fair, but for your mobile service provider, for example.

I think it goes back to companies essentially proving their trustworthiness. I do not mean that then it does not matter what the terms and conditions are, but I guess that sometimes it can feel that the terms and conditions are there as protection for the company perhaps rather than the individual or consumer.

Q14 **Carol Monaghan:** When individuals, possibly at a later stage, realise or become more aware of what potentially they have signed up to, are you aware of any way in which they can remove their anonymised data from the databases that have been generated, or once they have ticked that box is that the end of the story for them?

Dr Clancy: I think it is possible to ask for the data print, but not once it has been anonymised. That would be the same as for a research project. You can withdraw your participation and data up to the point of

anonymisation, but once it is anonymised we do not know whose data it is, if that makes sense.

Q15 **Carol Monaghan:** We could have people currently signing up to data held by companies such as 23andMe for many years to come without fully understanding the implications.

Dr Clancy: I think that is the case.

Q16 **Dawn Butler:** Carol asked the question I was going to ask in regard to signing up or opting out of information and whether that needs to change.

You say it is protecting the company in the main and it is anonymous up to a point, but do you think you should be able to opt out and still have access to the services?

Dr Clancy: I am pretty sure that with the commercial genomic testing there could be tiered ways you could agree to things. You could just agree to whatever the test is that you are interested in having done, and then I assume—I do not know—you can say that, unless the data is anonymised, you do not want it used for anything else.

I must admit I have not trawled through the terms and conditions of service to see if that is the case, but it certainly would be possible. Whether or not that is what is available is a different question. I am sure the companies could give you a better idea of that than I can.

Q17 **Dawn Butler:** Is there any way of ensuring that one's data cannot be misused?

Dr Clancy: In a very general sense. I do not think we are suggesting that commercial companies are deliberately setting out to misuse data. I think it is important for people to know that it is probably pretty hard truly to anonymise data. Somebody could probably work backwards and find out where the data come from, but, like universities and the NHS, I would not expect commercial companies to be intending to misuse the data.

Q18 **Carol Monaghan:** The Nuffield Council has raised some concerns about non-invasive pre-natal testing leading to sex-selective abortions in some cases. How much evidence is there of this?

Dr Clancy: I think there is evidence internationally, but there is not much evidence about NIPT being used for this purpose in the UK. For example, NIPT for trisomy 21, 13 and 18 is already available in Wales; it is not yet available in England, Scotland or Northern Ireland, but the sex of the foetus is not disclosed then. In that way, NIPT could not be used for sex selection. I think it would be different for the commercial sector. People may be able to know about the sex of the foetus.

Q19 **Carol Monaghan:** I am looking at some evidence in a Nuffield Council report in 2017 on non-invasive pre-natal testing. It says there is some

evidence that sex-selective abortions have happened in the UK.

Dr Clancy: I think that is based on anecdotal evidence. A group in Reading is looking into this, but it has not published anything as yet.

Q20 **Carol Monaghan:** Do you think there are enough protections in place to prevent that from happening in the future?

Dr Clancy: Certainly through the NHS, because the sex of the foetus will not be disclosed.

Q21 **Carol Monaghan:** What about pre-natal testing?

Dr Clancy: There is probably less interest—I am not sure that is quite the right word—in people in the UK to use pre-natal testing of any kind purely for sex selection.

Q22 **Carol Monaghan:** What conditions do you think pre-natal testing should be used for, and how do we decide which ones we should and should not test for?

Dr Clancy: I think the Nuffield Council report is arguing that it would be for significant medical conditions where the test gives an accurate prediction of whether the foetus will be affected, but we fully recognise that defining "significant medical conditions" is contentious.

We acknowledge that women and couples with a family history of an adult onset condition that they have experienced would consider pre-natal testing and termination of pregnancy, and there will be many others who would not consider it.

Q23 **Katherine Fletcher:** I want to step back slightly to some of the questions colleagues were raising about the anonymisation of data. I understand anecdotally that some of the data reside on servers in America, and there has been a push to use familial genetic relationships to catch perpetrators of serious crimes—for example, a cousin or sibling relationships. People have been apprehended on the basis of their relatives engaging in these commercially available tests. Do you see any way in which this could affect UK citizens engaging in commercial tests that perhaps are based in other countries?

Dr Clancy: From my understanding, the cases where people have been apprehended have been largely but not exclusively in the US, and the law enforcement agency has loaded the data on to, for example, an ancestry company's website. It is not that the commercial companies have agreed to give the data. My understanding is that commercial companies do not want to get involved in forensic genomic testing in that sense.

Q24 **Katherine Fletcher:** Would you suggest it should be made extremely clear to anyone participating in the UK that that is a possibility? It is not just your genetics; you are exposing your heritage genetics effectively.

Dr Clancy: I assume that would come up mainly through ancestry-type databases, and one needs to be aware of it. There is probably a little

more awareness of it, because in the lead-up to Christmas there is quite often publicity—"Do you really want to give your nearest and dearest a genomic test for Christmas?" There are examples of people who found out their parents were not necessarily who they thought they were, or they had half-siblings they had not known about before. I think that kind of warning up front from that point of view is important. I guess they would want to know there is protection and that it is not being collected and used for forensic purposes.

Chair: Thank you very much, Dr Clancy. It was the Nuffield Council that recommended to our predecessor Committee that this inquiry be conducted. We need to reflect on the case that has been made, but it is important when public policy interventions are made that there is a very clear problem to be solved. I think we will need to delve a bit more to see whether there is any greater evidence of that. We are very grateful to you for speaking on behalf of the Council today. Thank you for your evidence.

Examination of witness

Witness: Graeme Tunbridge.

Q25 **Chair:** I am very pleased to welcome Graeme Tunbridge, a director at the Medicines and Healthcare products Regulatory Agency, the MHRA. Thank you very much indeed for joining us to help the Committee with its inquiry.

I did not feel that we got a clear impression of the problem to which new regulation might be the solution. Perhaps you could help us from your perspective as a regulator.

Graeme Tunbridge: Perhaps I can talk about how the regulations currently work and some of the future change that is envisioned.

Genomic testing is regulated as an in vitro diagnostic device, which means where it is providing medical diagnosis or predisposition to disease, so it comes under the auspices of the MHRA. The legislation that regulates it is an EU directive that was first brought in in 1998 and took full effect in 2003. That was transposed into UK legislation later. Therefore, the legislation has been around for a while.

Generally speaking, genomic testing falls into the lowest risk category. There is relatively little in the way of pre-market scrutiny, so it is incumbent on the company providing it to do what is necessary in making sure that the test is accurate and provides good results in the way they are presented to consumers.

There is relatively little in the way of regulation where the test is provided outside the EU. There are some aspects that are regulated but others will not be.

Q26 **Chair:** You have certain regulatory powers, but they are limited. What

are the principal problems that fall outside your regulatory competence and might need to be corrected?

Graeme Tunbridge: I tend to break it down. Commercial genomic testing tends to be the provision of a sample by a person in the form of a tube full of saliva. That goes off for extraction and sequencing on some sort of platform. The genetic information that comes out of it is then subjected to some sort of bioinformatic software. That bioinformatic software compares it with a database and pops up some results, which say, "You're normal here; you're normal here."

The current regulations mean that some of those bits are regulated and some are not, and they are regulated in different ways. The sample collection will always be well regulated because you need to make sure you can collect things properly, but, as I mentioned, where the testing happens outside the EU none of that equipment has to fulfil the requirements of the legislation as it currently stands.

Currently, the provision of clinical evidence alongside the test is relatively limited as well, so there has to be only a basic analytical correlation between a marker that has been detected and a clinical condition for that to be reported. I think the prevailing view is that you want to see a bit more in the way of clinical validity. For example, is the result a consumer is getting relevant to them? What is the scientific basis, and how is it relevant to them based on various things, including, for example, their ethnicity?

The other aspect is the software and databases that are used. At the moment it is essentially up to the company to determine some of those things. What is the link between a particular genotype or particular mutation and a disease, or predisposition to a disease? As you are aware, the scientific literature is often conflicting, and I think we would like to see a bit more rigour when it comes to the provision of information in that sense.

Q27 **Chair:** The MHRA has very broad regulatory competence. In the scheme of things, how important do you think a reappraisal of regulation is here compared with other areas of your purview?

Graeme Tunbridge: What is very relevant is that the European Union has recently gone through a process of completely revising the existing legislation. That legislation was published in 2017 and is due to take full effect in 2022. It was based on looking at the deficiencies in current legislation, international best practice and what is happening globally and looking to align with that as much as possible.

A lot of work went into that new legislation. It falls outside the transition period, so it will not apply automatically to UK law, so there is then a question about what the UK chooses to do following the end of the transition period. But the amount of work and effort that went into the

revision of legislation at EU level pointed to the need to revise what is currently in place.

