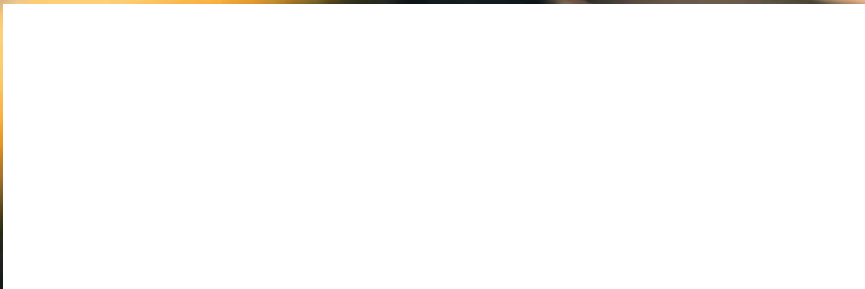


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A New Era of Blood Donor Eligibility





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Moving Toward Individual Donor Assessments

For the past few years, there has been an ongoing conversation in our community about transitioning to an individual donor assessment approach to determine blood donor eligibility.

This monumental change for our field is now closer than ever, following FDA's January 2023 draft guidance recommending the elimination of time-based deferrals related to sexual orientation and the implementation of an individual donor assessment approach.

This issue of *AABB News* focuses on the timely issue of changes in blood donor eligibility. Our first feature explores the nuances and history of individual donor assessment and what blood collectors can expect in the near future. An accompanying article also highlights the growing number of countries that have changed donor assessment screening protocols in recent years. Another feature article provides insight from AABB institutional members about preparations to implement the FDA eligibility changes.

In This Together

As blood collection centers throughout the nation anticipate the forthcoming final FDA guidance, the community is preparing for the implementation process. Although this is an exciting time in the blood community, AABB understands that this historic transition represents a big lift for blood collection facilities and their staff.

AABB is here to help with these challenges. Your Association is



Brian Gannon, BA,
MBA

committed to providing blood collection centers with resources and support to ensure a successful transition. Throughout the coming weeks and months, AABB will be rolling out a wide variety of resources to assist with implementation, including a dedicated web page, educational materials, interactive training opportunities, an updated donor health history questionnaire and much more. Please visit aabb.org/ida to find a library of resources to assist you.

AABB is here for you. As always, I am confident that if we work together as a community, we can overcome the challenges and will successfully usher in a new era for our field. ■

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AABB President

President

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Donate to the AABB Foundation today and join us in supporting the future of patient and donor care.

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The Power of Mentorship: Paying it Forward

By Kendra Y. Applewhite, MFA
Managing Editor

In celebration of Global Pay It Forward Day on April 28, the AABB Foundation is excited to highlight mentorship within the AABB community throughout the month of April. Mentors play an important role in our community and help to ensure the next generation of leaders in blood and biotherapies are prepared for challenges and are well-suited to continue to advance the field.

The AABB Professional Engagement Program (PEP) mentoring program pairs experienced AABB members with colleagues who have worked in blood banking, transfusion medicine or biotherapies for less than five years. The six-month informal program provides a way for experienced AABB members to share their expertise, expand their professional network and engage in an exchange of ideas with early-career AABB members.

The following mentor-mentee pairs share their mentorship experience and discuss the PEP mentoring program's impact on their professional growth.

GIVING BACK

Donate to the AABB Foundation in honor of a mentor who positively impacted your life professionally or personally. Visit <https://www.aabb.org/foundation> today to support the AABB Foundation and pay it forward.





HELPING THE NEXT GENERATION OF SCIENTISTS

Meet Mentor: Vasiliki E. Kalodimou, BSc (Hons), MSc, PhD, CABP(H)

Vasiliki Kalodimou, BSc (Hons), MSc, PhD, CABP(H), is an assistant professor of histology in the School of Medicine at the European University-Cyprus Ltd. Frankfurt Branch; the director at the Flow Cytometry-Research and Regenerative Medicine Department of IASO Maternity-Pediatric and Research Hospital in Athens, Greece; and the cord blood bank director and processing facility director at MedStem-Cryobanks of IASO. She joined AABB in 2008. Her first volunteer experience was as an AABB assessor, followed by committee membership. Eventually, she became a mentor herself and was elected to the AABB Standards Committee.

AABB NEWS: WHY DID YOU WANT TO BECOME A MENTOR?

KALODIMOU: I've been an AABB member since 2008. As the years passed, I became more involved with many AABB activities, such as subsections and assessor teams. When the opportunity to become a mentor through the PEP mentoring program became available, I was thrilled. I thought this would be a perfect fit for me to help young scientists who had just started their career in biotherapies and share knowledge I had gained all these years while working in the field. In addition, I could be there to support, encourage and enable their professional development—something I did not have when I started my career.

AABB NEWS: CAN YOU SHARE THE MENTORSHIP GOALS YOU AND YOUR MENTEE DEVELOPED FOR THE PROGRAM?

KALODIMOU: I've been a mentor since 2017. First, I listen to my mentees' needs and what they want to gain from the program, then we set the goals. Every mentee has different goals and needs, so my role is to help them achieve as much as we can until the end of the mentoring program.

With my current mentee, we set goals to help him better understand the biotherapies field and the possible applications and accreditation needs when it comes to starting a new company in the field, and to get him more involved with AABB activities.

Most of the time I'm working and helping my mentees even after we have finished the program. I try to be there for them when they need my advice. For me, mentorship is a long-lasting relationship, and I can say that I have gained wonderful colleagues/friends throughout the world.

AABB NEWS: YOUR RESEARCH INTERESTS INCLUDE MOLECULAR GENETICS, IMMUNOLOGY AND STEM CELLS. HOW DID YOUR CLINICAL EXPERIENCE AND

PROFESSIONAL BACKGROUND IN REGENERATIVE MEDICINE HELP TO GUIDE AND SUPPORT YOUR MENTEE THROUGHOUT THE PROGRAM?

KALODIMOU: My background and experience gained over the years helps me guide my mentees to avoid mistakes I've made because I did not have any guidance or mentors. I let them see what it takes to be a researcher in the biotherapies field by sharing my experience, and I also help them gain more connections and understand the cellular therapy standards.

For example, my previous mentee was interested in my research, and when COVID-19 started, she asked if we could collaborate to help patients in her country using my current research protocols in stem cells in combination with hers. We did it, and we managed to publish two articles. We also presented our data at two conferences.

As mentors, we need to keep in mind that we need to be there for our mentees, help them, listen to them and make it easy for them because they will be the ones that will continue working in the field. If they have a positive mentoring experience, they will help the next generation of scientists and so on.

AABB NEWS: WHAT DID YOU ENJOY MOST AS A MENTOR?

KALODIMOU: Helping and sharing my experience in the biotherapies field, especially in flow cytometry, stem cells and regenerative medicine applications, and finding ways to inspire mentees about the biotherapies field to give/find opportunities for developmental experiences for my mentees.

Mentoring helps me develop coaching, leadership and community skills and expand my professional network. It also gives me the opportunity to collaborate, help and exchange ideas with scientists from all over the world. Mentoring is a win-win situation. I want to thank AABB and PEP mentoring program for this opportunity.



LEARNING FROM THE EXPERTS

Meet Mentee: Mana Alshehri, PhD, MSc, CABP

Mana Alshehri, PhD, MSc, CABP, is a research fellow at the Connell and O'Reilly Families Cell Manipulation Core Facility at the Dana-Farber Cancer Institute, Harvard University; and a research scientist at King Abdullah International Medical Research Center in Riyadh, Saudi Arabia. Alshehri holds a PhD in cancer biology from the University of Calgary in Canada and completed the high-impact cancer research program at Harvard University. He has won several scientific awards from different international institutions, including the Arnie Charbonneau Cancer Institute, Canadian Institute of Health Research, Dubai Harvard Foundation for Medical Research and Middle East Molecular Biology Society.

AABB NEWS: WHAT INSPIRED YOU TO PARTICIPATE IN THE MENTORSHIP PROGRAM?

ALSHEHRI: As an early-career scientist in biotherapies, I always look for opportunities to gain more experience, skills, networking and professional growth. After reading about the AABB PEP mentoring program, I found it was a perfect program to expand my knowledge, expertise and networking in biotherapies by interacting with experienced AABB members who have a strong and wide experience in biotherapies, blood banking and transfusion medicine.

AABB NEWS: CAN YOU TELL US ABOUT YOUR MENTORSHIP EXPERIENCE? WHAT MENTORSHIP GOALS DID YOU SET OUT TO ACHIEVE?

ALSHEHRI: So far, it has been a great experience to work with Dr. Vasiliki E. Kalodimou and learn from her a lot of leadership skills, particularly in establishing and supervising cord blood banks, how to solve all difficulties during the journey of establishing cord blood banks, and the potential of using them as viable resources for developing a wide range of cellular therapies that can be used to treat a variety of patients with diseases, including different types of cancer and genetic diseases.

AABB NEWS: WHAT WAS YOUR BIGGEST TAKEAWAY?

ALSHEHRI: Participating in the PEP mentoring program offers me several valuable benefits, but the major takeaway is the opportunity to gain guidance and insight from an expert in the field of biotherapies. These insights are very helpful in building professional skills and expanding networking that provide mentees access to new opportunities and resources.

AABB NEWS: WHAT ARE YOUR CAREER GOALS? HOW WILL THIS MENTORSHIP EXPERIENCE AND LESSONS LEARNED FROM YOUR MENTOR HELP YOU ADVANCE AS A RESEARCH SCIENTIST AND BIOTHERAPIES PROFESSIONAL?

ALSHEHRI: One of my main career goals is to contribute to advancing the biotherapies field in my country Saudi Arabia and the whole Middle East region by transferring knowledge, implementing quality measures and working with the experts in the region to establish more cord blood banks, cellular therapy centers and regenerative medicine programs to help in treating a wide range of patients. During the PEP mentoring program, Dr. Kalodimou shared her experience in establishing and directing cord blood banks and flow cytometry facilities and the quality and operational standards that should be considered to establish and operate such new facilities.

AABB NEWS: WHAT WAS YOUR FAVORITE ASPECT OF THE PROGRAM?

ALSHEHRI: One of my main favorite aspects of the program is the flexibility and informal nature of the meeting and discussion. During the meetings, we discussed lots of topics, including science, new and exciting biotherapies products in the market, leadership skills and others. I would like to express my gratitude to Dr. Kalodimou for the insight and expertise she shared with me during the past six months. Thank you, Dr. Kalodimou.



