POLICY IN CONFIDENCE

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Date: 7 January 1994

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(minute only)

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File

BIOLOGICAL SAFETY OF BLOOD: SCREENING FOR RARE VIRAL INFECTIONS

Thank you for your note of 24 December covering Perm Sec's comments on my earlier draft submission. I have discussed the comments with Dr Rejman.

We have expanded the submission to include an Annex B which contains data about the lack of cost effectiveness of anti-HTLV screening and the hypothetical cost of ex gratia payments for those who develop clinical disease through transfusion transmitted HTLV. We enclose the relevant part of the draft submission (paragraph 12) and the draft Annex.

We were uncertain about your suggestion to compare the justification for screening HTLVI and HTLVII. The same screening test identifies both and supplementary testing is required to separate I from II, so the major costs would be the same. Moreover HTLVII is not yet associated with clinical disease and therefore there would seem to be little merit in demonstrating the cost benefit of this particular test.

J CANAVAN

ANNEX B

COST BENEFIT CONSIDERATIONS – HTLV
(Human T-cell leukaemia/lymphoma virus)

(i) Introduction

The question of testing blood donations for HTLV has already been considered on several occasions and Ministers accepted the expert advice that it should not be introduced at present. New combined tests for HIV and HTLV may make testing worthwhile in future but at present the cost/benefit considerations of separate HTLV testing are highly unfavourable. By way of an example of the cost benefits of screening for rare viruses this note outlines the risks associated with HTLV, the costs of screening and the hypothetical cost of ex gratia payments for those who develop HTLV associated disease as a result of a transfusion.

(ii) Morbidity and mortality

HTLVI is a human retrovirus but is not associated with HIV and does not lead to AIDS. HTLVI is endemic in some parts of the world but not in Europe. The virus can be transmitted by breastfeeding, sexual intercourse and, less commonly, by blood transfusion. HTLVI infection may result in Adult T-cell leukaemia/lymphoma (ATLL) or tropical spastic paraparesis (TSP), both of which are incurable.

There is a similar virus HTLVII but as yet no clinical disease has been generally accepted as being caused by this latter virus.

(iii) Incidence of HTLV in the donor population

In early 1991 a survey was carried out by the North London Regional Transfusion Centre to determine the incidence of HTLV among their donor population. Screening tests do not differentiate between HTLVI and II, for which supplementary testing is required. The true incidence of HTLVI was small at 4 donors in 96,720 tested which is 0.004%. (One donor was positive for HTLVII). All 4 of these HTLVI antibody positive donors had sexual partners with connections with endemic areas of the world. Therefore the donors themselves would not have been excluded by applying racial exclusion criteria. The incidence in other parts of the UK is likely to be even less as a smaller proportion of the population comes from endemic areas.

(iv) Risk of Transfusion Transmitted Disease

Clinical studies in naturally occurring HTLVI (ie HTLVI which has not been transmitted through blood transfusion) show life time risks for developing TSP of 0.25% and of developing ATLL of between 2% and 4%. There have been no reports of ATLL developing following HTLV infected blood transfusion. However in our consideration of cost benefit we included ATLL as a

risk. Taking the two figures together every year up to 6 people may be put at risk of HTLVI associated disease in their lifetime. This figure is approximately halved by virtue of recipients of half of the blood dying of their primary condition within 1 year of transfusion.

(v) Cost of screening

In view of the false positive/negative rates with HTLV tests initial screening and confirmatory testing would be required. The cost of the screening programme including confirmatory testing and staff time is estimated at £3.5m a year.

(vi) Ex Gratia Payment

The calculations of the cost of ex gratia payments are based on lifetime risk and in the first years there would be very few actual cases. Based on the North London study, the minimum cost of preventing a single transmission by transfusion, which is not in itself harmful in the vast majority of cases, is about £25,000 and of preventing the risk of HTLVI associated disease developing in a recipient's lifetime, about £1.2 million. This is on the assumption that ATLL can occur after transmission.

Based on the lifetime risk the cost of payments in line with those for HIV infected haemophiliacs and blood transfusion recipients would be as follows:

Cost per case (assuming an infected person married with children) = £80,500 - the maximum amount paid to any individual.

TSP -	1 case every 5 years	
	Annual cost of ex gratia payment	£16,100
	Annual cost of screening	£3.5m
	Cost to prevent 1 Case	£18m

If ATLL does occur following transfusion of HTLVI positive blood (ie ATLL plus TSP) then the cost of 3 cases of ATLL/TSP per year is estimated at:

Annual cost of ex gratia payment (ATLL plus TSP)	£257,600
Annual cost of screening (ATLL plus TSP)	£3.5m
Cost per case of preventing clinical disease	£1.2m

complexities of handling and processing the larger number of tests. There is the problem of increased chances of missing a positive, increased documentation, the risk of including donations which should have been quarantined etc.

10. Another aspect that needs to be considered is to ensure that the supply of blood and organs is not restricted by testing and excluding donors to such an extent that there is greater morbidity and mortality due to lack of supply than there is saved by non transmission of infection.

11. It is also important to take into account that the recipients of 50% of blood donations will die within 1 year from their primary illness.

12. Additionally the costs of introducing a test must be considered and these include the cost of the kit (which range from 50p to £2.30 for tests currently used by the UKBTS), and any confirmatory tests, staff time and the replacement cost of donors and counselling and possibly treatment of positive donors. The overall cost can be very substantial as over 2 million donations are collected annually in the UK. Annex B contains an example of the cost benefit considerations for testing for an example of a rare virus (HTLVI) which did not support its introduction.

13. If a test is expensive and the number of people who will benefit by the test is very small, then consideration needs to be given to whether some form of recompense to the few individuals who are infected would be more appropriate than carrying out the test. We have payment schemes for those who were infected with HIV through treatment, for their own benefit, with blood products, blood transfusion or tissue transfer. There is a possible parallel with the vaccine damage infants, but in that case infants were vaccinated to generate herd immunity, more than for their own individual benefit.

PRESENT POSITION ON COMPENSATION

14. Apart from the HIV cases, compensation for individuals