Q28 **Chair:** Did the MHRA have a significant role in the design of that European regulation?

Graeme Tunbridge: We were heavily involved. From inception in 2010, when it was first mooted, through seven years of tortuous negotiations we played quite a leading role. I think the UK was one of the most influential member states when it came to shaping what came out at the end.

Q29 **Chair:** The UK's position in genomics is world leading, so one would hope and expect we had a strong influence. Is there anything material in that new European regulation that, from a UK point of view, we were against?

Graeme Tunbridge: When it came down to the end of it, I do not think there were any particular red lines we felt we could not sign up to. As ever in agreeing legislation at European level, you end up with compromise and areas where perhaps you take a position that satisfies the interests of the greatest number of member states rather than one that necessarily works in the best interest of an individual member state. When we look at the IVD regulation, I am sure there are instances where we would say, "Perhaps this is something we could do better or differently to reflect the specificities of what happens in the UK."

Q30 **Chair:** Is it your understanding that the Medical Devices (Amendment…)(EU Exit) Regulations 2019 mean that provisions of the European directive will come into effect in UK domestic law in 2022, notwithstanding the fact that we have left the European Union?

Graeme Tunbridge: No. The 2019 regulations will be amended later this year such that the full provisions of the IVD regulation will not take direct effect in UK law. That is the intention of the Government.

Q31 **Chair:** To step back from that, if the UK Government did nothing, the regulations that have already been passed by Parliament would bring into effect the pan-European regime. Is that correct?

Graeme Tunbridge: In May 2022; that is correct.

Q32 **Chair:** But you have an understanding that it is the intention of the Government to change the regulations that have been passed. Is that right?

Graeme Tunbridge: That is correct, and I think that reflects a couple of things. It reflects the fact that the Government have taken a different position when it comes to the relationship they wish to have with Europe. Previously, there was much greater intention in the way of strict regulatory alignment, whereas now I think the position is more nuanced and we are looking at something more akin to mutual recognition. Clearly, that does not mean that regulations have to be identical between the EU and UK.

The other material aspect is that we now have the new Medicines and Medical Devices Bill making its way through the Houses. That will allow the UK on a sovereign basis to change the legislation in future, and that was not the case previously. Therefore, while nothing is taken for granted and we cannot assume that the Bill will become an Act of Parliament, I think it is fair to say that the Government have a clear intention to allow us to change and shape UK legislation in a way that was not necessarily there before when the original 2019 regulations were made.

Q33 **Chair:** I understand. In your assessment, in effect is this a matter of principle, that we should set our own regulations domestically, or are there particular aspects of the new European regime from 2022 that we have decided we do not want to be part of? Is it the structure and the process or is it content that causes the Government to intend to have different regulations?

Graeme Tunbridge: It is a matter of principle in that space. Having said that, it is of course an opportunity to examine everything that is in there. For example, I know—this may be touched on later—that the issue of genetic counselling is included in the EU regulation, albeit in a way that references exactly what I was describing. It is a Euro fudge. It was a position that ended up being agreed that satisfied nobody but everyone could agree to it, if that makes sense. There are certainly areas where, taking that principle on board, we would look to change and shape things in a domestic context.

Q34 **Chair:** In what timeframe would you expect this legislation to be worked up and presented to Parliament? I assume the MHRA is involved in the drafting of the legislation.

Graeme Tunbridge: I expect we would be. I think there is a strong driver to remain aligned to the timescales of the EU as much as we can. We do not want to fall behind when it comes to patient safety and making changes that are for the benefit of patients and the UK public. Equally, from an industry perspective, certainly in the short term, it appreciates the degree of regulatory certainty that some alignment can bring.

Having said that, there are benefits in being able to do things domestically and be a bit more deft in a way than perhaps we have not been under the EU architecture. We had a bunch of legislation in 1998, and 19 years later a new bunch of legislation came in. Each time there is a five-year transition period. I do not think we need to regulate like that any more. We can be much more selective and nuanced, and where a particular policy or PR problem comes up we can take action, do it much quicker and get it through Parliament in a way that is reflective of the issue at hand without having to wait a very long time.

Q35 **Chair:** I think I heard you say you would expect the MHRA to be involved in the drafting of the legislation. Do I infer from that that you have not been so far?

Graeme Tunbridge: No; we are.

Q36 **Chair:** Is there a draft of the regulations, as I suppose they will be?

Graeme Tunbridge: It is in preparation. We are still in negotiations at a European level, so the legislation will need to reflect the outcome of those negotiations.

Q37 **Chair:** It is tied up in that overall end of the transition period and free trade agreement.

Graeme Tunbridge: Everything depends on that, and probably any regulations will come before Parliament in the autumn.

Q38 **Aaron Bell:** Mr Tunbridge, thank you very much for your time. I accept that you are unsighted on a certain amount of what goes on outside the EU. That obviously raises its own issues about how we can regulate genomics, but, leaving that aside, many submissions have raised concerns about the frequency of false positives, false negatives and misleading results of tests sold to consumers. Based on what you do have sight of, do you share those concerns?

Graeme Tunbridge: I think there is legitimate concern about the provision of results, false positives and so on. As I described, you have quite a lengthy process from sample collection through to sequencing and interpretation of the results. At every stage you have the potential for error to come in. Clearly, a responsible company will be making sure that the end-to-end process is as robust as possible; it will be making sure that where the sequencing is flagging up some rare variants it does some confirmatory testing according to its understanding of how its kit works.

There are things you can do to mitigate that. At the moment the issue is that, in a way, we have to take the company's word that it is doing that. That is why the regulatory change would bring in that degree of additional scrutiny by a third party to say, "We want to see much more in the way of data to make sure we are happy that when you are reporting something it is reported properly, that the risk of failure is properly reported as well and that the consumer can properly understand the result based on all those factors."

Q39 **Aaron Bell:** You obviously welcome further regulation in the support the Government could provide, but at the moment that is taken care of basically by dialogue with the companies. Is that correct?

Graeme Tunbridge: Indeed, and that reflects the MHRA's role, which is largely by way of post-market surveillance. We have been pleased where companies have taken the opportunity to come and speak to us about the services they are offering in the UK because it means we can have that dialogue, albeit at the moment, as you say, it is one whereby we can encourage and nudge, and until there is some sort of egregious breach of the rules we do not formally step in.

Q40 **Aaron Bell:** You have already spoken about relevance to some extent. What do we have to ensure that these products are relevant to the

specific consumer who is taking the test? What do we have to ensure that all parts of a genome that might be relevant to the particular condition are tested? How do we make sure that companies stay up to date with these things, because there seems to be a risk that you come up with a product and just let it roll on forever? It might make you some money, and there is no incentive for you to update that based on advances in science.

Graeme Tunbridge: You point to some very real problems. There is no simple solution to that. What I would say is that the regulatory change planned at EU level we would certainly intend to bring in at UK level. It moves to a more life-cycle approach. The presumption is that where a company is providing a product such as this it should be constantly updating its clinical evidence attached to the services it is providing. Therefore, it is always re-evaluating that so we can ensure it is reflecting the state of the art in medicine and what is known.

As to ensuring that the entire genetic aspect is taken care of, that is a really tough one. We know that for some diseases there are hundreds or thousands of potential mutations that could have an impact. How you can take that information and present it in a way that is meaningful to the consumer is a tricky one. You almost need to take it on a case-by-case basis and understand what is of relevance, what we know about what this particular mutation means for predisposition to a disease and then make sure the information is presented in a way that is understandable to and digestible by the consumer.

Aaron Bell: That is very helpful.

Q41 **Katherine Fletcher:** By pure coincidence, I am on the Medicines and Medical Devices Bill Committee. I notice the important role that the MHRA has to play in regulating medical devices. Would you suggest that tests such as these will be categorised as a medical device for regulation purposes?

Graeme Tunbridge: Where genomic testing is providing a medical diagnosis, or an indication of predisposition to disease, it currently falls as an in vitro diagnostic device and is covered under the broader medical device umbrella.

Q42 **Katherine Fletcher:** Therefore, the proposed setting up of a register and the powers of review, control and, in the extreme, a sanction, if necessary, that the MHRA regulates would cover all of these devices.

Graeme Tunbridge: That is correct.

Q43 **Katherine Fletcher:** As you are suggesting, the specifics are in the weeds. Given this Bill is still passing through Parliament, is there anything that you would want to have registered as part of that with reference to genomic tests?

Graeme Tunbridge: The Bill, as you are very well aware, is quite high level; it sets out a range of enabling powers, and we have had a huge influence on its drafting. I am happy that there is sufficient ability and flexibility to alter and change, and do what we need to do to bring in the necessary provisions in this area.

