

A B C N E W S L E T T E R

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #33

September 15, 2023

Supplemental Findings from 2021 NBCUS Published

Supplemental findings from the 2021 National Blood Collection and Utilization Survey (NBCUS) have been <u>published</u> in *Transfusion*. The data reported represents 92.5 percent of community-based blood centers, 76.3 percent of transfusing hospitals, and 74.7 percent for hospital-based blood collection centers. The authors explained that a 5.5 percent decrease in the number of presenting donors occurred in 2021. Additionally, 54.1 percent of presenting donors were female, an increase from 49 percent in 2019.

The 2021 findings indicated an 18.7 percent decrease took place in total donor deferrals as 2,010,000 [95 percent CI, 1,921,000–2,099,000] versus 2,472,000 from 2019. "Donor deferrals were mostly driven by low hemoglobin or hematocrit followed by other non-medical reasons (24.6 percent), pulse (6.9 percent), and blood pressure (6.4 percent)." The authors did find that a 26.4 percent increase in deferrals for medication use occurred. Additionally, a 4.8 percent increase took place in 2021 for successful donations 11,507,000 [95 percent CI, 10,866,000–12,149,000] when "compared with 2019 (10,981,000). [The] total number of successful racial or ethnic minority donations" declined by 35.4 percent.

The authors explained that, "[m]ost successful donations during 2021 were from donors aged 25–64 years, with 68.8 percent (7,920,000/11,507,000) of successful donations occurring in this group." Specifically, donors between the ages of 45–64 "accounted for 42 percent of successful donations during 2021, and donors aged 25–44 years accounted for 28 percent. The age group that saw the greatest increase in successful donations between 2019 and 2021 was donors aged 65 years and older (40.7 percent increase)." Younger donors experienced declines in successful donations (31.9 percent for donors aged 19–24) and 60.7 percent for those between the ages of 16 and 18). "Repeat allogeneic donors who donated successfully decreased by 4.5 percent [and] [f]irst-time allogenic donors also decreased, by 22.3 percent, between 2019 and 2021, with 2,213,000 first-time donors in 2019 and 1,719,000 (95 percent CI, 1,594,000–1,844,000) first-time donors in 2021."

The data revealed increases overall in "per unit cost of blood products reported by hospitals." According to the authors, the 2021 NBCUS findings showed "increases in prices [for] leukoreduced apheresis platelets (\$516 per unit in 2019 vs. \$567 per unit in 2021), pathogen-reduced apheresis platelets (\$617 per unit in 2019 vs. \$660 per unit in 2021), and leukoreduced RBCs (\$208 per unit in 2019 vs. \$214 per unit in 2021)." The median price paid per leukoreduced red blood cell (RBC) unit varied by region with a cost as low as \$203 to as high as \$225. The median cost of apheresis platelet units ranged from \$537 to \$589.

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The authors further explained that, "most transfused RBCs (80.9 percent) were aged 1–35 days at the time of transfusion," which is similar to the finding of the previous NBCUS." The data also showed that, "molecular genotyping to identify non-ABO RBC antigen expression among blood donors and recipients remains uncommon, although it increased somewhat in 2021." The authors mentioned that, "the number of reactions per 100,000 components transfused also decreased slightly between 2019 and 2021, with 293.7 reactions per 100,000 components transfused in 2019 and 273.8 (95 percent CI, 255.6–291.9) reactions per 100,000 components transfused in 2019 and 273.8 (95 percent CI, 255.6–291.9) reactions per 100,000 components transfused adverse reaction was febrile, nonhemolytic transfusion reaction, with an estimated 18,918 (95 percent CI, 17,085–20,751) reactions occurring during 2021." The authors concluded that, "the ongoing COVID-19 pandemic has likely caused continuing disruptions for blood collection centers and transfusing facilities. Despite these disruptions, data from the 2021 NBCUS suggest a reversal in the trend of declining blood donations."

Citation: Kracalik, I., Sapiano, M., Wild, R., *et al.* "Supplemental findings of the 2021 National Blood Collection and Utilization Survey." *Transfusion*. 2023.

Blood Community Requests Reimbursement Reform

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies, and the American Red Cross have submitted joint comments to the Centers for Medicare and Medicaid Services (CMS) advocating for reimbursement reform, a priority of the 2023 <u>ABC Advocacy Agenda</u>.

The first comment letter, a response to the CY 2024 Physician Fee Schedule Proposed Rule, asks CMS to:

- establish a new clinical labor code for a therapeutic apheresis nurse with a labor rate reflecting the required skills and experience; and
- increase the payment rates assigned to these CPT codes to reflect the total cost of the procedures.

