SUMMARY OF THE RESULTS OF THE NATIONAL INSTITUTES OF HEALTH CONSENSUS DEVELOPMENT CONFERENCE STATEMENT ON THE IMPACT OF ROUTINE HTLV-III ANTIBODY TESTING OF BLOOD AND PLASMA DONORS ON PUBLIC HEALTH

Held on 7-9 July 1986, at the National Institutes of Health, Bethesda, USA.

1 **How safe is the blood supply?** The supply is much safer than 2-4 years ago. The tests have been refined and are more accurate and they have essentially removed all antibody positive persons from the donor pool.

2 **What are the chances of contracting AIDS from blood transfusions?** In the USA the chance is now less than one in 10,000 and this compares favourably with the risk of dying from general anaesthesia which may be greater than one in 10,000 general anaesthetics.

3 **The antibody test.** The Elisa test has produced a number of false positives because of its sensitivity which is a requirement to endeavour to exclude <u>all</u> levels of antibody positive status. The Western Blot test which takes a few days to complete is used to confirm the reactivity displayed on the Elisa test. However, a repeatedly reactive Elisa test, even though negative on Western Blot, cannot be used in the case of blood samples which are to be added to the donor pool. This is to be entirely certain that no virus enters the donor pool.

Units of blood which show repeated activity or even an initial reactivity on the Elisa test, irrespective of the "confirmatory" Western Blot test have to be wasted and in America at the present time this means that 20,000 units of blood per year are being poured away. Under current arrangements the persons donating this blood are <u>not</u> notified and are therefore ignorant of the test situation. Accordingly, they may well donate on regular occasions but in each case their donation is discarded.

4 **A perfect test.** At the present time the technique of using Elisa initial testing systems with confirmatory Western Blot test, suffers from technical problems. Essentially, the Elisa test will not only show reactive ('positive') in respect of antibody to HIV but also to other antibodies, or other serum substances, in some individuals. The Western Blot test is specific for antibody to AIDS virus, but again is not 100% confirmatory. What is needed is a specific antigen test which will always in 100% cases demonstrate the presence of infection. Such tests are under development currently in the USA and possibly elsewhere.

5 **What is the current status of the virus infection in the USA?**

(i) 12,000,000 donations of whole blood are given each year.

(ii) 12,000 of these donations present with evidence of possible virus infection.

(iii) 99% such donations are screened out by effective Elisa screening and Western Blot confirmatory testing. In the USA, between a third and a tenth of all "reactive" blood samples will be shown to be positive by

confirmatory Western Blot technique. However on the basis of the present small inadequacies in the technology of the testing systems approximately 120 infected units of blood may theoretically get through the system.

(iv) In the situation that each unit of blood has several uses, on average 1.5 - 3 persons may be infected by subsequent use of the blood donated.

(v) However, it is not exactly known how many 'positive' donations contain infectious virus but all 120 possible donations must be suspect.

6 **The "look back" procedure.** Since January 1983 it has been known that possible contamination of the USA blood bank system has occurred due to the level of infection and the problems associated with accurate testing. Since that point in time there has been a "look back" procedure which means that when a blood donor is now found to have a positive response to antibody testing, his background donations or persons receiving blood in the past must be examined to investigate the possibility of previous donations having been used and thereby contaminating further individuals. It was decided at the Consensus discussions that persons who received blood transfusions over the past 4 or 5 years should now consider it important to investigate their antibody status. The mechanism for initiating such investigation may come either from the individual or from his medical advisors and blood bank professionals.

7 **Confidentiality of persons identified to be antibody positive.** Test results should be released to parties other than the patient only when there is a demonstrated and scientific need to know for public health purposes and, in principle, with the patients specific consent.

8 **The consideration of false positive donations and the individuals concerned.** In the USA according to the previously discussed problem of inadequate testing systems, there are now 20,000 individuals whose donations are being discarded because of initial or repeated reactivity on the Elisa test. These individuals have not been contacted or notified or counselled in relation to this test result. This contrasts strongly with the situation in the UK where all persons found to be "antibody positive" are offered counselling and support and discussion regarding the test.

