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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #27 **July 26, 2013**

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2011 NBCUS Report Confirms Downward Collection, Transfusion Trend

The Department of Health and Human Services published this week the highly-anticipated results of the 2011 National Blood Collection and Utilization Survey (NBCUS), conducted under contract by AABB. The NBCUS Report highlights the rise of patient blood management (PBM) and confirms downward trends in whole blood (WB) and red blood cell (RBC) collection and transfusion that are being observed by blood centers.

The survey, sponsored by the Assistant Secretary for Health, along with the DHHS operating divisions, has been conducted every two years by AABB since 1998, and remains the major mechanism for assessing blood collection and utilization in the US. The 2011 survey includes a PBM section with questions regarding transfusion training, highlighting the expansion of PBM programs.

Blood Collection and Utilization Trends. The overall response rate for the 2011 NBCUS survey was 44.1 percent. For blood centers, the response rate was 94.1 percent (128/136); for hospitals it was 42.3 percent (1,342/3,175); and for cord blood banks it was 28.6 percent (20/70). The survey found that a total of 15.7 million WB/RBC units were collected, a statistically significant decline of 9.1 percent from the 17.3 million units collected in 2008. The trend of increasing collections that had been reported since 1998 was reversed in the period between 2008 and 2011.

The decrease in WB/RBC collections was likely driven by the decrease in demand; the estimated total number of WB/RBCs transfused in 2011 was 13.7 million units, 8.2 percent fewer units transfused than in 2008. The WB/RBC transfusion rate in 2011 was 44 allogeneic units transfused per 1,000 overall population, compared to 48.8 per 1,000 in 2008. Between 2001 and 2008, utilization grew at a slower rate than did collections.

The available allogeneic supply of WB/RBC units, after accounting for testing and other product loss, was 14,472,000 units. This exceeds transfusions of allogeneic WB/RBCs by a margin of 752,000, approximately 5.2 percent of the available supply. The available supply of WB/RBCs was sufficient to meet transfusion needs in 2011; shortages were rare and significant for only a very few hospitals.

(continued on page 3)

OUR SPACE

Matt Granato, ABC's Executive Vice President, Operations

To Shape the Future, Get Involved

Earlier this week, the Department of Health and Human Services published the 2011 National Blood Collection and Utilization Survey (NBCUS) Report (see page 1). The results will come as no surprise to blood bankers: blood collections are down, driven by the decrease in demand and perhaps the increase in patient blood management strategies. Overall, there has been about an 8 percent decrease in whole blood and red blood cell (RBC) transfusions – echoing what ABC members have reported and similar to rates reported by European Blood Alliance members.

Experts identify the usual causes of this trend – evidence-based conservative transfusion, the recent economic crisis, anticipation of the new healthcare law implementation – driving hospitals to cut costs (i.e., "blood management"), and the emergence of new medical treatments that replace blood-intensive therapies. The US dropped from 48.8 RBCs transfused/1,000 population in 2008 to 44 RBCs/1,000 population in 2011. However, this rate remains high compared to some of our European and Canadian colleagues. In essence, that rate will likely continue to drop, and this means a *major* landscape change for US blood providers. Consolidation, diversification, and supply chain integration are all options on the table.

Major changes for our members mean big challenges for the association. It is not ABC's mission to "save" any one blood center, but to collectively provide one voice and arm them with the resources that, like a digital compass, will enable them to navigate the changing landscape with much-needed precision. ABC's incoming leadership will undoubtedly spend much of their time on ABC's national advocacy agenda. With so many of the variables impacting blood centers originating at the federal level, ABC is best positioned to speak up on behalf of blood centers and work with partner organizations and our allies in Washington to mitigate the impact of these policies and carve a path of certainty amid uncertain times.

Providing education and information to our members, something which ABC has succeeded in historically, will remain critical and most likely intensify. However, in order to help shape the future of blood banking in the US, we will not only seek out, analyze, and relay data and information, but we will also rely on the collective brain power of our members. Now is the time to get involved, either by joining a committee, attending a meeting or workshop, or simply responding to a survey: have your voice heard. The ABC membership profile will likely change (a prediction at a recent meeting suggested "20 independent blood centers will be left in the next 10 years") but ABC's core values of advocacy, education, and data will not. ABC will always stand by and speak up for the independent blood program. To shape the future of blood banking – your future – I urge you to get involved.

mgranato@americasblood.org

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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2011 NBCUS Survey Report (continued from page 1)

The total number of all components transfused in 2011 was 20,933,000, a decrease of 11.6 percent from 2008. The transfusion of WB-derived platelets decreased by 23.6 percent from 2008 (although the difference was not statistically significant), while apheresis platelet transfusions increased 11.9 percent. Transfusion of plasma decreased by 13.4 percent. Autologous WB/RBC collections totaled only 113,000, a decrease of 55.5 percent from 2008.

"It is possible that this decline in transfusion rate is a residual of the recession, but more likely it is an indication of the growing adoption of blood management practices," said the report. While this is one possible explanation, it is important to note that the survey results do not establish a relationship or asso-association between PBM and the decreased WB/RBC collection/utilization trends. Blood centers have grappled over the past couple of years with decreasing demand at hospitals that seek to decrease transfusions, improve patient care, and cut costs.

