

ABC Newsletter will not publish next week and will resume publication July 14.

Issue #24
June 30, 2017

Risk-Based Decision Making Framework Applicable to the Blood Industry

The Advanced Medical Technology Association (AdvaMed), in coordination with Deloitte Consulting LLC, published a report called "[A Framework for Comprehensive Assessment of Medical Technologies](#)." They recommend a framework to more accurately assess the value of emerging diagnostic technologies and tests for patients, manufacturers, health systems, payers, and other stakeholders. Parallels with the risk-based decision-making (RBDM) framework that has been developed by the Alliance of Blood Operators are striking, and suggest much common ground with the companies from whom the blood community sources tests and devices.

"The U.S. health care system is undergoing rapid change, moving toward a system that puts a premium on value rather than simply reimbursing costs. But assessing value properly is critical to support continued innovation and medical progress, so that the evolving system can work properly for patients and for society," said Scott Whitaker, president and CEO of AdvaMed in a press statement. "AdvaMed's Value Frameworks are crucial tools in this process, reflecting the needs of all stakeholders, and recognizing the unique features of a wide range of medical technologies. It is not a formula for pricing a product, but will inform decisions about how to assess the value of a product in terms not just of its price but its overall cost and benefits."

The report is premised on movement in healthcare away from fee-for-service to a value-based-care model—creating a shift in the payment process and improving patient care as well as their overall satisfaction. The blood

community has seen this shift in many venues, for example in the rise of evidence-based patient blood management programs.

The AdvaMed framework rests on eight core principles: comprehensive consideration of patient-centric value, a rigorous evidence base; consideration of costs both in and outside the health care context; understanding the performance of



candidate technologies an all relevant populations; selection of appropriate impact assessments; broad stakeholder engagement in a transparent process; and recognizing that value assessment is iterative as evidence and contexts evolve over time. This kind of solid foundation of principles can be applied to nearly any healthcare setting, including blood. The elements of the AdvaMed framework can be directly mapped to those of the [ABO RBDM framework](#).

"Value-drivers" are used to structure evaluations for the effectiveness and efficiency of care. The four value drivers here include: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and public population impact. The report split these drivers into subcategories with sample questions to

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OUR SPACE

ABC Chief Medical Officer and interim CEO Louis Katz, MD

The Light at the End of the Tunnel, Or Is It an Iron Horse?

Back again to [opine](#) about iron.

- Iron depletion is a public health issue independent of blood donation...
 - ...but blood donation does contribute to iron depletion in the population.
- There is no agreement about the clinical impacts of donor iron depletion.
 - Concern centers on teens, who are the foundation of our mission for decades to come, but includes menstruating women and “frequent” donors.
 - Assessing the impacts is a difficult, lengthy task so...
 - ...the “precautionary principle” has been invoked, telling us to do something until we know more—i.e. *primum non nocere*.

Who is and who ought to be driving the train?

- We (i.e., docs) in the blood community are the prime movers—this is fundamentally a question of science and medicine.
- “Civilians” in the blood community are the stakeholders who will foot the bill for “doing the right thing(s).”
- Donors need to be informed, engaged, and heard.
- The larger clinical and public health communities need to take ownership of population iron status, including the contribution of blood donation. We need these folks on board, giving their audiences positive, balanced messages about blood donation.

Where is the train headed?

- An *ad-hoc* group of experienced collection facility docs, convened by ABC, American Red Cross, and Blood Systems, Inc. (alphabetical order) reached consensus in April that the *long-term goal* should be preventing iron depletion by blood donation in ALL donors.
- AABB Association Bulletin (17-02) suggested a series of complementary (as opposed to alternative) strategies, including a list of at-risk donor cohorts to target for initial interventions. A formal risk-based decision-making process to evaluate those options is underway (with robust participation from ABC members). Expect to see an interim AABB *Standard* by the first of the year (my [guess](#) without inside information or any clear sense of its content).
- Ordered, as I see them, from most to least likely to work considering both donor iron balance and robustness of the blood supply, are interventions I would consider (if I worked at a blood center).
 - Hand replacement iron and a positive message to appropriate donors when they are sitting in front of you (my preferred approach).
 - If you can’t/won’t hand it to them, facilitate access to iron via vouchers or some similar expedient.
 - Limit donation frequency for the highest risk donors (e.g., teens) who cannot or will not commit to taking iron supplements, recognizing the impact on the blood supply.
 - Measure iron stores in those at risk and respond appropriately, *ex-post facto*, to the lab test.
 - Tell donors about iron, that they should increase their iron intake, how they can do so, and hope for the best.