MAKING A POSITIVE IMPACT

Meet Mentor: Arwa Z. Al-Riyami, MD, FRCPc

Arwa Z. Al-Riyami, MD, BSc, FRCPc, is a senior consultant hematopathologist working at the Sultan Qaboos University Hospital (SQUH) in Muscat, the Sultanate of Oman. She joined AABB in 2012 and has been to every AABB Annual Meeting since. In this time, she has volunteered as an assessor and in the Professional Engagement Mentorship Program. She is a member in both the Transfusion Medicine and Cellular Therapies sections and a member of the AABB Cellular Therapies Section Coordinating Committee. She has also served as a member of the AABB Global Transfusion Forum Steering Committee, which addresses how to improve transfusion on a global scale. She is an AABB ambassador and was involved in the regional committee that organized the 2019 annual meeting highlights conference in the Middle East.

AABB NEWS: WHY DID YOU WANT TO BECOME A MENTOR?

AL-RIYAMI: Becoming a mentor has been one of my most rewarding experiences! Not only does it provide the opportunity to positively impact someone's life, but it also allows me to share my knowledge and expertise in a meaningful way.

As a mentor, I have the opportunity to share my experiences with others and provide feedback, advice and encouragement. I also get the opportunity to guide, empower and motivate my mentee to reach their full potential. It can help them develop new skills, gain confidence and overcome challenges they may face along the way.

But it's not just about what you can give as a mentor. It's also about what you can gain. Mentoring can be an incredibly enriching experience, as you learn from your mentee and gain new perspectives in the world. I have been a PEP mentor since 2018, during which I mentored eight mentees from different countries. I learned from every mentee I encountered! Mentorship is a two-way street, and you can also learn a lot from your mentee in the process, including developing new skills and insights yourself.

AABB NEWS: CAN YOU EXPLAIN WHAT YOU AND YOUR MENTEE FOCUSED ON DURING THE MENTORSHIP PROGRAM?

AL-RIYAMI: During my mentoring session, I had the pleasure of working with a transfusion medicine fellow who was eager to learn about career preparedness and professional development. Together, we explored the various opportunities available through AABB for individuals at the early stages of their career, such as volunteering for committees and becoming an AABB assessor.

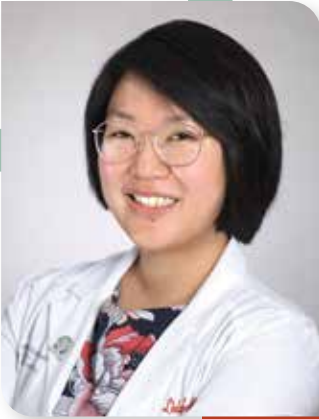
In addition to discussing these opportunities, we also talked about the significance of creating a personal presence on professional social media accounts and building networks. Through our conversation, we were able to provide valuable insights and strategies that hopefully will help my mentee succeed in their career path. We also discussed the latest updates presented in the 2022 Virtual AABB Annual Meeting in transfusion medicine and biotherapies.

AABB NEWS: HOW DID YOUR PROFESSIONAL BACKGROUND IN HEMATOLOGY HELP YOU IN YOUR ROLE AS A MENTOR?

AL-RIYAMI: My qualifications in both transfusion medicine and cellular therapy made me a good fit for my mentee's needs in this mentorship program. Additionally, I have four years of experience as a program director for one of the residency programs in Oman, which has helped me develop important mentorship skills, such as reflecting on my own career experiences, applying the lessons learned from them, practicing active listening and building trust and rapport with my mentees.

AABB NEWS: WHAT WAS THE BEST PART ABOUT HAVING A MENTEE?

AL-RIYAMI: As a mentor, you can make a difference and help someone reach their goals. It's an exciting opportunity to share knowledge, inspire others and make a positive impact!



GETTING PLUGGED IN

Meet Mentee: Linda Song, MD, MSPH

Linda Song, MD, MSPH, is a clinical fellow ('22-'24) at the National Institutes of Health's department of transfusion medicine and Center for Cellular Engineering. She completed her residency training at the University of Maryland Medical Center in Baltimore, Md., during which she served as chief resident. She is board-certified in anatomic and clinical pathology, soon-to-be board eligible for transfusion medicine and a member of the Gold Humanism Honor Society. Although she still considers herself a bit of a 'pluripotent stem cell' when it comes to professional interests in transfusion medicine, she says she has always had a passion for medical education, professional ambassadorship and systems/operations improvement.

AABB NEWS: WHAT INSPIRED YOU TO PARTICIPATE IN THE MENTORSHIP PROGRAM?

SONG: There are many reasons I was excited to participate in the AABB PEP mentorship program. I wanted to get more experience in transfusion medicine matters from outside of the institutions where I have trained and am currently training. Secondly, I just started my transfusion medicine fellowship and wanted to hit the ground running in terms of preparing for the job market and knowing how I should take advantage of my fellowship training time. Additionally, I wanted to become more familiar with other AABB members and find out more ways to be involved in the Association.

AABB NEWS: CAN YOU TELL US ABOUT YOUR EXPERIENCE? WHAT DID YOU DISCUSS/WORK ON DURING YOUR SESSIONS?

SONG: Despite being several time zones away, Dr. Al-Riyami was always gracious and kind when finding time to speak with me—even doing it quite late in the evening so that we could line up our schedules. We spoke primarily about ways to get more involved in the community: through AABB committees and taking part in the AABB assessor program; through ISBT participation; and through various conferences. Additionally, she shared her own recent training experiences and reasons to dive into biotherapies.

AABB NEWS: WHAT KEY TAKEAWAY POINTS DID YOU LEARN FROM YOUR MENTOR?

SONG: Get involved! After working with her, I didn't hesitate to sign up for junior committee memberships when the opportunity arose. Committees are not

only a great way to meet people but also a great way to get involved with work and research in topics you are interested in. Biotherapies is a fast-growing field, so I need to take advantage of the built-in training and get even more involved in the biotherapies department during my two-years of transfusion fellowship at NIH.

AABB NEWS: HOW WILL THIS EXPERIENCE AND LESSONS LEARNED DURING THE MENTORSHIP PROGRAM HELP YOU ADVANCE IN YOUR CAREER IN TRANSFUSION MEDICINE?

SONG: I know this experience has really put me into the right gear to get my transfusion career going! I will continue to have an amazing mentor in Dr. Al-Riyami and am also now equipped with the knowledge and tools to dive into participation with AABB and its many members.

AABB NEWS: WHAT DID YOU ENJOY MOST ABOUT THE PROGRAM?

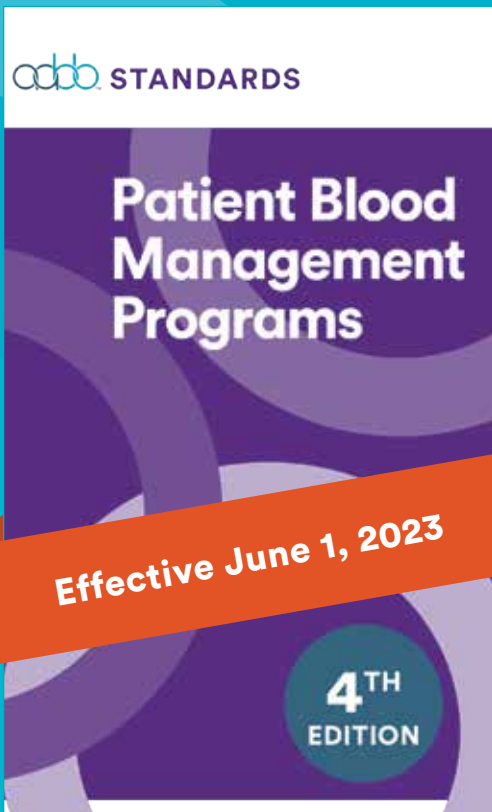
SONG: Other than getting to meet and know someone in the transfusion medicine world, it would be getting to hear about someone else's story of getting into this field and how this field is ever-growing, which is confirmation that we are all life-long learners. I can't wait to meet Dr. Al-Riyami and others at the next AABB Annual Meeting!



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(2022, AABB, 47 pages, ISBN 978-1-56395-455-9)



Individual Donor Assessment: The Next Phase

New Inclusive Screening Process Expands Donor Eligibility

By Kendra Y. Applewhite, MFA
Managing Editor

In late January 2023, the U.S. Food and Drug Administration (FDA) issued a draft guidance with revised recommendations for determining blood donor eligibility. In the draft guidance, FDA proposed for the first time the elimination of time-based donation deferrals for men who had sex with men (MSM) and women who have sex with MSM. The draft guidance recommends an evidence-based approach to individual donor assessment (IDA) for all blood donors – regardless of sexual orientation and gender identity – to reduce the risk of transfusion-transmitted HIV.

“This represents a huge paradigm change for our field,” stated Julie Karp, MD, director of transfusion medicine at Thomas Jefferson University Hospital. “The way we screen blood donors has largely been the same for many decades. The past several years have made our community very comfortable with change, and I’m excited to embrace these new draft recommendations.”

The policy set forth in the draft guidance represents a significant change for determining blood donor eligibility. At the height of the AIDS epidemic in 1983, FDA instituted

policies to mitigate the risk for transfusion-transmitted HIV, prohibiting sexually active gay and bisexual men from donating blood in the United States in the absence of effective donor testing options to protect the safety of the blood supply. As more comprehensive testing methods became available, FDA shifted to a 12-month deferral for MSM in 2015, and subsequently, a three-month deferral in 2020 based on new scientific evidence, epidemiological data, available data from the Transfusion Transmissible Infections Monitoring System (TTIMS) and the continued improvements in HIV testing for donors.

The draft guidance retained many of the existing HIV deferral recommendations and added several significant changes to the donor eligibility policy. In addition to eliminating the time-based deferrals for MSM, and women who have sex with MSM, the new proposed guidance includes the following notable changes:

- The next version of the donor history questionnaire will be revised to ask all prospective donors about new or multiple sexual partners in the past three months.
- A prospective donor who reports having a new sexual partner, or more than one sexual partner in the past three months, would then be asked about a history of anal sex in the past three months to evaluate the risk for a newly-acquired HIV infection.
- A prospective donor who reports having a new sexual partner or more than one sexual partner and had anal sex in the past three months would be deferred from donation for three months from the last date of anal sex.
- A prospective donor who does not report having new or multiple sexual partners, and anal sex in the past three months, may be eligible to donate, provided all other eligibility criteria are met.
- An individual who has ever had a confirmed positive test for HIV or who has taken any medication to treat HIV infection would continue to be permanently deferred for HIV infection.
- An individual taking oral medications to prevent HIV infection such as pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) would be deferred for three months from their most recent dose.
- An individual who has received any medication by injection to prevent HIV infection would be deferred for 2 years from their most recent injection.