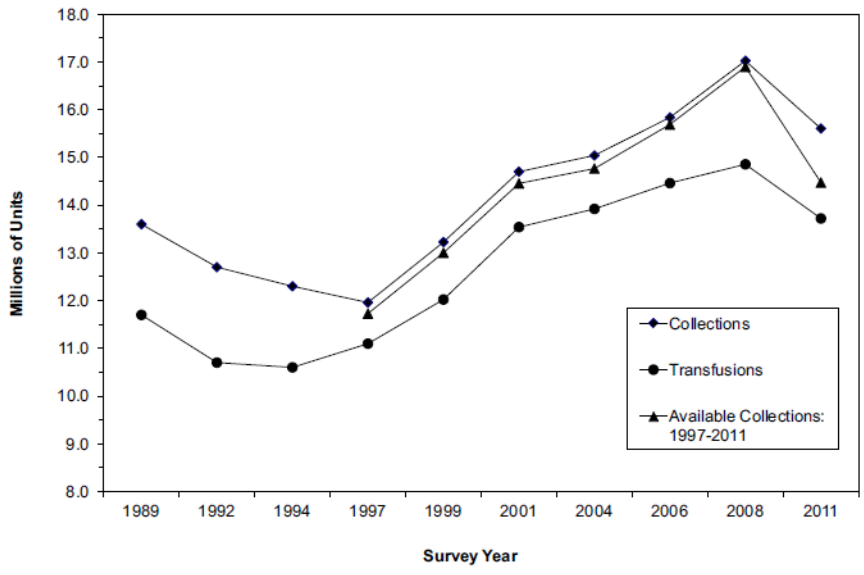


Figure 8-2. Allogeneic whole blood and red blood cell collections and transfusions, 1989-2011.

Source: 2011 National Blood Collection and Utilization Survey Report, Department of Health and Human Services, AABB.

These trends were discussed at a recent meeting of HHS's Advisory Committee on Blood and Tissue Safety and Availability, which explored whether the current US blood center system is sustainable and designed to deliver optimal service going forward (see *ABC Newsletter*, 6/14/13). Experts at the meeting said they foresee further blood center consolidation as decreasing blood use and other healthcare trends continue to impact blood banking.

Patient Blood Management and Transfusion Training. For the first time, the NBCUS included questions about PBM to "assess the degree to which this evidence-based, patient-oriented initiative has gained traction in US hospitals and blood centers." Of responding facilities, 30 percent reported that they have a PBM program. While many facilities do not have formal programs, there is a broad implementation of initiatives focused on reducing blood loss and associated allogeneic transfusions in patients. The most common programs existing in hospitals were preoperative and intraoperative interventions, including parenteral iron supplementation (in 82 percent of reporting hospitals), intraoperative blood recovery (in 64 percent of reporting hospitals), and preoperative laboratory assessment for anemia (in 47 percent of hospitals).

(continued on page 4)

2011 NBCUS Report (continued from page 3)

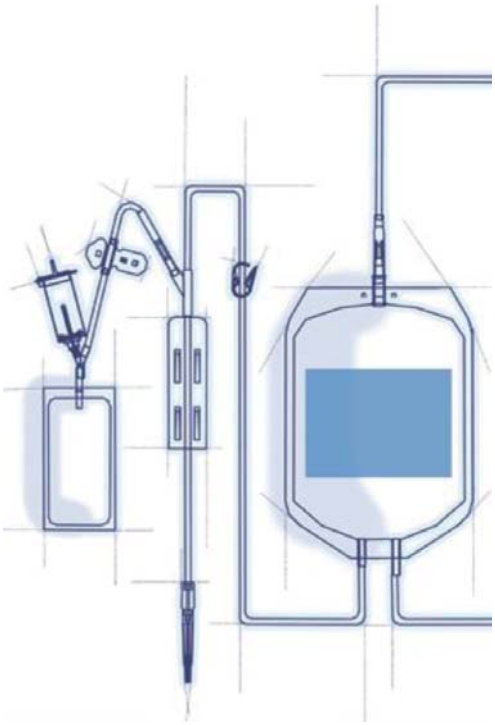
"I am very pleased to see the inclusion of PBM in the NBCUS report. It is encouraging to see that as many as 30 percent of reporting facilities have a PBM program, that 15 percent of hospitals now have either full- or part-time transfusion safety officers, and that 35.2 percent of hospitals use some measure to evaluate preoperative patients for anemia," said Mary Townsend, MD, senior medical officer at Blood Systems, and ABC board of directors member. "The effectiveness of these PBM programs may partially explain the reduction in transfusion of red cell products and plasma."

As many blood centers are aware, proper transfusion training for healthcare providers is essential to a successful blood management program. The NBCUS results provide some insight into hospital transfusion training. "While 94.6 percent of hospitals report formal transfusion training for nurses, only 23.4 percent have similar programs for physicians and other ordering providers, suggesting room for improvement in this aspect of PBM. Overall, I found the report encouraging," said Dr. Townsend. The report also showed that 57 percent of transfusing hospitals report having an established program to treat patients who refuse any or all blood components for religious, cultural, or personal reasons, compared with only 15 percent in 2008. The results illustrate the growth of various PBM initiatives.

Other Findings. The report also included survey results regarding hemovigilance and biovigilance programs, component modification, current issues in blood collection and screening, current issues in blood transfusion, component costs, and cellular therapy products.

The 2011 report and past reports can be downloaded for free at www.hhs.gov/ash/bloodsafety/nbcus/. (Sources: NBCUS Report, 2011, 2009)

Advertisement



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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

ABC Launches Supply Chain Optimization Listserv

America's Blood Centers launched this week the Supply Chain Optimization Listserv. ABC provides its member blood centers the opportunity to interact and communicate with other blood center staff of the same discipline through the ABC Listservs. A Listserv is a fast and easy way ABC member blood center staff to begin a discussion thread, ask the group a question, share best practices, and discover the latest issues affecting the day-to-day blood center operations directly from their peers.

