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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #17 **May 10, 2013**

INSIDE:

FDA Publishes Abbreviated Donor History Questionnaire Guidance

The Food and Drug Administration has released its final guidance on the abbreviated Donor History Questionnaire (aDHQ) titled, "Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components." This guidance finalizes the draft guidance of the same title dated October 2011 (see *ABC Newsletter*, 11/4/11).

To ensure a blood donor's overall good health and to prevent transfusion-transmitted diseases, all donors must respond to a donor health history questionnaire at every donation, which is used in conjunction with a physical assessment to determine donor eligibility. However, it has been recognized that the full-length-DHQ (FL-DHQ) is long and tedious, especially for frequent blood donors. FDA's recent guidance recognizes the aDHQ and accompanying materials, version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations.

The first formal uniform questionnaire developed for blood donor screening was implemented nearly 60 years ago. While the donor interview process is helpful in excluding ineligible donors, errors in this process occur when some information is not understood or captured during the donor screening process. At workshops sponsored by FDA, as well as meetings of the FDA Blood Products Advisory Committee (BPAC) meetings, experts have noted that the donor screening process should consider factors such as question complexity, donor recall ability, donor health and safety, donor satisfaction and willingness to return, any further processing which a product may undergo prior to use, and risk to the blood product recipient.

Self-administered, computer-assisted and abbreviated questionnaires have been suggested as strategies to improve donor understanding and satisfaction with the donor screening process, particularly for frequent donors. FDA issued a guidance in July 2003 explaining how blood and plasma establishments can simplify the donor screening process by allowing certain donors to use self-administered DHQs. Currently, frequent donors use the AABB FL-DHQ at each donation, the length and repetitiveness of which may discourage donors from returning for

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OUR SPACE

ABC Vice President of Administration and Communications Matt Granato

Building a Strong Foundation

Since we realigned and streamlined our core values, we came to the realization that not all values are created equal. Some values depend on others to thrive and accomplish their goals. We rely on three values to deliver ABC's mission of helping community blood centers: advocacy, networking and education, and data integration and benchmarking. Data, however, is at the foundation of our core values and it is through data that we meet goals related to the other two core values.

Last week, ABC President Dave Green described the three key elements of a fully operational ABC Data Warehouse (DW). I'd like to use this opportunity to let you know how we will get there. Led by ABC's Director of Regulatory Services Ruth Sylvester, a team of ABC IT/DW and Scientific, Medical, and Technical staff, along with ABC's IT consultants, have developed a plan to review the DW processes with the ultimate goal of ensuring that the data going into and coming out of the DW is accurate (counting correctly), valid (right answers), and usable (readily retrievable and displayable).

With an ambitious timeline of six months beginning in April 2013, the team will execute the plan in two steps. The first step is data verification, which includes developing a streamlined process for members to verify that their data has uploaded correctly. This will be followed by script development to automate the mapping process (each data element sent from a blood center into the DW needs to "fit" into it). And finally, a review of the available reports will take place to verify their accuracy. Step two is for data validation. This step will ensure that data transmitted by members is not "lost in translation" once it hits the DW, but rather equals the information relayed by the MicroStrategy software for aggregate data reporting and benchmarking.

Since much is dependent on accurate and valid data, we are "crossing all the t's and dotting all the i's" to ensure that the foundation of our core values is sound and solid. After all, we rely on it to build a strong association. As members, we hope you agree and let us deliver this fundamental resource to you.

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.

America's Blood Centers
President: Dave Green
Interim Chief Executive Officer: William M. Coenen
ABC Publications Editor: Betty Klinck
Business Manager: Leslie Norwood
Annual Subscription Rate: $390

Send subscription queries to
mnorwood@americasblood.org.
America's Blood Centers
725 15th St. NW, Suite 700, Washington, DC 20005
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

FDA aDHQ Guidance (continued from page 1)

future donations, states FDA in its guidance. "Streamlining of the donor screening process may enhance the availability of safe blood and blood products from frequent donors," said FDA.

The AABB task force has sought to create an abbreviated donor screening since the group's inception in 2000, but task force members determined that the existing AABB FL-DHQ had to be revised before they could tackle the aDHQ, said Debra Kessler, RN, MS, director of Special Donor Services at New York Blood Center, and a member and past chair of AABB's Donor History Task Force. This involved seeking input from experts in questionnaire development and reading comprehension, as well as from FDA and blood centers. Focus groups were used to review the draft questions and individual cognitive interviews by the National Center of Health Statistics were performed to validate that the questions elicited the information intended. By 2006, many blood centers were using the FL-DHQ and final guidance on its use was issued in October 2006.

The AABB task force developed the aDHQ documents to focus on changes in medical, behavioral, and travel information since the donor's previous donation. Using the FL-DHQ as a basis, the task force reviewed the document to determine which questions did not have to be repeated and which questions only had to be asked referring to the time frame "since your last donation." The task force submitted the aDHQ to FDA in April 2006.

