ABC Comments to FDA on ‘Burdensome’ Regulations

America’s Blood Centers (ABC) recently submitted comments to the U.S. Food and Drug Administration (FDA) as part of the review of existing Center for Biologics Evaluation and Research regulatory and information collection requirements. ABC based its comments on the feedback provided by 80 responses to a survey of the ABC membership that ranked the most important issues faced by independent community blood centers.

ABC suggested reforms that could result in more than $50 million in reagent costs savings per year. Its response to the request for public and stakeholder comments to help identify existing regulations and paperwork requirements “that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing (FDA) to achieve (their) public health mission and fulfill statutory obligations.” Additionally, regulatory improvements were noted that could lead to greater efficiencies.

A few key areas of high priority for ABC members included modifying the licensure requirement from the current standard of licensing each variant of a particular product to only the primary product. This change would assist in alleviating the burden for smaller blood centers in complying with the statistical methods for determining sample size for apheresis platelets. Additionally, ABC recommended reducing the infectious disease testing burden through the elimination of syphilis and hepatitis B virus surface antigen testing, along with shifting human T-lymphotropic virus (HTLV) to a one-time test for the donor similar to Chagas.

The removal of the restriction of not allowing plasma collected concurrently with other cellular components to be used for non-transfusion needs until expiration was also addressed by ABC, in addition to harmonizing freezing requirements between source and transfusable plasma. ABC also stated that the current consolidation of manufacturing operations has led to products being collected in one state and transported to another for processing. Unless and until those products are licensed, they may not be sold in the state of collection or a third state because of the prohibition of using unlicensed products in interstate commerce, despite having met all applicable product specifications during the validations that precede licensure. ABC proposed the FDA allow such transfers during the validation and licensure of new procedures since they are subjected to quality control and validation testing assuring they meet those specifications. Additional information is available to ABC members in MCN 18-009, including the complete set of comments. ABC thanks all members that provided feedback and will share additional updates as necessary.

(Source MCN 18-009) ✶
ABC Sends Congratulatory Letters to Azar and Giroir

ABC President Martin Grable sent congratulatory letters to the Department of Health and Human Services (HHS) Secretary Alex Azar and Assistant Secretary of Health Brett Giroir, MD on their confirmations. The letters indicate that ABC and the blood community look forward to collaborating on efforts related to patient health, emergency preparedness and response, and infectious disease prevention, and continuing to work with the Blood, Organ, and Tissue Senior Executive Council (BOTSEC), the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), and the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP). ABC members can view copies of the letters sent to Mr. Azar and Dr. Giroir respectively on the ABC member website.

Debra BenAvram Named AABB CEO

Debra BenAvram, FASAE, CAE will be AABB’s new CEO on June 1st announced AABB President Mary Beth Bassett, MT(ASCP) in an email to members on Thursday. Ms. BenAvram replaces Tom Hopkins who has filled the role of interim CEO since 2016. “Debra is a dynamic leader whose proven track record of success, as well as her belief in our mission, make her the perfect choice to take AABB to new heights,” said Ms. Bassett in a news release. “We’re thrilled to welcome Debra to the AABB family.” Ms. BenAvram currently serves as the CEO of the American Society for Parenteral and Enteral Nutrition (ASPEN), a position she has held since 2007. “I am honored and excited to lead AABB and build on its rich history as the leader in the fields of transfusion medicine, cellular therapies, and patient blood management,” said Ms. BenAvram. “AABB’s commitment to providing the safest and best care possible for donors and patients, and building an environment where its members can succeed and thrive, are second to none. I look forward to collaborating with the staff and members to advance our mission of making transfusion medicine and cellular therapies safe, available and effective worldwide.” In addition to her extensive association management and experience, she is a fellow of the American Society for Association Executives and a Certified Association Executive including recognition as a “Forty Under 40 Business Leader by the Washington Business Journal in 2015.”

(Source: AABB News Release, 2/22/18)
Registration is open for ABC’s 56th Annual Meeting in Scottsdale, Ariz. March 17th – 19th at the Scottsdale Plaza Resort. Don’t miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Celso Bianco, MD Lectureship, the Scientific, Medical, and Technical Forum, and the 21st Annual Awards of Excellence. Additionally, ABC member Blood Systems Inc. will host a networking event at the Musical Instrument Museum. Please make your hotel reservations by February 23rd to ensure best availability and the group rate. Click here for additional details. Contact Leslie Maundy for available sponsorship opportunities.

SAVE THE DATES

• ABC SMT Journal Club Webinar
  March 29th at 2 PM EST
  Additional details coming soon!

