Pharmacy News

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Newark, New Jersey

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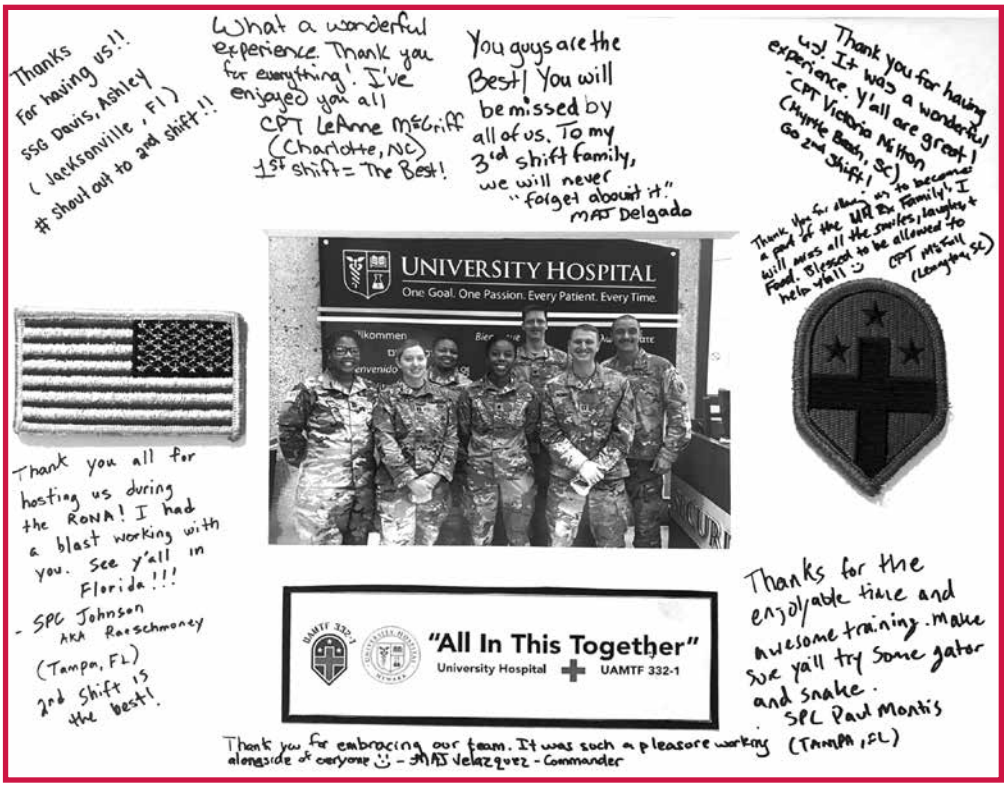
Special Points of Interest:

- A Thank You Note for the US Army from the Pharmacy Department
- P&T Update-Formulary Additions/ Deletions
- Policy and Procedure Update
- Gastrointestinal Health and Function
- Hemophilia A
- Six-Year Follow-up of a Trial of Antenatal Vitamin D for Asthma Reduction
- Welcome to our New Pharmacist

A Thank You Note for the US Army from the Pharmacy Department



The University Hospital welcomed approximately eighty-five healthcare workers from the Army's Urban Augmentation Medical Task Forces in mid-April 2020, to meet the demands of high patient volumes during the peak of the COVID pandemic and strained staff resources, courtesy to the efforts of the State of New Jersey.

The University Hospital leadership generously allocated seven of the US army personnel including four pharmacists and three technicians to the Pharmacy Department to assist with the heightened needs of reviewing/verifying the provider orders, compounding the critical medications, dispensing, delivering medications promptly to the patient care areas and various other functions as necessary. They worked diligently and with dedication alongside with our pharmacy staff to rise to the challenge and deliver the best possible patient care. They lent support to us through mid-May 2020, always displaying initiative, team participation and an eagerness to help.

A Thank You Note for the US Army from the Pharmacy Department

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As a token of heartfelt appreciation, the Pharmacy Department hosted a farewell luncheon, to honor these heroes who not only prevail to safeguard the nation but always could be counted upon to fight the real life predicaments. The Pharmacy Department remains truly indebted to them for their devotion and commitment, and wishes them the best in their endeavors.