All employees currently on the Supply Chain Optimization Forum have been automatically added to the new Supply Chain Optimization Listserv. Any ABC members who are not active on the Supply Chain Optimization Listserv or any additional ABC Listserv and would like to join, should view MCN 13-100 for further instructions: http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4432.

Questions may be directed to Abbey Nunes at anunes@americasblood.org.

ABC Invites Members to Learn About Partnership Marketing

America's Blood Centers will hold a webinar on Aug. 7 at 2 p.m. ET discussing "Partnership Marketing." Community Blood Center of Greater Kansas City created mutually beneficial marketing partnerships with a goal of driving traffic and creating awareness for both the blood center and the partnering brand. During this webinar, the center's marketing director, Stann Tate, will walk attendees through this targeted approach and the successes that have been achieved.

Questions or concerns may be directed to Abbey Nunes at anunes@americasblood.org. Members can find login details in MCN 13-099 at:
http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4431.

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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Every two seconds,
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A blood banker's job is like no other. At the end of the line, someone like Benjamin is in real need. We know how critical safety is, how vital efficiency–we talk to hundreds of blood bankers every year. We're using your input to create smarter, more intuitive blood analyzers. For science-driven safety and efficiency. For you. For Benjamin.

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RESEARCH IN BRIEF

Research published on July 19 in *Blood* explored a novel approach involving treatment of neonatal alloimmune thrombocytopenia (NAIT) *in utero*. The study was conducted by Tamam Bakchoul and colleagues at the Institute for Immunology and Transfusion Medicine at Ernst Moritz Arndt University in Germany. NAIT is typically discovered when an otherwise healthy infant is found unexpectedly to have severe thrombocytopenia and bleeding immediately after birth. NAIT results from maternal immunization against fetal-specific human platelet antigens (HPAs). Similar to Rhesus D incompatibility, maternal antibodies to antigens on fetal platelets can result in the destruction of fetal platelets after transplacental transport to the fetal circulation. Alloantibodies against the epitope HPA-1a on glycoprotein (GB) IIb-IIIa are responsible for most severe cases of NAIT. Mothers with a history of NAIT require treatment during subsequent pregnancies to reduce the risks to the fetus. The current mainstay of therapy is antenatal intravenous immune globulin administered to the mother in high doses at weekly intervals from the second trimester until delivery, with or without corticosteroids. While this approach is effective at preventing intracranial hemorrhage in the infant, it is costly and cumbersome, and is associated with significant side effects. The current study moves scientists one step closer to a targeted therapy for women with NAIT. The investigators produced a modified monoclonal anti-HPA1a antibody with preserved Fab-binding capacity but impaired Fc-mediated phagocytic potential. This could be used to shield fetal platelets from destruction by maternal alloantibodies. In a mouse model, the researchers showed that their designer antibody crosses the placenta, binds to HPA-1a, and rescues platelets from anti-HPA-1a alloantibody-mediated destruction. "This study provides important lessons on how to deliver an effective treatment directly to the fetus," writes Donald M. Arnold, MD, a professor of hematology and thromboembolism at McMaster University in Canada, in an accompanying editorial. The treatment's "clinical application will require a humanized form of the antibody," he adds. The study can be accessed at http://bloodjournal.hematologylibrary.org/content/122/3/321.full.

Citation: Bakchoul T, *et al*. Inhibition of HPA-1a alloantibody-mediated platelet destruction by deglycosylated anti-HPA-1a monoclonal antibody in mice: toward targeted treatment of fetal-alloimmune thrombocytopenia. Blood. 2013 July 18; 122(3):321-7.

Statistical modeling estimates published in the open-access journal *PLOS Medicine* suggests that the global burden of sickle cell anemia (SCA) will continue increasing over the next several years. Sickle cell disease is caused by an abnormal type of hemoglobin that can make red blood cells assume crescent shapes and become more "sticky." This leads red blood cells to then get stuck in small blood vessels and interrupt blood flow, causing organ and tissue damage, pain, stroke, and sometimes death. As awareness of SCA and access to treatment (frequent red blood cell transfusions) have increased, so has the survival rate of SCA patients. The global burden of SCA is predicted to rise as a consequence of improved survival of SCA patients in high-prevalence low- and middle-income countries and population migration to higher-income countries. Using population and mortality projections, the researchers predicted an increase in the numbers of newborns with SCA from 305,800 in 2010 to 404,200 in 2050. They also estimate the potential mortality effects of four potential care-provision scenarios, with a best-case scenario predicting between 7.5 and 15.5 million newborn lives could be saved, most of them in Africa. "Our quantitative approach confirms the global burden of SCA is increasing, and highlights the need to develop specific national policies for appropriate public health planning, particularly in low- and middle-income countries," conclude the authors. They note that further epidemiological studies are needed to assess future healthcare needs. The study is available at http://bit.ly/14X4DNz.

