HOUSE OF COMMONS

Science and Technology Committee

Oral evidence: Blood, tissue and organ screening, HC 990

Wednesday 30 April 2014

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Written evidence from witnesses:

- Public Health England
- Department of Health
- NHS Blood and Transport

Watch the meeting

Members present: Mr Andrew Miller (Chair); Jim Dowd; Mr David Heath; Stephen Metcalfe; Stephen Mosley; Pamela Nash; Sarah Newton; Graham Stringer; David Tredinnick

Questions 240-328

Witnesses: **Professor James Neuberger,** Associate Medical Director, NHS Blood and Transplant, **Dr Lorna Williamson**, Medical and Research Director, NHS Blood and Transplant, **Dr Paul Cosford**, Director for Health Protection and Medical Director, Public Health England, and **Dr Katy Sinka**, Consultant Epidemiologist and Head of CJD Section, Public Health England, gave evidence.

Q240 Chair: Good morning. I welcome our four witnesses this morning. This is the penultimate evidence session of this inquiry. We have six or seven questions that we want to go through with you. For the record, would you kindly introduce yourselves?

Professor Neuberger: I am James Neuberger. I am an associate medical director in NHS Blood and Transplant. I am also a liver physician in Birmingham.

Dr Williamson: I am Lorna Williamson. I am a consultant haematologist and medical and research director with NHS Blood and Transplant.

Dr Cosford: I am Paul Cosford. I am the medical director and director for health protection for Public Health England.

Dr Sinka: I am Katy Sinka. I am a consultant scientist and epidemiologist at Public Health England's centre for infectious disease surveillance and control. I have been head of the CJD section there for the last two years.

Q241 Chair: Thank you very much. In your view, when someone in the UK receives a blood transfusion, can we be confident that they are not being infected with abnormal prions?

Dr Williamson: There is a good deal of uncertainty about the risk of variant CJD from transfusion. Since 1996 there has been collaboration between the UK blood services and the CJD Research and Surveillance Unit, in a study called the transfusion medicine epidemiology review, to try to establish whether there is any link between receiving a transfusion and acquiring variant CJD. That study found that with about 50 million individual components transfused since 1996, sadly, three patients developed variant CJD between six and eight years after a blood transfusion, and their donors also went on to develop variant CJD, suggesting that their transfusion may have been the source of the infection. There was a fourth recipient who had no symptoms during life but who at post-mortem showed signs of variant CJD. Importantly, all four patients were transfused in the 1990s before the onset of leukocyte depletion, which we implemented in 1999. A further six patients who were transfused also, sadly, developed variant CJD, between four and 16 years after their transfusion, but the donors have remained well. We have tracked over 100 donors to those recipients for periods up to 20 years and none has yet developed variant CJD. So in those six, the source of the infection is not known; it might be diet or it might be the transfusion. Of those, five were transfused before leukocyte depletion, and the sixth in 2002. We have not had any notifications of transfusion recipients developing variant CJD since the last case transfused, in 2002.

With regard to the future, there is a good deal of uncertainty. Therefore, we still want to keep and, if possible, improve the preventative steps that we take against variant CJD, which I am sure we will come on to discuss.

Dr Cosford: From the point of view of Public Health England, we are absolutely clear that the most precautionary steps need to be taken. What we have is the prevalence that we see in the Appendix 2 study of potentially one in 2,000 people with prion protein within appendices, but that not being reflected in the numbers of cases of variant CJD. We believe that the mix of both standard universal precautions in the blood supply system and the specific precautions that are taken when we identify somebody as being at risk for public health purposes of CJD, where extra precautions are taken, is the right set of precautions in order to minimise risk. Dr Williamson is correct, obviously, but you cannot abolish risk completely; it is about minimising risk as far as possible.

Q242 Chair: Taking into account practices elsewhere in the world, the advancement of science and the information you have gathered, is there anything more that you could feasibly do to reduce risk?

Dr Williamson: At this point, we have nothing on the table today that has been proven to be effective that would reduce risk further. The two technologies that we are tracking very carefully are the development of blood tests, of course, and for a number of years we have also worked on the assessment of prion filtration. These technologies remain of interest, but today there is nothing on the table that we could implement.

One safety step that may be useful in the future is that we have young donors coming through born after 1996 when the food chain was deemed to be BSE-free, if you like. They are now turning 17 and 18, and are old enough to be blood donors. We do not know

for sure that that population is entirely risk-free, and there is an ongoing study of appendix samples in that cohort. We also need to be sure that they are not going to pose any new risks, given what 17 and 18-year-olds get up to. For example, we are doing a study of Epstein-Barr virus—the glandular fever virus—and others to make sure that we do not inadvertently bring in new risks. If we are to use such donors for transfusion of babies or children, we need to know as much about the profile of safety as possible. It will take several years for that cohort of donors to produce enough donations to have a reliable supply for vulnerable recipients. We do a lot of marketing with 17 and 18-year-olds, but we know they are busy people. They have a lot going on; they travel and so on. That is something for the future, but it is not robust at this point.

Q243 Chair: In the appendix study to which you referred, are there any early indications of where that is leading us? When do you expect the findings to be presented?

Dr Cosford: The Appendix 3 study, which is currently under way, we expect to be complete in 2015. They are keeping under review any findings as they come through, but the importance is for the findings to be fully reviewed by the Advisory Committee on Dangerous Pathogens, and we will have the outcome of that in 2015. The Appendix 2 study, which you will be aware was the study on 32,000 specimens, suggested a prevalence of abnormal prion protein in appendices of one in 2,000 across the population that it studied.

Going back to your previous question, the difficulty we have is that we do not know what that means in terms of prion presence in the blood, and we do not yet have a testing procedure to find that out. What we do know is that that does not appear to be reflected in clinical cases of variant CJD, so that is the important balance and consideration we are taking into account here.

Q244 David Tredinnick: You have already touched on tests. If a prion blood screening test capable of being used on an industrial scale were to become available tomorrow, would NHS Blood and Transplant implement it? If not, why not?

Dr Williamson: There are really two issues. First, would such a test have utility? I think we are all in agreement that the next step, if there were a medium throughput test available, would be to conduct a study of the UK population using blood samples to understand what the frequency of prion infection in the blood actually is, as opposed to the appendix samples. One in 2,000 is quite a high number, but we are not seeing that number of cases or, thankfully, anything like the number of transmissions you might expect. We need to understand how risky blood actually is.

You are quite right to mention throughput. The criteria we would want—we discussed these with Professor Collinge in 2011—would be a test of adequate sensitivity that would pick up a high proportion of infected people and, importantly, a test of high specificity, in other words, that does not throw up a lot of false positive reactions. Professor Collinge's recent data using US samples are very encouraging, because in 5,000 US samples, which are all assumed to be truly negative, there were no reactions. They were all tested three times. Nevertheless, that provides encouraging information.

The key thing is availability of the test at volume, because we test over 7,000 donors every day in the UK. All of our virus-screening tests come from manufacturers who have a track record in producing those to high consistency and with reliability of supply. That is really what we would need for a variant CJD test as well. It would need to be capable of a high degree of automation, because we need the result within 24 hours of the sample arriving at a blood centre to be able to release blood components in a timely fashion. The automation would need to include electronic transfer of the results to the computer so that the quarantined donations could be released. That is really a task for test kit manufacturers, to get what is essentially a prototype research test to high throughput; it is not something blood services have the capability to do.

Q245 David Tredinnick: On that point, are you aware of Prionics, the commercial diagnostics developer, and its eQuIC technology?

Dr Williamson: Yes.

Q246 David Tredinnick: It is in the process of evaluating a new test. Do you know what that evaluation involves, and what the next steps are?

Dr Williamson: eQuIC was begun by Prionics and is now being further developed and evaluated in collaboration with NHS Blood and Transplant. Professor David Anstee's group in NHSBT Bristol is taking forward that test. It is clear that potentially it would be a good confirmatory test, but not, for various technical reasons, suitable for mass screening. If we were to implement mass screening, we would need at least one confirmatory test with which to retest any samples that appeared to be positive. That eQuIC assay is now being taken through the agreed evaluation process, overseen by the National Institute for Biological Standards and Control—NIBSC—who have an agreed protocol against which all candidate tests are being evaluated, and we await the results of that.

