

Letter from the President – Sherri Ozawa, RN



We are beginning to see positive signs of recovery throughout the nation. Our minds and hearts are full of thoughts and feelings for lives lost, the widespread pain and suffering, also deep admiration for the dedication to our patients and to our calling that we see in one another. PBM continues to advance in

relevance and importance, particularly in the face of this most challenging of times, and SABM has been proud to adapt educational offerings, mentorship opportunities, projects, and communication to the changes that this past year has brought about.

There are exciting recent developments – we have completed a memorandum of understanding with The International Foundation for Patient Blood Management, www.ifpbm.org, an organization with an aligned philosophy to SABM's but a different organizational structure, allowing for access to expanded opportunities for collaboration and international impact. Our recent change to include “patient” in the name of our Society also echoes the growing fibers of global collaboration: practitioners, educators, and thought leaders understand how the promoting of PBM benefits all involved.

Along these same lines, we have created a structure for affiliate organizations, as around the world different geographical regions have formed PBM organizations whose approach to PBM implementation mirrors SABM. The first three groups that have applied for organizational affiliation are the Asia Society for PBM, the Malaysian Society for PBM, and the Bloodless Medicine and Surgery Society in Africa. We are delighted to deepen our relationships with such organizations and the many others to follow.

There are also exciting developments in Asia – SABM has been asked to partner with the Nepal Medical Association,

and with IFPBM; we will be virtually supporting the first South Asia PBM conference. Medical leaders across Nepal have been engaged in months of discussions, and are planning not just a conference, but also the formation of an organized PBM society. These clinicians are particularly interested in the impact of widespread iron deficiency and anemia, the pressing issue of maternal hemorrhage, and how PBM strategies can support improved patient care. Additionally, they are currently translating our SABM Standards into Nepalese.

Along these lines, we are ahead of schedule on our plans for translation of our Standards into other languages. As you may have noted, Portuguese has been completed and posted to our website, with big thanks to our institutional affiliate, Heart Institute (InCor) in Sao Paulo, Brazil. The Korean and Chinese version of the standards have also been completed and are in review; we expect the Spanish translation to be completed by the end of the 2nd quarter of this year.

Hopefully you were able to join our recent webinar series on Optimizing Care of the Surgical Patient, under the guidance of our outstanding President Elect Carolyn Burns, MD. These webinars featured SABM members and leaders: Matt Warner, MD, Pierre Tibi, MD, Susan Goobie, MD, Aryeh Shander, MD, and David Faraoni, MD, our most recently appointed advisory board member.

While we are eagerly awaiting our Annual Meeting in September, the content is shaping up to be another excellent scientific and academic event. With the leadership of Co-Chairs Rita Schwab, CPMSM, and Micah Prochaska, MD, we are confident that the conference will be of the highest caliber.

I thank each of you for your perseverance during this most challenging time, and for all you do both for SABM and the patients under your care.

Sincerely,

Sherri Ozawa, RN

**SABM NEWSLETTER
MAY 2021
ISSUE**

Donate to SABM

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

**SABM 2021 Newsletter
Publication**

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Featured Affiliates

Platinum Level Corporate Affiliate Member

Gold Level Corporate Affiliate Member

Table of Contents

- 1 Letter from the President
- 2 Featured Affiliates
- 3 SABM Virtual Annual Meeting
- 4 SABM News
- 6 A Small Program Delivers Large Benefits
- 6 SABM Opinion – Iron Deficiency in PREVENTT Trial
- 7 Call for Interesting Case Studies
- 8 COVID-19 Vaccine Updates
- 10 Bloodless Medicine and Surgery Society 2020 Features SABM Members
- 11 Patient Blood Management: Utilizing Acute Normovolemic Hemodilution (ANH)

PBM GLOBAL PROGRAMS: REPORT

- 13 The Journey of Patient Blood Management in Malaysia
- 15 Safehands Medical Centre, Amuwo Odofin Lagos, Nigeria
- 17 Bloodless Caesarean Section in a High-Risk Pregnancy – Case Report

- 18 2021 CME Webinar Series



**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](#)**

SABM VIRTUAL ANNUAL MEETING 2021 SEPT 22-25

Society for the Advancement of Patient Blood Management, Inc. 2021 Annual Meeting Announcement

Dear SABM community,

While we had all intentions of hosting a live in-person meeting this upcoming Fall, after much discussion and feedback from the membership we are building on the success of the last Fall meeting and using the virtual format again this year. Many new members and participants were able to view the sessions from the comfort and safety of their own environments and feedback have shown us that an overwhelming majority of members are now ready to travel or meet just yet. While we make this decision with a heavy heart, we are also energized by the prospect of continuing to offer our attendees the exceptional learning and community experience you deserve. Offering a virtual meeting will help make the excellent speakers and content available to a wider audience and we are excited at the prospect of growing our SABM community.

SABM has chosen a state-of-the-art virtual meeting platform that combines an innovative learning environment with reliable functionality and intuitive navigation. The schedule will include a mix of live and on-demand sessions, along with an interactive exhibition hall, networking spaces, and poster hall.

We understand schedules are challenging as many of us are managing new work and home demands during this time. To ensure you have ultimate flexibility, we are excited to offer 24-hour access to the virtual Annual Meeting platform—allowing you to learn and engage at your own pace no matter where you are in the world or your day. Attendees will also be able to access the platform for an additional month following the conclusion of the meeting.

SABM will provide continuous updates about the 2021 Annual Meeting in the coming days and weeks as planning continues.

Whether this is your first SABM Annual Meeting or you have attended many SABM Annual Meetings, we will make history together in September as we celebrate you, your accomplishments, and this remarkable community.

We look forward to seeing you in September.

SABM is renamed The Society for the Advancement of Patient Blood Management

When founded in 2001, the early leaders of SABM intended to create a framework and language that demonstrated that identified an evidence-based approach to anemia management, blood conservation, and coagulation optimization. The vision was to shift the conversation from a blood transfusion centered discussion to one that is patient-centered. The term “blood management” was coined, but quickly came to be associated more with donor blood management, transfusion, blood banking, and other related issues. Around the world, clinicians involved in this new way of thinking struggled with nomenclature. However, the term “Patient Blood Management” has gained recognition and wide acceptance over the past decade. There are now thousands of references in the peer-reviewed medical and nursing literature which use this term to define this patient-centered way of thinking. It has also become a commonly used term in both the pharmaceutical and medical device industries, as well as in numerous educational and academic settings.

As such, the Board of Directors of SABM is proud to announce the decision to change the name of the organization to The Society for the Advancement of Patient Blood Management, to better reflect the principles and values to which it subscribes. The logo of the organization will remain unchanged.

“This change to SABM’s name is one that aligns the organization with both the philosophy and patient safety and quality-centered discipline which is making great strides around the world”, said Sherri Ozawa, RN, current SABM President.

SABM New Executive Director: Haley Brust



We are thrilled to announce that Haley Brust has joined the Society for the Advancement of Patient Blood Management as Executive Director. Haley has been an executive director with Talley Management Group for 15+ years and is excited to take on this new role for SABM.

Haley’s proficiency is in finance, organizational management, meeting planning, membership development and project management- resulting from more than 28 years of progressive experience in the association management arena. Haley’s organizational and communication skills enable her to foster board succession planning through strategic development for clients. Her problem resolution knowledge helps to maximize client potential and build member satisfaction. Haley provides outstanding leadership and guidance to her current clients and is pleased to have SABM as part of her client team.

Haley is a graduate of Mary Baldwin University in Staunton, VA, where she received a BA in History. Haley and her family live in Austin, TX, where she is the Past President of the PTO for her daughter’s school. Haley loves to golf and spend time with her family. Fun fact: She has a twin brother, who is a pilot.