Citation: Piel FB, *et al*. Global burden of sickle cell anemia in children under five, 2010-2050: Modeling based on demographics, excess mortality, and interventions. PLoS Med. 2013 July;10(7). ♦

America's Blood Centers® It's About *Life.*

SAVE THE DATE

America's Blood Centers' Medical Device Data Systems (MDDS) Workshop

January 15-16, 2014 – Washington, DC

DoubleTree Washington, DC - Silver Spring
Negotiated hotel room rate: $139 + tax

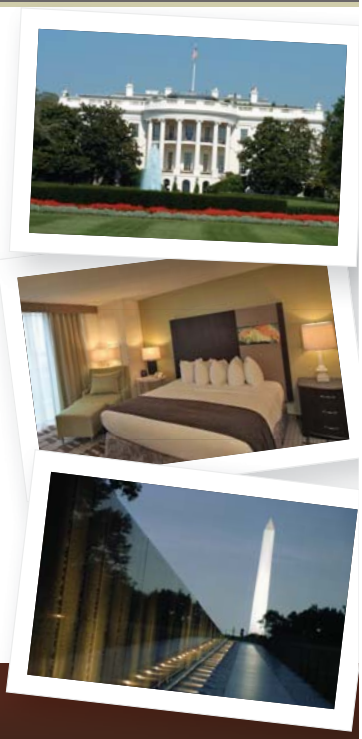
2014 Workshop Fees
Member Registration: $375 (early bird); $425 (regular)
Non-Member Registration: $745

There are four (4) $800 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. The application form and details will be made available once registration opens.

Sponsorship opportunities available. Contact Abbey Nunes at *anunes@americasblood.or*g for details.

Medical Device Data Systems, or MDDS, are devices intended to transfer, store, convert data from one format to another according to preset specifications, or display medical device data. They function solely as a conduit through which medical device data flows, is stored, or displayed. MDDS are regulated by FDA. In 2011, the FDA issued a final rule reclassifying MDDS to Class I, the lowest of the three regulatory classifications which are based on the level of control necessary to assure the safety and effectiveness of the device. Though issued in 2011, the impact is just beginning to be felt in blood centers, hospitals and other areas where medical devices are used.

This workshop will look at the MDDS requirements from all sides: the FDA, medical device manufacturers, blood centers, hospitals, and industry experts, and will cover the effects of this change on blood centers and other impacted health care institutions as well as provide direction on implementation of the FDA guidance requirements. Participants will learn what an MDDS is, the actual requirements, and how to navigate FDA device inspections and development in a quality systems environment.



There are three convenient airports that service the Washington area – Dulles International Airport, Reagan National Airport and Baltimore/Washington International Airport – which are served by all major US airlines. Please note that the closest airport is National. Hotel is metro accessible.

BRIEFLY NOTED

In a special issue of the *Journal of Clinical Apheresis*, the American Society for Apheresis (ASFA) recently published the 6th edition of the "Guidelines on the Use of Therapeutic Apheresis: An Evidence Based Approach." The ASFA Special Issue Writing Committee reviewed, updated, and categorized indications for therapeutic apheresis to create the guidelines. Beginning with the 2007 AFSA Special Issue (Fourth Edition), the committee has incorporated systematic review and evidence-based approach in the grading and categorization of indications for therapeutic apheresis. The committee worked for a year and a half to create a document that "will appeal to both practitioners of apheresis medicine and other physicians who may need to utilize therapeutic apheresis for the care of their patients." The guidelines use four categories to describe indications for therapeutic apheresis and also uses a grading system for each recommendation. The guidelines are available to subscribers or for purchase at http://onlinelibrary.wiley.com/doi/10.1002/jca.21276/abstract.

Citation: Schwartz J, *et al*. Guidelines on the use of therapeutic apheresis in clinical practice: evidence-based approach from the writing committee of the American Society for Apheresis: The sixth special issue. J Clin Apher. 2013 July;28(3).

BRIEFLY NOTED (continued on page 8)

BRIEFLY NOTED (continued from page 7)

A commentary published in *Transfusion* on July 19 suggests that there may be appropriate situations for the use of hemoglobin-based oxygen carriers (HBOCS) when red blood cell (RBC) transfusion is not an option. HBOCs are one of two main types of oxygen-carrying blood substitutes, which despite decades of research, are approved for use only in South Africa and Russia. Studies from 2008 and 2009 and an assessment made at a Food and Drug Administration workshop held in April 2008 (see *ABC Newsletter*, 5/2/08) concluded that the increased risk of heart attacks and death outweigh the possible benefits of HBOCs. No reevaluation has appeared since these assessments, although there has been limited clinical development in Europe. Commentary authors Richard B. Weiskopf and Toby A. Silverman examine these issues and suggest where the risk-benefit calculus could be favorable for the use of HBOCs. They write that in thinking about the use of an HBOC when RBCs are not available, either due to incompatibility issues or refusal of transfusion for personal reasons, "the focus should be on the relative risk of the underlying process and on the potential benefits and relative risks of use of an HBOC or other therapeutic intervention." Despite uncertainties about the relative risks of anemia and appropriate RBC transfusion thresholds, "we believe the aggregate data suggest that administering an HBOC when blood is indicated but cannot be used is likely to outweigh the risks and is an acceptable and perhaps superior alternative to other interventions," conclude the authors. However, they note that access to HBOCs in the US is hampered by the time-consuming investigational new drug application process through the Food and Drug Administration, and may be limited by corporate uncertainties.