Respectfully submitted by,

Nishat Faruqui, R. Ph., Pharm. D., BCPS

Clinical Pharmacy Specialist

P&T Update

Formulary Additions

- **Entecavir (Baraclude)**
  Entecavir is indicated for the treatment of Hepatitis B (HBV) infection and prophylaxis for HBV reinfection in post liver transplant patients. Formulary addition of Entecavir (Baraclude) – Approved

Formulary Deletions

Bacitracin IV

- FDA requests withdrawal of bacitracin for injection from market. FDA is aware that it is commonly used but concerned about safety, such as anaphylaxis and neurotoxicity. Motion approved for withdrawal of Bacitracin IV and gradual phase out of practice

Policies & Procedures/Floorstocks

- 707-1400-101 Patient Care Event Reporting: ADR & ME
  Retired. Elements were incorporated into the comprehensive administrative Policy – Policy removal approved
- 707-400-108 Resuscitation equipment check & exchange policy
  Policy modified to reflect the revisions. The revisions have been approved by the Drug Equipment Subcommittee. – Approved
- Post-exposure prophylaxis (PEP) for sexual assault
  This new guideline policy was presented to address continual care needed for sexual assault post exposure prophylaxis – Approved
- 707-900-102 University Hospital Antimicrobial Stewardship Program Policy – Approved
- 707-600-176 Order Entry Verification and Provision of Restricted Anti-Infectives – Approved
- Standard Concentrations for Intravenous (IV) Infusion Medications (Adult and Pediatrics) - Approved
- Warming of IV/irrigation solutions and Contrast Media: The policy is updated to reflect the current practices on warming solutions. – Approved
- Refrigeration Units and Temperature Monitoring, Validation, and Documentation- The policy is updated to reflect that allergens must be stored on a different shelf from the medications. – Approved
- Multi-Dose/Single-Dose Injectable Vials/ Expiration dating of medications - Discussed that opened topicals, creams, and eye drops that are returned to the pharmacy - will be discarded. – Approved
- Low dose IVPB Ketamine for the treatment of Pain in ED - To avoid opioid use – Approved

- ADULT Potassium chloride or phosphate replacement guideline - Guideline states when supplementation requires ICU monitoring, when repeat labs are necessary, and when labs samples must be drawn. – Approved
- P&T Committee was presented with UH Antibiotic Stewardship Programs (ASP) Assessment of CDC Core Elements of Hospital Antibiotic Stewardship Programs: CY 2020 – Approved
- Review of UH CY 2019 Antibiograms - P&T Committee was presented with draft of University Hospital Calendar Year 2019 Antibiograms (Antibiotic Susceptibility Reports) – Approved

Anti-Infective Subcommittee

- UH Antimicrobial Stewardship Program (ASP) Strategic Action Plan
- COO update Antimicrobial Stewardship
- In calendar year 2019, we successfully sustained coordinated interventions to use antimicrobials responsibly. Activities included audit and feedback for antimicrobial prescriptions. In 2019, 31,328 patients' charts were reviewed by Antimicrobial Stewardship Program (ASP) team.
- Update of the yearly antibiotic susceptibility report (antibiogram) which includes 5 different location/site specific reports.
- The yearly anti-infective expenditures in 2019 was $3,132,655.02. Antibiograms updated (8 antibiograms available), including an antifungal antibiogram added.
- Annual Review of Updates to ASP-related Guidelines - P&T Committee reviewed the following guidelines, for annual continuity and re-evaluation - approved
  - University Hospital Adult Anti-Infective Dosing Adjustment Guideline
  - University Hospital Adult Antiretroviral Dosing Adjustment Guideline
  - University Hospital Adult Clostridioides difficile ["C. diff"] Infection (CDI) Guideline
  - University Hospital Adult Anti-Infective Dosing Adjustment Guideline
  - University Hospital Adult Antiretroviral Dosing Adjustment Guideline

Gastrointestinal Health and Function

The gastrointestinal tract is a group of hollow organs joining the mouth to the anus. It is responsible for numerous essential processes including the mixing and squeezing of food in the stomach, the digestion of proteins, fats, carbohydrates, vitamins, and minerals, and the protection of the body from harmful microorganisms. Given the complexity of this intricate system, it is no surprise that it may be affected by many different variables. Diet, lifestyle factors, and pharmacologic therapy can all play a role in how the gastrointestinal tract functions.

