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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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INSIDE:

2012 #38 **October 19, 2012**

Fresh Blood Provides No Benefit Over Stored Blood in Very Low-Birth-Weight Infants

Although a number of observational studies have suggested that changes occurring during the storage of red blood cells (RBCs) have negative consequences for transfused patients, researchers have not established a clear link between clinical consequences and RBC age in high quality studies. A randomized controlled trial presented at last week's AABB Annual Meeting in Boston, published simultaneously in *The Journal of the American Medical Association*, showed no changes in prospectively specified outcomes among very low-birth-weight infants randomized to use of fresh RBCs, compared with those stored according to the existing standard of care.

Dean A. Fergusson, PhD, of the Ottawa Hospital Research Institute, led the study, a double-blind, randomized controlled trial in premature infants transfused in six Canadian neonatal intensive care units (NICU). They found that about 53 percent of infants had at least one of the adverse outcomes, regardless of whether they received fresh or standard RBCs.

Observational studies have reported associations between prolonged storage and negative outcomes, such as increased infection rates, organ failure, death, and longer hospital stays. However, it has been difficult to separate the contribution of the RBCs to these negative outcomes from confounding factors related to unmeasured differences among patients receiving fresher or older blood.

The investigators sought to determine whether fresh RBCs decreased serious neonatal morbidity and mortality when compared with standard blood bank issue. A "dedicated donor policy," wherein a single unit of RBCs is designated for transfusion to one infant over the course of his/her stay to reduce the risk of transfusion-transmitted disease, results in infants receiving older RBCs.

Between May 2006 and June 2011, 1,752 infants in six Canadian neonatal intensive care units were screened and 377 premature infants weighing less than 1,250 g were randomized to receive ether fresh or standard storage RBCs. The clinical consequences of transfusing RBCs stored for seven days or less (fresh) vs. standard practice storage RBCs were compared using a composite primary outcome of necrotizing enterocolitis, retinopathy of prematurity, bronchopulmonary dysplasia, and intraventricular hemorrhage, and death. Secondary outcomes consisted of

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OUR SPACE

ABC Vice President of Administration and Communications Matt Granato

A Good I.D.E.A. is Worth Exploring

A few months ago, ABC President Dan Waxman, MD, wrote editorials on ABC's core values: **I**nnovation, **D**ata integration, **E**ducation, and **A**dvocacy (I.D.E.A.). Since then, we have been working to streamline ABC's services and programs and learn more from members on what is useful and needs revamping to stay true to our core values. Last month, we launched the second SEQuaLS (Strategies for Enhancing Quality, Loyalty, and Satisfaction) assessment, a customer service initiative that solicits feedback from our members on ABC's activities. The initial 2008 feedback from hundreds of member blood center employees helped us shape some of the largest changes ever to ABC's direction. One such change was to improve and increase networking opportunities with colleagues. We also increased our focus on hospital issues to help members better understand trends that will affect local hospitals. The assessment just closed, and it is too early to tell what members had to say, but we are very satisfied with the participation: 53 ABC CEOs, 43 medical directors, and 560 other staff responded. The newly appointed ABC Membership Committee will look at the data and make recommendations to the ABC Board of Directors.

We have also been working on our education and professional development offerings. To make these services more accessible, ABC published its 2013 meeting calendar all in one place (see pg. 13) and standardized registration fees, allowing members to better plan and budget in advance. We also recently expanded our portfolio, adding IT and supply chain management to the education topics, and in July, we announced the addition of ProGuide's advanced lean training program, BOOTS, to our 2013 lineup. In the small and risk-averse blood banking community, there's nothing better than a meeting or workshop to learn about a tested policy, procedure, or program, or find out what opportunities and challenges lie ahead. In addition, workshops and meetings serve as a prime networking and "matchmaking" mechanism. From "borrowing" ideas to striking merger deals, nothing is off the table during an ABC meeting break or evening event.

The free flow of ideas has always been ABC's strong-point. We are working to ensure all members can take advantage of one another's collective knowledge. Besides providing educational opportunities to members, this knowledge exchange also educates and develops ABC staff, feeding into our other three core values, and helping us fulfill our mission of serving members.

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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Fresh Blood vs. Stored Blood for Infants (continued from page 1)

the individual events in the composite, as well as nosocomial infection. The infants were assessed during the NICU stay and for up to 90 days after randomization.

The mean age of transfused blood was 5.1 days in the fresh RBC group and 14.6 days in the standard of care group. Among neonates in the fresh RBC group, 99 (52.7 percent) had the primary outcome, compared with 100 (52.9 percent) in the standard RBC group. The rate of clinically suspected infection in the fresh RBC group was 77.7 percent vs. 77.2 percent in the standard RBC. The rate of positive cultures was 67.5 percent in the fresh RBC group, compared with 64 percent in the standard RBC group.

"Among critically ill premature infants, fresh RBC transfusions compared with standard RBC transfusion rates of complications or death in our composite measure. We did not find any clinically meaningful or statistically significant differences in individual complications, in secondary or tertiary outcomes, or in the pre-specified subgroup analysis," wrote the authors. This likely means that "the many laboratory changes that occur with prolonged RBC storage may not be as important as once thought," they add.

The authors note that their findings may not apply to more mature or less ill infants. Also, they write that their study population presents difficulties for analysis as the biochemical, physiological, and clinical effects of interaction among the various storage times are not known. However, based upon these findings the authors "do not recommend any changes to storage time practices for the provision of RBCs to infants admitted to neonatal intensive care."

America's Blood Centers Executive Vice President Louis Katz, MD, commented that these findings were welcome by the blood community, since they suggest that complicated inventory management schemes to provide fresh blood to neonates may not be needed. However, the ability to generalize these findings to US neonates is not clear, given differences in the processing and storage of RBC concentrates, for example the additive solutions used in Canada and the US, he added. Whether units significantly older on average than those received by the standard of care group may be associated with worse outcomes cannot be assessed, he added.

Citation: Fergusson DA, *et al*. Effect of Fresh Red Blood Cell Transfusions on Clinical Outcomes in Premature, Very Low-Birth-Weight Infants: The ARIPI Randomized Trial. JAMA. 2012 Oct. 8: 1-9. [Epub ahead of print.] ♦

Reminder: AIM Software Overview Webinars Approaching

Don't forget to mark your calendars for the upcoming Appropriate Inventory Management (AIM) software overview webinar series. The first webinar will be held on Oct. 24 at 2 p.m. ET and the second on Nov. 6 at 2 p.m. ET. These webinars will familiarize participants with the AIM-I and AIM-II software capabilities. Login details are available at http://bit.ly/THWcD2. Further questions or concerns can be sent to Luleaday (Lula) Jembere at ljembere@americasblood.org.

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Patient Blood Management Recognized as Key Goal at AABB's Annual Meeting

While patient blood management has been of interest to the blood community for the last few years, it became clear at the AABB Annual Meeting in Boston last week that more hospitals and blood services are implementing patient blood management efforts, large and small. From the educational sessions, to the exhibit hall, to the abstracts, patient blood management was all around, signaling that improving blood utilization is a key goal for blood services and transfusion medicine practitioners in the US and abroad.

Patient blood management came to the forefront in June 2011 when experts at a Health and Human Service's Advisory Committee on Blood Safety and Availability meeting stressed the importance of strengthening blood management systems to promote the rational use of blood, cut down on the number of unnecessary transfusions, reduce transfusion risks, improve patient care, and save hospital resources (see *ABC Newsletter*, 6/10/11). The Joint Commission, a hospital accreditation organization, has even included appropriate blood management, specifically reducing over-transfusion of red blood cells (RBCs), in its initiative to address overuse of medical tests and procedures (see *ABC Newsletter*, 9/28/12).

Physicians' Workshop. As patient blood management becomes more recognized in healthcare as a valuable patient safety and cost-saving measure, AABB made it a hot topic at the annual meeting with more than a dozen patient blood management educational sessions, numerous abstracts, and a pre-convention Physicians' Workshop on the subject.

Eleftherios C. Vamvakas, MD, PhD, author of *Decision Making in Transfusion Medicine*, began the workshop with an explanation of the rationale for patient blood management, and a need to break from the transfusion status quo that many doctors have followed for years. Other topics included hemovigilance and transfusion safety, RBC transfusion guidelines based on trial data, algorithm-driven practice, preoperative anemia management, and point-of-care coagulation testing.

When Blood is not an Option. Areyh Shander, MD, chief of the Department of Anesthesiology, Critical Care Medicine, Pain Management, and Hyperbaric Medicine, at Englewood Hospital and Medical Center in New Jersey, discussed blood management when a patient refuses transfusion. Dr. Shander is also executive medical director of the hospital's Institute of Patient Blood Management & Bloodless Medicine and Surgery. The hospital treats many Jehovah's Witness patients, who refuse blood transfusions of any sort for religious reasons, leading the hospital to develop specific blood management programs for bloodless procedures.

Dr. Shander explained that while any type of blood transfusion is not acceptable to most Jehovah's Witness patients, sometimes these patients will accept plasma derivatives, intravenous immunoglobulin (IVIG), and hemoglobin-based oxygen carriers. Furthermore, pharmaceuticals not derived from blood and recombinant factors are almost always acceptable to these patients, as well as certain cell salvage techniques in which the patient's shed blood is re-infused into the patient's body, said Dr. Shander.