Update: SABM Standards Language Translations

We are pleased to report that the Portuguese translation of Standards is now available on the website. Additionally, the Korean and Chinese translations are in the final review stage and we hope for release by end of 2nd Quarter 2021. The Spanish translation is ongoing with the anticipated release later this year. A recent request by the Nepalese PBM group has also been submitted. We continue to grow the SABM Standards outreach!

Translations Complete and Available on Website

- Portuguese

Translations in Process

- Chinese (near completion)
- Korean (near completion)
- Spanish (near completion)

SABM Launches Organizational Affiliate Program

The SABM Organizational Affiliate Program is developed with the aim of creating partnerships with entities and organizations that value Patient Blood Management (PBM). A SABM organizational affiliate is an entity or organization that aligns and partners with SABM, aligns with the SABM patient centered definition of PBM, to support and promote PBM as the gold standard in healthcare practice. It is hoped that these partnerships will create a stronger voice for PBM in the global arena. Qualifying organizations (US based or international) might include but are not limited to PBM societies, healthcare associations, authorities, businesses, and regulatory agencies. Interested organizations and entities can reach out to the SABM Membership Committee at membership@sabm.org to learn more about this program or express their interest in becoming a SABM Organizational Affiliate.

Call for Abstracts – Closing Saturday, May 15, 2021

The Society for the Advancement of Patient Blood Management (SABM) invites members and non-members to submit abstracts related to the field of Patient Blood Management. Accepted abstracts will be published in the SABM Supplement of Anesthesia & Analgesia and will be presented at the SABM 2021 Annual Meeting in Cleveland, Ohio. Accepted case reports will be presented at the SABM 2021 Annual Meeting and will not be published in Anesthesia and Analgesia.

Abstract Submission Deadline: Saturday, May 15, 2021

The top three abstracts will be selected for oral presentation and given an award.

Please Note: The topic Selection step is at the end of the submission process.

[CLICK HERE TO SUBMIT YOUR ABSTRACT](#)

Abstract categories

1. Clinical Research

- A. Anemia Detection/Treatment/Management
- B. Coagulation Issues/Management
- C. Blood Conservation Modalities/Devices/Techniques

2. Quality and Safety

- A. Patient Blood Management Outcomes
- B. Morbidity and Mortality
- C. Patient Experience/Patient-Centered Care

3. Medical Economics and Regulatory/Advocacy

4. Medical Ethics

5. Basic Science

6. Telemedicine

7. Population Health

8. Case Series/Reports Note: these abstracts will not be published in the A & A.

9. Additional

Stay tuned for additional information on the 2021 SABM Virtual Annual Meeting!

A Small Program Delivers Large Benefits

Patient Blood Management at MultiCare Health System

Tacoma, WA, USA



MultiCare Health System has a long history that began in 1882 with just one hospital. We are now the largest not-for-profit, community-based, locally owned health system in the state of Washington. In 2020 approximately 25,000 blood products were transfused within MultiCare's 11 hospitals and medical centers.

I manage the self-described “small but mighty” Patient Blood Management (PBM) program at MultiCare and have spent the last year learning and adapting as a newcomer to the world of PBM. At my previous job I worked as a nurse in blood collection and apheresis medicine, then in early 2020 pivoted from the community blood center into the hospital. While orienting to my job during the ensuing Covid-19 global pandemic, I embraced a shifted focus to blood utilization.

Our program had its beginnings in 2005 serving transfusion-free patients and in the following years expanded to promote wider PBM initiatives. In 2017 a Transfusion Safety Officer was added to the team of advocates. Although not operating within a formal Bloodless Institute framework, we have employed many industry best practices to increase patient safety and decrease costs within the MultiCare system structure.

Ensuring patient safety in the context of blood transfusion supports the MultiCare mission of “Partnering for Healing and a Healthy Future.” PBM contributing work includes daily blood product order review and the oversight and tracking of blood administration documentation compliance as a core system quality measure. We participate in CDC Hemovigilance data monitoring to add to the larger understanding of transfusion safety throughout the nation.

Our team provides continuous education for staff through video-based learning modules, regular sharing of standard PBM metrics, and special events such as community forums and PBM awareness week celebrations. We have started piloting a pre-op anemia management clinic in partnership with our cardiac surgery program, and hope to widen the scope to include all surgical patients in the coming years.

These tactics to support safety and improve patient outcomes have, as an additional benefit, led to significant financial savings for our laboratory. In 2014 intense work began to align MultiCare practices with SABM standards and AABB guidelines. We improved from an RBC transfusion for hemoglobin < 7.0 g/dL rate of 25% to nearing 75% in 2020. Transfusions (all products) per 1000 patient days decreased from 91 to 69. From 2014 to 2020 there was an average of 1300 units saved each year – resulting in approximately \$300,000/year in direct savings and an estimated \$1,100,000/year in indirect savings for associated costs. MultiCare's example proves there is monetary value for any size health system to transfuse in a conservative, evidence-based way.

Beyond the clear financial and safety benefits of our program, involvement in PBM has reinforced to me the core values which guide our work. There is value in employing surgical techniques to minimize blood loss and in providing pharmaceutical alternatives to blood. Decreasing transfusions as a patient safety measure adds worth to our comprehensive quality system. The time spent and the gift given by community blood donors contributes altruistic value. Finally, we recognize there is value in the sacredness of blood to patients with religious or conscience-based convictions. All these values can exist simultaneously and respectfully in a PBM program, and I am proud to honor them as a newer member of the larger PBM community.

Contributor: Jeannie Nielsen, RN, BSN, HP(ASCP)

SABM Opinion—Iron deficiency in PREVENTT Trial

Reprint from Correspondence www.thelancet.com Vol 397 February 20, 2021

Toby Richards and colleagues¹ found no difference in the need for blood transfusions between the group receiving preoperative intravenous iron versus those receiving placebo. This finding is not surprising and was a consequence of poor study design that disregarded all knowledge on preoperative anaemia treatment, iron

metabolism, and ferric carboxymaltose indications and contraindications.

Ferric carboxymaltose is used to treat iron deficiency in cases where oral forms cannot be given or are ineffective.² Laboratory tests, which were not done in the study by Richards and colleagues,¹ are essential to diagnose iron deficiency. Additionally, patients with preoperative anaemia were included even though anaemia not caused by iron

SABM Opinion—Iron deficiency in PREVENTT Trial

deficiency is a contraindication. Iron parameters were rarely measured and not specified as an inclusion criterion. Even if iron parameters were considered, anaemia of inflammation (also known as anaemia of chronic disease) frequently occurs preoperatively.

In elective cardiac surgery nearly 50% of patients have C-reactive protein higher than 5 mg/L.³ The pathophysiology of anaemia of chronic disease is characterized by functional iron deficiency and reduced erythropoietin;⁴ therefore, the specific treatment is a combination of intravenous iron and subcutaneous erythropoietin.⁴ This combination of treatment was shown to be successful.⁵ The absence of a transfusion algorithm is another design flaw of this trial,¹ which possibly contributed to the negative result with no difference seen between groups. Finally, the primary outcome was defined as blood transfusion, which also included plasma and platelets. However, there was no rationale given by Richards and colleagues¹ on how intravenous iron supplementation would reduce the need for plasma and platelet transfusions. From this trial, we can only conclude that preoperative anaemia needs to be characterised in detail and treated specifically. A one treatment fits all is substandard.

AH, IG, MA, AH, and DRS report competing interests (for full details see appendix). All funding is unrelated to this Correspondence. IG retired in 2019.