Citation: Weiskopf RB, Silverman TA. Balancing potential risks and benefits of hemoglobin-based oxygen carriers. Transfusion. 2013 July 19. [Epub ahead of print]

The Centers for Medicare & Medicaid (CMS) released on July 17 new data that demonstrate that doctors and hospitals are using electronic health records (EHRs) to provide more information securely to patients and are using that information to help manage patients' care. Doctors, hospitals, and other eligible healthcare providers that have adopted or meaningfully used certified EHRs can receive incentive payments through Medicare and Medicaid EHR Incentive Programs. Already, approximately 80 percent of eligible hospitals and more than 50 percent of eligible professionals have adopted EHRs and received incentive payments from Medicare or Medicaid, said a CMS press release. "By meaningfully using EHRs, doctors and other healthcare providers prove they have been able to increase efficiency while safeguarding privacy and improving care for millions of patients nationwide," said CMS. Since the EHR Incentive Program began in 2011:

- More than 190 million electronic prescriptions have been sent out by healthcare providers using EHRs, reducing the chances of medication errors;
- Healthcare professionals sent 4.6 million patients an electronic copy of their health information from the EHRs;
- More than 13 million reminders about appointments, required tests, or check-ups were sent to patients using EHRs;
- Healthcare providers have checked drug and medication interactions more than 40 million times through EHRs; and
- Healthcare providers shared more than 4.3 million care summaries with other providers when patients moved between care settings.

"Electronic health records are transforming relationships between patients and their healthcare providers," said CMS Administrator Marilyn Tavenner. "EHRs improve care coordination, reduce duplicative tests and procedures, help patients take more control of their health, and result in better overall health outcomes." The Obama administration has encouraged the adoption of health information technology starting with the passage of the Recovery Act in 2009. (Source: CMS press release, 7/17/13) ♦

REGULATORY NEWS

AABB recently published a "Summary of Significant Changes to the Standards for Immunohematology Reference Laboratories, 8th edition." This summary details edits made to AABB's 8th edition of the Standards. The summary of changes can be downloaded at www.aabb.org/sa/standards/Pages/sigchngirlstds8.aspx ♦

INFECTIOUS DISEASE UPDATES

HEPATITIS E VIRUS

A study in *Transfusion* on July 7 provides an assessment of hepatitis E virus (HEV) in a small group of US blood donors and recipients. The researchers, led by Harvey Alter, MD, of the National Institutes of Health, tested for immunoglobulin (Ig)G and IgM antibodies to HEV and for HEV RNA in 1,939 unselected NIH volunteer blood donors. They also tested the same variables in pre- and serial post-transfusion samples from 362 prospectively followed blood recipients to assess transfusion risk. I(g)G anti-HEV seroprevalence in the total 1,939 donations was 18.8 percent. A significant stepwise increase in anti-HEV seroprevalence was seen with increasing age. Eight of 1,939 donations tested anti-HEV IgM positive; no donation was HEV RNA positive. Two transfusion recipients had an apparent anti-HEV seroconversion, but temporal relationships and linked donor testing showed that these were not transfusion-transmitted infections. No transfusion-transmitted HEV infections were observed in 362 prospectively followed blood recipients, despite an anti-HEV seroprevalence among donations exceeding 16 percent. "Overall, this study concludes that past exposure to HEV is common in the US donor population, that a small proportion of such donors have IgM antibody suggestive of recent exposure, and that a very small proportion harbor HEV RNA. Thus, the potential for HEV infection clearly exists and indeed has been confirmed in several case reports," write the authors. They add that further studies are necessary to determine whether donor screening for HEV is appropriate. Specifically, the authors suggest that "the most immediate need for the study of HEV and blood transfusion is to test tens of thousands of donors for HEV RNA and then to follow those found positive to determine the duration of viremia."

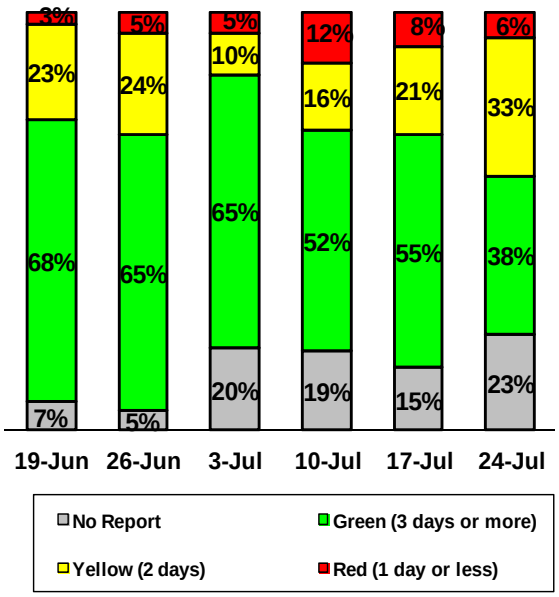
Citation: Xu C, *et al*. An assessment of hepatitis E virus (HEV) in US blood donors and recipients: no detectable HEV RNA in 1,939 donors tested and no evidence for HEV transmission to 362 prospectively followed recipients. Transfusion. 2013 July 7. [Epub ahead of print] ♦

We Welcome Your Letters

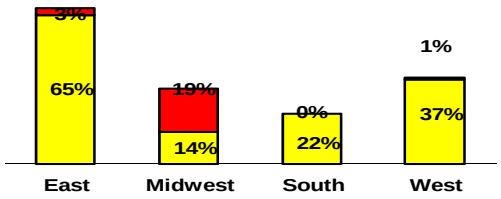
The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

STOPLIGHT®: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, July 24, 2013



Percent of Total ABC Blood Supply Contributed by Each Region

East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily Updates are available at:
www.AmericasBlood.org

COMPANY NEWS

SynGen, a Sacramento, Calif.-based medical device startup that develops stem cell harvesting systems, announced last week that it was granted Food and Drug Administration 510(k) clearance to market its three related products to process cord blood, reported the *Sacramento Business Journal*. The approval allows the company to commercialize its products in the US. SynGen's products are designed to work together to harvest cord blood or bone marrow so that the products can be used in the operating room within 15 minutes. The company will be rolling out its products this summer. SynGen gained clearance for its programmable control module SynGenXTM-1,000 System, its CryoPRO-2TM Cryopreservation/Storage Bag Set, and its SynGen Data Trak Software. (Source: *Sacramento Business Journal*, 7/15/13) ♦

America's Blood Centers® It's About *Life.*

REGISTRATION IS NOW OPEN

America's Blood Centers' Financial Management Workshop

September 19–20, 2013
Dallas, Texas

Hotel Information
Rate: Single/Double $134 per night plus tax.

