

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2018 #14

April 27, 2018

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CMS Releases 2019 IPPS Proposed Rule

This week, the Centers for Medicare and Medicaid Services (CMS) has published the 2019 Inpatient Prospective Payment System (IPPS) proposed rule. The agency believes the changes in the proposed rule will promote improved accessibility for patients to hospital price information and electronic health records.

The proposed rule would result in a \$4.1 billion increase in Medicare patient funding for hospitals according to a report in *Modern Healthcare*. Additionally, hospitals would now be required to post standard charges, a change from previous requirements that allowed hospitals to choose either listing such charges or providing them to the public if requested.

"We seek to ensure the healthcare system puts patients first," said Administrator Seema Verma in a news <u>release</u> issued by CMS. "Today's proposed rule demonstrates our commitment to patient access to high quality care while removing outdated and redundant regulations on providers. We envision a system that rewards value over volume and where patients reap the benefits through more choices and better health outcomes. Secretary Azar has made such a value-based transformation in our healthcare system a top priority for [the Department of Health and Human Services], and CMS is taking important, concrete steps toward achieving it."

America's Blood Centers is in the process of fully reviewing the proposed rule for its potential impact on member blood centers and will provide updates and report on any implications in a timely manner. Comments on the proposed rule are open until June 25th. Additional information, including a <u>fact sheet</u> on the proposed rule is available on the CMS website.

(Sources: CMS News <u>Release</u>, 4/24/18; *Modern Healthcare*, <u>CMS urges hospitals</u> to disclose prices, revamps meaningful use program, 4/24/18) ♦

Light at the End of the AIDS Tunnel?

Little has greater impact on the blood community than the explosion of the HIV/AIDS epidemic and its penetration of the donor base and recipients in the early 1980s. Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, an HIV/AIDS investigator and longstanding advocate, has summarized what he believes will be required to end the pandemic. Dr. Fauci dichotomizes the needed initiatives into individual and global strategies.

(continued on page 2)

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AIDS TUNNEL (continued from page 1)

The former (individual strategies) relates, largely but not exclusively, to developing and deploying the processes and resources needed to identify individual HIV infections and initiate and sustain antiretroviral therapy for infected patients that will render them noninfectious (i.e. "treatment as prevention"). Continued research to optimize and simplify effective regimens is key here. Preexposure prophylaxis (PrEP) is a second proven tactic for individuals at risk for which priority and funding will be critical. Global strategies are the development and implementation of the infrastructure needed to attain articulated goals like those of the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 goals: diagnosing ≥90 percent of HIV infections globally, providing effective, affordable, tolerable antiretroviral therapy to 90 percent of those infected, and achieving effective viral suppression in 90 percent of those treated patients by 2020.

Progress is lagging on this timeline and on the "grail" of an effective vaccine. According to the authors, persistent "challenges include structural, legal, and social barriers resulting in inequalities of access to and uptake of HIV testing and treatment; lack of retention in care; social networks; stigma and discrimination; poor adherence to PrEP; limited access to special populations; and difficulty meeting the UNAIDS targets for enrolling persons living with HIV into treatment programs."

Citation: Eisinger, R.W. and Fauci, A.S. Ending the HIV/AIDS Pandemic. *Emerging Infectious Diseases*. 2018. doi: 10.3201/eid2403.171797.

Common Rule Compliance Extended for Six more Months?

This week, the U.S. Department of Health and Human Services and several other government agencies and departments proposed a further six-month delay of the "Federal Policy for the Protection of Human Subjects," or Common Rule. It governs most human-research financed by the federal government and was scheduled to take effect July 19th after an initial six-month delay from the January 19th deadline after being in the *Federal Register* a year earlier. The delay will require compliance by January 21, 2019. Comments must be received by May 21, 2018.

(Source: Federal Register Proposed Rule, 4/20/18)

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The <u>calendar of events</u> includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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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 thoughtleader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America's Blood Centers

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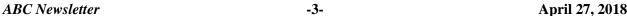
America's Blood Centers

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Send news tips to newsletter@americasblood.org.







