



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Interim Meeting Will Take ABC Members to the Windy City

America's Blood Centers' Interim Meeting will start in three short in Chicago, where attendees will be treated to full days of information sessions, forums, and the Medical Directors Workshop. The Interim Meeting will also feature an architectural boat tour and a dinner at the Art Institute of Chicago, both hosted by LifeSource, a division of Institute for Transfusion Medicine (ITxM).

The Interim Meeting itself runs Sunday, Aug. 8, and Monday, Aug. 9. In addition, Group Services for America's Blood Centers will host its board meeting on Thursday and Friday, Aug. 5 and Aug. 6; the Medical Directors Workshop will happen on Saturday, Aug. 7; the board meeting for the Foundation for America's Blood Centers will be on Monday, and the BCx Annual Members Meeting and Board Meeting will occur on Monday, Aug. 9, and Tuesday, Aug. 10.

ABC members can access the program for the meeting and related events, registration information, accommodation details, and information about visiting Chicago through ABC's Members Website, at <http://members.americasblood.org/go.cfm?do=Page.View&pid=33>.

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BPAC to Consider Issues Related to Babesia and Hemoglobin

The Food and Drug Administration's Blood Products Advisory Committee will consider *Babesia* screening options for blood donors and whether to change donor hemoglobin acceptance standards when the panel meets on July 26-27 in Gaithersburg, Md., according to materials posted on Wednesday.

On the first day of the meeting, the committee will hear reports from this June's meeting of the Department of Health and Human Services' Advisory Committee on Blood Safety and Availability, which focused on MSM deferrals; this May's FDA workshop on emerging infectious diseases; the December 2009 FDA workshop on emerging arboviruses; and the ongoing Q fever epidemic in the Netherlands. The committee will also hear informational presentations on the potential association of xenotropic murine leukemia virus-related virus (also known as XMRV) and chronic fatigue syndrome.

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OUR SPACE

ABC CEO Jim MacPherson is on vacation. His column will return when he gets back.

Changes to be Discussed at BPAC Meeting (continued from page 1)

On Monday afternoon, the committee will consider strategies for mitigating the risk of *Babesia* infection by blood transfusions and the status of screening tests. On Tuesday it will consider the current requirements for pre-donation levels of hemoglobin/hematocrit and whether the required period between donations should be changed.

On *Babesia*. *Babesia spp.* is a parasite transmitted by deer ticks that causes babesiosis, a malaria-like disease. Most people infected with it experience no symptoms or mild symptoms that can be mistaken for the flu; however, the disease can be severe and even fatal in individuals who are immune suppressed or have had their spleen removed. Asymptomatic carriers may have parasites in their circulation for up to 27 months, according to FDA's briefing document for the meeting. That document also indicates that transfusion-transmitted babesiosis (TTB) has been recognized as a major emerging threat to blood safety in the US, with more than 100 cases of transfusion-associated infections documented since 1980 and many more cases suspected. Furthermore, there has been a significant increase in the reported number of TTB-associated deaths.

Currently, blood centers ask potential donors whether they have a history of babesiosis but there are doubts about the effectiveness of the question. There is no FDA-approved screening test, but as of December 2009, the American Red Cross (ARC) had developed investigational new drug proposals for testing donated blood in Puerto Rico and in states that it serves in the Northeast and the upper Midwest where the disease is endemic (see *ABC Newsletter*, 12/18/09).

Presentations at the BPAC meeting will focus on incidence of *Babesia* infections in different parts of the US, the number of TTB cases, and a risk assessment model intended to help overcome limitations in TTB reporting. The committee will be asked to advise FDA on the following:

- Do the FDA risk analysis and the available CMS and CDC datasets together support the concept of regional testing of blood donors for *Babesia* infections?

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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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Changes to be Discussed at BPAC Meeting (continued from page 2)

- Given the current sensitivity limitation of nucleic acid-based testing (NAT) for *Babesia*, please comment whether the public health benefits of NAT testing warrant consideration of broad-based regional testing of donors by NAT.
- Considering the current technologies, please comment on the suitability of antibody testing for *Babesia* infections in blood donors.

On Hemoglobin and Hematocrit Levels and Interdonation Intervals. In 1999, FDA published a final rule that established a minimum hemoglobin eligibility level of 12.5 g/dL (or a hematocrit level of 38 percent) for both male and female allogeneic blood donors. That rule also established that people must wait eight weeks between whole blood donations.

However, in its briefing for this meeting, FDA acknowledged that these requirements are controversial because they may allow “anemic” males to donate blood even as they exclude some “normal” females. The agency pointed out that low hemoglobin concentration is the most common cause of donor deferral and that 95 percent of the donors deferred for low hemoglobin rates are women. It also mentions that as many as 67 percent of deferred female donors have hemoglobin levels between 12.0g/dL and 12.4g/dL, which are considered normal in most females. The document also indicates that donating a unit of blood can cause a healthy blood donor to lose about 200-250 mg of iron and that the time needed to replace that iron depends on the volume of blood collected, the frequency of donation, the donor’s diet and supplement intake, age, and gender. For some donors, the iron may not be fully replaced before they are eligible to donate blood again. Iron depletion can result in a number of symptoms, including fatigue, restless leg syndrome, pica, and anemia. It can also be related to impaired cognitive functioning, depression, and anxiety.

BPAC will be asked to consider the following questions:

- Does available scientific evidence support changing the donor hemoglobin acceptance standard for males and/or females? If yes, what hemoglobin acceptance standards does the committee recommend?
- Does available scientific evidence support changing the interdonation interval for males and/or females? If yes, what interdonation intervals does the committee recommend?
- If any changes are recommended, what mitigations can be considered to lessen possible adverse effects on the blood supply?

More Meeting Information. The deadline for submission of written comments is Monday, July 19. Full information about the meeting is available at www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm205013.htm. ♦

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 Newsletter* Editor Robert Kapler at rkapler@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.

ABC's Interim Meeting (continued from page 1)

Medical Directors Workshop. Saturday's workshop on medical issues is open not just to medical directors, but also to others interested in the topics. The morning's presentations will focus on transfusions for trauma patients, transfusion protocols, blood preservation, and the role of medical directors in blood centers. In the afternoon, topics addressed will include pathogen inactivation, emerging infections, and research in transfusion medicine. A discussion of case studies and a reception will close out the workshop.

SMT Forum. Medical aspects of transfusion will also be the focus of the Scientific, Medical, and Technical (SMT) Forum on Sunday afternoon. The forum will feature presentations on the status of research on xenotropic murine leukemia virus-related virus (also known as XMRV), which may be associated with chronic fatigue syndrome; new AABB standards on bacterial detection in platelets; and the results of the recent meetings of the Department of Health and Human Services' Advisory Committee on Blood Safety and Availability and the Food and Drug Administration's Blood Products Advisory Committee.

Executive Leadership Forum (ELF). This forum is a special feature of ABC's interim meetings; this is the fourth annual ELF. This year's theme is "Confronting the Status Quo – Changing Times/New Opportunities," and presentations will focus on ways that blood centers can respond to new realities and challenges in uncertain economic times. Speakers will discuss innovative business models, identify new opportunities, and offer insight into blood's place in the healthcare supply chain. In the afternoon, a panel will discuss new opportunities, mergers, and collaboration and independence for blood centers.

