American Red Cross

National Headqua

To: Blood Services Management Group

Date: March 31, 1982

From: Dr. Dodd

Subject: Attached

The attached report is a first draft of background material to be presented to the Blood Services Committee. I have also attached a copy of a publication discussing the ALT research study and a manuscript summarizing the current status of ALT testing.

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RYD:ms
Enclosures

Blood Donor ALT Testing

A high incidence of liver dysfunction has been found to occur among recipients of blood transfusion. Some 10 to 12% of recipients develop elevations of the enzyme, alanine aminotransferase (ALT, SGPT) in their serum. This event has been defined as hepatitis, although only 20% of the cases show any additional signs or symptoms of liver damage.

Two recent studies have shown that blood from donors who themselves have elevated ALT levels is more likely to result in post-transfusion liver dysfunction in the recipient. This has led to suggestions that, if blood with elevated ALT levels is withheld from transfusion, then the incidence of post-transfusion NANB hepatitis might be reduced by some 30%. It should be emphasized that these predictions actually apply to post-transfusion ALT elevations rather than to clinically apparent hepatitis and it is not yet clear how much significant disease might be prevented by ALT testing. Prospective studies of this type suggest that there may be 10 to 30 cases of this form of hepatitis infection per 1,000 blood units transfused while only 13 clinical cases are reported for every 100,000 units issued by the American Red Cross Blood Services. On the other hand, approximately half of the post-transfusion infections appear to last for more than six months, indicating a potential for the development of progressive liver disease.

Because of the implications of these post-transfusion studies, a number of ad hoc committees and steering meetings have discussed the issue of donor ALT testing. The three major blood collecting organizations have

established the position that there is currently not enough information upon which to base a firm policy decision on this issue. It has been agreed that any decision should reflect a general consensus and that more data must be available before such a consensus can be developed. The position is effectivly summarized in the statement of the AABB ad hoc committee which is attached to this report.

The Blood Services Transmissible Diseases and Immunology Laboratory has examined the the distribution of ALT levels among 23,000 Red Cross donors from five different regions. This study has clearly shown that the proportion of donors with ALT levels greater than a certain value varies significantly from region to region. In other words, it may be necessary to reject 2 1/2% of the donors in one region but 5 1/2% in another. It has also been shown that the overall rejection percentage may vary during the year rising from a mean value of 3.2% to a peak of 4.3% in December and January. A number of factors associated with a donor's genetic makeup or life-style also lead to ALT elevations. These data show that ALT elevations cannot be used to identify donors who may transmit hepatitis viruses.

Two other factors should be mentioned. First, as a result of contact with manufacturers, the Red Cross has stimulated interest in the development of ALT tests which can be performed upon a finger-stick sample prior to phlebotomy. Thus, if ALT testing should become mandatory, we believe that at least two such test methods will be available. Their use will prevent the wastage of blood which will occur if testing has be be performed on blood units which have already been collected. Second, a

careful cost-benefit analysis has shown that at this time, there is insufficient information about clinical forms of post-transfusion hepatitis to determine whether or not donor ALT testing would be advantageous.

In summary, post-transfusion NANB hepatitis has been perceived as a significant problem. However, the true magnitude of this problem cannot be properly estimated at this time. Nevertheless, it has been suggested that rejection of donor blood with high ALT levels would reduce the incidence of this infection. This proposal has not yet been tested by controlled studies. Evaluation of the expected effects of ALT testing upon the blood delivery system has identified a host of real or potential problems. The magnitude of these problems is such that a full analysis of all advantages and disadvantages of ALT testing must be performed before policy decisions are made. Therefore, it is recommended that Blood Services should not implement donor ALT testing at this time.