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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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INSIDE:

The FABC and SCDAA to Co-Host Unity Gala, Co-Chaired by Congressman Jessie Jackson, Jr.

The Foundation for America's Blood Centers (FABC) is teaming up with the Sickle Cell Disease Association of America (SCDAA) to co-host this year's Unity Gala in Baltimore, Md.'s lively Inner Harbor on Thursday, September 27. Rep. Jessie Jackson, Jr. (D-Ill.) will be co-chairing the gala, which will support the life-saving work of the FABC and the SCDAA.

The FABC funds initiatives of America's Blood Centers' members that help to improve the availability, quality, and safety of the blood supply. The SCDAA works to advocate for and enhance its membership's ability to improve the quality of health, life, and services for individuals, families, and communities affected by sickle cell disease, while promoting the search for a cure for people affected by this disease. Since sickle cell disease (SCD) patients require frequent blood transfusions, the partnership seemed like a natural fit for these two organizations.

"We are thrilled to co-host this year's Unity Gala with the SCDAA." said the FABC Chair Michelle Stefan. "Sickle cell patients require frequent blood transfusions, and our blood centers strive to not only make sure the blood is available for sickle cell patients when it is needed, but also to ensure the blood is the right match to best suit the patients' needs"

Last year's Saving Grace dinner gala in New York City, co-hosted by the FABC and the Preeclampsia Foundation, raised $550,000 to support the work that these organizations do on behalf of mothers and their babies suffering from the pregnancy-related disorder, preeclampsia. The FABC hopes this year to raise awareness and support for another disease closely related to the need for blood donation.

"SCDAA is elated to be partnering with the FABC for this very important event," said SCDAA President and CEO Sonja Banks. "This partnership is so important because it not only raises awareness about the importance of blood donation to sickle cell disease patients, but will also raise needed funds to create new prog-

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OUR SPACE

ABC CEO Jim MacPherson

Sustainability

Maybe it is just me, but until recently I thought the term sustainability was all about the environment. (In full disclosure, and in my defense, my younger son is a graduate student majoring in sustainable energy systems.) Obviously, the health of our planet is important to future generations, and someone also needs to be sure there will be a sufficient food supply for our growing worldwide population.

But serving on the board of the school that my two younger kids attended has given me a whole new perspective on the term. Indeed, every question about current practice and new ideas contains the query, "Is it sustainable?" Can our student body continue to grow by two percent each year? Can parents continue to pay our tuition increases? How do we maintain the quality of our teachers? What is the best way to impart our religious values in a student population that is increasingly non-Christian?

I started thinking: What are our sustainability issues in blood banking? Some of them are easy. With a shrinking eligible donor population and a projected increase in blood demand for our aging population, how will we maintain the needed future blood supply? With diseases increasingly crossing borders, how will we best maintain blood safety? Will our suppliers still be responsive to our particular needs as they consolidate? Can "community" blood centers be locally responsive to their hospital needs if the centers keep merging? How can community blood centers continue serving hospitals as they too merge and look to suppliers to cut costs? Which model is more sustainable: a blood commodity supplier or a transfusion/cell support service provider?

You see where I am going with this. Yes, just as we now have incorporated lean principles (and ethics, I hope!) into our everyday operations, we should add questions and goals about sustainability. Actually, in researching this topic, I have learned that high level Six Sigma is all about assuring your efforts in lean can be sustained. So, one last question on sustainability: What do you need to do to endure?

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Unity Gala (continued from page 1)

-rams and expand existing ones that help provide quality healthcare and supportive services to those living with sickle cell disease and their family members."

Sickle Cell Disease and Blood Donation. SCD is hereditary and is caused by an abnormal type of hemoglobin that can make red blood cells assume crescent shapes and become more "sticky." The misshapen red blood cells then get stuck in small blood vessels and interrupt blood flow, causing organ and tissue damage, pain, stroke, and sometimes death. Frequent red blood cell transfusion is the most common therapy for these patients because it raises the hemoglobin levels, reducing the proportion of abnormal hemoglobin.

Rep. Jesse Jackson, Jr. is supporting sickle cell disease and blood donation awareness by co-chairing the Unity Gala.

SCD affects 8 to 10 percent of African-Americans, and some people from South and Central America, the Caribbean, and the Middle East. Recruiting minority donors, particularly black donors, is vital to ensuring that SCD patients have blood available. Blood from a person's own racial or ethnic group is often the best-matched donation due to various blood traits that determine compatibility. The FABC has supported several ABC member initiatives to diversify the blood supply to better serve minority transfusion recipients who are more likely to suffer from certain diseases, such as sickle cell.

Diversifying the Blood Supply. Blood Systems recently received a $40,000 grant from the FABC for its "Recruiting African-American Donors" initiatives, the materials and outcomes of which will be shared with ABC's member centers to help better meet the needs of minority patients, including sickle cell patients. The FABC also supported Blood Centers of the Pacific in creating the Blood Bytes Broadcast public service announcement video series in 2009 to improve recruitment of minority donors, O-negative donors, young adult/student donors, and bone marrow donors. ABC members are dedicated to finding treatments for SCD, as the National Institutes of Health recently awarded a $7.3 million grant to Puget Sound Blood Center Research Institute's José A. López, MD, and Barbara A. Konckle, MD, to research a potential therapy for the disease.

In January, the Illinois Coalition of Community Blood Centers kicked off its "Make Every Drop Count" campaign, aimed at increasing blood donations among the state's African-American population. Several ABC members worked with an African-American service fraternity to hold blood drives at its various chapters and with black legislators who promoted the need for minority donors.

