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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #26
July 21, 2017

CMS Proposes 2018 Outpatient Payment Rates for Blood Products

The Centers for Medicare and Medicaid Services (CMS) published its notice of proposed rulemaking for the Calendar Year 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. The plan, as proposed, would significantly cut Medicare payment rates for a number of blood products transfused in the outpatient setting. Cryoprecipitate, for example, is slated for a 27.8 percent drop.

Two other significant decreases in reimbursement include apheresis, leukoreduced, cytomegalovirus-negative (CMV) platelets from $422 per unit to $328.98 (a 22 percent decrease) and whole blood from $151.51 per unit to $119.39 (21.2 percent drop). See the table on page three for a breakdown of reimbursement proposals for several key blood products.

More troubling are some discrepancies among like products. For example, apheresis, leukoreduced, cytomegalovirus-negative platelet is priced more than $150 below a leukoreduced apheresis product.

"Continued downward pressure from CMS on pricing for blood products does not seem rational given the value they bring to health care and the fragility of our source of raw materials (donors)," said ABC CMO and interim CEO Louis Katz, MD. "CMS' funding formulae do not consider those external factors, based as they are on hospital cost and charge data. Further, we have serious concerns about the completeness and accuracy of hospital reporting, leading to the apparent disconnects in the proposed rates. Because the methods CMS must use capture only components actually transfused and billed, they are incapable of recognizing the value of a robust inventory in anticipation of extremes of need, e.g. clinical emergencies, natural and man-made disasters. Our advocacy efforts around this proposed rule will include those issues prominently. A meeting with CMS is being requested in time to inform our comments to the proposed rule."

The OPPS is revised every year as a proposed rule and made available for public comments before the final rule issues in late fall for implementation in January of the following calendar year. This rule sets the payment rates at which hospitals and ambulatory clinical facilities are reimbursed in the outpatient setting. The

reductions are not new to blood centers or hospitals, who have felt the pinch from CMS lowering rates for blood product reimbursement in nearly every OPPS plan for the last five years. In the proposed rule, the same complex methods for rate calculation are applied as have been since 2005, using actual or simulated cost-to-charge ratios from recent hospital cost reports.

"We are extremely troubled by the rate cuts for blood products in the CMS proposed OPPS," said ABC President and CEO of the Community Blood Centers of the Carolinas Martin Grable. "The cuts proposed this year to blood products and reimbursement to the nation's blood centers are extremely short-sighted and need to be examined with a realistic eye

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INSIDE:

CMS 2018 PROPOSED RATES (continued from page 1)

on the importance of maintaining a safe and available blood supply. ABC will be working diligently to bring our concerns about these proposed cuts directly to CMS as they would only serve to further exacerbate the very issues we are trying to solve."

ABC applauds CMS for considering blood establishment stakeholder input, including ABC's, by establishing separate Healthcare Common Procedure Coding System codes (HCPCS) for pathogen reduced apheresis platelets and the platelets undergoing bacterial testing—a change ABC commented on and requested. The HCPCS code Q9988 will be used for pathogen reduced apheresis platelets in 2018 and a separate code, Q9987, will be for rapid bacterial testing. Separate coding for pathogen reduced apheresis platelets was requested to reflect both the higher costs associated with pathogen reduction and especially the much broader rationale for its use compared to rapid bacterial testing. These codes replace the P9072 code that combined the two interventions.

ABC is reviewing the proposed rule and will call on member blood centers to provide data to ABC Chief Administrative Officer Kate Fry and Dr. Katz on the impact of the proposal and information to help support our position that these payment rates are unrealistic and not reflective of the cost associated with providing a safe and adequate blood supply. Comments are due before September 11, 2017.

Recent rates and rates proposed for 2018 in the notice of proposed rulemaking from CMS for key blood components.

Product	2016	2017	2018 Proposed	% change 2016-18	% change 2017-18
Cryoprecipitate, each unit	$59.64	$53.03	$38.29	-35.8	-27.8
Plasma, frozen w/in 8 hours	$72.56	$73.73	$71.96	-0.8	-2.4
Plasma, frozen w/in 8-24 hours	$73.08	$74.00	$75.50	3.3	2.0
Platelets, pheresis	$425.15	$412.10	$435.88	2.5	5.8
Platelets, pheresis, irradiated	$528.11	$556.58	$541.23	2.5	-2.8
Platelets, pheresis, LR	$488.29	$499.95	$481.24	-1.4	-3.7
Platelets, pheresis, LR and irradiated	$641.85	$647.40	$627.56	-2.2	-3.1
Platelets, pheresis, LR, CMV negative	$462.48	$422.00	$328.98	-28.9	-22.0
Platelets, pheresis, LR, CMV negative, Irradiated	$443.65	$618.89	$589.67	32.9	-4.7
RBC	$145.79	$142.36	$143.27	-1.7	0.6
RBC, LR	$184.34	$185.82	$184.23	-0.1	-0.9
RBC, LR and Irradiated	$267.63	$266.28	$259.89	-2.9	-2.4
Whole blood derived platelets	$118.03	$96.49	$113.58	-3.8	17.7
Whole blood	$221.62	$151.51	$119.39	-46.1	-21.2

Find the full OPPS notice of proposed rule-making here.

Taking a Data-Rich Approach to TACO

A number of studies in the last decade have led to an intense look at Transfusion-Associated Circulatory Overload (TACO) and the development of algorithms using risk factors and biomarkers to help predict, prevent, and mitigate TACO.