Different lifestyle factors may impact gastrointestinal health. For example, stress may play a role in gastrointestinal issues. Through the gut-brain axis, stress can impact colonic motor activity by altering the composition of the gut microbiome. For example, stress may decrease levels of Lactobacillus, a beneficial bacterial species. According to a research group led by GI expert Dr. Lin Chang at the University of California, Los Angeles, it has been found that people that have early life stress have a greater likelihood of developing Irritable Bowel Syndrome (IBS). However, the risk of IBS decreased when these individuals confided to someone about their stress. This suggests that managing stress in a healthy way is an important component in maintaining gastrointestinal health.

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Gastrointestinal Health and Function

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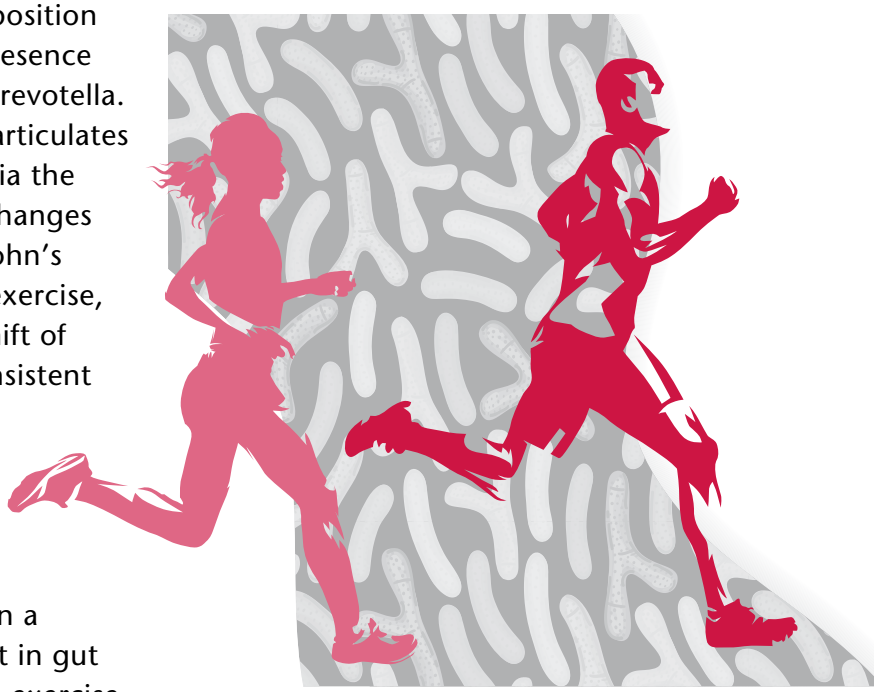
Another lifestyle factor that may impact gastrointestinal health is the choice of dietary intake. Many processed foods utilize emulsifiers as a way of improving textures and extending shelf-life. However, according to research conducted by Dr. Andrew Gewirtz at Georgia State University, emulsifiers and other food additives may have negative impacts on gut microbiota and promote inflammatory diseases. Consequently, the consumption of less processed foods may be of benefit to gastrointestinal health.

Smoking and a lack of exercise can also have significant effects on the gastrointestinal tract. Particularly, these lifestyle choices may impact the large bowel and are risk factors for colorectal cancer. Smoking also influences the composition of gut microbiota and can increase the presence of bacterial species, such as Bacteroides-Prevotella. These changes occur as air-borne toxic particulates are capable of reaching the large bowel via the lung's mucociliary clearance. With such changes to the local flora, an increased risk for Crohn's Disease develops. In regards to a lack of exercise, inadequate exercise is influential in the shift of the gut microbiome to a composition consistent with microbial populations found in obesity. For instance, in human and animal models with obesity, increases in Firmicutes and Bacteroides bacteria may be observed which may contribute to adiposity and greater energy harvest. In a study conducted by Clarke et al., this shift in gut microbiome composition as a response to exercise was demonstrated in professional athletes. Overall, while the aforementioned evidence provides a promising start in regards to showing a connection between these lifestyle factors and gastrointestinal health, more data is needed to produce a more definitive correlation.

