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Blood Bank Week

AMERICAN ASSOCIATION OF BLOOD BANKS

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This Week...

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FDA ADVISORY PANEL RECOMMENDS SURROGATE TESTING FOR NANB

The Blood Products Advisory Committee of the Food and Drug Administration will recommend that both ALT and anti-core testing be performed on donated blood to reduce the incidence of transmission of non-A, non-B hepatitis through transfusion. In a February 13-14 meeting, the panel received reports on two studies showing that recipients of blood from donors with elevated ALT and anti-core had a higher incidence of NANB hepatitis. While questions were raised about the data, it was noted that the carrier rate of NANB is higher than previously thought, that cases are underreported and that NANB is now considered to be a much more serious disease.

A Red Cross study using anti-core tests on 103,662 samples from 69 centers in late January found a core positivity rate of 0.5 percent to 4.8 percent, with the higher percentage at a center outside the continental United States. The overall average was 2.57 percent. As expected, the larger centers in metropolitan areas had higher frequencies. The Red Cross data, which is still in the preliminary stage, also indicated a loss of about four percent from the donor population. It was estimated that the cost of the tests and technologist time was approximately $7.07 per unit to perform both procedures. This does not include the cost of replacing the lost donors.

The studies considered by the panel were performed before donor self-deferral was implemented in 1983. Many attendees at the meeting theorized that studies performed now would show a lower incidence of NANB due to self-deferral. The panel recommended that both ALT and anti-core procedures be performed because they identified different populations that appear to transmit NANB. While there is some overlap, it is not complete.

The advisory panel makes its recommendations to FDA staff; the recommendations are not binding at this time. FDA will consider the recommendations and issue proposed actions in the Federal Register if staff determines regulation necessary. There will be a comment period when the proposed regulations are published.

The advisory panel also recommended changing the outdate on platelet bags from seven to five days. Contaminated bags and septicemia in recipients were reported, possibly from long-term storage in seven-day bags. The panel requested that studies be performed on seven-day bags and sterility testing be performed before seven-day licensure is reconsidered.

The American Red Cross requested amending its license to allow collection of pilot samples by filling them indirectly from the bag after the needle is withdrawn from the donor's arm. This technique is cited in the AABB Technical Manual. Currently, the Red Cross is licensed to collect pilot samples

with an in-line needle. The panel did not recommend the change, citing lack of data on safety, particularly on bacterial contamination from the pilot tube to the container by backflow.

The American Red Cross also requested that certain donors be brought back into the donor pool who were repeatably reactive on HTLV-III antibody testing and are currently being excluded. The group in question represents .24 percent of Red Cross donors over a 10-month period, or 5000 donors and 12,000 units of blood. The donors were repeatedly reactive on a sample to cut-off ratio of two or less on the original donor sample. The same samples were sent to Abbott Laboratories and were negative on both ELISA and Western blot. The frozen original sample, when retested, was negative, as was a second sample four months later. The donors have not been notified. The panel was unable to recommend that these donors be readmitted into the pool at this time, and noted that it hoped to see more specific confirmatory tests available soon. It was noted that the Western blot test is not licensed by the FDA.

Also discussed was whether the six month deferral for blood donation after transfusion should be extended, in view of the long incubation period for AIDS. The panel recommended that this deferral period remain at six months for the present time.

* * *

NEW LAV ANTIBODY TEST LICENSED; FEDERAL TESTING REGS FORTHCOMING

The first antibody test based on lymphadenopathy-associated virus (LAV) has been licensed by the Food and Drug Administration for use in screening blood donors for the AIDS virus. Genetic Systems Corporation received word that its new LAV-EIA test kit was licensed on Wednesday, February 19. Genetic Systems is the first company to be given approval which was not one of the original five companies given the license in March, 1985, to produce the test. Other companies are awaiting licensure on their versions of the test.

Genetics Systems maintains that the test is 100 percent sensitive and 99.8 percent specific, with no false positives due to HLA antibodies. It includes color-coded reagents, dry incubation and is micro-titer based. For more information, the company may be contacted at: (800) 472-8378.

According to federal sources, proposed federal regulations requiring anti-HTLV-III/LAV testing of donor blood are expected to be published in the Federal Register shortly.