Q247 Chair: For clarity, historically the NHS has not been very good at procuring from smaller companies, however successful they are. Are all businesses working in this field in an equal position, or is there a tendency to deal with only the big players?

Dr Williamson: The large virus test kit manufacturers with whom we deal mostly have not approached us with candidate variant CJD tests. The companies we have worked with through the prion assay working group since 2007 have all been fairly small. In collaboration with NIBSC we have a standard protocol, with NIBSC leading on assessment of sensitivity, and the blood services leading on assessment of specificity. That protocol is in the public domain and was provided to all the manufacturers, so I think there has been a level playing field for candidate assays.

Q248 David Tredinnick: There seems to be evidence that the prototype test developed by the MRC prion unit could potentially be developed into something suitable for larger-scale use. In your opinion should the Government support further development of this test?

Dr Cosford: We would support the ability to screen the blood supply for abnormal prion protein. The facts of the epidemic of variant CJD related to the period of time in which exposure was through the meat supply system would suggest that the cause and effect is quite clear, but we cannot be absolutely certain. There are many uncertainties, so, in addition to monitoring the patterns of disease, the fact that the last variant CJD cases from 2013 appear to be tailing off would give us some reassurance that the variant CJD epidemic is through, or at least into what may be a long tail of cases, but we cannot be certain of that and we must maintain our monitoring systems, which we do. We would certainly support the development of a system to screen blood.

Dr Williamson: I would concur with that. It has been difficult to know what more could have been done until it was established that the test had good specificity—in other words, until the results of the US study were available. These were published at the end of January. The UK blood services prion working group met in the middle of February and discussed those results, and we have written to Professor Collinge suggesting further discussions, to include Public Health England, because we think that a population study is the next step.

I know that potentially there are questions about the sensitivity of the assay, which would need to be worked through with the team developing it, and it would also be good to compare it with other candidate tests side by side on the question of sensitivity. We have not had a chance to do that yet, but there is certainly scope for further discussion on progress.

Q249 Stephen Metcalfe: Dr Williamson, it is nice to see you again. Am I right in saying that at the moment every donated amount of blood goes through leucodepletion? Is that right? It is filtered.

Dr Williamson: Yes.

Q250 Stephen Metcalfe: The reason it goes through that is that it has the potential to reduce the number of prions in the blood. Some newer technologies have come along, one of them being P-Capt, which is prion filtration. What is your experience and understanding of how effective that is on blood that has already had leucodepletion applied?

Dr Williamson: In parallel with our work on candidate assays, since 2006 UK blood services have had a prion reduction working group to look at candidate filters. You are quite right that the P-Capt filter, initially developed by ProMetic, was a technology that we evaluated quite carefully. The way the group worked was that we met with manufacturers on a regular basis so that they were clear from the outset what our requirements were. In 2006, as with tests, we developed an evaluation protocol that all manufacturers and filters had to follow.

Based on evidence from the manufacturer, we then proceeded to the next step. The Spongiform Encephalopathy Advisory Committee at that point recommended that candidate filters be independently evaluated for a number of reasons. The technologies were developed by manufacturers who were bringing results to us. Normally, we would be able to see whether we could repeat those in the manufacturing context. That is not

possible with a prion filter, because we do not have human blood samples that we know are infected, and we cannot take infectious material into the manufacturing environment. SEAC recommended commissioning independent evaluations to a standard protocol, partly so that different manufacturers' filters could be considered side by side to the same protocol. In the event, only the P-Capt filter reached that point, and some studies were commissioned and performed by the Health Protection Agency, as was at the time, according to the recommendations of SEAC.

The final reason that was particularly important for the P-Capt filter was that the results the manufacturers had brought to us had been on a prototype. The active ingredient was a resin that bound abnormal prions. The prototype had put that resin into a column. In a manufacturing environment, that had to be manufactured into a filter, and the company Macopharma picked that up and took it on. The company had produced no data to the same quality on the final filter as we were going to use it in the blood services. That was what went through the independent evaluation. The results of that have been provided to the Committee in confidence, since they are commercial. The results were also reviewed by SaBTO in December 2012. At that point SaBTO concluded that this technology should not be implemented.

One point I can make in open session is that in the independent evaluation there was a leucocyte depletion step prior to the prion filtration step. The results of that were very encouraging in confirming the high effectiveness of leucocyte depletion in removing infectious prions, which we had not established in the blood services until that point.

Q251 Stephen Metcalfe: One of the concerns about the way the P-Capt prion filtration was assessed was that it was tested on sheep, but it had already been identified that sheep were not a particularly good model for this particular filter. Why was it tested on sheep when it had already been identified that that would not necessarily give correct results?

Dr Williamson: SEAC had recommended that, if possible, new filtration technologies be assessed in small animal models, which tend to be the standard ones, but also, if possible, in a large animal model. There was a study running in Scotland on sheep to assess transfusion risk in general—a model for leucocyte depletion and prion filtration. That was an opportunity to follow SEAC's recommendation, but it is fair to say that when all the results came to SaBTO there were sheep data but also data from the standard small animal models which HPA had run, both spiking studies, where blood is mixed with a mixture of infected brain material, and more importantly endogenous studies, which use the blood of infected animals, thus better mimicking the transfusion situation. Those were the standard accepted models, the small animal study being quite similar to what the manufacturers had used themselves.

Q252 Stephen Metcalfe: You think that the filter was treated fairly by testing it on sheep, even though that was identified as a not particularly good model.

Dr Williamson: I think it was a case of looking at all the evidence together, from the spiking studies in small animals, the endogenous blood study in small animals and also the sheep study, so the results were considered in the round.

Q253 Stephen Metcalfe: In your view, adopting the P-Capt device would not improve the safety of blood in the transfusion service.

Dr Williamson: The value of leucocyte depletion was shown to be high in that particular study. Taking all of that into account, and also revised estimates of the amount of infectivity in blood—the Advisory Committee on Dangerous Pathogens had reassessed that and concluded there was less infectivity in blood than had originally been thought—led SaBTO to recommend that prion filtration not be implemented.

Q254 Stephen Metcalfe: You are happy with that as a recommendation.

Dr Williamson: Yes.

Q255 Stephen Metcalfe: Therefore, you think leucodepletion is a good system and you have confidence that it is working well.

Dr Williamson: Yes. We have an ongoing quality control programme. A certain percentage of donations are tested to make sure that the white cell removal is as expected and is working consistently across all of the blood components we produce, so we apply it to red cells, platelets and plasma.

Q256 Stephen Metcalfe: Presumably, there is a cost in this filtration, and you do a cost-effectiveness study on leucodepletion. How often is that undertaken, and when was the last one and what was the outcome of that assessment?

Dr Williamson: When leucocyte depletion was implemented, the filters had to be purchased separately and attached to the blood donations, but nowadays the filter is an integral part of the blood bag. The costs relative to everything else have gone down considerably since this was first implemented in 1999. We estimate that all the costs of leucocyte depletion are in the order of £4 million to £4.5 million per year, but there are other benefits of leucocyte depletion. A number of countries uninfected by variant CJD also have this technology as a standard of care. For example, it removes cytomegalovirus in the white blood cells. SaBTO recommended two or three years ago that, given the effectiveness of leucocyte reduction, testing was not additionally required to protect vulnerable patients from cytomegalovirus—CMV—so that is an additional benefit of leucocyte depletion, as well as avoiding the very unpleasant reactions patients sometimes have to the white cells in the transfusion. These white cells do the patient no good at all; they are of no benefit, but can cause very unpleasant chills, fevers and reactions, so many countries have adopted this as a standard. Personally, I would not like to revert to a non-leucodepleted blood supply.[1]

[1] Following this evidence session, SaBTO made the following clarification: "Leucodepletion filters are integral to blood collection bags and the value of leucodepletion is well accepted, not only as a vCJD risk reduction measure but also in other ways - for example in protecting against the transmission of cytomegalovirus. SaBTO reviewed the use of vCJD risk reduction measures in 2013 and agreed that has been no suggestion that it should be discontinued, and so no clinical and cost effectiveness analysis by SaBTO has been required."

Q257 Stephen Mosley: Dr Williamson, you are answering a lot of the questions. I am afraid that mine are the same. I know that you chaired the working group on pathogen reduction technology. Could you tell us a bit about what pathogen reduction technologies have so far been adopted by NHSBT?