Exploring Chicago. The boat tour and the dinner at the Art Institute will highlight the distinctive features of Chicago. Transportation to the events will be on Chicago Trolley, a transportation service reminiscent of the historic electric trolleys that ran through the city in the 1920s and '30s, according to LifeSource's director of purchasing and facilities, Robert Miller. The 90-minute tour on the boat Chicago's First Lady, Mr. Miller said, will allow participants to learn about the history of the city through its landmark architecture and to discover how the city has repurposed former factories and manufacturing sites into residential homes, new businesses, and river-front property. The tour guide will point out examples of building styles from beaux arts to ultra modern. The dinner will feature foods that were invented in Chicago and that have made the city one of the food destinations of the country, Mr. Miller added. ♦

Save It or Shave It

On Saturday, Aug. 7, at America's Blood Centers' Interim Meeting, the suspense about the beard of Louis Katz, MD, will finally come to an end, when the results of the "Save It or Shave It" campaign are announced. During ABC's Annual Meeting in March in Fort Lauderdale, Fla., Lauren Larsen, president and chief ambassador of the Foundation for America's Blood Centers (FABC), launched the fundraising program, during which contributors to FABC could vote to either save or shave the beard of Dr. Katz, executive vice president of Medical Affairs at Mississippi Valley Regional Blood Center in Davenport, Iowa. If \$100,000 has been raised since then, the fund that has collected the most money by the Interim Meeting will decide the fate of Dr. Katz's beard. Ms. Larsen has not been allowed to reveal the status of the two funds prior to the meeting; however, she told ABC staff, "There's a lot of passion around this beard. Some folks feel it's time to move on and want the beard gone. Others are afraid Dr. Katz will not be the same without his furry friend. Fortunately for FABC, both camps are voting with their checkbooks. At this point, it's hard to tell what the outcome will be." ABC Newsletter readers can cast last-minute votes by contributing now to either <http://bit.ly/savelou> or <http://bit.ly/shavelou>.

Blood Centers Denied HIT Funding Despite Inclusion in HITECH Act

Two federal agencies this week published final rules for implementation of electronic health record systems (EHRs) that leave blood centers out of the funding competition designed to foster the creation of a nationwide health information technology (HIT) network.

The American Recovery and Reinvestment Act (ARRA) of 2009 includes several HIT grant programs for which America's Blood Centers (ABC) members should be eligible to apply. Title VIII of ARRA contains most of the Health Information Technology (HITECH) provisions, including grant programs, technical assistance, and hospital and eligible provider incentives. Section 13101 defines "health care provider" for the purposes of Title VIII as including "blood center." However, blood centers have been stymied in applying for HIT funding.

ABC staffers have repeatedly advocated on behalf of members at meetings of the Health IT Policy Committee, which reports to the Office of the National Coordinator of Health IT (ONC). Staff also submitted comments asking that transfusion services be added to the definition of "meaningful use of health IT," which is a major criterion for qualifying for funding. ABC staff, assisted by ABC members and ABC's Capitol Hill representatives, submitted comments to ONC and the Centers for Medicare and Medicaid Services (CMS) earlier this year on a proposed rule on EHR incentive programs, as well as on an ONC Interim Final Rule that sets out standards, implementation specifications, and certification criteria for EHR technology.

The CMS final rule issued this week responds to comments and questions from organizations like ABC by making clear that eligibility is limited to direct Medicare and Medicaid billers, such as hospitals and physician groups, and a list of Medicaid "eligible professionals." The rule includes this explanation:

We note that the commenters are correct to recognize that this is a statutory issue. The definition of a "Medicaid Eligible Professional," at 1903(t)(3)(B) of the Act, lists five types of professionals that are eligible for Medicaid incentive payments: physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in an FQHC [federally qualified health clinic] that is led by a physician assistant or RHC [rural health clinic] that is so led. Additionally, the statute at 1903(t)(2)(B) designates acute care hospitals and children's hospitals as the only two types of facilities eligible for the Medicaid incentives. These providers must also meet all other program requirements, including Medicaid patient volume thresholds. Since the commenters recommend including providers that are not among those explicitly mentioned in the statute, these providers cannot be eligible for the incentive payments. Additionally, professionals who do not participate in either Medicaid or Medicare are also not eligible for incentives due to the statutory requirements associated with each program.

The ONC's final rule, which contains a vague reference to "blood banks" among the order types for meaningful use certification criteria, does not shed any more light than does the proposed rule, despite entreaties by ABC.

As a national association of non-profit community blood centers whose members provide half the nation's volunteer blood supply, ABC represents community blood centers that are implementing IT systems that will support processes to track blood from donor to patient. Its projects include the development of a common interface standard based on an existing standard already used by hospitals, new radio frequency identification and bar-coded labeling systems that aim to reduce the number of transfusion errors and transfusion-transmitted infections in the hospital setting, data miners and a data warehouse system that will help hospitals benchmark blood use with other hospitals, and the monitoring of disease markers in blood donors as early public health warnings of national disease trends. ♦

Medical Device Excise Tax Law Leaves Discretion on Exemptions to Treasury Secretary, But the Categories Are Narrow, say Presenters during Webinar

If independent community blood centers are going to obtain an exemption from the new medical device excise tax on items they purchase, it will most likely take a legislative amendment, even though the statutory language of the act allows the secretary of the Department of Treasury to create a list of exempted products. That's because the parameters for what Treasury is allowed to exempt are limited to retail items sold to members of the public for their own use – things like toothbrushes.

That was one of the points made during a webinar, “The Medical Device Excise Tax: What You Don't Know Could Cost You,” presented on Thursday by Patton Boggs LLP, which represents America's Blood Centers on federal legislative issues. The presentation featured remarks by Patton Boggs partners Rosemary Becchi, Darryl Nirenberg, Paul Rubin, and George Schutzer, as well as associate Joanne Perry Hodge.

The Health Care and Education Reconciliation Act of 2010 imposed a 2.3 percent excise tax on the sale of medical devices starting in 2013. Though technically the tax is imposed on the sale of a taxable item by its manufacturer, producer, or importer, the tax will likely be passed on in one form or another to distributors and wholesale and retail customers, possibly as a line item on the invoice.

The only exemptions to the tax set out in the Internal Revenue Code are on eyeglasses, contact lenses, hearing aids, and devices determined by the Treasury secretary “to be of a type which is generally purchased by the general public at retail for individual use.” The exemptions are not limited by any device class laid out in Section 513 of the Federal Food, Drug, and Cosmetic Act (FFDCA). (Devices are categorized as Class I, Class II, or Class III.)

So while blood centers can point to the precedent law in 2006 that exempted them from paying excise taxes on the fuel, tires, vehicles, and communications used to recruit donors and to collect and transport blood, they will have to seek redress in Congress on this tax. That may take a clarification of the intent by members in Congress who helped write the healthcare reform act, as well as legislation to broaden the exemption categories that Treasury may grant.

A speaker on the webinar said that sales to state and local governments, non-profit educational organizations, and qualified blood collector organizations are not exempt at this point.

Based on comments made during the presentation, it seems that blood center centrifuges and other lab equipment most likely will be taxed, as will apheresis machines, blood bags, infusion pumps, and blood center computer software systems. Asked whether the tax would apply to the reagents that blood centers purchase (along with kits) to detect the presence of infectious diseases in donated blood samples – a gray area during the debate on the tax – one panel member said that was a “good question” and a “tough case” but added that the tax most likely would apply.

The new tax law looks to Section 201(h) of the FFDCA, which defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement of them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or animals... .”

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Excise Tax and Blood Centers (continued from page 6)

The Food and Drug Administration also has asserted that “laboratory developed tests” are medical devices and considers any accessory to a medical device to be a medical device, according to panel members.

The medical device tax provision does not mention combination products, and it is unclear whether they would be subject to the tax. In 21 USC, a combination product is “a product composed of any combination of a drug and device; a biological product and a device; a drug and a biological product,” according to a slide of the presentation.

