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DRAFT STATEMENT

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With permission Mr Speaker I wish to make a statement about a blood transfusion incident involving variant Creutzfeldt-Jakob Disease (vCJD).

It might assist the House if I begin by setting out the basic facts before coming on to discuss the implications.

In March 1996, a blood donor, who was at the time free of the signs of vCJD, donated blood to the National Blood Service. Shortly after this the donated blood was transfused into a patient who underwent surgery for a serious illness.

In continuing my description of these events to the House, I will from now on refer to these individuals as the 'donor' and the 'recipient' of the blood.

The donor showed no signs of vCJD at the time blood was given, but developed the disease three years later – i.e. in 1999 – and died from it. The recipient of the blood died in the autumn of 2003. Initial post-mortem examination of the recipient of the blood showed changes in the brain indicative of CJD. Further examinations and tests of this patient's brain confirmed the diagnosis of variant CJD. The link between the donor and the recipient was first reported to officials in my Department on 9 December 2003 at which time the diagnosis of vCJD in the recipient was still being confirmed.

I was first alerted to the developments on Friday 12 December and was briefed by the Chief Medical Officer on Monday and Tuesday this week. Today I am bringing this information to the House at the earliest opportunity. I have given the minimal clinical details of the recipient because the family has indicated that they wish to have their privacy respected.

In the light of the facts which I have outlined, it is therefore possible that the disease was transmitted from donor to recipient by blood transfusion, in circumstances where the blood of the donor was infectious, three years before the donor developed vCJD, and where the recipient developed vCJD after a six and a half year incubation period. This is a possibility not a proven causal connection. However, it is also possible that both individuals separately acquired vCJD by eating BSE (Bovine Spongiform Encephalopathy) infected meat or meat products.

This is a single incident, so it is impossible to be sure which was the route of infection. However, the possibility of this being transfusion-related cannot be discounted. That is the conclusion of the Chief Medical Officer and experts.

It is because this is the first report from anywhere in the world of the possible transmission of vCJD from person to person via blood that I thought it right to come to the despatch box to inform the House on a precautionary basis.

This incident was discovered by good surveillance. In 1997, the Department of Health funded a research study, the Transfusion Medicine Epidemiology Review (TMER) study to examine links between all vCJD cases and any form of blood transfusion. It is through this research study that the association between these two patients was identified. I should also point out that this emphasises the importance of post-mortem examination. Without it we would never have known about these matters. I would like to thank our NHS pathologists for their expertise and constant vigilance.

I can inform the House there is as yet no blood test for vCJD (or for that matter BSE) let alone one that could detect the disease years before symptoms develop. So, there is no way yet of screening blood donations for the presence of the CJD group of diseases.

Fortunately, however, a range of precautionary measures have been put in place by the Government since 1997, even though there was at that time no evidence of the risk of person-to-person transmission of the disease via blood. For the reassurance of the House, I will briefly set out the action that has been taken to date and the further action that we now propose.

Firstly, since 1997 all cases of vCJD that are reported to the National CJD Surveillance Unit and diagnosed as having 'probable' vCJD, result in a search of the National Blood Service blood donor records. If the patient has given blood, subsequently any stocks of that blood are immediately destroyed.

Secondly, on 17 July 1998 acting on expert advice, the Government announced a £70 million programme to remove most of the white cells from blood destined for transfusion. White cells were considered by experts at the time to be a potential source of infection. This process of so-called leuco-depletion was then a highly precautionary measure to reduce what was then a hypothetical source of infectivity. The process of leuco-depletion was implemented by the National Blood Service over time and completed by October 1999.

Thirdly, on 12 November 1998, again acting on expert committee advice, the Government announced a £30 million programme to phase out the use of United Kingdom-sourced plasma in the manufacture of blood products. This was at the time (in the absence of any defined risk) another highly precautionary measure. From the end of 1999 all blood products have been made using plasma sourced from the United States of America. To ensure continuity of supply the Department of Health purchased on 17 December 2002 the largest remaining independent US plasma collector, Life Resources Incorporated.