The <u>second comment letter</u>, a response to the CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule, encourages CMS to revise its proposed essential medicines policy to:

- include blood and blood products, and
- ensure that the payments are sufficient to cover all costs associated with procuring and maintaining essential medicines, including a "buffer stock" of blood and blood products.

ABC will continue to provide updates on its advocacy efforts as they become available.

(Sources: <u>CMS Fee Schedule Joint Comments</u>, 9/11/23; <u>CMS OPPS Joint Comments</u>, 9/11/23)

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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 recognizes 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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RESEARCH IN BRIEF

ABC Newsletter

Intracerebral Hemorrhage: Is There a Link Between Donor and Recipient? A study in the Journal of the American Medical Association used "the assumption that some observed intracerebral hemorrhages (ICHs) are due to underlying cerebral amyloid angiopathy (CAA), [and] hypothesized that transfusion transmission of CAA may manifest through an increased risk of spontaneous ICH among transfusion recipients exposed to a donor with spontaneous ICH." In the study [were], "patients who underwent transfusion and blood donors from 1970 to 2017 in Sweden (main cohort) and from 1980 to 2017 in Denmark (validation cohort). [It was] comprised [of] all patients who underwent transfusion with a red blood cell unit (RBC) between ages 5 and 80 years...A total of 759,858 patients were included in Sweden and 329,512 [from] Denmark...[The] median follow-up for patients exposed to blood donors who developed multiple spontaneous ICHs was 8.2 (IQR, 1.8-19.4) years; follow-up for blood donors 22.2 (IQR, 15.8-26.7) years." The authors explained that, "[c]ompared with receipt of transfusions from donors who did not develop spontaneous ICH, receipt of RBC transfusions from donors who subsequently developed multiple spontaneous ICHs was significantly associated with developing a spontaneous ICH in the Swedish cohort (18 vs 5,185 events; unadjusted incidence rate [IR], 3.16 vs 1.12 per 1,000 person-years [and the] Danish cohort (6 vs 1,901 events; unadjusted IR, 2.82 vs 1.09 per 1000 person-years)." The study concluded that this "may suggest a transfusion-transmissible agent associated with some types of spontaneous ICH." An accompanying <u>editorial</u> asks: "[i]s misfolding of the amyloid ß peptide, the primary constituent of senile plaques in Alzheimer's disease and toxic cerebral vessel wall deposits in CAA contagious?" The author noted, "[d]ata argue that prion-like transmission of amyloid β misfolding can indeed occur...There are good reasons to treat the possibility of CAA transmission via blood transfusion seriously...A powerful argument in support of the findings is the robust study methodology...Other supportive features are the striking similarity in results from the two independent national registries." The editorial also explained that "[t]he arguments [against] the association center on the weakness of evidence for a plausible biological mechanism for blood from a donor with future CAA to rapidly transmit CAA-related hemorrhage." The author concluded that the, "current study is not yet a reason for alarm, certainly not a reason to avoid otherwise indicated blood transfusion, but it is a strong call for more scientific digging."

Citations: Zhao, J., Rostgaard, K., Lauwers, E., et al. "Intracerebral Hemorrhage Among Blood Donors and Their Transfusion Recipients." JAMA.2023.

Editorial: Greenberg, S.M. "<u>Blood Transfusion and Brain Amyloidosis: Should We Be Worried</u>?" *JAMA*. 2023.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

COLLABORATE

NEW on CollABOrate

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC CollABOrate Online Member Community include:

- <u>Regulation/Standard for Culturing Eyewash Stations</u> (QUALITY BYTES)
- <u>Saline Washed Apheresis Platelets</u> (ALL MEMBER FORUM)
- Post-donation Callback Instructions (MEDICAL ISSUES)

ABC members are encouraged to login and join the conversations today!



America's Blood Centers® **INSIDE ABC**

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staffs only, unless otherwise specified.

ABC on Steering Committee of Prehospital Blood Transfusion Initiative Coalition

A Prehospital Blood Transfusion Initiative Coalition (PHBTIC) has been PREHOSPITAL established to help address the availability of and access to blood products **BLOOD TRANSFUSION** INITIATIVE COALITION on emergency medical response vehicles. According to a news release, the PHBTIC will be led by a steering committee, which America's Blood Centers is serving on, that is, "building a multi-disciplinary, collaborative initiative to advance four pillars of focused activity to promote prehospital blood transfusion programs: establish reimbursement for blood products transfused in the prehospital setting; EMS scope-of-practice allowing the initiation of prehospital blood products in states where it currently is not allowed; strategic preparedness for homeland defense and mass casualties; [and] outreach and education, including regulatory, protocols, and best practices for programs based on experiences of agencies currently conducting programs."