He emphasized that the key to blood management with these patients is discussing blood conservation strategies ahead of the procedure. Many efforts can be made preoperatively, such as managing coagulation and treating anemia, said Dr. Shander. He stressed that all patients, not just Jehovah's Witnesses, can benefit from preoperative measures to manage bleeding and reduce the need for transfusion.

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Patient Blood Management (continued from page 4)

Shifting Hospital Culture. Sherri Ozawa, RN, clinical director of Englewood Hospital and Medical Center's Institute for Patient Blood Management & Bloodless Medicine and Surgery, discussed the relationship between an institution's culture and patient blood management. She explained that incorporating patient blood management into a hospital means influencing perceptions about blood, among both patients and clinicians. A successful blood management program should have a physician in transfusion medicine to champion the initiative and get the institution motivated, said Ms. Ozawa. Also, a successful program should be directed by some type of medical governance with a director of patient blood management, to whom the medical directors of the major specialties report, she added.

Some hospital staff may resist patient blood management changes at first, but education tailored to each hospital sector – physicians, nurses, executive leadership – can help to get everyone onboard. Ms. Ozawa emphasized the importance of having some type of corrective action for physicians that administer inappropriate transfusions or fail to properly document the transfusion.

To further motivate physicians, the hospital also conducts retrospective reviews of transfusion practice and prospective reviews to ensure that physicians are aware of where their blood-use stands in terms of evidence-based transfusion guidelines, said Ms. Ozawa. Aside from changing physician culture regarding blood, Ms. Ozawa noted that patient blood management programs often provide an optimal opportunity for external messaging to show patients that the hospital is making this additional patient safety effort.

Another AABB meeting session focused on a patient blood management program at a private community hospital, Baptist Hospital in Pensacola, Fla., which showcased what started as a small grassroots initiative and grew into a successful hospital-wide program. Regina Castor, MT(ASCP), of Baptist Hospital, emphasized that blood management can be simple and can be done on a small budget, so-long as there is an enthusiastic and dedicated staff driving it.

Report Promotes Blood Utilization Improvements. Last week, Premier healthcare alliance published the largest comparative effectiveness analysis of blood utilization in scope and scale conducted to date, which showed that hospitals can reduce blood utilization to save on costs, while maintaining positive patient outcomes. As AABB Annual Meeting attendees learned about patient blood management, this report, published in the fall edition of *Economic Outlook,* promotes benchmarking transfusion data among hospitals to encourage appropriate blood use.

Using a clinical and financial outcomes database, Premiere examined blood use across 7.4 million de-identified discharges from 464 hospitals form April 2011 to March 2012 and found an opportunity for these hospitals to save $165 million annually in purchasing costs alone by reducing blood usage by 802,716 units, without compromising patients, said the report. The authors found, as many in the blood community would expect, large variation in blood use among hospitals due to lack of adherence to clinical transfusion guidelines. The full report is available at http://bit.ly/T0yawe. (Source: Premier *Best Practices in Blood Utilization* report, 10/9/12)

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September 19 - 28, 2012: Early bird registration; $375
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To view agenda, go to *http://bit.ly/agenda_scm*
To register, go to *http://bit.ly/registration_scm*

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- Linda Myers, President/COO, QualTex Laboratories

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NHSBT Making Progress in AIM-II Trial in England

In November 2011, the UK's NHS Blood and Transplant (NHSBT) and America's Blood Centers announced a trial program using ABC's Appropriate Inventory Management-II (AIM-II) software, in an effort to better understand how hospitals in England are using blood and blood products (see *ABC Newsletter*, 11/10/11). NHSBT reported in the September issue of *Blood and Transplant Matters* that the trial is well underway and a report should be completed sometime this month.

AIM-I helps hospitals to manage their blood product inventory, using software that ABC initially acquired in an open-source agreement from NHSBT in 2008. ABC later developed AIM-II, which aids hospitals in aggregating data to track blood utilization and patient outcomes. Physicians and hospitals can benchmark their blood utilization against one another to address discrepancies and decrease unnecessary transfusions. A project team from NHSBT has been working with ABC and key stakeholders from four hospital Trusts since September 2011 to test whether data can be extracted from hospital IT systems for analysis and benchmarking using the AIM-II software.

The Trusts selected for the trial are: The Dudley Group of Hospitals NHS Foundation Trust, the Newcastle Upon Tyne Hospitals NHS Foundation Trust, University Hospital of South Manchester NHS Foundation Trust, and Oxford University Hospitals NHS Trust. The trial sites are currently extracting data from their hospital systems. The data file from one Trust has so far passed the initial data quality control at ABC and is currently being validated prior to analysis. The data from the other three Trusts has been extracted and will be submitted shortly.

Once all of the data has been extracted and accepted, a series of reports will be provided for each hospital and for comparison between hospitals. There will be a dashboard for each blood component comparing the Trust's usage with others in the trial. A series of codes have been selected to provide benchmarking information on blood component usage by procedure/diagnosis. There will also be international benchmarking opportunities, as AIM-II is implemented in 15 US hospitals and is in the process of being adopted in the Netherlands.

Pending the results of this trial, AIM-II could be implemented in all of NHSBT's hospitals in England and North Wales. To read the entire *Blood and Transplant Matters* article about the AIM-II trial, visit http://hospital.blood.co.uk/library/pdf/bm37.pdf. (Source: *Blood and Transplant Matters*, 9/1/12) ♦

Speakers Explore How Blood Centers Can Create Socially Responsible Cultures

One session at AABB's Annual Meeting provided a closer look at a topic that is often overlooked or taken for granted in an industry built on civic-minded altruism: how blood organizations can more fully support their local communities while working toward global sustainability.

Moderated by Margaret Ostrowski, RN, the session focused on corporate social responsibility (CSR), the idea that organizations should conduct themselves in ways that benefit not just owners and shareholders, but employees, stakeholders, and society in general.

Lisa Walters, PhD, a visiting professor at the State University of New York at Fredonia and a medical technologist specializing in blood banking, kicked off the session. During her talk, she defined CSR, showed how the idea has evolved over the decades, described some formal efforts to provide a framework for CSR, and argued that true CSR must be integrated into the cultural fabric of an organization.

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Corporate Social Responsibility (continued from page 6)

Dr. Walters began by recalling that when she told a friend she would be speaking on corporate social responsibility, "She said 'Isn't that an oxymoron?'"

Though that quip got a laugh, the concept is real and has been around since the business boom of the early 1950s. Yet to this day, there is still no one standard definition of CSR (one study found 37 different definitions). The social scientific literature, however, has identified five CSR "dimensions" – environmental, social, economic, stakeholder, and voluntariness. Research also found that CSR seems to embrace distinct "audiences" – shareholders, employees, stakeholders, and people concerned about global issues and sustainability.

Over the years, different organizations have attempted to develop CSR models or codify its components. In 1971, for example, the Committee of Economic Development published its "Social Responsibilities for Business Corporations," a three-tiered model of CSR that divided audiences into shareholders and employees, stakeholders, and the global community. Years later, the United Nation's Global Compact initiative outlined 10 principles within the areas of human rights, labor standards, environmental concerns, and anti-corruption activities. In September 2010, the International Organization for Standardization published guidelines for social responsibility named ISO 2600.

These efforts and others have made CSR a catch phrase and have inspired a number of global corporate initiatives, including the "green" movement and related advertising. While promoting environmental sustainability is a valid and well-intentioned objective, she said, many corporations have engaged in "green washing" – creating a fake pro-environmental image to encourage environmentally conscious consumers to buy certain products. Many of these ads, she said, are a disingenuous "appropriation of environmental virtue" motivated by: "I'm going to put a pine tree on my product, and it's going to sell!"

Real CSR, she said, is functionally integrated across silos and is part of the business strategy and culture of an organization. A competitive culture focuses on controlling others and exploiting conflict, while CSR is more likely to spring from a humanistic culture that is supportive of others, open to diverse ideas, and creates an expectation that departments and employees will demonstrate an interest and concern for others.

CSR in the Blood Community. Next up was Robert J. Bayer, director of Quality Assurance at LifeStream and a past AABB assessor, who discussed "what CSR actually is in our industry." Mr. Bayer presented the results of a survey on CSR of 24 blood and transfusion centers. While few respondents said their organization had a clear definition of CSR or had an integrated CSR decision-making structure, over three-quarters believed that those same organizations engage in CSR-related activities.

Only about one-third of respondents said CSR was part of their strategic planning, and the survey indicated that CSR activities seem to be more focused on the community – both locally and globally – than on the activities of employees and suppliers. "In our industry, the CSR activities are more ad hoc and they lack functional integration," he said.

When asked for examples, respondents mentioned fundraisers benefiting a school in Africa, blood programs in Third-World countries, collections of donated supplies for needy people, and community fundraising walks and health fairs. When asked what motivates CSR activities, respondents mentioned the desire to give back to the community and increase awareness about the benefits of donation.

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Corporate Social Responsibility (continued from page 7)

A Texas Case Study. The third speaker was Suzanne Talley, director of Marketing and Public Relations at Coffee Memorial Blood Center, in Amarillo, Texas. "Now I'm going to try to build on that and give you some real examples that you can take back to your blood center," Ms. Talley said.

At Coffee Memorial there is no formal policy for CSR, but the idea of "doing the right thing" and "giving back" are ingrained into the corporate culture. She described an array of ways that the blood center and its employees work to protect the environment, donate time, equipment, and services and play a role in the concerns and ongoing efforts of other community groups.