Mary Townsend, MD, vice president corporate medical director of Vitalant in Scottsdale, Ariz., and chair of the AABB Donor History Task Force, described the updated draft guidance as a “new chapter in the blood community.”

“Truthfully, it will change everything. Bringing on a brand-new questionnaire is not an easy task, so it’s going to be complicated,” Townsend said. “The best part is that it will open up blood donation to potential donors who were previously excluded. I love that it removes a deferral policy that upset many people, while still maintaining a safe and available blood supply.”

Expanding Eligibility

Since its inception in 2000, the AABB Donor History Task Force has worked with FDA to identify and incorporate new FDA regulations and recommendations in the donor history questionnaire. The Task Force developed an example model Individual Risk Assessment Donor History Questionnaire based on the Canadian criteria and shared it with FDA in late 2022 to help the agency, AABB members and other stakeholders visualize the DHQ system of documents for individual donor assessment if implemented in the U.S. This example model was also intended to support advance preparations for FDA’s highly anticipated policy changes, which were issued in FDA’s January 2023 draft guidance.

AABB’s Department of Regulatory Affairs submitted the Donor History Questionnaire version 4.0 (DHQ v4.0) System of Documents to FDA for formal review and acceptance in March. The advanced preparation of the Donor History Task Force made it possible to submit these documents early and facilitate planning and education to support a smooth transition, effective implementation, and the continuation of a safe and adequate blood supply. The DHQ v4.0 will be finalized and available for implementation only after FDA issues a final guidance and formally recognizes the DHQ v4.0 in a level 2 guidance. AABB is preparing comprehensive resources to support a safe and effective transition for blood collection facilities.

Nicole Verdun, MD, director of the Office of Blood Research and Review at FDA’s Center for Biologics Evaluation and Research, noted that two staff members within the Office of Blood Research and Review currently serve as FDA liaisons to the AABB Donor History Task Force. Their participation helps to ensure direct and timely communication with AABB and Task Force members and provides clarification on regulatory questions. This facilitates the FDA’s review of the donor history questionnaire and accompanying materials, Verdun added.

“We appreciate AABB’s leadership in convening the Donor History Task Force and facilitating the development and maintenance of a uniform donor history questionnaire available for use by all blood establishments,” Verdun told *AABB News*. She noted the availability of a uniform donor history questionnaire

ensures consistency in donor questioning and allows for more rapid implementation of the FDA's revised recommendations by blood establishments.

"AABB and members of the Task Force have been instrumental in ensuring the donor history questionnaire and accompanying materials are consistent with the FDA's requirements and recommendations for donor eligibility," Verdun added.

Townsend reflected on working with FDA to develop the first uniform donor questionnaire in 2000. "The FDA liaisons were intimately involved in every meeting, whether in person or email, and they actively participated in our deliberations," Townsend recalled. "The Donor History Task Force and FDA have had a long, great working relationship building donor questionnaires for the past 23 years. We are always responsive to input or any questions they have about submitted materials. I really respect our FDA colleagues." In support of blood safety in the U.S. and internationally, AABB posts the DHQ system of documents and supporting documents available to all blood collectors, without requiring AABB membership or accreditation.

Collecting Scientific Data

FDA's draft recommendations are based on scientific data from several sources, most notably the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study. The groundbreaking FDA-funded study, which began in 2020 and concluded in December 2022, assessed approaches for selecting sexually active gay and bisexual men who have lower risk of HIV infection who may be eligible to donate blood. FDA has determined that the results demonstrated policy

changes could be made without affecting the safety, quality or availability of the nation's blood supply.

As part of the ADVANCE Study, Vitalant Research Institute, OneBlood, the American Red Cross and partnering LGBTQ+ organizations enrolled participants and collected data to assist the FDA in evaluating alternatives to the time-based donor deferral policy for MSM.

In addition to preliminary findings from the ADVANCE study, Verdun noted the FDA considered surveillance data from TTIMS and information from other countries, such as the United Kingdom and Canada, with similar HIV epidemiology as the U.S. that previously adopted an individual risk approach.

TTIMS was implemented in 2014 to facilitate monitoring of the safety of the U.S. blood supply. "Overall, TTIMS combines data from four U.S. blood collection organizations comprising approximately 60% of all donations to monitor demographic and temporal trends in infectious disease markers – including donor and donation prevalence and residual risk for HIV, HBV and HCV," Verdun explained. "The FDA will continue to monitor the safety of the blood supply using TTIMS to evaluate any changes in HIV incidence and demographics among blood donors following revisions in recommendations for donor eligibility."

Brian Custer, PhD, MPH, director of Vitalant Research Institute and primary investigator on the ADVANCE Study, said it was important that there was a scientific basis for making policy changes. "We are pleased that data from the ADVANCE Study, along with data from TTIMS and information from the U.K. and Canada, have been helpful in the FDA's decision to recommend an individual donor assessment policy," he said.



A Step Forward: Nursing Student Advocates for Gender-Inclusive Donation Policies

Cole Williams founded Pride and Plasma in 2022 shortly after the American Red Cross declared a national blood shortage crisis. The University of Cincinnati senior spoke to AABB News about the group's mission to fight policies preventing men who have sex with men from donating blood and to advocate for the removal of all blood donation deferral policies and screening questions related to sexuality.

"I'm a nursing student, and this policy impacts the patients I will be taking care of," Williams said, noting the idea for

the advocacy group took root during his congressional internship. "I read about the FDA-funded ADVANCE study, but it focused on scientific research. I didn't see too many people working on public opinion, so I saw this as a good opportunity to put some additional pressure on the FDA. There were a lot of people who weren't aware of the policy because it didn't impact them directly."

Williams and his team conducted research and reached out to 70 blood collection facilities across the nation for statements regarding the current blood

shortage and its impact on their ability to serve their patients and communities. They also compiled press releases and public statements from national organizations, including AABB, American Medical Association and GLMA: Health Professionals Advancing LGBTQ Equality. He presented his message in front of the FDA's Blood Advisory Committee during its public comment period last December.

Williams noted the policy hit close to home. "We are in the worst blood shortage in more than a decade, so blood centers cannot afford to turn away healthy

Safety First

Following the release of FDA's draft guidance, AABB, America's Blood Centers (ABC) and the American Red Cross issued a joint statement in February to reiterate their commitment to maintaining the safety of the nation's blood supply while making blood donation a more inclusive process that treats all individuals with fairness, equality and respect. The organizations also thanked the stakeholders who participated in efforts to expand donor eligibility and committed to working diligently to complete the complex transition to individual risk assessment as soon as possible.

"A safe and reliable blood supply for patients in need of lifesaving blood transfusions is of the utmost importance. All patients should feel comfortable and trust that the blood they receive is safe," stated Susan Stramer, PhD, vice president of scientific affairs at the American Red Cross. Years of data have demonstrated that modifications to the eligibility processes in the U.S. have not compromised the safety of the nation's blood supply, Stramer pointed out.

"Since Canada and the U.K. implemented an individual donor assessment system for blood donation eligibility, there have been no changes in infectious disease rates and no cases of HIV or other transfusion transmissions in either country," Stramer said. "Additionally, data from TTIMS and the recently completed ADVANCE Study are anticipated to further support this new screening process. We are excited to welcome new donors while maintaining the same level of safety for donors and patients."

Moving Forward

Verdun told *AABB News* the FDA is committed to

finalizing the draft guidance as quickly as possible and working with its partners to revise the donor history questionnaire materials. The FDA will continue to follow the best available scientific evidence to maintain an adequate and safe blood supply, she noted.

All blood collectors in the U.S. are at a minimum required to follow FDA's regulations and recommendations regarding blood donation eligibility. To that end, once FDA issues the final guidance, AABB's Donor History Task Force will finalize the donor history questionnaire and conduct an internal review. FDA will review the donor history questionnaire and recognize it in formal guidance and then coordinate with AABB to publish the approved questionnaire. Once the approved donor history questionnaire is available on the AABB web page, blood collectors can begin the implementation process.

Michele Klawitter, executive director of process excellence at the American Red Cross, said the Red Cross is preparing now to ensure the organization is positioned to implement the changes swiftly. This process will take time and coordination across the blood community, she pointed out.

"The Red Cross understands the importance of implementing the FDA's final guidance as quickly as

(Continued on page 29)

The new recommendations will take effect after FDA issues its final guidance and formally accepts an updated Donor health History Questionnaire. AABB is here to support and help blood collection facilities navigate through the implementation process. For comprehensive resources, visit aabb.org/ida. For additional details on AABB's support of blood safety in the U.S. and internationally, visit AABB's webpages for the DHQ, Regulatory Affairs, Advocacy and others.

donors," Williams stated. "I want to personally donate blood, and I know there are plenty of other queer men who want to donate. Although the ADVANCE study is great, we can also look at other countries. They are making steps toward decreasing the deferral policies impacting this specific community. We have new research and data, but discrimination is wrong, and we don't need science to prove that."

Williams pointed out that removing all gender language is a huge step forward for transgender women and non-binary individuals who were assigned male at birth and previously subjected to the MSM deferral policy at blood centers that were not

gender-affirming or did not include a third gender marker on their surveys.

