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From the Director's Desk: Is it Time to Take the Foot Off the Pedal?

Johnson Haynes, Jr. MD, Director
University of South Alabama Comprehensive Sickle Cell Center

While the answer to this question is no, there is some good news. The number of COVID–19 cases are dropping in every state along with the number of hospitalizations and deaths. Also of note is that the share of regional daily tests that are coming back positive has declined even more than the number of cases. This decline is explained by behavior that fosters social distancing, mask-wearing, warmer weather, partial immunity and the vaccines that are now available to fight this virus.

Since the World Health Organization (WHO) deemed the COVID–19 outbreak a public health emergency in January 2020 and a pandemic in March 2020, there have been 28,399,281 cases identified in the U.S. The CDC estimates 15 to 30 percent of Americans have now been infected with COVID–19 and individuals recovering from COVID-19 typically develop lasting immunological protection for many months. This finding is significant because COVID-19 needs an individual, or host, not previously infected to survive and grow and now it has fewer hosts in which it can survive. The limited number of available hosts contributes in part to the existing "partial immunity" seen, which should not be confused with "herd Immunity" (see below).

To date there are two synthetic-mRNA vaccines approved for emergency use authorization (EAU), Pfizer-BioNTech and Moderna. Both vaccines are highly effective at preventing infection, and at reducing symptomatic illness, long-term hospitalization and death. On February 27, 2021, the application for EAU of the Johnson & Johnson vaccine, which is a double-stranded DNA vaccine against COVID-19, was approved by the Federal Drug Administration. It is the first vaccine that requires only one dose and does not require ultra-cold temperatures as required by the Pfizer-BioNTech vaccine.

All three vaccines work by training the body's immune systems to make antibodies, against the spike proteins located on the surface of the coronavirus which then kills the virus. The goal of having effective

vaccines is to achieve indirect protection with vaccination and enhanced antibody production against COVID-19 rather than antibody production from previous infections which contributes to unnecessary illness and death. Ultimately when a substantial proportion of the population has been vaccinated, "herd immunity" is achieved. Herd immunity limits the overall amount of COVID-19 able to spread in the whole population and breaks any chains of transmission. What the actual proportion of the population that must be vaccinated against COVID-19 to begin inducing "herd immunity" is not known.

Putting the impact of COVID-19 deaths in perspective, COVID-19 deaths have surpassed the number of Americans killed during the Civil War (498,332); World War I and World War II (116,516 and 405,399, respectively); and all American wars since 1945 combined.

As the U.S. surpasses 500,000 deaths due to COVID-19, certain facts still remain true, particularly for the sickle cell community:

1. Sickle cell disease (SCD) is most common in Black/African American and Latinx communities,
2. Death rates in Black/African American and Latinx communities due to COVID-19 infection exceeds that seen in white communities,
3. SCD is clearly a high-risk population for COVID-19 infection,
4. There is a significant proportion of individuals with SCD that are hesitant to take a vaccine against COVID-19 as is also seen in the general population.

The more common reasons for vaccine hesitancy given in the adult outpatient sickle cell clinic are, "the vaccine was made too fast" and "I don't trust it." To address this, what can be said is that the mRNA technology is relatively new but this platform for vaccine development has been studied for more than ten years.

More importantly, mRNA vaccines do not contain a live virus, posing no risk of causing disease in the vaccinated person. In fact, mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices and the Federal Drug Administration assures that all steps were taken to document safety and efficacy of the mRNA vaccines. For more information, please go to CDC's COVID-19 mRNA vaccine webpage.

The issues of trust are harder to address. In Black and Brown communities', implicit and explicit bias have plagued the U.S. delivery of health care for centuries. This has been compounded by the lack of diversity, equity and inclusion in health care. According to the CDC, "health equity is achieved when every person has the opportunity to attain his or her full health potential," and no one is "disadvantaged from achieving this potential because of social position or other socially determined circumstances." While this article cannot effectively address the issue of trust or mistrust, a more diverse and inclusive health care system is essential to building trust with those who have been excluded for so long. Building a health care system that is diverse, equitable and inclusive is essential to change the paradigm of mistrust to trust.

