



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2022 #12

April 8, 2022

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ABC Publishes Statement on MSM & the ADVANCE Study — White House Responds to Lawmakers' Concerns Regarding FDA's Deferral Policy

This week, America's Blood Centers (ABC) [released](#) an updated statement regarding the U.S. Food and Drug Administration's (FDA's) blood donor deferral policy for men who have sex with other men (MSM). The statement also addresses the ongoing work of the FDA-funded "[Assessing Donor Variability And New Concepts in Eligibility](#)" (ADVANCE) Study." This pilot, featuring three blood collection organizations, including ABC-member blood centers OneBlood and Vitalant, is focused on the agency's donor deferral policy for MSM which is viewed as an initial step towards FDA potentially changing the eligibility criteria for MSM to donate blood if the scientific evidence supports a policy change.

ABC expressed in the statement, "[a] call for a safe and available blood supply that treats all potential donors with fairness, equality, and respect" and highlighted its support of "the FDA change in 2020 that reduced the donor deferral period from 12 to three months for [MSM]." The statement also emphasized ABC's support of the steps underway to gather scientific evidence "to further evaluate the current policy." ABC endorsed "this effort as a pathway to the establishment of donor-screening based on individual risk behaviors, not sexual or gender identity. The use of rational, science-based deferral periods must be applied fairly and consistently among blood donors."

ABC concluded the statement by explaining that enrollment is ongoing for the ADVANCE study at eight locations throughout the U.S. that are seeking participation from interested gay and bisexual men in order to "collect data on the performance in assessing risk of new questions that may be added to the donor history questionnaire in the future. The results, which are expected in late 2022, will be submitted to the FDA for review and the agency will then decide the next steps in this process, including how the data will be released to the public."

A copy of the full [statement](#) is available for download on the ABC website. [Talking points](#) for ABC members to use when responding to media inquiries on the MSM blood donor deferral and the ADVANCE study can be found on the ABC member portal or within MCN 22-036.

Congressional Members Discuss MSM Deferral with President Biden. Rep. Ritchie Torres (D-N.Y.) and other co-chairs of the Congressional LGBTQ+ Equality Caucus (Reps. David Cicilline (D-R.I.), Mark Pocan (D-Wis.), Mondaire Jones (D-N.Y.), and Sean Patrick Maloney (D-N.Y.)) recently discussed the FDA MSM

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White House Response to FDA MSM Deferral Policy (continued from page 1)

blood donor deferral policy in a meeting with President Biden according to a [report](#) from *Gay City News*. “I made the case to the president that the FDA’s policy is a relic of the past, it’s a relic of the 1980s, and it’s relic of a time when we had more homophobia than we do now,” stated Rep. Torres in the article.

Rep. Torres expressed his views that the FDA’s blood donation policy for MSM is discriminatory and that changes to the policy in recent years by the agency are insufficient. “It is unreasonable to expect anyone, straight or gay, to defer sex for months in order to contribute blood...Even though I was one of the few providers of antibodies [for COVID-19 convalescent plasma] in March of 2020, I could not donate blood because of my sexual orientation, and I could not donate blood to save lives during a national emergency — during a severe blood shortage.”

The article quotes Rep. Torres as stating “[e]ven though the president was sympathetic to my message, he was also deferential to the process of the FDA, and he is loath to intervene.” Rep. Torres indicated that he and other members of the Congressional LGBTQ+ Equality Caucus will continue to advocate for a policy change. “We just want to keep up pressure on the White House and the FDA. The FDA’s discrimination against the LGBTQ community...is no longer acceptable.” The publication also contacted the FDA for comment and an update on the ADVANCE study and received the following response, “The scientific information that is needed to further change blood donor policies does take time and effort... We do not have a specific timeline for when these studies may be completed, but remain committed to gathering the scientific data that can support alternative donor deferral policies that maintain a high level of blood safety.”

(Sources: ABC MSM and ADVANCE Study [Statement](#), 4/4/22; *Gay City News*, [In Historic Meeting with Biden, Torres Advocates for End to Blood Ban](#), 4/7/22) ♦



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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.

