Democratic Presidential hopefuls called attention to the U.S. Food and Drug Administration’s (FDA) 12-month blood donor deferral of men who have sex with other men (MSM). Several candidates recently indicated that the deferral should be lifted. Pete Buttigieg, mayor of South Bend, Ind., addressed the MSM deferral during the nationally televised CNN Equality Town Hall, co-hosted by the Human Rights Campaign, by sharing his own account of watching an annual blood drive take place at his office. “I remember the moment when I realized that, unlike most initiatives that I spearhead, I can’t lead by example on this one, because my blood’s not welcome in this country,” he said. “And it’s not based on science, it’s based on prejudice. So when I’m president, I will direct the FDA to revise the rules based on evidence, based on individual risk factors, and without regard to the prejudice that has driven the current policy.” Sen. Cory Booker (D-N.J.) also added “two words: absolutely yes,” when asked if he would work to change the deferral.

Earlier this year, other candidates, including Sen. Kamala Harris (D-Calif.), former Rep. Beto O’Rourke (D-Texas), Sen. Bernie Sanders (D-Vt.), and Sen. Elizabeth Warren (D-Mass.) have expressed through their campaigns their support for revising the FDA’s MSM deferral policy, according to The Independent, a London-based news organization. It quoted a spokesperson for Mr. O’Rourke’s campaign as stating, “[t]he one-year deferral period for male blood donors who identify as gay and bisexual has nothing to do with science or medicine and everything to do with outdated stigmas against the LGBTQ community. Our blood screening policies must be based on 21st-century medical evidence, not outdated biases about which populations carry more risk of HIV transmission. These policies serve no one and will only limit access to life-saving blood donations.”

America’s Blood Centers (ABC) and others in the blood community have supported the use of rational, science-based deferral periods that are applied fairly and consistently among blood donors who engage in behaviors that pose similar risks, while adding that ongoing research initiatives should continue that are designed to determine if donor-screening alternatives based on individual behaviors, not based on sexual or gender identity, will provide equivalent or superior transfusion safety. Talking points are available to ABC members on the member site.

(Sources: CNN, LGBTQ Town Hall, 10/11/19; 9 takeaways from CNN’s Equality Town Hall, 10/11/19; The Independent, 2020 Democrats call to end ban on gay men donating blood, 6/8/19) ☚
REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has announced that it will hold a public hearing entitled “Use of Fecal Microbiota for Transplantation (FMT) to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies.” The hearing will take place on November 4th at the FDA’s White Oak campus with the purpose to “obtain public input on the state of the science regarding FMT to treat *Clostridium difficile* infection not responsive to standard therapies, including the available clinical evidence for safety and effectiveness of FMT for this use and to better understand the impact of FDA’s enforcement policy on product development.” Registration is currently open for both in-person attendance (until October 22nd) and webcast participation (until the day of the hearing).

(Source: FDA Website, 10/9/19)

The FDA’s Center for Devices and Radiological Health (CDRH) published its proposed guidances for fiscal year (FY) 2020. The list is divided into three segments:

- A-list – prioritized guidance documents that the agency intends to publish in FY 2020;
- B-list – guidance documents that the agency intends to publish as resources permit in FY 2020; and
- Retrospective review list – final guidance documents previously issued going back to the 1980s.

The complete listing is available on the agency’s website and includes the “Safer Technologies Program for Medical Devices.

(Source: FDA CDRH Announcement, 10/11/19)
Transfusion-Related Immune Modulation Affects OB Patients

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.**

A study in Vox Sanguinis notes that “approximately one-quarter of maternal deaths are secondary to major obstetric hemorrhage (MOH).” Key to successful resuscitation is transfusion of red-blood cells (RBC) as soon as available. “Increased fetal and maternal infections are reported to be associated with blood transfusion.” Though blood transfusion is suggested to be associated with transfusion-related immune modulation (TRIM) in surgical patients, the effects of TRIM in MOH patients remains uncharacterized.

This two-year, single-institution study involved 355 MOH patients, 138 patients who received a transfusion and 217 who did not to serve as controls. MOH was defined as blood loss that exceeded 500 ml after vaginal delivery or more than 1,000 ml after a caesarean section. Blood products transfused included RBC, fresh frozen plasma (FFP) and platelets (PLTs). Reverse transcriptase PCR (RT-PCR) was used to quantify gene expression.

