



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2015 #1

January 9, 2015

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FDA Plans to Endorse One-Year MSM Deferral

The Food and Drug Administration will issue a draft guidance this year that will address changing the current policy permanently deferring men who have sex with men (MSM) from donating blood to a one-year deferral, announced FDA Commissioner Margaret A. Hamburg, MD, in a Dec. 23 [statement](#). FDA has also “taken steps to implement a national blood surveillance system that will help the agency monitor the effect of a policy change and further help to ensure the continued safety of the blood supply,” said Dr. Hamburg.

The statement comes shortly after a November meeting of the Department of Health and Human Services’ (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), which voted overwhelmingly in favor of moving to a deferral of one year after MSM behavior (see [ABC Newsletter, 11/14/14](#)).

Experts at that meeting heard updates on long-awaited research relevant to the MSM blood donor policy, which provided evidence that switching to a one-year MSM deferral would likely not measurably decrease the safety of the blood supply, that the shorter deferral may result in improved compliance with donor qualification requirements, and that a sustainable transfusion transmitted infections (TTI) surveillance system is feasible. Following the review of this research and the committee’s recommendations, “the agency will take the necessary steps to recommend a change to the blood donor deferral to one year since the last sexual contact,” said Dr. Hamburg.

It’s Show Time!

Experience blood bankers and friends of America’s Blood Centers like you’ve never seen them before in the first-ever ABC’s Got Talent show! See page 3 for more details.

“This recommended change ... will better align the deferral period with that of other men and women at increased risk for HIV infection,” continued Dr. Hamburg. She added that FDA is working with the NIH’s National Heart, Lung, and Blood Institute to implement the national blood surveillance system. FDA plans to issue the draft guidance this year and offer stakeholders the opportunity to review and comment on the suggested policy.

America’s Blood Centers, AABB, and the American Red Cross (ARC) issued a [joint statement](#) supporting FDA’s proposed change in the MSM deferral. “The

(continued on page 3)



OUR SPACE

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

Vote Early and Vote Often

Brace yourself. Get ready ... “ABC’s Got Talent” has arrived! Experience ABC supporters including CEOs, blood center employees, and even family members and friends of blood centers like you’ve never seen them before, all while raising money for a good cause. This week kicks off “ABC’s Got Talent,” a truly fun fundraiser. So, what do you need to do?

Vote Early and Vote Often. From now until March 6 you can vote for ABC’s top acts by following the links to view the performers’ videos, featured on page 4, and voting for your favorite. Or, vote for all the participants if you believe there can never be enough recognition for effort! Votes are a suggested minimum donation of \$10 apiece and all proceeds benefit an excellent cause – supporting the Foundation for America’s Blood Centers (FABC) and the continuing education and staff development programs that will constitute the ABC Professional Institute.

And what about the talent competition? The five contestants with the most online votes will be invited to perform live at the ABC Annual Meeting in Washington, D.C. this March. And it doesn’t stop there! In addition to enjoying premier entertainment, ABC members and their guests will have the honor of choosing the very top talent in the ABC community, who will receive an exciting first place prize and be featured in an *ABC Newsletter* article.

Everyone Can Vote. From ABC members and non-ABC members, to family and friends, to colleagues and competitors – if you are reading this article, you can vote! To track the competition in a friendly, fiercely competitive way, check the *Newsletter’s* weekly ABC’s Got Talent scorecard. We seek to raise \$50,000 for the FABC through this effort.

And Finally, a Big HOOORAH and THANK YOU to Our Talented Contestants. You have stepped up to the plate to raise money for the FABC in a very public way and we all benefit by relishing your incredible talent. Thank you Jim AuBuchon, MD, Sharon Birzer, Sher Patrick, Deon Smith’s wife Mindy, Mary Townsend, MD, Chris Staub, Pascal George, Kim-Anh Nguyen, MD, PhD, Eric Stone, Dan Eberts, Kevin Belanger & Team, Laurett Gannon, and Emily Shenk-DeMay.

We never knew that such serious talent existed in our ranks, and now that we do, ABC events will never be the same! I, for one, will now picture a mandolin, a kilt, or a lasso when I see certain colleagues at future meetings. What lasting memories will you take away from the first-ever ABC’s Got Talent?

Christine S. Zambricki

czambricki@americasblood.org 

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

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DID YOU KNOW...?

‘26’ is the number of educational and professional development webinars that America’s Blood Centers hosted in 2014, ranging in topics from TRALI mitigation, to simulation training for blood centers, to bullying and resolving conflict in the workplace, to best practices for high school blood drives.

America’s Blood Centers’ staff, board of directors, and committee members are working daily to support the needs of ABC’s member blood centers. Whether it is through public, regulatory or legislative advocacy, educational meetings and webinars, or disaster preparedness assistance, ABC strives to support the continued success and development of independent community blood centers and their employees. Every quarter, ABC staff reports on a series of metrics to the board of directors through the ABC Balanced Measures Report. The ABC Newsletter will highlight one metric each week. Be sure to check it out to find out how ABC is working on behalf of your blood center.

MSM Deferral Change (continued from page 1)

FDA’s decision to take steps to recommend a change in the blood donation deferral for MSM from a lifetime deferral to a one-year deferral is consistent with the position of our organizations that the current lifetime deferral is unwarranted,” stated the three organizations.

The joint statement also notes that “this process is just beginning and that the lifetime blood donation deferral for MSM is currently still in place.” Blood centers must continue to comply with FDA donation eligibility criteria until there is final guidance, and the process to change and implement a new MSM deferral policy will take time, they added. ABC, AABB, and ARC said they will review the draft guidance when it is issued and will implement the guidance after it is finalized.

“The top priority of AABB, ABC, and the ARC is the safety of the ultimate recipients of blood and our volunteer blood donors. Our organizations strongly support the use of rational, scientifically-based deferral periods that are applied fairly and consistently among blood donors who engage in similar risk activities. We also support the advisory committee’s recommendations for sustainable monitoring of changes in blood safety following implementation of a new deferral policy,” they concluded. (Sources: FDA statement, 12/23/14; ABC, AABB, ARC joint statement, 12/23/14) ♦

ABC Launches First-Ever ABC’s Got Talent Show to Benefit the FABC

What do belly dancing, playing the bagpipes, and singing in French all have in common with blood banking? These are just a few of the impressive talents that will be featured in the first-ever ABC’s Got Talent show to benefit the Foundation for America’s Blood Centers (FABC). ABC and the FABC have officially launched the fundraising competition, beginning with the opportunity to view online videos of each contestant’s act and vote for your favorite, all while supporting the FABC.