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 2018 Meetings & Workshops at a Glance

| Meeting/Workshop | Dates | Location | Hotel | More Information |
|---|--|----------------------|--|---------------------------|
| Human Resources & Training/Development Workshop | May 8-10 | Dallas, Texas | Fairmont Dallas | Register Here |
| ADRP Annual Conference | May 9-11 | Dallas, Texas | Fairmont Dallas | Register here |
| Medical Directors Work- shop* | July 31 (precedes Summer Mtg) | Montreal, Québec* | Hotel Omni Mont- Royal, <u>\$234 CAD</u> /night | Registration Opening Soon |
| Summer Meeting* | August 1-2 | Montreal, Québec* | Hotel Omni Mont- Royal, <u>\$234 CAD</u> /night | Registration Opening Soon |

Notes:

For the most up-to-date information on all events, members of ABC may check the <u>calendar</u> on ABC's Member Site.

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

* Non-Canadian residents will require passport for travel

ABC Has Moved

ABC moved on April 1st. Our new mailing address is, 1717 K Street NW, Suite 900, Washington, DC 20006. All telephone numbers will remain the same except the fax line which changed to (202) 899-2621. Please update your records accordingly and contact <u>ABC Member Services</u> with any questions.



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 the Editor at newsletter@americasblood.org 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.







RESEARCH IN BRIEF

Can the level of core antibody predict the presence of occult hepatitis B virus (HBV) infection? Italian investigators suggest that the titer of isolated hepatitis B core antibodies may be useful to predict who has occult HBV infection (anti-core in the absence of hepatitis B surface antigen (HBsAg), with infection detectable only by the presence of HBV DNA). High levels of anti-core were correlated with the presence of DNA at a sensitivity of 93 percent and specificity of 48 percent. Levels of antibody beyond the threshold value were associated with an odds ratio for measurable *intrahepatic* DNA of 8.5 among the 100 liver transplant patients with isolated anti-core that they studied.

Citation: Caviglia, G.P., Abate, M.L., Tandoi, F. *et al.* Quantitation of HBV cccDNA in anti-HBc-positive liver donors by droplet digital PCR: a new tool to detect occult infection. *J Hepatol.* 2018. <u>doi:</u> 10.1016/j.jhep.2018.03.021.

Progress in Red Blood Cell (RBC) "pharming" The transfusion medicine community is well aware of the barriers to providing extended phenotype-specific RBC transfusions, especially to chronically transfused, frequently alloimmunized patient populations. Investigators in the United Kingdom, expanding on their prior work to generate sustainable cell lines for *in vitro* RBC production (RBC-pharming) have used CRISPR-mediated genome editing to produce a cell line lacking the five most common antigen groups responsible for incompatibility. The line has Bombay (ABO), Rh_{null} (Rh), Rh_{0} (Kell), Rh_{0} (Duffy and Rh_{0}), Rh_{0} (Fig. 1) phenotypes.

Citation: Hawksworth, J., Satchwell, T.J., Meinders, M. *et al.* Enhancement of red blood cell transfusion compatibility using CRISPR-mediated erythroblast gene editing. *EMBO Molecular Medicine*. 2018. <u>doi:</u> 10.15252/emmm.201708454.





2018 SUMMER MEETING SCHEDULE

Monday, July 30 ABC Board Meeting
Tuesday, July 31 Medical Directors Workshop

Wednesday, August 1 SMT Forum Business Forum

Host Event by Héma-Québec (off-site)

Thursday, August 2 ABC Members Meeting

All of us at Héma-Québec look forward to hosting our ABC colleagues, family and friends at the 2018 ABC Summer Meeting in Montréal. A striking union of European charm and North American attitude, Montréal seduces visitors with a harmonious pairing of the historic and the new, from exquisite architecture to fine dining. We hope you can take the opportunity to see what Montréal has to offer and discover its many colorful and vibrant neighborhoods which overflow with markets, museums, boutiques, restaurants and local cafés—diverse expressions of the inhabitants "joie de vivre."



Luc Vermeersch,
 Acting Chief Executive Officer
 and Vice-President, Finance
 and Strategic Project Management

Hotel Information

Hotel Omni Mont-Royal Hotel room rate: \$234 (CAD) + tax

For registration information, visit http://bit.ly/abc_summer_meeting.

