



OHIO ASSOCIATION OF BLOOD BANKS



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From The OABB President

Dear OABB Members,

Looking back at our successful Annual Meeting on May 1st, and having an amazing 64 attendees, I took some time to think back on other OABB Annual Meetings. I remember in the mid-1980s I attended my first OABB meeting at Quaker Square in Akron. I didn't know much about the organization at the time but was proud to be attending as a new SBB graduate. I was reminded, too, of how I became involved in OABB—first, volunteering with the Education Committee and later as Secretary on the Board. There were many Annual meetings along the way!

But I think the thing that stands out the most—is exactly the one that outgoing President Gregg Witham commented on at the May 1st meeting—the element of friendship.

We have great speakers and wonderful locations, but the best thing is always visiting with others from across the state, renewing friendships, sharing stories and pictures, and catching up with what's going on in our facilities.

Many other state blood banking organizations have failed, yet OABB continues to have good attendance at our meetings. What makes OABB successful is the great members we have. Yes, we struggle with membership numbers—but we have found that OABB is worth belonging to and worth working at to keep it going. The great meetings are not only good educational opportunities, but also provide us time to meet others and share our ideas with them—and in some cases, the friendships formed have lasted throughout the years.

As I begin my term as President, I am proud of the organization and proud to be part of it. I hope OABB remains a strong state organization and I hope that all of its members will take time to reflect on their experience with OABB. Whether you have been a member for a long time (like me!) or whether you are just new to OABB, please take some time to think about the organization and how you can help to keep it going and keep it a strong state organization.

Sincerely,

Mary Schumacher, MS, MT(ASCP)SBB
OABB President

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The Role of Blood Banks in Tissue Services

The first tissue bank was established for the U.S. Navy in 1949, and as it grew, smaller hospital programs started. The smaller hospital surgery departments recovered skin and bone from deceased donors for later use in reconstructive procedures.

As these programs grew, organization and coordination of tissue harvesting, banking, and distribution were needed. Lack of proper donor screening led to transplantation of HIV, HBV, bacterial, and fungal contaminated tissues, resulting in extensive recalls of donated tissues. The *New York Daily News* reported a landmark case in 2005, about a medical director in Denver who discovered errors for failure to document screening test results and to provide correct contact numbers for information requests. Recipients were not documented by end users, so recipients were not informed of recalls. These issues led to voluntary standards set by the American Association of Tissue Banks (AATB), Eye Bank Association of America (EBAA) and the College of American Pathologists (CAP). Mandatory standards are also set and are enforced by the Joint Commission and the Food and Drug Administration.

Regulations exist for the three areas of tissue banking: 1) donor suitability assessment, recovery, and tissue processing 2) tissue distribution intermediaries, which store tissue for further distribution and 3) tissue dispensing services, which are responsible for issuing tissue for transplantation.

The AATB provides a series of voluntary standards for all aspects of tissue banking. Founded in 1976, the AATB's mission is to provide guidance to improve tissue quality and safety. The organization's standards address many of the areas of current concern such as donor records, processing standards and final disposition accountability.

CAP, Joint Commission, and AABB standards hold the laboratory responsible for monitoring member hospitals' tissue transplant quality. This does not prevent another department, such as a surgery, from maintaining records, but the standards must be met by that department for the lab's accreditation.

FDA performs inspections of any tissue bank, distributor, or final dispenser of tissues for transplant. In 2005, the FDA issued its "Final Rule" for "Human Tissue Intended for Transplantation" (21CFR Parts 16 and 1270). Part 1270 provides the mandated guidelines for donor screening, testing, procedures, general requirements for records, inspections, recall and destruction of human tissues. EBAA, ATBB, CAP, and AABB voluntary standards must meet or exceed the FDA regulations in all areas. The FDA requires testing donors for HIV 1 and 2, Hepatitis B, and Hepatitis C. Guidelines for testing neonatal, pediatric, or transfused donors are described. A donor's medical record must be reviewed for medical and social risk factors for disease. 21CFR 1270.31 states that written procedures must be established by a tissue bank for disease testing, record review, and processing to prevent cross-contamination of tissue. Rules detailing the process of quarantining tissues pending final review must also be written. A final review must include a check that all records are complete and accurate and testing has been done and is acceptable before tissues are released from quarantine. Transplant acceptable tissues must be accompanied by a summary of records completed by a responsible person.

