

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2016 #1

January 8, 2016

FDA Reduces Permanent MSM Blood Donor Deferral to 12 Months

The Food and Drug Administration (FDA) is ending its longstanding permanent deferral of male blood donors with a history of sex with other men (MSM) even once since 1977. When blood centers implement the new deferral policy, MSM will be able to donate blood if 12 months have passed since the most recent male-to-male sexual contact and they meet all other eligibility requirements, according to FDA's <u>final guidance</u> on preventing HIV transmission by blood products. The revised guidance supersedes the 1992 guidance on this subject.

"I applaud this result of more than 15 years of collaboration between the blood, general medicine, and scientific communities, and the gay community and FDA. It optimizes transfusion safety using valid science and epidemiology with attention to fairness," said America's Blood Centers Chief Medical Officer Louis Katz, MD. (See also 2000 AABB Statement on MSM)

The guidance has been anticipated since FDA <u>announced</u> in December 2015 its intention to change the policy, culminating a more than two-decade-long effort to amend the deferral policy. ABC, AABB, and the American Red Cross have long-supported moving to a 12-month MSM deferral, because it "aligns the MSM donor deferral period with those for other activities that may pose similar risks for transfusion-transmissible infections," according to a <u>joint statement</u>.

The permanent MSM deferral was implemented in the early days of the HIV/AIDS epidemic in the 1980s, when thousands of blood recipients were infected by HIV before its discovery and before the first donor screening tests were approved in 1985. Since then, blood donor tests have improved greatly, resulting in an extremely low risk of HIV transmission by blood – about 1 in 1.47 million transfusions, according to the guidance. In light of incredibly sensitive HIV screening tests, social activists and scientists alike began calling for regulators to reexamine the policy by the late 1990s.

The Department of Health and Human Services' (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) and FDA's Blood Products Advisory Committee (BPAC) met several times since 1997 to explore changing the policy, alternative MSM deferral options, and their impacts on blood safety. HHS sponsored rigorous investigations by transfusion medicine stakeholders, public health experts, and the gay community to understand these issues.



OUR SPACE

ABC CEO Christine S. Zambricki, DNAP, CRNA, FAAN

We Love You, We Love Our Mission, We Want You to Become Part of Us

Sound familiar? For most organizations contemplating partnership opportunities, mergers, or acquisitions, this sentiment serves as a foundation for considering opportunities with a trusted partner.

In recent months, ABC and ADRP have been engaged in exploratory discussions regarding the potential for coming together to deliver more and better services to our members at lower cost. Based on the opportunities identified so far, ABC and ADRP have taken the formal step of signing a confidentiality agreement and a letter of intent to protect both parties as we complete due diligence and discuss business points of embarking on a new partnership. The letter of intent is non-binding and can be terminated by either party at any time. The letter of intent does prevent either organization from having merger discussions with other organizations at this time.

Most non-profits undergo some serious contemplation before considering a merger or acquisition. ABC is pursuing this route to potentially create more value for members and make the best use of globally scarce resources. Currently, both ABC and ADRP provide educational content and learning opportunities for blood banking professionals who focus on the donor experience. Consolidating these offerings will reduce unnecessary duplication and prove to be a growth strategy as we leverage the <u>ABC Professional Institute</u> (API) and <u>member website</u> to deliver content in a more far reaching and cost effective manner, thus better serving our members.

The majority of ADRP members and conference attendees are affiliated with ABC member blood centers. Conversations between the leaders of the two organizations have highlighted potential advantages to moving forward. We intend to create an improved meeting program by integrating complementary offerings. We believe that the total administrative costs can be reduced and anticipate stronger strategic positioning with vendors and others interested in the field.

This is the most current status update on ABC and ADRP's endeavors. ABC and ADRP leadership thus far is encouraged and excited by the gains that can be made for both of our organizations, and we are feeling that the title of this article is correct. The letter of intent is not a final commitment, and details of the arrangements will be finalized with the approval of both organizations and their boards. Additional information will be forthcoming as both organizations perform their due diligence in a transparent manner to align their educational visions where commonalities exist, always with the commitment to provide the best resources in education to each of their members.

Christine S. Zambricki

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

America's Blood Centers

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MSM Deferral Changed (continued from page 1)

After hearing research updates providing scientific evidence supporting the safety of a 12-month MSM deferral, the <u>ACBTSA voted in November 2014</u> in favor of the 12-month deferral, followed shortly by a <u>BPAC meeting</u> where a majority of committee members favored the change. Both committees emphasized the imperative of establishing a nationwide infectious disease monitoring system to assess any impact of the deferral change upon blood safety.

FDA and the National Institutes of Health (NIH) <u>launched the U.S. Transfusion-Transmissible Infection Monitoring System (TTIMS)</u> in October 2015 to meet this strong recommendation, awarding contracts to the American Red Cross and Blood Systems Research Institute to lead the system. ABC members One-Blood and the New York Blood Center will also participate.

