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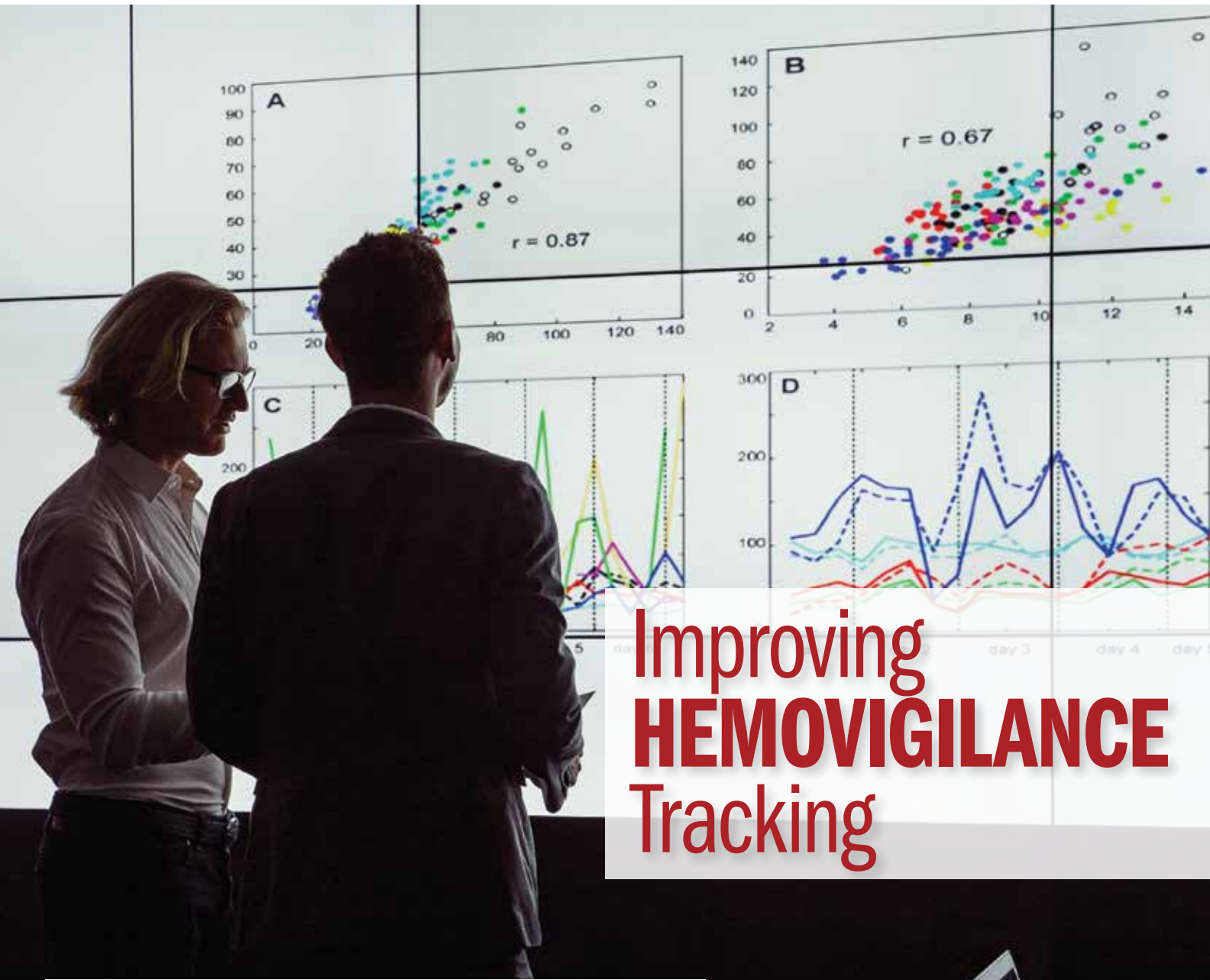
AABB News



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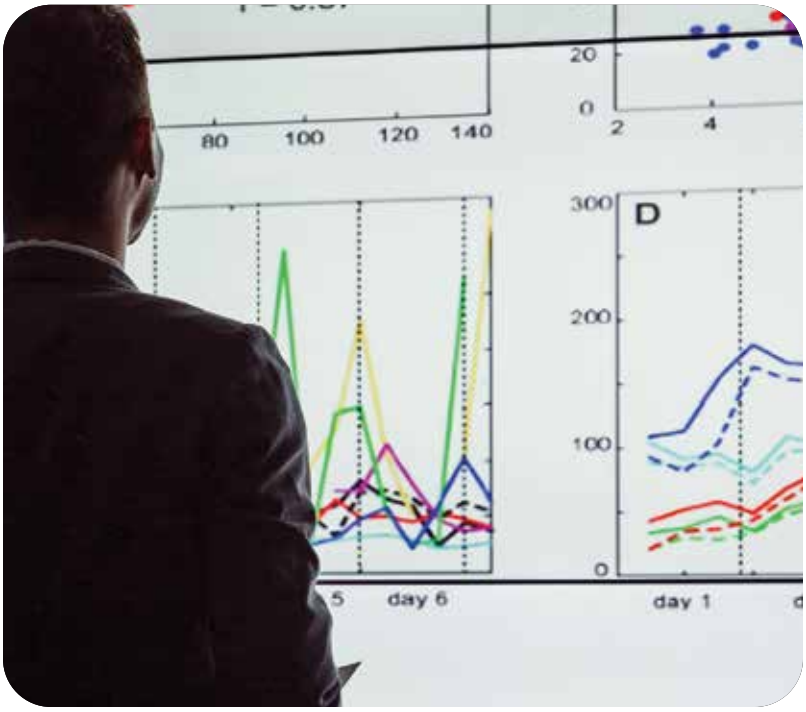

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Potential Benefits of Improving Hemovigilance Programs

The United States has required the reporting of blood collection and transfusion deaths since 1976, although the only state currently requiring adverse event reporting is Massachusetts. Otherwise, the Centers for Disease Control and Prevention's National Healthcare Safety Network's Hemovigilance Module is a voluntary system. Yet hemovigilance reporting could help us better understand adverse events associated with blood collection and transfusion — thus leading to improvements.

This month's first feature article, starting on page 6, examines the future of hemovigilance in the U.S. and abroad, and the benefits of tracking and reporting adverse transfusion events. The second feature article, beginning on page 11, provides two pull-out pocket quick reference guides for hemovigilance, the pocket guide to "Standard for Surveillance of Complications Related to Blood Donation" and the "AABB Quick Reference Guide to the NHSN Hemovigilance Module: Adverse Reaction Definitions." These guides are designed to fit in lab coat pockets, and AABB is providing access to these guides to be used in daily practice as well as educational resources.

2021 AABB Annual Meeting

As you likely already know, AABB has decided to host a virtual annual meeting in place of an in-person event this year. AABB is pleased to be able to provide the most exceptional Annual Meeting experience while protecting the health and safety of our attendees, exhibitors and staff.

David Green, MSA

This year's Virtual Annual Meeting will be held Oct. 17-19, 2021. In response to feedback we received last year, this year's meeting will be held on Sunday, Monday and Tuesday to make it as convenient as possible for attendees to participate in as many sessions as possible. There will be a few pre-meeting events on Friday, Oct. 15 and Saturday, Oct. 16. As they did last year, meeting attendees will have access to the platform before the meeting begins.

As we look to October, we are excited to build on all the successes of last year. Although we won't be able to see each other in person this year, the virtual platform will allow us to expand access to the meeting to colleagues throughout the world, many of whom might not have been able to attend an in-person event.

Registration for the meeting will open for AABB members on June 23 and general registration opens June 30. ■

David Green, MSA
AABB President

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Targeting Malarial Anemia Using the Second Transferrin Receptor

By Jerilyn Schweitzer, MA
Managing Editor

Antonella Nai, PhD, is the group leader of the of the Regulation of Iron Metabolism Unit at the San Raffaele Scientific Institute in Milan, Italy. Nai received a National Blood Foundation early-career Scientific Research Grant in 2018 for her project, "Targeting the second transferrin receptor for amelioration of severe malarial anemia." *AABB News* spoke with Nai about her research and how receiving the NBF grant helped her advance her research and her career.

AABB News: *How did receiving an NBF early-career Scientific Research Grant help your research and career?*


Antonella Nai, PhD

Nai: I was awarded the NBF early-career grant in a critical stage of my career: the shift from senior post-doc to independent researcher. NBF funding, together with the awarding of other national and international grants, and my scientific production, was instrumental to my promotion, after the evaluation by the Commission of Appointment and Promotion of the Institute, to group leader of the Regulation of Iron Metabolism Unit at San Raffaele Scientific Institute. In addition to my career advancement, this grant provided me with the unique opportunity of investigating the role of transferrin receptor 2 (TFR2) in malarial anemia, contributing to the main goal of my current research activity, which is the validation of TFR2 targeting as a novel general "erythropoiesis-stimulating approach."

AABB News: *Can you elaborate on your findings regarding the relationship between TFR2 and malaria risk?*

Nai: *TFR2* is known as one of the genes responsible for hereditary hemochromatosis, an iron-overload disorder, since it acts as a regulator of systemic iron homeostasis in the liver. Less is known about the function of the protein in erythroid cells. We previously demonstrated that erythroid TFR2 is a negative modulator of erythropoietin signaling, and its deletion stimulates erythropoiesis in wild-type mice and improves anemia in a murine model of non-transfusion dependent beta-thalassemia.
Our preclinical studies in murine models supported by the NBF grant suggest that selective inactivation of *Tfr2* in the erythroid compartment delays the onset of anemia following *Plasmodium chabaudi chabaudi (Pcc)* infection. Also, recovery from anemia was faster and erythropoiesis was more effective than in control animals. Even more interestingly, the degree of parasitemia was strongly reduced in mice that lack erythroid *Tfr2*, suggesting that *Tfr2* inactivation might not only ameliorate anemia due to malaria infection, but also limit Plasmodium growth. Overall, our results suggest that TFR2 might be a candidate therapeutic target for malarial anemia. However, despite promising, these findings are preliminary and require further confirmation. In addition, the mechanism of parasitemia reduction by *Tfr2* deletion, as well as the definition of an appropriate tool for therapeutic targeting of TFR2 remain to be identified.

AABB News: *Your research findings suggest that TFR2 could be a potential therapeutic target for malaria treatment. How would this potentially work?*

Nai: First of all, since the erythropoietic response to circulating erythropoietin is dramatically reduced in malaria infection, the inactivation of *Tfr2* in erythroid cells, where it acts as a brake of erythropoietin signaling, is expected to rescue — at least partially — this defect, thus increasing the production of new red blood cells. Furthermore, our finding that *Tfr2* deletion, besides ameliorating anemia, might reduce red blood cells' infection by Plasmodium opens new possibilities. Indeed, *Tfr2* deletion in the erythroid

compartment leads to the production of smaller red cells each containing less heme/hemoglobin than normal cells. Being heme essential for *Plasmodium* growth within erythroid cells, this is in keeping with the reduced parasitemia observed in our mice. In addition, reduced levels of heme would limit the production of hemozoin, a derivative of heme degradation by the plasmodium, which is toxic to erythroid cells and has been proposed to contribute to erythropoiesis inhibition during malaria infection. Thus, the benefits would be multiple.