Patton Boggs encouraged webinar attendees to file comments on any regulations on the tax issued by Treasury. Such comments should include recommendations for procedures to be used to identify products eligible for exemption and recommendations for more generic exclusions.

There has been some speculation in recent months that the 2.3 percent tax rate will actually bring in more revenue than the Congressional Budget Office predicted before passage of the healthcare reform bill. AdvaMed, the trade association of medical device manufacturers, is expected to seek a reduction in the sales tax rate if tax revenues seem likely to exceed the \$20 billion mark over 10 years.

Panelists also reviewed Republicans’ four attempts to repeal the device tax during healthcare reform debate. Each of those amendments was tabled by a floor vote. Since the enactment of the healthcare law, Republicans have introduced two standalone bills to repeal the medical device tax – HR 5095 and HR 5615 – both referred to the House Ways and Means Committee. One Republican amendment was offered for a recent tax bill, but it too was tabled by a floor vote. ♦

Study Notes that the Number of Blood Donors with HIV and HCV Has Fallen – But Also Finds an Uptick in Incidence in Recent Years

Researchers at the American Red Cross (ARC) have found that the numbers of blood donors with human immunodeficiency virus (HIV) or hepatitis C virus (HCV) have been lower in recent years than they were before nucleic acid testing (NAT) for the viruses was introduced in 1999. However, in 2007 through 2008, they found troubling increases in the number of repeat donors who newly tested positive for one of the viruses.

The researchers were led by Shimian Zou, PhD, of the American Red Cross Biomedical Sciences offices. They analyzed ARC’s data on the approximately 66 million blood donations collected by the ARC between 1999 and 2008. Because of the size of the data pool, the researchers call their results, which were published in the July issue of *Transfusion*, “the most reliable assessments of viral risks of the US blood supply using currently implemented safety measures.”

Methodology. ARC has tested its blood donations for antibodies to HIV and HCV, as well as for viral RNA for both viruses and for several other markers. For this study, the researchers considered units confirmed positive if they tested reactive on a screening test and then on more specific follow-up tests.

The research team determined, for both viruses, the prevalence (how many donors tested positive) and the incidence, which they defined as the number of donors who had previously tested negative for the viruses but later donated a confirmed-positive blood unit. The researchers determined these figures for donors in various demographic groups, including first-time and repeat donors, donors in particular areas

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HIV and HCV Among Donors (continued from page 7)

of the country, donors of certain ages, and donors in various racial and ethnic groups. The researchers also identified the NAT yields for both viruses: the numbers of donations that were positive by NAT but negative by antibody testing.

Findings. From 1999 to 2008, NAT yields were 32 units of donated blood for HIV (1 in 2,000,000 donations) and 244 for HCV (1 in 270,000 donations). Assuming that 1.5 transfusable components are generated from each donated unit, the researchers posited that NAT prevented the release of approximately 48 HIV RNA-positive components and 366 HCV RNA-positive components.

The analysis uncovered “clear fluctuations” in incidence for both HIV and HCV from year to year. However, it also revealed significantly increased incidence for both viruses in 2007 through 2008, as compared to 2005 through 2006. In the latter period, HIV incidence was 3.11 per 10⁵ person-years (py, each representing 12 months of exposure), with a residual risk (RR) estimate of 0.68 per 10⁶ (1 in 1,467,000) donations; HCV incidence was 5.14 per 10⁵ py, with an RR estimate of 0.87 per 10⁶ (1 in 1,149,000) donations. For 2005 through 2006, the incidence was 2.25 for HIV and 3.38 for HCV. In 2007 through 2008, there were 92 HIV incident cases and 127 HCV incident cases, while in the earlier period, those numbers were 67 for HIV and 84 for HCV.

Upon further analysis, the researchers attributed most of the excess cases of HIV to male donors, aged 16 to 19. Of those donors, 11 of 21 were African Americans, although they represented only about 5 percent of the male donors in that age group. Incidence for African-American and Caucasian donors was about 2.4 times as high in 2007-2008 as it was in 2005-2006. The researchers call the rise in HIV cases among young African-American donors “particularly alarming” because the infected donors in this study were repeat donors and thus presumably have lower incidence than the population at large. They do not speculate about what may have caused the uptick, but they do say it suggests that donor-selection procedures may need to be revised.

For HCV, it was blood donors who were more than 50 years old, mostly Caucasian, who contributed most to the increased incidence of the virus. The authors say that the rise in cases of HCV among these donors “is not readily explained,” but they do suggest that it may be linked to increased use of nonhospital healthcare facilities and that endoscopy may be a risk factor.

In an accompanying editorial, Jay Epstein, MD, of the Food and Drug Administration’s Office of Blood Research and Review, and Jerry Holmberg, PhD, of the Department of Health and Human Services, write that while the study shows that NAT has contributed to good progress in blood safety, the increased incidence of HIV and HCV highlight the need for determining donors’ underlying risk factors. Dr. Epstein and Dr. Holmberg call, then, for follow-up questioning that could help identify the high-risk behaviors that donors may have engaged in. That information, in turn, could help with the development of policy decisions, recruitment strategies, and screening practices.

Dr. Epstein and Dr. Holmberg also point out that studies like this one – and another led by Dr. Zou, also in the July issue of *Transfusion*, that analyzes blood-borne infections among ARC’s donors from 2004 to 2008 – are made possible by the collection of hemovigilance data from blood establishments. Because hemovigilance systems help identify “opportunities for advancements in prevention and control” of transfusion-transmitted infections, Dr. Epstein and Dr. Holmberg say, they will play crucial roles in improving blood safety.

(continued on page 9)

HIV and HCV Among Donors (continued from page 8)

Citations. Zou S, *et al.* Prevalence, incidence, and residual risk of human immunodeficiency virus and hepatitis C virus infections among United States blood donors since the introduction of nucleic acid testing. *Transfusion*. 2010 July;50(7):1495-1504. Zou S, *et al.* Prevalence, incidence, and residual risk of major blood-borne infections among apheresis collections to the American Red Cross Blood Services, 2004 through 2008. *Transfusion*. 2010 July;50(7):1487-94. Epstein JS and Holmberg JA. Progress in monitoring blood safety. *Transfusion*. 2010 July;50(7):1408-12. ♦

Study: RFID Has Minimal Impact on Blood Temperature, RBC Integrity

Even under extreme exposure conditions, radiation emitted by radio frequency identification (RFID) technology had little to no effect on the temperature and biologic functions of red blood cells (RBC) and platelets derived from whole blood, a study has found.

The limited study, which used a protocol approved by the Food and Drug Administration, was conducted by a team of six researchers led by Rodeina Davis, chief information officer and vice president of the BloodCenter of Wisconsin (BCW), based in Milwaukee. BCW; Carter BloodCare, in Bedford, Texas; and Mississippi Blood Services, in Jackson, have been working with several hospitals and vendors to develop RFID technology for transfusion medicine delivery processes. These processes include “the automatic identification, tracking, and condition-monitoring of blood and blood products across the entire transfusion medicine supply chain,” the authors say.

RFID does not require the line-of-sight reading that bar coding requires, and RFID transponders allow multiwrite capabilities and more data storage than bar code labels. The transponders also can be integrated with sensors that facilitate time and temperature tracking, the authors note. RFID can be based on a variety of different frequency bands, but the International Society for Blood Transfusion (ISBT) working party on RFID has recommended the globally available 13.56 MHz band as the international standard for transfusion medicine.