ABC’s Got Talent – a virtual talent show allowing ABC community members to showcase their talents and raise money for the FABC – officially kicked off today with 13 videos now available to begin the online voting. Contestants are competing for votes, which can be made via donations to the FABC for a

(continued on page 4)

ABC's Got Talent (continued from page 3)

suggested minimum of \$10 each, although they can be made in any denomination and there is no limit. Votes are made through the contestants' online campaign pages, linked below. The top five acts to earn the most donations will be invited to perform live at the ABC Awards of Excellence event on March 23 during the ABC Annual Meeting in Washington, D.C. Online voting is open to the public – ABC members and non-members alike – until March 6.

The videos feature talented executives, donors, family members, and friends of ABC member blood centers performing a variety of exciting talents from rope tricking to standup comedy. Contestants and their affiliated blood centers are sharing their videos with family members, friends, and their blood center community to raise money for the FABC and help their chances of making it to DC!

During the live performances at the ABC Annual Meeting, the top five contestants will perform their talents for the audience of ABC members, award winners, and their guests, who will have the chance to vote live. Guests will have numerous opportunities to submit ballots for their favorite performances throughout the night. The live talent show begins the scoring anew, putting all contestants on an even playing field, regardless of their online campaigns. So guests will have to vote big and vote often to ensure their favorite talent wins! Tickets to this event are included at no additional cost with registration for the ABC Annual Meeting, offering attendees the chance to network and have a little fun while supporting a good cause.

The winner of the live talent show will receive a generous grand prize; more details to come in a future *Newsletter*. To keep track of the competition, the *Newsletter* will publish a weekly ABC's Got Talent Scorecard and will highlight different talent show acts each week. Stay tuned to see who will be making it to DC for a chance at the grand prize!

Listed below are the contestants and links to their campaign pages where you can watch their videos and submit votes via donation:

- **James AuBuchon, MD**, Puget Sound Blood Center, bagpipe playing: <http://bit.ly/DrAuBuchon>;
- **Sharon Birzer**, Blood Centers of the Pacific, standup comedy: <http://bit.ly/SharonBirzer>;
- **Dan Eberts**, OneBlood, "Songs for All Seasons:" <http://bit.ly/DanEberts>;
- **Laurett Gannon**, Central Jersey Blood Center, <http://bit.ly/LaurettGannon> (Note: the video for this campaign is coming soon);
- **Pascal George**, Central Jersey Blood Center, French song on mandolin: <http://bit.ly/PascalGeorgeCJBC>;
- **Kim-Anh Nguyen, MD, PhD**, Blood Bank of Hawaii, ballroom dancing: <http://bit.ly/DrNguyen>;
- **Sher Patrick**, Community Blood Center, Dayton, belly dancing: <http://bit.ly/SherPatrick>;
- **Emily Shenk-DeMay**, Mississippi Valley Regional Blood Center, singing "God Bless America:" <http://bit.ly/EmilyShenkDeMay> (Note: the video for this campaign is coming soon);
- **Shepard Blues Band**, Shepard Community Blood Center, "Shepard Man of Sorrow:" <http://bit.ly/ShepardBluesBand>;
- **Mindy Smith**, Oklahoma Blood Institute, singing "Art is Calling Me" from *The Enchantress*: <http://bit.ly/MindySmithobi>;
- **Chris Staub**, Unyts, "Appalachian Instrumental Tune & Original Song" with brother Tony Staub: <http://bit.ly/StaubBrothers> (Note: the video for this campaign is coming soon);
- **Eric Stone**, Blood Systems, musician, <http://bit.ly/EricStoneBSI> (Note: the video for this campaign is coming soon); and
- **Mary Townsend, MD**, Blood Systems, rope tricking: <http://bit.ly/DrTownsend> (Note: the video for this campaign is coming soon). 💧



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JOIN US FOR AMERICA'S BLOOD CENTERS' 53RD ANNUAL MEETING

A MUST-ATTEND EVENT, REGISTER NOW!

March 20-24, 2015 – Washington, DC | Ritz-Carlton (Pentagon City)

SIGNATURE NETWORKING EVENTS

Benefiting the Foundation for America's Blood Centers

A Monumental Affair: Delight in a performance by world renowned political satire and musical comedy act "[The Capitol Steps](#)" while enjoying great food and a monumental view of the Washington skyline at DC's famed Top of the Town (Sunday, March 22)

FABC VIP Tour: Experience the history and beauty of the Washington DC monuments and landmarks through the eyes of luxury, as you embark on a moonlight limousine tour with other VIP guests (Sunday, March 22)

18th Annual Awards of Excellence & Talent Show: Join us as we recognize community and industry leaders alike, while being entertained by the best in the business at the inaugural "ABC's Got Talent" show – NEW! Free ticket with Annual Meeting registration (Monday, March 23)

“Come for the networking and education – stay for the experience. Washington, DC is a world-class city with something for everyone – history, monuments, Smithsonian museums, the Cherry Blossom Festival and of course, politics!”

– Christine Zambricki, DNAP, CRNA, FAAN
Chief Executive Officer, America's Blood Centers

2015 ANNUAL MEETING SCHEDULE

Download full schedule details, including speakers and presentation descriptions.

