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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2014 #5 **February 7, 2014**

INSIDE:

Gulf Coast Regional Blood Center Among First to Implement Abbreviated Donor History Questionnaire

Gulf Coast Regional Blood Center, based in Houston, began offering the abbreviated Donor History Questionnaire (aDHQ) to donors on Dec. 31, 2013, becoming among the first blood centers to implement this process. The aDHQ eliminates redundant questions in the donor interview process for frequent donors, saving time and rewarding donors who give blood regularly.

Currently, most blood centers use the full-length DHQ (FL-DHQ), which must be administered at each donation along with a physical assessment, to determine donor eligibility. The blood banking community has recognized over the years that the FL-DHQ is long and tedious, especially for frequent blood donors, whose responses to many of the questions would not have changed since their last donation.

"Regular donors have commented that because they donate so frequently, most of their answers remain the same from donation to donation," said Cortney Martin, manager of Communications at Gulf Coast Regional Blood Center. "By allowing them to bypass questions that they would answer the same away again and again, the shorter questionnaire saves them time and rewards them for their continued commitment to donating." This reinforces the center's *Commit for Life* program, which encourages donors to give at least once a quarter.

The AABB Donor History Task Force developed the aDHQ, which the Food and Drug Administration recognized in a May 2013 guidance document as an acceptable alternative to the FL-DHQ (see *ABC Newsletter,* 5/10/13). The aDHQ eliminates redundant questions about events or behaviors that cannot have changed since the previous donation and allows frequent donors to enjoy a shorter, more streamlined donor qualification process, said Susan Rossmann, MD, chief medical officer at Gulf Coast Regional Blood Center, and chair of the AABB task force.

The aDHQ can be used to qualify donors who have made at least two donations using the FL-DHQ, most recently within the past six months. Once a donor qualifies to use the aDHQ, he or she may continue using it as long as he or she donates once every six months. Donors who do not give blood every six months must re-qualify by making the next two donations with the full-length questionnaire.

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OUR SPACE

ABC President Dave Green

Framing the Challenge: Decline or Shift

Not surprisingly the pace of change in how we interact with and support our hospitals continues at a brisk pace: hospitals joining systems, systems merging with systems, and mega-systems forming purchasing umbrellas. Our members are demonstrating creativity in expanding relationships with their customers, partnering to deliver unprecedented value, and forging new networks to extend their reach according to the evolving footprint of their customers. Amid these dramatic responses to an increasingly complex service environment, what responsibility do we have in making our donors aware of these changes?

We all know our donors do not donate because of the cookies in the canteen; the cookies simply aren't that good. Donors always have and always will donate for the patient – the patient they will likely never meet. This connection is powerful and has always struck me as one of the most amazing examples of altruism. But how effective are we in stretching that relationship between the donor and patient to span an increasingly great distance?

I believe there are likely many member centers that have done an excellent job at creating such an elastic connection between the donors and patients in the face of our ever-changing environment. Some have formed an identity without geographic limitations or based on a preference for local vs. national support – a motivation that keeps the visualization of the recipient real and meaningful without attaching a parochial sense of "ours." But I also believe the increasing pressure on type-specific donor recruitment exacerbates the challenge of messaging our cause in a way that resonates with donors, while national coverage characterizes blood use as declining. Regardless of how well we have communicated the need for blood to our donors in the past, the new realities posed by a shifting demand and associated type-specific requirements, coupled with a fluid healthcare delivery environment pose new challenges to proven donor recruitment systems.

The work for donor recruitment professionals has never been more daunting, but at the same time the wealth of support available has never been greater. America's Blood Centers offers an excellent forum for exchanging ideas, inviting perspectives from other industries on new approaches, and facilitating a productive dialogue to design solutions that meet the needs of our hospital customers and the patients they serve. Collaboration will ensure that a successful outcome will never be out of reach.

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Gulf Coast aDHQ (continued from page 1)

"The abbreviated questionnaire encourages the donor to give blood frequently and to think of himself or herself as a regular blood donor," said Dr. Rossmann. She added that many of the questions in the aDHQ are reworded to ask the donor about relevant events or behaviors since the last donation, rather than at some point in the past. "This gives the donor a much more finite period of no more than six months to think about while answering the questions. And from what we know about questionnaires, this should lead to more accurate answers, as well as be easier for the donor to recall the necessary information."

Developing and Implementing the aDHQ. The AABB taskforce began developing the aDHQ in 2002, first redesigning the FL-DHQ and later working with focus groups and reading comprehension experts to create and test the aDHQ. The task force worked diligently for more than 10 years to generate easily understood questions and to gain FDA approval of the aDHQ. Some challenges included the aDHQ's reliance on information from past donations (FDA requires donors to be qualified on the day of donation) and ensuring appropriate guidelines to ensure the aDHQ is given to the right donors, said Dr. Rossmann.

Gulf Coast Regional Blood Center staff began discussing the aDHQ in mid-2011 and began the implementation process in September 2013, only a few months after FDA approved the aDHQ via the May 2013 guidance. The center first conducted research on how to maintain regulatory compliance while using the aDHQ, and contacted the center's consumer safety officer at the FDA. They then began discussions with Healthcare-ID, which provides a computer program called Donor-ID that Gulf Coast uses for donor screening.

Engaging Healthcare-ID was crucial to implementing the aDHQ because the center's collections processes have been computerized since 2000 using Donor-ID, said Bart Block, Gulf Coast's director of Management Information Systems. Mr. Block met several times with Healthcare-ID and gained feedback at America's Blood Centers, AABB, and user-group meetings to integrate the aDHQ into the Donor-ID program. Since the software already supported multiple questionnaires, Gulf Coast and Healthcare-ID added some logic to support the aDHQ and its rules.

"Properly administering the questionnaire and determining who qualifies would not be practical without computer support," said Mr. Block. "We are now able to leverage the computers to improve the screening process further." Dr. Rossmann noted that some blood centers' computer systems may be currently unable to support such features, potentially creating a barrier to using the aDHQ.

