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# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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**2015 #40** **November 6, 2015**

**INSIDE:**



## Final CMS Rule Reports Error in Proposed Blood Product Reimbursement Rates

America's Blood Centers initiated an advocacy campaign in August to oppose draconian and inexplicable cuts to Medicare reimbursement for blood products outlined in the Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment System (OPPS) proposed rule for 2016 (see *ABC Newsletter*, 9/4/15). ABC's efforts and those of its blood community colleagues have been successful, as CMS reported in the final rule this week that these proposed cuts were calculated erroneously.

In the final rule, CMS acknowledges on page 111 that the agency made an error in calculating the proposed 2016 payment rates for blood products included in the proposed rule. The agency states:

"**Comment:** Numerous commenters (various hospitals, blood centers, associations, and other stakeholders) expressed concern regarding the proposed CY 2016 payment rates for blood and blood products. The commenters believed that the proposed payment rates do not accurately reflect the cost of collecting, processing, and distributing blood products to patients. The commenters noted that the payment rates did not align with the costs statistics data provided with the proposed rule, and therefore the commenters believed that the CY 2016 proposed payment rates for blood and blood products were produced in error.

**Response:** We acknowledge that an error occurred in the calculation of the proposed CY 2016 payment rates for blood and blood products included in the proposed rule. The payment rates included in the proposed rule erroneously were not calculated using the hospital-specific simulated blood-specific CCR [cost-to-charge ratio] methodology described in the proposed rule (which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs). As a result of correcting this error, payment rates for blood and blood products increased approximately 10 percent to 60 percent from the proposed CY 2016 payment rates. We have corrected this error in this final rule with comment period and the final CY 2016 payment rates reflect this correction."

The payment rates in the proposed rule would have caused Medicare reimbursement for blood products to be cut from 23 to 66 percent, depending on the product. The new addendum (2016 OPPS FR Addendum B.10.26.15) outlining

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## OUR SPACE

**Beth Shaz, MD, Chief Medical Officer, New York Blood Center**
**Louis Katz, MD, Chief Medical Officer, ABC**

### What are the Realities to Consider as We Think About Implementing Pathogen Reduction of Platelets in the US?

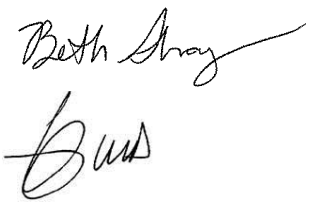
The transfusion medicine community welcomes approval of Cerus's Intercept Blood System for pathogen-reduced (PR) platelets. It is an important safety step that will nearly eliminate bacterial contamination episodes, and be particularly valuable if paired with decreased testing, increased shelf-time, and the elimination of product irradiation. It is a first step to future PR systems that will be easier to use.

As transfusion medicine physicians, we have heard concerns about adverse clinical and operational outcomes, the real importance of which only experience will tell us. The former include lower corrected count increments (CCIs) after transfusion that may require more platelet transfusions (as in the SPRINT trial), more days of high grade bleeding (as in a meta-analysis by EC Vamvakas; a second one available here), a potential need for more red blood cell (RBC) transfusions (as presented in IPTAS Study in AABB Annual Meeting Abstract P2-030A), and concern with the long term safety of S-59, the active chemical agent in Intercept. Operational concerns relate to process-associated product loss and tight procedural guard bands (e.g., product platelet counts) that will certainly require increased platelet collections to maintain a robust platelet supply.

Future regulatory approvals may address these concerns. First, seven-day storage will decrease outdates and thus collection requirements. Next, an expeditious approval for use on triple collections will maximize products available for Intercept treatment. Based on the product information and expected platelet losses during processing, platelet counts at collection have to be higher, which decreases the split rate for current processes at New York Blood Center by 10 percent. Finally, approval of PR in platelets stored in plasma (vs. platelet additive solution) and from all collection platforms (i.e., Terumo BCT and Haemonetics) will simplify its adoption, reducing the required changes for clinicians and collection facilities. Lastly, approval for use with pooled whole blood derived platelets will expand PR to all platelets transfused in the US.

With PR of all components (RBCs, cryoprecipitate, platelets, and plasma), we should be able to decrease donor screening and still mitigate recognized and emerging infectious risks, and retire the cesium gamma radiation sources that create security and regulatory headaches. Short of these additional approvals and resulting efficiencies, hospital blood banks may rather keep costs in-house by performing point-of-release platelet bacterial testing, or may opt for delayed, high-volume cultures from their supplier in lieu of PR to make seven-day platelets available.

In the era of risk-informed decision-making and constrained resources, each physician and organization must balance cost with donor and patient outcomes. We have the beginnings but have to admit we are far from making the case to all stakeholders for universal adoption of platelet PR.



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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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CMS Final OPPS Rule (continued from page 1)

the new payment rates can be downloaded here. A further analysis by ABC of the new rates shows on average that the Medicare reimbursement rates for various blood products is down more than 5 percent from 2014, but far less than the average of more than 30 percent in the proposed rule.

Also included in the final rule are Healthcare Common Procedure Coding System (HCPCS) codes to cover the transfusion of pathogen-reduced platelet and plasma products. ABC, AABB, and American Red Cross submitted a joint statement to CMS in May expressing the importance of creating new P-codes to allow for appropriate billing of pathogen-reduced platelets and plasma to provide patients with access to these new products that can improve patient safety. The new codes are described on page 112-113 of the final rule.

In response to the proposed rule, ABC initiated a grassroots advocacy campaign, asking member blood centers to write letters to their members of Congress and to CMS to express the blood community's concern regarding the significant cuts to the Medicare reimbursement rates for blood products. Below are some outcomes of that campaign.

- 44 of ABC's 64 member blood centers participated in the campaign (sent letters to their legislators, CMS, or both),
- 48 letters were sent to CMS from member blood centers and other partner organizations (e.g., regional health associations).
- 130 members of Congress were contacted by ABC blood centers and partner organizations.
- Eight of those legislators contacted CMS on ABC's behalf.

ABC members can find more information about the outcomes of the campaign here. ABC's formal comments to CMS can be viewed here.

"I want to personally thank each and every one of the individuals at our blood centers who helped ABC get this message across to CMS. The clearly stated principles delivered loud and clear with one voice was essential to our success. Thanks to you and our fellow national blood organizations, CMS recognized and corrected this error, which would have placed further financial strain on the nation's blood delivery system. We also thank CMS for being receptive to receiving and appropriately committed to stakeholder concerns," said ABC CEO Christine Zambricki, DNAP, CRNA, FAAN.

ABC has been in touch with CMS representative Lela Strong to thank the Medicare agency for recognizing the payment rate error and for responding to the blood community's comments. ABC continues to review the final rule and will submit comments on any additional issues that arise following in-depth analysis. ABC members with questions or concerns may contact Christine Zambricki at czambricki@americasblood.org.

