

2019 #32

September 20, 2019

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NEJM Publishes Results of Gene Editing Used to Treat HIV

The *New England Journal of Medicine (NEJM)* has reported results of the use of clustered regularly interspaced short palindromic repeats (CRISPR), a gene-editing tool, in an attempt to cure HIV. Chinese Scientists used the CRISPR on a 27-year-old male patient, “HIV was determined to be CCR5-tropic” who also had acute lymphoblastic leukemia (T-cell type). They attempted to examine the “feasibility and safety” of transplanting CRISPR modified hematopoietic stem and progenitor cells (HSPCs) into the patient and performed whole-genome sequencing on edited cells after both genome editing and engraftment to study any “off-target effects” of CRISPR.

The patient’s cancer did go into remission following the transplant and the CRISPR-edited cells continued to function more than a year and a half later. “The acute lymphoblastic leukemia was in morphologic complete remission at week 4 after transplantation; this remission continued over the 19-month follow-up period. In addition, minimal residual disease remained undetectable for leukemia-associated phenotypes on the basis of flow cytometry.”

The patient was not cured of HIV, as had occurred in two previous patients who were cured of both HIV and cancer after receiving edited genes from donors who cells are naturally HIV resistant. The researchers noted that “[t]he low efficiency of gene editing in the patient may be due to the competitive engraftment of the coin-fused HSPCs in CD34-depleted cells and the persistence of donor T cells. To further clarify the anti-HIV effect of CCR5-ablated HSPCs, it will be essential to increase the gene-editing efficiency of our CRISPR–Cas9 system and improve the transplantation protocol.”

Additionally, they concluded that the transplantation CRISPR-edited cells resulted in a less than eight percent gene disruption of circulating bone marrow cells and did not note any off-target effects, a characteristic that plagued early versions of CRISPR gene editing that could potentially lead to unintended consequences.

(Source: Xu, L, Wang, J., Liu, Y., *et al.* CRISPR-Edited Stem Cells in a Patient with HIV and Acute Lymphocytic Leukemia. *NEJM*. 2019. Doi: [10.1056/NEJMoa1817426](https://doi.org/10.1056/NEJMoa1817426).) ♦

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 [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your



REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) issued a draft guidance entitled “[Safer Technologies Program for Medical Devices](#).” It is designed as a complement to the Breakthrough Devices Program and will encourage innovation and provide patients with access to devices that are ineligible for the Breakthrough Devices Program by speeding up their development, assessment, and review, while maintaining the standards for premarket approvals, De Novo Marketing authorization, and 510(k) clearance. “Because technology continues to advance, patients are benefitting from more innovative medical devices that can help improve their health and even save their lives. Safety and innovation are both important priorities for the agency. Improvements in each of these areas are expected to result in increased quality of life and health benefits for patients, while simultaneously providing a reasonable assurance of both safety and effectiveness,” said Jeff Shuren, MD, JD, director of the FDA’s Center for Devices and Radiological Health (CDRH) in agency news release. “To promote these goals, today we’re issuing a draft guidance on a new voluntary pathway for certain medical devices and device-led combination products that do not otherwise meet the criteria for our Breakthrough Devices Program, but through innovative designs, have the potential to be significantly safer than currently available treatments or medical diagnostics. We believe the Safer Technologies Program for Medical Devices will help ensure that we’re giving patients timely access to safe, effective and high-quality medical devices by expediting their development, assessment and review, and by facilitating the generation of the robust evidence required to support product marketing authorizations. We will do this without changing our statutory standards, data requirements or quality of review.” Comments are due to the agency by November 18th.

(Source: FDA Draft [Guidance](#), 9/18/19; FDA News [Release](#), 9/18/19))

Acting FDA Commissioner Ned Sharpless, MD published an *FDA Voices* article that examined the agencies comprehensive response to HIV. It explores the FDA’s support of the development of new treatments such as anti-retroviral drugs (ARVs), research into potential vaccines, increased awareness and education efforts that encourage the general public to get tested, and policies and advances in the screening of blood donations to protect the U.S. blood supply. The piece also explores the agency’s work throughout the years with the President’s Emergency Plan for AIDS Relief (PEPFAR). “FDA has approved or tentatively approved 216 applications for single and combination antiretroviral drugs for use by PEPFAR. Further, because each application can contain multiple drug products, these 216 applications contain more than 270 ARVs. Although some of these applications have been withdrawn, many are still available for use by PEPFAR. Increased availability of FDA-reviewed ARVs for PEPFAR has resulted in reduced costs and increased access. PEPFAR, now works in more than 50 countries and supports more than 14 million people

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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.

