Michigan Association of Blood Banks presents

Summer 2009

In A Different Vein

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PRESIDENT'S MESSAGE

By Suzanne Butch, MA, MT(ASCP)SBB

Join us at the MABB Annual Meeting Sept 16-17 and the series of Fall Rap Sessions in Grand Rapids, Gaylord and Southfield. More information on the Rap Sessions will be posted on the web site and sent in emails.

Inside This Issue

- President's Message 1
- Invitation to the 55th Annual Meeting..... 1-3
- Why We Do What We Do 3-8
- Method Correlation or Madness?.....8-10
- 55th Annual Meeting Agenda..... 11
- Send Articles To Editors 11
- 2009 MABB Officers..... 11
- Admin/Web/Newsletter Contact Information..... 11

With the merger of the National Credentialing Agency for Laboratory Personnel (NCA) and American Society for Clinical Pathology (ASCP) Board of Registry (BOR), obtaining Continuing Education Credits (CEU's) to maintain certification becomes more important. One cost effective method of obtaining CEU's and maintaining the new title of Medical Laboratory Scientist (MLS) is through attending MABB educational events. For those of you who are not familiar with the recent events on the NCA/BOR merger, you can visit the NCA or ASCP BOR web sites: http://www.nca-info.org/ or http://www.ascp.org/FunctionalNavigation/certification/relateddocument.aspx. The MABB is a provider of P.A.C.E. credits for our sessions. In addition to the CEU's, attending MABB events provides networking opportunities and vendor contacts.

We have posted the lists of past MABB Presidents and Award Winners under committees. If you have suggestions for other information to be posted, please let us know. See you soon at a MABB Education Session.

JOIN US!

55th MABB Annual Meeting: September 16 - 17, 2009

INVITATION TO THE 55th ANNUAL MEETING

By Allyson Henstock, MSM, MT(ASCP)SBB
President-Elect, Michigan Association of Blood Banks

Dear fellow members of the MABB,

I would like to invite you to our 55th Annual Meeting in September. We have a wonderful program planned that we hope you will enjoy. There are many exceptional and qualified speakers.

Coming from my own facility, Mount Clemens Regional Medical Center, are Drs. Dorothy Halperin, MD and Mandip Atwal, DO.

Continued on Page 2...

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Dr. Halperin is our Transfusion Service Medical Director. She will be speaking about the unique aspects of Blood Banking/Transfusion Medicine as it relates to obstetrics.

Dr. Atwal will be speaking about massive transfusion and emergency blood from his own experience as a surgeon in trauma.

Speakers from other local institutions include Suanne Dorr, Amy Dixon and Gerard Van Grinsven.

Ms. Dorr is Administrative Director for the J. P. McCarthy Cord Stem Cell Bank of Karmanos Cancer Institute Bone Marrow Transplant Clinical Laboratories. She will discuss *Umbilical Cord Blood Donation*.

Ms. Dixon is a Senior Leadership Development Specialist for Wm. Beaumont Hospitals. She has been a popular, well received speaker at our meetings in the past. This time her topic is how to cope with burnout on the job.

Mr. Van Grinsven is the President and CEO of the new Henry Ford West Bloomfield Hospital. His title is intriguing….*Blue Ocean Strategy in a Difficult Economy*.

Coming a little further are six presenters from three of Michigan's fine universities, Michigan State University and Oakland University and University of Michigan.

John Gerlach, PhD is someone MSU Med Tech grads should know. He is Professor and Director of the Biomedical Laboratory Diagnostics Program at MSU. Dr.Gerlach's subject is an introduction to Molecular Diagnostics. Dr. Gerlach says he'll have to speak fast in order to say as much as he can about a pertinent topic in only 40 minutes.

Also from MSU is Dr. Ken Schwartz MD, Professor Hematology/Oncology. His subject is *Prophylactic Platelet Transfusion*.

Lynne Williams, PhD, is Professor and Program Director, Medical Laboratory Sciences at Oakland University. She will talk about career opportunities for Med Techs.

Clinical Cases are being presented by Drs. Laura Cooling, Associate Professor of Pathology, and Melissa Bombery, House Officer and Resident in the Department of Pathology. Both are from University of Michigan Hospitals.

Finally, three speakers come from far away.

First is Katharine A. Downes, MD. Dr. Downes is from Case Western Reserve School of Medicine in Cleveland, OH. As Chair of the CAP Transfusion Resource Committee, Dr. Downes (Also see Chapter 15 of your current MABB Technical Manual.) has two presentations. They are *Current Practices in Pretransfusion Compatibility Testing* and the *Selection and Use of Automated Methods in the Transfusion Service*.