Sheraton DFW Airport Hotel
www.sheraton.com/dfwairport

2013 Workshop Fees (early bird/regular)
Registration: $375/$425

There are four (4) $800 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. Contact Abbey Nunes at *anunes@americasblood.org* for more information.

"This is a workshop you really can't afford to miss! In addition to the workshop's peer-networking value, you will be empowered by attending sessions on fraud, the current state of the industry from different perspectives, and you will leave with ways to improve the bottom-line."

– William M. Coenen
Interim Chief Executive Officer
America's Blood Centers

Sponsorship opportunities available. Contact Abbey Nunes at *anunes@americasblood.org* for details.

Dallas/Fort Worth International Airport (DFW) is served by all major airlines, and serves as a hub for American Airlines. Visit *www.dfwairport.com* for more information.

MEETINGS

Oct. 7 **FDA Public Workshop: "Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products," Silver Spring, MD.**

The Food and Drug Administration's Center for Biologics Evaluation and Research will hold a public workshop titled "Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products" on Oct. 7 from 8:30 a.m. to 4:30 p.m. at the FDA White Oak Campus in Silver Spring, Md. The purpose of this workshop is to bring together a broad range of stakeholders to discuss current and future standards development activities involving cellular therapies and regenerative medicine products. There is no fee to join the workshop. Registration information (including name, title, firm name, address, telephone, and fax numbers) must be sent to CBERPublicEvents@fda.hhs.gov. More information is available at www.gpo.gov/fdsys/pkg/FR-2013-07-22/html/2013-17528.htm.

Oct. 22-23 **FDA Cellular, Tissue, and Gene Therapies Advisory Committee Meeting, Silver Spring, Md.**

The Food and Drug Administration will hold a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee on Oct. 22 from 8 a.m. to 5:30 p.m. and Oct. 23 from

(continued on page 12)

MEETINGS (continued from page 11)

8 a.m. to 5 p.m. at the FDA White Oak Campus in Silver Spring, Md. On Oct. 22, the committee will discuss oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility. On Oct. 23, the committee will hear updates on guidance documents issued from the Office of Cellular, Tissue, and Gene Therapies, and will discuss considerations for the design of early-phase trials of cellular and gene therapy products. FDA will make background material available at www.fda.gov/AdvisoryCommittees/Calendar/default.htm. More information is available at www.gpo.gov/fdsys/pkg/FR-2013-07-23/html/2013-17600.htm. ♦

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE:

Collections Supervisor - Donor Centers. Are you a self-starter? Do you excel leading teams? Are interpersonal and problem-solving skills a core competency? Community Blood Center, Inc., a provider of high quality blood products and services, is seeking a Donor Center Supervisor to oversee blood collections at our centers. The Collections Supervisor of our Donor Centers fosters an environment where staff growth and development are promoted. Candidates to possess a bachelor's degree and/or relevant work experience. Minimum of three years of supervisory experience, excellent written and communication skills, and strong computer aptitude needed. Position travels to our centers on a regular rotation. Submit your resume to join our team: https://home.eease.adp.com/recruit/?id=5981531. Community Blood Center, Inc., 4406 W. Spencer St., Appleton, WI 54914. www.communityblood.org. www.facebook.com/cbloodcenter.

Night Manager, Laboratory Services. LifeStream, a $53M healthcare organization providing blood service to more than 80 hospitals in Southern California, is searching for a Night Manager, Laboratory Services. This position performs, reports and reviews test results for Reference and Quality Control procedures in an accurate and timely manner in compliance with Federal and State Regulations, AABB Standards, Manufacturer's recommendations, and internal operating procedures. Demonstrates proficiency, competency and understanding of fundamental principles of the immunohematology, hematology and microbiology laboratory procedures. Requirements: Four-year bachelors of science degree (BS) in Clinical Laboratory Science or related field (e.g. Medical Technology). Minimum two years as a Generalist required. Five years' experience preferable focused in areas of hematology and transfusion medicine. Current California Clinical Laboratory Scientist License. MUST PASS PRE-EMPLOYMENT BACKGROUND CHECK, DRUG SCREEN AND PHYSICAL EXAM. Apply online: www.LStream.org. LifeStream is an Equal Opportunity Employer, M/F/D/V.

West Coast Account Manager. Develop and maintains relationships that lead to sales of blood bank filters, equipment, and related products. 75 percent travel. Must live near a major airport in the Western US. Responsibilities: develops and implements strategies to maintain and expand sales within assigned territory, with an account by account plan. forecasts demand for products within assigned territory, provides budget and sales activity reports, interfaces with the customer to understand the customer's overall objectives and requirements, contacts customers and potential customers on a regular basis to maintain account relationship, advise of new product and service offerings, and obtain feedback on products, provides post implementation support to customers, serves as point of escalation for issues that the customer encounters during product utilization, expedites resolution of problems/complaints, prepares/conducts technical/product presentations and

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POSITIONS (continued from page 12)

demonstrations, participates in tradeshows, provides feedback for future product enhancements. Required experience: bachelor's degree from four-year college or university. Minimum five years' experience in blood banking or related industry; or equivalent combination of education and experience. Please send resume and salary requirements to careers@macopharmausa.com; no calls.