The Atlantic summarized best where we are today in the mist of the COVID-19 pandemic: "The lesson is not to let today's good news become tomorrow's bad news, again. Until much of the population is vaccinated, don't interpret the decline in cases as a green light to resume your pre-pandemic behavior."

It's not yet time to take our foot off the pedal. Vaccination against COVID-19 is essential in the fight to stop the havoc brought to bear by COVID-19.

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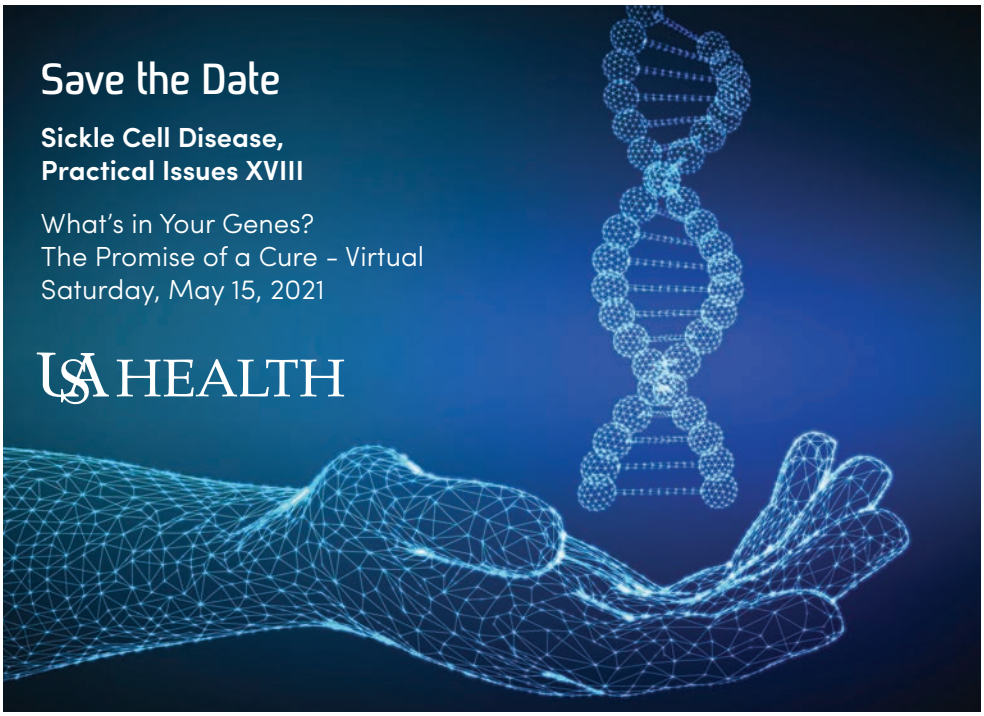
Sickle Cell Disease Practical Issues XVII: What's in Your Genes? The Promise of a Cure

On Saturday May 15, 2021 the USA Health Comprehensive Sickle Cell Center will host its 18th Annual Regional Sickle Cell Conference in Mobile, AL. This year's conference will be virtual but none-the-less dynamic. The conference will feature national and local experts addressing topics ranging from recent advances in the medical treatment of sickle cell disease to bone marrow/stem cell transplants, gene therapy and gene editing. The meeting will be highlighted by the testimonial of a client with sickle cell disease who has been treated using gene therapy. To conclude, the impact of COVID-19 and unconscious bias in the sickle cell community will be addressed. For more information on the conference visit www.southalabama.edu/colleges/com/research/sicklecell.html., email: cme@southalabama.edu, or call 251-470-5893. Register online at: https://www.usa-cme.com.



What is all the Chatter about Vitamin D?