The aDHQ eliminates questions about events or behaviors that cannot have changed since the previous donation, if a donor has previously answered "no" on the FL-DHQ. It allows frequent blood donors, for whom a record of their medical, behavioral, and travel history has been established, to be interviewed using an abbreviated process. The User Brochure defines a frequent donor as a donor who has previously donated at least two times using the FL-DHQ, one donation of which occurred within the previous six months.

"The AABB Donor History Task Force has been working on bringing forward an abbreviated donor history screening form for about 10 years. We are so pleased to have the finalized guidance issued so that this long sought document can be used by the blood collection community. We believe that it will be an improvement over the FL-DHQ for frequent donors by focusing their attention to recent medical events, travel, and possible risky behaviors, as well as increasing the donor's attention by asking less questions," said Ms. Kessler. "Furthermore, donor satisfaction should be improved through a more efficient process that perhaps will result in a higher rate of return."

Some changes made in the final guidance after receiving public comments on the draft guidance include: referencing the most current version of the acceptable aDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and editorial changes to improve clarity.

The guidance also lists several minor modifications that blood centers can make to the AABB aDHQ, so long as they are noted in the center's annual report. Those modifications include adding more restrictive selection criteria that are specific to the blood establishment and omitting questions that FDA does not require or recommend. Blood centers may also modify the flow charts into another format that is compatible with their current processes, provided that there is no change to the aDHQ content related to FDA required/recommended donor deferral criteria. Modifications may be made by reformatting any of the acceptable aDHQ documents to be consistent with the establishment's current processes, provided that the wording and order of content in the aDHQ document is not changed. Any other changes require a

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FDA aDHQ Guidance (continued from page 3)

prior approval supplement. During an FDA BPAC Meeting, the AABB task force presented a study design for evaluating the aDHQ post-implementation, and has agreed to submit the summary data to FDA once the study is complete. FDA's final guidance can be accessed at http://1.usa.gov/10q02il. (Source: FDA guidance, 5/8/13)

Q&A with ABC's *IT Department*

America's Blood Centers' Staff Answers your Questions

America's Blood Centers recently conducted its SEQuaLS assessment, a customer service survey that solicits feedback from member blood centers on ABC's activities. Through this assessment, members were able to pose questions to the ABC staff. Each ABC department will respond to these questions through this weekly Q&A column in the Newsletter.

Q: How does ABC use the data gained through the daily Stoplight reports from ABC's member blood centers and what value does this offer to members?

A: We have been using the Stoplight reports (a report given daily by each member blood center regarding its blood supply) daily for the past three years. We take the red/yellow/green status and back-calculate an estimate of the number of "days of supply" of blood on the shelf. We do this by using the annual collection data that we get from our member blood centers to calculate an average daily value. From that, we can estimate the amount of blood currently available. While that number may not be exact, the trends and the relative numbers are valid.

ABC, Blood Centers of America, and the American Red Cross report blood supply data on a daily basis to the AABB. AABB then aggregates the data and reports it to the Department of Health and Human Services weekly. This information is also vital during and following disasters when the blood supply level is reported daily. See page 10 for this week's Stoplight data.

RESEARCH IN BRIEF

A study published in *Vox Sanguinis* this month confirmed previous findings that capillary hemoglobin measurements are typically higher than those determined from venous samples. However, the researchers concluded that the false-pass and false-fail rates were low and acceptable in the donor screening setting, with the "true" hemoglobin values not differing by a clinically significant degree from threshold values to assess acceptability for blood donation. The Food and Drug Administration requires that blood donors have a hemoglobin level of at least 12.5 g/dL to give blood, which most blood centers determine through capillary blood samples taken by a fingerstick technique. However, the accuracy and reproducibility of hemoglobin assessments based upon capillary samples has been questioned. Previous studies have suggested that capillary Hemoglobin values taken using the HemoCue point-of-care device are higher than venous HemoCue hemoglobin values, and that HemoCue hemoglobin values were reproducible using venous and arterial but not capillary samples. Accurate hemoglobin level measurements are important to protect donor iron stores. (However, researchers have found that hemoglobin measurement is a poor indicator of donor iron stores, with ferritin providing a more accurate assessment.) This study sought to determine the accuracy and agreement of capillary and venous hemoglobin measurements performed on the HemoCue device, and to compare these results with a venous hemoglobin determination

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RESEARCH IN BRIEF (continued from page 4)