Supporting the Cause. Many people do not realize the scope of this disease, as more than 70,000 to 100,000 individuals in the US have SCD, and it is estimated that about 1,000 babies are born in the US with the disease every year. Likewise, minority donors are often unaware that their blood would be life-saving for patients suffering with SCD – a very small percentage of the US blood supply comes from African-Americans. The Unity Gala will educate and motivate guests to get involved in the fight against SCD, including diversifying the blood supply, while raising funds to fulfill both organizations' missions.

"I personally encourage everyone to unite and support this worthy event. Your attendance and participation will surely champion both SCDAA's and the FABC's missions to serve and save lives," said Ms. Banks.

The gala will be held at the Baltimore Marriott Waterfront Hotel, with general admission tickets available for non-sponsors for $125 and VIP Reception tickets available for non-sponsors for $250. More details will be coming soon and will be posted on the FABC's website (www.theFABC.org). Those interested in sponsorship opportunities can visit www.thefabc.org/events_unity_gala.html for more information.

Australian Blood Service Committee Suggests 6-Month Deferral For MSM

An expert committee commissioned by the Australian Red Cross Blood Service to reconsider blood donor deferrals based on sexual activity recently recommended that the current 12-month deferral for men who have sex with men (MSM) be changed to a six-month deferral, pending the results of ongoing research. MSM deferral is meant to protect the blood supply from transfusion-transmitted infections, such as HIV and hepatitis C, which are more prevalent among gay males, but as blood screening tests have become more advanced, blood services around the world are rethinking their MSM deferral policies.

The Australian committee, led by Professor Steve Wesselingh, dean of the Faculty of Medicine at Monash University in Australia, said in the 80-page report that there is "sufficient evidence to support" reducing the current MSM deferral period "without compromising the safety of the blood and blood products in Australia." The committee received 34 submissions from the public for consideration on this topic and also reviewed findings and observations from previous anti-discrimination challenges involving the Blood Service.

Since 2000, Australia has been one of several countries that has changed the lifetime ban to a 12-month deferral for MSM, and the UK announced moving to a 12-month deferral in September 2011 (see *ABC Newsletter,* 9/9/11). In July 2010, Australian scientists published research in *Transfusion* showing that adopting the 12-month MSM deferral did not lead to an increased risk that donated blood or blood products would be infected with HIV. In September 2011, Canadian Blood Services' board of directors passed a motion committing the organization to reexamine its lifetime deferral policy, possibly switching to a fixed period deferral of no less than five years and no longer than 10 years.

In the US, the Food and Drug Administration still enforces the lifetime ban for MSM, but a recent FDA Blood Products Advisory Committee Meeting highlighted ongoing studies commissioned by the Department of Health and Human Services to explore whether the MSM deferral policy can be changed to permit certain low-risk gay men to donate without compromising the safety of the blood supply. America's Blood Centers, the American Red Cross, and AABB have long advocated a reduction of the lifetime ban to a 12-month deferral.

The Australian committee emphasized that changing from a 12-month to a six-month deferral period is contingent upon the results of an ongoing compliance study, as the effectiveness of such deferral periods relies on donors being honest about their sexual behaviors and complying with deferral policies. The blood service will partner with the Kirby Institute of the University of New South Wales in Sydney, Australia to conduct this compliance study, reported the blood service in a press release. The committee also discussed that MSM in monogamous relationships are at significantly lower risk of acquiring HIV than those who have non-monogamous sex partners.

Other key points that the committee considered were the advancement of current screening tests, whether sexual transmission remains a risk-factor for HCV transmission, and whether the new deferral time accounts for the window period for both HIV and HCV. The window period is the time when a person is infected with the disease, but tests cannot yet detect the infection. Future research will explore these topics, as well as risk-factors for HIV transmission, the use of pathogen-reduction technologies in red blood cells to protect against transfusion-transmitted infections, and whether people currently deferred for sexual behaviors should be allowed to donate plasma.

"The process has been extremely thorough, and we are confident that this evidence-based approach will ensure the safety of the blood supply is protected," Professor Wesselingh said in the release. The press release and the link to download the report are available at: http://bit.ly/KbZvfb. (Source: The Review of Australian Blood Donor Deferrals Relating to Sexual Activity, 5/24/12; Australian Red Cross Blood Service Press release, 5/24/12) ♦

Managing Donor Hemoglobin in Denmark: How it Works and How They Got There

A European Blood Alliance workshop in February sought to explore differences in international donor deferral processes to help minimize the number of donors deferred. In discussions about deferral for low hemoglobin (Hgb), which is the most common reason for blood donor deferral in many countries, Denmark's system was of particular interest since blood services there defer a low percentage of donors.

Deferring donors for low Hgb is meant to protect them from iron deficiency and anemia, but it is well-known that Hgb is a poor indicator of donor iron stores. In the US, Hgb is measured at each donation, and the Food and Drug Administration mandates that blood donors must have a Hgb level of no less than 12.5 g/dL to donate. Since March 2011, Denmark has implemented a Hgb management process that is more donor-specific, sending all samples to one centralized hemoglobin center and making decisions about how to best manage the donor's hemoglobin levels and iron stores based upon multiple test results.

The *ABC Newsletter* received questions regarding this Hgb process in Denmark, as the system differs vastly from the procedures in the US (see *ABC Newsletter*, 5/11/12). Karin Magnussen, MD, medical director of the Center for Donor Hemoglobin and Iron and the Department of Immunology and Blood Center of Copenhagen University Hospital in Denmark, explained the process in detail for the newsletter readership.

Hemoglobin Testing: The Danish Process. A first-time donor in Denmark would have his or her Hgb tested before the donation with a venous sample using the HemoCue device and would be deferred if the level is too low. In Denmark, low Hgb is defined as less than 12.5 g/dL in women and less than 13.5 g/dL in men. After the first donation, Hgb is only measured before the donation if the donor had low Hgb in the previous donation or if there is any other suspicion of anemia. A donor is deferred if the Hgb is found to be low in pre-donation testing using the HemoCue.