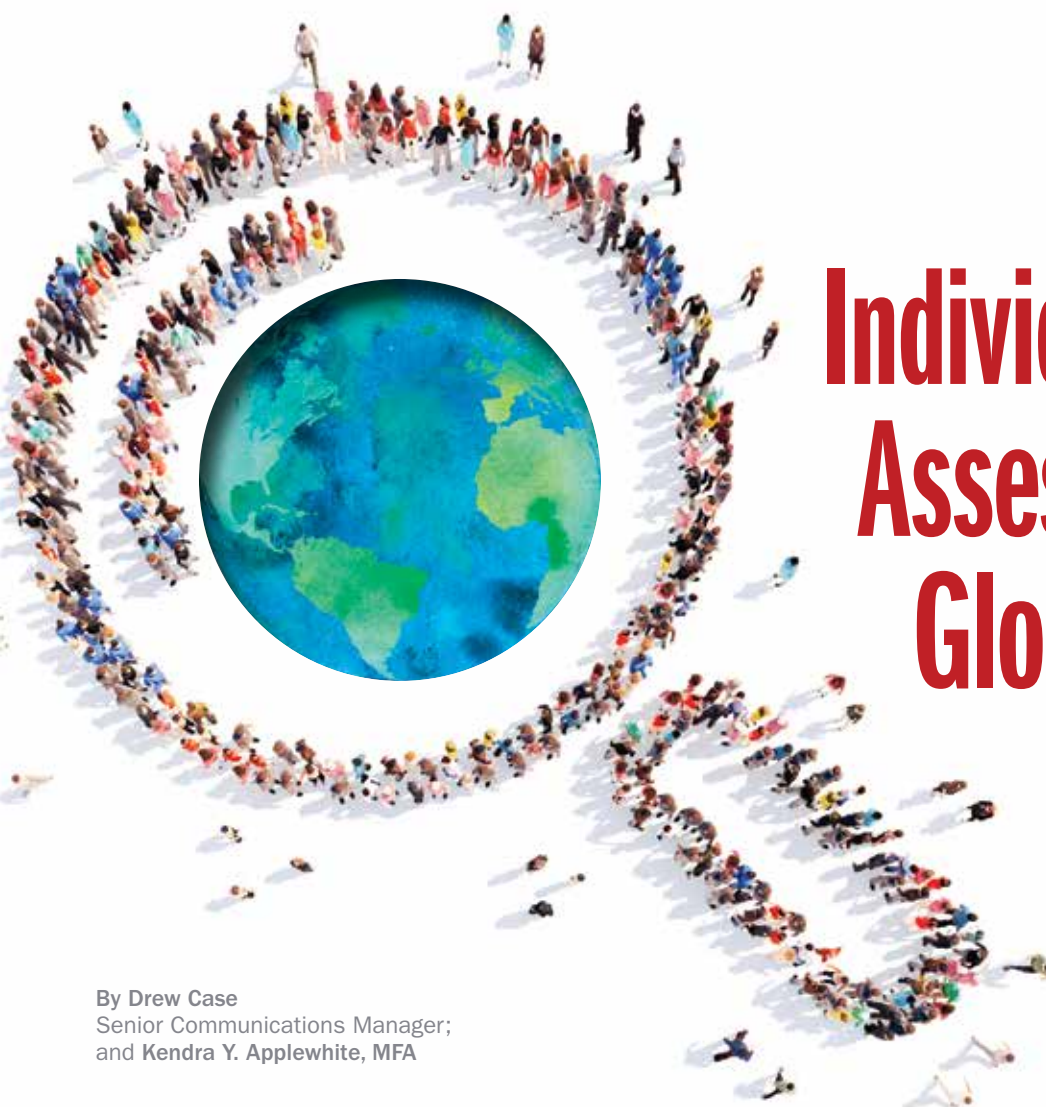
"This is also a huge win for any queer man who has been in a long-term monogamous relationship or married since we got the legal right to marriage equality. It also impacts anyone who is solely practicing oral sexual activity," Williams stated. "For the first time in a long time, it is more scientifically sound. The policies impacting prophylactic HIV exposure are also a big step forward and align with



other countries."

Williams hopes the FDA will continue to fund research studies and review new data to revise policies that may continue to unnecessarily defer healthy donors.

"The blood product shortage in this country is not going anywhere. We do not have the same number of donors we had a decade ago, and facilities are really hurting," Williams noted.



Individual Donor Assessment: A Global View

By Drew Case
Senior Communications Manager;
and Kendra Y. Applewhite, MFA

In recent years, a growing number of countries, including Canada, France, Ireland and the United Kingdom, have removed donor eligibility questions related to sexual orientation and have implemented new policies in favor of individual donor assessments. Data from various countries that use individual donor assessment screening protocols confirm that such policies do not compromise the safety, quality or availability of the blood supply.

The U.S. Food and Drug Administration (FDA) reviewed data from numerous sources, including data from other countries with similar HIV epidemiology that have implemented this gender-inclusive, individual risk-based approach for assessing donor eligibility, and issued guidance in January recommending an individual donor assessment to determine blood donor eligibility. To that end, the U.S. is joining a long list of countries that have made significant changes to determine donor eligibility in the past few years.

“AABB has been following other countries’ implementation of individual donor assessments devoid of any mention of donors’ sexual orientation or gender,” stated Mary Townsend, MD, vice president corporate medical director of the national office at

Vitalant in Scottsdale, Ariz., and chair of the AABB Donor History Task Force. “We were waiting for FDA to give us the go-ahead, and we are ready to go. Now is the time, and we are so pleased to see the U.S. moving in this direction.”

Here’s a look at how several other countries have changed their donor eligibility criteria and process in the past few years:

2023

JANUARY



GERMANY

Federal Minister of Health Karl Lauterbach, PhD, introduced an amendment to German law that would require the German Medical Association (BÄK) to introduce individual donor assessment to determine blood donor eligibility for all donors. The amendment was scheduled to be implemented April 1, and BÄK is required to revise the donor eligibility criteria within four months.

Currently, German policy requires that MSM in monogamous relationships who meet all other eligibility criteria may donate blood in Germany

with no waiting period. Those with a new partner or multiple partners are eligible four months after their most recent sexual contact with a new partner. Heterosexuals who have “regularly changing partners” must also wait four months after their most recent sexual contact with a new partner.

MARCH



THE NETHERLANDS

Sanquin, the agency responsible for the collection and distribution of blood in the Netherlands, announced it would introduce individual donor assessment to determine donor eligibility in 2024. Under its proposed “universal assessment of sexual risk,” all donors will receive an identical questionnaire about sexual behavior. Currently, the donor eligibility period in the Netherlands varies for MSM based on their relationship status. MSM in long-term monogamous relationships are eligible to donate without a deferral period (if they meet all other eligibility criteria) while non-monogamous MSM are eligible to donate four months after their most recent sexual contact with another man.

2022

JANUARY

FRANCE



Minister of Social Affairs and Health Olivier Véran announced that France will remove donor screening questions related to sexual orientation in March. Instead, France will introduce a revised donor questionnaire that addresses treatment before or after exposure to HIV, such as pre-exposure prophylaxis (PrEP).

The decision concludes a years-long evaluation process that included an independent analysis focused on the conditions necessary to evolve the selection criteria and two surveys of French donors and collection staff on issues related to risk perception and acceptability of the questionnaire for selecting blood donation candidates. French MSM were deferred indefinitely from blood donation between 1983 and 2016. Since 2019, MSM have been able to donate blood four months after their most recent sexual contact with another man.



GREECE

Health Minister Thanos Plevris and Deputy Minister of Health Mina Gaga signed

a ministerial decree on Jan. 10, 2022, that removes questions related to sexual orientation from the country’s donor history questionnaire. Prior to the eligibility change, MSM in Greece were deferred indefinitely from blood donation if they had had sexual contact with another man even once since 1977.

APRIL



CANADA

Health Canada approved a request from Canadian Blood Services (CBS) to replace donor eligibility criteria specific to MSM with individual risk assessment for all donors, regardless of their sexual orientation.

The new eligibility criteria will ask all donors, regardless of their gender or sexual orientation, if they have had new or multiple sexual partners in the past three months. All donors with a new partner or multiple partners will be asked if they had anal sex in the last three months. If so, they will be deferred from donation for three months from when they most recently had anal sex. Other donors, if they are otherwise eligible, will be able to donate.

MAY



NORWAY

Norway’s Ministry of Health and Care Services announced its plans to commission the Norwegian Directorate of Health to assess changes in the blood donation deferral period for MSM. Previously, under Norway’s donor eligibility process, MSM were eligible to donate blood 12 months after their most recent sexual contact with another man.



AUSTRIA

Health and Social Affairs Minister Johannes Rauch announced that Austria will amend its blood donation ordinance to introduce individual donor risk assessment to determine donor eligibility. Austria previously deferred potential donors for 12 months after “high-risk contact,” which excluded most MSM and transgender donors from blood donation.

Under the amended ordinance, potential donors with more than three sexual partners within the past three months of their donation will be deferred for three months, irrespective of their sexual orientation or gender identity.

SEPTEMBER



MALTA

Health officials in Malta revised the country's one-year blood deferral period for MSM. An announcement of the policy change by Maltese Health Minister Chris Fearne coincided with the beginning of Malta Pride on Sept. 2, 2022.

The new policy in Malta states that anyone who wants to donate blood, irrespective of their sexual orientation, will be able to do so if they have had just one sexual partner for at least four months and meet all other eligibility criteria.

Prior to 2019, MSM in Malta were indefinitely deferred from blood donation, but health officials reduced this period to one year after the introduction of nucleic acid testing in the country.

NOVEMBER



Ireland

The Irish Blood Transfusion Service (IBTS) introduced individual donor assessment for all blood donors in November 2021. Under the new donor eligibility process, all potential donors – irrespective of their sexual orientation – will be asked if they have had a new sexual partner or more than one sexual partner in the four months prior to donation. Donors who answer “yes” will be asked if they had anal sex.

In addition, IBTS's Social Behaviors Review Group recommended that questions about drug use, use of pre- or post-exposure prophylaxis (PrEP or PEP) to prevent HIV infection, and intravenous drug use during sex should be added to the donor health and lifestyle questionnaires for all donors. IBTS previously announced a four-month deferral for donors taking PrEP or PEP.

DECEMBER



QUÉBEC

Héma-Québec, the blood provider for the Canadian province of Québec, officially introduced individual donor assessment to determine donor eligibility in December 2022. The change to donor eligibility criteria – approved by Health Canada in September 2022 – will allow more MSM to donate blood without a deferral period. Under the new donor eligibility process, Héma-Québec will ask all donors about sexual behavior and pregnancy history, regardless of their sexual orientation or gender

identity. Those who report having a new partner within the past three months, or multiple partners, will be asked additional questions. Previously, MSM were required to wait three months from their most recent sexual contact with another man and meet all other donor eligibility criteria to be eligible to donate.

2021

SEPTEMBER



ICELAND

Iceland's Minister of Health submitted a draft amendment to the Regulation on the Collection, Treatment, Preservation and Distribution of Blood. The proposed regulation would eliminate Iceland's indefinite deferral of MSM from blood donation. Instead, it proposed a four-month deferral for all donors who have engaged in “risky sex,” defined as “sex that significantly increases the risk of contracting serious blood-borne infectious diseases.” The regulation also stipulates that blood donors may not be discriminated against on the basis of gender, sexual orientation, origin or other status.