Q44 **Katherine Fletcher:** But we can look forward to any genomic test that is being used as a medical device being part of the register and, therefore, being subject to a certain amount of scrutiny and feedback from the medical profession.

Graeme Tunbridge: The intention would certainly be to register them. As we bring in the new regime, the intention would be to subject them to more pre-market checks before they can even be offered to consumers. That is the absolute intention.

Q45 **Chair:** When we have a UK domestic regime would you expect the regime for commercial genomics to be different from the standards that apply within the NHS?

Graeme Tunbridge: That is a very good question. I would like to think that the same principles would apply to both. Commercial genomics will be subject to the full provisions of any new legislation; they will need to comply with everything from pre-market review down to markets and post-market returns, and so on.

There has always been a principle that where services are provided in-house by the NHS we give it a greater degree of flexibility. We do not say, "You have to go through all the same exhaustive pre-market checks that are in place," because there are other checks and balances when tests are provided through the NHS.

The IVD and EU regulation reflected that, but put in place some additional controls on what the NHS does effectively in-house for its own patients to make sure, for example, there is more publicly available information about what tests it does and how it has gone through the process of scientific validation and all the things we have spoken about that are very important when it comes to making sure testing is relevant and accurate.

Q46 **Chair:** The Bill is going through Parliament, but, as you and Katherine said, it is a high-level Bill. I imagine the regulations for genomics and commercial genomics will be separate. Is there an intention to hold consultations on what those regulations should be?

Graeme Tunbridge: Absolutely, and that is one of the principles embedded in the Bill. One of the areas where perhaps EU legislation has not been as strong is taking into account the views of patients, consumers and people who use the tests. At a UK level we can have a meaningful dialogue with consumers, patients and the UK public about what they expect to see in regulation.

You spoke to Dr Clancy earlier about consent, for example. We can have that dialogue with patients and understand what we think is most useful. For me, that is the most important form of consultation we can do. Clearly, we have to take into account broader interests as well.

Q47 **Chair:** If those regulations are to be in force by 2022, that is not terribly far away. You have two years to be able to design a consultation, take evidence and review it, take the regulations through Parliament and enact them, with sufficient time for people to be able to prepare to bring them about. Do you have an idea of when the consultation on the regulations might be expected?

Graeme Tunbridge: I do not want to make any assumptions about the passage of the Bill, but once we have got over the many hurdles there our thoughts are already turning to what the future will look like.

There are some things that need to happen. We need to understand what the future relationship with the EU is going to look like. Certain things need to happen, but if the past three months have taught us anything it is that we can do some amazing things at a pretty heroic speed. Two years, to me, feels like a breeze compared with some of the stuff we have been dealing with lately.

The most important thing is not to compress or miss out that consultation step, because that is where we can bring some real added value when it comes to regulating in the interests of patients and the public.

Q48 **Chair:** We admire your energy and sense of pace and want to encourage that. Without wishing at all to be sceptical, if for whatever reason the regulations are not adopted and approved by 2022—perhaps Parliament gets in the way—what would happen? Do your current powers under the EU directive expire in 2022? Would we have a vacuum?

Graeme Tunbridge: We will not have a vacuum. Subject to the outcome of negotiations, we will roll over the existing regulatory regime, so it will simply carry on. The Medical Devices Regulations 2002 will apply until we replace them with something else, so the existing provisions of the IVD directive carry on until we do something else.

Q49 **Chair:** All the powers that you have will continue unless and until they are replaced.

Graeme Tunbridge: Indeed.

Chair: We are very grateful for your evidence today. Thank you very much. That was extremely clear.

Examination of witnesses

Witnesses: Lord Bethell, Professor Sir Mark Caulfield and Graeme Tunbridge.

Q50 **Chair:** I am delighted to say that Graeme Tunbridge is staying on to

answer some further questions from the Committee.

We are very pleased to welcome Lord Bethell of Romford in his first appearance before the Committee. He is the Minister for Innovation at the Department of Health and Social Care.

We also have Professor Sir Mark Caulfield, the chief scientist at Genomics England.

Thank you very much indeed for coming.

Minister, I understand from something you have put out this morning that the question of genomic testing has some relevance to your personal experience. Perhaps you would share that with the Committee.

Lord Bethell: It is a very personal subject for me. My father, whom some of you may remember, had Parkinson's disease from the age of 55, which he really struggled with. It was a tough time for the family. His mother—my grandmother—also had Parkinson's disease. I always wondered whether I would get Parkinson's disease.

When the first commercial genomic outfits turned up in Britain I jumped at getting a test and was one of the very earliest subscribers. I spat in a tube and sent it to America to be tested to find out whether I had the LRRK2 genetic mutation in my genes, which gives a very strong prevalence of Parkinson's. For some people, it is between 30% and 70%. If so, I would probably have had to undertake massive changes to my life to try to mitigate the danger of Parkinson's. I would have to undertake fitness, change my diet and de-stress my life. There are things you can do to try to reduce your chances of getting Parkinson's.

As it happened, I did not have the marker, which was a huge relief. That insight is very valuable. Therefore, it has given me a real interest in this area.

I am aware of the concerns others have spoken about before. Graeme put it all very well. There are concerns about privacy and about the way in which the information is shared. There are concerns about whether the accuracy of some of these markers is oversold in some way, which others have referred to.

None the less, it did give me an appetite to find out more about how this service could make a contribution to research, how it could encourage people to engage in their health, as it did for me, and how the actual individual insight might change the way people lead their lives.

Q51 **Chair:** It is obviously a great relief that you did not have the marker, and manifestly the knowledge you gained from that has proved very important in the way you live your life. You had to, as you put it, send away your sample to the US to be analysed. Was it available on the NHS?

Lord Bethell: I do not think it was then. I was an early adopter and it was a time when you had to employ an American firm. The American firms had not set up shop in the UK then, so I was quite early into the

whole game. Since then, some of the companies have had a turbulent time with their regulators and things have settled down, but I have tracked it carefully and remain very interested in the sector.

Q52 **Chair:** I think you said in the piece you put out earlier that if you had the marker there would be a very high chance you would develop Parkinson's. Is that right?

Lord Bethell: You put your finger on a key point. It is very difficult to say, and even scientists cannot be very clear about it. The range put to me was between 30% and 70%. Clearly, it is a lot more than 1%, which is the typical demographic prevalence.

I have common sense; I think I can mediate complicated information, and I can understand it means a much greater chance, even if no one can give me a precise percentage. It gives me the option of deciding whether I want to make fundamental changes to my life.

Had I had the positive marker I would have sought expert opinion to understand the data better. I would not have undertaken a massive transformation of my life without getting under the skin of it.

You allude to something that is very important in all of this, which is that no one should undertake massive changes in their life on the advice of an app. They should consult human specialists and get proper counselling before they go about either stressful assumptions about their lives or major changes in the way they live their life.

Q53 **Chair:** As you said, given the likely range you were told about if you had the marker—on average, there was a 50-50 chance you might develop Parkinson's—did you have counselling in conjunction with this test? Was that part of the service you commissioned?

Lord Bethell: I did not get counselling. You raise a very important point that I was conscious of at the time. Had I been given a positive result, they would have gone about it in a different way. The fact it was a negative result meant that I went through a screen—I remember it very well—and was told, "You are about to enter a special zone where you will be told important information about your genetic make-up." I thought, "Oh, here we go; fingers crossed," and then I was told, "Good news; you haven't got it."

I think that had it been positive it would have been done in a different way, but as I did not experience it I cannot tell you exactly what it was.

Chair: That is a very helpful introduction because it raises various things, such as whether counselling should be required, whether the results can be life changing and the accuracy of the tests when so much depends on it. This was one of the reasons our predecessor Committee decided to undertake this inquiry. We are very grateful for that.

Q54 **Andrew Griffith:** As a scene-setter, we understand that genomics is

going to transform healthcare; it is an amazing opportunity. Perhaps you as the Minister can talk briefly about your vision for that and what the policy initiatives are to make sure the UK is absolutely world leading in this space. I will then follow up with Sir Mark Caulfield.

Lord Bethell: I will defer to Sir Mark for some of the detailed policy work, but definitely the Department has a real ambition in this area to seek to embrace the insight from genomics. The particular part of it I am interested in is personalised medicine.

It is everyone's experience that medicines and conditions affect individuals in very different ways. I am a relatively new Minister. I have been living through Covid. One of the most extraordinary things about this wretched disease is how profoundly differently it affects one person from another. Andrew, I know you have had personal experience of this yourself. Why is it that one person is really hit hard by it and another is not? Why does a medicine that works well on one person not work on another?

