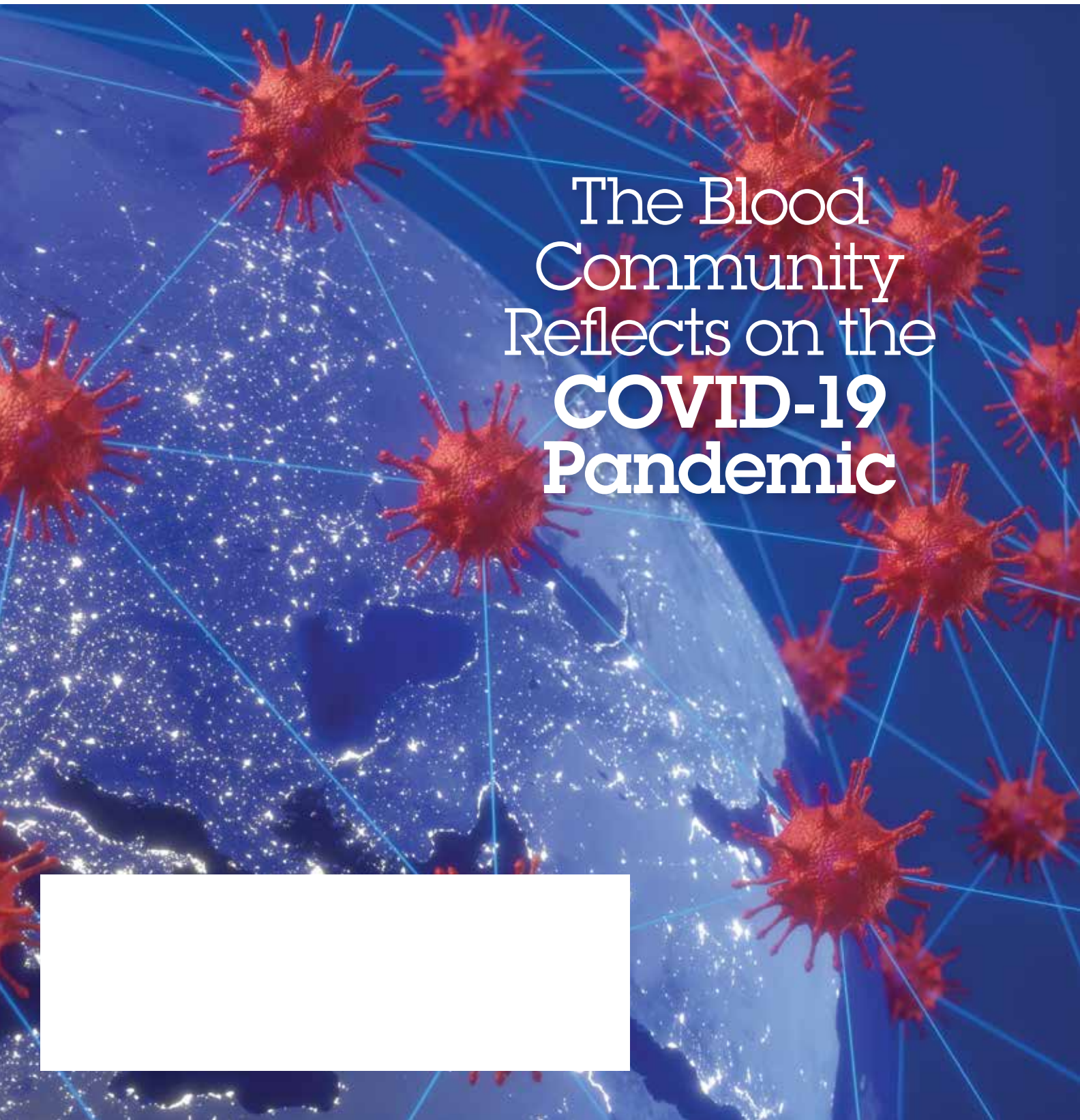
MAY 2021
Vol. 23 No.5

AABB News



The Blood Community Reflects on the COVID-19 Pandemic

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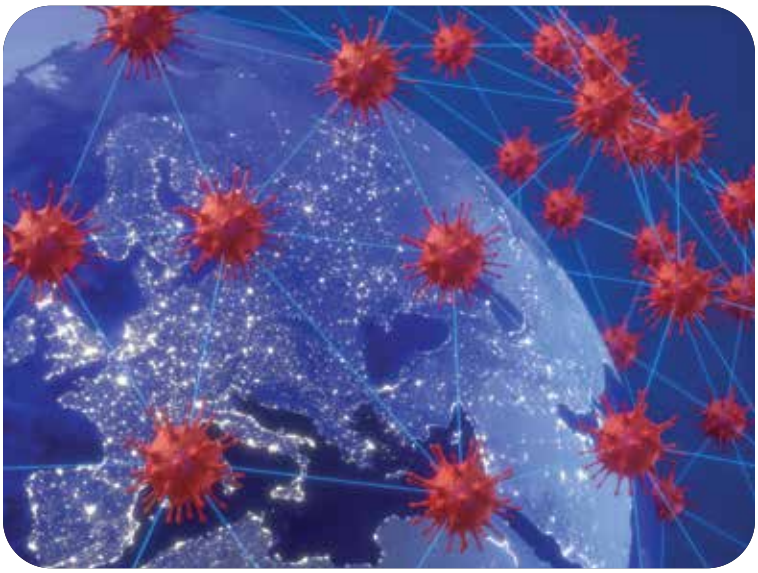
Contents



10
Lessons Learned During a Global Pandemic

Forced to adjust on the fly, blood centers have come away from the COVID-19 pandemic with new perspective and renewed commitment

15
The Evolution of CCP

Convalescent plasma was widely used as a treatment for patients with COVID-19 before other therapeutic options and vaccines were available.

20
Social Media Is Changing How Transfusion Medecine Professionals Connect and Learn

The COVID-19 pandemic has led members of the blood and biotherapies community to utilize social media apps more than before.

Reflecting on the Pandemic

A year ago, we were in the early stages of a pandemic caused by a novel pathogen with no vaccine and limited therapeutic options. Treatments for COVID-19 were not supported by research; in fact, research on the efficacy of COVID-19 convalescent plasma (CCP) was being conducted even as CCP was being administered to patients as a bridge therapy under the Expanded Access Protocol.

A year later, we now have wide access to vaccines that are effective at preventing severe disease among those infected with the virus, as well as a better array of treatments. At this juncture, *AABB News* decided to take a look back at the pandemic and at how the blood and biotherapies community has responded to the crisis.

Rising to the Challenge

Beginning last March, blood centers were forced to find new ways to collect blood during the shutdown, while being simultaneously called upon to develop procedures and begin collecting CCP at breakneck speed, and they responded to that call. The first feature article in this issue, which starts on page 10, discusses how blood centers responded when they were faced with the sudden shutdown of schools and offices, which necessitated finding new ways to collect blood in a changed world of masks and social distancing. The second feature, beginning on page 15, examines how CCP became a treatment for COVID-19, even as it was being studied as a therapy, collected by blood centers that had to come up with a new set of policies, protocols and procedures, and administered as a form of compassionate care to patients with few treatment options.

David Green, MSA

Social media has become a lifeline for some during the COVID-19 pandemic. The third feature, starting on page 20, looks at the ways members of the blood and biotherapies community have turned to social media platforms as a means of seeking and sharing information and connecting with their colleagues.

As I reflect on what members of our community — as well as people throughout the world — have dealt with during this challenging time, I do so with a sense of pride. The blood and biotherapies community has faced unprecedented challenges and been forced to quickly adapt to new realities. But, as always, this community continues to adjust and respond accordingly — and continues to ensure that a safe and adequate blood supply is available for patients in need. ■

David Green, MSA
AABB President

AABB News
MAY 2021 | Vol. 23 No. 5

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AABB News
(ISSN 1523939X) is published monthly, except for the combined November/December issue for the members of AABB; 4550 Montgomery Avenue; Suite 700 North Tower; Bethesda, MD 20814.

AABB is an international, not-for-profit association representing individuals and institutions involved in transfusion medicine, cellular therapies and patient blood management. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety.

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Periodicals postage paid at Bethesda, MD, and at additional mailing offices.

Views and opinions expressed in *AABB News* are not necessarily endorsed by AABB unless expressly stated.

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Addressing Remaining Questions About the Use of CCP

By Claudia S. Cohn, MD, PhD
Chief Medical Officer

COVID-19 convalescent plasma (CCP) has been widely used since April 2020, when the virus began to spread rapidly throughout the United States and the world. Its positive safety profile[1] and the lack of other proven therapies made CCP a popular option for the treatment of patients with COVID-19. In the U.S., approximately 530,000 units had been distributed to hospitals at press time; however, we still do not fully understand the best ways to use CCP in regard to timing, dosage and patient population.

By early 2021, the supply of CCP was outstripped by demand as COVID-19 cases surged. The need for evidence-based guidelines led AABB to assemble a group of experts from the transfusion community, with representatives from critical care, anesthesiology, microbiology, hematology and Cochrane, as well as a patient representative. Based on the available evidence, this group developed interim recommendations for CCP use.[2] These interim recommendations will be updated as more peer-reviewed clinical trial data are published.