* * *

DR/PR PRACTITIONERS DISCUSS "COPING WITH AIDS"

Blood bank donor recruiters and public relations practitioners gathered in Arlington, VA, on February 13-14 to discuss "Coping with AIDS and Donor Attitudes," the subject of a workshop sponsored by the AABB. Approximately 150 blood bankers heard presentations on a variety of issues and shared ideas and information on the effect of AIDS on donors and blood banks' images.

Following opening remarks by Jane Mackey, chairman of the AABB's Administration Section, attendees heard presentations on handling AIDS and public relations, a detailed explanation of the AABB national opinion poll, and specific responses to the AIDS problem. Bebe Smith, Jon Hutchens and Bob Seltzer, public relations consultants who assisted with the AABB Public Education Campaign on AIDS, advised attendees that AIDS needed to be addressed directly to alter public opinion. They also stressed that the message to the public must motivate donors and reassure people that they cannot get AIDS by donating. The speakers also emphasized the need for educating the public, not just defending the blood bank.

Jeanine "Andy" Murphy, director of public relations for the Central Indiana Regional Blood Center, in Indianapolis, discussed her experiences played as a spokesperson on AIDS issues over the past three years and the pro-active activities the Center has undertaken. When the blood center was sued for an alleged transfusion-associated AIDS, she became the primary spokesperson for the organization. Responses to public questions about AIDS and blood were prepared and circulated to the blood center staff. A state AIDS task force was formed and the blood center was frequently asked to provide speakers on AIDS. The requests were turned into a positive opportunity to promote the blood program, Murphy said. Regular meetings were held with the media to provide information and gradually, Murphy said, their confidence was won. She was very active in a number of AIDS-related support activities, turning the crisis into an positive opportunity for the center.

On the second day, during a morning "rap session," donor recruiters and PR personnel shared experiences with AIDS. While a few noted no significant problems, others divulged anecdotes and reported on actions taken in their areas to combat the AIDS problem.

This was followed by a briefing from NIH physician Susan Leitman, MD, on the technical aspects of AIDS. Attendees were then given the opportunity to grill members of the press about media coverage of AIDS. Larry Thompson of The Washington Post and Henry Tenenbaum, of WRC-TV (NBC), in Washington DC, spoke about media coverage of AIDS and how PR practitioners can improve relationships with the press. Both reporters advised

establishing an honest, forthright relationship with the local media and being persistent in attempting to communicate your message to the press. The reporters also advised having a spokesperson available at all times. Shelly Lengel, director of public affairs for the Public Health Service, spoke about the PHS response to AIDS.

The final session consisted of a stimulating presentation by Joseph Feldschuh, MD, medical director of a private frozen autologous blood facility in New York, speaking about such operations and the impact on blood banks. He noted that securing insurance coverage for these operations is extremely difficult and expensive, and that it may be years before they can be profitable. He termed the emergence of frozen blood services as an "evolution, not a revolution" and that "if their concept is that they're going to make a quick buck on this, they're going to be sadly mistaken." He predicted that long-term storage of blood would eventually be phased into the regular system of blood banking.

Gilbert Clark, JD, AABB executive director, addressed legal issues surrounding donors and patients, stressing ways in which the blood bank could be liable in AIDS-related cases. "Blood banks need to be responsible for risk management," he said. He also cautioned that blood centers be careful about donor selection, especially concerning 17-year-old donors being screened and tested. He stressed that blood centers should document when testing began and any other significant steps taken to protect the blood supply, including keeping on file joint statements from blood collecting organizations. "Review your procedures and policies with an attorney," he advised. He also pointed out that it is essential that the blood center staff communicate the facts, and follows up on donors who have reactions, regardless of how mild. In the informed consent procedure with donors, all risks should be explained, he emphasized.

Brian McDonough, executive director of Irwin Memorial Blood Bank, San Francisco, presented data on that center's autologous and directed donations program, representing 8-12 percent of the total supply. Seventy percent are first time donors. In the Irwin study, there were no significant differences between directed donors and first time donors in test results. He also noted that the number of requests for directed donations increased whenever there was an increase in media coverage of AIDS. Peter Page, MD, executive director of the American Red Cross Blood Services Northeast Region, related the successful outcome of a legal decision against directed donations concerning his blood center and argued that there was no need for directed donation programs. His position is supported by his local medical society and state hospital association. He emphasized the importance of education regarding transfusion need and safety. Directed donations "abrogate the responsibility we have to educate the public and donors," he said.

