

POLICY IN CONFIDENCE

*Blood
Safety file*

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Copies:
See list attached

Implications for UK Blood Supplies of Deferral by the USA and Canadian Authorities of Blood Donors who have been resident in the UK for six months or longer between 1980 and 1992.

Introduction

My note of 2 June (attached) alerted Ministers to the possibility that the US might defer US blood donors resident in the UK. On 17 June the US FDA Blood Safety Committee advised all blood authorities indicating that US donors who lived in the UK for six months (cumulative) or more between 1980 and 1992 should not give blood. Canada has also followed suit and there is a reference to this in last week's Sunday Times. Implementation is expected shortly. In addition several European countries are considering similar action, though we have not had any direct communication about this. The implication of this action is that these donors and de facto all UK donors may be at risk of vCJD because of eating beef in the UK over a prolonged period, and passing the agent on through blood donation.

Issue

2. The US/Canadian decision may be seen as questioning the safety of the entire UK blood supply, and raises the prospect of exploring 'international blood markets' to secure a supply from countries free of BSE/vCJD. The issue of a formal search for an alternative source of blood was raised by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) at their last meeting 3 June. Members recommended that Ministers be approached for a view. This note outlines the issues and seeks your advice.

Safety of UK Blood

3. Patients who are advised to receive labile blood components do so because they are ill or injured and in need of blood replacement. The choice is between the risk to their life or health of not receiving red cells, platelets, fresh frozen plasma or accepting the theoretical and very likely much longer term risk of possible transmission of vCJD from using blood from UK donors. Put simply it is a balance of risk where the immediate need for blood outweighs the long term theoretical and unquantifiable risk of vCJD.

Current UK need for blood

4. The current approximate need/use of the main blood components in the UK is:

3 million units of blood	-2.5 million for England
1 million units of platelets	-0.8 million for England
0.5 million units of fresh frozen plasma	-0.3 million for England

Apart from the scale of the need and the logistics of securing a supply of each of these components there are significant clinical/scientific issues relating to each product which would add to the complexity of the supply arrangements should an alternative source of large quantities of blood be identified. The shelf life of blood for example is 35 days when stored at 4 degrees Centigrade, while that of platelets which need to be stored at 22 degrees Centigrade with constant agitation is only 5 days. The shelf life of blood, for example, is thirty five days. Fresh frozen plasma lasts a year.

Requirements of an alternative supply of blood components

Quality.

5. Any alternative supply would need to come from a source licensed by the Medicines Control Agency. The quality of the supply would need to measure up to current UK standards in particular taking account of donor selection and screening. UK blood is from voluntary unpaid donors and is amongst the safest in the world. Our surveillance systems indicate that levels of transmission of infection -HIV, Hepatitis B and C, and bacteria -are unlikely to be matched by any other Blood Service. This has important implications for the very real risks of infection through blood from sources outside the UK compared with the theoretical and unquantifiable risks of vCJD.

Security of supply.

6. The reliability of any alternative source of labile blood components would need to be guaranteed and capable of delivering a constant steady supply to meet the UK's daily needs until such time as screening for vCJD or epidemiological studies could allow confidence in the home supply. This would require a guarantee from the supplier.

7. It is very unlikely that either of these requirements, and certainly not both, could be satisfied even if a supply could be identified.

Brief outline Costs

8. For England -based on the data given above -the cost of the components alone at current prices is a minimum of £300 million per annum. This does not take account of profit, transport, storage, or distribution. Costs would also need to take account of the capital costs of expanding the providing countries donor bases, remuneration of donors, and the potential costs relating to the risk any blood supplying organisation would run were the UK to revert to the national supply -in the event of developing a vCJD screening test or proof that vCJD is not transmitted through blood transfusion.

Possible sources of an alternative supply

9. It is unlikely that any country in Europe could provide this because of their size, relative lack of donors and certain national regulations prohibiting the sale of blood. Currently Holland and Switzerland are the only countries we know of which export blood components but this is not on anything near the scale of current UK need. Neither would be likely to be able to gear up to this given the size of their population. WHO and other intelligence indicates no other active sources.

10. Realistically we would be looking at the larger developed countries with large populations which could support the development of a large donor base and where the

epidemiology indicated low levels of diseases transmissible through blood transfusion. This would rule out the larger countries like Russia, China, as well as those in Africa and Asia. In addition none of these countries has a blood donor system which would allow them rise to the challenge of procuring almost 5 million extra blood components (presuming all the UK countries would have to act as one) nor would their blood organisations have the capacity or infrastructure to process this extra volume.

11. The only real alternative is the US. It is likely that the independent sector here could and would realise the enormous financial incentive of this new market and have the capacity to gear up to meet this new demand. However this would by necessity involve paid donors whose transmissible disease markers are significantly higher than in unpaid donors and therefore those in the UK. Unlike plasma where this can be frozen and quarantined until the next donor visit, blood components are labile and cannot be stored and quarantined in this way. This is therefore likely to result in increased viral disease transmission from blood transfusion in the UK. In addition bacterial transmission would also be likely to increase because of the long time to transport these labile components to the UK resulting in the transfusion of older and more risky blood.

12. The US decision on donor deferral has obvious implications for the US blood supply and therefore for the capacity of the US as a potential supplier of blood to the UK. The current restriction will significantly reduce the US national blood supply and they are already planning donor recruitment campaigns. Some European countries notably the Netherlands are also considering similar deferral criteria for donors who visited or lived in the UK and this would almost certainly reduce any extra capacity they might have of meeting our needs.

The four UK National Blood Services

13. Because the Scottish, Welsh and Northern Irish national blood services are significantly smaller than England's, organising an alternative supply would be more feasible. Individual decisions might be taken at national level, though it is highly unlikely that they would wish to proceed unilaterally. Colleagues in the UK countries have not gone to their Ministers yet on this issue.

Other options

14. It might be less difficult from the supply point of view and scientifically justifiable to consider a range of options where imported blood might be used for the young -say those under 25 years of age - on the basis that the natural history of vCJD indicates that the development of disease is likely to take up to 30 years. This would mean introducing a two tier blood transfusion system which would not be manageable and totally unacceptable to the public and the professions. It would of course also make our blood donation campaigns very difficult to justify and maintain with the prospect of blood donors defaulting en masse.

Implications of providing an alternative blood supply

15. If this could be done there would be several knock-on effects. The NBS would act more as a supplier than a provider, the donor base would be run down, bulk processing and testing would be done abroad, current stocks would need to be run down or destroyed, contingency planning would be difficult to say the least, the

technical side of blood processing would not be required with redundancies, and the whole organisation of transfusion medicine would change irreparably. In addition the country would be at the mercy of the supplier country or countries who might not always remain friendly.

16. The current leucodepletion programme would be widely interpreted as having been a waste of public money.

Implications of exploring alternative supplies of blood

18. Officials believe it will be very difficult to identify a source of labile blood components that is large enough to satisfy the UK's requirements or of equal safety in respect of blood borne viral and other infections.

17. If any approach to potential alternative suppliers were to become public there would be national concern about the safety of the UK blood supply. It would be very difficult to be anything but open about exploring alternative blood supplies and there would need to be a major media handling strategy in place.

Action

While it is very unlikely that the provision of an alternative blood supply for the UK would be feasible in the short or medium term, Ministers' advice is requested on whether we should formally explore the position. Do Ministers wish us, nevertheless, to explore whether there are any other alternative supplies so that, if challenged, we can confirm that every avenue has been explored?

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