One size will not fit all, despite my oft repeated (*ad nauseum*?) [opinion](#) “we are taking it out and we should be putting it back”. However you combine these options, measure the impact or we will never learn the optimal strategies.

lkatz@americasblood.org ♦


ADVAMED FRAMEWORK (continued from page 1)

consider and sample value metrics. Concentrating on clinical utility and benefits, economics for all those involved, and the overall societal impact goes beyond the traditional patient-level economic measures of value and considers the global impacts of care delivered.

Key stakeholders regarding tests and devices relevant for the blood community include: patients, clinicians, blood center(s), hospitals and hospital transfusion services, government agencies (non-regulatory), regulatory bodies, insurance providers, ethicists, and others. Each of these stakeholders wants to see a value assessed for blood to determine the impact on public health and society at large, but must balance individual patient considerations with more global issues like health care economics.

“This framework brings an important external stakeholder group into the equation—the device and diagnostics industry. I wonder about the degree to which its execution in the for-profit sector might “bias” the results of value-estimates toward increased sales. That is an issue for the transparency and inclusiveness of the process,” said Louis Katz, MD, ABC CMO and interim CEO.

Using this framework, the device industry could contribute to the blood industry’s own RBDM assessments in an independent manner.

“The AdvaMed framework contributes to the growing recognition on the importance of implementing an RBDM framework for the blood industry and defining the ‘value’ of blood. Optimizing safety while appropriately balancing resources and contributing to a growing, solid base of evidence is essential to our industry’s mission,” said Martin Grable, ABC president and CEO of the Community Blood Centers of the Carolinas. 



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)

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.

“ 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





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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.

2017 ABC Summer Meeting Scholarship Winners Announced

America's Blood Centers' Scholarship Program, made possible by a grant from the Foundation for America's Blood Centers, provides funds to ABC members to supplement costs for attendance to an ABC Specialty Workshop or Meeting. We are pleased to announce the recipients of the three (3) ABC Professional Institute Future Leader scholarships for the upcoming Summer Meeting:

Alyssa Drown, marketing manager at Central Jersey Blood Center; Kimberly Gitt, area manager at Bloodworks Northwest and James Randle, assistant director of Donor Services at South Texas Blood & Tissue Center. The scholarship will help offset the costs associated with attending the Summer Meeting registration fee and/or supplement any travel/lodging costs associated with attendance.

This is the fifth year of the scholarship program. Read below to see letters sent from scholarship winners of the 2017 ABC Technical & Quality Workshop held in Omaha, Neb.

Congratulations to all the scholarship winners! 📌

Workshop Scholarship Winners Letters to the Editor

The following are edited letters from the ABC and Foundation for America's Blood Centers (FABC) scholarship winners of the 2017 ABC Technical & Quality Workshop in Omaha, Neb., June 6 to 8.

“Attending the 2017 Technical & Quality Workshop proved to be a stimulating and informative experience for me. It was refreshing to be in an environment of industry peers and experts willing to share their knowledge and experiences in handling the latest trends in blood banking.

Many industry hot topics were at the forefront of the workshop. Of particular interest were the presentations on pathogen reduction, blood center 2016 challenges (Final Rule, ZIKA, Haemonetics recall), and social media. The ABC workshop provided ample opportunities to network with peers, both professionally and socially. Being able to meet new people, reconnect with colleagues, or put a face to an email name was invaluable.

I would like to sincerely thank the FABC and Americas Blood Center API scholarship program for enabling me to attend the 2017 Technical and Quality Workshop. I would not have been able to attend without your generous support and commitment to education. I encourage anyone who has never attended an ABC workshop to participate in this worthwhile event. I would also like to give kudos to the awesome organizers for selecting an enjoyable event location and for making available the ABC App to manage workshop schedules, view presentations and complete evaluations. A special thanks to Leslie Maundy.”—Kim Ruechel, senior director of Technical Services, Blood Bank of Alaska

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LETTERS TO THE EDITOR (continued from page 4)

“As a recipient of a 2017 ABC Technical & Quality Workshop scholarship, I would like to thank ABC and FABC, and associated committee members, for extending this opportunity to me to network with all the wonderful ABC members at this exciting three-day event. The agenda topics were spot-on with all current events and challenges that our blood center can relate to and I met many new people that I can reach out to and network with in the future.