In addition to working with Healthcare-ID, Gulf Coast designed the qualification workflow and then revised it based upon FDA's guidance document, said Mr. Block. The center put together a team of key personnel and in a period of three months installed, configured, and validated the new software, as well as created or updated the relevant standard operating procedures and trained staff on the new abbreviated process.

Results and Next Steps. "Currently, about 30 percent of our donors are using the aDHQ, and the feedback has been very positive. Donors are appreciative of the fact that we are committed to making the donation experience more convenient for them. It's also an incentive for donors to come back," said Ms. Martin. In the coming months, Gulf Coast plans to integrate the aDHQ into its *CFL express* module, which enables donors to complete the questionnaire from home, print the results, and bring them into the blood drive or donor center.

As more donors use the aDHQ, Gulf Coast staff will carefully assess whether the questionnaire is being properly administered to the correct donors, said Dr. Rossmann. She added that the center will use its quality system to detect any issues, although none have been found thus far. FDA's final guidance on the aDHQ can be accessed at http://1.usa.gov/1atTOsl. ♦

Cesar E. Chavez Blood Drive Offers Platform to Increase Donor Diversity

LifeStream, headquartered in San Bernardino, Calif. recently became a blood center partner with the Migrant Students Foundation (MSF) as part of the National Cesar E. Chavez Blood Drive Challenge. This event, founded in 2009, seeks to celebrate Cesar E. Chavez's legacy by engaging college students to promote health education, health science careers, civic engagement, and saving lives. Over the past five years, the program has collected more than 60,000 units of blood from blood drives across the country, while also educating students about the increased need for blood donors, especially within the minority population.

Through this national service learning initiative, US Latino/Hispanic college students are encouraged to organize a blood drive campaign on their campus, competing with other blood drives across the country to win the coveted title of "Most Successful Blood Drive." Each campus campaign is led by a selected student organizer who is responsible for designing a donor recruitment campaign in collaboration with their local blood center. Student organizers whose schools place in the top 50 nationally can also win a $1,000 scholarship.

Above is the winner of the 2013 Best Picture Award, featuring two students donating at Citrus College in Glendora, Calif., during the 2013 Cesar E. Chavez Blood Drive Challenge.

This year, the MSF announced the Chavez Challenge Partner Program, as a way to partner with blood centers looking to take their campus programs to the next level. These dedicated partnerships will allow the organization to be more strategic and efficient in their efforts. The MSF will assist Chavez Challenge Partners by facilitating communication with college campuses and student leaders in the area, expanding the reach and relationships with new campuses and other community organizations, providing training and onsite support, as well as numerous other benefits. In return, partner blood centers provide the necessary support to host and grow the annual Cesar E. Chavez Blood Drive Challenge in its service region.

LifeStream recently became the first blood center to become a Chavez Challenge Partner. "The challenge is an opportunity to bring attention to two of LifeStream's main objectives going forward: bridging the generations of blood donors and diversifying our donor base," said Frederick B. Axelrod, MD, LifeStream president, CEO, and medical director. "More specifically, the initiative and scholarship help focus attention on the Latino community, which is underrepresented in the blood donor community at large. With the challenge as a rallying point, we look forward to engaging this growing, vibrant sector of the US population in the cause of saving lives through voluntary blood donation.

While LifeStream is the first to join the new Chavez Challenge Partner Program, many ABC blood centers have been participating in the blood drive challenge for the past few years. Blood Centers of the Pacific (BCP), headquartered in San Francisco, began participating in the challenge in 2009 and has attracted a greater number of Latino and minority donors at these blood drives, said Lisa Bloch, BCP's director of Communications.

"Being located in California – a state which has a very high percentage of Latinos and farm workers – it is important for us to recognize the contributions of Cesar Chavez and to provide the Latino community with a way to give back in honor of Chavez's legacy," said Ms. Bloch. Mr. Chavez was an American

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Cesar E. Chavez Blood Drive (continued from page 4)

farm worker, labor leader, and civil rights activist who with Dolores Huerta co-founded the National Farm Workers Association in 1962.

BCP's blood donors are largely Caucasian, yet the general population of this region is highly diverse with a large number of Latinos, a trend observed throughout the US. The blood drive challenge helps to educate the Latino community about the importance of blood donation and dispel any myths, said Ms. Bloch. "Latinos are the fastest growing minority in the nation. Their participation in blood donation is crucial if we are to continue to have enough donors to support patient needs," said Ms. Bloch.

Heartland Blood Centers began participating in the blood drive challenge last year, also seeking to increase donor diversity. "This challenge is an opportunity for college students to honor the legacy of Cesar E. Chavez by practicing grass roots organizing with the 'yes, it can be done' attitude that Chavez is famous for," said Jill Moeggenberg, director of Mobile Recruitment at Heartland Blood Centers.

"Heartland Blood Centers serves a very diverse donor base, and as such, continually works to educate healthy individuals on why their donation is critical to the health of their own community," added Ms. Moeggenberg. "Latino blood donors are in the best position to help Latino patients in need of blood transfusions because of the unique antigens on their red blood cells." She encourages other blood centers to get involved in the blood drive challenge because "it serves as the perfect platform to create awareness among the Latino population of how very much they are needed."

More information about the Cesar E. Chavez Challenge is available at www.chavezchallenge.org. The Chavez Challenge Partner Program application can be downloaded at http://bit.ly/1keaW8X. Those wishing to participate in the blood drive challenge or who have additional questions may contact Glen Galindo at ggalindo@migrantstudents.org. (Source: *The Press-Enterprise*, 2/19/14)

FDA Workshop Explores IVIG-Related Hemolysis Risk Mitigation Strategies

The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER), in partnership with the Plasma Protein Therapeutics Association (PPTA) and the NIH's National Heart, Lung, and Blood Institute, held a public workshop from Jan. 28 to 29 in Bethesda, Md. to discuss strategies to address hemolytic complications of immune globulin infusions.