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REGULATORY NEWS (continued from page 2)

with FDA-reviewed ARVs. FDA's work with PEPFAR has been integral to the program's success, by focusing on the safety, effectiveness, and quality of ARV treatments for use in PEPFAR countries... a 2017 analysis by FDA found that about 45 percent and 83 percent of FDA-reviewed ARVs were utilized by WHO and Global Fund, respectively, to enhance their own formularies." Commissioner Sharpless also expresses the FDA's intent to continue supporting a global network to fight HIV. Parts [I](#) and [II](#) of the of the article are available on the FDA website.

(Source: FDA Voices Parts [I](#) and [II](#), 9/19/19) 

How are Transfusions Determined in the ICU?

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. 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. If you are interested in contributing an article for potential publication please contact us [here](#).

Anemia is a common condition in intensive care unit (ICU) patients. During an ICU admission, 60 percent of patients develop a hemoglobin (Hb) below 9.0 g/dL. More than 25 percent of these patients receive at least one red blood cell (RBC) transfusion. A restrictive transfusion threshold of 7.0 g/dL has been established as safe for stable nonbleeding critically-ill patients. Uncertainty remains regarding the generalization of this across heterogeneous critically-ill patients. ICU physicians often need to decide if a transfusion might have an overall positive effect on the outcome of each patient. Laboratory measurements, clinical parameters, and certain patient characteristics influence this decision. Such variables likely confound the observed effect of RBC transfusion on clinical outcome. A recent study published in *Vox Sanguinis* aims to assess the potentially relevant clinical characteristics that influenced the decision to transfuse RBCs in critically-ill patients in the ICU with low Hb (6.0–10.0 g/dL).

This retrospective observational cohort study included anemic adult, critically-ill patients without significant acute bleeding admitted between November 2004 and May 2016 to a 29-bed ICU at a university hospital in the Netherlands. Hb measurements, clinical variables, and the subsequent transfusion decisions were extracted from the electronic health records and clinical variables grouped by organ system (which included cardiovascular, pulmonary, renal, hemostasis and bleeding, liver, immune system and others). The study examined the association of each of the clinical variables with the decision to transfuse during the six hours after a Hb measurement using generalized estimating equations. It then compared the predictive abilities of single variables within an organ system and the predictive ability of an organ system's combined variables.

The median age was 66 years, and 59 percent of the patients were male. A total of 83,394 Hb measurements were performed with 10,327 (12.4 percent) resulting in transfusion of one or more units of RBCs within six hours after the Hb measurement. The association between many of the clinical variables and the decision to transfuse RBCs often depended on Hb. The higher the Hb concentration, the more other clinical factors co-determined the decision to transfuse and the lower the Hb, the less other clinical factors played a role. Also, Hb was the most predictive clinical variable for RBC transfusion followed by the combined variables for general health, then the cardiovascular and pulmonary organ systems. The Acute Physiology, Age, Chronic Health Evaluation (APACHE) II score (measure of severity of disease for adult ICU patients), referring department, APACHE admission diagnosis subgroup, troponin concentration, lactate concentration, respiratory rate, PaO₂/FiO₂, and ventilation mode had the highest predictive ability within these organ

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Transfusions in the ICU (continued from page 3)

systems. The authors conclude RBC transfusion is a titrated therapy predominantly influenced by Hb, similar to many other treatments in the ICU. Within certain ranges of Hb, other clinical factors are important in the physicians' decision to transfuse RBCs and can also modify the effect of transfusion. Additionally, this study identified multiple possible effect modifiers of RBC transfusion. It suggests the need for further research to quantify the joint effects of different combinations of these effect modifiers to more personalize transfusion strategies in critically ill patients with anemia.