“Risk factors for blood transfusion included maternal age, gestational age, preterm labor and instrumental delivery.” The infants of the transfused arm were an earlier gestational age at delivery and had significantly lower birthweight and Apgar scores at one and five minutes. The study measured the mRNA expression levels of genes in the CD4 T helper (Th) pathway. FoxP3 gene, a transcription factor utilized by naturally occurring CD4+ CD25+ Treg cells, had significantly lower mRNA expression at 24 h following delivery in the transfusion group (P < 0.05). The mRNA expression levels of both T-bet, transcription factor utilized by Th1 Cells, and GATA3, transcription factor utilized by Th2 Cells, were significantly lower in transfusion group suggesting both Th1 and Th2 pathways were suppressed after transfusion for MOH (P < 0.05). Interestingly, mRNA expression of IL-10, a cytokine produced by a variety of T cells including Th2 and regulatory Tr1 cells and macrophages, increased in transfusion group (P < 0.05).

Blood transfusion is the most important lifesaving treatment in the management of obstetric hemorrhage. This study characterized the effect of blood transfusion in MOH on gene expression within Th1, Th2 and Treg pathway at 24 hours following delivery. The “results suggest[ed] that in the obstetric patients, the immunosuppression of Th cells in response to blood transfusion was non-specific, probably via suppression of Th precursor, the naive Th cells. This phenomenon might be attributed to the unique physiological conditions in pregnant women where non-specific immunosuppression was pre-existing and could have been exacerbated by blood transfusion. In the meantime, some unknown component in the stored blood could stimulate IL-10 expression.” According to the authors, these results demonstrated that similar to other surgical patients, blood transfusion in MOH patients was followed by cytokine expression modulation. They acknowledge that the study strength was limited by a small sample size. The authors also stated that in order to mitigate TRIM more stringent criteria for blood transfusion should be considered.

BRIEFLY NOTED

The Centers for Disease Control and Prevention (CDC) published its annual Sexually Transmitted Disease (STD) Surveillance Report. STDs rose with primary and secondary syphilis cases increasing by 14 percent reaching its highest reported levels since 1991. Gonorrhea increased by five percent and Chlamydia by three percent. The U.S. Department of Health and Human Services (HHS) is creating a federal action plan that should be introduced in 2020 to combat the rise in infections. Fact sheets and graphics are available as resources to download. The report attributes the increase in STDs to several factors including:

- “drug use, poverty, stigma, and unstable housing, which can reduce access to STD prevention and care;
- decreased condom use among vulnerable groups, including young people and gay and bisexual men; and
- cuts to STD programs at the state and local level – in recent years, more than half of local programs have experienced budget cuts, resulting in clinic closures, reduced screening, staff loss, and reduced patient follow-up and linkage to care services.”

(Source: CDC News Release, 10/8/19)

A sickle cell disease (SCD) patient is undergoing treatment as part of a study using the gene editing tool CRISPR in hopes of providing her with healthy red blood cells following infusions of genetically modified bone marrow cells that they are hoping will result in the production of fetal hemoglobin. Vertex Pharmaceuticals and CRISPR Therapeutics are performing the study that is currently enrolling as many as 45 patients in the U.S., Canada, and Europe. According to the report from NPR, a similar treatment was applied to a patient with beta thalassemia earlier this year and that individual’s edited cells did begin functioning in the bone marrow. “This is a big [moment] and for this pivotal trial,” said Haydar Frangoul, MD, the physician of the SCD patient currently participating in the study. “Because if we can show that this therapy is safe and effective, it can potentially change the lives of many patients.”

(Source: NPR, A patient hopes gene-editing can help with pain of sickle cell disease, 10/10/19)

PEOPLE

Kim van Antwerpen has been named chief operating officer (COO) at Oklahoma Blood Institute (OBI). According to an OBI news release, she will expand her current manufacturing, testing, inventory and distribution responsibilities to include donor recruitment, donor collections, donor center operations, and volunteer services. “Kim’s leadership experience and expertise have been invaluable as our blood center grows to serve more patients and hospitals in communities throughout Oklahoma and the region,” said OBI President and CEO and America’s Blood Centers Board Member John Armitage, MD. “We would like to congratulate Kim on her new position as COO, and we know she will bring incredible proficiency as we continue to advance our operations.” Ms. Van Antwerpen previously served as the organization’s vice president of Technical Operations since 2004, playing an important role in innovating new products, services, and programs for OBI. She was also recently announced as the founding President of Testing Laboratory United, Inc., a national joint venture for blood donor screening. Ms. Van Antwerpen is a certified medical technologist who received her MBA from the University of Central Oklahoma in addition to a master’s degree in Computer Information Systems from the University of Phoenix. She previously held leadership roles at Genzyme, Inc. and Organon Teknika Corp. before joining OBI.

