

2018 #30

September 7, 2018

INSIDE:

2018 ABC Financial Ratio
Survey Launches.....2

SMT Journal Club
Recording Available2

Upcoming ABC Webinars
– Don't Miss Out!.....3

RESEARCH IN BRIEF3

RECENT REVIEWS3

INFECTIOUS DISEASE
UPDATES4

BRIEFLY NOTED.....4

REGULATORY NEWS....5

PEOPLE.....5

IN MEMORIAM6

STOPLIGHT®: Status of
America's Blood
Centers' Blood Supply .7

MEMBER NEWS.....8

COMPANY NEWS8

CALENDAR.....9

POSITIONS.....9

Treating Hemophilia A without Factor VIII: Emicizumab Prophylaxis in Patients Who Have Hemophilia A without Inhibitors.

Results from a recent phase three, multicenter, randomized clinical trial examined the use of emicizumab, a “monoclonal antibody that bridges activated factor IX and factor X to replace the function of missing activated factor VIII... for the prevention of bleeding in hemophilia A [patients] without factor VIII inhibitors.”

It focused on the rates of “treated bleeding” that manifested in two groups of experimental, prophylactically managed patients (groups A and B) who received 1.5 mg drug/kg body-weight weekly and 3.0 mg drug/kg every two weeks respectively, compared to a cohort of control patients (group C) who received no prophylaxis. The results were impressive, with a 96 percent reduction observed in the annualized bleeding rates between groups A and C (medians: 1.5 versus 38.2 events per year; $p < 0.001$) and a similar, statistically significant differential (97 percent) seen between groups B and C. A sub-analysis, involving 48 participants who previously had been managed prophylactically with factor VIII, demonstrated a 68 percent reduction in bleeding rates after their factor VIII was discontinued and they were transitioned to prophylaxis identical to that used for patients in group A ($p < 0.001$).

Adverse effects were minimal and no evidence was observed for development of thrombosis or thrombotic microangiopathy, anti-drug antibodies, or factor VIII inhibitors.¹ The accompanying editorial discussed the importance of developing new therapeutic agents, such as emicizumab, for the restoration of hemostasis in patients with hemophilia while also cautioning that research into this new drug – with an emphasis “on risk, cost, benefit, and participation in observational studies and clinical trials” – is still required at this time.²

Citations: Mahlangu J., Oldenburg J, Paz-Priel, I., *et al.* Emicizumab prophylaxis in patients who have hemophilia A without inhibitors. *New Engl. J. Med.* 2018. doi: [10.1056/NEJMoa1803550](https://doi.org/10.1056/NEJMoa1803550).¹

Ragni M.V. Mimicking factor VIII to manage the factor VIII-deficient state (editorial). *New Engl. J. Med.* 2018. doi: [10.1056/NEJMe1808789](https://doi.org/10.1056/NEJMe1808789).²

Contributed by Christopher Gresens, MD, Senior Chief Medical Officer, Blood Centers of the Pacific, Blood Systems, Inc. ♦



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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.

2018 ABC Financial Ratio Survey Launches

ABC has issued the 2018 Financial Ratio Survey. The results provide members with an important tool that can be used to assist with the management of blood programs, anonymously benchmark valuable operational data, and identify best practices. The deadline to complete the survey is October 12th. Only participating blood centers receive the final report. A link to the survey and the questions are available in [MCN 18-037](#), which was distributed to the ABC Chief Financial Officers Forum on August 31st. Most of the financial information requested is public information that blood centers report on IRS Form 990 or their audited financial statements. Individual center data is confidential and not shared. ABC encourages all member blood centers to participate. Please contact [Ruth Sylvester](#) for additional information or questions.

SMT Journal Club Recording Available

A recording of the August 2018 SMT Journal Club Webinar is [available](#) to ABC Members via ABC's listservs. The webinar included the review of three key scientific/medical articles, an editorial, and clinical evidence synopsis followed by open discussion by participants, presenters, and article authors. Members of ABC interested in accessing listservs may sign-up for an account [here](#). The publications can be found on the ABC Member [website](#):

- [Impact of Blood Type O on Mortality of Severe Trauma Patients](#)
- [How Do I Implement a Whole Blood Program for Massively Bleeding Patients?](#)
- [Pathogen-Reduced Platelets for the Prevention of Bleeding in People of Any Age](#)
- [Comparison of the Hemostatic Efficacy of Pathogen-Reduced Platelets vs Untreated Platelets in Patients with Thrombocytopenia and Malignant Hematologic Diseases-A Randomized Control Trial](#)
- [Pathogen Inactivation Strategies to Improve Blood Safety Let's Not Throw Pathogen-Reduced Platelets Out with Their Bath Water](#)

(continued on page 3)

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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INSIDE ABC (continued from page 2)

Upcoming ABC Webinars – Don't Miss Out!

