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SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT
NEWSLETTER
November 2020

Letter from the President – Sherri Ozawa, RN

As we continue to move through this year like no other, I hope each of you has found a level of balance and resilience in both your professional and personal lives. No doubt we have each struggled with unexpected challenges both at home and at work over these past six months – but it has been especially rewarding to see our SABM friends and colleagues support one another while we keep progressing toward realizing our vision of PBM as a standard of care.

Most recently, we thank our Planning Committee and all who gave support to our 2020 Annual Meeting, which was conducted completely virtually. While we all wish we had been able to be together in person, the electronic platform exceeded even the most optimistic expectations in its ability to deliver the quality educational content which SABM presenters produce year after year. You will read many of the specific highlights from the meeting in the following pages of this newsletter. It was beyond gratifying to have a record number of attendees from around the globe, many of whom would not have been able to attend a live meeting for any number of reasons but were able to join virtually. In addition, having recordings of the sessions available for an extended period will allow access to all presentations, including question and answer sessions, and will allow attendees to watch sessions more than once. We are deeply grateful to our sponsors and exhibitors, our speakers and moderators, our Management and technical team, our partners at NATA, and our attendees from around the world – all of whom contributed to an outstanding educational event.

While much attention was focused on our Meeting, thanks to our dedicated volunteers other SABM activities continued unabated. The COVID-19 resource page was created, and an organized process to choose high quality PBM related citations and articles was instituted. Our Educational Oversight committee under the energetic leadership of Carolyn Burns, MD, oversaw the first in a series of ongoing webinars by SABM members on a variety of topics, the first one on the basics of COVID-19 management and current evidence on therapeutic modalities. Stay tuned for more topical presentations in upcoming months.

We look forward to SABM's Patient Blood Management Awareness Week, November 2-6, 2020. SABM will continue to provide resources and suggestions various ways to recognize this special week in your setting, and we look forward to hearing about highlights from your institutions. As part of this special week of activity, experienced SABM members will be presenting on the patient, public and community communication around PBM as an important quality and safety initiative. An additional webinar will help learners understand the importance of PBM standards in their organization and how they can be operationalized in a practical way.

While it seems hard to believe that in a couple of months we will be in a new year, SABM continues to look forward at its ability to have an impact on both a national and global level, and plans for 2021 include formation of a global alliance of the existing and new Patient Blood Management organizations, to better coordinate efforts to bring progress and change to patient care worldwide.

On behalf of the entire Board of Directors, I thank each of you for your dedication to our collective goal of improving patient outcomes, and your continued support of SABM.

Sincerely,

Sherri Ozawa, RN

SABM NEWSLETTER
NOVEMBER 2020
ISSUE

Donate to SABM

Please consider making a donation to your Society. Your donations will help us to improve the lives of people throughout the world through Patient Blood Management.

SABM 2020 Newsletter Publication

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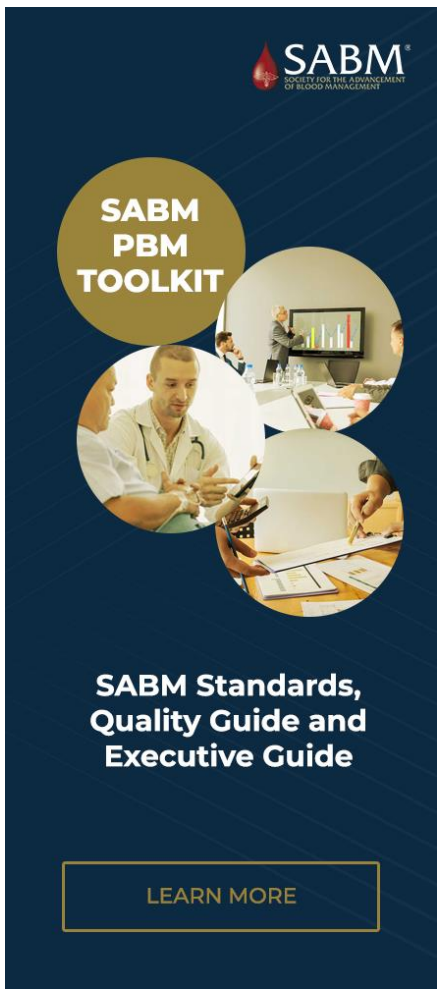

ANESTHESIA & ANALGESIA

Consider submitting your future manuscripts in PBM for peer review and publication in this new section. The success of this endeavor will depend on the provision of material to make it lively and attractive to our colleagues and other professionals in the field.

Members Invited to Submit Papers CLICK HERE

Upcoming Events

Annual Meeting Update

Thank you to everyone who contributed to the success of SABM 2020 Virtual Meeting. This has been a challenging year in the midst of COVID-19. After careful deliberation, with the support of SABM leadership and the planning committee, we were able to overcome these challenges and the decision was made to go virtual with the conference.

We are happy to report that there were 575 physicians, nurses, perfusionists and other allied health professionals from 25 countries who registered for this meeting. SABM brought together the latest research and practice changes from experts across the globe which afforded an opportunity for networking among the leaders in the field of PBM and the participants. The virtual platform was relatively easy to navigate and had amazing graphics and interactive components.

We had the pleasure of hearing from a dynamic keynote speaker Dr. Jack Cochran, MD with his exhilarating talk: From Marcus Welby to IBM Watson: Rebooting Hearth Care Leadership. We were also excited to be able to present “hot off the press” PREVENTT and HALT-IT results to the community.

The 2020 SABM President’s award went to Arthur Bracey, Jr, MD, Professor at Department of Pathology and Immunology at Baylor College of Medicine for his continued and lifelong contribution to patient blood management. Steven M. Frank, MD, Professor of Anesthesiology and Critical Care Medicine and Medical Director for the Bloodless Medicine and Perioperative Blood Management Services at Johns Hopkins received the Kathleen J. Sazama Award for his continued research, dedication and publications focused on blood conservation.

We want to give special thanks to Sherri Ozawa, RN, SABM president, our Hospital affiliates, Industry Sponsors, Talley Management Group, Mr. Matt Van Wie, Jason Sievert and his team at ProFusion Media, and especially the Annual Meeting planning committee for their contribution in making this event a wonderful success. We give a big Thank You to the speakers for sharing their time and expertise, without whom this meeting would never have happened!

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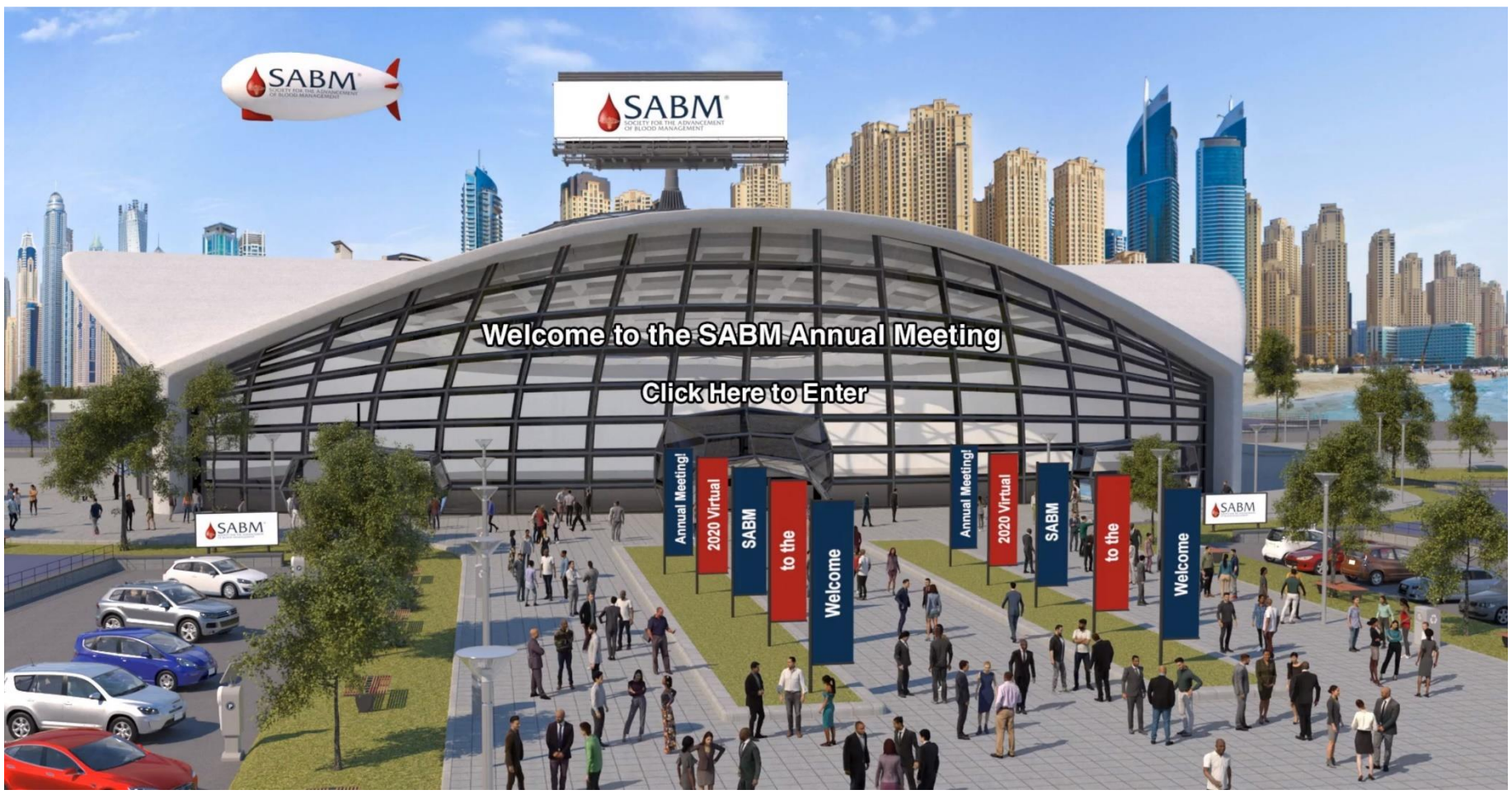