2018 ANNUAL MEETING SCHEDULE

<table>
<thead>
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| Saturday, March 17 | ABC Board Meeting  
Opening Session             |
| Sunday, March 18  | ABC Members Meeting  
SMT Forum & Celso Bianco Lectureship  
Host Event by Blood Systems |
| Monday, March 19 | General Session  
21st Annual Awards of Excellence |
| Tuesday, March 20 | NBF Leadership Forum                      |

Hotel Information
Scottsdale Plaza Resort
Hotel room rate: $219 Single/Double

For registration information, visit http://bit.ly/abc_annual_meeting.

For sponsorship opportunities, please contact Leslie Maundy at lmaundy@americasblood.org.

I look forward to welcoming America’s Blood Centers back to Scottsdale, where the organization began more than 55 years ago. Along with opportunities to discuss emerging issues in our field, the Annual Meeting is a great forum for exchanging ideas and developing collaborations. The more who attend – the greater the value to all involved!

— Dave Green, MSA, President and CEO
Blood Systems, Inc.
CMS Requests Information Regarding CLIA 88 Personnel Requirements & Other Issues

The Centers for Medicare and Medicaid Services (CMS) has issued a request for information (RFI) to assist in revising the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). The personnel requirements have not been significantly modified since the early 1990s. In this RFI, CMS seeks public input on several topics including qualifications of Bachelor of Science degrees in nursing and physical science for moderate complexity technical consultants and moderate and high complexity testing personnel. The agency requests that comments include information such as evidence, research, and trends to assist in updating existing CLIA regulations and future rulemaking. The ABC Quality Blood Regulatory Review Committee has reviewed the RFI and seeks ABC member input to develop comments that will represent the entirety of the membership. Please complete the survey by March 4th. Please direct questions to Ruth Sylvester.

Human Resources and Training & Development Workshop Launches Registration

ABC invites all human resources and training and development professionals to register for the 2018 ABC Human Resources and Training & Development Workshop in Dallas, Texas May 8th – 10th at the Fairmont Dallas. Attendees will have the opportunity to discuss industry challenges and trends with their peers and partake in joint sessions that will explore the current state of the blood industry, critical thinking skills, and disaster training/preparedness. Time will also be devoted for separate sessions focusing on hot topics specific to each discipline such as Human Resources as a Business Partner, Intermittent FMLA/ADA/LOA, Training Video Production, and Mobile Learning/Micro-Learning. Early bird discounts are available through March 2nd. HRCI and P.A.C.E. credits will be offered. Ten scholarships of $750 are available to attendees through a grant from the Foundation for America’s Blood Centers. The submission deadline for scholarships is March 9th. The schedule is available. Please contact Leslie Maundy for additional details and sponsorship opportunities. Registration rates are below:

- 3-day HR/TD Workshop (Tue-Thu) Early bird $485/Regular $540
- 2-day Training & Development (Tue-Wed) Early bird $410/Regular $465
- 2-day Human Resources (Wed-Thu) Early bird $410/Regular $465

(Source: MCN 18-011) ♦
RESEARCH IN BRIEF

How often does uncrossmatched blood lead to an acute hemolytic transfusion reaction (AHTR)? With increasing use of massive transfusion protocols for severe hemorrhage, transfusion prior to completion of routine immunohematology testing is common. A patient at McMaster University (Hamilton, Ontario) received uncrossmatched blood during trauma resuscitation and suffered a severe AHTR associated with preexisting anti-K and anti-Fy^a antibodies that were attributed to alloimmunization after remote prior transfusions. The authors present the case report and a literature review that estimates the rate at which this is recognized is 2/3,998 uncrossmatched transfusions (95 percent credible interval 0.01-0.21 percent).


Plasma or coagulation factor concentrates (CFC) to reverse the coagulopathy of trauma? The Reversal of Trauma-Induced Coagulopathy (RETIC) study using first-line coagulation factor concentrates or fresh frozen plasma was an Austrian single center, randomized, parallel group, open label (i.e. unblinded) comparison of the efficacy of fresh frozen plasma (FFP) compared to concentrates in injured patients for treating coagulopathy defined using rotational thromboelastometry (ROTEM). The primary endpoint was multiple organ failure. Secondary endpoints included normalization of ROTEM parameters and the need for massive transfusion. FFP was started with a dose of 15 mL/Kg. The coagulation concentrates used included “primarily fibrinogen concentrate” at 50 mg/Kg. With inadequate response, the study interventions could be repeated. One hundred of 292 screened patients were included, with 44 FFP and 50 CFC patients included in the final modified intention-to-treat analysis. The trial was terminated early when 52 percent in the FFP group, compared to 4 percent receiving CFC, “required rescue therapy” based on the ROTEM results and an unvalidated clinical bleeding score. In the respective FFP and CFC groups, rates of multiple organ failure were 66 percent vs. 50 percent, and rates of massive transfusion were 30 percent and 12 percent. All were statistically significant except multiple organ failure, which was significant only in a post hoc analysis of stratification variables (injury severity score and brain injury). In addition to fibrinogen concentrates, some patients received four-factor prothrombin complex concentrates and/or factor XIII concentrates. The lack of blinding, the initial administration of the FFP 40 minutes later than CFC, the dose of FFP, and the comparison of multiple different concentrates to plasma are among the potential shortcomings noted by the authors, who still conclude that early fibrinogen supplementation is critical, and suggest that first line FFP therapy should be reassessed.


