

# A B C N E W S L E T T E R

ABC Value of Blood Whitepaper Published

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#### 2019 #29

#### August 30, 2019

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Recognizing the vital role that independent community blood centers and blood components play in the U.S. healthcare system remains a priority of America's Blood Centers (ABC) and its advocacy efforts on behalf of its member blood centers. Declining margins and a reimbursement model that neither accurately reflects the full value of a robust blood supply nor promotes investment in innovation are both obstacles that continue to impact the blood banking community as a whole.

To assist with changing this paradigm, thanks to a collaborative

# Value of Blood to the U.S. Healthcare System





effort from the ABC Public Policy Council and the Scientific, Medical, and Technical (SMT) Committee, the <u>Value of Blood to the U.S. Healthcare System</u> whitepaper has been published to serve as a resource for member blood centers' education, advocacy, and awareness activities, while prioritizing the important work of blood centers in ensuring that a safe and robust blood supply is available when needed.

The paper addresses the resiliency of the blood supply and describes how "[m]ore than 11 million transfusions occur in the U.S. every year however, little attention is given to the requirement for a ready-to-use supply of blood. A more thorough recognition of the value of blood will drive allocation of adequate resources for a robust, safe blood supply and sustain the blood community's infrastructure, personnel, and ability to innovate and adopt new technologies." It explores a variety of topics that include:

- current challenges;
- safety of the blood supply;
- the clinical value of blood;
- areas of needed research;
- the insurance value of blood; and
- supporting a robust blood supply.

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#### <u>Value of Blood Whitepaper Published</u> (continued from page 1)

The authors conclude that "[t]he value of transfusion to patient care cannot be overestimated. We believe that concerted action in the blood and clinical communities, and those agencies of the federal government that regulate and reimburse for blood products, is urgently needed to ensure the sustainability of this resource so that it remains available for those whose lives depend on it." The contributors to this whitepaper included:

- Marsha Bertholf, MD;
- Richard Gammon, MD;
- Christopher Gresens, MD;
- Louis Katz, MD;
- Susan Rossmann, MD;
- Todd Straus, MD;
- Nancy Van Buren, MD; and
- ABC Staff.

ABC members can learn more about additional ways to use this whitepaper as a resource in <u>MCN 19-062</u>. For questions or feedback, please contact ABC's Director of Quality Service <u>Toni Mattoch</u>.

(Source: MCN <u>19-062</u>, 8/30/19)



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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

#### America's Blood Centers

Chief Executive Officer: Kate Fry Chief Medical Officer: Rita Reik Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

Send subscription queries to <u>Imaundy@americasblood.org</u> America's Blood Centers 1717 K St. NW, Suite 900, Washington, DC 20006 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>.



### ABC Continues Advocacy Efforts on Bacterial Risk Control Draft Guidance

America's Blood Centers (ABC) has submitted additional feedback in response to the December 2018 U.S. Food and Drug Administration (FDA) <u>draft guidance</u> entitled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion." These comments "represent significant operational concerns" that independent community blood centers have shared with ABC and stress the need for the agency to consider more strategies to prevent the potential for unintended consequences from the guidance to put patients at risk.

The <u>comments</u> in their entirety are available to ABC members. Please contact ABC's Senior Director of Federal Government Affairs <u>Diane Calmus</u>, JD with questions or more feedback.

(Source: MCN <u>19-061</u>, 8/29/19) •

#### **REGULATORY NEWS**

The Office of the Assistant Secretary for Health (OASH) in the U.S. Department of Health and Human Services (HHS) has <u>published</u> a "Request for Information: Regarding Revisions to the U.S. Public Health Service (PHS) Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation. The agency is requesting review and public comments for proposed changes to the current <u>Guideline</u> that aimed to improve patient safety by reducing disease transmission through organ donation. In April, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) made several recommendations to HHS to the Guideline. Based on the committee's feedback, the agency is considering:

- 1. "Test all organ donors for HIV, HBV, and HCV using serological tests (including total antibody to hepatitis B core antigen [total anti-HBc], hepatitis B surface antigen [HBsAg], and hepatitis C antibody [anti-HCV]) and nucleic acid tests (NAT).
  - a) For living potential donors, testing should continue to be performed as close as possible to the surgery, but at least within the 7-day time period prior to organ recovery.
  - b) For deceased donors, the donor specimen should be collected within 72 hours prior to organ recovery with results of these screening tests available at the time of organ recovery. If the donor sample used for testing was collected more than 24 hours prior to organ recovery, an additional donor specimen should be collected in the immediate 24 hours prior to organ recovery and tested for HIV, HBV, and HCV by NAT. Results of these screening tests should be made available as soon as possible, even if these results might not be available at the time of organ recovery.
- 2. Regardless of donor risk profile for HIV, HBV, or HCV, transplant programs should test all organ recipients:
  - a) Before transplantation for HIV, HBV, and HCV using NAT and serologic tests including total anti-HBc, HBsAg, anti-HCV, and hepatitis B surface antibody (anti-HBs);
  - b) At 4-6 weeks following transplantation for HIV, HBV, and HCV (with NAT); and
  - c) At 12 months following transplantation for HBV (with NAT).
- 3. OPOs should ascertain whether any of the following medical or social risk criteria were present in potential organ donors within 30 days prior to organ recovery:
  - a) Sex with a person known/suspected to be HIV, HBV, or HCV infected
  - b) Being a man who has had sex with another man
  - c) Sex in exchange for money/drugs
  - d) Non-medical drug injection



#### **<u>REGULATORY NEWS</u>** (continued from page 3)

- e) Sex with a person with history of non-medical drug injection
- f) Incarceration for >72 consecutive hours
- g) Child breastfed by a mother with HIV
- h) Child born to a mother with HIV, HBV, or HCV
- 4. OPOs should identify donors for whom medical and social history is unknown at the time of organ recovery, which is also considered a risk criterion. When donors with ≥1 of the criteria as specified under #3 are identified, OPO's should communicate this information to the appropriate transplant centers. Transplant centers should discuss this information with transplant candidates and families as part of transplantation-related informed consent discussions. Transplant centers should make efforts to contextualize these discussions and should include the following:
  - a) The risk of undetected HIV, HBV, or HCV infection is very low
  - b) Recipients are universally tested for HIV, HBV, and HCV after transplantation and should transmission occur, effective therapies are available
  - c) Recipients may have a higher chance of survival by accepting organs from donors with risk factors for HIV, HBV, and HCV compared with waiting for an organ from a donor without recognized risk factors
- 5. Remove any specific label (e.g., "increased risk donor") to describe donors with risk factors for undetected HIV, HBV, or HCV infection, with inclusion of additional strategies to enhance recipient safety.
- 6. No requirement for specific informed consent with recipients who are considering acceptance of these organs, though recipients would still be informed of certain donor risk factors.
- 7. All organ transplant candidates should be vaccinated for HBV per previous recommendations (<u>https://doi.org/10.1111/ctr.13563</u>).
- 8. HHS proposes no additional substantive changes to the following sections of the 2013 PHS Guideline:
  - a) Collection and/or storage of donor and recipient specimens
  - b) Tracking and reporting of HIV, HBV, and HCV infection in donors or recipients."

Additional information including the full request for information is <u>available</u> in the *Federal Register*.

(Source: *Federal Register*, 8/27/19)

The U.S. Food and Drug Administration (FDA) approved the biologics license application (BLA) of Bio-Rad Laboratories for the Geenius<sup>™</sup> HIV 1/2 Supplemental Assay. Under this license, FDA authorizes the company to manufacture the product which is a single-use immunochromatographic assay that is "intended for use as an additional, more specific test for human serum and plasma samples with repeatedly reactive results by an FDA licensed blood donor screening test for antibodies to HIV-1/HIV-2." More information can be found in the FDA approval letter and on the FDA website.

(Source: FDA BLA Approval Letter, 8/26/19) •

#### 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 and published after editorial review. Please send letters to the Editor at <u>newsletter@americasblood.org</u> or fax them to (202) 899-2621. 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.