In the past, FDA has raised concerns about the potential impact of radio frequency energy on exposed blood products, in terms of temperature elevation and adverse biological effects. To address these concerns, the RFID consortium designed and conducted a set of experiments using a special RF apparatus that allowed a test unit to be exposed to a uniform, in-phase 13.56 MHz magnetic strength. The study was published in *Journal of Blood Services Management*, a supplement to the July issue of *Transfusion*.

Methodology. The team obtained RBC and platelet components separated from whole blood collected from donors using standard procedures. The units were stored in 450-mL bags containing 63 mL of citrate phosphate dextrose anticoagulant/preservative solution and were separated using standard centrifuge methods. The packed RBCs had AS-1 added as a preservative and were stored at 1-6 degrees Celsius until the time of testing. Platelets were agitated at 22 +/- 2 degrees Celsius until that time.

The RBC and platelet products came from separate whole blood units of the same blood group collected on the same day. Three pairs of RBC units and three pairs of platelets were tested, with one test unit and one control unit per pair. Each pair of platelets was combined using a sterile connecting device, which drained one unit into the second unit to make a pool. The pool was mixed several times before being split back into platelet bags with weights within 1 g of one another. The RBC unit pairs had comparable but not equal weights.

(continued on page 10)

RFID and Blood (continued from page 9)

Testing methodology included three replicates with identical product exposure conditions under exposure guidelines provided by the Center for Devices and Radiological Health. The team exposed a test unit to approximately 100 watts of HF (13.56 MHz) radio energy for 23-25 hours for each test sequence. An 86 cm Helmholtz coil designed and built by Zebra Technologies was used; it produced a nominal magnetic field strength of 5 Amperes/meter at its center, the point of positioning for the test unit. A companion control unit was placed 2 meters outside the coil. Content samples of each test and control unit were obtained just prior to RF exposure, after 7 hours of exposure, and after 23-25 hours of exposure.

The expected maximum exposure to RF energy under normal operating condition for RFID tracking would be less than the maximum 4 watts allowed under Federal Communications Commission rules for about 20 minutes during the life of the blood product.

Results. There were no significant differences in complete blood count (CBC) results for individual RBC products and no significant differences in potassium between test and control units. Hemolysis after 23-25 hours of exposure was 0.09 percent and 0.05 percent, respectively, for test and control RBC units, and within FDA-approved acceptance criteria.

With the exception of slightly higher average platelet concentration in one control unit over its corresponding test unit, there were no differences in the white blood cell count, platelet count, or mean platelet volume between test and control units in all platelet pairs. The mean pH readings for test and control units were 7.27 and 7.19, respectively, well above the FDA acceptance limit. There was no detectable acceleration of cellular degradation of RBC and platelet products. While there was some temperature rise, the increase between test and control units never exceeded the 1.5 degree Celsius acceptance criterion.

“This study’s principal finding that 13.56 MHz RF radiation does not cause adverse thermal changes and cellular degradation in RBC and [platelet] products, even after extended exposure and at high power levels, results in approval to use transfusable RBCs and platelets in an RFID-enable pilot study,” the authors conclude.

The authors acknowledge a number of limitations: experiments were not done at various stages of product aging, and thus it is not known whether there would be different findings if the test were performed closer to outdate. No in-vivo survival studies were performed; therefore, the impact of prolonged exposure on RBC recovery and platelet survival is yet unknown. Additional testing is underway on thawed plasma and aged RBCs.

Citation: Davis R, *et al.* Absence of acute adverse in-vitro effects on AS-1 RBCs and whole-blood derived platelets following prolonged exposure to 13.56 MHz of radio energy. *Transfusion* 2010;50:1596-1603. ♠

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 Editor Robert Kapler at rkapler@americasblood.org. You will be sent a writer’s guide that provides information on style conventions, story structure, deadlines, etc.




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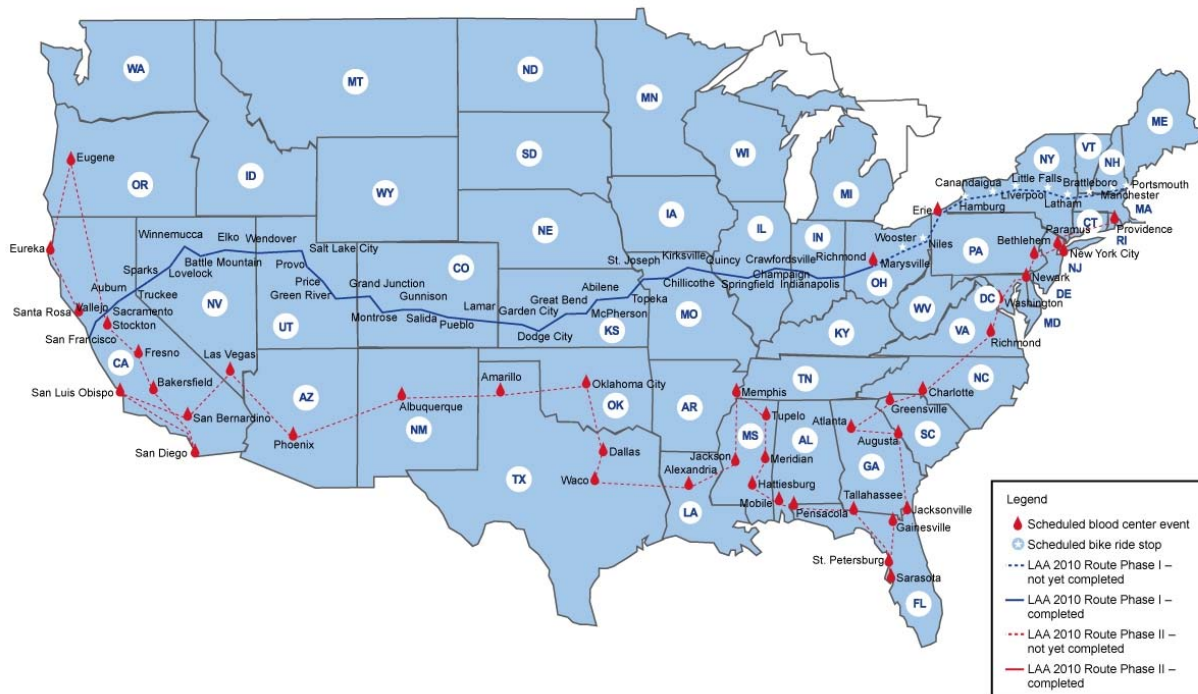
INSIDE ABC

Life Across America Nears the Home Stretch



Larry Frederick and his daughter Adella are nearing the end of their cross-country Life Across America (LAA) bike ride – if 820 miles can be counted as a home stretch! Adella and Larry, a blood recipient and a long-time blood donation advocate, began their ride on June 6, and as of today, they have completed more than 3,000 miles of their journey (see map below, and Adella celebrating their arrival in Missouri on July 4, at left). So 820 miles might not seem like far to them! They are currently in Ohio, and they aim to arrive in Portsmouth, N.H., on July 27. They'll rest for a day in Portsmouth and then head back to California by car. They have been visiting America's Blood Centers' member centers along their bike route, and they'll continue to do so on their way back, hosting blood drives and raising awareness of the importance of blood donation. All told, they'll work with local blood centers in more than 40 cities. Full information on their journey is available at www.lifeacrossamerica.com. 

LAA 2010 Route



DEAR ABBEY**. . . Questions and Answers about the Blood World**



Dear Abbey,

What is National Minority Donor Awareness Day and how can my center get involved?