TACO is acute pulmonary edema characterized by dyspnea, orthopnea (shortness of breath when lying down), peripheral edema, and associated with left-atrial hypertension occurring within six hours after a blood transfusion. The Food and Drug Administration lists TACO as the second most-commonly reported cause of transfusion mortality. The incidence of TACO, for those under active surveillance, is said to be at about 1 percent, though numbers as low as 1 in every 10,000 are published from more passive case accrual.

"TACO is an important complication to highlight," said Daryl Kor, MD, professor of Anesthesiology at the Mayo Clinic. "Though it is a far more frequent transfusion-related complication than TRALI (transfusion-related acute lung injury), it has received a fraction of the scientific investment that TRALI has received. Therefore, I think it's good we're having conversations like these about TACO so that we can improve the clinical awareness of TACO as well as related complications."

As hospitals and blood centers have begun to rely on electronic medical records (EMR) to collect and mine data, more information on the risk factors and biomarkers (including cytokine levels) associated with TACO have come to light. Those data-points are helping to generate predictive algorithms for patients at the highest risk for TACO.

"When most providers order blood products, they are not considering the recipient's risk for developing TACO. By enhancing their understanding of this risk, we can help them with decisions about the appropriateness of the transfusion therapy at the time of order entry," said Dr. Kor. "Additionally, when transfusions are in process, we are working on how we can identify patients who appear to be proceeding toward TACO. The earlier we can identify patients who may be experiencing a transfusion complication, the faster we can work to implement effective prevention/mitigation strategies, such as slowing transfusion rate or administering diuretics."

Chester Andrzejewski, PhD, MD, medical director of System Blood Banking and Transfusion/Apheresis Medicine Services at Baystate Health in Springfield, Mass., has been working with his colleagues over the past two decades developing paper-based and electronic documentation formats for hemotherapy (HT) within Baystate's patients' electronic medical records (EMR)—documentation that can positively impact transfusion safety and enhance care, particularly in the mitigation of TACO. Using their EMR platform as the foundation for these endeavors, a variety of biovigilance initiatives predicated on electronic HT documentation tags allows for automatic alerts to be sent to the in-hospital blood bank, e.g. when a nurse at the bedside records certain signs/symptoms the patient may be exhibiting in the context of HT. Such automated real–time alerting has allowed the blood bank staff to activate suspected transfusion reaction (STR) investigations earlier, while at the same time receive automated downloads of pre-determined data elements from the patient's EMR. These downloads are useful for the blood bank technical and medical staff to evaluate the STR. Using specially-designed algorithms, informed by results from the group's earlier studies, the introduction of a "provisional diagnosis" of the STR into the EMR has allowed for the more rapid communication of actionable data to colleagues outside the blood bank, potentially changing patient management.

Dr. Andrzejewski and colleagues authored a paper examining the use of vital sign monitoring at the bedside (Andrzejewski et al. 2012), which helped determine his hospital's perspectives on the value of using these clinical data in quality improvement initiatives. Data from a retrospective study of patients transfused between 2005 to 2008 showed marked vital sign changes, especially related to blood pressure, could be detected in patients experiencing suspected TACO as early as the 15-minutes into transfusion and post-

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TACO (continued from page 3)

transfusion. An unexpected finding was that a substantial number of patients experiencing TACO also exhibited inflammatory symptoms and/or signs, e.g., fever, as reported by the bedside caregivers—a finding which several groups around the world have validated.

"Along with temperature changes exhibited by patients during transfusion, we believe that changes in blood pressures are important heralds to potential adverse transfusion events," said Dr. Andrzejewski. "We designed our e-tags not only to have different types of blood pressures, for example pulse pressures captured during the hemotherapy event, but also to have the hospital's EMR automatically calculate differences from baseline values at the 15 minute and end of transfusion time-points. This has allowed a more rapid assessment by practitioners to assess trends in the different vital sign values. It works well for us and offers an advantage for suspected transfusion reactions recognition both at the bedside and in the blood bank when cases are evaluated."

Senior Investigator at the Blood Systems Research Institute and Professor at the University of California, San Francisco, Edward Murphy, MD, MPH, and Assistant Clinical Investigator at BSRI and Assistant Adjust Professor at UCSF Department of Laboratory Medicine Nareg Roubinian, MD, MPHTM, have been working in the Severe Transfusion Reactions including Pulmonary Edema (STRIPE*)*, part of the REDS-III study. This case-control study mines clinical and transfusion data to determine risk factors for TACO. STRIPE also includes the collection of biospecimens to allow the study of cytokines and other biomarkers for TACO.

"Cardiorenal biomarkers, such as cystatin C, may have increased utility in patients with pre-existing kidney disease to differentiate inflammatory and hydrostatic forms of pulmonary edema (TACO vs. TRALI). Current work through the NHLBI-funded STRIPE study will continue to examine the role of NT-proBNP in imputability criteria, severity, and differentiation of TACO from other pulmonary transfusion reactions," said Dr. Roubinian.

While inflammatory cytokines have been shown to be significantly elevated in those experiencing TRALI or possible TRALI, and potentially useful in differentiating TACO from other transfusion reactions —(Roubinian et al. 2015), cytokines are not practical for a clinical setting, noted Dr. Roubinian. To measure cytokine levels of each patient about to be transfused would be neither timely nor financially feasible.

"There is no magic bullet out there," said Dr. Murphy. "That said, combining risk factors into predictive electronic algorithms may help. I think the goal is to identify patients at highest risk for TACO. Then the doctor can do something different with them to reduce their risk."

For the STRIPE study, Dr. Murphy and Dr. Roubinian developed a four-prong system to find TACO cases, including chest x-rays, nurse screening, physician review, and a panel of experts. But Dr. Murphy explained this algorithm is not practical for clinical settings either as it was expensive and retrospective rather than predictive.

