



OHIO ASSOCIATION OF BLOOD BANKS



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From The OABB President

Now that we are in the middle of winter here in Ohio, I find myself thinking of spring and all the activities associated with warmer weather. Getting outside and working on the lawn or in the garden along with outside sports comes to mind. Another event that happens every spring is the OABB annual meeting of the membership. This year the meeting will be on April 29, 2010 in Columbus, Ohio to make traveling easier for all of the membership. Every year the Board of Director's goal is to put together a day of technical and managerial subjects that are relevant and timely. This year's agenda truly fits that bill again. Technical topics include platelet antibody and antigen testing, alternatives for serologically resolving warm autoantibodies and managing transfusion patients with medication-associated coagulopathies. The Management topic this year is cultural differences in the workplace. This year we also have a presentation of the use of "fresh blood" along with a representative from AABB discussing the US biovigilance network. For members, both institutional and individual, there will also be an amendment to the organization's Code of

Regulations to vote on. You will find the wording change for this amendment in this newsletter.

That leads me to my next favorite topics to talk about in this column, and that is membership and volunteerism. Existing members should have received their renewal information in January, and I hope that everyone took that opportunity to renew. If you were not previously a member, or you did not renew, the application process is very easy. Just go to the OABB website, <http://oabb4u.org/>, and fill out the application under the Membership tab. Membership not only gives you discount rates at the annual meeting and fall workshop, but also obtaining 2.0 contact hours when completing the educational opportunities through this newsletter.

Membership also gives you the opportunity to become even more active in the OABB by working on committees or on the Board. The best analogy that I can think of is the difference between watching have given. We have a few Board vacancies to fill this year at the annual meeting. If you would like to

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OABB Continuing Education Activity Performing Supplier Audits (0.5 CH)

After reading this continuing education article, the participant shall be able to:

- ◆ Recognize the importance of auditing critical materials suppliers
- ◆ List two ways to perform a supplier audit
- ◆ State two advantages and two disadvantages of each audit type
- ◆ Describe tasks involved in planning and conducting the audit
- ◆ Give examples of processes to assess during the record review

Why auditing suppliers is important

The quality and uninterrupted supply of raw materials used in blood and blood component manufacturing and testing are critical to blood banks and transfusion services' mission to provide patients safe, pure, and effective products. The AABB 26th edition of *Standards for Blood Banks and Transfusion Services* (BBTS 4.0) requires a process "to evaluate the ability of suppliers of critical materials, equipment, and services to consistently meet specified requirements." Supplier evaluation should be conducted at regular intervals and may include a site visit to the supplier's facility or a record review (paper audit). There are advantages and disadvantages related to both types of audit.

Advantages and disadvantages of the types of audits

Site visit advantages include opportunities to observe the cleanliness of the physical plant, the organization of processes in manufacturing materials or providing services, and partnership development. Physical layout of manufacturing or testing areas and conditions of sample storage, raw material, and records can also be observed. Several disadvantages of a site audit include the expense for one or more auditing representatives to travel to the supplier site, involvement of various staff at the supplier's site, and productivity loss inherent in such a process. In addition, the onsite audit may not be as thorough because time in the supplier's facility may be abbreviated to avoid the expense of the auditors' overnight accommodations.

As blood banks and transfusion services look for ways to decrease spending while remaining compliant, some organizations have opted to alternate conducting a paper audit with site visit audits. The paper audit reduces the cost of travel and provides the opportunity for a detailed record review in the auditor's own workspace. Staff members at the supplier site are able to continue with routine duties during the audit rather than dedicating one or more days to hosting auditors. Disadvantages include the cumbersome or problematic delivery and transfer of large documents and the ability to assess facility cleanliness and space utilization.

Planning and conducting the audit

Regardless of the audit method, there should be careful planning prior to the audit's start. Gaining supplier agreement to be audited should be the first task completed. Preparing an audit checklist should follow. Using a prepared checklist, shared with the supplier in advance, focuses the audit and informs the supplier of processes under review. The checklist should be designed to encompass elements of current good manufacturing practices (cGMP) such as process design, facility and equipment maintenance, storage and distribution, and staff training. During consecutive audits, the checklist may also include findings during the previous audit and address issues related to delivery of goods and services by the supplier (for example, customer complaints from the auditing facility).