What are the sources of the answer? It is not everything; it is not going to be a magic wand, but we are going to get profound insight from the genetic information we have. To give an example, which I hope Sir Mark will allude to, Genomics England is currently looking at a cohort of 35,000 patients to try to figure out what backgrounds—ethnic backgrounds, gender backgrounds or distinctive genetic backgrounds—are driving these variations. That is the essence of what we are trying to understand to move on to a new level of treatment where the genetic differences between all of us form part of the clinical decisions on how to treat disease. I do not know whether Sir Mark would like to add to that.

Sir Mark Caulfield: You ask a great question and a really important one. My sense, not being in the Government but being a clinician and academic and working with Lord Bethell and other Ministers to deliver state-of-the-art genomics in our nation, is that we are, for sure, world leading in the delivery of genomic healthcare, with 500,000 whole genomes planned to be sequenced over the next five years.

In my view, the Government have sought to try to maintain us at the absolute forefront with various investments. Around the areas where testing of individuals might still be uncertain they have commissioned research. A good example of what the Government have done is to commission the accelerating detection of disease cohort. An agenda of that cohort is to examine the genetic variants we were just talking about with Lord Bethell and their role in aggregate to predict risk over a life course, and deal with residual research uncertainties.

In the Covid-19 programme the Government moved extremely quickly to invest in a major programme to understand the variation in outcomes that we see among our population. In a health emergency, testing 20,000 severely ill people with whole genome sequencing, versus 15,000

asymptomatic or mildly affected, is likely to bring us answers that will help us in the secondary wave.

From work done overseas, we already have preliminary evidence that your blood group and possibly a transporter inside your body, which affects the receptor by which the virus enters the cells, can make a difference. The United Kingdom is leading the world in making these types of insights. One of the unique features of our free-at-point-of-care system is that we can make this equitably available across the entire 67 million people in our country.

The Government have moved really fast to try to harness genomics, but they have done it in a safe and measured way that means we can examine the evidence and bring it live in healthcare with proper preparation and, therefore, maximise benefit for our people.

Q55 **Andrew Griffith:** Thank you, Sir Mark and Lord Bethell. Thank you also for the work you are doing in this area, which, as you say, is absolutely at the forefront. We benefit from the unique asset of having a single national healthcare system, which I know enables us to move fast and gain much better access to sample sizes.

Philosophically, what regulatory structure do you think we should put in place? It is clearly an emerging area of science, but it also raises profound questions that we have heard today about privacy and the wider societal effects. I am almost looking for a bit of reassurance that we are getting this right, because it is very nascent. Instinctively, I worry a little when one tries to regulate nascent and fast-moving areas where one seeks to have competitive advantage.

Sir Mark Caulfield: You will have heard a lot about how the UK is approaching regulation in Graeme's earlier presentation.

In terms of how we manage the pipeline that we run for the health system, to return results to patients every step has to be regulated and conform to international standards, which means we can have confidence in the quality assurance of that pipeline so that the quality of the result for you is the same as it is for Lord Bethell and there is not variation that might introduce imprecision.

At Genomics England, for the health system everything of clinical grade is ISO accredited. Having accreditation in place and meeting the requirements of the forthcoming in vitro diagnostics legislation is very important for assuring quality and standards in this system and giving confidence to you as representatives of the British people that we are delivering at the level you would expect to be reliable in direct healthcare.

Lord Bethell: The only thing I would add, in terms of my own personal instincts on this, is that we are very good at getting the ethical frameworks right in regulation, and in that, as Sir Mark referred to it, I have a lot of confidence.

My instincts are that we should not put people in cotton wool on this issue. We allow people to buy their own pensions, get divorced and take exams, the results of which are posted to them in envelopes that are traumatic to open. We cannot expect people somehow to be protected from their own genetic data. We have to rely on their own common sense and sense of investigation to figure out and interpret the data properly.

One area where innovation could be stifled, which I am keen to avoid, is that somehow we get clinicians standing between people's perfectly reasonable right to know and understand their own data and that experience. That is one of the things that we are keen to clear out of the way.

Chair: That is very clear.

Q56 **Carol Monaghan:** I would like to tease out some of the concerns that have been raised about the impact of commercial genetic testing on the NHS.

I gently point out to my colleague Andrew that there is not one NHS in the UK—there is actually a number of them, and NHS Scotland is a different body.

Lord Bethell, you started by talking about your own personal experience. I think we would all agree that that is the very best of genetic testing, and it shows how it can be used to great advantage to an individual. There are some concerns about testing being done by those who can afford to pay for tests, who then gain fast-track access to the NHS before those who cannot afford to have the test, or would not think of having it in the first place. Is there a danger that we create two tiers, and how are the Government looking to address this?

Lord Bethell: We do have choice built into how we run our lives in Britain, so I would not want to stand in people's way of deciding to make a free choice to buy a test on any ideological grounds. My experience with my GP was not a great one, to be honest, as she did not know anything about the test and had absolutely nothing to contribute. When I tried to run her through my paperwork, she was not particularly interested. There is a huge gap there, and I think that we have to work harder to bring GPs with us in understanding the tests. We are at a very early stage.

Q57 **Carol Monaghan:** Was it as a result of having had the test that you had the conversation with the GP, or was it prior to having it?

Lord Bethell: It was subsequent to it. I sought to have a conversation about the value of the test and whether there was any insight to be had.

We are at quite an early stage. I am not a clinician, but my impression is that a lot of the information in these casual commercial tests is not particularly valuable, but they engage people in their health and, over time, will develop into something that can contribute to tailored medicine.

How I was going about it was more as a hobbyist rather than for something of massive clinical value.

At this stage, I do not worry about it particularly contributing to a two-speed or iniquitous NHS outcome—quite the opposite. One of our priorities is to get people to engage more with their GPs. I know that GPs may not welcome my saying that, but, actually, we are trying to encourage people to take more of an interest in their health, be more preventive in their outlook and make decisions earlier on any disease or morbidity that they have. If we can somehow encourage them to have a conversation with their GP on best practice, I think that is genuinely speaking a good thing.

Chair: We do not have that much time, so can we keep answers as crisp as possible?

Q58 **Carol Monaghan:** Is there a danger, as I think your example illustrates beautifully, that we have a raft of worried well who visit their GP as a result of these tests and, potentially, increase the demand on the NHS? I know that your predecessor, Baroness Blackwood, a former Chair of this Committee, said she was going to consider the impact on the NHS of the increased use of the NHS as a result of this testing. Has any work been done on that, to establish how much of an impact there is and to see whether we should be taking steps on that?

Lord Bethell: I am not aware of that work, but I remember her saying it. I defer to Sir Mark, if he knows the answer to that. I have not seen any evidence that GPs' surgeries are overwhelmed by worried well bearing genetic tests and scaring their GPs. I do not want to repeat myself, but, on the whole, I am pro things that engage people in their health.

Q59 **Chair:** Do you have anything to add to the Minister's answer, Sir Mark?

Sir Mark Caulfield: Thank you for that question. In the UK, 192,000 people have done 23andMe, and the evidence that we are aware of is that a very small percentage—around 3%—have consulted a clinician on their data. That is not to say that the point that you highlight is unimportant; it is not. What has been done in the last seven years is to increase the capacity of the workforce to meet the adoption of genomics into healthcare.

The Government have put £25 million into training and expanding the cadre of people who can relay this information. You may be familiar with the Topol report, which recommended some expansion of genomic counselling. That, taken with innovation, such as the use of automated counselling, as has been done in America, may help to address the workforce capacity to deal with this.

The evidence so far is that small numbers of people use this information to consult health professionals.

Q60 **Carol Monaghan:** That leads on nicely to my next question. Again, in the predecessor Committee, we took some evidence from 23andMe, Ancestry and DNAfit. Those companies expressed a willingness to support initiatives whereby there would be a financial contribution from them to the cost of counselling that then had to take place on the NHS. Has there been any progress on this?

Sir Mark Caulfield: I am not aware of that, but the Government are investing, alongside the expansion of use of genomics, in expanding that workforce anyway. I am not aware that has been taken up.

Q61 **Chair:** Minister, are you aware of any response to that?

Lord Bethell: I have heard that offer, but I am afraid that I am not aware of any formal response.

Chair: Perhaps you could write to the Committee after the meeting to check the current thinking on that.

Q62 **Katherine Fletcher:** Gentlemen, I asked an earlier witness a question that I want to repeat. Let us take a hypothetical spit test, Lord Bethell, and a hypothetical scenario. Let us say that you have family members in America. I know that there is evidence that whole genome sequences are being used by law enforcement in other countries to find familial offenders. It is a difficult one, with our genetic base being so small and postage being so cheap, but do you have any comment about giving greater clarity to users of these tests that that is a possibility, or about our ability to prevail on international bodies to prevent that from happening without permission?

Chair: Before the witnesses answer, will you explain, for people not aware of the case, what kind of use is being made?