Annual Meeting Awards

SABM President's Award presented to Arthur W. Bracey, Jr., MD

Arthur W. Bracey, Jr., MD, is chief of Clinical Pathology at Baylor St. Luke's Medical Center, Houston, TX, USA, professor of Pathology and Immunology at Baylor College of Medicine, assistant and associate professorships at the University of Texas Health Science Center at Houston, and medical director of Transfusion Services at St. Luke's Episcopal Hospital. Among his many other accomplishments is having previously served as president of SABM. Dr. Bracey has written or contributed to over 60 peer reviewed articles in transfusion medicine practice and peri operative coagulation disorders. He takes great pride in mentoring and teaching transfusion-free methods.

The SABM President's Award is presented annually at the SABM Annual Meeting in recognition of those who have made outstanding medical, scientific and/or educational contributions to patient blood management and that have contributed to the public good in the area of blood safety and the reduction of unnecessary transfusions. Sherri Ozawa, RN, presented the award to Dr Bracey.

Kathleen J. Sazama Award presented to Steven M. Frank, MD, FAAP

Steven M. Frank, MD, FAAP, is a professor, Johns Hopkins Hospital, Baltimore, MD, USA, Department of Anesthesiology and Critical Care Medicine, Division of Vascular, Thoracic, Transplant Anesthesia. He also serves as medical director for the Bloodless Medicine and Surgery Program and director of the Interdisciplinary Blood Management Program and of Perioperative Blood Management Services at Johns Hopkins; Dr. Frank has served on the board of directors for SABM. His research is focused on methods to improve blood utilization, blood conservation and bloodless medicine and surgery. His expertise is instrumental for patients who seek the very best healthcare, without the use of blood or blood products.

The Sazama award was created in recognition of Dr. Sazama's bold insights in the field of medical ethics, her selfless dedication to individual growth, her steadfast and responsible leadership through change and the field of blood management. Dr. Frank exemplifies these high standards and demonstrates his commitment to patient rights, as he selflessly serves for the well-being of the patient. He demonstrates consistent dedication to progress in the field of patient blood management.

2020 SABM Research Starter Grant Award presented to Justyna Bartoszko, MD

Justyna Bartoszko, MD, MSc, FRCPC, is a staff anesthesiologist, Toronto General Hospital, assistant professor anesthesia, Department of Anesthesia and Pain Management, University of Toronto, Ontario, Canada. The title of her proposal is: "Diagnosis and Management of Impaired Thrombin Generation in Liver Transplant Surgery."

SABM is ever so grateful because this grant award would not be possible without support from HemoSonics, LLC, a company with roots in Charlottesville, VA, specializing in coagulation testing by sonorheometry. Their Quantra hemostasis analyzer was FDA approved in early 2019 and is now the newest coagulation testing technology to become clinically available, a truly exciting advance for patient blood management.

SABM would also like to thank all of the investigators who put in the time and effort to write these detailed and high-quality grant proposals. There were 13 proposals submitted this year, which is more than ever in the seven years for which this grant has been offered. The grant review process was rigorous and involved all members of the SABM Scientific Committee who were non-conflicted, with conflict defined as having a grant submitted from their own institution. Each proposal was reviewed and scored by five different grant reviewers, three of whom scored all 13 proposals for consistency, with the two others drawn from the remaining Committee members.

It is exciting that coagulation testing in liver transplants is the topic of Justyna's study. With all the attention in the past two decades focused on red cell indications, we welcome a well-designed study on the "yellow products" (plasma, platelets, and cryoprecipitate), which are equally important in-patient blood management. Also, we are truly saving lives with liver transplants, and in many ways these surgeries are nothing short of miraculous.

We congratulate our award winner for 2020 and look forward to a bright future for this grant award program.

Supported by an educational grant from HemoSonics, LLC

COVID-19 Symposium: What We Have Learned Thus Far

Highlights from the 2020 SABM Annual Meeting

This unique symposium, as any other major conferences this year, was impacted by the COVID-19 pandemic and the required social distancing. Although this pandemic has isolated us in the name of safety, it has united the globe in a mass effort to study and share experiences in clinical management and treatment. Appropriately, SABM hosted a panel of experts to discuss current research on COVID-19 pathology, management, and potential treatments.

Beverly Hunt, MD, Kings College (London, England) spoke on COVID-19 associated thrombosis complications and the anticoagulation options. As we become more familiar with the pathophysiology of this virus a correlation between high rates of thromboembolism and infection has emerged. The mechanism is largely unknown but believed to be related to immobility, hypoxic injury, and a profound acute inflammatory state. Though this resembles a form of disseminated intravascular coagulation (DIC) both prothrombin time (PT) and activated partial thromboplastin time (aPTT) remain normal. In Covid-19 infection, coagulopathy is related to inflammation causing prothrombotic changes and endothelial activation induced by direct viral infection and not derangement of the coagulation cascade. The extent of hospital-associated thromboembolism has not been fully realized as the clot can occur up to 90 days post discharge and data is still being collected. As a result of the identification of this complication by front-line physicians, changes in anticoagulation thromboprophylaxis is now included in many treatment protocols but large variations exist in dose and timing and a general consensus has not been reached.

Jacob Gutsche, MD, University of Pennsylvania (Philadelphia, PA, USA) then shared his experience with COVID-19 and Extracorporeal membrane oxygenation (ECMO). Despite maximal oxygenation therapy, COVID-19 can progress to pneumonia and acute respiratory distress syndrome (ARDS). The utilization of ECMO was seen in early reports as a last resort in severe COVID-19 patients and reported almost 100% mortality with more recent mortality reported as approximately 50%. Current knowledge of changes in patients' coagulation profiles due to infection and hyper-inflammatory process have impacted the management of veno-venous ECMO and may account for the enhanced survival, though still dismal. Additionally, the lung compliance in these patients is initially better than typically seen in ARDS with impaired ventilation. This may support the hypothesis of a prothrombotic disease which causes a severe imbalance in bleeding and thrombosis risk impacting oxygen transport at the endothelial level. Newer evidence emerging also shows higher incidence of intracranial hemorrhage further complicating this treatment modality.

