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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #7 February 17, 2023

INSIDE:

Participant Demographic Data Studied for Blood Donation and Transfusion Clinical Trials

Researchers in *Transfusion and Apheresis Science* sought to examine participant representation by sex, race, ethnicity, and age in blood donation and blood transfusion clinical trials in the U.S. The authors performed a "cross-sectional analysis of U.S.-based interventional blood donation and blood transfusion clinical trials registered with Clinicaltrials.gov to ascertain the composition of participants' sex, race, ethnicity, and age, as well as diagnostic conditions and geographic trial locations. Eligible trials were undertaken between July 2003 and August 2020."

The study "identified" 152 trials from that time period with "38 [meeting] the inclusion criteria (seven blood donation and 31 blood transfusion trials)." The authors explained that while the "percentage of trials" reporting sex, race, ethnicity, and age varied, "All (100 percent; 7/7) blood donation trials reported sex, 71.4 percent (5/7) reported race, 42.3 percent (3/7) reported ethnicity, and 100 percent (7/7) reported age. 96.8 percent (30/31) of blood transfusion trials reported sex, 51.6 percent (16/31) reported race, 38.7 percent (12/31) reported ethnicity, and 100 percent (31/31) reported age. All blood donation (100 percent, 7/7) and blood transfusion (100 percent, 31/31) trials reported the source of funding. 85.7 percent (6/7) of blood donation trials were industry-funded, while the funder for one blood donation trial (14.3 percent) was termed 'other.' Funding sources for blood transfusion trials varied, with a diverse list of funders termed 'other' most common (96.8 percent, 30/31), followed by the National Institutes of Health (NIH) (41.9 percent, 13/31)."

The researchers further noted that "[w]hile 24,707 participants were enrolled in seven blood donation trials, sex data was not reported by investigators for 21,987 participants in one trial. Reported sex data for 2,720 participants show that 28.5 percent (95 percent CI, 25.2–31.8 percent) were female, and 71.5 percent (95 percent CI 67.5–75.5 percent) male, compared with 2019 U.S. Census data for females (50.2 percent) and males (49.2 percent)…Female [50.8 percent 95 percent CI 48.7–52.9 percent)] and male participants [49.2 percent (95 percent CI 45.2–51.2 percent)] were equally represented in blood transfusion trials (9,255 participants) compared to 2019 and 2003 U.S. Census data. Their study determined that "[a]mong blood donation trials that reported race data, participant enrollment was overrepresented for those that identified as White [73.4 percent (95 percent CI 61.5–85.3 percent)] and Asian [6.0 percent (95 percent CI 2.6–9.4 percent)] compared to 2019 U.S. Census data (White, 72.5 percent; Asian, 5.5 percent). Representation was lowest for participants that identified as American Indian or Alaska Native (0.4 percent), followed by Native Hawaiian or Other Pacific Islander (1.8 percent), more than one race (2.6 percent), and Black or African American [4.3 percent (95 percent

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Participant Demographic Data in Blood Donation & Transfusion Clinical Trials (continued from page 1)

CI 0.4–8.2 percent)], compared to 2019 U.S. Census data (Black or African American, 12.7 percent, American Indian or Alaska Native 0.8 percent, Native Hawaiian or other Pacific Islander 0.2 percent, and more than one race 3.3 percent)…Among blood transfusion trials that reported race data, participant representation was highest for those that identified as White [70.5 percent (95 percent CI 66.9–74.1 percent)] and Black or African American [22.4 percent (95 percent CI 20.6–24.2 percent)]. Representation was lowest for participants that identified as Native Hawaiian or Other Pacific Islander (0.3 percent), American Indian or Alaska Native (0.5 percent), more than one race (1.0 percent), other race (1.6 percent), and Asian (2.4 percent). Hispanic or Latino participants were underrepresented in blood transfusion clinical trials [8.2 percent (95 percent CI 6.6–9.8 percent)], compared to 2019 U.S. Census data (18.0 percent). [Most] trials (90–100 percent) consistently reported sex over the period in which blood donation and transfusion trials analyzed in this study."