Dr Williamson: Pathogen inactivation is a blanket term for a range of technologies designed to inactivate viruses, bacteria and other agents like malaria which might be in blood donation. To make it absolutely clear, they have no effect on prions. At this point there is no licensed technology for pathogen inactivation of whole blood as collected from the donor, nor indeed for red cell transfusions, which are the vast majority of transfusions. What we are really discussing are techniques either for platelets or for fresh frozen plasma for direct use. For platelets, SaBTO considered pathogen inactivation back in 2010. At that point there were concerns from trial data about the effectiveness of the platelets that had been through the pathogen inactivation process, so at that point SaBTO did not recommend PI.

Following that, NHSBT implemented an alternative to prevent bacterial transmissions, which can occur particularly from platelets because they are stored at 20 degrees rather than in the fridge. That has been extremely effective. In terms of the risk from platelets, we have had no bacterial infections since screening was implemented in 2009, and no viral infections from platelets since 2005.

However, because there is now a second, and indeed a third manufacturer with a platelet inactivation technology, and because there is more clinical trial data, SaBTO implemented a further review in 2013, and, as you say, I chaired the group which did that piece of work. The report was published two days ago on the SaBTO website. We looked at a large body of evidence on the effectiveness of the current programmes to keep platelets safe, and how effective the pathogen inactivation techniques were likely to be against a range of viruses and bacteria. We looked at the clinical trial data updated to see if there were side-effects, and also at data from countries which have begun to implement platelet pathogen inactivation. Then SaBTO and DH analysts looked at the cost-effectiveness. The conclusions were that the bacterial screening in place is highly effective, with no proven transmissions in over 600,000 units tested. We do not expect that technology to be 100% effective; we know that.

The group then concluded that in terms of bacteria more work probably needed to be done to understand whether there could be strains of bacteria that would be missed, or would not be inactivated, by the technology. The two candidate technologies depend on chemicals entering the bacteria and then a light step to inactivate. For some bacteria, the chemicals may not penetrate adequately, so we are going to do more work on that.

With regard to viruses, it looks as if pathogen inactivation of platelets would be highly effective against the current and emerging viruses that we worry about. In terms of clinical safety, it looks like there were no particular problems. The trial data showed good responses to platelets, although it is possible that we may have to produce more doses of platelets to compensate for losses during the inactivation process. However, SaBTO concluded—this is in the public report—that given the very high level of safety currently, the implementation of pathogen inactivation of platelets was very far from current cost-effectiveness benchmarks. In other words, the cost per quality of life saved would be over

£1 million per QALY—quality-adjusted life year—which is extremely high in relation to other health care interventions and the current safety parameters in place, so for platelets pathogen inactivation is not recommended at the present time.

That leaves fresh frozen plasma. Pathogen inactivation does not inactivate prions, so to protect young recipients in particular, who are likely to have had very little or no exposure to prions through diet, SaBTO recommended in 2004 that FFP for these patients should be imported from outwith the UK. We implemented that initially with US plasma. Because the background rate of viruses in that population is higher, we thought that rather than run the risk of preventing one risk and introducing a new one, we would pathogen-inactivate that imported plasma, which is done in the blood services in the UK using single donations—we do not pool them all together—using a technique called methylene blue and light inactivation. That is a standard product for young recipients.

In addition, there is a commercial product called Octaplas available from a company called Octapharma. It is a medicinal product licensed by the MHRA. It is manufactured by pooling 2,000 or 3,000 donations and subjecting them to a solvent detergent process to inactivate viruses. That is specifically recommended by the British Committee for Standards in Haematology for certain patients having plasma exchange procedures. It is quite a small percentage of the overall use of FFP. The product is available to hospitals; they can buy it directly from the manufacturer. Therefore, that is a choice that clinicians have as an alternative to standard FFP from NHSBT, which is not pathogen-inactivated.

Stephen Mosley: That was a very detailed answer, and I am happy, Chair.

Q258 Mr Heath: Dr Williamson, is the admonition against the use of fresh frozen plasma for young patients comprehensively applied within the UK?

Dr Williamson: As far as we know. Every hospital that treats children either purchases methylene blue plasma from NHSBT—I cannot speak so much for other UK services—or we are aware that they use Octaplas, so they use one or the other.

Q259 Mr Heath: Does the definition of "young" go up all the time, if it is dependent on exposure to diet?

Dr Williamson: Correct. Initially, it was children under 16, which matched the 1 January 1996 birth date, but now these are 17 and 18-year-olds and it applies according to your date of birth, not your age. That entire cohort gets imported plasma.

Q260 Graham Stringer: Dr Cosford, has the risk of prion transmission via surgery been mitigated almost completely now?

Dr Cosford: There is a range of both standard precautions and specific precautions for those who are identified as being at increased risk of variant CJD. Our view is that they are based on a precautionary principle and that the right methods are there to minimise risk as far as possible. I am going to ask Dr Sinka if she will come in and discuss some of the detail on that.

Dr Sinka: There are two suites of guidance in place, one of which is applicable to the general population. It uses the precautionary principle that there may be an unknown risk of variant CJD which we have yet to detect. Those are captured in the NICE interventional procedures guidelines 196, which came out in 2006. They make a number of across-the-board recommendations which use the precautionary principle that we should put in place general measures that will protect everyone. The first of them is specific to neurosurgical procedures and recommends that neurosurgical sets are kept together. The reason for doing that is that, should there be any exposure through an undiagnosed variant CJD incident, the number of subsequent patients exposed to those sets is very much limited; it is one person at a time rather than spreading the instruments out between sets and potentially proliferating infection that way. The other precaution is that neuroendoscopes should be rigid and able to be autoclaved, so that is across the board for procedures that contact brain tissue.

Finally, much like some of the precautions in place for younger populations, it is recommended that a segregated set of instruments is available for people born after 1996, so they are not exposed to the same instruments that are used on the general population who may have been exposed to BSE through their diet. That is a set of measures in place for the general population.

In addition, there are some very specific precautions and advice for people who have been identified as at increased risk of CJD and variant CJD. About 6,000 such people have been identified. For them, the advice is that single-use surgical instruments are used where possible. This is particularly for certain types of surgical procedure that might involve contact with tissues that are thought to be infective for CJD, so it is not for all types of surgery; it is for types of surgery where there may be an increased risk. Otherwise, if single-use instruments of sufficiently high quality are not available and reusable instruments have to be used, there are recommendations for the quarantining and disposal of those as required, so that they are not used on subsequent patients.

Q261 Graham Stringer: I have two slightly different questions following that answer. First, how effective have the NICE guidelines been? They were guidelines and were not mandatory, were they? Secondly, does the autoclaving technique always work? In previous oral evidence, given the particular way prions bond to surgical instruments, we were told that heat treatment does not work as effectively as it might.

Dr Sinka: What we know so far is that we have not identified any surgical transmission of variant CJD to date. We know that in the past there have been surgical transmissions of sporadic CJD, so we are being precautionary, knowing that there is a potential risk of this. There is very close follow-up of it through investigation of new cases that are diagnosed—investigating to see whether they have had surgical procedures in the past. As far as we know, there have not been any surgical transmissions.

On the second question about autoclaving, the NICE guidelines are in place for surgical procedures used in the general population—the population who are at a low and uncertain risk through their diet. That is not the recommendation for people where we know there is an increased risk because we have evidence that there has been potential exposure to a higher risk of CJD. For those individuals, it is recommended that instruments are disposed of and not autoclaved. The recommendation is to make sure that you are using instruments

that can be autoclaved at high temperature rather than instruments that require other forms of decontamination that do not use such high temperatures.

Q262 Graham Stringer: You are saying that the NICE guidelines have been effective and the evidence is that autoclaving works, or am I misinterpreting what you are saying?

Dr Sinka: No. The recommendations are put in place on a precautionary basis to implement measures that can be done across the board for every single circumstance where those instruments are used. For people where we know there is an increased risk, autoclaving is not used as a means of decontamination. Those instruments are destroyed.

Q263 Graham Stringer: Why is there a discrete review panel? Why is one required for assessment of technologies associated with hospital infection control? Could it not be assessed in the normal way by NICE?

Dr Sinka: Are you referring now to the rapid review panel?

Graham Stringer: I think so.