I found the guest speakers and presentations packed full of innovative ideas, knowledge, and methodology that completely enhanced and/or matched our position on most issues at the Community Blood Center (CBC). To know that fellow ABC members and CBC are all working toward the same goals with pathogen reduction for platelets, TRALI mitigation, and iron assessment for our donors was empowering. The speakers presenting “The Perfect Storm” presentation provided a quality perspective that I, personally, and our entire blood center can relate to. The take-aways from the process improvement discussion were great! Sharing the “what works” for best practice and improvement tools with others and hearing opinions on current quality issues once again, like cybersecurity and electronic storage of records, was invaluable as a reminder of how our risk management changes along with opportunities for new innovations to provide a safe blood supply to...save lives.” —Tina Larragoitiy, quality assurance specialist at the Community Blood Center (Appleton).

“I would like to express my sincere gratitude to the FABC and ABC’s API Scholarship Program for the funding to attend the Technical/Quality Workshop in Omaha, Neb. The workshop allowed me to connect with peers who provided thoughtful insight on several process improvements. A particular roundtable discussion regarding the Food and Drug Administration citations was very helpful as we identified several issues that our blood center needs to improve on. Specifically, I was able to take information and look back at our service records for pest control and determine whether or not the chemical being used was suitable and approved—which it was.

The presentations on the subject of social media and how Quality should be involved really struck a chord with me. We will be having a multi department meeting to discuss some of the specific case studies shared at the conference. I found it utterly intriguing how the other centers/speakers handled their post donation information and reactions. We will undoubtedly be using this information to help enhance our post donation information program - with the support and enthusiasm of our Marketing Department! Collaboration, col-laboration, collaboration!

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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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The exchanges at the swag table were also fun and interactive. All in all I was able to gain a rejuvenated spirit and learn new ways to solve old problems and identify creative ways to solve new problems. Had it not been for the generous scholarship, I would not have been able to attend. Thank you again for the opportunity to participate in the Workshop and bring home these great ideas.” —Pamela Starks, manager of Quality Assurance at Indiana Blood Center

“This was my first time attending an ABC function and I have to say that I was extremely impressed. I have attended other industry related conferences and can say unequivocally that the ABC Technical & Quality Workshop has been the most beneficial and enjoyable conference that I’ve attended to date.

The workshop had an inherent efficiency in its design, in that it had a packed schedule of carefully picked presentation topics, relevant roundtable discussions, and networking events that maximized the benefit to time ratio. I came to the workshop looking forward to a selection of topics that were to be discussed, but left feeling like I benefited from every presentation. A few presentations that I did not anticipate being particularly relevant to my organization, not only proved my expectations wrong, but also left me with tools to improve my organization.

I have a deepened sense of appreciation for ABC and its members after experiencing the comradery in person, along with the willingness to share lessons learned, and the joint understanding of the struggles we all face in this industry in the day to day operations. More so than having a common workload or similar challenges, I believe it is our common passion that brings us together and pushes us to improve. Thank you, for recognizing that we can accomplish far more united than apart, and organizing a wonderful event to prove that point.” —Eric Longacre MT(AAB), assistant director of Quality Assurance at Sheppard Community Blood Center

“I’m really a hospital lab manager, not a blood banker, but I took on a big job when I became the technical director in a small, independent blood center, and people are counting on me to become a blood banker – fast.

The educational sessions (at the TQ Workshop) helped me think more like a blood banker. We covered the big picture of the national blood supply, and we assessed how to maintain it while protecting our patients from TRALI and our donors from iron depletion. We drilled down to the details too – huddle meetings that improve production, social media, and the subtleties of gender issues. We looked into the future of transfusable whole blood, the opportunities of incompatible plasma, and the dangers of hackers and Facebook trolls. Again and again, we returned to how all of this effort depends on transparent, dependable quality that preserves the trust we enjoy from our patients, providers, and donors.