When receiving high-volumes of intravenous immunoglobulin (IVIG), some patients experience hemolysis. Attendees at the recent FDA workshop met to discuss the incidence, pathogenesis, and epidemiology of IVIG-related hemolysis to identify steps that should be taken to better prevent this adverse reaction.

A key issue that workshop attendees addressed was the sense that the rate of IVIG mediated hemolysis may have increased over the last four years across the different product types, despite the lack of active surveillance data. While still meeting regulatory specifications (i.e., titer $\leq$ 64), many new generation IVIG products have a 1-3 titer increase in anti-A titers compared to the "older" products, which could plausibly increase the risk of IVIG-related hemolysis.

Some of the speakers presenting epidemiologic data defined IVIG-related hemolysis as a new hemolytic process that occurs within 10 days of IVIG administration, with at least a 1g/dL decrease in hemoglobin, a positive direct antiglobulin test, and one or two of the following: increased reticulocyte count, increased LDH, unconjugated hyperilirubinemia, hemoglobinemia, hemoglobinuria, significant spherocytosis. The often delayed nature of these findings was recognized as confounding surveillance efforts.

There are currently no available data to reliably determine the incidence of hemolytic complications, explained workshop attendees. Surveillance is limited by reliance on passive event reporting, which is often accompanied by incomplete patient and product information. A majority of the epidemiologic studies presented suggest a fairly low incidence of IVIG-related hemolysis – FDA found 47 cases in an analysis of spontaneous reporting from 2007 to 2010, but without a denominator for rate calculation. However, it was noted that this complication is likely underreported. Active surveillance studies, improved adverse event reporting mechanisms, and epidemiologic review of large insurance billing databases were discussed as measures to improve the understanding of IVIG-related hemolysis.

IVIG-related hemolysis appears to be most common with higher IVIG doses (e.g., $\geq$ 2 gm/kg) and in non-group O patients (group A is most common, followed by AB and B blood types). Adverse reactions can be delayed from three to 14 days (rarely longer) after the last IVIG dose, and while patients may experience a 4-5 g/dL drop in hemoglobin, typically there are no or only minor adverse clinical complications. Patient variables were enumerated that may be associated with the risk of hemolysis, such as complement efficiency, macrophage activity, red blood cell membrane variables, and underlying patient inflammation. Product-related variables also under consideration include antibody subtype, antibody specificity, immune complex-like moieties, and others. All of these variables require further investigation.

Isohemagglutinin titers (i.e., anti-A and B) currently do not appear to be strongly predictive of hemolysis, but currently, these are one of the only readily modifiable product variables. Therefore, there has been an effort across the industry to reduce anti-A and anti-B titer levels. Whether this leads to a decrease in IVIG-related hemolysis requires further study.

The second day of the workshop focused largely on IG manufacturing and risk mitigation, with input from several industry representatives. Manufacturing steps proposed, or in process, to reduce

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FDA Workshop (continued from page 6)

isohemagglutin titers included exclusion of "high titer" donors, anti-A/anti-B immunoaffinity columns, and additional Cohn fractionation steps. Clinical methods to reduce IVIG-related hemolysis were also discussed and included use of lower doses, spreading doses out over longer intervals, dosing by lean body weight, concomitant corticosteroid administration, and developing tests to predict the patient response to IVIG. More active post-IVIG monitoring with serial laboratory studies will be critical as will be increased clinician education.

As the workshop concluded, it became clear that those interested in mitigating the risk of IVIG-mediated hemolysis, should consider the utility of:

- Better surveillance to understand the magnitude of the problem;
- Continued proactive product label updates that would be useful to clinicians (although some suggested this would not be effective);
- Increased physician education and better patient monitoring;
- Improved product testing methods for more predictive and more standardized results; and
- Further studies to evaluate the characteristics associated with hemolysis and possible patient factors involved.

The agenda from this workshop can be accessed at http://1.usa.gov/KfqvhO, and FDA will also post a transcript of the workshop here in the near future.

This article was written with the help of Jonathan A. Hughes, MD, associate medical director of BloodSource, who attended the meeting and provided a summary to ABC.

THE WORD IN WASHINGTON

Efforts to repeal the medical device tax have taken a back seat in recent months due to lack of legislative vehicles available. Under the 2.3 percent medical device tax, mandated by the Affordable Care Act, device manufacturers are required to pay an estimated average of $194 million per month in medical device tax payments. Last year, America's Blood Centers lobbied for, and succeeded in receiving an exemption from the IRS for blood tests and blood grouping reagents sold to blood centers (see *ABC Newsletter*, 1/27/12). The exemption saved independent blood centers about $8.9 million annually (assuming the tax would have been passed directly to consumers) or about $17.7 million for the entire blood industry. ABC continues to work to reinforce bipartisan support for the device tax repeal with a focus on future possibilities. These opportunities may include legislation for the debt ceiling, the fiscal year 2015 budget act, potential tax extenders, and any lame duck end-of-the-year packages. ABC recommends that its members stay tuned for more updates in this area, as member support will be required in support of ABC's grassroots advocacy initiatives.

Additional congressional retirements were recently announced, including veteran Rep. Jim Moran, (D-VA), freshman Rep. Trey Radel (R-FL), and Sen. Tom Coburn (R-OK). Rep. Moran is not running for reelection, while Rep. Radel has resigned. Sen. Coburn has said that his cancer treatments motivated his announcement to resign at the end of 2014, a year before the end of his turn. ABC encourages its members to stay updated on the whereabouts of their Congressional representatives.

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THE WORD IN WASHINGTON (continued from page 7)

Lawmakers continue negotiations over payment policy extenders and offsets as the House and Senate prepare to file identical legislation this week repealing the Medicare sustainable growth rate (SGR) physician funding formula. Lawmakers report that the bills provide a .05 percent annual payment update to physicians through 2018 at which time a merit-based payment system (MIPS) will be instituted. The bills give physicians a menu of quality measures to be used in scoring as the payment system moves from a volume-based system to one based on quality targets. The bills also authorize $40 million of funding over five years to provide technical assistance to physician practices of 15 or fewer members. This funding also establishes a technical advisory panel independent of the Department of Health and Human Services to advise the HHS Secretary on alternative practice models. If this legislation passes, the flawed SGR mechanism will be permanently repealed, averting a 23.7 percent SGR-induced physician funding cut scheduled for April 1.

