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POLICY-IN-CONFIDENCE

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THE BIOLOGICAL SAFETY OF BLOOD: SCREENING FOR RARE VIRAL INFECTIONS

1. The screening of donations for viral and other transmissible infections is one of the important safeguards for ensuring that the blood and blood product supplies are as safe as realistically possible. The range of tests available is gradually being extended but increasingly these are intended to detect very rare infections. Ministers' views are sought on the principle of whether an effective screening test for a very rare transmissible infection should be introduced, just because it is available, even when the cost of general introduction throughout the blood service would cost millions of pounds a year. For such rare infections, it can be argued that it would be more cost effective to provide ex gratia payment for the very small numbers of recipients whose infection was the result of transfusion or use of blood products.

Background

2. Blood and its constituent parts, red cells, platelets and plasma are biological substances collected from humans and as such carry risks of biological infection. Even with the best systems, there can never be an absolute guarantee of freedom from transmission of infection, particularly where the infective agent is either unknown or has not been demonstrated (the classic example was HIV). There are also other risks of the use of blood such as incorrectly cross-matched blood, fluid overload, etc, which cause morbidity and mortality but which are not considered here.

3. Many commercial companies are trying to produce synthetic products which will carry out the function of some of the

constituents of blood. Factor 8, used in the treatment of haemophilia, has recently been manufactured using recombinant technology. This is only licensed in two or three countries, not in the EC, and has additional clinical problems as well as high costs. Other constituents of blood are being tested in clinical trials but it is not known when they will be available for general use.

4. This submission is about screening of blood for markers of infection in the UK. Some tests also apply to plasma and are usually required of any licensed blood products imported into the UK. However, UK decisions not to test for a particular marker are not necessarily reflected in other countries and there are already examples of tests done elsewhere which are not done in the UK. For instance some imported blood products licensed in the UK are made from plasma tested for ALT. The UK can set minimum requirements for tests of imported blood products but any additional tests are a matter for the producer.

Screening and Testing for virological and other biological markers

5. The safety of the blood supply does not depend solely on the laboratory testing of the blood. The exclusion of donors who may be at risk of transmitting infection is an important safeguard. The self deferral and self exclusion system is particularly important, in that some infections, particularly HIV, have a "window period" when the test will not pick up a recent infection. Examples are risk activities for HIV or travel to tropical countries leading to long term self exclusion of donors or temporary self deferral. Currently donors fill in a form covering the relevant points, it is likely that in the near future donors will be individually interviewed prior to giving blood.

6. In the case of fractionated blood products such as albumin and Factor 8, there is an additional safeguard as the manufacturing process is designed to destroy the majority of infectious organisms, particularly HIV, Hepatitis B and Hepatitis C. However, EC and UK guidelines do not differentiate in most instances between plasma and blood in respect of tests that are to be applied to donations.

7. Annex A lists screening tests available on the basis of whether they are deemed compulsory by the EC. It includes brief notes on each test.

COST BENEFIT CONSIDERATIONS

8. The MSBT (The Committee for Microbiological Safety of Blood and Tissues for Transplantation) is the Committee that provides advice to Ministers on the introduction of new screening tests for blood and blood products and organs/tissues for transplantation collected in the UK. The Committee includes virologists, microbiologists, blood transfusion experts and fractionators. The Committee considers each suggested test under several headings:

(i) Morbidity and mortality
(ii) Incidence in the general population and donor population
(iii) Sensitivity of the test (number of false negatives)
(iv) Specificity (false positives)
(v) Confirmatory tests
(vi) Feasibility of use of tests
(vii) Costs

9. Each test that is added to the repertoire of testing of blood increases the risks of mistakes occurring because of the 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 harmed by blood transfusion or blood products could only be obtained either:

a. on the basis of product liability, or
b. by proving negligence

15. Under (a) the individual would not have to prove negligence, simply that the blood (blood product) supplied had been defective

and that it had caused injury. However, suppliers can rely on a 'state of the art' defence and whether the steps taken by the supplier to ensure the safety of the product were in keeping with those generally accepted as reasonable. Our understanding is that under the EC Directive on Product Liability a supplier would not be liable if he acted in accordance with national regulations. If the test were not to be mandatory, it would not, therefore, be certain that a person harmed by blood or blood products would have a case under the product liability law.