"FDA concludes that the available evidence most strongly supports a change from the indefinite deferral to a one-year blood donor deferral policy for MSM, and FDA expects that this change will maintain or improve blood safety with respect to HIV. FDA will continue to monitor the safety of the blood supply, including the effect of a change to a one year deferral," stated the FDA guidance.

While most recognize FDA's revised guidance is moving the agency's policy in the right direction, advocates in the LGBT community find the guidance persistently discriminatory and are advocating for a deferral based on sexual behaviors, not on gender and sexual identity. Some European countries have implemented such deferral schemes, but their impacts on transfusion safety are still poorly understood. Further, pending the completion of challenging research, it remains unclear whether such approaches would be effective and operationally feasible in a U.S. donor setting.

While ABC and the blood community applaud a scientifically rational policy change, "it is important to remember that implementing the new deferral and reinstating previously deferred donors will require time and rigorous efforts to update blood center policies and procedures in our cGMP (current Good Manufacturing Practices) environment," said Dr. Katz.

Consequently, blood centers must manage donor expectations, explaining that there will be a delay of many months before they can expect to see the new deferral criteria in play. Before implementing the 12-month MSM deferral and reinstating previously deferred donors blood centers will have to:

- Update and validate the deferral codes in their blood establishment computer systems (BECS);
- Update donor educational materials and donor history questionnaires, and have them accepted by FDA:
- Update standard operating procedures (SOPs) to reflect the new donor qualification and deferral criteria;
- Train staff to understand and correctly apply the new MSM donor deferral; and
- Design and disseminate donor communication materials.

These tasks must be prioritized and placed in the queue with the much more complex changes required in the <u>final rule</u> regarding blood donor eligibility and product suitability, which must be implemented in late May this year.

MSM Deferral Changed (continued from page 3)

The operational approaches to removing existing lifetime deferrals remain to be determined. For example, will blood centers be able to prospectively remove the historic MSM deferrals from their BECS or will they remove the previous permanent deferral on a case-by-case basis only as donors present?

ABC is conducting a survey of its membership to understand such details and the realities associated with the new deferral criteria. ABC members have been asked to complete the survey, available in MCN 16-001, by Jan. 18. Early conversations with ABC members indicate that the large majority of members plan to implement the 12-month MSM deferral, but may require up to nine to 12 months to complete the aforementioned procedural changes.

Also, while blood centers are eager to make this change, many centers are facing logistical and economic challenges in providing recovered plasma to fractionators in the European Union (EU) for manufacture into medicines like intravenous immunoglobulin. EU regulations do not currently permit the use of plasma from the newly qualified MSM donors. ABC executive staff has spoken with EU plasma manufacturers but it remains unclear whether and when they will accept plasma collected from MSM donors under the 12-month deferral.

Among other changes, the new guidance eliminates the requirement to provide educational materials listing the signs and symptoms of AIDS, which generally occur years after infection and test reactivity. Instead, it requires educational materials to provide the signs and symptoms of the acute retroviral syndrome, which can occur in the first weeks after infection. Also, blood centers will now record a donor's stated gender rather than having to determine their biological gender, as previously required.

Questions or comments regarding the survey and/or FDA guidance may be directed to Dr. Katz at lkatz@americasblood.org.





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INSIDE ABC

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

Advocacy Update: ABC Submits Three Comment Letters to Regulators

America's Blood Centers continues working in Washington to represent the interests of its member blood centers, having submitted three comment letters to federal agencies over the last two weeks to advance policies that benefit the blood center community. ABC executive staff submitted comments to the Centers for Medicare & Medicaid Services (CMS), the Office of Human Research Protections in the Department of Health and Human Services (HHS), and the Internal Revenue Service (IRS) on three separate proposed policies.

On Dec. 15, CEO Christine Zambricki, DNAP, CRNA, FAAN, submitted <u>comments</u> to the IRS about a <u>proposed rule</u>, which has since been <u>withdrawn</u>, regarding financial donations to charitable organizations. The proposed rule, "Substantiation Requirement for Certain Contributions," would require financial donors giving \$250 or more to a charitable organization to provide certain personal information, such as a social security number, to the charitable organization in cases where there is no contemporaneous receipt.

ABC commented to oppose this proposed rule, explaining that requiring financial donors to provide such personal information may hinder charitable contributions upon which many blood centers rely to help fund a variety of functions that enable blood centers to provide a safe and robust blood supply. Further, ABC notes that maintaining such personal information places undue regulatory burden upon blood centers and increases the risk of becoming targets of security breaches and cyberattacks. Advocacy efforts against this rule have been effective, as IRS published a <u>notice</u> today withdrawing the original notice of proposed rulemaking.