Diet plays an important role regarding the gut microbiome and decides whether one helps or harms the digestive system. Certain diets can reduce parasitism by altering the gut microbiome. Dietary factors such as prebiotics, probiotics, and increasing fiber intake are just some examples of how a person can help the gut microbiome. Prebiotics and probiotics maintain a balance between the nearly 1,000 different species of bacteria in the gut. Prebiotics assist the microbes already in the gut grow by giving them nutrients such as those found in asparagus, garlic, and other supplements. They are specialized plant fibers and act like fertilizers by stimulating the growth of healthy bacteria in the gut. Since prebiotics



contain complex carbohydrates that cannot be digested by the body, they are passed through the digestive system to become food for the bacteria or other microbes.

Probiotics are live microbes that are added directly to the gastrointestinal system and are similar to the flora found in the gut. A single

dose can contain a particular strain of helpful microbes or a blend of microbes. Probiotics can either be taken as a dietary supplement or be found in foods such as yogurt and kombucha. In these products, milk is fermented with different bacteria and it is left in the final product. Probiotics have been shown to be helpful in preventing diarrheas associated with antibiotics and improving symptoms of IBS, though more research is needed.

Nevertheless, when selecting a probiotic, always select a probiotic based on the condition and by researching the condition wished to be treated.

Fiber also plays a role in gastrointestinal health and function. While fiber is very important for constipation, people that do not eat a lot of fiber have to gradually increase fiber in the diet. Otherwise, problems such as bloating and gas may occur. An individual should eat at least 20-30 grams of fiber every day, spread out throughout the day, to prevent or help relieve constipation. The best way to improve fiber intake is by starting with small servings of fiber and gradually increasing them to avoid bloating, gas, or discomfort. An example of how to increase fiber in a diet is by eating a variety of fruits and vegetables at every meal because they will provide a healthy mix of different fibers and nutrients in the diet and therefore help the digestive tract. There are some fiber-rich foods, called FODMAP foods, that are difficult to digest and should be avoided in individuals with IBS. Examples of FODMAP foods are certain dairy products and wheat and rye products. There are even certain fruits and vegetables that are considered difficult to digest such as apples and cauliflower. When a person has IBS, he or she should limit consumption of FODMAP fruits and vegetables. Alternatives include blueberries and bean sprouts.

One specific diet that has gained popularity in recent years is the Mediterranean diet. The Mediterranean diet consists of many fruits, vegetables, bread and other grains, potatoes, beans, nuts, and seeds. It utilizes olive oil as its primary source of fat and limits dairy, eggs, fish, and poultry to low or moderate amounts. In a clinical trial examining the effect of diet on disease activity and symptoms in patients with ulcerative colitis, it was ascertained that the Mediterranean diet pattern demonstrates beneficial effects on intestinal bacteria and the immune system in diseases such as cancer and diabetes. This study utilized a randomized parallel treatment design and monitored clinical disease activity, gut microbiota, and fecal biomarkers. Furthermore, upon review, the American Heart Association found the Meditteranean diet to be a healthy dietary pattern. Ultimately, while more studies are required to confirm definitive benefits, this diet pattern seems to provide a protective effect in regards to gastrointestinal health.

Gastrointestinal health is important because many of these diets and practices can be used to treat symptoms of conditions of the digestive tract. However, this may not always be the case as some symptoms can be associated with more severe conditions and GI diseases. These conditions can range from acute to chronic conditions that may affect patients in the long run. It is important to be able to recognize symptoms related to gastrointestinal conditions because patients may ignore important signs and seek treatment via diet alterations and lifestyle modifications rather than seeking drug therapy.

Irritable bowel syndrome (IBS) and Irritable bowel disease (IBD) are two conditions affecting the gut that have two different treatment modalities. IBS is easily managed through over-the-counter products, a change in diet,

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Gastrointestinal Health and Function

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and lifestyle modifications. The other, IBD, is managed much more thoroughly with step by step pharmacotherapeutic management. IBD is an umbrella term for two chronic conditions, Crohn's Disease and Ulcerative Colitis, with similar mechanisms of action where the body has prolonged inflammation that results in damage to the GI tract. Conversely, IBS is a disorder that causes uncomfortable GI symptoms such as abdominal pain, diarrhea, or constipation. IBD is treated with different pharmacotherapeutic options, including aminosalicylates, steroids, immunosuppressants, and biologics. It is important to differentiate symptoms between a person experiencing discomfort and needing OTC medications versus a person that needs to seek help from a physician. A more common GI condition is gastroesophageal reflux disease (GERD) which can be controlled with a combination of both diet and lifestyle modifications in addition to pharmacotherapy. GERD may be treated with different classes of medications such as proton pump inhibitors, histamine 2 receptor antagonists, or antacids along with minimizing a diet rich in fatty foods and spices, ensuring proper sleep technique, and maintaining a healthy food schedule. Gastrointestinal infections are another major acute condition that can cause patients to experience digestive symptoms. In this case, pharmacotherapy is the preferred treatment with appropriate antibiotics to control the infection or supportive care in some situations.

