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FRESH FROZEN PLASMA: vCJD RISK REDUCTION

Summary

1. A risk assessment undertaken by the Department indicates that ceasing to use clinical Fresh Frozen Plasma (FFP) from UK donors could reduce the unknown risk of vCJD transmission through blood. This could be achieved by importing FFP from US donors via the American Red Cross and would be cost-effective for some patient groups. A switch to US FFP is supported by MSBT (the Advisory Group on Microbiological Safety of Blood and Tissues for Transplantation).

2. The patient group that would most benefit from this change would be neonates and children born after 1 January 1996 (ie those who should have had very little exposure to any food-borne vCJD risk). US FFP could be introduced for this group at an additional cost of £700K pa, although this cost will rise incrementally as the post 1 January 1996 population grows. The lead-in time before the US product becomes available to patient would be 6-9 months. The additional costs would therefore not begin to fall until 2003/2004.

3. A bid to cover the increased costs of UK FFP for some – but not all - patient groups (£8m pa) is included in SR2002. Even if this is not approved, we are confident that the relatively low cost of this measure for the very young - £700K - can be found from other blood budgets. We therefore believe that we should proceed immediately with importing US FFP for the very young and consider whether this can be done for other patient groups once central budgets under SR2002 are agreed.

[Note: This is a separate issue from Project Red, which is about securing ongoing supplies of US plasma for manufactured, pooled blood products. The plasma for FFP and for blood products comes from different groups of donors (eg unpaid and paid) and is collected differently.]

Recommendation

4. Given:

- the recently published study in sheep (which adds weight to evidence that vCJD may be transmissible through blood);
- the recent publicity about risks from UK FFP;
- advice from MSBT and the cost/benefit arguments;

we recommend that the National Blood Service is instructed immediately to begin importing US FFP for neonates and children born after 1 January 1996.

Risk Assessment

5. Assuming a vCJD epidemic of 10,000 cases, the Department's risk assessment calculated that importing US FFP for all patients would prevent 85 new cases of vCJD a year. MSBT therefore advised that importation should go ahead but took the view that the plasma should be:

- sourced preferably from single unit (ie unpooled) plasma from unpaid donors (pooled plasma carries an increase viral risk);
- virally inactivated using methylene blue treatment because of the higher prevalence of viruses, such as HIV and hepatitis, in the US population; [Methylene blue is a dye in use for the past 100 years or so. It is used, in conjunction with the application of light, to kill a range of transfusion-transmitted viruses, but not vCJD. The plasma is then filtered to remove most of the methylene blue, which is toxic in larger quantities.]

MSBT also advised that, if supplies were limited, priority should be given to neonates and children.

Cost Effectiveness

6. In addressing cost effectiveness, patients were divided into three groups:

(i) neonates and children born after 1 January 1996 (cost: £0.7m);

(ii) children aged between 6 and 16 and selected adults with conditions necessitating large quantities of plasma (cost: £7.4m);

(iii) all other recipients (cost: £56.9m).

The results are summarised at Annex A. These show that providing US FFP for group (i) can be justified on cost per-life year arguments alone and that there are good cost effectiveness arguments for extending this to group (ii). Group (iii) is much less cost effective unless we assume very high levels of vCJD prevalence.

Logistical Issues

7. The National Blood Service has prepared the ground for importing US FFP for group (i) by introducing methylene blue treatment for UK FFP for this age group from 1 July. This is line with MSBT advice at para 5 above. NBS is also confident that, once instructed, they can obtain the relatively small amounts of plasma needed from the American Red Cross. If this instruction is given now, patients in group (i) could be receiving US methlyene blue treated FFP by the start of 2003/2004.

Funding

8. An SR2002 bid to support the increased costs of US FFP was scaled back to £8.1m pa to meet the increased costs of providing US FFP for groups (i) & (ii) only. The outcome of this is still awaited.

9. The extra revenue funding factored in at present for supply and safety of blood in 2002-03 is £32m. Even if we only received a fraction of this, we can be confident of being able to find £700K to protect this vulnerable group of small children, who should not have been exposed to food-borne vCJD from an avoidable additional risk. There is therefore no reason to wait for the outcome of the SR before taking this decision, and delay increases our vulnerability to future claims for damages if it is later proved that vCJD can be transmitted through blood.

10. If the full £8m is provided, we will discuss with NBS and MSBT how best to use it.

Position in other UK Countries

11. Scottish Ministers have already agreed that FFP for group (i) should be sourced from the US, although money for this has yet to be found. Wales and Northern Ireland have not yet made a decision.

Publicity

12. If a decision to import US FFP for group (i) is made now, this can be announced along with the introduction of methylene blue treatment for the same group. We can discuss with Comms whether this announcement would provide an appropriate hook for a statement on the results of the sheep study.

Conclusion

13. Are you content:

(i) for officials to instruct NBS to start the process of importing US FFP for neonates and children born after 1 January 1996;

(ii) to issue a press statement as discussed in para 12 above.

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Annex A

POTENTIAL vCJD TRANSMISSION RISKS AND THE SOURCING OF FRESH FROZEN PLASMA (FFP)

1. This paper examines the cost-effectiveness of three options for reducing the potential transmission of vCJD from Fresh Frozen Plasma (FFP). Risks other than vCJD and supply considerations are excluded in this analysis.

2. Three options for the successive substitution of UK plasma for US plasma are considered for the following group of patients:

(i) **Cost £0.7m pa** - Neonates and under-6s (more precisely, children born after 1st January 1996, who should have had very little exposure to any food-borne vCJD risk)

(ii) **Cost £7.4m pa -**

a: Young people aged 6-16; and

b: Selected adults with conditions Coagulation Factor Defects (CFD), Thrombotic Thrombocytopenic Purpura (TTP) necessitating the use of large quantities of plasma

(iii) **Cost £56.9m pa** - All other recipients.

[NB: Costs are cumulative – the total cost to provide US FFP for all patients would be **£65m pa**].

3. As the prevalence of vCJD amongst donors is unknown, the table below shows the cost-effectiveness of the three options for a wide range of assumed prevalence. The measure of cost-effectiveness used is the cost per life year saved drawing on information from the National Blood Service (NBS) and infectivity estimates from the risk assessment by Det Norsk Veritas - "Risk assessment of vCJD infectivity in blood and blood products".

		Cost per life-year saved (£) for stated prevalence of vCJD			
Age/group at transfusion		1 in 100	1 in 1,000	1 in 10,000	1 in 100,000
Option (i)	<28 days <6years	86	860	8,600	86,000
Option (ii)	6 to16years adults- CFD adults - TTP	1,500	15,000	150,000	1.5 m
Option (iii)	Remaining adults	2,700	27,000	270,000	2.7 m

4. Taking the NICE "benchmark" of £30,000 per QALY as a very rough guide for these circumstances:

Option (i) can be justified on cost per-life year arguments alone even assuming a fairly low prevalence of vCJD.

Option (ii) is significantly less cost effective but could still be justified on the cost per life-year for 6-16 year olds together with the increased risk to specific adult groups (CFD, TTP) having large quantities of plasma.

Option (iii) is the least cost-effective but has cost per life year saved comparable to the NICE "benchmark" for scenarios involving high vCJD prevalence (1 in 1,000 or greater).