Second is our very own John Judd, Emeritus Professor of Immunohematology, University of

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Michigan. John is making his first appearance with the MABB since his official retirement to North Carolina three years ago. In fact he called me to offer to speak. He misses us and says he is looking forward to his visit to Michigan. John's subject is ABO discrepancies. His title is *What's My Type?*

Our farthest speaker comes from beautiful southern California. She is Patricia Arndt, Senior Research Associate at the American Red Cross Blood Services, Southern CA Region. Pat is presenting the Kay Beattie Lecture. Her topic is titled *Serologic Investigation of Drug-Induced Immune Hemolytic Anemia*. Pat is also going to present serology cases.

The meeting is at the wonderful facility, the VisTaTech Center at Schoolcraft College in Livonia. We meet Wednesday and Thursday, September 16-17, 2009. Please join us for a great meeting and great camaraderie. To register, please visit http://www.mabb.org/meeting.htm.

WHY WE DO WHAT WE DO – Biological Product Deviation

By Sharon Lowry, MT(ASCP)SBB CQA(ASQ)
University of Michigan Hospitals and Health Centers, Ann Arbor, MI

While working in the blood bank, you document certain problems that occur. Your manager investigates, takes necessary action, and sometimes reports the problems to the FDA. This article focuses on information for the hospital blood bank or transfusion service so they can answer the question "Why do we do what we do with those FDA reports?"

Manufacturers of biological products must file Biological Product Deviation (BPD) reports with the FDA for certain events. Biological products are listed below:

- Blood and blood components
- Source plasma from licensed plasma centers
- Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P), and
- Non-blood biological products, such as vaccines and derivatives

There are three classifications of manufacturers of blood and blood components:

- Blood establishments who collect blood and are licensed for interstate commerce, such as blood centers like American Red Cross or Michigan Community Blood Center. They are regularly inspected by the FDA.
- Blood establishments who are registered, unlicensed, and not involved in interstate commerce, such as hospital blood banks that collect homologous and/or autologous units. Even if units are not collected, registration is required for the following activities: irradiation, sterile welding, leukocyte reduction, rejuvenation, freezing, or washing cells. They are regularly inspected by the FDA.
- Transfusion services who are exempt from registration and licensure. They must be certified by Centers for Medicare and Medicare Services (CMS). They may perform compatibility testing and basic component preparation, such as thawing, pooling, aliquoting, and leukocyte reduction (when filtered at the bedside). In an emergency they may collect blood. The FDA has the authority to inspect transfusion services, but generally does not.

Continued on Page 4...

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Federal regulations require all manufacturers of blood and blood components to report BPDs. In the beginning, only licensed blood establishments were required to file reports for "errors and accidents". Later, registered unlicensed establishments and transfusion services were encouraged to voluntarily file reports. A final rule was published in 2000 which required all manufacturers of blood and blood components to file reports. In 2001, the regulations for this rule went into effect. This is the Code of Federal Regulations 21 CFR 606.171. At this time, the term "errors and accidents" was replaced with "biological product deviation".

For manufacturers of blood and blood components, a BPD is a manufacturing event which could affect the safety, purity, or potency of a distributed product. The event must have occurred in your facility, or a facility contracted by you, and your blood bank or transfusion service had control over the product when the event occurred. The reports are due within 45 days from the date the event was discovered. For instance, if an error was made on January 1st and discovered on April 1st, the report is due by June 15th.

Manufacturing in the setting of a transfusion service or a hospital blood bank that does not collect blood is the testing, processing, packing, labeling, storage, and distribution of blood and blood components. Some examples of manufacturing are listed below:

- Labeling of the patient's sample
- Testing of the patient's sample: ABO, Rh, antibody screen, crossmatch, and antibody identification studies
- Testing of the donor unit: ABO confirmation and Rh when indicated, antigen typing of the donor unit for patients with antibodies, bacterial testing of platelets if not performed by the supplier
- Preparing components: Pooling, aloquoting, thawing, irradiating
- Labeling blood and modified blood components
- Storing and distributing blood and blood components

Check your knowledge of when to report (*or not report!)* an event and the rationale behind the BPD regulations using the five events listed below:

#1 Plasma was thawed and the expiration date applied was incorrect.
- Report the event if the expiration date was lengthened.
- Do not report the event if the expiration date was shortened.
  Rationale: A shortened expiration date does not affect the safety, potency, or purity of the plasma.