Focus in gastrointestinal health is rising and more studies are being conducted regarding different lifestyle changes and diets that may play a significant role in overall health. As of now, there is not enough scientifically backed evidence to support that diet and lifestyle modifications can be used to prevent serious GI conditions. Gastrointestinal health is a complex topic and is influenced by many different factors. Lifestyle considerations may be beneficial or harmful to an individual's gastrointestinal health. Diet may also impact gut health via its effects on the microbiome and its modification can be useful in different disease states such as IBS, constipation, and diarrhea. Finally, pharmacologic therapy can be used to control various gastrointestinal disease states and currently has the most evidence in regards to their efficacy. Ultimately, gastrointestinal health is a multifaceted topic and through changing any of these variables, great changes may be observed on an individual's gut health. By keeping these factors in mind, changes can be made both personally and to the benefit of patients.

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Hemophilia A

Hemophilia A is a factor VIII (FVIII) deficiency, which is an X-linked inherited mutation that results in a deficiency in coagulation. The severity and frequency of bleeding can be variable. Most patients generally only have to worry about the potential for bleeding in an event of a trauma or surgery. However, those with severe forms of hemophilia may experience spontaneous bleeding after only minor injury. Hemophilia is classified into different severities based on FVIII activity in plasma: severe (< 1%), moderate (1-5%), or mild (> 5% to < 40%).

Hemophilia A occurs in 1 in 5,000 live male births. It is also four times as common as Hemophilia B. Hemophilia A screening should be done whenever unusual bleeding occurs in a male. The disease is confirmed by results from laboratory screening tests which include prolonged partial thromboplastin time, prothrombin time, and bleeding time. However, the definitive diagnosis depends on the specific assay of FVIII coagulant activity in plasma.

The condition usually begins to manifest as mild discomfort and a slight limitation in joint movement. This is usually followed by pain, joint swelling, and warm skin. Often times, the discomfort starts in the knees, elbows, and ankles. If untreated, movement becomes difficult and the condition can worsen even after the bleeding stops. This is because the inflammation continues to damage the blood-filled joints leading to synovitis, which in turn becomes a target for recurring bleeding. Lastly, this process can result in permanent disability from narrow joints and cartilage loss.

Intramuscular hematomas are a common manifestation of Hemophilia A, occurring in up to 25% of all cases. They are concerning because they can compress vital body structures, which can lead to pain, anemia, and decreased range in motion. Anyone experiencing intramuscular bleeding needs to seek medical attention as soon as possible. Gastrointestinal and urinary tract bleeding may also occur, but they are less frequently seen. Of all different types of