In subsequent donations, Hgb is tested after the donation with the Sysmex XE2100D instrument, using a venous sample secured from the pre-sample bag. This sample is sent to a team that performs the hemoglobin test and analyzes the results at the Center for Donor Hemoglobin and Iron, a centralized lab that deals solely with donor Hgb and iron management.

Healthy donors with consistently low hemoglobin are deferred, but the team also uses ferritin to determine if the donor is truly iron replete. Ferritin, a more sensitive measure of donor iron stores, is measured before the first donation, after every tenth donation, and in other donor-specific cases as warranted. The hemoglobin resource team investigates a specific case if:

- The Hgb is lower than 12.5 g/dL (women)/13.5 g/dL (men);
- The Hgb is higher than 16.5 g/dL (women)/18.5 g/dL (men);
- The Hgb dropped by 2 g/dL since the last donation; or
- The ferritin is lower than 60µg/L or higher than 300µg/L.

Maintaining Happy Healthy Donors. The Hgb team not only analyzes test results to determine donor edibility, but they also conduct donor follow-up in the case of abnormal test results and send iron replacement pills when necessary. The team uses an algorithm that takes into account both the Hgb and ferritin levels to determine if the donor should receive iron supplementation tablets. The tablets are sent by mail along with a letter and folder containing advice about blood donation, iron stores, and dietary recommendations. In certain cases, donors are recommended to see a doctor. Donors can also view their donation data, including Hgb concentration, online.

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Hemoglobin in Denmark (continued from page 5)

One of the main reasons for switching to a centralized donor hemoglobin and iron management system in Denmark was to improve the donor experience in relation to Hgb deferral, said Dr. Magnussen. Deferred donors are often unhappy donors, but providing more follow-up and donor-specific services about Hgb testing and deferral was thought to improve donor satisfaction with this process.

Although she cannot provide specific data currently, many of the donors seem more satisfied with this Hgb method, and staff find that it is working well, said Dr. Magnussen. She added that data regarding the results of this centralized Hgb management program will be published in the near future.

Preparing to implement the Hgb management system and centralized testing facility took lots of planning, including creating a resource team, choosing the instrument to test Hgb (Sysmex), setting up electronic transmission of test results, determining the logistics for sample transport, and forming standard operating procedures.

Improving Testing. Another reason for implementing this method was to improve the quality of the Hgb measurements and to measure ferritin in all donors, which was not possible before due to costs. The price for testing Hgb on the Sysmex device is about 25 percent of the price for testing Hgb on the HemoCue, which more or less pays for the ferritin testing and iron supplementation program, said Dr. Magnussen.

LifeSouth Community Blood Centers Faces Legal Difficulties

LifeSouth Community Blood Centers in Gainesville, Fla. recently had a setback in its ongoing litigation over the death of a seven-year-old who contracted West Nile Virus from a 2002 blood transfusion. The Florida Court of Appeals ruled on April 13 in favor of the boy's family, directing the case back to the trial court for a new trial.

At the time of the transfusion, there was no test that could screen for the virus. However, the boy's parents, Ross and Kaynan Fitchner, sued LifeSouth, claiming that the center was negligent in not providing an interpreter or a translator questionnaire for the donor, whose native language was Spanish. Blood centers now use either minipool nucleic acid testing (NAT) or individual donor NAT to screen for West Nile Virus, choosing the type of test based on the season and likelihood of infection in the region. In 2011, about 130 presumed West Nile Virus positive donors were confirmed through blood center testing, according to the Centers for Disease Control and Prevention.

When the Fitchners filed Fitchner v. LifeSouth Community Blood Centers, Inc. in 2004, in a Florida state court, they refused to comply with certain procedures related to filing a medical malpractice suit. The Fitchners argued that because their case was for standard negligence, not medical malpractice, that they did not need to comply with the medical malpractice procedures. The jury ruled that LifeSouth was negligent and awarded the Fitchners more than $8 million in damages. LifeSouth appealed this ruling, and the Florida District Court of Appeals reversed that verdict on Oct. 30, 2007, holding that blood banks provide medical services and the lawsuit should have been treated as a medical malpractice case and the Fitchners did not comply with the procedural requirements related to such cases.

The Fitchners moved for reconsideration of the case's dismissal, arguing that the 2003 amendment to the Florida medical malpractice statute, which defines blood banks as healthcare providers, could not be applied retroactively to the Fitchners' case. (The injuries were sustained in 2002 when the blood transfusion occurred, however, the child died after the change in the statute.) The district court ruled that this new argument was "meritorious," but denied it on procedural grounds, to which the Fitchners appealed back to the District Court of Appeals.

The Fitchner's appeal led to the most recent April 13 Florida Court of Appeals decision, in which the court ruled 2-1 in favor of the Fitchners. The majority ruled that although the lawsuit was filed in 2004, the 2003 statute defining blood centers as healthcare providers could not be applied to this case, as the injuries were sustained in 2002. The majority also rejected LifeSouth's various arguments that this appeal should have been barred by the Court of Appeal's previous decision. The judge in the minority filed a dissenting opinion that agreed with LifeSouth on most of the issues. (Source: Fitchner v. LifeSouth synopsis, David Nelmark, 5/14/12) ♦

Having Issues Receiving the *ABC Newsletter*?