Tranexamic acid (TXA) has been shown to reduce mortality, bleeding, and transfusion requirements after trauma—is there under or overuse and does it increase venous thromboembolism (VTE)? Well-designed trials have clearly demonstrated the beneficial effects of TXA after trauma (and in other clinical venues, like orthopedic surgery), and have not consistently suggested an increase in VTE. Now, military investigators have published a “real world” retrospective analysis of their experience with TXA in Afghanistan, and a single military facility stateside, between 2011 and 2015. Information from 455 patient records was abstracted. They suggest that overuse occurred in 3.3 percent of the 282 patients without the need for massive transfusion, and underuse in 46 of the 173 patients who required massive transfusion. They contend that overuse is increasing at a rate of 3.3 percent per quarter during the interval and underuse is decreasing by 4.4 percent per quarter. VTE was associated with TXA use with an odds ratio of 2.58 (95 percent confidence interval 1.20-5.56). They recommend “(a) reevaluation of the use of TXA” in combat casualties.

(continued on page 6)
RESEARCH IN BRIEF (continued from page 5)

The authors of an invited commentary accept that the demonstration of the association with VTE is important. They offer a strong set of critiques however. Applying military findings to civilian trauma is not appropriate given differences in injury mechanisms and severity and transport systems. Also, they express concern about the use of a non-consensus definition of massive transfusion that may bias results compared to prior TXA studies. Further, the paper does not recognize that TXA may have been preventing hemorrhage sufficient to require massive transfusion and caution against the use of this study to reduce TXA use given its well demonstrated mortality benefit in controlled clinical trials.


RECENT REVIEWS

(Yet) another systematic review and meta-analysis assesses the clinical impact of the storage age of red blood cells (RBC). Sixteen randomized trials that included more than 31,000 patients show no association of the age of RBCs with mortality and the evidence for this conclusion is considered “high quality.” Transfusion reactions and infections were marginally statistically significant and more likely with older RBCs. The relative risk for transfusion reactions was 1.35 (95 percent confidence interval 1.04-1.76), and for infection was 1.08 (95 percent confidence interval 1.00-1.17) for transfusion reactions. The authors conclude that “(t)he current evidence does not support a change from current usual transfusion practice.”


Blood reviews efforts to identify effective means for developing antithrombotic drugs that interfere less with coagulation. “[T]here is emerging experimental evidence that suggests that the molecular and cellular mechanisms of hemostasis and thrombosis can be separated, thereby raising the possibility of new antithrombotic therapeutic targets with reduced bleeding risk.” Patients treated with antiplatelet drugs and anticoagulants are at risk for life-threatening hemorrhage. This traditionally has been believed to be unavoidable, owing to an inextricable link between “physiologic hemostasis and pathologic thrombosis.” However, researchers have more recently discovered several different molecular targets that may lead to a new paradigm in antithrombotic therapy. One possible target resides on leukocytes and is known as integrin Mac-1. When blocked, this molecule interacts less efficiently with platelet glycoprotein Ib (GPIb), reducing the thrombogenic potential of platelets without compromising normal hemostasis. Other research is examining whether targeting coagulation factors XI and/or XII might have a similarly beneficial impact. The authors hope that, based upon these lines of research, antithrombotic therapy someday will better preserve healthy hemostasis, reducing its hemorrhagic complications.


*Contributed by Chris Gresens, MD, division chief medical officer, BloodSource, Blood Centers of the Pacific, Inland Northwest Blood Center, and United Blood Services.*
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BRIEFLY NOTED

The Centers of Medicare and Medicaid Services (CMS) Office of the Actuary recently issued projections for national health spending to grow annually at a rate of 5.5 percent through the year 2026. An accompanying paper appearing in Health Affairs states that this is expected “to represent 19.7 percent of the economy” by that year as well, versus 17.9 percent currently, accounting for increases in income, medical goods and services, and an aging population with “enrollment shifts from private health insurance to Medicare.” More information on the report and a detailed breakdown of projections is available.