AABB News: *What more needs to be studied to better understand TFR2?*

Nai: The precise mechanism of the TFR2-mediated regulation of erythropoiesis remains to be elucidated, and our studies are currently directed to this ambitious aim. In addition, the elucidation of the role of erythroid TFR2 in Plasmodium growth/invasion is critical and deserves further investigation.

AABB News: *Did the NBF grant open any additional opportunities for your career and research?*

Nai: As mentioned above, the NBF grant strongly contributed to the progression of both my career and research activity. Indeed, some of the results obtained thanks to this funding were used as preliminary results for the application to other funding agencies for projects aimed at evaluating *Tfr2* targeting as a potential novel general "erythropoiesis erythropoietic approach" for different forms of anemia. In addition, all the results so far obtained will be instrumental for applying to specific malaria-related grants, to the aim of expanding our project of the role of TFR2 in anemia.

AABB News: *What is next for your research?*

Nai: The next step will be to consolidate the results and to initiate in-depth mechanistic studies required to unravel the precise mechanism through which *Tfr2* inactivation ameliorates malaria anemia and reduces parasitemia. In addition, we are trying to identify a tool for translating our strategy of *Tfr2* inactivation, which at present is achieved through the technique of bone marrow transplantation, into a pharmacologic approach. This, in addition to malaria, might benefit other forms of common anemias as beta-thalassemia and anemia of chronic kidney disease.

AABB News: *From your perspective, why is it critical that the NBF supports early-career research?*

Nai: Early-career researchers need dedicated support for addressing their innovative ideas and producing preliminary results for applying as principal investigator to more substantial grants. This is essential for their growth and for reaching scientific independence. Funding from NBF perfectly fulfills this requirement and for this reason I am grateful to NBF and hope that it continues to support the scientific career development of excellent young scientists. ■

Scientific contributions like these are possible thanks to the generous donations of NBF supporters. AABB encourages members to donate today to support early-career investigators and have an impact on the health and safety of patients and donors both in their community and worldwide

The Future of HEMOVIGILANCE

Increased reporting, tracking of transfusion-related adverse reactions could benefit the field and the public.

By Leah Lawrence
Contributing Writer

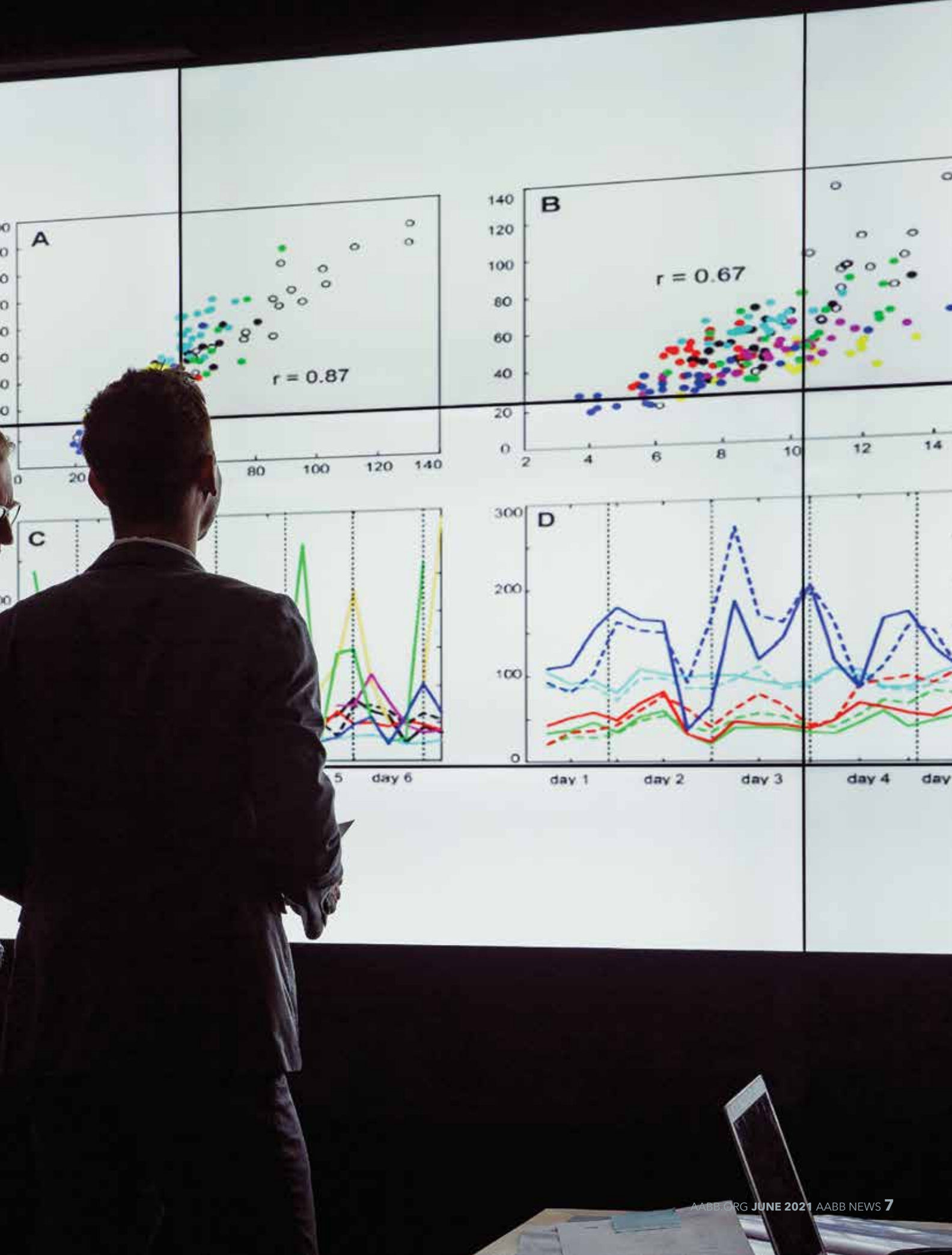
Since the introduction of blood transfusion into routine clinical practice about 100 years ago, practitioners have been aware of the risk for transfusion-associated adverse events.

"The spectrum of these events has changed over the decades, but accrediting bodies, regulatory agencies and professional societies all have expectations that transfusion services are monitoring for these events and doing due diligence in the work-up of the cases," explained Chester Andrzejewski, MD, PhD, FCAP, medical director of Baystate Health's System Blood Banking and Transfusion/Apheresis Medicine Services, and assistant professor of pathology at University of Massachusetts Medical School-Baystate in Springfield, MA.

The United States has required mandatory reporting of transfusion and blood collection deaths since 1976.[1] However, it was only more recently — in 2010 — that the Centers for Disease Control and Prevention (CDC) created the National Healthcare Safety Network (NHSN), which houses the U.S.'s national hemovigilance module (NHSN HM). The NHSN HM is a voluntary, passive system available for reporting of transfusion-related adverse reactions.

In the first year of the NHSN HM, 82 facilities enrolled; by 2016 that number had increased to 277, a minority of the more than 4,600 acute care facilities in the U.S. One-quarter of enrolled facilities are located in Massachusetts, where participation is mandatory. Reporting on total transfused components by enrolled facilities is estimated to represent about 10% of units transfused in the U.S.[2]

Without greater numbers of U.S. hospitals participating and contributing data to this effort, however, opportunities to improve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transfusion safety via national hemovigilance reporting and monitoring in the U.S. remain to be fully realized, Andrzejewski said, including efforts directed toward more in-depth routine analyses of large amounts of data that can further inform reaction taxonomy standardization, the identification and capture of additional data elements of interest pertinent to hemovigilance, and the potential for the introduction of automation involving hospital computer systems to help streamline data entry in the reporting process.

The Benefits of Tracking

The aim of any hemovigilance reporting system is to improve transfusion safety by analyzing reports of adverse events and errors in transfusion procedures and by making recommendations for changes in practice at the national level, explained Michael Murphy, MD, FRCP, FRCPath, FFPath, professor of transfusion medicine at the University of Oxford, and consultant hematologist for NHS Blood & Transplant and the Oxford University Hospitals NHS Foundation Trust.

In the United Kingdom, an increased focus on the transfusion process was prompted in part by a small study published in the early 1990s. The study surveyed 400 hematology laboratories in Great Britain and found that one-third of responding laboratories reported incidents in which patients received the wrong blood.[3]

"This finding showed these incidents resulting from errors in transfusion procedures were more frequent than expected," Murphy said. "We began to think about interventions to stop them."

Indeed, hemovigilance efforts in many countries began to attempt to track some of the commonest and deadliest transfusion-related reactions.

"When I begin a discussion on transfusion reactions, I start with the commonest [1 in 10 risk range] events" said Christine Cserti-Gazdewich, MD, FRCPC, assistant professor in the division of hematopathology and transfusion medicine at the University of Toronto, Canada.

The likeliest acute (same-day) disturbances to be on watch for include transfusion-associated circulatory overload (TACO), minor allergic transfusion reactions and febrile non-hemolytic transfusion reactions, according to Cserti-Gazdewich.

"These reactions happen in real-time, during, within hours of, or by the end of the day of the transfusion," she said. "There is a lot of promise for how technologies can screen for these top three most common transfusion disturbances."

The more daunting — less common but more serious — tier of reactions or adverse events are the ones that occur in the 1 in 1,000 to 1 in 100,000 risk range. These include transfusion-related acute lung injury (TRALI), higher-grade allergic reactions like anaphylaxis, bacterial contamination associated with transfusion (BaCon) or errors in the blood product received.

Tracking these adverse reactions is important, Cserti-Gazdewich said, especially given that even tracking the numbers likely underestimates the associated morbidity and mortality for each reaction.

"If a reaction increases the length of stay or throws a patient into the ICU, these could be associated with bad outcomes," she said. "If a reaction occurs, even in the 1 in 1,000 range, if you multiply that number by the number of units administered in each country, that adds up to a tremendous number of lives and a lot of traumatizing events for patients."

Barriers To Reporting

"The more we know and the better our numbers are, the more likely they will reflect the actual scope of the problem," Cserti-Gazdewich said.

However, one of the biggest barriers to accurate reporting, at least in the U.S., is voluntary participation in programs like the NHSN HM.

In stark contrast is reporting in the U.K. to its national program, Serious Hazards of Transfusion (SHOT), which tracks not just errors in transfusion but all adverse events related to transfusion.