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Call for Interesting Case Studies

Case studies can be instructive for those who encounter similar scenarios yet were managed differently leading to improved outcomes or at other times adverse outcomes. The decision-making process often includes a range of medical or surgical options, some of which may be considered novel approaches yet have been successfully applied at various institutions—with this in mind we look forward to your submissions.

Aim: To provide an educationally valuable case in each newsletter with interactive components

Authors: Can be submitted by any discipline (MD's, RN's, technologists, perfusionists, students)

Audience: SABM members and non-member

Description/Format/components:

- Patient history and diagnosis
- Problem statement
- Relevant laboratory results or tests
- Medical management
- Follow up
- Brief discussion of the disease/problem/condition with up-to-date literature
- Provide 3-4 multiple choice questions
- Answers to questions to be provided on SABM website 2-3 weeks after publication
- A comment board will be available on the SABM website with the answers for follow up discussion
- Tables/Figures/images are welcome
- 5-10 annotated references

It is Finally Here! COVID-19 Vaccine Updates

At long last, after facing the most challenging time in modern healthcare we concluded 2020 with unprecedented progress in vaccine production. Within almost a month, two COVID-19 vaccines have been approved by the FDA for emergency use authorization (EUA), BNT162b2 (Pfizer Inc. and BioNTech SE) and mRNA-1273 (ModernaTX, Inc.). Several million around the world have already been vaccinated with low occurrence of serious short-term side effects.

Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), aka COVID-19, is a large enveloped RNA virus in which 11 known open reading frames (ORF) have been discovered for genetic translation (Fig 1). ORF2 encodes the spike (S) surface glycoprotein, which is the virus entry protein that binds to the angiotensin-converting enzyme 2 (ACE2) receptor commonly found on respiratory tract epithelial cells. After the spike is bound to ACE2, S protein is cleaved by the host cell surface enabling entry of the virus.¹

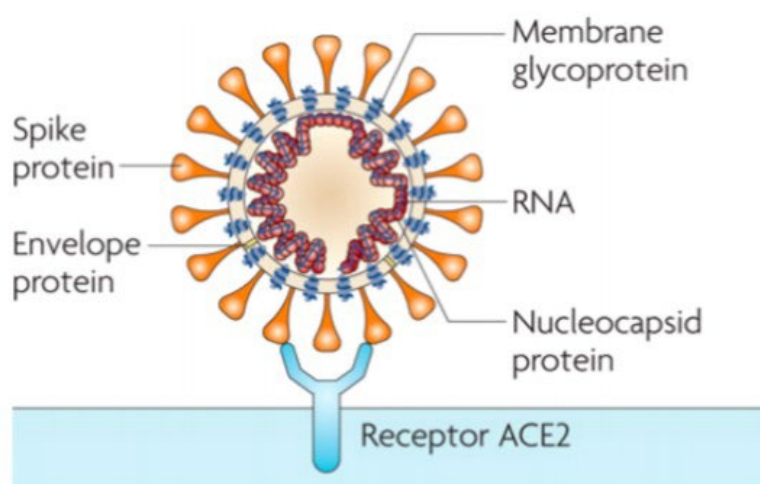


Figure 1: Coronavirus structure and ACE2 receptor on host cell surface. (From: Nature Reviews Microbiology 7 (3), 226-236)

Though this technology has been studied for decades, RNA vaccine technology has not been used in humans prior to COVID-19. Both approved vaccines contain COVID-19 messenger RNA sequence that encodes for a specific protein. The mRNA sequence enters cells through ACE2 receptors and triggers the production of the viral protein, which is then released into the tissues. This results in stimulation of the body's immune system to develop antibodies against the "foreign" protein, creating an immune memory. Two injections within few weeks apart are needed for either COVID-19 vaccine (3 weeks for Pfizer-BioNTech and 4 weeks for Moderna) because the mRNA is broken down within a matter of hours of administration.²

The advantages of an mRNA vaccine over inactivated and live attenuated vaccines include the ability to stimulate a more potent immune response as well as the ability to combine multiple mRNAs into a single vaccine.³ This may be important if the virus is found to rapidly mutate². The major challenge for mRNA vaccines is the cold chain requirements. They must be stored between -20°C (Moderna) and -70°C (Pfizer) making distribution difficult, especially those with tropical climates.²

Other COVID-19 vaccines are being developed in conjunction with the 2 current mRNA vaccines (Fig 2). Novavax is in phase III trial of its recombinant-subunit-

adjuvanted protein vaccine. This vaccine uses a stabilized form of the COVID-19 spike protein as well as proprietary adjuvants that enhance the immune response. It can be stored above freezing (1-8°C), an advantage for distribution. The Sanofi/GSK adjuvanted recombinant protein based vaccine has been delayed due to insufficient response in older adults. Expected availability for this product is now projected toward the end of 2021.⁴

Older vaccine technologies inject either inactivated or reconstructed particles from the infectious pathogen.² A replication-defective live-vector vaccine uses a small piece of viral material to stimulate the immune system. One such vaccine, developed by AstraZeneca and Oxford University has been approved for emergency use in the United Kingdom.

Very recently, the U.S. Food and Drug Administration issued approved a third vaccine for the prevention of coronavirus disease. Per the FDA website, the Janssen COVID-19 Vaccine is manufactured using adenovirus type 26 (Ad26). Ad26 is used to deliver genetic material that is makes the "spike" protein of the SARS-CoV-2 virus. This vaccine will be distributed in the U.S for use in individuals 18 years of age and older. Single dosing is the main advantage of this vaccine.

While we are hopeful, lack of manufacturing and distribution resources and health-care personnel in some area, and a degree of vaccine skepticism in the population may delay effective worldwide protection against COVID-19.

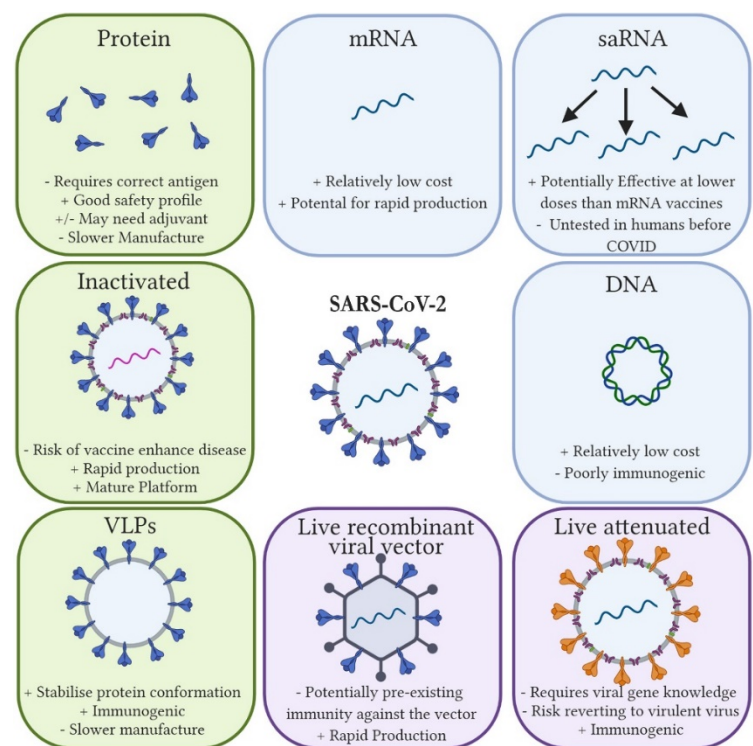


Figure 2: Vaccine Immunity Mechanisms (Adapted from Clinical & Experimental Immunology, 202(2), 162-192.)