At the beginning of the audit an opening meeting is held with supplier representatives. This meeting may be via teleconference if a paper audit is conducted. Agenda items may include review of the proposed checklist, a list of records and documents to be reviewed, and the manner in which follow up questions will be addressed. For the paper audit, there should be discussion and agreement about the method and timeline for requested documents and records.

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A tentative time for the closing meeting or conference call may be scheduled during the initial meeting. As records review progresses, the supplier may request updates from the auditor to prevent any surprises at the closing meeting. Additionally, updates afford the supplier an opportunity to perform corrective action in "real time".

For the paper audit, various document/record delivery methods may be employed. Electronic transfer using email, electronic media such as flash drives and/or CDs/DVDs, facsimile, and even expedited delivery of hard copies may be used. Keep in mind that the supplier may request the return of any provided documents or records regardless of the delivery method.

At the closing meeting, any findings or observations are reviewed and discussed. The supplier receives a preliminary copy of the audit report with a final copy provided as soon as possible. A mutually agreeable deadline for follow up and completion of corrective action is established.

In summary, regular evaluation of suppliers is an important part of the quality management system for blood banks and transfusion services. This activity can be performed on site or by paper audit. The use of a well-designed checklist and communication with the supplier can accomplish the goals and objectives while avoiding unnecessary expense and resources.

Submitted by:
Pamela F. English, MT(ASCP)SBB



Answers will appear in the next issue of the OABB Newsletter.

Questions

1. Auditing suppliers is important for the _____ and _____ of raw materials used in blood and blood component manufacturing and testing.
2. List two types of audit methods to evaluate suppliers.
 - a) _____
 - b) _____
3. Which of the following is a disadvantage of an on-site audit?
 - a. assessing how supplies are stored
 - b. observing the layout of the facility
 - c. partnership development
 - d. staff involvement time
4. Tasks involved in planning an audit include which of the following?
 - a. surprise visits and guarded list of elements for audit
 - b. facility agreement to be audited with no discussion of observations until the closing meeting
 - c. planned visits with a well-designed checklist provided ahead of time
 - d. surprise visit and a closing meeting with a list of observations

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5. Examples of processes to review during an audit include
 - a. timing of fire drills and cafeteria cleaning schedule
 - b. process design, equipment maintenance, staff training
 - c. minutes of staff meetings and problems logged
 - d. facility promotion flyers and supplier inserts



**Answers to
OABB Continuing Education Activity
Adverse Effects of Blood Transfusion (0.5 CH)**

After reading this continuing education article, the participant shall be able to:

- ◆ Define acute and delayed reactions
- ◆ Identify the hallmark symptoms of an acute hemolytic transfusion reaction
- ◆ Differentiate between a delayed and acute adverse reaction
- ◆ List findings in several categories of transfusion reactions

Questions

1. An acute reaction is defined by the
 - a. Affect on the patient's long-term outcome
 - b. Immune mechanism responsible for the reaction
 - c. Severity of the patient symptoms when it occurs
 - d. Timeframe in which it occurs in relation to the transfusion event**

2. Which of the following are the two critical signs in diagnosing an acute hemolytic transfusion reaction?
 - a. Fever and chills
 - b. Hemoglobinemia and hemoglobinuria**
 - c. Hypoxia and shortness of breath
 - d. Increase in bilirubin and LDH

3. Which of the following reactions are considered an acute reaction?
 - a. Detection of anti-c in a sample collected three days after transfusion that was not present in the pre-transfusion sample
 - b. Fever and chills during the transfusion due to cytokines in the unit of Red Blood Cells**
 - c. TA-GVHD as the cause of death
 - d. Iron overload contributing to the patient's cardiomyopathy

4. An allergic reaction to blood that is not controlled by antihistamines is:
 - a. Caused by bacterial contamination
 - b. Due to patient IgA-deficiency**
 - c. From rapid transfusion of cold blood
 - d. Indicative of donor lymphocyte engraftment

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be considered or would like to nominate someone for a directorship, please contact President Elect, Cathy Shirley. If you are interested in helping on one of the committees either indicate this on your application or contact the committee chair. Contact information for all of your leaders is also available on the OABB website.