A Congressional Budget Office analysis released Tuesday predicts the Affordable Care Act will reduce the workforce by the equivalent of more than 2.5 million full-time positions by the end of 2024. However, this is not due to the usual reason of employer-related reduction of private-sector job creation. Rather, the report projects that expansion of insurance coverage in the law will reduce hours worked and full-time employment. The budget office anticipates that more people will choose not to work or to work fewer hours than they would have needed to work in order to obtain employer-provided insurance. The analysis can be accessed at http://1.usa.gov/1bu452X. (Source: CBO analysis, 2/4/14)

Through the efforts of America's Blood Centers staff in Washington, D.C., Congress introduced and passed a resolution in January in recognition of National Blood Donor Month. The resolution honored blood donors and recognized ABC member centers for their contribution to providing a safe and adequate blood supply in the US. "America's Blood Centers, AABB, and the American Red Cross support and perform critical services collecting, processing, and distributing lifesaving blood and blood products to hospitals and health providers, and are instrumental in ensuring the safety of the blood supply and the need for blood donations," said the resolution. It can be accessed at http://1.usa.gov/Lwnh9Q. (Source: H. Con. Res. 80, 1/29/14) ♦

Hot on the Listservs: Blood Centers use Promotions to Boost Collections During Challenging Winter Months

"Hot on the Listservs" is a series that appears in the Newsletter once a month, exploring a different topic that has generated discussion via America's Blood Centers' e-mail Listservs. These Listservs allow ABC blood center professionals to discuss issues, ask questions, and gain feedback from colleagues.

Over the past month, blood center communications and donor management professionals shared ideas for promotional Valentine's Day blood drives through ABC's Communications & Donor Recruitment Listserv. Themed blood drives and other promotions are common throughout the winter months when blood centers often see a dip in donations.

Donating blood often falls off of the priority list for donors during the winter with hectic holiday schedules, inclement weather, and flu season creating barriers to making their usual donations, explained Chris Pilgrim, marketing manager at Community Blood Center of the Ozarks, based in Springfield, Mo. Closures of schools and offices due to winter weather also causes blood drive cancelations. Blood donor recruiters have found themed blood drives, special promotions, and forming community partnerships to be particularly effective in boosting blood donations during the winter and other tough recruitment times.

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HOT ON THE LISTSERVS (continued from page 8)

San Diego Blood Bank holds numerous promotional blood drives throughout the year, including the annual Chargers Blood Drive, hosted with the San Diego Chargers football team on the day before Thanksgiving. Donors have the unique opportunity to receive autographs from players and the cheerleaders after donating at the drive and receive commemorative T-shirts if they donated during Chargers Mania, the week before the blood drive. This year, the center collected 5,271 pints during the Chargers Blood Drive and Chargers Mania, and collected an additional 1,166 units in January when it issued Chargers T-shirts to celebrate the Chargers' playoff game.

"Plan ahead of time for the critical dates. Look at what days the holidays fall on and consider the impact of those particular closed dates ... Tie in your events with popular teams, stations, or celebrities in your area," said Lynn Stedd, director of Community Relations and Marketing at San Diego Blood Bank.

Blood Assurance, headquartered in Chattanooga, Tenn., has found that strong community partnerships can support the blood supply, not only during the winter holidays, but throughout the year. The University of Tennessee, Chattanooga, (UTC) partnered with Blood Assurance in 2009 to host "Bloodanooga," Chattanooga's largest community blood drive. Blood Assurance collected 827 units in its inaugural year and since then, the partnership has developed into an effort to support the local blood supply throughout the year, increasing the number of college-aged donors at the center's main facility from 1,135 in 2009 to 1,438 in 2013. UTC now hosts multiple blood drives each year, which contributed 896 units in 2013.

Another valuable partnership for blood centers is that with the local media. "Our media play a big role in our promotions ... We rely on our media partners to relay information to the public during times of shortage and to help us promote events and promotions," said Mr. Pilgrim. Community Blood Center of the Ozarks increases its media presence during the winter months by actively seeking forums to get the word out about holiday shortages, said Mr. Pilgrim.

"Make an extra emphasis on informing the public of your needs during this time of year. That may consist of phone calls to your area news directors or assignment editors to 'pitch a story,' or producing public service announcements. Get into the holiday spirit with a message of giving back," said Mr. Pilgrim. "Finally, take the time during the holidays to thank donors for their efforts, not only through the holiday season, but throughout the year ... Let donors know they are special, and they'll do special things for the benefit of others."

Blood Assurance drew in donors this winter with social media by launching an Instagram challenge in which donors submitted a photo of themselves at a blood drive or collection center using the hashtag "#balifesaver." The center received more than 100 photos and new followers on its Instagram account. The center also offered donors red holiday themed shirts in December to boost collections before the holidays. Blood Assurance collected 213 pints of blood on the Monday before Christmas, which was 57 units over the goal for that day.

Coffee Memorial Blood Center, headquartered in Amarillo, Texas, has used "cause-marketing" to increase awareness about why blood is needed while also helping others. For example, the blood center has paired up blood drive and promotional events with celebrating police and fire departments, supporting schools, raising accident awareness and first responder appreciation, and supporting a share the road with bicyclists initiative.

"In short, it is not just about us – we are the community's blood center and we believe our donors understand and respond to that favorably," said Julie M. Ontiveros, director of Donor Recruitment and Development at Coffee Memorial Blood Center. ♦

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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified. ♦

ABC Releases Second Tier Compensation Survey Results to Members

America's Blood Centers recently released its 2013 Compensation Survey Results. This second-tier management survey was designed by Gallagher Surveys, in collaboration with ABC's Human Resources Steering Committee.