performed by an automated hematology analyzer in a healthy donor population. The study was conducted in 150 healthy prospective blood donors undergoing whole-blood donation, plateletpheresis, or leukapheresis at the Department of Transfusion Medicine at the National Institutes of Health, in Bethesda, Md., during June 2006. Fingerstick samples from two sites, one on each hand, were obtained from a subset of 50 subjects. Concurrent venous samples were tested using both HemoCue and the Cell-Dyn (automated hematology analyzer) devices. Capillary hemoglobin values on the HemoCue were significantly greater than venous HemoCue hemoglobin values, which in turn were significantly greater than venous hemoglobin values on the Cell-Dyn (mean hemoglobin values: 14.05 $\pm$ 1.51, 13.89 $\pm$ 1.31, 13.62 $\pm$ 1.23, respectively). Nine donors (6 percent) passed hemoglobin screening criteria by capillary HemoCue, but were deferred by Cell-Dyn values (termed as "false-pass"). "These findings support previous observations, wherein hemoglobin measurements obtained in capillary blood using the HemoCue device were uniformly higher than those obtained in venous blood, regardless of the device used for the venous assessment," write the authors. True hemoglobin values on the false-pass donors (determined by the Cell-Dyn) ranged from 11.8 to 12.3 g/dL. Five donors (3 percent) were deferred by capillary sampling, but passed by Cell-Dyn values (termed "false-fail"). Both the false-pass and false-fail rates were judged to be operationally tolerable. Repeat fingerstick determination in 50 donors revealed substantial inter-sample variability, with differences as great as 2.5 g/dL per donor. An approach to implement venous hemoglobin measurements in blood donors after the donor has already given blood to determine whether they would qualify at the next donation has been implemented in Europe, but this method would not be useful if the donor does not return, said the authors. They conclude that there is "no evidence of compromise in donor health" caused by the false-pass and false-fail rates in this study, but emphasize that donor iron assessments using other indicators were not performed.

Citation: Bryant BJ, *et al*. Capillary versus venous haemoglobin determination in the assessment of healthy blood donors. Vox Sang. 2013 May;104(4):317-23.

Baxter International announced in a recent press release that its phase III clinical study of immunoglobulin (IG) did not meet its co-primary endpoints of reducing cognitive decline and preserving functional abilities in patients with mid- to moderate Alzheimer's disease. The study enrolled 390 patients in the placebo-controlled, 18-month trial called Gammaglobulin Alzheimer's Partnership (GAP). The poor results are in contrast with favorable results seen in a much smaller 24-patient phase II trial reported last year, in which IVIG appeared to reduce Alzheimer's disease progression over three years. Those results prompted concerns about a possible run on IVIG supplies, which are generally not considered robust. In the new study, patients were randomized to one of two IVIG doses (200 or 400 mg/kg every two weeks) or placebo. Primary endpoints were changes on the Alzheimer's Disease Assessment Scale (ADAS) cognitive subscale for cognitive impairment, and the Alzheimer's Disease Cooperative Activities of Daily Living (ADL) index as the measure of functional ability. There was a statistically insignificant advantage in the placebo group, compared to high-dose IVIG on the ADAS subscale (mean 7.4-point change vs. 8.9 with placebo). There was no difference in ADL scores. Although Baxter said it is discontinuing other ongoing studies of IVIG in mild to moderate Alzheimer's, the company added that it was not giving up on IVIG in Alzheimer's completely, because a subgroup analysis showed hints of effectiveness. "The study missed its primary endpoints, however we remain interested by the pre-specified sub-group analyses, particularly among patients with moderate disease and those who carry a genetic risk factor for Alzheimer's disease, two patient groups that are in great need of advances in care. A detailed analysis of the results from the GAP study continues, and we look forward to a greater understanding of the full data set," said Ludwig Hantson, PhD, president of Baxter's BioScience business. "We are grateful for the participation of the patients and physicians in the study and for the dedicated support of the patients' caregivers." Baxter will present these full results at the annual Alzheimer's Association International Conference in July. The press release is available at http://bit.ly/10fTCkJ. (Sources: Baxter press release, 5/7/13; *MedPage Today*, 5/7/13) ♦

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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.

Trudy Thompson Recognized for 30 Years Working at ABC

As of April 4, Trudy Thompson, America's Blood Centers' manager of General Accounting, has been employed with ABC for 30 years. When she began working at ABC, the organization had only two employees, and she has held a number of positions since then, becoming familiar to many ABC members over the years.

Ms. Thompson was first hired by ABC as a secretary, after which she became an administrative assistant and then the administrative and conference coordinator. In May 1990, she moved into the role of bookkeeper. From 1993-1995, Ms. Thompson was responsible for ABC's finances, office management, personnel, group purchasing, and resource sharing. In April 1995, Ms. Thompson became the assistant director of Administrative and Member Services, after which she then became manager of Finance, and finally manager of General Accounting, the position that she holds today.

"Trudy Thompson is one of those quiet, behind the scenes people who make things run smoothly. I had the pleasure of working with her in organizing an ABC meeting in Eureka, Calif., as well as working with her when I was treasurer of ABC," said Tom Schallert, the administrator of Northern California Community Blood Bank, also an ABC past president. "She is dedicated and committed to the mission of America's Blood Centers and she always makes sure the job is done."

Serving in several leadership capacities at ABC since the 1970s, including chief operating officer, ABC Interim CEO Bill Coenen has often worked closely with Ms. Thompson. "Trudy is one of the most dedicated, loyal, and fair individuals that I know," said Mr. Coenen. "She has always risen to the tasks given to her. Her commitment to detail and accuracy is one of the reasons that I cannot remember the last-time we have had an audit adjusting entry. Members of the four companies she performs the accounting functions for can rest comfortably knowing that she is watching over their finances. Trudy is fun to work with and continues to make me look good every day."