First, the blood center has designed its facilities and landscaping to conserve energy and water and be more environmentally friendly. The center has a "Green Team" that initiated a recycling program and an "Adopt a Highway" program to clean up litter and debris.

The center also encourages employees to get involved in different community charity events, such as Socks for Soldiers, and partner with organizations, such as the United Way, The Bridge, the American Cancer Society, the American Heart Association, the Transplant Recipient Organization, and LifeGift. One photo even showed former CEO Jim Rutledge getting hit with a pie in the face during a charity event. Coffee Memorial and its employees have teamed with local food banks to collect cans of food from donors and others, an initiative that is promoted with TV and radio partners and has led to nearly 400 pounds of food going to needy people in the community each year.

The center also holds family events for blood recipients and uses its website to develop the "Because of You" series, which enables blood recipients to share their personal stories and show their appreciation to donors. The unexpected result has been a number of in-kind and financial donations from the community.

Employees have participated in fundraisers to help recipient families cover medical costs and have reached out to a local cycling club to sponsor rides, related events such as cookouts, and find sponsors for Bike Month events each May. That relationship with local cyclists led to a partnership with the Share the Road safety campaign, a bike safety education day, and a Boy Scout ride.

Other events have included a Boots vs. Badges charity softball game between firefighters and police officers, and work with the 100 Club, which benefits the families of fallen Texas law enforcement officers. The blood center also participates in the Kids Inc. Donor Days (formerly Saturn National Donor Day). Kids Inc. builds playgrounds and donates vouchers so that underprivileged children can play sports. The blood center also invites donors to give blood in honor of specific service men and women during its M*A*S*H Blood Drive.

"Everyone defines CSR differently, but hopefully this workshop has inspired you with ways that your organization can further define social responsibility," Ms. Talley said. ♦

– Robert Kapler, rkapler@americasblood.org

AIM Company Adds New Board Members with Wealth of Healthcare Experience

James P. AuBuchon, MD, Mark Skinner, JD, and Joseph Mark have been elected members of the Blood Counts LLC, Board of Directors. Blood Counts is a subsidiary of America's Blood Centers, which shapes the direction and development of ABC's Appropriate Inventory Management (AIM) software.

Blood Counts Board Chair Jodi Minneman, chief operation officer of the Community Blood Center (Dayton), said, "We are honored to add such distinctive members to our board embodying a wealth of healthcare knowledge from the blood centers, hospitals, and patient perspective. Their skills and experience will help AIM achieve its enormous potential in benchmarking for and tracking optimal patient outcomes."

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James AuBuchon, MD

Dr. AuBuchon has served as the president and CEO of Puget Sound Blood Center since 2008. Prior to moving to Seattle, he spent 18 years at the Dartmouth-Hitchcock Medical Center as medical director of the Blood Bank and Transfusion Service, and later as chair of Pathology and professor of Medicine at Dartmouth College. Dr. AuBuchon's research focus includes transfusion safety and blood components. He has received numerous awards and given many lectures at national blood banking and transfusion medicine conventions. He has served on AABB committees and is a past-president of the organization. He is also currently a professor of Medicine (hematology) and Laboratory Medicine at the University of Washington and is the associate editor for *Immunohematology*, *Transfusion*, *Vox Sanguinis*, and *Blood Banking and Transfusing Medicine*. Dr. AuBuchon has served on national committees, such as the Department of Health and Human Service's Advisory Committee on Blood Safety and Availability (ACBSA).


Mark Skinner, JD

Mr. Skinner is currently the president of the World Federation of Hemophilia USA. WFH USA is the US's fundraising arm of the World Federation of Hemophilia, distributing more than $45 million in humanitarian aid around the world in 2011. Mr. Skinner is an advocate for the treatment of those living with bleeding disorders globally and has life-long involvement with the bleeding disorders community. He served as president of the World Federation of Hemophilia (WFH) from 2004 to July 2012. During his tenure, he led the WFH through significant expansion of programs. A member of the US National Hemophilia Foundation (NHF) Board of Directors from 1997-2003, Mr. Skinner has also served as the Foundation's president. He currently sits on NHF's Medical and Scientific Advisory Council. He has served as an advisor on blood safety issues to the ACBSA. He has been elected to the Board of Directors of the American Thrombosis and Hemostasis Network, beginning in 2013. Mr. Skinner is an attorney in Washington, D.C., and a senior consultant to the Workers Compensation Research Institute, headquartered in Cambridge, Mass.


Joseph Mark

Mr. Mark brings to the AIM Board years of hospital leadership experience. He has served in executive leadership positions at numerous hospitals since 1979, most recently as president and CEO of St. Joseph Hospital and Redwood Memorial Hospital in Eureka and Fortuna, Calif. He also served as a partner to Break-Through, LLC, a consulting practice to organizations committed to strengthening their operating performance results and aligning their key stakeholders behind a compelling strategic vision. He has proven experience as a visionary leader aligning constituencies to realize bold strategic objectives and in securing philanthropic support.

BLUE PLATELET SPECIAL

Lauren Ward Larsen

There, But for the Grace of God

Last month, I was scheduled to give a talk in Barcelona, followed by ten days of writing (read: playing) in Avignon and Paris. I was hoping to come across an appropriate story – someone interesting with a personal tie to the blood cause – for this column while traveling internationally. Turns out, I didn't have to wait very long. Despite my plan to sleep through the overnight flight to Spain, Brad, my seatmate, and I instead spent the better part of the flight in lively conversation about everything from business and travel to politics and religion (I know, I know – propriety was never my strong suit).

Ultimately, the conversation turned to blood, as it usually tends to do when you're seated next to me on a plane. A long-time blood donor, Brad expanded his efforts in this area 12 years ago by registering as a bone marrow donor. "A friend's son needed a transplant, so I signed up immediately. I wasn't a match for his child, but shortly after joining the registry I was told I was a near-perfect match for a 31-year-old man in Chicago."

Brad underwent local anesthesia for the surgical removal of bone marrow through his pelvic bone. The marrow was then flown to Chicago where it saved the life of the young man Brad has never met, but whom he's been told is doing well.

"I'm not going to lie, that procedure hurt," Brad confessed, rubbing his hip as if the cellular memory of physical pain were still present. "And the recovery period was rough for me, especially when one of my kids got the flu and I had to be quarantined from him. It's not easy being told you can't even play with your own son."

"So would you do it again?" I asked.

"I would and I did. Five years later, I was another perfect match, this time for a little boy with leukemia."

"Even though you'd had such a tough time with the first donation?" I asked, probing to understand my new friend's motivation.

Without a moment's hesitation, Brad replied, "I figure, 'there, but for the grace of God, go I.'" Having already discussed spirituality with him, I knew that Brad's reasoning wasn't based on religious dogma or duty, but rather an authentic sense of one human being wanting to help another human being – even if to do so was a pain in the…hip.

The second donation was also done surgically, and although his recovery period was easier, ongoing soreness was still an issue. I told him about the newer, more common, and simpler approach to bone marrow donations called peripheral blood stem cells (or PBSCs), which is performed much the same way as an apheresis blood donation. He'd never heard of this approach, nor was he aware that the majority of stem cell donations are now collected this way, rather than through the bone marrow. Brad then told me he'd recently received a third call regarding a possible match for his bone marrow. "Wow!" he said. "You've got me all excited about this now!"

Actually, Brad, I'm the one who's excited. You see, lately I've been feeling a bit overwhelmed by all the crap going on in the world – whether it's the shooting of a little girl in Pakistan who spoke up in favor of girls attending school, or the abduction and murder of a little girl who was walking to school less than 20 miles from my home – and I am saddened by the seeming lack of compassion that is exhibited daily. But you, Brad, serve as a reminder that there are good people out there, everywhere, everyday. I'm excited that people like you exist. Meeting you, Brad, was a reminder that if I pay attention, I don't have to wait long to cross paths with a truly good soul – a blood donor, a marrow donor, an organ donor. You're everywhere, Brad. And you make the world a much better place.

Lauren Ward Larsen is the author of "Zuzu's Petals: A True Story of Second Chances," which shares her story of becoming a 200-pint blood recipient and the unexpected life that unfolded as a result. She is a former president of the FABC and can be reached at laurenwardlarsen@me.com, or via her website at www.laurenwardlarsen.com.

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Through the generous support of **Incept**, ABC members have the opportunity to request an appearance from one of the inspiring blood donation advocates in our line-up of national speakers. Qualified ABC-member events (see requirements below) are eligible to host a speaker. This program provides the blood center a grant award from the FABC of up to $1,000; half of which is to be paid to the speaker for their services and the remaining $500 to be used to cover travel expenses and incidentals. Any additional expenses above and beyond the grant amount in relation to the speaker's appearance are the responsibility of the blood center.

Event Requirements:

- Ability to reach 200+ potential donors or blood drive sponsors through a live audience (can be an event sponsored by a blood center or a general community event in need of a motivational speaker; can also combine a number of events in one day; back-to-back talks are no problem!)
- Ability to reach a broader audience through media outreach, i.e., filling in the speaker's schedule with talk radio and television appearances, as well as newspaper interviews during the visit
- Ability to tap broad-based community audiences, not just those who have already bought into the cause
- In general, requests with a plan for broad reach (not just loyal donors and employees, but those we need to recruit to our cause) will be given the highest priority. Our speaker advocates are willing to do whatever it takes to help, so think outside the box!

