

NON SPECIFIC MARKERS FOR PERSONS AT RISK OF TRANSMITTING AIDS

NOTE FOR CBLA RESEARCH COMMITTEE AIDS WORKING PARTY 27.01.84

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1. This discussion paper is submitted in response to the Chairman's request, at the last meeting of the W.P., when it was reported that at least two RTC's had undertaken surveys of the prevalence of anti HBc in their donor population and there was discussion as to the further action which should be taken in relation to the donors found to be anti HBc positive. This will be a matter for individual Regional Directors. The comments below represent my own views.

2. Significance of non-specific screening tests applied to a donor population

In the absence of any specific tests for a causative agent of AIDS, or tests for a pathological feature specific for AIDS, a wide range of immunological and microbiological parameters have been studied in AIDS cases and high risk groups. The tables attached were presented by C.D.C. at the WHO AIDS meeting in Geneva, Nov. 1983. They show the high proportion of abnormalities in "control" persons in high risk groups. Similar findings are reported by Pinching et al (1983) in homosexual men in the U.K. A small percentage of apparently healthy controls without known risk factors also show abnormalities.

It is not known what proportion of apparently healthy homosexual or heterosexual people with abnormal test results are in process of developing AIDS, nor what proportion are capable of transmitting AIDS. The value of these tests for donor screening cannot therefore be determined at present.

3. Consequences of donor screening for non specific markers possibly related to AIDS

We know that a small proportion of donors will be found to have positive results (eg 0.5 - 2% will be HBc positive). The Transfusion Director responsible will, at present, have several options open to him including:-

- (i) Ask the donor to stop donating. If this is done it will be necessary to explain to some (or all) the donors concerned why the action has been taken.

- (ii) Investigate further to determine if the donor is in a risk group or not. If this is to be done thoroughly it will involve not only further laboratory tests but also interviewing the donor about his personal behaviour.
- (iii) Restrict the use of the donor's subsequent donations. One possibility is to use only the plasma and commit it exclusively for production of albumin and/or immunoglobulin.
- (iv) Continue to accept the donor normally.

Options (i) and (ii) may lead to difficulties, especially if donors come to feel that they are being subjected to screening tests primarily directed to identifying homosexuals.

4. Further investigation of donors already known to be Anti HBc positive

My own view is that very valuable data could be obtained by extensive laboratory investigation of these donor samples, in comparison with a carefully matched control group, to see if there is a high proportion of other relevant abnormalities in the Anti HBc positive group. If this was found, it would greatly strengthen the case for the value of Anti HBc screening.

I would be reluctant to undertake follow up interviews of donors found to be Anti HBc positive unless some form of prior consent had been obtained to carry out the screening test.

5. Evaluation of non specific tests which could be applied to the donor population

Prospective studies are already in progress to follow up asymptomatic homosexual men who have non specific markers. These studies should eventually show to what extent the tests indicate a "pre AIDS" condition rather than being secondary phenomena related to other infections common in homosexual men.

It would be valuable to have data from donor populations on the prevalence of abnormalities in these tests, and their relationship to behaviour patterns. Before undertaking a study of this type it would be important to reach a decision on two points.

- (i) Should donors be asked to give consent to additional laboratory tests being done on their blood and to possible requests for further samples and an interview?

- (ii) Should donors found to have one or more positive tests be asked to stop donating until they have been fully investigated: if this is not done, what use should be made of their donation?

6. Implications for supply of Hepatitis B Immune Globulin

If a decision were made not to accept donors with a positive anti HBc test, a further decision would be needed about the selection of donors for HBIG production. One possibility would be to restrict the collection of this plasma to female donors. Alternatively plasma containing HBsAb could be directed exclusively to the production of HBIG on the basis that there is no evidence whatsoever that this product has transmitted AIDS, and that conventional IgG preparations have an extremely good record of not transmitting viral infections.

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