## Don't Miss Your Chance to Participate in ABC's 19th *Awards of Excellence*!

The Nov. 20th deadline is quickly approaching to submit your nominations for America's Blood Centers' 19th Annual *Awards of Excellence* and the 2015 FABC Awards. ABC members can offer national recognition to local individuals, civic groups, media, and corporations for their commitment to community blood programs. Submit your nominations by **Friday, Nov. 20**. ABC members can find more information and nomination instructions in MCN 15-088. Questions may be directed to Jodi Zand (jzand@americasblood.org).

## AABB Annual Meeting Highlights Need to Protect Donors From Iron Depletion

It is no news to any blood banker that repeat blood donation causes iron depletion and clinical consequences may be important – from fatigue, to pica (unusual craving for non-food items like ice or dirt),to restless leg syndrome and diminished cognitive performance. Experts at the AABB Annual Meeting in Anaheim, Calif. last week overwhelmingly urged blood centers to implement measures to mitigate blood donor iron depletion, sharing a wide range of experiences and studies examining the role of iron supplementation, improved donor education, and ferritin testing.

**The Problem.** Low hemoglobin, an indirect and imprecise measure of donor iron stores, remains the most common reason for blood donor deferral in the US and many other countries. Further, a number of studies, including the National Institutes of Health (NIH)-funded REDS-II Donor Iron Status Evaluation (RISE) study, have shown that iron depletion is quite prevalent among frequent blood donors, and that lengthening the inter-donation interval or implementing iron replacement programs would help to correct this issue, noted Joseph Kiss, MD, of the Institute for Transfusion Medicine (ITxM), at the AABB workshop on donor iron depletion (9116-S).

Alan Mast, MD, PhD, of the BloodCenter of Wisconsin's Blood Research Institute, pointed out that measuring a donor's hemoglobin level does not accurately assess a donor's iron level. A large proportion of blood donors with acceptable hemoglobin levels are permitted to donate blood despite being iron deficient according to more sensitive measures of iron stores. An abstract presented by Mindy Goldman, MD, of Canadian Blood Services (CBS), shows that 17 percent of iron deficient men and 11 percent of iron deficient women in a recent study had hemoglobin levels at or above the minimum threshold to donate. This finding was consistent across the board in US, Danish, and Australian data presented at the meeting.

Not only can iron deficiency cause a range of negative consequences in donors, but a study conducted in mice, presented as a plenary abstract at the meeting, suggested that blood drawn from iron deficient individuals may be less effective after transfusion. Steven Spitalnik, MD, of Columbia University, and colleagues collected blood from mice in three groups – iron-replete, mild iron deficiency, and severe iron-deficiency. They found that the donor iron depletion significantly reduced 24-hour post-transfusion recovery of transfused red blood cells (RBCs). Follow-up studies on the relevance of this observation are underway.

**So Now What?** Options to mitigate this issue include the extension of the minimum interval between donations, currently eight weeks in the US, but the amount of time it takes for a donor's iron stores to recover following blood donation varies greatly, as documented during the NIH-funded REDS-III Hemoglobin and Iron Recovery Study (HEIRS), noted Dr. Kiss, lead investigator of the study. The HEIRS investigators also found that providing donors with iron supplement pills significantly sped hemoglobin recovery, suggesting that iron replacement may be a more effective option than extending the inter-donation interval.

**Iron Supplementation.** A number of studies and experiences in both the US and abroad presented at the AABB Annual Meeting suggest that iron replacement not only effectively protects donors against iron deficiency, but is operationally feasible. The results of the NIH-funded REDS-III Strategies to Reduce Iron Deficiency (STRIDE) study, presented in an abstract (S34-030E) by Dr. Mast, showed that blood centers have options for donation education and iron supplementation dosing that may effectively reduce iron depletion (see *ABC Newsletter*, 10/23/15).

(continued on page 5)

Mitigating Iron Depletion in Donors (continued from page 4)

The randomized, blinded, placebo-controlled study investigated the effects on blood donor iron stores of providing varying levels of iron supplements or post-donation written information about iron deficiency. Interestingly, among the 393 donors who completed final visit, the researchers found that providing 19 mg of iron, 38 mg of iron, or simply providing a letter about their iron level were equally effective in raising the donors' hemoglobin and ferritin levels. Further, analysis of donor behavior in STRIDE showed that while donors in the iron supplement pill group were more likely to de-enroll than those in the control group, donors who received information about their iron level were more likely to take self-purchased iron than to delay donation. Donors receiving information about their iron status were also more likely to take action to correct their iron levels than were donors who did not receive this information.

Karin Magnussen, MD, of Copenhagen University Hospital in Denmark, presented the iron deficiency mitigation approach in Copenhagen, which provided some insight into how ferritin testing might be used to guide selective iron deficiency mitigation strategies. In Copenhagen, the blood service uses hemoglobin and ferritin testing results in an algorithm to determine whether a donor receives iron supplementation, written information, a call from the donation center, or a combination of these strategies. The blood service also implemented centralized hemoglobin/ferritin testing with a resource team to follow up with donors and answer any questions relating to iron status.

Since 2011-2012, ferritin in Copenhagen testing has been conducted for all first-time donors and on every $10^{th}$ donation, as well as in donors who had low or high hemoglobin or ferritin results at their last donation. Since 2012, the blood service has seen a significant drop in the percentage of donors with ferritin <60 µg/L and/or low hemoglobin. This strategy has allowed the blood service to implement graded iron supplementation restricted to only those donors who would benefit, and led to a reduction in the number of donors with low hemoglobin, said Dr. Magnussen.

**Value of Ferritin Testing.** Experts also explored how ferritin testing can be used to guide iron mitigation strategies without providing iron supplements from the blood center. Dr. Goldman, of CBS, described a study investigating the operational feasibility of integrating ferritin testing, which tested the ferritin levels of 6,029 donors. They found that 79 percent of females and 64 percent of males who donated four or more times a year were iron deficient and that a significant proportion had hemoglobin in the acceptable donation range.

Canadian donors with a ferritin level <25 µg/L or >336 µg/L were sent information about their iron level. Donors with low ferritin received information about iron supplementation and were recommended to see a doctor, cancel donations for the next six months, and to stop donating until the cause of the low ferritin has been identified and iron stores are normal. Nearly all donors who completed the survey felt the blood center should be conducting ferritin testing and about two-thirds were surprised by their results. Seventy percent sought more information, mainly from their doctor or pharmacist and 26 percent started taking iron supplements. Notably, 88 percent said they plan to return to donate – which is important given that other deferrals often lead to donor loss. While the blood service feels ferritin testing is feasible, Dr. Goldman noted that the IT system would need to be updated to allow for more targeted testing and integration of test results into the donor letter.

Similarly, Hany Kamel, MD, of Blood Systems, headquartered in Scottsdale, Ariz., presented a Blood Systems study investigating providing an iron deficiency mitigation program that uses ferritin testing and improved donor education. Through this program, male donors with hemoglobin levels between 12.5-

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Mitigating Iron Deficiency in Donors (continued from page 5)

13.4 g/dL and female donors with hemoglobin from 12.5 to 12.9 g/dL receive ferritin testing. Those with ferritin <12 µg/L receive a letter informing them of:

- Their ferritin results;
- Ineligibility to donate red blood cells (deferred for 24 weeks);
- Helpful information (e.g., tips for increasing iron stores) and frequently asked questions about ferritin testing and iron stores; and
- A donor counseling toll-free number.