For sponsorship opportunities, please contact Leslie Maundy at Imaundy@americasblood.org





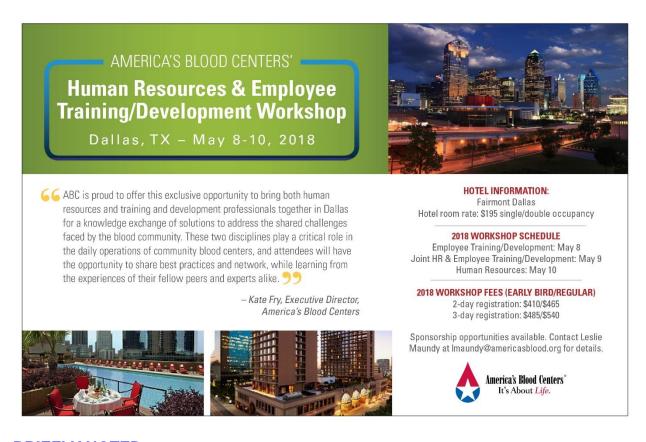
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RECENT REVIEWS

ABC Newsletter

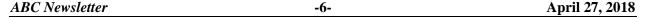
Transfusion-transmitted Cytomegalovirus (CMV). Serological screening of donors for antibody to CMV eliminates as many as three quarters of otherwise qualified potential donors to supply immunocompromised patients at risk from the virus. Many programs have tried to minimize antibody testing, arguing that white cell removal is an adequate intervention. This is a controversy that will not disappear, largely because the sorts of pivotal trials needed to finally determine that antibody testing is unnecessary across high-risk cohorts (especially neonates) in the face of contemporary prestorage leukoreduction have not been done. German authors provide a review of recent literature and argue that "only the conduction [sic] of well-designed studies addressing strategies to prevent transfusion-transmitted(TT)-CMV and the thorough examination of presumed cases of TT-CMV" will provide closure to the argument.

Citation: Ziemann, M. and Thiele, T. Transfusion-transmitted CMV infection – current knowledge and future perspectives. Transfusion Medicine. 2017. doi: 10.1111/tme.12437.



BRIEFLY NOTED

The Centers for Disease Control and Prevention (CDC) launched the new and improved 2017 National Blood Collection and Utilization Survey (NBCUS) on April 23rd. The launch has been delayed since late February due to a requirement by the Office of Management and Budget to approve the data being requested by CDC and the U.S. Department of Health and Human Services (HHS). Blood centers are encouraged to participate. This survey seeks data on the collection and transfusion of blood for the 2017 calendar year. "The NBCUS is our premier recurring assessment of the status of blood collection by U.S. blood centers and blood use in hospitals," said ABC Chief Medical Officer Louis Katz, MD. "It is an invaluable resource to many of us trying to understand where our advocacy efforts should be aimed and to identify and quantify, with minimal sampling bias, the trends that are so critical for both operational and



BRIEFLY NOTED (continued from page 5)

strategic planning in the blood community. CDC has made improvements to the process that should result in easier participation and more timely reporting. The agency has reached out to ABC members individually to request participation. Virtually all ABC members have committed to responding, for that the ABC staff is most grateful." All participants will receive e-mails from CDC with a secure web-link to complete the survey. Upon receipt of the launch notification e-mail from CDC, you may contact <u>Jefferson Jones, MD, MPH</u> in the CDC Office of Blood, Organ, and Other Tissue Safety with questions or issues.

The HHS Tick-borne Working Group will hold an online meeting on May 10th. This will be the group's fourth meeting and will address "the findings and basis for the draft reports from the work of the six Subcommittee Working Groups that were established" last December. The virtual meeting will be webcast for interested individuals, who may register for free here. The interface of tick-borne infections and transfusion is not a primary focus of the group. Additional information including the meeting agenda is available on the HHS site.

(Source: Federal Register Meeting Notice, 4/9/18)