Even more important were the relationships I made. People I knew only as names on email lists became familiar faces. I left Omaha with a stack of business cards and a sense that I am not alone as I help chart my center’s course. Best of all were the reminders of the reasons why we do this. The pioneers of our discipline have turned what used to be a risky and questionable practice into a routine, lifesaving part of modern health care. Today, a new generation is pushing the boundaries of traditional blood banking, helping save lives with data and finding cures for diseases using our industry’s waste products. My favorite moment of all was when Margaret Hannan from Blood Bank of Delmarva shared her reason – a patient named Andrew who died of acute myelogenous leukemia at age 14. Before he died, he and his family were blessed with 167 “bonus days” of life thanks in part to the work of Margaret and her blood center. Someday, I hope to look back and realize that my efforts helped bring bonus days to people like Andrew. That’s when

LETTERS TO THE EDITOR (continued from page 6)

I'll feel comfortable claiming to be a blood banker. My heartfelt thanks go to FABC and the many colleagues who shared time, money, and talents to help me get one step closer.” —Adam L. R. Summers, CLS, MLS(ASCP), technical director at Northern California Community Blood Bank

“The recent ABC Technical & Quality Workshop was an extremely valuable experience. The Speakers provided excellent information, and the topics provided great oversight of current trends within the industry. The speakers presented a new perspective on processes, products and problems we may be facing.

The roundtable discussions were extremely helpful not only in trying to find solutions for challenges that all blood centers struggle with. It also provided opportunity to get to know one another and become familiar with other centers. Learning about other aspects of blood banking that I am not as familiar with helps me see a bigger picture. There are always opportunities for growth and improvements within an organization and providing me the opportunity to meet and share in experiences was extremely beneficial.” —Zachary D. Eblen, manager of Production and Distribution at Community Blood Center (Kansas City).

“Without this scholarship, I would not have been able to attend this educational and enjoyable meeting. The topics presented were timely to our current struggles within the blood banking community. Each presenter gave interesting perspectives on their respective subjects and provided me with many ideas to bring back to my center and share with my peers. Meeting and socializing with other blood bankers from across the country afforded me an opportunity to expand my knowledge base. It was great to “talk shop” with people who really understood the problems we all face. I thought the ABC app was a fantastic tool that helped engage attendees. It was not only a great place to locate the presentations for further study, but it also allowed easy networking among the participants and instant feedback for the presenters. I feel it is a step in the right direction for reaching and interacting with those of my generation.

The workshop was an invaluable experience. I know I will be able to use the knowledge I gained to improve the processes and communication at my center. The people I met helped to make this a great first ABC meeting for me and I look forward to attending future workshops.” – Alexandra Pike, quality and regulatory specialist at LifeShare Blood Centers. 💧

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

The following articles and editorial will be presented and discussed:

- [Obstetrics and gynecology physician knowledge of Rh immune globulin prophylaxis](#)
- [Encouraging single-unit transfusions: a superior patient blood management strategy?](#)
- [Single-unit transfusions and hemoglobin trigger: relative impact on red cell utilization](#)
- [Storage medium of platelet transfusions and the risk of transfusion-transmitted bacterial infections](#)

Registration information coming soon!

RESEARCH IN BRIEF

The current bacterial screening protocol at Canadian Blood Services (CBS) is effective, but false negative early cultures still occur. Platelet concentrates are among the highest at-risk blood products for causing infections post-transfusion due to bacterial contamination. CBS reported on the effectiveness of their bacterial screening process from 2010 to 2016, on 601,988 buffy coat pools and 186,737 apheresis platelet concentrates. They confirmed other studies that demonstrated early cultures to be effective for interdixing Gram-negative bacteria. Frequent isolation Gram-positive organisms on outdated quality-control testing and septic transfusion events demonstrated a residual safety risk that merits further intervention. Data from routine screening, quality-control testing, and surveillance for septic reactions found a rate of one per 100,000 for nonfatal septic reactions and approximately one fatality per 500,000 platelet concentrates. Delayed, high volume early cultures like that done in the U.K. and Québec is being considered to address the persisting risk.

Citation: Ramirez-Arcos S., DiFranco C., McIntyre T., and Goldman M. Residual risk of bacterial contamination of platelets: six years of experience with sterility testing. *Transfusion*. June 26, 2017. DOI: 10.1111/trf.14202.