Citations: Kranenburg, F.J., Cessie, S.I., Deelder, C.C., *et al.* Determinants of transfusion decisions in the ICU: hemoglobin concentration, what else? – a retrospective cohort study. *Vox Sanguinis*. 2019. Doi: [10.1111/vox.12831](https://doi.org/10.1111/vox.12831). ♦

WORD IN WASHINGTON

The Senate Appropriations subcommittee on Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies approved a FY2020 spending bill that would provide the FDA with \$80 million more than 2019 funding levels. It also features \$10 million for pathogen reduction technology, which America's Blood Centers has supported in previous letters to Senate leadership. The bill still awaits approval from the full Appropriations Committee and Senate, before being reconciled in conference prior to final passage votes in both the House and Senate. The House version of the bill, approved in June, would also include funding for pathogen reduction technology and \$184 million in increased funds for the FDA.

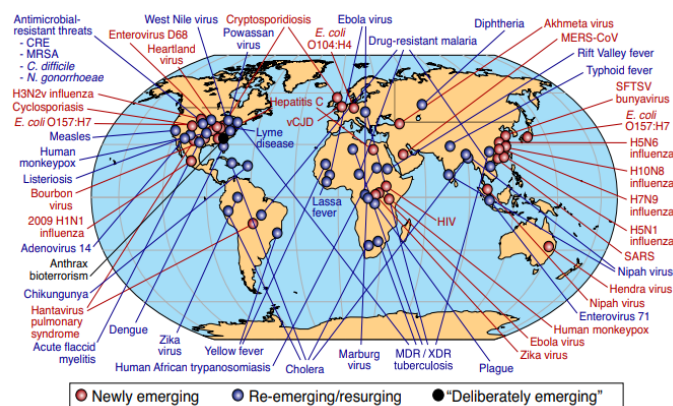
(Source: *Inside Health Policy*, [Senate Approps subcommittee](#), 9/17/19) ♦

GLOBAL NEWS

Malta is revising the current lifetime blood donation deferral of men who have sex with other men (MSM) to 12 months. According to the *Times Malta*, the National Blood Transfusion Service indicated that the deferral could eventually be reduced down to as few as four months. The 12-month deferral will begin this month.

(Source: *Times Malta*, [Gay men will be allowed to donate blood as of next week](#), 9/14/19)

The Global Preparedness Monitoring Board (GPMB), a group initially co-convened by the World Health Organization (WHO) and the World Bank Group, has released the 2019 Annual Report on global preparedness for health emergencies entitled "A World at Risk." The [publication](#) questions whether nations are prepared for potential pandemics and state that the "world is at acute risk for devastating regional or global disease epidemics or pandemics that not only cause loss of life but upend economies and create social chaos." It outlines actions to prepare and combat the threat of global health emergencies including:



Global examples of emerging and re-emerging diseases over the past 50 years from the National Institutes of Health, National Institute for Allergies and Infectious Diseases

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GLOBAL NEWS (continued from page 5)

- commitments by government leaders around the world to preparedness strategies;
- fulfilling financial commitments to invest in preparedness; and
- improved preparedness coordination efforts between countries.

The report notes that WHO tracked close to 1,500 epidemic events in, more than 170 countries between 2011-18. The full report and additional resources are available on the GPMB [website](#).

(Source: GPMP 2019 Annual [Report](#), 9/17/19)

Zipline, a robotics organization known for its drone delivery services that supply blood and medical products to remote areas, is expanding operations. The company announced plans to increase the number of hospitals it serves from 25 to 100 by the end of 2019 according to [KT Press](#). “We are increasing the system capabilities in general, though I can’t announce the number of drones to be used, there is enough capabilities,” said Zipline National Implementation Program Manager Israel Bimpe to the news organization. “Available drones have the capacity to reach and serve the 100 hospitals and health centers, which is our target.” Zipline began servicing Rwanda in 2016 and its drones have logged 16,000 flights in that time. The 3rd generation drones currently in use by the company can fly more than 160 kilometers carry as much as 2 kilograms.



Photo courtesy of KT Press & Zipline

(Source: [KT Press](#), [Zipline Targets 75 New Blood Supply Destinations In 3 Months](#), 9/18/19)

Kenya has added a Malaria vaccination to the immunization schedule for kids. It becomes the third country in Africa to do so, as kids under the age of two will receive the vaccine in hopes of preventing the disease that currently is responsible for the most deaths in children under the age of five in east Africa. “We still have an incidence of 27 percent (malaria infection) for children under five,” said Kenya Health Ministry, Director General Wekesa Masasabi to [Reuters](#). The news organization reports that Kenyan officials intend to deploy the vaccine in eight counties over the next two years. Pilot programs are also underway in Ghana and Malawi.