Capt. Michael Ward of the Military Blood Program discussed recent policy changes in recruiting active duty donors on military bases. Results of testing such donors must be reported to the appropriate authority on that base, according to a recent decision by the Department of Defense. It is important, Ward said, that permission to draw donors on a base be procured from the senior military officer on that installation. Results of testing should be passed confidentially to the senior medical person on the base.

* * *

INFORMED CONSENT DECISION REPRESENTS NEW TURN IN JUDICIARY

A recent decision in Massachusetts Supreme Court may represent a change in the outcome of informed consent cases. In an article in the February 13 New England Journal of Medicine, William J. Curran, JD, SMHyg, said that until this decision, "the trend of unrealistic and oppressive damages decisions seemed unbroken across the country."

In the case, a patient required surgery to remove pieces of metal from his eye. After surgery, he was treated with prednisone. Further surgery was performed later to remove scar tissue, and prednisone was again prescribed. While the physician did advise the patient of the risk of surgery, he did not indicate the risk of aseptic necrosis from prednisone with which the patient was afflicted. The physician considered it a remote risk, he said, although it was listed in the Physician's Desk Reference as one of 41 risks from prednisone. The physician had treated 50 to 75 percent of his patients with the drug and had never had the complication occur.

The trial court refused to direct a verdict favorable to the physician and sent the case to a jury. The jury returned a verdict of $1 million against the physician, and the judge denied a motion for a new trial on the condition the damages be reduced by $100,000. The physician appealed the decision. Amicus curiae briefs were submitted by the state medical society and other medical groups. The briefs argued that the decision would make physicians "virtual insurers of all risks of every drug they prescribe and every medical procedure they undertake, however infinitesimally remote, unless they explain every potential side effect of every drug and procedure to every patient, at a cost of time and resources that will be detrimental to good patient care and medical practice..."

The Massachusetts high court held that the verdict should be reversed, with all justices agreeing that there was no evidence that a person would develop the disease after taking

the drug or that the physician knew the likelihood was other than negligible. "There seems little doubt that this decision will be helpful in moving American law away from serious collision with the realities of what physicians can and cannot do to inform their patients of the risks and benefits of proposed treatments," Curran said.

(Reference: Curran WJ: Informed Consent in Malpractice Cases (Medical Intelligence). N ENG J MED, 1986:314(7);429.)

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MISSOURI SENATE CONSIDERING AIDS-RELATED DONATIONS BILL; SOUTH DAKOTA TABLES PROPOSED DIRECTED DONATIONS BILL

The Missouri State Senate is considering a bill making it a criminal offense for anyone with an infectious disease, specifically AIDS, to give false information when donating blood. Senate Bill 697 was proposed by Attorney General William Webster and introduced by 12 senators. Punishment would include a $5000 fine plus up to five years imprisonment. While it was orginally introduced to refer only to plasma donations, it has been amended to include blood or blood products. The Heart of America Association of Blood Banks reported that an individual in the attorney general's office was "convinced that deliberate donations of blood by persons with AIDS was common."

The blood banking community is responding to the bill, which will be considered prior to the legislative session ending in April.

Meanwhile, the South Dakota legislature has indefinitely tabled a bill that would have required blood banks to perform directed donations. It was opposed by the South Dakota Medical Association and the Sioux Falls Community Blood Bank. It would have provided hospitals and blood banks immunity from liability if blood from the general supply was used in an emergency. It was tabled by a five to two vote in the Senate's Health and Welfare Committee. South Dakota has three cases of AIDS, the latest in a hemophiliac.

* * *

PHYSICIANS ASKED TO DONATE TO EASE AIDS FEARS

Two recent blood drives encouraged physicians to give to help ease donor fears about AIDS. Although the drives received media attention, few physicians actually turned up to donate, according to the February 14 American Medical News.

One drive was sponsored by the Academy of Medicine of Cleveland on February 2 for physicians and their families. Louise Keating, MD, a member of the AABB Board of Directors and director of the Northern Ohio Red Cross Blood Services, was one physician who did contribute. In Wichita, KS, late last year, the Medical Society of Sedgwick County in conjunction with the Red Cross held a Doctor's Donor Week which received heavy radio and TV promotion. About 50 physicians turned out. They are considering making it an annual event. The Cleveland experience will be presented at the American Medical Association leadership conference later this month.