(Source: PHBTIC News Release, 9/13/23)

It's About *Life*.

FINAL CALL: Register for the ADRP Masterclass: Change is Good — The Journey of Donor Eligibility

Registration is still open for ADRP's Masterclass, "Change is Good — The Journey of Donor Eligibility," taking place next week (September 20th-21st). While navigating changes in donor eligibility can feel overwhelming at times, this virtual conference is designed to equip industry professionals with invaluable insights, strategies, and best practices to confidently address such challenges and turn them into opportunities. This Masterclass is about more than just implementing a single deferral change. Instead, attendees will hear from award-winning leaders from outside the blood community. These speakers will share insights into building a culture that helps your blood center be more adaptable to future changes, tips for managing challenging conversations on and offline, and cutting-edge strategies being embraced across other industries so they can thrive in a challenging environment. Participants will also receive the latest industry data, hear best practices, and be a part of thought-provoking conversations with industry peers.

New ADRP Resources Available: Toolkits for September Awareness Initiatives

ADRP, the Association for Blood Donor Professionals has developed three new toolkits to support efforts in raising awareness for upcoming recognition events during the month of September. Each toolkit aims to provide blood centers with resources that can be customized and tailored to fit their specific needs to assist with community engagement efforts. These resources include:

- Childhood Cancer Awareness Month Toolkit includes social media graphics, a draft press release, and more:
- Sickle Cell Disease Awareness Month Toolkit includes social media graphics and community resources from the Sickle Cell Disease Coalition; and
- International Donor Recruitment Recognition Day Toolkit includes social media graphics in • English, French, and Spanish, a draft blog post, and more.

Contact info@adrp.org with questions or trouble accessing the toolkits.

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WORD IN WASHINGTON

ABC Newsletter

The U.S. Department of Health and Human Services (HHS) has <u>published</u> the "Toward the Development of a National Red Blood Cell Antibody Patient Data Exchange (RBCAX): 2023 Interim Report." The document explains, "barriers and facilitators to the development of a national red blood cell antibody patient data exchange (RBCAX) in the U.S. and suggest examples of pilot opportunities for such a system. The bulk of this report examines case studies of existing and attempted red blood cell antibody exchanges and registries as well as other health information exchanges (HIEs), nationally and internationally. The goal is to provide a more nuanced understanding of the considerations required for the development, implementation, and sustainment of a successful national exchange...The successful implementation of a national RBCAX would be a critical instrument in the equitable treatment of all patients. Such a system holds the potential to enhance health outcomes in all transfused patients, including those in underserved populations, while also serving as an avenue for patient education. Additionally, a national RBCAX would provide researchers with a valuable data set to better understand disease complexities, including sickle cell disease (SCD) and thalassemia, and clinical phenomena, such as evanescent antibodies."

(Source: HHS Interim Report, 9/14/23)

The Health Resources and Services Administration (HRSA) and HHS included a <u>notice</u> in the *Federal Register* announcing upcoming meetings of the Advisory Council on Blood Stem Cell Transplantation. Two half-day meetings have been scheduled for September 28th and October 26th. While the agendas for the meeting are being finalized, potential topics could include: "the periodic review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering potential inclusion of such new therapies in the C.W. Bill Young Cell Transplantation Program; criteria for defining a high-quality cord blood unit for banking specifications; the unmet needs in blood stem cell transplantation and cellular therapy; strategies to improve rates of donation for adult blood stem cell donors; and other areas to increase blood stem cell donation and transplantation."

(Source: *Federal Register* Notice, 9/8/23).



MAJOR BLOOD CENTERS ACROSS THE U.S. TRUST **GUARDIAN** BY ISENSIX. SHOULDN'T YOU?



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- 24/7/365 live person back-up support