"Through this collection of data around all hospitals in the U.K., we can analyze the data, present findings in an annual report, and get people thinking about interventions to reduce these events," Murphy explained. "For example, the use of only male fresh frozen plasma to reduce the risk of TRALI came out of an analysis of SHOT data."[4]

Each year SHOT releases an annual report and summary. In 2019 — among other important

information — it reported 17 transfusion-related deaths including five that could have been prevented and confirmed that TACO and delays in providing blood are the most prevalent causes of transfusion-related deaths year over the year.[5]

Reports on these adverse reactions in the U.S. are more challenging, according to Aaron Hettinger, MD, medical director and director of cognitive informatics at MedStar Health Research Institute.

"There are challenges related to not only detecting the cases, but getting the right information, formatting it and submitting it," he said. "There might be inconsistencies across health systems, across team members or even across departments. There need to be efforts for widespread standardization."

This lack of standardization and the burdens associated with reporting in the U.S. leaves a very incomplete picture of safety events.

> "The more we know and the better our numbers are, the more likely they will reflect the actual scope of the problem."
>
> *—Christine Cserti-Gazdewich, MD, FRCPC*

Some of the burdens include finding the right information in the electronic health record (EHR), transferring the data in a reporting format, and securely transmitting the data. According to Dr. Hettinger, these can be a challenge for those who report infrequently and are less familiar with the process, or time consuming for those that oversee large programs that may have frequent reporting needs.

"These [hemovigilance] programs have the potential to be helpful and may be free to join, but practices are then responsible for the equipment, personnel to input data, and other associated costs," said Jason E. Crane, DO, Medical Director of Vitalant-Illinois. "Anytime you are requiring something like this, it will come down to whether practices have the money and staff available to participate."

In addition, reporting hemovigilance data to the CDC does not replace mandatory or regulatory reporting requirements to FDA, or the practices' state agencies, or any other agency with required reporting.

Automation

Although the U.K.'s SHOT program in considered to be a successful example of a hemovigilance program, it does not collect data electronically, Murphy said.

"That idea is of interest," he said. "Whether trying to collect the data that is currently reported to the electronic health records will be effective in picking up errors and adverse events has yet to be proven. It may be that some aspects will and some won't be well picked-up. We just don't know yet."

One of the ways that the U.S. is attempting to streamline hemovigilance reporting is with FDA's Biologics Effectiveness and Safety (BEST) Initiative. The vision for BEST is for it to be "the pre-eminent resource for evaluating biologic product safety and effectiveness that leverages high-quality data, analytics and innovation to enhance surveillance, real-world evidence generation, and clinical practice that benefits patients."

According to Barbee I. Whitaker, PhD, lead general health scientist, Office of Biostatistics and Epidemiology (OBE) within FDA's Center for Biologics Evaluation and Research (CBER), the FDA is cognizant of the burden on transfusion services for hemovigilance reporting.

"It is our goal to make it as easy as possible to conduct safety reporting so that we are able to ensure blood and blood products are safe and effective and to identify emerging risks," Whitaker said.

Hussein Ezzeldin, PhD, senior staff fellow, co-lead of BEST Innovative Methods (IM) initiative OBE/CBER, said that the hope for BEST is that it will reduce burden on clinical transfusion staff, enhance detection of transfusion events, and provide a standardized review of the cases by the transfusion medicine clinicians.

Currently, the BEST program is contracting with companies to develop methods and tools, BEST prototype, for using electronic health records to establish semi-automated adverse events reporting for therapeutics including blood and blood products.

"Electronic health records are a wealth of information and this semi-automated program is hoping to pull out pertinent information and have it in front of the clinician to review," Hettinger explained.

The program is currently in a pilot phase with data being reviewed and validated to make sure it is meaningful in order to fine tune the artificial intelligence (AI) algorithms that aim to assist clinicians and practitioners.

Hettinger is involved in projects designed to help understand the workflow involved in gathering hemovigilance data and reporting it to the right places.

"We are trying to understand the gap between work as imagined and as performed," he said. "The FDA is

"We are trying to understand the gap between work as imagined and as performed. The FDA is trying to understand that workflow, cut down on excess burden and make it easier to report."

—Michael Murphy, MD, FRCP, FRCPath, FFPath

trying to understand that workflow, cut down on excess burden and make it easier to report."

At the 2019 AABB Annual Meeting, Whitaker reported information on the BEST initiative. In the study, the program's algorithms were trained using 727 transfusion adverse events documented in NHSN hemovigilance reporting from 2014 to 2018. Subsequent active learning-based development and validation will allow the system to use automated transfusion adverse events detection from electronic health record data.[6]

The auto-detection will flag and rank cases to be reviewed by the clinicians. This automation will attempt to modernize the current manual process clinicians undergo by automatically populating supporting data for a case and facilitating semi-automated verification and reporting of adverse events. The process can be complemented with computational phenotypes, which are EHR-based algorithms to flag possible adverse events that can then be selectively reviewed in more detail, optimizing reviewer time.

"The more we can do to get consistent, accurate and timely reporting across the country, the better off we will be," Hettinger said.

Additionally, Ezzeldin said, after this review and clinician assessment, with a click of a button, the software will automatically fill out the clinical information to create an Individual Case Safety Report (ICSR). After the reporter reviews the ICSR and the software runs a last check to ensure it completeness, it produces an ICSR xml file to send to the FDA.

"This will reduce a lot of time and effort by bypassing the information collection and re-entry steps into creating the ICSR," Ezzeldin said.

The system remains in its pilot phase and has some additional hurdles to clear before it can be extended further and is ready to scale on a national level, Ezzeldin said.

Health Benefit

"Anytime we can use data to help determine the best practices for transfusion, we may be able reduce the incidence and cost of adverse reactions," Crane said. "These efforts should be looked at as both a cost-savings and a lifesaving effort."

Cserti-Gazdewich added that although these efforts would likely have a larger public health benefit, it is also important to remember the benefit that any avoided reactions would have on each individual patient. She described seeing a patient chart recently that described the patient having post-traumatic stress after a transfusion-related adverse reaction.

"Even though I walk among my patients every day, I haven't imagined how often flashbacks and fears affect them." she said.

Cserti-Gazdewich said she also has a greater understanding for how one bad experience can negatively bias future encounters for patients who are transfusion-dependent, describing the worry of recurrences as "heartbreaking."

Despite the work left to be done, there is hope for the further improvement of hemovigilance and transfusion safety, Cserti-Gazdewich said. TRALI is one of the best examples of how studying the problem led to a great solution.

"We are getting better at all of this, and I maintain hope that we will continue to identify areas for potential improvement and will act quickly and effectively to do things better," Cserti- Gazdewich said. ■

Endnotes

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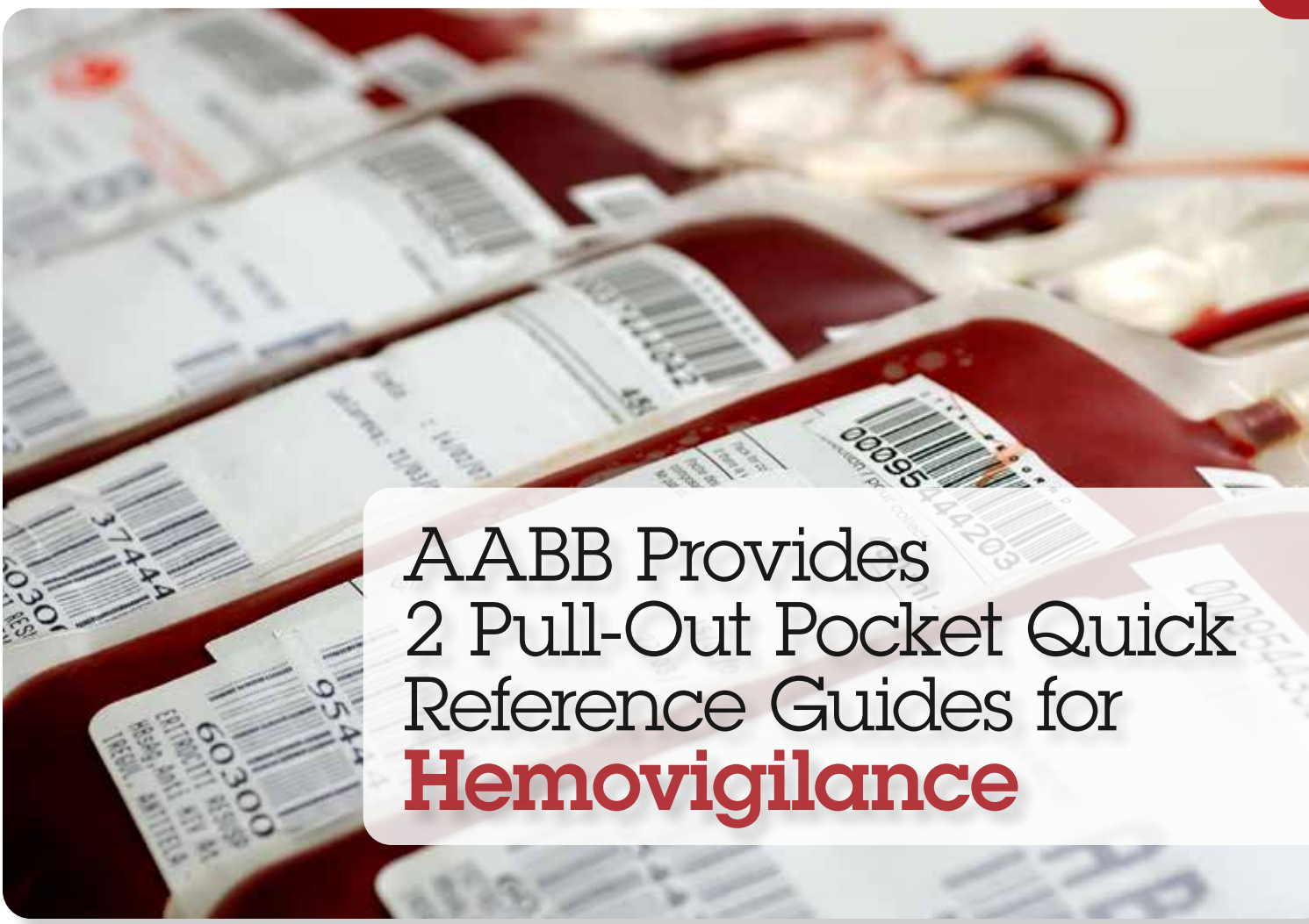

AABB Provides 2 Pull-Out Pocket Quick Reference Guides for Hemovigilance

AABB is providing two pull-out quick reference guides for hemovigilance in this issue (see pages 13-16). These guides have been designed as tools to offer reference to adverse reaction definitions related to transfusion and donation.