The recommendations (see Table 1) addressed the four most important questions surrounding CCP use: whether CCP is a safe therapy for most patients; when in the disease course it should be given; what titer is needed to be effective; and if it is safe to transfuse out of ABO-group CCP units.

Safety: The first interim recommendation notes that CCP and conventional plasma carry the same level of risk. This is based on strong evidence from multiple randomized controlled trials (RCT), studies and case reports. In a paper from the Mayo Expanded Access Protocol, a 0.39% rate of adverse events was reported after 20,000 units of CCP were transfused.[1] No deaths were ascribed to transfusion of CCP. No evidence was found that CCP caused other adverse events such as thromboembolism or antibody mediated enhancement.

Timing of CCP transfusion: The second interim recommendation stated that CCP should be given as early as possible after symptom onset and emphasized that CCP should not be given late in the disease course or if a patient is on mechanical ventilation. Since the SARS-CoV-2 virus is generally cleared from a patient's system 9 days after infection,[3] it seems likely that CCP will only be effective during the early viremic stage of the disease. Nearly all trials to date have given CCP to inpatients who have moderate to severe COVID-19 and often are aviremic; these trials have found that CCP confers no benefit when compared to controls. One trial, however, tested CCP in the outpatient setting and found that recipients of CCP were significantly less likely to progress to severe respiratory disease when compared to other outpatients given placebo.[4] But another trial (C3PO) also tested CCP in the outpatient setting and closed due to futility. The details of why C3PO ended early have not yet been released. Until more data are available, the best evidence suggests that the earlier CCP is given, the more likely it is to confer some benefit.

Titer: The interim recommendations

Table 1: Interim Recommendations for COVID-19 convalescent plasma use

Interim Recommendation 1: When making risk benefit decisions, one should consider the risk of CCP as comparable to standard (SARS-CoV-2 non-immune) plasma.
Interim Recommendation 2: CCP is optimally effective when transfused as close to symptom onset as possible. CCP is unlikely to provide benefit for patients with late-stage disease or on mechanical ventilation.
Interim Recommendation 3: The effectiveness of CCP is related to the antibody quantity within a unit; high-titer CCP is superior to low-titer CCP. A single high-titer unit should be sufficient for most patients.
Interim Recommendation 4: If group B or group AB CCP is unavailable, transfusion of group A or group O CCP with low anti-A/B titer may be acceptable for group B and group AB patients

support the use of high titer, rather than low titer, CCP. CCP titers indicate the level of neutralizing antibodies that can bind and inhibit the SARS-CoV-2 virus. The higher the titer, the greater the number of neutralizing antibodies and the greater the therapeutic potential. Nearly all trials strive to use high titer units, and a dosage effect was seen in one trial in which patients receiving the highest titer units did significantly better than patients receiving lower titer units.[4] FDA now requires all CCP units released under the emergency use authorization (EUA) to be high titer.

ABO compatibility: The fourth interim recommendation states that in the absence of group B or group AB CCP, the transfusion of group A or group O CCP with low anti-A/B titer may be acceptable for group B and group AB patients. Usually, transfused plasma is ABO-identical or ABO-compatible with the recipient in order to prevent passive hemolysis of the recipient's red cells. For patients with lower prevalence ABO groups, such as blood groups B and AB, ABO-identical or -compatible CCP may not be available. Evidence and clinical experience have shown that incompatible plasma, such as group A with low-titer anti-B, is safe in situations when compatible plasma is not available.[5,6]

The interim recommendations were based on the best available evidence at the time of writing. They were designed as a guide to maximize the potential benefit of CCP for COVID-19 patients. Additional data from ongoing RCTs will lead to more robust clinical practice guidelines in the future. ■

Citations

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A Q&A with Paul Molfese

By Christopher Bocquet
Director of Standards

Paul Molfese, BB(ASCP), is a compliance officer with UCLA Blood and Platelet Center at UCLA Health.

TMSCC: How did you come into your role?

Through a bit of a journey coupled with some serendipity. I started my career at the Children's Hospital of Buffalo in 1968 as a lab trainee working in the Transfusion Service. For the next 35 years, I gained experience and took on increasing responsibility, eventually becoming supervisor of the transfusion service, core laboratory supervisor and then serving as an interim lab manager. While all of this was going on, I earned a Bachelor of Science degree in biology and a Master of Science in health services administration.

Paul Molfese, BB(ASCP)

Prior to my serving as interim lab manager, four Buffalo hospitals merged into one entity, Kaleida Health. This was a full merger with one administration, one human resources department and one department of pathology. Eventually, Kaleida hired a team of consultants who made a series of observations and suggestions, one of which was that the laboratory — which had six managers at the time — really only needed five.

During my time as interim lab manager, I was approached by a recruiter who was looking for a compliance officer for HemaCare, located in Los Angeles. At this time, HemaCare managed blood drives for client hospitals and ran their own fixed site for collection of apheresis platelets. I accepted the position at HemaCare as a compliance officer, with Lieta Maffei as the director of quality. After Lieta accepted a similar position at the San Diego Blood Bank, I receive a call from Maryanne Anthony, who was a blood bank supervisor at what is now the Ronald Reagan UCLA Hospital. Maryanne said that UCLA needed a compliance officer for their donor center and strongly suggested that I apply. I was hired and have been a compliance officer assigned to the Division of Transfusion Medicine for the past 15 years. My primary area of responsibility is the UCLA Blood & Platelet Center, though for the past year I have also served as compliance officer for the Transfusion Service.

TMSCC: Was there someone who mentored you along the way?

Yes, John Fitzpatrick, MD, who was my medical director at Children's. John and I had long discussions concerning blood banking and lab operations. He gave me encouragement and, when needed, a swift kick. Together we worked to improve operations at the Transfusion Service. One of our accomplishments was to move from tube testing to Ortho's gel technology.

TMSCC: What is one thing every leader should know and apply daily?

A leader is only as good as the support staff working with them. If you encourage and mentor your staff, the department will shine and some of that shine will rub off on you.

TMSCC: What are the top challenges you face in your segment of the industry?

Like everyone else, adjusting to and recovering from COVID-19. The pandemic presented us with multiple significant challenges. As the pandemic appears to be winding down, the challenge is to rebuild our donor base and to collect enough apheresis platelets and whole blood to support the needs of the hospital while upgrading equipment and computer systems to improve collections and maintain compliance with regulatory needs. Equally, and maybe more importantly, maintaining the confidence and enthusiasm of our staff. ■

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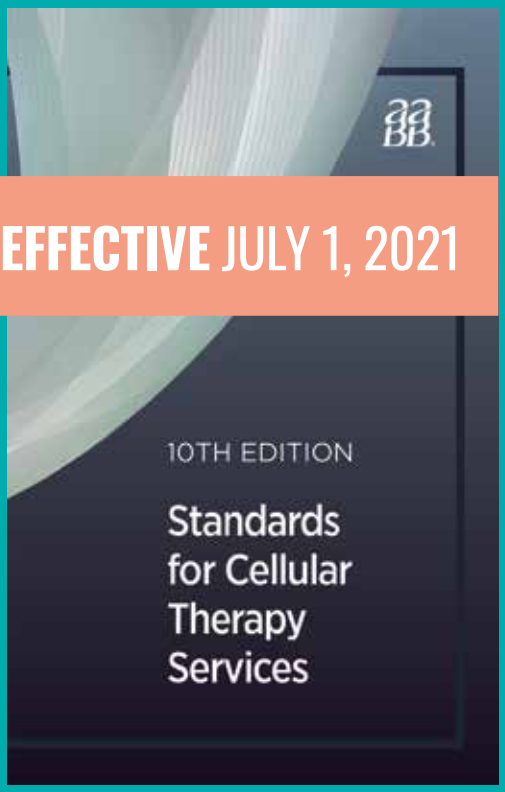

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- Standard 5.12.2.10 has been edited to require that facilities have policies, processes and procedures to ensure that when a new infectious disease emerges, action is taken.
- New standard 5.30.1 requires clinical facilities to provide data to their chosen registry in a manner that is consistent and appropriate.

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NBF Grant Recipients Contribute to COVID-19 Research

By Drew Case
Senior Communications Manager

A surprisingly large percentage — about 25% — of those who have received a National Blood Foundation early-career Scientific Research Grant have contributed to important COVID-19 research. The early-career Scientific Research Grants Program helps NBF achieve its mission of "fueling innovation in transfusion medicine and cellular therapies for the benefit of patients and donors." The NBF also fosters collaboration and networking to maximize impact on industry research. Below is a small sample of some of the COVID-19 research published by NBF grant recipients.

Larry Luchsinger and Christopher Hillyer Publish Research Letter in *Science*


Larry L. Luchsinger, PhD

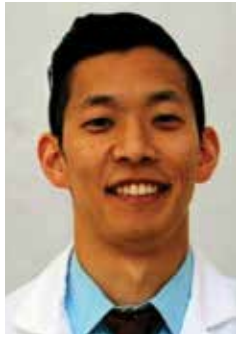

Christopher D. Hillyer, MD

Two past recipients of National Blood Foundation early-career Scientific Research Grants published a research letter in *Science* in March 2021 on the probable efficacy of the three authorized COVID-19 vaccines against disease variants.[1] In the letter, Larry L. Luchsinger, PhD, and Christopher D. Hillyer, MD, examined vaccine efficacy measured by neutralization antibody (nAb) levels in non-human primate challenge experiments. According to Luchsinger and Hillyer, data from Moderna, Pfizer and Johnson & Johnson suggest that these vaccines are likely to be effective against mutant strains of COVID-19, despite differences in nAb levels.