The cost-benefit of various HIV, hepatitis B and C screening strategies varies greatly depending on the country. The cost of safety interventions like infectious disease screenings is increasingly a driver of decisions about implementing blood safety interventions. As part of the Alliance for Blood Operators' project on risk-based decision-making, an assessment of eight Western countries (Australia, Canada, Denmark, Finland, France, The Netherlands, U.K., and the U.S) was performed. The cost-utility ratio for serologic screening varied between \$-11,000 to \$92,000 per quality-adjusted life year (QALY), and nucleic acid testing ranged from \$-12,000 and \$113,000 per QALY, depending on the country, when compared to no screening. The authors conclude that, "combined serology and NAT ranges between \$600 and \$217,000 per QALY. The incremental cost-utility of nucleic acid testing after implementation of serology screening ranges from \$2.231 million to \$15.778 million per QALY."

Citation: Janssen M.P., van Hulst M., Custer B., *et al.* An assessment of differences in costs and health benefits of serology and NAT screening of donations for blood transfusion in different Western countries. *Vox Sanguinis*. June 22, 2017 online. DOI: 10.1111/vox.12543. ♦

RECENT REVIEWS

T-cell mediated alloimmunity in transplantation reviewed. Alloreactive T-cells play a central role in transplantation: they are key mediators of tolerance, rejection, and graft-versus-host disease (GVHD). However, there are still a number of unanswered questions regarding mechanisms in which T-cells become alloreactive and how they mediate rejection and GVHD. In this review, methods for measuring alloresponse like mixed lymphocyte reactions (MLR) and cell-mediated lympholysis (CML) assays; CML/T-cell receptor (TCR) sequencing approaches and the production of alloreactive clones, and the clinical implications for transplant are all covered with suggestions for future directions.


Citation: DeWolf S. and Sykes M. Alloimmune T-cells in Transplantation. *Journal of Clinical Investigation*. June 19, 2017 online. DOI: 10.1172/JCI90595.

The residual risk of transfusion-transmitted cytomegalovirus (TT-CMV) is very low, but optimal contemporary studies for at-risk populations are not available. Measures to reduce the risk of TT-CMV include leucocyte depletion of cellular blood products, with or without selection of CMV seronegative donations, and pathogen reduction. In their review from 2001 forward, the authors confirm that leukoreduction and

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RECENT REVIEWS (continued from page 8)

provision of blood products from seronegative donors are effective. If universal leukoreduction is used, along with seronegative blood, the residual risk to transmit CMV via blood products is close to non-existent, noted the study. Whether serological testing has added value in the face of universal leukoreduction remains a controversy.

Citation: Ziemann M. and Thiele T. Transfusion-transmitted CMV infection – current knowledge and future perspectives. *Transfusion Medicine*. June 23, 2017 online. DOI: 10.1111/tme.12437. 

BRIEFLY NOTED

A survey of ABC and American Red Cross (ARC) blood centers was completed in June to assess implementation of the revised men who have sex with men (MSM) deferral criteria. Forty-nine ABC member centers and the ARC responded, representing approximately 85 percent of all U.S. blood collections. Eighty percent (40 respondents) had already changed their criterion and an additional 12 percent (6 centers) will do so by mid-2018. Two centers are undecided, and two do *not* intend to modify their lifetime deferral—with all four of these centers citing the adverse impact on their ability to ship recovered plasma to their fractionator as their rationale. Only five facilities will, or intend to, undertake proactive notification of historically deferred donors. (Source: [MSM deferral survey report](#))

A Boston startup aims to develop an alternative platelet product made on-demand from stem cells. Platelet BioGenesis is making human adult platelets from human pluripotent stem cell (hiPSC) cultures using a patented microfluidic bioreactor. The company notes on their website that they collaborated with Ocata Therapeutics in 2014 to demonstrate functional megakaryocytes that could be generated using research-grade hiPSC cultures. The company has raised \$10 million to support a preclinical trial of their technology. (Source: Xconomy, [Harvard Biotech Spinout Lands \\$10M to Make Platelets from Stem Cells](#). June 8, 2017.)

Citation: Moreau T., Evans AL, Vasquez L., *et al.* Large-scale production of megakaryocytes from human pluripotent stem cells by chemically defined forward programming. *Nature Communications*. April 7, 2017. DOI: 10.1038/ncomms11208.