The *ABC Newsletter* has been experiencing some technical difficulties related to ABC's e-mail server. If you or a colleague have not been receiving the newsletter each Friday by e-mail, please contact Editor Betty Klinck at bklinck@americasblood.org. While we work out this issue, members who are not receiving the newsletter may access it through the members' website, where the most recent newsletter is posted on the homepage each week, as well as in the Publications section. Non-member subscribers may contact Ms. Klinck to request the most recent edition while we repair the e-mail problem. We thank you for your patience and are working to have the issue resolved as soon as possible.

Better Understanding RBC Alloimmunization in Sickle Cell Disease Patients

Frequent red blood cell (RBC) transfusion remains the most widely used therapy to manage sickle cell disease (SCD). However, frequent transfusions can lead to RBC alloimmunization, which can cause life-threatening complications such as delayed hemolytic transfusion reactions (DHTRs). A recently published journal article sheds light on risk factors for RBC alloimmunization in SCD patients, as well as transfusion management strategies aimed at prevention.

Karina Yazdanbakhsh of New York Blood Center, Russell E. Ware of Baylor College of Medicine, and France Noizat-Pirenne of the Establissement Francais du Sang Ile de France wrote the review, which was published online in *Blood* on May 4.

Background. SCD is caused by an abnormal type of hemoglobin, which under certain circumstances causes RBCs to assume crescent shapes and become more "sticky." The misshapen RBCs then get stuck in small blood vessels and interrupt blood flow, causing organ and tissue damage, pain, and sometimes stroke. Frequent RBC transfusions are used in managing SCD because they raise the hemoglobin levels, reducing the proportion of the abnormal hemoglobin.

These frequent RBC transfusions can lead to alloimmunization and, subsequently, the development of potentially life-threatening DHTRs. While other patients receiving frequent transfusions can experience alloimmunization, SCD patients have been shown to have far higher rates of alloimmunization (about 20 to 50 percent) than other highly-transfused groups. This is because a high percentage of SCD patients are of African descent and often have antibodies to antigens expressed on the surface of RBCs in blood donated by Caucasians. In other words, blood from a black donor is more likely to be compatible for a black transfusion recipient; unfortunately, the majority of blood donors are Caucasian.

Risk-Factors Caused By Racial Differences. While SCD patients have about a 20 to 50 percent alloimmunization rate, patients with thalassemia, who are also highly transfused but often share similar ethnic backgrounds with their blood donors, have about a 10 percent alloimmunization rate. The authors

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Alloimmunization in SCD (continued from page 8)

explain some antigeneic differences between SCD patients and their donors that may contribute to this higher alloimmunization rate. For example, some highly immunogenic antigens differ substantially between donors and transfusion recipients. Specifically, C and E in the Rhesus (Rh) blood group, K in the Kell (KEL), Fy^a in the Duffy (FY), Jk^b in the KIDD (JK), and S in the MNS blood groups are more frequently encountered in Caucasians than people of African descent.

Matching for E, C, and K reduced the rate of allloimmunization in chronically transfused SCD patients from 3 to 0.5 percent, write the authors, and extended matching for RH, KEL, FY, JK, and MNS has been shown to be even more effective. The most common RH phenotype in SCD patients is D+C-E-c+e+, which is found in less than 2 percent of Caucasians. SCD patients are generally transfused with either units of the same phenotype from donors of African descent, or units with D-C-E-c+e+ phenotype.

While transfusing RH compatible units to SCD patients helps to reduce the chances of alloimmunization, it does not totally prevent it, write the authors. Within the five main RH antigens (D, C, E, c, e), two types of variants ("partial" and "weak") have been described. Individuals with partial RH antigens should receive RH antigen negative RBCs, write the authors. There are also many other low incidence antigens that are described in blacks and have resulted in alloimmunization. In some cases, the recipient has a rare blood type, lacking an antigen that is expressed in almost all donor RBCs, otherwise referred to as a "high incidence" antigen. Transfusion management can be especially difficult for this group due to the high prevalence of the antigen in the donor population.

Individual-Specific Risk-Factors. The specific genetic make-up of the individual can also predispose them to alloimmunization, as the human leukocyte antigen II (HLA II) genotype of the patient is a key predictor of an individual's response to RBC antigens. The authors present data suggesting that beyond the direct link between HLA II and antibody specificity, HLA alleles may also modulate alloimmunization at a non-antigen specific level.

SCD-Specific Risk-Factors. Some risk factors for alloimmunization in SCD patients are caused by the disease, write the authors. For example, a main feature of SCD is a chronic inflammatory state, and some mouse models have shown that certain pro-inflammatory stimuli enhance alloimmunization, say the authors. It is currently unknown whether alloimmunization rates differ depending upon the presence or absence of clinical complications of SCD, such as vaso-occlusive crisis (VOC). VOC is associated with increased inflammatory factors, which should affect alloimmunization rates, but further studies are needed.

The authors also note that the age of transfusion initiation may affect alloimmunization rates in SCD patients. Studies have shown that the number of cumulative transfusions increases the rate of alloimmunization, but it is unknown whether chronic transfusions initiated at an early age can lower alloimmunization rates in SCD patients, perhaps by inducing immune tolerance. Besides acquired factors, the authors say that identification of genetic markers predictive of immunization in SCD is important to investigate.

Autoantibody Formation After Alloimmunization. Rates of developing RBC autoantibodies following alloimmunization are much higher in transfused patients with thalassemia and SCD, with a cumulative incidence of about 6 to 10 percent. "Possible theories to explain this phenomenon include failure to regulate alloantibody-induced lymphoproliferation, as well as altered processing and presentation of alloantigens to T-cells," write the authors. The clinical significance of these RBC autoantibodies is

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Alloimmunization in SCD (continued from page 9)

unclear, but their presence does indicate that autoimmunization is underway, suggesting that careful serial monitoring of these patients is warranted.

