

# Advocacy | Availability | Compassion | Prevention

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## FALL 2024 - NEWSLETTER

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### It's the Fall Season and Time to Review Adult Vaccination Recommendations

1. COVID Vaccine- If you are 65 years old, or older, or immunosuppressed, the Center for Disease Control and Prevention (CDC) and world authorities are recommending that you receive the recently released new COVID vaccine at your pharmacy. This is not a booster. It is a vaccine which contains protection against the newer strains of the virus causing infection and illness. You are encouraged to take a COVID vaccine every four months. These vaccines produce a robust immune response which only last four months.

Younger adults can take this vaccine annually. If you have just recovered from a COVID infection, take your vaccine three months after recovery. The vaccines by Merck and Pfizer will reduce the likelihood of you becoming sick enough to require hospitalization or of dying.

2. Influenza Vaccine - Individuals younger than 65 can take the standard influenza vaccine. It is available in most physicians' offices and in most large pharmacies. Individuals older than 65 years should be receiving the senior HD influenza vaccine which has been shown to be far more effective in the older age group than the standard product. Those younger than 65 should be receiving their flu shots now with their immunity being prolonged. Those over 65 years of age should remember their peak immunity after vaccination lasts about 90- 120 days, so the timing of the injection should be based on when flu usually arrives in your community and when it peaks. In South Florida, the flu appears around Thanksgiving and usually peaks at the end of January beginning of February. For this reason, we suggest our seniors over 65 take the vaccine after Halloween and before Thanksgiving
3. Respiratory Syncytial Virus Vaccine - This product has been available in the community for almost two years. RSV falls right behind COVID and Flu in terms of hospitalizing seniors and causing their death. It is a one-time vaccine available in most pharmacies and best taken in late fall or early winter.
4. Pneumonia Vaccines- The landscape on preventing bacterial pneumonia which kills the infirm, the elderly and immunosuppressed has changed the last few years with numerous products available and guidance provided by a CDC website. It should be administered at age 65 or older
5. Shingles Vaccine - To prevent herpes zoster, or shingles, we recommend Shingrix given as two immunizations two months apart. It is very effective at preventing post herpetic neuralgia - the post rash chronic pain syndrome.
6. Tetanus Vaccine - Every seven to ten years a booster should be taken. If you are not current and sustain a puncture wound, then receiving the vaccine within a few days should prevent the development of the disease.

## Screening For Lung Cancer in Smokers Is Available & Recommended

The American Lung Association conducted a survey of adults asking if they knew of the availability of CT Scan screening for lung cancer in adults. They polled 4,000 adults and less than 40% of them knew that screening was available and suggested for smokers or patients with a smoking history. Seventy-three percent had never discussed lung cancer with a physician and less than 30% knew that lung cancer is the leading cause of death from cancers. Almost 90% did not think lung cancer was likely to occur in women.

These disturbing findings were presented by Harold Wimmer, President of the American Lung Association. He made a strong point of reminding the public that finding a tumor on CT Lung screening raises the odds of surviving 5 years by 63%.

The guidelines for CT Lung Cancer Screening are simple. Adults with a 20-pack year smoking history or greater (smoke one pack per day for twenty years or 2 PPD for 10 years) and are between the ages of 50 and 80 should have an annual low dose chest CT scan. This includes current and former smokers.

If you meet the inclusion criteria for lung cancer screening, please speak to your doctor about scheduling your lung CT Scan screening.

## FDA Approves New Gel to Stop Severe Bleeding in Seconds

The Food and Drug Administration (FDA) has approved a new gel product made from plant-based algae designed to stop major bleeding in seconds rather than minutes. It will be used in situations of major trauma with major bleeding such as penetrating wounds, gunshot wounds and injuries from motor vehicle accidents.

Most existing medications and products designed to slow down and stop bleeding require the use of constant pressure and take several minutes to work during which blood loss can lead to major organ damage and death. The product was developed and produced by Cresilon and will be available in the last quarter of 2024. It will be distributed in a pre-filled syringe. Currently the cost of the product is not known. This is certainly a major advancement for emergency medical services (EMS) worldwide.

