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# FALL 2019 - NEWSLETTER

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#### Influenza Vaccination in Adults

It is time once again to be thinking about taking your flu shot. A recently published study by the National Foundation for Infectious Diseases (NFID) estimated that only 52% of US adults plan to take the flu shot. Reasons for not being vaccinated include:

- 1) I do not believe it works (51%)
- 2) Concern it would cause an adverse effect (34%)
- 3) Concern that the vaccine would give them the flu (22%)

Health and Human Services Secretary Alex M. Azar II said, "Each season, flu vaccination prevents several million illnesses, tens of thousands of hospitalizations and thousands of deaths. Over recent years, on average, flu vaccination has reduced the average adult's chance of going to the doctor by between 30 - 60%.

A recent study performed by the northern California Kaiser Permanente Group, using seven years of flu season data, shows the immunity from the shot is near perfect for the first six weeks and then begins to wane. They estimate your post-vaccination chance of getting the flu, even if immunized, increases by 16% every 28 days after the shot but is near perfect for the first 42 days.

It is believed the Center for Disease Control (CDC) will recommend in future years that adults receive two flu shots each season. One will be administered at the beginning of the season and one six weeks later. For the moment, the CDC acknowledges the flu season begins at different times in different regions of the country and suggests you receive your vaccination about two weeks before it arrives.

In South Florida, we typically see the arrival of the Influenza A virus <u>after Thanksgiving</u>. It peaks the last two weeks in January and first two weeks in February. For this reason, we suggest taking the shot later in the fall.

We already have the vaccines in the office with the Quadrivalent Vaccine available for the adults younger than 65 years old and the Senior High Dose Trivalent Vaccine for those 65 or older. All the vaccines are inactivated meaning **they are not live and cannot give anyone the flu**!

The office still provides vaccination for influenza, tetanus, tetanus and whooping cough. In recent years, the Center for Medicare Services (CMS) has decided to pay for the shingles vaccines (herpes zoster) called Shingrix through the private Medicare Part D prescription drug plan. This means the shot's wholesale cost is about \$200 and you require two shots at least two months apart. The same policy applies to the community acquired pneumonia preventive shot Prevnar 13. We no longer stock these in the office because insurers do not pay for them when administered in the doctor's office and patients do not want to pay \$200 out of pocket for something they can get for a copay cost in their pharmacy.

# Who Is Addressing the Availability, Safety and Efficacy of our Medications?

I watched all three presidential debates this summer with health care being a time-consuming topic for all. Universal health care and Medicare-for-All, with or without an option for private insurance, were debated and discussed at length.

At the same time NBC Nightly News presented a story documenting that all our antibiotics come from production in China. With globalization policies, which promote moving production to lower cost overseas factories, there is no longer any production of antibiotics in the USA. A former member of the Joint Chief of Staffs, citing the current trade conflicts and China's aggressive military stance in the Pacific, considers this a security issue. I have heard not one question or comment on this topic in the debates?

This week, once again, the blood pressure medicines losartan and valsartan were recalled because they contained potential carcinogens. These generics were produced in India, Asia and Israel. These same drugs have been recalled multiple times in the last few years for similar problems.

Due to reduction in funding for FDA inspections, many of these foreign plants have not been inspected for years. We can add recalls of generics to drug shortages. We suffered a shortage of intravenous fluids for hydration because the primary production site in Puerto Rico was destroyed in a hurricane. We had shortages of morphine and its derivatives for treatment of orthopedic trauma and post-surgical pain. They substituted foreign-produced short acting fentanyl. I saw pediatric ER physicians unable to administer the most effective treatments for sickle cell crisis in children because it required the use of a narcotic drip to offset the dramatic pain the treatments induce as they stop the crisis.

Then there are the psychiatric patients on antidepressant generics who are paying hundreds of dollars per month for products that wear off in 16 hours rather than 24 as the brand product did. Their symptoms creep back in allowing them to *tell time* based on the reduced efficacy of these products. By law, generics are required to provide 80% of the "bioavailability" of the brand product but what does that mean and who is testing?

This all began when the Reagan Administration closed the FDA research lab. Prior to that, all new products were sent to that lab for approval prior to being released in America. On their watch, a pharmaceutical product never had to be recalled. Big Pharma complained they took too long as did some consumer groups. This resulted in the defunding and closing of the lab. Products are now outsourced to private reference labs and their reports are sent to the FDA for review. The frequent drug recalls contrast to the success of promoting safety when the FDA did it themselves.