(CMS Report, 2/14/18)

The Biomedical Excellence for Safer Transfusion (BEST) Collaborative announced that it is reviewing its scientific membership and accepting applications for membership through May 1st. Interested individuals may submit applications online along with a current curriculum vitae (CV). Areas of concentrations and the team leads are: cellular therapy, Dave McKenna, MD, clinical studies/transfusion safety, Mark Fung, MD, PhD and Alan Tinmouth, MD, MSc; conventional components, Dana Devine, PhD, and donor studies, Marc Germain, MD and Ralph Vassallo, MD. BEST is an international research organization that aims to improve the safety of transfusion and cell therapy and related services through standardization of analytic techniques, development of new procedures and execution of clinical trials in hematology and cell therapy. More than 118 scientific publications have resulted from the Collaborative’s work. Additional details are available on Best’s website.

(BEST Collaborative Announcement, 2/21/18)

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

The order of the bars is (from top to bottom), red, yellow, green, and no response

No Response Green: 3 or More Days Yellow: 2 Days Red: 1 Day or Less

Daily updates are available at:
www.AmericasBlood.org
INFECTIOUS DISEASE UPDATES

INFLUENZA

The Centers for Disease Control and Prevention (CDC) reported the flu vaccine’s “adjusted vaccine effectiveness (VE) against influenza A and influenza B virus infection was 36 percent (95 percent confidence interval [CI] = 27-44 percent). Influenza A(H3N2) strain has been present in 69 percent of cases. Flu remains widespread in 48 states and Puerto Rico. More than 21,000 hospitalizations have been linked to flu as of CDC’s latest figures from October 1, 2017 – February 17, 2018. Due to the severity of this season, there have been questions raised about the efficacy this year’s vaccine. The estimate of 36 percent protective efficacy is better than some early estimates (approximately 10 percent), but remains low by historical standards. The hospitalization rate is 74.5/100,000 compared to 64.2 during the end of season rates for 2014-15. Ninety-seven children have died this season from flu. CDC officials note that the best defense against the flu remains the flu vaccine and that it’s not too late to get vaccinated.

(Sources: CDC Summary of Weekly FluView Report, 2/23/18)

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) published a final rule amending regulations regarding the “acceptance” of data from clinical investigations for medical devices that take place both outside and within the U.S. to ensure the “quality and integrity” of the investigation data. The rule stipulates that data from such clinical investigations “intended to support an investigational device exemption (IDE) application, a premarket notification (510(k)) submission, a request for De Novo classification, a premarket approval (PMA) application, a product development protocol (PDP) application, or a humanitarian device exemption (HDE) application be from investigations conducted in accordance with good clinical practice (GCP).” This includes receiving and documenting the review and approval of the clinical investigation by an independent ethics committee, and the “freely given informed consent of subjects used” as a part of medical device investigations. The rule also amends regulations concerning the requirements of clinical investigations that take place within the U.S. for IDEs, HDEs, and 510(k) submissions, “requir[ing] a statement regarding compliance with FDA regulations for human subject protection, institutional review boards, and IDEs.”

(Source: FDA Final Rule, 2/21/18)
PEOPLE

Jose Cancelas, MD, PhD has been named director of Hoxworth Blood Center (Cincinnati, Ohio). Dr. Cancelas joined the organization in 2002. During that time, he has served in a number of roles, including medical director of the cellular therapies division, and most recently as deputy director. “We are thrilled to be able to have strong leadership continue at Hoxworth Blood Center,” says William Ball, MD, University of Cincinnati (UC) senior vice president for health affairs and dean of the College of Medicine. “We have confidence that Dr. Cancelas can build on the accomplishments of Dr. Ronald Sacher, who helped Hoxworth become one of the leading blood banking centers in the United States.” Dr. Cancelas obtained his medical degree at Autonomous University of Madrid (Spain) and his doctorate from University of Alcalá de Henares in Madrid. He replaces Ronald Sacher, MD who stepped down last month as director, a position he held since 2000. Dr. Cancelas also serves as a professor in the UC Department of Pediatrics and faculty in the medical scientist training, cancer, and cell biology programs at the UC College of Medicine.