The pocket guide to "Standard for Surveillance of Complications Related to Blood Donation" provides information on common blood donor reactions, including complications related to apheresis, allergic reactions and other potential adverse events related to blood donation. The "AABB Quick Reference Guide to the NHSN Hemovigilance Module: Adverse Reaction Definitions" includes definitions of the most common transfusion reactions, including transfusion related acute lung injury (TRALI) and the recently revised definition for transfusion-associated circulatory overload (TACO) based on CDC's National Healthcare Safety Network (NHSN) Hemovigilance Module Surveillance Protocol. According to Srijana Rajbhandary, MPH, AABB's director for Research and Data, the guides were designed for easy use by members. "These handy, foldable pocket guides are most popular among residents," Rajbhandary said. "They are designed to fit in lab coat pockets so they can be used easily by residents during rounds. They are well-liked by our members as great educational tools." Rajbhandary suggested that members might find these resources useful in their daily practice in addition to as an educational tool. "This is an open resource, and AABB would like everyone in the field to have access," she said.

Revised Definition of TACO

Jo Wiersum, MD, PhD, national coordinator for the Dutch hemovigilance and biovigilance system in the Netherlands, worked with Rajbhandary on the development and validation of the revised international TACO definition. She told *AABB News* that she has been actively involved in working on definitions for

many years, mainly in the setting of the International Haemovigilance Network (IHN) and the International Society of Blood Transfusion (ISBT) working party on hemovigilance. "The ISBT first published definitions for non-infectious adverse transfusion reactions in 2011," she said. "This was at the time that awareness of TACO was increasing — since male-only plasma had brought about a reduction in TRALI cases. Several hemovigilance systems had the experience that cases that were clinically recognized and treated as TACO did not meet the criteria for the definition. It was also pointed out that patients can be hypotensive rather than showing increased blood pressure, and that tachycardia is very non-specific. So, at the ISBT working party meeting in Amsterdam in 2013, a group was formed to work on a revision of the TACO definition."

The definition of TACO was revised through expert opinion in light of the evidence at that time. "The updated definition was circulated to working party members and contacts for comment, and it was 'put to the test' by asking members to provide cases from their own hemovigilance systems and score them against the updated criteria," she continued. "In 2015, I had to report back to the working party that the revision was more 'sensitive' than the original definition, i.e., more reactions which people were collecting as TACO met the criteria for the revised definition. But the improvement was very marginal and we were losing a lot of cases because of the emphasis placed on cardiac enlargement. So, it was back to the drawing board!"

Wiersum noted that as the process continued, the group was joined by Chester Andrzejewski, Jr., PhD, MD, FCAP, medical director, System Blood Banking and Transfusion/Apheresis Medicine Services, and assistant professor in the Department of Pathology, University of Massachusetts Medical School-Baystate; Barbee Whitaker, PhD, lead general health scientist, Center for Biologics Evaluation and Research, FDA; Gabriela Perez, MS, statistician, previously at AABB; and Rajbhandary, so the result carries the three logos of ISBT, IHN and AABB.

"A new proposal for revision emerged and was tested in a two-phase validation project," Wiersum added. "At various stages, the draft was circulated as widely as possible for comment. Input was received from 14 hemovigilance systems and experts from 20 countries during the validation exercise, so we can say the work was transparent and international."

Rajbhandary expanded on the revised TACO definition. "CDC incorporated the revised TACO definition in the recent [2021] NHSN Hemovigilance Module release," she said. "The revised definition is applicable to cases that occur up to 12 hours after transfusion. While either the evidence of acute or worsening respiratory distress or/and evidence of acute or worsening pulmonary edema [radiographic or clinical] is/are mandatory, combinations of signs and symptoms can add up to meet the surveillance diagnostic criteria that will help qualify cases as TACO. The definition will be also helpful in cases where there may be no chest x-ray and/or record of elevated BNP concentrations."

Severity Grading Tool for Donor Adverse Events

In January 2018, a sub-group of the AABB Donor Hemovigilance Working Group undertook the task of developing the Severity Grading Tool for Donor Adverse Events to enhance objective assignment of Donor Adverse Events (DAE) severity. The severity assignment tool is designed to be used with the 'Standard for Surveillance of Complications Related to Blood Donation.' "The tool aims to avoid subjective terms such as mild, moderate and severe," Rajbhandary explained. "It is patterned after an established clinical severity scale, Common Terminology Criteria for Adverse Events [CTCAE1] v 5.0, which rates severity by Grades 1-5. The tool, along with a user brochure, is now publicly available on the AABB website, and results of the formal validation have been published in *Transfusion*." ■

TRANSFUSION-ASSOCIATED GRAFT VS. HOST DISEASE (TAGVHD)

The introduction of immunocompetent lymphocytes into susceptible hosts. The allogeneic lymphocytes engraft, proliferate, and destroy host cells. If performed, marrow study shows hypoplasia, aplastic anemia, or marked hypocellularity with a lymphohistiocytic infiltrate.

Definitive: A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by:

- Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.
- Diarrhea
- Fever
- Hepatomegaly
- Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin)
- Marrow aplasia
- Pancytopenia

AND

Characteristic histological appearance of skin or liver biopsy.

Probable: Meets definitive criteria

EXCEPT

Biopsy negative or not done.

Possible: N/A

POST TRANSFUSION PURPURA

Thrombocytopenia usually arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.

Definitive: Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia

AND

Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count).

Probable: Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia.

AND

Decrease in platelets to levels between 20% and 80% of pre-transfusion count.

Possible: PTP is suspected, but laboratory findings and/or information are not sufficient to meet defined criteria above. For example, the patient has a drop in platelet count to less than 80% of pre-transfusion count but HPA antibodies were not tested or were negative. Other, more specific adverse reaction definitions do not apply.

UNKNOWN

Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused those symptoms could not be classified.

TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

Acute hypoxemia with PaO2/fraction of inspired oxygen [FIO2] ratio of 300 mmHg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion.

Definitive: **NO** evidence of acute lung injury (ALI) prior to transfusion

AND

ALI onset during or within 6 hours of cessation of transfusion

AND

Hypoxemia defined by any of these methods:

- PaO2/FiO2 less than or equal to 300 mmHg
- Oxygen saturation less than 90% on room air
- Other clinical evidence

AND

Radiographic evidence of bilateral infiltrates

AND

No evidence of left atrial hypertension (i.e., circulatory overload)

Probable: N/A

Possible: N/A

TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

Infusion volume that cannot be effectively processed by the recipient either due to high rate and/or volume of infusion or an underlying cardiac or pulmonary pathology.

Definitive: New onset or exacerbation of 3 or more of the following within **12 hours** of cessation of transfusion:

(At least 1 of the following from A & B:)

A. Evidence of acute or worsening respiratory distress (dyspnea, tachypnoea, cyanosis and decreased oxygen saturation values in the absence of other specific causes) **and/or**

B. Radiographic or clinical evidence of acute or worsening pulmonary edema (crackles on lung auscultation, orthopnea, cough, a third heart sound and pinkish frothy sputum in severe cases); **or both**

AND

- Elevated brain natriuretic peptide (BNP) or NT-pro BNP relevant biomarker
- Evidence of cardiovascular system changes not explained by underlying medical condition (Elevated central venous pressure, evidence of left heart failure including development of tachycardia, hypertension, widened pulse pressure, jugular venous distension, enlarged cardiac silhouette and/or peripheral edema)
- Evidence of fluid overload

Probable: N/A

Possible: N/A

TRANSFUSION-TRANSMITTED INFECTION (TTI)

A bacteria, parasite, virus, or other potential pathogen transmitted in donated blood to transfusion recipient.

Definitive: Laboratory evidence of a pathogen in the transfusion recipient.

Probable: N/A

Possible: Temporarily associated unexplained clinical illness consistent with infection, but no pathogen is detected in the recipient. Other, more specific adverse reactions are ruled out.

Note: Possible cases cannot meet the definite or probable imputability criteria.

Advancing Transfusion and Cellular Therapies Worldwide

QUICK REFERENCE GUIDE

NHSN Hemovigilance Module: Adverse Reaction Definitions

ALLERGIC REACTION

The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It may present with only muccocutaneous signs and symptoms.

Note: Minor allergic reactions (non-severe) do not have to be reported to NHSN.

Definitive: **2 or more** of the following occurring during or within 4 hours of cessation of transfusion:

- Conjunctival edema
- Edema of lips, tongue and uvula
- Erythema and edema of the periorbital area
- Generalized flushing
- Hypotension
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Respiratory distress; bronchospasm
- Urticaria (hives)

Probable: **ANY** 1 of the following occurring during or within 4 hours of cessation of transfusion:

- Conjunctival edema
- Edema of lips, tongue and uvula
- Erythema and edema of the periorbital area
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Urticaria (hives)

Possible: N/A

TRANSFUSION ASSOCIATED DYSPNEA (TAD)

Respiratory distress within 24 hours of cessation of transfusion that does not meet the criteria for TRALI, TACO, or allergic reaction. Respiratory distress should not otherwise be explained by a patient's underlying or pre-existing medical condition.

Definitive: Acute respiratory distress occurring within 24 hours of cessation of transfusion

AND

Allergic reaction, TACO, and TRALI definitions are not applicable.

Probable: N/A

Possible: N/A

OTHER

Use this option if the recipient experienced an adverse reaction that is not defined in the Hemovigilance Module Surveillance Protocol (e.g., transfusion-associated acute gut injury (TRAGI), transfusion-associated immunomodulation (TRIM), iron overload, microchimerism, hyperkalemia, thrombosis).

FEBRILE NON-HEMOLYTIC TRANSFUSION REACTION (FNHTR)

Fever and/or chills without hemolysis occurring in the patient during or within 4 hours of cessation of transfusion. If transfusion-related, the most common cause is a reaction to passively transfused cytokines or a reaction of recipient antibodies and leukocytes in the blood product. If blood culture of patient or residual component is performed, the results should be negative. Laboratory findings should show no evidence of acute hemolysis.

Note: Reactions may be classified as FNHTRs in the absence of fever if chills or rigors occur.

Definitive: Occurs during or within 4 hours of cessation of transfusion

AND EITHER

- Fever (greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F from pre-transfusion value)

OR

- Chills/rigors are present.

Probable: N/A

Possible: FNHTR is suspected, but reported symptoms and/or available information are not sufficient to meet the criteria defined above. Other, more specific adverse reaction definitions do not apply.

HYPOTENSIVE TRANSFUSION REACTION

A drop in blood pressure occurring during or within 1 hour of cessation of transfusion. Other symptoms, such as facial flushing, dyspnea, or abdominal cramps may occur, but usually hypotension is the sole manifestation.

Definitive: All other adverse reactions presenting with hypotension are excluded

AND

Hypotension occurs during or within 1 hour after cessation of transfusion.