International Blood Safety Forum (IBSF): Co-hosted by Global Healing – Engage in dialogue with leading experts from around the world who are forging into the next horizon of global blood safety (Friday, March 20)

Business Forum: *The Economics of Plasma* – Stay up-to-date on the business of plasma for fractionation and learn how to optimize plasma collections (Saturday, March 21)

ABC Members Meeting: Hear how ABC is working for you and make your voice count (Sunday, March 22)

SMT Forum: Learn from the experts as they address hot topics in blood science impacting care provided to patients and donors (Sunday, March 22)

Blood Center Leadership Forum: Discuss legal and strategic aspects of cooperation in blood banking, navigating the hospital supply chain, board engagement and leadership succession (Monday, March 23)

Advocacy Forum: Learn from a US Congressperson what's ahead in the healthcare horizon and join your fellow advocates in educating Members of Congress about the issues affecting blood centers (Tuesday, March 24)

ABC AND EBA MEMBER FEES

ANNUAL MEETING: \$945 (register and book hotel by February 27, 2015)

Business Forum through Advocacy Forum (Sat. through Tues.): \$725

IBSF & Business Forum (Fri. & Sat. only): \$395

IBSF (Fri. only): \$265

ABC and EBA Members register through direct email invitation or contact Lori Beaston at lbeaston@americasblood.org.

Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation and registration fees and information. Sponsorship opportunities available. Contact Abbey Nunes at anunes@americasblood.org for details.



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INSIDE ABC

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

ABC to Hold Webinar on Gaining Leadership Support for Employee Development

America's Blood Centers' Member Employee Training and Development Committee will hold a webinar on Jan. 22 titled "How to Secure Support from Senior Management for Employee Development Programs. Catalin Hrisafi, director of Training and Education at LifeShare Blood Center, will share strategies to identify common obstacles for upper echelon support, discuss why support from upper management is crucial to success, and identify a workable plan for boosting support from senior management.

This webinar will also present the ABC membership with an opportunity to more actively participate in the program. About a week before the webinar, Mr. Hrisafi will distribute, via ABC, some examples of challenging issues surrounding obtaining support from senior management for employee development programs. Members will then have a chance to ponder the examples and provide potential solutions for improving executive support within ABC member blood centers during the last part of the webinar. The ultimate goal is for members to learn from each other's experiences.

Questions can be directed to Leslie at mnorwood@americasblood.org. More information is available to ABC members in [MCN 15-003](#). ♦

Letter to the Editor – Experiences and Insights in Donor Motivation

Dear editor,

Recently, a good friend and colleague asked an industry veteran for donor recruitment advice. I was fortunate to be copied in the reply and found the response to be a succinct summary of what motivates different donors to give and to consider returning. I have often used the phrase, "It Takes All Types," in regard to the variety of people who come to donate and the rewards they seek. This summary helps to define the different types of donors, and with the permission of the author, who wishes to remain anonymous, I share it with you below. I hope that you find this beneficial and can share it with fellow blood center colleagues.

Sincerely,

Daniel Eberts
Community & Donor Relations
OneBlood

Below is my empirical, 100 percent-non-scientific, gut-level advice based on 20-plus years' experience with donor recruitment.

There are two dimensions to donor recruitment success – recognition and repetition.

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LETTER TO THE EDITOR (continued from page 5)Recognition

Recognition is giving the donor the emotional reward they seek. I believe there are five types of donors, based on motive (i.e., emotional reward):

1. **Honest Altruism** – Folks who truly want to help a fellow human being. Economic motivation or rewards do not motivate them. Providing “impact stories” (how their product helped someone in need) is most effective with this group.
2. **Public Recognition** – Economic motivation or rewards do not work, but social status does. Examples include creating donor “levels,” publishing names in newspapers or newsletters, plaques on the wall, appreciation events, etc.
3. **Heroes** – These folks respond best in a crisis or other high urgency events. These folks usually show up for weather or other natural disasters, terrorism, etc. They can also be motivated to donate if the inventory is low, a holiday is coming up, etc.
4. **Medical Information** – Economic motivation or rewards do not work, but getting medical info (e.g., cholesterol, blood pressure, etc.) does. For these folks, donating blood is a way to get regular and free insight into key health metrics. Plus the mini-physical is further proof they are in good health.
5. **Rewards** – These are the loyalty point “hounds,” who want a reward in exchange for donating blood and are therefore economically motivated. These donors fall into two categories: experiential rewards (e.g., movie tickets) or physical rewards (the typical swag you’ll find in any donor loyalty store).

A good donor loyalty program will address the needs of all the above and allow each type to draw on the benefits that reward them most. Interestingly, many donors fall into multiple categories.

Figure out what type of motive(s) drive each donor and deliver the emotional reward consistently. The old “shotgun” approach works too (deliver all of the above) but in today’s economically constricted blood market, a more targeted reward structure can save big bucks.

Repetition

Touch points = donations. Quantity matters. Call, e-mail, text, tweet, friend, and send postcards in two “modes:”

1. **Retention mode** (the period of time between donation and eligibility) – The goal is to deliver the emotional reward(s) I described previously in “recognition.” Most blood centers go silent when the donor is not eligible, which is unwise. That’s precisely the time to contact your donor – a lot.
2. **Recruitment mode** (the period of time after eligibility and before the appointment) – The goal is to remind the donor of the emotional rewards so they repeat. Again, knowing what motivates will shape the call to action.

Conclusion

Anyone who says donors do not ask “What’s In It For Me” (WIIFM) is wrong. WIIFM applies to all donors, including true altruists. WIIFM addresses a basic human characteristic: as humans, we do (and

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INSIDE ABC (continued from page 6)

repeat) actions that give us a positive experience (see Recognition).

Additional Reading

I believe this article references just about every study ever done on donor recruitment and incentives (that I know of): www.ncbi.nlm.nih.gov/pmc/articles/PMC2847338/ ♦