A report appearing in the *Medical Laboratory Observer's LABline* raises awareness of the need to recruit the next generation of medical laboratory professionals. Results from the 2016-17 ASCP Vacancy Survey highlight an ongoing transformation within the workforce, as "retirement rates of laboratory professionals (for those retiring in the next five years) are at their highest across the majority of departments since 2012. Moreover, the rate of supervisory retirements is higher compared with staff. Data suggest that these fields will soon be experiencing a drain in personnel who have been working for a long period of time and have a vast amount of experience." The disparity between the number of retirees and new professionals entering the medical laboratory field has led to a trend in some areas of hiring non-certified staff. "In Oklahoma City and the South, there is a big movement of hiring people who are just meeting CLIA [Clinical Laboratory Improvement Amendments] requirements, which does not require certification, said Carlo Ledesma, SH(ASCP)CM, MT(ASCP), program director for the medical laboratory technician and phlebotomy programs at Rose State College, in Oklahoma City, Okla. Mr. Ledesma and his staff performed a study to test if a difference in quality was apparent between certified and non-certified lab professionals. "What has driven the hiring of nontraditional people is the mass exodus of techs. There were increased errors in nontraditional hires (who lack certification) compared to traditional hires. They take longer to train, which means allocating more financial resources. They failed to recognize critical results because they don't know the clinical difference in a test." ASCP has several initiatives underway to combat the shortage of medical laboratory professionals and to recruit new individuals to the field.

(Source: LABline, Certified medical laboratory staff needed to supply future workforce, 4/6/18) •

REGULATORY NEWS

The 2018 Health Datapalooza Conference took place this week in Washington, D.C. and featured an update from U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD on the agency's commitment to using technology to advance innovation, the regulatory process, patient health, and safety. "The FDA's usual approach to regulation is not always well suited to digital health's rapid pace of change," said Dr. Gottlieb according to *Healthcare Informatics*. "The FDA must be as nimble as the technology we are asked to regulate." He described the FDA's efforts to streamline and modernize its submissions process(es) to become more efficient, "Internal surveys found [medical offices at the FDA] spend 16 percent of [their] time managing paper-based reports," said Dr. Gottlieb. "A big portion of that time was spent on administrative file management tasks...it is a fragmented workflow badly in need of



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REGULATRORY NEWS (continued from page 6)

change." He also noted the Information Exchange and Data Transformation (INFORMED) initiative underway at FDA that focuses on improving disease outcomes through big data and analytics.

(Source: Healthcare Informatics, FDA launches tech incubator called Information Exchange and Data Transformation, 4/26/18)

U.S. Department of Health and Human Services Secretary Alex Azar announced the appointment of Adam Boehler as deputy administrator and director of the Centers for Medicare and Medicaid Innovation CMMI. Mr. Boehler previously founded both Landmark Health and Avalon Health Solutions, in addition to being an operating partner at Francisco Partners, a global private equity firm focused on investing in healthcare technology and services. CMMI was established under 115A of the Social Security Act, as added by section 3021 of the Affordable Care Act, to test "innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits.

(Source: HHS News Release, 4/6/18) •



WORD IN WASHINGTON

U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD testified at a hearing on Capitol Hill this week before the Senate Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies regarding the agency's 2019 budget. Dr. Gottlieb noted during his testimony that "[t]he [fiscal year] 2019 Budget includes \$100 million to advance the use of real-world experience to inform patient care and provide efficient and potentially lower cost ways to develop clinical data to expedite medical product development." In President Trump's 2019 budget request, he included an increase to \$5.8 billion for FDA including increase in budget authority and user fees. "The proposal would create the capability to conduct near-real-time evaluation down to the level of individual electronic health records for at least 10 million individuals from a broad range of healthcare settings. This will enrich our tools for evaluating safety and can reduce the cost of medical product development."

(Source: FDA Statement, 4/17/18)

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WORD IN WASHINGTON (continued from page 7)

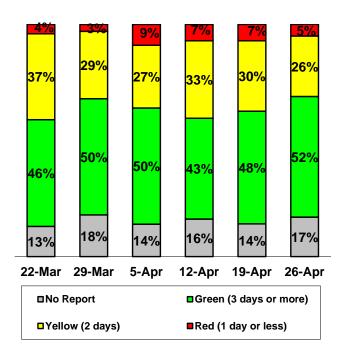
The House Energy and Commerce Committee is requesting <u>information</u> on legacy technology challenges, opportunities, considerations, and suggestions in the healthcare industry by May 31st. Interested individuals or organizations can submit feedback to the committee <u>directly</u>. The request comes amid concerns over cybersecurity following last year's WannaCry ransomware attacks, which exploited vulnerabilities in a 30-year old software protocol still found throughout the healthcare industry in both computers and medical devices, "the existence of this severely outdated protocol throughout modern medical networks—including within devices such as MRIs and X-Ray machines, in addition to traditional desktops—alerted stakeholders to the pervasiveness and severity of the legacy problem in health care. The WannaCry outbreak occurred primarily because of one protocol embedded within dozens of unique medical technologies. In the aftermath of the outbreak, health care stakeholders were faced with a troubling question: how many other potential 'WannaCrys' lurk within their environments?" The Subcommittee on Oversight and Investigations held a hearing in April 2017 on cybersecurity within the healthcare industry at which, full committee Chairman Greg Walden (R-Ore.) stated, "as technology becomes increasingly integrated with all levels of our health care, cyber threats pose a challenge to the entire sector. Everyone – from the smallest rural hospitals, to large providers and device manufacturers – faces some level of exposure and risk."

