

## House of Commons Statement by the Secretary of State for Health Development in vCJD

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.