Ardie Pack-Mabien, Ph.D., FNP-BC

Vitamin D is a fat-soluble vitamin naturally found in dairy products, orange juice, and certain foods such as tuna, salmon, cereal, and eggs. However, ultraviolent rays from the sun is the primary source of Vitamin D. At adequate levels, Vitamin D plays a vital role in the absorption of calcium and bone development, and has a potential benefit in relation to our adaptive or acquired immunity. There is some evidence that Vitamin D deficiency may be associated with an increase of diabetes, cardiovascular disease, pregnancy complications, auto-immune disorders, and allergies (Hossein-nezhad, A., & Holick, M., 2013). Additionally, there is some evidence that Vitamin D deficiency may be associated with an increase in inflammatory markers, risk for pneumonia, viral upper respiratory tract infections, and thrombotic episodes frequently seen with coronavirus 2019 infection (COVID-19) (Weir et al., 2020). However, there is *insufficient evidence* for and against the use of Vitamin D supplement as a protection against and treatment of COVID-19 according to the National Institutes of Health and the World Health Organization (National Institute of Health,

2020). There are ongoing observational studies evaluating the immunological role of Vitamin D against COVID-19 infection or decrease the severity of COVID-19 illness (National Institute of Health, 2020).

Vitamin D deficiency is defined as a serum 25-hydroxyvitamin D (25OH) level of 20ng/ml or less, Vitamin D insufficiency as 21 to 29ng/ml, and Vitamin sufficiency as 30ng/ml or greater for adults and children (Hossein-nezhad, A., & Holick, M., 2013). Factors associated with Vitamin D deficiency include race, poor health, obesity with a body mass index (BMI) > 30, a total cholesterol >200mg/dl, diabetes, smoking, lack of dairy intake, and age > 65 years (Parva et al., 2018). In regards to these associated risk factors, researchers found the prevalence of Vitamin D deficiency is 39.92% in the general US population (Parva et al., 2018). Amongst individuals with Vitamin D deficiency in the general population, the highest prevalence was found among African Americans at 39.3% followed by Hispanics and Mexican Americans at 21.82% compared to non-Hispanic Whites at 19.03%. Researchers believe this increase prevalence of Vitamin D deficiency among individuals of color is related to the level of melanin (pigmentation) in the skin, which has been found to interfere in the production and slow the synthesis (breakdown) of Vitamin D (Hossein-nezhad, A. & Holick, M., 2013; Parva et al., 2018). Among Vitamin D deficient individuals, Parva et al. (2018) found 24.03 % reported poor or fair health status.

In regards to sickle cell disease (SCD), Nolan et al., (2015) found the prevalence of Vitamin D deficiency among individuals with SCD range between 56% and 96% when compared to the general population (Han et al., 2018; Nolan et al., 2015). Research studies have shown individuals with HbSS (homozygous sickle cell anemia) and HbS β0-Thalassemia have the highest prevalence of Vitamin D deficiency (Han et al., 2018; Nolan et al., 2015). Additionally, there is some evidence in the literature that Vitamin D deficiency may be associated with a sickle cell vaso-occlusive pain episode requiring emergency room and/or hospital admission for pain management (Brown et al., 2020; Hood et al., 2020). This finding was plausibly associated with an increased expression of a protein involved in neuronal pain pathways (Han et al., 2018).

Given all the chatter about Vitamin D, here are a few tips!

1. Speak with your health care provider about your Vitamin D level status and risk factors for Vitamin D deficiency.
2. Consume foods that naturally contain and/or fortified with Vitamin D such as dairy products, juices, margarines, eggs, cereal, mushroom, oyster, tuna, and salmon. *(Fortified means Vitamin D added to the food).*
3. Check and read all food labels.
4. Speak with your health care provider before beginning Vitamin D supplement to determine the correct recommended daily allowance that is age appropriate.
5. Discuss with your health care provider to determine how much time you should spend outdoors in the sunlight in order to avoid excessive exposure and risk of skin cancer.
6. Avoid tanning beds.
7. Take all medications and supplements as directed by your health care provider.
8. Keep all follow-up appointments with your health care provider as directed.
9. Maintain a healthy weight and dietary intake. If recommended by your health care provider lose weight with exercise and healthy living habits.

