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HEMOPHILIA NEWSNOTES

January 17, 1983

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MEDICAL BULLETIN #5
CHAPTER ADVISORY #6

AIDS: - NHF MEDICAL AND SCIENTIFIC ADVISORY COUNCIL DEVELOPS POSITION
- NHF AND INDUSTRY MEET

Chapters - *Please distribute this information to all chapter members.*

Physicians - *Please distribute this information to all providers who treat patients with hemophilia in your area.*

NOTE: Any questions concerning the following information should be referred to your treating physician and/or NHF.

On Friday, January 14th, 1983 The National Hemophilia Foundation Medical and Scientific Advisory Council was convened in New York City to develop a position on AIDS in relation to blood product procurement and use in hemophilia. MASAC reviewed NHF/CDC data that had been reported at a Centers for Disease Control meeting on January 4th, in Atlanta. Bruce L. Evatt, MD and Lawrence D. Zyla, MPH of CDC, provided updated information based on data collected since January 4th. Based on these reports, as well as additional published and unpublished data, MASAC issued 12 recommendations (attached).

On the same day, NHF held a meeting with the commercial and voluntary blood industry and government officials to review the MASAC recommendations and identify specific steps to be taken to reduce the risk of AIDS. This meeting was moderated by NHF Board Chairman Charles J. Carman, and co-moderated by NHF Medical Co-Director Louis M. Aledort, MD. A full listing of participants is attached.

The following press release detailing information about these two meetings was issued on January 17, 1983:

PRESS RELEASE

ACQUIRED IMMUNE DEFICIENCY SYNDROME:

NATIONAL HEMOPHILIA FOUNDATION DOCTORS ISSUE POSITION

New York - January 17, 1983 - In response to the growing incidence of Acquired Immune Deficiency Syndrome (AIDS) among hemophilia A patients and the increasing concern that AIDS may be transmitted through blood products, the 14-member Medical and Scientific

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Advisory Council (MASAC) of The National Hemophilia Foundation (NHF) was convened by NHF leadership in New York City, on Friday, January 14th, to develop a position with respect to the relationship of AIDS to blood product procurement and use in hemophilia.

The MASAC reviewed survey reports from the Centers for Disease Control (CDC) as well as published and unpublished scientific data related to AIDS. MASAC Chairman, Leon W. Hoyer, M.D., acknowledged that "issues surrounding AIDS remain complex and do not allow for simple answers."

Based on the information available, MASAC issued 12 recommendations addressed to physicians treating patients with hemophilia; factor VIII concentrate manufacturers; and the blood banking industry.

The major thrust of these recommendations is as follows: MASAC reiterated NHF's earlier position that cryoprecipitate should be used, unless there is an overriding medical indication, to treat patients who have not previously used factor VIII concentrate,such as newborn infants, newly diagnosed patients, and those with clinically mild hemophilia. There is still insufficient data to develop specific recommendations with respect to preferred blood product use (i.e., factor VIII concentrate or cryoprecipitate) in the treatment of severe hemophilia; and MASAC further recommended that it is important to screen and exclude high risk donors from the blood and plasma supply used in the production of material prepared for the treatment of hemophilia.

On Friday afternoon these recommendations were presented to representatives of the commercial fractionation industry, the blood banking industry, and government agencies. The fractionation industry was supportive of the recommendations and have initiated steps to respond.

National Hemophilia Foundation Board Chairman, Charles J. Carman, expressed concern about the psychological impact of AIDS, and urged hemophiliacs and their families to "remember that only a fraction of one percent of the nation's hemophiliacs have been diagnosed or suspected as having AIDS."

The Medical and Scientific Advisory Council is comprised of prominent medical clinicians and scientists from throughout the United States.

Attached is a copy of the full text of MASAC recommendations, as well as a summary of NHF AIDS-relatedwork.

326

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Recommendations of
the Medical and Scientific
Advisory Council submitted
to the NHF Board of Directors

THE NATIONAL
HEMOPHILIA FOUNDATION

THE NATIONAL HEMOPHILIA FOUNDATION
MEDICAL AND SCIENTIFIC ADVISORY COUNCIL
January 14, 1983

RECOMMENDATIONS TO PREVENT AIDS IN PATIENTS WITH HEMOPHILIA

I. 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.

C. 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.

II. Recommendations to factor VIII concentrate manufacturers:

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

1. Identification, by direct questioning, individuals who belong to groups at high risk of transmitting AIDS, specifically male homosexuals; intravenous drug users; and those who have recently resided in Haiti.

2. Evaluation and implementation (if verified) of surrogate laboratory tests that would identify individuals at high risk of AIDS transmission.

3. 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.

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C. There should be an evaluation of the possibility that the 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. While this will certainly be more costly, it may be the only way to break out of the present dilemma without going to an all-cryoprecipitate effort.

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

III. 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.

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