

## D R A F T

## POLICY IN CONFIDENCE

PS/S of S

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cc:

## HIV INFECTED BLOOD TRANSFUSION AND TISSUE RECIPIENTS

Summary

1. Now that it has been decided to give financial help to the blood transfusion and tissue recipients infected with HIV, we are devising the arrangements for the assessment of claims and payment. In this submission we are seeking the Secretary of State's agreement to the outline of a scheme.

General

2. We are following the principle that the blood and tissue recipients will be put on broadly level terms with the HIV infected haemophiliacs. Many aspects of the proposed scheme are therefore modelled on the arrangements and conditions made for the haemophiliacs. However, as the Secretary of State knows, there will be particular problems over the validation of claims from blood and tissue recipients and we shall need an expert panel to sift the available evidence and make decisions which will be difficult in some cases. This will mean that the process of making payments will be more protracted than for most haemophiliacs.

3. The main features of the <sup>proposed</sup> scheme we are ~~proposing~~ are outlined in the Annex. Many of the details will need to be refined after discussion with the CDSC and the National Blood Transfusion Service. We ~~propose to start the discussion as soon as an announcement is made. At this stage, though~~ it would be helpful to know if Secretary of State is content with the type of scheme outlined and to have his views on the issues considered in the following paragraphs. *and others* *At this stage*

Scope of Scheme

4. The campaign for compensation has focussed on the blood transfusion and tissue recipients. However, we think it will be necessary to include those non-haemophiliacs infected with HIV through treatment with blood products. These people do not qualify for the payments to haemophiliacs and it will be difficult to defend excluding them from the new arrangements. Our ring fence would then be round those who acquired HIV through medical treatment. One case of a non-haemophiliac infected through blood products has recently come to light in Northern Ireland. The CDSC tell us there are reports of eight such cases.

*Verdall*

*but it would be difficult to  
apply a cut-off date*

5. Most HIV infections from blood/tissue will have occurred between 1979 and October 1985 when testing was introduced. However, it is still possible that infection could be transmitted from a donor who was in the 'window period' at the time of testing.

*Moreover*

However, one of the reported tissue cases was infected in 1986 as the donation was used before the test results for the donor were known. ~~(This ongoing risk has been virtually eliminated for blood products because of the ? steps in the manufacturing process.)~~

*that*

Apart from one tissue case there have been no reports of infection from blood/tissue transmitted since 1985 but we think it would be better to avoid having a rigid cut-off date for the new scheme. However, claims of infection from blood or tissue after 1985 would have to be examined particularly closely in view of the safeguards then in place.

*Leave the scheme open sufficiently far into the future which might result in bad cases a closing date*

6. In accepting claims after 1985 it is possible that negligence will have been a factor in the transmission of the HIV. However, it would be difficult to refuse payments from the scheme in such cases as this would require the panel to make decisions about culpability which may or may not match any subsequent decision by a Court. However, we are proposing that in any subsequent Court award for medical negligence a credit should be given for payments under this scheme. This will limit the demand on the health budget overall even though the Department will have to fund the award under the scheme.

*those grounds*

#### Validation of claims

7. This will be a particularly difficult area and we propose to have early discussion with the CDSC and MBTS on the extent to which validation of claims will be possible. In some cases the examination of existing records or testing of stored samples will resolve the question whether the HIV infection arose from the blood or tissue used.

8. Beyond these cases the position is much more difficult. We assume that Ministers would not endorse any follow-up to obtain further samples from donors so that HIV could now be carried out. The options are therefore:

- i) To make payments to all those infected with HIV who have had a blood transfusion or received tissue. However, this is potentially an expensive and open-ended commitment.
- ii) To make payments unless examination of existing records can eliminate the donation as a source of infection.
- iii) Where the status of the donation cannot be firmly established to consider the case on the balance of probabilities; this would include the timing of the transfusion/tissue transplant; clinical history of the case and limited consideration of lifestyle, eg is there a record of treatment for drug abuse; questions could be asked about associations with high risk countries.

Officials favour the third of these options.