- Adults (≥18 years): Drop in systolic BP of greater than or equal to 30 mmHg and systolic BP less than or equal to 80 mmHg.
- Infants, children and adolescents (1 year to <18 years): Greater than 25% drop in systolic BP from baseline (e.g., drop in systolic BP of 120mmHg to below 90mmHg).
- Neonates and small infants (<1 year old OR any age and <12 kg body weight): Greater than 25% drop in baseline value using whichever measurement is being recorded (e.g., mean BP).

Probable: N/A

Possible: Hypotension occurs, does not meet the criteria above. Other, more specific adverse reaction definitions do not apply.

Taken from NHSN Biovigilance Component:
Hemovigilance Module Surveillance Protocol v2.6 | March 2021

For more information, please contact AABB :
+1.301.215.6588 | hemovigilance@aabb.org

DELAYED HEMOLYTIC TRANSFUSION REACTION (DHTR)

The recipient develops antibodies to RBC antigen(s) between 24 hours and 28 days after cessation of transfusion. Clinical signs of hemolysis are usually present. If performed, post-transfusion LDH and bilirubin levels increase and subsequently fall back to baseline in the following days.

Note: Report all hemolytic reactions, including when the recipient is intentionally transfused with incompatible blood components.

Definitive: Positive direct antiglobulin test (DAT) for antibodies developed between 24 hours and 28 days after cessation of transfusion

AND EITHER

- Positive elution test with alloantibody present on the transfused red blood cells

OR

- Newly-identified red blood cell alloantibody in recipient serum

AND EITHER

- Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels

OR

- Otherwise unexplained appearance of spherocytes.

Probable: Newly-identified red blood cell alloantibody demonstrated between 24 hours and 28 days after cessation of transfusion

BUT

Incomplete laboratory evidence to meet definitive case definition criteria.

Note: Patient may be asymptomatic or have symptoms that are similar to but milder than AHTR; symptoms are not required to meet case definition criteria.

Possible: DHTR is suspected, but reported symptoms, test results, and/or available information are not sufficient to meet the criteria defined above. Other, more specific adverse reaction definitions do not apply.

DELAYED SEROLOGIC TRANSFUSION REACTION (DSTR)

Demonstration of new, clinically significant alloantibodies against red blood cells between 24 hours and 28 days after cessation of transfusion despite an adequate, maintained hemoglobin response.

Note: DSTR should only be reported for patients transfused at your facility.

Definitive: Absence of clinical signs of hemolysis

AND

Demonstration of new, clinically-significant antibodies against red blood cells

BY EITHER

- Positive direct antiglobulin test (DAT)

OR

- Positive antibody screen with newly identified RBC alloantibody.

Probable: N/A
Possible: N/A

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ACUTE HEMOLYTIC TRANSFUSION REACTION (AHTR)

Rapid destruction of red blood cells during, immediately after, or within 24 hours of cessation of transfusion. Clinical and laboratory signs of hemolysis are present.

Note: Report hemolytic reactions resulting from immune or non-immune causes, including when the recipient is intentionally transfused with incompatible blood components.

Definitive: Occurs during, or within 24 hours of cessation of transfusion with new onset of **ANY** of the following signs/symptoms:

- Back/flank pain
- Chills/rigors
- Disseminated intravascular coagulation (DIC)
- Epistaxis
- Fever
- Hematuria (gross visual hemolysis)
- Hypotension
- Oliguria/anuria
- Pain and/or oozing at IV site
- Renal failure

AND

2 or more of the following:

- Decreased fibrinogen
- Decreased haptoglobin
- Elevated bilirubin
- Elevated LDH
- Hemoglobinemia
- Hemoglobinuria
- Plasma discoloration c/w hemolysis
- Spherocytes on blood film

AND EITHER

IMMUNE MEDIATED

- Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3

AND

- Positive elution test with alloantibody present on the transfused red blood cells

OR

NON-IMMUNE MEDIATED Serologic testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed.

Probable: Meets signs and symptoms criteria for acute hemolysis

AND EITHER

IMMUNE MEDIATED Physical cause is excluded but serologic testing is incomplete

OR

NON-IMMUNE MEDIATED Physical cause is suspected and serologic testing is negative.

Possible: AHTR is suspected within 24 hours of cessation of transfusion, but symptoms, test results, and/or information are not sufficient to meet the criteria defined above. Other, more specific adverse reaction definitions do not apply.

COMPLICATIONS RELATED TO APHERESIS

CITRATE REACTION

Definition: Neuromuscular hyperactivity related to reduced ionized calcium levels.

Mechanism: Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion.

Signs and symptoms: Numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath.

Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions (tetany), shock, irregular pulse and cardiac arrest.

HAEMOLYSIS

Definition: Donor red cells may be damaged, releasing haemoglobin.

Mechanism: There may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W, may be used in error.

Signs and symptoms: Pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection.

AIR EMBOLISM

Definition: Air bubble introduced into the donor's circulation.

Mechanism: Air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain.

Signs and symptoms: Bubbling sound or feeling at the venipuncture site. Cough, dyspnea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting.

OPTIONAL CATEGORY: INFILTRATION

Definition: *Intravenous solute (saline solution) enters the extravascular tissues during volume replacement (generally only applicable to double red cell procedures).*

Mechanism: *The needle is no longer positioned in the intravascular space, so fluids enter the surrounding tissues.*

Signs and symptoms: *Swelling of the tissues at the venipuncture site.*

ALLERGIC REACTIONS

ALLERGY (LOCAL)

Definition: Red or irritated skin at the venipuncture site.

Mechanism: Reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur.

Signs and symptoms: Itching and redness at the venepuncture site, the bandage site, or the entire skin disinfection area. In a true allergic reaction, there may be a raised rash or hives in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in the hours to days post-donation.

GENERALISED ALLERGIC REACTION (ANAPHYLACTIC REACTION)

Definition: Anaphylactic type reactions usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

Mechanism: Extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilize some collection kits.

Signs and symptoms: Apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mentation.

OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION

MAJOR CARDIOVASCULAR EVENT (MCE)

- **Acute cardiac symptoms** (other than myocardial infarction or cardiac arrest)
- **Myocardial infarction**
- **Cardiac arrest**
- **Transient Ischemic Attack**
- **Cerebrovascular accident**
- **Death**

Reporting is encouraged of MCE or death from any cause up to 24 hours after donation, with an assessment of imputability. Only cases with definite, probable or possible imputability should be included in international reporting. Major cardiovascular events, including death, may occur in the hours after attending the collection centre for blood donation. This can occur without any relation to the donation (for deaths, this is described by the term actuarial deaths).

OTHER COMPLICATIONS

Other systemic reactions or complications that do not fit into the above, such as chest pain that may have been investigated as angina, but was actually musculoskeletal, or transmission of infection to a donor through erroneous re-use of equipment.

Contact:

www.isbtweb.org/working-parties/haemovigilance/

ISBT International Society of Blood Transfusion

AABB Advancing Transfusion and Cellular Therapies Worldwide

IHN International Haemovigilance Network

Standard for Surveillance of Complications Related to Blood Donation

Donor vigilance: monitoring and improving safety for blood donors

December 2014

The great majority of blood donors experience no complications. By monitoring complications, blood establishments can take measures to further reduce them.

COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS

These complications are directly caused by the insertion of the needle. Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain.

Complications mainly characterized by the occurrence of blood outside the vessels

HAEMATOMA (BRUISE)

Definition: A haematoma is an accumulation of blood in the tissues outside the vessels.

Mechanism: The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. For apheresis procedures, haematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure. Large haematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome.

Signs and symptoms: Bruising, discolouration, swelling and local pain. Accumulation of blood in deeper tissues may result in more serious pain and pressure syndromes listed below.

ARTERIAL PUNCTURE

Definition: Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding the donor.

Mechanism: Because of the rapid blood flow, the risk of a large haematoma is increased and thereby risks of more serious pain and pressure syndromes listed below.

Signs and symptoms: A lighter red colour than usual of the collected blood can be seen. The needle and tubing may appear to pulsate; the blood bag fills very quickly. There may be weak pain localized to the elbow region.

CONTINUED ON BACK

COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS (CONT'D)

Complications mainly characterized by the occurrence of blood outside the vessels (cont'd)

DELAYED BLEEDING (RE-BLEEDING) - OPTIONAL CATEGORY

Definition: *Leakage of blood from the venipuncture site after the initial bleeding has stopped.*

Mechanism: *Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the clinic, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.*

Signs and symptoms: *Spontaneous recommencement of bleeding from the venipuncture site, after pressure has been applied and the initial dressing has been removed, or leaking through the dressing.*

Complications mainly characterized by pain

NERVE INJURY/IRRITATION

Definition: Injury or irritation of a nerve

Mechanism: A nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a haematoma or inflammation of the soft tissues. Include medically diagnosed cases, as well as cases reported on the basis of documented 'nerve' type symptoms.

Signs and symptoms: Radiating, often 'electrical' sharp pain moving away from the venepuncture site, and/or paraesthesias such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venepuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a haematoma, pain may not be apparent at the time and may start when the haematoma has reached a sufficient size, some time after insertion of the needle. Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm may develop.

Optional split by duration of symptoms:

Symptoms resolving within 12 months: *Symptoms usually resolve within days, but rarely may persist for months or become permanent.*

Symptoms lasting more than 12 months.

OTHER PAINFUL ARM – OPTIONAL CATEGORY

Definition: *Pain in the arm is the primary symptom, without the characteristics of nerve irritation outlined above, or the presence of a large hematoma or other defined complications that may be painful..*

Mechanism: *Pain may be related to tissue injury, possibly due to hematoma in the deeper tissues.*

Signs and symptoms: *Pain in the arm, without characteristics of nerve irritation. May be described as an ache or heaviness in the arm, similar to that experienced after vaccination. Include all cases where arm pain is the main symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognised by trained staff.*

COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS (CONT'D)

Localised infection/inflammation

LOCALISED INFECTION/INFLAMMATION

Definition: Inflammation along the course of a vein, which may progress to localised infection several days after phlebotomy. There may be clotting in the vein.

Mechanism: Tissue damage and introduction of surface bacteria into the deeper tissues with venepuncture. The superficial vein itself (thrombophlebitis) or the surrounding subcutaneous tissue (cellulitis) may be predominantly affected.

Signs and symptoms: Warmth, tenderness, local pain, redness and swelling at the site of phlebotomy. The site and the vein may feel tender, firm, and warm to the touch. Fever may be present.

Optional split into 2 categories:

Thrombophlebitis: *The redness, swelling, and tenderness extend along the course of the vein.*

Cellulitis: *The redness, swelling and tenderness affect the soft tissues, and are not localised to the course of the vein.*

Other major blood vessel injury

These rare, serious conditions must always be medically diagnosed.

DEEP VENOUS THROMBOSIS (DVT)

Definition: Thrombosis of a deep vein in the donor's phlebotomy arm.

Mechanism: Superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT may also rarely occur without previous signs and symptoms of superficial thrombosis. An additional risk factor for thrombosis, in particular, the use of oral contraceptives, may be present in these donors.