Katherine Fletcher: I apologise. I have a biology degree, and I have gone into full nerd mode. Thank you, Chair. This is in relation to ancestry sites. An individual whom we shall call Bob had put their full DNA genome on, in an attempt to understand whether they were Irish, and law enforcement officials spotted that there was an unprosecuted rape and murder case and that the profile was very similar. So individual X was identified, and it turned out to be a blood relative of his who had committed those crimes. But he did not know, by putting forward his DNA for a seemingly innocent test, that it had law enforcement ramifications. That is a positive, in that an evil man has been caught, but it is not clear to individuals who purchase these tests.

Chair: That was crystal clear. Thank you very much, Katherine. Do the Minister or Sir Mark want to comment?

Lord Bethell: Thank you very much indeed. You hit upon a profound ethical dilemma. I remember the case: my heart was in my mouth, and I thought, "Crikey, that's a hell of a thing." But you know I felt the same when they started opening CCTV up in Wandsworth, where I was living,

and I felt the same when I found out that people were listening in on Zoom calls. Privacy is a hugely contentious issue at the moment.

I am afraid that I cannot give you a huge amount of insight. I defer to Sir Mark on the progress of the bioethics, but you raise an important point, and I hope very much indeed that we can navigate around it to benefit from clinical advances.

Sir Mark Caulfield: In the summer of 2019, we conducted public and patient research around the application of the NHS social contract in genomics. One of the red lines for participants was the use of this information for a surveillance society. Some years ago we started the 100,000 genomes project, and I put into the consent materials that the data cannot be used for law enforcement purposes, so the only basis on which the police or other agencies could access that data is through a court order.

Similarly, another unacceptable use would be for insurance purposes; in the United Kingdom, that is protected under an agreement with the Association of British Insurers. There is a moratorium on use of that information, in the main.

One thing that you are highlighting strongly is the importance of protecting those who might not engage in something that could be of great value to them if they think that some other use of the information could occur. My feeling is that the Government—and, acting on their behalf, Genomics England—have moved to protect the public and health system from this type of use, and suppliers of these kits should do similar things. This will lead only to people not doing it and, in the health system, that is massively important—in the direct-to-consumer space it is possibly less important. If we find ourselves in a loss of trust position, people will not take up genomics when they really need it the most in the health system.

Katherine Fletcher: Thank you so much for sharing the details of the 35,000 people Genomics England test around Covid. We have been raising questions about immunotype for a number of hearings, and I am really looking forward to those results coming through.

Q63 **Chair:** I have a quick question to Graeme Tunbridge. As the regulatory body, do you have regulatory powers to prevent agencies from accessing databases for which the individual has not given consent?

Graeme Tunbridge: Generally speaking, not. The example here is where you start to get into some of the cracks between regulations. What would happen is that someone would have gone to an ancenstry.com, or that kind of website, and extracted the information, uploaded it somewhere else and then paid £10 for getting some information back. What you do not realise when you tick that box is that you are consenting to that information then being in some publicly available forum. So not directly, no; regulation starts to become a bit tricky.

Q64 **Chair:** Is this in scope for the drafting of the new regulations, on which we have had our previous conversation?

Graeme Tunbridge: That entirely depends on for what purpose that genetic information is being taken in the first place.

Q65 **Graham Stringer:** Good afternoon, Minister. It is good to see you.

When will the genomic volunteer service start, and what form will any consultation take about the setting up of this body?

Lord Bethell: I am going to defer to Sir Mark, but I would like to say how excited we are about it. It is a massively important initiative, and I am particularly grateful to those who have stepped forward to join it. Sir Mark, would you like to talk about the details?

Sir Mark Caulfield: You will recall the genomic volunteers possibility last year. I was asked by the Office for Life Sciences to assemble a task and finish group to advise on this, which I did.

The advice that we gave back to the Government, which they acted upon, was that, to ensure equitable access to a genomic volunteer scheme, and given where we were with the evidence base at the time, we should include the generation of that evidence in the new cohort that the Government had funded in a public-private partnership called accelerating detection of disease, rather than embark on a fee-for-service provision at that time, so we could gather more evidence for the value of a risk assessment and do it in an equitable manner, which would reach all our population.

That is how that initiative has been taken forward by Government, and accelerating detection of disease is now fully funded and about to start—and that cohort will reach 5 million UK citizens on an absolutely equitable basis.

Q66 **Graham Stringer:** What criteria will be used to return the genetic information to volunteers?

Sir Mark Caulfield: Those are not yet defined; it is in the process of definition at the moment. Lord Bethell's team at the DHSC and I inquired in preparation for this, because we knew that you would ask, and it has not settled on them yet.

In essence, it is looking at what would be medically useful, but this will also test the research context, so we will research the value of risk scores where you aggregate genetic variants, so-called polygenic risk scores, and see whether they can be useful, and where they can be useful, in the health service. That means then using mechanisms such as we have done at Genomics England to migrate that into direct care.

Q67 **Graham Stringer:** You mentioned research, and there is going to be a huge amount more information about the genetic inheritance of people in this country because there is so much private testing going on. Will that

be of value to research in this country? Are attempts being made to make it possible to use that information by making private companies' storage systems compatible with NHS and Government storage systems?

Sir Mark Caulfield: We have had discussions with direct-to-consumer testing organisations, such as 23andMe, but we have not had direct conversations about data sharing. The type of data that they collect is slightly different from that which we collect in Genomics England, but none the less the two could be shared for research.

In the United Kingdom, the Government have brought together all the groups trying to form a new UK national genomics strategy, which will be UK-wide, about how we use our public research assets such as UK Biobank, the 100,000 Genomes Project and data from the new genomic medicines service and combine that to best effect.

Private resources are being used for research and are regarded as useful research assets. We may explore that in future in potential partnerships for the greater good of our nation, and to make observations that will ramify across adoption worldwide.

Q68 **Graham Stringer:** 23andMe told this Committee that there were technical problems on the Government/NHS side in sharing data. Is that true and, if so, are you trying to resolve them?

Sir Mark Caulfield: To answer that question directly, the tests that we do that we return to the health system are from an accredited clinical grade pipeline. At present, some tests done by direct-to-consumer providers meet that standard but some do not.

That answer is given in the context that we could not necessarily take 23andMe data and give it back to the health system as a clinical-grade test; we need to meet the regulatory standards for that return and, therefore, do it in a certain way.

However, that is not to say that the test is invalid, nor that it could not be useful for healthcare. It is simply that, if we are returning direct to patients, we have to have an end-to-end picture of the quality of that data and how it has been gathered.

Q69 **Chair:** Thank you very much indeed. That is an extremely helpful session. We will consider what we now know about the development of new regulations that will be given rise to by the Bill before Parliament, and we are very grateful for your time.

We want to talk a bit about test, track and trace, as obviously this is a very important part of the scientific response to the pandemic. The Minister has been doing some very important work on that, so I would like to turn to it.

Mr Tunbridge, we are very grateful for your evidence. You are welcome to stay, but if you need to get on with other things we quite understand.

The intention is that the testing, track and trace system should be world beating. By when do we expect it to be world beating?

Lord Bethell: It is not a very precise term. In many ways, it already is. The scale of it is enormous; there is no country doing it at such a great scale.

The other thing that has worked very well is that it is a through-the-line system: we know from the moment you book your test which well it is going to go into and how you are going to get your response.

It is a very thorough system and it is now highly centralised. It has taken time to develop some of these aspects. At the very beginning, when we were doing 2,000 tests a day, the big system was not in place. I am very proud of what we have put together, and it is already showing some features which, frankly, are totally world beating.

Q70 **Chair:** What would make it world beating? You mentioned the scale of it as one of the dimensions.

Lord Bethell: There are three main things that we are working on. The turnaround speed is very important, which has become more and more apparent as we try to trace people. Already our turnaround has increased dramatically, and the proportion of tests done under 24 hours has gone up dramatically.

Q71 **Chair:** What is the current proportion?

Lord Bethell: I can write to you with today's number.

Q72 **Chair:** What was yesterday's?

Lord Bethell: I do not know yesterday's number. Candidly, Chairman, one of the difficulties is actually in measuring that number, to be honest, because we have thousands—or not thousands but hundreds—of laboratories around the country, each one of which measures turnaround time in a slightly different way. Therefore, trying to consolidate that information all around one metric is genuinely quite difficult.

You are asking me for operational data that is very difficult to pin down. Baroness Harding is doing an amazing job of trying to nail some of this down. I can tell you that a very large proportion of tests have turned around within 24 hours. I took a blind shopper test in the last fortnight, and it worked incredibly smoothly and quickly.

So turnaround time would be one. Accuracy remains a very important one. I think we have some of the highest accuracy in the world, but we continue to work on trying to produce the best tests and ensuring that they are checked and validated extremely well.