"These studies show that what appears to be magnitudes of difference in nAb activity may not necessarily correlate with clinical immunity," Luchsinger and Hillyer wrote. "As variant strains emerge, we will need to reevaluate vaccine efficacy by testing the inhibition of viral infection in vivo rather than by quantifying the antibodies produced after in vitro exposure."

Luchsinger, assistant member, Stem Cell Regenerative Medicine, at the New York Blood Center (NYBC), received an NBF grant in 2020 for a research project to study whether plasma membrane signaling pathways underpin hematopoietic stem cell (HSC) function and to develop HSC expansion methods to generate blood products in vitro. Hillyer, president and CEO of NYBC, is a past president of AABB and an inaugural member of the NBF Hall of Fame. He received an NBF grant in 1991 for research related to peripheral blood stem cells for allogeneic transplantation.

David Roh Publishes Research in *Journal of Trauma and Acute Care*


David Roh, MD

David Roh, MD, a 2020 recipient of an NBF early-career Scientific Research Grant, published an analysis of hypercoagulable characteristics in critically ill COVID-19 patients using rotational thromboelastometry (ROTEM) in the January 2021 issue of *Journal of Trauma and Acute Care*.[2] The study also explored the relationships of D-dimer and ROTEM measurements with thrombotic complications.

Roh and his colleagues identified elevated D-dimer levels and hypercoagulable blood clot characteristics from increased fibrinogen on ROTEM testing in critically ill COVID-19 patients. However, they also identified lower but hypercoagulable ROTEM fibrinogen measurements in COVID-19 patients with thrombotic complications than in patients without thrombotic complications. They

The NBF also fosters collaboration and networking to maximize impact on industry research. Below is a small sample of some of the COVID-19 research published by NBF grant recipients.

concluded that further work is required to externally validate these findings, investigate the mechanistic drivers for these relationships and identify the best diagnostic and treatment approaches for these patients.

Numerous Grant Recipients Collaborate to Publish COVID-19 Research

Seven NBF grant recipients contributed to pre-print research suggesting that the low oxygen levels seen in many patients with COVID-19 may be the result of damage to the membranes of red blood cells caused by the virus. The investigative team included Tiffany Thomas, PhD, (2019); Angelo D'Alessandro, PhD, (2016); Richard O. Francis, MD, PhD, (2014); Krystalyn Hudson, PhD, (2014); Eldad A. Hod, MD, (2011); James C. Zimring, MD, PhD, (2004); and Steven L. Spitalnik, MD, (2003). Spitalnik is also a member of the AABB Board of Directors. The team published the findings on pre-print server *medRxiv* ahead of peer review, and it was subsequently published in the *Journal of Proteome Research*.[3] Several national publications highlighted the findings following coverage by Reuters.

Three other NBF grant recipients — Luchsinger; Karina Yazdanbakhsh, PhD, (2000); and Hillyer — published findings from a serological analysis of New York City's CCP donors. The findings indicated that CCP donors have a wide range of neutralizing antibody concentrations against SARS-CoV-2, which suggests varying levels of immunity in preventing future infections. Investigators published the findings on *medRxiv* ahead of peer review, and the article was later published in the *Journal of Clinical Microbiology*.[4] National publications, including the Los Angeles Times and *Time*, covered the findings.

Additional research on antibody responses to SARS-CoV-2 included contributions from grant recipients Sean Stowell, MD, PhD, (2013), and John Donald Roback, MD, PhD, (1998). In this study, investigators determined that a robust humoral immune response occurs early during severe or moderate COVID-19 infections. *Cell Reports Medicine* published the findings.[5]

A review published last year in the *Journal of Clinical Investigation* also included contributions from two previous grant recipients. AABB Past-President, Beth Shaz, MD, (2008), and Spitalnik contributed to a review of the use of convalescent plasma, including evidence of benefit, regulatory considerations, logistical workflow and proposed clinical trials.[6] ■

Endnotes

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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

Lessons Learned During a Global Pandemic

Forced to adjust on the fly, blood centers have come away from the COVID-19 pandemic with new perspective and renewed commitment.

By Leah Lawrence
Contributing Writer

Blood banks were in the news again in March, when a new study estimated that more than one-fifth of blood donations from unvaccinated people had COVID-19 antibodies present.[1]

This news story and others like it detailing antibody testing or convalescent plasma for COVID-19 have put blood banks into the national news in a way they haven't been in years, according to John Armitage, MD, chief executive officer of the Oklahoma Blood Institute.

"Convalescent plasma has provided us with more free media coverage than we have ever had," Armitage said. "We took advantage of this by making sure that when we told the convalescent plasma story that we also told the blood donation story, too."

Just like everyone else, blood banks and transfusion services have had to adapt to the COVID-19 pandemic. *AABB News* recently spoke with representatives of several blood banks throughout the country about what the world of blood banks looks like 1 year after the start of the pandemic.

Part One — Pandemic

When looking back at the last year, Armitage said that he has begun to view it in three parts. Part one was the shutdown.

"Everything came to a grinding halt," he said. "With school and office closures our entire playbook was thrown out the window."

Few probably felt that halt in quite the same way as Vicki Finson, executive vice president, Blood Services at Bloodworks Northwest, based in Seattle.

"We were at the epicenter of the early COVID-19 pandemic, which hit us overnight," Finson recalled. "In those early days, I talked to colleagues throughout the country that hadn't yet felt the impact."

Finson said Bloodworks Northwest went from steady, reliable local blood donations and a strong inventory to hitting rock bottom within the first week. That was when the decision was made to activate the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (the Disaster Task Force).

"Many colleagues and centers sent in almost 600 units of red blood cells within a short amount of time to get us back on our feet," Finson said.

Shortly after that, hospitals shut down for elective procedures, driving transfusion needs down overnight, she said.

"This gave us a few weeks to reinvent ourselves," Finson said.

Soon enough though, similar challenges were faced by blood banks throughout the country, and everyone was forced to think of new solutions for getting donors in the door.

Brian Gannon, chief executive officer of Gulf Coast Regional Blood Center, was only a couple of weeks into his term as chair of the Disaster Task Force when faced with the challenge of how to aid blood banks.

"Donors were just not showing up. This was not just here in the Gulf region, but around the country," Gannon said. "We were trying to adapt and set up social distancing, but many members of the public were afraid to come out."

Gannon and others began to get out the word that the United States could see blood supply shortages quickly if donors did not return.[2] His concerns were echoed shortly thereafter by U.S. Surgeon General Jerome Adams and other high-profile government and public health officials whose calls for people to visit their local blood centers helped bring donors back.

Part Two — Pivot

Granted a temporary reprieve when most hospitals shut down or limited elective surgeries, blood banks were forced to re-think everything when the demand for blood components began increasing in the summer of 2020.

"Like many others, we right away shut down all blood mobiles," said David Wellis, PhD, chief executive officer at San Diego Blood Bank. "We actually had a green light from the county to use them, but capacity-wise it did not make sense to cut what typically was four beds down to only two."

Instead, Wellis said, they created pop-up sites and were able to set up two additional regular donor centers.

"We found that landlords with empty space in shopping malls were very generous in allowing us to go in for free and set up donor centers," Wellis said.

In Seattle, Finson was making similar adjustments. All donation centers were socially distanced and by appointment only. The hours were also extended in order to maximize the donations.

"Now 75% of our collections are in centers compared with about 45% before the pandemic," Finson said.

Bloodworks Northwest also developed a pop-up model working with local venues that allowed the drives to stay set up for a few weeks or months.

"Our first pop-up was at Mariner's field at T-Mobile Park in downtown Seattle," Finson said. "They were awarded the ABC Outstanding Blood Drive of the Year for the way they stepped up."

Soon after, other sports arenas followed, as well as local museums and theaters.

"In addition to being places to donate, these were fun locations for people to get out of their houses to visit," Finson said.

She also encouraged local organizations, companies and schools — places that would have traditionally held mobile drives — to participate in virtual blood drives. They were able to track and report back to the blood drive sponsors that participated on their organization's behalf.

Armitage said that some blood banks were also able to offer some incentives to donors in the form of antibody testing, which he says helped save the Oklahoma Blood Institute's summer.

According to Gannon and the others, the local communities really answered the call.

"People showed up in droves to donate, and although some came for antibody testing, others came out of the goodness of their heart," Gannon said. "They wanted to do anything they could to be a part of the solution for this situation."

Donations were so high, Gannon said, that they had to completely stop collecting for 2 weeks.

Finson, Wellis and Armitage all said that their relationships with local government offices were strengthened during the pandemic. In fact, Wellis said, many of the local government press conferences discussing the pandemic would often include a reminder to get out and donate blood.

"It almost worked too well," Wellis said. "I've been here 8 years now and I have never seen our blood supply so high."

Part Three — A New Normal

Only recently have blood banks started to move into what Armitage called phase three, the "post-COVID-19" phase. In this phase, hospitals are operating on a fairly normal surgical schedule and donations have leveled off to a more reliable number.

Now, he said, blood banks are left to try to figure

out how to bridge back to their old "playbook" and decide whether they even want to go back.

"This whole journey has been one of constant reinvention, constant monitoring and constant adjusting," Armitage said.