Dr Cosford: That is a very good question. We set up the rapid review panel in the early 2000s at the specific request of UK chief medical officers. It is a specific means of rapidly reviewing new technologies and new ways of providing for hospital infection control, as you know. Given the particular concerns in place then around hospital infection control, which continue, it is appropriate to have a specific mechanism. We have not looked specifically at whether that is something NICE should take over instead of us doing it, but at the moment we continue to run that programme and we are confident in the processes that the panel undertakes.

Q264 Mr Heath: I want to ask about the at-risk cohort, but before I do that, Dr Sinka, I was just thinking about what you were saying. I can understand entirely the rationale of using single-use instruments on at-risk patients. I could understand the concept of keeping discrete sets of instruments and not mixing them if we were dealing with something where you could reasonably expect to diagnose infection within a limited period, but this disease has a long latency. Unless you are going to keep very prodigious lists of what instruments were used on what patient and at what time, you do not have traceability, do you?

Dr Sinka: There are fairly detailed lists of what instruments have been used on what people and at what time, but I am referring to keeping together complete sets rather than splitting the various instruments between different sets; otherwise, the discrete sets are for people born after 1996—that is, for all people born after 1996.

Q265 Mr Heath: I can see an underlying logic, but in practice it would seem to me that, by the time you have any reasonable knowledge of infection, that set will have been used on a great number of patients, if you have as comprehensive a record as you would like, and therefore the traceability is extremely limited, but perhaps I am just being stupid.

Dr Sinka: Very good traceability has now been introduced. That has been one of the recommendations that came about through the fairly intensive scrutiny that decontamination and instrument management have been under over the last decades. When we have had look-backs on surgical incidents, people have been able to trace quite carefully what instruments have been used on what patients for the look-back period required.

Q266 Mr Heath: Let us move on. Dr Sinka, I think you are probably the right person to answer the next question, but, Dr Cosford, if it is you, please do so as well. When you have identified somebody as belonging on an at-risk register for either classical CJD or variant CJD, what actually happens? How are they notified?

Dr Sinka: It may depend on how many people are involved. Sometimes one or two people are identified in relation to a particular incident; sometimes there are tens, and sometimes even more. In all cases the aim is to provide as much information and support as possible. Usually, it involves the patient's GP, or, if they are under the care of a clinical specialist, that person as well, so there is someone who is able to support them and explain the risks. A whole suite of written information has been produced, which has been refined over the years, to try to make it as clear and comprehensive as possible.

Q267 Mr Heath: Could we have a copy?

Dr Sinka: Yes, you certainly can. That information is provided both to the person who has been informed that they are at increased risk and to their general practitioner. We usually also involve the public health team locally, because usually there is a further amount of public health follow-up required. All of this is co-ordinated, in particular to make sure that the timing is right so that people do not find out about their risk through, for example, the media before the systems are set up to support them. For large-scale notification exercises, there is usually a helpline. That has been done through NHS Direct previously, but it may vary depending on the circumstance. There is usually a great deal of planning and involvement of the relevant national services who are there to advise, be it an incident that relates to blood, plasma products or surgery.

Q268 Mr Heath: That follow-up would include psychological support, if required, and some surveillance for any neurological signs that may develop.

Dr Sinka: The addresses and contact details for support for people who are informed they are at increased risk are for the two national centres: the National Prion Clinic and the CJD Research and Surveillance Unit in Edinburgh. People are provided with those contact details and also, where appropriate, details of the CJD support network, a patient group who are used to counselling families and people affected by CJD.

There is follow-up. We know that it may be required for the long term, given the potential low doses of exposure in some cases, and the long incubation period. That is set up to follow up long term any development of neurological symptoms or CJD in people who have been told that they are at increased risk. That is both to understand what the risks are

by iatrogenic transmission and also to provide a means to monitor that the public health measures in place have been effective.

Q269 Mr Heath: Early on in that process, is the question of consent to post-mortem examination raised?

Dr Sinka: So far, it has been raised with a subset of individuals who were invited to take part in research activities. When they were invited to take part, they were asked if they wished to consent to post-mortem, and there was a mixed response to that.

Q270 Mr Heath: You say "mixed response." What sort of proportion?

Dr Sinka: Not everybody was asked. Not everybody was in a good position to be asked. Either they were in a fragile health condition, or it was not thought appropriate for other reasons. Twenty-seven people were asked, 11 of whom said yes; eight were not asked, and six declined. More people who were asked said yes than no, but it still was not very high.

Q271 Mr Heath: This poses quite a significant problem in terms of overall epidemiology, does it not, in being able to separate dementias from CJD at later stages and identify whether you are at risk, or were at risk at all.

Dr Sinka: Those 27 people are from the small cohort that Public Health England follows up, of around 400 people. There are a larger number among the 6,000 identified in total, who are also being followed up, primarily by the UK haemophilia doctors organisation. There are other methods in place to identify whether people have developed neurological symptoms, or whether they have developed and died from variant CJD. To date, other than the two asymptomatic infections discussed previously, there have not been any deaths or other identification of CJD in this cohort.

Q272 Mr Heath: There are various recommendations in terms of what somebody who is at risk should or, more importantly, should not do. Have you any view as to to what extent those precautions are working? To what extent do people do as they are asked to do? Do their GPs monitor whether that is the case? In other words, how do you know that the precautions you suggest are put in place in practice?

Dr Sinka: Speaking about the cohort that we have responsibility for, we ask the person's GP to confirm that they have been notified and have received the information. I receive an awful lot of calls—it is a two-way process—mostly from infection control teams who are double-checking. They have a patient in front of them who has answered yes to a number of screening questions that are put before surgery, and they are often phoning to confirm or clarify the information they have been given. I know that screening pre-surgery is in place. I have also heard from patients themselves who are calling to understand their risk better. It is anecdotal evidence, but I receive a good number of calls—at least one a week—from infection control teams who are implementing the guidance and also taking surgical precautions.

Q273 Mr Heath: That pre-surgical screening and set of questions is universal; it is standard practice.

Dr Sinka: It should be. It has been guidance published by the ACDP TSE sub-group. It is part of a suite of guidance that an infection control team should be aware of.

Q274 Mr Heath: Dr Cosford, you looked as if you wanted to add something.

Dr Cosford: No.

Q275 Mr Heath: You are happy with that response.

Dr Cosford: The whole issue of look-backs is a very delicate one, because usually when we are looking back and identifying patients who have been exposed to risk it is because there is a potential benefit to them as an individual. In this case, being at risk of CJD, we want them to take precautions on the very precautionary principle to prevent the opportunity for further transmission if they do happen to be infected. The actual benefit to them as an individual is very limited, so it is a very delicate area, and we are aware of that.

Our emphasis is to do two things: one is to enable and encourage them to take those precautions, and the second is to be aware of the potential implications for them and the psychological concerns they will have, and to make sure that both their GP and normal family doctor arrangements are in place to support them and that there is specific support through the CJD network and others where they can get support and advice. As you have heard, Dr Sinka herself receives calls directly, so we do all we can to make sure that both sides are taken account of.

Q276 Sarah Newton: Professor Neuberger has been sitting there very patiently. This is a very important subject area for the staff of the Royal Cornwall hospital in my constituency and patients in my constituency who are waiting for transplants. I am sure that all my colleagues here know of people who are desperately waiting for transplants. Can you give us an update on what progress has been made to date in implementing the "Taking Organ Transplantation to 2020" strategy?

Professor Neuberger: It is a broad front. One of the key issues is that it is a strategy for the UK, not just NHSBT, and it involves looking at all aspects of the journey from the general public engaging in the concept of donation and agreeing to donation, right to the other end of making sure that we encourage surgeons to use all organs, wherever appropriate for the patients, making the appropriate risk decisions—the risk management. As you know, transplantation compared with blood transfusion is a risky process; it involves a balance of risks, so it is across the board.

We have set up an oversight group, which is chaired by Elisabeth Buggins. She is making sure not only that NHSBT does its bit, but that the Department of Health, the professions, the organisations and hospitals also do their bit. We are making overall progress, in that donation and transplants are continuing to increase. We reached the 50% target by a

whisker last year, and donations have increased by a further 10% this year. We are making progress, but there is still a long way to go and we need to work right across the piece.

The biggest challenge, as you know, is the consent rate or refusal rate. The UK was just pipped by the Netherlands last year for having the highest refusal rate. That involves a strategy. A paper went to the board of NHSBT to try to understand why people say no, and how we can work with our specialist nurses to encourage people to make the right decision. That is a major piece of work.