America’s Blood Centers

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NYBC Taking Part in HIV Vaccine Research Trial

New York Blood Center (NYBC), a member of America's Blood Centers, recently announced a partnership with Columbia University and New York City in a National Institutes of Health (NIH)-funded clinical trial exploring the use of “messenger ribonucleic acid (mRNA) technology in an HIV preventive vaccine.” According to an NYBC [news release](#), the phase I trial plans to enroll 108 participants at 10 sites throughout the U.S. to test “[three] different experimental vaccines against HIV using the mRNA vaccine technology that has been successful in fighting COVID-19. The vaccines are experimental, meaning that they have not been approved by the U.S. Food and Drug Administration (FDA). Researchers will study the safety of and immune responses to the different vaccines, focusing on which might be the best vaccine candidate as well as what might be the best dosage.”

The mRNA technology used for the vaccine expands on the mRNA technology previously developed by Moderna for the COVID-19 vaccine. The news release states, “[i]nstead of showing the immune system pieces of HIV, the study vaccines carry instructions that show human muscle cells how to make small pieces that resemble parts of HIV but are not actual pieces of the virus. Therefore, participants cannot get HIV from the vaccines. When people get a vaccine injection in the muscle of their arm, the cells in that muscle will get the instructions and start to make the different types of HIV pieces and display these pieces on the surface of the muscle cell. The immune system will then be able to see these HIV pieces and learn how to recognize them. Researchers hope that the immune system will respond by making antibodies and T-cells that could fight HIV if a person is ever exposed to the virus in the future.”

Hong Van Tieu, MD, MS, head of the Laboratory of Infectious Disease Prevention at LFKRI and NYBC's Project ACHIEVE stated in the news release, “[s]eeing the first participant in HVTN 302 receive their initial injection of the study vaccine at our clinic site provides me hope that we can make a major contribution to the scientific community's goal to prevent the spread of HIV. Globally more than thirty-seven million people are living with HIV. There have been major advances in HIV prevention, care, and treatment, but a vaccine will impact the broadest segment of society. We're looking forward to applying what we learned from the COVID-19 vaccine trials to our research on this potentially groundbreaking vaccine.” Anthony Fauci, MD, director of NIH's National Institute of Allergy and Infectious Diseases added in the agency news release, “[f]inding an HIV vaccine has proven to be a daunting scientific challenge. With the success of safe and highly effective COVID-19 vaccines, we have an exciting opportunity to learn whether mRNA technology can achieve similar results against HIV infection.”

(Sources: NYBC & Columbia University [News Release](#), 3/21/22; NIH [News Release](#), 3/14/22)◆

RESEARCH IN BRIEF

Challenging the 30-Minute Rule. A recent study in *Vox Sanguinis* focused on the point that “international standards have established a ‘30-min rule’ that requires the discard of red blood cell (RBC) units that are exposed to uncontrolled temperature for >30 minutes.” This is due to the concern of bacterial contamination. The researchers explained “[a]lthough similar studies have not been conducted with thawed frozen plasma (FP), transfusion services often extrapolate these ‘rules’ to FP storage leading to wastage.” They noted that wastage data from Canada “demonstrates that it is important to collect evidence to support or deny the 30-minute rule for thawed plasma.” For this study “at each site[,] FP units collected were produced following each organization's standard procedures...Plasma units were stored at <18 C for < 90 days prior to testing for the following quality parameters: FVIII, FVII, FV, prothrombin time and fibrinogen content...Bacterial strains used in this study were chosen based on their ability to grow in platelet components (*Staphylococcus epidermidis*) or cryoprecipitate (*Serratia liquefaciens*, *Pseudomonas aeruginosa*, and *Pseudomonas putida*). Maximum plasma unit core temperatures during room temperature (RT) exposures for 30 (T30) or 60 (T60) minutes were determined using temperature data loggers.” The researchers stated