MEET JENNI, A FEATURED SPOKESPERSON ON AMERICA'S BLOOD CENTERS' SPEAKERS BUREAU

Suggested Audiences: *high school and college students and donors, donor recognition events, blood drives, special events and banquets*

Pop songstress Jenni Alpert is a powerful sultry voice whose honest rich songwriting and soothing musical melodies grab listeners in every corner. This Los Angeles native singer/songwriter has been traveling the world with her music, supporting great artists like Loudon Wainwright III, Jon Allen, Kaki King, and has shared stages with Regina Spektor, Giovanca, and Sarah Bareilles.

Adopted as a child, Jenni was reunited with her biological family and discovered that a relative was surviving off of weekly blood transfusions to treat red blood cell aplasia. After having dealt with losing her adopted father to cancer and watching his challenges and need for blood, she spent a few years helping her cousin through some of his hardest days. During that period Jenni learned a lot about the value of donating blood and how important it is to do so because donating blood and bone marrow saves lives.

To help raise awareness and encourage blood donations, she created the 'Blood Driven' tour, performing at blood drives, blood centers, and children's hospitals by day and local venues by night touching over 5,000 miles to encourage more people to donate blood to save a life. Jenni's passion for music and blood donation alike, converge to make her a unique and inspiring guest speaker/singer for listeners of any age! Her goal is to thank those who donate and inspire more to do so – bringing communities together through music! For more information about Jenni's music visit *www.jennialpert.com*.

To find out more about the Conversations About Life program, Jenni Alpert and the other spokespersons available visit *http://bit.ly/Conversations_About_Life*.

ABC, the FABC, and Global Healing Announce International Blood Safety Forum

America's Blood Centers, the Foundation for America's Blood Centers, and Global Healing recently announced that they will host an International Blood Safety Forum on March 15, before ABC's 2013 Annual Meeting in Washington, D.C. This forum will be focused on how to better match resources and specialists in the US with blood safety projects in the developing world. Global Healing and ABC members will discuss effective ways to collaborate with one another to assist developing countries.

There is much progress being made around the world to reform outdated blood systems, improve clinical outcomes, and share modern, evidence-based knowledge between medical professionals. Global Healing is an American-based charity dedicated to promoting healthcare reform in areas of the world where modern medical healthcare is not available. Similarly, many ABC members participate in programs to improve the blood supply in the developing world.

Registration for the forum will become available through ABC in conjunction with its Annual Meeting. For more information, contact contact@globalhealing.org.

AABB Attendees Discuss how to Best Mitigate Iron Depletion in Blood Donors

Attendees at last week's AABB Annual Meeting in Boston shared data and experiences about maintaining blood donor iron stores, as well as possible interventions to mitigate iron depletion. Over the last several years, regulatory officials and blood banking experts have met several times to discuss solutions to help protect blood donor iron stores, while also maintaining an adequate blood supply.

The blood banking community has been aware for several years that frequent blood donation can cause iron depletion. The REDS-II Donor Iron Status Evaluation (RISE) study provided a clearer picture of the issue, confirming that there is in fact a high prevalence of iron depletion among frequent blood donors and that lengthening the interdonation interval or implementing iron replacement programs may help to correct this issue (see *ABC Newsletter*, 4/27/12). The RISE study showed that about 16 to 28 percent of repeat blood donors are actually iron deficient, despite having a normal hemoglobin measurement. Several speakers at AABB referenced this study.

The Food and Drug Administration mandates that blood donors have a minimum hemoglobin level of 12.5 g/dL, although hemoglobin is a late marker of iron depletion, as Louis Katz, MD, America's Blood Centers' executive vice president, pointed out during a session on hot topics about blood donors at the AABB meeting. Dr. Katz noted that the rate of absent iron stores in female donors is more than twice that of the general population. He went on to discuss the various possible interventions, such as providing iron supplementation, and concluded that "we need to refocus our efforts on measuring iron stores and driving down inappropriate blood utilization" to reduce the pressure for the most frequent donors.

Changing the Hemoglobin Cutoff and Interdonation Interval. At another AABB Annual Meeting session, the speakers discussed the effect of increasing the hemoglobin cutoff in male donors and increasing the interdonation intervals in whole blood donors, as it is well known that anemic men are permitted to donate at the current hemoglobin threshold. Jed Gorlin, MD, medical director and vice president of Medical and Quality Affairs at Memorial Blood Centers, emphasized variation internationally in hemoglobin standards and interdonation intervals. Many other countries implement gender-specific hemoglobin standards, as well as longer interdonation intervals than used in the US. Dr. Gorlin also

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Iron Deficiency in Donors (continued from page 11)

mentioned the joint study between his blood center and Mississippi Valley Regional Blood Center that will measure the effectiveness of providing iron replacement on donor retention, donor commitment, and improvement of donor iron status. The two blood centers are currently awaiting an FDA variance determination on collecting units from female donors with a hemoglobin of 12.0 g/dL while checking their ferritin levels.

Joseph Kiss, MD, medical director of Hemapheresis at Central Blood Bank at the Institute for Transfusion Medicine, discussed some possible side-effects of iron deficiency such as fatigue, decreased cognitive function, restless leg syndrome, and pica, which is a craving to eat non-nutritive substances (most commonly ice). Dr. Kiss also discussed more accurate measures of donor iron stores, including ferritin and soluble transferrin receptors (sTfR). He reviewed a 2011 study published in *Transfusion*, which showed that routine ferritin measurements at each blood donation followed with medical counseling for iron deficient donors led to an increase in the donors' overall hemoglobin level, a decrease in anemia (based on hemoglobin level), a decrease in hemoglobin deferrals, and a slight decrease in the donor return rate.

Manish Ghandi, MD, medical director of Donor Services at Mayo Clinic, presented his institution's experience with increasing the male hemoglobin cutoff to 13.0 g/dL and increasing the interdonation interval. The Mayo Clinic analyzed a 12-month blood donation pattern at the blood center, experimenting with different combinations of increasing the male hemoglobin cutoff to 13.0 g/dL, maintaining the current 12.5 g/dL cutoff for females, changing the female cutoff to 12.0 g/dL, and changing the interdonation interval to 12 or 16 weeks. The results showed that changing the male hemoglobin criteria and/or the interdonation interval led to about a 5-20 percent or higher loss of red cell products.

Potential Blood Center Interventions. The AABB Annual Meeting also featured a Research and Progress session, during which speakers discussed blood center strategies to mitigate or prevent blood donor iron depletion.

Bryan Spencer, researcher and REDS Program Manager at the American Red Cross, presented the results of a continued REDS-II analysis, in which the RISE data was extended to the full REDS-II dataset. This analysis predicted that various combinations of changing the minimum hemoglobin cutoff and/or the interdonation interval would lead to about a 10 percent or more decrease in red cell collections. The researchers predicted that lengthening the interdonation intervals should measurably reduce the prevalence of low iron in donors, but that raising the male hemoglobin cutoffs does very little to reduce the prevalence of low iron in the donor pool. Reducing the female hemoglobin standard to 12.0 g/dL may boost collections considerably, while only modestly increasing the prevalence of low iron, added Mr. Spencer.

Barbara Bryant, MD, presented a 39-month National Institutes of Health study examining the role of iron replacement therapy in the routine management of blood donors through the I.R.O.N. Protocol, which included additional health history screening questions about pica and restless leg syndrome, extra lab tests to better measure iron stores, and oral iron replacement therapy for iron deficient donors. The results showed that the lab parameters normalized for blood donors taking iron supplementation and continuing to donate blood. Blood donors on iron therapy also reported that pica symptoms abated rapidly with oral replacement, while restless leg syndrome symptoms improved more slowly and less completely than with oral iron. Screening questions for pica may help to identify donors who would benefit

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Iron Deficiency in Donors (continued from age 12)

from iron replacement, as 73 percent of all donors reporting a history of pica were iron depleted or deficient, said Dr. Bryant.

Dr. Gorlin discussed AABB Bulletin #12-03, "Strategies to Monitor, Limit, or Prevent Iron Deficiency in Blood Donors," available online for AABB members (see *ABC Newsletter*, 10/16/12). Mindy Goldman, MD, executive medical director of Donor and Transplantation Services at Canadian Blood Services (CBS), then shared several changes that CBS has made to mitigate donor iron depletion, as well as strategies under consideration.

CBS now has iron supplementation regimens and deferral policies for anemic and iron deficient donors, as well as a preventive iron supplementation protocol. Post-donation educational materials also contain information about iron and blood donation. CBS is considering improving the informational letter and giving it to all donors deferred for low hemoglobin, as well as implementing a six-month deferral for low hemoglobin. Since almost all donors failing the initial hemoglobin stick and passing on the second stick are iron deficient, CBS is considering only repeating the measurement if there was a technical difficulty. Measures to protect females from iron deficiency are also being mulled over.

Kevin Land, MD, senior medical director of Field Operations at Blood Systems, discussed Blood Systems' data from 2010 about first-time donors, which showed that among donors with a hemoglobin of 12.5 to 13.4 g/dL, 52 percent of men had adequate iron stores (ferritin > 30 mcg/L) and 57 percent of women had adequate iron stores (ferritin > 20 mcg/L). Also, according to Blood Systems' data, the hemoglobin level at the previous donation was more strongly associated with deferral than the interdonation interval. He concluded that Blood Systems' data support using pre-donation hemoglobin levels and possibly prior donation frequency to target interventions to donors at the greatest risk of deferral/iron-depletion.