Over the 25 month study period, 136,677 donations were tested for ferritin, and 50 percent of those indicated iron depletion, with returning donors having much higher iron deficiency than first time or lapsed donors. Their results confirm previous findings that relying on hemoglobin testing alone permits many iron deficient blood donors to give blood. He added that ferritin testing could be used to provide more targeted mitigation techniques to protect donor iron stores in those at the highest risk of iron deficiency.

**Blood Centers Must Protect Donors.** Experts from the three major national blood organizations – America's Blood Centers, AABB, and the American Red Cross (ARC) – seemed to agree in a panel discussion at the AABB meeting that blood centers must protect blood donors from iron mitigation in some way but disagreed on the best methods. The panel responded to three questions regarding the implementation of iron supplementation, ferritin testing, and operational barriers.

When asked whether blood donors should take iron supplements, ABC Chief Medical Officer Louis Katz, MD, responded with an emphatic, "YES. If we're taking iron out of donors then we ought to be putting it back in." He added that he believes blood centers should directly provide iron supplements for the convenience of the donors because "we" are contributing to their iron depletion, but noted that exceptions would have to be made for donors with hemochromatosis or other health conditions where iron supplementation is not appropriate.

Dr. Katz feels that ferritin testing may be unnecessary if widespread iron supplementation were implemented, however, Steven Kleinman, MD, senior medical advisor to AABB, noted that ferritin testing may have a role in providing targeted iron supplementation. Mary O'Neill, MD, interim chief medical officer of ARC, added that ARC has primarily focused on improving donor education surrounding iron stores and would caution blood centers in providing iron supplementation to donors.

All three speakers acknowledged that significant operational barriers exist no matter what method is implemented. Dr. Katz added that the group purchasing organizations will need to work together to obtain affordable iron supplementation options. In his earlier presentation, Dr. Kamel spoke to operational barriers regarding ferritin testing, noting that increasing the male hemoglobin cutoff and using parameters like history of red cell donations, age, and sex for targeted ferritin testing may be operationally complex, but could help to better identify donors at risk of iron deficiency.

Mitigation of iron deficiency is particularly important given the Food and Drug Administration's new regulations, effective in May 2016, which changes the minimum hemoglobin for males from 12.5 g/dL to 13.0 g/dL. This will result in loss of an appreciable percent of otherwise qualified male donors. The minimum requirement for female donors remains 12.5 g/dL, however, female donors will be permitted to donate at 12.0g/dL provided that additional steps are taken to assure donor safety with regard to iron status. It remains unclear exactly what mitigation strategies will meet this new requirement, but may include assessment of iron stores and/or iron supplementation.

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# SAVE THE DATE

API ABC Professional Institute

## 54th Annual Meeting

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Sponsored by oneblood

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**2016 Annual Meeting Schedule**

| | |
|---|---|
| **Saturday, March 12:** | Business Forum |
| **Sunday, March 13:** | ABC Members Meeting<br>SMT Forum<br>Host Event by OneBlood<br>*(off-site event)* |
| **Monday, March 14:** | Blood Center Leadership Forum<br>19th *Annual Awards of Excellence*<br>& Casino Night |

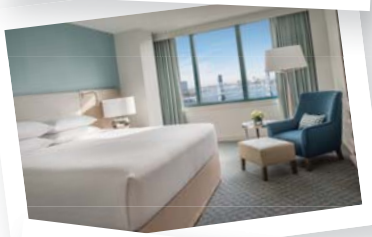
"The Annual Meeting provides a chance for us to learn, discuss and decide important issues for ABC, as well as meet old and new friends. In this time of rapid change in our arena, it is particularly important for us to stay in touch with what is going on in the field, and to keep ABC responsive to the needs of our members."

Susan Rossmann, M.D., Ph.D.
ABC President

**Future Leader Scholarship Program**
Supported by the FABC, these scholarships offer non-C-suite blood center executives the opportunity to advance professionally by attending the ABC Annual Meeting. Details available upon registration.

**Registration Fees**
ABC Annual Meeting: $725
Non-members (non-vendor), contact Lori Beaston at *lbeaston@americasblood.org* for invitation, registration fees and additional information.

Sponsorship opportunities available. Contact Jodi Zand at *jzand@americasblood.org* for details.



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## Overcoming Barriers to Implementing Pathogen Reduction Technology

A growing number of US blood centers have become more interested in using pathogen reduction technology (PRT) to improve patient safety by inactivating both infectious and white blood cells in donated blood. There was robust discussion about PRT at the AABB Annual Meeting in Anaheim, Calif. last week focused on how blood centers can overcome operational barriers to implement PRT and the clinical efficacy of PR blood products.

Many meeting attendees and speakers, including Jim AuBuchon, MD, FCAP, president and CEO of Bloodworks Northwest, are enthusiastic about the patient safety benefits offered by PRT. It will nearly eliminate the risk of bacterial contamination in platelets, which remains an important infectious risk in transfusion medicine with a residual risk of contamination of about 1 in 2,000 platelet units transfused, said Dr. AuBuchon in his talk at the meeting. Further, he and other attendees noted it can protect against a wide breadth of known and emerging infectious diseases, including dengue and chikungunya virus, for which there are no available screening tests.

**Are PR Platelets Clinically Efficacious?** However, clinicians are concerned about the clinical efficacy of PR platelets, including platelet recovery and survival, corrected count increments (CCI), hemostasis, and component usage. While studies, including the 2004 SPRINT Trial, have shown lower CCIs with the

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Barriers to Implementing PR (continued from page 7)

transfusion of PR platelets, which may require more platelet transfusions, data from Alsace, France show no increased platelet usage with the implementation of Intercept platelets, said Dr. AuBuchon.

Other studies have also suggested a modest increase in high grade bleeding and a potential need for increased red blood cell (RBC) transfusions, as highlighted in a study presented at AABB (Abstract P2-030A), which examined the clinical efficacy of platelets treated by the Cerus Intercept Blood System or Terumo BCT Mirasol Pathogen Reduction System. This study, although not suitably powered to make definitive conclusions, found that red blood cell use was 19 percent higher with Intercept and 26 percent higher with Mirasol.

Some speakers expressed concern over allergic reactions and adverse pulmonary events caused by the amotosalen, the active chemical used (with ultraviolet light) to treat platelets and plasma in the Intercept Blood System. However, adverse reactions related to Intercept-treated products appear extremely rare according to French hemovigilance data and other studies.