State regulations vary widely. Most states have little or no regulation for how tissue banks are established or run. As of 2005, only New York and Florida require tissue banks to be licensed and inspected by state agencies. California, Georgia and Maryland have licensing requirements, but don't perform a state-guided inspection. Ohio has only limited requirements for tissue banks. According to the Ohio Revised Code, a tissue procurement agency is defined as an agency meeting the designation of an organ procurement organization by the Secretary of Health and Human Services, an eye bank accredited by the EBAA, or a tissue bank accredited by the AATB. So, while Ohio doesn't specifically have their own standards, tissue agencies located in Ohio must be in compliance with the professional standards of the accrediting agency governing their services.

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So what is the role of the blood bank or transfusion service in all this? First, blood banks have experience recruiting, screening, and testing donors. Medical oversight in accepting or deferring tissue and blood donors is almost identical. Second, blood banks are well versed in record keeping, processing, inventory control, storage, and transport logistics of biologic products. Current standards for blood banks require traceability of records be maintained, a new requirement for tissue banks. Many of the new quality controls required of tissue banks are those already practiced by blood banks. Just like blood banks are required to track and trace each processing step and document that shipment procedures assure appropriate temperature until delivery, tissue banks must now document these same types of quality issues. As for the hospital based transfusion service, all the end user monitoring of blood products is applicable to tissues. Tissues should be inspected upon receipt, stored in monitored refrigerators and freezers, and final disposition documented to facilitate easy recall.

Currently, very few hospital based transfusion services control the tissue dispensed in their institutions. In 2005, about 6 months before the Joint Commission standards went into effect, a survey of AABB accredited hospitals was conducted. Results indicated that about 66% of the respondents felt the AABB should provide additional guidance for hospital handling of tissue services, yet less than 10% indicated that they were planning to increase their role.

Nicole Milano, MT(ASCP)SBB

Suggested reading

Woll, Judith E. Tissue banking overview. *Clinics in laboratory medicine*. Vol. 25, no 3 (2005 Sep): 473-86.

Eisenbrey, A Bradley; Frizzo Wendy. Tissue banking regulations and oversight. *Clinics in laboratory medicine*. vol 25, no 3 (2005 Sep): 487-98.

Humphries, Linda K.; Mansavage, Vicki L. Quality control in tissue banking-Ensuring the safety of allograft tissues. *AORN Journal*. vol 84, no 3 (2006 SEP): 386-398.

Kuehnert, Matthew J.; Morita, Kristal L., et al. Human tissue oversight in hospitals: an AABB survey. *Transfusion*. vol 47 (2007 Feb): 194-200.

Homes, MD. Practical issues in tissue banking. *Am J Clin Pathol*. 1997 Apr: s75-81.

Code of Federal Regulations, Title 21 Part 1270 Human Tissue Intended for Transplantation.

Accessed via internet at <http://ecfr.gpoaccess.gov>.

Ohio Revised Code section 2108.01 Human body or part definitions. Access via internet at

<http://codes.ohio.gov/orc/2108.01>.

Warwick, R. M.; Eastlund, T.; Fehily, D. Role of the Blood Transfusion Service in Tissue Banking. *Vox Sanguinis*. vol 71, no 2 (1996 Aug): 71-77.

OABB Continuing Education Activity

Serologic Approach to Identifying an Antibody to a High-Incidence Antigen (0.5 CH)

After reading this Continuing Education article, the participant shall be able to:

- Identify testing to determine whether reactivity is a multiple antibody or an antibody to a high incidence antigen.
- Name two high-incidence antigens lacking in associated ethnic backgrounds.
- State how to determine whether antigen-negative units of Red Blood Cells are necessary.
- Identify a mechanism to obtain rare units.

