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FRESH FROZEN PLASMA

Issue

1. We have some potential handling difficulties around our policy on FFP brought into focus by the introduction this month by NBS of methylene blue treatment of FFP for neonates and children **born after 1 January 1996**. As the rationale for choosing this date relates to vCJD, this raises a number of questions which are difficult to answer in the absence of a decision to import US FFP for this age group.

2. This position is exacerbated by:

- recent PQs and correspondence questioning our continued use of non-virally inactivated UK sourced plasma;

- the same challenge from Octapharma who produce a commercially available solvent detergent treated, pooled FFP made from US plasma but at a significantly higher cost than NBS FFP. As well as lobbying MPs and clinicians, Octapharma are mounting legal challenges, arguing that (a) the pricing policy on NBS FFP is anti-competitive (ongoing for the past four years and currently with the European Commission) and (b) that NHS purchasing policy for FFP breaks European procurement rules (a new challenge on which SOL are obtaining Counsel's advice).

Recommendation

3. To invite Ministers to agree that NBS should begin the process immediately of importing US FFP for neonates and children born after 1 January 1996 (the lead in time is 6-9 months). This is on the grounds that:

- we would be hard placed to defend a decision not to adopt this precautionary measure for this particularly vulnerable group given the outcome of the risk assessment, the cost/benefits analysis and the feasibility study. Therefore, if we are going to have to do it at some point, it may be wise to reduce the risk of future criticism by going ahead now;

- the introduction of MB treatment for this age group does not make sense without the decision to import from the US.

These two points are developed further below. I am also arguing that we can be confident of finding the funding for the relatively low cost of this initiative - £700K in 2003/04 – from whatever is made available for blood in the SR, even if there is nothing specifically earmarked for FFP. Lack of identified funding for this initiative should not, I feel, be a reason at this stage for delaying a decision any further.

Current Position

4. Up to now we have been holding the line that MSBT is reviewing the position on FFP. However, as a result of discussions in MSBT, NBS have pressed ahead with the introduction of MB treatment for UK FFP for neonates and children born after 1 January 1996. They planned to issue a press statement announcing this last week but have postponed release, at our request, until our lines are clearer.

5. An announcement on MB treatment of FFP raises a number of questions to which we do not have adequate answers, including:

- why this age group/why now?

- does this mean that UK non-MB treated FFP is less safe? What risks are patients/me/my child being exposed to?

- When are you going to extend MB treatment to FFP for other age groups?

6. These questions can only be answered honestly, and without casting doubt on the viral safety of the bulk of UK FFP, if they are directly linked to a decision on importing US FFP. It can of course be argued that MB treating paediatric FFP (as they already do in Scotland) adds an extra margin of safety for a particularly vulnerable group. But the choice of the post 1 January '96 group can only be explained in the context of vCJD risk reduction, and MB treatment of FFP for this group makes even more sense if it can be put into the context of the increased viral risk from US plasma.

7. This development is one I should have anticipated, as we were aware (however dimly) that NBS were pressing ahead with the introduction of MB treatment. I therefore apologise for raising this after the event. However, I feel that, nonetheless, there are good reasons for taking a decision now on the provision of US FFP for this high risk group:

- it is immediately do-able and cost-effective;

- given the vCJD risk assessment considered by MSBT, the favourable cost/benefits analysis, and the ready availability of the small quantities of plasma needed from the American Red Cross (from non paid donors), I do not see how we could justify continuing to use UK FFP for a group not exposed to vCJD through the

food route. It is known publicly that MSBT are considering the issue and at some point soon we are going to have to explain the outcome;

- the cost is low (approx £700K pa, although this cost will rise incrementally as more children fall into the post 1 January 1996 category);

- the 6 to 9 month lead-in time to bring in US FFP means that the costs will not fall until 2003/2004. It will then be 2 years after MSBT advised that we should switch to US FFP subject to sorting out supply and logistical issues;

- even if no money is earmarked for US FFP in the SR, we can be confident of finding £700K from whatever is made available for blood;

- Scottish Ministers have already taken a decision to import US FFP for this group, although the money has not yet been found to do it. Wales and Northern Ireland anticipate doing it from 2003-4.

8. In addition, the newly published results of the sheep study (on the Journal of General Virology website) provide further evidence of the risk of TSE infection via blood.

Conclusion

9. Are you content for us to go to Ministers now recommending that NBS are instructed immediately to begin the process of importing US FFP for neonates and children born after 1 January 1996? If you are agreeable, I would like to get this to Hazel Blears by 24/25 July in the hope of obtaining a decision before her summer break.

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