Thirdly, which seems like a lesser point, is the logistical support of making sure that tests are delivered to care homes and homes on time, and picked up on time—that whole backbone is two thirds of the effort.

The actual PCR testing bit of it is relatively straightforward. The logistical backbone and sheer size and ambition of what we have put in place there is fantastically complex, and we are working really hard to improve it.

Fourthly, and lastly, is what I call the consumer proposition. We want people to trust the system. It is a scary thing for people to approach, but we are working hard to make sure that people's personal experience is good. On the whole, people's personal experience is good, and one thing that we are learning is that people like to have a personal touch. They like to have a telephone call rather than a text, and we are building on that insight to make sure that that local connectivity is in place and people have a good experience.

Q73 **Chair:** So the dimensions of being world beating are scale, turnaround speed, accuracy, logistical support and trust. Would that be a fair reflection?

Lord Bethell: I think it would be.

Q74 **Chair:** Looking around the world, as I am sure you have in constructing this, how do you think we are doing compared with others in the world?

Lord Bethell: It is a very difficult thing to compare, because different countries do it in different ways. In America, there is no central testing facility; every state does it in different ways. Even in Germany, it is a very diffuse model. In parts of Asia, Korea and Taiwan, they have much lower levels of prevalence, so the sheer level of testing is minute compared to what we are doing. So it is very difficult to make a direct comparison.

What I would say is that, having had very high levels of prevalence here in the UK, we have put together a massive machine that is capable of doing hundreds of thousands of tests a day. It will be in very good shape for the winter, which is the peak period that we have on our mind when there may be a second spike and lots of other competing flus, which will create a lot of turbulence in the system, and there will be a huge increase in demand, whether or not Covid comes back.

Q75 **Chair:** Would the proportion of those infected who are tested be an indicator of whether it is world beating or not?

Lord Bethell: I am not sure. We want to encourage people to have a test. It would be counterproductive to measure ourselves against that metric. It is also frustratingly difficult to find the symptoms. I think all countries struggle with this, which is why doctors are doctors. If it was easy to say who had Covid and who did not, we would not need the tests. We have refined the symptom definition and done a huge amount of work to try to correlate published symptoms with how the tests work, but we would prefer to have a broad funnel at the top rather than try to bring in some kind of efficiencies and thereby miss people.

Q76 **Chair:** Specifically, you would want to have anyone who had the disease

having a test, wouldn't you, as an aspiration?

Lord Bethell: We want anyone who has any symptom to have a test, because people just do not know whether they have the disease or whether they have a different flu. We do not mind—if you have a different flu and you test negative, that is absolutely fine. It is better to have you checked off the list and for you to go about your normal life.

Q77 **Chair:** On how it is going and increasing, do you have a feel for how many people were tested last week?

Lord Bethell: In terms of people, I would prefer not to do that number off the top of my head. I could probably do it, if you gave me five minutes, but I would prefer to write to you with that, please.

Q78 **Chair:** Do you have a feel for what it is to the nearest thousand?

Lord Bethell: Baroness Harding is going to go into those figures at 5 o'clock tomorrow afternoon, and I would prefer to leave it to her to publish the figures—not least because we have been working with the statisticians to regularise our numbers.

On the point of numbers, at first we were seeking to be as transparent as possible and were giving out numbers on the fly the whole time. Now part of our trust-building exercise is to regularise the number publication, which is one reason why we have become more conservative about issuing numbers.

Q79 **Chair:** So tomorrow we will be able to know how many people were tested, as well as the number of tests that have taken place.

Lord Bethell: I have not seen her published slide, so I am not certain whether that will be included or not.

Q80 **Chair:** We know from the statistics that came out in the first release of the test, track and trace operation that 8,117 people were referred to the track and trace organisation. Is that right?

Lord Bethell: You mean that 8,000 indexed cases were sent to the tracing operator.

Chair: Correct, yes.

Lord Bethell: That sounds about right.

Q81 **Chair:** During that period of 20 May to 3 June, there were over 13,000 positive tests that were part of the daily disclosure at the press conference. What happened to the 5,000-odd—we can perhaps take a few off, as Scotland, I think, is not part of it—or the several thousand at least who we know tested positive but were not disclosed as transferred to the track and trace system? What happened to them?

Lord Bethell: There is a mixture of reasons why that might have happened. Some of them might already have been in some kind of

confined arrangement; they might have been in a prison or a hospital bed, but they were somehow in those figures. For some of them, the contact data simply was not there. That has not been a huge problem, but for some people it has been difficult to get back into contact with them.

Q82 **Chair:** Sorry, people have had the test, but they did not leave their contact details, or they proved too hard to access.

Lord Bethell: Correct. It is not a large proportion, but there will be some. Then there is a small proportion of people—and it is relatively small—who do not wish to collaborate with the tracing programme. We are improving, and that proportion is coming down. I think I mentioned the work that we have done on focus groups and understanding better why people might not wish to participate. The personal touch of telephone calls from trusted clinicians definitely encourages people to participate.

Q83 **Chair:** I understand that, but that is a separate group of people. We are talking about the number of people who tested positive and then were transferred to the test and trace scheme. There is a gap of several thousand there, and I am genuinely interested to know what you think has happened to them. You said that for a few their email address did not work and some of them were in prison, but surely not thousands.

Lord Bethell: Some are in the healthcare system anyway. If, for instance, they are in social care and are in a care home that is already being handled by the local director of public health, we do not necessarily need to put them into the tracing system, because their circumstances are already being investigated.

Q84 **Chair:** I thought these were related to people in the community rather than regulated settings.

Lord Bethell: I am not sure which number exactly you are presenting me with. I am just trying to explain a number of reasons why someone might test positive but not be referred to the tracers.

Chairman, I am not trying to avoid your point: there is a gap between the number of people who test positive and those sent to the tracers, and we are working on closing that gap. We have thrown this system up very quickly, and there are a number of operational challenges. Baroness Harding has spoken very openly and transparently about that. There is a massive effort going on to try to close all those operational wrinkles, and improvements are happening very quickly.

Q85 **Chair:** So those are the people who are tested, who have a positive test, and there is a gap between those and those who are transferred to the contact tracing service. We now have the benefit of the ONS prevalence study that looks at how many people are infected who are tested in the community. The data from the ONS suggests that around 4,500 people a day have new infections, but we have only about 1,500 people testing

positive a day, which suggests that about one half to two thirds of those contracting the infection are not tested. Is that your understanding?

Lord Bethell: It is. The ONS figures make that very plain. There are two things about it that we have to recognise. First, a large number of people are asymptomatic; they show absolutely no symptom whatever, and if you asked them whether they were ill they would say that they were not. It is not a resistance to getting tested. In fact, the people who were poorly show a very high incidence of applying for a test—it is people who simply do not have any symptom at all.

The other thing that the ONS figures show clearly is that there are a very large number of people who think they have Covid who it turns out do not have Covid. So, in the Venn diagram of people of people who think they have Covid and people who think they are well, we capture a bit in the middle of people who think they are poorly and genuinely have Covid, and that is the number that you describe.

There are two things that we have to do. One is to focus on getting people to understand the symptoms better and encouraging them, the moment when they display symptoms, so we capture them. The moment that they are traced, we then track down everyone, because a lot of them are asymptomatic, which is one of the reasons for doing the tracing: we are trying to capture the people who did not know that they were ill.

Q86 **Chair:** Given that the ONS data is picking up people who have tested positive, who have the disease but have no symptoms and therefore are unaware of it, and given the importance of a rigorous system in identifying as many people as possible who have the disease so they can be isolated, does that not imply that we should have a mass programme of testing even asymptomatic people to be able more comprehensively to detect and isolate those who have the infection?

Lord Bethell: There can be some settings where that is relevant. I would applaud my NHS colleagues who have stood up a very large asymptomatic testing programme and have made a commitment to testing NHS frontline staff once a week.

At the moment, we have a prevalence of about one in 1,000, and it is going to be one in 10,000 quite soon. That is a tiny proportion of people. The ONS study did 10,000 tests and got only about 10 people who tested positive—and quite soon it will be only one in 10,000 tests. That is a huge undertaking.

It is an unfortunate fact that there is such a thing as an inaccurate or false positive, and once you are at the stage of trying to spot one in 10,000 you will start finding that your false positives are higher than your actual positives, which is when the effectiveness of that kind of regime begins to break down.

Q87 **Chair:** Do you think that is already a problem for the ONS study, when it is broken down by region, because the numbers of people testing positive

are very low? Are you concerned that it might be difficult to extrapolate rigorously from very low numbers of people?

Lord Bethell: It is, and there are confidence ratings, which you will see—and those confidence bars start getting wider and wider sometimes. I do not think that we are in the realms of it being problematic, but it is true that some of the ranges of numbers start to get quite wide.