Each blood donation and blood transfusion trial included in the study "reported age." The authors explained that "[m]ost (85.7 percent, 6/7) blood donation trials enrolled adults only, while 14.3 percent (1/7) enrolled both adult and child/adolescent participants. Older adults (≥ 65 years of age) were included in 57.1 percent (4/7) of blood donation trials. The paucity of child/adolescent blood donation trials is consistent with age eligibility requirements for blood donors. Among blood transfusion trials, 61.3 percent (19/31) reported including adults only, 9.7 percent (3/31) reported inclusion of both adults and child/adolescents, and 22.6 percent (7/31) reported including child/adolescents-only…Of the twenty-four blood transfusion trials enrolling adult-only or adult and child/adolescent participants, only 8.3 percent (2/24) reported including older adults, despite data demonstrating these patients are more likely to receive blood transfusions…Device interventions were the most common (85.7 percent, 6/7) in blood donation trials, while biological interventions were the most common (100 percent, 31/31) in blood transfusion trials."

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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 health care 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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Participant Demographic Data in Blood Donation & Transfusion Clinical Trials (continued from page 2)

The study concluded that "that many researchers are not reporting demographic data in Clinicaltrials.gov, despite U.S. Food and Drug Administration (FDA) guidance which provides recommendations for a standardized approach regarding collection and reporting of these data. This is both a finding and a limitation of our study. This finding is consistent with other studies that have reported a similar issue…Analyses of trial results also revealed that trial site locations were geographically skewed. Regions with historically larger percentages of underrepresented groups including Alaska, Hawaii, and the U.S. Southwest, had minimal to no clinical trial locations…[The study] results indicated disparities in the enrollment of females and those that identified with some underrepresented racial and ethnic groups in blood donation trials; and revealed that inclusion of multiple underrepresented racial and ethnic groups were consistently at low levels, and older adults were rarely enrolled in blood transfusion trials…[The study] findings indicate progress is being made [and] demonstrate an opportunity for further introspection and the adoption of patient-focused studies that explore barriers to participation for some underrepresented groups in blood donation- and transfusion-related trials, and appropriate interventions to increase participation in trials among these groups."

Citation: Muir, R., Jacobs, J., Flores, L., *et al*. Examining participant representation by sex, race, ethnicity and age in United States blood donation and blood transfusion clinical trials. *Transfusion and Apheresis Science*. 2023.

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) published approved variances this week "Exceptions and Alternative Procedures Approved Under 21 CFR 640.120 (a) during July 2022 and December 2022." The document is available of the FDA website. "Under title 21 of the Code of Federal Regulations 640.120(a), the Director, Center for Biologics Evaluation and Research, may issue an exception or alternative to any requirement in subchapter F (Biologics, Parts 600-680) of Chapter I (Food and Drug Administration, Department of Health and Human Services) of title 21 of the Code of Federal Regulations regarding blood, blood components or blood products."

(Source: FDA Announcement, 2/14/23)

RESEARCH IN BRIEF

Antibody Titers in Transfusion Medicine. A study in *Archives of Pathology and Laboratory Medicine* by the College of American Pathologists (CAP) was conducted "to critically evaluate the extent to which operator and laboratory factors influence the variability of antibody titer results." The authors described CAP's Antibody Titer (proficiency testing) PT survey which "is conducted biannually (surveys A and B) for anti-A and anti-D antibody titration." For this study, they "examined results from 2014 through 2018." The uniform procedure [was] a titer procedure specifically described by AuBuchon *et al*. Those using the tube technique would need to report the highest titer that gives a weak (barely visible agglutination) serologic reaction (as opposed to a 1+ reaction). Those using the gel technique would need to report the highest titer that gives a 1+ serologic reaction (small agglutinates)." The uniform procedure was "compared to all other procedures." The researchers explained that "[o]verall, only 5,874 anti-D (54.1 percent) and 3,843 anti-A (63.4 percent) reported responses that were within one titer of the supplier's intended result." For anti-D, there was a higher percentage of responses within one titer when using the other procedure ($P < .001$) and when using a tube technique ($P < .001$). Additionally, there were statistically significant performance differences ($P < .001$) based on the titer result (QC titer) with the lowest accuracy for the titers of 16 and 32 for both uniform and other procedure." The study found "[f]or anti-A, there were more responses within one titer when using the other procedure ($P < .001$) compared with the uniform procedure ($P < .001$)…There