As you think of spring, think of the OABB annual meeting. I hope to see and meet all of you on April 29th.

Best wishes,

Gregg Witham
Past President



Proposal to change the Ohio Association of Blood Banks Code of Regulations

Members: Please read the proposed addition to the Ohio Association of Blood Banks Code of Regulations. The proposal will be voted on at the Annual Meeting April 29, 2010.

ARTICLE VI

MEETINGS OF TRUSTEES

ATTENDANCE: Members of the Board of Trustees are expected to attend at least three-fourths of the regular or special meetings. Any member of the Board not meeting this requirement will be contacted by the President to determine if they wish to continue in their position. The officers of the corporation will approve any member not meeting the attendance requirement, but wishing to continue on the Board. Any vacancy created by this attendance rule should be finalized before the next annual meeting so that the position can be filled at that time.

**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.

OABB vander Hoeven Award Program

The Ohio Association of Blood Banks (OABB) vander Hoeven Award Program offers financial awards to those students completing post graduate education in Blood Banking, Immunohematology, Cellular Therapy, and other related areas of study assessed by the AABB. Following oral presentation at the OABB annual meeting, the award recipient is selected by a panel of judges appointed by the OABB President.

ELIGIBILITY

All applicants must either be attending an Ohio accredited program or be an Ohio resident attending an accredited program in another state

Note: To be classified as a resident, a person must have lived in Ohio for at least one year either as self-supported or lived with a parent(s) or guardian who has been in Ohio for at least one year.

Each individual must be an OABB member in good standing since July 1 of the previous year.

CONDITIONS

- ◆ The winner of the award is given \$250.
- ◆ The award is made based on the excellence of presentation for content, delivery, and impact to the field.
- ◆ The presentation must be the applicant's independent work, and may not have been published prior to its submission for the OABB vander Hoeven Award. Previous oral presentations and posters are acceptable.
- ◆ The presentation must be based on work during the year(s) of post graduate studies.

SUBMISSIONS

- ◆ Students must apply for the award no later than April 1 of the calendar year immediately following the completion of training.
- ◆ Submissions are sent to the OABB Annual Meeting Coordinator.
- ◆ Submissions should be in abstract style with no more than 500 words printed in no less than 11 font size. The abstract should include a title, name of presenter, name of institution, background, methods, discussion, and conclusion. The abstract may include no more than one separate sheet of charts or graphs. The PowerPoint presentation in handout form may also be submitted with the abstract.



News from the Educational Wet Sample Coordinator

January's Educational Wet Sample (01-2010) contained anti-P₁. The antibody reacted at immediate spin, LISS-IAT, PEG-IAT and Gel. Solid phase testing was not performed by the shipping facility.

Antibodies with P₁ specificity often do not react with all P₁+ cells because of variation in antigen strength among individuals. The reactivity can lead to panel studies where all alloantibodies have been ruled out but all reactive cells are P₁+. Most participants identified anti-P₁ or responded to send the sample to a reference lab. Nearly half of those testing only by gel called the sample negative and none of the facilities using solid phase detected anti-P₁.

Thanks to everyone who participated and look for the next sample in April!

Sue Vonderwell, MT(ASCP)SBB^{CM}

Education Opportunities In Ohio

Cincinnati: Lectures presented for the Hoxworth Blood Center graduate programs in the Blood Transfusion Medicine (SBB) track and the Cellular Therapy track are open to anyone who would like to attend. Please contact Pam English at pamela.english@uc.edu or 513-558-1275 for a schedule and more information.

Hoxworth Blood Center participates in many of the AABB audioconferences offered on Wednesdays from 2-3:30P. All are held at Hoxworth's Central location - 3130 Highland Ave, Cincinnati, OH 45267. Please contact Pam English at pamela.english@uc.edu or 513-558-1275 for a schedule and more information.