That is one reason why we have done massively more surveillance than would be normal. You asked me about world beating, and in the area of surveillance few countries are doing the numbers that we are doing on a regular basis. I cannot think of one; one does not spring to mind.

Q88 **Mark Logan:** Lord Bethell, what is the rate of false negatives for tests used in the test and trace system?

Lord Bethell: That is a very difficult question to answer. We do not know whether someone is a false negative, because we do not track them afterwards. The machines themselves are very highly sensitive and capture very accurately the people who pass through.

The biggest problem is infectiousness that is asymptomatic. A person who caught the disease a couple of days before, and the virus has not lodged in the back of their throat yet, will go on to be infectious in a couple of days. The system simply cannot capture that, and it is the type of false negative that we have to be aware of.

Q89 **Mark Logan:** Do we know how accurate overall is the system we have in place?

Lord Bethell: Yes, because we validate the machines rigorously and almost every tray has a validation. In a tray of 100, you will have four or five that are validation wells. The system is incredibly thoroughly tested, so that is not an area of concern. What is an area of concern is the nature of the disease, which is, more than most viruses, prone to very long infection periods: you can carry it for days and days, even 13 days, and pop up with it long after you have been infected.

Q90 **Mark Logan:** At the moment, contacts are asked to self-isolate only once an initial case has tested positive for Covid-19, which appears to go against the SAGE advice from 1 May. Why have the Government not followed the SAGE advice on that specific point?

Lord Bethell: We have taken advice from lots of people. Ultimately, we take advice from the CMO, not from SAGE. SAGE informs the CMO, and it is the CMO's view that, because of the negative infectiousness, it is best to ground people the moment we identify them as a contact of an indexed case.

It is quite tough to tell someone that they are grounded, even if they do not have symptoms, but we believe that that is the way to contain the virus.

Q91 **Graham Stringer:** During the whole of this epidemic, there have been hotspots, and it has been quite important to identify where they are. When I speak to the leaders of local authorities in Greater Manchester, and the Mayor of Greater Manchester, they say that they cannot get the information back that will give the locations of those hotspots, where the tests have been carried out at the Etihad stadium and Manchester airport by private testers. Do you know why that is, Lord Bethell, and what is being done about it? It is a real barrier to being effective in fighting this disease.

Lord Bethell: You are entirely right. The most effective way in which to deal with the disease is to mobilise local action. Trying to do that from a national platform has been very difficult, but we have made huge amounts of progress, particularly in the past few weeks. I pay tribute to Tom Riordan of Leeds, whom you will know; he has really put some muscularity in our local outreach.

The system for doing that is through the Joint Biosecurity Centre, which is taking all the data from the Etihad stadium and all the different testing locations, synthesising it and then pushing it back out to directors of public health, local resilience forums and local infection control directors in trusts to care homes, making sure that the right local actions are mobilised.

That has come a hell of a long way in the past six weeks, and my impression is that it is now working much better. As you know, the north-west is an area that we are particularly focused on at the moment, and my understanding is that the teams have worked a lot better and that, therefore, things like mobile testing units and expert advice has been sent to the north-west to supplement and support the local response.

Q92 **Graham Stringer:** As far as I know, it is still not coming back, unless it has happened in the last few days. Why is the information that has been secured for testing by private labs not been sent back to the local authorities and public health bodies?

Lord Bethell: My suggestion is that it is now, but to give you a sense of it, we have thrown up a platform that does 200,000 tests a day. The journey of an individual swab from the Etihad stadium to a laboratory in, say, Alderley Park, then to a JCB computer in Whitehall, then back to the director of public health in, say, Manchester, is logistically quite complicated. We have really focused on this specific challenge, because we recognise that it is absolutely the most important thing in the chain to get right so we are match fit for the winter.

It has been really difficult to do, and we are throwing everything we can at it. There is no ideological or philosophical objection; it is simply one of ironing out the operational requirements.

Q93 **Graham Stringer:** I find that surprising. Why is it difficult, if the test is done in Manchester and it goes to London, to send that information back?

It does not seem to be fundamentally problematic.

Lord Bethell: The issues involved, for instance, are that not everyone who turns up at the Etihad stadium is necessarily from that immediate area. The catchment areas of some of these testing centres are enormous. We have heard lots of stories of people driving for hours to get their tests. When they pop up, spotting patterns is not as straightforward as you might think.

The tests come in in a massive aggregate form, and you need to use software and artificial intelligence to understand where the patterns are. I assure you that we have mobilised the best possible minds in pattern identification and epidemiological thought to try to put in place systems to flag outbreaks when they happen. The response to the Weston is an indication that we are on the right lines.

Q94 **Graham Stringer:** I move on to the app being tested in the Isle of Wight. When will it be available for general use in this country?

Lord Bethell: The app pilot on the Isle of Wight has gone very well indeed and has led to some infections being avoided. One thing that it taught us—and I have alluded to it already—is that it is the human contact that is most valued by people. In fact, there is a danger of being too technological and relying too much on texts and emails and alienating or freaking out people, because you are telling them quite alarming news through quite casual communication.

The call centres that we have put together, although there has been a lot of press comment on them, have worked extremely well. We have had to deal with people working from home and on new computer systems, but, actually, the training and the effectiveness of them has been proven. We are very confident about that. So that is where our focus is at the moment.

Apps around the world have been challenging—I note that the Norwegians, Singaporeans, French and others have all been working on their app releases—and we are seeking to get something going for the winter, but it is not the priority for us at the moment.

Q95 **Graham Stringer:** I asked when it was going to be introduced, but that sounded like an argument against introducing it at all.

Lord Bethell: No, it was an expectations management answer, which said that I cannot give you a date, but I acknowledge the importance of the question.

Q96 **Graham Stringer:** So it is still the Government's intention to introduce it.

Lord Bethell: Yes, it is.

Q97 **Graham Stringer:** Why is it necessary to hold the data that is acquired for 20 years?

Lord Bethell: I do not know whether it is necessary to hold it for 20 years—I agree. What is necessary, in answer to your previous question, is to have the epidemiological insight of where outbreaks are happening. One reason we have gone down the route of having a centralised rather than dispersed database is to get exactly the insight that is necessary to find out whether there is an outbreak in Manchester or somewhere else. If we do not get the data sent to the centre, we can never find that out.

Q98 **Graham Stringer:** You have given a case that people want person-to-person interaction if they are going to get bad news rather than be told by text or email. I understand that, and it is a fair point. I do not know about you, but I do not remember all the people I have met in the past 24 hours, and for how long. What has been the experience of the test and trace of people's memory?

Lord Bethell: We have 3,000 or 4,000 clinicians, or retired clinicians, who have stood up to become the indexed case interrogators. Although I have not had to do it myself, I know people who have, and there is a skill to winkling out of people what movements they have made and who they have seen in a significant way in the last few days. That is a skilled role, and we have thousands of people who have exactly the right kind of clinical background to do that job. They then pass those contacts up to the second layer of people, who do the telephone call to those who need to isolate. But it is a specialist skill to winkle out of you who you have been seeing in the last few days.

Q99 **Chair:** Minister, when you say that the tests in the Isle of Wight have gone extremely well, is that because you have discovered that it is better to do it by manual contact tracing means rather than the app?

Lord Bethell: It means that, first, people in the Isle of Wight really supported the app. They were not frightened of it, as we were worried that they might be. Actually, a very large proportion downloaded it and participated.

Secondly, there were concrete examples of where people who had tested positive shared their contacts, and those people were then grounded. Therefore, there were strong examples of how it had actually broken the chain of transmission.

Thirdly, yes, you are right: as often happens with pilots, you find out something that you did not know was the question or was a bit of a black swan answer. It was a reminder that you cannot take a totally technical answer to a problem. You have to put the human, local touch at the front of your strategy.

Q100 **Chair:** That is the point of piloting things. If the first two were so great, why is it not being rolled out in other parts of the country?

Lord Bethell: First, operationally, we are focused on getting the manual tracing correct. At current prevalence levels, we have plenty of capacity for handling the amount of tracing that is necessary. I will not hide from

you that there are technical challenges with getting the app right, and we are really keen to make sure that we get all aspects of it correct. We are not feeling under great time pressure and, therefore, we are focusing on getting the right app.

Q101 **Carol Monaghan:** Graham Stringer obviously has a far more exciting life than I do!

Lord Bethell, a recent study by the London School of Economics has shown that people are torn about using the app due to civil liberties concerns. Obviously, public confidence is key to the uptake of this app. Are there any moves to bring forward a legislative framework or some sort of independent oversight of how the app is used and data is stored, to increase people's confidence and encourage them to use it and to put in protections for human rights?

