455/18/12 URGENT NOTE

SofS
You saw an earlier pre-warning on this. Just to confirm – scientists are handling the media (Para 16)
Para 8 explains that all precautions necessary are taken on blood.
To learn.

RESTRICTED - POLICY

Lord Hunt

From: Jill Taylor
HSD2

Date: 13 September 2000

Cc: See attached list

GRO-C 14/09

LATEST vCJD RESEARCH FINDING:
ARTICLE TO BE PUBLISHED IN THE LANCET 15 SEPTEMBER
"TRANSMISSION OF BSE BY BLOOD TRANSFUSION IN SHEEP"

Issue

1. On 15 September The Lancet will publish a paper which reports positive transmission of BSE in a sheep following transfusion of blood from an infected donor sheep which was half way through the incubation period before the onset of clinical symptoms. The donor animal was fed with BSE infected cattle brain and earlier studies have confirmed that BSE can be transmitted experimentally in this way.

2. It is anticipated that publication will result in considerable media interest because it raises the possibility that blood donated by people who may have pre-clinical vCJD may represent a continuing risk of spread of vCJD in the UK. There may also be food safety implications.

3. A line to take and Q&A are attached.

Timing

4. Immediate.

Background - The Study

5. The Department of Health is funding this work by the Institute of Animal Health. The preliminary findings suggest that it is possible to transmit BSE to sheep by transfusion with whole blood taken from sheep during the pre-clinical phase of an experimental BSE infection when the donor animal appears healthy. To date 19 transfusions from "BSE challenged" sheep have been performed, some with buffy coat preparations (containing a high concentration of white blood cells) but most using whole blood. Infected sheep, as expected, harbour the BSE agent in peripheral tissues and provide a model similar to vCJD.

6. The research is still in its early stages. However, having observed BSE clinical signs and pathology in one sheep which received blood from a BSE infected animal, the Institute has decided to report this important development now, rather than wait until the study is completed several years from now.

7. The main concern will be that a blood donor in the pre-clinical stage of vCJD could transmit infection to a patient through a blood transfusion. There is no evidence that CJD has ever occurred as a result of blood transfusion or blood products but vCJD is a new disease and may present different risks.

Safety of UK blood

8. There is no evidence that CJD or vCJD have ever been transmitted through blood or blood products in the UK. All blood products supplied to the NHS are now made from non-UK plasma, imported from countries where there is no evidence of vCJD. In addition all blood for transfusion is now being leucodepleted (removal of the white blood cells). These measures were put in place to reduce the theoretical risk of transmitting vCJD. The national haemovigilance system (SHOT – Serious Hazards of Transfusion) indicates that blood safety in the UK is excellent and is amongst the best in the world.

Food safety implications

9. The FSA advise that the findings could give rise to additional questions about the adequacy of the current food safety controls in relation to the theoretical risk of BSE in sheep. However, SEAC have already taken into account from other experiments the possibility that, if BSE is in sheep, it might affect blood.

10. There is a long-recognised possibility that BSE may have entered the national sheep flock. Research is underway to try and find out whether this is the case, but to date, no sheep in the national flock has tested positive. The risks of BSE in sheep are still therefore theoretical.

11. In the meantime, SEAC has advised on a precautionary basis on those parts of the sheep that should be banned from the food chain ('specified risk material' - SRM). The approach taken by the Committee has been one of going for risk reduction rather than risk elimination and the list of sheep SRM recommended is not so extensive as it is for cattle. Yet we know, from experiments, that the BSE agent would be more widely distributed in the body of a genetically susceptible sheep than is the case with cattle. In the event of finding BSE in the national flock, the adequacy of the current sheep meat SRM controls would therefore be called into question. The new findings on blood serve to underscore the need to have in place a rapid method to screen sheep for BSE.

12. Turning to cattle, no parallel blood transfusion experiment has been carried out to date. Nonetheless studies have been undertaken involving various blood components from infected cattle having being injected into mouse brains. No evidence of BSE infectivity was found. Furthermore, spleen from BSE infected cattle has failed to generate infection in cattle to cattle transmission, in contrast to the position for sheep. These findings provide some reassurance.

Line to Take

13. The Department of Health is funding this research and is aware of the preliminary findings. Ministers have asked the UK Spongiform Encephalopathy Advisory Committee (SEAC) to consider them when it meets later this month.

14. There is no evidence that CJD or variant CJD has ever been transmitted through blood or blood products. However, we have already taken significant action to reduce the theoretical and unquantifiable risk of transmitting vCJD through the blood supply.

- on the advice of SEAC, all blood for transfusion has the white cells removed through a process called leucodepletion. This is because current research indicates that any infectivity from transmissible spongiform encephalopathies that might be present in blood would be most likely to be linked to white blood cells. It should be noted that the experimental transmission of BSE between sheep through blood transfusion was with whole blood, including the white cells.

- on the advice of the Committee on the Safety of Medicines all blood products used in the UK are made from plasma imported from countries where there is no evidence of vCJD. This measure should help avoid any risk there may have been from infectivity in these products.

- Stringent control measures to protect public health from the risk of exposure to BSE from farm livestock have been in place for several years and progressively strengthened over recent years.

15. The measures to protect the blood supply were introduced on the basis that transmission of vCJD through blood might possibly occur in the absence of clinical disease. They therefore anticipate the findings of this study, which was put in place to provide the best animal model of vCJD in humans.

Media Handling

16. Professor Chris Bostock, SEAC member and one of the authors of the article, and Professor Peter Smith, Chairman of SEAC will be available to handle media enquiries. A senior doctor at the National Blood Authority (Dr Tim Wallington) will also be prepared to take enquiries.

17. Any queries about food safety issues should be referred direct to the FSA Press Office (Richard Billinge tel: GRO-C).

Recommendation

18. That you agree the line to take.

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