(Source: [Reuters](#), [Kenya becomes third African nation to introduce malaria vaccine](#), 9/13/19) ◆

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 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.



INFECTIOUS DISEASE UPDATES

EBOLA

The outbreak continues to spread to new areas in the Democratic Republic of the Congo (DRC). U.S. Secretary of Health and Human Services (HHS) Secretary Alex Azar visited the region, including Rwanda and Uganda, this week with representatives from other agencies to discuss ongoing efforts to contain the outbreak and the commitment of the U.S. government to provide support.

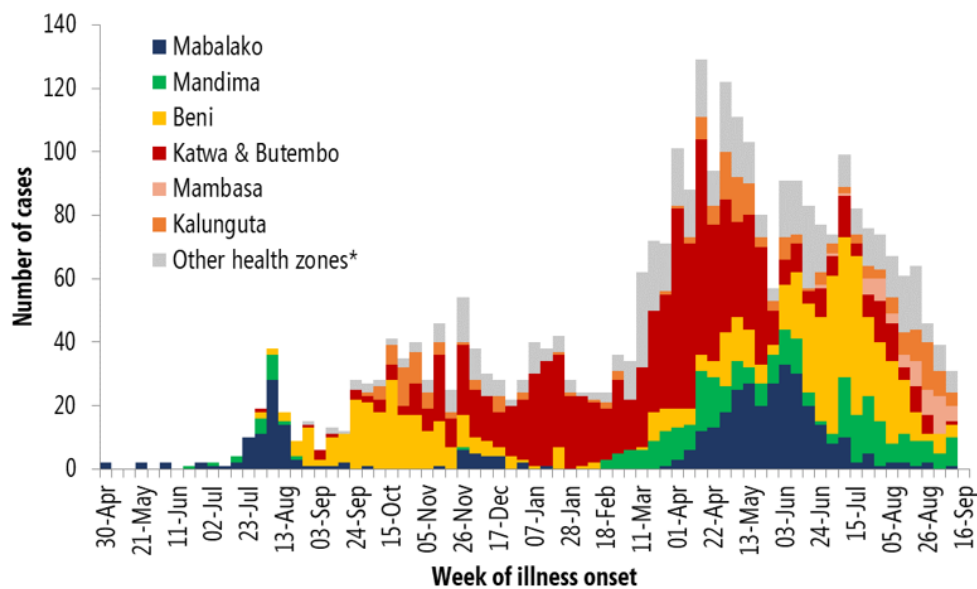


Photo courtesy of HHS: Secretary Alex Azar (left) meets with President Yoweri Museveni of Uganda (right).

The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have not classified the affected areas as having “widespread transmission of Ebola virus,” which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) [guidance](#) requires that “in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2).

As of September 17th, there were 3,034 confirmed cases with 2,103 confirmed deaths.

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of September 17th*



*Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Trends during this period should be interpreted cautiously.

(Sources: [Ebola virus disease – Democratic Republic of the Congo](#), 9/19/19; HHS News [Release](#), 9/17/19)





America's Blood Centers
It's About *Life*.

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 Seeks Member Participation in 2019 Service Fee Survey

America's Blood Centers has launched the annual survey of member service fees. Members are encouraged to participate by completing the online survey available in [MCN 19-065](#). The results from this survey are important in assisting ABC in its advocacy efforts on behalf of member blood centers for better reimbursement for blood products. Only aggregate data will be reported and no individual data or identifiable information from any center will be shared. A copy of the survey questions is also available in the MCN.

(Source: MCN [19-065](#), 9/19/19)

Member Response Requested for ABC Gender Identification Blood Collection Survey

The 2019 ABC Gender Identification Blood Collection Survey seeks to obtain more information on how a blood donor's gender or sexual identification impacts blood collection at ABC member blood collection facilities. Members can find a link to the survey on ABC's [Listserv](#). The data from this survey will be shared with the ABC membership and also used during a discussion of these issues at a workshop at the AABB meeting in San Antonio, Texas.