As part of her responsibilities, Ms. Thompson also does the accounting for Group Services for America's Blood Centers. "Even though Trudy is an ABC employee, she is a very important part of the GSABC team," said Jerry Haarmann, president and CEO of GSABC. "Her knowledge and expertise has been vital to our ongoing success. All members should realize that her 'behind-the-scenes' work benefits our industry tremendously."

The ABC staff would like to thank Ms. Thompson for her hard work over the last 30 years, and congratulate her on this important milestone.

REGULATORY NEWS

The Centers for Medicare and Medicaid Services (CMS) announced last week that it is going to remove eight hospital-acquired conditions from its website that publishes data about potentially life-threatening errors made in hospitals. Two years ago, CMS announced that it would add data about life-threatening errors made in hospitals to a public website that people can search to check on safety and performance. Now, CMS is going to strip the site of eight of these conditions, including infections and mismatched blood transfusions, while it comes up with a different set, reported Bloomberg on May 2. The agency said it's taking the step because some of the eight are redundant and because an advisory panel created by the 2010 Affordable Care Act recommended regulators use other gauges. The decision to pull the measures is a retreat from a commitment to transparency, according to organizations representing employers that help pay for health insurance. The initial proposal CMS has made for new safety-assessment data suggests the Hospital Compare website will not be as comprehensive as it is now, Leah Binder, president of the Washington-based Leapfrog Group, told Bloomberg. Bill Kramer, executive director for national health policy at the Pacific Business Group on Health, told Bloomberg that removing the data "would be a significant step backwards." The coalition, including Wal-Mart Stores Inc. and Walt Disney Co., was among 33 business, labor, and consumer organizations that argued against taking the hospital-acquired conditions off the site. The Bloomberg article is available at http://bloom.bg/18uhVQX. (Source: Bloomberg, 5/2/13)

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) published a report last month titled "Strengthening Our National System for Medical Device Postmarket Surveillance – Update and Next Steps." This report is a follow-up to a previous CDRH report on this subject published in September 2012. FDA seeks to create a national medical device postmarket surveillance system that:

- Communicates timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high quality, standardized, structured, electronic health-related data;
- Identifies potential safety signals in near real-time from a variety of privacy-protected data sources;
- Reduces the burdens and costs of medical device postmarket surveillance; and
- Facilitates the clearance and approval of new devices, or new uses of existing devices.

This report provides an update on FDA's progress toward establishing this system and sets forth the following concrete steps to accomplish this goal in 2013:

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REGULATORY NEWS (continued from page 7)

- Establish a medical device postmarket surveillance system governance;
- Establish a unique device identification system and promote its incorporation into electronic health information;
- Promote the development of national and international device registries for selected products;
- Modernize adverse event reporting and analysis;
- Develop and use new methods for evidence generation, synthesis, and appraisal.

The report can be accessed at http://1.usa.gov/UxzcmZ and the action plan is available at http://1.usa.gov/174ZndH. ♦

INFECTIOUS DISEASE UPDATES

AVIAN INFLUENZA A(H7N9)

On April 22, the Taiwan Health Department reported that a Taiwan man contracted the H7N9 strain of bird flu while traveling to China, reported NBCNews.com. This is the first case of H7N9 reported outside of mainland China. The man was hospitalized after becoming ill three days after returning from Suzhou on April 9, Health Department Minister Wen-Ta Chiu said in a news conference. Mr. Chiu said the patient was diagnosed with H7N9 virus and was in serious condition. The US Centers for Disease Control and Prevention published in the May 1 *Morbidity and Mortality Weekly Report* (MMWR) a summary of its findings regarding the avian influenza A(H7N9) virus outbreak in China. As of April 29, China had reported 126 confirmed H7N9 infections in humans, of whom 24 (19 percent) died. Cases have been confirmed in eight contiguous provinces in eastern China (Anhui, Fujian, Henan, Hunan, Jiangsu, Jiangxi, Shandong, Zhejiang), two municipalities (Beijing and Shanghai), and now, Taiwan. No evidence of sustained human-to-human transmission has been found, and no cases of H7N9 virus infection have been detected outside of China. CDC's report summarizes recent findings and recommendations for preparing and responding to potential H7N9 cases in the US. CDC recommends that clinicians consider the diagnosis of avian influenza A(H7N9) virus infection in persons with acute respiratory illness and relevant exposure history and should contact their state health departments regarding specimen collection and facilitation of testing. The report can be accessed at http://1.usa.gov/16pP4QZ. (Sources: NBCNews.com, 4/24/13; CDC MMWR, 5/1/13)

HEPATITIS C VIRUS

An investigational protease inhibitor for hepatitis C virus (HCV) achieved high response rates in treatment-naive patients, according to an abstract presented at the European Association for the Study of the Liver by Michael Manns, MD, of Hannover Medical School in Germany. The drug (MK-5172) rendered the virus undetectable 24 weeks after the end of therapy in almost 90 percent of patients with the difficult-to-treat HCV genotype 1, reported *MedPage Today*. In contrast, treatment with an approved protease inhibitor, boceprevir (Victrelis), led to a sustained virologic response after 24 weeks of just 54 percent. Both drugs were combined with pegylated interferon and ribavirin. The direct-acting agents, such as boceprevir and MK-5172, attack elements of the virus, in contrast to the interferon and ribavirin, which respectively boost the immune system and target general viral replication. Interferon and ribavirin have a range of serious side effects and interferon in particular is seen as both difficult to tolerate and to use. More information is available in the *MedPage Today* article at http://bit.ly/13EdX7k. As possible treatments for HCV advance, healthcare providers are still struggling to ensure those at risk for HCV receive