One great lesson from the pandemic, according to Wellis, is how nimbly blood banks were able to adapt.

"Before, if the FDA made a change or was thinking about making a change, it would be at least a couple of years before those changes were put into place," Wellis said. "In the last year we have been making changes dictated on a daily basis. We had not seen that kind of speed before and we were able to respond in an amazing way."

In this "post-COVID-19" era, Wellis said that many of the changes made at the San Diego Blood Bank in the last year will be permanent ones. For example, he doubts that they will return to walk-in donations.

"Relying on walk-ins left a certain amount of uncertainty in the forecast for our collections numbers," Wellis said. "When we work on an all-appointment basis, it makes it easier to know what is coming in."

Finson emphatically agreed that Bloodworks Northwest will also stay appointment only.

"We believe the predictability is good for the donor and good for us," she said. "They arrive and can start right away. It is great for the process."

Finson said they also plan to re-assess what "mobile" drives will look like when social distancing requirements relax. She said that there is not much desire to go back to running more than 7,000 mobile events a year.

"I do believe that someday there will be one-day events again, but we are hoping to work with the community to continue the idea of a mobile venue that hosts more than just a one-day event," Finson said.

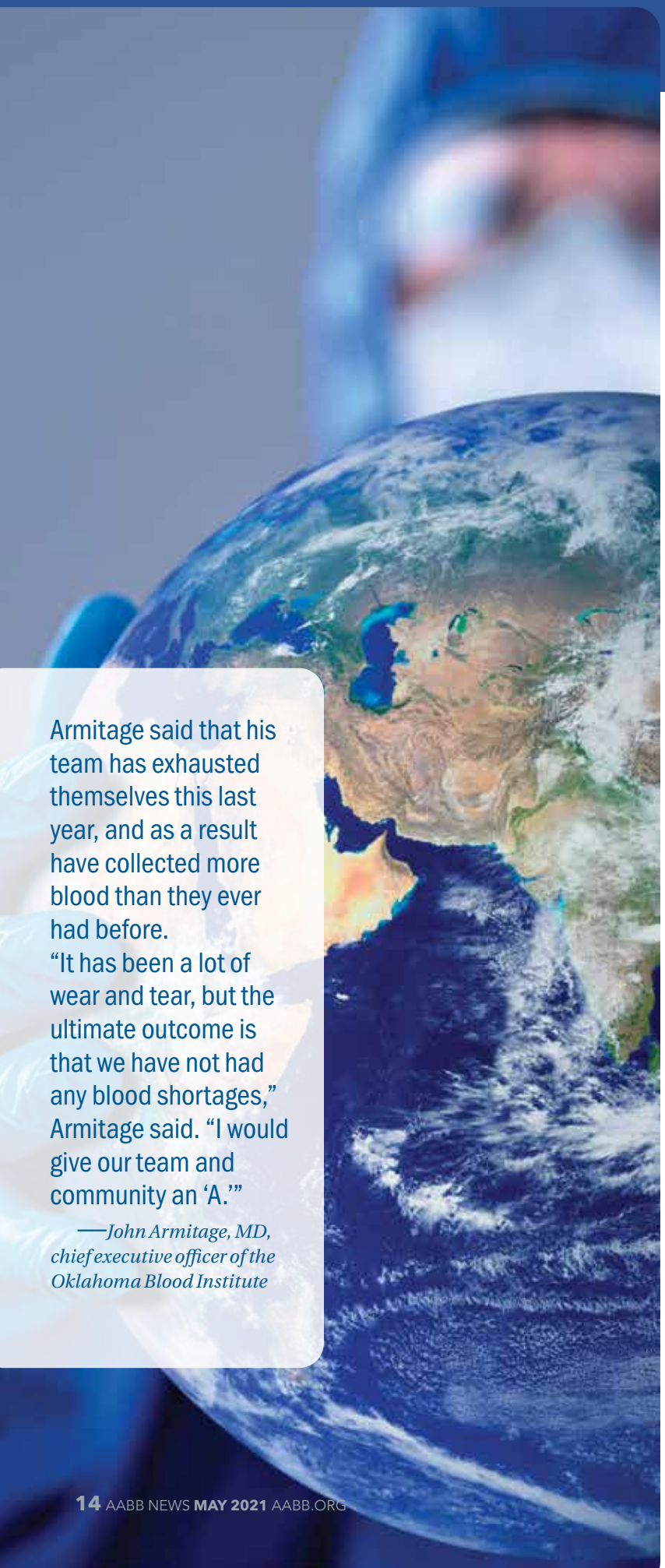
Additionally, Finson said they plan to put more focus on their permanent donation centers. Hours may be increased to make donation more convenient and approachable.

A Changed Industry

Armitage said that the community has to accept that things are likely never going back to exactly the way they were pre-COVID-19. At a minimum, reliance on corporate America for blood drives may be a thing of the past, as it seem clear that at least some of the workforce will not be returning to an office environment.

"Donors were just not showing up. This was not just here in the Gulf region, but around the country," Gannon said. "We were trying to adapt and set up social distancing, but many members of the public were afraid to come out."

—Brian Gannon, chief executive officer of Gulf Coast Regional Blood Center



That goes for blood bank staff as well, Gannon said.

"We have looked around at who actually needs to work in our office and who can work from a distance," Gannon said. "In an area like Houston, commutes can be very long, and we have actually found that since people are working from home, productivity has gone up."

Similarly, Armitage said that his team has exhausted themselves this last year, and as a result have collected more blood than they ever had before.

"It has been a lot of wear and tear, but the ultimate outcome is that we have not had any blood shortages," Armitage said. "I would give our team and community an 'A.'"

He and the others had nothing but praise for the efforts of their staff.

When faced with new stringent disinfecting protocols and adjusting donation sites for social distancing, everyone on staff stepped up, Wellis said.

"It was a little overwhelming at first because we rely heavily on volunteers, but we trained them," Wellis said. "They stepped up and just did it."

Operationally and culturally, staff at blood banks and donation centers have been through quite a lot in the last year and it has brought everyone closer, Wellis said.

"We survived and we made a difference," Armitage said. "I recently sent an email to my staff saying that when they look back in 20 years, they can say they were part of a team that was life-saving, essential and that made a difference. When everyone was running for the exit, you were brave enough to go out and run blood drives. We survived and are stronger for having come through this successfully." ■

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"It has been a lot of wear and tear, but the ultimate outcome is that we have not had any blood shortages," Armitage said. "I would give our team and community an 'A.'"

—*John Armitage, MD, chief executive officer of the Oklahoma Blood Institute*

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The Evolution of CCP

COVID-19 convalescent plasma was widely used as a treatment for patients with COVID-19 before other therapeutic options and vaccines were available.

By Jerilyn Schweitzer, MA
and Jay Lewis, MPH

When the COVID-19 pandemic began in the United States more than a year ago, there was little known about the new pathogen or how to treat patients infected with it. The health care community was only just beginning to understand the novel coronavirus and there were no known treatments at the time. Early on, COVID-19 convalescent plasma (CCP) was discussed as a potential therapy for patients with COVID-19. The Food and Drug Administration reached out to blood collection facilities in late March 2020 regarding the collection of CCP as an investigational treatment until more advanced therapies could be developed. Blood collection facilities promptly began to develop processes for collecting CCP from those who had recovered from COVID-19. Ultimately, CCP collections were limited to areas where the infection was spreading and were possible only after patients had time to recover from the infection.

AABB News interviewed experts working in different areas of the blood community to provide a look-back at how CCP became a bridge treatment for COVID-19 and the evidence for its continued use.

Why Convalescent Plasma?

"There is a long history of using convalescent plasma in epidemics going back to the early 20th century," said Arturo Casadevall, MD, PhD, chair of molecular microbiology and immunology at Johns Hopkins Bloomberg School of Public Health. "In fact, it was used successfully during the 1918 flu pandemic. In the 21st century, it was used during the SARS epidemic in 2003 and in the recent Ebola outbreak in West Africa. I believe

CCP was used first in China and then in Italy, since those countries experienced COVID-19 before the U.S."

Casadevall said that based on evidence from other forms of convalescent plasma, the safety of CCP was not in question, and there were no other therapies available. "Hence, with plasma, you had something in plentiful supply that had a good safety profile and a long history of use in a setting where you had very few therapeutic options," he said. Making the treatment even more promising, convalescent plasma needs no development — just recovered patients willing to donate their plasma. "Furthermore, the U.S. has a well-developed and efficient blood banking industry that was able to rapidly make plasma available," he said. Subsequently, many physicians embraced it.