– *Missing Out on Minorities*

Dear Missing Out,

National Minority Donor Awareness Day, celebrated on Aug. 1, was established by the Minority Organ and Tissue Transplant Education Program, based at Howard University (in Washington, DC), and was recognized by President Bill Clinton in 1996. According to the United Network for Organ Sharing, there are three main goals of this national celebration, now in its 15th year:

- Dispel myths, fears, and obstacles associated with donation;
- Encourage healthy living and disease prevention; and
- Promote life-saving organ, eye, and tissue donation.

Now I know what you may be thinking: “What does this holiday have to do with blood donation?” And you are correct ... partially! In previous years, this national celebration was geared toward creating awareness for organ, eye, and tissue donation. But this year, why not make it about blood donation, too?

We already know that organ, tissue, and blood donors share at least one similar characteristic: altruism. And we also know that many of the life-saving organ transplantations that are performed each year require the patient to receive blood transfusions as well. So, in honor of this national celebration, America’s Blood Centers is encouraging blood centers across the nation to take the opportunity to both recognize their current minority donors and also educate and encourage the minority population in their communities.

Resources that will help you celebrate this Aug. 1, such as *Mi Sangre, Tu Sangre* (our Spanish version of *My Blood, Your Blood*) and the Multicultural Donor Recruitment and Marketing Plan, can be found on ABC’s Members Website at <http://members.americasblood.org/go.cfm?do=Page.View&pid=19> .

Let the celebrations begin!

– Abbey

P.S. – Please send me (at aspittle@americasblood.org) your questions about ABC, aspects of blood center operations or science, or blood banking in general. I’ll go to the experts at ABC for answers and include my findings in a future column. Feel free to include your real name or use a pseudonym!

GLOBAL NEWS

A lawsuit filed by a gay man in China against the Beijing Red Cross Blood Center has been rejected by a district court. The man, an editor identified by his pen name Wang Zizhenheng, sued the blood center after he was told in early June that he could not donate blood. He had identified himself as gay in his health questionnaire (see *ABC Newsletter*, 7/9/10). His suit was rejected on July 8 by a judge in the Haidian district court, who did not provide a reason for the dismissal or issue a written certificate.

(GLOBAL NEWS continued on page 13)

GLOBAL NEWS (continued from page 12)

The judge did tell him that the decision was made after a consultation with the Beijing High People's Court. "The court would not tell me for what reason my case was rejected," Mr. Wang told *Global Times*. He added that he was contemplating his next move. "I believe this regulation is discriminatory, but I don't know what to do to change it," he said. Li Yinhe, China's leading sexologist and one of the country's first scholars of homosexuality, called the ban on homosexuals and people with multiple sex partners "China's last discriminatory regulation against homosexuals," and she said this is the first effort that has been made to change it. (Source: *Global Times*, China, 7/9/10) ♦

REGULATORY NEWS**FDA Gives Baxter Specific Requirements for Recalling Its Pumps**

The Food and Drug Administration on Tuesday issued specific instructions to Baxter Healthcare Corp. that detail how the company must carry out the recall of its Colleague Volumetric Infusion Pumps (CVIPs).

The recall was announced in April, and it covers as many as 200,000 CVIPs, which are used to administer blood components to patients and for other purposes. FDA specified that Baxter must provide customers with a refund, a replacement pump, or a lease termination, and that it must complete those programs by July 14, 2012. The new requirements add that the company must also provide a transition guide by Sept. 11, 2010, to facilities using the pumps. The guide will include a list of FDA-cleared or approved pump alternatives, suggestions to help minimize disruption and patient risk during the transition period, and detailed information on the refund, replacement, and lease termination programs.

In an FDA press release (7/13/10), Jeffrey Shuren, MD, director of the agency's Center for Devices and Radiological Health, said, "This action reflects the agency's commitment to protect patients by removing unsafe infusion pumps and to promote public health through assuring the availability of safe and effective alternatives." He also explained that, since the pumps are still used in many hospitals and facilities, the agency "reached out directly to the hospital community in order to determine what would best fit their needs in a transition plan."

The news release also makes clear that the company will continue to provide batteries, spare parts, and service for the affected pumps during the transition period for customers who submit a Certificate of Medical Necessity to Baxter. According to Baxter's website, the certificate is still being finalized but will need to be completed by Nov. 14, 2010. Once it is ready, Baxter will make it available online. Information about the certificate is available at www.baxter.com/information/safety_information/colleague_certificate.html.

The recall of Baxter's CVIPs is based on the company's failure to correct many serious problems with the pumps, which it has not sold in the US since 2006, when FDA issued a consent decree to the company. This May, the agency ruled that its schedule for correcting the flaws with the devices was unacceptable (see *ABC Newsletter*, 5/7/10).

Because there have also been problems with other types of infusion pumps by various manufacturers, FDA developed the Infusion Pump Improvement Initiative. More information on the initiative is at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm. FDA also has posted a list of questions and answers about the recall of Baxter's pumps, at www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm210768.htm#14. ♦

INFECTIOUS DISEASE UPDATES

DENGUE

More than 1,000 people in Key West, Fla., an estimated 5 percent of the population, apparently had been recently exposed to the dengue virus, according to a study conducted in 2009. The results are contained in a report from the Centers for Disease Control and Prevention (CDC) and the Florida Department of Health. On Sept. 1, 2009, a New York state physician notified health authorities of a suspected dengue case in a New York state resident whose only recent travel was to Key West. In the next two weeks, two dengue infections in Key West residents who had not recently traveled were reported and confirmed. That led to the study, which scientists from the CDC and the state health department used to estimate the potential exposure of the Key West population to the dengue virus. A total of 240 blood samples were collected from randomly selected households in Key West and tested for the presence of the virus or evidence of a previous dengue infection. Among the samples, 5 percent contained active dengue or had dengue antibodies, suggesting that the people who gave the samples had experienced the disease within the previous three months. Key West residents, physicians, and hospitals were enlisted in a surveillance program to identify new cases, and mosquitoes were tested for the virus. As of the end of June 2010, there have been 12 additional cases of locally acquired dengue reported from Key West and surrounding areas. In November 2009, Kay Tomashek, MD, a CDC medical officer in San Juan, Puerto Rico, told the Food and Drug Administration's Blood Products Advisory Committee that "the US blood supply is at risk" of the spread of dengue from imported blood and travelers who bring the disease from other countries (see *ABC Newsletter*, 11/20/09). The mosquitoes that carry dengue, *Aedes aegypti* and

(INFECTIOUS DISEASE UPDATES continued on page 15)

Clarification: Origins of the National Voluntary Blood Policy

Two readers wrote in this week to point out that a story published in the July 9 issue of the *ABC Newsletter* that summarized a *Vox Sanguinis* paper on the merits of paid vs. unpaid blood and plasma donors wrongly identified the developer of the National Blood Policy. It was the federal government, namely agencies of the Department of Health, Education and Welfare, that developed the National Blood Policy, they said, not the American Blood Commission, as was stated in the front-page story.

The paper by Farrugia A, *et al.*, contained the following sentence: "The American Blood Commission established in 1973 developed a National Blood Policy, which advocated, amongst other measures, the phasing out of compensated blood donation." The paper provided this citation: Kennedy L. Health policy and the blood market. *J Health Polit Policy Law* 1978; 3(1):5-6.

Thus, the *Newsletter* story accurately reflected the substance of the paper. While the *ABC Newsletter* strives for accuracy in its reporting, it should be noted that, under normal circumstances, the editors do not fact check peer-reviewed articles such as those found in *Vox Sanguinis*. However, we are grateful to Paul Schmidt, MD, the historian for AABB, and William V. Miller, MD, of the St. Louis Cord Blood Bank, for pointing out the error. All correspondence about the substance of the paper should be addressed to Albert Farrugia, Plasma Protein Therapeutics Association, 147 Old Solomon's Island Road, Annapolis, MD 21401; e-mail: afarrugia@ppta.org.