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The Importance of Daily Medication Adherence: The Health Care Provider's Role

Jessica King, MSN, FNP-BC

In the September 2020 edition of Sickle Cell Today, the article entitled, "The Importance of daily medication compliance," focused on the importance of patient compliance in sickle cell disease (SCD). Now, this article focuses on the healthcare provider's role in patient medication adherence.

Often the terms compliance and adherence are used synonymously. However, the term compliance refers to how the patient's behavior aligns with the health care provider's advice. The term adherence differs from compliance by signifying that both the patient and health care provider work together as a team to improve health by aligning the patient's lifestyle, values, and preferences for health care with the medical advice of the health care provider (Bosworth, et al., 2016).

Despite the many reasons for medication non-adherence – whether it is intentionally refusing to take medication or nonintentional due to cost, lack of understanding, side effects, and/or forgetfulness – it places individuals living with a chronic disease at risk for health complications. In order to improve daily medication adherence, the healthcare provider should focus on the steps they can take in order to facilitate improved medication adherence (Bosworth, et al., 2016).

Below I have listed some tips to improve medication adherence:

1.) Incorporate a health care provider and patient team approach when prescribing medications.

2.) Simplify medication regimens as much as possible by either decreasing the frequency of administration, reducing the number of medications when possible or if applicable, replace with combination products.

3.) Explain key information when prescribing a medication such as the purpose, potential side effects, health benefits of daily medication adherence, and need for follow up with drug monitoring labs, etc.

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Walter-Henderson Higher Education Achievement Award Available to Graduating Seniors with Sickle Cell Disease

Ardie Pack-Mabien, Ph.D., FNP-BC

The financial obligation required to further your education can be overwhelming. To help ease this financial burden, Mr. Sylvester Mabien and Ardie Pack-Mabien, PhD, FNP-BC have established the Watson-Henderson Higher Education Achievement Award. The award, which totals $500 per person, is open to young adults with sickle cell disease who are participants of the University of South Alabama Sickle Cell Center Pediatric to Adult Care Transition Program (PACT) and graduating high school in May 2022.

To qualify for the Watson-Henderson Higher Education Achievement Award, applicants must meet the following criteria at least one year prior to transfer to adult care:

• Visit the Learning Resource and Development Center and attend at least one educational session on sickle cell disease and the transition process with the transition coordinators at the University of South Alabama Comprehensive Sickle Cell Center.

• Attend at least two USA Sickle Cell Center adult care open house events, independent of a parent on at least one occasion and accompanied by a family caregiver on at least one occasion.

• Attend at least two Money Matter Sessions offered at the USA Learning Resource and Development Center.

• Attend at least two Human Growth and Development Sessions at the USA Learning Resource and Development Center.

• Participate in at least two self-care and self-management activities at the USA Learning Resource and Development Center.

• Complete the Hope and Destiny Jr. Transition Workbook and obtain documentation confirming the attendance of programs sponsored by the PACT program.

• Provide written documentation of acceptance and enrollment in a career development program, vocational/trade school, community college, or a four- year university.

• Attend the award ceremony in professional attire.

• Consent to photography and/or video used on social media by USA Health and the Comprehensive Sickle Cell Center.

For those clients who are a freshman or sophomore in high school, the time is now to start working on meeting the criteria to earn dollars to aid you in your quest for a higher education.

If you are a junior in high school and will be graduating May 2022 but have not meet the criteria for the Watson-Henderson Higher Education Achievement Award, you still have time to meet the criteria. However, May 2020 will be here before you know it and you don't want to let this great opportunity to earn dollars for your higher education to slip through your hands.