The Hard Work of Beginning CCP Collections

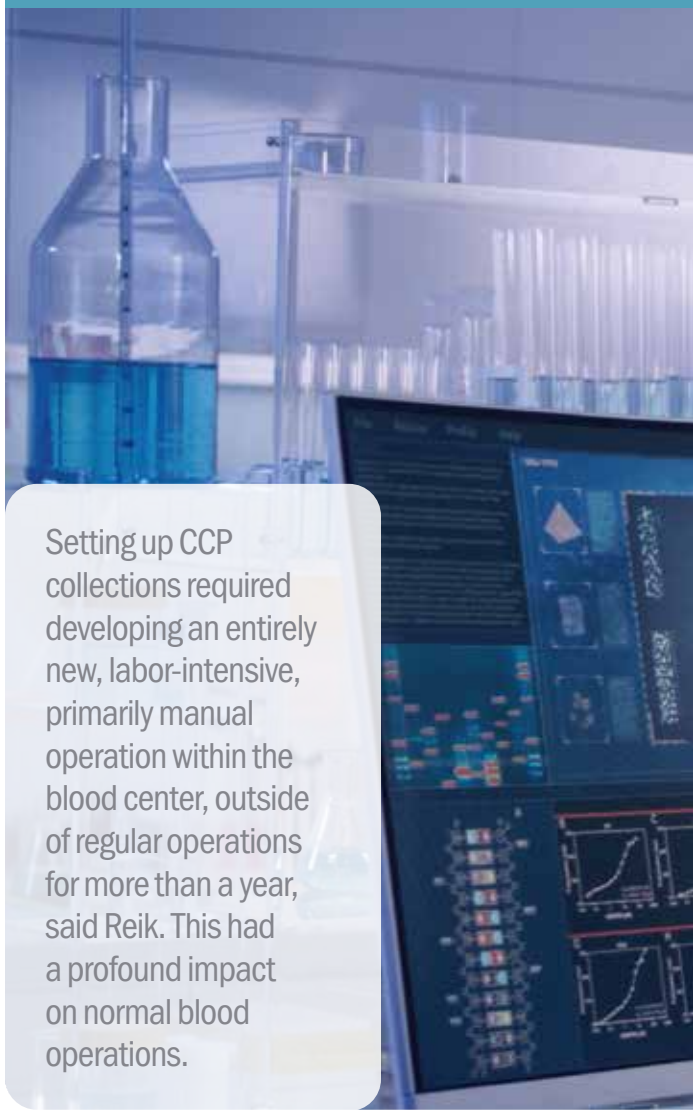
Although interest in CCP emerged in the U.S. in March 2020, said Michael Joyner, MD, a professor of anesthesiology at Mayo Clinic, there was no organized national program to generate donations in a coordinated way. There were "early adopters" of this treatment, such as Houston Methodist and Mt. Sinai in New York, which had local sources via their blood banks — including New York Blood Center, whose staff was responding to unprecedented patient needs. In fact, noted Joyner, an almost gray or black market emerged as families of patients attempted to locate donors for family members.

Beginning to collect CCP was a tremendous ordeal for blood centers, and even making the decision about whether or not to collect it was a challenge.

"As a first step, blood centers had to decide whether they were going to bring up CCP or import it from elsewhere as needed," said Rita Reik, MD, FCAP, chief medical officer of OneBlood. "At the time the Food and Drug Administration authorized the use of CCP in late March 2020, the pandemic was affecting different regions of the country in different ways. Not every blood center decided to move forward with CCP at that time, as some centers' service areas remained relatively unaffected." The New York Blood Center and Bloodworks Northwest were two of the very earliest blood centers to begin collecting CCP in large quantities.

Reik explained that when FDA announced the Expanded Access Protocol (EAP) and Emergency Investigational New Drug (eIND) pathways for collecting CCP in late March, OneBlood decided to move forward as quickly as possible to collect CCP in response to intense demand by the hospitals in its service area.

Reik said that once the decision to collect CCP was made, the blood center had to develop a new process and identify and train staff to perform the collections. "This was the most challenging aspect, as CCP was a novel product with specific donor requirements that it be collected from a person who had recovered from a documented case of COVID-19 within a certain timeframe," she said. "These donor requirements were outside of routine blood center operations." This required OneBlood to develop an entirely different process for collecting CCP. This multi-step process ranged from identifying and recruiting appropriate donors and developing a robust donor database to finding a way to verify SARS-CoV-2 test results that met FDA requirements and reconfiguring collection sites and schedules to accommodate proper social distancing.



Setting up CCP collections required developing an entirely new, labor-intensive, primarily manual operation within the blood center, outside of regular operations for more than a year, said Reik. This had a profound impact on normal blood operations.

As complex as the process was, developing a means to collect CCP was only the starting point. There was also the issue of providing an adequate supply to transfusion services since the demand for CCP varied over time and by region. Reik said that her region in the Southeast U.S. was in an early COVID-19 hotspot, making it difficult for OneBlood to keep up with demand for CCP in the early months of the pandemic.

Setting up CCP collections required developing an entirely new, labor-intensive, primarily manual operation within the blood center, outside of regular

operations for more than a year, said Reik. This had a profound impact on normal blood operations. "Additionally, there were challenges with new testing and supplies that created backlogs and confusion at times," she said. "But perhaps the most impactful facet of CCP collection involved coping with the constantly changing regulations regarding donor screening, product specifications and testing. The whiplash pace at which these changes came precluded hardwiring them into the computer systems on which we rely for high volume production, resulting in a separate, high-maintenance CCP operation at the blood center that stretched resources to the limit. Fortunately, the financial resources needed to make this work were forthcoming. In addition, global donor SARS-CoV-2 antibody screening played an important role in boosting production by expanding the eligible donor database."

Community Collaboration

As the blood community developed protocols for collecting and distributing CCP and learned more about optimal treatment options using CCP, community collaboration was essential. Sharing knowledge and resources became a key factor in developing best practices and expanding the community's collective knowledge about CCP.

"There have been, and continue to be, an incredible array of very smart people working on CCP as a treatment option for COVID-19. They range from lab techs, logistics experts, young physicians and scientists and administrators all the way to senior scientists and well-known medical leaders," Joyner said. "The ability of this group to generate a network out of thin air in a matter of days early in the pandemic and then respond to new challenges has been most remarkable."

To assist the blood community as it expanded its role with CCP, AABB worked with partners across the field to develop resources and foster the spread of information. As an example, AABB began hosting calls with Evan Bloch, MD, MS, associate professor of pathology, associate and director of transfusion medicine at Johns Hopkins University School of Medicine. Bloch led a bi-weekly call with researchers conducting FDA-approved studies on CCP as an investigational treatment. In addition to clinical trials, this collaboration also focused on challenges, operational considerations, safety and clinical outcomes, as well as emerging treatment options. Following Bloch's early success engaging the research community, AABB added a second call for a broader segment of the blood community led by Jed Gorlin, MD, MBA, vice president and medical director of Innovative Blood Resources in St. Paul, Minn., the medical director of the Community Blood Center of Greater Kansas City and the transfusion service medical director at HCMC and Children's Hospitals and Clinics of Minnesota. These weekly calls were open to all in the blood community and designed as a forum to share and discuss research on CCP as pandemic challenges continued to evolve.

"These calls proved that we could collaborate and organize at a national, and, often, at an international, level. The marvelous thing about these calls was the open exchange of information, even before publication — not something that academic centers are, frankly, always open to doing, since their entire existence depends upon a sort of competition that discourages information sharing, at least until publication is secured," Gorlin told *AABB News*. "The calls promoted and facilitated the sharing of submitted research papers, even before their acceptance. The pros of this include the rapid dissemination of the latest knowledge; the risk is that some of what was shared was later not confirmed."

AABB also provided opportunities for the community to hear directly from officials from FDA, particularly Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research (CBER); and Nicole Verdun, MD, director of the Office of Blood Research and Review.

On several occasions, Marks and Verdun participated in AABB-hosted events, answering questions and providing guidance on regulatory issues regarding CCP.

In addition, AABB developed a number of other resources, including a new website — CovidPlasma.org — that offered information for donors, patients and health care providers about CCP; "Hot Topic Discussion" webinars featuring information on the critical research; a "Town Hall" education series that examined vein-to-vein considerations for collection and administration of CCP; and educational videos offering further insight about efficacy and best practices of CCP.

Ensuring the Safety of CCP

Once blood centers decided to collect CCP, they had to make sure the plasma they collected was safe to transfuse. According to Larry Dumont, MBA, PhD, director and senior investigator at the Vitalant Research Institute in Denver, to ensure its safety, CCP was treated exactly the same as all other blood and plasma donations. In addition, all CCP donors needed to meet the current FDA/AABB requirements for allogeneic, volunteer donation as assessed through responses to the standard donor questionnaire and screening tests for the standard panel of infectious diseases. "The processes used to collect CCP were standard, validated processes performed by qualified and trained staff in FDA registered facilities," explained Dumont. "In addition, to protect against viral transmission to staff and the theoretical possibility that virus could be in the plasma, FDA established a minimum wait period following resolution of COVID-19 signs and symptoms prior to donation. Early on, there was also a requirement for a negative RT-PCR nasopharyngeal swab for SARS-CoV-2 prior to donation. The latter has been adjusted over time." All donors were required to be healthy and free of symptoms prior to donation.

To ensure the safety of CCP, added Joyner, "we relied on the superb safety systems and procedures that are baked into the U.S. blood banking system."

The Question of CCP Efficacy

In the beginning, there was little evidence to support the clinical efficacy of CCP. "CCP was collected to support clinical use under FDA approved INDs to accumulate data on the specific safety and efficacy of CCP when used in the targeted populations defined within each IND," Dumont said, noting that efficacy related to dose, timing and patient population remains an active area of research.

It is believed that CCP with higher titer antibodies to SARS-CoV-2 will be more effective in fighting the virus than CCP with lower titers. "First principles in passive antibody therapy suggest that the higher the dose of

neutralizing antibody provided, the more effective is the inactivation and clearance of the virus, thus mitigating disease progression," said Dumont.