INFECTIOUS DISEASE UPDATES (continued from page 14)

Aedes albopictus, are present in the Southern and Southeastern parts of the US. The virus is usually transmitted from person to person by mosquito bites, but it can also be transmitted through blood transfusions, transplants, and needlesticks. Dr. Tomashek said that in 2007, 25 units of blood donated to the Red Cross in Puerto Rico tested positive for dengue. Twelve of those units had been shipped to the US. Dengue is the most common virus transmitted by mosquitoes in the world. It causes an estimated 50 million to 100 million infections a year. Like those infected with West Nile virus, the majority of dengue-infected people develop no symptoms. However, a small number will experience a serious disease that is sometimes fatal, which results in about 25,000 deaths each year. From 1946 to 1980, no cases of dengue acquired in the continental US were reported, and there has not been an outbreak in Florida since 1934. "We're concerned that if dengue gains a foothold in Key West, it will travel to other southern cities where the mosquito that transmits dengue is present, like Miami," said Harold Margolis, chief of the dengue branch at CDC. (Source: CDC press release, 7/13/10) ◆

PEOPLE

Harold E. Varmus, MD, was sworn in on Tuesday as the director of the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). In late 2008, President Barack Obama appointed Dr. Varmus as co-chair of the President's Council of Advisors on Science and Technology; this May, Mr. Obama tapped him to direct the NCI. Dr. Varmus, a co-recipient of the Nobel Prize in Physiology or Medicine in 1989 for studies of the genetic basis of cancer, has been president of Memorial Sloan-Kettering Cancer Center in New York City since 2000. He was director of NIH from 1993 until the end of 1999, during which time he helped initiate a five-year doubling of the NIH budget. Before that, he spent 23 years as a faculty member at the University of California, San Francisco School of Medicine.

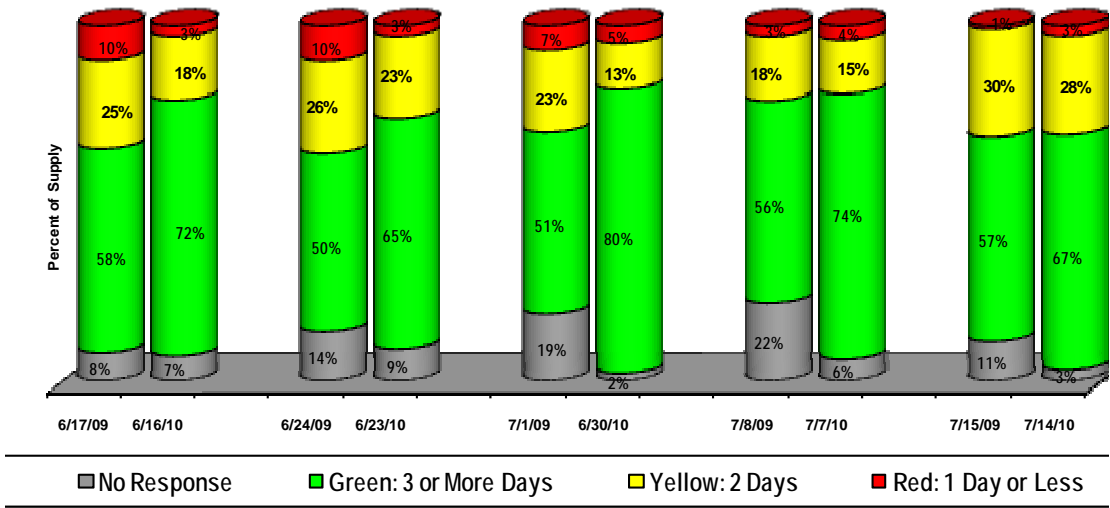


His research there focused on the replication cycles of retroviruses and hepatitis B viruses, the functions of genes implicated in cancer, and the development of mouse models of human cancer. He has been a member of the US National Academy of Sciences since 1984 and of the Institute of Medicine since 1991, and he has received the National Medal of Science, the Vannevar Bush Award, and several honorary degrees and other prizes, in addition to the Nobel Prize. (Source: NIH news release, 7/12/10)



Pharmaceutical Research and Manufacturers of America (PhRMA) announced Tuesday that **John J. Castellani** will become its next president and CEO, as of Sept. 1. For the last nine years, Mr. Castellani has held those positions with Business Roundtable, an association of corporate chief executive officers. The previous president and CEO of PhRMA was Billy Tauzin, who transitioned to a role as senior advisor earlier this year. Mr. Castellani also has served in leadership positions at Tenneco Inc., National Association of Manufacturers, and TRW Inc. He began his career as an environmental scientist at General Electric. He received his undergraduate degree from Union College. PhRMA represents the country's leading pharmaceutical research and biotechnology companies, according to its website, and these include a number that work on blood-related medicines and devices. (Sources: www.phrma.org, accessed 7/16/10; PhRMA press release, 7/13/10) ◆

STOPLIGHT: Status of the ABC Blood Supply, 2009 vs. 2010



The order of the bars is (from top to bottom), red, yellow, green, and no response

MEETINGS

July 19-20 Food and Drug Administration, Public Meeting on Oversight of Laboratory-Developed Tests, Hyattsville, Md.

The meeting location has been changed, due to high response after the original announcement (see *ABC Newsletter*, 6/18/10). Discussion at the meeting will focus on the regulatory status of laboratory-developed tests, patient considerations, challenges for laboratories, direct-to-consumer marketing of testing, and education and outreach. More information is available at www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm.

Contact: Katherine Serrano, FDA. Phone: (301) 796-6652; e-mail: katherine.serrano@fda.hhs.gov.

Sept. 1-2 Centers for Disease Control and Prevention (CDC), Clinical Laboratory Improvement Advisory Committee (CLIAC), Atlanta

The CDC's CLIAC is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director of the CDC about the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances. At this meeting, the committee will hear updates from the CDC, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration. In addition, the committee will discuss issues pertaining to cytology testing and workload recording; the electronic exchange of laboratory

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MEETINGS (continued from page 16)

information; and consideration of proposals from the CLIAC proficiency testing workgroup. Information about the committee is available at www.cdc.gov/cliac/default.aspx.

Contact: Nancy Anderson, CDC. Phone: (404) 498-2741; fax: (404) 498-2219; e-mail: Nancy.Anderson@cdc.hhs.gov.

Oct. 7 **Food and Drug Administration, Town Hall Discussion with the Director of the Center for Devices and Radiological Health (CDRH) and Other Senior Center Management, Irvine, Calif.**

The meeting will include a presentation of CDRH's priorities for FY 2010, as well as a discussion of issues of importance to the medical device industry. CDRH has said that it welcomes feedback and ideas about how it might facilitate two-way communication between itself and the medical device industry, and comments from the public will be accepted. For details and registration information, see www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215113.htm.

Contact: Heather Howell, CDRH. Phone: (301) 796-5718; e-mail: heather.howell@fda.hhs.gov. 💧

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available & wanted, are published free of charge for a maximum of three weeks for ABC institutional members. There is a charge of \$100 per placement for ABC Newsletter subscribers & \$250 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Deanna Du Lac at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: ddulac@americasblood.org.

EQUIPMENT AVAILABLE:

For Sale. Two 2003 Ford E450 2 bed Bloodmobiles, 29,000 and 32,000 miles. Please contact Britt Chewing for more information. Phone: (804) 213-4104; e-mail: bcchewing@vablood.org.