Fourthly, the National Blood Service has informed us that 15 people received donations of blood from donors who subsequently developed vCJD. Of the 15 individuals, we have been informed that five received blood after leuco-depletion had been implemented, the remainder before. The earliest such transfusion was in 1993 and the latest in 2001. Working with the National Blood Service, the Health Protection Agency is in the process of contacting these individuals. All will be told about the circumstances of their case and have the opportunity to discuss the risks with an expert counsellor.

Many more patients of course, including haemophiliacs, will have received plasma products before plasma was sourced from the USA. They will have received products derived from large pools of plasma donated from many thousands of people and thus heavily diluted. The UK-wide CJD Incidents Panel considers the risks for this group to be even lower than for those who received whole blood. It is very difficult to trace all individual recipients of products made from these plasma pools. However, the CJD Incidents Panel will be advising on a case-by-case basis which recipients will need to be contacted as the necessary information becomes available. This group of patients will also have the opportunity for a discussion with an expert on an individual basis. Any person with concerns may ring NHS Direct on 0845 4647.

Fifthly, before these events, expert groups were already deliberating on whether further measures were required in relation to vCJD and blood. In October of 2003 our expert committee on the Microbiological Safety of Blood and Tissues for Transplantation advised, on the basis of a risk assessment, that further action such as stopping people who have received a blood transfusion from giving blood was not necessary.

However, in the light of today's statement, we have asked this Committee to look comprehensively at whether further precautionary

measures could be taken which would not adversely impact on the safety or availability of blood.

Sixthly, it is apparent that much more blood and blood products are used clinically, than need to be. There have been many past attempts to reduce the use of blood to situations where it is absolutely needed medically, but these have only been partially successful. I will be asking the National Blood Service to have urgent discussions with the medical Royal Colleges and NHS hospitals to address this area of clinical practice. More appropriate blood usage will reduce all the risks associated with blood and will make more effective use of our precious blood supplies.

A finding of this kind, albeit one whose full medical significance is still far from clear, inevitably will give rise to concern. It is therefore important to take account of the wider context in two respects.

Firstly, since the events in 1996, approximately 24 million units of blood or blood components have been given to patients in the United Kingdom. Blood transfusion can be a life saving treatment but no medical treatment is free of all risks. Indeed it is an unfortunate fact that already each year approximately 12 die as a complication of blood transfusion. Many people receiving blood transfusion are already very ill, some in life and death situations. A wide range of measures are routinely used to reduce the risks of transfusion by screening for HIV/AIDS, hepatitis B and C and other infections. For specific high risk patients even more detailed screening takes place.

These wider measures should be seen in the context of the precautionary action already taken on vCJD, and a recognition that so far we have only one single report of a possible link between a single donor and a single recipient.

We are generally regarded internationally as having a very safe Blood Service, especially because of our precautionary approach to screening for infection, careful donor selection and the tradition of volunteering which means that our donors generally have a lower incidence of many viral diseases compared to those in other countries who are paid for their donations.

Secondly, as for the wider situation for vCJD, thankfully we have not so far seen the thousands of cases of vCJD that some projections suggested. As of 1 December 2003 there had been a cumulative total of 143 cases of vCJD in the United Kingdom. Over the last three years the annual number of new cases has fallen. However, there should be no complacency. It remains premature to conclude that the epidemic has peaked. Any case of vCJD is tragic for the patients and families concerned.

I hope that my statement has given the House a clear and accurate account of this finding in the full context in which it needs to be seen. I have asked the Chief Medical Officer to oversee the further work and investigation required and to keep me closely informed. I will of course keep the House informed of any major developments in this area.

Is there a risk associated with sheep meat?

Issue

People may be concerned about possible risk from sheep meat

Lines to take

- The FSA have carried out a consultation on possible risks associated with sheep meat. No action is necessary at this stage.
- Together with Defra and DH the issue is being kept under **close review.**

Safety of blood supply

Issue

This case raises questions about the general safety of blood used in transfusions in the NHS and action being taken to minimise the risk of vCJD being passed through blood and whether this is adequate.

Lines to take

- The safety of blood and blood products used in the NHS is of paramount importance. Every reasonable step has been taken to minimise any risks during blood transfusion.

- Patients can have confidence in the safety of blood used in the UK. Since 1999 all blood has been leucodepleted and plasma has been sourced from the USA.