Cleveland: Audio-conference schedule for 2010 is pending for American Red Cross, Northern Ohio Blood Services Region. For more information, contact Marlene D'Amico: damicom@usa.redcross.org

Columbus: The following continuing education is offered by American Red Cross, Central Ohio Blood Services Region. For more information, contact Deb Breech: MarshallD@usa.redcross.org

Date	Topic
Feb 24	Problem Solving: It's Not All About the Reactions
Apr 28	Update on Platelet Transfusions
May 5	Addressing Common Citations: AABB and CAP

Dayton: For continuing education offered by Community Blood Center /Community Tissue Services™ contact Laurie Carolus at 937-461-3580 or email lcarolus@cbccts.org for more information.

PREVIEW

OABB Annual Meeting Program, April 29, 2010

- | | |
|---------------|---|
| 8:30 – 9:15 | Meet the Vendors |
| 9:15 - 10:15 | Cultural Differences in the Workplace
Kathy Lechman
Leadership Consultant & Trainer
OSU Leadership Center |
| 10:15 - 10:45 | Break and Visit Vendors |
| 10:45- 11:00 | Platelet Antibody and Antigen Testing Application in the Clinical Laboratory
Brian R. Curtis, MS, MT(ASCP)SBB
Technical Director, Platelet & Neutrophil Immunology Lab
BloodCenter of Wisconsin |
| 11:00 – 11:45 | Warm Autoantibodies: Alternatives
Joanne Kosanke, MT(ASCP)SBBCM
Manager, Immunohematology Reference Laboratory
American Red Cross Central Ohio Blood Services |
| 11:45 – 1:00 | Lunch and Visit the Vendors / Physicians' Roundtable |
| 1:00 – 1:30 | Annual Meeting of the Membership |
| 1:30 – 2:15 | Fresh Blood: What is it all about?
Gerald A. Hoeltge, MD
Quality Review Officer, Pathology and Laboratory
Medicine Institute
Director, Perioperative Autotransfusion Service
Cleveland Clinic |
| 2:15 – 2:45 | Break |
| 2:45 – 3:30 | Managing Transfusion in Patients with Medication-Associated Coagulopathies
Mary R. Smith, MD
Professor of Medicine and Pathology
The University of Toledo College of Medicine |
| 3:30 – 4:15 | Getting on Board: US Biovigilance Network
Katharine A. Downes, MD, FCAP |

After attending the meeting, participants will be able to

- ◆ Identify hidden cultural biases
- ◆ Step outside of their cultural comfort zones
- ◆ List several causes for thrombocytopenia
- ◆ State platelet-specific antigens of high prevalence
- ◆ Select techniques to detect alloantibodies when autoantibody is present
- ◆ Evaluate alternatives for providing units of Red Blood Cells
- ◆ Identify how Red Blood Cell storage may impair patient outcomes
- ◆ Differentiate observational studies from randomized controlled trials
- ◆ List the types of medication associated with coagulopathies
- ◆ Describe transfusion products for treating drug-associated coagulopathies
- ◆ Get on board with the US Biovigilance Network

Biovigilance: Why bother?

Over the last few years, we have received information about development of the *US Biovigilance Network*, a national reporting system for untoward and unexpected events of blood transfusion and transplantation of tissues, cells and organs. The network's *Hemovigilance module* is specific for transfusion recipients and will soon be open to all hospitals. However, with our costs increasing, our budgets tightening, and our staff shrinking, do we want to add one more report system to our full schedules? What will we get out of it? Will it be worth the bother?

Brief history: In 2006, the Department of Health and Human Services (HHS) endorsed the network's development based on international program successes, including the UK, Europe and Canada. A public-private collaboration among the CDC (Centers for Disease Control and Prevention), AABB and other organizations involved in blood collection, transfusion, and tissue and organ transplantation was formed to develop a secure and standardized reporting system as well as facilitate funding to support the network. Additional network background information and modules under development can be found at: [http://www.aabb.org/Content/Newsletters and Journal/Biovigilance Update/biovigilanceupdate.htm](http://www.aabb.org/Content/Newsletters_and_Journal/Biovigilance_Update/biovigilanceupdate.htm).