Dr. Zambricki <u>commented</u> on the <u>final CMS rule</u> regarding the 2016 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System (OPPS). This rule, which designates the agency's plan for reimbursing hospitals and ambulatory surgical centers in 2016, originally included significant cuts to Medicare payment rates for a variety of blood products. These cuts were reversed thanks to the advocacy efforts of ABC, its blood community partners, and member blood centers.

In ABC's <u>comments</u> on the final rule, Dr. Zambricki draws attention to discrepancies in the pricing tables for certain blood products, urging the agency to correct these anomalies before implementing the final rule. Further, she emphasizes that CMS must be cognizant of larger issues surrounding the sustainability of the U.S. blood supply, and should participate in the remediation of such threats.

ABC Chief Medical Officer Louis Katz, MD, submitted <u>comments</u> to HHS on Dec. 22 regarding a <u>proposed rule</u> that would update the regulations regarding the protection of human subjects in research – collectively referred to as the Common Rule. In his comments, Dr. Katz urges HHS to adopt the recommendations contained within the proposed rule that reduce the burden, delay, and ambiguity for both investigators and research subjects.

INSIDE ABC (continued from page 5)

Further the comments suggest HHS reconsider the classification of leftover, de-identified samples as "human subjects." This rule would require opt-in consent for use of these samples in research, despite addressing no risk to the source of the samples and hindering important studies. Lastly, ABC asks HHS to remove language proposing that informed consent waivers should be "extremely rare" and sustain the current policy under which institutional review boards can approve or disapprove waivers.

ABC monitors federal regulations and legislation that may affect community blood centers. Please contact Dr. Zambricki (<u>czambricki@americasblood.org</u>) or Betty Klinck (<u>bklinck@americasblood.org</u>) if there is an important policy issue you feel ABC should address.

Celebrate National Blood Donor Month with ABC on Social Media

January is National Blood Donor Month and America's Blood Centers wants to celebrate with you, ABC members, and your donors. ABC kicked off its National Blood Donor Month social media campaign this week, asking member blood centers and their donors to post selfies using the hashtag #AmericasGot-Blood.

With the goal of recognizing all of the individual donors who comprise a strong national network of volunteer



blood donors around the U.S., while also increasing visibility of ABC member blood centers, ABC will re-post photos shared using the #AmericasGotBlood hashtag on its <u>Facebook</u>, <u>Twitter</u>, and <u>Instagram</u> pages. At the end of the month, ABC will create and share a blood donor collage – to illustrate to donors how important their donation is in ensuring a readily available blood supply in the U.S.

While ABC is aware that many member blood centers have National Blood Donor Month campaigns of their own, ABC encourages member blood centers to consider adding the #AmericasGotBlood hashtag to some of its National Blood Donor Month posts. Many blood donors are already posting blood donor photos on social media, so why not ask them not be a part of something bigger by joining the national blood donor community?

Participating is simple; all it takes is:

- 1. Share the #AmericasGotBlood hashtag and selfie campaign on social media and/or through blood center signage, e-mails, and other communications.
- 2. Ask donors to post their selfies to your blood center's social media page(s) using the hashtag #AmericasGotBlood and to tag @America's Blood Centers on Facebook, @americasbloodcenters on Instagram, or @AmericasBlood on Twitter.
- 3. Watch your social media posts gain national visibility and await the blood donor collage!

You can ask donors to post the photos directly themselves, or your blood center can post them – whatever is easiest and most comfortable for your center. ABC members may direct questions or request additional social media campaign materials from Betty Klinck (bklinck@americasblood.org).

INSIDE ABC (continued on page 7)

INSIDE ABC (continued from page 6)

ABC Winter 2015 Blood Bulletin on Age of RBCs Now Available

America's Blood Centers' Scientific, Medical, and Technical (SMT) Publications Committee announced the publication of the Winter 2015 issue of the *Blood Bulletin*, a quarterly medical publication intended for ABC member blood centers to distribute to their hospital customers. This issue is titled, "Red Blood Cell Transfusion: Does Storage Age Matter?"

The article was written by Kyle Annen, DO, adjunct assistant professor at the McGaw Medical Center of Northwestern University, Chicago. The *Blood Bulletin* is reviewed and edited by the SMT Publications Committee. ABC members can access current and past *Blood Bulletin* issues here.

