Health and Social Services Committee
HSS-05-03(p.7)

Date:	**Wednesday 26 March 2003**
Venue:	**Committee Rooms 3 & 4, National Assembly for Wales**
Title:	**Update on the Safety of blood and blood products**

Purpose

1. The committee was provided with a paper to note, on 13 March 2002 ref. no. HSS-07-02(p.5), on current issues relating to the safety of blood and blood products in Wales. Members asked for an update on that paper.

Summary

2. This paper summarises the current position on the key issues relating to the safety of blood and blood products as documented within HSS-07-02(p.5). For background information reference will need to be made to the previous paper.

Background

3. Currently the commissioning of blood services in Wales is the responsibility of health authorities. With effect from 1st April 2003 Health Commission Wales will be responsible for commissioning Blood Transfusion and Tissue Typing Services.

Creutzfeldt Jakob Disease (CJD)/ variant Creutzfeldt Jakob Disease (vCJD)

4. To date there is no evidence world-wide that CJD or vCJD has ever been transmitted through blood or blood products in humans, although the theoretical risk cannot be ruled out. CJD occurs in, roughly, one in a million people world-wide. Transmission by blood transfusion has been demonstrated in sheep with both natural scrapie strains and the BSE strain.

5. So far 10 people with vCJD are known to have been blood donors and 33 people have been identified as receiving transfused blood from donors who later developed vCJD. There is currently no diagnostic test available for detection of vCJD in blood anywhere in the world and there is no treatment for the disease.

Fresh Frozen Plasma (FFP)

6. Fresh Frozen Plasma is produced in the UK by using plasma from UK donors which has been leucodepleted. The Microbiological Safety of Blood and Tissue for Transplantation Advisory Committee (MSBT) has recommended that FFP used for neonates and children born since January 1996 should be of non-UK origin. The cut-off date was chosen to coincide with the additional precautions that were put in place to remove BSE tissue from the food chain. Thus, those born after 1996 are least likely to have been exposed to BSE from their diet. This is to reduce the theoretical possibility of transmission of vCJD for this patient group. However, this non-UK origin plasma may carry the risk of carrying other viral infections. To counteract this Methylene Blue treatment, a viral inactivator, will need to be carried out to reduce any such risk.

7. The WBS are purchasing supplies of Methylene Blue treated UK sourced plasma from the NBS and have been supplying this since August 2002. The NBS are currently issuing a tender for the supply of USA sourced plasma and this product is forecast to be available in approximately 9 months time.

Plasma

8. The exclusive use of non UK-sourced plasma followed the confirmation from the Committee on the Safety of Medicines in May 1998 that to reduce any possible theoretical risk manufactured blood products should not be sourced from UK plasma at the present time. The Bio-Products Laboratory is part of the National Blood Service and supplies blood products to the NHS in England and Wales.

9. It had become increasingly difficult for Bio Products Laboratory to source US raw plasma, to secure their future supply of plasma. In December 2002, the Department of Health secured the purchase of Life Resources Inc, a US plasma supplier. The purchase of this company will secure sustainable long-term supplies of non-UK blood plasma and avoid serious plasma product shortages and will secure the provision of plasma in Wales from 2004.

Possible reduction in the Donor Base

10. The UK Health Department's Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation asked the Department of Health's Economics and Operational Research Division to assess the impact of excluding blood donors who had previously received a blood transfusion on the grounds of possible secondary infections of vCJD, assuming blood to be infective. This risk assessment is still in progress and consequently no decision has been taken into the possible exclusion of transfusion recipients giving blood.

11. However, it is estimated that there would be between a 7.7% to 14.5% reduction in the donor base if people who have previously received a blood transfusion were excluded from donating blood as a precautionary measure to minimise the theoretical risk of transmitting vCJD through blood.