The results include trends in compensation programs and practices of more than 50 ABC member blood centers, with data effective as of July 1, 2013. Now in its second year, the survey collects salary data by individual incumbent, as opposed to the organizational averages. This methodology allows the survey to present data that is more accurate, detailed, and far more reflective of the actual market. The survey included 15,993 incumbents and surveyed 67 titles.

The results are available only to ABC member blood centers. ABC members who participated in the survey can order the results for $225, while non-participant ABC members can order it for $675. Those interested in placing an order may e-mail Annmarie Flaherty at Annmarie_Flaherty@HRadv.com. ♦

RESEARCH IN BRIEF

Scientists reported Jan. 30 in *Nature* that they have found a simple way to reprogram mature animal cells back into an embryonic-like state that may allow them to generate many types of tissue. The research suggests human cells may be reprogrammed by the same technique, offering a simpler way to replace damaged cells or grow new organs. Haruko Obokata, PhD, and colleagues of the RIKEN Center for Developmental Biology in Kobe, Japan, allowed skin and blood cells to multiply and then subjected them to stress "almost to the point of death," by exposing them to various stimuli including trauma, low oxygen levels, and acidic environments. After simply bathing the cells in a weak acid solution for about 30 minutes, the researchers found that within days, the cells had not only survived, but had also reverted into a state similar to that of an embryonic stem cell. These stem cells – dubbed Stimulus-Triggered Acquisition of Pluripotency (STAP) cells – were then able to differentiate into different types of cells and tissue, depending on the environments into which the cells were placed. Interestingly, the STAP cells can also form placental tissue, something that neither induced pluripotent stem cells (iPS) nor embryonic stem cells have done. "The findings are important to understand nuclear reprogramming," Shinya Yamanaka, who pioneered iPS cell research, said in a *Nature* news article. "From a practical point of view toward clinical applications, I see this as a new approach to generate iPS-like cells."

Citations: Cyranoski D. Acid bath offers easy path to stem cells. Nature. 2014 Jan 30;505(7485):596.

Obokata H, *et al*. Stimulus-triggered fate conversion of somatic cells into pluripotency. Nature. 2014 Jan 30;505(7485):641-7.

Obokata H, *et al*. Bidirectional development potential in reprogrammed cells with acquired pluripotency. Nature. 2014 Jan 30;505(7485):676-80.

RESEARCH IN BRIEF (continued on page 11)

RESEARCH IN BRIEF (continued from page 10)

A study published in *Blood* Jan. 30 provides an estimate of the global anemia burden from 1990 to 2010, estimating an anemia prevalence in 2010 of 33 percent, resulting in 68.4 million years lived with disability. Several previous reports have investigated the global prevalence of anemia with estimates ranging from 20 to 40 percent. The current study, conducted by Nicholas J. Kassebaum at the Institute for Health Metrics and Evaluation at the University of Washington and colleagues, provides estimates of the prevalence and epidemiology of anemia, its impact on global health, and its key determinants, stratified by age and sex, from 1990 to 2010. The authors used 409 data sets from the Demographic and Health Surveys (national, weighted surveys of health status supported by the US Agency for International Development, the United Nations, and the World Health Organization). Seventeen specific causes contributing to anemia were determined using data from the WHO Global Burden of Diseases, Injuries and Risk Factors 2010 (GBD 2010) study. The authors estimated the impact of anemia on global health (disease burden) using disability weighting, which represents the severity of health loss associated with a clinical condition. They estimate that anemia accounted for 8.8 percent of the total disability from all conditions in 2010. Children less than five years old and women still have the highest burden. However, the prevalence of anemia worldwide has decreased from 1990 to 2010, with most of the improvement coming from a genuine reduction in the conditions that cause anemia. The main causes of anemia worldwide in all time periods and both genders were iron deficiency, hookworm, sickle cell disorders and thalassemia, schistosomiasis, and malaria. South Asia accounted for 38 percent of the global anemia burden, whereas sub-Saharan Africa contributed 23.9 percent. "Despite causing so much disability, anemia does not receive its requisite attention in many public health spheres," wrote the authors. They add that they hope their analysis helps health specialists, doctors, and policymakers to more clearly understand the multiple causes for anemia to better facilitate the formation of strategies to further reduce anemia's burden." "The results emphasized the important contribution made by anemia to the overall global burden of disease and should help focus attention and resources toward this problem," wrote Sant-Ryan Pasricha in an accompanying editorial.

Citations: Kassebaum NJ, *et al*. A systematic analysis of global anemia burden from 1990 to 2010. Blood. 2014 Jan 30;123(5): 615-24.

Pasricha SR, *et al*. Anemia: a comprehensive global estimate. Blood. 2014 Jan 30;123(5):611-2.

BRIEFLY NOTED

The American Association of Critical-Care Nurses (AACN) – as part of the Critical Care Societies Collaborative (CCSC) – has identified five routine critical care practices that should be questioned because they may not always be necessary. Among other measures, the AACN recommends that clinicians do not "transfuse red blood cells in hemodynamically stable, non-bleeding critically ill patients with a hemoglobin concentration greater than 7 mg/dL." The organization's efforts support Choosing Wisely, an initiative of the ABIM Foundation intended to spur conversations between patients and healthcare providers on what tests and procedures are really necessary. AACN is the first nursing organization to collaborate on development of a Choosing Wisely list. The other recommendations include:

- Do not order diagnostic tests at regular intervals, but rather in response to specific questions;
- Do not use parenteral nutrition in adequately nourished critically ill patients within the first seven days of a stay in an intensive care unit;

BRIEFLY NOTED (continued on page 12)

BRIEFLY NOTED (continued from page 11)

- Do not deeply sedate mechanically ventilated patients without a specific indication and without daily attempts to lighten sedation; and
- Do not continue life support for patients at high risk for death or severely impaired functional recovery without offering patients and their families the alternative of care focused entirely on comfort.