Lastly, Evan Bloch, MD, Johns Hopkins University (Baltimore, MD, USA) illustrated the benefits of convalescent plasma usage in COVID-19 management. Covid-19 convalescent plasma (CCP) emerged early as a promising intervention to prevent and/or treat COVID-19. The premise of passive immunity has been used to treat other viral infections, most notably during the Spanish flu pandemic. Collection, distribution, and transfusion of CCP for use in hospitalized patients with COVID-19 has been undertaken through a government-initiated expanded access program (EAP). Observational data from the EAP, shows CCP to be safe with encouraging signs of efficacy. Many clinical trials are underway to address efficacy of use by disease stage (prophylaxis versus treatment) and/or severity (mild to critically ill). Despite major achievement in record speed, obstacles identified have provided direction and lessons for future emergency responsiveness. Current challenges include the ability to meet demand of plasma as well as appropriate dose and titer measurement.

Contributors:
Christine Cahill, BSN, MS, RN; Majed Refaai, MD

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Do We Really Need a: PBM Coordinator for a Successful PBM Program?

The 2nd session of the SABM Annual Meeting considered the theme question, which was directed at hospital administrators: Do We Really Need a PBM, TSO, Bloodless coordinator.

This presentation was a well-rounded discussion led by three experienced SABM members, Rita Schwab, CPMSM, Becky Rock, RN, and Tiffany Hall, RN, with a very appropriate patient story intertwined throughout. Alexander's story caught our immediate attention and kept our interest in his outcome. This experience emphasized the need to have a patient focused team that brings together different specialties and departments for difficult medical cases while abiding by the patient's refusal of blood transfusion.

Along with formulating the answer to the title question, Tiffany and Becky discussed six (6) pertinent questions regarding the necessity of a PBM Program lead. The first question guided listeners to choosing a position that fulfilled SABM Program Standard 1: Leadership and Program Structure. The skill set of this person should be carefully assessed to meet the needs of the hospital and community.

Question two focused on the goals of the organization that should be considered when starting a PBM Program. The organization should consider the needs of their community such as patients refusing blood transfusions, or possibly addressing patient satisfaction or patient outcomes may be considerations. Many times, a position in the quality or patient safety department proves to be a good fit for this position.

Question three addressed: How can an organization align a PBM position to meet the hospital and community needs? Question four considered the roles needed when choosing a coordinator; six, innovative positions were listed to meet those needs. Question five asked: What do current leaders say about the position and skills needed to lead a PBM Program?

As these questions were analyzed, we heard about Alexander's experience at one hospital when offered the option of being placed into hospice. From there, Alexander was helped to find a PBM program that gathered a focused team of medical professionals to coordinate and collaborate, with a commitment to find a successful solution for this patient refusing transfusion. They did not give up easily when the first attempt at an interventional radiology technique was unsuccessfully attempted. They re-evaluated his needs as a coordinated team leading to a successful solution.

Our last and final question included a list of resources to answer the all-important "how to" question of the training needed for this position; SABM provides a useful toolkit to implement a successful program. The SABM Executive Guide, Administrative and Clinical Standards along with the Quality Guide for those standards is available. Meaningful participation in hospital committees, C-suite endorsement and of course the position of a medical director as champion of the program was emphasized.

The successful outcome to Alexander's experience reinforces a resounding "YES" in answer to the question raised regarding the need for a position that not only focuses on patients yet also on blood avoidance and proper resource stewardship.

Contributor: Jessica Varisco

Summary of Anemia Management Topics

The SABM Annual Meeting delivers the latest science, best practices, and networking opportunities for PBM. Managing Anemia is one of 4 foundational principles of PBM and this year a key learning objectives for the Annual Meeting was to assess the latest research-based recommendations for the detection, evaluation and treatment of anemia in hospitalized and non-hospitalized patients. There were several excellent topics presented at the meeting to address this important PBM pillar.

Breakout Session #1: PBM in Obstetrics

Yulia Lin, MD, (Sunnybrook Health Sciences Centre, University of Toronto, Ontario, Canada) presented *Antepartum Management of Anemia*. Anemia occurs in up to 40% of pregnancies with iron deficiency anemia as the most common cause. There is strong evidence that antepartum anemia is associated with both adverse maternal health outcomes in terms of quality of life, morbidity and mortality and fetal and neonatal health outcomes. Guidelines recommend screening for anemia in first trimester for all pregnant women. In pregnant women with iron deficiency, iron supplementation is key as dietary supplementation alone is not sufficient; intravenous iron is safe and should be considered in women failing oral iron therapy or with severe anemia and short time to delivery/surgery.[1]

Richard Verstraete, RN, (MedStar Georgetown University Hospital, Washington, DC, USA) presented *Ironing Out Maternal Fatigue: Anemia Management for the Postpartum Mom*. While obstetric patient-centered blood management has focused almost exclusively on the antenatal setting, missed opportunities for PBM are occurring on the maternity unit post- delivery. Moderate to severe postpartum anemia (PPA) may be associated with short and long-term health issues. Currently there are no standards for anemia screening in the aftermath of delivery. The maternity unit provides a unique opportunity to enhance a patient-centered blood management initiative. Diagnosis and treatment should begin on the maternity ward; IV iron provides safe and rapid medical treatment for PPA. Attendees left this breakout session informed, inspired and better equipped to tackle the issue of ID and anemia in the postpartum mother in their own hospitals. [2]

The Use of Telemedicine to Expand PBM

This session was presented by **Christian Mabry, MD.** (NYU Langone Health, New York, New York, USA) developed a Preoperative Anemia Clinic with the goal to diagnose and treat iron deficiency anemia in preoperative patients which was successfully implemented in 2019. The clinic is run by the on-site anesthesiologist in the Preoperative Optimization Clinic (POC) and information for the patient was given by a traditional land-line telephone call. After successful implementation, which focused on anemia management, the program planned on expanding the preoperative anemia evaluation to include a comprehensive pre-anesthesia evaluation. The global events of 2020 with the COVID19 pandemic postponed the complete implementation of their expansion, but the POC implemented the use of anesthesia leveraging telemedicine visits to allow for anesthesiologists to perform the pre-anesthesia assessment virtually and remotely. As staff members from both the anesthesia and surgical teams became more comfortable with this new workflow, the goal was to expand these pre-anesthesia evaluations to include anemia management discussions when appropriate. In this way, an anemic patient would get information about their plan for anesthesia, the plan for iron infusions if indicated, and an airway exam that could be saved to their chart by leveraging a telehealth platform. The success of both the remote visits and the anemia clinic indicates that the merging of these two evaluations should be successful in the future.

Breakout Session #4: PBM in Hematology/Oncology Patient

Todd Liu, MD, (Memorial Sloan Kettering Cancer Institute, Stafford Township, NJ, USA) presented *PBM in Oncology Patient: Recurrence and Outcomes*. Oncologic surgical patients often pose significant challenges in regard to transfusion medicine given that anemia is both an independent negative prognostic indicator and frequently under-treated (Fischer et al. Red blood cell transfusion and its alternatives in oncologic surgery-A critical evaluation. Clinical Reviews in Oncology/Hematology 2018 134: 1-9.1). Researchers and clinicians alike have searched for various methods to mitigate these risks, but one of the most persistently controversial alternatives is intraoperative cell salvage. The main concern for the usage of intraoperative blood salvage is potential and theoretical reinfusion of malignant cells that would increase the risk of recurrence and lower disease-free survival. Through the evaluation of cellular evidence from blood salvage filters and meta-analysis of outcome studies one may better assess the risks and benefits of utilizing this alternative method for oncologic surgeries. Clinicians can then form a practical and informed framework to determine whether intraoperative blood salvage is an alternative to allogenic blood transfusion for oncologic surgery patients. [3]

Patricia A Ford, MD, (University of Pennsylvania School of Medicine, Philadelphia, PA, USA) presented *Anemia in Cancer Patients*. Anemia in cancer patients is common and may be due to multiple causes including a direct effect of the cancer, an effect of products released by the cancer, or an effect of treatment. Any anemia of inflammation including malignancy causes a blunted response to erythropoietin and impaired iron homeostasis with increased expression of hepcidin.