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RESEARCH IN BRIEF (continued from page 3)

also were statistically significant performance differences based on the titer results, with the lowest accuracy rates differ[ing] by procedure (other procedure, titers 8 and 64; uniform procedure, titers 8 and 128)…Overall, 3,139 (of 4,004; 78.4 percent) of all evaluable laboratory responses for anti-A fell within one titer of the mode value for each procedure and technique, and 9, 655 (of 10,852; 89.0 percent) of laboratory responses for anti-D fell within one titer of the mode value (P <.001)…Between the A and B anti-D mailing [both anti-D titer 16], laboratories using the uniform procedure had a greater proportion of responses falling within one titer (uniform procedure, 367 of 434 [84.6 percent]; other procedure, 458 of 576 [79.5 percent]; P = .04)." The authors stated that "this study represents the largest and most comprehensive evaluation of antibody titer assay performance to date [and] demonstrated continued significant challenges with assay accuracy and reproducibility." They concluded that "[t]ube-based titer assays continue to be the most commonly used technique, despite their challenges, and despite suggestions that the gel technique and the uniform procedure may be helpful in reducing assay variability. The role of this assay in clinical decision-making should be critically reevaluated, and future research should focus on incorporating novel emerging technologies that minimize the established operator- and instrument-specific biases noted with our current methods."

Citation: Karafin, M.S., DeSimone, R.A., Dvorak, J., *et al*. Antibody Titers in Transfusion Medicine: A Critical Reevaluation of Testing Accuracy, Reliability, and Clinical Use. *Arch Pathol Lab Med*. 2023.

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

One-time Selective Testing Approach for Human T-lymphotropic Virus (HTLV). Authors in *Transfusion* "report[ed] HTLV-1/2 seroprevalence, incidence, and residual risk for the American Red Cross Donor population from 2008-2021." The study provided their "rationale for an HTLV one-time, selective testing approach by coupling the results of testing with successful mitigation/removal technologies (leukoreduction)" as similar methods have been "used successfully outside of the U.S." The researchers noted that ARC used their database containing "demographic and testing data for all donations since 1995" to "identify all allogeneic donations, and associated donors, tested for anti-HTLV-1/2 and those that were anti-HTLV-1/2 repeat reactive and confirmed positive." They excluded autologous donations. The study found that "75,687,426 were tested for anti-HTLV, and 1,550 donation (from 1,549 donors) were confirmed positive for a prevalence of 2.05 per 100,000…1,438 (92.8 percent) anti-HTLV positives were from 13.9 million first-time donors (a rate of 10.32/100,000) while 112 (0.18/100,000) were from 61.8 million donations from repeat donors (p <.0001). The rate of HTLV antibodies was three times more frequent among female donors than male donors (3.14/100,000 vs. 1.06/100,000) (p <.0001)...Seroprevalence decreased over the study period from a high of 2.52 per hundred thousand in 2008-2009 to 1.55 per hundred thousand in 2020-2021 (p = .01)." Additionally the authors explained that "[o]f the 1,549 anti-HTLV seropositive donors identified between 2008 and 2021, 112 were repeat donors having one or more previous non-reactive donations in [the] database" They concluded that "considering the findings reported here, and with the support of the successful implementation of such regulatory practices in other countries, it is the opinion of the authors that the U.S. should consider an updated testing strategy, moving from universal testing to one-time testing for first-time donors only."

Citation: Crowder, L., Haynes, J., Notari, E., Dodd, R., and Stramer, S. Low Risk of Human T-lymphotropic Virus Infection in U.S. Blood Donors; Is it time to consider a one-time selective testing approach? *Transfusion*. 2023.

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.