Contact Betty Klinck (bklinck@americasblood.org) with questions or suggestions for topics to be addressed in future issues. •

RESEARCH IN BRIEF

The results of a survey conducted among blood donors in Québec suggest that reasons for lapsing or reducing the frequency of blood donation may be related to demographic factors like age and gender. Johanne Charbonneau and colleagues of the Institut National de la Recherche Scientifique (INRS) conducted the survey among 1,897 whole blood, plasma/platelet, and lapsed whole blood donors at Héma-Québec to better understand deterrents to blood donation among these donor groups and the relationship between donor demographics and deterrents to blood donation. The most frequently cited reason for lapsing or reducing the frequency of donation was "time constraints related to work or studies, accounting for 43 percent of all respondents. The seven deterrents listed varied between whole blood, lapsed whole blood, and platelet/plasma donors. For example, platelet/plasma donors more often cited time constraints related to leisure/sports, moving or being further away from the blood drive, or difficulty accessing the blood drive as key reasons for reducing their donation frequency. This serves as a reminder that apheresis donation is more frequent, requires more time, and is more physically demanding - meaning that it can be difficult for donors to fit into their daily lives, according to the authors. Further, the authors found differences in the reasons for lapsing donation between demographic groups. For example, women were more likely to cite medical reasons including childbirth for lapsing in donation, while men were more likely to be affected by difficulty integrating blood donation into their busy lives. They were more likely than women to state that they had a hard time fitting donation into their schedules and donated less frequently because of "too much time spent donating blood." Donors with an elementary or high school education were most likely to cite health reasons to explain changes in their donation habits. These donors are most likely to rely on reminders from the blood center and to feel annoyed by completing the health questionnaire. "A better understanding of the relation between donor demographics and deterrents for blood donation among platelet/plasma donors, regular whole blood donors, and lapsed whole blood donors should help blood centers develop new strategies to achieve the goal of donor selfsufficiency by increased retention of non-remunerated blood donors," conclude the authors.

Citation: Charbonneau, J. Why do blood donors lapse or reduce their donation's frequency? Transfus Med Rev. 2015 Dec 15. 30:1-5. ♦



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BRIEFLY NOTED

AABB received a restricted charitable grant from Cerus Corp. in the amount of \$60,000 to support AABB's effort to further develop hemovigilance program participation in the U.S., reported AABB in a Dec. 16 statement. "This one-year agreement further underscores that an investment in hemovigilance is critical to ensure quality patient outcomes," said Miriam A. Markowitz, AABB CEO. "With the establishment of the AABB Center for Patient Safety in 2008, AABB has been at the forefront of hemovigilance activities dedicated to improving patient safety and the quality of health care delivery. We appreciate the support from Cerus Corp. to further our mission." The restricted grant will be used to:

- Engage in hospital outreach efforts to expand hemovigilance activities by hospitals to increase the hemovigilance commitment and permit statistically meaningful analysis.
- Provide hemovigilance training to hospital sites participating in the hemovigilance program.
- Develop a U.S. hemovigilance protocol, using the framework of the National Healthcare Safety Network (NHSN) Biovigilance Component's Hemovigilance Module, to collect reported adverse event data associated with the use of pathogen-reduced products.
- Review and harmonize data collection forms and processes to encourage innovation and adoption in all blood components, transfusion medicine and blood banking practices.
- Pursue dissemination of scholastic findings resulting from research.

"We are proud to support AABB in their endeavor to further advance a U.S. hemovigilance system," said William 'Obi' M. Greenman, president and CEO of Cerus. "AABB's efforts to collect adverse event data are in line with our work to reduce the risk of transfusion-transmitted diseases through pathogen reduction." More information can be found here. (Source: AABB press release, 12/16/15) ◆



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oneblood

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2016 Annual Meeting Schedule

Saturday, March 12: Business Forum

Sunday, March 13: ABC Members Meeting

SMT Forum & Celso Bianco

Lectureship

Host Event by OneBlood (off-site event)

Monday, March 14: Blood Center Leadership Forum

19th Annual Awards of Excellence

& 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.







REGULATORY NEWS

The Food and Drug Administration published a <u>Draft Guidance for Industry</u> titled "Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271." The guidance is intended for establishments that manufacture non-reproductive human cells, tissues, and cellular and tissue based products regulated under the aforementioned regulations. ABC's staff and relevant committees are reviewing the draft guidance. ABC members with questions or comments may contact Ruth Sylvester at rsylvester@americasblood.org.

The Food and Drug Administration granted orphan drug status to Global Blood Therapeutics' drug candidate for sickle cell disease called Fast Track-tagged GBT440. The drug is an oral, oncedaily sickle cell therapy that works by increasing the hemoglobin's affinity for oxygen via its binding to 20 percent of the total hemoglobin in the patient's blood. Oxygenated hemoglobin does not polymerize which prevents the trademark sickling of red blood cells caused by sickle cell disease. It is being investigated in an ongoing phase 1 and 2 study, of which full results should be available in 2016. More information about ongoing clinical trials on this drug can be found here. (Source: Seeking Alpha, 12/31/15)