Blood Services Account Executive AD003. Responsible for developing and managing critical relationships between South Texas Blood Center and its Hospital customers. Responsible for working with all stakeholders, both internal and external, to ensure the entire blood services supply chain is complete and efficient. Provide strategic planning, direction and leadership. Demonstrates skill in organizing, leading and inspiring individuals toward pursuit of customer satisfaction in a rapidly changing environment. Bachelor's in marketing or healthcare sciences or related field required Master's degree preferred. To apply, please e-mail resume to hr_dept@bloodntissue.org and include job code AD003.

Project Administrator. Gulf Coast Regional Blood Center is currently seeking two Project Administrators. Reporting to the Project Manager, the Project Administrator provides administrative support to coordinate project teams and perform system administration functions for software often associated with projects. In addition to possessing two years' experience in Computer Support/Training preferably in a blood or tissue center or blood bank, the successful candidate will also possess a bachelor's degree from an accredited college or university; experience in systems administration, software validation, risk analyses and table configuration; and the skills necessary to successfully coordinate project team activities from initiation to closing. Gulf Coast Regional Blood Center is a non-profit 501(c)(3) organization and is accredited, licensed and inspected by the Food and Drug Administration (FDA), and AABB as well as local and state authorities. The Blood Center is a proud member of AABB, America's Blood Centers, Blood Centers of America, South Central Association of Blood Banks, and the Texas Medical Center. Please visit our website for more information about our organization and to apply online: www.giveblood.org. Lori Pireu – Recruiter – Phone: (419) 517-9918 – lpireu@giveblood.org.

Clinical Education Consultant (LZR00004). Fenwal, Inc., a Fresenius Kabi company, is a global blood technology company dedicated to supporting transfusion medicine and cell therapies. We currently have an opportunity for a Clinical Education Consultant based out of Dallas, Chicago, or St. Louis to work collaboratively with the customers and the sales teams providing clinical support for Fenwal product's supporting the US. Requirements include: MT(ASCP) certification. SBB and/or CQA(ASQ) preferred; bachelor's degree preferred; five plus years progressive working experience in clinical laboratory operations (preferably blood banking) in quality and compliance activities; knowledge of AABB Standards and regulatory requirements (FDA, CMS) preferred; experience presenting QC data findings, root cause analysis, and recommended solutions to staff, QA, and Sr. Management; ability to travel 70 percent across the US. For more information to apply, please visit our website at: www.fenwalinc.com and click on the Careers tab and search for job: LZR00004. Fenwal is an Equal Opportunity Employer.

Laboratory Technologist. The Main Lab at the Rhode Island Blood Center has a part time Laboratory Technologist position available on second shift with rotating weekends and holidays. Responsibilities include: routine testing of donor blood samples with proper technique and documentation, labeling of blood components, performing and documenting quality control procedures, and generating client reports for donor testing. Lab Tech I: MLT (ASCP) certification. Lab Tech II: BB(ASCP), MT, OR SBB (ASCP) certification. RI license as a Clinical Laboratory Scientist or Technician is required and can be obtained within six months of hire. Please apply online at www.ribc.org. Only applicants who are selected for interviews will be contacted directly. JOIN THE TEAM THAT GIVES THE GIFT OF LIFE!!! As a blood center employee, you'll truly make a difference in the lives of Rhode Island residents. We are an Equal Opportunity Employer and participate in E-Verify to confirm work authorization.

Associate Director of Validation/Equipment. The Rhode Island Blood Center is seeking an Associate Director of Validation/Equipment for the QA department. Responsibilities include: ensure all regulated areas achieve and maintain compliance with the FDA, AABB and any other accrediting agency that inspects/audits Rhode Island Blood Center, lead company-wide validations and maintenance activities of critical equipment, and mentor staff in achieving quality outcomes in everyday activities and during audit/inspections. Bachelor's degree required and MT (ASCP), BB(ASCP), or SBB(ASCP) certification required. Significant experience in a related field in lieu of educational and certification requirements will be taken into consideration. Please apply online at www.ribc.org. Only applicants who are selected for interviews will be contacted directly. JOIN THE TEAM THAT GIVES THE GIFT OF LIFE!!! As a blood center employee, you'll truly make a difference in the lives of Rhode Island residents. We are an Equal Opportunity Employer and participate in E-Verify to confirm work authorization.

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POSITIONS (continued from page 13)

IRL Clinical Lab Manager. Blood Systems Laboratories is searching for a Clinical Lab Manager to assist its busy Immunohematology Reference laboratory (IRL) in Phoenix, AZ! The successful candidate must be highly organized, able to multi-task in a busy office environment, as well as work successfully in a team environment. Responsibilities will include managing the overall activities and providing skilled technical oversight in the laboratory. This position will work with other team members to ensure timely, quality, test results. Education/Knowledge: Bachelor's degree required. Master's degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Licenses/Certifications: SBB or CHS certification required. Experience: Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous experience in molecular techniques, immunohematology techniques, automated testing and computerization preferred. For consideration, please submit resume via e-mail by **08/02/2013** to: jobs@bloodsystems.org ATTN: HR/2013/82. We offer a competitive benefits package as well as matched 401(k), education assistance, relocation and much more! Pre-employment drug testing is required. Visit our website at: www.bloodsystems.org. EOE M/F/D/V