- **Quality Integration Part I** – September 18th at 3 p.m. EDT. Additional details available in [MCN 18-038](#).
- **Development and Implementation of a Platelet Prediction Model** – October 25 at 3 p.m. EDT. Additional details forthcoming!
- **Quality Integration Part II** – November 29th at 3 pm. EST. Additional details forthcoming!

RESEARCH IN BRIEF

Thawed cryoprecipitate? Cryoprecipitate must be used within six hours of thawing and within four hours after pooling, mainly over concern about loss of clotting factor activity, but also bacterial proliferation. Citing the growing clinical use of cryoprecipitate as a source of fibrinogen in the management of major hemorrhage, and its favorable cost comparison to fibrinogen concentrates, investigators in Houston, Texas have done a small study of its extended room temperature storage. Ten pools of five thawed units were each kept at room temperature for six hours, then 1-6 degrees Celsius for an additional 18 hours. Mean fibrinogen levels and von Willebrand (ristocetin cofactor) factor levels were unchanged at zero, six, and 24 hours. As expected, factor VIII levels fell (although cryoprecipitate is rarely used to supplement VIII activity). Bacterial growth was not detected at the end of the room temperature hold. The authors point out the operational advantages of extended storage and call for larger studies.

Citation: Soundar, E.P., Reyes, M., Korte, L. and Bracey, A. Characteristics of thawed pooled cryoprecipitate stored at refrigerated temperature for 24 hours. *Blood Transfusion*. 2018. doi: [10.2450/2017.0133-17](https://doi.org/10.2450/2017.0133-17). 💧

RECENT REVIEWS

A primer on extracellular vesicles and their roles in health and disease. Cells release membrane-bound vesicles containing a wide array of cell-derived biomolecules under normal circumstances as well as during cell damage and death. These are known by many names (ectosomes, microparticles, microvesicles, exosomes, oncosomes), and are the topic of a burgeoning research agenda aiming to define their functional importance and potential roles in pathogenesis, diagnosis, and therapy. Their ability to move biologically active molecules from cell-to-cell and tissue-to-tissue raises the possibility of myriad functional activities. The transfusion medicine literature contains an increasing number of references, largely related to the presence of cell-derived extracellular vesicles in stored components for transfusion and their potential impacts on recipients. Developers of products including platelet substitutes and cellular therapies are increasingly asked by the U.S. Food and Drug Administration (FDA) to characterize their microvesicle content.

This review, with an excellent bibliography, introduces relevant definitions, the potential of extracellular vesicles as biomarkers and effectors of physiologic processes, and for diagnostic and prognostic applications in an array of health states. Major challenges for investigators and potential influences on clinical practice are discussed. While specific reference is absent, the review is a concise introduction to a topic that will impact transfusion medicine.

Citation: Shah, R., Patel T., Freedman, J.E. Circulating extracellular vesicles in human disease. *N. Engl. J. Med.* 2018. doi: [10.1056/NEJMra1704286](https://doi.org/10.1056/NEJMra1704286).



INFECTIOUS DISEASE UPDATES

EBOLA

Cases of Ebola from the latest outbreak in the Democratic Republic of the Congo (DRC) continue to rise. The latest figures include 98 confirmed and 31 probable cases as of September 4th. Mitigation initiatives include standard epidemiological tools (case finding, contact tracing, etc.) in addition to the use of experimental antiviral medications and “ring vaccination” of high risk individuals around cases and healthcare providers. The U.S. Centers for Disease Control and Prevention (CDC) has not classified the affected areas as having “widespread transmission of Ebola virus,” which would trigger donor interventions in this country. 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).”

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in Blood Banking and
Transfusion Medicine

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Sources: (ProMed Mail, [Ebola update \(83\): Congo DR \(NK\) case update, Butembo fatalities](#), 9/6/18; DRC Ministry of Health [Announcement](#), 9/6/18.