POSITIONS AVAILABLE:

Regional Sales Director Donor Recruitment. LifeSource Blood Center is not-for-profit organization & major provider of products that support Chicago's blood supply. LifeSource's committed professionals believe in core values of providing reliable & safe blood products to community. LifeSource is made up of quality minded individuals who demonstrate team work, open communication, continuous learning & excellent customer service. Regional Director Donor Recruitment develops & directs regional team of Account Managers to achieve annual blood collection objectives. Develops & implements short & long term plans to achieve goals, tactical plans & programs. This individual will manage metrics & performance indicators. Provide ongoing analysis & team direction. Works with team members to set specific, measurable, attainable & relevant objectives. Position will conduct ongoing assessments of Account Manager

territories & provides actionable coaching, identifies new strategies & tactics for market development with Vice President of Programs to increase blood collection. Regional Director Donor Recruitment will effectively participate in planning of special recruitment events & media promotions, recognition programs, workshops & seminars. This individual will build & maintain strategic relationships within marketplace & interacts with senior leaders in community donor group sectors. Bachelors degree in business, marketing, communications or related discipline req'd. Five plus years

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POSITIONS (continued from page 17)

of field based management exp. in sales or development environment is needed. Five plus years of field based management experience in a sales or development environment is key. Experience in a not for profit or healthcare environment highly pref'd. Qualified candidates will be able to demonstrate effective problem solving skills. Must have analytical skills, set expectations & communicate results & feedback as needed & highly developed communication & customer service skills. Glenview/Full Time & Evenings/Weekends. Contact: Nancy Sifuentes; e-mail: nsifuentes@itxm.org; Tel: (847) 803-7845; Fax: (847) 803-7870; Address: 1205 N Milwaukee Ave, Glenview, IL 60025.

Quality Assurance Specialist II. Kentucky Blood Center seeks MT or CLS to support, implement & monitor quality assurance program plan to ensure adherence to standards & guidelines issued by regulatory agencies & accrediting organizations. Will assist in development & performance of quality systems & focused audits to ensure AABB & FDA requirements are met; with oversight of quality matters & problem solving; & with the document control system including SOP's, audit reports, FDA documentation & organizational forms & documents. Will participate in departmental & organizational planning & training as appropriate & departmental on call rotation. Qualified applicants will be registered MT or CLS. Exp. with MasterControl pref'd. Must practice good customer service with both internal & external customers. Must be proficient with MS Office products, including Word, Access & Excel. Must be flexible, creative, adaptable & able to handle multiple tasks under pressure, able to work efficiently, tactfully & effectively with people at all levels of organization. Strong written & oral communication skills, do-what-it-takes work ethic & team player attitude req'd. Medical Insurance, Life Insurance, Dental Insurance, Paid Vacation, Paid Sick Days, Paid Holidays, Long Term Disability, 401K/403b Plan & Pension/Retirement. Please apply at: www.kybloodcenter.org/careers.php.

Assistant Medical Director. The American Red Cross Blood Services Southern California Region in Pomona, California seeks Assistant Medical Director with guidance, leadership & oversight of all matters relating to medical practices & research of blood region. Support medical services of regional centers. Responsible for medical policies & procedures of blood region. Monitors medical aspects of regional blood centers operations, including reference laboratories, research, medical community relations & collections. Provides medical consultations on transfusion medicine issues to regional physicians & other healthcare professionals. Qualifications: MD or DO degree with post graduate training in blood banking/transfusion medicine req'd. Board certified or eligible in internal medicine, pediatrics or clinical pathology. Board certified or eligible in blood banking/transfusion medicine desirable. Knowledge of current/projected trends in transfusion medicine/blood banking & hospital health care desirable. Must be licensed in state of primary site of region and all banking/transfusion medicine, or related field, or completion of a blood banking/transfusion medicine

fellowship req'd. Apply on-line:
<http://americanredcross.apply2jobs.com/>.

Medical Technologist. Join San Diego Blood Bank Reference or Quality Control Laboratory & make difference in lives of patients, staff & community. Work in one of finest cities in America, sunny San Diego with mountains, beaches & average temperature of 75 degrees year round! SDBB is not-for-profit community blood center that provides blood services for region. SDBB offers ideal location to start career, opportunity to take on leadership roles & ability to grow within organization. We are looking for qualified candidates: California licensed or eligible Laboratory Scientist &/or ASCP Licensed Medical Technologist. Specialty in Blood Banking pref'd. Blood Bank/Immunoematology exp. with minimum three to five years. Willing to relocate & work independently, trouble shoot, problem solve & accept responsibility. We offer generous paid time off program, 100% employee paid health benefits; pension plan & 403(b). For more information contact: Marci Swearingen (619) 400-8320. EOE/AA/M/F/V/D

Director of Blood Donor Services. Upstate New York Transplant Services located in Buffalo, New York seeks dynamic, clinically-skilled leader for our community blood service. Ideal candidate will assure that blood collection teams maintain highest regulatory standards while delivering exceptional customer service. In addition, this individual will have proven track record of successful leadership in diverse, fast paced & progressive environment. RN license & blood banking exp. strongly pref'd. Individual must possess excellent verbal & written communication skills. Please forward cover letter & resume to: Upstate New York Transplant Services, HR, 110 Broadway St. Buffalo, NY 14203; e-mail to: hr@unyts.org. EOE/AA. You've been given the Gift of Life. Give it Back. Upstate New York Transplant Services is among the leading procurement organizations in United States & is the first organization nationwide to offer opportunities for organ, eye, tissue & community blood donation under one roof.

Director of Donor Services (Collections). Central California Blood Center, located in Fresno, CA, seeks business minded management-focused individual to direct all aspects of blood donor program with annual draw of 70,000 +. Includes managing efforts of Donor Services Dept. including Donor suitability, phlebotomy, care & handling of blood units & Donor care post donation on Mobile & Field Drives in our five co area, as well as our five Inbank locations. In addition, ensure regulatory compliance, manage quality systems, SOP's & training requirements for CCBC Donor Services (Collections) staff. Qualified professional will possess strong leadership skills including prior management exp., proficiency in process improvement strategy with implementation of initiatives req'd, MPH w/exp. in medical regulatory environment plus. Competitive compensation & benefits. Apply online at: www.donateblood.org with resume & salary history.

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POSITIONS (continued from page 18)

Advanced Clinical Lab Specialist. Blood Systems has exciting opportunity for full-time Medical Technologist (MT) to work in our Immunohematology Reference Laboratory (IRL). Position responsible for performing advanced immunohematology test procedures & interpret complex test results for AABB accredited IRL. In addition, successful candidate will resolve compatibility problems & provide reference/consultation services to hospitals & transfusion facilities. Position also provides skilled technical support in laboratory & will require individual to be able to work independently with sound judgment while following Standard Operating Procedures (SOP's) & industry regulations. Bachelor's degree req'd. MT (ASCP) by recognized certifying agency req'd. SBB pref'd. CLIA requirements for high complexity testing req'd. California testing requirements must be met within one year req'd. Three years clinical laboratory testing exp. req'd. Successful candidate must possess excellent verbal & written communication, organizational & computer input/retrieval skills. In addition, position requires comprehension & application of clinical laboratory procedures & theory & ability to work in team environment. Previous exp. in immunohematology reference lab highly desired. Shift for position is Wednesday thru Saturday from 6:00pm – 4:30am. Blood Systems offers extensive benefits package that includes tuition & certification reimbursement, full benefits, competitive salary & work schedules. For consideration, please email your resume by **7/23/2010** to: jobs@bloodsystems.org. **ATTN: HR/2010/61**. Please visit our website at: www.bloodsystems.org. Pre-employment drug testing req'd. EOE M/F/D/V