Laurence Corash, MD, chief scientific officer of Cerus, discussed the importance of hemovigilance and postmarketing studies to enable more widespread implementation of PRT. Active hemovigilance programs are vital because relying on passive reporting does not provide denominator data, making it difficult to draw reliable and useful conclusions from the data. Intercept has proven effective in preventing sepsis according to both French and Swiss hemovigilance data. Additionally, French and Swiss blood services have been able to discontinue irradiation to prevent transfusion-associated graft vs. host disease, as well as bacterial culture and cytomegalovirus (CMV) testing where these platelet systems are in use. Dr. Corash noted that Cerus conducts ongoing hemovigilance and is conducting a phase IV postmarketing study as part of its FDA approval examining adverse pulmonary events in hematology/oncology patients, comparing Intercept platelets with conventional platelets.

**Operational Concerns.** Operationally, implementing PR platelets within the current confines of most US blood collection facilities' collection procedures is a bit of "square peg round hole," as Dr. AuBuchon put it. Intercept is not approved to treat all platelet types and blood centers that have examined implementing Intercept have found that restrictive procedural guard bands will cause product loss. For example, Intercept is not currently approved to treat whole blood derived platelets or platelets stored in plasma. Productivity of Intercept-treated platelets is also reduced because it is not yet approved for use in triple collections and Intercept platelets cannot be collected on all collection platforms.

Willy Flegel, MD, of the National Institutes of Health (NIH), talked about overcoming some of these operational challenges to move to 100 percent PR-platelets at the NIH Clinical Center, a small collection operation in Bethesda, Md. In examining six months of platelet collection data from the NIH Clinical Center to compare it with the Intercept guard bands, they found that of 1,007 successful collections, 5 percent fell outside the guard bands but 75 percent of those may be recouped through altering collection and storage procedures. They found that by using dual storage kits only and adjusting the parameters for 5 percent of collections, the center would have a possible product loss of <1 percent of collections.

The Clinical Center has submitted a request for variance from AABB *Standards* to replace irradiation with pathogen reduction, as well as the necessary biologics license application, written validation plans and standard operating procedures, and just began staff training in the last week of October. By January 2016, the center plans to have moved to 100 percent PR apheresis platelets in additive solution (PAS-C).

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Barriers to Implementing PR (continued from page 8)

Joanne Becker, MD, shared her experience overcoming operational obstacles to implement PR platelets at the Roswell Park Cancer Institute, Buffalo, N.Y. Despite manufacturing, cost, and distribution concerns, she is hopeful that PR will be implemented in 2016. Importantly, if the institution has a dual inventory (some platelets are PR and others not), point-of-release testing may still be necessary for non-PR platelets – a tough sell for the C-suite. While there is currently no reimbursement for point-of-release testing, the Centers for Medicare & Medicaid Services (CMS) published just this week new P-codes to ensure reimbursement for pathogen reduced products (see page 1), which will help offset increased costs.

Numerous speakers highlighted potential cost-savings that reduce the net cost of implementing PR; however many of these rely on additional regulatory approvals. For example, a move to seven-day storage with PR would decrease the number platelets that outdate, decreasing waste and collection requirements. Bacterial screening with early culture will become unnecessary. Further, pathogen reduction could (eventually) allow blood centers to forgo some currently FDA-required donor screening tests and irradiation, but this would likely require more widespread adoption of PR across all blood products (red blood cells, platelets, plasma, etc.), and of course FDA approval.

**What's On the Horizon?** Cerus is seeking a number of FDA approvals over the next six to 12 months that would address some of these issues, according to Richard Benjamin, MD, PhD, chief medical officer of Cerus, who presented during the Cerus Corporate session. Importantly, Cerus plans to submit approval applications to FDA for the extended shelf-life of Intercept-treated apheresis single/double platelets, as well as triple storage in 2016. Further, Dr. Benjamin noted that FDA may address seven-day pathogen reduced platelets in its final guidance regarding detection of bacterial contamination in platelets, anticipated to be published by year's end.

Attendees at the AABB meeting also heard in a separate session an update from Raymond Goodrich, PhD, on the status of Terumo BCT's yet to be FDA-approved Mirasol Pathogen Reduction Technology (PRT) System. Mirasol has received the CE Mark for use in a number of plasma and platelet products since 2007, and FDA approved Terumo BCT to begin the US MiPLATE study in July 2015 under an investigational device exemption (IDE) approval to support the system's approval in the US. Patient enrollment should begin soon.

Research presented by Terumo BCT at the meeting, the African Investigation of Mirasol System for Whole Blood (AIMS) Study, demonstrated that Mirasol-treated whole blood significantly reduced the incidence of transfusion-transmitted malaria in Ghana. They also found no difference in the incidence of transfusion reactions between the treatment and control groups, and no safety issues were reported from Mirasol-treated blood. This could be a big step toward transfusions safety for resource-scarce areas where infectious disease prevalence is high because costly infectious disease blood screening tests could be foregone in favor of pathogen reduction, which may more reliably protect recipients from infectious disease.

Meeting attendees and speakers seemed enthusiastic about PR but await further regulatory approvals that would help assuage the cost, operational, and clinical concerns currently restraining the technology from being more widely implemented. Currently, only two America's Blood Centers' members, SunCoast Blood Bank, Sarasota, Fla., and Blood Bank of Delmarva, Newark, Del., have begun producing Intercept-treated blood products. Several more centers have signed contracts with Cerus and plan on implementing Intercept soon. Both Cerus and Terumo BCT expressed optimism about advancing their respective PRT systems.

## San Diego Blood Bank Launches Precision Medicine Pilot Study

San Diego Blood Bank (SDBB) announced to donors and the public on Tuesday that it is launching a pilot program that will enable community volunteers to participate in genomics research as part of the Precision Medicine Initiative (PMI), launched by President Obama earlier this year in his 2015 State of the Union Address. The PMI is intended "to bring us closer to curing diseases like cancer and diabetes – and to give all of us access to the personalized information we need to keep ourselves and our families healthier," said President Obama.

PMI seeks to usher the US into an era that embraces and applies innovative technologies to tailor and specifically target medical treatments to each patient. To pursue this goal, the National Institutes of Health, leading the PMI charge, seeks to apply recent advancements in genomic technologies, digital health records, data collection, and data storage and analysis in a longitudinal study involving 1 million or more participants – called the PMI cohort. SDBB and BloodCenter of Wisconsin, part of Versiti, have been actively engaged in the NIH's process to launch this research project – identifying opportunities for blood centers to participate in PMI (see *ABC Newsletter*, 10/9/15).

Public outreach, education, and recruitment for SDBB's pilot program will begin this month, and the blood center will highlight the study at the Chargers Drive XXXVII, a large annual blood drive hosted with the San Diego Chargers football team, on Nov. 24. This event draws up to 4,000 people for blood donation, wellness screening, and research education. During the Chargers Drive, up to 100 pre-selected consented pilot study participants representing the county's diverse population will be donating an extra tube of blood to be sequenced for the genomics research study. Participants will have the opportunity to learn about their individual results in the context of an educational event in March 2016 called Understand Your Genome, hosted by Illumina, Inc., a global leader in DNA sequencing.