The other major piece of work we are involved with is working particularly with surgeons to try to ensure that all usable organs are used. That is a difficult piece of work. We can influence surgeons and support them. That is the other major piece, but there are lots of other bits of work in between.

Q277 Sarah Newton: You have given us some very encouraging news about progress towards very clearly defined targets, and you have laid out the overall strategy. There was a commitment that there would need to be detailed operational plans across the various organisations you mentioned. I understand that a lot of people are involved in driving the change that we want to see. Have those detailed operational plans been submitted? If they have not, why not?

Professor Neuberger: As far as NHSBT is concerned—I can speak only for ourselves—we have agreed our short-term and our longer-term plans. They are in place. We have already delivered on some of the targets that we set, and we are working on others. The strategy to increase public behaviour has gone to the board, and then it will go up for discussion with the Department of Health. There will be resource implications in that. There is work force planning to see how our specialist nurses can work more effectively to obtain consent, whenever it is appropriate and possible. That is another major piece of work going on. We are working with clinicians to provide, and have recently reissued, guidance and support. We are working with them and the commissioners to get peer review, to get the clinicians themselves to take ownership of this, and provide support and guidance to make sure they make the right decision, and, when they do not use organs, to understand very clearly why not. We are on target against our own strategy.

Q278 Sarah Newton: What about the detailed operational plans of the other partners you mentioned?

Professor Neuberger: The departments can probably best speak for themselves. As an organisation, we can only work through influence; we cannot tell professional organisations and hospitals what to do. We can work with them. On the whole, they engage well. There are some areas where we do not get good engagement from hospitals, but we are working hard to improve that.

Q279 Sarah Newton: You mentioned that recommendations have gone to the Department of Health which have resource implications. When do you think they are going to be considered?

Professor Neuberger: We have to make a strong business case. At the moment it has gone to the board and, when it is approved, it will go to the Department.

Q280 Sarah Newton: When would you expect the Department of Health to receive it?

Professor Neuberger: If the board approve it, I would certainly hope it would be this calendar year, if not earlier.

Q281 Sarah Newton: A lot of us have been contacted by the major organisations working with cystic fibrosis. I visited the unit in my own hospital. They are very keen that we reconsider how we go about allocating suitable lungs, and whether we should have a more national allocation basis over the regional ones. To what extent have you considered the representations you have heard on cystic fibrosis and other illnesses or conditions about enabling organs to be allocated in a different way?

Professor Neuberger: We have worked closely, and have had calls—though infrequent—with Ed Owen in the Cystic Fibrosis Trust. We are not wedded to any one particular allocation scheme. We operate across the different organs, sometimes zonal allocations and sometimes national allocations. For example, we have a national allocation at the moment for kidneys after brain death but also a local one. As far as lungs are concerned, there are constraints with a national allocation scheme because of the time frame between retrieval and implantation. We discussed this yesterday at our cardiothoracic advisory group and agreed that we would move towards a national allocation scheme for urgent lung recipients and a zonal allocation for non-urgent patients.

We need to model this first, because we have to make sure that the allocation is right. For lung transplants in particular, you have largely two broad groups: one is cystic fibrosis patients and the other is those with pulmonary fibrosis, which is scarring of the lungs. Cystic fibrosis patients tend to be younger and tend to have a much more generalised disease. They tend to have infections in the lungs and elsewhere; they tend to have diabetes and they tend be malnourished. Pulmonary fibrosis patients tend to be older and otherwise fitter, so that gives rise to several problems. First, how do you have a system that takes these two very different populations and puts them in ranking order? Secondly, you need to match your donor lungs or other organs with your recipients, not only on issues such as blood group, height, volume of lungs and so on, but if you have a lung that may not function well, you want to put it into a fitter patient, so you need to mix and match.

Even with kidneys, where we have a national allocation scheme—this is paralleled across other countries—where a kidney is allocated to a specific appropriately matched patient, in only about 35% of cases does the first-ranked patient get the organ. We need to model a national allocation scheme first and make sure that, if we go down that route, we can do it safely and effectively and achieve the desired effect. In other countries that have introduced national allocation schemes we have seen unintended consequences. For example, in Germany, where they had a liver national allocation scheme, results were a lot worse. On the other hand, in the US, where it was done, deaths on the waiting list fell dramatically; outcomes were not significantly adversely affected and resource utilisation was increased. We would need to be sure if we did move to that. We are very happy to do

it if it is going to produce a better outcome for patients. Of course we will implement that. Clinicians have accepted the proposals, and if the modelling suggests the scheme benefits patients, we will introduce it for urgent lung patients and monitor it. If we get the desired improvement in outcomes, we will extend it to other patients; if not, we will modify it. We are not wedded to any one model.

When you have an allocation scheme it is difficult, because you are trying to balance a number of competing constraints. You want to reduce deaths on the waiting list; you need to ensure equity of access so that people with different conditions can all benefit; and you also need to look at some degree of outcome. Historically, people used to transplant very sick patients. They did not die on the waiting list, but they died shortly afterwards, so it was not a good use of the organ, which somebody else could have had. You have to balance different components, which are sometimes conflicting. That is why they are not always straightforward; you do not always get the right outcome. We have national schemes for some organs and we have agreed to adopt this, subject to the modelling showing it is likely to benefit patients. I am sorry for the long answer.

Sarah Newton: I am very pleased. I am sure we would all like to discuss this further, but I think we are out of time.

Chair: We are running out of time, because we have the Minister waiting for us outside. Thank you very much indeed for your contribution this morning.

Examination of Witnesses

Witnesses: **Jane Ellison MP**, Parliamentary Under-Secretary of State for Public Health, Department of Health, and **Professor Dame Sally Davies**, Chief Medical Officer, Department of Health, gave evidence.

Q282 Chair: Minister and Dame Sally, thank you very much for coming this morning. We realise that people are on a pretty tight timetable, so we will get straight in. I want to start the questioning simply by asking why the decision was made to dissolve the Spongiform Encephalopathy Advisory Committee—SEAC—in 2011. Did you support that decision?

Jane Ellison: Thank you very much for asking us here today. I say up front that this is a highly technical and scientific area, so there will be many occasions when I defer to the CMO. The decision you are referring to took place before I was a Minister. My understanding is that it was felt that the advice that committee supplied could equally well be supplied by other expert committees, but, as Sally was in post at the time, perhaps she could comment further.

Professor Davies: As you know, we have not had a new case of variant CJD since 2010.[2] There was an effort to rationalise all our scientific committees to make sure that we were not wasting scientists' time but that for policy development we had the best advice. We rationalised them, and what we have here to share with you are the before and after charts of the committees. You may want those to look at. I did support the decision. The committee had done a very good job, but we remained with two major advisory committees: SaBTO—Safety of Blood, Tissues and Organs—and ACDP, the Advisory Committee on Dangerous Pathogens. There had always been a bit of an overlap, but now between them they deal with that.

Q283 Chair: I have not seen the before and after charts yet, but my understanding is that there are still multiple bodies advising on CJD.

Professor Davies: Yes.

Q284 Chair: Does that remain sensible, or would you want to rationalise it further?

Professor Davies: It is functioning well at the moment. I see no reason to alter it at this time, but of course I look forward to hearing your advice.

Q285 Chair: What role do you play in advising the Minister on matters related to blood safety?

Professor Davies: As CMO, I am the independent medical adviser on all medical things to the UK Government in England, and on public health, to the Department of Health. I review the advice in these areas, as in all public health areas, to ensure that it has been properly based on science, and looks rigorous and sensible. That is supported by the fact that I am also the chief scientific adviser to the Department, as you know. Meanwhile, I

[2] The witness later clarified that, there has been one new UK case since 2010.

am also the head of the research division, so I am aware of, and sign off to a certain extent, the research that has been advised in this area.

Q286 Chair: How do you ensure that there is an integrated approach that covers Scotland, Northern Ireland and Wales as well?

Professor Davies: As UK CMOs, we meet three or four times a year to discuss issues of public health and policy, and if we had concerns in this area it would be on the agenda. We have not needed to since I have been CMO, but the committees have representation from across the UK and the policy teams talk regularly, as do the blood transfusion services. Ours are for England and Wales, but Public Health England is in regular communication on all these issues with the public health services of Scotland and Northern Ireland, so there is a lot of cross-talk in the interests of ensuring that our public and patients are well served.