* * *

RESEARCH UPDATE

Repeated Antigenic Stimulation May Affect AIDS Latency Period

Long-term cultures of HTLV-III infected T4 cells from AIDS patients were established and compared with T4 cells from normal donors after infection of the cells in vitro, according to study in the February 21 Science. By reducing the number of cells per milliliter of culture medium it was possible to grow the infected cells for 50 to 60 days. Immunologic activation of the HTLV-III infected cells and uninfected cells with phytohemagglutinin led to patterns of gene expression typical of T-cell differentiation, such as production of interleukin-2 and expression of the interleukin-2 receptors, according to the authors, from French and Israeli research laboratories and Robert Gallo, MD, of the National Cancer Institute. In the infected cells, however, immunologic activation also led to expression of HTLV-III, then cell death. "The results revealed a cytopathologic mechanism that may account for T4 cell depletion in AIDs patients and suggest how repeated antigenic stimulation by infectious agents, such as malaria in Africa, or by allogenic blood or semen, may be important determinants of the latency period of AIDS.

(Reference: Zagury D, Bernard J, Leonard R, Cheynier R, Feldman M, Sarin PS, Gallo RC: Long-term cultures of HTLV-III infected T cells: a model of cytopathology of T-cell depletion in AIDS. Science, 1986:231(4740);850.)

Should Persons Seropositive for HTLV-III Antibody Have TB Test?

Persons found positive for antibody to HTLV-III should be advised to have a tuberculin skin test, according to a letter to the editor in the February 13 issue of the New England Journal of Medicine. Tuberculosis is becoming increasingly common as an

opportunistic infection associated with AIDS. It is treatable by chemical prophylaxis, and the results may show important information about further subclinical T-cell immunodeficiency, AIDS-related complex or AIDS, authors said. Testing may also help to prevent the spread of tuberculosis in AIDS high risk areas.

(Reference: Pitchenik AE, Burr J, Cole CH: Tuberculin testing for persons with positive serologic studies for HTLV-III (correspondence). N ENG J MED, 1986:314(7);447.)

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GULF COAST BLOOD CENTER AWARDS FOUR RESEARCH GRANTS

Gulf Coast Regional Blood Center, Houston, TX, has awarded four research grants for studies related to blood and blood transfusion. Funds for the grants were made possible through the "responsible management of revenues derived from the provision of blood banking services" in the region, according to a press release. Funded are:

- Kim M. Fehir, MD, PhD, Baylor College of Medicine, to research cryopreservation of human platelets;
- Donald M. Marcus, MD, Baylor College of Medicine, to research the immunochemistry of the Lutheran blood group system;
- Saiubha S. Kulharni, PhD, University of Texas System Cancer Center, MD Anderson Hospital and Tumor Institute, for investigation into the tolerance phenomenon in bone marrow radiation chimeras; and
- F. Blaine Hollinger, MD, Baylor College of Medicine, to study interaction between HTLV-III and HBV in HTLV-III infected humans.

* * *

RFP ISSUED FOR EVALUATING NEW HTLV-III SCREENING TESTS

A request for proposal (RFP) has been issued by the National Heart, Lung and Blood Institute for development and evaluation of new screening tests for HTLV-III antigens, antibodies or nucleic acids as part of tests to identify infection of blood donors, according to Health Grants and Contracts Weekly. Applications are due May 1. For further information, contact NHLBI, BDR Contracts Section, Federal Building, Rm. 5C14, 7550 Wisconsin Ave., Bethesda, MD 20892, reference #NHLBI-HB-86-09.

* * *

NORTH AMERICAN BIOLOGICALS PURCHASES CRYOSAN

North American Biologicals, a Miami-based firm, plans to purchase 100 percent of the outstanding capital stock of Cryosan Inc., Newton, MA. Cryosan is presently owned by Continental Pharma Cryosan Inc., Montreal, Canada. Cryosan markets finished plasma fractionation products.

* * *

MEETINGS

- American Red Cross/American Association of Critical-Care Nurses, "A Gift for Life, Organ and Tissue Donation and Transplantation." Washington DC, March 14-15. Contact: Linda Waite, (714) 644-9310 or Susan Alford, (202) 639-3084.

- FDA Device Good Manufacturing Practice Advisory Committee Meeting, March 20-21, Washington DC, to consider if some blood products used with devices or administered by devices should be regulated under device good manufacturing practices. Contact: Sharon Kalokerinos, Center for Devices and Radiological Health, (301) 427-7984.