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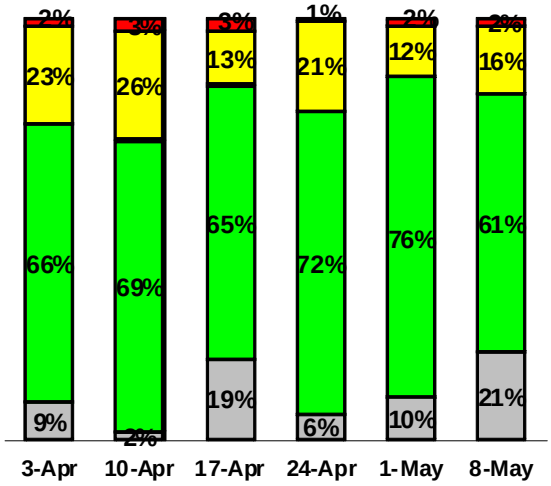
INFECTIOUS DISEASE UPDATES (continued from page 8)

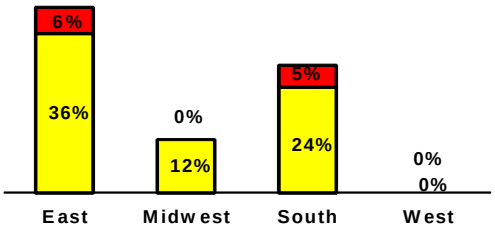
proper testing, and that those infected receive proper follow-up treatment. The Centers for Disease Control and Prevention reported this week in its *Vital Signs* publication that only half of Americans identified as having had HCV received follow-up testing showing that they were still infected. "Many people who test positive on an initial hepatitis C test are not receiving the necessary follow-up test to know if their body has cleared the virus or if they are still infected," said CDC Director Tom Frieden, MD. "Complete testing is critical to ensure that those who are infected receive the care and treatment for hepatitis C that they need in order to prevent liver cancer and other serious and potentially deadly health consequences." CDC researchers examined data from eight areas across the nation funded by CDC to conduct enhanced surveillance for HCV infection. Of the HCV cases reported in these areas (i.e., those cases with antibody-positive results), only 51 percent of the cases also included a follow-up (RNA) test result that identified current infection. Without follow-up testing, the other half are likely unaware if they are currently infected and therefore cannot get medical care, said CDC. This data also underscored the severe impact of HCV among baby boomers. In the eight areas, 67 percent of all reported cases of current infection were among those born from 1954 to 1965. Deaths among people with HCV were also more common among the baby boomers (72 percent of all reported deaths). In light of increasing evidence that many patients are not receiving the follow-up test, as well as recent changes in testing technologies and the availability of new effective treatments for HCV, CDC is issuing updated guidance for healthcare providers on HCV testing. These guidelines reinforce the recommended process for HCV testing and underscore the importance of providers conducting follow-up RNA testing for all patients with a reactive antibody screening test result. CDC recommends that everyone in the US born from 1945 through 1965 and other populations at increased risk be tested for HCV. CDC's *Vital Signs* report, which coincides with Hepatitis Awareness Month, is available at www.cdc.gov/vitalsigns/hepatitisc/index.html. (Source: *MedPage Today*, 4/28/13)

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, May 8, 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

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REGISTRATION NOW OPEN

America's Blood Centers' Fund Development, Communications and Donor Management Workshop

San Antonio, TX – June 18-21, 2013

Hosted by **South Texas Blood & Tissue Center**

Negotiated hotel room rate: $159 + tax (incl. free internet and fitness center access)
www.hotelvalencia-riverwalk.com

2013 Workshop Schedule
Fund Development topics: June 18-19
Communications topics: June 19-20
Donor Management topics: June 20-21

2013 Workshop Fees (early bird/regular)
2-day registration: $375/$425
3-day registration: $440/$490
4-day registration: $490/$540

Contact Lori Beaston at *lbeaston@americasblood.org* for registration information.

"South Texas Blood & Tissue Center is proud to support this year's Fund Development, Communications and Donor Management Workshop and is looking forward to welcoming ABC members from across the country to our vibrant city for a week of learning, sharing and networking. We hope to see you there!"

- Carmen Davila
Vice President of Corporate Communications
South Texas Blood and Tissue Center

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

San Antonio International Airport (SAT) is served by all major US airlines, including discount carriers Southwest and AirTran. It offers non-stop service to/from 27 major and secondary US airports; check www.sanantonio.gov/aviation for more information.