The Office of Safety and Health Administration (OSHA) recently updated its injury reporting website to include online filing. To help employers comply with new requirements to report severe worker injuries, OSHA has created a streamlined reporting webpage, including the option to report incidents online. The expanded requirements, which took effect in 2015, require employers to report within 24 hours any severe injury. (Source: OSHA e-mail update, 1/4/16) ◆

INFECTIOUS DISEASE UPDATES

EBOLA VIRUS DISEASE

A non-randomized, comparative study of 99 patients undergoing convalescent plasma transfusion to treat Ebola virus disease found that the treatment was not associated with a significant improvement in survival. The study, published in *The New England Journal of Medicine*, included 84 patients in the final analysis who were treated with convalescent plasma in Guinea, Africa. These patients were compared to 418 historical controls. The primary outcome was the risk of death from three to 16 days after diagnosis. Mortality was 31 percent in the convalescent-plasma group and 38 percent in the control group. However, the difference was reduced after the researchers adjusted for patient age and polymerase chain reaction (PCR) cycle-threshold value (an estimate of patients' viral burden). No serious adverse reactions were associated with the use of convalescent plasma. Critically, titers of Ebola neutralizing antibody in the transfused plasma have not been analyzed. "We found that treatment with convalescent plasma was feasible to organize and administer ... Although uncertainty remains about our findings because of the nonrandomized nature of the study and the use of historical controls, we could not detect a marked survival effect of the administration of a dose of 200 to 250 ml of convalescent plasma twice daily," concluded the authors.

Citation: van Griensven J, *et al.* Evaluation of convalescent plasma for Ebola virus disease in Guinea. N Engl J Med. 2016 Jan. 7;374(1):33-42.

INFECTIOUS DISEASE UPDATES (continued from page 9)

CREUTZFELDT-JAKOB DISEASE

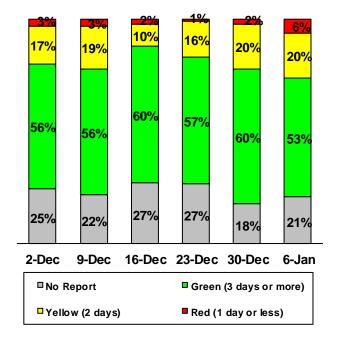
An update of the UK Transfusion Medicine Epidemiology Review Study recently published in *Vox Sanguinis* confirms that there have been no new cases of transfusion-associated variant Creutz-feldt-Jakob disease (vCJD) since 2007 and there is no evidence of transfusion-transmitted sporadic CJD (sCJD). The paper reports the results of an ongoing study in the UK through May 31, 2015, looking for additional cases of vCJD transmitted by blood and to determine if other CJD subtypes can be transmitted by blood. To date, three clinical cases of vCJD and one case of apparent transmission without disease at the time of death have occurred in 67 recipients of vCJD-infected blood. There is also no evidence of transfusion-transmitted sCJD. vCJD, often referred to as "mad cow" disease, was first identified in the UK in 1996.

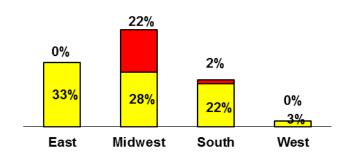
Citation: Urwin PJ, *et al.* Creutzfeldt-Jakob disease and blood transfusion: updated results of the UK Transfusion Medicine Epidemiology Review Study. Vox Sang. 2015 Dec 28. [Epub ahead of print] ◆

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

Total ABC Red Cell Inventory

Percent of Regional Inventory at 2 Days Supply or Less, Jan. 6 2016





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

MEMBER NEWS

Lifeblood, Memphis, Tenn., recently held two exciting events – one recognizing local schools and volunteers, and a second giving back to a local children's hospital. On Dec. 10, Lifeblood and the Bartlett, Arlington, and Lakeland Donor (BALD) Council recognized its 2015 group and individual volunteers at a holiday reception. Rev. Lynn Butler at Ellendale Baptist Church was named Volunteer of the

Year for his work organizing five blood drives in 2015. The award for Best Faith Based group of 2015 went to New Hope Christian Church. Bolton High School won Group Achievement for 2015 Oliver Creek and Church of Christ won the Newcomer of the Year award. The awards were presented by BALD Council Chairwoman Jane Garrett, Lifeblood Executive Director Danny Garrick, and City of Bartlett Chief Administrative Officer Mark Brown. "Seeing our 100 club grow



Lifeblood, Le Bonheur and AutoZone employees pose with more than 1,000 stuffed bears delivered to Le Bonheur Children's Hospital during the holidays.