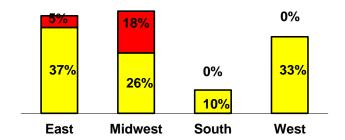
(Sources: House Energy and Commerce Committee News Release, 4/20/18; House Energy and Commerce Committee, News Release, 4/4/17) ♦

STOPLIGHT®: Status of the ABC Blood Supply, 2017 vs. 2018

Total ABC Red Cell Inventory

Percent of Regional Inventory at 2 Days Supply or Less, April 26, 2018





Percent of Total ABC Blood Supply Contributed by Each Region East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:

www.AmericasBlood.org





PEOPLE



Crane Harris has joined San Diego Blood Bank as chief business officer with a focus on driving diversified business through various initiatives, as well as providing strategic input to hospital contracting. He previously spent 13 years in the biotech industry with Illumina closing many strategic business collaborations, negotiating supply contracts, and licensing intellectual properties. Additionally, Mr. Crane received several awards during his career at Illumina including the Values Award, the Pillar Award, and the President's Club. Prior to joining Illumina, he held leadership positions at La Jolla Pharmaceuticals, Pharmacia, LLC (formerly Monsanto Company), and the Environmental Protection Agency. Mr. Crane received his BA in Psychology from Vanderbilt University and his MBA at the University of Virginia's Darden Business School.

(San Diego Blood Bank Announcement, 4/25/18)

Learn • Grow • Lead Shed Light on Your Future



This Month's Featured API Resources

1. Jerry Haarmann Leadership Program
Six courses on leading teams

"This course gave me many ideas on how to work with the team in my department as well as working with other teams outside my department."

- API pilot participant

Strategic Leadership Program
 Six courses on change management and communication challenges

Effective Leadership: How Do You Rate?

Check your leadership effectiveness by answering yes or no to the following questions:

- Do you know exactly what you want employees to understand, think, and do in response to your communications?
- Are trust and commitment part of your team's DNA?
- Do you know what motivates your employees?



Start Developing Your Skills Today

Log on at: www.americasblood.org/education



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Courtesy of CBS News

The Federal Aviation Administration (FAA) will choose five drone-based projects within the U.S. as part of the Unmanned Aircraft Systems Integration Pilot Program that fosters partnerships between the public and private sectors. Stanford Blood Center and MatterNet have teamed up as part of a proposal from Palo Alto, Calif. that includes the potential delivery of blood. "We aim to use [unmanned aerial vehicles] in very limited clinical settings where timely delivery of blood products or diagnostic specimens is of the utmost importance," wrote

Stanford Blood Center in a statement, according to *The Mercury* News. "Examples include emergent delivery of blood products

from Stanford Blood Center when there are patients whose usage outpace the available in-house inventory at the hospital." Zipline, a company similar to matter MatterNet, based in California has been using drones to deliver blood in Africa including more than 5,000 units over the past year. "We are using an active recovery system that...takes inspiration from an aircraft carrier," said Zipline CEO Keller Rinaudo, according to CNBC. "We track the plane with centimeter-level accuracy and can pluck it out of the air, then basically swing it down so that flight operators can immediately grab it, load a new package, and launch it again. The speed and ability of the drones to transport products quickly in emergency situations is one of the benefits of the technology over traditional courier services. "You can't plan for emergencies and that's where time becomes even more crucial, said Tho Duc Pham, MD, medical director of Clinical Services at Stanford Blood Center to CBS News. "[This] can make a difference in a lot of people's lives," he added.