AACN joins the multitude of other health-related organizations that have made recommendations on how to reduce the use of potentially unnecessary medical procedures, treatments, or tests. Many of these recommendations have included patient blood management tactics to reduce unnecessary transfusions. More information about the Choosing Wisely project can be found at http://bit.ly/MvtWS3. (Sources: NewsMedical.net, 1/29/14; Choosing Wisely website, 2/6/14) ♦

REGULATORY NEWS

The Department of Health and Human Services published its final rule on patient access to lab test results. The rule, jointly issued by the Centers for Medicare and Medicaid Services (CMS), amends the Clinical Laboratory Improvement Amendments (CLIA), giving patients and their designees direct access to laboratory test reports. The current CLIA regulations restrict CLIA-certified labs to releasing test results only to the person responsible for using the test results in the diagnosis and treatment context, and to the laboratory that initially requested the test. Given this restriction, the current HIPAA Rule includes an exception to the Privacy Rule for test reports and other protected health information at CLIA and CLIA-exempt laboratories. HHS states in the rule that it believes patients have the right to their own health information to "empower them to better manage their health and take action to prevent and control disease" and take active involvement in their own healthcare. The removal of the restrictions from the CLIA rule would further support implementation of electronic health records. The new CLIA rule will allow the disclosure of lab test reports to the individual. CLIA laboratories that are also HIPAA-covered entities are required to provide, upon request by an individual or the individual's personal representative, access to the protected health information. Those CLIA laboratories that are *not subject* to HIPAA will have the *discretion* to provide patients with direct access to their laboratory test reports, subject to any applicable state laws that may constrain access. The changes in the final rule permit, but do not require release of completed test results. Of note, the final rule does not require that laboratories interpret test results for patients. America's Blood Centers staff contacted CMS regarding the applicability of this final rule to blood donor testing and was informed that there are no exceptions to the rule for laboratories that perform blood donor testing. The preamble to the final rule discusses a similar interpretation in response to comments submitted to the proposed CLIA rule by organ procurement organizations. The Patient Access Rule applies to *all* laboratory testing that is subject to CLIA regulations, including testing that is performed in blood donor centers. If a test is performed in a CLIA lab, a patient will have the right to request those test results from the lab. A CMS webpage that provides information for covered entities and business associates on HIPAA can be found at http://1.usa.gov/1lE1FZq. A flowchart by CMS to assist organizations in determining whether or not they are HIPAA-covered entities can be found at http://go.cms.gov/1cxjNtG. The final rule can be accessed at http://1.usa.gov/1gQYxr3. (Source: HHS final rule, 2/5/14)

The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) published the list of guidance documents that it plans to publish in 2014. The list includes topics that currently have no guidance associated with them, topics where updated guidances may be helpful, and

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topics for which CBER has already issued draft guidance documents. CBER notes that it is not bound to this list of topics, nor required to issue every guidance on this list. The agency is also not precluded from developing documents on topics not on the list. Guidance documents to be issued regarding blood and blood components include:

- Draft Guidance of Industry: "Use of Bacterial Detection Tests by Blood Collection Establishments and Transfusion Services to Mitigate the Risk of Bacterial Contamination in Platelets for Transfusion;"
- Final Guidance for Industry: "Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis;"
- Final Guidance for Industry: "Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture."

The document also lists guidance documents to be released regarding cellular, tissue, and gene therapy, as well as vaccines. It can be accessed at http://1.usa.gov/MvzuMj. (Source: FDA, CBER Guidance Calendar 2014, 2/5/14) ♦

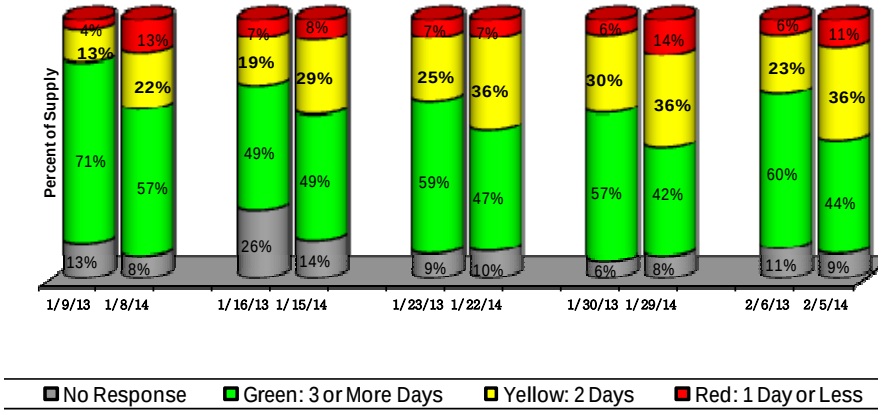
GLOBAL NEWS

The Finnish Medicines Agency, the regulatory agency in Finland, issued a new regulation changing the deferral period for men who have sex with men (MSM), announced the Finnish Red Cross Blood Services on Dec. 13. The new regulation changes the permanent MSM deferral to one of 12 months since the last sexual contact with another man. "This change is based on a careful risk analysis and will not impair the safety of blood components in Finland," said the Finnish Red Cross Blood Service press release. As blood safety tests have become more sensitive and sophisticated, several countries have shortened their MSM blood donor deferrals, including England, Canada, and Australia. The updated Finnish regulations make several other amendments, including implementation of a 12-month temporary deferral for the selling and buying of sexual services. More information can be found in the press release www.veripalvelu.fi/news/2728. (Source: Finnish Red Cross Blood Service press release, 12/13/13) ♦

Upcoming ABC Webinars – Don't Miss Out!