Register for 2023 Day on Capitol Hill

Register today for America's Blood Centers' (ABC) 2023 Day on Capitol Hill on April 26th. This virtual event now takes place as part of Blood Advocacy Week April 24th-28th. Advocacy Day provides an opportunity for member blood centers to connect with members of Congress and their staffs to discuss the ongoing work at your blood center and the work done collectively by ABC and community blood centers to advance the ABC Advocacy Agenda. We encourage individuals to let your voice be heard as ABC will arrange virtual meetings for you with your members of Congress and provide additional resources to help inform them and their staff about the latest policies impacting the blood community. This is your chance to easily meet with your local Congressional leaders and build relationships. Each person from your blood center who would like to participate in the Day on Capitol Hill must register individually. ABC will arrange for group meetings but will need information for each person in attendance. Additional details, including the 2023 Advocacy Agenda, will be forthcoming. Please direct any questions to ABC Senior Director of Federal Government Affairs Diane Calmus, JD.

(Source: ABC Announcement, 1/18/23)

Upcoming ABC Webinars – Don't Miss Out!

- **ABC Human Resources Forum Call** – February 27 from 2-3 PM EST. More information available in MCN 23-014 including a link to join the call.
- **ABC Scientific, Medical, and Technical Committee Journal Club Webinar** – March 29 from 3-4 PM EDT. More information coming soon.

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

ADRP An International Division of ABC

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 support and participation!

INFECTIOUS DISEASES UPDATE

Chikungunya

The Pan American Health Organization (PAHO) issued an epidemiological alert due to an increase in the number of cases and deaths from chikungunya in the Region of the Americas. According to the February 13th alert, PAHO and World Health Organization (WHO) are recommending member states "intensify actions to prepare health care services, including the diagnosis and proper management of cases, to face possible outbreaks of chikungunya and other arboviral diseases, to minimize deaths and complications from these diseases. In 2022, the region had a "total of 271,176 cases of chikungunya, including 95 deaths, were reported in 13 of the countries and territories of the Region of the Americas. This figure is higher than that observed in the same period of 2021 (137,025 cases, including 12 deaths). During the first four epidemiological weeks of 2023, 30,707 cases and 14 deaths due to chikungunya were reported." Chikungunya virus is transmitted by the same mosquitoes that spread dengue virus (*Aedes aegypti* and *Aedes albopictus*). It is an arbovirus and some arboviruses, such as dengue and West Nile virus, have been transfusion transmissible.

(Source: PAHO Alert, 2/13/23)

WORD IN WASHINGTON

The Administration for Strategic Preparedness & Response (ASPR) a division within the U.S. Department of Health and Human Services has updated its organizational structure according to a blog post by the Assistant Secretary for Preparedness and Response, Dawn O'Connell. In the blog, Assistant Secretary O'Connell states, "[o]ur reorganization establishes a structure that accounts for our expanded mission, addresses our new capabilities, prioritizes program accountability, and is clear and straightforward in its naming conventions." Examples include:

- "the Strategic National Stockpile, whose work has grown significantly in scale and scope, will become its own Office reporting directly to the ASPR;
- HHS Coordination Operations and Response Element (H-CORE) will now officially be reflected on our organizational structure as its own Office reporting directly to the ASPR;
- Throughout the pandemic, ASPR has been tasked with securing the public health supply chain and expanding the industrial base to ensure PPE and other critical supplies can be manufactured in the United States. This program will become its own Office reporting to the ASPR. It will be called the Industrial Base Management and Supply Chain Office;
- In addition, several ASPR-wide functions that have been buried within the organization such as Communications, Policy, Legislation, and Stakeholder Outreach will move into the Immediate Office of the ASPR to ensure seamless coordination across the entire enterprise;
- Finally, we have simplified the names of the Offices within ASPR. ASPR will now have an Office of Preparedness; an Office of Response; an Office of Administration; Office of Industrial Base Management and Supply Chain; Office of BARDA; Office of HCORE; and Office of the Strategic National Stockpile. This simplification of our naming convention is intended to increase role clarity both inside and outside of ASPR."