Q287 David Tredinnick: The Government have acknowledged the potential value of a blood test capable of detecting variant CJD, but could they be doing more to support the development of such a test?

Jane Ellison: My understanding is that quite a lot is going on in this area. As a Minister, I am open-minded to receiving advice on this, but, like many other things, it will be based on it being evidence-based and cost-effective. Quite a lot of work is going on in this area. The Department are funding not only ongoing surveillance work but a number of studies, and other non-DH-funded studies are going on. I am pretty satisfied that, proportionate particularly to the number of cases and deaths over the last 10 years or so, there is a good body of work going on at the moment. I am open-minded; if evidence is presented to me that we can do something that is cost-effective and evidence-based, we would look at that.

Q288 David Tredinnick: In 2013, Professor Collinge submitted a proposal to the MRC worth approximately £750,000 to conduct further work to validate a test that he had developed and that was in use at the MRC, but it was turned down. Do either of you have any comment on this, and whether the Government propose to take it forward? What strikes me is that the amount of money is tiny in the scheme of things. We have a test that was working effectively on a small scale, and it seems very strange to me that nothing has been done to take it forward.

Professor Davies: Clearly, we have limited budgets for health care, public health and research. The MRC gives core funding to Professor Collinge's unit—the MRC prion unit—every year, and they used some of that to develop the test. They also gave an additional £300,000 to help develop that blood test. There was an application last year that was turned down by peer review because of a number of issues, one being insufficient justification for its use for screening. He has not gone back to them with any further applications. Indeed, he has led them to believe that he is exploring other avenues of funding for the blood test project.

The MRC and ourselves have given a lot of money to this area of prion research, particularly to Professor Collinge. We from the Department have given him about £14

million over the last 10 years from our policy research programme, which is more than any other individual gets from the policy research programme for any subject.[3] The MRC gives the prion unit £6 million each year, in addition to supplementary funding of a further £5 million since 2007, so he is in receipt of significant funds. Meanwhile, I understand from the NIHR biomedical research centre at University College that about £100,000 each year has been used, at the discretion of University College academics, to support his work; and he receives funding from the university because he is listed on the HEFCE QR submissions—the RAE submissions. They get significant funding.

Q289 David Tredinnick: I understand that. Thank you for explaining the amount of money that goes across. In this instance, I am interested to hear you say that Professor Collinge has apparently moved on. I understand this was turned down because of the issue about sensitivity, but he says that 71% "is perfectly adequate to do the study that we propose to do…it could be that only 70% of people with vCJD have prions in their blood," and the test is therefore "picking up all of them." Is this not something that perhaps should be reconsidered, and, if the MRC are not going to do it, it should fall within one of the funding schemes you described, Dame Sally?

Professor Davies: The integrity of research in this country is based on the peer review system. I would not want to second-guess the peer review of the Medical Research Council.

Q290 David Tredinnick: Minister, you referred to a number of studies in answer to my opening question. Could you be a bit more specific and tell us what studies have been undertaken?

Jane Ellison: I am going to ask the chief medical officer to look at that. I think Dame Sally referred to some of those going on in her previous answers. Some of them have been conducted by Professor Collinge. I believe that 20% of the funding that has been given to prion research has been given to projects led by him. I will ask Dame Sally to comment on some of the specific projects.

Professor Davies: Since 2002, he has had from us over £3 million for the national prion monitoring cohort. Starting in 2006—I was personally involved in ensuring this grant—he received over £7 million for the development of effective treatments for prion infection, working with GlaxoSmithKline looking at their library of compounds. I was the one who asked GSK to open up their library, and negotiated that. We gave him £2.75 million for the prion 1 clinical trial, and £1.6 million for some animal work involving transgenic mice. That is the last decade.

Of course, we have funded a lot of other work. For instance, at the moment we have £49 million-worth of active research under way including on decontamination across the UK, so we continue. At the moment, we have a ring-fenced budget—it is the only ring-fenced budget in the Department of Health's budget—of £5 million annually.

[3] The witness later clarified that, the Department had given £16,294,648.

Q291 David Tredinnick: You are saying that overall there is a lot of research and a lot of money available for this area. Is that right?

Professor Davies: There is a fair amount of money, and we have to balance everything together.

Q292 David Tredinnick: I have a couple of further questions on a related but different subject. How many blood samples from known variant CJD patients are currently held in the UK? Related to that, how many of these are available to commercial test developers?

Professor Davies: I know it is one and a half tablespoons at NIBSC. I am looking for the actual numbers. We have seven individual cases held in citrate anticoagulant and nine individual cases held in pink bottles—EDTA anticoagulant. That is 16 patients. The National Prion Unit itself holds other ones. In the *Lancet* paper on Professor Collinge's test showing the 70% sensitivity, I think he used 21 samples from patients. They, the NIBSC samples, are available, following a proper protocol, to all people.

Q293 David Tredinnick: Are you saying that the number of samples that he used was small? Is that what you are implying?

Professor Davies: It was large compared with what anyone else will be able to use, being 21. We only have 16 held at NIBSC.

Q294 David Tredinnick: Why was the Prionics test validated on the basis of only two samples when that could not possibly have given a statistically significant result?

Professor Davies: I do not have the details. We will send them to you, but it is not a test in routine use, as far as I am aware. We will send you the details.

Q295 Chair: Before we move off the issue of money, you talked about a ring-fenced budget. Minister, is it the intention that that ring fence remains after 2015?

Jane Ellison: No proposal has been put to me to remove it. I cannot commit to what would happen in the future and what any future Government might think, but it seems to me that we have established an approach to this particularly serious issue that is extremely precautionary, looking at the amount of money spent, the ring-fenced budget and the number of actual cases. I think it is right to take an extreme precautionary position. I have no intention to challenge that. Obviously, successive Governments might take a different view, but it seems to me that has been a consistent picture since the height of the whole crisis. Successive Governments have taken that precautionary principle.

Q296 Graham Stringer: NICE issued guidelines in 2006 to help stop the transmission of CJD during surgical operations. We have been told that that has not been universally implemented. What are the consequences of that, and what are you doing about it, if anything?

Professor Davies: I brought for you, if you needed it, all the official guidance, so the NICE guidance, which is significant, is in there. You will know that when NICE issues guidance the NHS is expected to implement it within three months. I was not aware—this is the first I have heard—that places are not using the guidance. We would have to ask the CQC, as our agency for inspection, whether they had picked that up, and probably talk to the Royal College of Surgeons. Because if that is the case, it is unacceptable, because we are concerned about the transmission of disease—not only prions but other diseases.

Q297 Graham Stringer: I cannot give you the reference, but our notes say that in 2011 a study found that the guidance had not been fully implemented in a number of trusts, partly because of resource issues. I am slightly surprised that you are not aware of that, but if you can give us a note on what you think about it that would be helpful. What do you think generally about the measures currently in place to prevent the transmission of prions? Do you consider them to be adequate?

Professor Davies: In the light of our present knowledge, our scientific advisory committees advise us that they are in the right place. We have implemented everything that the scientific advisory committees have said is effective, and cost-effective.

Q298 Graham Stringer: A Department of Health working group has acknowledged that the standard wash procedures do not clean surgical instruments; they do not get rid of the prions, yet there is technology available for doing that. Are you trying to solve that issue? To go back to the discussion with the previous panel, is it your understanding that autoclaving surgical instruments gets rid of prion contamination, or not?

Professor Davies: My understanding is that because they are hydrophobic they are difficult to get off surgical instruments.

Q299 Graham Stringer: They bond in a particular way.

Professor Davies: Yes, and autoclaving on its own does not remove them. If I am wrong, I will have to tell you.

Q300 Graham Stringer: That was my understanding.

Professor Davies: That is my understanding. We have clearly moved on a precautionary principle back in 2007 to single-use dental reamers and dental equipment for root canals, and it was a precautionary principle that took us there. We tried single use in tonsillectomy, and brought it in rather fast. There were patients who bled, and sadly a death, so we had to reverse that, but there is a lot of work to make sure that, where possible, there is single use and that decontamination is properly done. There is more to do. We have £46 million-worth of research ongoing, which started in 2011, including on decontamination, and most of that will be reporting later this year. Following that, clearly we may need to change what we are doing.

Q301 Graham Stringer: We are told that there is technology available for doing it. Do you accept that? Are you looking to put it into standard procedures?