SDBB is collaborating on this pilot study with Illumina; Private Access, a pioneer in online privacy and health information access; the Genetic Alliance, the leading non-profit health advocacy organization with a network of thousands of disease-specific organizations; researchers at Baylor College of Medicine and Harvard Medical School; local healthcare provider organizations, including Rady Children's Hospital; and academic research institutions, including the Clinical and Translational Research Institute at UCSD.

"This collaboration demonstrates an innovative example of academia, industry, and not-for-profits coming together in the spirit of the PMI and to help drive its sustainability and success. It is a practical strategy that reaches beyond traditional infrastructures and mitigates significant research challenges such as public trust, recruitment, and diversity during a ten-year plus study," said SDBB CEO David Wellis, PhD.

"This community program is designed with national extensibility in mind to leverage our nation's blood center infrastructure as an established network for volunteer participant education, recruitment, consent, sample and data donation, and continuous engagement to support both PMI and future population-scale genomic studies," said Dawn Barry, vice president of Applied Genomics at Illumina.

"Precision medicine is the future of health care delivery and I am passionate about bringing genome information and education into the care of children at Rady Children's Hospital," said Stephen Kingsmore, MD DSc, president and CEO of the Rady Pediatric Genomics and Systems Medicine Institute. "We are

(continued on page 11)

SDBB and PMI (continued from page 10)

delighted to lend our support to this pilot study as a community partner and myself as an individual study participant whose genome was sequenced for research."

"SDBB is proposing to leverage an established and proven informed consent and return of results process that, combined with its trusted status with the community and its donors, will enable SDBB to collect DNA and provide ongoing engagement with participants in an efficient and scalable model," said Robert C. Green, MD, MPH, a medical geneticist consulting to the project who directs the Genomes2People Research Program at Brigham and Women's Hospital and Harvard Medical School. (Source: SDBB press release, 11/3/15)

## RESEARCH IN BRIEF

**The national blood services from Canada and England/North Wales both reported in abstracts presented at the AABB Annual Meeting in Anaheim, Calif. last week that switching from a permanent deferral of men who have sex with men (MSM) to fixed interval deferrals did not lead to an increase in HIV risk.** Sheila O'Brien, PhD, of Canadian Blood Services (CBS) presented an abstract reporting the impact on donor compliance of changing from a permanent MSM deferral to a five year deferral, which was implemented in July 2013. CBS randomly distributed electronic surveys asking about MSM activity to male donors before and after the five-year deferral was implemented. They also monitored HIV rates of all donations between January 2010 and March 2015. Survey respondents included 9,691 male donors (49 percent response rate) before and 6,881 (36 percent response rate) after implementation. There were 77 donors (0.8 percent) pre-implementation and 75 (1.1 percent) post-implementation who had a history of an MSM partner in the last five years. The number of HIV positive donations ranged from two to five (0.2 to 0.51 per 100,000 donations) from 2010 to 2012. There were six HIV-positive donations in the 20 month period from implementation to March 2015 (0.38 per 100,000 donations). Of those, two were female repeat donors and three of the male donors denied risk factors. The percentage of donors with MSM history within the last five years was unchanged from pre- to post-implementation, and there was only a modest increase in newly eligible MSM. Importantly, there was no increase in the HIV rates over the two years of post-implementation monitoring. Dr. O'Brien noted that Canada is looking to eventually move to a 12-month deferral. Katy Davidson, of NHS Blood and Transplant (NHSBT), the blood provider of England and North Wales, presented similar results regarding compliance and HIV risk after moving to a one-year deferral in 2011. In November 2013, Public Health England launched a large-scale, unlinked, anonymous web-based survey asking about donor sexual behaviors. Donors reporting MSM behavior were identified to assess their compliance with the 12-month deferral, and UK surveillance data were analyzed to assess HIV risk before and after the new deferral. Among 65,439 respondents, 22,776 (35 percent) were male and 242 (1 percent) were MSM, of whom 168 were compliant with the 12-month deferral; compliance among respondents was 99.7 percent. More eligible MSM donors are donating in the UK now than prior to the change. Among non-compliant MSMs donors, sexual behavior appears to be risker but this did not appear to lead to an increase in infections. Both blood services reported that ongoing monitoring continues.

**Citation:** O'Brien SF, *et al*. Impact of a 5-year deferral for men who have sex with men on donor compliance. Transfusion. Oct;55(3S):21A.

Davidson K, *et al*. Completing the picture: what do we know about blood donors who are men who have sex with men? Findings from the UK Blood Donor Survey. Transfusion. Oct;44(3S):21A.

**RESEARCH IN BRIEF** (continued on page 12)

**RESEARCH IN BRIEF** (continued from page 11)

**An abstract presented at the 2015 Clinical Congress of the American College of Surgeons showed that an electronic transfusion tracking system and clinician education significantly reduced red blood cell use in a 22-hospital integrated healthcare system over two years.** Intermountain Healthcare, Salt Lake City, Utah, implemented an electronic blood ordering and tracking system to monitor packed red blood cell (RBC) ordering and administration to encourage appropriate transfusion using a more restrictive transfusion strategy where appropriate, co-author Mark J Ott, MD, FACS, of Intermountain Healthcare explained at the convention. The hospital system also initiated a system-wide educational effort regarding patient blood management and appropriate transfusion triggers. Clinicians received referential performance via a monthly e-mail. Patients receiving RBCs decreased by 30 percent from Jan. 1 2012 to Jan. 31, 2015. The number of RBC units transfused decreased from 49.64 units per 1,000 patient days to 34.55 units per 1,000 patient days after the program was implemented. The percent of patients transfused with a hematocrit $\geq$23 percent also decreased from 60 to 34 percent during that time. The drop in transfusions led to an estimated savings of about $2.5 million over the two year period, assuming that each unit of RBCs cost the hospital $300. This study confirms previous research indicating that clinician education and transfusion data benchmarking can be effective in guiding appropriate transfusion strategies. (Source: 2015 Clinical Congress-American College of Surgeons abstract)

**Swedish researchers found through a recent analysis that there is no association between the age of red blood cells (RBCs) and adverse outcomes in patients who underwent cardiac surgery.** Blood undergoes several physiological changes during storage, which observational studies have suggested may be harmful to transfusion recipients. These results are inconsistent and large, randomized, controlled trials have shown no associations of negative outcomes with the age of transfused RBCs. This nationwide cohort study, published in the *Journal of the American Medical Association*, examines the effects of the age of RBCs in cardiac surgery patients. Ulrik Sartipy, MD, PhD, and colleagues of Karolinska University Hospital, Stockholm, Sweden, reviewed transfusion data from the SCANDAT2 database, a nationwide register of blood transfusions, for all patients who underwent coronary artery bypass graft surgery, heart valve surgery, or both between 1998 and 2012. Similarly to the US, blood systems in Sweden transfuse the oldest available blood unit first to minimize unit outdating and waste. They divided patients into groups based on the storage length of the RBCs transfused – 14 days, 14-27 days, or 28-42 days, and a mixed storage category for patients receiving blood of mixed age. Compared with recipients of RBCs stored for less than 14 days, there was no association between transfusion of RBCs stored 14-27 days or 28-42 days; the risks of death at two years were 49.5 per 1,000 person years, 45.4, and 41.1 respectively. They also found no association between 30-day and 10-year mortality, and none between the number of transfused units stored 28-42 days and risk of death. Further, older RBCs were not associated with a number of selected complications. The authors conclude that their findings support those of randomized, controlled trials that have shown no association between the age of RBCs and mortality and/or adverse outcomes, and provide "further reassurance of the safety of current blood storage practices."