Understanding DHTR. DHTRs are unpredictable and under-recognized, because they appear similar to VOC. DHTR usually occurs between five to 15 days following a transfusion, and is characterized by a drop in the hemoglobin level with the destruction of both transfused and autologous RBCs, and exacerbation of SCD symptoms. Additional transfusions can result in life-threatening anemia. DHTR can often result from lack of detailed and longitudinal transfusion records, as alloantibodies may develop in the patient that were not detected in the serum during pre-transfusion screening. DHTR can also occur where no detectable antibodies are found in the post-transfusion screening; these cases are poorly understood and difficult to explain, prevent, or treat.

Diagnosis and Management of DHTR. DHTR should be suspected whenever patients develop vaso-occlusive symptoms of post-transfusion hemolysis; the diagnosis of DHTR is often characterized by the disappearance of transfused HbA donor RBCs. Current management of DHTR in SCD patients remains controversial because some of the treatments used for DHTR may be harmful for SCD patients. For example, corticosteroids can reduce antibody-mediated hemolysis, but may lead to a rebound phenomenon with an increase of SCD-related symptoms. Intravenous immunglobulin (IVIg) is commonly used for DHTR, but carries a small risk of thrombotic complications. While more transfusions will exacerbate an ongoing hemolytic reaction, clinicians should weigh the risks and benefits of withholding transfusions since it could increase likelihood of stroke in patients with cerebral vasculopathy.

Transfusion Management Strategies. Keeping detailed records, using appropriately phenotypically matched blood, and frequently monitoring SCD patients are all vital components of a transfusion management strategy that will help to reduce the likelihood of alloimmunization and DHTR. Transfusing leukoreduced RBC units, which are phenotypically matched for immunogenic RH/KEL blood groups and then cross-matched with a recent serum sample, should be the minimum standard of care for patients with SCD, write the authors. Despite the associated costs, the authors also recommend additional extended phenotype to other blood groups, as it can save valuable time in the transfusion management of patients with multiple allo- and autoantibodies during acute situations.

The authors predict that high throughput DNA typing platforms will become cheaper for donor typing, which should reduce the need for rare serological reagents to find rare compatible donors. For each transfusion, it is critical that all known antibodies in the patient's history be considered to minimize the risk of antibody-mediated DHTR. Keeping well-maintained records is key, and if possible, monitoring patients with antibody screening following every transfusion by testing for development of antibodies that may become undetectable before the next transfusion. According to one study, post-transfusion screening tests should ideally be performed twice, shortly after transfusion (about three to seven days) and also after a longer period of time after transfusion (four to eight weeks) for optimal antibody detection.

Recruit Donors of African Descent. Increasing the proportion of blood donated by people of African descent remains crucial to preventing alloimmunization and DHTR in SCD patients. Blood centers should explore specific recruitment strategies that focus on African-Americans. Increasing the number of African-American donors also helps to prevent blood shortages for SCD patients.

Future Strategies in Alloimmunization/DHTR Prevention. Ongoing studies should explore novel approaches to inhibit alloimmunization in SCD, such as immunomodulatory therapies, including the use

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Alloimmunization in SCD (continued from page 10)

of immune-cell depleting agents, costimulatory blockade, and cytokine blockade. Genetic modifiers and risk factors should continue to be studied so that transfusion recipients who are genetically predisposed can be carefully matched and monitored to avoid development of alloimmunization.

The authors recommend extended phenotype for all patients with SCD at diagnosis, careful monitoring of lab tests before and after each transfusion, and well-kept electronic records. Ongoing studies to determine the incidence of clinically significant antibodies against variants are needed to develop cost-effective genotyping tests for these antigens whose associated antibodies are clinically significant, write the authors.

Citation: Yazkanbakhsh K, Ware RE, Noizat-Pirenne F. Red Blood Cell alloimmunization in sickle cell disease: pathophysiology, risk factors, and transfusion management. Blood. 2012 May 4. [Epub ahead of print] ♦

BRIEFLY NOTED

A new treatment that involves spinning bone marrow stem cells to enhance their healing potential may help people with advanced heart failure feel and function better, a small study suggests. The study was funded by treatment manufacturer Aastrom Biosciences, and the results were presented on May 10 at the Society for Cardiovascular Angiography and Interventions Annual Meeting in Las Vegas, reported *HealthDay*. Researchers developed the treatment by culturing a patient's own bone marrow for 12 days. This process helped increase the amount of immune cells and stem cells that can differentiate into several different cell types, including heart cells. Those cells were then injected into the heart muscle. According to the findings, this treatment was safe, helped repair the damaged heart muscle, and reversed some heart failure symptoms, when compared to a placebo injection. The study included 22 participants with advanced heart failure and an enlarged heart whose current medication regimen was no longer effective. They either received an injection of the stem cell therapy treatment into their heart muscles or a placebo shot. After 12 months, there were no complications and no difference in side effects among those who received the stem cells and the control group. Individuals who received the novel stem cell therapy did have a lower number of major heart-related events and were more likely to see improvements in their ability to walk without growing breathless. Those who received the stem cell treatment also showed marked improvements in their ejection fraction, which is a measure of how much blood leaves the heart with each pump. Because this study was presented at a medical meeting, the data and conclusions should be viewed as preliminary until published in a peer-reviewed journal. (Source: *HealthDay*, 5/10/12)

Canadian regulators recently gave approval to what it says is the first manufactured drug based on stem cells, reported *The New York Times* on May 17. The company, Osiris Therapeutics of Columbia, Md., reported last week that Canadian regulators had approved its drug Prochymal, to treat children suffering from graft-versus-host (GVHD), a potentially deadly complication of tissue or bone marrow transplantation. Prochymal is a preparation of mesenchymal stem cells, which are obtained from the bone marrow of healthy young adult donors. The stem cells are separated out from the marrow and expanded in the culture, so that one donation is enough to make as many as 10,000 doses of the drug. GVHD occurs when the immune cells in the transplanted tissue or bone marrow recognize the recipient as "foreign" and attack the host's body cells. The risk of GVHD is higher when the patient and donor are not an exact match. Using steroids or other drugs to lessen the immune attack may work, but in many cases the GVHD is fatal. Prochymal is approved in Canada for children whose condition is not controlled