To get assistance with meeting the criteria for the Watson-Henderson Higher Education Achievement Award of $500.00, the applicant and parent/caregiver should contact Ms. T'Shemika Perryman, RN, at (251) 470-5875 or Ms. Cimone Smith at (251) 470-7714 to schedule an in-person appointment at the USA Learning Resource and Development Center or zoom visit to establish a plan of action.

Remember, a higher education can yield knowledge, success, and power!

Sickle Cell Disease Associations Assists Clients with Needs

Aleida Q. Johnson, Interim Executive Director
Sickle Cell Disease Association of America – Mobile Chapter, Inc.

Economic hardship and the looming prediction of a resurgence of the coronavirus casted a dim light on the 2020 holiday season. Despite the bleak conditions surrounding the pandemic, the Sickle Cell Disease Association of America – Mobile Chapter, Inc. (SCDAA-MC) worked to help bring some joy into the lives of many of its clients during the holiday season. With the help of organizations throughout the city, SCDAA-MC was able to provide food, toys, and even cookies for Santa on the night before Christmas to families of individuals living with sickle cell disease.

The pandemic was, however, responsible for one giveaway during the holiday season. The association's social worker, Aisha Davis-Williams, offered, "During these times, one of our clients' greatest needs is to be protected against transmission of the COVID virus." As a sub-recipient of a HRSA grant from the national office of the Sickle Cell Disease Association of America, SCDAA-MC was able to provide clients with what they called a Pandemic Safety Kit.

The safety kit included bleach, hand soap, individual size bottles of hand sanitizer, masks, disinfecting wipes, and Lysol

disinfectant Spray. "By supplying the clients with protective aids and sanitation cleansers, that are now so expensive, it will help those already facing economic hardships", Davis-Williams added.

SCDAA-MC continues, even after the holiday season, to provide clients with those safety aids. It is also providing additional support to its clients to help with needed medical care. Individuals living with sickle cell disease in Mobile, Baldwin, Clarke, Choctaw, Connecuh, Covington, Escambia, Monroe, and Washington counties are encouraged to reach out to the association to find out what assistance is available. The contact phone number is (251) 432-0301.

Pediatric to Adult Care Transition Program: Transferring to Adult Care Services

T'Shemika Perryman, RN-PACT Coordinator
Cimone Smith, Transition Coordinator, Study Facilitator

The Pediatric to Adult Care Transition Program (PACT) was started in 2012 to bridge the gap between the pediatric and adult healthcare systems for sickle cell disease participants between the ages of 13 and 21. The goal of PACT is not only to educate participants, but to also ensure they are prepared to transfer and navigate through the adult healthcare system with as few obstacles as possible. Transition encompasses disease education, feedback, goal setting, self-care, and self-advocacy. Transfer is the process of leaving pediatric healthcare services to establish and maintain care with adult healthcare services.

The following PACT participants' tasks are imperative for a successful transition:

1. Keep all scheduled appointments, especially during the last year on pediatric service,
2. Identify a primary care provider PCP prior to transfer. The adult healthcare sickle cell providers are not their PCP,
3. Obtain a referral from your PCP (if insurance requires a referral) prior to the first adult clinic visit. Referrals should be faxed to: 251-470-5895 ATTN. Ms. T'Shemika Perryman,
4. Maintain communication with transition coordinators. Transition coordinators meet with patients during visits in the pediatric sickle cell clinic,
5. Contact the transition coordinators if any pediatric sickle cell visits are missed six months prior to your 19th birthday.

The following provider-oriented (Physician, Nurse Practitioner, Sickle Cell Clinic Nurse, and Transition Coordinator) tasks are equally imperative for a successful transition:

1. Provide a synopsis of the participants' medical regimen and plan of care to ensure continuity of care
2. In preparation for transfer, inform patients that are seen at USS Hope contact the adult sickle cell nurse, T'Shemika Perryman, at 251-470-5893 or 251 470-5875 6 months prior to their 19th birthday,
3. Ensure all participants schedule an appointment with an adult healthcare provider within 30 days or less of their 19th birthday.