More mining of data, as in STRIPE and hospital EMRs data, has brought to light risk factors associated with higher instances of TACO—such as previous fresh frozen plasma transfusions and kidney disease. Other risk factors like emergency surgery are being added to the list (Clifford et al. 2017) and being shown to shorten one-year survivability in certain subsets of TACO patients, like the elderly.

Much current transfusion work is centered on evaluating the potential for taking a 'big data' approach toward individualizing transfusion decisions according to Dr. Kor. "What we're attempting to do with each transfusion episode is to leverage all of the available data in the health record to better inform the provider

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TACO (continued from page 4)

of the likelihood that a patient will experience benefit from a transfusion episode; and to further suggest the likelihood of the patient experiencing a transfusion-related complication. As the overall volume, variety, and quality of data improves, we hope to be able to leverage more advanced analytic approaches to help make these individualized transfusions decisions right at the bedside."

"Identifying and categorizing TACO remains very resource-intensive and active surveillance has been mostly limited to research settings," said Dr. Roubinian, adding that with further refinement of risk factors will come better criteria for diagnosing TACO, which should help improve the efficiency of screening and reporting capabilities.

"I think often there are two very passionate camps—those who really like to focus on the clinical data from the electronic health record as predictors of transfusion complications, and those who are more passionate about laboratory methods such as biomarkers and cytokines assays. While each camp feels passionately about the importance of their domain of data, the answer is probably some combination of both if we want to most accurately identify those who are at risk for developing TACO," said Dr. Kor.

Citations: Roubinian N.H., Looney M.R., Kor D.J., et al. Cytokines and clinical predictors in distinguishing pulmonary transfusion reactions. *Transfusion*. February 23, 2015. DOI: 10.1111/trf.13021.

Roubinian N., Murphy E., Adjusting the Focus on Transfusion-associated Circulatory Overload. *Anesthesiology*. March 2017. DOI: 10.1097/ALN.0000000000001507.

Clifford L., Jia Q., Subramanian A., *et al*. Risk Factors and Clinical Outcomes Associated with Perioperative Transfusion-associated Circulatory Overload. *Anesthesiology*. March 2017. DOI: 10.1097/ALN.0000000000001506.

Andrzejewski Jr. C., Popovsky M.A., Stec T.C., *et al*. Hemotherapy bedside biovigilance involving vital sign values and characteristics of patients with suspected transfusion reactions associated with fluid challenges: can some cases of transfusion associated circulatory overload have proinflammatory aspects? *Transfusion*. March 12, 2012. DOI: 10.1111/j.1537-2995.2012.03595.x.

America's Blood Centers
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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.

Discounted Pricing Ends Today for the ABC Financial Management & IT Workshops

Today is the last day for ABC Members to receive early-bird discount pricing on their Financial Management & IT Workshops registrations. The Workshops will be held at the Hotel Derek in Uptown Houston, Texas and begin on September 25 with a Blood Centers of America (BCA) members-only metrics dinner. A BCA metrics workshop will take place the following day, September 26.

On September 27, the ABC Financial Management Workshop will run concurrent to the IT Workshop and start with a joint breakfast and presentation from Brian Gannon, president and CEO of the Gulf Coast Regional Blood Center (GCRBC)—the host blood center for the Workshops. Mr. Gannon will be presenting the "Current State of the Industry Through the Eyes of a Blood Center Executive," which will discuss the major challenges and different strategies blood centers can take in this ever-changing industry. There will also be a joint session on cybersecurity, presented by CIO of IT Synergistics Brian Reithel, PhD, and Kelley Sidow, assistant vice president of Cyber Broker.

The two workshops will then separate with the Financial Management attendees discussing cost, contract negotiations, hospital reimbursement, and risk management issues. The IT workshop will host roundtable discussions on cybersecurity and interfacing with blood establishment computer systems and leave time for open discussion during the last hour, followed by a joint networking reception at the hotel.

The next day, September 28, will again start with the two groups together for breakfast and will continue joint sessions in the morning. The first presentation will be from Director, Finance and Supply Management at Mississippi Valley Regional Blood Center Kathye Brammann, and Assistant Director, Accounting and Purchasing at Community Blood Center (Kansas City) Jim Tompkins. They will discuss automation of accounting processes, and will be followed by Steve Player, CPA, managing partner of the Player Group, to present "More Effective Planning and Control in Uncertain Times." The final joint talk will be on the importance of metrics from ABC Director of IT & Business Intelligence Sameer Ughade and Director of IT and Enterprise Business Intelligence at OneBlood Mahfuz Bhuiyan.

The Workshops will separate again for the afternoon with financial attendees participating in a talk from GCRBC's CFO Eric Eaton, CPA, on "Responding to Reduced Demand for Blood Products and Cost Savings Opportunities" and end with a roundtable discussion. The IT attendees will spend the afternoon in roundtable discussions on business intelligence and metrics as well as business continuity and disaster preparedness as presented by John Holder, Business Continuity Planning Administrator & InfoSec Manager at OneBlood.

The Data Warehouse/Requirements Advisory Committee members will have their meetings to discuss business requirements and any questions the members might have. The Committee will meet again the next day, on September 29, as well.

The integrated, yet separate, approach to this workshop will be very beneficial to attendees in both the financial and IT fields. To read the full agenda, with presentation topics and speakers, please click here.

Regular rates will begin tomorrow for the workshop, so sign up today!

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ADRP celebrates Donor Recruitment Professionals Day and Blood Collectors Week

ADRP is proud to sponsor International Donor Recruitment Professionals Day on Wednesday, September 20, 2017. This special day recognizes the hard work and dedication of those who recruit donors to save lives across the globe.