- The current high levels of safety are achieved by screening out potential high risk donors and then further testing of every unit of donated blood for the presence of HIV, hepatitis C, hepatitis B and Syphilis before it is released to hospitals.

- Expert advice is that, if vCJD is transmissible through blood, the infection is most likely to be contained in the white cells and plasma.

- We have taken several precautionary measures.

    - instituted universal leucodepletion (removal of the white cells) of all blood for transfusion from 31st October 1999.

    - from1998, we instructed the fractionation laboratories to make blood products only from plasma imported from countries where there is no evidence of vCJD

    - instructed the National Blood Service to import US Fresh Frozen Plasma for neonates and children born after 1 January 1996 (ie those who should not have been exposed to BSE through the food route).

Diagnosis and treatment

Issue

There are likely to be questions on whether there is any way of telling how many people may be incubating vCJD or detecting whether blood is infected. There will also be interest in what treatments are available.

Lines to take

- There is no diagnostic test for vCJD.
- As there is no blood test, there is therefore no test to screen potential blood donors.
- We currently have no way of telling how many people may be incubating vCJD and who may be at risk of transmitting the disease to others.
- Until there is a rapid simple test we are not going to be in a position to answer this. Research is in progress with the aim of providing a diagnostic test.
- There is no treatment for the disease.
- Claims have been made for Pentosan, a drug which is not currently licensed in the UK, but is used in the United States for cystitis, and a small number of patients have been treated with quinacrine (a licensed anti-malarial drug).
- There is some very limited evidence from animal studies that Pentosan may be an effective preventative, although the Committee on Safety of Medicines have advised that there is no rationale for its use.
- As a result of a request from the High Court, the Department of Health continues to work to facilitate access to Pentosan treatment for patients with clinical symptoms, in those cases where the clinicians and the families concerned consider the risks acceptable and manageable.

Risk to humans from blood in meat?

Issue

If CJD can be transmitted via blood, can lean meat such as beef or lamb steaks be infected with BSE, as cow/sheep blood runs through them?

Lines to take

- There is to date no evidence from ongoing studies that either blood or muscle from cattle can transmit BSE to uninfected cattle. Therefore if infection is present in cattle blood, it is likely to be present at a very low level. Nevertheless BSE in cattle may have a different pattern of infection from that in man.

- BSE has not been found in sheep, although sheep have been *experimentally* infected with BSE. BSE has also been experimentally transmitted between sheep via blood transfusion.

- Controls have been introduced to reduce any risk to consumers from eating beef to an extremely low level. In addition measures to reduce any potential risk from sheep meat have been implemented by the Foods Standards Agency.

- Blood is considered to be of low infectivity compared with brain, spinal cord and lymphoid tissues.

Compensation

Issue

There will be a clear expectation that all patients who develop vCJD and their families should receive compensation. It may also be suggested that all recipients of contaminated blood should receive compensation because of the distress this involves.

Lines to take

- Sympathise with all those who have received implicated blood or blood products. Recognise that this ~~may~~ will be very distressing.

- Individuals who develop probable or confirmed variant CJD and their families are entitled to compensation under the variant CJD Compensation Scheme. The Scheme is run by independent trustees.

- We announced a financial assistance scheme earlier this year for those who had contracted hepatitis C from contaminated blood and blood components following NHS treatment. Details of the scheme are still being worked out and we hope to make an announcement soon.

- No plans for general compensation of patients who may have received implicated blood or blood products. Remain willing to consider groups which are affected in particular ways, eg haemophiliacs. [The existing variant CJD Compensation Scheme could not be used for this purpose]

Plasma recipients

Issue

Large numbers, possibly thousands, of patients who received blood plasma-derivatives (rather than whole blood) may be at risk. Particular concern over the 6,000 haemophiliacs (approx) in the UK.

Lines to take

- CJD incidents panel has taken a highly-precautionary view of the risk to plasma-derivative recipients. The risk is even lower than for whole blood recipients.
- Further detailed assessments have been commissioned on the basis of emerging information from the producers, and experts will advise on which recipients need to be contacted.
- There have already been discussions with patient-interest representatives, under the auspices of the CJD incidents panel.
- Haemophiliacs should seek advice from their doctors.
- Since 1999 the risk has been removed because from that date plasma has been sourced from the USA.
- It is possible that donors who donated pre-1999 could come to light, if they subsequently developed CJD.