## More on Coffee, Tea, and Dementia

Several scientific research studies in the last few years have extolled the benefits of drinking coffee to maintain brain volume and slow the cognitive decline seen in dementia. Several observational studies (these are not double blinded random control studies) suggest that drinking coffee and tea has beneficial effects on stroke, heart disease and failure, cancers, diabetes, and Parkinson's Disease.

Kelsey R. Sewell, PhD, of Advent Health Research Institute in Orlando, Florida reminds us that "too much of anything is not good. It is all about balance so moderate coffee consumption is okay but too much is not recommended." Her remarks came after she presented a research paper at the 2024 Alzheimer's Association International Conference and were summarized in the online journal *MDedge Neurology*.

Her paper looked at 8,451 adults older than 60 years of age in the United Kingdom. They were divided into high coffee consumption (four or more cups per day), moderate consumption (1-3 cups per day) and no coffee consumption. The same criteria were used for tea drinkers. None of the participants had a diagnosis of cognitive impairment. Sixty percent were woman.

They found that those with no coffee intake or moderate coffee intake had a slower decline in "fluid intelligence" when followed over the next 8 - 9 years than those with high coffee consumption. Tea drinkers had a different result with moderate to high tea drinkers having a slower decline in fluid intelligence than non-drinkers of tea.

The message is that coffee and tea in moderation are fine. The results of this observational study will be used as the basis for a more definitive controlled study incorporating other data such as the smoking history of coffee versus tea drinkers. They will look at the effects of different methods of preparing coffee and tea plus different types of coffee and teas.

## CoQ10 and Cardiovascular Health

I have encouraged the lowering of cholesterol with my patients through dietary changes, exercise and weight loss. When improving lifestyle did not lower the cholesterol to levels that were sufficient to protect you from atherosclerotic vascular disease of the heart and blood vessels, we added medications called “statins”. These medications managed to reduce the cholesterol sufficiently to lower your lipid levels and reduce your chances of having a heart attack, stroke or consequences of poor blood supply to a limb or extremity.

Commonly prescribed statins include Lipitor (atorvastatin), Crestor (rosuvastatin), Pravachol (pravastatin), Zocor (simvastatin) and Livalo (pitavastatin). Whenever physicians prescribed these medications, we are notified that, while lowering the cholesterol to safe levels, we were also lowering your Coenzyme Q10 level or Ubiquinol level. The drug manufacturers always suggest that we prescribe a supplement of CoQ10 along with the statin.

Patients have commonly asked me, “What diseases are caused by low CoQ10 levels?” I would answer that I don’t know of any. When I did a literature search on the subject there were no diseases that came up directly due to a lack of Coenzyme Q10. I remember talking about enzymes and coenzymes in my university and medical school biochemistry courses. Enzymes are proteins produced by living cells that cause or accelerate a chemical reaction. Coenzymes help enzymes work better by facilitation of that practice. CoQ10 happens to be a substance that works in our mitochondria helping to produce energy (ATP) to help cells perform their work effectively.

Dr. Julian Borgeina, an endocrinologist and researcher in nutrition and metabolism, decided to be much more thorough than I was in my research and looked at published research papers discussing whether CoQ10 could help the heart work better. He managed to collate the data from five separate well done studies encompassing about 1,200 subjects, half of whom were men and the other half women.

The studies showed that by introducing CoQ10 in the 200 mg to 400 mg dose, heart muscle cells produced more energy (ATP) and their respiratory function improved. This was exhibited by the improvement of the ejection fraction of the heart muscle (how much blood the heart pumps out per contraction). The studies also showed that the endothelial function of the cells improved and were more efficient (endothelial cells line our blood vessels and prevent the blood from clotting spontaneously as it flows through them). His research has been presented at international cardiology meetings and is pending approval for publication.

This data did not actually answer the question of what happens if you take a prescribed statin and you do not take CoQ10 with a result of depleting these coenzymes. It did however show that CoQ10 can improve heart muscle function.

For this reason, I will continue to suggest to my patients who are taking statins that they take a daily dosage of CoQ10 in the 200 mg to 400 mg range. The product should be inspected by a USP approved lab to ensure that what is on the label is the only thing in the supplement you are taking. Further research will need to be done on the optimal dosage and delivery method of CoQ10 for the most effective outcomes.