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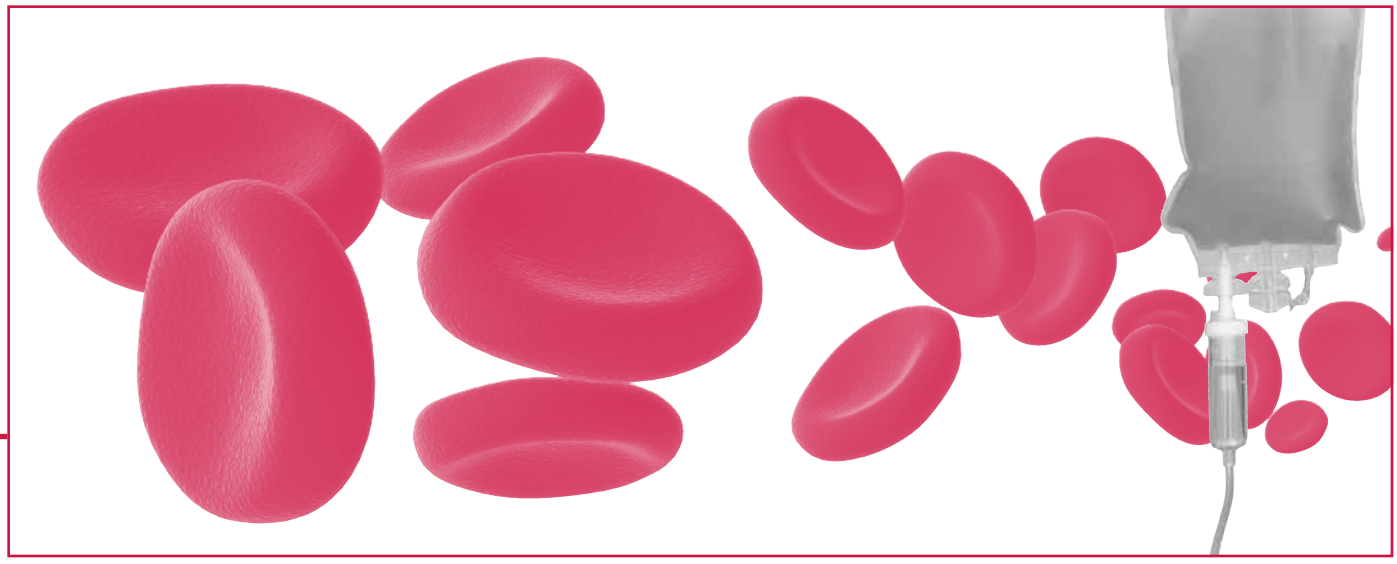

Hemophilia A

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bleeding, cerebral bleeding is the most severe. Symptoms often occur soon after trauma, but sometimes bleeding may be delayed. For this reason, hemophilic patients who experience frequent and/or persistent headaches should seek medical attention as they can be suspected of having subdural or epidural hematomas. Elderly and newborn patients are especially susceptible to spontaneous intracranial bleeding. Thus, this age group of patients should be monitored closely for this complication.

The current treatment of hemophilia A started in the 1970s with the industrial development of plasma-derived FVIII products. These products are categorized based on purity. Greater purity reflects a higher ratio of factor VIII to non-factor VIII proteins. Intermediate purity products typically contain 6 to 10 units of factor VIII/mg protein. High purity products contain at least 50 units of factor VIII/mg protein (range 50 to 150 units/mg protein), excluding albumin used for stabilization. Ultrahigh purity products are monoclonal antibody (mAb) affinity-purified and contain 3000 units of factor VIII/mg protein, excluding albumin used for stabilization. This concentration is essentially identical to the purity of recombinant products.

With improving medical innovation, plasma-derived FVIII products were largely replaced by recombinant FVIII products which were eventually classified into three separate generations, which reflects decreasing exposure to animal proteins. The first generation products use animal-derived proteins with human serum albumin to stabilize the final FVIII formulation, carrying a theoretical risk of viral exposure. The second generation products use human-derived proteins without albumin to create the final formulation. The third generation products are created with no protein other than the FVIII in the culture medium.

In the case of mild hemophilia A, FVIII products are generally avoided and instead, synthetic vasopressin analog desmopressin acetate is used. To use desmopressin as a therapeutic drug, patients must first undergo a test infusion. It is generally understood that a FVIII post-infusion level of at least 30% is sufficient for the treatment of minor bleeding events. On the contrary, levels higher than 50% post-administration are required for surgery.

Another common treatment for Hemophilia A is emicizumab. It works by binding to factor IXa and factor X, and bringing these together. This monoclonal antibody can be used regardless of inhibitor involvement.

Treatments can differ slightly between hemophilia A without an inhibitor and hemophilia A with an inhibitor. Without inhibitors, patients can receive an initial dose of factor VIII of 50 units/kg to raise the factor VIII level to 100 percent. This calculation assumes a starting factor VIII activity level close to 0 percent, a desired factor activity level of 100 percent, and a volume of distribution of approximately 0.5. For people without inhibitors who are using emicizumab for prophylaxis, factor replacement is needed for acute bleeding.

Treating hemophilia A with an inhibitor can be challenging because inhibitors bind to the infused factor and render it ineffective. Inhibitors with a titer of < 5 BU despite repeated factor infusions are referred to as low-responding inhibitors. Any inhibitor ≥ 5 BU/mL is considered high responding. Classically, high-responding inhibitors rapidly increase upon re-exposure to infused factors, which delays the onset of action up to 7 days.