with the involvement from the Bartlett, Arlington, and Lakeland communities is very encouraging," said Mr. Garrick, "The blood drive coordinators and donors at each of the businesses, schools, and places of worship recognized today are to thank for making sure that local patients have blood when they need it." More information can be found in the Lifeblood press release. Also during December, more than 1,000 Lifeblood donors took part in the center's "Bears for Le Bonheur" campaign. As part of a generous gift from AutoZone, Lifeblood and its donors were able to send holiday cheer to patients spending time at Le Bonheur Children's Hospital this winter. Lifeblood and AutoZone employees visited Le Bonheur on Dec. 16, 2015 to deliver 1,000 stuffed animals to the hospital's patients. Each stuffed animal represented a Lifeblood donor who gave blood or platelets the first two weeks of December. Donors also had an opportunity to sign a holiday tag with well wishes for patients. More than 3,000 stuffed bears have been donated to Le Bonheur Children's Hospital since Lifeblood's "Bears for Le Bonheur" program began in December 2013. "Lifeblood donors feel a strong connection to the patients at this special hospital," remarked Mr. Garrick. "One way to show the strength of that connection is to give blood. We are so fortunate our donors recognize that the children here always have a need for blood, and we hope that these bears will bring a smile to the kids during their stay in the hospital." After brief remarks from Garrick and AutoZone's Kristen Wright, AutoZone and Lifeblood employees delivered bears to several patients and their families. (Sources: Lifeblood press releases, 12/10/15, 12/16/15)

Three members of America's Blood Centers' recently entered into agreements with Cerus Corp. for the use of Intercept platelets and plasma. Intercept is the first and only Food and Drug Administration approved pathogen reduction system, used to reduce the risk of transfusion-transmitted infectious pathogens in the blood supply. Rhode Island Blood Center, Providence, R.I., announced its agreement on Dec. 23; Blood Systems, Inc. (BSI), Scottsdale Ariz., announced its agreement on Jan. 5; and LifeShare Blood Centers, Shreveport, La., announced its agreement on Jan. 7. As a collective organization, BSI is

MEMBER NEWS (continued from page 11)

the largest blood banking organization in the contiguous U.S. to sign on with Cerus thus far for the use of Intercept platelets and plasma. "We believe that pathogen reduction may play an important role in protecting the U.S. blood supply," said David Green, president of BSI's Blood Centers Division. "This agreement will allow us to move forward with Intercept implementation at Community Blood Services in the near term, and potentially streamline the addition of other BSI centers in the future." More information about these agreements can be found in the Cerus <u>press releases</u>. (Source: Cerus press releases, 12/23/15, 1/5/16, 1/7/16)

BloodCenter of Wisconsin (a part of Versiti) honored James Jasso Dec. 17 as the 100,000th rare blood donor registered in the American Rare Donor Program (ARDP). Mr. Jasso has a rare type of

O-negative blood, Yta -negative, which is needed by both adults and newborn infants with under-developed immune systems. Mr. Jasso, 30, is a loyal donor whose life-saving blood donations have been shared by Blood-Center of Wisconsin with patients living not only in Wisconsin, but also Florida, New York and Pennsylvania. "I donate blood, because I enjoy helping," said Mr. Jasso. "Just to know that my rare blood type can help people across the country gives me a really good feeling." There are approximately 3,000 blood donors from Wisconsin registered as part of the ARDP program. BloodCenter of Wisconsin has been a member of ARDP since its inception in 1998, providing nearly 200 rare blood units to the program in 2014. ARDP tracks and



James Jasso (left) with BloodCenter of Wisconsin's Greg Denomme, PhD.

organizes rare donor information in an effort to better meet the needs of patients with rare blood types. "Finding rare blood donors is critically important to providing better patient outcomes," says Greg Denomme, PhD, director of immunohematology at BloodCenter of Wisconsin. "As more people donate, we can identify those with rare blood types. From there, we can match up their donations with patients that have specific blood needs. Thanks to the generosity of donors like James, we now have 100,000 rare donors in the ARDP program." BloodCenter of Wisconsin is a leader in providing rare or uncommon blood to patients across the country, serving patients with unique needs, ensuring they will receive the appropriate care. Patients with rare or uncommon blood types rely on the efforts of organizations like BloodCenter of Wisconsin to identify matching donors who can provide life-saving treatment. (Source: BloodCenter of Wisconsin press release, 12/23/15)

We Welcome Your Articles

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

PEOPLE

LifeStream, San Bernardino, Calif., ended 2015 with a bang on Dec. 31, 2015 by welcoming **Dennis Schall** as its fourth donor of the year and eighth overall to reach 100 gallons in blood donations. Adding

poignancy to the milestone donation was the presence of Mr. Schall's brother, Richard, as it was brotherly love that inspired Mr. Schall to first donate blood in 1982. "My brother was undergoing surgery and would need blood," recalled Mr. Schall. "I thought if he could go through that, I could certainly donate blood." Joe Chaffin, MD, LifeStream's vice president/chief medical officer, outlined to staff and fellow donors how Mr. Schall began donating platelets in December 1990 and the grit and determination he needed to overcome a serious medical challenge in 2010. "A very observant friend noticed that Dennis didn't look quite right, and he was absolutely correct," said Dr. Chaffin. "Dennis was diagnosed with pancreatic cancer, which is typically an extremely dangerous disease." But Mr. Schall quickly added that he was lucky, as it was caught early and immediate surgery excised the tumor. A year after being declared in remission, Mr. Schall returned to the donor's chair. Mr. Schall was presented a framed cer-



