SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE

SEAC PS1

SEAC MEETING PUBLIC SUMMARY

SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE MEETING
24 October 1997

The Spongiform Encephalopathy Advisory Committee (SEAC) met on 24 October 1997 at the offices of the Ministry of Agriculture, Fisheries and Food, Tolworth.

The Committee conducted its regular review of the emerging experimental data and of the epidemiology of BSE and nvCJD.

The number of cases of BSE continues to be in line with predictions about the decay of the epidemic.

No new confirmed cases of nvCJD in the UK had been notified by the CJD Surveillance Unit since the last meeting. Subsequent to the meeting, however, a single case has been confirmed taking the total to twenty-two.

The Committee reviewed the safety of blood and blood products and has provided advice to Government on these matters (copy attached).

The Committee considered further papers relevant to the hypothesis that the organophosphate, Phosmet, is in some way causally linked to the BSE epidemic. It was noted that the epidemiological evidence is better accounted for by the view that the BSE epidemic is due to the widespread use of animal feed contaminated with the transmissible agent of BSE than by the OP theory. Central to the latter is the bio-accumulation of OP in treated animals however the available evidence does not support such accumulation. The Committee concluded that experimental evidence would be required to justify further

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consideration of a role for organophosphates in the epidemiology of BSE. Proponents of the theory were free to apply to funding agencies for resources to conduct such experiments. However, on the evidence to date the Committee did not feel that special priority should be given to this area of research.

The Committee reviewed the production and use of tallow. It noted the restrictions in the UK on the sources of raw material used in the production of tallow for food, feed, cosmetic, medical or pharmaceutical products and was impressed by UK tallow production controls. The Committee noted that imported tallow was not subject to the same restrictions nor required to reach the same standards but that the implementation of Commission Decision 97/534/EC would result in the exclusion of Specified Risk Materials from the production of tallow across all Member States from January 1998.

The Committee also reviewed the production and use of gelatin. It noted that plants in the UK manufacturing gelatin for food, feed, cosmetic, medical or pharmaceutical use have been brought under official control. The Committee also noted that all UK gelatin manufactured for these purposes from bovine raw material utilised only imported ingredients. They noted that implementation of Commission Decision 97/534/EC would exclude Specified Risk Materials from the source materials used for gelatin manufacture in all Member States.

The Committee is due to meet again in December.

SPONGIFORM ENCEPHALOPATHY COMMITTEE - ADVICE TO MINISTERS

HUMAN BLOOD AND BLOOD PRODUCTS

The Committee have recently concluded that the transmissible agent of nvCJD is indistinguishable from that of BSE but distinctly different from any of the forms of classical CJD. Recent research (some unpublished) suggests that the pathogenesis of nvCJD differs from that of classical CJD and the former may have more involvement of lymphoreticular tissues possibly involving circulating lymphocytes. Therefore it is logical to seek to minimise any risk from blood or blood products by reducing the number of lymphocytes present.

SEAC recommends that the Government should consider a precautionary policy of extending the use of leucodepleted blood and blood products as far as is practicable. It will be for the National Blood Authority to devise a strategy to implement such a policy. It will take time to achieve full implementation and SEAC recommends that planning begins soon while the risk assessments suggested below are carried out.

It is not possible at present to estimate accurately the risk of transmitting nvCJD by blood transfusion. The magnitude of the risk will depend, *inter alia*, on the number of blood donors who are incubating nvCJD and this is not known. However, SEAC recommends that risk assessments, making assumptions of various possible incidences of nvCJD, be carried out to inform decisions on any measures which may be necessary to protect recipients.

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.

The Committee conclude, therefore, that no further measures governing beef and beef products for human consumption, are necessary.

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. The NBA have made a preliminary assessment of costs in the region of £50m per year, if the risk assessment shows that this is advisable; clearly this will need to be looked at again when the further work that the NBA are carrying out is complete.

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 tsest 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 he 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 from two donors 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 Propriety 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 this action has been recommended by CPMP 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 subseqently identified as having developed nvCJD. The tracing exercise, which was announced at the scientific briefing on nvCJD given to the media by theChief 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.