Elitza Theel, PhD, D(ABMM), director, Infectious Diseases Serology Laboratory, Mayo Clinic, agreed, adding that the concept behind treatment with convalescent plasma is that passive administration of antibodies from recovered patients, specifically neutralizing antibodies, are able to intercept and inactivate the virus prior to or alongside the development of a natural immune response by the patient. "Simply put," she said, "the higher the antibody level, the higher the probability that they will inactivate more viral particles."

It was a challenge early on to assess COVID-19 antibody titers in donated CCP because there was limited guidance, according to Theel. "The FDA initially indicated that donated plasma should have neutralizing antibodies levels of at least 1:160, but the challenge was that there were no widely available neutralizing antibody tests and there was no standardization between the neutralizing antibody assays that were being developed in the academic or research labs," said Theel. "So, what we did very early on was work with academic

Elitza Theel, PhD, D(ABMM), director, Infectious Diseases Serology Laboratory, Mayo Clinic, agreed, adding that the concept behind treatment with convalescent plasma is that passive administration of antibodies from recovered patients, specifically neutralizing antibodies, are able to intercept and inactivate the virus prior to or alongside the development of a natural immune response by the patient.

collaborators who had developed a neutralization assay, and we identified a minimal threshold on the SARS-CoV-2 IgG ELISA we were using in our clinical laboratory, above which the neutralizing assay had a titer of at least 1:160." She explained that they used that approach at the Mayo Clinic until they validated their own neutralizing antibody test, which was then used to qualify convalescent plasma until the first high-throughput SARS-CoV-2 serologic assay got FDA Emergency Use Authorization (EUA), specifically for the manufacture of COVID-19 convalescent plasma.

Distributing CCP to Patients With COVID-19

What was needed in the early months of the pandemic, according to Joyner, was a coherent way to provide access to CCP across the country outside of trials and a mechanism for collecting information on its use and outcomes. The earliest media reports of compassionate use of CCP occurred in late March 2020, when the first patient was treated at Houston Methodist.[1] FDA began receiving hundreds of compassionate use requests, creating an untenable situation and one in which no safety or efficacy information was being collected. This led to the creation of the EAP, which provided a regulatory pathway for compassionate use of CCP as an investigational therapy to treat patients with severe or life-threatening illness based on the lack of alternative treatments and the expectation that CCP might successfully treat COVID-19.[1]

The Evidence for CCP

Claudia Cohn, MD, PhD, associate professor in the University of Minnesota Medical School's Department of Laboratory Medicine and Pathology and AABB's chief medical officer, noted that most of the randomized controlled trials have not shown CCP as providing a benefit for patients with COVID-19. "However," she stressed, "nearly all of the trials have involved patients who have moderate to severe disease and probably were given CCP once they were in the aviremic phase — that is, when all of the detectable virus was cleared from their system and the damage from the inflammatory response had begun. If there is no virus present, then it makes sense that CCP would not provide any benefit."

Cohn said that some research indicates that clinical benefits of CCP could be maximized based on the stage of disease progression in which the treatment is given. "There is one randomized controlled trial, led by Libster et al.,[2] in which patients were given CCP or saline control as a placebo within 3 days of symptom onset," said Cohn. "These recipients were still at home with very mild symptoms. They hadn't even gone to the emergency department! For those who received CCP, 16% went on to have advanced respiratory disease. This is in comparison to the placebo cohort, in which 31% experience severe respiratory disease. This is the best evidence to date that CCP can provide some benefit if high titer units are given very early after infection. However, there is a caveat. The C3PO trial was testing CCP in the outpatient setting, and it closed early due to futility. The data has not been released so we still don't understand why it was closed early — whether it was due to CCP not showing benefit or some other reason."

Cohn stressed that more research is needed to better understand how CCP could most effectively be used to treat patients. "We need more trials in the outpatient setting with high titer CCP," said Cohn. "The trials need to be large enough to perform subgroup analyses to understand patients with comorbidities such as diabetes or other conditions so CCP can be used in patients who will benefit the most."

Endnotes:

1 Joyner, M and Casadevall, A. For early testing of convalescent plasma, we were 'building the plane while we were flying it.' *STAT*. Accessed 4.19.21. https://www.statnews.com/2021/03/04/for-early-testing-of-convalescent-plasma-we-were-building-the-plane-while-we-were-flying-it/

2 Libster, R, Gonzalo Pérez, M, Wappner, D, et al. Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults. *N Engl J Med*. 2021; 384:610-18. DOI: 10.1056/NEJMoa2033700.

Social Media is Changing How Transfusion Medicine Professionals Connect and Learn

By Marian Mostovy
Contributing Writer

Social media had been taking root in the transfusion medicine community for several years when the COVID-19 pandemic swept through the world, leading physicians and laboratory scientists to tap into apps even more for educational exchanges, networking and building a sense of community.

Twitter appears to be the favored app among transfusion medicine professionals, with its social media champions citing its ability to transcend time, geography and hierarchies. The platform is free and versatile. Tweets must be short — 280 characters max — but can be made longer by linking them together through a "thread." Users can include images, GIFs, videos, polls and links to the publications or studies they are interested in sharing with their followers. Tweets can reach a broader community by the use of hashtags. And anyone with a smartphone can access it 24/7, from anywhere in the world.

One of the earliest appearances of Twitter and similar apps for the transfusion medicine and biotherapies community was at conferences. Justin Kreuter, MD, transfusion medicine physician at Mayo Clinic, began tweeting at professional conferences in 2015, sharing major points about presentations. He has since expanded his use of social media, which allows him to "maintain that annual conference experience, where you can be chatting with colleagues in the hallway throughout the year."

In the past few years, individual Twitter "champions" have taken to creating blood-related content, and AABB has made inroads into developing a social media community. "AABB has embraced social media to help drive the development of an online community and increase educational opportunities for members and nonmembers. It's a warm and vibrant community," said Daniela Hermelin, MD, medical director of Transfusion Services at SSM Health St. Louis University Hospital.

Twitter serves as a teaching tool in a variety of formats. Among AABB's initiatives are programmed Twitter chats and a virtual journal club. Other content creators post presentations, or tweetorials, related to transfusion medicine topics — often tagged #blooducation. "Someone might tweet a case from the past that's scrubbed for patient-specific information to showcase how to deal with issues, such as massive transfusion or how to use your inventory wisely during COVID-related shortages," said Kreuter.

Shorter Twitter exchanges can also be edifying. Phil Accooe, MLS(ASCP)CM, SBBCM, CLS, transfusion service laboratory supervisor at the VA, Long Beach, Calif. and a member of the AABB Board of Directors,

uses Twitter to find or post blood-related information and seek input from peers — for example, on getting buy-in from the entire facility for a new transfusion committee. "I've reached out for feedback from others regarding how they handle issues within their respective facilities. Twitter is particularly useful because there's a really quick exchange of information," he said.

> "AABB has embraced social media to help drive the development of an online community and increase educational opportunities for members and nonmembers."
> *-Daniela Hermelin, MD*

For some, Twitter provides an ideal platform for advocacy. "At any one institution, we in transfusion medicine are generally a small cohort, but nationally we're mighty," said Kreuter.

Nour Hisham AL-Mozain, MD, consultant in hematopathology and transfusion medicine at King Saud University Medical City, Riyadh, Saudi Arabia, added, "It all began for me when I thought Twitter might be an effective platform to advocate for the transfusion medicine specialty to educate doctors from other specialties, including clinical hematologists/oncologists, surgeons, obstetricians and gynecologists, about how to choose wisely and share recent updates in the field. They get to know the specialty within your facility and worldwide. It's invaluable, and it wouldn't happen without social media."

Expanding importance during pandemic

The pandemic gave rise to transfusion medicine professionals using Twitter to conduct urgent clinical dialogues about the COVID-19 virus and for emotional support during the turmoil it created.

"Social media use increased because, as a society, we were all in physical or emotional isolation. We turned to social media, even more, as a way to support each other," Hermelin said. "At this crucial time, the blood banking community was focused on implementing and gathering knowledge on the topic of convalescent plasma, because it was one possible therapeutic modality we could begin to access. Social media continued to be a comfortable space for us to communicate in real-time."

Working in hospitals has been especially stressful during the pandemic. "There's a lot of social isolation. We struggle with challenging decisions and moral distress," said Kreuter. "We weather it on our own, but social media is a way to relax with our community, to talk about or at least share some of our softer side. It's a nice way to decompress."

Social media has become a hub to inspire and obtain new insights on medical education, and learn from different international practices. When the pandemic prevented AL-Mozain from doing a transfusion fellowship in the United Kingdom to gain the international experience she needed for a promotion, she got the experience via social media. "I got insight into the international experience and invaluable connections and mentorship — not just to the U.K., but worldwide."

It's clear social media will continue to inspire new ways of learning and growing professionally in the transfusion medicine field. "In-person contact is often preferred, but for efficiency's sake, social media is a great tool that is underutilized," said Accooe. "We're already seeing some, but it's going to be relied upon a lot more."

Dana Powell Baker, MLS(ASCP)CM, assistant professor of clinical laboratory sciences at The University of Kansas Medical Center, sees social media being used more to promote the medical laboratory profession and to meet the needs of learners in formal medical education. "Social media will definitely expand because ingenuity has come into play," said Baker. "For example, this pandemic has impacted students getting into clinical practicum sites completing a full residency experience. How can we supplement those educational experiences using social media? I've seen other institutions accomplish this successfully — like pathology programs that are doing grand rounds on Twitter."