(Source: ASPR Blog Post, 2/16/23)

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WORD IN WASHINGTON (continued from page 6)

The Centers for Disease Control and Prevention (CDC) published a notice in the *Federal Register* indicating that the agency has "modified" its structure through the "establishment of the Coronavirus and other Respiratory Viruses Division (CRVD) and other organizational components within the National Center for Immunization and Respiratory Diseases (NCIRD), Deputy Director for Infectious Diseases (DDID), CDC. According to the notice, the new structure took effect on February 8th as CRVD aims to preven[t] disease, disability, and death through immunization and control of coronaviruses, respiratory, and other related viral diseases. In carrying out this mission, CRVD [will] conduc[t] surveillance and related activities to determine patterns of infection and disease and impact of prevention programs [and] epidemiologic and laboratory studies to define patterns of, and risk factors for, infection, disease, and disease burden."

(Source: Federal Register Notice, 2/13/23)

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Tissues and Advanced Therapies (OTAT) has announced a virtual public listening session "on capturing post approval safety and efficacy data for cell and gene therapy products." The meeting will take place on April 27th from 12 – 4:30 p.m. EDT. The agency is "seeking input on methods, approaches, logistics, privacy concerns, and other aspects related to efficacy and safety data collection in the post-approval setting for cell and gene therapies." Registration is open and more information is available on the FDA website.

(Source: FDA Announcement, 2/13/23)

BRIEFLY NOTED

***Bloomberg Law* reported this week that the American Red Cross (ARC) has been sued by Verax Biomedical Inc.** According to the report, ARC is "facing antitrust litigation over claims that its push to handle all blood platelet safety services in-house threatens to worsen a 'national blood crisis'…[Specifically,] Verax [is challenging ARC's] new policy of pre-treating all platelets it sells to hospitals rather than letting them choose among various ways of ensuring platelet safety." An ARC spokesperson told *Bloomberg Law* "ARC mitigates bacterial risk in platelets and complies with FDA guidance primarily by using pathogen inactivation, a solution that reduces bacterial risk while also mitigating other pathogen threats and safety risks. We believe pathogen inactivation is critical to maintaining a safe and readily available platelet supply for patients in need."

(Source: *Bloomberg Law*, American Red Cross hit with antitrust suit over blood safety, 2/15/23)

COMPANY NEWS

Terumo Blood and Cell Technologies announced this week that it has received clearance from the U.S. Food and Drug Administration (FDA) for it IMUGARD® WB Platelet Pooling Set. According to the company, the product "supports extended shelf life of whole blood-derived platelets from five days to seven days [and] is the first platelet pooling set approved for seven-day storage in the U.S. The February 14th announcement served as the product's official launch. "We continue to invest in innovations that help blood centers to positively impact patients," said Chetan Makam, general manager of Global Solutions at Terumo Blood and Cell Technologies, in the news release. "IMUGARD® opens the possibility for U.S. blood centers to use the platelets from their whole blood donations to increase the number of platelets available for transfusion. We are the first company to provide seven-day shelf life of both apheresis and whole blood-derived platelets in the U.S., adding flexibility to the platelet supply. This is especially important now with

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COMPANY NEWS (continued from page 7)

the increased demand for platelets and the challenges blood centers face with recruiting new apheresis platelet donors."

(Source: Terumo Blood and Cell Technologies News Release, 2/14/23)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2023

Feb. 23. **Centers for Disease Control and Prevention (CDC) Public Health Webinar Series on Blood Disorders: From Zoomer to Boomer: Aging with Hemophilia.** Registration is open. Additional information available here.

Feb. 27. **ABC Human Resources Forum Call.** Additional information including a link to join the call available here.

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** Registration is open. Additional information is available here.

Mar. 29. **ABC Scientific, Medical, and Technical Committee Journal Club Webinar**. More information coming soon.

April 24-28. **ABC Blood Advocacy Week.** More information available here.

April 26. **ABC Day on Capitol Hill.** Registration is open. More information available here.

April 27. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Tissues and Advanced Therapies (OTAT) Public Listening Meeting: Methods and Approaches for Capturing Post-Approval Safety and Efficacy Data on Cell and Gene Therapy Products (Virtual).** More information available here.

May 9-11. **2023 ADRP Conference, Charlotte, N.C.** Registration is open. Additional information is available here.

May 10-11. **29th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Bologna, Italy.** More information available here.