### Follow-up of potential claimants

9. The examination of particular claims may bring to light that a donor was infected and other recipients of blood/tissue were at risk. We shall need to decide whether in such circumstances we should seek out the other recipients to invite them to be tested for HIV and to claim help under the scheme, if appropriate. There are arguments for and against a pro-active approach.

- The recipients of blood/tissue may benefit from early intervention if there is infection. On the other hand they would have to live with the social, insurance and other consequences of knowing they are positive. Moreover those who tested negative would still have been caused anxiety while awaiting the results.
- The partner of the recipient may avoid infection if the recipient of blood/tissue is told of the risk. We could be in a difficult legal position if someone became infected after we had identified a risk from blood/tissue.
- In the public health interest it could be argued that it is important to tell blood/tissue recipients of the HIV risk to help prevent further transmission in the community.

10. A pilot follow-up study ran into difficulties at the time HIV testing of blood donations was first introduced. Some Consultants and local ethical committees resisted efforts to trace recipients. They argued there was no benefit to the patient who was likely to die from his primary disease in the near future and additional distress would be caused to the patient and his family from knowing he was infected with HIV when he was dying of another disease. Current policy is swinging towards follow-up testing and last year when a potential risk to patients from an infected medical worker was identified the patients were contacted and offered fast track testing. However, there are difficult medical, ethical and legal issues to be discussed further with colleagues and we shall put forward advice on ~~follow-up~~ as soon as possible.

### Payments

11. The payments proposed in the Annex are those paid to the infected haemophiliacs and infected partners and children. The litigation settlement also provided a payment of £2,000 for those uninfected family members taking legal action on the grounds that they were at risk from the haemophiliac. This claim was not well founded but it would have been difficult to end the litigation without making some payment. Relatives outside the litigation were not paid the £2,000.

12. We propose not to make such payments in the blood transfusion/tissue cases. To entertain claims from uninfected relatives could prompt claims from the non-litigant relatives of haemophiliacs.



## Special Needs

13. The haemophiliacs have access to special needs payments through the original Macfarlane Trust. In order to make a clean break with the problem of the blood transfusion/tissue cases it will be necessary to make some arrangement for a special needs fund for this group. This could be done by extending the remit of the Macfarlane Trust, if the trustees agreed, or by setting up a new charitable trust. It is likely that some money, say £½ M, would have to be found to endow a new trust or to avoid the appearance of diluting the haemophiliac fund (the Macfarlane Trustees have already asked for a meeting with officials to discuss future funding). There is some flexibility over timing as blood/tissue cases will have to establish their entitlement under the new scheme before they could have access to the special needs fund; they will also be receiving considerable sums which should defer the need to call on a special fund.

14. However, Ministers may be asked ~~before too long~~ about their intentions and would probably wish to confirm that the blood transfusion/tissue recipients will have access to a special needs fund. ~~We could also find out after the announcement whether the Macfarlane Trustees would be willing to extend their activities to the new group. Administratively it is probably easier to change their deed than set up a new trust. There may also be presentational benefits from linking the blood and tissue cases with the haemophiliacs.~~

### Expert panel

Mr Benet Hytner QC, who is an experienced personal injuries lawyer, has agreed to chair the expert panel. Medical colleagues are considering who might be approached to serve as medical assessors and we shall let Secretary of State know the names as soon as possible. The panel will need a formal remit and we now propose to begin discussing this with Mr Nytner.

### Summary/Decisions

16. We need to have detailed discussions with CDSC, NBTS, the Panel Chairman, Macfarlane Trustees and the Plaintiffs' Solicitors before finalising a scheme for the infected blood transfusion and tissue cases. At this stage <sup>though</sup> it would be helpful to know if S of S is content:

- i) that we should begin those discussions on the issues <sup>raised</sup> discussed in the submission;
- ii) with the broad proposals outlined in the Annex and in particular with the proposals:
  - a) to include infected non-haemophiliac recipients of blood products;
  - b) not to have a rigid cut-off date for transfusion/tissue transfer ~~to allow for the window period;~~ <sup>infection;</sup>

- c) for claims to be determined on the balance of probabilities;
- d) to exclude uninfected relatives from the scheme;
- e) to provide access to a special needs fund and for us to explore the possibility of extending the Macfarlane Trust *and to consider the options for funding the arrangement.*