Aaron Shmookler, MD, assistant professor of pathology, anatomy and laboratory medicine, West Virginia University School of Medicine, believes social media will become an integral part of continuing medical education and accreditation, and academic promotions will pivot on social media activity, just as they now do on publishing. "More and more of us will have a digital professional identity and look to social media to for updates on different aspects of the sciences."

Shmookler also envisions changes to academic publishing itself. "Now, you submit a paper and it's peer reviewed. Social media offers a novel platform for developing creative research ideas and establishing new collaborations between colleagues, so more contributions to the literature will have peer input before they are submitted."

Meanwhile, Hermelin hopes more people will see the benefits of social media. "If you want to stay on the pulse of academic medicine or the field you're in and connect to the people who want to grow educationally and build a community, you want to be on Twitter." ■

EAP Investigators Release Summary Of Patient Characteristics

By Drew Case
Senior Communications Manager

The Expanded Access Program (EAP) for COVID-19 convalescent plasma (CCP) led by Mayo Clinic enrolled 105,717 hospitalized patients with severe or life-threatening COVID-19 between April 3 and Aug. 23, 2020, according to a summary of demographic and clinical patient characteristics published Sunday on the pre-print server *medRxiv*.

Among all patients in the EAP, 57.8% were older than 60 years of age, 58.4% were male and 83.8% were overweight or obese. A total of 61.8% of enrolled patients had severe or life-threatening COVID-19, and 18.9% of patients were mechanically ventilated at the time of CCP infusion. Notably, the EAP included a substantial percentage of minority and underserved populations: 46.4% of patients were of a race other than white and 37.2% of patients were Hispanic. In addition, data showed that, chronologically and geographically, increases in EAP enrollment closely followed confirmed infection rates across all 50 states. Nearly all national hospital referral regions enrolled patients in the EAP.

According to investigators, the EAP's study design may serve as an example framework for future efforts when broad access to treatment is needed in response to a disease affecting demographic groups and areas that have historically been underrepresented in clinical studies.

mRNA COVID-19 Vaccines Effective Under Real-World Conditions

Findings from a prospective cohort study of health care personnel, first responders and other essential and frontline workers confirmed that authorized messenger RNA (mRNA) COVID-19 vaccines from Pfizer-BioNTech and Moderna are highly effective in real-world conditions. The prospective cohort included 3,950 essential and frontline workers from eight different locations who completed weekly SARS-CoV-2 testing for 13 consecutive weeks. Investigators published their findings in *Morbidity and Mortality Weekly Report*.

Vaccine effectiveness of full immunization with two doses of mRNA vaccines was 90% against reverse transcription polymerase chain reaction (RT-PCR)-confirmed SARS-CoV-2 infection, whereas partial immunization (greater than 14 days after the first dose but before the second dose) provided preventive benefits with vaccine effectiveness of 80%.

According to the authors, these findings are consistent with clinical trials and recent observational studies of the mRNA vaccine effectiveness against severe COVID-19. They also stated that the findings "complement and expand upon these preceding reports by demonstrating that the vaccines can also reduce the risk for infection regardless of COVID-19-associated illness symptom status." The authors concluded that the findings reinforce the Centers for Disease Control and Prevention's recommendation of full 2-dose immunization with mRNA vaccines.

Treatment With Hyperimmune Globulin May Not Reduce Risk of COVID-19 Disease Progression

Treatment with anti-coronavirus hyperimmune intravenous immunoglobulin (CoVIg-19) did not reduce the risk of progression to severe COVID-19 when added to standard care including remdesivir, according to findings from the phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin clinical trial. Representatives from the CoVIg-19 Plasma Alliance, which formed in April 2020 to help develop CoVIg-19 as a potential therapy for COVID-19, announced recently that the trial did not meet its endpoints to show efficacy in adults hospitalized with COVID-19.

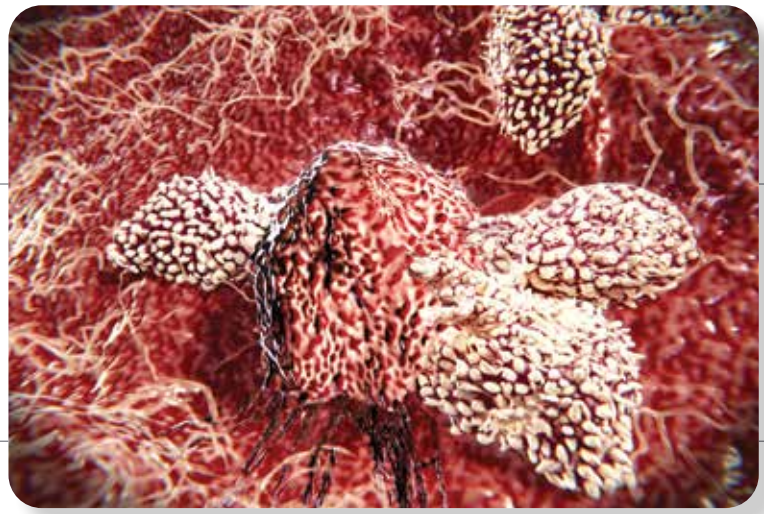
CoVIg-19 is manufactured from COVID-19 convalescent plasma (CCP) and contains a highly concentrated solution of antibodies intended to neutralize SARS-CoV-2. Investigators randomized 600 adult patients at 63 sites in the United States and 10 other countries to receive either CoVIg-19 plus standard care or placebo plus standard care. Patients were eligible for the trial if they had been hospitalized for COVID-19 and had symptoms for 12 days or less without life-threatening organ dysfunction or end-organ failure.

In light of these findings, co-leader of the CoVIg-19 Alliance Bill Mezzanotte, MD, MPH, executive vice president, head of Research and Development and chief medical officer at CSL Behring, announced that the work of the CoVIg-19 Plasma Alliance will conclude.

"While the results of this particular clinical trial are disappointing, we are proud that as an industry we proactively and collaboratively pursued this work, and that the program may contribute to a growing understanding of this challenging virus and strategies for patient care," Mezzanotte said.

In response to the findings, AABB's Chief Medical Officer Claudia S. Cohn, MD, PhD, noted that many factors — including the timing of administration — may affect the clinical benefit of CoVIg-19. "The results of this trial are certainly disappointing," Cohn said. "While I thought that the greater dose of anti-SARS-CoV-2 antibody would show benefit for COVID patients, it is possible that the CoVIg-19 was administered too late in disease. Of course, many other factors may be involved.

"Passive immune therapies such as CoVIg-19 and CCP have not shown significant benefit for COVID patients with the notable exception of the Argentine trial, in which patients were treated with CCP very early in disease. We must wait for the results of the trial testing CCP in outpatients that is being led by David Sullivan, MD, of Johns Hopkins to see if the findings from Argentina can be confirmed."



CD8+ T Cells May Boost Immunity to SARS-CoV-2 Variants

CD8+ T-cell response in individuals who have recovered from COVID-19, and most likely in those who receive COVID-19 vaccines, are largely unaffected by mutations in the spike protein found in COVID-19 variants, according to findings published recently in Open Forum Infectious Diseases.

In this study, investigators from the National Institute of Allergy and Infectious Diseases (NIAID), Johns Hopkins University and ImmunoScape analyzed blood cell samples from 30 people who had contracted and recovered from COVID-19 prior to the emergence of virus variants. The researchers determined that SARS-CoV-2-specific CD8+ T-cell responses remain largely intact after SARS-CoV-2 infection and recognized virtually all mutations in three COVID-19 variants: B117, first detected in the United Kingdom; B1351, found in South Africa; and B11248, first seen in Brazil.

According to investigators, the findings suggest that these CD8+ T-cells may offer protection against emerging COVID-19 variants. However, they noted that larger studies are needed to monitor the breadth, magnitude and durability of the anti-SARS-CoV-2 T-cell responses in recovered and vaccinated individuals to determine if booster vaccinations are needed. ■

PEP Volunteer Spotlight

Kyle Annen

Medical Director of Transfusion Services and Patient Blood Management at Children's Hospital Colorado, and Associate Professor of Pathology at the University of Colorado-School of Medicine

How long have you been an AABB member?

I joined in 2010 when I was a senior resident in clinical pathology.

In which AABB volunteer activities are you currently active? In which have you participated?

I have been both mentee and mentor for PEP, and both experiences have been great — it has opened so many opportunities for collaboration. My mentor has become one of my dearest friends, and I learned from my mentee — and I hope he benefitted as much from me! I am also on the Pediatric Transfusion Medicine Sub-committee: because the pediatric world is so small (pun intended) and there isn't as much literature available, is it so helpful to have colleagues from all over to reach out to for practice standards. Most recently, I have been part of the Convalescent Plasma Forum, where I was asked to give a talk on shipping COVID-19 convalescent plasma (CCP) over state lines for facilities that hadn't done it before. My hospital was one of the first CCP collectors (we were 3rd in the U.S.), and we figured out shipping issues early on when there was greater need for CCP out of state than in Colorado.

What motivates you to volunteer?

Being a part of the AABB community, developing relationships and knowing that someone is benefitting from what I have to offer.

How has your volunteer work affected your professional work?