**Citation:** Sartipy U, *et al*. Red blood cell concentrate storage and survival after cardiac surgery. JAMA. 2015 Oct 20;314(15):1641-3.

## We Welcome Your Letters

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

## BRIEFLY NOTED

**The International Coalition for Commonality in Blood Banking Automation (ICCBBA) announced last week that it is currently accepting applications for its 2016 board of directors.** More information about these positions, for which the term begins early 2016, can be found online. Qualified applicants can send a CV or resume to the ICCBBA Nominating Committee. All applications must be received by **Nov. 30**. (Source: ICCBBA e-mail update, 10/30/15)

**Experts from international blood organizations and blood industry vendors met on Oct. 25 during the AABB Annual Meeting in Anaheim, Calif. to discuss the potential banning of the plasticizer 2-(diethylhexyl)phthalate (DEHP) used in blood storage bags.** DEHP is the primary plasticizer used in polyvinylchloride (PVC)-based medical devices, including blood bags. It is added to blood bags to increase bag flexibility. Controversial data have accumulated suggesting it may have reproductive toxicity, and this has prompted some European political parties to push for its removal from medical devices. International blood community members met to discuss European initiatives to ban DEHP and challenges that would arise should they succeed. Meeting attendees heard a presentation summarizing the European legislative efforts surrounding banning DEHP, which has both technical and political aspects. Representatives from European blood organizations agreed that a likely future compromise may lead to a requirement to label items containing DEHP as hazardous, rather than an outright ban. However, it was noted that this would likely lead to a banning of DEHP by 2024 or later. The group discussed the numerous impacts of a ban on the blood banking industry, particularly since DEHP's presence has been shown to be beneficial for red cell storage. The issues include: development expense for new storage options, redirection of efforts from other research and development initiatives, and poorer product performance (shorter RBC storage times without DEHP with currently approved additive solutions). Further, long-term studies on cost, clinical outcomes, and surveillance would likely be required for any new storage systems and this change would necessitate new labeling requirements. As 28 countries depend on CE Marks for approval of medical products and other countries are considering a DEHP ban, meeting participants advised all manufacturers to begin considering how they would address this issue. While a common validation process across many countries is unlikely, The Alliance of Blood Operators and the Biomedical Excellence for Safer Transfusion (BEST) Collaborative will be tasked with tackling this issue. The *Newsletter* will follow up when European Union (EU) outcomes regarding the ban become clearer in December of this year. ♦

## REGULATORY NEWS

**The Food and Drug Administration (FDA) published a draft guidance titled "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P)."** The draft guidance is intended to provide manufacturers, healthcare providers, and FDA staff with recommendations for applying the criterion of "homologous use" as it applies to HCT/Ps. The draft guidance uses a question and answer format to assist manufacturers in determining "homologous use." America's Blood Centers Quality HCT/P Regulatory Review Group is reviewing the guidance to determine if comments are warranted. Contact Ruth Sylvester (rsylvester@americasblood.org) if you have any comments/concerns about the guidance. Comments can be submitted online to docket number FDA-2015-D-3581 at http://www.regulations.gov. Comments must be submitted by April 29, 2016. ♦

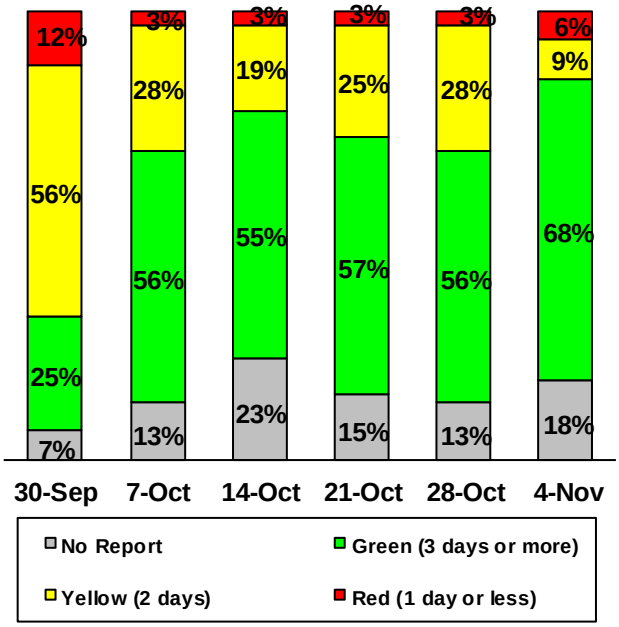
## GLOBAL NEWS

**Blood services in both the Netherlands and France announced within the last week that they will change their current lifetime blood donor deferrals for men who have sex with men (MSM) to one year.** The Dutch Minister of Health announced last week that following advice from Sanquin, the blood supplier of the Netherlands, the MSM deferral period will change to one year beginning Dec. 1, reported the European Blood Alliance (EBA) in a recent newsletter. "I am a staunch supporter of emancipation and equality of people, and at the same time responsible for the safe blood supply in the Netherlands," said Health Minister Edith Schippers. "I'm happy to change this policy because it might solve a long discussion between human rights and patients safety. I'm convinced that patient safety will not be influenced by this change, given the research done." The change, however, will not apply to apheresis and recovered plasma that is collected for plasma-derived therapies, for which the lifetime MSM deferral will still apply. French Health Minister Marisol Touraine announced that France will also lift the current lifetime deferral in favor of a one-year deferral, reported *The Telegraph* on Nov. 4. The 12-month deferral applies to donors giving whole blood, while a four-month deferral will be in place for men giving plasma who have only had one sexual partner within the last four months. Health authorities in both countries will conduct follow up studies to assess the impact of these changes. France and the Netherlands join the growing number of countries, including the UK and Australia, that have changed from a lifetime deferral to a deferral of one-year. (Source: EBA Newsletter, 10/30/15; The Telegraph, 11/4/15)