(Source: Oklahoma Blood Institute Announcement, 10/16/19)
INFECTIONIOUS DISEASE UPDATES

EBOLA

The outbreak has slowed in the Democratic Republic of the Congo (DRC) in recent weeks as 15 new confirmed cases were reported between October 7th-13th. The World Health Organization’s (WHO) International Health Regulations Emergency Committee for Ebola virus disease is scheduled to meet to address whether the outbreak should continue to be declared a Public Health Emergency of International Concern (PHEIC). The Centers for Disease Control and Prevention (CDC) and the WHO 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 October 15th, there were 3,113 confirmed cases with 2,154 confirmed deaths.

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of October 15th*

(Source: Ebola virus disease – Democratic Republic of the Congo, 10/17/19)
MEMBER NEWS

Stanford Blood Center and Data Science for Social Good fellowship program at Stanford University teamed up to find data-driven solutions in forecasting platelet demand. The fellowship program pairs students with organizations that are using data science research with social impact in mind. The nine-week program enabled the fellows to assist the blood center with data analysis outside of the classroom. “We had to use [data] to figure out how much [demand for platelets] we think the hospital is going to need today, tomorrow, the day after that and the day after that – so a four-day prediction,” said Emily Guthrie a student who worked on the project team. “The long-term goal of the project is to get as close to zero waste as possible. With coursework, there are usually beautiful datasets and instructions of what to do and something close to a ‘right’ or ‘wrong’ answer. In this case, though, we have to spend a lot of time cleaning messy data and thinking about a strategy with which to approach the problem. It’s not obvious what decisions to make when you find that there’s an error in the data or what modeling technique to use.”

(Stanford University Announcement, 10/10/19)

San Diego Blood Bank recently celebrated blood donor Stephen McMeeken donating his 170th gallon. Mr. McMeeken achieved this milestone by being a frequent platelet donor, as he first began donating blood in 1976 awaiting the birth of his first child. The impact that blood donors make resonates with Mr. McMeeken and is a cause the he is particularly passionate about having lost a nephew to a blood disease almost a decade ago. He donates in his memory and previously told The San Diego Union-Tribune in a feature story in recognition of him achieving 150 gallons in 2016 that, “I was donating in his honor. It’s giving back life. Every little bit is needed and there’s always going to be people who have a need.”

(Sources: San Diego Blood Bank News Release, 10/11/19; The San Diego Union-Tribune, Focus: Blood Bank’s top donor at 152 gallons, and counting, 9/13/16)

Community Blood Center (Kansas City, Mo.) recognized Gwen Hutton for making her 200th platelet donation. Ms. Hutton has also made 100 whole blood donations and typically donates platelets every two weeks. According to WDAF-TV FOX4 News, she is motivated by the opportunity to help patients in need and has been a giving blood since her 20s. “To donate blood, it doesn’t take but a few minutes, and platelets, it takes a couple hours depending on how much they’re able to take,” said Ms. Hutton to FOX 4 News. “Everybody is so nice, and it’s just a fun group like family.”

(Source: WDAF-TV FOX 4 News, 79-year-old Olathe woman honored for making 300 blood and platelet donations, 10/16/19)

Upcoming ABC Webinars – Don’t Miss Out!

- **Staffing Success & Challengers at Blood Centers Webinar** – November 19th from 3 - 4:30 p.m. (ET). Additional details coming soon!
- **SMT Journal Club Webinar** – December 5th from 12 – 1 p.m.(ET). Additional details coming soon!
- **Irradiator Replacement at Blood Centers Webinar** – January 21st from 3 – 4:30 p.m. (ET). Additional details coming soon!
2020 ADRP Annual Conference Now Accepting Abstracts

ADRP, an international division of America’s Blood Centers, is encouraging donor collections, donor recruitment, and marketing or communications professionals to consider sharing their knowledge at the 2020 ADRP Annual Conference by being a presenter. The call for speaker abstracts is open until December 31st. Topics that have been the most requested by attendees include:

- **Leadership and team development:**
  - Critical thinking
  - Time management
  - Staff adequacy and talent level
  - Managing change

- **Blood Type Management:**
  - Collecting correct units based on blood type
  - Maintaining inventory during time of need
  - Rebooking donors and drives with emphasis on time of need

- **Donor and sponsor communication strategies:**
  - Diversification of the donor base
  - Addressing donor apathy
  - Communications strategies

Additional information about the conference is available on ADRP’s website.

(Source: ADRP Announcement, 10/10/19)

ABC Seeks Member Participation in 2019 Service Fee Survey

America’s Blood Centers is encouraging members blood centers to participate in the annual survey of member service fees by completing the online survey available in MCN 19-065 by Friday, October 25th. 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)

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.
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


2020


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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.

EQUIPMENT AVAILABLE

For Sale. 50 Genesis Mixers Model CM375A and 22 Ohaus portable digital scales. All in working order. For additional details or to make an offer contact Jahn Legh-Page at (559) 389-5440 or jlegh-page@donateblood.org.