MEMBER NEWS

Blood Bank of Delmarva (BBD) honored Robert Moley on April 30 for making his 300th platelet donation. Mr. Moley is only the second donor in BBD history to reach this milestone, according to the BBD press release. Upon making his 300th platelet donation at BBD's Christiana Center in Newark, Del., Mr. Moley was presented with a commemorative pin and special engraved award by BBD CEO Roy Roper for his dedication to saving local lives. BBD notes that platelets have a very short shelf-life and are needed to help cancer patients during chemotherapy treatments, as well as others with bleeding disorders. (Source: BBD press release, 4/30/13)

Robert Moley (left) receives recognition for making 300 platelet donations from BBD CEO Roy Roper.

COMPANY NEWS

Haemonetics, a blood management systems provider, announced last week that it will close its plant in Braintree, Mass. and move manufacturing of disposable products to its facility in Mexico, reported the *Boston Business Journal* on May 2. Haemonetics said in its earnings report on May 1 that it is in the process of transitioning its manufacturing of equipment to a contract manufacturer and transferring manufacturing of its disposable products from Braintree to Tijuana, Mexico. The move, which will take place over 12 to 18 months, will mean 320 job cuts, Haemonetics Vice President of Investor

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COMPANY NEWS (continued from page 11)

Relations Gerry Gould told *Mass High Tech.* The decision comes after Haemonetics acquired the business assets of the blood collection, filtration, and processing product lines of Pall Corp., which included the acquisition of facilities in Mexico. The *Boston Business Journal* article is available at http://bit.ly/ZCsrVG. (Source: *Boston Business Journal*, 5/2/13)

MEETINGS

June 11-13 **FDA Workshop: "Redefining the 'C' in cGMP: Creating, Implementing, and Sustaining a Culture of Quality."**

The Food and Drug Administration is co-sponsoring with the International Society of Pharmaceutical Engineering a workshop titled "Redefining the 'C' in cGMP: Creating, Implementing, and Sustaining a Culture of Quality." The workshop will be held from June 11-13 at the Renaissance Baltimore Harborplace Hotel in Baltimore, Md. The conference is dedicated to teaching the principles of current Good Manufacturing Practices (cGMP), reaping the benefits that come from establishing and maintaining a state of control, implementing continual improvement, enhancing regulatory compliance, and meeting quality objectives every day. More information and registration details can be found at http://www.ispe.org/CGMP.

Contact: Nancy Berg, president of the International Society for Pharmaceutical Engineering at 600 North Westshore Blvd., Ste. 900, Tampa, FL, 33609.

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:

Reference Technologist. Resolves serologic problems **Assistant, Associate, or Co-Medical Director of Clinical Services at Stanford Medical School Blood Center.** The Department of Pathology at Stanford University School of Medicine seeks a full-time physician clinician educator to serve as the assistant, associate or co-medical director of Clinical Services and Operations at the Stanford Blood Center (SBC). This position is in the Clinician Educator line, with the rank based on years of relevant experience. The ad in its entirety is available at: http://stanford.io/112Sfx2.

Chief Operating Officer of QualTex Laboratories-LA002. QualTex Laboratories an affiliate of the South Texas Blood & Tissue Center (STBTC) screens millions of whole blood and plasma donations for infectious agents each year for biotechnology companies locally and across the globe. This global leader in the biotechnology area, is seeking a Chief Operating Officer (COO) who will report directly to the Chief Executive Officer. This key position will manage, supervise and coordinate the daily operations for QualTex Laboratories to ensure an efficient, effective and financially sound organization. This individual will be responsible for creating a culture of continuous improvement in order to achieve and sustain performance excellence. The successful candidate will have a proven track record of providing leadership in the areas of strategic planning and strategy execution. Qualifications required include a bachelor's

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degree, fifteen years clinical laboratory, management, quality, customer operations, and/or related experience. Computer three years driving experience with a good driving record required. Texas Operators Driver's License and a US Passport are required. Certified MT (CLS) (SBB) or equivalent preferred. For information, contact Sandra Munoz at (800) 292-5534, Ext. 1544. To apply, e-mail résumé to sandra.munoz@bloodntissue.org or fax to (210) 731-5549.

Lab Technologist II – Consultation & Reference Lab (full-time) (Gulf Coast Regional Blood Center). Scope of Responsibility: Under moderate supervision of Consultation Management, prepares special blood components and performs patient and donor tests. Essential duties and responsibilities: perform, interpret, and document compatibility testing, simple antibody identification, and donor serological testing; evaluate and process requests and patient samples per established guidelines; record, place and fill orders for antigen-negative red blood cells; monitor inventory of components; prepare washed and deglycerolized RBCs; perform quality control and preventative maintenance as assigned; prepare reagents; enter rare cell and serum samples into database; management retains the discretion to add to or change the duties of the position at any time. Education and Experience: MLT degree from an accredited college or university with certification (ASCP or equivalent) or; MLS new graduate eligible to take certification exam with certification obtained within six months of employment. Certificates, Licenses, Registrations: American Society of Clinical Pathologists (ASCP or equivalent certification); if new graduate, certification must be obtained within six months of employment. Please contact: Lori Pireu, Recruiter, lpireu@giveblood.org. Or apply online at: http://giveblood.org/career.