## Maintaining A Balance of Donor Eligibility and Recipient Safety

#### Contributed by Richard Gammon, MD, Medical Director at OneBlood

\*\*Please note: The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers.\*\*

Two articles recently published in *Vox Sanguinis* study the safety of the donor and the recipient respectively. The donor safety article discussed the avoidance of risk for allogeneic transfusions in healthy bone marrow (BM) donors by collecting 1 to 2 preoperative autologous blood donations (PAD) before the BM harvest. Donors received oral ferrous sulphate and folate supplementation prior to PAD. The minimum interval between two PADs was seven days; the minimum interval between the last PAD and BM harvest was seven days. The study analyzed the hematological parameters in BM donors before and after the harvest to assess the efficacy of this practice in limiting the post-harvest anemia. Overall, 102 consecutive donors underwent BM harvest preceded by one (26 cases) or two PAD (76 cases), which were infused during BM collection. This study found that PAD induced a significant decrease in hemoglobin (Hb) from a median 14.6 g/dl to 12.9 g/dl (P < 0.0001) in all donors. The lowest Hb level was recorded after BM harvest (median 10.5 g/dl) and the decrease was still evident one week after BM collection (median 12.2 g/dl). The PAD-related Hb decrease was independent of sex or number of PAD, and inversely related to the time elapsed from first or last PAD. The BM harvest produced an additional Hb decrease, accounting for a median Hb loss of 18.9 percent. A Hb concentration between 7 and 8 g/dl was recorded in two female donors receiving one PAD and in three donors (two females and one male) receiving two PAD. No donor required allogeneic transfusions. The authors conclude that the data showed that two PAD did not carry any advantage over one PAD. As with any autologous donations, a benefit of PAD could only be achieved if an adequate interval between PAD and BM harvest elapsed. They recommend prospective randomized studies to establish if there remained a role for PAD in BM donors.

The second article from Australia began with a discussion of the conflicting evidence in the literature regarding whether a blood-borne virus (BBV) risk associated with tattoos in licensed facilities exists. Currently, blood donors in Australia are deferred from blood donation for four months after any tattoo. The study aimed to assess the incidence of BBVs in blood donors who stated they received a tattoo and evaluated the risk to blood safety through risk modelling. Donors from 2013 to 2016 with a tattoo deferral with preand post-BBV testing were analyzed to determine incidence of BBVs. This was compared to a 2014 cohort of whole blood donors with a deferral of 4 months due to travel to a malaria endemic area. This group was chosen as it provided a large number of donors subject to a similar deferral period (four months). Using the incidence of tattoos and BBV risk, the total residual risk estimate of allowing tattooed donors to be reinstated was calculated. The incidence rate of BBVs in blood donors following tattoo deferral was 13.26 per 100,000 person-years (all were males with hepatitis C virus) compared to 9.26 per 100,000 in blood donors following malaria risk deferral. Risk factor reporting for the three HCV infections that occurred in the tattoo deferral cohort indicated one donor whose only significant disclosed risk factor was tattooing and acupuncture in licensed facilities in Australia, with the two other donors reporting additional undeclared intravenous drug use and sexual contact with a HCV positive partner, respectively. If these risk factors were taken into consideration, the risk in tattoo donors decreased to 4.4 per 100,000 person-years. The total residual risk calculation if Australian donors with a tattoo were allowed to donate was estimated at 1 in 34 million. The authors conclude that this minimal residual risk should allow for elimination of this deferral.

**Citations:** Teofili, L., Valentini, C.G., Bianchi, M. Preoperative autologous blood donation in adult bone marrow donors: reappraisal of a single-centre experience. *Vox Sanguinis*. 2019. Doi: <u>10.1111/vox.12834</u>.

Hoad, V.C., Guy, R.J., Seed, C.R. Tattoos, blood-borne viruses and blood donors: a blood donor cohort and risk assessment. *Vox Sanguinis*. 2019. Doi: <u>10.1111/vox.12832</u>.