Isn't it time for the health care debate, especially the presidential debates, to discuss the safety, efficacy, supply and cost of pharmaceutical products? I am all for bringing production home to the USA, restoring the FDA funding for the reopening of their lab as an impartial test site and putting the cost of repeatedly testing the generics for efficacy even after approval and release on the backs of Big Pharma. Let's see these topics introduced to the health care debate too.

# Should We Discontinue Statins in the Elderly?

For years now my patients have been extremely concerned about their cholesterol levels. Many access our portal to obtain them. Others have us mailing, faxing and copying the results for their records. It is an obsession I have

never quite understood. If they have significant cardiovascular risk factors and have not been able to lower their cholesterol with dietary choices, weight loss, smoking cessation then they need medication.

Statin drugs have worked wonders in reducing heart attacks, strokes and limb amputations due to vascular disease and probably have other unintended positives. When I prescribe them, and review the pros and cons, I am always questioned about potential side effects such as thyroid disease, dementia, diabetes and cancer. There is always a family member using "Doctor Google" who quotes "Worst Pills, Best Pills" and asks the question, "When is the patient too old to start these medications?"

At the European Society of Cardiology meeting in Paris, France, Dr. Joern Dopheide, of Bern University Hospital in Sweden presented a paper on statin use and peripheral artery disease (PAD). He noted that patients with peripheral artery disease were at increased risk of heart attack and stroke. Those with PAD and not taking a statin had a mortality rate of 34% - more than three times that of patients on an intensified statin regimen. He also noted that patients previously on a statin, who abruptly stopped taking the statin, also had a mortality rate of 33%. Dr. Dopheide decided to investigate the relationship between PAD and stopping a statin. He presented those results at the Paris meeting.

He included 691 patients with peripheral arterial disease, all of whom were symptomatic from it. He looked at their statin dosage, LDL cholesterol levels and survival. He found that those who adhered to the statin regimen, over the four plus years of the study, lowered their mortality. The mortality rate was about 20% for those on low dose statins but dropped to 10 % on a more intensive regimen. To his surprise and dismay, those patients who discontinued their statin, or abruptly reduced the dosage, had a mortality rate that increased to 43%.

The message he left was that individuals with peripheral arterial vascular disease (PAD), who have symptoms of PAD, are at a much higher risk for coronary artery disease if they reduce their statin dosage or stop it. This risk is much higher than clinicians anticipated so we must be much more vigilant in educating our patients with PAD about the necessity of continuing their statin medications whether they are elderly or not.

# Sodium Chloride Salt Substitution Works in a Community Trial

At a meeting of the European Society of Cardiology, J. Jaime Miranda, M.D. PhD, of the University of Peruan Cayetano Heredia in Lima, Peru reported that substituting artificial salt substitute potassium chloride for table salt lowered the blood pressure of participants, reduced the number of new cases of hypertension and ultimately reduced stroke and heart disease mortality

For this study, researchers enlisted the assistance of six semi-rural agricultural fishing villages in the Tumbes region of Peru. All adults 18 and older were approached and over 91% of the 2,605 potential enrollees agreed to participate. Patients with chronic kidney disease, known heart disease or digoxin use were excluded because of the use of potassium and potential cumulative effects of this element.

The study area and residents historically have very little high blood pressure. In Peru, 140 systolic blood pressure and 90 diastolic blood pressure are considered the upper limits of normal.

The researchers replaced the sodium chloride used in food preparation with potassium chloride salt distributing it free to all families, shops, restaurants and bakeries over a three-year period. The results revealed a very small reduction in systolic blood pressure which still reduced the risk of stroke by 10% and ischemic heart disease by 7 %. The drop-in blood pressure was more definitive in the 18% having hypertension at the time they entered the study and those 60 years of age or older.

This study raised the possibility of researchers approaching food manufacturers around the world to substitute potassium chloride artificial salt for sodium chloride as a means of lowering blood pressure and its stroke, cardiac, renal and vascular complications. It reinforced the suggestions to stop adding sodium chloride salt at the table or in food preparation if you wish to keep your blood pressure under control.

# **Courtesy Blood Draws**

Patients often request us to draw blood on them which has been ordered by other physicians. Their physician provides the patient with a written request or prescription, with the desired tests listed, with the intention of the patient going to a lab drawing station to have the blood drawn.

As a courtesy to our patients we will draw the blood and send it out to the designated lab if we receive a written request from the doctor. Patients will be asked to sign a Medicare ABN notice. A \$15 fee may apply.

The results will be sent to the ordering or requesting physician who will be the one to interpret the results and report them to the patient. At the time of the blood drawing appointment, you will be asked to sign a form acknowledging this.

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