RESEARCH IN BRIEF

A recent study in *Anesthesiology* suggests that a more liberal transfusion strategy with a higher hemoglobin transfusion trigger is beneficial for cancer surgery patients when compared with a restrictive strategy. A number of studies published over the last several years and recently published randomized controlled trials have suggested that a restrictive transfusion strategy – using a lower hemoglobin threshold – is as effective and safe as a more liberal transfusion strategy. However, because cancer patients are typically not included in these studies, it remains unknown whether a liberal or restrictive transfusion is superior in oncology patients undergoing surgery, many of whom require transfusion. In the current study, Juliano Pinheiro de Almeida, MD, and colleagues of the hospital at the University of Sao Paulo in Brazil, compared the mortality rates and severe clinical complications in high-risk abdominal oncological surgery patients managed using a restrictive or a liberal red blood cell (RBC) transfusion strategy. In their randomized, controlled, parallel-group double-blind superiority trial conducted in the intensive care unit (ICU) of the hospital at the University of Sao Paulo, the authors randomized all adult patients with cancer having major abdominal surgery to receive either liberal transfusion (with a 9 g/dL transfusion trigger) or restrictive transfusion (with a 7g/dL transfusion trigger). The authors enrolled 198 patients in the study – 101 in the restrictive group and 97 in the liberal group. Major complications – including intra-abdominal infections, cardiovascular complications, and 60-day mortality – were nearly twice as common in patients managed with the restrictive transfusion strategy as those managed with the liberal strategy (36 vs. 20 percent). “This study supports a more liberal transfusion strategy in major cancer surgery,” write the authors. The authors note that there are several limitations, including those inherent to a single-center study and lack of long-term follow-up. “Until oxygen delivery can be monitored more precisely, perioperative physicians must rely on a hemoglobin value to ‘safely’ transfuse or not patients during and after surgery. The work by Almeida *et al* supports previous studies, indicating that perioperative anemia is the predictor of mortality in patients with cancer,” writes Juan P. Cata, MD, in an accompanying editorial. “Their work indicates that maintaining a hemoglobin concentration above 9 g/dL is prudent in cancer surgery patients.”

Citations: Pinheiro de Almeida J, *et al*. Transfusion requirements in surgical oncology patients: a prospective, randomized controlled trial. *Anesthesiology*. 2014 Nov 14. [Epub ahead of print]

Cata JP. Perioperative anemia and blood transfusions in patients with cancer: when the problem, the solution, and their combination are each associated with poor outcomes. *Anesthesiology*. 2014 Nov. 5 [Epub ahead of print]

Research presented at the American Society of Hematology’s 56th Annual Meeting in December shows that an investigational drug reduced the need for transfusion in anemic patients with myelodysplastic syndromes (MDS). This new research suggests that treatment with a novel agent could offer

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RESEARCH IN BRIEF (continued from page 7)

an alternate treatment option to erythropoiesis stimulating agents (ESAs) and reduce the burden of regular blood transfusions for anemic patients with MDS. After treatment with sotatercept – a first-in-class activating type 2A receptor fusion protein – 45 percent of 54 evaluable MDS patients experienced either a reduction in the need for transfusions or an increase in hemoglobin levels, reported lead author Rami S. Komrokji, MD, from the Moffitt Cancer Center in Tampa, Fla. Additionally, 19 of the 45 patients considered highly transfusion-dependent experienced a reduction in the need for transfusions after treatment, five of whom became transfusion-independent. This ongoing phase 2 study is evaluating patients with low- or intermediate-risk MDS or non-proliferative chronic myelomonocytic leukemia. The drug was tolerated well, with 20 patients (37 percent) reporting one or more suspected treatment-related adverse event, most commonly fatigue, headache, decreased appetite, and nausea. Dr. Komrokji and colleagues plan to continue the current study and plan to evaluate longer-term treatment in the future. More information is available in an [abstract](#) online.

Citation: Komrokji RS, *et al.* An open-label, phase 2, dose-finding study of sotatercept (ACE-011) in patients with low or intermediate-1 (INT-1)-risk myelodysplastic syndromes (MDS) or non-proliferative chronic myelomonocytic leukemia (CMML) and anemia requiring transfusion. ASH Annual Meeting abstract 3251. 2014 Dec 7.

The January issue of *Anesthesiology* published a clinical commentary about pretransfusion testing and the transfusion of uncrossmatched erythrocytes. Michael L. Boisen, MD, and colleagues of the University of Pittsburgh, review key points related to pretransfusion testing with an emphasis on the electronic crossmatch, as well as the use of uncrossmatched erythrocytes in situations where crossmatch-compatible units are not immediately available for transfusion. The authors discuss preoperative blood orders, emphasizing that the decision to reserve blood for surgical patients should be made preoperatively based on the individual judgment of the physician, the patient's preoperative hemoglobin, and the institution's maximum surgical blood order schedule (MSBOS). They also review the elements of pretransfusion compatibility testing conducted to prevent potentially fatal hemolytic transfusion reactions. "The pretransfusion testing process demands accuracy at each step, and for maximum efficiency should be completed before the day of surgery. For most surgeries, a type and screen is sufficient, particularly given the rapidity with which blood can be issued by blood banks using the computer crossmatch," write the authors. "When crossmatched blood is not yet available, the published experience supports the safety of transfusing uncrossmatched erythrocytes; clinicians should not hesitate to use them when clinically indicated in the management of patients with life-threatening hemorrhage," they conclude. The clinical review is available [here](#).

Citation: Boisen ML, *et al.* Pretransfusion testing and transfusion of uncrossmatched erythrocytes. *Anesthesiology*. 2015 Jan 1. ♦

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 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 Society of Blood Transfusion (ISBT), in collaboration with the International Hemovigilance Network, released a [revised classification system](#) with updated definitions for complications related to blood donation. Working groups from the three organizations revised definitions from the 2008 ISBT standard, which were too general and required information that was difficult to obtain in many places, reported the Dec. 19 *AABB Weekly Report*. AABB has provided the full rationale [online](#). The revisions seek to simplify definitions so they can be applied consistently by many countries and to provide minimal requirements for international comparison that meet the needs of a basic surveillance system. They also aim to suggest additional attributes that can be collected nationally when feasible and to align definitions with those from AABB's Donor Hemovigilance Program so they can be entered into an adapted version of the Donor Hemovigilance Analysis and Reporting Tool (donorHART) software and used for comparison purposes. With these definitions now available, Knowledge Based Systems Inc. has updated donorHART to include the harmonized terminology and definitions. Those who are interested in joining the AABB Donor Hemovigilance Program may contact Barbee Whitaker, PhD, at hemovigilance@aabb.org. America's Blood Centers' Chief Medical Officer Louis Katz MD, notes that the availability of these consensus definitions opens the door to the automation of collecting consistent donor event data, uploading of this data to the ABC Data Warehouse, and broad ABC participation in national and international benchmarking and mitigation efforts – topics that can be considered in the future as the Data Warehouse matures. (Source: AABB Weekly Report, 12/19/14) ♦