Inhibiting GTPase proteins in refrigerated platelets could reduce platelet injury in the cold. Shailaja Hegde, MD, with ABC member center Hoxworth Blood Center and the University of Cincinnati's College of Medicine, presented at the European Hematology Association Annual Congress and described studies showing normal survival and hemostatic activity in vivo of treated platelets. If the findings are confirmed in human allogeneic transfusion, this method may be a valid alternative to product testing or pathogen reduction for reducing the risk of platelet-associated sepsis and “may be a valid alternative to extend the shelf-life of platelets,” said Dr. Hegde to ABC Newsletter. (Source: [EHA press release](#), June 23, 2017.)

Iranian engineering professors devised a mathematical model to help blood centers with platelet collections. A major challenge in blood centers and transfusion services at hospitals are to keep enough blood inventory to avoid shortages and minimize the number of outdated units. Using a Markov chain model to predict the number of donors in each time period, a two-stage stochastic model was developed by the researchers. They developed a mathematical model using data from the Iranian Blood Transfusion Organization to optimize the number of platelet units blood centers collected and how many platelet units the hospital transfusion services should transfuse to avoid shortages and waste. The study considered three types of patients: those requiring a stem cell transplantation; frequent or high dose recipients, such as hematology patients and oncology patients; and those with low-dose needs, as such with patients undergoing general surgery.

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BRIEFLY NOTED (continued from page 9)

Citation: Ensafian H., Yaghoubi S., Yazdi M.M. Raising quality and safety of platelet transfusion services in a patient-based integrated supply chain under uncertainty. *Computers and Chemical Engineering*. Pre-publication. DOI: <https://doi.org/10.1016/j.compchemeng.2017.06.015>.

A new cyberattack spread ransomware from the Ukraine to the U.S. and throughout the world on Monday. The ransomware named Petya was allegedly an attack on the Ukrainian government. Those affected by Petya were asked to pay to have their stolen files back and as of Wednesday morning Eastern time, the bitcoin account for Petya perpetrators had [received around \\$10,000](#). Paying the ransom, however, does not guarantee receiving the files and the email used by the hackers is now defunct. Petya affected computers from the Ukrainian Chernobyl nuclear plant to U.S. pharmaceutical company Merck and has the capability of infecting medical devices as well. Petya used the same National Security Agency hacking tool, Eternal Blue, as the WannaCry ransomware did just last month. Microsoft released a patch in March to the vulnerability—which is now said to be traced to tax software—however, thousands of users have not updated properly. It has been reported that this attack affected significantly less total users than last month's attack. (Source: *New York Times*, [The National Security Agency has not acknowledged its tools were used in WannaCry or other attacks](#). June 27, 2017; *NPR*, [Petya' Ransomware Hits at Least 65 Countries; Microsoft Traces it to Tax Software](#). June 28, 2017.) ♦

REGULATORY NEWS

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced updates to ISBT 128 Standard Technical Specification (ST-001). This [document](#) is a comprehensive description of the rules surrounding the use of ISBT 128 as well as guidance in the interpretation of these rules. A new version of the Product Description Code Database v 7.4.0 is now available to licensed facilities and can be downloaded as a [Microsoft Access database](#).

The Registered Facilities Database has also been updated and is now available to licensed facilities. The database contains the names and locations of all ICCBBA-registered facilities worldwide and their assigned Facility Identification Numbers (FINs). Click [here](#) to download the database as an Excel or text file. (Source: ICCBBA, April 18, 2017.) ♦