## ECMO and 21<sup>st</sup> Century Healthcare

In a *New Yorker* magazine article, writer Clayton Dalton explores a commonly used healthcare technology unfamiliar to most, ECMO (Extracorporeal Membrane Oxygenation). Developed by a surgical resident in Boston in 1952, the ECMO machine bypasses the heart and lungs and supplies oxygen to the blood, while removing carbon dioxide, allowing a surgical repair of a diseased heart.

Since then, the ECMO technology has been further refined and is regarded as **the backbone of today's heart bypass surgery**. Studies have shown a survival rate of greater than 30% of the patients put on ECMO upon arrival after an out-of-hospital cardiac arrest. Emergency Medical Services in France have used ECMO successfully since 2011.

ECMO technology has reached the point where individuals with severe respiratory failure can be maintained for weeks to months on the equipment while they await a successful treatment or a compatible lung or heart for transplantation. The major drawbacks to using ECMO are problems with blood clots, severe bleeding infection and cost.

The data proving the effectiveness of using ECMO is overwhelmingly positive including:

- Several young patients with end stage lung disease from cystic fibrosis functioning fully and normally in the intensive care unit while attached to the life extending ECMO machine.
- In the pediatric age group, ECMO has been used to treat infants in respiratory distress for nearly 50 years. Situations which had a mortality rate approaching 100% suddenly had a survival rate of 80%.
- Although results for adults were not as positive, that changed when physicians began using ECMO for acute respiratory failure associated with the H1N1 influenza in 2008.
- **Patients in respiratory failure due to infection who required ventilators, but were treated with ECMO alone, did better than patients treated with both a ventilator and ECMO.**

A portable ECMO machine, called Crank-Mo, is available for use by paramedics. Unfortunately, not many are in use across the U.S. Portable ECMO machines are also being developed for home. However, the cost for treatment is a huge drawback as it's estimated at approximately \$875,000 per patient treated.

Our local hospital's chief medical officer told me he was trying to initiate an ECMO program, which the intensivists were excited to develop. The nursing staff cited the long hospital stay of patients successfully treated and were concerned about having enough beds during our busier seasons.

With the affluence in this community, I fully expect an ECMO program will be initiated soon. Just like when it was unheard of to place defibrillators throughout the community to treat out-of-hospital cardiac events, the day will soon come when your 911 call for a cardiac arrest will be answered by paramedics trained to start ECMO treatment upon arrival.

## **New Urine Test Developed to Accurately Detect High Grade Prostate Cancer**

Coming out of medical school in the 1970's, prostate cancer was treated from a teaching standpoint as a disease of old men with little interest or funding of research for the disease. Breast cancer received most of the attention primarily because the wives of wealthy politically noteworthy politicians were diagnosed with the disease and their families invested heavily in research on the topic. As medical science and lifestyle changes improved, the longevity and survival of both men and women, diagnosing and treating prostate cancer became an issue to be addressed.

The digital rectal exam plus the PSA (prostate specific antigen) became the early mainstays of detection of prostate cancer. Researchers learned that PSA numbers could be elevated by multiple non-cancerous issues including prostatitis, normal prostate enlargement or hypertrophy, manual manipulation of the gland (from a digital rectal exam) and an orgasm from sexual activity. A biopsy became the gold standard for diagnosis and was performed by a urologist through the rectum using ultrasound guidance.

Since the rectum is part of the intestinal tract, bacteria associated with fecal matter often infected the biopsy site leading to infection post procedure. Noninvasive blood testing with fewer drawbacks than the PSA are in development. New techniques of evaluation are becoming available as well. Imaging the prostate with the

state-of-the-art MRI machine T3 or newer can spot a lesion requiring biopsy. The biopsy is now performed by an interventional radiologist through the perineum which has been anesthetized. Since the needle does not pass through an anatomical region containing fecal matter, the infection rate is markedly diminished.

Despite this, the first patient I sent for this procedure locally developed a lingering prostate infection which was difficult to eradicate. If no mass or lesion is seen on MRI, the data reflects no cancer being present or cancer so early in its course that no action is necessary other than repeating the MRI and PSA months later in a process called active surveillance.