Risk of transmission via surgical instruments

Issue

There has been concern about the risk of transmission of vCJD via surgical instruments. Guidance issued in January 2001 recommending the use of single use instruments for tonsillectomies was withdrawn in December 2001 because of problems with the quality of the instruments then available.

Lines to take

- Committed to minimising risk of transmission of vCJD via surgical procedures.

- Government is investing £200m in improving decontamination standards. Recent review by NHS Estates has found standards improving. We are driving for further improvements.

- Some surgeons were unhappy with quality and reliability of single use instruments which were then available. There were also issues about training of surgeons in techniques using new instruments.

- NHS Purchasing Agency working with manufacturers to improve quality and reliability of single use instruments.

1. What measures has the Government taken in recent years to ensure blood safety?

A range of precautionary measures, have been put in place since 1997.

- **All cases of CJD are reported to the CJD surveillance unit. If the patient has given blood, stocks are destroyed.**
- **In July 1998 we announced a £70m programme to remove white cells from blood for transfusion (a process known as leucodepletion). This programme was completed in 1999.**
- **- in November 1998 we announced a £30m programme to phase out the use of UK-sourced plasma. From October 1999 all blood products have been made using US-sourced plasma.**

2. Do the Government's moves in 1999 look apposite/well thought through?

Our actions have at all times been guided by expert advice. We have at all stages followed the highly precautionary approach recommended to us.

3. Where should people who are concerned look for help?

Anyone who is concerned can ring NHS Direct on 0845 46 47. NHS Direct are being advised on this issue by the Health Protection Agency.

Individuals with specific concerns, for example haemophiliacs, may want to consult their GP.

The 15 patients who received possibly contaminated whole blood

Issue

What has happened to these patients. What will Government do about informing and supporting them.

Lines to take [NB: patient details are confidential]

- There are 15 recipients (now living) of blood from 14 donors.
- 5 of these received leucodepleted red cells after 1999.
- The earliest transfusion was in 1993 and the latest in 2001.
- The National Blood Service are tracing the patients concerned. The Health Protection Agency will then contact them and will provide information and counselling to help them understand their position.

Action was already proceeding on risk assessment and risk communication in this complex area. A number of expert committees were involved. The process of risk assessment for individual patients who may have received plasma is not yet completed. I am informed that the UK-wide CJD Incidents Panel at its meeting in October 2003 received a report that the complex risk calculations for the blood and plasma products were nearing completion. They recommended that when this process was completed a package of action should be designed by the Health Protection Agency to communicate risk for individual patients. Today's action clearly initiates the first steps in this process.

CHRONOLOGY AND KEY POINTS

Chronology

27 November 1995 – Statement to the House about the organisation of the blood service in England – Mr Stephen Dorrell

8 April 1998 – Statement to the House on the National Blood Authority – Mr Frank Dobson

17 July 1998 – Press Release announcing leucodepletion on the basis on SEAC advice – includes statement from Mr Frank Dobson

12 November 1998 – new variant CJD Private Notice Question

CJD & BLOOD KEY ISSUES:

- New finding – patient who recently died from vCJD, confirmed as having received blood from a donor who subsequently developed vCJD raising the possibility that vCJD was transmitted in this case by blood.

- The National CJD Surveillance Unit and National Blood Service (NBS) have identified 15 individuals who have received blood from donors who subsequently developed vCJD.

- Need to contact these individuals and the Health Protection Agency and NBS are taking this forward as rapidly as possible.

- Additionally there is a large number of plasma derivative recipients who are at lower risk than whole blood recipients – a further detailed assessment is underway on this group on the basis of emerging information.

- The Department has taken all necessary steps on the basis of expert advice to date to minimise the risk from blood. Experts have been asked to advise on any further steps in light of new information.

- Since 1999, all blood has had white cells removed to reduce the risks from vCJD and all plasma is sourced from the USA.

- Infectivity in blood in cattle, if present, is likely to be at a very low level.

- Blood transfusion can be a life saving treatment but no medical treatment is free of all risks.