Aug. 1-3. **ABC Medical Directors Workshop and Summer Summit, St. Louis, Mo.** More information available here.

Sept. 17-20. **American Association of Tissue Banks Annual Meeting, National Harbor, Md.** More information available here.

Oct. 9-11. **Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif.** More information available here.

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** More information 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, e-mail: newsletter@americasblood.org

POSITIONS

Chief Executive Officer (Flowood, MS). Mississippi Blood Services makes a difference in people's lives every day. With the support of the community and voluntary blood donors, we have been serving the needs of hospital patients since 1979. To help us meet our mission, as part of a planned retirement, we are looking for a new Chief Executive Officer with the necessary expertise to direct all functions of the corporation in accordance with Board directives and regulatory guidelines in order to attain strategic objectives. The CEO will provide leadership to provide exceptional service and products to hospitals giving maximum consideration to the safety and efficiency of those products and services, direct overall operation of the corporation, ensure implementation of established policies and acts as liaison with the Board of Directors, and maintain positive relationships with the business and medical community, civic groups, and other blood banking organizations. Education and/or Experience: Bachelor's degree (B.A.) or higher from a four-year college or university; 10 years of related experience preferably with either large nonprofits or blood services/products organizations; or equivalent combination of education and experience. Click here to view the full job description. Mississippi Blood Services is an equal opportunity employer and makes employment decisions without regard to race, color, sex, religion, national origin, age, disability, veteran status, genetic information, sexual orientation or gender identity. Please submit cover letter, resume and salary requirements to Kiffany Lee, Director of Human Resources klee@msblood.com.

Content Design Strategist (Oklahoma City, Oklahoma). Our Blood Institute is seeking a Content Design Strategist to join our community relations team. This role will function primarily as a graphic designer who will illustrate concepts based on discussions with internal stakeholders. The ideal candidate has the imagination, ability, and good humor to help bridge the gap between broad idea strategy and final execution of design, which includes a proficiency with copywriting. Duties include intensive collaboration with team members to establish design needs, using design software to complete projects, and revising projects based on internal feedback in a timely, positive manner. This role requires excellent time management skills and flexibility and an unflappable demeanor to handle ever-changing priority projects. The Content Design Strategist will design and manage effective graphic content and communications including but not limited to print and digital advertising, print publicity pieces, promotional T-shirt designs, branded templates, social media posts, web content, brochures, and more. Qualifications: Associates degree required, experience in graphic design required, experience with Adobe Creative Suite programs for creative development, etc. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement, and holiday pay. **How to apply:** http://obi.org/careers/

Director, Scientific and Technical Operations. America's Blood Centers (ABC), North America's largest network of community-based, independent blood programs, is seeking a **Director, Scientific and Technical Operations**. The position will lead the association's evaluation and response to new Scientific, Medical, Technical Operations, Quality and Regulatory (SMTQR) developments, including the development of programs and resources. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on emerging trends in the blood community and transfusion medicine to help shape strategies that leverage the ABC membership to drive ABC's advocacy work. Primary Responsibilities: Direct the development of programs and resources that support member activities in SMTQR and operational areas, including Journal Club, Blood Bulletin, workshops, and webinars. Convene ABC members to share best practices and collaborate in advancing ABC's advocacy agenda and hot topics of importance to blood centers. Assist in the analysis of new standards, guidelines, and regulations. Provide consultative services to ABC member requests for information and assistance in SMTQR areas. Serve as the primary staff liaison to the ABC Quality Committee and subcommittees, and Quality and HR Forums. Oversee ABC's research, benchmarking, and survey programs, including the use of the data to improve member blood center operations and the identification of best practices. Educational Requirements: Bachelor's required. Experience, Knowledge, Skills, and Abilities: A minimum of five years of experience in blood banking, with emphasis in any of the areas of scientific, medical, quality, technical operations, and/or regulatory affairs. Blood center operational experience a plus. Possesses demonstrated analytic and communication skills. Strong customer service orientation and ability to navigate and respond to sensitive/difficult situations. Self-motivated, flexible, creative, innovative, and goal oriented. This position is virtual. Click here to view the full job description. Interested applicants should send a cover letter and resume to careers@americasblood.org.