Signs and symptoms: Swelling and pain in the upper arm. May be accompanied by symptoms of superficial inflammation and thrombosis (see above).

ARTERIOVENOUS FISTULA

Definition: Acquired connection between the vein and artery due to venepuncture lacerations.

Mechanism: A channel forms between the lacerated vein and artery immediately post-venepuncture, or in the healing process. May be related to arterial puncture.

Signs and symptoms: Pulsating mass with a palpable thrill and associated bruit. The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present. The distal veins may be dilated and may pulsate.

COMPARTMENT SYNDROME

Definition: Increased intracompartment pressure leading to muscle and soft tissue necrosis.

Mechanism: Blood may accumulate in the frontal deep areas of the forearm, closing small blood vessels and resulting in muscle and nerve tissue necrosis. May be related to arterial puncture.

Signs and symptoms: Painful arm, particularly on movement; swelling, paresthesias and partial paralysis.

COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS (CONT'D)

Other major blood vessel injury (cont'd)

BRACHIAL ARTERY PSEUDOANEURYSM

Definition: Collection of blood outside an artery, contained by adventitia or the surrounding tissues alone.

Mechanism: After a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space.

Signs and symptoms: Pulsating mass in the arm. May be accompanied by pain and paraesthesias. May be preceded by a large hematoma following arterial puncture.

COMPLICATIONS MAINLY WITH GENERALIZED SYMTOMS: VASOVAGAL REACTIONS

Definition: A vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation.

Mechanisms: Both physiologic and psychological factors may be important. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume.

Signs and symptoms: Usually several of the following: discomfort, weakness, anxiety, light-headedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements. Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site. Most reactions occur within 12 hours of phlebotomy. Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions).

Vasovagal reactions are divided in two main subgroups:

- **Without loss of consciousness (LOC)** – the donor does not faint
- **With loss of consciousness (LOC)** – the donor faints for a period of time

Optional subdivision for donors with LOC:

- ***LOC < 60 seconds*** *– without other signs and symptoms*
- ***LOC ≥ 60 seconds*** *– or with complications of convulsive movements, urinary or faecal incontinence*

Optional subdivision:

- ***With injury*** *– Injury caused by falls or accidents in donors with a vasovagal reaction*
- ***Without injury***

Optional subdivision:

Location of reaction:

- ***On collection facility**** *– Symptoms occurred before donor has left the donation site*
- ***Outside collection facility*** *– Symptoms occurred after donor has left the donation site*

**In area within which staff can observe the donor and be responsible for the care of donors with complications.*

CONTINUED ON BACK

APHERESIS:
PRINCIPLES AND PRACTICE
4th Edition
Volume 2: Collection of Blood Components by Apheresis

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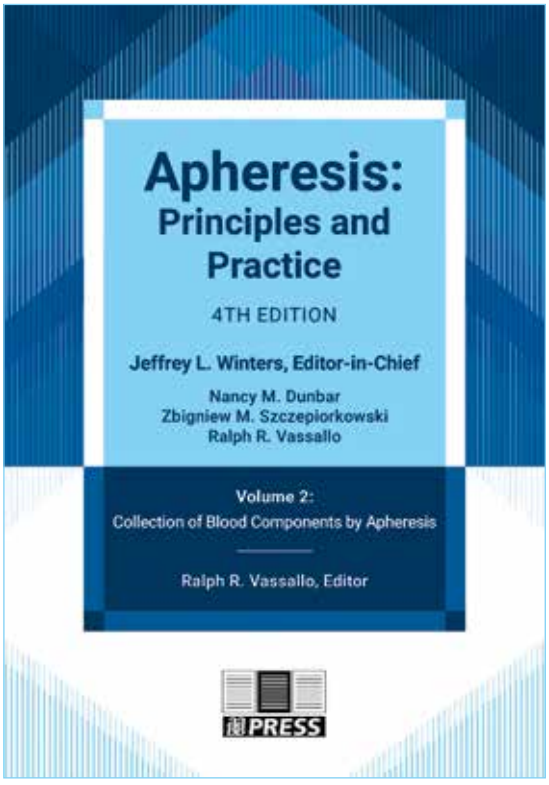

This thoroughly updated volume is an essential resource for learners and staff of all levels involved in donor blood collection, component processing, and instrument development—including physicians, scientists, technologists, trainees, students, administrators, and program support staff.

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- Review of apheresis instrument developments and a useful comparison of the capabilities of current instruments
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- Important sections on bacterial contamination and pathogen inactivation of components
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(AABB Press, 2021, 226 pages, ISBN 978-1-56395-416-0)

mRNA Vaccines 94% Effective in Study of Health Care Workers

By Drew Case
Senior Communications Manager

COVID-19 mRNA vaccines reduced the risk of getting sick with COVID-19 by 94% among fully vaccinated health care personnel, according to findings from the Centers for Disease Control and Prevention (CDC) published May 14. Among those partially vaccinated (defined in this study as 14 days following receipt of the first dose through 6 days following the second dose), mRNA vaccines reduced the risk of getting sick with COVID-19 by 82%.

The study compared the vaccination status of participants who tested positive for SARS-CoV-2 (n=623) with the vaccination status of those who tested negative (n=1,220). Investigators calculated vaccine effectiveness estimates by comparing the odds of COVID-19 vaccination in cases and controls.

According to the CDC, the study independently confirms the vaccine effectiveness findings among health care workers that were first reported in March. The findings also support CDC's recommendation that everyone get both doses of an mRNA COVID-19 vaccine to get the most protection.

Use of a Novel, Personalized Plasma Nomogram May Safely Increase Volume Of Plasma Collections

Use of novel, personalized plasma nomogram (PPN) software achieved an 8.2% increase in the volume of plasma collected per donation without increasing the risk to donor safety, according to findings from the IMproving PlasmA CollecTion (IMPACT) trial published recently in Transfusion. The research expands upon clinical trial data presented by Jan Hartmann, MD, vice president, Medical Affairs, Clinical Development and Medical Safety at Haemonetics Corporation, during the Plenary Oral Abstract Session at AABB's 2020 Virtual Annual Meeting.

The nomogram included body mass index (BMI) and hematocrit to increase the yield of plasmapheresis compared to current practice, a weight-based nomogram introduced in 1992. To evaluate the nomogram, Hartmann and his colleagues randomized consenting donors to intervention (modified novel PPN software) or control (standard nomogram software) arms. For the novel PPN, investigators set a collection target of 28.5% of total plasma volume with a 1,000 mL collection cap. The primary endpoint was the incidence rate of significant hypotensive adverse events (AEs), while the secondary endpoint was collected plasma volume.

In total, the IMPACT trial included 23,137 donations from 3,443 donors. Investigators observed a total of 10 significant hypotensive AEs: six in the control group and four in the intervention group. Model-based estimates (95% CI) of AE incidence rates were 0.051% (0.020% - 0.114%) and 0.035% (0.010% - 0.094%) for the control and PPN arms, respectively.

Non-inferiority of the PPN arm was met at an upper limit of 0.043% versus the predefined non-inferiority margin (0.15%). A safety analysis showed no statistical difference between non-hypotensive AE rates and total AE rates between the two arms. Mean plasma collection volume estimates were 777.8 versus 841.7 milliliters (mL) in the control and PPN arms, respectively, yielding 63.9 mL (8.2%) more plasma in the experimental arm.

According to Hartmann and his colleagues, the data demonstrate for the first time that plasma collections of up to 1000 ml can be conducted safely in some donors using a novel plasma collection nomogram. They also noted that the study is the first of its kind and scale to provide prospectively collected AE frequency data for donor plasmapheresis in a real-world setting.

Tranexamic Acid May Reduce Incidence of Postpartum Hemorrhage Following C-Section

Treatment with tranexamic acid resulted in a lower incidence of postpartum hemorrhage among women who underwent cesarean delivery (C-section) and received prophylactic uterotonic agents compared to placebo, according to findings published recently in the *New England Journal of Medicine*. However, tranexamic acid did not result in a lower incidence of secondary clinical outcomes, such as gravimetrically estimated blood loss, provider-assessed clinically significant postpartum hemorrhage, use of additional uterotonic agents and postpartum blood transfusion, when compared to placebo.

Investigators in the multicenter, double-blind, randomized controlled trial randomly assigned 4,431 women undergoing cesarean delivery before or during labor at 34 or more gestational weeks to receive an intravenously administered prophylactic uterotonic agent and either tranexamic acid (1 g) or placebo. The primary outcome was postpartum hemorrhage (defined as a calculated estimated blood loss greater than 1000 ml) or receipt of a red cell transfusion within 2 days of delivery.

Primary outcome data were available for 2,086 patients in the treatment group and 2,067 patients in the placebo group. In the treatment group, 556 (26.7%) patients experienced postpartum hemorrhage or received a red cell transfusion within 2 days of delivery. In the placebo group, this was 653 (31.6%) patients. Investigators reported that there were no significant between-group differences in mean gravimetrically estimated blood loss or in the percentage of women with provider-assessed clinically significant postpartum hemorrhage, use of additional uterotonic agents or postpartum blood transfusion.

ASCP Report Explores Challenges, Future Needs of Clinical Laboratory Workforce

Leveraging the COVID-19 pandemic's spotlight on the clinical laboratory workforce may highlight opportunities to improve recognition of the clinical laboratory workforce and enhance careers in the field, according to a recent report from investigators at the American Society for Clinical Pathology (ASCP) and the Center for Health Workforce Studies at the University of Washington (CHWS UW).

For this study, investigators sought to examine the current challenges facing the clinical laboratory workforce and how to best meet the field's current and future needs. They conducted a literature review, along with semi-structured interviews with stakeholders who represented clinical laboratory education, employers and professional organizations. Investigators also conducted focus groups with individuals in clinical laboratory occupations

Results suggested that meeting future workforce needs will require actions by, and collaboration among, education and training programs, employers and professional organizations. The report outlines these actions through three overarching areas: improving the visibility of clinical laboratory occupations, improving workforce recruitment and retention, and focusing on diversity and inclusion in the laboratory. If implemented, the authors believe action in these areas will contribute to increases in the availability of clinical laboratory workforce supply and strengthen the pathways into and among these careers long into the future.

NBF Scholar Publishes Commentary In *Blood*

Angelo D'Alessandro, PhD, a 2018 National Blood Foundation (NBF) Scholar and 2016 NBF early-career Scientific Research Grant recipient, recently published a commentary in *Blood* on the red blood cell storage lesion. In the commentary, D'Alessandro discussed recent findings that suggest a negative correlation between storage-induced microerythrocytes (SME), which investigators determined represent about 24% of the entire RBC population in a unit by the end of its shelf life, and post-transfusion recovery.