- **"World Blood Donor Day 2014"** – Feb. 20 at 2 p.m. ET. Contact: Abbey Nunes, anunes@americasblood.org.
- **"What Employers Need to Know About Healthcare Reform in 2014"** – Feb. 20 at 3 p.m. ET. Contact: Lolita Hampton, lhampton@americasblood.org
- **"Train the Trainer"** – Feb. 26 at 2 p.m. ET. Contact: Leslie Norwood, mnorwood@americasblood.org
- **"Understanding ABC's Strategy for Transfusion Safety and TSO Support"** – Feb. 27 at 2 p.m. ET. Contact: Leslie Norwood, mnorwood@americasblood.org

STOPLIGHT®: Status of the ABC Blood Supply, 2013 vs. 2014



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

MEMBER NEWS

The Blood Assurance Foundation (BAF) will celebrate 15 years of serving the community this year, announced Blood Assurance, headquartered in Chattanooga, Tenn. BAF was established through Blood Assurance in 1999 as a separate 501(c)3 non-profit organization, and is also based in Chattanooga. BAF serves a 46-country region that includes parts of Tennessee, Georgia, Alabama, North Carolina, and Virginia. Programs facilitated through BAF include the Crystal Green Memorial Scholarship (CGMS) fund, the Excellence in Education program (EIE), and Be the Match. CGMS presents scholarships to local high school seniors, and has awarded 154 scholarships since its inception in 1999. EIE offers grants to area schools, awarding $6,550 in 2013. BAF plans to include securing contributions for new lab equipment, bloodmobiles, and/or donor beds. BAF is accepting contributions as part of a "15 for 15" campaign in celebration of its 15th anniversary. (Source: Blood Assurance press release, 1/31/14)

Oklahoma Blood Institute (OBI) launched the state's only public umbilical cord blood center on Jan. 28. It is one of only 24 centers worldwide, said OBI in a statement. Without a local, public umbilical cord blood bank, most Oklahoma mothers had no option to donate their babies' cord blood. Now, mothers of diverse racial and ethnic backgrounds, delivering at OU Medical Center can donate their babies' umbilical cord blood. Other hospitals will be enlisted in the future. Thousands of people necessitate stem cell transplants to treat a variety of diseases of disorders, yet seven out of 10 of these people cannot find a matching donor in their family. Many donors are even unable to find a match through the national registry, and adding stem cells derived from cord blood increases the chances that patients in need will find a match. OBI emphasizes that collecting cord blood from a diverse population will help minority patients become more likely to find a matching stem cell donation. After initial processes for hospital and

A cassette of stem cells from donated cord blood is cryopreserved in liquid nitrogen tanks indefinitely until a life-saving match for a patient is needed.

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MEMBER NEWS (continued from page 14)

OBI collaboration are perfected, opportunities for partnership will expand to other state hospitals that have desired patient diversity and administrators and physicians with interest, stated OBI in the release. "As a national leader in transfusion medicine, partner with Native American tribes, and other minority groups, and an affiliate of the National Marrow Donor Program, Oklahoma Blood Institute is well positioned to make sure diverse needs are better met," said John Armitage, MD, President and CEO of OBI. "Ours is the only organization in Oklahoma where required blood processing and testing technology and expertise exists." OBI is completing the final phase of the Food and Drug Administration licensure requirements for the cord blood facility. (Source: OBI press release, 1/28/14)

COMPANY NEWS

The Food and Drug Administration on Jan. 28 cleared the granulocyte, or polymorphonuclear (PMN) cell, protocol for clinical use on the Terumo BCT Spectra Optia system. Clinicians now have the ability to perform PMN collections with greater choice and flexibility to customize each procedure, according to a Terumo BCT statement. This approval follows Terumo BCT's recent announcement that FDA cleared the red blood cell exchange protocol and therapeutic plasma exchange with single-needle access on the Spectra Optia system. The Spectra Optia system also offers nine protocols in Europe, Australia, Africa, the Middle East, and select areas of Asia. FDA clearance was received following a premarket notification file review, including US PMN clinical trial data, which showed that the Spectra Optia system is able to collect granulocytes efficiently. Clinical trials also showed that the new protocol is platelet sparing and preserves granulocyte viability throughout the collection process. The mean collection efficiency for the 32 granulocyte collections was 53.7 percent $\pm$ 6.91 percent, as compared to the COBE Spectra system's collection efficiency of 43.2 percent $\pm$ 6.23 percent. More information can be found in the press release at http://bit.ly/1b8LJtH. (Source: Terumo BCT press release, 1/28/14)

MEETINGS

March 26-28 **Mayo Clinic TransFuse 2014, Phoenix, Ariz.**

The Mayo Clinic will host a three-day multidisciplinary conference called "TransFuse 2014: Transformative-Fusion of Innovative Patient Blood Management" from March 26 to 28 at the JW Marriott Desert Ridge Resort in Phoenix, Ariz. The conference explores current state-of-the art techniques and program development to implement a blood management program in hospitals. This summit is organized by leaders in blood management from the Mayo Clinic, Hartford Hospital, Loyola University, and Cleveland Clinic, with faculty participation from all four organizations. More information and registration details can be found at www.mayo.edu/cme/anesthesiology-2014r455.

Sept. 23-24 **IPFA/BCA Global Symposium on the Future for Blood and Plasma Donations, Sacramento, Calif.**

The International Plasma Foundation Association (IPFA) and Blood Centers of America (BCA) will host the inaugural IPFA/BCA Global Symposium on the Future for Blood and Plasma Donations from Sept. 23 to 24 at the Sheraton Grand Sacramento in

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California. The symposium will identify and address the increasing global patient need for essential life saving plasma-based therapies. Hosted by BloodSource, a comprehensive range of topics will be discussed, such as clinical developments in plasma product use, quality management of plasma, plasma supply, and regulatory issues. More information and registration details can be found at http://bit.ly/1fDqJrX. ♦

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 $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. 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:

Community Chief Executive Officer (CCEO) Oakland, Calif. The American Red Cross is a visionary humanitarian organization that fulfills the needs of the American people for the safest, most reliable and cost effective blood services though voluntary donations. If you share our passion for helping people, join us in this excellent career opportunity. The American Red Cross is seeking a Community Chief Executive Officer (CCEO), Biomedical Services, for the Oakland and central California regions. The CCEO is responsible for the overall development and management of donor recruitment and collections. This role also establishes strategic direction for recruitment efforts, oversees staffing/deployment policies, remedies efficiency issues, and ensures compliance with all regulatory requirements. The CCEO will also be required to travel as needed to off-site facilities. Qualified candidates possess a bachelor's degree/equivalent experience (master's degree is preferred) and 10-plus years of experience in a multi-task operational environment with budget responsibility or a profit/loss focus. Experience in the blood industry is essential and healthcare experience is preferred. To apply, visit http://bit.ly/1kkcB8w. We offer a competitive salary as well as excellent employee benefits and working conditions. Relocation Assistance will be provided. The American Red Cross is an Equal Opportunity/Affirmative Action Employer.