Professor Davies: If you are talking about the DuPont decontamination product, I can tell you that the rapid review panel gave it a level 2 assessment.

Q302 Graham Stringer: Which means?

Professor Davies: It means that basic research and development has been completed and the product may have potential value. In-use evaluation trials are now needed in an NHS clinical setting. It is for the company to do that. We have been told that DuPont have not chosen to do that at this time. I should perhaps highlight to you that, even if effective, it would be quite a difficult product to introduce in the NHS, because it would involve changing the central sterile departments of every hospital, and their processes and some of their other machinery. Were it proved to be perfection, it would not be just the cost of it; it would have massive knock-on costs elsewhere in the sterilisation department system.

Q303 Pamela Nash: Minister, we have been hearing this morning in the last session and this one about the new technologies that are being developed with the support of the Government and the MRC. We know that they have not been adopted more widely. What message is that giving to companies who are looking at developing products in this field? We have received some criticism about that. Do you think there is anything the Government can do to make it clearer to those companies exactly what technologies the Government would want them to invest in for the future?

Jane Ellison: Ms Nash, are you talking principally about the RelyOn surgical wash? Obviously, that is the one I am aware of. I have met Professor Collinge. I had a meeting with him shortly after I was appointed and discussed that. I am aware of the criticism. I am not a scientist; this is very technical for me, so as Minister I have to ask simple common-sense questions. Is someone presenting to me evidence that something can be very effective on the basis of evidence, and also cost-effective? Even if that was the case, it would not be my decision as Minister to say that is something everyone must use, because obviously there are other people producing products that the NHS might want to buy and use. But the first test that has to be met is whether something has passed an evidence test of effectiveness, and could it potentially be implemented in a cost-effective way?

As far as I understand it, there is nothing to stop the company that developed this one taking matters further, going back to the rapid review panel and doing further development and further tests. Nothing has been put in the way of that. From my point of view as a Minister, it would be completely inappropriate to sit in my office and pick winners that have not gone through a proper process. I rely on the evidence presented to me of things having gone through a process. As far as I can see, no barriers have been put in the way of this product, but there is still some way to go for the people behind it to prove that it can be effective and cost-effective.

Q304 Pamela Nash: I appreciate that, and I understand where you are coming from, Minister. Just playing devil's advocate, perhaps barriers might not be put up, but a company

would want to know that a product might be used. You might not be picking winners in terms of the companies and the producers but, perhaps, giving an indication of what technologies are being looked for and would be invested in. Would the Government subsidise technologies if it became clear that they would be very helpful in protecting public health, but would not be profitable for the companies producing the products?

Jane Ellison: Our starting point is funding the research. We have given evidence that a lot of research is being funded. The issue would then come to me. It would be put to me that this is effective, but there are already processes in place for the NHS to consider the use of products. Do not forget that it would be for NICE, for example, to recommend the use of something that became a gold standard. We have existing processes that I think are pretty robust, and have to be; otherwise, you would never be able to make decisions in this area. It is so complex, and so much money is involved, that you have to have robust processes. I cannot see anything in the processes we already have that would stop an evidence-based effective product that could be used cost-effectively being recommended to the NHS.

Q305 Pamela Nash: My understanding is that the technologies that we have mentioned—the prion filter, the MRC projects as well, blood tests and the prion inactivator—were evaluated by different processes and different bodies at the time. Has that system now been rationalised as part of this diagram we have, or is it separate? My concern would be that a complex system of this sort would put off companies, and it might be costly both for them and the Government to have those different processes. Has that now been rationalised?

Professor Davies: It is a fairly smooth process. It is quite clear that the rapid review panel reviews technologies to reduce hospital-acquired infection. SaBTO reviews issues around blood safety. I do not think that any part of the industry worth their salt has problems with the system. If they do, they only have to ask us.

Q306 Chair: Is that advice available equally to companies, irrespective of size?

Professor Davies: Of course it is.

Q307 Chair: You are open to propositions from small companies.

Professor Davies: If they are asking how the system works and who will be assessing them and to what criteria, that is easily available to everyone.

Q308 Mr Heath: Minister, following on from that, does it not make a difference that in this particular area NHS England, or certainly the British NHS, would be one of the biggest markets—almost an exclusive market—for a product of this kind? Therefore, it is not quite the same as, say, a drug of general applicability where markets can be found anywhere and Britain can either buy in or buy out. Companies need that confidence to know there is a buyer for this.

Jane Ellison: I understand the point you are making.

Professor Davies: This is not just a British problem.

Q309 Mr Heath: It is not exclusively British but we are the biggest market.

Professor Davies: The market would take in other countries in Europe as well.

Q310 Mr Heath: But not if the British NHS does not buy; there won't be a market without the British NHS.

Professor Davies: Unfortunately, there is a complaint from the medical devices industry that it is difficult to sell devices to the NHS even when they have been developed in the UK. They find it easier to sell abroad, and this may be no exception.

Q311 Mr Heath: I just think the normal market model does not necessarily apply when we have a centre of infection here. There is not a North American market, for instance.

Jane Ellison: Mr Heath, I understand the point you are making, but equally the conversation at the meeting in my office hinted at what you are saying, which is effectively should we almost say, "If you get this right, we will recommend"? If somebody developed a scientifically evidenced, cost-effective product that could, as Dame Sally said earlier, be incorporated without disproportionate cost to make our NHS safer, I see no reason why our NHS would not want to look at it. It would be irrational if they did not. The question then is, are we funding and supporting the development of some of this work? I think the answer to that is yes. I came at this very fresh. The meeting I had with Professor Collinge and others was very early on as a Minister, so I had no preconceptions. It seems to me that we have put investment and support in the way of developing these technologies, but there is a point at which either the company involved or the market has to do some of that work. Equally, there is an evidence level of effectiveness and cost-effectiveness that has to be met.

Q312 Mr Heath: I do not dispute that. Let me talk about something completely different. The CJD incidents panel disappeared last year, I think. Are you confident that local management and local reporting structures are sufficiently robust for CJD?

Professor Davies: Yes. I think that in this country people have a very high index of suspicion about CJD. The number of referrals outnumbers the number of cases, so we have a high index of suspicion. We had an incident panel which set up the processes and advice, and we stood it down. The standard operating procedures should be good enough for anything that comes up, but if something new and different comes up we will seek advice from the ACDP and other experts. I think it is still a robust system.

Q313 Mr Heath: You think it should be, and there is evidence to suggest that it is.

Professor Davies: Yes.

Q314 Mr Heath: Dealing with the cohort of at-risk patients identified, are you satisfied that they are getting both the support they need and the continuing surveillance that gives us a clear picture of what is happening to them, if anything?

Professor Davies: As I understand it, there are two groups: those who have been labelled at public health risk because they received pooled products that may have had an infective load, but that, probably because it was pooled, is very low, and those where, through a look-back, we know that they received blood products where the donor subsequently developed disease. Both are very difficult for the recipient of that advice and how you follow them, but I believe that the clinicians are giving good support and following those at highest risk very carefully. The other public health at-risk group are mainly people with inherited bleeding disorders, and they get support through their routine management at haemophilia centres where they have counsellors and everyone there.

Q315 Mr Heath: One area of the surveillance system, as I suppose you could call it, which is clearly not desperately successful at the moment, is post-mortem examination of people within that at-risk group who subsequently die. First, is that a concern in terms of getting accurate figures for infection levels; and, secondly, if it is a concern, what have you done to improve it?

Professor Davies: There are two problems. One is that the rate of post-mortem examinations has gone down dramatically from being the norm to very low anyway, and that is a cultural issue. People do not want them, so not everyone consents. If an at-risk person's family consents, the post-mortem is done to the standards we would expect. There is not a drop-off in quality of post-mortems, and we will know whether the spleens, tonsils and so on have relevant changes.

There is then an issue of post-mortem studies to look at prevalence. There is some discussion at the moment with my research team as to whether we could and should fund an elderly cohort through post-mortems to look at prevalence, and we are looking at that to see whether it is doable and cost-effective.

Q316 Mr Heath: Without that, if an elderly person contracts dementia, distinguishing it from CJD prior to death is clearly quite difficult, so we do not really know the prevalence.

Professor Davies: We do not know the prevalence, but it is before the BSE problem arose. The assumption in our elderly people—it is an assumption and not proven by science—is that it will be low or negligible, but without doing such a study we do not know.