REGULATORY NEWS

The Food and Drug Administration recently published two Draft Guidance documents regarding human cells, tissues, and cellular and tissue-based products (HCT/Ps), as well as a proposed rule regarding these products. On Dec. 23, FDA issued the Draft Guidance “[Human Cells, Tissues, and Cellular and Tissue Based Products \(HCT/Ps\) from Adipose Tissue: Regulatory Considerations](#).” The draft guidance is intended to provide sponsors, clinicians, and other establishments that manufacture and use HCT/Ps from adipose tissue with recommendations for complying with the necessary regulatory requirements for HCT/Ps as set forth in the Code of Federal Regulations (CFR). FDA issued this draft guidance in response to numerous inquiries regarding HCT/Ps manufactured from these tissues. Comments on the draft guidance must be submitted by Feb. 23 to www.regulations.gov. More information on submitting comments can be found in the [Federal Register](#) announcement. On Dec. 22, FDA issued the Draft Guidance “[Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products](#).” The purpose of the draft guidance is clarify the interpretation of minimal manipulation criterion and definitions of related key terms as described under Title 21 of the CFR Part 1271.10(a)(1). Comments on the draft guidance must be submitted by Feb. 23 to www.regulations.gov. More information about submitting comments can be found in the [Federal Register](#) announcement. On Dec. 31, FDA issued a [proposed rule](#) to amend certain regulations regarding donor eligibility, including the screening and testing of donors of particular HCT/Ps and related labeling. FDA is proposing this action in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos. Comments must be submitted by March 31 to www.regulations.gov. (Source: FDA draft guidances, 12/31/14, 12/23/14; FDA proposed rule, 12/22/14)

The International Council for Commonality in Blood Banking Automation (ICCBBA) recently announced the release of the new ISBT 128 Product Description Code Database v6.1.0. All databases are listed in the version control sheet, and the new database can be downloaded as a Microsoft

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REGULATORY NEWS (continued from page 9)

Access database. ICCBBA will continue providing the original tables for a period of time to allow software developers to adapt their software to the new tables of the database. The new databases can be downloaded [here](#). The supporting document for the new database is [ST-010](#). New product description codes for medical products of human origin can be requested via their respective request forms found on the ICCBBA website. In conjunction with the Product Description Code Database, ICCBBA has released [Standard Terminology v6.1](#) online. (Source: ISBT 128 e-mail update, 1/5/15)

The Food and Drug Administration recently approved Roche Molecular Systems' biologics license application (BLA) for cobas TaqScreen MPX Test, version 2.0 for use with the cobas s 201 system. FDA approved the use of HIV-1 Group O and M, HIV-2, HCV and/or HBV (HIV-1/HIV-2/HCV/HBV/Multiplex Discriminatory NAT) with the cobas s 201 system, a qualitative in vitro test for the direct detection of HIV-1 Group M RNA, HIV-1 Group O RNA, HIV Type 2 RNA, hepatitis C virus (HCV) RNA, and hepatitis B virus (HBV) DNA in human plasma. The assay both detects and discriminates the target pathogens in a single step using multi-dye technology. This test is intended for use to screen HIV RNA, HCV RNA, and HBV DNA in plasma specimens from human donors, including donors of whole blood, blood components, source plasma, and other living donors. The test is also intended for use in testing plasma to screen organ and tissue donors when specimens are obtained while the donor's heart is still beating. More information can be found in the [FDA approval letter](#). (Source: FDA approval letter, 12/19/14) ♦

THE WORD IN WASHINGTON

The new 114th Congress was sworn in on Jan. 6th, and America's Blood Centers CEO Christine Zambricki, DNAP, CRNA, FAAN, visited Capitol Hill to meet new members of the House and Senate and their staffs and to reconnect with Congressional blood banking friends. Of interest to ABC members, Dr. Zambricki discovered in speaking with Rep. Chris Collins (R-NY-27), that he chairs the board of directors for a company called ZeptoMetrix, which performs quality control testing for blood banks and labs. Due to this experience, Rep. Collins is very knowledgeable about the Food and Drug Administration and blood banking issues. This Congress will differ substantially from the Congress that just adjourned in December. With 61 new members, the new 435-member House will have the largest Republican majority since the 1920s. While the previous Senate had a Democratic majority, the new 100-member Senate will have 13 new Senators and a 54-46 Republican majority, with Republicans chairing all committees and subcommittees. Several deadlines drive Congress' early 2015 agenda. The President's 2016 budget is due to be released in February, a month when homeland security funding expire, prompted by disagreement between congressional Republicans and the Obama Administration over immigration policy. On the last day of March, relief from Medicare "sustainable growth rate" cuts expires, hammering physician specialists and other healthcare providers with Part B payment cuts exceeding 20 percent unless Congress enacts temporary or permanent relief in time (which they do every year, kicking the can forward once again). Uncle Sam's statutory debt limit will be reached later in the spring, prompting another reckoning over paying government bills that Congress has already obligated. See new members of Congress at <http://bit.ly/1AjbdQW>. See all members of the 114th Congress at www.c-span.org/congress/members/.

Most health policy critical to the blood banking community moves through specific congressional committees – and it is critical for America's Blood Centers to get to know members of those committees in the new 114th Congress. This week, the *Newsletter* highlights the key Senate committees with links to each committee roster. Next week, the *Newsletter* will highlight House committees.

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THE WORD IN WASHINGTON (continued from page 10)

- [Senate Finance Committee;](#)
- [Senate Committee on Health Education Labor & Pensions;](#)
- [Senate Veterans Affairs Committee.](#)

ABC advises its member blood centers to review the members of each of these key committees. If you reside or work in their state – reach out and let them know about your blood bank and ABC. ♦

ABC CEO Christine Zambricki Advocates for ABC in Washington



ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, met with several members of Congress this week as the 114th Congress was sworn in on Tuesday. From left to right, Dr. Zambricki met Sen. Gary Peters (D-MI), Rep. Chris Collins (R-NY-27), Rep. John Moolenaar (R-MI-4), (bottom row) outgoing Sen. Carl Levin (D-MI), Rep. Debbie Wasserman Schultz (D-FL-23), and Rep. Debbie Dingell (D-MI-12).