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GLOBAL NEWS

ABC Newsletter

The European Parliament recently voted to adopt the proposed new rules regarding the use of substances of human origin (SoHO) intended for human application. According to a report from *Euractiv*, the new rules seek to "provid[e] both donors and patients with a future-proof and harmoni[z]ed framework for transplants and donations while maintaining some limits on the supply side of these therapies." When it comes to donor compensation, Euractiv explained that, "lawmakers have now settled that donation should be based on the principle of voluntary unpaid donation (VUD), agreeing with the Commission's proposal. The approved report also agrees to define 'compensation' as 'making good of any quantifiable losses and reimbursement of expenses associated with donation' and adopts the principle of 'financial neutrality of donation' - meaning that no financial gain or loss will be incurred by the donor as a result." The Plasma Protein Therapeutics Association (PPTA) issued a news release in the wake of the vote that voiced its opposition to the new rules. "Most European countries already provide some form of monetary or nonmonetary donor compensation to blood and plasma donors. Therefore, maintaining a broad and open definition of SoHO donor compensation would allow Member States to choose whether and how to compensate donors within the framework of the Voluntary Unpaid Donation (VUD) principle. Moreover, the rationale for this proposed change has no basis, with published data (most recently in *Transfusion*) showing that repeat plasma donation is safe and does not adversely impact donor health." PPTA Executive Director Maarten Van Baelen added in the news release, "[t]he restrictive amendments proposed by the European Parliament, permitting donor compensation only for 'quantifiable' losses, is at odds with guidelines on donation ethics from respected organi[z]ations such as the Council of Europe and the Nuffield Bioethics Committee." European Blood Alliance Executive Director Peter O'Leary told Euractiv, "the report strengthens 'the protection of the health and wellbeing of our donors and patients.' [He also added] that the agreement on voluntary unpaid donation increases the resilience and continuity in the supply of SoHO."

(Sources: *Euractiv*, "<u>EU Parliament approves text on donation of substances of human origin</u>, 9/12/23; PPTA <u>News Release</u>, 9/12/23) ♦

COMPANY NEWS

Terumo Blood and Cell Technologies <u>announced</u> an upcoming clinical expert meeting on September 19th titled "The Journey of HSCT and Gene Therapy: Unveiling the Art of Red Cell Exchange and Cell Collection for Sickle Cell Disease." The meeting will be a webinar from 3-4:30 p.m. EDT and feature Vanderbilt University Medical Center's Jennifer Andrews, MD, MSc, Deva Sharma, MD, and Adetola A. Kassim, MD, MS, all from Vanderbilt University Medical Center discussing:

- "the role of transfusion in preparing for hematopoietic stem cell transplantation (HSCT) and gene therapy for patients with sickle cell disease;
- cell collection process and considerations for patients with sickle cell disease; [and]
- gene and cellular therapy for sickle cell disease."

Registration is open.

(Source: Terumo BCT <u>Announcement</u>, 9/7/23) ♦





Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

• ADRP Masterclass: Change Is Good – The Journey of Donor Eligibility – Sept. 20-21. <u>Registration</u> is open. More information available <u>here</u>.





CALENDAR

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

2023

Sept. 17-20. American Association of Tissue Banks Annual Meeting, National Harbor, Md. <u>Registration</u> is open. More information available <u>here</u>.

Sept. 19. Terumo Blood and Cell Technologies Clinical Expert Meeting: The Journey of HSCT and Gene Therapy: Unveiling the Art of Red Cell Exchange and Cell Collection for Sickle Cell Disease (Virtual). Registration is <u>open</u>.

Sept. 20-21. ADRP Masterclass: Change Is Good – The Journey of Donor Eligibility (Virtual). <u>Registration</u> is open. More information available <u>here</u>.

Sept. 20. The Department of Transfusion Medicine, National Institutes of Health (NIH) Clinical Center, NIH, and the American Red Cross 42nd Annual Immunohematology and Blood Transfusion Symposium. <u>Registration</u> is open. More information available <u>here</u>.

Oct. 9-11. Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif. <u>Registration</u> is open. More information available <u>here</u>.

Oct. 14-17. AABB Annual Meeting, Nashville, Tenn. Registration is open. More information available here.

Oct. 18-20. American Society for Clinical Pathology (ASCP), Long Beach, Calif. More information available here.

Oct. 31. U.S. Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (Virtual). More information available <u>here</u>.

Nov. 18-21. ISBT Regional Congress, Cape Town, South Africa. <u>Registration</u> is open. More information available <u>here</u>.

2024

Feb.7-8. International Plasma and Fractionation Association & EBA Symposium on Plasma Collection and Supply. Leiden, Netherlands. More information available <u>here</u>.

Mar. 4-6. ABC Annual Meeting, Arlington, Va. More information available here.

May 14-16. 2024 ADRP Annual Conference, St. Louis, Mo. 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 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

EQUIPMENT AVAILABLE

For Sale. Two refurbished Aurora Plasmapheresis System devices with Certificate of Compliance for each device. Both devices have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email <u>latrinamorman@lifelinebloodserv.org</u>.

For Sale. Two NEW Aurora Plasmapheresis System devices with Certificate of Compliance. NEVER USED. Currently, both have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email <u>latrinamorman@lifelinebloodserv.org</u>.