When All Panel Cells are Positive

When all panel cells are reactive and the auto control is negative, the reactivity can be either due to multiple antibodies or an antibody to a high-incidence antigen. When the reactivity is variable, so that some cells are strongly positive and others weakly positive, it usually indicates multiple antibodies. However, reactions with all cells approximately the same strength can be either an antibody to a high-incidence antigen or multiple antibodies.

Important information at this point is the patient's own antigen typing (phenotype) for C, E, c, e, S, s, K, Fy^a, Fy^b, Jk^a, and Jk^b (the common antigens). Once the person's phenotype is known, evaluate the tested panel cells to see if any panel cell lacks the same antigens the patient lacks (phenotypically similar). If no cell is found on the panel, evaluate whether another panel in inventory has a phenotypically similar cell and test that cell. A positive reaction indicates an antibody to a high-incidence antigen is present. A negative reaction indicates multiple antibodies.

Determining the Presence of Antibodies to Common Antigens

Although an antibody to a high-incidence antigen is suspected, the presence of antibodies to common antigens may also be present. An adsorption procedure to remove the antibody to the high-incidence antigen allows detection and identification of antibodies to common antigens. Large volumes of group O cells from a phenotypically similar donor are used to adsorb the antibody to the high-incidence antigen

and leave behind any alloantibodies to common antigens that may be present. The adsorbed plasma is then used to detect alloantibodies to common antigens.

An added benefit of adsorbing onto these phenotypically similar cells is that only the antibody to the high-incidence antigen is adsorbed to the cells. An elution from the aliquot of adsorbing cells provides another source of the antibody to test a battery of rare cells lacking antigens of high-incidence. Since the eluate would have no ABO antibodies, it provides more flexibility in selection of test cells since ABO compatibility would not be of concern as it would with patient plasma.

Focusing on Identification of the Antibody to the High-Incidence Antigen

Ethnic background often gives focus to which high-incidence antigen the patient may lack. If the patient is of African background, antibodies to U, Js^b, hr^B, and hr^S, are considered first. If the patient is of Hispanic background, antibodies to Ge2, Di^b, and hr^B are considered first. If the person is of European background then Kp^b, Co^a, Yt^a, and Lu^b are considered first.

Other tools to determine which blood group systems to focus on include treating test cells with enzymes and with 0.2M DTT. Charts exist listing which antigens are denatured with enzymes, with 0.2M DTT, and by neither or both. Examples of antigens denatured by enzymes include Ge2 and Yt^a. Examples of antigens denatured by 0.2M DTT include Js^b, Kp^b, Yt^a, and Lu^b.

Once it is known if the antigen is denatured by one of the two chemical treatments as evidenced by non-reactivity with the patient's plasma, then definitive determination can be made by testing the patient's plasma or eluate from the adsorbing cell with rare test cells lacking specific antigens. Once a non-reactive cell is found, at least one more cell lacking that particular high-incidence antigen is tested. The patient's cells are then usually antigen typed for the corresponding antigen.

Selection of Red Blood Cells for Transfusion

References exist that give information about the clinical significance of antibodies to high-incidence antigens. Not all antibodies cause significant decreased cell survival, and incompatible units are appropriate for transfusion.

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When Red Blood Cells negative for the high-incidence antigen are needed, blood centers may have units in their frozen inventory. If not, then the blood center's Immunohematology Reference Laboratory (IRL) contacts the American Rare Donor Program (ARDP) to request units. The ARDP faxes the request to all AABB accredited IRLs to search their inventory for compatible units. The IRLs reply back to ARDP if units are available, and then ARDP puts the requesting and responding facility in contact with each other.