Dr. Gorlin discussed some ongoing studies in this area that may provide an answer to some of the questions surrounding maintaining donor iron stores, such as the Strategies to Reduce Iron Deficiency (STRIDE) study and the REDS-II Hemoglobin and Iron Recovery Study (HEIRS). Although many different potential solutions were posed during the AABB Annual Meeting, it was clear that all of the speakers felt something must be done to prevent iron deficiency in blood donors, whether it is providing iron supplementation, measuring ferritin levels, changing the interdonation interval, or altering the hemoglobin threshold for men. ♦

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

America's Blood Centers®
It's About *Life.*

INSIDE ABC

ABC Meetings & Workshops At-A-Glance				
Meeting/Workshop	**Dates**	**Location**	**Hotel/Hotel Rate**	**Registration Dates & Fees**
2012:				
Supply Chain Management Workshop	Dec. 3-4	San Antonio, Texas	Hotel Valencia Riverwalk, $159/night	Sept. 19-28: Early bird, $375; Sept. 29-Nov. 9: Regular, $425
2013:				
BOOTS	January – May (10 sessions, various dates)	Orlando, Fla.	The Grand Bohemian, $189/night	Registration opens Nov. 14, 2012
International Blood Safety Forum	March 15	Washington, D.C.	The Ritz-Carlton (Pentagon City), $239/night	Jan.9-Feb.22
2013 Annual Meeting	March 16-19	Washington, D.C.	The Ritz-Carlton (Pentagon City), $239/night	Jan 9-Feb. 22, $695
2013 Technical/Lab Directors & Quality Workshop	May 7-9	Atlanta, Ga.	Sheraton Atlanta, $159/night	Feb. 20-March 1: Early bird, 375/$400 (2- or 3-day sessions); March 2-April 12: Regular, $425/$490 (2- or 3-day sessions)
2013 Fund Development, Donor Recruitment & Communications Workshop	June 18-21	San Antonio, Texas	Hotel Valencia Riverwalk, $159/night	April 2-12, Early bird, $375/$440/$490 (2-, 3-, or 4-day sessions); April 13-May24: Regular, $425/$490/$540 (2-, 3-, or 4-day sessions)
2013 MD Workshop	Aug. 3 (precedes Interim Meeting)	Milwaukee, Wis.	InterContinental Milwaukee, $160/night	May 22–July 12, $395; Option (+SMT Forum Aug. 4), $425; Option (+SMT Forum & Interim Meeting Aug. 4-5), $695
2013 Interim Meeting	Aug. 4-5	Milwaukee, Wis.	InterContinental Milwaukee, $160/night	May 22-July 12, $595; Option (+MD Workshop Aug. 3), $695
2013 Financial Management Workshop	September	TBD	TBD	Early bird, $375; Regular, $425
2014 Meetings/Workshops: Annual Meeting; Human Resources/Employee Training & Development Workshop; Fund Development, Communications; and Donor Recruitment Workshop; IT Workshop; and Supply Chain Management Workshop. Other workshops may be added at a later date. Check http://members.americasblood.org/go.cfm?do=Page.View&pid=34 for the most up-to-date information.				
Anyone wishing to attend these meetings/workshops as a sponsor should contact Abbey Nunes at anunes@americasblood.org or (202) 654-2980.				

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ABC Member Workshop Registration Fees		
Workshop Length	Early-Bird Registration	Regular Registration
1-day	N/A	$395.00
2-day	$375.00	$425.00
3-day	$440.00	$490.00
4-day	$490.00	$540.00

Note: these fees do not apply to the Annual and Interim Meetings.

AABB Workshop Explores Advances in Blood Donor Screening for Babesiosis

The epidemiology and potential interventions for transfusion-transmitted babesiosis (TTB) were discussed at a workshop chaired by David Leiby, MD, from the American Red Cross (ARC). The workshop speakers agreed that some type of donor screening test is necessary to mitigate the risk of TTB, but noted that there are still many unanswered questions.

Barbara Herwaldt, MD from the Centers for Disease Control and Prevention covered the histories of both tick-borne and transfusion-transmitted babesiosis, and also reviewed the data she published last year in the *Annals of Internal Medicine*, which described more than 160 cases of TTB. Al Demaria, MD, from the Massachusetts Department of Health and the Council of State and Territorial Epidemiologists discussed the intricacies of reporting requirements and the role of surveillance in policy development. He emphasized that surveillance cases and clinical cases are not the same, and that surveillance data are best used to identify trends that demand new policy initiatives.

Carolyn Young, MD, from Rhode Island Blood Center, described the center's donor screening investigational new drug application that is allowing the center to provide babesia-screened blood components to neonates and selected pediatric patients. The center is selecting units for both serologic (IFA) and polymerase chain reactive (PCR) screening by Imugen. Serologically reactive donors have been identified and deferred, but no PCR positive donors have been found. The data set remains too small to demonstrate a statistically significant decrease in TTB cases, but are suggestive.

Sue Stramer, PhD, discussed the ARC progress in evaluating an automated IFA and PCR screening by Imugen in high- and moderate-risk regions under investigational new drug status and testing to date. ARC is finding exposed and infected donors, as expected, in their high risk areas (Connecticut and Massachusetts), and have identified a small number of PCR-positive, seronegative donors (i.e., window cases). Whether these findings will justify the use of both test methods is not yet clear.

Mike Busch, MD, PhD, of Blood Systems Research Institute (BSRI) discussed the development of a peptide EIA babesia screening test by Immunetics, and the strategy at BSRI and Creative Testing Solutions, in collaboration with New York Blood Center, to evaluate serological screening in high-, moderate-, and low-risk donors. Their IND will begin during the next season.

The speakers agreed on the need to mitigate TTB risk with donor testing, but it remains unclear which is the most appropriate test(s), which donors to screen, and in what geographic regions testing should occur.

The Foundation For America's Blood Centers

Support the Legacy of Dr. Celso Bianco with the Dr. Celso Bianco Lecture Series Endowment.

To honor his achievements in blood banking and transfusion medicine and to celebrate his retirement from America's Blood Centers, the Foundation for America's Blood Centers is pleased to announce the Dr. Celso Bianco Lecture Series.

The Dr. Celso Bianco Lecture Series is an endowment that will fund the search, travel and lodging to honor a leading physician and/or scientist to speak on an emerging issue related to transfusion medicine.

This lecture series is an outstanding opportunity to honor over 40 years of contributions in transfusion research, as well as blood and donor safety that Dr. Bianco has provided to donors, patients, and blood center staff. We encourage everyone in the blood banking, pharmaceutical and government communities to support this endowment as a way of ensuring Dr. Bianco's achievements and contributions to the industry continue.

To contribute to the Dr. Celso Bianco Lecture Series Endowment, please visit *http://bit.ly/OWITIw*.

For more information, please contact Jodi Zand at *jzand@americasblood.org* or 202.654.2994.

RESEARCH IN BRIEF

During AABB's Annual Meeting in Boston, two groups of investigators reported studies suggesting that platelets derived from double and triple plateletpheresis procedures are not less safe in terms of bacterial contamination than those derived from single plateletpheresis collection. Some have hypothesized that the longer phlebotomy needle dwell time for double and triple collection procedures, along with other procedure characteristics, might increase risk from split donations. Eder *et al* presented data from January 2007 through December 2011, documenting culture results of more than 4 million distributed platelet doses and reports of septic transfusion reactions reported to the American Red Cross hemovigilance program. Although contamination rates were higher in double and triple collections than single collections, reports of sepsis were statistically identical for single, double, and triple components (8.9, 8.3, and 11.2 cases per million doses). A three-year study of 268,702 aerobic BacT/ALERT plateletpheresis cultures at Blood Systems found no differences in either bacterial detection rates or the time to positive results in contaminated units. The rates of true positives in this study per 1,000 collections were 0.08 for single collections, 0.13 for doubles, and 0.10 for triples. Both studies confirmed that true positive cultures were primarily skin flora or known pathogens.

Citations: Eder AF *et al*. Comprable Bacterial Safety of Platelets Collected from Single, Double, or Triple Apheresis Procedures. Transfusion. 2012 Sep; 52 (Supplement s3): 12A. Abstract P5-030A.

Vanderpool SK, *et al*. Three Year Study Comparing Bacterial Detection Rates for Single, Double, and Triple Apheresis Platelet Collections. Transfusion. 2012 Sep; 52 (Supplement s3): 45A. Abstract S81-030M.