POSITIONS

Medical Director (Memorial Blood Centers). Memorial Blood Centers (MBC.ORG), a division of Innovative Blood Resources, now a major partner in the NYBC Enterprise, has been saving and sustaining lives since 1948, and we're seeking a Medical Director who will help further our efforts and expand our success. This challenging medical directorship serves as co-medical director at a nationally recognized Children's hospital transfusion service, a national quality leading safety net hospital that is the largest local level 1 trauma center (both adult and pediatric), and associate medical director for blood centers in Minnesota (Duluth and Twin Cities, Nebraska (Lincoln and Omaha) and Greater Kansas City (Kansas and Missouri). The role will provide medical support across the Enterprise and for the assigned blood centers and transfusion services. Memorial Blood Centers supplies blood and blood components, state-of-the-art laboratory services, and biomedical expertise to area healthcare partners, national blood centers, biotechnology companies, research institutions, and international clients. The blood centers in Minnesota, Nebraska and the Greater Kansas City area serve nearly 100 hospitals and more than a dozen air ambulances with life-saving blood. Ample opportunity for research and clinical publication as well as direct patient and donor involvement. Click here to apply: https://www.kleinhersh.com/positions/medical-director2/.

Director, Public Relations and Marketing. Mississippi Blood Services (MBS) is seeking the right candidate for the highly visible position of Director of Public Relations & Marketing. We are looking for an individual with flexible skills who can oversee our Communications and Public Relations efforts to ensure we are able to collect and distribute the much-needed resource of blood donations! As the face of the company, the ideal candidate will be responsible for all aspects of Public Relations and Marketing, which includes recruitment of blood drives and telerecruitment. This individual will work with Public Relations, Marketing Representatives, Telerecruitment manager, and other managers to coordinate and organize ample daily collections of whole blood, double red cells, apheresis platelets, and plasma collections for the organization. They will also work in conjunction with other MBS management to set strategic goals and objectives for the company. Must have a bachelor's degree (BA) from a four-year college or university; three to five years' related experience; or equivalent combination of education and experience. Visit www.msblood.com to apply online.

Assistant Manager - Product Quality Control (Carter BloodCare). Principal Accountability: The Assistant Manager Product Quality Control reports to the Manager of Product Quality Control and will be responsible for all daily, routine departmental activities and operations, consulting with the Manager, as needed. This position will oversee strict fiscal adherence to the budget and other administrative activities for the department, as assigned by the Manager, Technical Director, or Medical Director. The Assistant Manager is able and willing to perform any departmental task, as needed, to ensure efficient workflow within the department. Education: Bachelor of Science Degree and Minimum MT/MLS ASCP, or equivalent, required. Experience: Working knowledge of Product Quality Control instrumentation and parameters associated with donor collections. Strong working knowledge of blood bank policies and procedures. Comprehensive problem-solving skills. Good written and verbal communication skills. Excellent interpersonal and conflict resolution skills. Very strong customer service practices. Advanced computer skills. Comprehensive knowledge of administrative functions, including budget activities. Effective organizational skills, to include the ability to organize and prioritize workload, attention to detail, and consistently follow through with a commitment to excellence. Equal Opportunity Employer:

(continued on page 9)

Disability/Veteran. Apply at <u>www.carterbloodcare.org</u>, click Careers & search for job **Assistant Manager Prod**uct Quality Control.

Quality Systems Director. Rock River Valley Blood Center, based in Rockford IL, is looking for a Quality Systems Director to oversee the strategic planning, development and execution of all quality systems and process improvement initiatives center wide. This includes business operations relating to blood collection, testing, manufacturing, distribution, document control, customer service, safety, risk management, training, internal and external audits/inspections. The position is responsible for ensuring the organization is in full compliance with all applicable federal and state regulations and professional contract requirements. The successful candidate is a self-starter who will lead and champion all quality initiatives from start to finish, taking an influential, collaborative, team-oriented and business friendly approach. Must possess strong leadership skills with advanced knowledge and business acumen in quality system concepts and process improvement. Must have advanced analytical and problem-solving skills; exceptional attention to detail; ability to prioritize tasks; effective communication skills both verbally and in writing. Strong skills in Microsoft Office applications. Qualifications include: five-plus years' experience in a progressive quality systems role within a highly regulated environment, three-plus years supervisory and leadership experience, previous experience interpreting and implementing regulatory/accrediting standards, bachelor's degree in health science, quality management or related field. M.T. or M.L.S. (ASCP) a plus. CMQ/OE and/or CQA (ASQ) highly preferred. Please visit our careers site online to apply https://www.rrvbc.org/careers/.



Purchasing Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Purchasing Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Purchasing Manager oversees daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!