WORD IN WASHINGTON

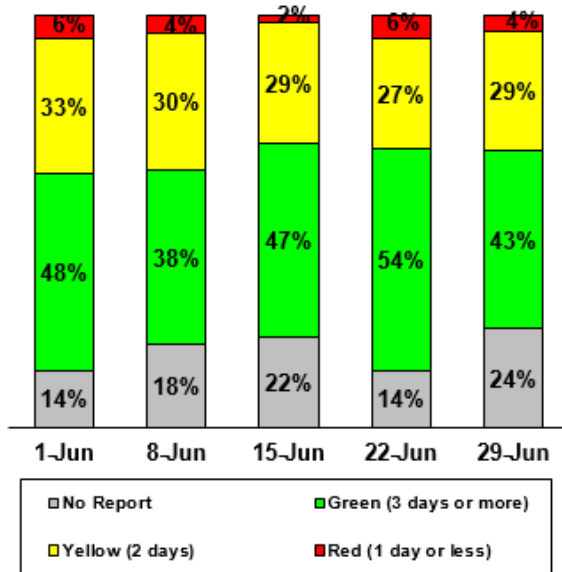
The Senate Majority Leader Mitch McConnell (R-Ky.) said he plans to revise the Senate health care bill looking to repeal and replace the Affordable Care Act (ACA) as early as Friday (today). The Congressional Budget Office (CBO) released its “score” of the Senate bill on Monday, and estimated that 22 million people would lose their health care coverage by 2026—15 million of them from Medicaid—under the plan. Medicaid provides health insurance to millions of low-income people, including children, pregnant women, veterans, and seniors in nursing homes. CBO estimated that the plan would cut federal deficits of more than \$321 billion however by 2025. The bill was not expected to pass in its current condition and hence is being revised. (Source: *Washington Post*, [McConnell is trying to revise the Senate health-care bill by Friday](#). June 28, 2017.)

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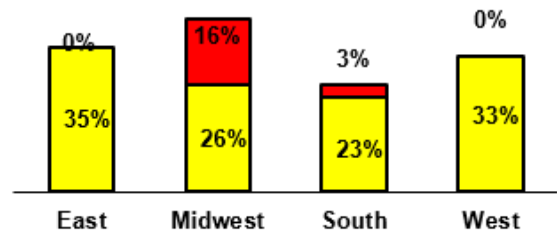


STOPLIGHT®: Status of the ABC Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, June 29, 2017



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

7th Annual Links for Life Golf Tournament



Warwick Country Club

SAVE THE DATE
08.03.2017

To sign up, visit: <http://bit.ly/fabcevents>



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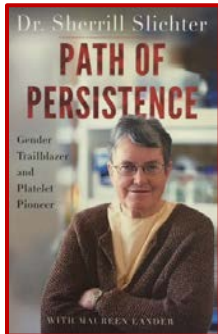
WORD IN WASHINGTON (continued from page 11)

Food and Drug Administration (FDA) Spending Bill Advances. A subcommittee within the House Committee on Appropriations is moving forward with its spending bill for 2018, a bill that would cut \$1.126 billion from agencies and programs, including the FDA. The bill sets aside \$2.8 billion in discretionary spending for the FDA to keep with current levels; however, they noted that spending does not factor in proposed user-fee recalibrations. The total allotment would be \$5.2 billion including industry user fees, an overall increase from fiscal 2017. The subcommittee noted it does not factor in the proposed user fee recalibration. (Source: [Bloomberg Government](#)) ♦

PEOPLE



John Spinosa, MD, PhD, is the new Chief Medical Officer at the San Diego Blood Bank (SDBB). Dr. Spinosa has a broad background in clinical and anatomic pathology, hematology, molecular diagnostics and informatics. He spent 20 years at Scripps Memorial Hospital as Medical Director, Chief of Staff and Chair of Pathology, and has extensive experience in blood delivery to patients. At the same time he is entrepreneurial, serving as CMO/Medical Director of local clinical laboratories at Lexent Bio, Avera, Trovogene, Verinata Health, Prometheus, Esoterix Oncology and other specialty labs. Dr. Spinosa fills a seat that has long been vacant at SDBB, which CEO David Wellis, PhD, said a few months back was awaiting the perfect candidate with the blend of external business knowledge and internal blood industry expertise.



Sherrill Slichter, MD, director of the Bloodworks Northwest platelet transfusion research Slichter laboratory, has published an autobiography in association with the center where she spent most of her career. Her new book titled, “Path of Persistence: Gender Trailblazer and Platelet Pioneer,” is a memoir recounting her upbringing, her journey toward becoming a world-renowned platelet pioneer, and a trailblazer for women in medicine. She talks about the influence of her patients over the years, and the lessons she learned from patient cases as well as the road to becoming a researcher focused on extending the shelf-life of platelets—from cold storage to freeze-dried. She also writes about her namesake laboratory, and the innovative work she and her team have done within it. She ends by thanking her fellow co-workers, especially Velma Brooks, who have kept her attached and “never-bored” at Bloodworks over the past 45 years. (Source: “Path of Persistence: Gender Trailblazer and Platelet Pioneer,” Bloodworks Northwest, 2017)