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BRIEFLY NOTED (continued from page 11)

by steroids. In a small trial, about 60 percent of such children had a clinically significant response to the drug, reported Osiris. C. Randal Mills, MD, CEO of Osiris, told *The New York Times* that the company would apply to the Food and Drug Administration for approval to sell the drug in the US later this year. Stem cells are already used in medicine but stem cell transplants are medical procedures, not products sold by a drug company like Prochymal. *The New York Times* article is available at http://nyti.ms/LsZccb. (Source: *The New York Times*, 5/17/12) ♦

REGULATORY NEWS

The Centers for Disease Control and Prevention published last week proposed recommendations to test all people born between 1945 through 1965 for hepatitis C (HCV). The recommendations come not long after CDC researchers found that about 75 percent of HCV infections in the US are in the baby boomer generation, people born between 1945 and 1964 (see *ABC Newsletter*, 2/24/12). CDC estimates that some two million Americans born from 1945 to 1965 are infected with HCV – that's about 3 percent of the boomer generation. But because many years elapse before noticeable symptoms develop, most don't know they are infected. The risk factors that CDC currently uses as indicators for hepatitis screening normally do not present in the baby boomer generation. Those risk factors include use of illegal intravenous drugs, receiving blood products or organ donation transplants before 1992, known exposure to HCV, presence of hepatitis symptoms, and HIV infection. Vietnam era veterans are a well known risk group due to blood exposure in military fields hospitals, as well as drug use. CDC believes this approach will address the largely preventable consequences of the disease, especially in light of newly available therapies that can cure up to 75 percent of infections. The proposed recommendations are available for public comment through June 8. The recommendations and directions for commenting can be found at: www.cdc.gov/Hepatitis/HCV/BirthCohortTesting.htm. ♦

GLOBAL NEWS

The European Union (EU) recently held a high level conference called "EU Health Programs: Results and Perspectives," featuring a workshop organized by DG SANCO called, "Improving Citizens' Health and Safety, and the Quality of Organs, Substances of Human Origin, and Blood," reported a European Blood Alliance (EBA) Blog. The workshop summarized the progress of several blood-related programs in Europe focusing on blood donation. Wim de Kort, MD, PhD, the director of Donor Services at Sanquin Blood Bank in The Netherlands, reported on DOMAINE. This is a program in Europe that compares and recommends donor management practices to ensure that there is a sufficient donor population. Alessandro Nanni Costa of the National Center of Transplantation of the National Institute of Health in Italy, presented on the "European Union Standards and Training for the Inspection of Tissues Establishments". The program provides practical tools for the implementation of regulations for human tissues and cells in Europe. Deirdre Fehily of the National Center of Transplantation of the National Institute of Health in Italy, presented on the "Vigilance and Surveillance of Substances of Human Origin" program. This project included a survey on the reporting practices and produced a guidance document on illegal and fraudulent activities. Ms. Paoli Testori Coggi, director general of DG SANCO, presented some plans of the program "Health for Growth" for 2013 to 2020. The program intends to help member states implement EU Directives, maintaining the perspective that good health is a key factor of smart, sustainable, and inclusive growth of blood programs. There was also much discussion surrounding voluntary non-remunerated donations, stressing the importance of maintaining an all-volunteer blood supply. (Source: EBA Blog, 5/16/12) ♦

INFECTIOUS DISEASE UPDATES

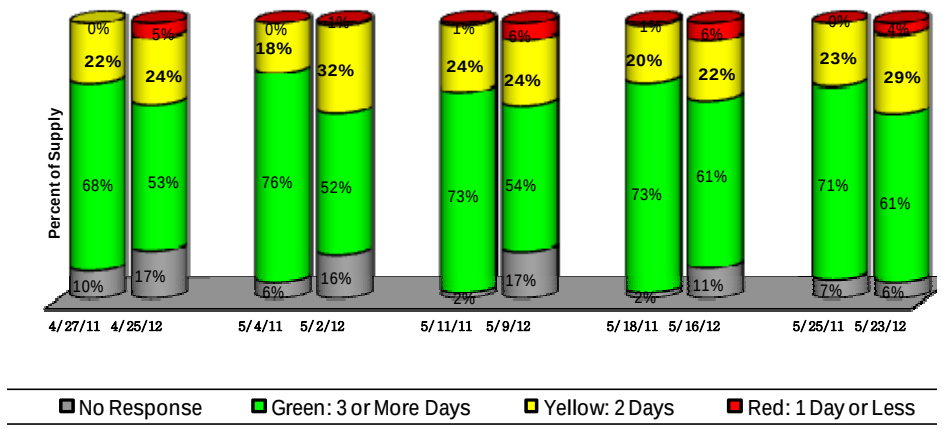
Hepatitis

The Centers for Disease Control and Prevention recognized the first-ever National Hepatitis Testing Day in the US as part of the agency's 17th Hepatitis Awareness Month, reported the CDC's May 18 *Morbidity and Mortality Weekly Report.* In 2011, the US Department of Health and Human Services developed a comprehensive action plan that outlines areas to improve viral hepatitis infection care, prevention, and treatment in the US. Part of this action plan established May 18 as National Hepatitis Testing Day, since testing for viral hepatitis is the first step in linking infected persons to the recommended care and treatment. More than 3 million Americans have a chronic hepatitis C infection, and up to 75 percent are unaware of their infection, says CDC. National Hepatitis Testing Day gives CDC an opportunity to remind healthcare providers and the public who should be tested for chronic viral hepatitis. National Hepatitis Testing Day is part of the "Know More Hepatitis" campaign, announced on World Hepatitis Day on July 28. This is a national education campaign to educate people about viral hepatitis and encourage people to get tested. More information about Hepatitis Awareness Month is available at: http://www.cdc.gov/hepatitis/HepAwarenessMonth.htm (Source: CDC *Morbidity and Mortality Weekly Report*, 5/18/12) ♦

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.