Hepatitis C

Screening for Hepatitis C

12. Nucleic Acid Testing (NAT) testing was introduced by the WBS in February 1999, on cellular

products (red cells, platelets and plasma). NAT testing detects the viral genome itself. The testing is able to detect the presence of Hepatitis C infective virus during the "window period" of infectivity – the period following infection of the donor by the virus and the virus being detected by the current testing method (still in place), which detects the presence of antibodies to the virus. To date five confirmed window period NAT positive serology negative cases have been identified by the WBS.

Hepatitis C litigation

13. A class legal action against the National Blood Service in England and the Velindre NHS Trust in Wales was brought under the Consumer Protection Act 1987, which revolved around the alleged delay by the UK Government to introduce screening prior to September 1991, when the United States introduced screening in May 1990.

14. The judgement in the Hepatitis C court case was delivered on 26 March 2001 against the National Blood Service and Velindre NHS Trust. All 117 claimants in the group action who were infected with Hepatitis C via blood transfusions between March 1988 (the coming into force of an anti Hepatitis C screening programme in the UK) won damages. Seven claimants are from Wales, 5 of those 7 have now had their cases settled, with the remaining 2 still in negotiation.

Situation in Scotland

15. The Scottish Expert Group on Financial and Other Support published a report in September 2002, containing its preliminary conclusions and a number of recommendations surrounding the issue of providing financial and other support for all patients who have contracted Hepatitis C through blood and blood products, regardless of whether negligence has been proven. There are a number of complex issues in relation to this report that still need to be addressed by the Scottish Executive including whether it has the devolved power to introduce any proposed compensation scheme and if any proposed scheme would affect social security payments that potential recipients might receive. Detailed discussions with the UK Government in Westminster are ongoing. In addition, the exact details of any scheme including people’s eligibility and the level of compensation they might receive are still being discussed by Scottish Ministers and their Health and Community Care Committee and will take account of the final report and recommendations from the Scottish Expert Group.

Other Blood Issues

Human T – cell Lymphocyte Viruses (HTLV) Testing

16. HTLV is a human retrovirus that is associated with a rare form of leukaemia and paralysis and is the same family as HIV. It is uncommon in the UK and for most individuals, infection with HTLV is asymptomatic. Disease when it occurs does so many years after infection. Infection can be transmitted through blood transfusion, breast-feeding, sexual contact and injection drug misuse.

17. The Microbiological Safety of Blood and Tissues for Transplantation Advisory Committee (MSBT) advised that HTLV testing should be added to the current screening programme. It was introduced by the Welsh Blood Service in October 2002. To date, no positive confirmed cases have been found by the

WBS.

Perioperative Cell Salvage and Autologous Transfusion

18. Perioperative Cell Salvage (PCS) where the patients own blood is circulated through a machine, cleansed and returned has promising potential to reduce the exposure of patients to donor blood and to reduce the quantity of blood used in an increasing range of surgical operations. Throughout the UK a number of NHS Trusts have introduced PCS and last year guidance was issued to encourage all NHS Trusts in Wales to consider the introduction of PCS techniques.

19. In April 2002, the WBS introduced a scheme whereby the costs of consumables used by hospitals in undertaking cell salvage activity would be reimbursed to the hospitals. This initiative should lead to a reduction in the use of red cells.

West Nile Virus

20. West Nile Virus is a disease, which can be passed from animals to humans. It is from the group of viruses known as arboviruses, as the viruses are largely transmitted by insects. Birds are the normal hosts to become infected with West Nile virus. The virus circulates in the bird's blood, so when a mosquito takes a blood meal from an infected bird they may take up the virus as well. The mosquito can then pass on the virus when feeding on another bird. The virus is amplified by continuous transmission in this way. This was considered an exotic disease until transmission began to occur initially in New York and more extensively in the USA recently.

21. Animal to animal, animal to person and person to person transmission is thought to be rare. It is an enveloped virus, which is destroyed by Methylene Blue treatment. It is not likely to become a problem endemic in the UK, as the density of potential mosquito vectors is low.

