

## SEAC ADVICE ON BLOOD AND BLOOD PRODUCTS - Q&A BRIEFING

### Are there any measures which could be taken to reduce the risk of nvCJD transmission in blood?

We do not know whether nvCJD is transmissible in this way, but that we cannot assume it behaves in the same way as classic CJD. We will be considering whether there are additional measures which we could take.

### SEAC have recommended leucodepletion - will you introduce that now?

SEAC did not recommend leucodepletion - they recommended that Ministers consider a precautionary policy of extending the use of leucodepleted blood "as far as is practicable". They also recommended that a risk assessment be carried out to assess the risk of the transmission of nvCJD by blood or blood products and that this assessment should inform any decision on what further action should be taken to protect patients. This is exactly what we are doing.

Meantime, the National Blood Authority is working on a planning strategy to implement that policy, should the risk assessment indicate that this would be a sensible precautionary measure.

### How long would it take to set it up?

That is precisely the sort of question the NBA needs to assess in their planning strategy.

### What would leucodepletion cost?

As part of their preparatory work, the NBA will be assessing the costs to the NHS of introducing leucodepletion of blood. 11X

### Will you guarantee that money will be made available for this?

We have accepted SEAC's advice to carry out a risk assessment. We need to see what it shows, and make the decision in that light. The Government will continue to take whatever steps are necessary to protect the public.

### What about the research by Oesch et al published in *Nature* on 6 November describing a test to detect nvCJD - can you use this to test blood?

This work is an important step in the development of an in-vivo test for BSE and nvCJD. Further research is still required to validate the efficacy of this test and to extend it to the detection of very small amounts of abnormal prion in fluids such as blood.

MAFF and the Department of Health have been in discussion with Professor Oesch and others on the development of this kind of approach into a simple on-line test for TSEs.

**BEEF**

Does SEAC's advice on human blood have any implications for the safety of beef - what about the blood in beef?

SEAC reviewed the safety of beef in the light of its discussion on human blood and blood products. Transmission experiments in mice have not found infectivity in the spleen, tonsil, lymph nodes or white blood cells of BSE infected cattle.

SEAC therefore concluded that no further measures governing beef and beef products for human consumption are necessary.

**BLOOD PRODUCT RECALL**

Background

In line with the views of the European expert Committee on Proprietary Medicinal Products (CPMP) that plasma derived blood products identified from nvCJD donors should be recalled as a precautionary measure, the UK has recalled products on two occasions within the last week.

Why are these products being recalled?

The products were derived from plasma from a blood donation by a person who has subsequently been confirmed as having died of new variant CJD. The Medicines Control Agency has instructed the Bio Product Laboratory, in line with the views of the Committee on Proprietary Medicinal Products (CPMP), to recall the product. This is a purely precautionary measure which we hope will reassure the public about our safety procedures.

What are the products?

Albumin and Factor VIII

What are they used for?

Albumin is used in the treatment of burns, shock and chronic liver disease. Factor VIII is used in the treatment of haemophilia.

Will patients have received other components from this donation?

Yes. The red cells and platelets are likely to have been used within 1 to 5 weeks of donation.

Which hospitals and Centres have received products?

Our ethical advice is that no benefit would be served by naming these and it would only lead to unnecessary concern on the part of patients attending those hospitals.

In CMO's statement of 6 October he said that there had been no withdrawal of blood products where one of the contributing donors had developed CJD. Why the

recall in the case of nvCJD? Doesn't this mean that there are real risks to patients of nvCJD transmission through blood transfusion or use of blood products?

There is no epidemiological evidence to suggest that classic CJD can be transmitted between humans through blood transfusions or the use of blood products. We do not know whether the same will apply to nvCJD. That is why we are taking this action as a precautionary measure.

I must stress that patients who receive blood transfusions are in urgent need of blood and usually have a severe illness. Without a transfusion, they may be at immediate risk of losing their life, or of sustaining severe and possibly permanent damage to their health. All clinical procedures have some element of risk attached - it is the balance of the risk which is important. Any negligible risk of nvCJD transmission is far outweighed by the immediate benefit to the patient of the medical treatment.

You have previously said that one suspected and three confirmed cases where patients died of nvCJD were blood donors - have these all been traced?.

We understand that the second blood product recall (on 4 November) is the final stage of the exercise to trace the fate of the donations made by the four donors who were subsequently identified as having developed nvCJD. The tracing exercise, which was announced at the scientific briefing on nvCJD given to the media by the Chief Medical Officer on 6 October, is now complete. We are pleased that the National Blood Authority (NBA) have been able to complete this exercise so quickly.

Clearly you are concerned that there is a risk of nvCJD transmission in the blood or blood products. What action has been taken to trace the recipients of the blood?

Recipients of blood components will be identified as a part of the research being carried out by the CJD Surveillance Unit.

What are you telling them?

Recipients of implicated blood components are not being told that they have received them - this follows from ethical advice.

You are withdrawing a product because it might cause harm and yet people who might already have been affected won't be told? Don't they have a right to know?

At present there is no benefit to recipients in informing them that they might possibly have come in contact with the nvCJD agent, as what evidence there is suggests that any risk is negligible. There is no way of telling whether any recipient has contracted nvCJD, and even if there was, there is no treatment that could be offered to them.

These are very difficult decisions which have been considered on more than one occasion by the Ethical Committee overseeing the epidemiological study. They took the view that the study to trace the recipients should be carried out anonymously, in view of the very low risk of transmission, the lack of a diagnostic test and the absence of any treatment for the condition.

This will of course be kept under review in the light of scientific advances and the advice from national and international expert committees.

If you are not telling them, what are you doing to ensure that those people who have received nvCJD implicated blood do not pass it on - ie donate blood or organs?

The Department and the NBA are actively considering what further measures, if any, might be necessary to reduce any risk of a transmission of that nature.

What are you going to do to protect the blood supply from nvCJD?

We are doing whatever the experts, the Committee on Propriety Medicinal Products (CPMP), the Spongiform Encephalopathy Advisory Committee (SEAC) and the advisory Committee on the Microbiological Safety of Blood and Tissues (MSBT), advise us is necessary. The issue is under continual review.

Current steps form a three pronged attack (in line with Council of Europe guidelines, and the advice of CPMP, SEAC, and MSBT).

#### 1. Surveillance

- \* The CJD surveillance unit will continue to monitor closely the prevalence of CJD.
- \* Current epidemiological investigation of cases will continue with the aim of identifying any possible risk factors.

#### 2. Research

- \* DH hosted two expert workshops in TSEs and blood transfusion in June 1997 to determine the current knowledge base, what research was already underway and what more needed to be done.
- \* Some £50 million has been spent on TSE research over the last 5 years and over the next 3 years a total of around £68 million has been allocated. This includes research now in progress to develop diagnostic tests and the testing of blood transmissibility in animal models.

#### 3. Screening

- \* Blood donors are carefully questioned to screen out those who may be at risk.

Shouldn't you only take blood from vegetarians?

We would simply not be able to meet the demand for blood if we were to rely on vegetarian donors alone. This would put the lives of countless patients at risk. We transfuse over 800,000 units of blood in our hospitals every year.

Our blood stocks are already under severe pressure and we need, now more than ever, to increase - not decrease - the number of regular donors. It is therefore vital that this latest

information does not put people off donating.

**Are blood donors at risk?**

Categorically no. The gift of blood is a very precious one which is invaluable to the work of our health service and to the health of patients.