Questions have been raised recently regarding the donor history questions to be asked when donors decline to select the male or female gender options, the impact of nonbinary identification on TRALI mitigation efforts, and how to screen transgender potential donors for sexual risk factors for infection with HIV. This is in the context of appropriate blood donor screening and the most current guidance wherein, "FDA recommends that male or female gender be taken to be self-identified and self-reported." Definitions for the purpose of this survey are found within the survey itself. Please complete the survey no later than October 2nd. If you have questions about the survey, please contact [Suchitra Pandey, MD](#) or [Louis Katz, MD](#).

(Source: ABC [Listserv](#), 9/19/19) 💧

ABC 2020 Meetings & Workshops				
Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9 th -11 th	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19 th -21 st	Phoenix, Ariz.	Hyatt Regency	More details coming soon!
Notes:				
For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site.				
Non-members may attend all events; information will be updated on ABC's Public Site .				



MEMBER NEWS

LifeShare Blood Center opened a new donor center in Baton Rouge, La. The new facility is more than 5,000 square feet and will allow individuals to donate platelets. “Not only can donors give blood but they can also donate platelets as of today,” said LifeShare Regional Director Stephanie Duplessis in a blood center announcement. “In the past, platelets going to help patients in Baton Rouge had to come from donors in Shreveport, Monroe or Alexandria. Now blood donors in Baton Rouge can provide platelets to their own friends and family through this expanded option.”



Photo courtesy of LifeShare Blood Center

(Source: LifeShare Blood Center [Announcement](#), 9/18/19) ♦

COMPANY NEWS

Fresenius will not sell its blood transfusion business according to a report from Reuters this week. “I confirm that the transfusion business will continue to be operated by Fresenius,” [said](#) a company spokesman to the news agency via an email correspondence. In May, the *Reuters* reported that Fresenius had informed potential suitors that the company was exploring the sale of their blood transfusion business unit and had retained the firm Goldman Sachs as a part of the process. The Fresenius spokesman also told *Reuters* that the company will continue developing the transfusion business with investments.

(Source: *Reuters*, [Fresenius drops possible sale of blood transfusion unit – spokesman](#), 9/15/19) ♦

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) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

2019

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 [here](#).

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 [here](#).

2020

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Location to be announced.** More details available [here](#).

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

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**CALENDAR** (continued from page 8)

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand.** More details available [here](#).

April 14-15. **16th Annual U.S. Food and Drug Administration and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** 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 [here](#).

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: lmaundy@americasblood.org.

POSITIONS

Senior Director of Donor Services. MEDIC Regional Blood Center, Knoxville, Tennessee, is seeking to fill the position of Senior Director of Donor Services. The ideal candidate would be a highly motivated individual with exceptional customer service skills and able to work independently while managing multiple priorities. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. This position reports directly to the Chief Executive Officer and is responsible for defining the strategy, goals and objectives, and operational structure of Donor Services; provides management, supervision, and coordination of all day-to-day operations of fixed-site and mobile donor collections; key responsibilities include donor registration, eligibility screening, and phlebotomy for whole

blood and apheresis donations. Specific duties consist of defining staffing needs, establishing hours of operation, monitoring of operational productivity, allocation of resources, ensuring the adherence to organization and departmental policies and procedures, and coordinating with other areas of operations. Qualifications: BSN required; (RN license in state of Tennessee); ten years of progressively responsible management experience and demonstrated ability to effectively manage multiple initiatives. Experience in blood banking preferred. For complete job description and to apply, send resumes to hr@medicblood.org.

Assistant Director Technical Services. 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 Technical Services Assistant Director. Under the direction of the Sr. Operations Director and the Medical Director, the Technical Services Assistant Director will set the strategy, goals, objectives and structure of Technical Services. Core Duties: Manage, supervise and coordinate the day-to-day operations and TS organizational structure which consists of five leaders and approximately 42 team members, and three distinct functions; Component manufacturing and distribution, Processing laboratory, and Product QC laboratory. In partnership with SBC Leaders, coordinate activities and goals of departments within the Blood Center. Manage implementation of policies and procedures, and ensure that employees understand and adhere to established policies and procedures. Qualifications: Four-year college degree and four years laboratory experience required. Four years of progressively responsible management experience and demonstrated ability to effectively supervise varied activities or functions required. Medical Technology (ASCP) license required. Must hold or qualify for California Clinical Laboratory Scientist (MTA) license. For complete job description and to apply, visit <https://www.stanfordhealthcarecareers.com/> and reference job #53404.