AUGUST



ISRAEL

Israeli Health Minister Nitzan Horowitz announced that Israel will revise its donor eligibility process to allow more MSM to donate blood. Israel previously deferred all MSM from blood donation for 12 months following their most recent sexual contact with another man. Under the revised donor eligibility process, potential donors who engage in “higher-risk” behaviors (such as sex with new or multiple partners) will be deferred for three months, regardless of their gender or sexual orientation. The revised process went into effect in October 2021. ■





Preparing for Change

By Kendra Y. Applewhite, MFA
Managing Editor

Blood collection centers throughout the United States are planning their implementation processes to ensure adherence to the U.S. Food and Drug Administration's (FDA) final guidance on evaluating donor eligibility once it becomes available to reduce the risk of transmission of HIV through blood and blood products. Implementing individual blood donor assessments to determine eligibility, as recommended by the final guidance, will still take time. Doing so will require staff training, as well as changes to donor management software, screening protocols and standard operating procedures.

The following AABB institutional members discuss this historic policy change and how they are preparing to implement the FDA eligibility changes.

ImpactLife

"Implementing these changes based on FDA final guidance is a huge step for every blood center and the entire field. This will help to change the perception that blood banks discriminate against gay and bisexual men and will lead to stronger relationships with the LGBTQ+ community." - Pete Lux, RN

ImpactLife, formerly known as the Mississippi Valley Regional Blood Center, provides life-saving blood

products to more than 120 hospitals in a four-state region. The community blood center is headquartered in Davenport, Iowa, and has distribution hubs and donor centers in Iowa, Illinois, Missouri and Wisconsin.

ImpactLife's leadership team began preparing for potential changes to eligibility requirements for blood donation after FDA issued the draft guidance on donor eligibility in late January. Pete Lux, RN, vice president of donor and patient services at ImpactLife, noted that developing a strong communication strategy is a top priority for the center.

"Focusing on our change control process was one of the first things we did internally," he stated. "We issued a press release to inform people about the changes because we were getting phone calls. We are being proactive in our communication to ensure our staff and the public understand these changes and how we are addressing them."

Lux anticipates that training blood center employees will be the most challenging part of the implementation process. He noted the center will also provide talking points and sex positivity training to help staff navigate sensitive topics and prepare them for questions.

"Updating our computer system is the easiest change because we have a process in place and we do it routinely, but the biggest hurdle will be getting the staff ready, and responding to questions," Lux told *AABB News*. "We don't want staff to shy away from screening a donor because they might be reluctant to talk about the upcoming change. Our goal is to ensure that our staff is comfortable and equipped to have necessary conversations with the donor, regardless of how the donor responds. If the donor is upset and finds the screening invasive, we want them to be prepared

for that. We want to make sure they can respond to any negative feedback from the public as well.”

Lux noted that the donor services staff will receive the most intense training to prepare them to have one-on-one conversations with donors. Staff from other departments will receive training to prepare to answer any questions they may get from family and friends. We don’t want anyone to be caught off guard, he added.

“Some of these topics are sensitive and unusual to talk about at work, even though it’s for a medical reason, so we are trying to figure out how we can help them,” Lux said. “There may be some donors who are upset because they are now deferred when they were not before. We want our staff to be knowledgeable to have a conversation about the deferral. We’re working hard to ensure everyone in the organization knows about these changes.”

University of California at Los Angeles (UCLA)

“This change is in alignment with UCLA’s values on equity, diversity and inclusion. We are excited to make these changes, and we are happy to have the ability to increase our donor base and help supply transfusion needs for our patients.” - Dawn C. Ward, MD, CABP

The UCLA Blood and Platelet Center opened its doors in 1975. The center provides a healthy blood component supply for patients at the Ronald Reagan UCLA Medical Center, the UCLA Mattel Children’s Hospital and the Santa Monica UCLA Hospital. The UCLA Blood and Platelet Center collects approximately 60,000 donations per year.

Dawn Ward, MD, CABP, medical director for the UCLA Health, Blood and Platelet Center, associate medical director of transfusion medicine service, discussed her center’s plans to form a project management team to revise its current standard operating procedures and donor history questionnaire.

“We’re starting the process now in anticipation of guidance approval of the donor history questionnaire version 4.0,” Ward told *AABB News*. “Making changes to our system will be challenging, which is why we are starting early to make them available once the guidance is approved.”

Ward noted UCLA Blood and Platelet Center will place a substantial amount of effort into educating current donors and potential donors and partner with undergraduate campus organizations to raise awareness and disseminate information.

“We’ve partnered with them in the past on the deferral with MSM. We would like to continue after the final approval to help share the new FDA changes to recruit additional donors and continue our collaboration with our undergraduate partners,” she said. “Providing proper education is extremely important.”

In addition, the UCLA Blood and Platelet Center will create educational materials and use social media to communicate the change to donors, staff and the public, Ward added.

“We recently started discussing potential changes with our staff to allow them to ask questions in advance. We’re also preparing for frequently asked questions we anticipate from donors,” Ward said. “Prior to the implementation, we will share the information in our donor centers on our screens and on flyers. We will likely send communication to all our current donors in an email to provide updates and changes based upon FDA guidance. We’ll also have regular meetings to update procedures and create training for staff.”

Marsh Regional Blood Center

“This change is long overdue. Some of these updates were really needed. Instead of using the shotgun approach, this is much more targeted and does not penalize donors – who are likely low or no risk – just because they fall into a particular category. It’s all about the individual donor and conducting an individual assessment whenever they come in to donate. And it should be that way across the board.” - Jean Reece

Marsh Regional Blood Center has been the largest hometown supplier of blood and blood products for those in need in the Appalachian Highlands – North-east Tennessee and Southwest Virginia – for more than 70 years. Headquartered in Kingsport, Tenn., Marsh Regional Blood Center is the sole provider of blood for all 21 Ballad Health hospitals.

Jean Reece, donor services quality specialist, spoke to *AABB News* about her center’s plans to update its paper-based system and standard operating procedures based on the final guidance. It’s going to be a big change, she noted.

“We are still paper-based with everything – our donor history questionnaire and educational materials – so it’s a cumbersome process for us,” she stated. “We just changed our standard operating procedures and processes when the FDA issued final guidance for the Creutzfeldt-Jakob Disease (CJD) and malaria last year, but we didn’t change the donor history questionnaire. It will make a big difference in our processes, but we will handle the individual donor assessment in the same way we handled the previous guidance issued during the COVID-19 pandemic.”

Reece noted her center will train staff and prepare for implementation shortly after final guidance issuance. “We’ve circulated a draft of the guidance to our operations team and medical directors, along with information that AABB has released, and we are prepared to follow and implement the template AABB has developed,” Reece said. ■



Recap: AABB Virtual Journal Club Discussion

By Nalan Yurtsever, MD; Daniela Hermelin, MD; and Aaron Shmookler, MD, QIA^{CM}
Contributing Writers

The AABB Virtual Journal Club (#AABBjc) continues to offer education and networking with the blood bank Twitter Community (#Bloodeducation). A thoughtful and information-rich discussion took place on Twitter on Tuesday, March 14, and Wednesday, March 15; the conversation focused on a recently published article in *Transfusion* examining patient perspectives on intraoperative red blood cell transfusion and their willingness to engage in transfusion prevention strategies. Social media users from throughout the world participated in two synchronous one hour-long sessions and an asynchronous barrage of responses to the following questions:

Q1. Can you share your experience describing the risks and/or benefits of blood transfusion with presurgical candidates?

Q2. Do you or another member of the health care team (e.g., anesthesiology) discuss a patient's blood transfusion experience after a procedure or surgery?

Q3. What elements are required to provide a blood transfusion consent that creates a discussion providing adequate information about risk and therapeutic outcomes while offering patient autonomy?

Q4. How should we train residents to collect a patient's blood transfusion consent?

Nalan Yurtsever, MD, chief resident at North Shore University Hospital and Long Island Jewish Medical Center's Anatomic and Clinical Pathology program, reflects on her experience with #AABBjc below:

"I found the experience to be engaging and informative. The virtual format allowed for easy access and participation from different locations, which

made it convenient for busy schedules. The moderators provided a clear structure for the discussion and thought-provoking questions for us to consider.

What I appreciated most about the AABB Virtual Journal Club was the opportunity to hear perspectives from a diverse group of professionals. Each participant brought unique insights and experiences to the discussion, which enriched my understanding of the topic. It was also helpful to have access to the full-text article beforehand so that we could all read and analyze it prior to the discussion. Overall, I found the virtual journal club to be an excellent learning experience. It allowed me to engage with a topic of interest, connect with other professionals and gain new insights that I can apply in my own work."

According to Symplur, which provides data analytics for health care communities on social media, this most recent edition of #AABBjc made nearly 2.7 million impressions. The journal article at the center of the discussion emphasizes the importance of the surgical patient's perspective, from patient consent to post-recovery time period, on receiving personalized blood product and blood transfusion information. Although medical laboratory scientists do not consent patients for transfusion, their perspective shed light into the important role they play in ensuring consent is properly obtained.

Furthermore, social media user @Jewly_SBB, describes how her blood center has created letters that are meant to educate donors about their antibodies and offer a starting point for them to talk with their health care team about consent for possible blood products. Points like these, as well as others during the session, provide a real-time, diverse platform to crowd source and optimize one's own personal practice.

Stay tuned for the next #AABBjc taking place in May. We look forward to seeing you there. ■

Julia_D
@Jewly_SBB

Replying to @AABB

A3 Again from a blood center standpoint, we have created (input from Blood Center Medical Directors, Specialists in Blood Banking, and Medical Laboratory Scientists) and started to mail out letters explaining to patients and donors antibodies and possible 1/ #AABBjc

8:39 PM - Mar 14, 2023 · 1,220 Views



Julia_D @Jewly_SBB - Mar 14

Replying to @Jewly_SBB and @AABB

Implications for future transfusions. These letters are meant to educate as well as offer a starting point for patients to talk to their healthcare team about options and consent to possible blood products transfusion 2/end #AABBjc #Bloodeducation

The Power of Positive Thinking: Six Techniques for Cultivating a Positive Mindset

By Edward Griffin MBA, MS, MLS(ASP)SBB, CLS, CQA(ASQ), PMP
Contributing Writer

“Believe in yourself! Have faith in your abilities! Without a humble but reasonable confidence in your own powers, you cannot be successful or happy.” —Norman Vincent Peale

We all know that thinking positively can make us feel better, but did you know that it can also have a profound impact on our overall wellbeing? Cultivating a positive mindset can help us cope with stress, increase our resilience and even boost our immune system. This article will explore the power of positive thinking and offer techniques for cultivating a positive mindset.