Additional reading

Reid ME, Lomas-Francis C. The blood group antigen factsbook,. San Diego: Academic Press, 2004

Answers will be given in the next issue of the OABB Newsletter

Questions

1. What is the first step to determine if reactivity observed in a panel of cells is multiple antibodies or an antibody to a high-incidence antigen?
 - a. Absorb the antibody onto phenotypically-matched cells
 - b. Enzyme treat test cells and run with the patient's plasma
 - c. Test a phenotypically similar cell with the patient's plasma
 - d. Test an auto control to determine if the antibody is allo
2. If a patient has Hispanic ethnicity and has an antibody to a high-incidence antigen, which test cells would be tested first?
 - a. Co^a and Js^b
 - b. Di^b and Ge2
 - c. hrB and Kp^b
 - d. Yt^a and Ge2
3. When a patient has an antibody identified to a specific high-incidence antigen and determining whether antigen-negative blood is needed, the next step is to:
 - a. Chemically treat the cells for cross match and issue cross match compatible
 - b. Give antigen-negative blood if the antibody reacts by the indirect antiglobulin test

- c. Inform the physician and allow them to sign for incompatible blood
 - d. Research textbooks on whether the antibody is responsible for rapid red cell clearance.
4. When high-incidence antigen-negative blood is needed the next day and is unavailable at the local blood center, the best option for the blood center IRL is to call:
 - a. AABB
 - b. American Rare Donor Registry
 - c. Family members
 - d. Other blood centers

Answers to CE Activity Immunization to Red Cell Antigens

Questions:

1. Early investigations suggest the minimal red cell dose for a recipient to form anti-d is: **B) 1.0 mL**
2. The percentage of recipients who are non-responders for developing red cell antibodies is: **A) 15%**
3. Which correctly reflects the immunogenicity of red cell antigens? **C) K > c > Fy^a > Jk^a**
4. Selection of matched units in the Rh system and for K in the sickle cell population is based on: **B) Reducing antibody formation**

**Check out OABB's new web site at
www.oabb4u.org**

OABB Newsletter Submissions

Letters, articles, and announcements of upcoming events may be submitted at any time.

Classified advertisements will be accepted from any member institution and printed at no charge.

**Ohio Association of Blood Banks
Proficiency Sample Testing Program
Summary of Results – April 2008**

Mailed: 48
Responses: 38
% Participation: 79%

Results:

ABO/Rh: O, Rh-Positive
Antibody Screen: Positive
Antibody (ies) Identified: Alloanti-E and -S
Antigen typing (if applicable): E-; S-

WELCOME NEW MEMBERS!

Nancy Fulton, MT(ASCP)
OhioHealth

Kelly A. Laguna, MT(ASCP)
American Red Cross

Susan K. Vonderwell, MT(ASCP)
American Red Cross

Yu-Ching Yeh, MT(ASCP) CLS(NCA)
OSU Medical Center

Jo Bruner, MT(ASCP), NCA
Fulton County Health Center



Annual Meeting 2008 Review

The Ohio Association of Blood Banks Annual Meeting was held on May 1, 2008 at the Sheraton Suites at Crossroads in Columbus, Ohio. Seventy people participated in the daylong event, and most people gave the meeting an overall excellent rating.

Immucor, Inc., Ortho-Clinical Diagnostics (OCD), and Charter Medical were on site on the day of the meeting and displayed the latest products and technologies offered by their companies. Kathy Shortridge and Ed DeRose presented and explained the benefits to the blood banks of products offered by Immucor and OCD respectively. Meeting attendees had ample opportunity throughout the day to visit with the vendors and pick up informational brochures to take back to their institutions to evaluate current and future purchases.

Following the presentations from Immucor and OCD, Susan Johnson from the BloodCenter of Wisconsin discussed drug-induced hemolytic anemias. Ms. Johnson wittingly paralleled drugs in the workplace to patients with drug-induced hemolytic anemias. She refreshed participants on the expected test results for the Direct Antiglobulin Test (DAT), Eluate, and serum. She reminded everyone of the differences between Drug Induced Hemolytic Anemias (DIIHA) and Auto Immune Hemolytic Anemias (AIHA), stressed the importance of persistence in getting an accurate patient history to properly identify DIIHA, and reviewed the three mechanisms of DIIHA (Type I – Hapten-Dependent, Type II – Autoantibody, Type III – Drug Dependent). Ms. Johnson summarized to the group that in the blood bank the antibody in the eluate or serum will best be detected using drug treated red blood cells or by showing reactivity in the drug's presence. A strongly reactive DAT and weakly reactive eluate is a finding in DIIHA.