Equally important in our lifesaving mission are the donor collections professionals who complete the donation process. We encourage your center to join ADRP in celebrating the 12th annual Blood Collectors Week September 3 to 9, 2017. Download the tools and use the planning calendar to engage your staff. Learn more and access resources here.

ADRP wants to join you in celebrating your recruitment and collections teams on social media. Tag posts #ADRPcelebrates, and *two complimentary 2018 ADRP Annual Conference Registrations* will be awarded to the recruitment and collections post with the most "likes." Share a group photo, team party, or special interaction between a team member and donor to celebrate these special professions!

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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RESEARCH IN BRIEF

Use of cost-ineffective transfusion-avoidance measures declines in the Netherlands, independent of formal interventions. In this study of 21 Dutch hospitals, data was gathered on a total of 1,964 patients' undergoing knee and hip arthroplasty over a nine-month intervention period. The authors described a cluster-randomized study of the effect of a multifaceted intervention on decreasing use of cost-ineffective blood conservation measures in primary arthroplasty. Erythropoietin administration and perioperative blood salvage both declined markedly in both the intervention and control settings, and was likely due to adoption of local infiltration anesthesia and use of tranexamic acid. Transfusions were unchanged in both the intervention and control groups, but length of stay was shorter and postoperative hemoglobin levels were higher in the intervention groups.

Citation: Voorn V.M.A., van de Mheen P.J.M., van der Ho A., *et al.* The effectiveness of a de-implementation strategy to reduce low-value blood management techniques in primary hip and knee arthroplasty: a pragmatic cluster randomized controlled trial. *Implementation Science*. May 30, 2017 online. DOI: 10.1186/s13012-017-0601-0.

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RESEARCH IN BRIEF (continued from page 7)

Optimal hematocrit for oxygen delivery in the microvasculature depends on perfusion pressure, concludes a new *in vitro* study. A higher hematocrit proportionally increases the oxygen-carrying capacity of blood, but also increases blood viscosity that can impair tissue oxygenation by reducing blood flow. Conversely, decreased blood viscosity in anemia might improve oxygen delivery in specific clinical circumstances. In this *in vitro* study, the authors have measured the hematocrit at which oxygen delivery can be optimized and find it dependent on perfusion pressure, suggesting that anemia may be beneficial for oxygen delivery in situations of cardiovascular impairment with low perfusion pressures in the microvasculature.

Citation: Piety N.Z., Reinhart W.H., Stutz J. *et al*. Optimal hematocrit in an artificial microvascular network. *Transfusion*. July 5, 2017 online. DOI:10.1111/trf.14213.

Hyperactive platelets are not any better. In a semi-randomized trial of 100 transfused patients (about half of whom were randomized) from the U.K., there was no difference in survival of platelets after transfusion from donors with platelets highly responsive to agonists compared to the low-responder donor set. No differences in one-hour platelet recovery or 24-hour survival after prophylactic transfusion were seen between transfusions from the two donor groups. The data are applicable only to prophylactic platelet transfusions in patients with chemotherapy-induced thrombocytopenia. In an accompanying commentary, the author notes that there is a list of factors affecting platelet activation and this latest study does not support adding genetic makeup for intrinsic hyperactivity to the list. More *in vivo* transfusion trials will be needed before generalizing these observations for other patient populations.

Citation: Kelly A.M., Garner S.F., Foukaneli T., *et al*. The effect of variation in donor platelet function on transfusion outcome: a semirandomized controlled trial. *Blood*. July 13, 2017. DOI: 10.1182/blood-2017-01-759258.

Kickler T.S. Bruised platelet transfusions work. *Blood*. July 13, 2017. DOI: 10.1182/blood-2017-05-786277.

A study from Australia and Japan demonstrates the feasibility of using CRISPR gene editing to increase fetal hemoglobin levels to ameliorate the signs and symptoms of beta-hemoglobinopathies, like sickle cell disease. By introducing the "British-198" single nucleotide polymorphism responsible for a benign condition causing persistence of fetal hemoglobin, the team turned on fetal hemoglobin production, which is known to be associated with clinical benefit in sickle cell patients. The mutation produces a new binding site for a transcription regulator called KLF1, that increases fetal hemoglobin production. In theory, the mutation can be introduced into autologous stem cells, then subsequently used for transplantation.

Citation: Wienert B., Martyn G.E., Kurita R., *et al*. KLF1 drives the expression of fetal hemoglobin in British HPFH. *Blood*. June 28, 2017 online. DOI: https://doi.org/10.1182/blood-2017-02-767400.

RECENT REVIEWS

There was neither benefit nor detriment from using a 1:1:1 over a 1:1:2 ratio of fresh frozen plasma (FFP), platelets, and red blood cells (RBC) for massive transfusion patients in a new review. Accumulating observational data has suggested that higher ratios of FFP and platelets to RBC transfusion are associated with improved mortality and morbidity rates. However, the optimal doses, timing, and ratios for massively bleeding patients to reduce their mortality and morbidity rate are unknown. A new review, with limited data from two randomized controlled trials, found no evidence to recommend the ratio of 1:1:1 over a 1:1:2 or standard care for adult patients with critical bleeding requiring massive transfusion. The larger

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RECENT REVIEWS (continued from page 8)

of the two trials found no evidence of a difference in co-primary outcomes of 24-hour or 30-day mortality between a 1:1:1 (FFP:PLT:RBC) compared with 1:1:2. The second study found no difference in 28-day mortality nor morbidity.

Citation: McQuilten Z.K., Crighton G., Brunskill S., *et al*. Optimal dose, timing and ratio of blood products in massive transfusion: Results from a systematic review. *Transfusion Medicine Reviews*. July 2017. DOI: 10.1016/j.tmrv.2017.06.003.