Quality Systems Specialist. Blood Systems, one of nation's largest blood services provider, seeks enthusiastic individual to join our corporate office Quality team in Scottsdale, AZ. Under minimal supervision, individual will be responsible for review & approval of all regulated documents for all areas of technical & clinical operations for compliance. Individual will serve as resource to operations on quality issues & participate in Six Sigma & other performance improvement initiatives. Candidate must be proficient in MS Excel, have strong organizational & planning skills, excellent customer service skills & effective verbal & written communication skills. Moreover, this individual must be able to work independently, as well as work in & support team environment. Initiative & follow-through are also crucial to ensure tasks are fulfilled on tight deadline. Bachelor's degree in related area with minimum of four years related exp. to include: two years exp. in quality, regulatory &/or auditing environment req'd. CQA, CQE &/or CMQOE certification within two years req'd. Certification as Medical Technologist or SBB & previous exp. in regulated industry highly pref'd. Knowledge &/or exp. in regional viral marker testing laboratory pref'd. For consideration please send resume via e-mail to: jobs@bloodsystems.org **ATTN: HR/2010/60**. Resumes must be received no later than **7/23/10**. Blood Systems offers comprehensive benefit package that includes 401K, employer paid pension plan, relocation & much more! Visit our website at:

www.bloodsystems.org. Pre-employment drug testing req'd. EOE M/F/D/V

Clinical Laboratory Scientist, Reference Laboratory. Blood Centers of Pacific in San Francisco seeks Clinical Lab Scientist to perform complex serological testing; including red cell antibody ID, compatibility testing & platelet testing. Communicates with physicians & hospital personnel to explain results & provide appropriate skills. Requires current California CLS license & at least three years of relevant exp. with emphasis on antibody ID, SBB pref'd. Submit resume to: Blood Centers of the Pacific, Human Resources, **Job Code: MTREF**, e-mail: resumes@bloodcenters.org or Fax: (415) 749-6620. EOE/AA

Director, Recruitment. Community Blood Services is independent blood center that collects blood donations, offers cord blood banking & operates one of NMDP's largest bone marrow registries. Founded in 1953, Community Blood Services is not-for-profit organization devoted to serving community's transfusion medicine needs. We have immediate business need for results driven Director Recruitment. Position responsible for providing necessary direction & leadership to ensure recruitment goals & new business opportunities within blood donor recruitment are met; identify, cultivate, solicit, negotiate & secure donor & corporate relationships to meet expanding business goals; satisfactorily maintain & grow these relationships to maximize their long-term value to Community Blood Services. Additionally, position must develop tactics & strategies in collaboration with colleagues & other partners to provide optimal business growth, client satisfaction & financial return. Qualifications include: bachelor's degree; master's pref'd. Four to six plus successful years of exp. in sales & sales management. Proven track record of successfully managing & motivating a sales team. Excellent PC skills, leadership & strategic thinking ability req'd. Superb oral & written communication skills req'd as well as strong negotiation, presentation & liaison skills. Community Blood Services offers team orientated work environment, competitive compensation, benefits & relocation package. Qualified candidates, please send your resume & cover letter along with salary requirement via email to: careers@cbsblood.org or Fax: (201) 265-4021. EOE

Assistant Medical Director. Blood Centers of Pacific seeks Assistant Medical Director to join our team. Will provide transfusion medical consultation to external customers, blood center staff, donors & general community. Will assist Medical Director in TM educational endeavors, including supervision of TM fellow & rotating residents or fellows, staff training, lectures & grand rounds at area hospitals. Will provide medical oversight for staff safety program & assist Medical Director in medical oversight of policies & procedures in donor collection, technical operations, hospital services, recruitment & clinical services. Will participate on Medical Scientific and Advisory Committee of Board & Technical Advisory Committee. Requires M.D., fellowship training or two years' exp. in transfusion medicine

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POSITIONS (continued from page 19)

req'd. Previous exp. in blood center pref'd. Valid California Medical license (or acquires license within three months of employment). Board Certified or Board Eligible in Pathology, Internal Medicine, Pediatrics or Anesthesia. Board Certified or Board Eligible in Blood Bank/Transfusion Medicine (TM). Board certification in BB/TM req'd within three years of employment. Forward resume with **JOB CODE: Asst Dir to Blood Centers of Pacific**: resumes@bloodcenters.org or fax: (415) 749-6620. EOE/AA

Director of Development, Puget Sound Blood Center, Seattle, WA. Play Pivotal Role in Advancing Transfusion & Transplantation Research. Established in 1944, Puget Sound Blood Center has long history providing safe, reliable blood supply across Western Washington. Research is core of its vision of "advancing health, shaping future of transfusion & transplantation medicine". In its 65 years, Puget Sound Blood Center has sponsored groundbreaking research leading to major advances in blood storage & treatment of blood disorders such as sickle cell disease & hemophilia. It has made significant strides in understanding of platelets (blood clotting cells), positively impacting fight against cancer, malaria & thrombosis (clotting of blood when & where it should not), leading cause of fatal heart attacks & strokes around world. Offering new opportunity to structure & lead Development Team, Puget Sound Blood Center seeks strong, multifaceted fundraising professional to provide strategic leadership & hands-on implementation of all fund development activities. New Development Director will be member of Leadership Team & will work collaboratively with CEO, Executive Vice President of Research, other Directors, development staff & partner organizations to identify & cultivate donor opportunities & implement comprehensive development plan to support research goals of organization. We seek visionary leader who can express genuine commitment to mission of Puget Sound Blood Center. Extensive exp. leading & managing fund development programs, including strong track record in major

gift cultivation & solicitation desired. Director of Development should be exp. manager skilled at motivating, mentoring & training staff to enhance department's success. Working knowledge of Pacific Northwest fundraising climate pref'd. Minimum of seven to ten years of exp. in fund development, including staff responsibility & leadership of fundraising programs req'd. Exp. in healthcare, scientific or academic environments, in organizations of similar size & complexity to Puget Sound Blood Center highly desirable. Bachelor's degree req'd. We welcome & encourage qualified applicants from diverse backgrounds. Salary: \$120,000 – \$140,000. Please send resume & cover letter by **August 31, 2010** to: info@waldronhr.com. Tel: (206) 441-4144. Committed to workplace diversity; EOE/AEE

Hospital Services Manager. Kentucky Blood Center, located in Lexington, Kentucky, seeks customer-focused detail-oriented professional to oversee daily operations of Hospital Services Department. Responsibilities will include consignment blood component inventory management; transportation & distribution of blood components; technical support for hospital blood banks; & hospital customer account management. Qualified applicants must have four-year degree, MT(ASCP) or exp. deemed equivalent including working knowledge of hospital blood banks. Three years management exp. working in organization regulated by good manufacturing practice with FDA, AABB, CLIA & EU regulated exp.; & three or more years exp. working with blood component inventory management in Hospital Services/Product Management Department in blood center pref'd. Exp. with data analysis & equipment/process validation pref'd. Must be proficient with MS Office products. Must be highly organized, reliable & have outstanding interpersonal skills. Strong written & oral communication skills, do-what-it-takes work ethic, & team player attitude req'd. Competitive salary, comprehensive benefits including health/dental/life, LTD, paid vacations/holidays, EAP, 403(b) retirement savings plan & pension plan. Apply online at: www.kybloodcenter.org. Drug free & EOE/AAP ♦