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

MEMBER NEWS

In a ceremony held on May 24 at Frederik Meijer Gardens and Sculpture Park, Michigan Blood was awarded the EPIC Award from the Grand Rapids Area Chamber of Commerce for Excellence in Business, Michigan Blood reported in a press release. The EPIC (Entrepreneurial, Progressive, Innovative, and Collaborative) Awards recognize businesses and individuals that support the community, demonstrate growth, are innovative, and have worked with others as mentors and collaborators. "This is an incredible honor for us," said Bill Rietscha, president and CEO of Michigan Blood, who accepted the award on Michigan Blood's behalf. "We've made remarkable progress as an organization and it's all due to the hard work, commitment, passion, and talent of our nearly 1,000 employees and volunteers across the state. This award belongs to them." Michigan Blood was recognized by the Grand Rapids Area Chamber of Commerce for significant market growth, operational improvements, and improved employee relations during a faltering economy. Over the past three years, Michigan Blood has increased the number of hospitals it serves by 65 percent and has entered several new markets. Embracing process improvement has made it possible for Michigan Blood to reduce expenses, improve efficiency, and enhance service to donors and clients. Information technology infrastructure has also been completely replaced and updated, and the blood inventory management system has been redesigned to assure optimal product availability. Facility updates have created better environments for blood donors and employees. Michigan Blood has also accomplished a complete re-branding, including changing its name, that has resulted in an increase in the organization's awareness and image across the state. (Source: Michigan Blood press release, 5/24/12)

The Michigan Blood leadership team with EPIC Award for Excellence in Business (from left to right): Char Mello, director of Finance; Jim Childress, VP of Community Relations; Mark Palkowski, VP of Operations; Bill Rietscha, CEO/president; Lee Ann Weitekamp MD, VP of Quality & Medical Services; and Lori Ross, Director of Human Resources.

MEMBER NEWS (continued on page 15)

MEMBER NEWS (continued from page 14)

The Institute for Transfusion Medicine (ITxM) has recently signed an agreement in principle with Creative Testing Solutions (CTS) that will likely result in the ITxM laboratory becoming part of CTS by Jan. 1, 2013. The ITxM agreement was announced shortly after an agreement with the same structure was announced with Puget Sound Blood Center (PSBC) (see *ABC Newsletter*, 5/4/12). All three organizations share a strong commitment to quality patient care, customer service, and innovation, while at the same time focusing on cost control, CTS said in an announcement for the *ABC Newsletter*. The ITxM lab in Chicago tests 550,000 donations annually for internal and external customers in Florida, Illinois, Indiana, Pennsylvania, Ohio, and Wisconsin. As previously reported, the PSBC laboratory is located in a newly designed facility in the Seattle area and tests 460,000 donations annually from internal collections in Washington and for external customers in Alaska, Hawaii, Oregon, and California. The two agreements are proceeding separately through due diligence processes. Once that work is done, the three organizations will develop an integration plan. If approved, the laboratories will use CTS procedures, policies and systems, and the staff of the two labs will become CTS employees. "Partnering with both ITxM and PSBC is consistent with the CTS strategic plan to increase our geographic footprint and extend service to clients, in order to realize additional economies of scale," said Sally Caglioti, president of CTS. "Once combined, CTS will have an annual blood donation testing volume of approximately 5.5 million, with additional capacity for growth. This will enable CTS customers to offer top quality testing services at a competitive price to current and new customers." (Source: CTS submission to *ABC Newsletter*, 5/22/12)

Corrections

In the May 18 issue of the *ABC Newsletter*, three errors were recognized in the front-page story, "BPAC Says Yes to In-Home HIV Test, Benefits of Plasma Stored up to 24 Hours at Room Temperature Outweigh Risks." On the first page, we incorrectly stated that the OraQuick In-Home HIV Test would be the first available over-the-counter test for HIV. Actually, it would be the first over-the-counter test for HIV ***that uses a saliva specimen***. On page three, in discussing current plasma regulations, we incorrectly stated that, "Plasma separated from whole blood within eight hours may also be stored at 1 to 6 degrees C for up to a total of 24 hours and labeled as frozen plasma (FP)." The current practice is actually that whole blood is cooled after collection, and the plasma is separated from the whole blood within 24 hours. The plasma is ***not necessarily*** separated within eight hours. Page four contained a typo in discussing the questions brought before the committee. The question read: "Should any special precautions be taken regarding the use of PF24RT24 as thawed plasma? (precaution meaning, should liquid storage up to five days be allowed?)" It should have read "... should liquid storage up to five days be ***disallowed.***" The *ABC Newsletter* would like to apologize for these errors, and thanks readers that bring these issues to our attention.

