Date: **Wednesday 13 March 2002**

Venue: **Committee Room 2, National Assembly for Wales**

Title: **Safety of Blood and Blood Products**

Purpose

1. To provide the committee with a paper to note on current issues relating to the safety of blood and blood products in Wales.

Summary

2. This paper summaries the key issues and developments relating to the safety of blood and blood products.

Background

3. In Wales, the commissioning of blood services is the responsibility of health authorities. The Welsh Blood Service (WBS) is the sole provider of all blood and blood products for South, Mid and West Wales. The National Blood Service (NBS) caters for North Wales, with its services from Manchester and Mersey centres.

4. From April 1999, funding for the blood service was ring fenced within health authority discretionary allocations as a means of stabilising the WBS financial position in the face of sharply escalating blood processing costs. The funding then goes to the blood services who in return provide blood, at previously agreed volumes, to the trusts. Trusts must manage within their agreed quotas, any blood supplies used over above their quota have to be paid for, thereby building in some incentive for efficient and effective use of blood. Assembly Government policy is to encourage Trusts to use blood supplies effectively and to explore alternatives to blood transfusion.

5. The Welsh Assembly Government continues to support blood transfusion as a medical treatment where effective and appropriate and it maintains efforts to increase the number of people who donate blood. However, almost every medical treatment or intervention including blood transfusion is

associated with some risk. The safety of the UK blood supply is widely acknowledged as a major health policy issue. Safety and quality are addressed through independent regulatory systems and audit. Annex 1 lists details of the various UK and Welsh advisory groups for blood and blood products. Four major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion in the UK is safe and that it is becoming even safer with improving technology and clinical audit. Every donation of blood is tested for HIV, Hepatitis B, Hepatitis C and Syphilis. Most of the hazards associated with blood usage lie in its administration to the patient.

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

Background

6. 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, which supplies England and Wales, obtains all its plasma from the United States.

7. Expert advice is that if vCJD is transmissible through blood, the infection is most likely to be contained in the white cells and plasma. In July 1998 the Government instructed the UK blood services to implement a programme of removing the white cells from donated blood (leucodepletion), as a precautionary measure to reduce the theoretical risk to the blood supply of the transmission of vCJD following advice from the Spongieform Encephalopathy Advisory Committee (SEAC).

8. 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 possibility of the risk cannot be ruled out. Experimentally, sheep to sheep transfer has been demonstrated on one occasion in an on-going experiment.

9. CJD occurs in, roughly, one in a million people world-wide. It is a rare slow progressive fatal disease, caused by an infectious agent called a prion, an altered form of a normal protein about which little is known, with a incubation period of around 20 years. Variant CJD is a newly recognised condition with cases mainly in the UK and a small number in France and the Republic of Ireland. It is presumed that vCJD has been transmitted to humans by eating beef from cattle with Bovine Spongieform Encephalopathy (BSE). If this is so, anyone who has eaten contaminated beef may be at risk of developing vCJD. However, of the cases of vCJD to date, all have a similar genetic pattern that is common to about 40% of the UK population. This genetic group would appear to be at greater risk, at least for early (10-20 years) development of the disease.

Blood

10. So far in the UK, 8 people with vCJD are known to have been blood donors and 22 people have been identified as receiving transfused blood from donors who later developed vCJD. There is currently no diagnostic test available for vCJD and there is no treatment for the disease.

11. vCJD cases are notified to the blood services by the CJD Surveillance Unit in Edinburgh so that a search can be made to identify any blood donors. In the event of a blood donor being identified, donation records are obtained and the fate of donations is traced.

12. The US, Canada, Australia, Japan, New Zealand, Austria, Hong Kong, Germany, Italy, Switzerland. Finland, France and Israel do not accept blood donations from people who have visited or lived in the UK for six months or more between 1980 and 1996. This is the period when BSE was epidemic in UK cattle and when the risk to the population of acquiring variant vCJD might be greatest. There is no evidence world wide that CJD or vCJD have ever been transmitted to humans through blood or blood products. Neither is there any evidence that excluding people who have visited or resided in the UK between 1980 and 1996 will make the blood supply safer. Work from France and the Netherlands suggests a theoretical minimal 1-2% reduction of risk from this kind of regulatory action.

Current Position

13. The risk of vCJD transmission through human blood transfusion remains theoretical. It is for each country to consider the evidence, weighing up the balance of risks - the theoretical risk of vCJD transmission and the impact of any donor deferral action on the blood supply - and take any precautionary action they might decide is required.