USA Pediatric Sickle Cell Center's Experience with Crizanlizumab (Adakveo) infusion therapy

Jennifer G. Williams, CRNP
Preethi Marri, MD,
Chibuzo Ilonze, MD
Hamayun Imran MD

Sickle cell disease (SCD) is a genetic disorder that results in the formation of sickled red blood cells (RBCs). It affects approximately 100,000 Americans and millions of people worldwide. SCD is characterized RBC sickling, blockage of blood flow, RBC destruction, chronic anemia, inflammation, pain, and frequent hospitalizations. Recurrent episodes of this process can lead to end-organ injury, reduced quality of life, and premature death. This eventually places a significant burden on patients and their families. White blood cell migration towards the site of sickle related blood vessel injury and resultant inflammation is considered to be the corner stone of this complex process causing pain.

The development of novel treatments in SCD is an area of active research. One such agent, Crizanlizumab (Adakveo®) has been shown to significantly reduce inflammation in well controlled clinical trials.1 Crizanlizumab is an antibody molecule made in the laboratory to block P selectin protein found on the surface of the cells that line the inner walls of blood vessels. This blockade prevents the white blood cells response to inflammation and helps maintain normal blood flow therefore reducing pain. It is given as an intravenous infusion over 30 minutes to 2 hours and, after two initial biweekly doses, the treatment is administered once per month. Crizanlizumab was approved by the U.S. Food and Drug Administration (FDA) in November 2019 for use in sickle cell patients 16 years and older, after the SUSTAIN clinical trial showed a 45% reduction in frequency of pain episodes, as well as increased time intervals between episodes.2

The University of South Alabama (USA) Pediatric Sickle cell program started administering Crizanlizumab in April of 2020, at the USA Children's and Women's (USACW) Pediatric Infusion Center. To date five patients are currently being treated with Crizanlizumab infusions (3 HbSS and 2 HbSC genotype), one of which recently transitioned to adult care and continues the therapy. All of them have been on Hydroxyurea with variable compliance. All were initiated on Crizanlizumab infusions due to having frequent pain episodes, requiring increasing doses of opioids, and frequent clinic visits and/or emergency room (ER) visits or hospitalizations. At the time, two of three patients with HbSS were receiving red blood cell (RBC) transfusion therapy for intractable pain. Both patients were able to discontinue RBC transfusions after 6-8 weeks of Crizanlizumab therapy. One had a reduction in ER visits and hospitalizations overall, as well as a reduced pain prescription requirement. The other patient continued to have frequent ER visits and hospitalizations for pain and/or severe acute chest syndrome. We, therefore had to resume RBC exchange transfusions in addition to continuing monthly Crizanlizumab infusions. One of the three remaining patients has continued to require the same amount of opioids with no decrease in ER visits or hospitalizations, while the other 2 patients have reported reduced pain and opioid requirements and no ER visits.

These are encouraging results considering the small numbers and preexisting patient related factors. We hope to continue Crizanlizumab infusions as a therapy for eligible sickle cell patients.

In summary, all five patients have reported reduced pain severity especially in the first 2-3 weeks of treatment. As Crizanlizumab becomes more available to our patients, it is possible that we will find more beneficial effects. An ongoing clinical trial elsewhere using Crizanlizumab in children with SCD ages 6 months and above3 may also provide more clinical information in the future.

Lastly, USA is in the process of opening a clinical trial for sickle cell patients 12 years and older, with Inclacumab in the summer of 2021. Inclacumab is another antibody molecule that is quite similar to Crizanlizumab and works in the same manner with hopes to have more effective pain relief, as well as less frequent infusions. Inclacumab will be given every 12-weeks, so stay tuned to hear more about this possible new treatment option that we could offer to our children with SCD!

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