Benefits and issues: There are many benefits to participate in the hemovigilance module, and some are listed below. But, there are still many questions to consider for whether to participate and when to start.

- ◆ **Standardization:** Currently, procedures defining and evaluating adverse events in the US vary widely. The hemovigilance module provides a standardized system to report adverse reactions and incidents. It also allows more accurate analysis of available data and detection of trends.
- ◆ **Patient safety:** International programs demonstrated that when best practice recommendations were developed from good data collection and analysis, it can reduce adverse events and improve patient outcome. Similar results are expected in the US.
- ◆ **Financial impact:** Adverse event detection and reduction will help to reduce direct patient care costs.
- ◆ **Reports:** Participants have the opportunity to generate local tracking and analysis reports along with group and national data in aggregate form.

Participation: Participation is *voluntary* and there is *no fee* to enroll. This is a national program, so all hospitals involved with blood transfusions can participate, regardless of size or affiliation. AABB institutional membership is not required. Institutional Review Board (IRB) approval is not required. As more hospitals enroll and participate in hemovigilance, data accuracy and reliability will increase the benefits gained.

Data security: The hemovigilance module was developed through CDC's secure National Healthcare Safety Network (NHSN) internet-based surveillance system. This is the same system hospitals use for other patient safety and healthcare related information. All entered information is maintained in *strict confidence* and is not legally discoverable under federal law. Each enrolled user applies for a digital certificate to prove identity and allow access to the secure system. Ownership of all data entered by the hospital remains with the enrolled hospital. Hospitals may give permission to share data within a specified group to identify or develop best practices and improve patient safety (see Groups in Biovigilance).

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Staff involvement: Consider presenting information about the hemovigilance module to the Transfusion Committee or similar quality review program to determine the appropriate direction. The Transfusion Service and/or the hospital's designated Transfusion Safety Officer (TSO) are logical choices to manage the module. However, all staff involved in transfusion-related processes should participate in data collection and evaluation.

Time commitment: As with any new process or procedure, the largest amount of time is in the preparation. Initially, at least a month may be needed to plan, document, train and enroll in the program. However, once these are completed, the time required to enter adverse events into the system is minimal – a few minutes per reaction or incident. Adverse reactions and incidents are entered retrospectively after investigation is completed. A monthly report is submitted to provide summary data and totals for analysis. Although data entry is manual, interface methods are being developed.

The biovigilance network has completed the hemovigilance pilot studies and is preparing for open enrollment in the first quarter of 2010. Announcements should be forthcoming. Until then, take a look at the Hemovigilance forms and training documents available on the CDC website: <http://www.cdc.gov/nhsn/bio.html>. There is a lot that you can do now to prepare.

- Check if your hospital is already enrolled with NHSN (check with Infection Control). If so, this can make your enrollment easier. If not, training on how to complete the process is provided through the CDC website.
- Print the Annual Facility Survey and begin gathering information to complete. Requested information allows accurate analysis of captured adverse event data. Your completed survey is needed once you enroll, so start now and save time.
- Review the Hemovigilance Module Protocol which contains the signs and symptoms, adverse reaction definitions, and case definition criteria to be used. Even if you do not participate early on, you can begin to move towards the hemovigilance *standard* for future benchmarking. Plan now how to educate staff involved in transfusion-related adverse event reporting.
- Review the Hemovigilance Adverse Reaction and Incident forms. Consider now how you can incorporate these into your current processes in order to make future documentation and reporting more efficient.

On Thursday, April 29, the 2010 OABB Annual Meeting will include a presentation by AABB on the US Biovigilance Network. Dr Katharine Downes from University Hospitals Case Medical Center in Cleveland, Ohio, will present her experiences from the recent biovigilance pilot. She will describe key activities in the program and review adverse event/transfusion reaction reporting with attendees. She will also share highlights of her experiences with data analysis and interpretation review.

This presentation will be a great opportunity for all of us to learn more about Hemovigilance and why we should bother to take the time. Be sure to mark your calendars and join your peers! Let's make this system work!

Colleen McGuinness Slapak
MS, MT(ASCP)SBB