EC Directive

22. The draft EC directive for setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components sought to achieve a comparable level of quality and safety throughout the blood transfusion chain in all member states of the EU. This will be achieved by the setting of minimum standards, inspection and licensing systems, adverse reaction monitoring system and a new committee to update regularly the technical requirements as set by the directive.

23. The Department of Health is taking the lead on this policy for the whole of the UK. The directive on blood and blood products successfully passed through the Health Council in England in November 2001. It appeared in the Official Journal of the European Union on 8 February 2003 as 'Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human and blood components and amending Directive 2001/83/EC. Member States will have 2 years from the publication of the Directive in the Official Journal to transpose it into Domestic Legislation.

24. Subsequently, the EC have produced draft Annexes which contain the technical requirements for consultation. The UK Blood Services will be setting up a joint working group to assess the implications of the Directive on the Blood Service and implement action as required.

Better Blood Transfusion

25. The four UK Chief Medical Officers held the Second 'Better Blood Transfusion' conference in October 2001. The main aim of this conference was to help set the priorities for blood transfusion in the NHS for the coming three to five years. One of the important issues discussed was how to avoid the unnecessary use of blood in clinical practice in the face of decreasing supplies and numbers of blood donors. The Assembly Government are taking work forward on this and other issues considered at the conference.

26. The Welsh Assembly Government published a Welsh Health Circular on 23 December 2002, ' Better Blood Transfusion WHC (2002)137, which detailed a new programme of action for the NHS in Wales :-

- to ensure that *Better Blood Transfusion* is an integral part of NHS care
- to make blood transfusion safer as part of clinical governance responsibilities
- avoid the unnecessary use of blood in clinical practice
- to provide better information to patients and the public about blood transfusion.

27. The appropriate use of donor blood and the use of effective alternatives to blood are becoming increasingly important public health and clinical governance issues.

- Appropriate blood transfusion is an essential support to many medical treatments and is life-saving.
- Donated blood is a limited resource. As a result of further measures that may have to be taken to reduce the unknown risk of transfusion of vCJD by blood transfusion, such as the introduction of a future screening test and limitations on the number of donors, blood supplies may be considerably reduced.
- The safety of blood transfusion is highlighted yearly through the Serious Hazards of Transfusion (SHOT) scheme (a confidential enquiry for the reporting of serious complications of blood transfusion and near miss events in the UK). This scheme has shown that avoidable, serious hazards of blood transfusion continue to occur in Trusts, the most common being giving the wrong blood to patients.
- There is continued wide variation in the use of blood (particularly surgical specialities) even with the existence of national and local clinical guidelines developed by clinical professionals on the appropriate use of donor blood.

Use of blood in the treatment of cancer

28. The blood is used extensively in the treatment of cancer particularly in cases of cancer related

anaemia. About 18,000 blood transfusions are given each year in the UK to patients with anaemia resulting from chemotherapy.

29. We are aware of a growing campaign to use alternatives to blood to treat this group of patients, in particular the use of erythopoietin. The use of this drug in the treatment of chemotherapy induced anaemia is being consider for inclusion in the NICE 9th wave work programme.

30. The Welsh Assembly Government continues to support blood transfusion as a medical treatment where appropriate and maintain efforts to increase the number of people who donate blood. However, we recognise that the option of and use of blood treatment alternatives are both relevant for certain patient groups and desirable where they are considered to be more clinically effective.

Additional Investment by the Welsh Assembly Government

31. On 16 October 2002, I announced an additional £1 million for blood services to fund improved screening tests in relation to Neucleic Acid Testing of blood and Transfusion Nurses/Practitioners which are critical to the improved education and training for staff involved in blood transfusion practice leading to a reduction in the usage of blood and improved patient safety.

Action for the Committee

32. To note the up to date position on the areas covered in paper HSS-05-03(p.6) relating to the safety of blood and blood products.

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