Director of Volunteer Services. The Blood & Tissue Center of Central Texas, located in Austin, is seeking an enthusiastic, self-starter to oversee our volunteer program. This position will develop, manage, and coordinate the volunteer activities to meet the needs of the organization, as well as maintain strong working relationships with the volunteer staff in order to retain their services. The director manages all volunteer recruitment efforts, works closely with management to identify volunteer opportunities, and selects volunteers for placement within the organization. Qualified candidates must have a high school diploma or equivalent; college degree preferred. Requires five to seven years of experience working in a volunteer program. Prefer at least one year experience recruiting, scheduling, and supervising volunteers or high level administrative experience or the equivalent combination of education and experience. Must have excellent communication, presentation, and interpersonal skills. Ability to prioritize under changing conditions, manage multiple projects, and handle stressful situations is needed. Must be at least 21 years of age, have a valid Texas driver's license, proof of insurance, and an acceptable driving record. Please visit http://inyourhands.org to apply.

Director, Transfusion Services Laboratories. Recognized as a leader in transfusion medicine, Puget Sound Blood Center is seeking a transfusion services laboratory director to organize and direct laboratory activities at multiple sites, evaluate and implement tailored customer solutions, while balancing financial viability and commitment to the blood center's mission. Requirements include: MT(ASCP) SBB or equivalent experience with a minimum of six years of managerial experience in a Transfusion Service; experience managing an effective and comprehensive quality assurance program and laboratory information systems management; knowledge to create, review, and interpret financial and business documents; and experience in developing and meeting budgets. A successful candidate will manage projects and workforce through collaboration, communication with stakeholders, and ensure proper allocation of resources. Interested candidates should send their resume and cover letter to HumanResources@psbc.org. More information at http://psbc.org. Please indicate job number 6953 on all correspondence. EEO/AA

Manager – IRL (Community Blood Center of Greater Kansas City). Oversight in the Immunohematology IRL, including Platelet laboratory operations and personnel. Provide consultation to staff and clients. Duties: assess personnel competency proficiency/adherence to guidelines/policies/procedures; conduct staff performance evaluations/assessments/oversee training; participate in recruitment/selection of employees; assure adequate continuing education opportunities for staff; preparation of annual department budgets/monthly budget variances; review and revision of applicable agreements/contracts with customer and suppliers; assure review of test results/worksheets/reports/bills/quality control/quality assurance records; assure review/approval patient records; provide continuing education presentations in-house and/or at profession meetings; review/maintain appropriate procedure/policy manuals; develop/validate/implement new procedure/policy manuals; develop/validate/implement new procedures; assure adequate staff coverage; assure maintenance of laboratory records/supplies/equipment/reagent inventory; assure fulfillment of CBC/IRL financial/quality goals; and participate in regional/national professional blood bank associations or be an active AABB or CAP assessor. Requirements: MT(ASCP) or equivalent, SBB preferred, antibody identification experience; ASQ Certification as CQA and/or CMQ/QE preferred; minimum five years IRL and/or transfusion service laboratory experience or equivalent and management experience. Skills and Knowledge: Advanced problem-solving skills, good verbal/written communication

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skills, customer service and time management. Please apply via our website: http://savealifenow.org. EEO/AA/M/F/D/V

Medical Technologist II (ASCP) – 3rd Shift. United Blood Services, a non-profit organization in sunny Scottsdale, Ariz. seeks a medical technologist (ASCP) to work in the QC Laboratory on 3rd Shift. Responsibilities include: quality control testing and high complexity testing on components produced from whole blood, platelet apheresis, and apheresis red cell products; participates in technical investigative studies; evaluates and participates in selection of new equipment and develops validation protocols in accordance with internal and external policies/regulations. Hours: 3rd Shift: (4-10 hour shifts) with varied days/rotating weekends. Requirements: bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science (CLS) required. Certification as a medical technologist (MT) by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure. Three years experience in a clinical laboratory setting required. Must be able to stand for long periods of time, bend, and lift up to 50lbs. Competitive benefits package! Position Closes: **May 10, 2013** (Ref: 210-1001-2013-027) – Please send resume and salary history to United Blood Services, c/o: C. Maksinski, 6220 E. Oak St., Scottsdale, AZ 85257 or email: cmaksinski@bloodsystems.org or fax: (480) 675-5448. Drug testing & background checks required. EOE/M/F/D/V.

Director of Donor Recruitment. Blood Bank of Hawaii is looking for a dynamic person to join our management team and lead our statewide recruitment efforts to realize annual red blood cell distribution of 55,000. This position oversees a department of 18 telerecruiters and field representatives. Responsibilities include staff and performance management, training, budgeting, and strategic planning. The ideal candidate will demonstrate strong leadership and communications skills with five to ten years of blood bank and customer service experience. Hemasphere and eDonor expertise preferred. We offer a competitive salary and excellent benefits. Please apply via our website: http://BBH.org. EOE