Best Offer. PK7300 microplate blood donor typing system, Two (2) Pluggo decappers, Two (2) Immucor microplate washers for manual Capture assays, Two (2) Immucor microplate incubators for manual Capture assays. For additional details or to make an offer contact Joseph Hulina at jhulina@cbccts.org.
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

Manager, Plasma Operations. Blood Centers of America (BCA) is a national cooperative comprising over 50 blood center members. BCA is seeking an individual with industry experience to serve as Manager, Plasma Operations. This position is responsible for specific aspects of the Plasma for Fractionation Program including managing day-to-day inquiries and operational tasks for this business unit. The person in this role must be successful in understanding the technical requirements of multiple agreements and assisting members with plasma optimization and contract compliance. The ideal candidate will possess outstanding communication abilities, relationship development talent and strong customer service skills. Five to 10 years of progressive experience in blood banking or similar field is required. Proven track record in managerial role is a plus. BCA is based near Providence, Rhode Island. Will consider remote location for the right candidate. Position requires up to 20 percent overnight travel. Please submit resume to careers@bca.coop.

Immunohematology Reference Laboratory Manager (FT). Miller-Keystone Blood Center (MKBC) focuses on our mission to save lives by partnering with our community to provide a continuous supply of blood products and services. The core values Integrity, Passion, Trust, and Customer Centricity have made MKBC one of the nation’s best-regarded, highly experienced blood centers, and our history of compliance with FDA and AABB requirements demonstrates our commitment to quality and service excellence. We are looking for a detail-oriented and passionate professional with a BS in biologic or clinical laboratory science, ASCP certification and SBB (or eligible) to join our management team in the Immunohematology Reference Laboratory. Responsibilities include supervising and training reference lab staff. Position oversees reference lab testing including reagent quality control, release of products and equipment maintenance. Approves patient and donor antibody work-ups and provides written and verbal consultations regarding transfusion recommendations. Writes, revised and reviews SOPs and equipment/testing validations. Duties include preparation of washed, frozen and deglycerolized components, testing, and maintenance of red blood cell phenotype database and data entry. Manages customer service and is available for on-call duties. Applicants must have a minimum five years of clinical laboratory experience in Blood Banking and three years supervisory/management experience. To apply go to our website at: www.hesc.org. Miller-Keystone Blood Center is an EEO/AA Employer Minority/Female/Disabled/Veteran/Sexual Orientation/Gender Identity

Clinical Lab Specialist (Med Tech) (San Francisco, CA). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Requirements: Bachelor’s degree required. Must satisfy CLIA requirements for High Complexity Testing required. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency required. Valid CA CLS license required. Five years clinical laboratory testing experience required. One-year IRL experience preferred. Please apply here, EOE

Clinical Lab Supervisor (San Francisco, CA; Req: 190704). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Requirements: Bachelor’s degree required. Must satisfy CLIA requirements for High Complexity Testing required. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency required. Seven years clinical laboratory testing experience required. To include: Two years supervisor experience required. Two years IRL experience preferred. Apply here, EOE

Medical Technologist II (San Francisco, CA; Req: 191052). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Bachelor’s degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years’ experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Apply here, EOE

(continued on page 10)
POSITIONS (continued from page 9)

Assistant Lab Supervisor (San Francisco, CA; Req: 191123). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. Requirements: High School graduate or GED required. CLIA equivalent for moderate complexity testing required. Medical Laboratory Technician (MLT) or Clinical Laboratory Scientist (CLS) certification/licensed required. One-year laboratory experience required. Please apply here. EOE.

Senior Regulatory Affairs Officer (Macopharma USA). Responsibilities include: Develops appropriate regulatory strategy for bringing Macopharma Transfusion and Biotherapy products (Medical Devices and Drugs to the US). Identifies the status of the product according to the country (Medical Device, medicine ). Sets the elements necessary for the compilation of files according to the regulations and regulatory guidelines. Collects data to assess compliance with the expectations of the authorities. Edits and submits the registration file to the competent authorities or notified bodies. Develop good relationships with the authorities. Keeps abreast of regulatory changes and analyze whether these changes have an impact on our business. Exchange with the service Materio/Pharmaco/ Biovigilance as part of risk management plans, the submission of periodic reports vigilance and change requests for medical information. Skills and requirements: Education and experience required. Expertise with Microsoft Package. Excellent organization and follow-up skills. High level accuracy and attention to detail. High level of discretion and confidentiality. Ability to communicate in a clear and articulate manner. By interest please forward your application to stephanie.ehrenberg@macopharma.de.

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

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.