#2 A red cell was transfused to the wrong patient.
- Report the event if the transfusion service labeled the product with the wrong patient's identification.
- Do not report the event if nursing transfused the wrong patient.
  Rationale: Administration of blood products is not part of the manufacturing process. However, if the patient expired, the fatality must be reported to the FDA Centers for Biologics Evaluation and Research (CBER).

Continued on Page 5…

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#3 The wrong product was issued.
- Report the event if platelets were ordered and red cells were issued.
- Do not report the event if an allogeneic unit was issued when an autologous or directed unit was available.
  Rationale: The safety, potency, or purity was not affected.

#4 A product was not dispensed in the computer.
- Do not report the event if an alternate record is available, such as the dispense was recorded on a paper log before dispense in the computer.
- Report the event if the computer is the sole record of issue.
  Rationale: Clerical and visual checks must be documented.

#5 Testing was performed using a mislabeled specimen.
- Report the event if blood was issued, even if it was not transfused.
- Do not report the event if crossmatched blood was set up but never left the transfusion service.
  Rationale: Only events with distributed products are reportable.

In fiscal year 2008, there were 44,740 BPD reports. Licensed and Unlicensed blood establishments and Transfusion Services accounted for 32,311 (73%) of the reports.

2008 BPD Reports				
	Reports		Establishments	
	Number	Percent	Number	Percent
Licensed Blood Establishments	26,655	60	231	16
Unlicensed Blood Establishments	3,798	9	384	26
Transfusion Services	1,858	4	460	31
Licensed Plasma Centers	11,814	26	287	19
HCT/P and Non-blood Manufacturers	615	1	119	8
Total	44,740	100	1,481	100

For manufacturers of blood and components, 82% were filed by licensed blood establishments, 12% by unlicensed registered blood establishments, and 6% by transfusion services. Since some transfusion services filed zero reports, there may be under reporting. 67% filed 1 or 2 reports and 14% filed more than 5 reports.

The FDA categorizes the blood and blood component reports by manufacturing system. The table below lists the number of events by category. The number of donor related events for unlicensed establishments was not included in the table.

Continued on Page 6...

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	Manufacturing System				
	QC & Distribution	**Labeling**	**Routine Testing**	**Component Preparation**	**Miscellaneous**
Unlicensed Establishment	1,798	948	444	67	20
Transfusion Service	993	519	338	8	0

Examples of events by category are listed in the table below:

Category	Subcategories	Examples
QC and Distribution	Distribution not performed in accordance with specifications	• Unit not issued in computer system • Unit not irradiated as required • Improper ABO/Rh selected • Wrong product issued or issued to the wrong patient • Unit released without a current type and screen • Unit not leukoreduced as required • Visual inspection not performed • Unit returned and re-issued inappropriately • Unit outdated
	Testing not performed, incomplete, or not documented	• ABO/Rh testing • Antibody screen • Antibody identification • Antigen typing
	Shipping and storage	• Unit stored or at incorrect temperature • Shipping and storage temperature not documented • Unit not packed according to specifications
Labeling	Crossmatch tag or tie tag labels, or transfusion record incorrect or missing information	• Recipient identification (name or medical record number) incorrect or missing • Unit/lot/pool number incorrect or missing • Crossmatch tag switched and both units intended for the same patient • Product type incorrect or missing • Crossmatch tag or tie tag missing or attached to incorrect unit • Unit ABO and/or Rh incorrect or missing

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	Labels applied to component incorrect or missing information	• Extended expiration date or time • Missing expiration date or time • Donor or lot number incorrect or missing • ABO and/or Rh incorrect or missing • Product type or code incorrect • Unit volume incorrect or missing • Machine readable barcode incorrect or missing
Routine Testing	Testing performed, interpreted or documented incorrectly	• ABO/Rh, antibody screen or identification, compatibility test, antigen typing • Wrong crossmatch performed (immediate spin instead of AHG) • Reagent QC incorrectly performed • Expired reagents used • Mislabeled, unsuitable, or incorrect sample used
Component Preparation	Sterility compromised	• Leaking at sterile connection site • Air contamination
	Component not prepared in accordance with specifications	• Unit processed at incorrect centrifuge speed or temperature setting • Documentation of irradiation process incomplete or missing • Product irradiated more than once • Incorrect number of units pooled • Incorrect or missing documentation of weld inspection while sterile docking

The most significant problem in 2007 for unlicensed registered blood banks and transfusion services remains the most significant problem in 2008: “Product not documented or incorrectly documented as issued in the computer”.