- CDC Course on Laboratory Diagnosis by Serologic Methods, March 24, Atlanta, GA. Contact: Mrs. Gloria Kovach, Division of Laboratory Training and Consultation, Laboratory Program Office, Centers for Disease Control, Atlanta, GA 30333, (404) 329-3837.

- Seventh National Lesbian/Gay Health Conference; Fourth National AIDS Forum, March 13-16, Washington DC, with co-sponsorship by NIAID, NIAAA, NIDA, NIMH, NIH and others. Contact: NLGHF Conference, PO Box 65472, Washington DC 20035, (202) 797-3708.

- "A Gift for Life," workshop on organ/tissue donation and transplantation sponsored by the American Association of Critical Care Nurses and the American Red Cross, March 14-15, 1986, Washington DC. Contact: (714) 644-9310.

- National Committee on Clinical Laboratory Standards Annual Meeting, March 20-21, 1986, Baltimore, MD. Contact: NCCLS, 771 E. Lancaster Ave., Villanova, PA 19085.

- 33rd National Health Forum, sponsored by the National Health Council, Washington DC, March 24-25, "Biomedical Research at the Critical Crossroads." Contact: NHC, 622 Third Ave., New York, NY 10017-6765, (212) 972-2700.

• American Society of Law and Medicine, "AIDS: A Modern Plague? The Medical, Legal, Ethical and Public Policy Issues," April 3-5, Boston, MA. Contact: (617) 262-4990.

• American Society of Clinical Pathologists/College of American Pathologists Spring Meeting, April 19-24, 1986, Washington DC. Contact: (800)621-4142 for in Illinois, (312) 738-4890.

• XVIII Annual Red Cross Scientific Symposium, "Transplantation: Progress and Prospects." April 28-30, 1986, Washington DC. Contact: (301) 530-6040.

• The XIX Congress of the International Society of Blood Transfusion will be held May 11-16, 1986, in Sydney, Australia, in conjunction with the International Society of Haematology. The call for abstracts has been announced and the closing date is December 31, 1985. For further information, contact: Congress Secretariat, Box 2609 G.P.O., Sydney, NSW 2001, Australia, telephone (61-2) 241-1478, telex AA 74845 Consec.

• An International Conference on AIDS will be held June 23-25, 1986, in Paris, France, to cover all aspects of contemporary research. The deadline for abstracts is February 1. Contact: Dr. Jeane-Claude Gluckman, Faculte de Medecine Pitie-Salpetriere, 91 Boulevard de l'Hopital, 75634 Paris CEDEX 13 (FRANCE); telephone: (1)45 70 27 02.

• NHLBI, NIAID, and NCI will sponsor a program on the "Impact of HTLV-III Testing and Public Health," a consensus development conference, with transfusion as its main concern. July 7,8, 8:30 am to 5:00 pm, and July 9, 8:30 am to noon, Masur Auditorium, NIH, Bethesda, MD. It will be open to the public.

• NHLBI, FDA and the Office of Medical Applications of Research consensus development conference on platelet utilization, October 6-8, 1986, Bethesda, MD. To consider appropriate indications for platelet transfusion; merit of products available for transfusion; risks associated with platelet therapy; and needs for future research. Contact: (301) 496-4236.

Mr Franklin

BLOOD DONATIONS FOUND AND CONFIRMED POSITIVE FOR HTLV III ANTIBODY BY THE NATIONAL BLOOD TRANSFUSION SERVICE FROM 14 OCTOBER TO 31 DECEMBER 1985

Since the minute of 8 January 0873 the figure for blood donations tested up to the end of December has become available.

Throughout the UK the total donations tested were 593,396. Of these 13 donors have been confirmed as positive giving a figure of 1:45,646 or .002%.

The increase is associated with the detection of 4 donors in Scotland and 1 in Northern Ireland where 67,335 and 15,539 donations have been collected respectively.

The press announcement has been amended as requested and now includes a reference to the SNBTS which is a separate oganisation from the NBTS.

GRO-C

Dr A Smithies

Principal Medical Officer
Room GRO-C
Hannibal House
Ext: [redacted]

20 January 1985

cc: Ms Doran
Dr E Harris
Dr D Ower
Mr Harris
Dr Sibellas
Mr Murray
~~Dr Moore~~
Mrs Cunningham