A historical review of blood transfusion methods, storage, and shipment as well as messaging in wartime shows us how far the blood community (and especially the military blood program) has come. In this look-back of the messaging and media used to recruit blood donors in Spain, Britain, Canada and the U.S. during wartime—from World War I through post-World War II—and the methods in which they stored, shipped, and delivered blood, the author talks about how the public felt empowered to be able to help during wartime as blood donors. Campaigns in the absence of such a multi-national war have turned to altruistic and empathy-provoking messaging.

Citation: Wang J.C.W. A Call to Arms: Wartime Blood Donor Recruitment. *Transfusion Medicine Reviews*. July 2017. DOI: 10.1016/j.tmrv.2017.06.004.

BRIEFLY NOTED

Novartis' chimeric antigen receptor T-cell (CAR-T) cell therapy has received unanimous support from a Food and Drug Administration (FDA) advisory committee. Novartis' CAR-T cell therapy, CTL019, targets pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL). In ALL patients (pediatric and adult), there is a five-year disease-free survival rate of 10 to 30 percent. CTL019 is an investigational autologous CAR-T cell therapeutic that cryopreserves apheresis leukocytes which then are infused and immunologically kill cancer cells. FDA is not obligated to approve the pharmaceutical because of the committee's vote. (Source: Novartis press release, July 13, 2017)

The top researchers are getting the bulk of the funding. Of nearly 90,000 principal investigators in the National Institutes of Health (NIH) database, NIH ExPORTER, from 1985 to 2015, the top 10 percent received about 40 percent of the total research funding. The lower 40 percent received only about 11 percent. The analysis, from the Berkman Klein Center for Internet & Society at Harvard University, found that the disparity was even greater when looking at organizations, the top 10 percent of whom received 80 percent of the funding. (Source: Harvard website, July 11, 2017)

New device detects breast cancer cells in blood. Continuous surveillance for cancer recurrence and progression in oncology patients can become invasive and costly. A new non-invasive device, developed at the Universitat Rovira i Virgili in Spain, uses a low-cost hydrodynamic optofluidic chip with all integrated optics to identify and quantitate tumor cells in peripheral blood. The device's performance was tested on three healthy donors and five breast cancer patients for nine months in 2016, and accurately predicted both their clinical course.

Citation: Pedrol E., Garccia-Algar M., Massons J., *et al*. Optofluidic device for the quantification of circulating tumor cells in breast cancer**.** *Science Reports*. June 16, 2017 online. DOI: 10.1038/s41598-017-04033-9.

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BRIEFLY NOTED (continued from page 9)

Google's life science branch, Verily, is releasing bacterially-infected mosquitoes in California to reduce wild-type *Aedes aegypti* populations. Fresno got its first delivery of what will be 1 million mosquitoes by the end of the week as part of the Debug Fresno project, which aims to release 1 million mosquitoes every week for 20 weeks. The mosquitoes are infected with the *Wolbachia* bacteria, rendering the males sterile. Debug Fresno is a field study that aims to eliminate the *Aedes aegypt*i mosquito population—potential carriers of Zika, dengue, chikungunya, Yellow Fever, and other infectious diseases. The mosquitoes are raised in an automated environment that attempts to increase the efficiency of the process. Concerns are being raised by some ecologists that the mass sterilization and decline in mosquito populations could have a detrimental effect on the local and global ecosystem, including bird populations. (Source: *Wired*, Verily's Mosquito Factory Accelerates the Fight Against Zika. July 14, 2017)

INFECTIOUS DISEASES UPDATES

Two experimental vaccines can restrict Zika virus transmission from pregnant mice to their fetuses. Zika virus in pregnant women is linked to serious birth defects like microcephaly. Scientists from the National Institute of Allergy and Infectious Diseases (NIAID) and extramural collaborators studied two Zika vaccine candidates in mice: a live, attenuated preparation from the University of Texas Medical Branch (UTMB) and an mRNA vaccine candidate from Moderna Therapeutics, a biotechnology company in Cambridge, Mass. Both platforms produced high-titer neutralizing antibodies, blocked transmission to the fetus, and prevented placental and fetal injury.

Citation: Richner J.M., Jagger B.W., Shan C., *et al*. Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease. *Cell***.** July 13, 2017. DOI: http://dx.doi.org/10.1016/j.cell.2017.06.040.

Person-to-person contact probably caused the spread of Zika, the Centers for Disease Control and Prevention (CDC) and public health officials said in Utah case. In a case first reported in the *New England Journal of Medicine* in 2016, a family caregiver to the index patient—who likely acquired infection in Mexico, became ill and was confirmed to have Zika infection. After an extensive epidemiologic investigation, 218 community members, including 19 family members and 86 healthcare providers, were interviewed and among the 28 who had signs/symptoms of Zika, no other person had laboratory evidence of a recent Zika infection. No mosquitoes from the area tested positive. The authors conclude that, while the definite source of the caregiver's infection remains a mystery, it was "likely person-to-person contact" with the index, high-viral load, patient.

Citation: Krow-Lucal E.R., Novosad S.A., Dunn A.C., *et al*. Zika Virus Infection in Patient with No Known Risk Factors, Utah, USA, 2016. *Emerging Infectious Diseases.* August 2017. DOI: 10.3201/eid2308.170479.

SET YOUR CALENDAR

ABC SMT Journal Club Webinar
Date: July 25, 2017
Time: 12:00 to 1:00 p.m. EDT

Register here.