Chief Executive Officer (CEO) Portland, Ore. The American Red Cross is a visionary humanitarian organization that fulfills the needs of the American people for the safest, most reliable and cost effective blood services though voluntary donations. If you share our passion for helping people, join us in this excellent career opportunity. The American Red Cross is seeking a Chief Executive Officer (CEO), Biomedical Services, for the Pacific NW and Northern California regions. The CEO leads region-wide activities to accomplish goals and objectives; develops and implements projects to increase collection efficiency/totals and to exceed hospital customer expectations; and insures that all region activities are carried out in compliance with standard operating procedures. Additionally, the CEO monitors budgets, forecasts, and operational results. Qualified candidates possess a bachelor's degree/equivalent experience (master's degree is preferred) and 10-plus years of experience in a multi-task operational environment with budget responsibility or a profit/loss focus. Experience working in the blood industry is critical; healthcare experience is a plus. To apply, visit: http://bit.ly/1iy8eYM. We offer a competitive salary as well as excellent employee benefits and working conditions. Relocation assistance will be offered for this position. The American Red Cross is an Equal Opportunity/Affirmative Action Employer

IRL Advanced Clinical Lab Specialist (3rd Shift). Blood Systems Laboratories is searching for an experienced lab professional to join its immunohematology reference lab in sunny Phoenix, Ariz.! The busy IRL team performs complex antibody identification, red cell and platelet molecular genotyping and platelet testing for hospitals throughout the country. Work schedule: Wednesday – Saturday (2130-0800; includes 13 percent shift differential). Requires: Bachelor's degree; must satisfy CLIA requirements for High Complexity Testing; California testing requirements must be met within one year; certification as a Medical Technologist or Blood Banking Technologist (BB) by a recognized certifying

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POSITIONS (continued from page 16)

agency; three years clinical laboratory testing experience; one year of transfusion service experience. For consideration, please submit resume via e-mail by **02/14/2014** to: jobs@bloodsystems.org ATTN: HR/2014/10. Blood Systems offers a competitive benefits package, include: affordable medical/dental/vision coverage, education assistance, matched 401(k) and much more! Pre-employment drug testing is required. For more information, please visit our website at: www.bloodsystems.org. EOE M/F/D/V. *Find the Hero in You. Donate blood three times a year!*

Reference Laboratory Technologist. Community Blood Services has an exciting opportunity in our Montvale, N.J. facility for a FT Reference Laboratory Technologist performing antibody testing, antigen typing, and providing consultation to hospital staff as needed. The schedule is Monday-Friday 12 p.m. to 8 p.m., including on-call rotation for nights, weekends, and holidays. Candidates are encouraged who possess MT/MLS certification with ASCP or equivalent. SBB a plus, but not required. Ideally, candidates will have two years of blood banking experience in the past five years. EOE. Interested candidates may visit: https://home.eease.com/recruit/?id=8101851

Medical Technologist – Technical Services. Community Blood Services has an exciting opportunity in our Montvale, N.J. facility for a FT Medical Technologist in our Technical Services Department performing routine donor testing and utilizing automated lab instruments or equipment. Medical Technologist degree required. NYS license required. ASCP preferred. One to two years experience in blood banking or chemistry preferred. The schedule is 3 p.m. to 11 p.m., four weekdays and one weekend day, including on-call rotation for nights, weekends, and holidays. EOE. Interested candidates may visit: https://home.eease.com/recruit/?id=7884661

Immunohematology Reference Laboratory Supervisor IRL001. QualTex Laboratories a subsidiary of BioBridge Global seeks a skilled individual for the Immunohematology Reference Laboratory at our San Antonio, TX location. The ideal candidate will have experience supervising staff on compatibility testing, and complex secondary procedures, such as antibody identification, antibody titration and RBC genotyping/phenotyping. Must be able to prioritize, reprioritize, and handle deadlines and emergency requests. QualTex Laboratories is the largest, independent non-profit testing laboratory in the U.S. for blood and plasma products. Qualifications include five years lab, recent Transfusion Lab/Blood Bank experience. Bachelor's degree in CLS or Applied Science. Must be MT/CLS or MLS (ASCP) or equivalent and prior Blood Bank experience preferred. For further information, visit our website www.qualtexlabs.org. Please include job code from website on all submissions. We EEO-AA employer M/F/D/V and maintain a Tobacco/Drug-Free workplace. Salary will commensurate w/your experience and education $27.12 - $40.67.

Laboratory Technologist. QualTex Laboratories a subsidiary of BioBridge Global seeks several skilled individuals for the Immunohematology Reference Laboratories at our Norcross, Ga. & San Antonio, Texas locations. Duties include compatibility testing receiving/processing orders and complex secondary procedures, such as antibody identification, antibody titration, and RBC genotyping/phenotyping. Must be able to prioritize, reprioritize, and handle deadlines and emergency requests. QualTex Laboratories is the largest, independent non-profit testing laboratory in the U.S. for blood and plasma products. Qualifications required include, one year Blood Bank, Bachelor's of Science degree, national certification such as MT/CLS or MLS (ASCP) or equivalent and prior BB experience. For further information, visit our website www.qualtexlabs.org. Please include job code from website on all submissions.