However, it was the consensus agreement that the USA should now make definite efforts to contact all 20,000 donating individuals to explain the system regarding the tests and advise them that their blood samples are not being added to the donor pool for technical reasons, and that they are unable to continue donating blood.

9 **Methods of notification in the wide spectrum of blood bank systems used in the USA.** It is found that the notification regarding tests is carried out in various ways which include: a general letter telling donors that there are problems and that they should discuss the matter with the blood bank department or a specific letter indicating that a 'false positive' or dubious test result has been obtained or a personal

telephone call is made to the person donating the blood to arrange for a personal meeting. Subsequent face to face discussions are arranged and in the case of truly positive donors, education and video systems are used to ensure that the information regarding their new status and the dangers of donating blood and unprotected sex are made clear.

10 **The "false positives".** The great majority of such units of blood are perfectly safe, however, they will continue to be removed from the system and as discussed above such donors will be informed in future.

The names of such persons will be maintained on "internal lists" in the blood-taking organisation. The donors will be told of these lists and the names will not be made public or even offered to state authorities. Such people should be counselled tht although the blood is 'reactive' and not useable, there is very little chance that they have been infected.

11 **Neonates.** Young infants may obtain blood donations from a large number of sources. In the USA an average number of 6-8 individual units of blood may be used, in small quantities during the period of treatment of neonates. This means that they are in an unusual situation and at a higher risk than the normal population undergoing hospital treatment. Furthermore, babies are very susceptible to infection because of their immature immune status during the period of early post natal development.

12 **Surgical patients.** It has been recommended by the Consensus Development Panel that patients in the USA should consider the use of autologous blood transfusions. This means that some weeks prior to the surgical technique they will donate their own blood which will be prepared in the eventuality that they need a transfusion at the time of the operation. This has the backing of the Consensus Panel.

However, the use of 'directed transfusions', that is the soliciting of friends or relatives to donate blood for an individual, prior to surgical need, is <u>not</u> supported by the Consensus Panel. It has been found, interestingly, that such donations are <u>no</u> more likely to be safer than the general pool of blood available for the transfusion service, and its use could lead to <u>two</u> blood transfusion systems in the USA.

13 **Directions for the future.** It is clear that the present test technology is imperfect. However the use of any one of the licensed Elisa test kits, followed by confirmatory and more technically difficult, Western Blot techniques has shown that 99% of blood presented for the transfusion service in the USA can be cleared.

In the absence of a 100% antigen specific test or any practical specific virus culture techniques it is clear that at least two directives must be followed:

(i) All persons who are or may be antibody positive must be persuaded to leave the donor pool and to refrain from giving blood ever more. The panel also urged all blood banks to develop confidential procedures under which individuals who might be infected with HIV but who nevertheless

felt social pressure to donate blood, could do so, while indicating privately that their blood should not be transfused.

(ii) Public health education activities must be increased to ensure that everyone understands the problems of donating infected blood and this will include improvements in the questionnaire or screening procedures used prior to the actual physical technique of taking blood.

14 The Essential requirements for the prevention of transfer of the virus by intimate contact between homosexuals or I.V. drug abusers etc. must be reinforced and all efforts must be made to educate the population at large.

Considering that the next great threat from AIDS may come from heterosexual spread, means should be found to educate young, sexually active persons about the hazards of AIDS and how the infection can be avoided.

SUMMARY

A policy of protection of the individual donor's privacy should be vigorously pursued; however, blood banks must be responsible for properly informing the individual and arranging for counselling, as well as for protecting the individual's sexual contacts. Much needs to be learned about the short- and long-term psychosocial adjustment problems of healthy people who are told they have a disease that may prove fatal.

Every aspect of the problem requires continuing research. More sensitive tests that more specifically identify infectivity must be developed and tested in epidemiologically sound ways. Better methods of discouraging possibly infected donors and handling the psychosocial problems occurring in those with positive tests must be discovered through sound research projects.