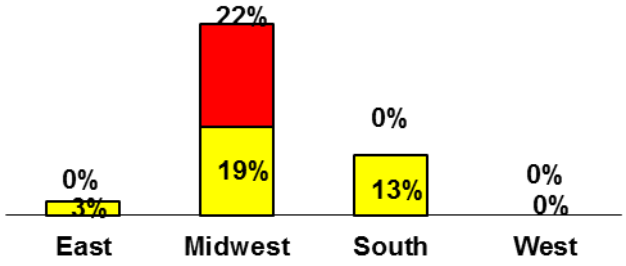
**The National Institute for Health Research (NIHR) and NHS Blood and Transplant (NHSBT), the blood provider of England and North Wales, announced in September that a new £3 million ($4.5 million) NIHR Blood and Transplant Research Unit (BTRU) will be built to advance the pioneering research on the manufacture of red blood cells from stem cells and their translation from lab to human.** The unit is a partnership between the University of Bristol, England, and NHSBT. It will conduct research to advance the development of new red blood cell products to support the transfusion needs of patients with rare blood groups and those with complex and life-threatening blood conditions. The unit is one of four new NIHR Blood and Transplant Research Units for which NIHR has committed £15.1 million ($22.7 million) of funding through a competitive process. The BTRUs are all partnerships between top universities and NHSBT, according to the NIHR/NHSBT press release. These research units focus on investigating the routine practice in blood donation and transplantation of stem cells and organs. More information can be found here. (Source: NHSBT press release, 9/10/15)

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

**Total ABC Red Cell Inventory**




**Percent of Regional Inventory at 2 Days Supply or Less, Nov. 4 2015**




**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

## GRANT OPPORTUNITIES

**The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) released four announcements to express interest in funding AIDS-related heart, lung, blood, and sleep research.** Information about these grants can be found by following the links below.

- Multidisciplinary Studies of HIV/AIDS and Aging (R01);
- Administrative Supplements to Enhance HIV-related Heart, Lung, Blood, and Sleep Research;
- Basic Research in the Pathologies of HIV-Related Heart, Lung, and Blood Diseases in Adults and Children (R01);
- Clinical Research in the Prevention, Diagnosis, and Treatment of HIV-Related Heart, Lung, and Blood Diseases in Adults and Children.

More funding opportunities through the National Institutes of Health can be found any time at http://grants.nih.gov/grants/oer.htm. (Source: NIH announcement, 10/28/15)

## PEOPLE

**Army Lt. Col. Wilbur Malloy** recently received this year's Lifetime Achievement Award from the Armed Services Blood Program (ASBP), announced ASBP in an Oct. 19 press release. Lt. Col. Malloy has more than 23 years of military blood banking experience and "embodies the true spirit of the award," according to the ASBP statement. "It is my honor to recognize Lt. Col. Malloy with this year's Lifetime Achievement Award," said Navy Capt. Roland Fahie, ASBP director. "His achievements over the course of his career have gone a long way towards helping the Armed Services Blood Program save lives. He is a role model and mentor for many of our blood bankers and is very deserving of this special honor." Established in 2009, the Lifetime Achievement Award recognizes those who exemplify tireless dedication to military blood banking. "When I received the phone call from Capt. Fahie, initially I was speechless, in a mild state of shock, and yet very excited about receiving such a prestigious award," Lt. Col. Malloy said. "I am also humbled that the Armed Services Blood Program would select me for this award. It is truly the highlight of my military and civilian career and ranks in personal significance with receiving the Legion of Merit." Lt. Col. Malloy's notable military career began in 1970, upon commissioning as a second lieutenant in the Army, at Fort Bragg, N.C. He is a 1972 graduate of the Medical Technology Internship-Clinical Laboratory Officer Course and a 1977 graduate of the Specialist in Blood Banking Fellowship Program. Lt. Col. Malloy has served in various distinguished blood banking positions in the US and worldwide. By 1982, he was serving as the Korea Area joint blood program officer and the laboratory manager for the 121st Evacuation Hospital, 8th Medical Command in the Republic of South Korea. During his tenure, the blood bank inventory was vastly improved to meet the peacetime, emergency, and contingency requirements for blood and blood products. He also deployed the blood bank team to numerous exercises such as Team Spirit – a joint military training exercise of the US Forces Korea and the Military of South Korea – in 1982 and 1983. This accomplishment, which Lt. Col. Malloy says is one of the highlights of his career, was a "significant improvement in the blood bank and mobile donor center operations and the availability of blood product inventories to support the expansive Pacific theater." In 1987, Lt. Col. Malloy assumed command of the US Army Europe Blood Bank in Landstuhl, Germany. He provided invaluable insight, leadership and assistance in the development, implementation, and prepositioning of 30,000 units of frozen red cells in the European Command Contingency Frozen Blood Program. In 1990, Lt. Col Malloy served as the first director of the US Central Command Frozen Blood Depot located at Al Jubail, Saudi Arabia with the primary responsibility of supporting the deploying troops in support of Operations Desert Shield and Desert Storm with liquid and frozen blood products. Within a matter of 60 days, he converted an abandoned health clinic into a frozen blood storage depot with functioning freezers, supplies, and cell washers. "He's dedicated more than 38 years of his career to the military blood program," Lt. Col. Angela Hudson, director of the Air Force Blood Program, said in the press release. "He has been, and continues to be, a leader in ensuring ill or injured service members, veterans, and their families receive quality blood products and services. He has saved lives and we will always be extremely grateful." Today, he "continues to work for our warriors," retired Army Col. Richard Gonzales, former director of the Army Blood Program said. He is a health science program manager at the US Army Medical Research and Material Command at Fort Detrick, Md., where he provides medical research management oversight for numerous projects such as advanced blood products, deployed biologics, information management, and traumatic hemorrhage and resuscitation. After spending a few more years in his current position, Lt. Col. Malloy said he intends to establish a small business providing consulting services to the medical research community. (Source: ASBP press release, 10/19/15)

**Dean Eller,** president and CEO of Central California Blood Bank, recently authored a commentary published in *The Fresno Bee*, commemorating his daughter, Jenny Eller, who passed away from leukemia in October 1994. The commentary was written as a first-person letter from Ms. Eller, as she looks down from heaven and admires the work of Central California Blood Bank and the generosity of blood donors

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**PEOPLE** (continued from page 17)

whose donations save lives. Ms. Eller received many blood transfusions when she was undergoing chemotherapy before she lost her battle with leukemia. "I know you donate blood out of the kindness of your heart (and maybe because of the Twinkies), but don't underestimate the far-reaching impact you have on society. When the day comes for you to join me here, I will show you the ripple effect you've had on all of humanity," wrote Mr. Eller. The complete article can be found here. (Source: The Fresno Bee, 10/23/15)

**Donna M. Regan, MT(ASCP)SBB,** director of the St. Louis Cord Blood Bank and Cellular Therapy Laboratory at SSM Health Cardinal Glennon Children's Hospital, was installed as president of AABB for the 2015-2016 term at the AABB 2015 Annual Meeting in Anaheim, Calif. Ms. Regan succeeds Lynne Uhl, MD, as president. Ms. Regan has been an active member of AABB since 1998, serving as chair of the Clinical, Scientific and Regulatory Council, the Governance Committee, and the Human Resources Committee, according to an AABB press release. In addition, she has served two terms as an appointee to the US Department of Health and Human Services' Advisory Council on Blood Stem Cell Transplantation. Ms. Regan currently serves on the Food and Drug Administration's Cellular, Tissue, and Gene Therapies Advisory Committee as well. In these and other advisory and collaborative roles, she has worked to influence regulation, legislation and public policy related to cellular therapies. In the course of her career, Ms. Regan assisted the development of a pediatric stem cell transplant program and a mission-driven public cord blood bank. She has participated in a number of clinical research studies, and led the St. Louis Cord Blood Bank's successful pursuit of FDA licensure for their allogeneic cord blood product. Ms. Regan has also authored a number of manuscripts and book chapters and served as a faculty moderator and director for many professional meetings. Ms. Regan received her bachelor's degree in medical technology from St. Louis University and later earned her Specialist in Blood Banking. AABB members also elected **Zbigniew M. Szczepiorkowski, MD, PhD, FCAP,** as the 2016-17 president; **Mary Beth Bassett, BS, MT(ASCP)**, as vice president; and **Michael F. Murphy, MD, FRCP, FRCPath,** as secretary of AABB's board of directors. More information about AABB's board can be found here. (Source: AABB press release, 1028/15