(Sources: CBS News, Drones delivering blood in emergencies: The future of health care?, 4/25/18; CNBC, Zipline's new drone can deliver medical supplies at 79 miles per hour, 4/3/18; The Mercury News, Palo Alto: Drones could shuttle blood in trial program, 1/5/18)

Rock River Valley Blood Center (Rockford, Ill.) recently held the 15th Annual Red Shoe Run for Donor Awareness at Northern Illinois University's Rockford campus. The event attracted hundreds of runners/walkers, who showed their support for a worthy cause. Rock River Valley Blood Center hosts this event annually during National Donate Life Month to recognize the lifesaving and life-restoring benefits of blood, organ, tissue, eye, and marrow donation, as well as the goodwill created in the community by donors. "This event continues to grow and sustain itself and people tell us all the time they enjoy the message and that they think we are providing some good," said Rock River



Courtesy of WIFR (Rockford, III)

Valley Blood Center's Public Relations and Marketing Manager, Jennifer Bowman. "That makes us really happy and makes it seem all worthwhile." The top female runner was Deysi Torres of Rockford, Ill., and the top male runner was Tom Lichty of Monroe Center, Ill.

(Sources: WIFR, Hundreds of runners lace up for the Red Shoe Run, 4/14,18; WREX, 15th Annual Red Shoe Run brings in hundreds to Rockford, 4/14/18)

COMPANY NEWS

Cerus reports that Health Canada has approved commercialization of INTERCEPT platelets. "The approval marks another important step in our mission to establish INTERCEPT as the global standard of care

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WORD IN WASHINGTON (continued from page 10)

for transfused blood components," said Cerus' Carol Moore, senior vice president of regulatory affairs and quality in a news <u>release</u>. "The approval provides blood centers [in Canada] the flexibility to pathogen inactivate platelets derived from whole blood or apheresis collections, and stored in either platelet additive solution or plasma." Canada distributes 150,00 units of platelets annually.

(Source: Cerus News Release, 4/25/18)

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 (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2018

Apr. 24-25. International Consensus Conference "Patient Blood Management," Frankfurt, Germany. More details available here.

May 8-10. ABC Human Resources & Training/Development Workshop, America's Blood Centers, Dallas, Texas. More details available here.

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.

May 15. **2018 NJABBP Spring Seminar & Annual Conference, Woodbridge, NJ.** <u>Join</u> NJABBP by March 15th to be eligible to receive benefits. More details available <u>here</u>.

June 2-6. 35th International Congress of the ISBT, Toronto, Canada. More details available here.

June 25-26. FDA 2018 Center for Biologics Evaluation Research Science Symposium, Silver Spring, MD More details available here.

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available here.

Sept. 12. 8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD. More details available here.

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available here. **♦**

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Systems Analyst (Department: Management Information Systems). Position reports to the MIS Project

Manager and is responsible for performing software

ABC Newsletter







POSITIONS (continued from page 11)

testing and validation of the enterprise software and computer systems. Duties include: Analyze software modsets and patches to develop comprehensive test cases; validate that the change is functioning properly and meet the requested user requirements. Analyze software modsets and patches to ensure (risk analysis) changes will not have a negative impact on company's software enhancements. Execute test cases and complete all required supporting documentation per SOP(s). Assist in reviewing, developing and training SOPs. Assist with new equipment installations and user training, as needed. Assist with keeping the Development and Test environment up to date and current Act as the primary Help Desk contact for SafeTrace. Act as primary contact with software vendor for software problems, updates and documentation. Education and Experience: Bachelor's degree from an accredited college or university in Computer Systems or Life Sciences. Minimum of three years works experience in Computer Support/Training preferably in a blood or tissue center or blood bank. Strongly prefer experience working with SafeTrace. MLS or MLT desirable, but not required. Valid Texas Driver's license and an acceptable driving record are required. Please apply at: apply at https://jobs.giveblood.org.

Consumer Safety Officers - GS-0696-13 (Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), Department of health and human services (HHS)). OBRR is recruiting medical technologists to serve as Consumer Safety Officers (CSOs) for the Division of Blood Components and Devices, Blood and Plasma Branch. CSOs will participate in the regulatory oversight of establishments involved in Whole Blood, blood components and Source Plasma manufacture including the review of biologics license applications, and inspections of new blood and blood component manufacturing establishments and Source Plasma facilities. CSOs serve as subject matter experts in interpretation of applicable federal regulations, in developing FDA policies, and as liaisons to international and national governmental and non-governmental professional organizations. CSOs also serve as regulatory and technical advisors and reviewers for investigational or new drug/device submissions. Prior blood banking experience required. Certification as MT(ASCP)SBB or equivalent, with strong background and experience in blood and blood component manufacturing preferred. Please see the official job vacancy announcement for specific education and qualification requirements. Salary: \$96,970 -\$126,062 annually. Location: Silver Spring, MD. How to Apply: Applicants must apply through the official job vacancy announcement located at: https://www.usajobs.gov/Get-