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RESEARCH IN BRIEF (continued from page 3)

that “[t]emperature measurements were taken with exposures on days 0, 2, and 5 of plasma storage...On Day 5, test units were exposed once to RT for 5 hours...No significant differences ($p < 0.05$) in quality were seen between T30 and T60 units and after a final 5 hour excursion for any of the factors...*S. liquefaciens* proliferated in cold-stored plasma, while *P. putida* showed variable viability...*S. epidermidis* and *P. aeruginosa* survived but did not grow in cold-stored plasma...Overall, no statistical differences in bacterial concentration between T30 and T60 units and after a final 5 hour excursion were observed ($p < 0.05$).” The authors concluded that the “results of our study demonstrate that it is safe to expose thawed plasma to temperatures of 20–24 C for periods of 60 min, up to twice in addition to a single 5-hour exposure, during 5 days of refrigerated storage.” They also added that “[d]ata from this study served as the basis to update the current 60-min rule in Canada to include plasma units.”

Citation: Ramirez-Arcos, S., Howell, A., Bearne, J., Bhakta, V., Bower, L., Cardigan, R., *et al.* [Challenging the 30-min rule for thawed plasma](#). *Vox Sang*. 2022.

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

BRIEFLY NOTED

The College of American Pathologists (CAP) issued a [statement](#) on April 5th regarding the U.S. Food and Drug Administration’s (FDA’s) blood donor deferral policy for men who have sex with other men (MSM) and the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study. The statement expresses that “[t]he CAP strives for inclusivity and diversity in all our endeavors, and strongly supports gender-neutral blood donor screening based on individualized risk assessment for HIV infection instead of sexual identity...More inclusive and more objective blood donor screening may increase both the safety and the availability of the nation’s blood supply...The CAP supports participation in the ADVANCE Study, and the ability of safe and eligible individuals, regardless of sexual identity, to give life-saving blood donations needed every day.”

(Source: The CAP [Statement](#), 4/5/22) 💧

INFECTIOUS DISEASES UPDATE

CREUTZFELDT-JAKOB DISEASE (CJD)

Researchers at the Medical Research Council (MRC) Prion Unit at the University College London [announced](#) “promising early results” from a trial of a monoclonal antibody treatment from Creutzfeldt-Jakob disease (CJD). The preliminary data has been published in *Lancet Neurology* and “shows the treatment is safe and able to access the brain. In three patients, disease progression appeared to stabiliz[e] when dosing levels were in target range. Given the small number of patients treated, researchers say the findings should be regarded as preliminary and further studies are needed to draw more comprehensive conclusions. None of the six patients experienced side effects while receiving the treatment but all sadly died as a result of their condition.”

(Source: University College London [News Release](#), 3/17/22) 💧



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.

Recording Available for ADRP Webinar: Now Hiring? The Challenges of Getting and Keeping Donor Services Staff

A recording of the March 30th ADRP Webinar: “Now Hiring? The Challenges of Getting and Keeping Donor Services Staff” is [available](#) to ADRP subscribers. The webinar featured Versiti’s Monica Zendejas and LifeShare Blood Center’s Benjamin Prijatelj sharing the experiences and strategies at their blood centers with hiring and retaining donor services staff. An archive of previous ADRP webinars can also be accessed by ADRP subscribers at the ADRP *CollABORate* [Community](#).

Photos Available from the 25th Annual Awards of Excellence

America’s Blood Centers recently honored the recipients of the 25th Annual *Awards of Excellence*, during the 60th ABC Annual Meeting. These awards allow ABC to recognize individuals and organizations that have made outstanding contributions in promoting blood donation and improving transfusion medicine. All photos from the General Session, awards ceremony, and the Casino Night event celebrating ABC turning 60 are available [here](#). ♦

NEW on CollABORate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC [CollABORate](#) Online Member Community include:

- [Donor Identification/DIN Verification](#) (COLLECTIONS & DONOR SERVICES)
- [Tall Refrigerator Options](#) (QUALITY BYTES)
- [Radsure Irradiation Indicators](#) (TECHNICAL DIRECTORS)
- [Driver Policy](#) (HUMAN RESOURCES)
- [Investigating Possible Duplicate Donors](#) (COLLECTIONS & DONOR SERVICES)
- [Pediatric Out-of-Group Platelet Transfusion/Donor Notification HLA Antibodies](#) (MEDICAL ISSUES)
- [Compomats G5 For Sale](#) (ALL MEMBER FORUM)
- [ABC Roundup](#) (ALL MEMBER FORUM)

ABC members are encouraged to [login](#) and join the conversations today!