Pictured left, Dr. Zambricki meets with W. Keith Hoots, MD, director of the Division of Blood Diseases and Resources at the National Heart, Lung, and Blood Institute (NHLBI), to brief him on ABC's initiative on the value of blood. Dr. Zambricki also met with Gary H. Gibbons, MD, NHLBI director (right), who provided a comprehensive review during a stakeholder briefing on Wednesday of the Institute's leading edge projects. NHLBI will formally seek ABC's input on NHLBI research priorities in the coming weeks.

GLOBAL NEWS

Recently, the [Alliance of Blood Operators \(ABO\)](#) collected information from seven blood suppliers around the globe about their respective cord blood banking programs. ABO is an international network of non-profit blood services with voluntary non-remunerated blood donor bases, which seek to drive member performance improvement, knowledge exchange, and resolution of issues for the benefit of the patients and health systems they serve. Its members include America's Blood Centers, the American Red Cross, the Australian Red Cross Blood Service, Blood Systems, Inc., Canadian Blood Services, the European Blood Alliance, and the UK's NHS Blood and Transplant. In August 2014, ABO initiated a "Knowledge Exchange" regarding cord blood banking programs on behalf of Canadian Blood Services. Knowledge Exchange allows ABO members to share data, information, and best practices with one another for the betterment of their fellow blood services. Canadian Blood Services is in the midst of building a national public cord blood bank, and for this reason requested information from ABO members about whether their blood service operates a cord blood bank and if so, the staffing model, long-term strategy, the organizational structure, and other elements relevant to cord blood banking. Two ABC member centers responded to the query, one of which was able to provide insights regarding its cord blood bank, which it operates as a department, or additional business line, of the blood center. This center conducts planning for its cord blood bank at a regional level, while certain international blood services reported that cord blood banks can only be operated by a hospital or a university. Canadian Blood Services was able to gain valuable information from this Knowledge Exchange as it continues to grow its cord blood banking program. (Source: ABO Knowledge Exchange, 12/17/14) 💧

INFECTIOUS DISEASE UPDATES

CHIKUNGUNYA VIRUS

A study in *The Lancet* provides early evidence that a new candidate vaccine for chikungunya virus is safe, well-tolerated, and effective. Lee-Jah Chang, MD, of the National Institutes of Health (NIH), and a large team of researchers, conducted a phase 1 clinical trial in which a virus-like particle (VLP) vaccine – VRC 311 – was administered to 25 healthy adults ages 18 to 50 enrolled at the NIH Clinical Center in Bethesda, Md. The primary goal of the dose-escalation, open-label study was to test the safety and tolerability of the vaccine, and the secondary goal was to assess the immunogenicity based on serologic responses. The authors reported that 73 vaccinations were administered, and that all were well tolerated with no serious adverse events reported. Neutralizing antibodies were detected in all dose groups after the second vaccination, and a significant boost occurred after the third vaccination in all dose groups. The authors conclude that this research "represents an important step in vaccine development to combat this rapidly emerging pathogen," but that further studies are needed in larger numbers of participants and in more diverse patient populations.

Citation: Chang LJ, *et al.* Safety and tolerability of chikungunya virus-like particle vaccine in healthy adults: a phase 1 dose-escalation trial. *Lancet*. 2014 Dec 6; 384(9959):2046-52. 💧

GRANT OPPORTUNITIES

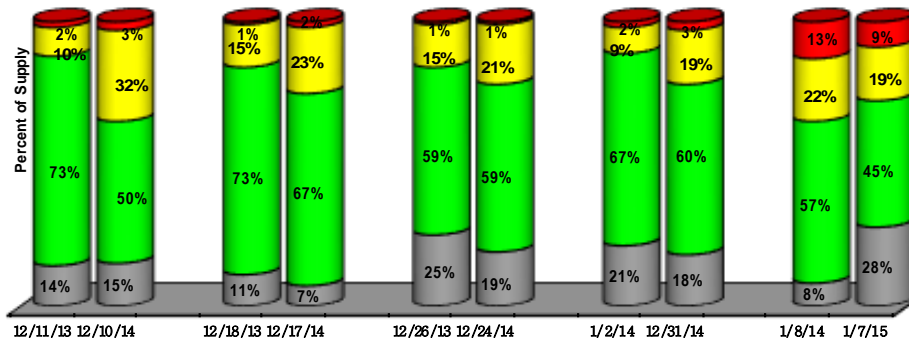
The National, Heart, Lung, and Blood Institute (NHLBI) has joined two other institutes of the National Institutes of Health to offer two funding opportunities in support of research on "New

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GRANT OPPORTUNITIES (continued from page 12)

Technologies for Viral Hepatitis” through its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant programs. These grants – PA-15-076 and PA-15-077 – encourage small business companies to address viral hepatitis research opportunities as delineated in the Department of Health and Human Services Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis. For example, research to develop means of pathogen reduction for blood components that might be practical, particularly for resource-limited countries, as well as research to develop means for rapid, sensitive, and specific detection of hepatitis virus infections among blood donations, would be within the research mission of NHLBI. More information about funding opportunities [PA-15-077](#) and [PA-15-076](#) can be found online. Questions regarding these opportunities can be sent to Shimian Zou, PhD, of NHLBI at (301) 435-0065 or shimian.zou@nih.gov. 💧

STOPLIGHT®: Status of the ABC Blood Supply, 2014 vs. 2015



No Response
 Green: 3 or More Days
 Yellow: 2 Days
 Red: 1 Day or Less

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

MEMBER NEWS

Central California Blood Center recently donated a 23-year-old bloodmobile to the University of Uyo Teaching Hospital in Nigeria, reported *The Fresno Bee* on Dec. 22. The blood center teamed up with Rotary International’s Safe Blood Africa Project to donate the bus and contributed \$5,000 to help pay for it to be trucked and shipped, which will cost about \$14,300. The bloodmobile will be stationed at the teaching hospital in Uyo, which has a blood bank that Rotary International helped establish about a