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Next, Karen King, MD from John Hopkins School of Medicine, discussed transfusing patients with Warm Autoimmune Hemolytic Anemias. She explained to the attendees that physicians are trained to only transfuse cross match compatible blood, and they struggle with the concept of transfusing cross match incompatible blood due to the patient's autoimmune state. Dr. King explained the urgency in transfusing is based upon the patient's degree of anemia, vital signs, and mental state. Determining patient phenotype is a necessity in order to select blood for future transfusions since these patients routinely return for additional care. In her facility, a patient receives phenotyped matched units and subsequent samples do not have alloantibodies performed.

Following a lunch of deli sandwiches, and the OABB Annual Meeting of the Membership, the afternoon session began with a talk from Rita Ratcliffe, MD the Principal of Medical Excellence from New York. Dr. Ratcliffe poignantly discussed several cases in which mistakes occurred in a hospital (or between hospitals) causing patient fatalities. As a whole, the healthcare system has not implemented systemic improvements to correct past mistakes due to barriers in what Dr. Ratcliffe terms as the Four "F's"—Fear, Facts, Funds, and Folks. In order to make the healthcare system safer, better systems needed to be developed to prevent errors, and approaches such as Lean, Six Sigma, ISO Quality Management System, and the Baldrige Quality Program should be explored.

Lastly, Colleen McGuiness Slapak from the Community Blood Center/Community Tissue Services™ (CBC/CTTS™) in Dayton, Ohio spoke on Transfusion Safety. Ms. McGuiness Slapak explained the importance of establishing a data collection program to collect, analyze, and report data relevant to transfusion medicine and cellular therapies, and outlined the Biovigilance Program currently being established in the Dayton area. She cited AABB, CAP, and JCAHO requirements that support the importance of patient safety. Ms. McGuiness Slapak concluded with informing the attendees of some current and future measures being taken to expand transfusion safety (i.e. Green arm bans for blood transfusion, bar code technologies between specimen and blood administration, and "Intelligent" storage of products).

All in all the day was a great success. Participants learned and refreshed themselves on the differences between Drug Induced Hemolytic Anemias (DIHA) and Auto Immune Hemolytic Anemias (AIHA), and how to meet and understand the transfusion needs of the latter. They became better informed of medical mistakes, the importance of a systems approach in correcting them, and received insight of how a data sharing program in the Dayton area is trying to improve patient safety.

Submitted by:
Kathy Wheeler, MT(ASCP)SBB, CQM(ASQ)

**Teleconferences Sponsored By
American Red Cross Central Ohio Region
995 East Broad Street
Columbus, Ohio
Call (614) 253-2740, ext. 2215 to Attend**

Date	Teleconference Title
Feb 27 2:00 – 3:30 PM	Mechanisms of Drug-Induced Hemolytic Anemia
Mar19 2:00 – 3:30 PM	Serological to Molecular Testing: Points to Consider for Successful Conversion
May 16 2:00 – 3:30 PM	(ASCP) Eliminating ABO Incompatible Transfusions—No More Excuses!
Jun 4 2:00 – 3:30 PM	(ASCP) The US Biovigilance System: Surveillance, Safety, and Savings
Jun 26 2:00 – 3:30 PM	(ASCP) Transfusion-Transmitted Cytomegalovirus (CMV) Infection
Jul 30 2:00 – 3:30 PM	Coagulation Case Studies for Blood Bankers
Sep 10 2:00 – 3:30 PM	Managing Massive Transfusion: Clinical and Blood Bank Perspectives
Oct 22 2:00 – 3:30 PM	Intravenous Immunoglobulin (IVIG): Intended Use and Administration
Nov 19 2:00 – 3:30 PM	Platelet Refractoriness: Causes and Treatments
Dec 10 2:00 – 3:30 PM	Differential Diagnosis of Suspected Pulmonary Transfusion Reactions