D'Alessandro suggested that future studies could borrow some of the tools and workflows developed by the investigators to address the question of whether SME accumulation also reduces the efficacy of transfused units. He also noted that the heterogeneity of SME accumulation identified in the study further fuels the concept that the molecular or metabolic age, rather than the chronological age of the blood unit, may be clinically relevant. D'Alessandro concluded by noting that the findings provide "a clear advance for the field of transfusion medicine" and that the observations and tools that the authors developed may also affect the field of hematology in general. ■

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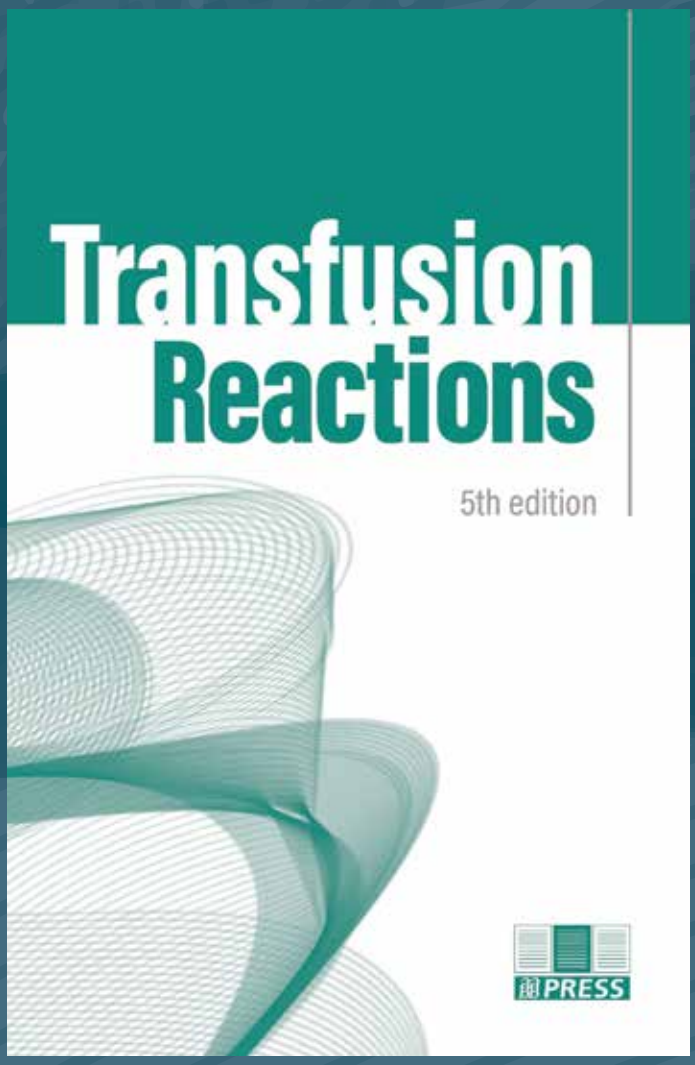
TRANSFUSION REACTIONS 5TH EDITION

Transfusion Reactions, 5th edition examines aspects of common and uncommon transfusion reactions with updates reflecting the latest scientific literature. This trusted reference offers subtopics and tabular material that provide easy access to critical information for clinical providers at all levels, as well as laboratory staff, involved in the care of transfusion recipients.



IMPORTANT FEATURES:

- Two new chapters cover unconfirmed transfusion reactions and hemovigilance.
- Specific chapters devoted to nursing practices, prevention, and low-resource settings.
- Significant changes in TRALI and TACO reflected since the previous edition.
- Thirteen other chapters cover complications by type of reaction, procedure, or product used.

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(AABB Press, 2021, 732 pages, ISBN 978-1-56395-413-9)

AABB

AABB Updates Publications in 'Guide to' Series

AABB is in the process of revising some of its Guideline series books and introducing its new "Guide to" series. Five have been published so far this year:

- *AABB Guide to Patient Blood Management and Blood Utilization*
- *AABB Guide to Blood Recovery and Reinfusion in Surgery and Trauma*
- *AABB Guide to Pneumatic Tube Delivery Systems: Validation and Use to Transport Blood Components*
- *AABB Guide to Antibody Identification*
- *AABB Guide to Quality Assessment of Transfusion*

Three more are in development and expected to be released later this year:

- *AABB Guide to Prenatal/Perinatal Immunohematology*
- *AABB Guide to Blood Warming*
- *AABB Guide to Laboratory Evaluation of Transfusion Reactions*

What's in a Name? "Guideline" versus "Guide"

The history of AABB's Guideline series dates back to the mid-1990s, when AABB developed a template for AABB standards based on quality system essentials, rather than proscribed tasks.

AABB published the first "Guideline" books under the direction of the Scientific Section Coordinating Committee (SSCC). "The goal of these publications was to capture the details removed from standards and to help facilitate continuous improvement in all aspects of transfusion medicine, to improve processes and, in doing so, to improve patient outcomes," said Jeffrey Winters, MD, chair of the Transfusion Medicine Section Coordinating Committee (TMSCC).

A decade ago, "Guideline" was given a special meaning at AABB to match industry practices, according to Laurie Munk, MLS, AABB's director of publications. "Guideline" has come to mean a clinical practice guideline, with best practice being determined through a meta-analysis of the literature and the strength of the evidence being assessed using the GRADE system.

The "Guide to" series was born both to differentiate the former "Guideline" books from the new meaning and to update the science, which had changed considerably since the books' initial publication. The books in the newly renamed "Guide to" series were developed by small working groups overseen by the TMSCC, which is the successor of the SSCC.

The "Guide to" series has become popular, according to Winters, based on the assistance and guidance the publications offer with common, everyday issues faced by those working in our profession.

"Because there is still a need for direction and instruction in many of the areas covered in the original series," said Winters, "the TMSCC has revised and updated many of the original publications to ensure that they represent the most current science, practice and regulatory requirements. Although the content of these publications represents best practices and meets compliance with regulatory requirements, they are not intended to replace or redefine regulatory or accreditation requirements but rather to assist transfusion services in providing quality care that fulfills such requirements."

Collaboration Among the TMSCC Work Groups

For those members who participate on one of the writing groups, the experience brings many benefits. "Working on the Guides is always a fantastic experience, because I am able to meet and learn from incredibly knowledgeable colleagues," said Wen Lu, MD, who chaired groups working on two of the books (*AABB Guide to Antibody Identification* and *AABB Guide to the Laboratory Evaluation of Transfusion Reactions*). "Work group meetings were always intellectually stimulating, and wonderful opportunities to dig deeper into my own understanding and practices."

Richard Gammon, MD, also chair of two work groups (*AABB Guide to Patient Blood Management and Blood Utilization* and *AABB Guide to Blood Recovery and Reinfusion in Surgery and Trauma*) agreed about the benefits of collaborating with others in the field on the books. "Although group members may have different opinions about how to address a topic or concern, in the end, the central focus of everyone is the care and well-being of donors and patients," Gammon said. He also noted that during 2020, when most of the group discussions were held, it was very helpful to hear how each of the work group members' facilities were addressing the COVID-19 pandemic from both the collection center and hospital perspectives.

What About "Guidance"?

The terms "Guide" and "Guideline" are not to be confused with a "Guidance," which is the word the Food and Drug Administration uses to describe information denoting the Agency's expectations for compliance with regulations and a term AABB uses to describe content ancillary to its standards — both in print and in the Standards Portal.

- AABB Guide: a publication with practical information to assist blood centers and transfusion services in providing quality care that fulfills regulatory requirements
- Guidelines: documents that describe the specific way a practice should be performed and represent the medical standard of care based on published evidence
- Guidance: Information denoting FDA's expectations for regulatory compliance; these represent FDA's interpretation and thinking about how to comply with the law found in the Code of Federal Regulations (CFR)

"The CFR tells you WHAT you need to do but the FDA guidance documents tell you HOW to do it," said Winters. "If you are not following the Guidance documents when FDA shows up to inspect, you WILL have some explaining to do, and you had better have very good documentation of what you did to validate what you are doing if it is different from what is in the Guidance!" ■

A Duty to Protect Our Donors and to Provide Safe Blood and the Best Choice of Blood Products

Mary J. Townsend, MD

Bringing hemovigilance to low- and middle-income countries is a good example of how the work of hemovigilance is never done. While high-income countries typically have well-organized and high-functioning hemovigilance systems, that is not always true everywhere in the world. Hemovigilance is all about protecting donors and blood recipients. As new threats to the blood supply arise, hemovigilance systems are poised to respond to potential threats. For instance, hemovigilance systems helped to rapidly evaluate whether COVID-19 was bloodborne, and safety processes were put in place in blood collection establishments to keep donation safe for staff and donors.

Mary J. Townsend, MD, is the medical director of Vitalant (formerly Blood Systems) in Scottsdale, Arizona. She serves as the ISBT/IHN representative on the AABB Hemovigilance Committee and the chair of the donor hemovigilance working group, as well as a liaison on the Donor Health and Safety Committee and a consultant to the Donor History Task Force. *AABB News* spoke to Townsend about her career, hemovigilance and the COVID-19 pandemic.

> I am fascinated by the nuances of transfusion medicine, both from the donor and recipient perspective. And, frankly, I am never bored.

AABB NEWS: **CAN YOU DESCRIBE YOUR CAREER PATH THAT LED TO YOUR CURRENT POSITION?**

Townsend: I believe that all careers take the "long and winding road." My road was no different. I started out with two degrees in chemistry (B.S. and M.S. in physical chemistry) and taught science in our local high school. But I wanted more of a challenge, so I decided to go to medical school, where my first interest was obstetrics and gynecology. I did the first 2 years of a residency at the University of Pennsylvania, but I met my husband (a surgeon) and decided someone had to raise the kids. So, I switched to clinical pathology, which seemed a great way to combine my love of chemistry and medicine. I fell in love with blood banking and haven't looked back. I spent my first 26 years at a small blood center (Coffee) in Amarillo, Texas, but moved my career and family to Scottsdale in order to work with Vitalant (formerly Blood Systems). Having mentors who believed in me and pushed me to achieve was the impetus to my career.

AABB NEWS: **WHAT INFLUENCED YOU TO PURSUE THIS LINE OF WORK?**

Townsend: I am fascinated by the nuances of transfusion medicine, both from the donor and recipient perspective. And, frankly, I am never bored. Transfusion medicine is always evolving, which makes it both fun and challenging.

AABB NEWS: **YOU SERVE ON THE AABB HEMOVIGILANCE COMMITTEE. WHAT ARE SOME OF THE KEY INITIATIVES ON WHICH THE COMMITTEE COLLABORATES?**

Townsend: The Hemovigilance Committee is focused on safety in transfusion medicine, for both the donor and recipient. We have a duty to protect our donors, who voluntarily roll up their sleeves to give the gift of life. We also have a duty to provide safe blood and the best choice of blood products to recipients.