Dennis Schall and LifeStream Vice President/Chief Medical Officer Dr. Joe Chaffin, Thursday, Dec. 31 during Schall's blood donation that enabled him to reach 100 gallons in blood donations.

tificate of appreciation from LifeStream, and what Dr. Chaffin called a "very, very rare" polo shirt, both signifying 100 gallons in blood donations. (Source: LifeStream submission, 1/5/16) ♦

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 Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: nmaundy@americasblood.org.

POSITIONS AVAILABLE

President/CEO. Small southern blood center in Jackson, Tenn. seeking a president/CEO. The successful candidate will be the third CEO in the 70-year history of the organization. Demonstrated leadership in blood center management or related industry required; post baccalaureate degree or certification preferred. Please submit resume to Search Committee, LIFELINE Blood Services, 183 Sterling Farms Drive, Jackson, TN, 38305.

Recruitment Director. A regional blood services provider is seeking a recruitment director to lead a team of donor recruiters who cover multi-state territories. Minimum qualifications for success in this new role will include a bachelor's degree with at least five-10 years prior related experience managing a sales team in the blood banking or medical services industry. Other job requirements are advanced skills in influence and negotiation, communications, interpersonal relations with the

public, creative problem solving, analytics and reporting, customer service, multi-task prioritizing, organizing and public speaking. This is a management-level position that will require multi-state travel up to 60 percent of the time. Primary job responsibilities will involve building new and existing business relationships, developing team goals and holding staff accountable for meeting blood collection goals set for multiple mobile and facility locations, developing community partnerships for marketing and business expansion opportunities, executing the company's strategic business initiatives and developing staff skills in influence/ negotiation, customer service and relationships management. For consideration, please submit a resume and salary expectations to the following address: bbankdirector@yahoo.com.

(continued on page 14)

POSITIONS (continued from page 13)

Transfusion Medicine Physician. Bonfils Blood Center is seeking a full-time transfusion medicine physician to join its fast-paced, growing organization. Working directly with the president/CEO, this position is responsible for proactively coordinating medical and business communications between the blood center, the local medical community, and Blood Systems, Inc.'s Corporate Medical Affairs office. Responsibilities include consultation and visits with hospital partners, patient blood management oversight, CLIA laboratory directormedical direction to: collections, ship, manufacturing, research/specialized donations, NMDP and reference laboratory functions. Demonstrated excellence in blood banking / transfusion medicine-related topics and exceptional communication and collaborative skills are critical. Qualifications: MD or DO, board certification in CP with board eligibility / certification in Transfusion Medicine (within two years of hire) or certification in IM or Pediatrics with Hematology certification. Fellowship training in Blood Banking / Transfusion Medicine or two (and preferably five) vears' experience at a blood center or hospital with blood banking is required. Previous research and immunotherapy experience required. Current or prompt licensure will be required within Colorado and neighboring states. Relocation assistance will be considered. For a complete job description, please send your request to Employee Recruitment@bonfils.org. Applications accepted here: http://www.bonfils.org/index.cfm/aboutus/employment/.

Director of Collections. The director of collections (DC) provides effective leadership, supervision and direction for the operations of collections. Oversee the direction, coordination, and evaluation of collections, providing direction for subordinate management team members to ensure excellent services and an adequate, safe, pure and potent blood supply. Responsible for developing tissue related operational procedures and tasks that comply with core current good tissue practice (cGTP) requirements. Ensures all procedures and processes are performed as designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of human cells, tissue and cellular and tissue-based products (HCT/Ps). Effectively monitor production, inventory and performance in areas within the scope of assigned departments; develop, implement, monitor, and determine the effectiveness of department processes and plans; take appropriate corrective measures when necessary; and identify new applications, innovations, quality and/or safety improvements; report findings/results to the CFO and medical director, as appropriate. Employer will assist with relocation costs. Additional Salary Information: TBD. Please apply at www.BBH.org.