#### **BRIEFLY NOTED**

**ABC** Newsletter

The leadership of the Chilled Platelet Study (CHIPS) is having a clinical site recruitment meeting at the 2019 AABB Annual Meeting. CHIPS (CHIlled Platelet Study) is a 1,000-patient randomized controlled trial funded by the Department of Defense and is expected to start by August 2020. The trial will test the hypothesis that platelets stored at 4C reduce bleeding compared to room temperature stored platelets in actively bleeding cardiac surgery patients. The trial will include both children and adults and will use an adaptive design to determine the optimal storage duration of 4C platelets. If you are interested in hearing more details or have questions, you are invited to join CHIPS leadership on Monday, October 21st from 3:30 pm-4:30 pm in Crockett room C/D at the Grand Hyatt in San Antonio, Texas. If you are not attending AABB this year, you are encouraged to share this information along with anyone who may be interested in involving their site in this trial.

#### (CHIPS Announcement, 8/27/19)

**September is National Sickle Cell Awareness Month.** This year's theme for the Sickle Cell Disease Association of America, Inc. (SCDAA) is "Sickle Cell Matters." Additional information and resources are available on their <u>website</u> to help raise awareness and the need for research to treat Sickle Cell Disease. SCDAA has created multiple hashtags that it is encouraging partners, advocates, and supporters to use throughout the month on their social media channels:

- #SickleCellMatters
- #2019AwarenessMonth
- #SCDAA2019AwarenessMonth
- #SCDSCTMatters

(Source: SCDAA Website, 8/29/19)

#### Letter to the Editor – Immunoglobulin Therapies and Plasma Donation

\*\*Please note: The views/comments expressed in submitted letters from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers.\*\*

Dear Editor,

Considering recent media reports, PPTA appreciates the opportunity to provide information regarding immunoglobulin therapies and plasma donation. We are aware there are some patients who are not able to access their prescribed therapies and is working with members, patient advocacy groups, and regulatory agencies to better understand the situation and to help identify solutions. Ultimately, our mission focuses on ensuring patients have access to life-saving plasma protein therapies, and that drives the work of every member of our staff every day.

At PPTA, we know that plasma donors save lives, and we are grateful to every healthy and dedicated plasma donor – whether compensated or not – who commits to helping people with rare, serious, and often life-threatening conditions to live healthy, normal lives. In fact, plasma collections have <u>steadily increased</u> in the U.S. for at least the past decade, more than doubling since 2011 to reach nearly 49 million individual collections last year alone.

In response to recent reports of patients not accessing their therapies, PPTA has sought to be a trusted

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Letter to the Editor -Immunoglobulin Therapies (continued from page 6)

source of information and has created a range of <u>materials</u> that help illustrate the growth in plasma collections – the essential starting material for plasma-derived medicines – as well as the increase in the distribution of finished therapies. Just as importantly, we are seeking to help people understand the multiple variables that impact patient access to subcutaneous- or intravenous-administered immunoglobulin products, including government policies, physician and pharmacy protocols, manufacturer issues, distributor issues, and/or growing clinical need.

PPTA and America's Blood Centers are each working to ensure individuals who rely on IG therapies have access to their medicines. I look forward to working in partnership with each other so those seeking information receive the most relevant information and guidance from appropriate subject matter experts.

Sincerely,

Amy Efantis President & CEO Plasma Protein Therapeutics Association •

#### **MEMBER NEWS**

**Blood Bank of Delmarva** held a ribbon cutting ceremony on August 29<sup>th</sup> to unveil a new bloodmobile thanks to Discover Bank, Longwood Foundation, and the Delaware Community Foundation's commitment to increase blood donations across the state as part of the state's "Pay for Success" initiative. "Discover Bank is honored to join forces with these esteemed organizations to provide Delaware with a program that will do so much good for the community," said Jim Roszkowski, president of Discover Bank in an announcement by the blood center. Earlier this year, Delaware Governor John Carney <u>visited</u> the Blood Bank of Delmarva to sign "Pay for Success" legislation from the Delaware General Assembly to promote private funding for economic development and social impact initiatives.