Nevertheless, lack of manufacturing and distribution resources and health-care personnel, and a degree of vaccine skepticism/hesitancy in the population may delay effective worldwide protection against COVID-19.²

While we have gained much knowledge, questions remain. NPR hosted an expert panel podcast, which addressed the questions below:

It is Finally Here! COVID-19 Vaccine Updates

1. Can someone who has been vaccinated still spread the disease?

As stated by Dr. Marion Pepper, an immunologist at the University of Washington, WA; "When a person is infected or has received a vaccine the immune system is stimulated to produce antibodies that specifically target the virus. Over time, those antibodies naturally diminish but the immune system still holds a memory of the virus, allowing new antibodies to be produced. This process can take three to five days.

"It's a bit of a race between the immune system and the virus," says Dr. Michel Nussenzweig, a Howard Hughes Medical Institute investigator at the Rockefeller University. If the immune response kicks in quickly, little virus would be produced. Your ability to spread disease "is really a function of how much virus you're producing,"

2. Will the vaccine remain effective as the virus itself evolves?

Scientists thus far are not too concerned about the current strains of the virus that are spreading globally. Expert opinion believes the vaccines will likely still provide protection.

"Even though everyone is obviously concerned about a virus evolving, your memory B cell responsiveness also evolves over time," Dr. Pepper says.

Memory B cells are an important component of the immune system because they remember an infection. These lurk in your bone marrow and are ready to morph into antibody-producing cells if the virus they "remember" reappears in your body.

COVID-19 mutates much more slowly than the flu, but it is not confirmed whether memory B cells will be adaptable enough to permanently provide immunity.

Another piece to the immune system are T cells, which are prevalent in lungs and nasal passages. These cells rapidly identify cells that have been infected with a virus. This type of T cell is inside tissues not in blood, therefore difficult to study.

T cells help bridge the gap between the time of infection and the time of immune response in order to provide more immediate protection.

3. How long will the vaccine's protection last?

Vaccines trigger an immune response similar to an infection but may require a boost to keep that immunity strong. So far, scientists have observed that these memory B cells have lasted several months following infection with COVID-19, but more time and research is required to determine how long immunity will last.

In addition to vaccine development, COVID-19 convalescent plasma (CCP) is also being studied and utilized to treat and prevent COVID-19 complications in critically ill patients. Plasma therapy has historically been used to treat critically ill patients to minimize circulating cytokines and to regulate the immune response. CCP has also been used to reduce the viral burden in H1N, Ebola, and SARS. CCP administers COVID-19 antibodies into the bloodstream that help fighting the virus infection (passive immunity) and possibly allowing the patient's immune system to recover and start developing antibodies (active immunity). In order to neutralize active viral infection, CCP induces complement activation and reduces antibody-dependent cellular toxicity, and/or enhanced phagocytosis. The FDA has approved convalescent antibody therapy for emergency use in COVID-19, and studies have shown little prophylactic but some therapeutic value. Thus far, there is no documented transfusion transmission of SARS-CoV-2, though CCP poses a minor risk of contracting a blood borne pathogen or transfusion-related acute lung injury (TRALI) from the donor.⁵

Lastly, the U.S. FDA issued an EUA for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients using Bamlanivimab LY-CoV555 (Eli Lilly, Indianapolis, IN). Monoclonal antibodies are proteins that enhance the immune system in order to fight off harmful viruses. Bamlanivimab is a monoclonal antibody that is specifically directed against the Covid -19s spike protein inhibiting the attachment and entry into human cells. This investigational drug therapy can be used for confirmed COVID-19 positive patients age 12 and older and weighing at least 40 kilograms. Bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization occurrence and length of stay.

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

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Bloodless Medicine and Surgery Society 2020 Features SABM Members! – Calabar, Nigeria

Several members of SABM were featured at the 6th Annual Scientific Conference of the Bloodless Medicine & Surgery Society (BMSS), which held November 4-6, 2020 as a virtual meeting. The first keynote address was on the theme A Historical Perspective of Bloodless Medicine & Surgery, delivered by SABM Founding Member, Shannon Farmer, DHSc; Dr. Farmer also won the BMSS 2020 Award of Excellence “for his excellent contributions to the science and practice of Bloodless Medicine & Surgery.”

A highlight of the BMSS Annual Conferences since 2019 is the BMSS Aryeh Shander Lecture, in honor of another founding member and past president of SABM, Aryeh Shander, MD, who is also a member of BMSS. The Lecture at BMSS 2020 was on the theme Bloodless Medicine – Bridging the Gap Between Knowledge and Practice, and was delivered by Bruce Spiess, MD, a member of the SABM Board of Directors.

Former SABM Board member and SABM 2019 Kathleen J. Sazama Award recipient Irwin Gross, MD, spoke on Optimizing the Haematocrit in Bloodless Medicine – the Science and the Practice. SABM Board member and past president, Jonathan Waters, MD, spoke on Blood Salvage in Surgery & Obstetrics. The session enjoyed the peak conference attendance of 313, with a multidisciplinary audience from 38 countries on 5 continents.

SABM member Kelly Johnson-Arbor, MD, delivered a talk on Bloodless Medicine & Surgery Programmes – the MedStar Georgetown University Hospital Experience, followed by The Role of a Nurse Coordinator in Bloodless Medicine & Programme delivered by Cassandra Upchurch, RN, SABM Membership Committee. The final keynote address at BMSS 2020 entitled Bloodless Medicine & Surgery Programmes – a “win-win” for improving clinical outcomes was delivered by Steven Frank, MD, former SABM Board member and former chairman of the SABM Scientific Committee.

Several BMSS 2020 sessions were moderated by notable members of SABM, such as Sherri Ozawa-Moriello, RN, (SABM President) Sharon Sledge, RN, (SABM Board Member) Ananthi Krishnamoorthi, MD, (SABM Membership Committee) Kevin Wright, (SABM Newsletter Editor) and

new SABM members, Marcus Asuquo, MD, and Queeneth Kalu, MD. BMSS President, Nathaniel Usoro, MD, and BMSS 2020 Conference Chairman, Innocent Okoawo, MD, are long-time SABM members; Dr. Usoro is the 2016 recipient of the SABM Kathleen J. Sazama Award.



Nathaniel Usoro, MD

BMSS started as an idea discussed by three friends from three different countries who were together in Lusaka, Zambia in 2011 – Kevin Wright, (USA) Anton Camprubi, MD, (Switzerland) and Nathaniel Usoro, MD (Nigeria). All three were SABM members at the time invited by the College of

Surgeons of East, Central, & Southern Africa (COSECSA) to give talks on PBM at the Annual Meeting of the College. They considered developing a bloodless medicine and surgery group from Africa into an international society with a strong base in the sub-region similar to SABM in North America and NATA in Europe. The first annual meeting of the new society was held in Calabar, Nigeria in 2015, with the support of the University of Calabar and the local Bloodless Medicine & Surgery Group. After four successful annual scientific meetings, all of which featured at least one SABM member as a speaker, BMSS was issued with a Certificate of Incorporation as a professional society by the Corporate Affairs Commission of the Federal Republic of Nigeria in 2019.

SABM members are evidently world leaders in PBM and Bloodless Medicine & Surgery! BMSS is a multidisciplinary society which shares similar goals to SABM, including the protection of patients’ rights and the improvement of clinical outcomes through the promotion of education in non-transfusion techniques. BMSS has an informal relationship with SABM which may be formalized in the future to the benefit of both societies.