BRIEFLY NOTED

The Alliance of Blood Operators (ABO) is offering a streamlined Medical Leadership Development Scheme to members. This program aims to promote “the development of essential leadership capabilities” among aspiring blood center physicians. It has been modified from its original incarnation (highly praised by ABC participants) by eliminating the face-to-face component and trimming the all-online offerings to eight, one hour “virtual learning modules,” each requiring one hour of pre-reading homework. The offering is free to ABO members (ABC physicians included). The course will be run from November 2018 through June 2019. The descriptive [brochure](#) and application [form](#) can be accessed on the [ABC Member website](#).

Pharma Conference, Inc. announced that the 15th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference will be taking place in Washington, D.C. February 4th-5th, 2019 at the Grand Hyatt Washington. The meeting will feature FDA and industry experts including personnel from the FDA’s Center for Biologics Evaluation & Research (CBER). “One mainstay of all our programs is the opportunity for conference attendees to meet and visit with FDA representatives and industry experts,” said J.W. Smith, president of Pharma Conference, Inc. in a conference [announcement](#). “The learning opportunities are invaluable.” The conference brochure and additional details including registration information will be posted to the organization’s website as they become [available](#).

(Pharma Conference, Inc. [Announcement](#), 9/5/18) ♦





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SAVE THE DATE!
March 26, 2019

AMERICA'S BLOOD CENTERS'
CAPITOL HILL DAY
WASHINGTON, D.C.

More details coming soon!

REGULATORY NEWS

The [agenda](#) has been published for the Thursday, September 13th Meeting of the U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). It will take place from 8 a.m. – 5:30 p.m. at the Crystal City Marriott at Reagan National Airport located at 1999 Jefferson Davis Highway in Arlington, VA 22202. Both in-person and webcast [registration](#) is open and all interested individuals are encouraged to register. The Committee will discuss “defining a tolerable risk for infectious diseases from a patient’s perspective” and will consider the history of combating infectious disease risks to the blood supply along with “ongoing” mitigation efforts and “emerging considerations.” The opportunity for public comments will be available at the meeting and limited to five minutes per speaker for individuals that met the September 7th deadline. For additional information, contact ACBTSA@hhs.gov.

(Sources: HHS ACBTSA [Website](#), 9/4/18; Meeting [Registration](#), 8/31/18; *Federal Register* Meeting [Notice](#), 8/16/18) ♦

PEOPLE



Bloodworks Northwest President and CEO **Jim AuBuchon, MD, FCAP, FRCP (Edin)** will retire on September 3rd, 2019. Dr. AuBuchon has led Bloodworks Northwest (formerly Puget Sound Blood Center) since 2008 and has grown the organization from \$142 million in revenue to \$197 million according to the Seattle Business Journal. “I have enjoyed leading this organization, seeing our accomplishments, and taking on the challenges before us, yet I realize I cannot continue in this position indefinitely and still reach for further dreams my

(continued on page 6)



PEOPLE (continued from page 5)

wife and I hold dear,” said Dr. AuBuchon in an email to blood center staff. He has served on the U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability, the ABC Board of Directors, and has been President of AABB. Dr. AuBuchon was medical director of the Blood Bank and Transfusion Service at Dartmouth–Hitchcock Medical Center for 18 years, and his distinguished career also includes time at the National Institutes of Health and the American Red Cross. He has also been elected a Fellow by the Royal College of Physicians of Edinburgh.

(Source: Seattle Business Journal, [Bloodworks Northwest CEO Dr. James AuBuchon sets retirement date](#), 8/30/18)

Catherine Hartman has been named the next executive director of the European Blood Alliance (EBA). Ms. Hartman brings expertise in association management and governance, European Union (EU) health policies, and advocacy. She began working for the EBA on September 3rd, 2018 and will formally assume the role from current EBA Executive Director Kari Aranko, MD, PhD following the next EBA Board meeting. Ms. Hartman holds a degree in EU Public Law.



Catherine Hartman (left) pictured with Dr. Kari Aranko (right)

(Source: EBA [Announcement](#), 9/6/18)



The Commission on Office Laboratory Accreditation (COLA) appointed **Nancy Stratton** chief executive officer. Ms. Stratton most recently held the position of chief executive officer at Clinical Pathology Laboratories in Austin, Texas, a division of Sonic Healthcare, and brings 35 years of laboratory management experience to the position. “In Nancy, our organization gains a leader with an unmatched breadth of experience in the clinical laboratory field, understanding of the healthcare landscape, and reputation for developing and implementing strategic plans that produce positive results,” said COLA Board Chair Rick Eisenstaedt, MD. “We are extremely fortunate to have her at our helm as we work to help more laboratories across the country improve their practices.” Ms. Stratton succeeds Doug Beigel who retired after working at COLA for 29 years. “I have long been impressed with COLA as a champion for patient safety,” said Ms. Stratton. “I am honored to be a part of this mission to work in collaboration with our customers to ensure excellence in laboratory medicine on behalf of the patients.”