AABB has announced nominees for its Board of Directors. The 2017 Nominating Committee recommended the candidates for open officer and at-large director positions on the 2017 to 2018 AABB Board of Directors with a number of the nominees being from ABC member blood centers. Some of the nominees include AABB Secretary Dan Waxman, executive vice president and chief medical officer of Indiana Blood Center, and at-large director Dave Green, MD, president and chief executive officer at Blood Systems. (Source: [AABB site \(members\)](#))



Jerome Adams, MD, was nominated to be the new U.S. Surgeon General. Dr. Adams is a trained anesthesiologist and the current health commissioner for Indiana, having been appointed by Vice President Mike Pence for the role in 2014. He is an activist for the HIV Needle exchange program and has spoken out about the need to address the opioid crisis. (Source: New York Times, [Trump Nominates Indiana Health Commissioner as Surgeon General](#). June 29, 2017) ♦



MEMBER NEWS

New York Blood Center (NYBC) added three new trustees to its board. Ariel Fishman, PhD, Owen Garrick, MD, MBA, and Faye Wattleton joined the NYBC Board of Trustees this month. Dr. Fishman is currently assistant vice president of Academic Program Planning at Fordham University and a self-employed analytics/management consultant. He is also a motivational speaker and volunteers on behalf of NYBC, advocating for blood donation following his recovery from serious injuries in a motor vehicle accident in 2012. Dr. Garrick is a physician and former president of the American Medical Association. He is currently president and chief operating officer of Bridge Clinical Research, a contract research organization focusing on therapeutics. He is dedicated to increasing minority representation among principal investigators participating in clinical trials. Ms. Wattleton comes to NYBC's board as the Managing Director and Corporate Governance Practice Head at Alvarez & Marsal, a business management consultant group based out of Washington, D.C. Ms. Wattleton has served as CEO of a number of national nonprofit organizations and as a director of public and private corporations, academic institutions, board member of Columbia University, as well as director of high-impact philanthropic organizations, including chair of audit and corporate governance committees. (Source: [NYBC press release](#), June 13, 2017) ♦

COMPANY NEWS

The Food and Drug Administration (FDA) approved Octapharma's Fibryna, effective June 7, 2017. The drug Fibryna is a human fibrinogen concentrate and is to be used to treat adults and teenagers over 12 years old for congenital fibrinogen deficiency, including fibrinogenemia and hypofibrinogenemia. The company is based in Switzerland, but the drug will be manufactured in their Vienna, Austria plant. Administration of the drug, along with potential adverse effects, are [here](#) on the FDA's website.

Dova Pharmaceuticals, a North Carolina-based pharmaceutical company, just became a publically-traded company as of Wednesday, June 28. Dova is a clinical-stage pharmaceutical company and has completed two phase-three randomized, controlled double-blind trials of avatrombopag, an investigational second generation oral thrombopoietin receptor agonist that stimulates platelet production. Dova had hoped to raise \$69.1 million, before options, in the IPO, and exceeded their expectations by trading at \$17 per share, leaving them with \$75 million by the closing bell. (Sources: NASDAQ, [Hot blooded: Dova Pharmaceuticals prices upsized IPO at \\$17, the high end of the range](#), June 28, 2017; Marketwatch, [Dova Pharmaceuticals sets IPO terms to raise \\$69.1 million before options](#), June 19, 2017) ♦

CALENDAR

2017

July 13: **Meeting Global Blood Needs with Rotary's Help, Chicago Marriott O'Hare.** Blood center executives and interested parties discuss current projects and engage attendees on ways to have a meaningful impact with blood collection abroad through Rotary International and associated organizations. Contact [Chris Bollmann](#) for details.

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. **The 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.

(continued on page 14)

CALENDAR (continued from page 13)

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. 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

More openings available on our [website](#)

Therapeutic Apheresis Nurses. If you are looking for a challenging, yet rewarding career, OneBlood is currently recruiting for Therapeutic Apheresis Nurses (RN) to perform clinical apheresis procedures in various hospitals around Florida. Applicants must have an associate’s degree from an accredited college or university and one year of related experience; or an equivalent combination of education, training and/or experience. Applicants must also have a current and valid Florida RN license, current BLS CPR certification, and a valid and clear driver’s license. To apply and view a complete job description of these positions, go to www.oneblood.org and click on the Careers tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

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](#). ♦