Contributor: Nathaniel Usoro, MD



BMSS 2020 Award of Excellence Winner - Shannon Farmer, DHSc

Patient Blood Management: Utilizing Acute Normovolemic Hemodilution (ANH)

In Patient Blood Management (PBM) there are numerous techniques that a clinical practitioner can utilize to optimize hemoglobin (Hgb) or to reduce the risk of transfusions. In the ideal PBM world, identification of anemic or iron replete patients prior to surgery followed by treatment of the disorder would take place. Once optimized and lined up with a thorough pre-op workup the patient heads to surgery where the next level of Hgb care takes place. This time in the surgical arena also has numerous multidisciplinary techniques to continue the blood conservation process. Examples are proper fluid management, use of antifibrinolytics, Acute Normovolemic Hemodilution (ANH), cell salvage and even maximizing red cell recovery by squeezing/rinsing of the lap sponges for optimal RBC retrieval. Of the 5 previously mentioned techniques, ANH has the greatest present day challenges due to individual experience/exposure and the multidisciplinary efforts associated with it.

ANH is the method of removing single or multiple whole units prior to the surgical procedure in the operating suite. The replacement of volume removed with crystalloid or colloid that minimizes hypotension and the patient's heart may pump more efficiently due to decreased blood viscosity. (Frank MD, 2016) The utilization of ANH as a blood conservation technique dates back to close to 50 years (Monk & Goodnough, 1998) and since then, ANH has been utilized in areas where patients are at high risk for excessive bleeding (eg, major cardiac, orthopedic, thoracic, or liver surgery) and most recently for aneurysmal subarachnoid hemorrhage procedure. (Ping, Ying, & Xin-Huang, 2020)

Due to the variability in publication and practice/technique among healthcare providers, SABM convened a panel of experts to develop a standardized approach to the implementation and performance of ANH in adult cardiac patients. The panel worked through a modified RAND-Delphi method to identify which conditions would or would not be acceptable when using ANH, demonstrating that a standardized approach for the use of ANH is clearly possible. (Shander, 2020)

Because of the previous work standardizing the approach for ANH in one adult specialty (cardiac), there is an opportunity to look at other specialties and not limit this only to the adult population, but advance it toward the pediatric population. The recent evidence in the development of standards for Pediatrics was welcomed in 2019 with SABMs' own new Standard #13 (Patient Blood Management for Pediatric Patients) and other professional healthcare organizations' such as the American Society of ExtraCorporeal Technology

(AMSECT) (AMSECT, 2019) have also released their own standards for the field of pediatrics'.

This is just the tip of the iceberg when it involves ANH. Understanding ANH and how to utilize it as a blood conservation tool in pediatrics varies widely and the literature in this area has been limited over the last 15 years. A prospective observational study concluded that the use of ANH protects the platelets from the untoward effects of cardiopulmonary bypass. (Sebastian, Ratiliff, & Winch, 2017) This is in stark contrast to a recent randomized study (24 patients) that failed to show a reduction in perioperative transfusion or other postoperative outcomes. (Weronika, Miriam, & LeBlanc, July)

The evidence is clear that in the area of pediatrics, greater research and standardization is needed to help guide the management and inclusion of ANH.

Contributor: James Brown MHA, CCP, LP

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The Journey of Patient Blood Management in Malaysia

A journey has a starting point and a destination, which may be started intentionally or unintentionally. However, what makes a journey valuable are the people met along the way, the lessons learnt from successes and failures, as well as the determination of the ones involved to continue on. It is with this in mind that we embark on “The journey of Patient Blood Management (PBM) in Malaysia”.

As is the case in many regions, PBM, which is in essence patient-focused rather than product-focused, is at the fringe of medical practice in Malaysia, although it has been deemed as good medicine in the past and even more so now. And just as how ‘necessity is the mother of invention’, this journey in Malaysia was initiated by individual practitioners who were responding to requests of patients for whom blood is not an option, namely, Jehovah’s Witnesses (JW). This unusual or perhaps even daunting situation mirrors the pioneering of bloodless medicine and surgery in the world, whereby Denton Cooley, MD, generally recognized as the ‘father of modern bloodless surgery’ performed the first “bloodless” open heart surgery in 1962. Thanks to the courageous and gracious works of Dr. Cooley, this milestone enabled the world of medicine to be freed from the notion that all major surgeries must be accompanied by an allogeneic blood transfusion (ABT).

This stellar example was followed some 30 years later, in Malaysia, when the first blood-less procedure was performed in 1994, by pioneering consultant cardiothoracic surgeon Yahya Awang, MD, with consultant anaesthetist Kathiresan Valliappa, MD. The team performed a successful triple coronary artery bypass graft (CABG) on a JW patient with Takayasu arteritis. This was a feat, considering that the cardiothoracic fraternity was fairly young, as the establishment of the National Heart Institute (IJN) occurred just 2 years earlier, in 1992. This success was followed by another, in 1995, involving a limb amputation in a patient with trauma and a hemoglobin (Hb) of 5 g/dL. The patient was treated with intravenous (IV) iron and subcutaneous (S/C) erythropoietin; with an increase in Hb to 8 g/dL, the procedure was performed by Charles Vijaya David, MD, at a time when scarcely any surgeon was agreeable to utilizing transfusion alternative strategies.

The 1990’s also saw the start of the activities of the Hospital Liaison Committee (HLC) of Jehovah’s Witnesses in Malaysia. This group of individuals work together with health care professionals on alternative strategies through continuing medical education (CME) seminars and individual discussions; the goal is of building bridges to treating patients for whom blood is not an option. As evident by the two forerunners mentioned previously and the others that follow, this collaboration is beneficial for the patient and practitioner, while also promoting the growth of knowledge in the field of bloodless medicine and surgery and later PBM. The same decade saw the beginning of parallel efforts by the National Blood Centre (PDN), namely with the introduction of the rational use of blood products, by then PDN director, Yasmin Ayob, MD. The efforts would be a long haul one, in getting clinicians to change practice, and gain an understanding of the true sense of PBM, as we will later see.

The next decade saw further milestones and progress—in 2001, the documentary “Transfusion Alternative Strategies - Simple, Safe, Effective” by the Watch Tower Bible and Tract Society of Pennsylvania, was submitted to television (TV) station TV3 by Asia geographic director James Reynolds and

PBM enthusiast Ong Kwan Teng; the documentary was screened in whole, with Malay subtitles by this forward thinking TV station. The documentary also caught the attention of a number of doctors, who later wrote to TV3 and this society for further information. Subsequently, the increasing needs of patients propelled the use of alternative strategies (which were later established as pillars for PBM). In 2004, an 11-year-old girl with congenital scoliosis was successfully managed by a team of experts including Ahmad Hata Rasit, MD, in east Malaysia, (Sarawak) where they used cell salvage and meticulous surgery to perform their first “bloodless” scoliosis correction surgery. The successful use of cell salvage in this instance convinced the doctors that it may be a good strategy to utilize when performing similar surgeries, given the fact that this re-duces incidence of transfusion transmitted diseases.

It was in 2007, that another need arose in the cardiothoracic field, and Pau Kiew Kong, MD, a senior consultant cardiothoracic surgeon from IJN rose to the occasion; he performed the first bloodless aortic valve surgery in a JW patient, skillfully optimized the patient’s own blood preoperatively, and used techniques to minimise blood loss intraoperatively. Dr. Pau has continued to use PBM strategies in treating patients and plays a crucial role in the progress of PBM in this region. It was also during this time (2006) that the Master of Medicine (Transfusion Medicine) programme was established, ultimately developing doctors who would be involved in the governance of transfusion practices and later with PBM; the first group graduated in 2010. The end of this decade saw the Society for the Advancement of Patient Blood Management (SABM) come into the picture, and my exposure to PBM began in 2009, with SABM and the PBM/bloodless medicine and surgery programs in the United States of America (USA). SABM has played an important role in supporting and connecting the multiple pathways we have, so that a concerted effort for the development of PBM in Malaysia could eventually take place.