16. Under (b) an individual would have to show that a decision not to test for the virus which caused the harm was unreasonable. In determining whether this was the case the Courts would among other factors have regard to the practicalities of testing and the cost benefits of doing so. In the case of a very rare infection, it may be very difficult for an individual to prove negligence simply on the basis that an effective screening test was available but had not been used if the cost/benefit considerations were highly unfavourable.

17. In addition to the above methods of compensation, it is always open to Ministers to make ex gratia or other payments where the special circumstances warrant it, eg those mentioned in para 13.

Case For and Against Special Ex Gratia Payment Arrangements

18. The arguments in favour of such an arrangement are:

* it would be much less costly than moving towards a policy of screening for every virus for which a test exists, irrespective of the extent of the threat. Against the background of the events in France and Germany and the increased use of litigation, the MSBT may become more reluctant to advise against the use of effective screening tests solely on grounds of cost.

* decisions not to test for rare infections could be more easily defended if the small number of people harmed by that decision could be certain of recompense.

* we avoid having a multiplicity of tests which in itself could be a threat to the safety of the blood supply.

The arguments against special arrangements are:

* public perception about the safety of the blood supply could be undermined. Financial savings could be portrayed as being more important than maintaining safety and the risks could be considered greater than in fact was the case.

* there would be a two tier system for those treated with blood products which were untested for a particular rare virus. For those harmed as a result of our decision not to test there would be a special payment available; for those harmed by imported blood products also untested there could in logic be no claim to a special payment from DH as

the decisions about not testing would have been made elsewhere. (Individuals harmed by the imported blood product would have to rely on claims for negligence or under product liability.)

* any extension of Government payment schemes would further encourage groups such as growth hormone/CJD campaigners.

* pressure could increase for compensation for victims of other medical accidents. Many medical interventions carry a known risk of damage and those who do suffer may not see themselves as different from those knowingly exposed to a low risk from blood. Even though, we might argue in the case of blood that a deliberate decision had been made not to eliminate the risk of viral transmission through testing whereas with other treatments there may be no way of avoiding the risk associated with it.

* there would in fact be difficulty in deciding where to draw the line. High cost low risk presents little difficulty but there are grey areas where the decision is not so clear cut. Also there is the possibility that EC requirements or public pressure could result in testing where the cost benefit argument was not favourable eg another HIV. In consequence the policy might be perceived to be riddled with anomalies, and therefore difficult to defend publicly.

Implementation

19. If the principle of setting up an ex gratia payment scheme were accepted then the precise details of its operation would need to be fully considered.

SUMMARY

20. Blood transfusion is inherently unsafe. No matter how many tests are applied, transmission of infection will occur and this is something that the public and media seem to have difficulty in understanding. The tests themselves may not be infallible, and there is the risk of human and machine error.

21. However if a test is available for a rare infection but which satisfies all the normal criteria other than its expense, should testing be omitted and infected recipients who suffer clinical harm be recompensed in some form? Is there a difference between such individuals and victims of other treatments known to carry a small risk?

22. At this stage Ministers' views are sought on whether the principle of ex-gratia compensation should be further considered. The alternative will be the introduction of progressively greater numbers of screening tests for all blood donated in the UK, even when the number of recipients at risk of harm for rare and unusual infections transmissible by blood transfusion will be very small. More detailed economic analyses will be worked up if Ministers find the principle of ex-gratia payments acceptable.

23. Officials would be happy to have a meeting with PS(H) to discuss the issues involved.

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