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From: Mr M Harris HS1
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Para 6 overleaf is not entirely correct. The fact is DHC did not give this priority against other [redacted] bids. However let us see how FA respond.

TESTING BLOOD DONATIONS FOR ALT

3.2.88.

Summary

We have a potential problem which could involve writing off £40m of plasma stock, expenditure on imported blood products of £10m, and a recurrent bill to the BTS of £3m per annum. There is a good chance this could be avoided if we can find £72,000 to fund a study by 2/3 Regional Transfusion Centres.

Background

2. Non A non B hepatitis (NANBH) is an infectious disease which can be transmitted by blood and blood products. A test has been developed which can identify NANBH carriers by detecting raised levels of alanine transferase (ALT) in their blood. However raised ALT occur for other reasons, and not all NANBH carriers have a raised level. It is not therefore a test which we would want to introduce into the NBTS esp as a) it is not a good test; b) our donor pool is likely to contain few carriers (a by-product of eliminating those at high risk of AIDS); c) it would cost £3.5m p.a.

3. However all major producers of blood products now use plasma from ALT tested blood. This has put up commercial prices of factor VIII etc. They have introduced the test because a) their heat treatment process does not inactivate NANBH virus; b) to reduce the risk of being sued by being seen to do all that they could to reduce risk; (In fact once one manufacturer broke ranks commercial pressures dictated all had to follow); and c) pressure from the International Haemophilia Federation.

4. This puts pressure on BPL (CBLA). They (rightly) fear that this development makes their product appear 'second class'. Not using ALT tested plasma could leave them vulnerable if an action was brought against them (albeit that they believe their heat treatment process does inactivate NANB) under the new stricter product liability legislation (Consumer Protection Act 1987). Given the awareness amongst MPs and the media of haemophiliacs and AIDS I have no doubt the Haemophilia Society could mount a very successful political campaign to get us to test for ALT. They may not do so but if they or the clinicians treating them did so then the consequences would be grave. Achievement of self sufficiency depends on BPL running down stockpiled plasma while RTCs build up to their collection targets. We cannot test this stock pile for NANBH. We would need to continue to input products to the value of around £10 million, and write off the stockpile which is worth around £40 million.

5. We could reduce the likelihood of pressure from haemophiliac centre directors and the Haemophilia Society by attempting to demonstrate a) the low incidence of NANB carriers in the NBTS donor pool and b) the low utility of the ALT TEST. Dr Gunson CMO's Consultant Advisor (and RTD of NWRHAO has put forward proposals for a study to do this. Such a study could (against all expectations) prove the need for the ALT test, even so it would then have

provided scientific justification for the resulting expenditure. Even having a study in train, would give Ministers a valid reason for not being 'bounced' into accepting ALT testing.

6. The R & D programme cannot find room for this study - cost £72,000. In view of the serious financial consequences for the HCHS can it be exceptionally found from the HCHS central fund?

7. I feel that Ministers would not thank us for failing to head off this folly.

[redacted]

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