WORD IN WASHINGTON

The Administration [issued](#) a proclamation from President Biden on March 31st recognizing April as National Donate Life Month. The proclamation references blood donation as well, “we encourage Americans who can, to become organ, eye, tissue, marrow, and blood donors...Now, Therefore, I, Joseph R. Biden Jr., President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2022 as National Donate Life Month. I call upon every person who can, to share the gift of life and hope by becoming organ, eye, tissue, marrow, and blood donors.”

(Source: White House [Announcement](#), 3/31/22)

The U.S. Food and Drug Administration (FDA) [announced](#) that Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant. Sotrovimab is a monoclonal antibody therapy for COVID-19 from GlaxoSmithKline plc and Vir Biotechnology, Inc. The agency had previously limited its use in certain parts of the U.S.

(Source: FDA [Announcement](#), 4/5/22) ◆

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.)

2022

April 12-13. **17th Annual FDA and the Changing Paradigm for HCT/P Regulation, Cambridge Md.** Registration is [open](#). More information available [here](#).

May 10-12. **2022 ADRP Conference, Phoenix, Ariz.** Registration is [open](#). More information available [here](#).

June 4-8. **37th Annual International Congress of ISBT, Kuala Lumpur, Malaysia.** More information available [here](#).

Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop, Minneapolis, Minn.** More information coming [soon](#).

Sept. 21-22. **28th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal.** Registration is [open](#). More information available [here](#).

Oct. 1-4. **Association for the Advancement of Blood & Biotherapies Annual Meeting, Orlando, Fla.** More information available [here](#).

2023

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** More information coming soon.

May 9-11. **2023 ADRP Conference.** More information 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, e-mail: newsletter@americasblood.org

POSITIONS

Chief Medical Officer. Blood Assurance is seeking to fill an opening for **CHIEF MEDICAL OFFICER (CMO)** based in our Chattanooga home office. As a key member of the executive team reporting directly to the CEO, this role provides medical and professional guidance to employees of the company, represents the company to the medical community and provides guidance to area medical professionals. Minimum qualifications include: M.D. or D.O. degree with boards in clinical pathology required; boards in blood banking are preferred. License to practice medicine in Tennessee and Georgia or ability to obtain licensure. Minimum eight to 10 years of prior-related medical field experience, blood center experience is preferred. Three to five years senior-level leadership role with experience supervising others. Success in this role will require advanced skills in: verbal and written leadership communications with a servant-leadership philosophy, staff management, customer service, conflict resolution, decision-making, strategic planning, teamwork, flexibility, and adaptability. Proficiency in making Board room presentations and resolving complex medical issues is required. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Company Paid Time Off, 401K, Wellness Program and Relocation Assistance. Qualified candidates are encouraged to apply online at www.bloodassurance.org. Blood Assurance is an EOE and Tobacco Free.

Implementation Specialist (BBCS). Blood Bank Computer Systems (BBCS) is hiring for a remote implementation Specialist. Reporting to the Client Services Manager, this position will be responsible for establishing, maintaining, and managing client implementation work plans, assisting with the installation/upgrade of BBCS applications at client facilities, assisting the client in meeting the projected Go Live dates, new client management training, on-site consultations, and training. Requirements: Bachelor's degree, three plus years of successful project management/implementation experience, tradeshow participation, product and industry knowledge, experience with healthcare and/or IT implementation. To apply visit our BBCS careers website at: <https://www.bbcsinc.com/aboutbbcs/careers/>

Outside Sales Representative/Event Planner (Ardmore, Oklahoma). Outside sales representatives must develop new partnerships with targeted decision makers in community organizations, educational & 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. How to apply: <http://obi.org/careers/>

Territory Sales Consultant (Fort Smith, Arkansas). Outside sales representatives 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 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. How to apply: <http://arkbi.org/careers/>.