What is Positive Thinking?

Positive thinking is a mental and emotional attitude that focuses on the bright side of life and the potential for positive outcomes. It is not about denying negative emotions or events, but rather choosing to focus on the good in life and taking a proactive approach to problem-solving.

Benefits of Positive Thinking

Research has shown that cultivating a positive mindset can have numerous benefits for our mental and physical health. The following are just a few examples:

1. **Reduced stress and anxiety:** Positive thinking can help us cope with stress and reduce anxiety levels, which in turn can have a beneficial impact on our overall health.
2. **Increased resilience:** A positive mindset can help us bounce back from setbacks and adversity quicker, making us more resilient in the face of challenges.
3. **Improved immune function:** Positive thinking has been linked to improved immune function, which

can help fight illness and disease.

4. **Enhanced well-being:** A positive mindset can help us feel happier, more satisfied with life and more optimistic about the future.

Techniques for Cultivating a Positive Mindset

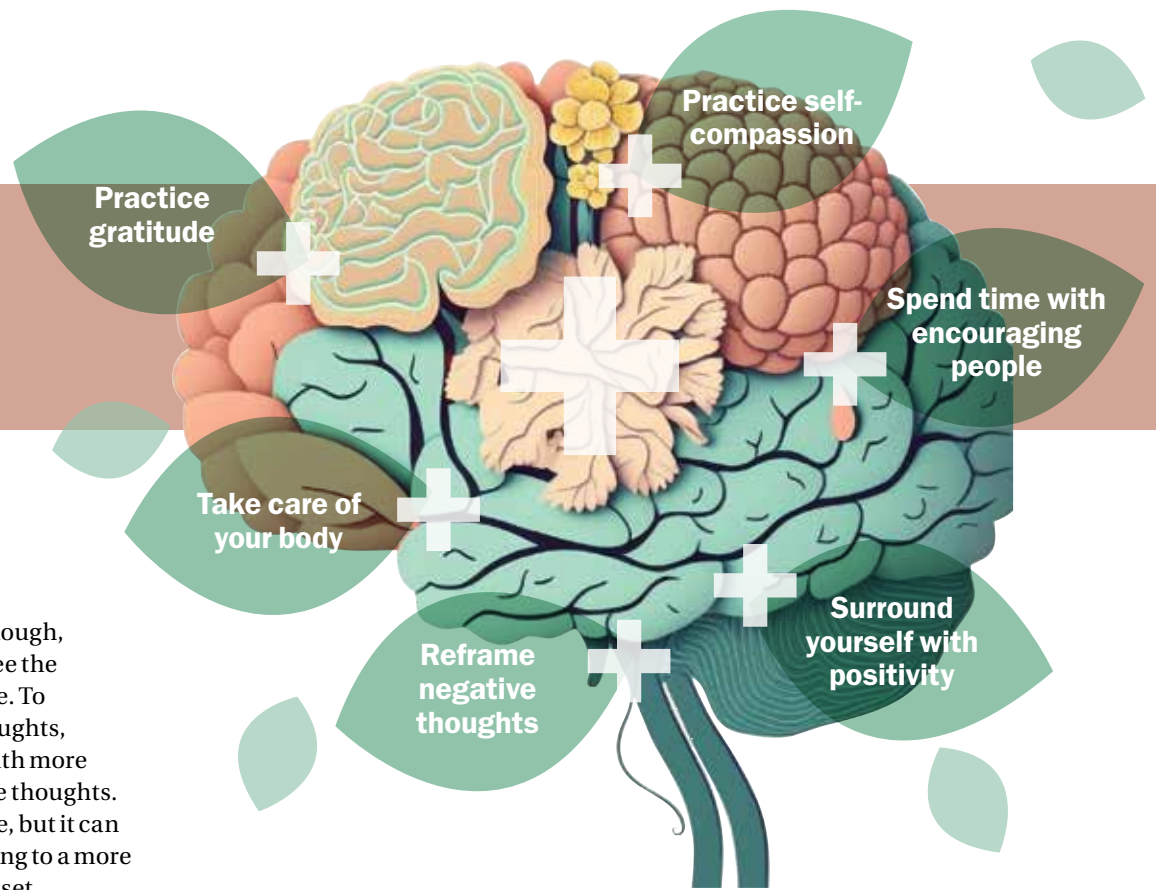
If you're looking to cultivate a more positive mindset, there are several techniques you can try. Here are six techniques to get you started:

1 Practice gratitude: Taking time each day to focus on what you're grateful for can help shift your perspective and cultivate a more positive outlook on life.

Gratitude is a powerful tool for cultivating a positive mindset. When we focus on what we are grateful for, we're reminded of the good in life, even during difficult times. To practice gratitude, set aside time each day to reflect on what you're thankful for. This could be as simple as writing down three things you're grateful for each day or taking a few moments to mentally list the things in your life that bring you joy and fulfillment.

2 Reframe negative thoughts: When you notice negative self-talk, try to reframe those thoughts in a more positive light. For example, if you catch yourself thinking, "I'll never be able to do this," try reframing it as "I can do it!"

Negative self-talk can be a major barrier to cultivating a positive mindset. When we're constantly telling ourselves that we're not good enough, smart



enough or capable enough, it can be difficult to see the positive aspects of life. To reframe negative thoughts, try replacing them with more positive, constructive thoughts. This can take practice, but it can become a habit, leading to a more positive overall mindset.

3 Surround yourself with positivity: Spend time with people who uplift you and engage in activities that bring you joy.

We are often influenced by the people we surround ourselves with, so it is important to spend time with people who uplift and inspire us. Seek out friends, family members or colleagues who are positive and supportive, and engage in activities that bring you joy and fulfillment. This could be anything from taking a yoga class to going for a nature walk or volunteering in your community.

4 Practice self-compassion: Treat yourself with kindness and understanding, just as you would a good friend.

Self-compassion is an essential component of cultivating a positive mindset. When we're kind to ourselves and treat ourselves with compassion, we are better equipped to cope with the ups and downs of life. To practice self-compassion, try to treat yourself as you would a good friend. This means being understanding and patient with yourself when things don't go as planned and recognizing that making mistakes is a natural part of the learning process.

5 Visualize success: Visualize yourself achieving your goals and living your best life.

Visualization is a powerful tool for cultivating a positive mindset. By imagining ourselves succeeding

and achieving our goals, we can begin to believe that it is possible. To practice visualization, take some time each day to imagine yourself achieving your goals. This could be anything from visualizing yourself giving a successful presentation at work to imagining yourself running a marathon.

6 Take care of your body: Exercise, eat well and get enough rest.

Taking care of your body is essential for cultivating a positive mindset. Exercise has been shown to improve mood and reduce stress levels, while a healthy diet can provide the nutrients our bodies need to function at their best. Getting enough rest is also important, as lack of sleep can lead to feelings of fatigue and irritability.

Cultivating a positive mindset takes time and practice, but the benefits are well worth the effort. By focusing on the good in life, we can reduce stress and anxiety, increase resilience and improve our overall well-being. So, take some time each day to practice gratitude, reframe negative thoughts, surround yourself with positivity, practice self-compassion, visualize success and take care of your body. With time and effort, you can cultivate a positive mindset that will serve you well in all areas of your life. ■

Highlights of Recent Research in Blood and Biotherapies

By Drew Case
Senior Communications Manager
and Kerri Wachter
Contributing Writer

Northeastern States See Dramatic Rise in Babesiosis Cases

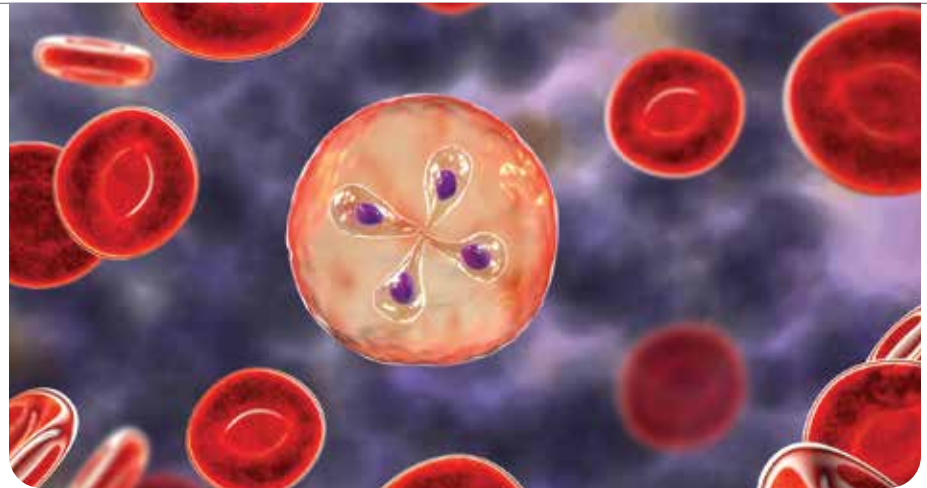
The incidence of babesiosis has increased exponentially in the U.S. Northeast from 2011 to 2019, particularly in Maine, New Hampshire and Vermont, which the U.S. Centers for Disease Control and Prevention (CDC) now considers endemic areas for the tick-borne infection.

Babesia microti, the pathogen species primarily responsible for babesiosis, is carried by black-legged ticks, *Ixodes scapularis*. Although generally asymptomatic, *Babesia* infection can be fatal in some cases.

“Reported case counts in Maine, New Hampshire and Vermont were similar to or higher than those in states previously identified as having endemic babesiosis, and annual incidences in these states have increased significantly,” according to a new report published in the March 17 issue of the *Morbidity and Mortality Weekly Report*.

Vermont experienced a 1,602% increase in cases from 2011 to 2019, up from two cases in 2011 to 34 in 2019. In Maine, the number of new cases jumped from nine cases in 2011 to 138 cases in 2019, a 1,422% rate increase. Reported new cases in New Hampshire increased by 372%, up from 13 to 63.

Babesiosis is already considered to be endemic in several states in the Midwest and Northeast. While not previously



considered to have endemic transmission, Maine, New Hampshire and Vermont should now be considered endemic regions, according to the report.

Babesia infection risk in these three states is now comparable to risk in Northeastern and Midwestern states where babesiosis is endemic. CDC previously considered babesiosis to be endemic and reportable in Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island and Wisconsin. FDA’s 2019 *Babesia* guidance recommends testing of blood donors for *Babesia* infection in 14 states – Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin and the District of Columbia.