Hemophilia A can potentially be a life-threatening chronic disease that can go undetected for years. Depending on the severity of the bleeding episode, many cases may be

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considered medical emergencies. However, with new treatment options and proper prophylaxis guidelines, patients with Hemophilia A have a greater chance to live longer lives without much side effects.

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Six-Year Follow-up of a Trial of Antenatal Vitamin D for Asthma Reduction

In recent studies, vitamin D deficiency has been hypothesized to contribute to asthma and other related allergies.[1] Since asthma can develop early on in life, studies regarding early-life risk factors are important for preventive care.[2,3] One study suggested that higher vitamin D levels are associated with a lower risk of asthma related events in children such as shortness of breath and wheezing.[7] Additional trials are needed to determine whether or not prenatal supplementation of vitamin D could prevent the development of asthma.[2,7] Previously, the Vitamin D Antenatal Asthma Reduction Trial (VDAART) researched prenatal vitamin D supplementation given to participants to prevent asthma in children up until their offspring's third birthday.[2] With secondary analysis, the effect of supplementation was strongly associated among children born to mothers who received vitamin D early on in pregnancy.[4] There is additional evidence from a meta-analysis study that prenatal vitamin D supplementation showed a protective effect on recurrent asthma related outcomes up to 3 years.[5] The current study continued to follow the children of the VDAART through their six birthdays, in which prenatal supplementation of 4400 IU vitamin D3 or 400 IU vitamin D3 per day would lead to a decreased incidence of asthma outcomes.[2]

Pregnant participants were recruited from several clinical sites across the United States including Boston Medical Center, Boston; Washington University, St. Louis; and Kaiser Permanente Southern California Region, San Diego. Inclusion criteria included women between the ages of 18 and 39 in which their pregnancy duration was between 10 and 18 weeks; history of asthma, eczema, and allergic rhinitis; nonsmoker; and English or Spanish speaking that will participate for 4 years.[2]

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Six-Year Follow-up of a Trial of Antenatal Vitamin D for Asthma Reduction

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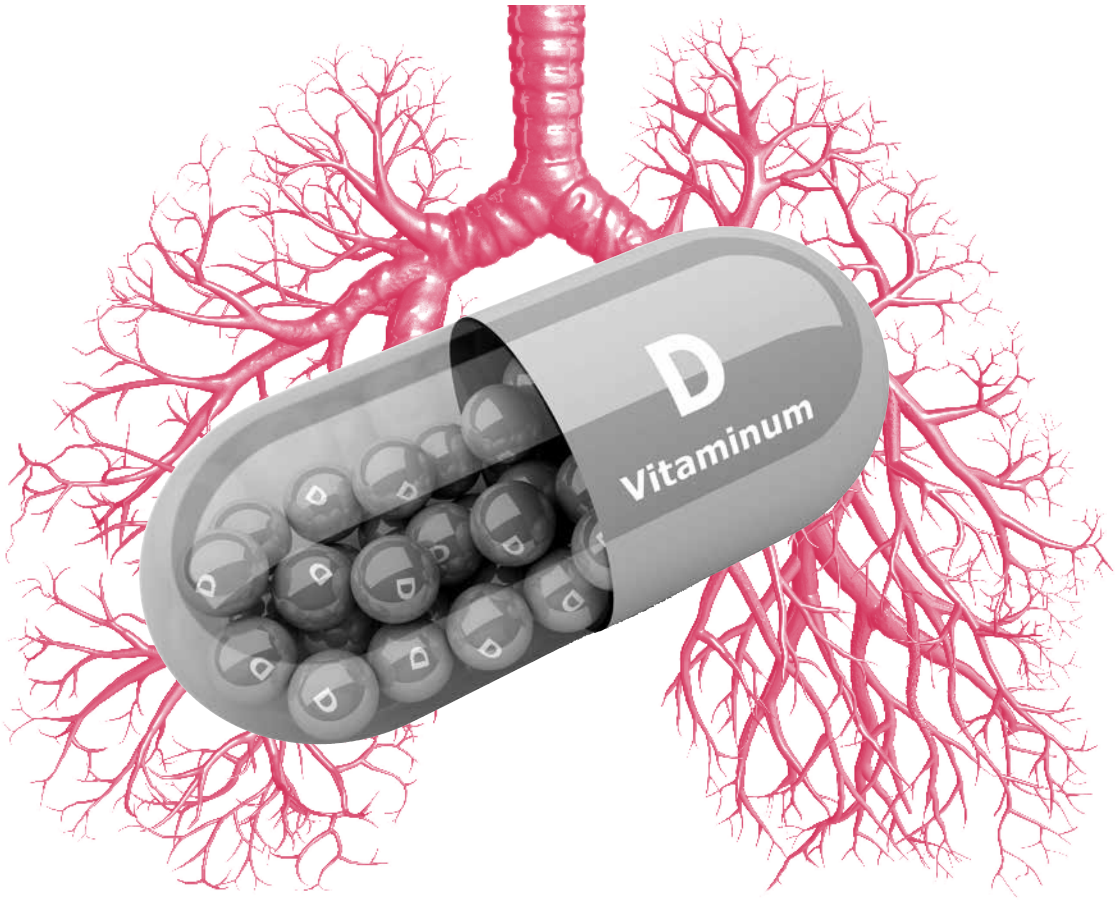