(Source: COLA News [Announcement](#), 8/28/18) ◆

IN MEMORIAM



JoAnn Hall, technical director at Unyts passed away suddenly on August 13th. Ms. Hall joined Unyts in 2009 and had many contributions during her tenure, while playing an integral role in the growing success of the community blood center. Her career began after graduating from D’Youville College in Buffalo, N.Y. with a B.S. in Medical Technology. After working in local hospital labs, Ms. Hall worked for the American Red Cross for 17 years in various locations including New York, Michigan, Ohio, and Indiana before joining the Unyts team. She is survived by her two sons, three grandsons, and a great-grandson, and predeceased by her daughter. Ms. Hall was an avid sports fan who could always be counted on for scores and insight on both professional and college

(continued on page 7)



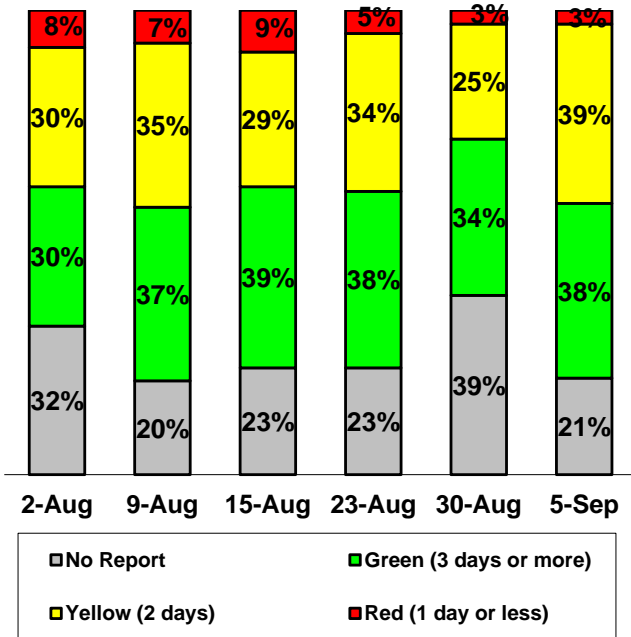
IN MEMORIAM (continued from page 6)

sports teams. Most beloved to her though were the New York Yankees. When travelling to industry conferences, Ms. Hall would always walk proudly through any airport with her Yankees jacket. “JoAnn as our colleague, mentor and friend will be sorely missed. She had a great sense of humor, was always willing to share her knowledge and was ready to step up to help when needed,” said Michael Wolter, vice president of blood services at Unyts. “We will miss her!” 💧

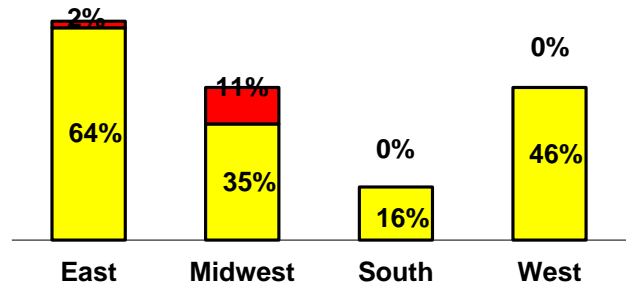


STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, September 5, 2018



Percent of Total ABC Blood Supply Contributed by Each Region
 East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org



MEMBER NEWS



From left to right: Pat Michaels, Stephanie Zaurin, Susan Forbes and Pablo Rendic Olivieri. Photo courtesy of the Orlando Sentinel

OneBlood recently received three Telly awards for their documentary *Lifeline: The Untold Story of Saving the Pulse Survivors*. The film is available on Amazon Prime and follows survivors of the Pulse nightclub shooting as they meet blood donors who helped save their lives. The documentary's worldwide debut took place during National Blood Donor Month in January 2018. The Telly Awards recognize the best creations and innovations in television and film. More than 12,000 submissions were received. A preview of the documentary can be viewed [here](#).

