American Red Cross

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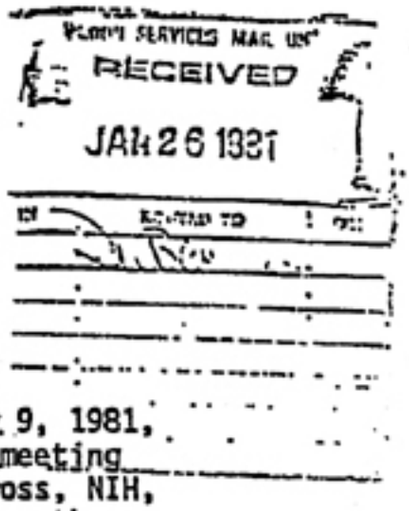

Louise J. Keating, M.D.
Director
American Red Cross Blood Services
Northern Ohio Region
3950 Chester Avenue
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Dear Louise:

As you know, I attended a meeting in Washington D.C. on January 9, 1981, that meeting called by Dr. Barker to discuss ALT testing. The meeting was attended by a variety of interested individuals with Red Cross, NIH, BoB, and AABB affiliations. After over four hours of discussion, the group summarized its feelings as follows:

1.) That the data was solid on the risk of hepatitis associated with increased donor ALT.

2.) That we should prepare to test all units and not transfuse units with abnormal ALT.

3.) We should inform and advise donors selectively.

4.) That standardized testing is needed.

5.) That there is need for further investigation of donors, other risk factors, specific tests, and the incidence of NANB post ALT testing.

6.) To consider some of the above issues, particularly standardized testing, a working committee consisting of Drs. Alter, Dodd, Kahn, Szmuness, Pindyck, and Zuck was organized.

7.) Dr. Barker will also consider a sounding board article for the New England Journal of Medicine to express the opinions of this group.

8.) A budget message will go out to all Red Cross Centers.

Now that I have shared the conclusions of the group, may I summarize the points of discussion, many of which led to no clear answer and some of which leave me uneasy.

1.) Is this test nonspecific? Certainly it is nonspecific for NANB, although a specific test(s) is unlikely at the earliest for two to

three years. Elevations of ALT may be associated with a variety of medications, and with alcohol, but some information presented at the meeting suggested that the particularly higher ALT levels were reproducable over weeks. Even if there were a substantial number of false positives, with implications for donors, the imperic association with recipient increase in ALT seems pretty solid. An unanswered question was whether ALT tracks with other, perhaps more important donor characteristics.

2.) Is NANB a significant disease, or are we being concerned about an expensive test for nondisease? Reports of post transfusion NANB hepititis to Red Cross appear to be underestimated by approximately one hundred fold; NANB probably has an incidence of approximately 10% following blood transfusion. Most NANB has been detected as a result of prospective study. Of all disease perhaps 30% is overt, 10% of patients may be hospitalized, and some may have severe disease. There is suspicion that perhaps much chronic hepatitis and perhaps "cryptogenic" cirrhosis is a result of NANB.

3.) Was the appropriate group involved in the discussion? Those around the table who had participated in the TTV study, or in other studies of ALT relationship to post transfusion hepatitis had their own bias, as they noted. Many of the remainder of us were talking about preventing a disease that we in fact help create through blood transfusion. Finally, the group evaluated the scientific evidence and judged it good, but there were those whose opinions were heavily influenced by legal and public relations considerations.

4.) Do we know that discarding units with ALT elevation will in fact work to reduce the incidence of NANB post transfusion hepatitis? The data presented suggests that if between 1.5 and 3 percent of donations are eliminated, there would be a maximum of approximately 30% reduction. The effect of ALT testing was deemed not likely to be studied prospectively due to ethical and financial considerations, and there was not much enthusiasm around the table for holding out for a study demonstrating such results. It appeared difficult to explain why you would not test, while a neighboring center made the decision to do so.

5.) What were the costs versus the benefits? Costs were estimated to be approximately $20,000,000 per year in the United States to test, to discard positive units, and to recruit additional donations. To that cost would be added the physician and laboratory fees for evaluating deffered donors. The cost of the disease to be offset was much more speculative, but probably of a similar order of magnitude. There was some suggestion that those around the table were perhaps not the most expert in doing this sort of analysis.

6.) What would be the effect on the donor? There was general recognition of clear need to study ways to proceed in this area. The possibilities included, informing the donor, excluding the donor temporarily or permanently, recording and/or retesting, doing nothing, or informing

the donor on a selective basis based on the level of ALT. The question was raised whether it was consistent to diagnose hepatitis in the recipient on the basis of an increase ALT, but not to do so for the donor. It was also recognized that donor visits to their own physicians might lead to diagnosis, but not likely to any treatment.

7.) What would be the effect on the national blood supply? The discussants recognized that there would be inpact, although its extent and timing was unknown. If as many as 3% of donations were lost, this would require increased recruitment effort nationwide (the loss might vary from region to region). This concern did not outweigh the medical, scientific, ethical, legal, and public relations judgement that it was incumbent upon us to prepare to implement ALT as a donor screening procedure, in order to decrease NANB hepatitis in recipients.

Much more information concerning these issues will no doubt be forthcoming from ARC Headquarters in the next weeks and months. I am sorry that you were unable to attend this session and I hope that the information above accurately reflects the flavor of the deliberations.

Sincerely,

Fred

Alfred J. Katz, M.D.
Director

AJK/lp

cc: Dr. Barker