Photo courtesy of Blood

(Sources: Blood Bank of Delmarva Announcement, 8/29/19; Delaware News, 8/8/18) ♦

Bank of Delmarva

# Upcoming ABC Webinars – Don't Miss Out!

ADRP Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers Webinar – September 12 at 2 pm EDT. Register <u>here</u>!

#### **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 and published after editorial review. Please send letters to the Editor at <u>newsletter@americasblood.org</u> or fax them to (202) 899-2621. 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.





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 Seeks BPAC Nominations and Feedback on Committee Structure**

America's Blood Centers (ABC) is seeking member input on the U.S. Food and Drug Administration's Blood Products Advisory Committee (BPAC). Specifically, we are looking for member suggestions on the on both the committee structure as well as the names of individuals you believe ABC should consider nominating for both the industry representative(s) and general committee positions. Please send any feedback to me by September 18<sup>th</sup> to ABC CEO <u>Kate Fry, MBA</u>. Additional details are available to ABC members in <u>MCN 19-059</u>.

(Source: MCN <u>19-059</u>, 8/22/19)

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#### August SMT Journal Club Webinar Recording Available

A recording of the ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar from August 19<sup>th</sup> is available to ABC members. The webinar explored:

- Financial impact of alternative approaches to reduce bacterial contamination of platelet transfusions (*Transfusion*);
- <u>Response to random apheresis platelets versus HLA-selected platelets versus pooled platelets in</u> <u>HLA-sensitized patients</u> (*Transfusion*); and
- <u>Platelets stored in whole blood at 4 C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function (*Transfusion*).</u>

Additional details including the presentations and a playback of the webinar are available to ABC members in MCN <u>19-060</u>.

(Source: MCN <u>19-060</u>, 8/26/19)

#### ADRP Webinar: Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers

<u>Register</u> today for the Thursday, September 12<sup>th</sup> ADRP Webinar entitled "Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers." This webinar will take place at 2 p.m. eastern and feature Mary Townsend, MD senior medical director at Vitalant. Attendees will receive information on research regarding vasovagal reactions and be presented with recommendations to prevent and manage these reactions in teenage donors. This webinar is designed for recruitment, collections, and medical personnel. ADRP subscribers may register for free and non-subscribers can participate for \$25.

(ADRP <u>Announcement</u>, 8/12/19) •

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#### **GLOBAL NEWS**

The National Blood Transfusion Service (NBTS) in Nigeria and transport partner LifeBank, a blood and oxygen delivery company, have collaborated with Google Nigeria to help get blood products to patients in need at hospitals in Abuja and Lagos. Leveraging and integrating Google Maps technology into its mobile application, LifeBank has been able to reduce the amount of time it takes to deliver blood to 45 minutes, a process which previously could take as long as 3 hours. "LifeBank's system shows just how much magic can happen when universally accessible tools and information meet human creativity, aspirations, and



Photo courtesy of CNN & LifeBank

resilience," <u>said</u> Mojolaoluwa Aderemi-Makinde, Google's Africa marketing lead in a statement to CNN. LifeBank drivers navigate Nigeria's roadways via motorbikes with blood stored in a cold chain transport box. The company was founded by Temie Giwa-Tubosun, who was inspired by a personal connection to blood donation due to complications she suffered while giving birth to her son, "I realized after I had my son that the highest cause of maternal mortality is postpartum hemorrhage, the most important thing you can do when a mum is hemorrhaging is replace the blood she has lost, even if you can't stop the bleeding."

(Source: CNN, This company is powering blood donations in Nigeria through Google maps, 8/23/19)

| Meeting/Workshop           | Dates                                   | Location            | Hotel                           | Registration Dates<br>& Fees |
|----------------------------|---|---------------------|---------------------------------|------------------------------|
| 2020 ABC Annual<br>Meeting | March 9 <sup>th</sup> -11 <sup>th</sup> | Washington,<br>D.C. | Ritz-Carlton<br>(Pentagon City) | More details coming soon!    |
| ADRP 2020<br>Conference    | May 19th-21st                           | Phoenix, Ariz.      | Hyatt Regency                   | More details coming soon!    |

Non-members may attend all events; information will be updated on ABC's Public Site.