Medical Technologist - IRL Lab. LifeSouth Community Blood Centers is currently seeking a skilled individual for a **Medical Technologist** position in our Immunohematology Reference Laboratory (IRL) in **Gainesville, FL**. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. This is a

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POSITIONS (continued from page 7)

full-time position. Starting salary range is \$27.00 - \$32.40 an hour. Shift differential may apply. LifeSouth offers a competitive benefits package and great career development opportunities. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. **Applicants should apply here:** <https://lifesouth.csod.com/ux/ats/career-site/5/home/requisition/2741?c=lifesouth>

Medical Technologist - Special Testing. LifeSouth Community Blood Centers is currently seeking a skilled individual for a **Medical Technologist** position in our Special Testing Laboratory in **Gainesville, FL**. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. This lab covers diverse testing methodologies in the areas of flow cytometry, molecular biology, coagulation, hematology, cellular therapies, histocompatibility, and serology. This is a full-time position. Starting salary range is \$27.00 - \$32.40 an hour. Shift differential may apply. LifeSouth offers a competitive benefits package and great career development opportunities. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. **Applicants should apply here:** <https://lifesouth.csod.com/ux/ats/career-site/5/home/requisition/2698?c=lifesouth>

Medical Laboratory Technologist (MLT). The Blood Bank of Alaska (BBAK) is seeking a MLT to join our team in Anchorage, Alaska. This position will be responsible for providing broad support and technical assistance in the product QC laboratory working under the direction of the Laboratory Services Director. Performing necessary duties for day-to-day operations in the product QC laboratory. Assisting management team with compliance related activities as qualified and other support duties as assigned. Working as a team player with other members of the product QC laboratory. Demonstrating ownership and accountability for product QC laboratory activities. Minimum: Bachelor's degree in biological science or associate's degree with MLT certification. Previous work experience in a blood bank/donor center laboratory preferred. MT/CLS or MLT or equivalent certification preferred. We are committed to providing our employees with the support they need. At BBAK we offer an attractive benefit package that includes: Medical, Dental, Vision, Life Insurance, Health Savings Plan, Paid Time Off, 401 K with matching and short Term & Long-Term Disability coverage. View the complete job description at www.BloodBankofAlaska.org. If interested, please contact or HR Director for additional information at MCannon@bbak.org.

Registered Nurse. LifeSouth Community Blood Centers is currently seeking experienced professionals to join our team as **Registered Nurses in Gainesville, FL, and Jacksonville, FL**. This position is responsible for traveling to hospitals to perform therapeutic apheresis procedures. Nurses will only care for one patient at a time and will work alongside hospital nurses and physicians to complete procedures. Nurses will also spend time at the LifeSouth office to coordinate upcoming apheresis procedures and organize necessary documentation. Training: Don't let a lack of apheresis experience stop you from applying! No previous apheresis experience is required. If hired, you will be given sufficient on-the-job training to learn the specialized skills this position requires. Training for this position will be conducted during regular business hours. This is a full-time position. Starting salary range is \$67,500 - \$74,250 annually plus travel and on-call bonus. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Applicants should apply [here](#) for the Gainesville, FL location. Applicants should apply [here](#) for the Jacksonville, FL location.

Specialist in Blood Banking Students. LifeSouth Community Blood Centers, Inc. is accepting applications for our accredited online SBB training program, class of 2022-2023. Please visit <https://www.lifesouth.org/specialist-in-blood-banking-certificate-program/> for eligibility, other application details, and application forms. The application period ends on April 15th, 2022. Starting date for the 12-month program is June 13, 2023. If interested, please contact Bill Martinez for additional information, gmartinez@lifesouth.org. ♦