From the year 2010 onwards, there were accelerated activities in PBM; SABM representatives Richard Melseth and James Reynolds presented the first CME on PBM at IJN. The next year saw our PDN director Yasmin Ayob, MD, participating as part of the WHO Global Forum for Blood Safety: PBM. The first Malaysian PBM symposium was held in 2012, with the involvement of SABM members (Pierre Tibi, MD, Richard Melseth, James Reynolds), also doctors from Asia (JongHyeon Lee, MD; Danilo Kuizon, MD), and IJN with Dr. Pau as chair and PDN as co-host. The symposium was made possible with the support of philanthropist Yanki Gan who believed in PBM as good medicine. The same year saw the beginning of parallel efforts by hematopathologist Asral Wirda, MD, and team, who actively conducted transfusion safety workshops on a regular basis. This team was proactive in incorporating transfusion alternative strategies into their program. The year 2013 was a pivotal one as this was when a strong proponent of PBM was discovered during a CME presentation on transfusion alternative strategies by Mr. Steven Siva, a member of the HLC. Simply put, someone with a heart of gold, came across a gold mine, and continued to work hard digging and sharing its benefits with others. This was Jameela Sathar, MD, a dedicated senior consultant hematologist who was with Dr. Wirda’s team, who was intrigued by this knowledge on transfusion alternatives strategies, recognized its worth, and kept on pursuing and propagating it.

PBM Global Programs: Report

From then on, workshops in 2014 onwards underwent a transformation from “transfusion safety” to “Patient Blood Management”; the 3 pillars of PBM were incorporated into the entire workshop program. Another advocate of PBM was discovered in 2015, when PBM was introduced to Carol Lim Kar Koong, MD, during a seminar on venous thromboembolism (VTE). Subsequently, there was no looking back as this team of clinicians gathered more advocates from various disciplines in different parts of Malaysia and the knowledge of PBM spread throughout the nation by means of PBM workshops. It has become an important part in training healthcare professionals in Malaysia to emphasize the true concept of PBM, which is patient-focused as well as incorporating PBM in different disciplines. Those few years also saw the parallel efforts of the Malaysian Blood Transfusion Society (MBTS) incorporate PBM as part of their workshops with the intention of providing education in PBM and improving the governance of blood products. MBTS conducted biennial meetings inviting experts such as Aryeh Shander, MD, and James Isbister, MD, to present. The exposure to the international experts on PBM moved proactive transfusion medicine specialist (TMS) Intan Iliana, MD, to work with the cardiothoracic team in the hospital to integrate PBM strategies into their practice.

Another special opportunity to work and grow together presented itself, when in 2016 the Asia Pacific Society for Patient Blood Management (APSBM) showed interest in Malaysia hosting their next symposium. Thus in 2017, the Malaysian Society of Patient Blood Management (MyPBM) 3rd ASPBM symposium was held in IJN, and I worked with Pau Kiew Kong, MD, Jameela Sathar, MD, Carol Lim Kar Koong, MD, along with the ASPBM team from South Korea.

The symposium also presented the opportunity to learn from Alhossain Khalafallah, MD, from Australia and Aryeh Shander, MD, from SABM on the significantly improved clinical outcomes possible with PBM including the attractive economic advantages. This symposium was a landmark for several reasons: the term MyPBM was coined here, the nucleus of the MyPBM society was formed here and the first PBM survey was launched at the outset of this symposium, collecting the valuable comments of more than 1000 clinicians. This symposium was also the platform of long term relationships with PBM organizations such as ASPBM and SABM; working on this symposium also propelled the efforts of collaborating with the Ministry of Health (MOH) to promote PBM. Hence the next couple of years saw the move of Dr. Jameela and team submit a proposal to the MOH for PBM implementation in hospitals across Malaysia. The move sent ripples across the medical fraternity, and so the effort to continue to promote PBM is now accomplished by the parallel paths of the clinicians and PDN. MyPBM was officially formed in 2019, with even more PBM advocates and the development of recent local PBM guides.

The journey that started almost 30 years ago, has brought together many beautiful people and we have gained valuable lessons. Just as in an orchestra, although individual musicians play different instruments and are in the limelight at different times, yet as an ensemble, it creates beautiful and meaningful music. That is the case with this journey of PBM in Malaysia, a journey that I anticipate may eventually create a concerted, beautiful outcome—that of optimal patient care, satisfying medical practice and abundant economic benefits.

Contributor: Ananthi Krishnamoorthy, MD



A Pictorial Review of the Accomplishments

Safehands Medical Centre, Amuwo Odofin Lagos, Nigeria

My journey in the field of Patient Blood Management (PBM) began in July 1997 when was asked to convince a patient who had refused blood transfusion to either change her mind or “be ready to die!”

This was my first experience: a patient who suffered post-partum uterine hypotonia with resultant massive post-partum hemorrhage (PCV: dropped to 12% from 34%) intraoperatively and immediately post operatively; she had been pregnant with a set of twins and attempted a spontaneous vaginal delivery. The patient struggled through prolonged labour and failure to progress which required a caesarean section for the set of twins. Since she was not ready to change her mind, I took up the challenge to manage her situation while respecting her wishes. She arrived semi-conscious and I actually utilized now proven PBM strategies: 12,000 units daily of IV erythropoietin, total dose IV iron and corticosteroids. She regained full consciousness after two days of management and was subsequently discharged on her 7th day post operatively; of note, she came to have a normal vaginal birth 24 months later.

It soon became clear to me that transfusion was being abused when in that same year while managing a post prostatectomy patient, the patient was scheduled to receive at least two units of blood. He experienced a transfusion reaction while receiving the first unit which then had to be stopped. The patient ended up not receiving any blood for fear of further reactions and was discharged home earlier than other patients who had received transfusion(s). Three years later, in 2000, I decided to establish *Safehands Medical Centre (Safehands)* exclusively for bloodless medicine and surgery procedures—this ultimately established an environment for various specialties to provide a higher quality of care, improve patient outcomes, respect the needs of patients for whom blood transfusion is not an option, and educate other medical professionals in PBM.

At *Safehands* I fulfil multiple roles: financier, chief executive officer, primary surgeon and Head of Surgical Critical Care. I also engage and oversee the services of obstetricians, gynaecologists, urologists, oncologic surgeons as well as medical oncologists, orthopaedic surgeons, and neurosurgeons.

Historically, there has been a gross shortage of doctors with the necessary lifesaving surgical skills and notwithstanding this, I found that there were no anaesthetists agreeable to care for patients if there were not at least “two units” of blood in the operating theatre. Therefore, I pursued a post graduate diploma in Anaesthesia and Critical Care at the College of Medicine University of Lagos (2008). This in addition to my Bachelor of Medicine and Bachelor of Surgery received from the University of Benin in 1996. I am a founding member of the Nigerian Faculty of the American College of Surgeon’s Advanced Trauma Life Support (2009); a Certified Provider in Advanced Cardiovascular Life Support, Pediatric Advanced Live Support of the American Heart Association, and a graduate of the SABM PBM Certificate Course. I have also been awarded Fellowship in Minimal Access Surgery and Gynecological Endoscopic Surgery by the World Association of Laparoscopic Surgeons, and a Diploma in Minimal Access Surgery from Asia’s Premier Institution for Laparoscopic Surgery: World Laparoscopy Hospital, New Delhi.