Chemotherapy induced anemia (CIA) is one of the most common consequences of chemotherapeutic agents where incidence of anemia is over 60% and prevalence is 30% to 90% particularly in patients undergoing multiple rounds of chemotherapy. The anemia associated with chemotherapy is

normochromic, normocytic but with an inappropriately low reticulocyte count. Serum Iron and Iron-binding capacity are low. The most common manifestations of anemia are fatigue, low energy, and poor quality of life. Patient outcomes could be compromised if the dose and frequency of chemotherapeutic regimens need to be reduced. The current treatment options for CIA are limited, and thus the anemia in most patients with CIA remains untreated. Although erythropoietic stimulating agents (ESA) have been approved for the treatment of CIA, its use has decreased due to safety concerns of risk of tumor progression, cardiovascular risk, and death. Transfusions are often the only treatment utilized, exposing patients to the risks of infection and immunosuppression. Our understanding of the pathophysiology of anemia of inflammation/malignancy expands as new agents are available and undergoing clinical trials to address this unmet need. Two such agents include Luspatercept and Roxadustat. Luspatercept is an erythroid maturation agent that can improve anemia due to beta thalassemia and myelodysplastic syndrome (MDS) by enhancing late-stage erythropoiesis. Luspatercept is approved by the FDA for treatment of anemia associated with MDS with ring sideroblasts or MDS with ring sideroblasts and thrombocytosis. Roxadustat is an orally administered inhibitor of hypoxia-inducible factor (HIF) HIF is a transcription factor that is believed to be the key element in the body's oxygen sensing mechanism and regulates expression of genes that modulate the acute and chronic responses to hypoxia. HIF-responsive genes regulate a wide range of processes, including erythropoiesis, iron metabolism, oxidation, cellular metabolism, cell cycle progression, and apoptosis. Session attendees learned the various challenges surrounding anemia management in cancer patients and introduction of two novel agents for improvement of anemia on the horizon.

Marcus Inyama Asuquo, MD, (University of Calabar Teaching Hospital, Calabar Nigeria) presented *Sickle Cell Anemia and PBM*. From an established paradigm, all patients with sickle cell anemia (SCA) will need a blood transfusion during their lifetime. This concept and established practice has its foundation on a very faulty foundation; diluting sickled cells in a patient with a non-sickled population of cells, dilutes the offending sickled population and resolves the clinical condition. Evidence is that the pathophysiology and the clinical manifestations are not resident on the sickled cells alone. The physician can dilute out the sickled cells but are still not going to solve half of the myriads of clinical phenotypes associated with the disorder. The platelets, endothelial cells, monocytes, neutrophils, and cytokines all have a role in the propagation of the multitude of organ affectation. Research findings have over the years makes clear that transfusion in SCA is not the standard of care as guidelines and skewed research findings appear to portray. Basic understanding of the role endothelial cell damage in sickling, nitric oxide depletion in chronic hemolysis, oxygen dissociation curve to the right and oxygen saturation, hemoglobin concentration, state of hydration, Bohr effect, exercise, and inflammation has improved the care of patients with SCA without blood transfusion. [4]

ASA/SABM Joint Session - Hot Topics in Perioperative PBM for 2020

Matthew Warner, MD, (Mayo Clinic, Rochester, MN, USA). presented *Hospital-acquired Anemia – Epidemiology, Impact and Prevention*. The common prevalence of anemia during hospitalization occurs in 30-75% of patients according to most studies. While allogeneic red blood cell transfusions have appropriately decreased over time, this has been associated with increased "anemia tolerance and neglect" (i.e. increasing prevalence and severity of anemia in hospitalized patients with limited efforts by clinicians to diagnose, evaluate, and address underlying causes). Importantly, there is mounting evidence that anemia experienced during hospitalization is not benign. For many patients, anemia persists long after hospitalization and is associated with poor clinical outcomes, including impairments in physical function and quality of life. Fortunately, there are multiple approaches available to prevent, attenuate, and treat anemia in hospitalized patients, though well-designed studies are necessary to assess the impact of such interventions on hemoglobin recovery and clinical outcomes. An important objective of this session is for clinicians to recognize the associations between anemia and clinical outcomes in hospitalized patients and appreciate opportunities to prevent and mitigate anemia in this population.

Contributor: Tiffany Hall, RN

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Summary of Anemia Management Topics

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PBM in Resource Poor Countries

“PBM in the Emerging World: A Moral Mandate for Action!”

When anticipating the “International PBM” panel at the recent Annual Meeting, it’s understandable for viewers to assume the talk on PBM in developing/emerging countries might center on a review of the current challenges, the available resources (or lack thereof), and how the Western world can ‘help’. However, for those who have had the privilege of hearing other talks given by Bruce Spiess, MD, it’s no surprise that he gives the audience much to think about.

The 2010 World Health Organization (WHO) statement describes the benefits of PBM and its importance in quality care. While the WHO and other organizations call us to action on PBM, Dr. Spiess notes that implementation across the globe isn’t and probably can’t be universal when the needs, resources and circumstances are anything but equal.

Viewers of the talk will hear striking examples of global inequality, including that among 194 countries, only 34 can be described as having ‘adequate or modern’ Transfusion Medicine services. Among those, there are further variations in terms of components/products available, how blood is managed and maintained, transmissible disease risk among donors, what testing is available for donated blood, and more. Differences in access to nutrition, prenatal care, and other factors also affects ‘who’ is most at risk for needing transfusion: in developed countries, the vast majority of recipients are older than 60 years of age, whereas in developing/emerging countries, most recipients are children under 5 years of the age. Amid high risks of transmissible disease in the emerging world, is it any wonder that transfusion is so feared when the most common recipients are the youngest of all?

As to how to best support our neighbors across the globe, Dr. Spiess noted that without ‘boots on the ground’ experience, it’s unfair for authors to pen papers calling for ‘modern Blood Banking’ in developing countries. Launching Western processes in systems that don’t have the resources or infrastructure to accommodate them isn’t likely to be successful, nor is it likely to be sustainable. Further, the focus on improving Blood Banking is transfusion-centric, whereas patient-centric solutions are most needed. It’s here where Dr. Spiess builds the case for PBM in emerging countries in terms of its relevance, ability to address root causes of health issues, and importantly—its ease of implementation and likelihood of sustainability amid varying resources.

A stand-out feature of Dr. Spiess’ talk centers around his admission of humility: that perhaps he isn’t the best person to offer a talk about PBM in emerging countries and maybe someone from within could better describe the issues, the challenges, and the outlook ahead. However, it might be this very so-called ‘Ivory Tower’ vantage point that enables Dr. Spiess to best call-out the attitudes and arrogance of the West—perhaps even a continued, colonial mind-set—that assumes what works in developed countries is best for all. It’s here where Dr. Spiess calls us to join the “Moral Mandate for Action”, under a pillar of respect, and help further the development of PBM as a global standard of care.

Contributor: Becky Rock, RN

When Blood Is Not an Option

Break-Out Session

The doors burst open and paramedics quickly push a gurney into one of the small ED cubicles. The staff begins to efficiently assess the patient, attach monitors, record vitals, and start fluid resuscitation. A physician scans the available data, notes that the patient has lost some blood and considers ordering a transfusion. He changes course however, when he sees the note on the record: patient declines blood transfusion.

Even in the presence of significant anemia, that restriction will likely not cause undue concern to a physician with expertise and confidence in the principles of patient blood management.

The SABM break-out session "When Blood is Not an Option" was a highly-anticipated presentation at this year's annual conference. As the decision to decline blood products, either for religious or personal reasons, is becoming increasingly common among hospitalized patients, forward-thinking clinicians in attendance at this year's conference were eager to learn the most effective ways to care for patients without the use of allogenic transfusion.

Sherri Ozawa, **RN**, SABM president and long-time director of the PBM program at Englewood Health, (Englewood, NJ, USA) kicked off the session by addressing the need for a multi-disciplinary, multi-modal approach, and well thought-out institutional anemia-management protocols. She spoke of the value of team collaboration as a way to:

- Develop patient-centered strategies for effective management of challenging cases
- Establish goals of care
- Provide consistent communication among team members and with the patient
- Identify any needed resources such as coagulation testing, cell-salvage, hemodilution, pharmaceuticals, etc.

Stephen Brower, MD, Chief of Surgical Oncology at Englewood Health, provided insight into surgical strategies employed at the well-known Bloodless Medicine/Patient Blood Management program at Englewood Hospital. He stated that transfusion has been found to be a negative prognostic variable in the management of oncology patients, and that his team works hard to avoid the need for transfusing patients who come to them for care. Englewood has established an institutional anemia management protocol used across service lines.

Dr. Brower emphasized the need for members of the multi-disciplinary team to remain open to modifying the treatment plan based on the recommendations and skills of others. Sometimes, as he pointed out, the initial plan may not work as expected and adjustments will be needed. He reviewed two challenging cases that required extensive planning and collaboration among many members of the treatment team.

Ashlee Howard, RN, PBM Navigator, Englewood Health, shared practical tips on scheduling and facilitating multi-disciplinary team meetings, including:

- Narrow down available meeting times by starting with the most difficult person to schedule
- Identify which specialties and service lines may be involved in the patient's care and invite representatives to the meeting
- Appoint a facilitator and a note-taker
- Make sure applicable images, records, and reports are available for review
- Provide team members with current documentation from the patient on personal choices, etc.
- Assure participants that the team approach is not because of any concerns for an individual's competency or skill, but as a method to map out the best treatment options for the patient
- Provide follow-up information after the meeting

Zenon Bodnaruk, Associate Director for Clinical Affairs, Hospital Information Services for Jehovah's Witnesses (Warwick, NY, USA) offered insight into the perspective of Witnesses who decline transfusion based on religious belief.

Mr. Bodnaruk reviewed:

- Jehovah's Witness' position on medical treatment
- The role of the Hospital Liaison Committee (HLC) network, comprised of 1700 committees world-wide
- Available resources for collaboration

The strategies encouraged for Witness patients are:

- Minimizing blood loss
- Helping the patient produce more of their own blood
- Supporting the patient during periods of anemia or thrombocytopenia

Mr. Bodnaruk noted that as with many areas of medicine not all patients think alike, so it is important to clarify individual choice as part of the informed consent process.

Jehovah's Witness patients ask that their physicians consider:

- Reviewing clinical strategies for transfusion alternatives and consult with colleagues
- Contacting their local Hospital Liaison Committee
- Transferring the patient if needed

Mr. Bodnaruk closed by thanking the clinicians, many of whom are SABM members, who have worked diligently over the years to develop expertise and refine treatment strategies to improve the use of transfusion alternatives.

The session provided a wealth of practical guidance for establishing and maintaining an effective hospital-based PBM program, and for safely managing the care of even complex patients without transfusion.

Contributor: Rita Schwab, CPMSM

Transfusion Trials – Important Questions Raised

The literature around restrictive and liberal transfusion trials has exploded in recent years. In an attempt to systematically search and summarize the results from these trials, we recently published an Overview of Systematic Reviews and Meta-analyses in *BMC Medicine.*[1] Our main finding was three-quarters of meta-analyses report no difference in death rates between transfusion strategies, and one-quarter report lower mortality with the restrictive strategies.

How should we interpret these results? Interestingly, our overview uncovered a number of concerns that limit the interpretation of results. Consequently, we encourage readers of clinical trials comparing transfusion strategies to ask the following three questions.

1: What was the actual difference in red cell units transfused between restrictive and liberal groups?

Surprisingly, many clinical trials compare small differences in red cell unit transfusions between groups. For example, after reviewing 68 trials we found nearly half reporting the units transfused had a mean difference between groups of less than one unit transfused per patient (14 out of 32). Of these trials half had a mean difference of half a unit of red cells or less.[2] Given evidence from observational data suggests the relationship between red cell transfusion and outcomes is dose-dependent, it is unlikely these small differences in units of blood transfused between groups would result in significant differences in patient outcomes.

2: What was the actual difference in hemoglobin concentrations between restrictive and liberal groups?

Clinical trials comparing hemoglobin thresholds for red cell transfusion can often have small *actual* differences in hemoglobin thresholds for transfusion between groups. The majority of clinical trials *plan* to compare a restrictive and liberal threshold with a difference of 2 g/dL (commonly comparing thresholds of 7 g/dL to 9 g/dL, or 8 g/dL to 10 g/dL). But what are the *actual* differences?

Trials that compare planned hemoglobin thresholds with a difference of 2 g/dL between groups are more likely to have differences closer to 1 g/dL. One Cochrane systematic review demonstrated a significant number (38%) of clinical trials had a mean difference in hemoglobin thresholds between groups of 1 g/dL or less.[3] It would be unlikely for such a small difference in hemoglobin thresholds to influence clinical outcomes.[4] We recommend interpreting the results of these clinical trials with this in mind.

3: Were there any red cell transfusions prior to randomisation?

Red cell transfusions administered prior to randomization is an issue not often discussed. In perhaps an extreme example, this can even result in patients in the restrictive transfusion group receiving more units of blood than patients in the liberal group.[5] Ignoring the number of units transfused prior to randomization can lead to a number of issues. It would be difficult to imagine other clinical settings where a randomized controlled trial researching the effect of an intervention on outcomes, ignores how frequently patients are exposed to the intervention prior to study inclusion.

How not to interpret these results

The majority of randomized controlled trials show no difference in mortality between transfusion strategies. Does this mean that transfusion is not associated with worse outcomes, and that observational studies consistently finding increased morbidity and mortality associated with transfusion are wrong? The reality is that these two types of studies cannot be compared as they investigate different interventions and comparator groups. They are, by design, attempting to answer very different research questions. The question of transfusion efficacy on outcomes cannot be answered by randomized controlled trials comparing higher vs lower hemoglobin thresholds for transfusion. This question is best answered by meta-analyses of observational studies comparing outcomes in patients transfused to patients not transfused.

Transfusion trials seek to find the answer to what is the optimal hemoglobin threshold for transfusion. When critically appraising the results of such trials we encourage readers to interpret these with care and keep in mind the three key limitations identified in our overview.

Contributor: Kevin Trentino, MPH

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HALT-IT Trial Outcome

Moderator Gee Mei Tan, MD, invited Ian Roberts, MD, a Professor of Epidemiology at the London School of Hygiene & Tropical Medicine for his presentation titled “TXA for Life Threatening Bleeding”. Professor Roberts has played lead roles in several large trials including the CRASH trials and the WOMAN trial. He was a lead investigator for the HALT-IT trial which would be a pragmatic, randomized, double-blind, placebo-controlled trial to determine the effect of tranexamic acid on mortality and morbidity such as re-bleeding or non-fatal vascular events, blood transfusion, surgical intervention, and health status in patients with acute gastrointestinal bleeding. Twelve thousand adult patients would participate.

Acute gastrointestinal bleeding (GIB) is an important cause of mortality worldwide. Professor Roberts recounted the benefits of TXA in the surgical setting, in traumatic brain injury, and in postpartum hemorrhage with observed reductions in blood loss, thus reducing blood transfusions and the risk of death.

How effective and safe did the HALT-IT trial show TXA to be in GIB? The professor reported that the trial showed no reduction in re-bleeding, no decrease or increase in all-cause mortality, no reduction in blood transfusion. Additionally, a significant increase in venous thrombotic events was observed. On balance however, Professor Roberts suggested that several confounding factors may have affected the results of this trial. These were presented in the form of questions with his comments as follows:

1) Was the trial too small? Ideally perhaps 20,000 participants might offer a large enough patient base to exclude modest treatment effects.

2) Was treatment with TXA started too late? A very important variable, yet it was impossible to know the time of onset of a GI bleed, so there was uncertainty if TXA was administered early enough.

3) Did the dose and duration of treatment affect results? Longer duration may possibly contribute to increase in venous thrombotic events?

4) Did the mixed fibrinolytic phenotype present in liver disease have an impact? Liver disease has a very complicated coagulation profile (i.e., bleeding while being prothrombotic.)

Contributor: Roland Dale Black

SABM Opinion

Aryeh Shander, MD, and Bruce Spiess, MD, were asked to provide observations on the HALT-IT trial discussion and the confounding factors presented.

Aryeh Shander, MD, commented: “These confounding factors plague the CRASH and WOMAN trials too. For example, P value is greatly affected by the number of participants. Suggesting more subjects might increase the likelihood of a statistically significant event, but it may still not meet clinical significance. Significant knowledge gaps remain on dosing, pharmacokinetics, mechanism of action, and clinical applications for TXA, which we have raised with the other trials. There is a need for “targeted” therapy, i.e., identifying those who may be helped with TXA vs those who might be harmed. Whether IV or PO, antifibrinolytics i.e., lysine analogues, may play a role in supporting other interventions in GI bleeding. (Tranexamic Acid for Acute Hemorrhage: A Narrative Review of Landmark Studies and a Critical Reappraisal of Its Use Over the Last Decade Lier, Heiko; Maegele, Marc; Shander, Aryeh *Anesthesia & Analgesia*. 129(6):1574-1584, December 2019)

Bruce Spiess, MD, commented: “GI bleeding is a catch all term with many heterogeneous causes. The release of tissue plasminogen activator (TPA) are hallmarks of cardiac, orthopedic and many other surgeries, but is not the case in GI bleeding. TPA activates the action of plasminogen phase change and protease activity to become plasmin. It is the TPA activated change of those proteins that TXA and Epsilon Amino Caproic Acid (Amicar) as lysine analogues can block. Remember that all GI bleeding is not the same, as for example, upper GI bleeding is dramatically different both in its causes as well as its course; the same can be true in the stomach. An understanding of clot dynamics, and plasminogen-to plasmin biochemistry is vital to consider if there are to be expectations that this drug would have an effect. One has to also consider the propensity for clot lysis, other causes of clot strength failure i.e., low platelet count, dysfunctional platelets, low fibrinogen concentration, low factor XIII levels, and even oxidized fibrinogen. TXA should not be expected to improve a wide variety or all coagulation problems. In the end, clotting is highly complex and it appears that the investigators expected more from this study than it could possibly achieve.”

These comments may give pause to those who are forming an opinion on the HALT-IT trial and its findings on the efficacy of TXA for GI bleeding.

Membership / Board Members Update

The mission of SABM Membership Committee is to engage individuals, hospitals, and corporates that share SABM's strategic mission to promote Patient Blood Management (PBM). The Membership Committee develops and implements recruitment and retention strategies and recommends activities that ensure value to membership.

The Mentorship Committee has now merged as part of Membership Committee. Mentors and mentees can apply through an online application in order to connect participants in one-on-one relationships, with the goal of providing coaching, support, encouragement and inspiration. This program provides newer SABM members with a resource for learning, guidance, and experience by mentorship of professionally compatible senior SABM members. Mentors can help mentees take their PBM or Bloodless Programs to the next level and help them navigate the many resources and benefits of SABM Membership.

The role of the Membership Committee Chair is to review and approve every application for membership and encourage new members to become involved in one or more of the many committees that contribute to SABM's success. In collaboration with the Communications Committee, the Membership Committee refines and updates the PBM online program list for accuracy and appropriate inclusion of listings. A future endeavor of the Membership Committee will be to formalize Organizational Affiliate Membership for SABM's global partners.

Contributor: Gagan Mathur, MD

SABM WELCOMES THESE NEWLY ELECTED AND RE-ELECTED BOARD MEMBERS

Gagan Mathur, MD, MBA

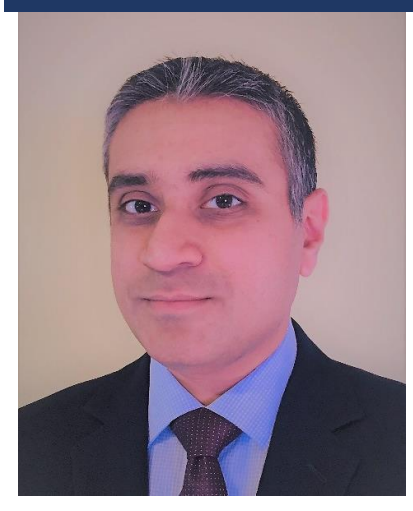
System Medical Director, Transfusion Service Saint Luke's Health System, Kansas City, MO

Gagan Mathur, MD, is a board-certified Clinical Pathologist and Transfusion Medicine/Blood Banking physician. Dr. Mathur also pursued a Master of Business Administration (MBA) from University of Iowa Tippie School of Management during his clinical training at University of Iowa Hospitals & Clinics, Iowa City, IA. He holds academic title of Associate Professor of Pathology at University of Missouri-Kansas City.

Currently, Dr. Mathur is serving as System Medical Director of Transfusion Service at Saint Luke's Health System, Kansas City, MO. He is passionately implementing a myriad of patient blood management initiatives throughout his health system. Utilizing his interest and training in business management, informatics and healthcare administration, he strives to provide effective and efficient patient care.

Dr. Mathur has been an active member of SABM since 2017. He is currently the Chair of the Membership Committee and a member of the Scientific Committee. Dr. Mathur is also an active member of several other medical societies and holds leading roles in organizations such as AABB (Team leader, Annual Meeting Education Committee and Member, Continuing Education Advisory Committee), ASFA (Member, Research Subcommittee and Clinical Applications Committee), and HAABB (President Elect 2020-21).

Prakash Patel, MD, FASE



Cardiac Anesthesiologist, Assistant Professor of Anesthesiology and Critical Care at the Hospital of the University of Pennsylvania Philadelphia, PA

Prakash A. Patel, MD, is a cardiac anesthesiologist and Assistant Professor at the University of Pennsylvania in Philadelphia, PA. He completed his medical training at Jefferson Medical College and his anesthesiology residency and cardiac anesthesia fellowship at the Hospital of the University of Pennsylvania. Dr. Patel has strong interests in blood conservation, and he has led several initiatives at his hospital to create an algorithmic approach to blood management and transfusion. Further interests include management of post-cardiopulmonary bypass coagulopathy with the appropriate use of factor concentrates in addition to routine clotting factors. His expertise in coagulation has made him his department's leader on the subject, and he has spoken both nationally and internationally on the topic.

Dr. Patel has been an active member of SABM since 2014 and has been involved in each Annual Meeting since 2015. He has participated in the Membership Committee, having served as committee Co-Chair from 2016-17. He also has served as Scientific Committee Chair (2018) and has been an active member of the Annual Meeting Planning Committee (AMPC) for the past two years. As AMPC Co-Chair in 2019, he worked with the committee to create an extremely successful meeting in Baltimore. This September, Dr. Patel will be joining the faculty at Yale University, with goals to expand the concepts of PBM in their perioperative arena as he has done at his prior institution.

Membership / Board Members Update

Linda Shore-Lesserson, MD, FAHA

Professor of Anesthesiology
Zucker School of Medicine at Hofstra Northwell
Vice Chair for Academic Affairs
Director, Cardiovascular Anesthesiology
Northshore University Hospital
Manhasset, NY

Linda Shore-Lesserson, MD, is Professor of Anesthesiology, director of Cardiothoracic Anesthesiology, and Vice Chair for Academic Affairs at Northshore-University Hospital in New York. She received her medical degree from the University of Pennsylvania and was an anesthesiology resident and cardiothoracic anesthesia fellow at Mount Sinai in NY. She is a diplomate of the American Board of Anesthesiology, and the National Board of Echocardiography. She is committed to multidisciplinary science and education.

Dr. Shore-Lesserson is a past president of the Society of Cardiovascular Anesthesiologists during which time she created alliances with the STS and Perfusion societies to create Guidelines for Best Practices in Perfusion Management. She is involved with other medical cardiovascular disciplines as well and is on the leadership committee of the American Heart Association Surgery and Anesthesia Council. She has chaired the Committee on Patient Blood Management for the American Society of Anesthesiologists and was instrumental in facilitating the "annual" ASA at SABM panel in which ASA members participate. She is also an active program committee member for the New York State Society of Anesthesiologists PGA Annual Meeting.

Dr. Shore-Lesserson has served as a member of the Associate Editorial Board for Anesthesia and Analgesia and she continues to review for the journal. She serves on the Editorial Board of the Journal of Cardiothoracic and Vascular Anesthesia. She was involved in the creation of the Joint SABM-ASA panel in which ASA/SABM members present topics of interest in perioperative medicine.

Bruce D. Spiess, MD, FAHA

Professor and Associate Chair (Research)
Department of Anesthesiology
University of Florida College of Medicine
Gainesville, FL

Bruce Spiess, MD, grew up the son of PhD academicians. He attended Denison University, Granville, Ohio, and been recognized by Denison with their highest achievement award. His medical degree is from Rush University, Chicago and his anesthesiology training was at The Mayo Clinic, Rochester, Minnesota. There he worked with Dr. Pepovsky, Dr. Faust and others learning blood banking techniques as well as developing an interest in “blood substitutes.” After residency Dr. Spiess returned to Chicago at Rush University where he began his research career into Perfluorocarbon compounds. From Rush he went to become Chief of Cardiac Anesthesiology at the University of Washington, Seattle. After 10 years he moved to Richmond, Virginia, Virginia Commonwealth University where he was appointed Vice Chair, Director of Research and Director of Cardiac Anesthesiology. He spent 17 years at VCU. While at VCU, Dr. Spiess was Director of VCURES (a collaborative effort by over 100 researchers to study trauma and critical oxygen delivery.