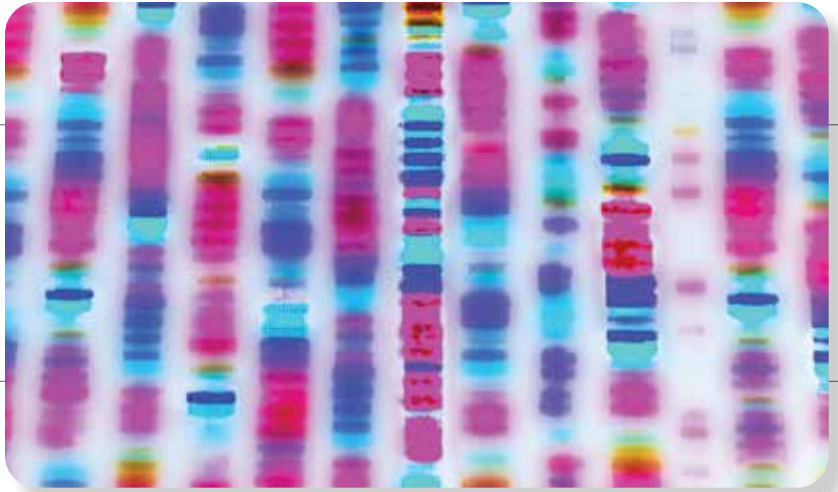
In states where testing is not required, FDA recommends addressing the risk of transfusion-transmission of *Babesia* by including a question on the donor history questionnaire (DHQ), “Have you ever had a positive test result for Babesia?” In addition, tick-borne and transfusion-transmission risks should be

evaluated in states that border those considered endemic for “the evaluation and evolution of babesiosis blood screening policy.”

AABB previously provided members with a *Babesia toolkit*, which includes information regarding the DHQ v2.0. The current donor screening criteria are included in AABB’s draft DHQ v4.0 System of Documents, which is set to be submitted to FDA for review and acceptance.

The new report from CDC is based on data from a national babesiosis surveillance system, including 41 states where babesiosis was reportable from 2011 to 2019, and is the first comprehensive national surveillance assessment and multistate analysis of babesiosis over time.

Symptoms of babesiosis are non-specific and include fever, muscle, joint pain and headache. Health care providers should be aware of *Babesia* infection risk in states with endemic disease and bordering states. In addition, people in endemic states who spend time outdoors should be advised to practice tick bite prevention.



DNA Sequencing May Help Identify AML Patients at Greater Risk for Relapse After BMTT

Screening adult patients in remission from acute myeloid leukemia (AML) for residual disease prior to bone marrow transplant (BMT) may help identify patients at higher risk for relapse, according to findings published recently in *JAMA*. BMT often improves a patient's chance of survival, but research has shown that lingering traces of leukemia may make a transplant less effective.

In this study, investigators used ultra-deep DNA sequencing technology to screen blood samples from 1,075 adults in remission from AML who were preparing for BMT (divided into discovery and validation cohorts based on BMT date). After screening for variants commonly associated with AML, researchers showed that the two most common mutations in AML – *NPM1* and *FLT3-ITD* – could be used to track residual leukemia.

In total, 822 patients had *NPM1* and/or *FLT3-ITD* variants present at their initial AML diagnosis. Investigators found that 142 adults still had residual traces of these mutations after therapy (an allele fraction of 0.01% or higher), despite being classified as in remission. Three years post-BMT, nearly 70% of patients with the lingering *NPM1* and *FLT3-ITD* mutations relapsed while 39% survived. In comparison, 21% of adults without evidence of trace leukemia relapsed after three years while 63% survived. Furthermore, results demonstrated that, among patients with persistent mutations, those who received higher doses of chemotherapy and/or radiotherapy as part of their transplant preparation were more likely

than those who received lower doses to remain cancer-free after three years.

According to investigators, the findings indicate that adults with persistence of *FLT3-ITD* and/or *NPM1* variants while in remission after their initial treatment for AML represent patients with unmet medical need. As such, they should be offered enrollment in a therapeutic clinical trial wherever possible.

“Having this increased risk for relapse may not impact a person's decision about having a bone marrow transplant, but it could influence their next steps in care,” Christopher S. Hourigan, MD, DPhil, senior investigator and chief of the Laboratory of Myeloid Malignancies in the National Heart, Lung, and Blood Institute's Intramural Program, said in a media release. “For that one person out of six, the transplant often isn't going to be enough. Other options might include also enrolling in a clinical research trial or considering additional or different therapies.”

Investigators concluded that further study is needed to determine whether routine DNA-sequencing testing for residual variants can improve outcomes for patients with AML.

Locally Acquired Dengue Infections Reported in Arizona

A new report in *Morbidity and Mortality Weekly Report* explores how health and environmental agencies in Maricopa County, Arizona, responded to an outbreak of locally acquired dengue virus (DENV) in November 2022. The outbreak consisted of two DENV infections and ended Jan. 4, 2023, after 45 days with-

out additional locally acquired cases.

Dengue is caused by a group of four related viruses spread by *Aedes* species (*Ae. aegypti* or *Ae. albopictus*) mosquito. In the United States, most DENV cases result from travel to endemic areas, but locally transmitted outbreaks have occurred in Florida (2020), Hawaii (2015) and Texas (2013).

In the report, the authors describe the actions of the Maricopa County Environmental Services Department and Maricopa County Department of Public Health to confirm and control the outbreak. This included canvassing and interviewing residents who lived near patients with confirmed DENV cases, launching a health care provider education program and conducting environmental assessments to locate mosquito breeding sites.

Additional information about DENV is available on AABB's dengue viruses fact sheet. ■



Inclusive Practices: Improving Access to Health Care for All



YVETTE MILLER, MD, ABIHM

Yvette Miller, MD, ABIHM, is the American Red Cross executive medical officer for the Donor and Client Support Center, headquartered in Charlotte, N.C., where she oversees the organization's donor eligibility determination, blood product management and donor management. Her areas of expertise include donor recruitment and retention in the Black community, and meeting the transfusion needs of patients with sickle cell disease (SCD). She is board-certified in clinical pathology and is a diplomate of the American Board of Integrative Holistic Medicine.

Miller volunteered as a blood donor and CPR instructor with the American Red Cross while preparing for medical school. She has worked for the American Red Cross for more than 25 years, serving in various leadership capacities, including regional medical director and director of apheresis donor collections and clinical services for the Arizona Region. She has training in leading critical conversations on structural racism and bias, diversity, equity and inclusion and community resilience development. Her other areas of interest include donor recruitment and education in the African American community and underrepresented communities, equitable access to health care in underserved communities, and use of integrative medicine modalities in community health and wellness and for self-care. Miller is co-chair of the Academy of Integrative Health and Medicine (AIHM) Board BIPOC Committee, which was created in June 2020 to serve as a catalyst for meaningful transformation toward racial equity in integrative health. She is also a member of the AABB Donor History Task Force and the AABB Diversity, Equity, Inclusion and Access (DEIA) Task Force. *AABB News* spoke to Miller about her long-distinguished career at the American Red Cross, as well as her efforts to reduce health disparities for patients with sickle cell disease and to improve access to health care for underserved and vulnerable populations.



“As blood collection organizations strive to be more inclusive of all communities to diversify the blood donor pool, the proposed FDA change to donor eligibility is a move in the right direction.”

AABB NEWS: WHAT INSPIRED YOU TO STUDY MEDICINE AND PURSUE A CAREER IN BLOOD BANKING?

Miller: From an early age, I wanted to be a doctor because my mother was interested in attending nursing school. When I was thirteen, my father died of cancer. This was a painful life-changing event for me. I made the commitment then to go to medical school and perhaps do cancer research. I actually did cancer research for a year after medical school, but I quickly realized I need interaction with people.

AABB NEWS: YOU HAVE LED CRITICAL CONVERSATIONS ON HEALTH INEQUITIES AND STRUCTURAL RACISM AND ITS IMPACT ON THE SOCIAL DETERMINANTS OF HEALTH, PARTICULARLY FOR PATIENTS WITH SICKLE CELL DISEASE (SCD). CAN YOU TALK ABOUT YOUR EFFORTS TO REDUCE RACIAL DISPARITIES IN TRANSFUSION MEDICINE AND INCREASE BLOOD DONATIONS IN THE AFRICAN AMERICAN COMMUNITY?

Miller: I worked in the blood bank when I was a resident. There were two patients with SCD, a set of African American twin boys. They both had developed multiple antibodies, and it was difficult to find optimal blood products for them. I was deeply affected by that experience. From that point on, it became my mission to focus on recruitment in the African American community and advocate on behalf of patients and communities affected by SCD. SCD is the most common inherited blood disease in the United States.

Although the condition affects individuals of any race, the population most affected in the U.S. are African Americans and people of African descent. Yet, until the last few years, research funding, drug treatment development and addressing health disparities and inequities affecting this population have been trailing behind other conditions that affect smaller and less diverse patient populations. The work I am most proud of is elevating the voices of Sickle Cell Warriors. Although I speak on behalf of these patients in some cases, I try to create space for Sickle Cell Warriors to speak for themselves.

AABB NEWS: THE AMERICAN RED CROSS LAUNCHED THE NATIONAL SICKLE CELL INITIATIVE IN 2021 TO INCREASE BLOOD DONORS IN THE AFRICAN AMERICAN COMMUNITY AND SUPPORT PATIENTS WITH SCD. WHAT IS THE MOST SUCCESSFUL STRATEGY YOU HAVE EMPLOYED TO RECRUIT MORE DONORS OF COLOR?

Miller: The most successful strategy that we have employed has been engaging and partnering with respected African American organizations. These trusted organizations became our voice in the community. Organizations have seen the excellent work we have done in the community and have reached out to partner with the American Red Cross.

AABB NEWS: BUILDING AND CULTIVATING AN INCLUSIVE BLOOD DONOR POOL REMAINS A PRIORITY. HOW CAN DONOR RECRUITERS DIVERSIFY BLOOD DONA-

TIONS AND ENGAGE DONORS FROM UNDERREPRESENTED COMMUNITIES?

Miller: The most important thing that recruiters can do is listen to the voices of their partners rather than approach the partner with a predetermined plan. They will tell you their needs and how to work with them to have a successful blood drive. The most valuable lesson for recruiters to learn is that if a blood drive does not meet the goal, don't blame the partner. Many partners from underrepresented communities have not had experience hosting a blood drive, and they will likely need significant support to execute the blood drive successfully.