Medical Technologist – Immunohematology. The Community Blood Center (Kansas City) provides blood for the majority of the hospitals in the region and is home to one of 56 AABB certified Immunohematology Reference Labs worldwide. The staff provides consultation to area hospitals, resolution of complex serological problems and supplies antigen-negative blood or other special units for transfusion recipients. The lab performs a variety of serologic procedures, and molecular phenotyping. Our career ladder allows individuals to continue to grow in their knowledge base and contribution to our lab. The Community Blood Center employs seven (7) SBB's who teach and mentor our new employees. Requirements: BS degree in medical technology or related field; registered MT (ASCP), CLS, or BB(ASCP); SBB preferred. Education assistance and tuition reimbursement is available to obtain SBB certification; and two to five years laboratory experience; blood bank experience preferred. Skills and knowledge: advance problem-solving, good oral and written communication, detail oriented, excellent customer service and time management. Hours during training are Monday-Friday 8:30-5:00 with periodic weekends (training is approximately six (6) months). 2 Position Openings: (1) 2nd Shift and (1) 3rd Shift with some weekends required. Must apply online at: www.savealifenow.org. EOE M/F/D/V

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail* (mnorwood@americasblood.org) *or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)*

2013

July 29-31. **18th Annual GMP By The Sea, Chesapeake Bay, Md.** More information is available at www.pharmaconference.com/index_pharm.htm.

July 30-31. **FDA Workshop: Battery-Powered Medical Devices Workshop: Challenges and Opportunities, Silver Spring, Md.** More information is available in the Federal Register notice at www.gpo.gov/fdsys/pkg/FR-2013-06-05/html/2013-13244.htm. E-mail: iacovos.kyprianou@fda.hhs.gov.

Aug. 2. **FDA Blood Product Advisory Committee Meeting, Bethesda, Md.** More information is available at www.fda.gov/AdvisoryCommittees/Calendar/ucm358793.htm.

Aug. 3. **Medical Directors Workshop, America's Blood Centers, Milwaukee, Wis.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 4-5. **Interim Meeting, America's Blood Centers, Milwaukee, Wis.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Sept. 5. **CLSI Workshop, Atlanta, Ga.** More information and registration can be accessed at http://bit.ly/10TIYFr.

Sept. 17-19. **BOOTS Session 11: "Demand-Based Recruitment and Collections," Orlando, Fla.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

September 19 **Red Cell Genotyping 2013: Clinical Benefits** BloodCenter of Wisconsin and The National Institutes of Health Clinical Center, Department of Transfusion Medicine will host the 3rd symposium on Red Cell Genotyping with sponsorship from Héme-Québec. This year's event will focus on clinical benefits

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of genotyping patients and donors on Sept. 19 from 8:25 a.m. to 4:30 p.m. It will take place in Lister Hill Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, MD. Registration fee is $95. Advanced registration is required. More information and a link to registration can be found at www.bcw.edu/rcg2013.

Sept. 18. **32nd Annual Symposium: Immunohematology & Blood Transfusion.** Advanced registration is required before Sept. 1. More information and a link to registration can be found at www.cc.nih.gov/dtm/research/symposium.html.

Sept. 19. **NIH Red Cell Genotyping 2013: Clinical Benefits, Bethesda, Md.** More information and registration can be accessed at www.bcw.edu/rcg2013.

Sept. 19-20. **Financial Management Workshop, America's Blood Centers, Dallas, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Sept. 21. **11th Annual Canadian Blood Services International Symposium - Utilization of Blood Products: A Focus on Platelets, Toronto, Ontario.** More information can be found at http://www.transfusionmedicine.ca/news/events/11th-annual-canadian-blood-services-international-symposium-utilization-blood-products-f.

Oct. 12-15. **AABB Annual Meeting and CTTXPO, Denver, Colo.** For more information: www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx.

Oct. 21-22. **AdvaMed Workshop: 501(K) Submissions, Arlington, Va.** More information and registration details are available at www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=208. Contact: skinchen@advamed.org (for group discounts).

Oct. 23. **AdvaMed Workshop: IDE Submissions, Arlington, Va.** More information and registration details can be found at http://www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=210.

Nov. 14. **FABC Joint Gala with WFH-USA at Biltmore Hotel, Phoenix, Az.** Contact: Jodi Zand Phone: (202) 654-2994; e-mail: jzand@americasblood.org.

2014

Jan. 15-16. **Medical Device Data Systems (MDDS) Workshop, America's Blood Centers, Washington, DC.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Mar. 22. **Annual Links for Life Golf Tournament at Desert Willow Golf Course, Palm Desert, Ca.** Contact: Jodi Zand Phone: (202) 654-2994; e-mail: jzand@americasblood.org.

Mar. 22-25. **Annual Meeting, America's Blood Centers, Palm Springs, Calif.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

May 11-15. **WFH 2014 World Congress, Melbourne, Australia.** For more information and to register, visit http://bit.ly/1227maC.

June 5-8. **5th International Monoclonal Antibody Workshop, New York, N.Y.** Contact: Gregory Halverson, New York Blood Center. Phone: (212) 570-3026; e-mail: ghalverson@nybloodcenter.org.

June 17-20. **Fund Development, Communications, and Donor Management Workshop, America's Blood Centers, Sacramento, Calif.** Contact: ABC Meetings Dept. Phone (202) 654-2901; fax (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 5 Tuesday (note: new date and day) **Medical Directors Workshop, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 6-7 Wednesday-Thursday (note: new dates and days) **Interim Meeting, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Oct. 25-28. **AABB Annual Meeting and CTTXPO, Philadelphia, Pa.** For more information: www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx.