

HEMOPHILIA

INFORMATION EXCHANGE



AIDS UPDATE

MEDICAL BULLETIN # 9

CHAPTER ADVISORY #12

THE NATIONAL HEMOPHILIA FOUNDATION
MEDICAL AND SCIENTIFIC ADVISORY COUNCIL
(Revised -- October 22, 1983)

RECOMMENDATIONS TO PREVENT AIDS IN PATIENTS WITH HEMOPHILIA

Recommendations for physicians treating patients with hemophilia.

A. It is recommended that cryoprecipitate be used to treat patients in the following groups except when there is an overriding medical indication:

- newborn infants and children under 4;
- newly identified patients never treated with factor VIII concentrate;
- patients with clinically mild hemophilia who require infrequent treatment;

Similar guidelines should be applied to factor IX deficiency patients where fresh frozen plasma can be used instead of concentrate.

B. The potential advantages and disadvantages of cryoprecipitate versus factor VIII concentrate therapy for severe hemophilia A are not clear at the present time and are controversial. The Medical and Scientific Advisory Council does not offer a specific recommendation at this time, but will continue to review the data.

DDAVP should be used whenever possible in patients with mild or moderate hemophilia A.

D. All elective surgical procedures should be evaluated with respect to the possible advantages or disadvantages of a delay.

Recommendations to factor VIII concentrate manufacturers:

A. Serious efforts should be made to exclude donors that might transmit AIDS.

1. Blood and plasma donation should not be obtained from prospective donors who are members of groups who are at higher risk of contracting AIDS. Such groups include: male homosexuals; intravenous drug users; those who have recently resided in Haiti; and sexual partners of members of those groups who are at higher risk. This effort should make use of educational materials and questionnaires in a discreet and sensitive manner.

2. Prospective blood donors should be excluded if they have symptoms associated with AIDS. This should be done by direct questioning and physical examinations as recommended by the Food and Drug Administration, Office of Biologics (March 24, 1983).

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3. Research is encouraged in the evaluation and implementation (if verified) of surrogate laboratory tests that would identify individuals at high risk of AIDS transmission.

4. In addition, the manufacturers should cease using plasma obtained from donor centers that draw from population groups in which there is a significant AIDS incidence. It is clear from the epidemiologic data that the pool of individuals at risk for AIDS transmission is not uniform throughout the country and that a great deal could be achieved by excluding donors from the "hot spots".

B. Efforts should be continued to expedite the development of processing methods that will inactivate viruses potentially present in factor VIII concentrates.

While heat treated products offer certain theoretical advantages, the data are insufficient at this time to assess their efficacy or to recommend that the presently licensed heat treated products be used instead of standard factor VIII concentrate, either for modification of the risk of hepatitis or AIDS. For this reason, prospective studies of the efficacy and safety of modified products are strongly encouraged.

C. There should be an evaluation of the possibility that yield of factor VIII in pheresis donors could be increased using DDAVP or exercise to maximize yield. This would permit a reduction in the size of the donor pool and would compensate for losses in plasma that might occur due to steps noted above.

D. There should be an evaluation of the feasibility of fractionating and processing plasma so that lyophilized small pool products are available.

E. Concentrate manufacturers should immediately cease purchase of recovered plasma for factor VIII concentrate from blood centers that do not meet the criteria listed in II.A above. These criteria should also apply to the production of cryoprecipitate.

F. Manufacturers should recall any lot of concentrate if it includes material from an individual that has been identified as having AIDS, or from an individual that, in the best medical judgement of the manufacturers, has characteristics strongly suggestive of AIDS.

G. Manufacturers should accelerate efforts towards the production of coagulation factor concentrates by recombinant DNA technology.

I. Recommendations to regional and community blood centers:

A. Those centers that are in regions in which there is a very low incidence of AIDS should increase capacity for cryoprecipitate production to be used locally and in other regions.

These centers should evaluate the feasibility of preparing small pool lyophilized cryoprecipitate for hemophilia treatment.

C. The production of cryoprecipitate should also adhere to criteria detailed in II.A above.

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