Lord Bethell: Carol, you are absolutely right. People's concerns about the app are enormous and right, and we are really conscious of them. That is one of the reasons why we have not rushed to put something out, because we would be concerned that, if we did not quite get it right the first time around, we might poison the pool and close down a really important option for the future.

I cannot stress to you how far we have had to travel in the last few months in understanding how these things work. Having some kind of oversight in time may be right; we have three or four different ethics committees overlooking different parts of privacy. I shall not reel them all off now, but we have an enormous amount of oversight and advice, including from the Information Commissioner, who submitted audited returns.

We have been extremely thorough about how things are going. But once we have a working model, it would only be right to look at whether legislation or some regulatory oversight would be right. At the moment, things are still moving around.

Q102 **Carol Monaghan:** If you find uptake is very poor, will you have to look again at how we have to legislate for people's protection?

Lord Bethell: There will be an ongoing battle to convince people that this app is safe and protects their privacy, and we are super-conscious of that. I cannot stress enough how much effort has been put into ensuring that the software, governance and how the app is constructed protects privacy and thoughtfulness. Yes, it requires a large critical mass of support, which is one of the reasons why we need to get it right and explain it from the outset.

Q103 **Aaron Bell:** Thank you for all the answers on test and trace. For the benefit of our inquiry more generally, I would like to go back a little bit earlier in the pandemic.

Scaling up our capacity and testing has, obviously, been a big challenge

for Public Health England and for the Government more widely. It is a challenge that we rose to ultimately, but we have heard evidence from some people—and there is a general perception—that perhaps we were not initially agile enough. Graham Stringer has raised a few issues with you today, and I know that I have raised some constituency issues with you, which I got good responses on, about turnaround time and regional availability.

For the benefit of this inquiry as a whole, can I have a general review of our testing approach from March to May, and what lessons we have learned to apply in the next phase?

Lord Bethell: The irony is that in the very initial days PHE's testing and tracing was very good. CTAS, the system that it has had for years and which it has applied to all sorts of diseases, worked very well. One reason why we are two or three weeks behind European partners is that it was very good at picking off the early contacts that made it to the UK. We owe credit to it for identifying that system and moving very actively.

It is no secret that we had no testing capacity, or very little, in the UK, with just 2,000 tests. There was a global paralysis about finding those tests. Therefore, we had to take a massive step forward initially, first to commit to 10,000 and then to 100,000 tests. That required us to completely start up a new organisation, in parallel with the NHS and PHE, to conduct those tests.

We made the commitment to the three big Lighthouse labs and the NHS scaled up its own testing to 25,000, and we mobilised some other major labs, such as the Sanger and others, to make a contribution.

I personally feel an enormous amount of pride in what I saw happen in those weeks and months. It is an awkward fact that, in Britain, we are very good at pharmaceutical development of the design and marketing of drugs, but we have not focused on diagnostics in the past. Given that background, we covered a huge amount of ground. We got in the Army, the private sector, universities, NHS pathology professionals and the British diagnostics industry; it was a massive collaborative effort and we covered a lot of ground. I think that we have something now that is world beating and which will make a huge difference when we go into the winter.

Q104 **Aaron Bell:** I completely acknowledge the effort that has gone into it and that what we have now is an awful lot better than what we had initially, from a position that was obviously not a great one to go into a pandemic with, because of our capacity. You mentioned turnaround times. Were there particular lessons in the last few months from that roll-out experience about turnaround times?

Lord Bethell: Yes. The heritage of the British pathology industry is that it is quite good at doing small numbers of tests of a very wide and complex variety, usually onsite or near site, in hospitals. That is a very different discipline to doing hundreds of thousands of exactly the same

test as quickly as possible. It is like moving from Savile Row to the Nissan plant in Sunderland—it is the difference of techniques.

We have had to be on that journey, and a lot of it, as I have said before, is logistical rather than diagnostic. When we faced problems with getting hold of swabs, vials and reagents, we were really focused on the practicalities of the diagnostic process. Once we began to solve that, we stepped back and began to focus on the logistical side of things, which was when we could start grinding down turnaround times.

Q105 **Aaron Bell:** Finally, looking forward again, where are we with antibody testing? How many have been done so far, and how does that fit into what we do in testing everybody through test, track and trace? What role is antibody testing going to have in the next few months?

Lord Bethell: We are very ambitious in the antibody test. Around the world, when I speak to other Health Ministers, we are the ones who are really trying to figure this one out. The science remains extremely ambiguous. Nobody can tell exactly what antibodies confer in terms of immunity. We are a long way from any kind of formal certification process, but we believe there is something there. Therefore, as is public, we have committed to a large amount of antibody testing through suppliers like Roche, Abbott and others. Those are being focused at the moment on NHS staff, who are committing to tens of thousands a day; they are being rolled out elsewhere.

We are trying to figure out what the rules of the game are in terms of what antibody testing confers. We have a massive study, the SIREN study, being led by the PHE, which is being focused on healthcare staff, to understand what happens to antibodies once you have had Covid. That is another area where we are trying to find insight into this disease.

Q106 **Aaron Bell:** You mentioned tens of thousands a day within the NHS. That is basically where we are right at the moment. Is that correct?

Lord Bethell: There are also other antibody surveillance studies going on. We also have a large one through Imperial College called REACT, and those will be published as well. They are adjacent to the ONS studies.

Aaron Bell: Thank you for your time, and best wishes for the ongoing work.

Q107 **Chair:** Finally, in terms of the future steps on testing, track and tracing, what is the argument against testing routinely and frequently everyone who works in the NHS or a care setting?

Lord Bethell: I do not think there is necessarily an argument against it. It is a reasonable ambition.

Q108 **Chair:** Why is it not policy?

Lord Bethell: There is an ethical element, which is that you waste people's time and create false expectations if you use tests where the dangers of a false positive are an issue.

It is quite time-consuming, logistically and practically. When prevalence is really low, I am not sure that it is a worthwhile exercise. But that might change.

We are seeing on the horizon some incredible new technologies. We are doing the best job we can possibly do with the existing range of technologies that are available, and we are absolutely bending them as much as we can to deliver a result for us. But on the horizon there may be tests that can turn around in 20 minutes, can be done hundreds or thousands at a time, are much cheaper and can be conducted by non-clinicians.

If we can get those tests, the scenario you describe will be much more realistic, will be less impactful on people's lives and times, and will deliver the security that you are aspiring to.

Q109 **Chair:** We know that the transmission has some concentrations in settings like care homes and hospitals, and we know that is a risk for flare-ups in future. We know that there is value in the current test. We know that there is no capacity constraint. I think that you will confirm that, at 200,000 a day, we have overcome the capacity constraint. Why not use that capacity to test those people who may be asymptomatic but are at a great risk of spreading, often to quite vulnerable people, an infection that they do not know that they have?

Lord Bethell: That is the operational guidance, and Simon Stevens has written to the NHS along those terms. There is work being conducted at the moment to introduce weekly testing for healthcare staff in, I think, exactly the terms that you just described.

Q110 **Chair:** All healthcare staff?

Lord Bethell: The focus will be on those in at-risk areas. One interesting thing about the nosocomial infection is that it is not necessarily where you think it might be. In fact, a lot of the infection in hospitals has been among backroom staff, among porters and security guards. This may come as a surprise, but the amount of PPE in frontline staff protects people, and their working regimes are very thorough. It is actually in places where you would not expect it that the infection has often arisen. So you cannot make easy assumptions about where you would necessarily find the infection.

Q111 **Chair:** Far from being a surprise, that was exactly my point: if the transmission in hospitals is less likely to be in the intensive care units and more likely to be in the canteens, for example, does it not make sense not to ration testing simply to those who are working at the frontline but to recognise the importance across all those settings, to give that confidence, if we really want to pursue a strategy—as I understand is the

Government's intention—to clamp down on areas where there is a risk of a flare-up?

Lord Bethell: You have explained the strategy very well. You are right that we have spare capacity at the moment, and that capacity is being directed at care and healthcare. There is no rationing. Healthcare directors are absolutely instructed to use whatever capacity they can to test asymptomatically to maintain the hygiene of their workplaces, and there is evidence that that is already bearing fruit and that the amount of nosocomial infection that we have appears to be coming down.

Q112 **Chair:** Would you go back to the Department with a recommendation that, across NHS settings and care settings, all workers that work there are routinely tested for Covid-19 frequently?

Lord Bethell: Chairman, I can assure you that I am a massive evangelist on this point and that there is not a single person in the NHS who has not heard me make it.

Chair: We are very grateful. We have kept you over time. We thank you and Sir Mark for your evidence today. You were very kind to accept an invitation to come to talk to us about commercial genomics, but you have been very good in answering our questions on the handling of the pandemic as well.