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MEMBER NEWS (continued from page 13)

decade ago, according to Warren Kaufman, a Rotary Club of Carmel member, who initiated the donation. Prior to the establishment of this blood bank, patients had to rely on donations from relatives, friends, or whomever else they could find to donate blood for payment. In February 2013, Uyo hospital staff traveled to Northern California to be trained on how to use blood donation equipment, an initiative carried out with the help and leadership of member centers of America's Blood Centers. Central California Blood Center President and CEO Dean Eller said he learned Rotary International was looking for a bloodmobile and approached the blood center's board of directors about donating the bloodmobile – called Bus One. “They thought it was a super idea,” he said. “We benefit here in Central California from the generosity of our blood donors and monetary donors. What better way to pay it back or pay it forward.” To read more about Bus One's story and its donation, see [The Fresno Bee](#) article. (Source: The Fresno Bee, 12/22/14)

More than 1,500 blood donors at Lifeblood, Memphis, Tenn., took part in the non-profit's “Bears for Le Bonheur” program, giving blood and platelets in the weeks following Thanksgiving. Donors

were asked to sign a holiday tag that accompanied a stuffed polar bear that will be given to every patient in Le Bonheur Children's Hospital's care for the holidays. Lifeblood employees visited Le Bonheur Children's Hospital on Dec. 16 and delivered the stuffed bears to the hospital's patients. Lifeblood uses this program to boost donations during the winter months, when donations tend to drop off due to the holidays and cold and flu season. “The connection that Lifeblood donors feel to patients is very strong,” remarked Lifeblood's CEO, Susan Berry-Buckley while speaking at Le Bonheur. “We are so fortunate to have people that answer the call when children here need blood.



Lifeblood and Le Bonheur employees pose with the stuffed bears at Le Bonheur during the delivery. Pictured (left to right) are Sarah Smith, Amy Ford, Demetricia Jefferson, Lorie Campbell-Nowlin, Debra Brown, Danny Garrick, Susan Berry-Buckley, Jennifer Balink, Monica Danner, Leslie Poole, Jason Sykes, Jennifer Gladstone, and Thomas Hobson.

This is just one way to show the strength of that connection. We hope that these bears will bring a little cheer to children during their hospital stay this holiday season.” After brief speeches from Ms. Berry-Buckley and Le Bonheur's Thomas Hobson, Lifeblood employees delivered bears to several patients and their families.

The founder of “because I said I would,” Alex Sheen, will speak at a luncheon on Jan. 15 at the DoubleTree Hotel in downtown Chattanooga, Tenn. to benefit the regional blood center, Blood Assurance.

“because I said I would” is a social movement and nonprofit dedicated to bettering humanity through promises made and kept. To encourage positive change and acts of kindness, “promise cards” are sent to anywhere in the world at no cost. More information about “because I said I would” can be found at <http://becauseisaidiwould.com>. Media sponsors WDEF FM Sunny 92.3 and WTVC NewsChannel 9 helped to bring this motivational and inspirational speaker to Chattanooga. More information about the event can be found at www.BloodAssurance.org.



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MEMBER NEWS (continued from page 14)

Blood Bank of Delmarva (BBD) has received licensure application approval from the Food and Drug Administration for Platelet Additive Solution (PAS) platelets for its Christiana Center. This, along with approval earlier last year for PAS platelets at the organization's Dover Center, positions the blood bank to collect and distribute more single donor platelets containing PAS, according to a Jan. 7 press release from the center. PAS replaces 65 percent of plasma that is normally used to store platelets, as reducing plasma volume may reduce the risk of some transfusion reactions. "Some patients who receive platelet transfusions have reactions due to antibodies in the plasma with platelets. By reducing the amount of plasma, you reduce the risk of reaction. Ultimately, I believe a single donor platelet product containing PAS is safer for the patient," said Chris Nare, BBD's lead executive of Laboratory Services & Distribution. "This demonstrates the Blood Bank's continued focus on innovation and providing new products to the community," he added. BBD is currently collecting and supplying PAS platelets within the state of Delaware and with this additional approval will now have more licensed PAS platelets available to distribute to the entire Delmarva region, according to the BBD press release. (Source: BBD press release, 1/7/15) ♦

**COMPANY NEWS**

Vanderbilt University Medical Center and The Royal Children's Hospital (RCH) in Melbourne, Australia recently received Terumo BCT's 2014 Advancing Apheresis Award. Through this program, Terumo BCT funds education grants for the advancement of apheresis. Garrett Booth, MD, MS, an assistant professor at Vanderbilt University Medical Center, and Anthea Greenway, MBBS, FRACP, FRCPA, a pediatric hematologist at RCH, each received \$10,000 for their separate projects. Dr. Booth is researching the potential of a mobile application to educate patients, nurses, clinical providers, and transfusion medicine trainees to raise awareness and understanding of apheresis medicine. Dr. Greenway will use the educational grant funding to establish standard operating procedures for red blood cell exchange at the RCH and improve educational support provided to children with sickle cell disease. More information can be found in the [Terumo BCT press release](#) (Source: Terumo BCT press release, 12/12/14) ♦

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: lnorwood@americasblood.org.

POSITIONS AVAILABLE

Medical Technologist – Manager Technical Operations – Blood Donor Testing (Inova Health System, Sterling, VA). Manager of Technical Operations will oversee ABO and infectious disease testing in a donor laboratory. Ideal candidate will have three years of experience in a donor testing lab as a Medical Technologist. Ideal candidate will have knowledge of FDA donor regulations and donor center software, cGMP (current good manufacturing practices) and knowledge

of lean processes. Ensure quality specimens for laboratory testing. Operates systems/methodologies in order to produce timely and accurate data for donor, QC, and proficiency testing. Reports clinical data accurately and

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POSITIONS (continued from page 15)

efficiently. Knowledge of component preparation and antibody identification necessary. Must be able to demonstrate knowledge of operational and regulatory standards. Requirements: Three years of experience in an accredited donor laboratory. BA/BS degree in Medical Technology or related field required. ASCP Certified Medical Technologist required, specialty in blood banking preferred (SBB ASCP certified). Please apply at www.inovacareers.org – Job ID# 8068BR.