#### CALENDAR

*Note to subscribers:* Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (<u>lmaundy@americasblood.org</u>) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

#### 2019

Sept. 13. Carter BloodCare 2019 Enrichment Lab, Euless, Texas. A continuing education program designed for medical technologists and clinical laboratory specialists, interested in transfusion medicine. Attendees can earn up to 6 hours of P.A.C.E.® credit. More details available <u>here</u>.

Sept. 19. National Institutes of Health Clinical Center Immunohematology and Blood Transfusion 38<sup>th</sup> Annual Symposium, Bethesda, Md. More details available <u>here</u>.

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<u>CALENDAR</u> (continued from page 9)

Sept. 20. Red Cell Genotyping 2019: Patients First, Bethesda, Md. This 9th annual symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. More details available <u>here</u>.

Sept. 23-25. The MedTech Conference, powered by AdvaMed, Boston, Mass. More details available here.

Oct. 15-16. Biomedical Advanced Research and Development Authority Industry Day 2019. Washington, D.C. More details available <u>here</u>.

Nov. 12-14. U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md. More details available <u>here</u>.

#### 2020

Jan. 15-16. IPFA/EBA Workshop on Plasma Collection, Location to be announced. More details available here.

Mar. 9-11. 2020 ABC Annual Meeting, Washington, DC. More details coming soon.

Mar. 25-26. IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand. More details available here.

May 13-14. IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal. More details available <u>here</u>.

May 19-21. 2020 ADRP Conference, Phoenix, Ariz. More details coming soon.

#### **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) 899-2621; e-mail: <u>lmaundy@americasblood.org</u>.

#### **POSITIONS**

Donor Services Director. Stanford Blood Center, a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation medicine by advancing science and technology. For more information, visit http://bloodcenter.stanford.edu/. We are seeking a Donor Services Director. Under the general operational direction of the Chief Operating Officer and the technical direction of the Medical Director, the Donor Services Director will set the strategy, goals, objectives and structure of Donor Services. Core Duties: Responsible and accountable for management, supervision, and coordination of day-to-day operations of departments involving donor collections and donor recruitment at a number of fixed sites and mobile locations. Responsible for using frequently changing customer utilization patterns to make decisions regarding staffing, center hours, and expenditures for areas of responsibility, coordinating with upper management for other operational areas. Oversee implementation of policies and procedures and assure that employees understand and adhere to established policies and procedures. Qualifications: Four-year college degree required; RN license, medical technologist license or MBA preferred. Five years of progressively responsible

management experience and demonstrated ability to effectively manage several functions required. For complete job description and to apply visit <u>https://www.stanfordhealthcarecareers.com/</u> and reference job #53086.

Chief Operating Officer. Stanford Blood Center (SBC), a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation medicine by advancing science and technology. For more information, visit http://bloodcenter.stanford.edu/. We are seeking a Chief Operating Officer. Under the general direction of the SBC Executive Director, and technical direction of the Medical Director, is responsible for the administrative and technical management of Blood Center operational departments. Core Duties: Lead annual operations planning to establish goals and metrics for blood collection, testing, manufacturing and distribution. Manage department heads and supervisors to develop, evaluate and adjust organizational structures and systems to assure accomplishment of Blood Center mission(s) in

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#### POSITIONS (continued from page 10)

the most effective and economical manner. Perform long range policy, personnel and fiscal planning for blood operations. Participate in, and analyze, budget preparation for the Blood Center. Authorize expenditures of approved funds. Recommend reallocation of funds based on spending trends and projections and program requirements. Qualifications: Bachelor's degree in Business Administration, public health or related field required. Minimum of five years blood bank or health care experience required. For a complete job description and to apply , please visit <u>https://www.stanfordhealthcarecareers.com/</u>, and reference job #52722.