In 2016, Dr. Spiess joined the University of Florida to be Associate Chair in charge of research. Dr. Spiess has focused his major research interests in blood, blood substitutes/oxygen therapeutics, decreasing excessive use of blood products and making the operating room environment safer. He was selected by the Department of defense to Co-Direct a select meeting of the Department of Defense, Combat Casualty Command, FDA, NIH and BARDA with regards to the state of the art in oxygen therapeutics at Ft Detrick, Maryland, February 2017. This two-day conference brought in 125 of the worlds thought leaders and made recommendations to Congress and the sponsoring agencies regarding directions for research.

Dr. Spiess is currently a member of the SABM Strategic Alignment Workgroup.

Membership / Board Members Update

Jonathan H. Waters, MD

Professor of Anesthesiology & Bioengineering, University of Pittsburgh
Chief of Anesthesiology, UPMC Magee Womens Hospital
Medical Director, UPMC Patient Blood Management Program
Pittsburgh, PA

Jonathan Waters, MD, is currently a Professor in the Departments of Anesthesiology and Bioengineering at the University of Pittsburgh; Chief of the Division of Anesthesiology at Magee-Womens Hospital of the University of Pittsburgh Medical Center and, a member of the McGowan Institute for Regenerative Medicine. In addition, he is Medical Director of the Patient Blood Management program of UPMC and Medical Director of the Blood Management Division for Procirca, Inc, a UPMC owned Biomedical Engineering Company. His areas of expertise primarily focus on transfusion management, blood salvage and obstetrics. He has been federally funded to support investigation in these areas with over 150 peer-reviewed publications, five books on the topic of blood management and a book on neurologic disease in pregnancy. In addition to conducting research, he has served on the editorial board of the journal, Transfusion, and is currently serving as an Associate Editor. He is a past president of SABM, and he served on the Board of Directors of the AABB between 2011 and 2015. He chaired the blood management technical advisory panel for the Joint Commission from 2007 to 2016.

SABM ACKNOWLEDGES THE SERVICE OF OUR OUTGOING BOARD MEMBERS

Susan M. Goobie, MD, FRCPC

During her time of service on the SABM Board of Directors, Dr. Goobie contributed invaluably to SABM's academic and scholarly endeavors. She was a key author in the updated 5th Edition of the SABM Clinical and Administrative Standards for PBM Programs with its addition of a Pediatric standard and indicators. In addition, she generously accepted the position as Section Editor of SABM's PBM section of the Journal *Anesthesia & Analgesia*; under her leadership, the quality and diversity of published work has grown even stronger. While she will be sorely missed on the Board, we are confident that her ongoing involvement with SABM and her energy and vision in PBM will continue to inspire and teach us.

NurJehan Quraishy, MD

From the moment Dr. Quarishy began her SABM Board service, fellow Board members immediately noted her calm and dignified demeanor – yet she never shied away from expressing her clear vision of the need for quality in all of SABM's work. She brought to SABM governance the important viewpoint of the Transfusion Medicine physician, while keeping focus on the larger clinical goals and patient centered philosophy for which SABM stands. Her leadership in organizing, advancing, and promoting the SABM Certificate course as its Co-Director has been invaluable. Dr. Quarishy elevated the course to a comprehensive, evidence-based, multidisciplinary curriculum in PBM, that has directly benefitted the hundreds of learners who have taken the course. We look forward to her wisdom and insight as we fully revamp the course for 2021 and welcome many new learners.

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- **Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.**
- **Observe for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following Feraheme infusion including monitoring of blood pressure and pulse during and after Feraheme administration.**
- **Hypersensitivity reactions have occurred in patients in whom a previous Feraheme dose was tolerated.**

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WARNINGS AND PRECAUTIONS, Serious Hypersensitivity Reactions: Fatal and serious hypersensitivity reactions including anaphylaxis, presenting with cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, or unresponsiveness have occurred in patients receiving Feraheme. Other adverse reactions potentially associated with hypersensitivity have occurred (pruritus, rash, urticaria, and wheezing). These reactions have occurred following the first dose or subsequent doses in patients in whom a previous Feraheme dose was tolerated.

Patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. Carefully consider the potential risks and benefits before administering Feraheme to these patients.

Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions. Closely observe patients for signs and symptoms of hypersensitivity including monitoring of blood pressure and pulse during and after Feraheme administration for at least 30 minutes and until clinically stable following completion of each infusion.

In a clinical study in patients with IDA, regardless of etiology, hypersensitivity reactions were reported in 0.4% (4/997) of subjects receiving Feraheme administered as intravenous infusion over at least 15 minutes. These included one patient with severe hypersensitivity reaction and three patients with moderate hypersensitivity reactions.

In clinical studies predominantly in patients with IDA and CKD, serious hypersensitivity reactions were reported in 0.2% (4/1,806) of subjects receiving Feraheme (administered as a rapid intravenous injection – prior method of administration no longer approved). Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.5% (63/1,806) of these subjects.

In the post-marketing experience, fatal and serious anaphylactic type reactions presenting with cardiac/ cardiorespiratory arrest, clinically significan t hypotension, syncope, and unresponsiveness have been reported. Elderly patients with multiple or serious co-morbidities who experience hypersensitivity reactions and/or hypotension following administration of Feraheme may have more severe outcomes.

Hypotension: Feraheme may cause clinically significant hypotension.

In a clinical study with Feraheme in patients with IDA, regardless of etiology, moderate hypotension was reported in 0.2% (2/997) of subjects receiving Feraheme administered as intravenous infusion over at least 15 minutes.

In clinical studies in patients with IDA and CKD, hypotension was reported in 1.9% (35/1,806) of subjects, including three patients with serious hypotensive reactions, who had received Feraheme as a rapid intravenous injection (prior method of administration no longer approved).

Hypotension has also been reported in the post-marketing experience. Monitor patients for signs and symptoms of hypotension following each Feraheme administration.

Iron Overload: Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Regularly monitor the hematologic response during parenteral iron therapy. Do not administer Feraheme to patients with iron overload. In the 24 hours following administration of Feraheme, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in the Feraheme complex.

Magnetic Resonance (MR) Imaging Test Interference: Administration of Feraheme may transiently affect the diagnostic ability of MR imaging. Conduct anticipated MR imaging studies prior to the administration of Feraheme. Alteration of MR imaging studies may persist for up to 3 months following the last Feraheme dose. If MR imaging is required within 3 months after Feraheme administration, use T1- or proton density-weighted MR pulse sequences to minimize the Feraheme effects; MR imaging using T2-weighted pulse sequences should not be performed earlier than 4 weeks after the administration of Feraheme. Maximum alteration of vascular MR imaging is anticipated to be evident for 1 – 2 days following Feraheme administration.

Feraheme will not interfere with X-ray, computed tomography (CT), positron emission tomography (PET), single photon emission computed tomography (SPECT), ultrasound or nuclear medicine imaging.

ADVERSE REACTIONS: The following serious adverse reactions are described elsewhere in the labeling: Serious Hypersensitivity Reactions, Hypotension, Iron Overload, Magnetic Resonance (MR) Imaging Test Interference.

Clinical Trial Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical studies, 3,968 subjects were exposed to Feraheme. Of these subjects 31% were male and the median age was 54 years (range of 18 to 96 years).

The data described below reflect exposure to Feraheme in 997 patients exposed to a 1.02 g course of ferumoxytol administered as two 510 mg intravenous (IV) doses: 992 subjects (99.5%) received at least 1 complete dose of ferumoxytol and 946 subjects (94.9%) received 2 complete doses. The mean cumulative IV Iron exposure was 993.80 ±119.085 mg.

The safety of Feraheme was studied in a randomized, multicenter, double-blind clinical trial in patients with IDA (IDA Trial 3). In this trial, patients were randomized to two intravenous infusions of 510 mg (1.02 g) of Feraheme (n=997), or two intravenous infusions of 750 mg (1.500 g) of ferric carboxymaltose (FCM) (n=1000). Both intravenous irons were infused over a period of at least 15 minutes. Most patients received their second infusion of Feraheme and FCM 7(+1) days after Dose 1.