Jane Ellison: If I may comment on your previous question, my postbag from Members of Parliament is a very good indicator of whether we are getting things right on all sorts of issues. It is extremely wide-ranging, as is my portfolio. To the best of my knowledge—I think I would remember it—I have not had a letter from a Member of Parliament on behalf of a patient. You asked whether we were looking after people and supporting them well enough. There are a number of other areas where I get many letters from Members of Parliament on behalf of their constituents. To date, this is not one of them. Inasmuch as my post bag is quite a good early warning signal about where we are not getting things right, it has not alerted me to the fact we are not getting that support right in this area.

Mr Heath: That is very helpful.

Q317 Chair: But that is no reason to be complacent, because this is a very serious condition.

Jane Ellison: Believe me, Mr Miller, this is one area where, given the history of this disease, I do not think any Minister would ever be complacent.

Q318 Stephen Mosley: I have just a couple of questions on the National CJD Research and Surveillance Unit. You will probably be aware that current funding goes up to 2015. Are there any plans to continue funding beyond that?

Professor Davies: They would need to make an application, but I would be surprised if they did not receive funding. However, I cannot promise it because that is in a different Government and a different Comprehensive Spending Review, and they have not submitted an application.

Jane Ellison: I cannot speculate on a hypothetical, but I said in my earlier evidence that the view successive Governments have taken in this area has been a very precautionary one, but clearly that has not come to me as a Minister for a decision.

Professor Davies: I have a correction. They have a contract until 2017; we are funding them until at least then.

Q319 Stephen Mosley: The unit is currently based at the University of Edinburgh, which is of course in Scotland. Have any negotiations and discussions taken place as to what would happen if Scotland votes for independence in September?

Jane Ellison: No. I do not think any part of Government is making any sort of pre-independence plan; that is not something we have had a discussion on.

Q320 Stephen Mosley: The unit has submitted to the Department a proposal for the investigation of atypical dementia in the elderly. Have you been able to look at that proposal? Have you given it any consideration at all?

Professor Davies: That is the proposal I just mentioned. The R and D team and policy team are going to discuss it with them.

Q321 Sarah Newton: Last but not least, may I move to the whole area of transplantation? Can you give us an update on the action that the Department of Health have taken to implement the "Taking Organ Transplantation to 2020" strategy?

Jane Ellison: Perhaps I can comment on one aspect of it as an example of where I am quite actively involved. I am very aware that one of the big challenges in this area is as much about consent as the number of people on the register. For the last year for which we have figures, about 100 families overrode the wishes of somebody who was on the organ donor register at that very difficult moment when the family was asked. Consent is a big

issue. Consent rates vary widely between different communities. For example, the family refusal rate in BAME communities is about 80% compared with 25% as the national average. That is where we get our 40% figure, so they are very divergent figures.

There are two actions that we are taking forward in that area. I am attending, I hope, diary permitting, the launch of the peer educator programme in Birmingham, where we are looking to create local champions within particular communities to champion both organ donation and the consent issue. We are planning some activities for transplant week in the second week of July in which I hope to involve parliamentarians, particularly those representing constituencies where raising the profile of these issues will be particularly helpful. Those are just a couple of examples of things directly within the Department of Health's remit that we are trying to take forward from the strategy.

Q322 Sarah Newton: That is extremely helpful. Professor Neuberger, from whom we took evidence this morning, also highlighted the issue of consent. There is a very good target of 80% consent within the strategy, so it is encouraging to hear of the activities you plan, particularly around community champions. Where you have examples of people coming forward, it is a very powerful thing. An 80% target is very ambitious, so do the Government have any plans to review their position on presumed consent?

Jane Ellison: We are certainly going to watch what happens in Wales. We have no current plans to go down that road ourselves, but I will be watching with interest. Clearly, there are potential risks as well as potential benefits, so it is important to assess those. Because of what we know about the problems of consent, it is really important not to think that the only issue is about the number of organs. It would not alter the pool of suitable donors in any given year. What you would be looking to do is raise the proportion of them on the register, but if you did not tackle consent rates you would not have anything like the impact. At the same time, although we don't know, there is quite a lot of research to suggest that it might have a negative impact on people being on the register. We will need to look at that. We will watch it with interest, but we have no current plans to go in that direction.

Q323 Sarah Newton: Professor Neuberger talked about issues around training health professionals. As you said, it is a very difficult moment to secure consent to enable organ donations when families are faced with the loss of a loved one. He was talking about this particular issue, which he felt was a barrier to hitting those targets. What plans have the Department got to work with professionals—nurses and doctors—in hospitals to drive up those consent rates?

Jane Ellison: Work is already going on. There is a group of highly trained professionals, in the case of nurses going by the somewhat unlikely acronym SNODs—specialist nurses in organ donation. They work embedded within intensive care units. They will start talking to families before death potentially, and look at how they can prepare to have that conversation. We already have those highly trained individuals. Where they are in place they can be very effective. It is really important to do that work. You cannot think of a more sensitive time to put a very difficult decision to people, so the more trained people are, the more likely we are to see consent rates rise. Some families consent to someone who is not on the register becoming an organ donor. That can happen. Many donations

come from people not on the register. That specialist medical support is already there and is effective.

Q324 Sarah Newton: Professor Neuberger also talked about issues to do with some surgeons accepting particular organs for transplantation. He felt that was an area that needed more attention. The strategy commits the Government to a whole series of action plans. To what extent are the Department monitoring the delivery of the strategy and specifically getting the different pieces of the jigsaw signed up to their implementation plans?

Professor Davies: There is an accountability meeting every three months, and a big one annually between NHSBT and the Department sponsors, and this plan and the metrics in it are part of that, so an eye is kept on it.

Jane Ellison: When I became a Minister one of the first things I did was to ask to meet NHSBT. I asked them what I could do to support their work, and where I could bring particular focus. I was directed to some of the work on consent rates in particular communities, which led to the things that I have in my schedule. It is a strategy that so far has produced some really good results. There is a terrific increase in registering for donation and donations themselves, but we know we have more to do. We aspire to be extremely good at this, but we keep pretty close to it. It is an area that I am personally very interested in. I know that a number of parliamentary colleagues have done work in their own constituencies to try to address some of these particular issues. As a Health Minister I am also looking to see where I can involve parliamentary colleagues in spreading the word in those areas that require it.

Q325 Graham Stringer: Professor Davies, in the mid-1990s we were getting horrific projections about this disease. They have not come to fruition. Over that period of time what have we got right and what have we got wrong in dealing with this disease? Have we been lucky or very effective?

Professor Davies: I do not think it was luck; I think it was a planned cross-Government movement, first with animal feed and the progress made on slaughtering older animals and so on to reduce the infectivity pool, and then on primary infection, which had a dramatic impact. Then we were concerned about secondary infection person to person, and blood transfusion is the most obvious way that that comes through. If you look at the data, as I know you have, you can see that leucodepletion filters probably remove about 40% of the infectivity. With other changes we have had an impact to try to make sure we do not get into a vicious circle where, despite its no longer being in the food chain and infecting, we are continuing it. I think we have made very good progress.

To date, all the probable and seriously likely cases have been MM genotype, though there is one possible case that was MV—a heterozygote. We remain open to the concerns that have yet to play out that there may be a longer incubation period in the heterozygotes, which is why we still are actively doing research. This is not something that we can ignore and get away from on the precautionary principle. Although that second epidemic has not hit us, it does not mean that we can sit back and say, "Problem solved, book closed."

Q326 Chair: My final question stems from earlier comments. In this particular area is there a case for scientific advisory committees that exist under the new structure being responsible for, or at least reporting on, the cost-effectiveness of new technologies?

Professor Davies: They do give advice on cost-effectiveness, but that has to be based on health economic modelling.

Q327 Chair: That is their advice but it is not a decision-making process; it is advice to you, is it?

Professor Davies: I would have to go back and look at where the advice goes, but I would highlight to you as the Science and Technology Committee that you would be very unhappy if I overruled expert scientific advice.

Chair: Absolutely.

Professor Davies: I do not make a habit of it. I cannot think when I have.

Q328 Chair: We get upset, especially when Ministers do it.

Professor Davies: My role is to give advice to Ministers.

Chair: Thank you very much for a very helpful evidence session.