(Source: *Orlando Sentinel*, [Pulse: 'Survivors' film wins 3 Telly Awards](#), 8/17/18) 💧

COMPANY NEWS

Blood Centers of America, Inc. (BCA) and Key Biologics LLC have announced a partnership to “broaden support for cell therapy and regenerative medicine,” according to a joint news release. The agreement paves the way for joint research and product development. “Working with BCA and their extensive network, we believe we can speed patients’ access to important new therapies formulated from allogeneic and autologous raw materials that can be used to effectively treat conditions such as cancer, immune-based disorders, and inherited genetic disorders,” said Edward Scott, MD founder of Key Biologics in the release. “The ability to access BCA’s unique database of well-characterized individuals who have explicitly expressed an interest in providing blood products to support research and product development will enhance our efforts significantly.” The organizations aim to improve the clinical manufacturing of cell-based therapies and access to preclinical raw materials. “We are enthusiastic about the complementary nature of Key Biologics’ and the BCA members’ expertise and BCA’s national coverage” said BCA CEO Bill Block. “We believe that, in addition, our combined nationwide coverage and each organization’s strategic relationships will create new opportunities for BCA members to fulfill their mission of providing lifesaving products to patients. We have successfully worked with Key Biologics and Dr. Scott for many years and look forward to expanding our relationship.”

(Source: BCA and Key Biologics Joint News [Release](#), 9/4/18)

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. 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.



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!

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) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2018

Sept. 11. **37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#).

Sept. 12. **8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Sept. 13. **Advisory Committee Meeting on Blood and Tissue Safety and Availability. Arlington, VA.** More details available [here](#).

Sept. 24-26. **The MedTech Conference, Philadelphia, PA.** More details available [here](#).

Oct 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#).

2019

Feb. 4-6. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available [here](#).

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** More details 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Marketing and Donor Recruitment. MEDIC Regional Blood Center, based in Knoxville, TN, seeks qualified applicants for its Director of Marketing and Donor Recruitment position. This position is responsible for developing and directing the blood center's donor recruitment staff and strategic plans to achieve collection goals and promote community participation. Scope of responsibilities includes oversight of all mobile and fixed site recruitment, marketing and social media campaigns. Must have the ability to oversee daily operations as well as plan for and execute strategic long-term

goals. Must be able to facilitate recruitment operations activities related to donors and management recruitment and marketing staff with budgetary responsibility. Position will require working closely with Collections staff to facilitate efficient and effective blood drives. Must be an effective leader with ability to adapt to change. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication, public speaking skills

(continued on page 10)

POSITIONS (continued from page 9)

and computer competency and literacy. Bachelor's degree required with a minimum of five years management experience. Prior blood center experience preferred. Competitive salary and benefits. This position reports to the Chief Executive Officer. MEDIC is an Equal Opportunity Employer. Apply online at hr@medicblood.org.

Director, Donor Recruitment. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Donor Recruitment position. This position is responsible for developing and directing the blood center's donor recruitment department/plans to achieve collection goals. Scope of responsibilities includes oversight of all mobile and fixed site recruitment. Requires the ability to oversee the daily operations, as well as strategically work toward the long-term goals. Must be able to facilitate all operational activities related to recruitment of donors and management of recruitment staff within the expected budget guidelines. Must be an effective leader and have the ability to adapt to change. Excellent salary (with bonus program) and benefits including relocation package. Bachelor's degree required. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication and public speaking skills and computer literacy. Prior blood center experience preferred. Minimum three years management

experience. Successful candidate must demonstrate ability to work closely with Marketing and Collections Managers/Directors to facilitate efficient and effective blood drives. This position reports to the Vice President/Operations. LifeStream is an Equal Opportunity Employer, M/F/D/V. Apply online at: <https://www.lstream.org/careers/>.

Blood Services Technical Manager. Unyts, Western New York's ONLY Organ, Eye, Tissue and Community Blood Donation Center has an immediate opening for a Blood Services Technical Manager. This position is responsible for the administrative and technical management of blood processing and distribution. Ensures compliance with the standards of the FDA, NYSDOH and for all other pertinent industry standards. Manages process for proficiency testing for the QC lab to meet CLIA requirements. Responsible for implementing and maintaining policies and procedures relevant to transfusable blood and blood products. Manages current and potential future technology needs of blood lab. Performs testing and other component processing procedures as necessary. Qualified individuals will have a bachelor's degree, plus a NYS Clinical Laboratory Science license with a minimum of six years experience as a Med Tech, with a minimum of two years in blood banking experience including component preparation preferred. Please visit this job listing at www.unyts.org/about/careers/ for full details and to submit your application. 💧