TOP 10 BPD Reports for Transfusion Services in 2008

1. Product not documented or incorrectly documented as issued in the computer (347 reports)
2. Recipient identification incorrect or missing on crossmatch tag or tie tag labels (90 reports)
3. Product not irradiated as required (64)
4. Procedure for issuing not performed or documented in accordance with specifications (62)
5. Unit/lot/pool number incorrect or missing on crossmatch tag or tie tag labels (61)
6. Crossmatch tag switched, both units intended for same patient (58)
7. Antibody screening or identification performed, interpreted or documented incorrectly (58)
8. Sample used for testing was incorrectly or incompletely labeled (58)

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9. Improper ABO or Rh type selected for patient (57)
10. Antibody screen or identification not performed, incompletely performed, or not documented (55)

The FDA website provides excellent resources and contact information. The guidance for industry document is especially useful. Recently, the annual summary report for 2008 was posted. See the links listed below under References.

Formal quality assurance programs are required for blood banks and transfusion services. Deviations and unexpected events are recorded so that processes can be continually improved. Staff must be trained to recognize these events.

Now that you know Why We Do What We Do for BPDs, use your reportable *and non-reportable* events to prioritize your quality improvement projects. Implement corrective and preventative actions to resolve and prevent reoccurrence of the problems. Evaluate the effectiveness of the actions. And most important,

Document what you did!

References

1. Food and Drug Administration. Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments. 10/18/2006. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation

2. Food and Drug Administration. Biological Product and HCT/P Deviation Reports – Annual Summary for Fiscal Year 2008. www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem

3. Food and Drug Administration. Vaccines, Blood & Biologics. Biological Product Deviations. www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem

4. Food and Drug Administration. Vaccines, Blood & Biologics. General Instructions for Completing the Biological Product Deviation Report (BPDR) – Form FDA 3486. www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem

5. Code of Federal Regulations. Title 21 Part 606

6. AABB Technical Manual, 16th Edition

METHOD CORRELATION OR MADNESS?

By Suzanne H. Butch, MA, MT(ASCP)SBB

First, let me say that quality control is important. As laboratorians, we have a responsibility to follow federal regulations. Furthermore, we have a responsibility to bring to the attention of our regulators when there are illogical and time consuming quality control requirements that fail both the purpose and spirit of quality management. One such example has recently come to my attention. In the newest (6/15/09) CAP Transfusion Medicine Survey is question TRM.31450 that asks "If the laboratory uses more than one instrument/method to test for a given analyte, are the instruments/methods checked against each other at least twice a year for correlation of results?"

The question and the explanatory note below is word for word the Chemistry/Toxicology question CHM.13800: "*NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods. This comparison must include all nonwaived instruments/methods. The laboratory director must establish a protocol for this check. Quality control data may be used for this comparison for tests performed on the same instrument platform, with control materials of the same manufacturer and lot number. Otherwise, the use of fresh human samples (whole blood, serum, plasma, urine, etc.) rather than stabilized commercial controls, is preferred to avoid potential matrix effects. In cases when availability or pre-analytical stability of patient/client specimens is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/methods involved. This checklist requirement applies only to instruments/methods accredited under a single CAP number.*"

My interpretation of the above is that every six months blood bank laboratories must now document correlation between all methods used to perform a Type, Screen, Crossmatch and antibody identification whether by tube, manual or automated microtiter plate, manual or automated Gel and by different phases. We must document that we get the same answer, regardless of method.

The rationale behind this CAP question is that correlation studies are a required by CLIA regulation. This appears to be an unintended consequence of the most recent revision of the CLIA quality control regulations where individual laboratory requirements were eliminated in favor of a single set of requirements.

This requirement makes sense when the results being reported vary from day to day and instrument to instrument. However, blood types do not change without cause. They are not variable from day to day. In addition, the ABO type is "controlled" by the use of a forward and reverse grouping. Tube Rh typing result vary by the clone(s), enhancement media, incubation time, cell suspension and other patient variables. It is well known that the various methods used for antibody detection and identification have differences in sensitivity and specificity. In addition, some antibodies are only recognized under very specific circumstances. No two antibody detection/identification methods get the exact same results. In fact, we employ this variation in methods to obtain different results when we use enzymes, PEG, LISS, etc. to help us

Continued on Page 10...