Five publications presented at AABB's Annual Meeting highlight the clinical value of OrSense's Non-Invasive Hemoglobin Monitor. OrSense's non-invasive hemoglobin measurement uses a ring-shaped sensor that is fitted on the donor's finger and applies pressure, temporarily occluding local blood flow. During the occlusion, optical elements in the sensor perform a sensitive measurement of the light transmitted through the finger. This provides a quick hemoglobin measurement without having to use the regular fingerstick method. The studies presented assessed the non-invasive hemoglobin monitor for measuring pre-donation hemoglobin, and concluded that OrSense's device is comparable to invasive, point-of-care monitoring solutions in terms of accuracy and reliability. One study conducted by M. Kim and colleagues compared the OrSense pre-donation hemoglobin measurement to venous and capillary hemoglobin measurement in 506 blood donors at Hanmaum blood centers in Korea. They concluded that the hemoglobin values determined by the OrSense device were comparable to those measured using the automated hematology analyzer. They noted that blood donors may benefit from painless blood screening with the non-invasive sensor. Another study by E. Castron, *et al* sought to determine the level of satisfaction with non-hemoglobin measurement of donors and blood center staff, as well as the possible effect on donor return rate. A survey was distributed to 1,000 blood donors and to 27 blood collection staff members at a center in Spain. A majority of blood donors found the non-invasive hemoglobin measurement to be simple, quick, and comfortable, however, most reported that it would not affect their decision to repeat donation. Among the staff, the majority rated the device to be simple, comfortable, and biologically safe, although some did not rate the device as being optimal in terms of time spent on the test compared to the fingerstick method. (Source: OrSense press release, 10/9/12)

Citations: Castro E, *et al*. The Impact on Blood Donors and Blood Centre Staff of a Non-invasive Predonation Hb Measurement System. Transfusion. 2012 Sep; 52 (Supplement s3): 242A. Abstract AP8.

Kim M, *et al*. Hemoglobin Estimation in Predonation Screening Using a Non-invasive Hemoglobin Sensor. Transfusion. 2012 Sep; 52 (Supplement s3): 93A. Abstract SP101. ♦

BRIEFLY NOTED

Two researchers, one British and one Japanese, won the 2012 Nobel Prize for Physiology or Medicine for their laboratory work on converting adult cells into pluripotent stem cells, officials of the Karolinska Institute in Stockholm announced on Oct. 8. Sir John B. Gurdon, PhD, of the University of Cambridge in England, and Shinya Yamanaka, PhD, of Kyoto University in Japan, were the winners, reported *MedPage Today* on Oct. 8. Dr. Gurdon's contribution was made in 1962 when he found that cell differentiation could be reversed by the process of nuclear transfer, according to a press release from the Nobel committee. Working with frog eggs, Dr. Gurdon replaced their nuclei with that from mature intestinal cells. These eggs cells were still able to develop into normal tadpoles, showing that the mature cells' genetic material was complete and contained all the instructions necessary for embryonic development. Dr. Yamanaka was born the same year that Dr. Gurdon completed his seminal work. In 2006, Dr. Yamanaka led a team that, by transferring a few key genes into mature fibroblasts, was able to transform the cells into immature, undifferentiated cells. These induced pluripotent stem cells could then be coaxed into re-differentiating to become other types of specialized cells, including neurons and intestinal cells, as well as fibroblasts. The latter work was welcomed as a potential alternative to human embryonic stem cells derived from human eggs discarded after in vitro fertilization procedures, for stem cell research and eventual clinical applications. Such research has been opposed by the Catholic Church and other right-to-life advocates. (Source: *MedPage Today*, 10/8/12)

The Transfusion Medicine RFID Consortium, which seeks to improve safety and reduce costs in the blood supply chain through use of radio-frequency identification technology (RFID), announced Friday that Beaverton, Ore.-based S3Edge has been tapped to commercialize a new RFID and barcode-based blood product tracking technology. Designed and built under a private, academic and public initiative funded by the National Institutes of Health, the Blood Product Tracking Suite consists of mobile, desktop, and server software applications that offer greater visibility to the physical movement of blood products, while improving the efficiency of blood center operations, reported *Healthcare IT News*. The RFID consortium includes BloodCenter of Wisconsin, Carter BloodCare, Mississippi Blood Services, the University of Iowa Hospitals and Clinics, Mississippi Baptist Health System, University of Wisconsin Madison – RFID Laboratory, Lenexa, Kan.-based Mediware Corp., Brookfield, Wis.-based SysLogic, and S3Edge. The suite of applications has been deployed in a production pilot at the BloodCenter of Wisconsin and the University of Iowa Hospitals and Clinics (UIHC) with promising results. "Thanks to the outstanding work of the entire consortium team, we have successfully piloted the new system to track blood products as they move from fixed and mobile donation sites, through the blood center, and to distribution," said Lynne Briggs, vice president and chief information officer for BloodCenter of Wisconsin. "After 24 weeks of running the system in a pilot mode here at the BloodCenter of Wisconsin, we have seen process efficiency and traceability gains, as well as marked improvements in reconciliation." The hospital transfusion services tracking module was piloted at the DeGowin Blood Center at UIHC, where it was run in parallel with IPR, an internally developed barcode-based tracking system. SysLogic will continue to spearhead efforts to obtain the 510(k) clearance for the blood product tracking suite of applications developed by the consortium, officials say. More information is available at http://bit.ly/PeSnn9. (Source: *Healthcare IT News*, 10/5/12)

A trial did not move forward as scheduled in September in the case of a man who claims he contracted a life-threatening infection as a result of a blood donation at Stanford Blood Center. Attorneys at Stanford asked for and received a continuance, and the two sides are working to set a new date, according to *San Jose Mercury News*. The plaintiff, Christopher Bui, is suing Stanford Blood Center, along with other entities connected to the university, for medical malpractice. The longtime blood donor claims a needle-stick caused a serious infection that eventually required surgery to remove most of

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BRIEFLY NOTED (continued from page 17)

his left collarbone. "While we cannot comment on the specifics of Mr. Bui's medical issue because of federal and state privacy laws, we can say that Stanford Blood Center complies strictly with FDA safety regulations, adhering to rigorous, long-standing procedures to maximize the safety of the blood donors, recipients, and staff," Stanford officials said in a statement. An America's Blood Centers' member received an inquiry from the press about this article, and ABC has made talking points available at http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=1804. (Source: *San Jose Mercury News*, 10/1/12) ♦

REGULATORY NEWS

The Food and Drug Administration posted "Information for Blood Establishments: Unavailability of CHIRON RIBA HCV 3.0 SIA (RIBA)" on its website on Oct. 5. FDA states that certain hepatitis C virus (HCV) nucleic acid testing (NAT) assays are labeled with a "limited supplemental claim" such that when a sample tests repeatedly reactive anti-HCV and reactive on the HCV NAT, the reactive NAT can serve as the supplemental test for donor notification and counseling, as well as in determining the need to notify transfusion recipients for lookback. When the anti-HCV is repeat reactive, but HCV NAT negative, blood establishments can apply to FDA for an exception or alternative procedure (a variance) to utilize a modified algorithm that requires testing anti-HCV using a different approved anti-HCV screening assay as a supplemental test in the absence of the RIBA-HCV assay. Using this approach would allow blood centers to use the results for donor notification and counseling, as well as recipient lookback. FDA suggests blood establishments contact their consumer safety officer at FDA's Center for Biologics Evaluation and Research, Division of Blood Applications regarding the submission of the variance under 21 CFR 640.120. More information is available online at http://1.usa.gov/Wsvv5z. During the "Ask the FDA" session at AABB's Annual Meeting in Boston last week, FDA officials made clarifications regarding the unavailability of CHIRON RIBA HCV 3.0. One question posed to FDA was "Is it necessary for blood establishments to request an exception or alternative procedure in order to remain compliant with 21 CFR 610.40(e)?" FDA responded "No, it is not necessary to seek a variance. Supplemental testing is for donor counseling and consignee notification. You do not need to seek a variance if the anti-HCV is Repeat Reactive (RR) and HCV NAT negative as long you take appropriate action on those results. Donor deferral, notification, and counseling may be done based upon the available results. Additionally, if you don't seek a variance, you will have to take additional measures relative to lookback and consignee notification. Lookback regulations state if supplemental testing results are not available, you have to notify consignees that results can't be confirmed and that they must take steps to notify recipients." FDA also noted that the need to notify consignees within 72 hours of test results remains in effect, which should be considered in the timing of an alternative procedure request if blood establishments choose this option. FDA stated that they plan to update the industry as additional information on the shortage becomes available. (Source: FDA Information for Blood Establishments, 10/5/12).

The Food and Drug Administration recently granted clearance to Terumo BCT for two plasma products and a data management system, the company announced in press releases last week. Terumo BCT announced on Oct. 5 that it received clearance for the preparation of plasma held at 1° to 6° C within eight hours and frozen within 24 hours after phlebotomy (PF24) and plasma held at room temperature for up to 24 hours and frozen within 24 hours after phlebotomy (PF24RT24) form apheresis plasma collected on Terumo BCT's Trima Accel Automated Blood Collection System. "The clearance of these extended handling capabilities enables blood centers to collect the right product at the right time and leverage the mobility of the Trima Accel system for collections farther from the processing