AABB NEWS: **YOU ALSO SERVE AS THE CHAIR OF ISBT HEMOVIGILANCE (HV) WORKING PARTY. CAN YOU DISCUSS SOME OF THE WORK BEING DONE BY THIS GROUP?**

Townsend: The ISBT HV working party has most recently been involved in partnering with the World Health Organization in bringing hemovigilance to low and middle-income countries that have had difficulty in kickstarting HV programs. Last fall, the WHO held a 4-day virtual conference with Burundi and Zambia, in both English and French. All presentations and support materials have been made available on the WHO website. ISBT and other HV organizations are going to put together a compendium of "tools" for use by countries struggling to introduce or expand HV. This has been a very rewarding endeavor.

AABB NEWS: **SOME SAY THE WORK OF HEMOVIGILANCE IS NEVER COMPLETE. CAN YOU ELABORATE ON THAT?**

Townsend: I think the example of bringing HV to low- and middle-income countries is a good one. While high-income countries have very well organized and functioning HV systems, that is not necessarily true worldwide. HV is all about protecting our donors and blood recipients. As new threats to the blood supply arise — for instance through new emerging diseases — HV systems are poised to respond to potential threats. The COVID-19 pandemic is a great example of this. HV systems rapidly evaluated whether the new virus was blood borne, and safety processes were put in place in blood collection establishments to keep donation safe for our employees and our donors.

AABB NEWS: **HOW HAS YOUR JOB BEEN AFFECTED BY THE PANDEMIC?**

Townsend: I think the pandemic challenged us all to learn new ways to work and new ways to protect staff and donors while maintaining an adequate blood supply. In addition, we were challenged with the introduction of COVID-19 convalescent plasma, forcing us to rapidly ramp up new processes, procedures and testing, all the while doing our usual work.

AABB NEWS: **WHAT ARE SOME ACTIVITIES YOU LIKE TO DO IN YOUR SPARE TIME?**

Townsend: My family and I have always enjoyed cooking together. My children grew up cooking with us and with their grandparents, and now we are all about getting together when we can to have fun in the kitchen. My husband and I enjoy drinking and collecting fine wine… to go with all that great food. We enjoy traveling with our adult children, and as soon as we can, we will be planning another family vacation together. Living in Arizona we enjoy year-round hiking with our two labs, Mocha and RuthRBG. ■

2021 AABB Annual Meeting to Be Held Virtually

AABB is pleased to announce that the 2021 AABB Annual Meeting will be held virtually on Oct. 17-19, with some pre-meeting events held on Friday and Saturday (Oct. 15-16). AABB plans to build on last year's successful event by harnessing the latest technology and community resources to provide attendees with the best virtual experience possible. The AABB Board of Directors, in collaboration with AABB's meeting planning partners, decided to move forward with a virtual meeting after reviewing feedback from the community and ensuring that this year's meeting will offer attendees the highest learning and collaborating experience possible. Given the ongoing international impact of COVID-19, a virtual event will provide AABB with the opportunity to produce the highest quality and exceptional learning and collaborating experience possible.

This year's meeting will emphasize accessibility and connections. All sessions at the meeting will be available with Spanish translations, with live and on-demand sessions to optimize accessibility and connections. There will also be a new track this year that focuses on the fundamentals of transfusion medicine — designed specifically for early-career colleagues. The virtual platform also offers exceptional networking features for enhanced business discussions and the capacity to connect with friends and colleagues from near and far.

This year's meeting will also emphasize content, featuring a robust program of education sessions led by world-renowned experts, a series of oral and poster presentations covering the latest cutting-edge research and a virtual exhibit hall showcasing new products and services from our industry partners.

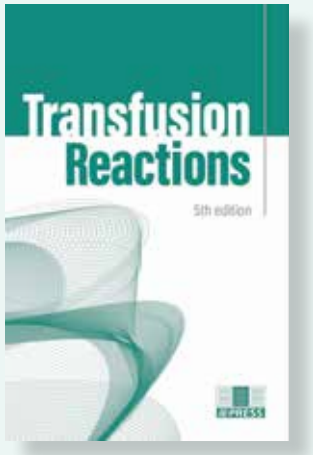
Finally, this year's meeting will emphasize convenience. The decision to hold the meeting on a Sunday, Monday and Tuesday this year was made directly in response to feedback telling us that holding the meeting on these days would make it easier for participants to take part in as much as possible.

Registration opens for AABB members on June 23 and for the general public on June 30. Additional information is available at aabb.org/annual-meeting.

5th Edition of *Transfusion Reactions* Now Available

The fifth edition of *Transfusion Reactions* is now available for purchase in the AABB Store. This trusted reference examines aspects of common and uncommon transfusion reactions with updates reflecting the latest scientific literature. The publication also offers subtopics and tabular material that provide easy access to critical information for clinical providers at all levels, as well as laboratory staff, involved in the care of transfusion recipients.

Important features in the fifth edition include two new chapters that explore unconfirmed transfusion reactions and hemovigilance; specific chapters devoted to nursing practices, prevention and low-resource settings; significant changes regarding transfusion-related acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO); and thirteen other chapters that explore complications based on the type of reaction, procedure or product used.



AABB Announces Slate of Nominees for 2021-22 Board Of Directors

AABB's 2021 Nominating Committee is pleased to present the slate of candidates for the 2021-22 Board of Directors. The slate includes the Committee's recommendations to fill the officer positions for 2021-22:

- Brian Gannon, MBA, for president-elect.
- Aaron Tobian, MD, PhD, for vice president.
- Jose Cancelas, MD, for secretary.

The Committee recommends the following three at-large Board members for re-election:

- Rachel Smith for position #1.
- Richard Schäfer, MD, PhD, for position #3.
- Jerry Holmberg, PhD, MS (Path, CLS), MT(ASCP) SBB, for position #5.

The slate also includes recommendations for this year's open at-large director positions:

- Nancy Dunbar, MD, for position #7;
- Sally Campbell-Lee, MD, for position #9.

The Committee carefully considered whether the at-large director positions should be opposed or unopposed. After extensive deliberation, the Committee determined that all positions on the slate would be unopposed again this year, so that the Committee's carefully considered view of the optimal slate of candidates — rich and varied in skill and experience — can be presented to the membership. The Committee believes the slate of nominees represents those best equipped to complement the talents of the continuing members on the Board of Directors and lead AABB to address the challenges and opportunities it faces in the short and long term.

On Aug. 6, electronic ballots will be distributed to all members in good standing. The election will close on Sept. 10, and the results will be published shortly thereafter.

Per AABB's bylaws, additional nominees for the open at-large director positions may be submitted using the petition process. Instructions for submitting a nomination by petition and related submission requirements are available on AABB's website. The deadline to submit nominations by petition is June 30 at 11:59 pm ET.

SunCoast Blood Center, Blood Bank of Delmarva Open New Donor Centers

SunCoast Blood Centers and the Blood Bank of Delmarva recently announced the openings of new blood centers. SunCoast held a grand opening on April 27 for a new location in Port Charlotte, Fla., hosted in partnership with the Port Charlotte Chamber of Commerce.

The Blood Bank of Delmarva opened a new location in Dagsboro, Del., on May 1. The blood bank has other centers in Delaware, Maryland, New Jersey and Pennsylvania.

MVRBC Announces Name Change to Impactlife

Mississippi Valley Regional Blood Center (MVRBC) announced recently that the organization will rebrand as ImpactLife. In addition to MVRBC, the organization operates in various parts of its service region as Central Illinois Community Blood Center and Community Blood Services of Illinois. At the event, speakers Mike Parejko, chief executive officer; and Chad Everitt, chair of the board of directors, emphasized that the new name better reflects the mission of the organization, rather than its service area. Additionally, Audrey Majeski, a member of ImpactLife's associate board, spoke about her own experience as a transfusion recipient and blood donor.

Karina Yazdanbakhsh, Larry Luchsinger to Co-Lead NYBC's Lindsley F. Kimball Research Institute

Karina Yazdanbakhsh, PhD, and Larry Luchsinger, PhD, will serve as co-leaders of the New York Blood Center's Lindsley F. Kimball Research Institute (LFKRI), NYBC President Christopher D. Hillyer, MD, announced recently. Hillyer will continue as chief scientific officer.

Yazdanbakhsh will serve as vice president and director of Research Development, LFKRI, where she will be responsible for faculty development and for building research collaborations internally and externally. Most recently, she served as LFKRI's executive director of Research.

Luchsinger will serve as vice president and director of Research Operations, LFKRI, where he will be responsible for setting LFKRI shared resource policies and promoting technology development strategies to strengthen LFKRI research capabilities. He continues to serve as head of the LFKRI Laboratory of Stem Cell Regenerative Research and director of the NYBC iPSC Program.

Both Yazdanbakhsh (2000) and Luchsinger (2020) are previous recipients of early-career Scientific Research Grants from AABB's National Blood Foundation (NBF). In 2015, Yazdanbakhsh was inducted into the NBF Hall of Fame for her contributions to research and to the Association.

Michael Deininger Named Executive Vice President, Chief Scientific Officer and Director of Versiti Blood Research Institute

Versiti, Inc. announced the appointment of Michael Deininger, MD, PhD, as executive vice president, chief scientific officer and director of the Milwaukee-based Versiti Blood Research Institute on April 22. He will begin his new position Sept. 1 and will succeed Roy Silverstein, MD, who is serving as the Institute's interim director.

Deininger joins Versiti after 11 years at the University of Utah/Huntsman Cancer Institute (HCI), where he served in its Department of Internal Medicine as professor and chief of Hematology and Hematologic Malignancies; senior director of Transdisciplinary Research; and director, Huntsman Center of Excellence in Hematologic Malignancies and Hematology. He previously held a number of positions at the Oregon Health and Science University, Portland, Ore., including chief, Hematological Malignancies Section.

"We are excited to have a world-renowned researcher and leader of Mike's caliber join Versiti as our inaugural Mike and Cathy White Endowed Chair," said Chris Miskel, president and chief executive officer of Versiti. "The Versiti Blood Research Institute is known globally for research related to blood health. Given his proven scientific excellence, translational research focus, leadership experience and clinical expertise, I am confident that Mike will take the institute to a new level. He is deeply committed to advancing scientific discovery in hematology, the science of blood in health and disease, and to translating the new knowledge into benefit for patients. ■

CALENDAR

June

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AABB eCast

9 Significant Changes to the 10th Edition of Standards for Cellular Therapy Services (21EL-644)
AABB eCast

10 Science & Innovation Forum - Thermal Cameras and FDA Guidelines: Fact vs. Fiction in Protecting Your Hospitals and Blood Centers
Presented by ICI/Infrared Cameras, Inc

30 Immunohematology Boot Camp: Basic Rh (21EL-648)
AABB eCast

July

21 Expanding Temp Ranges and Expiration Dates: Platelets and Cryo (21EL-656)
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AABB eCast

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