WORD IN WASHINGTON

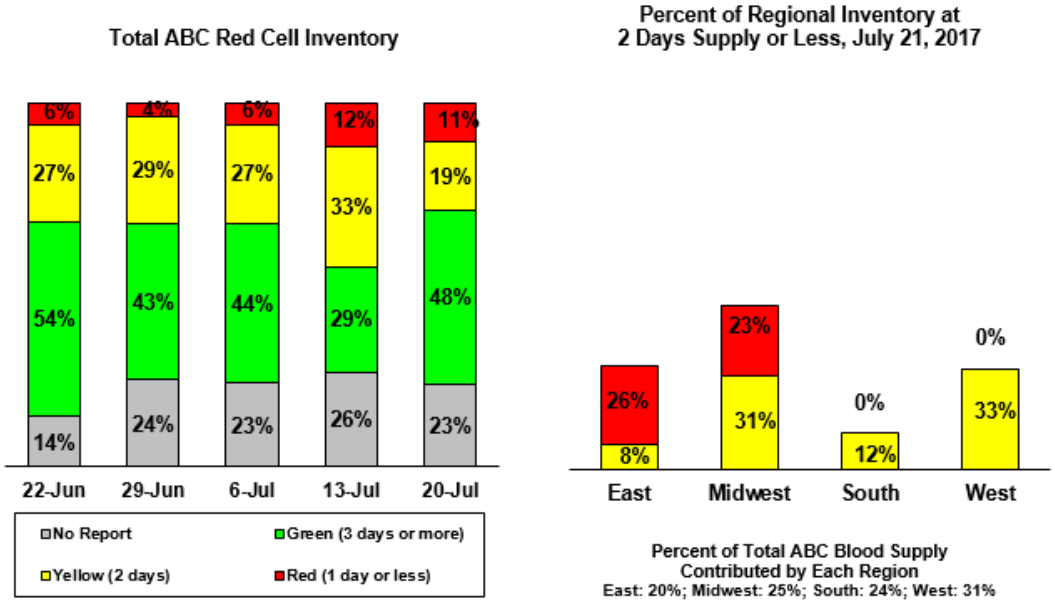
The House Appropriations Committee passed the Labor, Health, and Human Services, and Education Appropriations bill for fiscal year 2018 on Wednesday. The bill now moves to the House of Representatives for a vote after technical changes are made. We wrote about the bill in last week's newsletter, and here are additional areas of interest for the blood community: chronic disease prevention and health promotion, Biomedical Advanced Research and Development Authority (BARDA), National Institutes of Health (NIH), and cord blood.

- **Chronic disease prevention and health promotion.** Under this category is blood safety monitoring, and the Committee urged the Centers for Disease Control and Prevention (CDC) to provide "specific information to assist blood centers in responding to emerging infectious diseases that may be transmitted by blood transfusions." The Committee recommended: $15.1 million for blood disorders; $4.4 million for public health approach to blood disorders; $3.5 million for hemophilia activities; $5.1 million for hemophilia treatment centers, and $2.1 million for thalassemia blood disorders.
- **BARDA.** BARDA received an $8.3 million increase for total funding of $520 million, and $530 million for Project BioShield (a $20 million increase). The Committee also urged BARDA to continue funding the development of pathogen reduction technology for blood centers.
- **NIH**. The added $1.1 billion was approved and includes $34.36 billion in discretionary appropriations and $824.44 billion in set-aside transfers. The draft bill also specified $3.23 billion for the National Heart, Lung, and Blood Institute and $5 billion for the National Institute of Allergy and Infectious Diseases.
- **Cord blood**. A recommended $12.27 million for the National Cord Blood Inventory, the same as the FY2017 and $22.1 million for the C.W. Bill Young Cell Transplantation program.

A letter was sent by 32 Democrats urging the Food and Drug Administration (FDA) to end the men who have sex with men (MSM) one-year deferral policy. Representative Mike Quigley (D-Ill.), who serves as Vice Chair of the LGBT Equality Caucus, led the letter urging the FDA to update the MSM deferral policy and move to an individual risk-based deferral policy. Rep. Quigley also offered an amendment to the House Appropriations Committee, of which he is a member, for the National Heart, Lung and Blood Institute to work with the FDA to update the blood donor questionnaire to reflect such a change—an amendment that was struck down Wednesday night by the Committee. (Source: Office of Rep. Quigley press release, July 19, 2017).

The 2017 Medicare Trust Fund report was released. Each year, the Centers for Medicare and Medicaid Services (CMS) must make a determination if Medicare per-capita five-year average growth rate will exceed the targeted growth rate. The CMS Chief Actuary this year has said for the second year in a row that Medicare will not exceed the limits. The Independent Payment Advisory Board (IPAB), which was established under the Affordable Care Act (ACA), is charged with ensuring Medicare expenditures stay within the limits the ACA established. There is bi-partisan support to dismantle the IPAB, whose determinations and reductions in Medicare access and amounts are difficult to challenge or override. (Source: Health Affairs Blog, ACA Round-up: Medicare Trustees Report Does Not Trigger IPAB, and More. July 14, 2017; The Hill, Congress, cut loose ObamaCare's notorious Medicare board. July 16, 2017)

STOPLIGHT®: Status of the ABC Blood Supply



Daily updates are available at:
www.AmericasBlood.org

AMERICA'S BLOOD CENTERS'
55TH SUMMER MEETING
August 1-4, 2017 – **Providence, RI**

HIGHLIGHTS

Common Ground: The Impact of Reimbursement
Jack Berry, American Hospital Association's Regional Executive

Customers & Negotiations: Building Relationships
Andrea Coleman, Former Hospital CEO and VP with VHA West Coast

Pediatric Transfusion Thresholds Update
Steven Sloan, Blood Bank Medical Director, Children's Hospital Boston

Iron Mitigation at Blood Centers
Ralph Vassallo, EVP / Chief Medical & Scientific Officer, Blood Systems

***Members Meeting (ABC Members only)**

Links for Life Golf Tournament (Warwick Country Club)

"All of us at the Rhode Island Blood Center look forward to hosting our ABC colleagues, family and friends at the ABC Summer Meeting in August. New England, and Rhode Island in particular, are beautiful places to visit in the summer. We hope you have some extra time and can take the opportunity to see what Rhode Island has to offer this August."