Included below are a few of the notable cases:

- Massive 26 kg (57.3 pounds) fibroid tumour removed along with 32 other fibroid masses from same patient
- Mastectomies (unilateral and bilateral) for fungating breast tumours
- Open prostatectomies
- Thyroidectomies
- Massive gastrointestinal tumour removals
- Hip arthroplasties for Sickle Cell Anemia patients

Massive 26 kg Fibroid Tumour: Patient was a 36-year-old nulliparous lady who presented with an 8 year history of progressive abdominal swelling and associated weight loss. She had been diagnosed with uterine fibroids six years earlier but due to fear of surgery, she instead used herbal remedies which only made the situation worse. When she finally decided on surgery and could not find a doctor agreeable to perform the procedure without blood transfusion, she was referred to *Safehands*. Following a pre-operative evaluation and preparation for bloodless myomectomy, we decided to perform high spinal anaesthesia combined with epidural anaesthesia; we infused 1 litre of colloids for preloading with the patient in a semi-recumbent position. A cervical tourniquet was applied using an 18 French gauge foley catheter to ensure a bloodless field throughout the period of enucleation of the several myomas. Abdominoplasty was performed to reduce the laxity of the abdomen and dead space within the peritoneal cavity. The estimated blood loss was 1500 ml, and this patient received only intravenous iron for 5 days post operatively along with routine perioperative antibiotics. She was discharged two weeks post op.

16 kg Malignant Spindle Cell Tumour: We removed without blood transfusion using hypotensive anaesthesia, ultrasonic dissector and intestinal staples to achieve minimal intraoperative blood loss.

4.5 kg Areolar Rhabdomyosarcoma Left Mastectomy: Tumescence anaesthesia was used to raise superior and inferior flaps in addition to using ultrasonic tissue shears to achieve excellent haemostasis. Preoperative PCV was 27% and second day post-operative PCV was 20%. This was accomplished without blood transfusion which was also avoided during her course of chemotherapy.

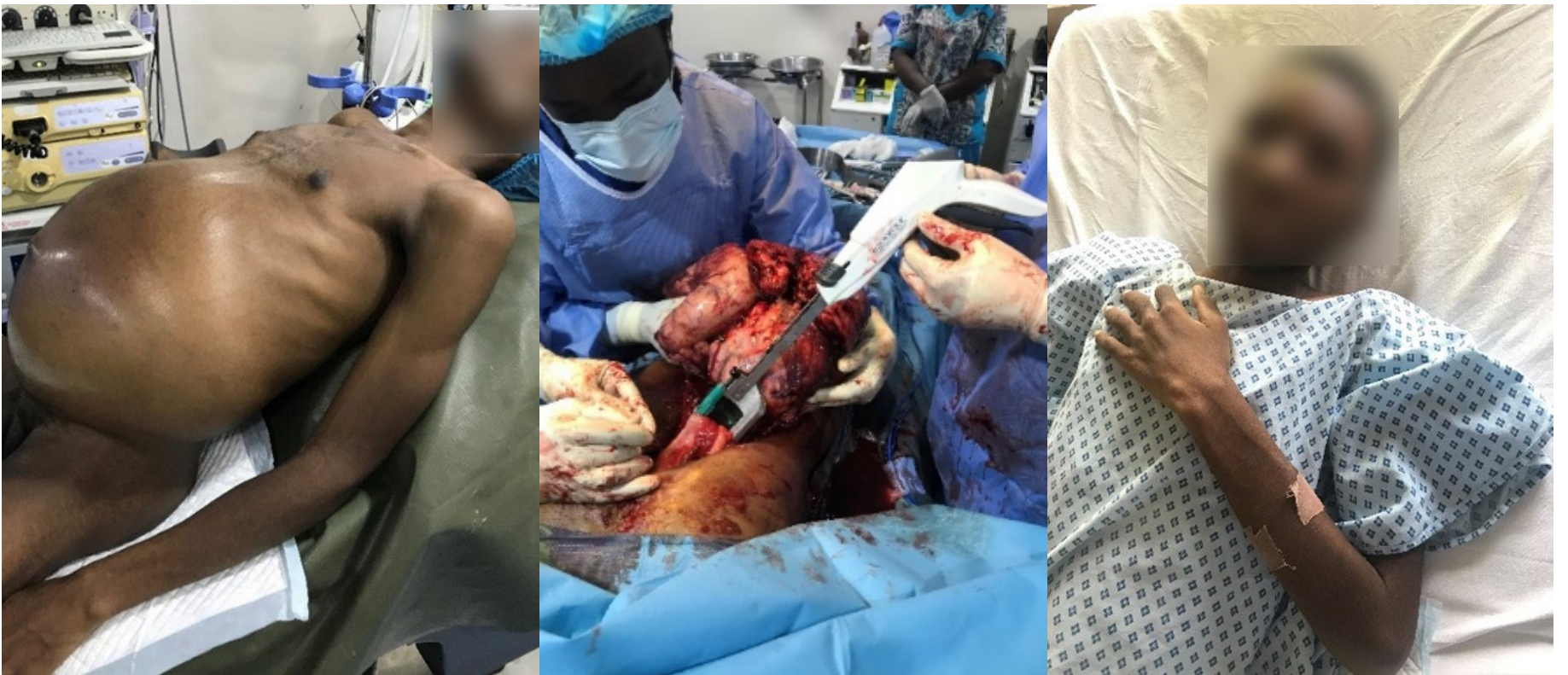
Safehands offers a progressive approach to blood management for all patients in our care. We are recognized as an established leader in transfusion-free medical and surgical techniques. Hundreds of patients from Nigeria and abroad have received medical treatment and even undergone highly complex procedures. Physicians from every discipline have been specially trained and utilize advanced medical and surgical techniques. Not surprisingly, physicians and other medical professionals from leading institutions across the country have also come to *Safehands* to learn how our physicians use proven, effective alternatives to blood transfusion to improve patient outcomes. Likewise, medical professionals from other countries have also consulted with us to learn how to apply blood management techniques in dealing with catastrophic situations when little or no blood is available.

*Contributor: Innocent Okoawo, MD
Medical Director, Primary Surgeon and Chief of Surgical Critical Care*

PBM Global Programs: Report



Massive 26 kg Fibroid Tumour



16 kg Malignant Spindle Cell Tumour



4.5 kg Areolar Rhabdomyosarcoma Left Mastectomy

Bloodless Caesarean Section in a High-Risk Pregnancy – Case Report Safehands Medical Centre, Amuwo Odofin Lagos, Nigeria

Introduction: Acute severe haemorrhage is common in obstetrics and poses a serious challenge, especially in high-risk pregnancies predisposed to uterine atony. This case report of the bloodless management of a high order multiple gestation patient with multiple uterine fibroids illustrates how adequate preparation, a multidisciplinary team utilizing bloodless surgery techniques and Patient Blood Management (PBM) protocols can be lifesaving and avoid the several deleterious effects of postpartum hemorrhage and allogeneic blood transfusion.

Case Report: A 32-year old female with quadruplets pregnancy, having a 6 cm anterior and a 14 cm posterior lower segment myomata and desired bloodless care. Patient's in vitro fertilisation procedure started on March 12, 2020 with blastocyst transfer five days later. She received oral iron and adjuncts during antenatal care and was scheduled for elective caesarean section at 35 weeks, 2 days gestation.

This patient presented to us on May 25, 2020 at 12 weeks, 4 days gestation as she had been informed by the IVF specialist that her cervical cerclage would be at 13 weeks gestation. A cervical cerclage was placed at 12 weeks, 5 days gestation and she was then placed on Dydrogesterone and Nifedipine as tocolytics for the duration of her pregnancy. Antenatal steroids were started at 30 weeks gestation since high order multiple gestations are at high risk for preterm labour and delivery. She was admitted for strict bed rest and close monitoring at 32 weeks gestation; premature uterine contractions were further treated with magnesium sulphate injections.