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problem solve when a patient has multiple antibodies, non-specific reactivity, and warm and cold auto antibodies.

The most important "control" we do in the transfusion service is the history check. We do this for every patient. If we find a discrepancy, we investigate. Doing a method comparison every six months will not improve patient care. Applying what is a rational requirement when doing biochemical tests to the serologic results produced by immunohematology testing is not appropriate. If the method comparison was easy to perform, one might decide to just comply. In this case, however, meaningful testing is cumbersome, difficult to structure and execution is expensive to execute. Significant time and resources would need to be devoted to this task. Testing enough samples to provide a valid comparison of methods is time consuming and illogical.

The references given for this new requirement are based on biochemical and hematological studies:

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24):5236 [42CFR493.1281(a)]
2) Podczasy JJ, *et al*. Clinical evaluation of the Accu-Chek Advantage blood glucose monitoring system. *Lab Med*. 1997;28:462-466
3) Ross JW, *et al*. The accuracy of laboratory measurements in clinical chemistry: a study of eleven analytes in the College of American Pathologists Chemistry Survey with fresh frozen serum, definitive methods and reference methods. *Arch Pathol Lab Med*. 1998;122:587-608
4) Miller WG, Myers GL, Ashwood ER, *et al*. State of the Art in Trueness and Inter-Laboratory Harmonization for 10 Analytes in General Clinical Chemistry. *Arch Pathol Lab Med 2008;132:838-846*
5) Clinical and Laboratory Standards Institute. *Verification of comparabililty of patient results within one healthcare system: Approved Guideline*. CLSI document C54-A (ISBN 1-56238-671-9).Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 190871898, USA, 2008.

For those of you who share my opinion and believe the arguments against method correlation on a 6 month basis are cogent, please write Judy Yost Director, Center for Laboratories US Dept of Health & Human Services Commission on Medicare & Medicaid Baltimore, MD or CLIA staff at (410) 786-3407 or (410) 786-3531. Her email is Judith.yost@cms.hhs.gov . I have heard her speak and she is a proponent of reasonable and effective quality control.

Reference:

CAP Transfusion Medicine and Clinical Chemistry/Toxicology Checklists. 6/15/2009. College of American Pathologists. College of American Pathologists, 325 Waukegan Road, Northfield, IL 60093-2750.

MABB 55th Annual Meeting Agenda

Wednesday, September 16th

8:00	Registration and Continental Breakfast
8:40	Introduction Suzanne Butch, MABB President
8:50	Molecular Diagnostics: Beyond NAT John Gerlach, PhD
9:40	ABO's and Ob(stetrics) Dorothy Halperin, MD
10:30	EXHIBITS
11:10	2009 Kay Beattie Lecture: Serologic Investigation of Drug-Induced Immune Hemolytic Anemia Pat Arndt, MS, MT(ASCP)SBB *(Lecture sponsored courtesy of Michigan Community Blood Center)*
12:00	LUNCH AND EXHIBITS
1:00	MABB BUSINESS MEETING
1:30	Prophylactic Platelet Transfusion Kenneth Schwartz, MD FACP
2:20	Current Practices in Pretransfusion Compatibility Testing Katharine Downes, MD FACP
3:10	REFRESHMENTS & EXHIBITS
3:40	Selection and Use of Automated Methods in the Transfusion Service Katharine Downes, MD FACP
4:30	Serological Case Studies Patricia Arndt, MS, MT(ASCP)SBB
5:00	Adjourn

Thursday, September 17th

8:00	Registration and Continental Breakfast
8:40	Introduction Suzanne Butch, MABB President
8:50	Blue Ocean Strategy in a Difficult Economy Gerard Van Grinsven
9:40	Umbilical Cord Blood Donation Suanne Dorr MBA, MT(ASCP)SC
10:30	REFRESHMENTS & EXHIBITS
11:10	What's My Type? John Judd FIBMS MIBiol
12:00	LUNCH
1:00	Beating Burnout With Balance Amy Dixon BA, MSBA
1:50	Career Opportunities for CLS/MT Lynne Williams, PhD
2:40	REFRESHMENTS
3:00	Emergency Blood and Massive Transfusion: The Surgeon's Perspective Mandip Atwal, DO
3:50	Clinical Case Studies Laura Cooling, MD Melissa Bombery, MD
4:30	Adjourn

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The deadline for next issue is October 1st!

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