– Larry Smith, President & CEO, Rhode Island Blood Center

Rhode Island Blood Center

Hotel Information
Renaissance Providence Downtown
Hotel room rate: $169 + tax

Registration is now open, visit www.bit.ly/abc_meetings
The Future Leader Scholarship will be available upon registration.

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

America's Blood Centers®
It's About *Life.*

MEMBER NEWS

New York Blood Center (NYBC) has joined Blood Centers of America (BCA). BCA is a member network of more than 50 independent blood centers and source plasma collection centers in North America.

"New York Blood Center's commitment to quality blood products, innovative research, and transfusion medicine leadership make them an ideal member of BCA," said John Armitage, MD, chairman of BCA and CEO of Oklahoma Blood Institute "We are excited to add New York Blood Center's unique services and expertise to our own, and collaborate to serve more communities across the country."

"We're extremely pleased to be partnering with such an excellent organization. NYBC is looking forward to working with all of the members of BCA to move our missions forward through the collaborative efforts of BCA," said Christopher D. Hillyer, MD, president and CEO of NYBC: (Source: BCA press release, July 20, 2017)

LifeServe Blood Center is opening a new lab and offices. LifeServe is expanding their mobile blood unit (MBU) facility to include a laboratory and administrative offices in Sioux City, Iowa. The facility currently houses about three vans, two buses, and a handful of other mobile blood units. The expansion is breaking ground this month and will move their current downtown administrative offices and laboratory into the new section of the facility. "The staff is very excited because we got all the latest and greatest state-of-the art equipment for the laboratory," said Danielle West, public relations and marketing manager. The downtown office will be sold and the move is expected by late 2017, early 2018. Their donation site will continue undisturbed at 4501 Southern Hills Drive. (Source: KSCJ, LifeServe blood center to open new lab & offices. July 14, 2017.)

Bonfils Blood Center hosted their inaugural Battle of the Badges and Pints for Pasta. The competition—Battle of the Badges, is between Team Fire, the local fire department, and Team Law, the police department, to encourage more donors during the summertime. The competition is a month long and is for bragging rights. The Pints for Pasta campaign is also during the month of July and who ever donates during the month is automatically given a $5 voucher for a $10 order at Noodles & Company. (Source: Fox 21, Bonfils Blood Center debuts Battle of the Badges, Pints for Pasta. June 28, 2017)

Central California Blood Center (CCBC) donated a mobile blood unit (MBU) to the Ukraine this week. The three-bed MBU was used at the blood center for a number of years, but with new and stricter emissions legislation in California taking effect, the unit would not have been cost-effective to keep any longer. The unit was presented during a ceremony at the Ukrainian Ministry of Health premises with the Deputy Healthcare Minister of Ukraine Oksana Sivak and Ukrainian blood team members who were trained on how to use the MBU. Leslie Botos, director of Community Relations & Development, said the MBU is the first in the country. Ms. Botos spent time in the Ukraine as part of a PEPFAR project years ago. She presented her idea to donate the MBU to CCBC's board of directors and former CEO Dean Eller. After thousands of dollars were donated from the Rotary Club, board members, Mr. Eller, and others, the MBU was shipped off. The Ukraine does not have a robust blood donor system, with many donors being family members of those in need or paid. (Source: Ukrinform, California blood center presents Ukraine with bloodmobile. July 18, 2017)

CALENDAR

2017

July 26. **Transfusion Safety Officer & Patient Blood Management Seminars (Advanced Program), Ft. Lauderdale, Fla.** If you are interested in taking part in one of these new and engaging programs, please contact: Cathy Shea, Executive Assistant or call (727) 568-1151.

July 31-Aug. 1. T**he Center for Medicare and Medicaid Services (CMS) Advisory Panel on Clinical Diagnostic Laboratory Tests annual public meeting, Baltimore, Md.** For more information and registration click here.

Aug. 1-4. **Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; Register here or e-mail: meetings@americasblood.org.

Aug. 4. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 11-12. **IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations, Atlanta, Ga.** Registration is open.

Sept. 18-19. **Public Workshop- Advancing the Development of Pediatric Therapeutics (ADEPT): Application of "Big Data" to Pediatric Safety Studies, Silver Spring, Md**. For more information, click here.

Sept. 27-28. **Financial Management & IT Workshops, America's Blood Centers, Houston, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 27. **7th Annual Symposium Red Cell Genotyping 2017: Patient Safety, Bethesda, Md.** The Department of Transfusion Medicine, NIH Clinical Center, National Institutes of Health, and the Blood Center of Wisconsin are co-hosting this symposium on the NIH campus. For information, registration fee and advance registration contact Phyllis Kirchner.

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** No registration fee. Advance registration is encouraged. Contact Karen Byrne or visit the website.

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md**. Advance registration is encouraged. Contact Karen Byrne or click here.

Oct. 7-10. **AABB Annual Conference, San Diego, Calif.** More information and registration here.

Oct. 19-20. **Austrian Red Cross Content Marketing Workshop, Vienna, Austria.** Email for more information.