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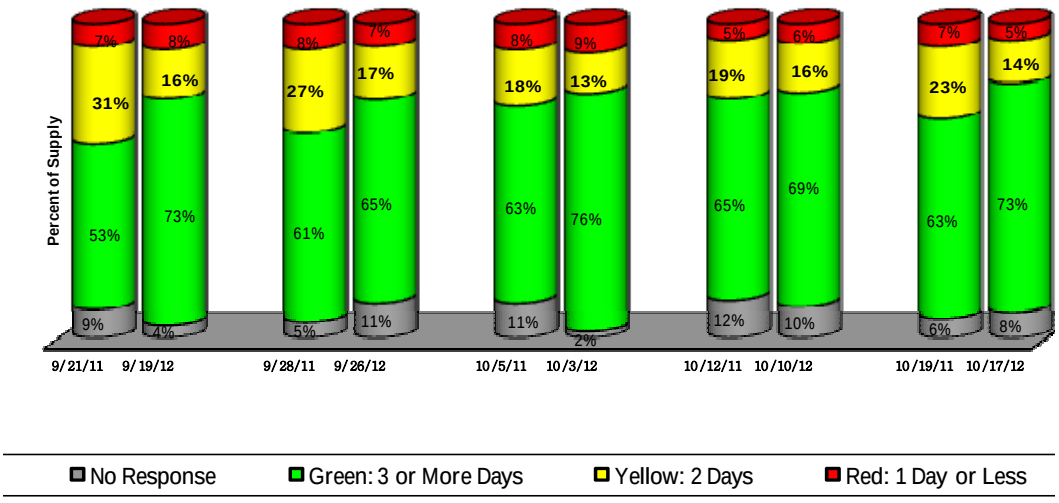
BRIEFLY NOTED (continued from page 18)

laboratory, such as satellite collection centers and mobile blood drives," said Terumo BCT. PF24 and PF24RT24 plasma products are indicated for replacement of non-labile clotting factors. Terumo BCT announced on Oct. 9 that FDA had cleared Terumo Medical Corp.'s TSCD II/Trucise Data Management System for use in the US. The TSCD II/Trucise system provides consistent, flexible and sterile tubing connections, in a functionally closed system, including wet-to-wet tubing connection capabilities and the added element of an automated data entry and process control system on a range of Microsoft Windows platforms, said the release. The TSCD II with the optional Trucise system is a Class II medical device used to connect two closed sterile components, such as blood collection container, apheresis set, transfer set, or needle set, by making a sterile weld in the PVC tubing connected to these components. The TSCD II system guides operators through the welding process with sensors that alert the user when to replace the wafer cartridge and when to empty the wafer disposal box. (Source: Terumo BCT press releases, 10/5/12, 10/9/12) ♦

GLOBAL NEWS

Canadian Blood Services (CBS) announced recently that it is recalling blood that was donated at its Regina donation center in the past 12 months because a step had been missed during the donor screening process, CBC News reported on Oct. 5. The voluntary recall affects all products sent to hospitals between Oct. 2, 2011 and Oct. 3, 2012 reported CBC News. Part of Canada's donor history questionnaire (DHQ) is self-administered by the donor, while the other part is staff-administered; the staff-administered section contains some of the high-risk questions, such as those concerning HIV or hepatitis risk. It was discovered on Oct. 1 that some staff members at the Regina site had not been asking all of the high-risk questions and documenting appropriately for repeat donors, explained Mindy Goldman, MD, CBS's executive medical director of Donor and Transplantation Services. Blood products included in the recall underwent routine donor screening for infectious diseases and all test results were negative prior to their release. The recall resulted in withdrawal of about 8,500 blood products, which were swapped out with products from other donation centers in the CBS system. "The inventory was robust enough to handle the recall," said Dr. Goldman. "We have a national inventory in Canada, so luckily in this kind of situation, we were able to swap those units out in the hospitals." CBS took two levels of action to prevent this type of event from occurring again – one was to close down the Regina operations for a day to have special meetings with the staff, emphasizing the importance of following quality and good manufacturing procedures. The second set of actions were taken on a national level, including corporate communications, blog postings, and communication with the public, said Dr. Goldman. CBS also met with Canada's National Advisory Committee on Blood & Blood Products to determine whether transfusion recipients needed to be notified in the case of this recall and determined that follow-up was necessary. Canada's National Advisory Committee on Blood & Blood Products provides a guidance document that helped make the process run smoothly, added Dr. Goldman. The document is available at http://bit.ly/Qxx37o. (Source: CBC News, 10/5/12) ♦

STOPLIGHT®: Status of the ABC Blood Supply, 2011 vs. 2012



The order of the bars is (from top to bottom), red, yellow, green, and no response

PEOPLE

Susan L. Stramer, PhD, executive scientific officer at American Red Cross Biomedical Services, was elected president of AABB for the 2012-2013 term, succeeding Darrell J. Triulzi, MD. Dr. Stramer assumed her new role at the AABB's Annual Meeting in Boston on Oct. 9. Dr. Stramer has been a member of AABB since 1998. She has served on several AABB committees and tasks forces, as well as on the editorial board of *Transfusion.* She also serves on Héma-Québec's Safety Advisory Committee, is a longtime liaison to the College of American Pathologists' Transfusion Medicine Resources Committee and is a member of several advisory committees for diagnostic test kit manufacturers. Dr. Stramer received the American Red Cross Tiffany Award for Employee Excellence in Management, the American Red Cross Spirit of Excellence Award, and the Center for Disease Control and Prevention's Charles C. Shepard Science Award. Most recently, she received the 2010 Herbert Perkins Scientific Lecture Award. Dr. Stramer has authored or co-authored more than 250 peer-reviewed articles and abstracts. She received both her bachelor's and master's degrees in biological sciences from Northern Illinois University in DeKalb, and her doctorate in bacteriology from the University of Wisconsin-Madison. Dr. Stramer also was a post-doctoral research fellow at the hepatitis branch of the Centers for Disease and Prevention and Control in Atlanta. AABB also elected Graham Sher, MD, PhD, as president-elect; Lynn Uhl, MD, as vice president; and Donna Regan, MT(ASCP)SBB, as secretary of the AABB Board of Directors. A full list of the AABB Board of Directors is available at www.aabb.org/about/governance/Pages/default.aspx.

The American Red Cross (ARC) has named **Cherae Bishop** as senior vice president, Government Relations. She assumed the post on Oct. 15, replacing **Neal Denton**, who left the ARC last month to take a job as senior vice president and chief Government Affairs officer for the YMCA. According to an ARC press release, Ms. Bishop joined the organization in 2008 as senior director of Legislative Affairs and

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Public Policy. Over the years, she has helped to secure federal appropriations for the ARC "and has a strong understanding of Congress, the members and their districts and opportunities to partner with the Red Cross," the release says. Since the 2010 earthquake in Haiti, Ms. Bishop has led the organization's efforts on behalf of the Haitian diaspora community and ARC work with members of the Congressional Black Caucus. Prior to joining the Red Cross, she served as vice president of Legislative Affairs and Public Policy at Volunteers of America Inc. She received a bachelor's degree from Wesleyan University and a law degree from the American University Washington College of Law. Mr. Denton joined the American Red Cross Government Relations team in January 2006. During that time, he and his colleagues worked with America's Blood Centers staff on several public policy initiatives. In his new role, Mr. Denton will lead the Y-USA's Washington, D.C.-based Government Relations and Policy office, which directs the Y's federal, state, and local advocacy efforts. "We were sorry to learn that our good friend Neal Denton had left the Red Cross, but we look forward to working with Ms. Bishop," said Robert Kapler, director of Government Relations at ABC. "We especially thank Neal for his outreach and fellowship, and for all the coalition work that he made possible during his tenure." (Sources: ARC press release, 10/2/12; YMCA press release, 10/1/12)

Dan Waxman, MD, and **Marion Reid, PhD,** were honored with Memorial Awards at AABB's Annual Meeting in Boston last week, and **Dale Malloy, MT(ASCP) SBB, Jay Menitove, MD,** and **Karen Shoos, JD,** received the AABB President's Award. Dr. Waxman, ABC president and executive vice president and CEO of Indiana Blood Center, was honored with the Hemphill-Jordan Leadership Award and Lectureship, which recognizes an individual who made significant contributions in the area of administration, quality programs, law and/or government affairs. Dr. Waxman's lecture was titled "Blood Center Leadership – The Path Leading to Your Seat in the Cockpit." He discussed what type of individuals lead blood centers, as based on a survey of 68 current CEOs. The lecture discussed how individuals become blood center CEOs, including the people and characteristics that shape these leaders. Marion Reid, PhD, head of immunochemistry at New York Blood Center, was honored with the Emily Cooley Memorial Award and Lectureship. Dr. Reid's lecture was titled "Emily Cooley, Techniques and Blood Groups." This lecture reviewed why the award is named after Emily Cooley, described how various techniques have revealed secrets about blood groups, and highlighted the power of collaboration. The Emily Cooley Memorial Award recognizes an individual who has demonstrated teaching ability and has made a major contribution to the field of transfusion medicine or cellular therapies. During the AABB Annual Meeting opening session, AABB President Darrell Triulzi, MD, awarded Mr. Malloy, retiring this month as president and CEO of The Blood Alliance, with the President's Award for his "many contributions to AABB" including serving on the Interorganizational Taskforce on Domestic Disasters and Acts of Terrorism. Dr. Menitove, president/CEO and medical director of Community Blood Center of greater Kansas City, also received the President's Award, for his contributions to AABB, including serving as the chair of the Standards Committee, the Transfusion Transmitted Diseases Committee, and as the associate editor of *Transfusion*. He has also acted as AABB's representative to the Department of Health and Human Service's Advisory Committee on Blood Safety and Availability. Ms. Shoos, AABB CEO received the President's Award "in honor of an extraordinary career" during which she led with a vision that allowed the association to advance the field of cell therapy and transfusion medicine, as well as for her unwavering commitment to advancing transfusion medicine in the developing world, said Dr. Triulzi. Ms. Shoos is set to retire in December. (Source: AABB press release, 10/8/12) ♦

MEETINGS

Nov. 15-16 **Blood Products and Cellular Therapies: A Symposium on Emergency Preparedness, Bethesda, Md.**

The US Department of Health and Human Services' Biomedical Advanced Research Development Authority (BARDA) will host a symposium titled "Blood Products and Cellular Therapies: A symposium on Emergency Preparedness" on Nov. 15-16 at National Institutes of Health Building 45 in Bethesda, Md. Pathogen inactivation technology and its potential role in protecting the blood supply from emerging and existing infectious disease threats will be discussed on day two of the symposium. More information and registration is available at http://1.usa.gov/T1Yu9o.