I think a lot of practical solutions for everyday issues aren't published, and volunteering has given me the chance to learn them. And the relationships — especially from the Professional Engagement Program — have had a huge impact. It is safe to say I wouldn't be in my current role without PEP.

What have you learned from volunteering with AABB? What advice would you give to someone who is thinking of volunteering?

I have learned that when I have a problem and I am trying to figure out what to do, there probably isn't a straightforward solution. Volunteering has given me perspective on how others are tackling similar issues. I would absolutely tell anyone to volunteer with AABB, it is such a great way to connect, and you can join any sub-committee you are interested in whenever you want, so that is a great place to start.

What do you like to do in your free time?

Pre-COVID, I loved to travel and would take any opportunity to play dress up along the way — I dressed as a Geisha in Kyoto, Japan, and brought a full Elsa costume up to the Arctic Circle in Sweden to take some very chilly pictures in the Ice Hotel. If AABB is in-person in Anaheim this year, you will find me afterwards dressed as Captain Marvel or Casual Elsa (a la Wreck-it Ralph 2) at Disneyland. ■

PEP Mentoring Program Accepting Mentor, Mentee Applications

AABB's Professional Engagement Program (PEP) team has openings in its mentoring program for both mentors and mentees. The informal, 6-month program provides a fun way for AABB members to share their expertise, expand their professional network and participate in an exchange of ideas. The program pairs experienced AABB members with colleagues who have worked in blood banking, transfusion medicine or biotherapies for less than 5 years. Mentors and mentees communicate by phone at least once per month. Those interested in participating can complete an online application. A link to the application and additional information on the program are available on the AABB website under Get Involved > Volunteer > Mentoring Program.

Effective Communication Among All Stakeholders Is Key to Keeping Updated and Connected During Pandemic

Hua Shan, MD, PhD

A critical task in the beginning of the COVID-19 pandemic was to conduct a timely assessment of the virus's potential to threaten blood safety. This assessment was possible because NHLBI has been building an international collaborative investigational mechanism for monitoring and evaluating microbial threats to blood safety.

Hua Shan, MD, PhD, is a professor of pathology and the medical director of the Transfusion Medicine Service at Stanford Healthcare. She has been in academic transfusion medicine for over 25 years following completion of her residency and fellowship training at the University of Pennsylvania. Shan served as the assistant medical director of the blood bank at Medical University of South Carolina before becoming an associate medical director of the transfusion service at Johns Hopkins Medical Center in 1998. While at Johns Hopkins University, Shan first led a program on international blood safety education and research funded by the National Institutes of Health Fogarty Program. Subsequently, she and her team successfully won a research contract from the National Heart, Lung, and Blood Institute to become a part of the REDS-II then REDS-III Program. As part of these programs,

Timely communication with patients, blood ordering physicians, blood donors and the community at large is key, especially when dealing with confusion and unpredictability.

Shan and her team worked with investigators at Chinese Academy of Medical Sciences on various research and education projects including studying residual risk and donor risk factors for transfusion transmitted infections, blood utilization in Chinese hospitals and evaluating new emerging infectious agents.

Shan has been an active AABB member, previously serving on the Transfusion Transmitted Disease Committee and currently serving on the Clinical Transfusion Medicine Committee. In addition, she is a current member of the ISBT's Workgroup on Transfusion Transmitted Infectious Disease and is a member of the editorial board of *Transfusion* and *Transfusion Medicine Review*. In 2018 Shan co-edited a book titled "Blood Safety: A Guide to Monitoring and Responding to Potential New Threats."

AABB NEWS: **WHAT INFLUENCED YOU TO PURSUE A CAREER IN PATHOLOGY AND TRANSFUSION?**

Shan: After medical school, I pursued a PhD in immunology at the University of Pennsylvania. There, I interacted with several outstanding transfusion medicine practitioners who also conducted immunological research. Their examples of combining clinical work with research and the synergy between immunology and principles of transfusion medicine attracted me to this field.

AABB NEWS: **HOW HAS THE COVID-19 PANDEMIC AFFECTED YOUR WORK?**

Shan: Social distancing necessitated the use of remote communication to manage a clinical service, which poses some challenges. Cancellation of work travel has given me more time to spend with my family. I miss seeing my colleagues and friends at meetings!

AABB NEWS: **WHAT ARE SOME OF THE MOST SIGNIFICANT WAYS IN WHICH THE BLOOD COMMUNITY HAS HAD TO MAKE ADJUSTMENTS IN RESPONSE TO THE COVID-19 PANDEMIC?**

Shan: Early in the pandemic, there were a lot of uncertainties about COVID-19. A critical task was to conduct timely assessment regarding COVID-19's potential threat to blood safety. Fortunately, over the past 30 years, NHLBI has been building an international collaborative investigational mechanism for monitoring and evaluating microbial threats to blood safety. Foundations from this kind of collaboration made it possible for our community to arrive at a timely science-based assessment. Many practical aspects of transfusion practice depend on the result of this assessment.

AABB NEWS: **WHAT LESSONS HAVE WE LEARNED AS A RESULT OF THE PANDEMIC THAT COULD INFORM FUTURE PRACTICE?**

Shan: Two things:
International collaborative research benefits our global community's readiness when dealing with emerging threats.
Timely communication with patients, blood ordering physicians, blood donors and the community at large is key, especially when dealing with confusion and unpredictability.

AABB NEWS: **WHAT IN YOUR PAST TRAINING HELPED PREPARE YOU FOR THE CURRENT PANDEMIC?**

Shan: I was very fortunate to have served as the principal investigator of NHLBI's REDS-II and REDS-III International China Program. The experience, knowledge and connections from that role have been valuable to keep me updated and connected during this difficult time. The experiences also helped me to continue collaborating with colleagues on both blood safety and availability work, as well as exploring the therapeutic use of COVID-19 convalescent plasma.

AABB NEWS: **WHAT HAS BEEN THE BIGGEST TRIUMPH OF YOUR CAREER?**

Shan: The most rewarding aspect of my career so far has been the opportunity to work together with many talented and supportive mentors and colleagues.

AABB NEWS: **WHAT ARE SOME LEISURE ACTIVITIES THAT YOU ENJOY PURSUING?**

Shan: I enjoy being outdoors. Since moving to the Bay Area, I have been exploring hiking on the beaches and in the Sierra Nevada mountains. ■

Aetna Recognizes AABB Accreditation for Facilities That Perform BMT

As a result of AABB's advocacy efforts in 2020, AABB accreditation is now recognized in Aetna's Institutes of Excellence policy for facilities that perform bone marrow transplants (BMT). The program criteria in the policy now include AABB accreditation and state that, "all bone marrow transplant (BMT) centers must be fully accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) and/or by AABB and be a National Marrow Donor Program transplant center." The policy is available to the public and located on Aetna's website, under "program criteria for transplant support."

Arthur Bracey Elected Chair of Harris Health System Board of Trustees

The Harris Health System Board of Trustees has elected Arthur Bracey, MD, a professor of pathology and immunology at Baylor College of Medicine and chief of clinical pathology at CHI Baylor St. Luke's Medical Center, as the governing body's next chair. As board chair, Bracey will collaborate with Harris Health System's CEO and board of trustees to implement a newly adopted 2021-2025 strategic plan for the system, which serves Houston, Texas and surrounding areas.

A longtime AABB member, Bracey has served on the AABB Board of Directors, on the editorial board of *Transfusion* and as chair of the AABB Annual Meeting Education Program Unit. He has also been active within the American Red Cross, the College of American Pathologists, the National Marrow Donor Program and the Society for the Advancement of Blood Management. In addition, Bracey is a former chair of the Advisory Committee on Blood Safety and Availability, which advises the secretary of Health and Human Services on policy issues related to blood, blood products and tissues.

AABB Releases New Educational Videos on CCP

To help health care professionals better understand the appropriate use and efficacy of COVID-19 convalescent plasma (CCP) as a treatment option for patients with COVID-19, AABB convened a panel of experts in the field to review the science and generate evidence-based interim recommendations. The recommendations were released in February and are consistent with the FDA's guidance to administer only high-titer units of CCP early in the course of the disease.

In April, AABB released two new videos, titled "Convalescent Plasma: Recommendations for Physicians Treating Patients With COVID-19," to accompany the recent recommendations. The videos are designed to provide further insight to clinicians across various subspecialties about the effective and appropriate use of CCP, as well as about the evolving state of research on this critical topic. AABB's Chief Medical Officer Claudia S. Cohn, MD, PhD, moderates the videos, which were developed by AABB with support from a grant from The Fight is in Us Coalition. "This program is intended to help physicians identify the subset of COVID-19 patients who are most likely to benefit from treatment with CCP," Cohn said.

In the first video, "Overview and Safety," Shmuel Shoham, MD, associate professor of medicine at Johns Hopkins University School of Medicine, provides an overview of CCP and outlines safety considerations. The second video, "CCP Efficacy: Timing and Titer," featuring Christian Merlo, MD, MPH, associate professor of medicine and epidemiology at Johns Hopkins University School of Medicine, provides information on the efficacy of CCP, with an emphasis on early administration of high-titer units.

CALENDAR

May

5 Immunohematology Boot Camp: HTLA (21EL-632)
AABB eCast

13 Ethical Issues in Transfusion Medicine and Blood Banking (21EL-636)
AABB eCast

June

2 Donor Hemovigilance During the COVID-19 Pandemic (21EL-642)
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)
AABB eCast

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