Director of Donor Services. Houchin Community Blood Bank (HCBB) is seeking a highly motivated individual who is responsible for management and operations of Donor Services department. The department is responsible for blood donor registration, eligibility screening, and phlebotomy for whole blood and apheresis donations. Director will lead a team of 30 plus staff at two blood donation centers in Bakersfield and blood drives covering over 8,000 square miles of Kern County. Director will coordinate with HCBB's Quality and Process Improvement department to ensure that Donor Services operations are in compliance with regulations set by the Food and Drug Administration, State of California, and American Association of Blood Banks. Director will coordinate closely with HCBBs Community Relations team who are responsible for organizing mobile blood drives and events. This ideal candidate will have a bachelor's degree in science, medicine, or operations management related fields. Ten plus years supervisory experience in operations management, preferably blood bank or hospital setting. Exceptional customer service, multi-task, work independently, excellent written and oral communication skills, extremely organized, and creatively and effectively solve problems. Send resumes to careers@hcbb.com.

Director, Blood Collection Operations (The Community Blood Center, Appleton, WI). Are you looking for a meaningful career creating a culture of highly engaged staff, collaborating to provide customers with exceptional service? Our organization is looking for a dynamic leader for our blood collection team. You will coach and engage a team of 60 staff, create and implement systems and processes to provide outstanding service and be part of a team of professionals united in the mission of Connecting Lives | Sharing Life. Responsible for oversight of the activities of Collections staff and ensuring all processes are compliant and safe. Oversight consists of allocation of resources, monitoring, correcting, improving and updating all technical, regulatory, administrative, and personnel functions. Responsible for accomplishment of key department and organizational objectives including assigned goals, operational productivity targets, compliance measures and staff engagement metrics. Ensure

compliance with quality control functions, documents and industry regulations. Develop plans to maintain or adjust operations as needed based on financial forecasting. Requires a bachelor's degree and 10 years management experience, ideally with increasing levels of responsibility. Medical background or blood center experience desired. Excellent leadership, staff development and team building skills. High level of data analysis skills. How to apply: <u>https://www.communityblood.org/careers</u>.

Medical Apheresis RN/Nurse (Houston, Texas). Gulf Coast Regional Blood Center is looking for a Medical Apheresis RN/Nurse for its newly expanded, state-of-theart apheresis center. This person is responsible for patient/donor care during apheresis procedures and must be able to apply the nursing process with patients and donors. Duties include assisting in the development of new procedures, performing required equipment maintenance, evaluating and maintaining technical procedures, communicating with physicians regarding patient status, remaining current on national standards and trends in the area of apheresis and making appropriate suggestions as to necessary changes or updates, maintaining all records required by AABB, FDA and other accrediting agency or vendor standards, participating in management and coordination of clinical research studies if necessary. Qualifications for this position are: a graduate degree from an accredited School of Professional Nursing, a current RN license, three years of recent direct patient care nursing experience (preferably in an acute-care setting), demonstrated proficiency in peripheral intravenous access, certification in Basic Life Support or ACLS (Advanced Cardiovascular Life Support). For more information or to apply, click here. Contact name, address and telephone number: Tracy Reynolds Talent Acquisition Manager, 1400 La Concha Lane, Houston, Texas 77054-1802; Phone: (713) 791-6395.

Medical Technologist II - San Francisco, CA (Reg:191052). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Founded in 1943, Vitalant is one of the nation's oldest and largest nonprofit transfusion medicine organizations. Bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years' experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Please click here to apply.

#### <u>POSITIONS</u> (continued from page 11)

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, earlyor mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and parttime staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Core Duties include: Review validation plans, procedures, training documents, PDIF records, product and equipment QC for regulatory compliance and assist with development and training as necessary. Develop, perform and generate departmental reports and system audits. Develop, revise, institutional QRA SOPs and training. Perform GMP, QRA and safety training. Perform trend analysis of events, complaints, and quality indicators with subsequent performance of root cause analysis, and process improvement. For complete job description and to apply, visit www.stanfordhealthcarecareers.com and reference job # 51343.



Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefit package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our Careers page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.