## MEETINGS

Nov. 9-10 **HHS Advisory Committee on Blood and Tissue Safety and Availability Meeting, Crystal City, Va.**

The Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will meet on Nov. 9-10 at the Veteran's Health Administration National Conference Center in Crystal City, Va. to continue a discussion that began at a December 2013 meeting surrounding the stability and sustainability of the current blood supply model. The public will have the opportunity to present their views to the committee during a public comment session scheduled for Nov. 10; pre-registration is required to participate in this portion. More details can be found on the Federal Register.

**Contact:** ACBTSA@hhs.gov

(continued on page 18)

**MEETINGS** (continued from page 17)

April 13, 2016 **FDA Public Hearing on HCT/P Regulations, Silver Spring, Md.**

The Food and Drug Administration will hold a public hearing on April 13, 2016 at its White Oak Campus in Silver Spring, Md. The hearing is meant to obtain input on four recently issued draft guidance documents relating to the regulation of human cells, tissues, or cellular or tissue-based products (HCT/Ps). More information can be found in the Federal Register.

**Contact:** Lori Jo Churchyard, lori.olsenchurchyard@fda.hhs.gov. ♦

## 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. A six (6) percent processing fee will be applied to all credit card payments. 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

**Recruitment (Sales) Manager.** Community Blood Center, Inc., a provider of high quality blood products and services, is searching for a Recruitment (Sales) Manager to provide leadership, focus to planning activities and vision for our Donor Recruitment Team. As an experienced sales leader, you will provide strategic direction to the Donor Recruitment Team responsible for managing blood drives and building relationships with area businesses, schools and communities. A proven track record in sales leadership, field sales, call center, and customer service is essential. Education: Bachelor's degree required with an emphasis in business/marketing preferred. Experience: Minimum five years sales management experience including experience in developing sales territories. Must have knowledge and supervisory, operations management, marketing and customer service experience. Additional Skills: Strong creative, strategic, analytical, organizational and personal sales skills. Ability to visualize opportunities in the short and long-term future. Computer literacy in word processing, database management and page layout. Commitment to working with shared leadership and in cross-functional teams. Strong oral and written communication skills. Ability to manage multiple projects at one time. Volunteer leadership experience preferred. To join our team, submit your resume to:
https://home.eease.adp.com/recruit/?id=6779911.
Community Blood Center, Inc. is an Equal Opportunity Employer M/F/Disability/Veteran.

**Field Representatives.** We are looking for Field Reps! This position educates and motivates new and existing donor groups, chairpersons and committees to meet Indian Blood Center (IBC) blood needs through sponsorship of successful blood drives. Responsible for the achievement of monthly/annual field recruitment collection goals in whole blood and other product lines. Ensures the adequacy of drive sites through the site inspection procedure. Complies with current donor incentive procedure and ensures all coordinators are trained and documentation is captured in Hemasphere. Plans/implements donor recognition and promotional activities as applicable. Builds relationships with coordinators/account leaders. Conducts strategy meetings with donor groups. Recruits donors at on-site drives as needed. Conducts training and promotes the use of DonorPoint and online schedules to maximize donor potential. Conducts cold calls on inactive/new territories and performs territory blitzes. Performs account sweeps and resolves internal coordination issues. Performs account assessments to help identify territory strategies. Positions are located in Muncie, Northern Indiana and Southeastern Indiana. BS/BA degree; three to five years sales experience required, with proven success in business to business sales preferred. Must have a valid driver's license, acceptable driving record and reliable transportation to reach communities in assigned territory. Must be proficient in all Microsoft Office products

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**POSITIONS** (continued from page 18)

as related to the position. Please apply at www.indianablood.org. EEO Employer/Vet/Disabled

**Director of Technical Services.** Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distribution annually), is seeking a strong leader to oversee all technical operations in the component manufacturing, quality control, and immunohematology reference laboratories and the 16-member team. Headquartered in Honolulu, we are the sole provider of blood to the state's hospitals. If you are a CLS and/or SBB with at least five years' technical and management experience in a blood bank setting, come join a dynamic, cohesive team that is effecting positive change. We offer a competitive salary and excellent benefits. Apply online now at http://www.bbh.org/about-bbh/employment.html.

**Director of Hospital Services and Facilities.** The Director of Hospital Services and Facilities is responsible for ensuring alignment of teams with organizational goals and compliance with regulatory guidelines. This position is accountable for ensuring a dedicated focus on the distribution of quality products in a timely manner while providing the highest level of customer service. This position will participate as a member of the blood bank's senior management team in planning, program formulation and decision making with particular reference to the role, functions and technical support of distribution of blood products and facilities maintenance. This position will be responsible for fostering and enhancing customer hospital relations. The Director of Hospital Services and Facilities will coordinate Blood Bank of Alaska's (BBA) Emergency Planning. This position is full-time exempt. BBA offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401(k) program are also available. BBA is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at www.bloodbankofalaska.org.

**Director of Laboratory Services.** The Blood Bank of Alaska (BBA) is looking for a Director of Laboratory Services. The Director of Laboratory Services is responsible for functions ensuring alignment with organization goals and compliance pertaining to regulatory guidelines within the laboratory environment. This position will participate as a member of the blood bank's management team in planning, program formulation and decision making with particular reference to the role, functions, and technical support of the blood collection and processing operations throughout BBA. This position will be responsible for compliance in regards to laboratory services. Position will serve on the executive group meetings. This position is full-time exempt. BBA offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401(k) program are also available. BBA is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at www.bloodbankofalaska.org.

**Quality Assurance Specialist.** Community Blood Center, Inc., a provider of high quality blood products and services located in Appleton, Wis. is seeking a Quality Assurance Specialist to join our team. In this role, you will ensure compliance with regulatory, accreditation, certification and customer requirements. A bachelor's degree with experience working in a blood center, biologics, pharmaceutical or medical industry manufacturing environment with base familiarity of quality assurance practices, training, and federal regulatory practices is preferred. If you are detail-oriented with excellent organizational, oral and written skill and enjoy problem solving, consider this opportunity. For further information and to apply online please visit www.communityblood.org. Community Blood Center, Inc. is an Equal Opportunity Employer M/F/Disability/Veteran