PEOPLE

Mary Bowden, MT(ASCP)SBB, will retire after serving for 23 years as the technical director at Rock River Valley Blood Center (RRVBC), announced the center in a press release this week. In her role, Ms. Bowden has been responsible for the management of laboratory staff, development and organization of daily business operations relating to patient reference testing, specialized testing, product acceptability testing, and quality control. Prior to RRVBC, Ms. Bowden served in many roles as a medical technologist at various hospitals. Ms. Bowden has been a respected member of the blood banking community and is a member of AABB, the American Society of Clinical Pathologists, and the Illinois Association of Blood Banks, where she served as a past Board member. She is also a peer assessor with AABB and has been a member of the ABC Technical Directors' Workshop Planning Group. RRVBC held an open house event on Thursday to celebrate Ms. Bowden's contributions to the center as she retires. (Source: RRVBC press release, 5/21/12)

MEETINGS

July 24 **FDA Workshop "Use of Computer Simulation of the US Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures," Bethesda, Md.**

The Food and Drug Administration has announced a public workshop titled "Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures." The workshop is set for July 24 from 8:30 a.m. to 5 p.m. at the Hyatt Regency in Bethesda, Md. The purpose of the workshop is to provide stakeholders a forum for discussion of data needs and to obtain feedback on possible modeling scenarios to explore emergency supply situations should a pandemic or epidemic disease or other events that could adversely impact the US blood supply occur. More information is available in the *Federal Register* notice at: www.gpo.gov/fdsys/pkg/FR-2012-05-24/html/2012-12593.htm

Contact: Mark Walderhaug, Center for Biologics Evaluation and Research, FDA, 1401 Rockville Pike, Suite 200N, Rockville, Md. Call (301)- 827-6028 or e-mail Mark.Walderhaug@fda.hhs.gov. ♦

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:

QA Manager. Join our friendly, caring team of employees and help save the lives of local residents here in Eugene, Oregon! As our QA Manager, you will ensure compliance with FDA and other regulatory standards; monitor control systems to ensure a safe blood supply; and oversee preventive and corrective action efforts. You will also conduct internal audits, help develop validation plans and supervise all regulatory affairs to

POSITIONS (continued on page 17)

POSITIONS (continued from page 16)

ensure optimal quality assurance in our blood center operations. As a key member of our leadership team, you will help solve organizational problems, improve processes, and contribute input to the strategic direction of our organization. Requirements: College degree, biologic science preferred; three to five years QA management experience in a regulated environment, preferably healthcare. Must have thorough understanding of FDA regulations, quality systems and cGMPs. Ability to think critically, solve problems, make decisions quickly, and manage projects successfully is essential. Ability to influence others and great customer service skills are also required. See full job description and how to apply at www.laneblood.org "Job Opportunities", Lane Blood Center, 2211 Willamette St, Eugene, OR; (541) 484-9112.

Manager, Donor Operations. LifeStream, a $53M healthcare organization providing blood services for more than 70 hospitals in Southern California, is searching for a Manager, Donor Operations to function as a member of the Donor Operations Management Team. The manager oversees donor operations including Manual, Special Services, and Automated Donation processes, and also advanced procedures where applicable. Responsible for overseeing, evaluating, making decisions regarding issues of customer service and compliance to cGMP Standards, equipment monitoring and Quality Control, staff training, assignments, scheduling daily breaks, and performance. Also, responsible for monitoring and trending Productivity and Facility/Equipment Management. Serves as an On-Site Emergency Coordinator and ensures a safe work environment. Manages budget in a fiscally responsible manner. Identifies opportunities for and cultivates community partnerships to enhance the LifeStream image. Excellent compensation and benefits plan. Apply online: www.LStream.org. Or send cover letter, resume and salary history to: LifeStream, Attn: HR, 384 W. Orange Show Rd. San Bernardino, CA 92408. E-mail: employment@LStream.org. EOE

CALENDAR –

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail* (mnorwood@americasblood.org) *or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)*

2012

May 29. **SCABBinar: Intervention to Reduce Vasovagal Reaction in Young Donors.** For more information and to register go to http://scabb.org/scabb-education-events/.

June 6. **South Central Association of Blood Banks (SCABB) Pre-Meeting Symposium at the 2012 Florida Association of Blood Banks (FABB) Annual Meeting.** For more information and to register visit www.floridaabb.org.

June 12. **FDA Blood Products Advisory Committee Meeting, Bethesda, Md.** More information can be found at: http://1.usa.gov/MrVN2N.

June 19-22. **Fund Development, Donor Recruitment and Communications Workshop, America's Blood Centers, Atlanta, Ga.** Attendance restricted to ABC members and invited guests. Contact: Abbey Nunes. Phone: (202) 654-2980; fax: (202) 393-1282; e-mail: anunes@americasblood.org.

July 7-14. **32nd International Congress of the ISBT, Cancun, Mexico.** Reduced registration rates end April 30, and the program is now available online. For more information visit: www.isbtweb.org/mexico/welcome.

Aug. 4. **Medical Directors Workshop, America's Blood Centers, Buffalo Niagara, N.Y.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 5-6. **Interim Meeting, America's Blood Centers, Buffalo Niagara, N.Y.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

CALENDAR (continued on page 18)

CALENDAR (continued from page 17)

Sept. 19-20. **IT/Benchmarking Workshop, America's Blood Centers, Fort Lauderdale, Fla.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Sept. 27. **Unity Gala with Sickle Cell Disease Association of American, in Baltimore, MD.** For more information, please contact Jodi Zand: (202) 654-2994; e-mail jzand@americasblood.org.

Oct. 6-9. **AABB Annual Meeting and CTTXPO, Boston, Mass.** For more information: www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx.

Oct. 22. **3rd Annual Links for Life Golf Tournament, Evans, GA.** For more information, please contact Jodi Zand: (202) 654-2994; e-mail jzand@americasblood.org.

2013

2014

June 5-8. **5th International Monoclonal Antibody Workshop, New York, NY.** Contact: Gregory Halverson, New York Blood Center, phone: (212) 570-3026 or e-mail: ghalverson@nybloodcenter.org.