NOTE TO CHARLES LISTER

AVAILABILITY / COST OF PLASMA FROM USA

In our memo of 1st August 2001, we highlighted the likely reduction in availability and increase in cost of US plasma for FFP provision. In the conversations between ourselves and with Martin Gorham on this issue during the first week of August, it was agreed that NBS would bring forward costed proposals for a selective, phased approach to provision of non-UK FFP. This approach has been endorsed by the NBS Executive. If required to move to non-UK plasma, our preferred option remains to source plasma from BSE-free areas, which in practice means the USA. A phased approach could be utilised to expedite protection of priority categories of patients who would benefit in the immediate term from any risk reduction strategy. Such patient categories can be identified based on likely post-transfusion survival, unusually heavy exposure to FFP and on likelihood of previous exposure to the vCJD agent via food.

The NBS proposal is to replace FFP for neonates, children and for selected adult patients (e.g. those with congenital factor deficiencies requiring FFP and patients undergoing plasma exchange procedures for TTP) PLUS all cryoprecipitate for neonates and children. This would provide an initial step towards implementation of a full non-UK FFP strategy, and would allow us to gain more concrete information regarding availability of larger amounts of plasma.

This option would require approximately 2 tonnes for neonates and 10 tonnes for other categories of patient. The neonatal products would be methylene blue treated in-house, as in our previous proposals. For other users, our preferred option remains solvent detergent (SD) FFP (option 2b, below) which could be implemented more quickly and is significantly less disruptive. The methylene blue option (either in-house, or externally contracted) remains open to us (option 2a, below). At this level of demand, it is likely that both SDFFP and source plasma (for methylene blue treatment) will be available in sufficient quantities from US voluntary sources.

Financial Implications

1. In house manufacture of methylene blue Neonatal FFP and Cryoprecipitate

Plasma Import Costs	£0.32M
Manufacturing Costs	£0.30M
Fixed costs	£0.05M
Transport	£0.06M
Total	£0.73M

This equates to approximately £27.56/unit compared to the current price of £13.33/unit

2a. Manufacture of special category methylene blue Adult FFP

Plasma Import Costs	£1.59M	
Manufacturing Costs	£1.19M	
Set Up/Fixed Costs	£1.82M	Inc. non recurring set up cost of £0.86M
Transport	£0.35M	
Total	£4.95M	

This equates to approximately £134/unit compared to the current price of £19.96/unit.

2b. Purchase & distribution of SD FFP

Product Cost	£6.03M	
Transport	£0.35M	
Set Up/Fixed Costs	£0.95M	Inc. non recurring set up cost of £0.1M
Total	£7.33M	

This equates to approximately £198/unit compared to a current price of £19.96/unit.

All of the above costings are based on a cost of $188/litre for sourced US Plasma and current exchange rates for the Dollar and Euro.

Costs should be considered as indicative only until detailed contract negotiations have concluded with SD FFP suppliers, MB FFP manufacturers, plasma brokers and others.

Summary

The NBS is faced with a number of competing initiatives for improvements to blood safety. This proposal would allow the NBS to take a first step towards universal replacement of UK plasma used in direct plasma components, with the additional benefit of these components being virus inactivated.

Notes

1. In considering FFP for children, we have not differentiated between those born before or after 1996. The usage of FFP in older children is low and not likely to have a major impact on availability.
2. The estimate of 10% replacement for adult usage is based on a questionnaire to the top 44 FFP users sent out in 2000. This related to the likely demand for MBFFP and did not specifically concern vCJD prevention. There has been no consultation with users yet on any proposals involving a selective approach.
3. This proposal places the responsibility for prescription of the non-UK product with users. This is analogous to prescription of CMV-negative components for high-risk recipients.
4. There seems little logic in replacing cryoprecipitate for all adults if FFP is to remain a UK-sourced product.

References

1. Safer plasma in components, paper for MSBT on options for future provision of clinical fresh frozen plasma; 6th January 2001.
2. Safer plasma in components, follow-up paper for MSBT on options for future provision of clinical fresh frozen plasma; 9th April 2001.

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