The original VDAART was a randomized, double-blind, and placebo controlled trial where the study group received prenatal supplementation of 4400 IU vitamin D3 and the control group received 400 IU vitamin D3 per day.[2] Participants were screened from October 2009 through July 2011 there the trial ended when the participants turned 3 years old. The present article's main purpose was to extend the follow up of the participants to the age of six, in which the last follow up was January 2018. The primary outcomes of the study included asthma, recurrent wheeze, or both. Recurrent wheeze was defined as an incidence of wheeze or the use of asthma medication two separate years over the first six years, and time of onset was the first report of wheeze or use of medication.[2] Lung function measures involved at least two spirometry or impulse oscillometry tests, in which the mothers provided vitamin D results at baseline or the third trimester. Before each follow up test, participants were instructed to avoid using bronchodilator medication or other asthma related medications 24 hours before the test.

Primary outcome was analyzed as an intention to treat analysis to focus on first onset of asthma or recurrent wheeze.[2] A hazard ratio model was used to compare low dose and high dose vitamin D while accompanied by P value. Lastly, for secondary outcomes, mean differences were reported.

There were no significant effects of maternal supplementation with 4400 IU of vitamin D per day on the incidence of asthma or recurrent wheeze at the age of 6 years, in which 184 events out of

401participants in the control group and 176 events out of 405 participants in the vitamin D group; interval-censored hazard ratio (control vs. vitamin D, 1.12; P = 0.25). Also, secondary analysis found no association with prenatal vitamin D supplementation for outcomes such as eczema, allergic rhinitis, or lower respiratory tract infections by 6 years of age.

Overall, vitamin D supplementation during the prenatal period alone did not prevent asthma and recurrent wheeze in offspring up to the ages of 6 years even though the VDAART suggested an association at an earlier age. Similar studies have shown prenatal supplementation is not enough to prevent mid childhood asthma.[6,7] Limitations of the current study included no postnatal vitamin D supplementation in children and initial vitamin D levels were not taken before prenatal supplementation; however, the trial was not designed for these measures, in which additional studies would be needed to validate these limitations. To surmise, prenatal vitamin D supplementation did not influence 6 year incidence of asthma and recurrent wheezing among children at risk for asthma.

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Welcome New Pharmacists

Jeffery Macaluso, Pharm. D., BCPS

Dr. Jeff Macaluso, PharmD, BCPS, is a graduate from St. John's University in Jamaica, Queens, NY. Prior to starting at University Hospital, Jeff worked for the Department of Veterans Affairs, initially in Buffalo, NY before transferring to VANJ Healthcare system in East Orange. Jeff enjoys communicating and working with patients directly and being a member of a health care team, collaborating with other providers to provide the best possible care for our patients. When not at the hospital, Jeff enjoys spending time with his wife and two sons. Jeff is excited about his new opportunity at University Hospital and looks forward to meeting and working with everyone.

Hany Fahmy, Pharm. D.

Dr. Hany Fahmy graduated from Fairleigh Dickinson School of Pharmacy (FDU) with PharmD in 2019. He previously worked as a lab technologist in many labs and hospitals in New York. His interest is cardiology and oncology. He is so happy to join the great team at University hospital.