Marketing Director. Community Blood Center of the Carolinas, located in Charlotte, NC is seeking an experienced Marketing Director to oversee all organizational marketing, branding and public communication activities of our growing blood center. Responsibilities include donor and sponsor marketing efforts, website development, social media and print materials, such as newsletters, press releases, etc. Additional duties include developing and maintaining media contacts/opportunities in the Central Piedmont region of the Carolinas. Our ideal candidate has a minimum of five years of experience in marketing and communications, demonstrated creative writing skills and the production of internal and external communications. Email resume and salary requirement to cbccteam@cbcc.us, resumes without salary requirements will not be considered. EOE/Drug Free Work Zone.

National Scientific and Technical Services Roles (Australia). The Australian Red Cross Blood Service is currently seeking a National Scientific and Technical Services Manager and two National Scientific and Technical Services Senior Advisers. These roles, based in Australia, will contribute to the leadership and implementation of scientific and technical processes within the manufacturing division to ensure the reliable, efficient and effective supply of blood and blood products within Australia. The roles require a university degree in science in a biomedical discipline, experience in a senior scientific and technical management role preferably within a manufacturing environment, experience leading and implementing change according to a national agenda and strong analytical and communication skills, including stakeholder engagement experience. Please contact the Australian Red Cross Blood Service before 30th January 2015 for further information international@redcrossblood.org.au.

IRL Technologist. Puget Sound Blood Center is seeking an experienced immunohematology reference Technologist on weekends. Technologists in this lab conduct workups on complex antibody problems and red cell reference testing, prenatal testing, testing for suspected hemolytic transfusion reactions, compatibility testing and antibody titration studies for potential donor/recipient of progenitor cells, bone marrow and solid organ transplants. Technologists also maintain a frozen

red cell inventory consisting of rare antigen negative units. Requirements include: BS CLS/MT or equivalent, MT(ASCP) or equivalent certification and two years of immunohematology reference laboratory experience. SBB(ASCP) strongly preferred. More information at www.psbcc.org. Qualified applicants send resumes to humanresources@psbc.org Attention: Job #7429ABC. Puget Sound Blood Center is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law.

Laboratory Technologist II. Duke University Health System, a progressive facility located in the heart of North Carolina, currently has a full-time position available for a Certified Medical Technologist on third shift in Transfusion Service. Applicants must possess a desire to become an integral member of a team providing blood products at a level I trauma center to patients in a safe, efficient manner. Strong interpersonal, written and verbal communication skills as well as the ability to solve problems are a must. Applicants must have a Baccalaureate Degree (preferably from a Clinical Lab Science program) and certification by a nationally recognized agency at the technologist level. Technologists perform complex serological testing using solid phase technology and prepare blood components for a diverse patient population. New grads welcome to apply. Relocation assistance is available. Duke University Health System offers an excellent working environment with a competitive salary and comprehensive benefits package. The Raleigh/Durham/Chapel Hill area offers broad academic, cultural and leisure opportunities. For more information, contact Mary Lee Campbell via e-mail at mary.campbell@duke.edu or call (919) 668-2236. More information is available at our website at www.hr.duke.edu. Duke University is an equal opportunity affirmative action employer.

Lead Blood Collection Technician/Glen Mills, PA. This is an opportunity to join a 60-year-old non-profit organization with a state-of-the-art blood collection center, and a history of investing in their valued employees. We seek a caring professional to join a team of life savers as a Lead Blood Collection Technician for their new facility located in Delaware County, PA. The Lead Blood Collection Technician is the face of the Blood Bank and sets the stage for a positive experience for the donor. Will greet donors and perform eligibility interviews, and monitors progress during the procedure. Will serve as a consultant to the staff, and assist other Blood Collection Technicians with difficult sticks and needle adjustments. Must also monitor for errors and adjust accordingly, and oversee work and donor flow.

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POSITIONS (continued from page 16)

Candidates must have one of the following: RN (licensed in PA), Medical Laboratory Technician (MLT), A.S. Medical Technology (MT), or ASCP certification with four years of blood bank experience. This position offers first class benefits including 401K, Tuition Reimbursement, Pension Plan, 100% paid dental and work life balance. For immediate consideration, please submit your resume to: lifesaver@thebigroup.com.

Supervisor, Blood Collection (Wilmington, DE). Join a 60 year old non-profit organization whose mission is saving lives one stick at a time. Working out of the Wilmington site, the Supervisor is accountable for management of employees in Blood Bank Donor Services with a new facility located in Glen Mills, PA. This individual is responsible for coaching, mentoring and supporting staff to meet performance standards. He/she is responsible for managing blood collection activities and monitoring technical compliance with SOP's, FDA, and AABB regulations. Additionally he/she manages projects, assists with the development and review of SOP's, oversees the deployment of new technology and procedures. Candidates must have one of the following educational requirements: RN, Medical Laboratory Technician (MLT), B.S. Medical Technology (MT), or an active ASCP certification. Additional requirements include four plus years of blood bank experience and one year in a leadership role. Ideally candidates will have a working knowledge of apheresis techniques, equipment and supplies. This position offers first-class benefits including 401k, Tuition Reimbursement, Pension Plan, and 100 percent paid dental. For immediate

consideration please submit your resume to: lifesaver@thebigroup.com.

Marketing and Communications Manager. We are seeking a highly motivated, independent leader with well-developed skills in marketing and media activities, public relations, event planning and customer service strategic planning. If you are a goal driven, results oriented leader with excellent time management skills, this position may be for you. Successful candidates will possess: Ability to develop a strong networking base in California and Nevada to assist with awareness, outreach, and collaboration. Ability to serve as spokesperson for the District. Ability to create and manage a vision for the customer service component of a non-profit blood center. Exceptional skills in determining marketing needs and analyzing opportunities. Bachelor's degree or equivalent combination of education and experience required. Must have three years related experience, two years supervisory experience, and a valid driver license with an acceptable driving record. Blood bank or other non-profit experience helpful. Position based out of Ventura, CA. Please mail resume to: United Blood Services, Human Resources Department, 4119 Broad Street, Suite 100, San Luis Obispo, CA 93401. United Blood Services is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected veteran status. ♠