

**GOVERNMENT ACCEPTS ADVICE ON LEUCODEPLETION FROM
SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE**

The Government today took action to safeguard further the safety of the blood supply by introducing leucodepletion - the removal of the white blood cells from donated blood. This was the advice recently confirmed by the Spongiform Encephalopathy Advisory Committee (SEAC).

In November last year the Government accepted SEAC's advice that a risk assessment of human to human transmission of new variant CJD (nvCJD) through blood should be carried out, and in the meantime the National Blood Authority was asked to make plans for leucodepletion of all blood supplies.

Frank Dobson, Secretary of State for Health, said:

"We will do whatever we are advised to reduce the theoretical risk to the blood supply of the transmission of nvCJD. We accepted SEAC's advice in November and the subsequent advice in February from the Committee on Safety of Medicines that plasma for the manufacture of blood products should be obtained from non-UK sources as a precautionary measure.

"SEAC have now confirmed their original proposals for leucodepletion and I have accepted their advice. The National Blood Service has at my request been planning since November for the introduction of leucodepletion. They will now implement these plans. Although the risks are still theoretical, it is better to be safe than sorry."

The Deputy Chief Medical Officer, Jeremy Metters, said:

"I should stress that this is a purely precautionary measure. Blood in the UK remains very safe and leucodepletion will make it even safer. Blood is essential to the life-saving work of the NHS especially for patients having surgery, and following severe accidents with haemorrhage.

"Leucodepletion will be rolled out in a systematic way, so that blood supplies are not interrupted and patients will continue to get blood when they need it.

"An adequate supply of blood remains essential for the work of the NHS. It is, therefore, more important than ever that blood donors continue to come forward to give blood regularly, as we need more of it to treat more patients in the NHS.

"I should emphasise that there is no risk of nvCJD whatsoever to those who donate blood.

"SEAC's expert advice is that leucodepletion would be a sensible and practical precautionary measure to take against the theoretical risk from nvCJD because if infectivity were to be present in blood, it would most likely be in the white cells.

"There are a variety of benefits for patients attributed to the use of leucodepleted blood. It avoids the risk of fever in patients who require repeated transfusions, reduces the risk of graft rejection in patients requiring bone marrow transplants, and prevents infections in babies younger than a year."

SEAC's advice on leucodepletion is attached.

TES FOR EDITORS

1 In November 1997 Mr Dobson announced that, following advice from SEAC and the Advisory Committee on the Microbiological Safety of Blood and Tissues (MSBT), he had asked the Department's Director of Research and Development to commission an assessment of the risks of human to human transmission, and that he had asked the National Blood Authority (NBA) to start work towards the possible extension of the leucodepletion of blood so that they would be prepared in the event that the risk assessment indicated that this would be a sensible precautionary measure. Details are in press release 97/335, available from Press Office on 0171 210 5221.

2 At its last meeting, SEAC reviewed the latest research and assessments of possible risks and whilst recognising that many areas of uncertainty remain, it recommended on a precautionary basis that the Government should extend the use of leucodepletion for all blood destined for transfusion.

3 To date there have been 27 cases of nvCJD. There is no evidence of nvCJD transmission via blood or blood products.

SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE PUBLIC SUMMARY OF SEAC MEETING, 15 JUNE 1998

The Spongiform Encephalopathy Advisory Committee (SEAC) met on 15 June at the offices of the Ministry of Agriculture, Fisheries and Food, Tolworth.

The Committee conducted its regular review of research findings and the epidemiological information on BSE and CJD.

The number of cases of BSE continues to decline and was down a further 20% from the equivalent period last year.

The Total number of definite and probable nvCJD cases in the UK was 26.

The Committee reviewed the latest research and assessments of possible risks on human blood and blood products. SEAC presented their advice to Ministers on 17 June 1998. A copy is attached.

Members noted a number of procedural improvements to the operation of the Committee and considered future proposals for putting more information in the public domain.

The Committee reviewed a proposal for research into the possibility that a hitherto unrecognised strain of BSE could exist in a sub-clinical form, i.e. cattle could be infected with BSE without ever showing clinical signs of the disease. They considered a number of methods of detecting a sub-clinical strain of BSE and the difficulty of distinguishing such an infection from pre-clinical BSE ie BSE that had not reached the stage at which clinical signs of disease were apparent. SEAC concluded that this area of research should be given high priority but noted that further refinements to the diagnostic tests and to the design of the possible studies were necessary.

**SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE
nvCJD AND LEUCODEPLETION - ADVICE TO GOVERNMENT**

SEAC previously provided advice to Government in October 1997 on human blood and blood products. The Committee notes the subsequent action taken by Government on blood products on the recommendation of the Committee on Safety of Medicines (February 1998). At its meeting on 15 June 1998 SEAC reviewed the latest research and assessments of possible risks and noted there is considerable uncertainty about whether or not the infectious agent may be present in human blood and, if present, to what extent it would represent any risk of transmission. However, if there were to be any infectious agent present in human blood then the Committee considered that it would most likely be in lymphocytes (one type of white cell).

The Committee agreed that leucodepletion (removal of the white cells) could be one way of reducing any risk that there may be. The precise impact of leucodepletion on reducing the theoretical risk of transmission of nvCJD is difficult to assess and varies depending on the assumptions made, for example about the level of infectivity present in the blood of an infected individual and the number of nvCJD cases over the coming years. However, the Committee agreed that there were a number of plausible scenarios under which leucodepletion could have a significant effect but equally there were others where it could have little effect.

Recommendations

On balance the Committee recommends that the Government should extend the use of leucodepletion for all blood destined for transfusion as soon as practically possible. Care should be taken that this does not impact adversely on the donation and supply of blood.

The Committee recommends that a review of relevant areas of research is carried out with a view to identifying areas where further research may resolve uncertainties. It also recommends that additional research is carried out to identify the most efficient of the methods for leucodepletion. It is recognised that it will be many years before some of the results will be available.

The Committee stresses that advice on such action was being recommended on a precautionary basis given the absence of a protective species barrier in human to human transfer. The Committee sees no reason to revise the advice it has already given on the safety of beef and bovine products.

SEAC - June 1998

[ENDS]