

4TH October 2004

SUBMISSION TO THE TRANSMISSABLE SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE MEETING

INTRODUCTION

-----independent campaign and support group in the UK for haemophiliacs infected with HIV and hepatitis viruses through blood products, and more recently exposed to v CJD as a result of their treatment. My husband, is a haemophiliac infected with HIV, hepatitis B and C, and exposed to the blood of donor(s) who have since died from v CJD, on at least 12 occasions in 1996 and 1997. We are currently waiting to discover whether my husband has had further exposures, following a recent “look-back” study commissioned by the government. My brother-in-law also a haemophiliac died of AIDS in 1986.

In 2000, our group was sent two “leaked” documents. One was a letter from a British plasma company BPL (dated 1997), and the second, was a letter from the NHS Executive (1998). The content of both, was that haemophiliacs had been exposed to the blood of donors that had died from v CJD, that products if not used should be withdrawn, but “don’t tell haemophiliacs”, as “it would blight their lives forever”. Naturally, after living with the past government cover-up over blood contamination, and the day to day problems of HIV, and hepatitis C, and being promised more openness with regard to any future blood borne viruses, prion diseases, we were furious to learn that once again our government was keeping information from us, which may in turn have put our families and other patients at risk. We went to the press in October/November 2000, and as a result the British government (Department of Health), were shamed into contacting all haematologists to advise them in turn to contact all haemophilia patients, (January 2001 notification), giving haemophiliacs the opportunity of knowing if they had received the implicated batch numbers.

The Westminster government in conjunction with the Scottish parliament have recently commissioned a vCJD blood risk assessment carried out by Det Norske Veritas Consulting, to identify those groups/individuals that have surpassed the “at-risk” threshold for public health purposes. This was as a result of the first death from vCJD related to a blood transfusion. A second probable case of v CJD related to blood transfusion was later identified, where a person was found to be incubating vCJD at post-mortem, but died from unrelated causes. As a result of information we have received from the Health Protection Agency (HPA) (and other sources), we have a number of concerns with regard to v CJD and blood which we wish to raise at the meeting.

ISSUES OF CONCERN

1. We are aware that since 1998 plasma has been imported from the USA for fractionation to manufacture plasma products, as we can no longer use our own plasma because of the risk of v CJD. I have some concerns about this as I am aware that over the years citizens from European countries with cases of BSE/v CJD have

sold their blood in the U.S. and been accepted as donors. Even if this practice has now stopped, if vCJD is transmittable via blood products, is there not a risk that vCJD could already have been in the blood supply and that American recipients may be incubating v CJD?

For example, my friend's son who has lived in the UK for the first 20 years of his life, (the UK has cases of BSE/v CJD), went to study in the U.S. in 1999. I discovered to my horror that he had seen a notice on campus for plasma donors, and had proceeded to sell his blood on several occasions. He wrote telling me that he had been economical with the truth as he had smoked dope on the way to donate, and was afraid he would be barred from donating. (This is one of the reasons why we have a volunteer donor system in the UK). Dr J Garrott Allen, (former Professor Of Surgery, Stanford University, USA), pointed out in a letter to Dr William Maycock, Head of Blood Transfusion Service, England, as far back as 1975, that paying donors tempted them to lie about their circumstances and compromised safety.

I checked with the CJD Surveillance Unit, Edinburgh, and they informed me that if a UK citizen dies from v CJD, they ask the family if they have donated blood in the UK, but they don't ask if they have donated in any other country. They give some details to the U.S. authorities but not the name of the person for reasons of confidentiality. If my friend's son were to be incubating v CJD when he donated in the U.S, and then died of the prion disease, how would recipients of his blood products be traced in the U.S.? How many citizens from European countries with BSE/v CJD have donated blood in the U.S. since 1980?

I am also aware of a French film crew, filming a documentary in 1999 on blood safety around the world, who stepped off a plane and headed for the nearest plasma centre on the U.S./Mexican border to sell their blood, and were accepted as plasma donors. (France has cases of BSE/v CJD).

It is pointless the UK importing plasma from the U.S. from 1998 onwards because of concerns over vCJD in this country, if the U.S. authorities allowed UK and other European donors from countries with BSE/v CJD to donate in America. UK donors that donated plasma in the U.S. in for example 1999/2000 could be incubating vCJD but be asymptomatic.

2. Recently a new rule came into being in the UK. This rule said that any person receiving a blood transfusion/blood products after 1980 can no longer give blood themselves because of the possibility of v CJD risk to others. Can you advise me, does the U.S. have this same exclusion rule for any person from the U.S. who has received a blood transfusion/blood products whilst a visitor to the UK, eg, if a person took ill/had an accident here whilst on holiday, or came to the UK for medical treatment requiring blood or blood transfusions. I am aware of the recent v CJD blood products notification to the American haemophilia community but I would have thought this might also apply to other U.S. citizens.

3. If U.S. haemophiliacs are identified as having implicated U.K.blood products, will the U.S. adopt the same safety measures with haemophiliacs in relation to v CJD as the authorities have in the UK?

4. If new cases such as U.S. haemophiliacs are identified as being “high-risk” in relation to vCJD for public health purposes, what measures will be taken with regard to surgical instruments used on high-risk groups? I note the following in the advice from the HPA:-

“Any risk of transmitting v CJD on such surgical instruments (that have come into contact with those “at –risk” of v CJD) will decrease each time they are used and decontaminated. After going through approximately ten cycles of use and standard decontamination, the instruments are unlikely to pose a significant risk of infection to others.”

5. If new cases such as U.S. haemophiliacs are identified as being “high-risk” in relation to v CJD for public health purposes, what advice will be given in relation to sexual transmission, given that in the UK, those identified as “at –risk” for public health purposes will no longer be allowed to donate sperm? What advice will be given to those who wish to conceive but who are identified as being in a “high-risk” category in relation to v CJD for public health purposes? As the haemophilia community learnt to their detriment in the early days of HIV and hepatitis C, no evidence of sexual or mother to child transmission at a particular time does not necessarily mean there is no risk.

6. If any U.S. haemophiliacs are identified as being exposed to v CJD from UK products, will there be guidelines for them on how to deal with a blood spillage in the community as well as for professionals in hospital? My husband recently had a burst vein in his foot, resulting in blood spillage. There were no guidelines in the community for our insurance company to follow, so as a precaution after speaking to the local HPA, men in full bio-hazard suits were dispensed to our home to remove our blood-stained carpet for disposal. Ironically if my husband bleeds onto his shirt there are no guidelines for me as the carer of a haemophiliac in the community!

I would be grateful if you could attempt to answer my questions, although I am not a U.S. citizen, many of our haemophilia community rely on plasma products made from plasma sourced in the U.S. I also have close connections to the U.S. haemophilia community. I have enclosed a copy of our letter to my husband’s consultant in the UK with regard to our concerns over v CJD and blood, to read at your leisure, as it may help you to understand some of the issues the haemophilia community are dealing with here at this present time. Unfortunately it may only be a matter of time before U.S. haemophiliacs or other U.S. citizens may find themselves in a “high-risk” group in relation to v CJD, and you may need to tighten or introduce new guidelines. Thank-you for your time.

Yours sincerely

----- (Haemophilia Action UK)