Nov. 7-8. **Transfusion Safety Officer & Patient Blood Management Seminars (Basic & Advanced Programs), Jacksonville, FL.** If you are interested in taking part in one of these new and engaging programs, please contact: Cathy Shea, Executive Assistant or call (727) 568-1151.

Nov. 8-10. **10th World Federation of Hemophilia Global Forum, Montreal, Canada.** For more information and to register, click 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 Lisa Spinelli at the ABC office. Phone: (202) 654-2982; fax: (202) 393-1282; e-mail: lspinelli@americasblood.org.

POSITIONS

Positions also available on our website

Immunohematology Reference Laboratory (IRL). The San Diego Blood Bank (SDBB) is looking for an evening shift IRL. The IRL performs essential job duties while providing guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. Essential duties include: participates in the Reference Lab on call rotation; performs red cell blood grouping and antibody identification on donor and referred patient blood samples; determines suitability for transfusion of donor units with discrepant ABO or Rh groups and unexpected red cell antibodies; performs molecular procedures and platelet compatibility work; provides verbal and written reports, technical assistance and consultation to customers; assist in maintaining rare donor files; investigate and review non-conformances through quality incident reporting; perform supervisory reviews and tasks as needed; perform validations and new process development; perform controlled document writing and revisions; assists with staff training and competency when applicable. The applicant must have an MT (ASCP) or equivalent experience; a California Clinical Laboratory Scientist License (CLS) or Calif. Clinical Immunohematologist Scientist License (CIS); specialist in Blood Banking (SBB) or equivalent education/experience. The evening shift is from 2:30 p.m. to 11:00 p.m. (hours may vary). EOE/Minority/Female/Disability/Vets. To apply, click here.

Assistant Manager Donor Testing Laboratory. Memorial Blood Centers in St. Paul, Minnesota, is looking for a full-time Assistant Manager of our Donor Testing Laboratory (Laboratory Supervisor). This day shift, Monday through Friday, 9:00 p.m. to 5:30 a.m. role manages the staff at the testing laboratory during the third shift. Benefits include medical, dental, vision, PTO/EST, 401K and more. This is a great next step for a lead technologist who is ready to take on more leadership duties. To apply, click here.

Donor Testing Lead Technologist. Memorial Blood Center in St. Paul, Minn., is looking to add a Donor Testing Lead Technologist to their Donor Testing Department. This full-time role will supervise donor testing technical staff and coordinate all operations on either a second or third shift schedule. Benefits include: medical, dental, vision, PTO/EST, 401K and more! Candidates with four or more years of laboratory experience are encouraged to apply with the following link: https://home2.eease.adp.com/recruit/?id=19228782.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Candidate must have a four-year college degree and a combination of three or more years of experience in blood banking\laboratory or manufacturing with solid familiarity of GMP, safety in a manufacturing setup, and CAL-OSHA regulations. Must have exceptional attention to detail, able to exercise flexibility, and prioritize tasks; strong collaboration and effective communication skills both verbally and in writing, able to problem solve, analyze and evaluate complex situations; work independently and initiate improvement ideas to enhance QRA program; proficient in Microsoft Office applications especially Word and Excel; be able to prepare and perform training of staff. MT or Specialist in Blood Banking (SBB) certification, CQA certification, Registered Nurse, knowledge of quality improvement concepts and quality management tools, are all highly desired. Stanford Blood Center. For more information about us, visit our website at http://bloodcenter.stanford.edu/. Apply online at http://www.stanfordhealthcarecareers.com, ref. job# 42175.

Clinical Laboratory Scientists (technologists). Stanford Blood Center Histocompatibility Lab has several openings for Clinical Laboratory Scientists (technologists) to perform highly complex human histocompatibility testing for organ transplantation, including molecular typing, HLA antibody identification, and crossmatch testing including both machine and manual assays. Test specimens, analyze, interpret, and report results. Clinical test results are used directly to inform patient care decisions, with errors potentially leading to adverse events. Experience in HLA is a plus, but we will train. The candidate must have a bachelor's degree in medical technology or a life science, and a 12-month internship in medical technology

(continued on page 16)

POSITIONS (continued from page 15)

or 12 months of work in an approved histocompatibility laboratory. The applicant must also hold or qualify for California license: Clinical Histocompatibility Scientist (MTR) license (qualify if you are certified by ABHI as CHS or CHT), or Clinical Laboratory Scientist (MTA) license (qualify if you are certified by ASCP or AAB as medical technologist). If currently out-of-state, California license must be obtained within 6 months of start date. For more information on Stanford Blood Center, click here. Please apply online at: https://www.stanfordhealthcare.org, reference job codes 41863, 41845, 41994, and 41995. Note: Specific work schedules are indicated on the individual job postings.

Medical Director. LifeShare Blood Centers is looking for a Medical Director (MD or DO) with appropriate specialty, such as hematology or pathology. Prior blood banking experience helpful with 15+ years of experience as a physician or medical practitioner, either in private practice or in association with a major hospital or medical teaching institution. Must have knowledge of regulations, laws, statutes and standards pertaining to blood donation, disease testing, and blood compatibility, transfusion of blood and blood components, and patient or donor reactions. The Medical Director is responsible for providing medical support and consultation to all LifeShare Blood Center locations as needed concerning donors, donor reactions, physician or hospital requests, apheresis services and related procedures. The Medical Director investigates all suspected TTD's and submits reports; reviews transfusion reaction reports and takes appropriate action; reviews all post-donation illness reports and makes decision concerning product disposition. The Medical Director reviews abnormal donor test results, including all HIV positive test results and makes notification to the donor. To apply, please go to http://www.lifeshare.org/careers.