AABB NEWS: MUCH OF YOUR WORK FOCUSES ON PATIENTS WITH SCD. WHAT ARE SOME COMMON MISCONCEPTIONS ABOUT THIS PATIENT POPULATION? WHAT BARRIERS PREVENT SICKLE CELL WARRIORS FROM RECEIVING PROPER TREATMENT AND QUALITY CARE?

Miller: One of the most common damaging and stigmatizing misconceptions about patients with SCD is that they are just seeking drugs when they present to the ER for pain control. These patients have a disease in which the primary symptom is intense pain. When they present to the ER, they are absolutely seeking treatment for devastating pain that most of us could never imagine having. To have health care providers who are supposed to help relieve the pain and suffering of patients, to refuse to provide timely, and adequate pain control in some cases, is unconscionable.

There are many barriers to sickle cell warriors receiving proper treatment, quality care and support, including shortage of compatible blood products, lack of access to health care providers familiar with treatment protocols for SCD, shortage of health care providers to treat adult patients with SCD and difficulty accessing non-medical support services, such as transportation, childcare and in-school educational support.

AABB NEWS: YOU HAVE BEEN WITH THE RED CROSS FOR MORE THAN 25 YEARS. WHAT DO YOU FIND MOST REWARDING ABOUT YOUR WORK? WHAT IS YOUR GREATEST ACCOMPLISHMENT THUS FAR?

Miller: The most rewarding part of my job is that the work that I do every day – determining donor eligibility and supporting the sickle cell initiative – saves lives. My greatest accomplishment so far is being a member of the Sickle Cell Initiative team and developing educational content for staff, donors and partners.

AABB NEWS: AS A MEMBER OF THE AABB DONOR HISTORY TASK FORCE, CAN YOU TELL US HOW THE CHANGES TO THE DONOR HISTORY QUESTIONNAIRE AND THE UPDATED FDA GUIDANCE WILL IMPACT THE BLOOD COMMUNITY MOVING FORWARD?

Miller: I believe that the FDA draft guidance, which proposes new blood donor eligibility criteria using a gender-inclusive, individual donor assessment, is a critical step toward the goal of achieving an inclusive blood donation process. The proposed changes treat all donors with respect and continue to support a safe blood supply that is readily available for patients in need. As blood collection organizations strive to be more inclusive of all communities to diversify the blood donor pool, the proposed FDA change to donor eligibility is a move in the right direction.

AABB NEWS: WHAT CHANGES HAVE SURPRISED YOU THE MOST ABOUT THE FIELD?

Miller: How quickly the FDA has made changes to donor eligibility criteria over the past five years.

AABB NEWS: WHAT ARE SOME COMMON OBSTACLES OR CHALLENGES YOU FACE IN YOUR WORK?

Miller: Honestly, I work with a great team. If there are challenges, we work together to solve problems.

AABB NEWS: WHAT'S ONE THING MOST PEOPLE DON'T KNOW ABOUT YOU?

Miller: I was an extra on the TV shows *Homeland* and *Outcast*.

AABB NEWS: WHAT ARE YOUR FAVORITE LEISURE ACTIVITIES OUTSIDE OF WORK?

Miller: Dancing, travel, acting and hiking. ■

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Volunteer Spotlight

James C. Zimring MD, PhD

Thomas W. Tillack Professor of Experimental Pathology
University of Virginia School of Medicine

How long have you been an AABB member? Since 2002.

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

I have been a member of the AABB Board of Directors, member of the Selection of Abstracts Committee, and chair and member of the AABB Foundation's Grants Review Committee. I am currently on the editorial board of *Transfusion*. I also serve on the Annual Meeting Scientific Program Task Force, appointed by the Board of Directors to review and advise AABB on the Annual Meeting's scientific content.

What motivates you to volunteer?

Blood transfusion is the single most common inpatient procedure, provided to approximately 1 in every 70 people in the United States each year. It is an act of medicinal altruism, by which donors save the lives of recipients whom they will never meet. The science behind transfusion is critical to continue improving efficacy, decreasing sequelae and maintaining transfusion medicine in general. Moreover, teaching and training the next generation, and learning new ideas from the next generation, is critical for the field. Finally, the evolving fields of biotherapies promise to extend our ability to cure disease and mitigate human suffering in ways that were science fiction only a decade ago. For each of these reasons, it is both my privilege and obligation to support AABB and its mission in any way I can.

How has your volunteer work impacted your professional work?

My volunteer work at AABB, in addition to whatever impact it may have had, has allowed me to be a part of a dynamic and multifaceted group of medical professionals throughout the world. This has had a profound impact on me far beyond the typical issues of social networking; it has led to an exchange of ideas and evolution of concepts that would never have occurred to me on my own. Each of us lives in a myopic bubble, but the combination of our personal observations, perspectives and interpretations generates both innovation and rational science. This is one of the reasons I am so passionate about the content (both scientific and administrative) of the AABB Annual Meeting. It is the only time the field can come together and combine the widespread talents from throughout the world into a single dynamic dialogue.

What have you learned from volunteering with AABB? And what advice would you give to someone interested in volunteering?

I have learned that I have much to learn, always. At times, I also have important concepts to share and always energy to contribute. But more than anything else, I have learned of the immense understanding I can only achieve through interaction and dialogue with others. To someone interested in volunteering, I would advise you to volunteer early and often. Be honored when you are chosen but not offended if you are not; it is a dynamic process that ebbs and flows.

What do you like to do in your free time?

I am sorry, but with all due respect to the authors of these questions, what is that odd and unintelligible term you used... "free time?" Clearly, I still have much to learn.



AABB Encourages Early Career Professionals to Take Advantage of PEP Mentoring Program

AABB encourages early-career professionals or those new to the field to take advantage of the Professional Engagement Program (PEP) mentoring program. Connecting with a mentor can help early-career professionals gain knowledge and form connections that add value at every stage of their careers. Right now, seasoned members of the blood banking, transfusion medicine and biotherapies community are ready and waiting to share their experience, time and talent with the next generation of AABB members.

The informal, 6-month program pairs experienced AABB members with colleagues who have worked in blood banking, transfusion medicine or biotherapies for less than five years. Mentors and mentees communicate at least once per month by phone. Individuals interested in being paired with a mentor can complete an online application. Additional information is available on the volunteer opportunities web page.

AABB Urges Congress to Include Laboratory Workforce in Health Care Workforce Legislation

AABB urged leaders of the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP Committee) to include medical and public health laboratory professionals when developing legislation to strengthen the health care workforce.

The Association shared its recommendations to strengthen the laboratory workforce serving in blood centers, hospital transfusion service laboratories and biotherapies laboratories in response to a request for information from HELP Committee Chair Sen. Bernie Sanders (I-Vt.) and Ranking Member Bill Cassidy, MD, (R-La.).

AABB's recommendations include expanding eligibility and funding for federal scholarships, fellowships and loan repayment programs to include the entire laboratory workforce and increasing available immigration options. In addition, AABB encouraged policymakers to dedicate federal funding to activities that will raise the visibility of laboratory medicine careers and provide funding to increase the availability and capacity of laboratory training programs.

Additional information on AABB's activities to strengthen the workforce can be found on AABB's Workforce Initiatives web page.

New AABB Web Page Focuses on Addressing Workforce Issues

AABB recently introduced a new workforce initiatives web page to help the blood and biotherapies field address workforce shortages and related issues. This new page, made possible thanks to the support of Abbott, highlights AABB's educational programs and leadership development resources. The page also provides links to research and articles from partner organizations that might assist health care leaders in advocating for resources within their organizations.

The workforce web page will also house a new video series focusing on how AABB members have addressed workforce challenges at their institutions. In the series' first installment, Don Siegel, MD, PhD, a pioneer in the biotherapies field from the Hospital of the University of Pennsylvania, describes the employee retention challenges facing his facility's cellular therapies technical staff and the initiatives he implemented to significantly increase employee retention.

AABB will provide updates on the AABB Newfeed as new resources are released on this web page.



AABB Will Resume Unannounced Accreditation Assessments May 12

Based on current COVID-19 trends and the January 2023 Administrative Policy Statement, the Department of Health and Human Services (HHS) is planning for the COVID-19 Public Health Emergency (PHE) declaration to expire at the end of the day on May 11.

To adhere to this HHS plan, AABB will resume unannounced assessments on May 12, 2023, and implement the processes and procedures that were in place prior to the PHE. Assessors should not contact facilities to schedule assessment dates on or after May 12.

AABB will resume the following assessment date notifications:

- AABB will notify all accredited domestic facilities the Friday of the week prior to the scheduled assessment date unless the facility is accredited by both the Joint Commission and College of American Pathologists (CAP).
- AABB will notify accredited facilities with both the Joint Commission and CAP accreditation one hour prior to the assessment.
- Assessments for initial (new) AABB accreditation and international facilities (including Canada) will remain announced.

This return to unannounced assessments allows AABB to comply with U.S. federal regulations pertaining to deemed providers of laboratory assessment and accreditation services.

AABB encourages individuals with questions or concerns to contact AABB's Accreditation Department at 1.301.215.6492 or accreditation@aabb.org.

(Continued from page 13)

possible so that individuals who have long desired to donate blood have the opportunity to do so," Klawitter said, noting that incorporating specific sensitivity training for employees and volunteers will be an important aspect of the organization's implementation process.

"We know conversations around individual eligibility can be tricky, and it's our goal to prepare employees and volunteers to engage in these nuanced conversations with knowledge and understanding and to treat all potential donors with dignity and respect," Klawitter added.

As an original member of the AABB Donor History Task Force, Townsend has witnessed firsthand the Association's commitment and efforts to change the deferral policy and implement an inclusive blood donor screening process. Achieving this goal after 23 years, she said, is a dream come true.

"It's been an adventure. We have really struggled at times. At first, we had so many FDA guidances we had to review and incorporate," Townsend said. "It's also been really gratifying over the years to watch as we have been able to change the deferral for MSM, and now we get to completely drop the term. This was my end-goal as the current chair, and when my chair term comes to an end, I can step down as a really happy woman.

"AABB and the AABB Donor History Task Force have long supported this initiative," Townsend continued. "We hope this will engage a whole new group of potential donors while enhancing the blood supply." ■



CALENDAR

April

12 Cell Analytics 101 (23EL-822)
AABB eCast

26 Genotype Matching and Best Recommendations for Transfusion (23EL-827)
AABB eCast

*For further information about AABB eCasts, contact the Educational & Professional Development and Meetings department:

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