Nov. 27-28 **FDA/NIH Course: "The Science of Small Clinical Trials," Silver Spring, Md.**

The Food and Drug Administration (FDA) together with the National Institutes of Health (NIH) Office of Rare Disease Research, National Center for Advancing Translation Sciences, is announcing a course titled "The Science of Small Clinical Trials." It will take place from 8 a.m. to 5 p.m. on Nov. 27 and from 8 a.m. to 3 p.m. on Nov. 28 at FDA's White Oak Campus in Silver Spring, Md. The course is intended to provide training in the scientific aspects of designing and analyzing clinical trials based on small study populations. The course will bring together subject experts and stakeholders to identify when such trials should be conducted, along with strategies and trial designs that are conducive to overcoming the challenges they present. Details and registration information are available at http://bit.ly/NImWyL.

Contact: Megan McNamee, Megan.Mcnamee@icfi.com.

April 23-24, **IPFA & PEI 20th International Workshop on Surveillance and Screening of the Blood Borne Pathogens, Helsinki, Finland.**

The International Plasma Fractionation Association (IPFA) and the Paul-Erlich-Institut (PEI) are hosting the 20th International Workshop on Surveillance and Screening of Blood Borne Pathogens on April 23-24, 2013 at the Crowne Plaza in Helsinki, Finland. The workshop is organized in collaboration with the Finnish Red Cross Blood Service and is sponsored by Abbott Diagnostics, Novartis Diagnostics, and Roche Diagnostics. Some main topics of discussion include safety and supply in developing countries; management of risk and costs; troublesome emerging infectious agents, hepatitis E; and diagnostic manufacturers developments. More information is available in the "Events" section at www.ipfa.nl. ♦

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $390 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE:

Director, Operational Policies/Procedures (Corporate Donor Recruitment). Blood Systems is seeking a Director to join our corporate team in Phoenix, AZ. This position will manage our corporate donor recruitment team and initiatives with a focus on the development and innovative support to field recruitment operations. Overview: Bachelor's degree in related area required. Knowledge of federal/state/local regulations as they relate to the blood industry manufacturing activities required. Six years of related experience required. To include: Three years supervisory experience. Six years experience in blood center technical operations. Three years experience in business software applications and blood bank manufacturing software. Previous experience supporting a multi-location environment preferred. Minimum five years direct work experience in Donor Recruitment senior level management preferred. For consideration, submit resume via e-mail by **10/19/2012** to: jobs@bloodsystems.org **ATTN: HR/2012/64**. We offer a competitive benefits package. Pre-employment drug testing is required. EOE M/F/D/V

Director, Regional Quality (Seattle, WA area). Blood Systems is seeking a Director, Regional Quality for operations in Puget Sound, WA. This individual will be managing the review of quality systems and compliance in all areas of technical and clinical operations. This candidate will serve as a resource to operations on quality issues. Bachelor's degree and five years of related experience in a regulated industry required. Certification as a Med Tech or SBB is preferred. Three years in a quality, regulatory, or auditing environment, two years of supervisory experience is required. Skills in process analysis, performance improvement, lean or Six Sigma preferred. For consideration, please submit resume via e-mail by **10/19/12** to: jobs@bloodsystems.org **ATTN: HR/2012/75**. We offer a competitive benefits package as well as relocation and more! Pre-employment drug testing is required. Visit our website at: www.bloodsystems.org. EOE M/F/D/V.

Director, Regional Quality (Chicago, IL area). Blood Systems is seeking a Director, Regional Quality for operations in Rosemont, IL. This individual will be managing the review of quality systems and compliance in all areas of technical and clinical operations. This candidate will serve as a resource to operations on quality issues. Bachelor's degree and five years of related experience in a regulated industry required. Certification as a Med Tech or SBB is preferred. Three years in a quality, regulatory, or auditing environment, two years of supervisory experience is required. Skills in process analysis, performance improvement, lean or Six Sigma preferred. For consideration, please submit resume via e-mail by **10/19/12** to: jobs@bloodsystems.org **ATTN: HR/2012/76**. We offer a competitive benefits package as well as relocation and more! Pre-employment drug testing is required. Visit our website at: www.bloodsystems.org. EOE M/F/D/V.

Blood Bank Laboratory Supervisor (MT/ASCP). United Blood Services of Billing, Montana is looking for a leader! Specifically, we need an experienced laboratory supervisor to lead our team of laboratory technicians. Blood banking or hematology experience strongly preferred. Responsibilities include: Hires, supervises, coordinates work schedules, trains and evaluates performance of assigned personnel. Identifies and effectively resolves personnel issues. Supervises and participates in the production and labeling of blood components. Assures adequate inventory of laboratory supplies and reagents. Assists in reporting and resolving deviations (e.g., errors, quarantine, recall, equipment maintenance, reagent failures and accidents). Skills/ Requirements: Bachelor's degree in a chemical, physical, biological, medical technology, or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required (ASCP) or CLIA equivalent for high complexity testing required. BB or SBB preferred. Skills/Abilities: One year of laboratory experience required and two years supervisory experience preferred. Excellent benefits including medical/dental/vision, relocation assistance available and 401k with company match. Medical/dental after 30 days! Please send resume and salary history to United Blood Services by **November 02, 2012**, c/o: C. Damm, 1444 Grand Avenue, Billing, MT 59102 or email: cdamm@bloodsystems.org or Fax: (208) 379-9500. Pre-employment and Background checks required. EOE M/F/D/V

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Mobile Recruitment Manager. LifeServe Blood Center is seeking a Mobile Recruitment Manager, either in the Sioux City or Des Moines, Iowa location. Essential duties and responsibilities include: responsible for planning, directing, staffing, and the controlling of a distinct department or functional unit, and also administering and controlling through direct supervision and delegation within their own department and associated staff within their own department responsible for recruitment and resource directives. Candidates must possess the ability to manage employees from multiple remote locations. Travel (some overnights) is required. Requirements include a bachelor's degree, at least four to five years of previous experience in a sales, marketing, or a similar position. Management experience is preferred. At least three years blood-banking experience required. Experience in strategic planning and execution; and ability to analyze, interpret and manage financial resources; ability to multi-task and set priorities are also required. Also, a demonstrated ability to motivate and lead is essential. Please visit our website for requirements and additional details at: www.lifeservebloodcenter.org. Click on "Join our Team," and "View Current Openings."

Chief Information Officer. Oklahoma Blood Institute is actively searching for a chief information officer, and as a member of the leadership team, will lead the Information Technology function for the organization across all locations in Oklahoma, Texas, and Arkansas. The CIO will be responsible for the planning, development, and implementation of long-range information technology strategies. This includes developing budgets, overseeing and managing staff, reviewing regulatory requirements, analyzing current business processes and recommending improvements. Is responsible for system analysis, networks, programming, database administration, computer operations, data and voice communications, field support, IT quality assurance, and data security in a distributed environment. Computer Science Degree, Math or Business Administration (required), master's degree in Management (preferred). Minimum 10 years managerial experience. You may apply online at http://obi.org/careers/. We are located at 901 N. Lincoln Blvd., Oklahoma City, OK 73104 and you may contact us at (405) 278-3201. EOE M/F/D/V Drug Free Work Environment

Manager of Clinical Services (full-time, day shift) (Gulf Coast Regional Blood Center). Scope of responsibility: Working under the general direction of the Medical Director, the position is responsible for management of specified clinical services, including therapeutic apheresis procedures and collections (including collection of Peripheral Blood Stem Cells), and the community-based transfusion safety program. Functions as the Apheresis Center Coordinator for National Marrow Donor Program (NMDP)-related activities. Coordinates efforts to provide specific apheresis services for donors and patients in addition to coordinating efforts to monitor transfusion practices and compliance in facilities for which we provide cross match and transfusion services. Education/experience: Graduate of accredited School of Professional Nursing, RN license in good standing, three plus years related clinical, transfusion service, supervisory or quality assurance experience and/or training, familiarity with automation, i.e. apheresis and dialysis, effective venipuncture skills along with a comprehensive knowledge of pathophysiology, hemo-dynamics, fluid and electrolyte balance are preferred. Please visit our website for more information about our organization and to apply online: www.giveblood.org. Lori Pireu – Recruiter – (419) 517-9918 – lpireu@giveblood.org.

Operations Manager (Oxford, Miss.). Mississippi Blood Services has an opening for a manager in our Oxford, Miss. office. The ideal candidate will have strong planning and organizational skills, and a commitment to high quality work. This individual will ensure collection goals are met, including apheresis platelets and double red cell collections. Will also develop and maintain standard operating procedures that ensure compliance with the requirements of all regulatory agencies and the MBS quality program. Bachelor's degree, problem solving ability, excellent communication skills, organizational and team building skills, and the ability to perform in a fast-paced environment required. A minimum of one to two years previous management and blood banking experience, or related experience in a regulated environment, highly preferred. FULL BENEFIT PACKAGE, including a generous 401(k) plan! To view the full description and apply online visit http://msblood.iapplicants.com. If you have questions, contact HR at (601) 981-3232. Drug Screen Required. EOE