Donor Recruitment Director II. United Blood Services in Scottsdale, Ariz has a great opportunity for a seasoned sales and marketing leader with a proven track record of achieving results. This senior level position is responsible for developing and directing the regional blood center's strategic donor recruitment and marketing plan to achieve monthly and annual collection goals. Responsibilities include: hires, trains, and evaluates work performance of department personnel; administers the department budget; directs marketing and public relation initiatives; represents the organization in the community, including public speaking engagements; develops recruitment forecasts and department performance reports; and develops and maintains effective communications and relations with key customers. Requirements: bachelor's degree in related field required (e.g., marketing, communication), five years related experience with three years supervisory experience required. Previous blood center management experience serving in a manager or higher level position preferred, excellent leadership skills to effectively motivate and develop personnel, effective public speaking and written communication skills and sales/territory management skills. Excellent benefits package! Position Closes: **May 24, 2013** (Ref: 210-1001-2013-025) – Please send resume and salary history to United Blood Services, c/o: C. Maksinski, 6220 E. Oak St., Scottsdale, AZ 85257 or email: cmaksinski@bloodsystems.org or fax: (480) 675-5448. EOE M/F/D/V Pre-employment & Background checks required.

CLS Technical Specialist – Training (GL011). QualTex Laboratories, an affiliate of the South Texas Blood & Tissue Center , seeks an individual to develop and implement specialized training programs for QualTex Laboratories in Norcross, Ga. You will deliver hands-on training for employees utilizing highly complex equipment and processes. Recognize unusual results/outcomes and resolve discrepancies. Maintain training documentation to meet all regulatory requirements. The incumbent must have a working knowledge of clinical laboratory techniques. Qualifications required include bachelor's degree in Medical Laboratory Science/Medical Technology. Two years of experience in the area of specialization preferred. Must be at least 21 years old with three years good driving record. Certification: Certified MT, CLS, or MLS required. Georgia Operators Driver's License. Offering competitive salary and benefits. E-mail résumé to hr_dept2@bloodntissue.org or fax to (210) 731-5581. For information, call Human Resources at (800) 292-5534, Ext. 1559. For further information, visit our website http://bit.ly/ZpLpir.

Laboratory Services Director – IRL & Specialty (GL005). QualTex Laboratories an affiliate of the South Texas Blood & Tissue Center (STBTC), seeks an individual to manage, supervise, and coordinate all activities for Immunohematology Reference and Specialty Laboratories (includes IRL, Confirmatory, Microbiology, and Research & Development) for QualTex Laboratories in Norcross, Ga. and San Antonio, Texas. The position will be based at the Norcross, Ga. facility. QualTex Laboratories at present screens millions of whole blood and plasma donations for infectious agents each year for biotechnology companies locally and across the globe. Qualifications required include a bachelor's degree in Science, Medical Technology, Microbiology or related discipline, six years laboratory experience and extensive management experience in laboratory operations.

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MT(ASCP), SBB certification is also required along with a working knowledge of clinical laboratory techniques and current knowledge of regulatory/quality requirements (national and international, e.g. FDA, EU, GHA, ISO, OSHA & cGMP). For information, call Human Resources at (800) 292-5534, Ext. 1559. To apply, e-mail resume to hr_dept2@bloodntissue.org or fax to (210) 731-5581. http://bit.ly/ZpLpir.

Lab Manager. The Blood & Tissue Center of Central Texas, located in Austin, is seeking a lab manager to supervise staff, day-to-day testing, and overall lab operations. This position will ensure compliance with applicable protocols, policies, and regulations; serve as subject matter expert for the lab; perform supervisory review of all testing records to include donor testing/reference bench, QC, and maintenance documentation; optimize workflow based on daily collection projections and patient testing needs; troubleshoot and solve problems arising from equipment, processes, or workflow as needed. Qualified candidates must have a four-year college degree and certification in a Laboratory Science field, as well as have an ASCP certification or be eligible to acquire within six months of hire. At least three years work experience in a blood bank laboratory required. At least three years work experience in production and process control in a biologic and/or GMP environment required. At least three years supervisory experience in a medical setting is required, preferably in a blood center. Knowledgeable in cGMP, FDA, and AABB regulations. Please visit http://inyourhands.org to apply.

Laboratory Manager (Blood Bank of Alaska). The laboratory services manager is responsible for over-sight of daily laboratory operations ensuring that laboratory product QC and donor test results meet CLIA, AABB, and FDA compliance standards/regulations for the manufacture of blood. Maintain competency to perform laboratory processes and procedures to include lot release. Performs investigation and review of occurrences and BPDs related to laboratory issues. Develops and makes revisions to laboratory SOPs as needed. Oversees receipt of TAD, TRALI, and BD reports and initial notification of in date product recall/quarantine/discard. Plans, writes, and validates new or revised QC/equipment/maintenance procedures and processes. Works with laboratory services director and appropriate management/project team to coordinate activities. Oversight of laboratory equipment QC and maintenance schedule. Reviews applicable QC and maintenance records. Ensures that proficiency testing for laboratory is ordered, assigned to staff on rotating schedule, performed and submitted on time and records reviewed. Responsible for oversight of blood product quality control assuring that QC activities are performed in a timely manner and meets regulatory requirements. Reviews end of month results and initiates appropriate investigations of nonconforming products. Interfaces with vendors, contracted service providers, and hospital customers as required. Send application to Tom Petersen – tpetersen@bbak.org.