We noted her preoperative haemoglobin to be 11.4 g/dL, all tocolytics were stopped 24 hours prior to surgery,

she received 2 g tranexamic acid 30 minutes prior to commencement of surgery; we combined spinal and epidural anaesthesia after preloading with 1 litre of colloids (I call this intracorporal isovolaemic haemodilution, since the blood in the lower extremities resulting from vasodilatation caused by spinal anaesthesia is not part of the circulation until compression stockings are applied). Patient was placed in a semi-recumbent position for the surgery and we inserted 800 mcg Misoprostol intrarectally just before making a skin incision, 100 mcg carbetocin IV bolus at the time of the uterine incision, 0.5 mg ergometrine intramuscularly after closing the uterine incision. We could not place uterine compression (B-Lynch) sutures because of the presence of multiple uterine fibroids. The surgery lasted one hour and was uneventful. Patient also received 20 IU of Oxytocin into every 500mls of infusion for 48 hours post operatively. Haemoglobin was 8.6 g/dl on 1st day postop and dropped further to 8.3 g/dL on post op day 2. Patient received intravenous iron postoperatively and was discharged home on the 6th post-operative day along with her quadruplets with a haemoglobin of 9 g/dL.

Conclusion: Proper preoperative planning aiming to optimize the haemoglobin and minimize blood loss are key pillars of bloodless surgery and PBM adopted by the World Health Assembly in 2010. Major obstetric haemorrhage can be avoided, among other techniques, by use of multiple uterotonics and modification of the timing of administration. A committed multidisciplinary team focused on taking advantage of PBM protocols is essential to avoiding the many complications of blood transfusion and to improve patient outcomes.

Contributor: Innocent Okoawo, MD



Immediately post op in the PACU room



Successful deliveries – Innocent Okoawo, MD (center) with staff

2021 CME WEBINAR SERIES

PBM: Optimizing the Care of Surgical Patients

With the onset and continued presence of the COVID-19 pandemic, global healthcare is challenged with critical shortages of equipment, facilities and impediments to blood supply. Implementation of PBM practices can help in this endeavor by focusing on evidence-based bundles of care to optimize both medical and surgical patients, thus limiting or eliminating the need for blood transfusions.

This webinar series will help in this endeavor by bringing the latest PBM information to healthcare providers globally.

PBM in the Pediatric Surgical Patient

April 29, 2021, 4:00 p.m. Eastern



David Faraoni, MD, PhD, FAHA
Associate Professor, Dept of Anesthesiology and Pain Medicine, University of Toronto
Staff Anesthesiologist, Division of Cardiac Anesthesia, The Hospital for Sick Children, Toronto, CA



Susan Goobie, MD, FRCPC
Associate Professor of Anesthesiology, Harvard Medical School
Senior Associate in Perioperative Anesthesia, Boston Children's Hospital, Boston, MA

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The Burden of Bleeding

May 20, 2021, 1:00 p. m. Eastern



Aryeh Shander, MD, FCCM, FCCP, FASA
Clinical Professor of Anesthesiology and Perioperative Medicine, Rutgers New Jersey Medical School
Clinical Professor of Anesthesiology, Medicine & Surgery, Mount Sinai School of Medicine, New York

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Current State-of-Science in Surgery: Bleeding and Hemostasis

June 24, 2021, 4:00 p.m. Eastern



Pierre R Tibi, MD
Chief, Cardiac Services, Yavapai Regional Medical Center

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PBM: A Call to Action During the Pandemic



Matthew Warner, MD
Assistant Professor of Anesthesiology, Mayo Clinic, Rochester, MN

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Course credit available March 18, 2021-March 17, 2022.

[Dr. Warner's slides are available for download.](#) He also answered additional questions from the audience in this document.

CME/CE Information

SABM 2021 CME Webinars: Patient Blood Management--Optimizing the Care of Surgical Patients

Jointly provided by the Postgraduate Institute for Medicine and Society for the Advancement of Patient Blood Management.

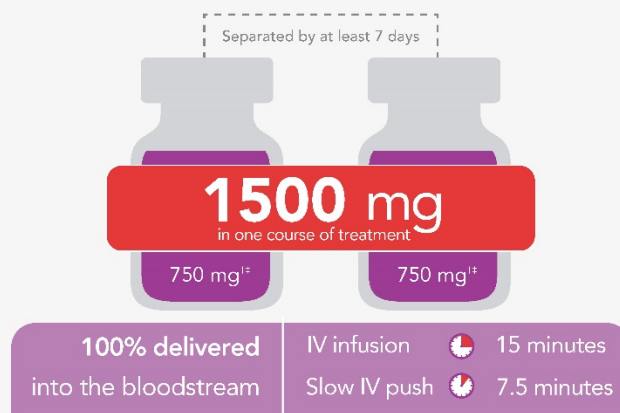


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Injectafer: Provide a maximum course of iron treatment

Up to 1500 mg of iron in 1 course of treatment for total iron repletion^{1,2*}



Injectafer treatment may be repeated if iron deficiency anemia reoccurs. Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.¹



Most studied IV iron treatment
with more than 40 clinical trials
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among oncologists
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Over 1 million patients
in the United States have been
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[†]1 course of treatment is 2 administrations of 750 mg separated by at least 7 days. [‡]For adult patients weighing less than 50 kg (110 lb), give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course of treatment. [§]When administered via IV infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not <2 mg of iron per mL, and administer over at least 15 minutes. When administered as a slow IV push, give at the rate of approximately 100 mg (2 mL) per minute. ^{||}Source: Trialtrove[®] | Informa, 2019. ^{||}Source: Symphony Health Solutions PHAST[®] Non-Retail September 2019-August 2020 (MAT August 2020). [#]Source: IQVIA[®] IV Iron Landscape (Dx and CDM Data, April-June 2020). [#]Source: IQVIA[®] IV Iron Landscape Claims Data Dx and CDM through December 2019 (delivered 20 March 2020).

INDICATIONS

Injectafer[®] (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-dialysis dependent chronic kidney disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

WARNINGS AND PRECAUTIONS

Symptomatic hypophosphatemia requiring clinical intervention has been reported in patients at risk of low serum phosphate in the postmarketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency and malnutrition. In most cases, hypophosphatemia resolved within three months.

Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs

and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥2% of Injectafer-treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following adverse reactions have been identified during post approval use of Injectafer. Because these 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 adverse reactions have been reported from the post-marketing spontaneous reports with Injectafer: *cardiac disorders*: tachycardia; *general disorders and administration site conditions*: chest discomfort, chills, pyrexia; *metabolism and nutrition disorders*: hypophosphatemia; *musculoskeletal and connective tissue disorders*: arthralgia, back pain, hypophosphatemic osteomalacia (rarely reported event); *nervous system disorders*: syncope; *respiratory, thoracic and mediastinal disorders*: dyspnea; *skin and subcutaneous tissue disorders*: angioedema, erythema, pruritus, urticaria.

CLINICAL CONSIDERATIONS IN PREGNANCY

Untreated IDA in pregnancy is associated with adverse maternal outcomes such as postpartum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Injectafer) which may cause fetal bradycardia, especially during the second and third trimester.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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References: 1. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; September 2020. 2. Koch TA, Myers J, Goodnough LT. Intravenous iron therapy in patients with iron deficiency anemia: dosing considerations. *Anemia*. 2015. doi:10.1155/2015/763576. 3. Data on file. Daiichi Sankyo Inc., Basking Ridge, NJ.



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