*JAMA Oncology* recently reported on a new urine test called MyProstateScore 2.0 investigated by Arul M. Chinnaiyan, MD, PhD, of the University of Michigan which uses material from 18 gene locations that accurately identifies high grade prostate cancer far better than existing bio marker tests. Their data suggest that their test would have safely avoided unnecessary additional testing with imaging or biopsy in 35% to 51% of men. The lead investigator said, "For clinicians, uniform use of MPS2 could avoid unnecessary biopsies while preserving immediate detection of 95% of cancers of Gleason Grade 2 or greater diagnosed using the biopsy all approach."

This test is now being evaluated in a large prospective trial against the use of multi parametric MRI imaging. Its cost to patients at this point is not available and where exactly in the diagnostic pathway it will be used remains to be determined.

The United States Preventive Task Force no longer recommends PSA testing in men 70 or older. It is called a low value test suggesting that the anxiety related with having an elevated PSA and the complications of performing a biopsy for prostate cancer present a situation where the benefits are outweighed by the risks.

In my opinion, the USPTF recommendations are all about cost and saving money. Male patients over 70 with new medications and lifestyle changes are now living into their late 80s and early 90s and they want to know and take stock of their overall health and future. When discussing prostate cancer with them, and reviewing the pros and cons of PSA testing, they still want the knowledge and the test. Hopefully this new urine-based genetic test will be more definitive and will be affordable so we can answer our patients' questions and reduce the number of invasive biopsies to truly high-risk individuals.

Another complaint about the statins involved elevation of the liver function tests such as ALT and AST. When these medications first were released, we were supposed to draw their liver blood tests every 8 weeks. One of my former teachers at the University of Miami Miller School of Medicine, Eugene Schiff MD, ran the Center for Liver Diseases, a world leader in the diagnosis and treatment of hepatic diseases. He taught us that he had never seen a case of true liver failure from statin drugs. In almost 50 years of practice, neither have I.

The problem with prescribing the statins was that patients with muscular pain just stopped taking them because they felt their aches and pains were directly related to these medications. To treat those patients, injectable medications like Repatha and Praluent were developed. These PCSK9 inhibitors were injected in a pre-filled syringe every 2 weeks and, while very expensive, were remarkably successful.

These products required preauthorization from health plan drug benefit managers and the retail cost for a month's supply averaged over \$1,200. The product needed to be stored in a refrigerator and warmed up for forty minutes prior to injection. In my internal medicine practice, we usually administered the first injections teaching the patients the process and when they felt comfortable doing it on their own, they continued at home. Cost of the medication and the time involved obtaining preauthorization remain the biggest drawbacks.

A new PCSK9 inhibitor, Lerodalcibep, has now completed phase III trials and is a monthly injection. Its lipid lowering effectiveness was discussed and presented at the annual meeting of the American College of Cardiology. Side effects were minimal and similar to Repatha and Praluent. The biggest drawback seems to be

its cost and if insurers cover all or part of it. There is no doubt that it works with a study of 9,222 adults from eleven countries conducted for one full year.

Will the convenience of once-a-month dosing result in its acceptance by insurers and patients? That remains to be seen.

## **More On Vitamin D and the Development of Diabetes**

Studies about Vitamin D levels and disease have been flooding the medical and lay literature for several years. In 2011, the National Academy of Medicine declared that a serum level of >20ng/ml was sufficient to maintain skeletal health. The Endocrine Society first recommended 28 ng/ml and now raised it to 30 ng/ml. Physicians in the United States have been measuring serum vitamin D Levels through reference labs for a decade or more now despite the United States Preventive Task Force concluding there is no benefit to screening adults for vitamin D level.

A current study in the *Journal of Clinical Endocrinology and Metabolism*, authored by Carolina Gonzalez- Lopez, MD and associates, used data from the British UK Biobank over fourteen years to show that maintaining a serum vitamin D3 level of 30 or greater is best to prevent normoglycemic individuals from converting to Type II diabetes.

Vitamin D is made by the kidneys if our body gets sufficient sunlight exposure. Patients with kidney disease have difficulty achieving normal Vitamin D levels.

This study and others showed that supplementation with Vitamin D orally helped individuals achieve a level which reduced the risk of developing diabetes. In a review of this material and study, David Rakel MD, FAFP and Sun H. Kim MD, MS agreed on a target normal level of 30 ng/ml.