14. Introducing a regulation like this in the UK would in effect exclude the whole population. This is not, therefore, an option for the UK as we use 3 million units of blood every year. This volume of blood cannot be replaced from any other source and there is no ready international market. Blood is needed in care of patients especially those who are critically ill, suffering severe accidents, patients with cancer and leukaemia, and those needing surgery.

Fresh Frozen Plasma (FFP)

15. 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 now recommended that FFP used for neonates and children born since January 1996 should be of non-UK origin. 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.

Hepatitis C

Background

16. Hepatitis C is a virus that can infect and damage the liver. The virus is found in the blood of people

who have this disease. Hepatitis C is spread primarily by contact with the blood of an infected person. Currently the main route of transmission in the UK is by the sharing of contaminated injecting equipment in drug misusers. Other more minor routes of transmission include from infected mother to baby at birth, or by sexual intercourse with an infected person. There is also a risk of transmission if skin piercing/tattooing is not carried out in a hygienic manner.

17. The majority of patients who contract Hepatitis C will live out their normal life span. Hepatitis C infection is cleared in about 20% of those infected, but persists in about 80% to become chronic infection. Most of those with chronic infection will have only mild liver damage, many with no obvious symptoms. About 20% of patients with chronic infection develop cirrhosis after 20-30 years. Studies carried out in a number of countries so far have generally indicated that about 1-5% of patients with chronic infection may develop liver cancer.

Screening for Hepatitis C

18. The Hepatitis C virus was first formally identified in May 1988. A first generation screening test became available in December 1989. The United States of America introduced this test in May 1990. In November 1990, following evaluation of the test by the National Blood Service it was agreed to introduce screening in the UK. However, shortly after a new second-generation test, which was more sensitive and specific, became available, a decision was taken to halt the introduction of the first test and evaluate the new one. The UK was one of the last European countries to introduce screening that began in September 1991.

19. Over the last 2 years Nucleic Acid Testing (NAT) testing has been introduced 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.

Hepatitis C litigation

20. A class legal action against the National Blood Service (NBS) 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.

21. The judgement in the Hepatitis C court case was delivered on Monday 26 March 2001 against the National Blood Authority and Velindre NHS Trust. All 117 claimants in the group action (including 6 from Wales), who were infected with Hepatitis C via blood transfusions between March 1988 (the coming into force of the Consumer Protection Act 1987) and September 1991 (the introduction of an anti Hepatitis C screening programme in the UK) won damages. Claimants will be entitled to additional damages if they develop more serious symptoms in the coming years. These cases are expected to be

settled during the next financial year.

Hepatitis C in relation to haemophilia

22. People with haemophilia are generally male, with women being carriers. Some female carriers also present mild symptoms of the disease and require treatment especially for surgery and at childbirth. Some rarer forms of haemophilia affect both sexes equally.

23. The UK Health Departments were aware in the late 1970s that Factor 8 (clotting factor), a blood product – used to treat haemophilia, carried a high risk of contamination. However, the technology for eliminating the Hepatitis C virus from blood products whilst maintaining their effectiveness, was not developed until the mid 1980s.

24. Since the mid 1980s, the human plasma used to make clotting factors has been treated to remove HIV and Hepatitis viruses. As a precautionary measure against variant CJD, all plasma-derived clotting factors now used by the NHS are made from imported plasma or are recombinant products (synthetically produced). Everything has therefore been done to ensure that the products needed and used by people with haemophilia are as safe as possible. Plasma derived clotting factors have had an excellent safety record since the introduction of viral inactivation in the mid 1980s.

Current position

25. The Haemophilia Society have long campaigned for a special payments scheme for people with haemophilia infected with hepatitis C through blood products, similar to that in place for HIV. Assembly Government and UK Government policy remains that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. The underlying principles are clear cut and independently established under common law. They apply to personal injury cases in general – not just those arising from health care. In general there is no ‘no fault compensation.’

26. There have also been many calls for a public inquiry into why so many haemophiliacs have been infected with Hepatitis C. It is a global problem linked to developing science and technology and it was not confined to the UK or linked to some local breakdown in blood product development. A public inquiry has been rejected by the UK Government and the Assembly Government as it is unlikely to provide a satisfactory answer.

Situation in Scotland

27. In Scotland, the Scottish Health Committee has published a report calling for financial and other support for all patients who contracted hepatitis C through blood and blood products regardless of whether negligence has been proven. Last year the Scottish Executive responded to this report in the Scottish Parliament by stating that the NHS should not pay compensation where there is no basis.