Job/ViewDetails/497421900. EOE & Smoke-Free Environment

Compliance/Quality Assurance Director. The Community Blood Bank of NWPA & WNY is seeking a Compliance/Quality Assurance Director. He/she must be thoroughly knowledgeable in AABB, FDA, CLIA, OSHA, and State Health Department regulations and standards. Must be familiar with the principles of risk management, corporate compliance and quality assurance. The incumbent must be available during outside agency inspections and maintain a positive professional rapport with inspectors. Candidates should have a minimum of a bachelor's degree in Medical Technology, Clinical Laboratory Science, or related science field, Masters or advanced certification (e.g.: SBB, ASQ) a plus; five years of blood bank quality and regulatory affairs experience preferred. Experience should include participation in FDA site inspections, experience with GMP requirements and application of quality assurance principles; three years of supervisory experience preferred. Must possess excellent conceptual, communication, and analytical skills, and be competent with Microsoft Office (Word, Excel, PowerPoint) and Crystal Reports. Office 365 knowledge a plus. To apply, please send a resume and any relevant documentation to: Deanna Renaud, Interim Executive Director, Community Blood Bank, 2646 Peach St., Erie, PA 16508; or email Deanna.renaud@fourhearts.org.

Associate Director, Donor Recruitment. Memorial Blood Centers in St. Paul, Minnesota, is looking for an Associate Director of Donor Recruitment Department. This role will be a leader to our leaders, as it oversees the Donor Recruitment and Contact Center Teams! The role is also responsible for maintaining and growing our donor base. Benefits include: Medical, Dental Vision, PTO/EST, 401K and more! Please click here to apply.

Director, Finance. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Finance position. This position is responsible for managing the daily activities of the general accounting/finance function. Scope of responsibilities include overseeing the completion of ledger accounts, payroll, A/P, A/R, fixed assets and financial statements; directing and supervising general accounting personnel; evaluating and making appropriate improvements to internal accounting processes ensuring that practices are in line with the overall goals of the organization. Must be familiar with a variety of the field's concepts, practices, and procedures and relies on extensive experience and judgment to plan and accomplish goals. Bachelor's degree in Accounting preferred or other closely related business degree may be acceptable. A CPA is highly desirable. Minimum ten (10) years combined experience in Public Accounting and or private industry; good understanding of accounting and business systems; prior management/supervisory experience required. Relocation package is available for qualified



POSITIONS (continued from page 12)

candidates. This position reports to the Vice President/CFO. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility. Apply online at https://www.lstream.org/open-positions/.

Clinician Educator Line/Medical Center Line. The Department of Pathology seeks an outstanding new faculty member to join Stanford Blood Center Histocompatibility, Immunogenetics, and Disease Profiling Laboratory at Stanford Medicine, for appointment in the Clinician Educator Line (Clinical Assistant Professor, Clinical Associate Professor, or Clinical Professor), or in the Medical Center Line (MCL) (Assistant Professor, Associate Professor or Professor). The individual will share oversight responsibilities with Directors of the Laboratory including clinical reporting, clinical consultation, research and development, implementation and validation of novel tests, administrative duties, and teaching of clinical residents and fellows. Service responsibilities include reviewing and reporting clinical cases, clinical consultation, methods development, safety, quality assurance, regulatory compliance, and management of personnel and budget. Participation in weekly clinical meetings with transplant services is required. Requirements for the position include an MD or PhD or MD, PhD with demonstrated and recognized experience in human clinical histocompatibility testing and demonstrated expertise in novel test development and/or experience in desensitization programs. Licensure, or eligibility for such licensure, by the State of California as a Histocompatibility Laboratory Director and Board certification at the Diplomate level, or eligibility for such certification, by the American Board of Histocompatibility and Immunogenetics (ABHI) are required. Please see full description at https://stanfordbloodcenter.org/about/sbccareers/current-job-openings/. •