Outside Sales Representative/Event Planner (Oklahoma City, Okla.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is

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POSITIONS (continued from page 9)

expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://obi.org/careers/> to apply.

Director, Marketing and Public Relations. Blood Assurance is currently seeking a Director of Marketing and Public Relations. As a member of the operations team, this role is responsible for strategically planning, communicating and executing Blood Assurance marketing and public relations efforts in multiple markets. Develops organizational strategies and executes departmental management plans that support all efforts of the organization as it pertains to marketing and communication needs. Prepares and manages marketing budgets, represents BA leadership internally and externally, and partners with all management levels to meet organizational Key Performance Indicators. Advanced leadership and management skills; advanced decision-making, judgment, negotiation and communications skills with ability to effectively collaborate, develop productive teams, manage complex responsibilities, plan and execute strategic operational initiatives and impact organizational KPI results/success; requires flexibility, customer/client service focus, analytical, budgeting, reporting, computer and organizational skills. Bachelor's degree required; master's degree preferred in business field. At least five to 10 years prior related sales, marketing, or public relations experience required. Qualified candidates are encouraged to submit an online employment application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

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 benefits 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.

Clinical Lab Manager (San Francisco, CA; Req: 191475). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. We are a globally-recognized

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POSITIONS (continued from page 10)

leader in blood transfusion medicine. Requirements: Bachelor's degree required. Master's degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Immunohematology Reference Laboratory (IRL). Specialist in Blood Banking (SBB) certification required. CA CLS/MT required. Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous supervisory experience and experience in molecular techniques, immunohematology/ IRL techniques, automated testing preferred. Please click [here](#) to apply. EOE

Outside Sales Representative/Event Planner (Wichita Falls, TX). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://txbi.org/careers/> to apply.

Chief Operations Officer (Oklahoma City, OK). Oklahoma Blood Institute, America's largest, self-sufficient blood center seeks a seasoned, successful, and inspiring leader to direct its core blood production enterprise from donor recruitment through to product distribution. The position requires professional passion for system optimization, problem solving, project execution, personnel development, and mission delivery. Candidates should

possess a diversity of progressively responsible experiences in blood center operations. They should also have a work history that evidences aptitudes for proactive innovation, team orientation, customer service, regulatory compliance, and financial discipline. Qualifications: Bachelor's degree from an accredited university, biologic sciences major preferred or graduate degree, management, administrative, or quantitative field preferred, 15 years of progressive responsibility in healthcare, having attained a senior executive position, 10 years or more blood center experience in a variety of operational areas, aptitude in budgeting, financial reporting, and economic decision making, self-starting mindset yielding proactive delivery of accountabilities with minimum direction, and residence within commuting distance of downtown Oklahoma City. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://obi.org/careers/> to apply.

Physician/Chief, Infectious Diseases Section. The Department of Transfusion Medicine in the Clinical Center, National Institutes of Health is recruiting a physician faculty member to oversee the Infectious Disease Section, provide medical support for Clinical Center patients and perform subspecialty consultation related to infection transmission through blood, blood components, and cellular therapies. The successful candidate will oversee a section of 14 staff including a CLIA-approved testing laboratory. Additional functions include research related to transfusion-transmitted infections, and teaching in an ACGME-accredited training fellowship in Transfusion Medicine. The Department of Transfusion Medicine is a full-service collector and provider of blood, blood components and cellular therapies. The position requires detailed knowledge of molecular, genetic testing for transfusion-transmitted agents. Candidates must be board certified or eligible in Blood Banking / Transfusion Medicine, Hematology, Infectious Disease, appropriate subspecialty certification(s) must have an M.D. or equivalent degree and must possess an active, current, full, and unrestricted license or registration as a physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. Salary commensurate with training and experience. Please submit your curriculum vitae and a letter describing your skills and experience by Nov. 4, 2019 to: Lacey Gholson, Administrative Officer, NIH/CC/DTM, 10 Center Drive, Building 10/Room 1C711 (MSC 1184), Bethesda, Maryland 20892-1184. DHHS AND NIH ARE EQUAL OPPORTUNITY EMPLOYERS. 💧