Donor Health Counselor (Medical Affairs). Blood Systems is searching for a donor health counselor to join its Medical Affairs team in Scottsdale, AZ. This position is responsible for verbally counseling donors, physicians, and customers on the medical significance of infectious disease markers and responding to questions and concerns. Supports blood center donor care staff in determining donor eligibility. Requirements: Bachelor's degree or equivalent combination of education and experience; RN license or MT certification; three years' experience in a healthcare environment to include experience in patient and/or donor education/counseling/communication. For consideration. please apply on Blood Systems' website: http://www.bloodsystems.org/careers.html 01/15/2016. Blood Systems offers an extensive benefits package that includes: affordable medical/dental, flexible spending, relocation, education assistance, 401(k) match and more! Pre-employment background check and drug screen required. Blood Systems Inc. is an eaual opportunity employer. EEO/Minorities/Females/Disabled/Veterans

Medical Director. Blood Systems is searching for a medical director to join its Medical Affairs team. Position will support a blood center located in Montvale, NJ. Under minimal direction, this position is responsible to the patients, donors, center staff, and healthcare professionals in assigned area(s). Requirements: MD, DO, or equivalent degree; medical license in the state(s) of work within six (6) months; transfusion medicine or board certification in hematology; fellowship training or equivalent experience in blood banking/transfusion medicine; experience at a blood center and/or hospital transfusion service. For consideration, please apply on the Blood Systems' website: http://www.bloodsystems.org/careers.html 01/22/2016. Blood Systems offers an extensive benefits package that includes: affordable medical/dental, flexible spending, relocation, education assistance, 401(k) match and more! Pre-employment background check and drug screen required. Blood Systems Inc. is an opportunity employer. eaual EEO/Minorities/Females/Disabled/Veterans

Director Client Services. (Department: Client Services; Location: St. Paul, MN; Status: Full-Time, 1.0 FTE (40 hours per week), Exempt) Position Summary: This position is responsible for Client Services that manages a broad range of sales and service activities across geographic locations. Generates new business opportunities to capture new markets and leads in delivering exceptional service while meeting vital account metrics and maintaining superior client relationships. Responsible for developing processes that proactively seek process improvement and customer solutions to enhance service.

POSITIONS (continued from page 14)

Develops sales goals and forecasts and works in conjunction with operations to recommend actions in response to changing market conditions. Responsible for creating infrastructure, processes, policies and procedures to support future organizational product and service growth. To apply please go directly to our website with an updated resume: https://home2.eease.adp.com/recruit2/?id=19040182&t=1

Mobile Operations Manager. (Department: Metro Collections Vans & Mobiles; Location: St. Paul, MN; Status: Full-Time, 1.0FTE, & Exempt; Schedule: Monday-Friday with availability and accessibility to staff all hours of operation) Position Summary: To ensure metro mobile collections operations are run in a manner that results in safe and compliant blood products and service that consistently delights donor and sponsors. To ensure a working environment for staff on the applicable team that is supportive and productive through recognition, feedback, coaching and development. To apply please go directly to our website with an updated resume: https://home2.eease.adp.com/recruit2/?id=19039962&t=1.

Vice President of Blood Services. Unyts, Western New York's only Organ, Eye, Tissue and Community Blood Donation Center has an immediate opening for a vice president of Blood Services. This executive leadership position will oversee donor recruitment, collections, component processing and distribution; is accountable for all blood clinical and operational objectives and will ensure strategic plan is met and, with the appropriate credentials, will also serve as the Medical Director for Blood Services. Maintain and cultivate supportive relationships within the regional health care sector and the community. In addition to oversight of daily operational functions, this position tracks and trends key performance indicators, quality metrics and financials and takes appropriate action to ensure business viability. Bachelor's degree with seven-10 years of related experience or a combination of equivalent experience and education or MD with NYS certificates of qualification, SBB preferred. Successful development and execution of strategic objectives. Demonstrable success utilizing technical and interpersonal skills to building teams to drive for operational success in challenging and highly regulated environments. Demonstrable success with implementing and sustaining process improvement. Five years progressive senior leadership experience required. Experience managing donor recruitment, donor services, component manufacturing, and product management distribution strongly desired. Please apply online at www.unyts.org/about/careers/.

Hospital Relations Manager. LifeStream, a Southern California blood center serving 80 hospitals with 200,000 blood products annually, is searching for a Hospital Relations Manager. Serves as technical resource for customer transfusion services: answering questions, providing training, and other support related to LifeStream's products and services. Also is a primary customer service contact, working to improve services, resolve any service issues, and build stronger relationships with customers. Promotes LifeStream's programs. Ensures excellent service is provided to hospitals and other customers. Four-year bachelor's degree (BA or BS) in biological sciences or medical related discipline, with MT(ASCP) or equivalent desirable. SBB desirable. Minimum four years' experience in blood banking or five years in hospital laboratory with transfusion service experience, (or equivalent). Must have exceptional interpersonal communicative skills developed and cultivated through extensive managerial and customer service experience. Current California driver's license required. LifeStream has an excellent compensation & benefits plan. For further information and to apply online please visit: www.LStream.org. Or fax cover letter, resume and salary history to (909) 386-6813. LifeStream is an Equal Opportunity Employer, M/F/D/V. Job Number: IN-4232655793