28. However in January this year, Scottish Health Minister announced the decision to set up an expert group to look at the possibility of establishing a system to offer financial and other support to those who have been harmed by NHS treatment in cases (not just Haemophiliacs infected with hepatitis C), where the NHS is not at fault.

Other Blood Issues

Human T-cell Lymphocyte Viruses (HTLV) Testing

29. HTLV is a human retrovirus that is associated with a rare form of leukaemia and paralysis and is from 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.

30. The Microbiological Safety of Blood and Tissues for Transplantation Advisory Committee (MSBT) has advised that HTLV testing should be added to the current screening programme.

31. The technique for HTLV screening has now been validated. There is currently only one test kit identified that will work with pooled sample, thus there is a risk associated with a single manufacturer. The Welsh Blood Service is currently considering the implications of introducing this screening.

Better Blood Transfusion

Perioperative Cell Salvage and Autologous Transfusion

32. There has been a shift towards using less blood in surgery and there is a widening appreciation of an increasing interest in autologous transfusion. Cell salvage can be used for a significant number of elective, trauma and emergency operations.

33. Perioperative Cell Salvage (PCS) where the patients own blood is circulated through a machine, cleansed and returned, has promising potential to reduce the exposure to 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.

34. The four UK Chief Medical Officers held the second "Better Blood Transfusion" conference on 29 October 2001. The main aim of the 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 will be taking work forward on this and other issues considered at the conference through its Blood Standards and Quality Group and further guidance will be issued to the NHS in 2002.

35. This guidance will cover:

- Safety and risk - The continuing concerns over blood safety in respect of viral infections and vCJD prompts continuing efforts to minimise blood usage and to educate both the public and professionals as to the comparative risks of transfusion.

- Blood conservation - Difficulties in maintaining blood donors numbers and the potential effects on donor numbers of CJD screening where available require a pro-active approach to blood stock conservation.

- Evidence based practice - The requirements of clinical governance place a greater emphasis on basing clinical practice on good evidence, where this exists. There is evidence of an over use of blood transfusion and that there are alternative methods of maintaining haemoglobin levels that are effective.

EC Directive

36. 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 seeks 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.

37. 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 on 15 November 2001. It is due to go before the European Parliament this month (March 2002).

Action for the Committee

38. To note the current issues regarding blood and blood product safety and the action that the Assembly Government is taking to address them.

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Annex 1

UK Advisory Groups relating to blood safety

Serious Hazards of Transfusion (SHOT) scheme

SHOT was launched in November 1996 and aims to collects data on serious sequelae of transfusion of blood components. All NHS Trusts are requested to participate. The information obtained contributes to improving the safety of the transfusion process, informing policy within the Transfusion Services, improving standards of hospital transfusion practice and aiding production of clinical guidelines for the use of blood components.

Advisory Committee on Dangerous Pathogens (ACDP)

ACDP advises on all aspects of hazards and risks to workers and others from exposure to pathogens.

Spongieform Encephalopathy Advisory Committee (SEAC)

SEAC was established in 1990 and advises on all matters relating to Transmissible Spongieform Encephalopathies, the group of diseases to which CJD and BSE belong.

Joint Working Group (JWG)

The JWG is a subgroup of the ACDP and SEAC, it advises on all aspects of hazards and risks to workers and others from exposure to pathogens.

CJD Incidents Panel

The CJD Incidents Panel was established to advise Health Professionals on the most appropriate action to take to handle incidents involving potential transmission of Creutzfeldt-Jakob Disease (CJD) between patients through clinical interventions, including via surgical instruments, tissues, organs and blood and

to keep the relevant devolved administrations informed. The Panel also advises on what studies or follow-up of patients may be needed, on patient tracing and notification exercises where these are indicated and on what should be done with any equipment that may have been contaminated.

Microbiological Safety of Blood and Tissues for Transplantation (MSBT)

The Committee was formed in 1993 and its role is to advise on measures to ensure the microbiological safety of blood and tissues for transplantation.

Committee on Safety of Medicines (CSM)

The CSM advises on the quality, efficacy and safety of medicines in order to ensure that appropriate public health standards are met and maintained.

Welsh Advisory Group

Blood Standards and Quality Group (BSQG)

The BSQG was established in 1999 by the Assembly Government to consider quality, efficient use of blood and development issues affecting the provision of blood services throughout Wales. The role of the BSQG committee is to enable standard setting for the monitoring of the quality of blood services, to provide a forum to enhance the development of policy relating to blood and blood products; to act as a vehicle for addressing service issues affecting blood services in Wales. The BSQG is also responsible for monitoring the implementation of the Better Blood Transfusion requirements.