The mean (SD) age of the study population (N=1997) was 55.2 (17.16) years. The majority of patients were female (76.1%), white (71.4%) and non-Hispanic (81.8%). The mean (SD) hemoglobin at baseline for all patients was 10.4 (1.5) g/dl.

Serious adverse events were reported in 3.6% (71/1997) of ferumoxytol- and FCM-treated patients. The most common (≥2 subjects) serious AEs reported in Feraheme-treated patients were syncope, gastroenteritis, seizure, pneumonia, hemorrhagic anemia, and acute kidney injury. In FCM-treated patients the most common (≥2 subjects) serious AEs were syncope,cardiac failure congestive, angina pectoris, and atrial fibrillation.

Adverse reactions related to Feraheme and reported by ≥ 1% of Feraheme-treated patients in IDA Trial 3 following administration of Feraheme 2 x 510 mg (N=997) or ferric carboxymaltose 2 x 750 mg (N =1000) were headache (3.4% Feraheme, 3.1% ferric carboxymaltose), nausea (1.8, 3.4), dizziness (1.5, 1.6), fatigue (1.5, 1.2), diarrhea (1, 0.8), and back pain (1, 0.4).

In IDA Trial 3, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included arthralgia (0.3%), dyspnea (0.3%), flushing (0.2%), chest discomfort (0.2%), chest pain (0.2%), nausea (0.2%), back pain (0.2%), dizziness (0.2%) and headache (0.2%).

Across two clinical trials in patients with IDA (IDA Trial 1 and 2), patients were randomized to: two injections (rapid intravenous injection - prior method of administration no longer approved) of 510 mg of Feraheme (n=1,014), placebo (n=200), or five injections/infusions of 200 mg of iron sucrose (n=199). Most patients received their second Feraheme injection 3 to 8 days after the first injection. Adverse reactions related to Feraheme and reported by ≥ 1% of Feraheme-treated patients in these trials were similar to those seen in Trial 3.

In Trials 1 and 2, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included hypersensitivity (0.6%), hypotension (0.3%), and rash (0.2%).

In addition, a total of 634 subjects enrolled in and completed participation in a Phase 3 open label extension study. Of these, 337 subjects met IDA treatment criteria and received Feraheme. Adverse reactions following this repeat Feraheme dosing were generally similar in type and frequency to those observed after the first two intravenous injections.

Across three randomized clinical trials in patients with IDA and CKD (CKD Trials 1, 2, and 3), a total of 605 patients were exposed to two injections of 510 mg of Feraheme and a total of 280 patients were exposed to 200 mg/day of oral iron for 21 days. Most patients received their second Feraheme injection 3 to 8 days after the first injection.

Adverse reactions related to Feraheme and reported by ≥ 1% of Feraheme-treated patients in the CKD randomized clinical trials following administration of Feraheme 2 x 510 mg (n=605) or oral iron (n=280) were nausea (3.1% Feraheme, 7.5% oral iron), dizziness (2.6, 1.8), hypotension (2.5, 0.4), peripheral edema (2, 3.2), headache (1.8, 2.1), edema (1.5, 1.4), vomiting (1.5, 5), abdominal pain (1.3, 1.4), chest pain (1.3, 0.7), cough (1.3, 1.4), pruritus (1.2, 0.4), pyrexia (1, 0.7), back pain (1, 0), muscle spasms (1, 1.4), dyspnea (1, 1.1), and rash (1, 0.4). Diarrhea (4%), constipation (2.1%) and hypertension (1%) have also been reported in Feraheme-treated patients.

In these clinical trials in patients with IDA and CKD, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included hypotension (0.4%), chest pain (0.3%), and dizziness (0.3%).

Following completion of the controlled phase of the trials, 69 patients received two additional 510 mg intravenous injections of Feraheme (for a total cumulative dose of 2.04 g). Adverse reactions following this repeat Feraheme dosing were similar in character and frequency to those observed following the first two intravenous injections.

Postmarketing Experience: Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following serious adverse reactions have been reported from the post-marketing experience with Feraheme: fatal, life-threatening, and serious anaphylactic-type reactions, cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, unresponsiveness, loss of consciousness, tachycardia/rhythm abnormalities, angioedema, ischemic myocardial events, congestive heart failure, pulse absent, and cyanosis. These adverse reactions have usually occurred within 30 minutes after the administration of Feraheme. Reactions have occurred following the first dose or subsequent doses of Feraheme.

See full Prescribing Information for Feraheme available at www.feraheme.com.

AMAG Pharmaceuticals, Inc. 1100 Winter Street.
Waltham, MA 02451. PP-FRH-US-00102

1. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc; 2018.

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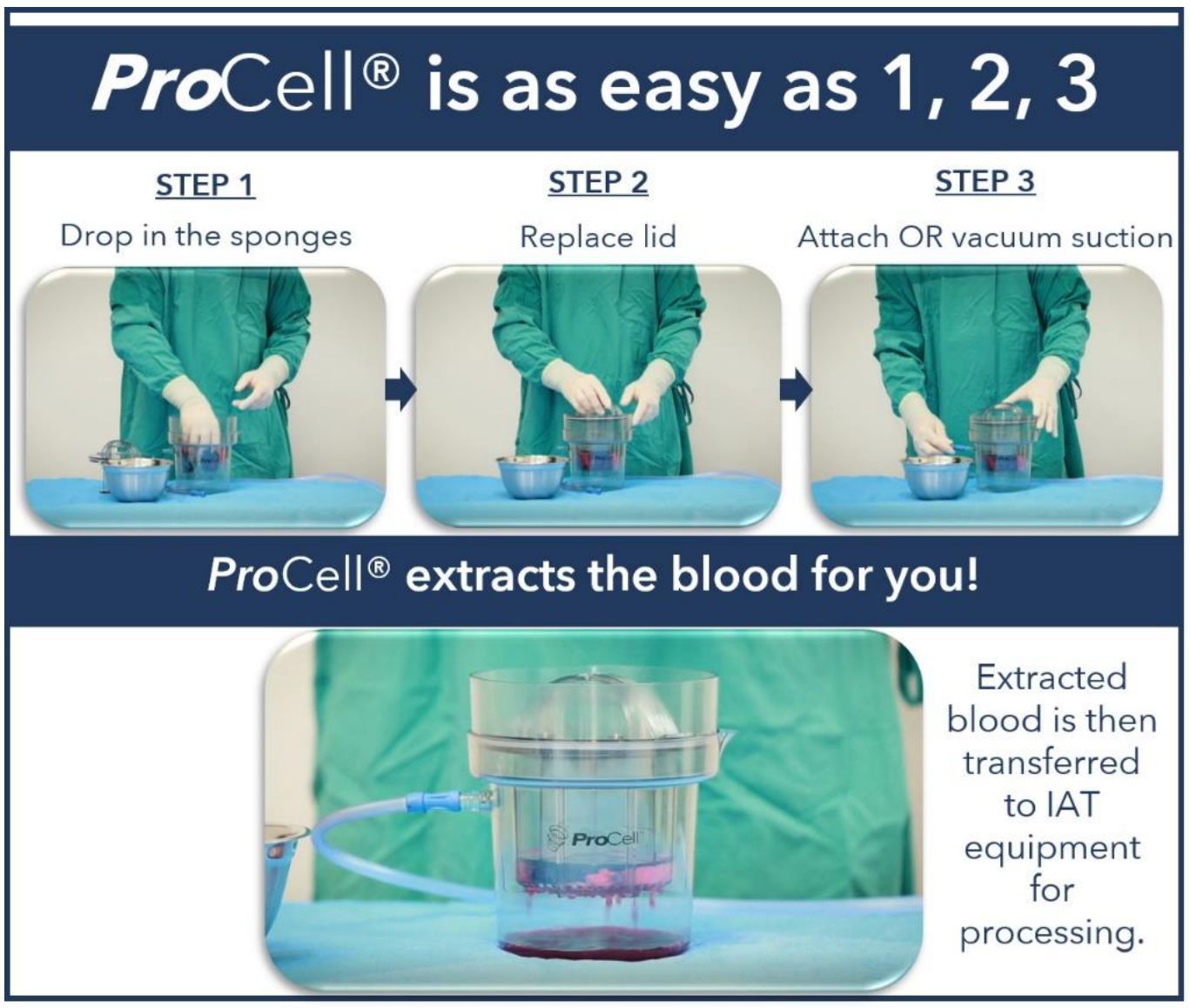

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