(Hoxworth New Release, 2/16/18) ✦

IN MEMORIAM

Ram Kakaiya, MD, passed away on February 11th. Dr. Kakaiya served as Medical Director at LifeSource from 2002-2014. He enjoyed research and contributed to the field in many ways including the Recipient Epidemiology and Donor Evaluation Study (REDS) II and III, in addition to several National Institutes of Health research projects. He was a recipient of the 2011 Chang Ling Lee Award from the Illinois Association of Blood Banks that honors an “outstanding contributor to transfusion medicine in Illinois through significant contribution to transfusion medicine research, teaching, or clinical practice.” Dr. Kakaiya also led the establishment of the Bernard Fantus, MD Symposium that celebrated the 75th anniversary of the first U.S. hospital blood bank at Cook County Hospital by Dr. Fantus. His career spanned more than three decades, as he held the position of medical director at the American Red Cross Blood Services in Connecticut and in St. Louis, Mo., and several Chicago-area hospitals in addition to the role of Assistant Professor at the University of Illinois. ✦

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!
MEMBER NEWS

Angel Flight West recently delivered platelets to LifeStream (San Bernardino, Calif.) completing the inaugural flight as part of their partnership. The volunteer-based organization coordinates free, non-emergency flights for “healthcare and other compelling needs.” Brad Smith flew the shipment from Oxnard Airport to San Bernardino International Airport to assist those patients in need. “Partnering with Angel Flight West compliments LifeStream’s mission of saving lives by connecting donors and patients through the gift of blood,” said Kevin Moore, vice president, operations at LifeStream according to Patch. “The generosity of the volunteer pilots will make platelets available for our community a full day ahead of our current schedule.”

(Source: Patch, LifeStream, Angel Flight West mark first flight of partnership, 2/21/18)
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.)

2018


May 8-10. ABC Human Resources & Training/Development Workshop, America’s Blood Centers, Dallas, Texas. More details available here.

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.


Sept. 28. 36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. 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) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Community Development. Houchin Community Blood Bank is a local, non-profit community blood bank, centrally located in Bakersfield, California, serving all of Kern County for over 60 years. We operate in a state-of-the-art, 42,000 square foot facility. Our Director of Community Development is a key employee of the blood bank and an integral member of the management team. This individual will direct and coordinate activities related to: community development, marketing, field recruiting, and account management. The Director will foster a strong community relationship and a strategic balance between fixed site and mobile collection operations. In doing so, the Director will manage staff, maintain adequately developed goals and plans, and be responsible for the attainment of those goals. Qualifications include a minimum of BS/BA degree in business, marketing, sales, public relations or related field; minimum three years of managerial responsibility; minimum five years of technical experience in sales or marketing-related role; excellent oral and written communication (continued on page 13)
**POSIIONS (continued from page 12)**

skills, leadership and management skills, business and financial planning skills. We offer a competitive salary, positive work environment, excellent benefits, including two retirement plans, and more. For more information on our company, please visit us at www.hcbb.com. Interested applicants may email resumes to careers@hcbb.com.

**Quality Assurance Director.** The Blood Bank of Alaska is seeking a Quality Assurance (QA) Director. The Quality Assurance Director is responsible for ensuring all areas of the Blood Bank of Alaska (BBA) are operating in compliance with applicable government regulations, accrediting agency standards or consignee requirements related to the collection, processing, testing and distribution of blood products, cellular therapy products and services. The QA Director participates as a member of the BBA management team in planning, program formulation, and systems development. The QA Director is responsible for designing, implementing, and monitoring the quality assurance program for all operating divisions of BBA. The incumbent for this role must possess excellent conceptual, communication, and analytical skills. Must understand general work flow processes and equipment used in a medical facility. Must have excellent interactive skills necessary in communicating with coworkers and regulatory officials. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply via our website at www.bloodbankofalaska.org.

**Recruitment and Retention Manager (Charlotte, N.C.)** Come apply your blood banking and recruitment management experience in one of the fastest growing and best cities to live in the country! Community Blood Center of the Carolinas is seeking an experienced and analytical professional for the Recruitment and Retention Manager position in Charlotte, NC. The position is responsible for the development and direction of programs related to recruitment and retention of blood drive sponsors and donors, in order to meet the needs of patients and hospitals in our region. This position works closely with the Director of Marketing, Recruitment and Collections to ensure efficient operation of both center and whole blood, red cell, plasma and platelet collection. Supervisory, sales and data analytic skills, as well as blood bank experience highly preferred. Essential functions include, 1) implementing departmental and organizational goals by using planning and strategic agility as the foundation for successful results in meeting objectives; 2) ensuring that qualified and adequately trained personnel are available, and that company personnel policies and standards are administered equitably and consistently; and 3) leading and managing group through further development and emphasis on team building concept. Incorporates integrity and trust within group through example of leadership. Applications should send a resume to Ben Pryor at bpryor@cbcc.us or apply online at www.cbcc.us/careers.