

HPS NEWSLETTER

HOSPITAL PHARMACY MANAGEMENT

1st QUARTER

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Small Doses.....

by

Mike Petry, MS, RPh
Clinical Pharmacist

New Drugs for 2009

The United States Food and Drug Administration (FDA) approved a total of 37 drugs, vaccines, and blood products in 2009. Listed below is a selection of these new products that health care providers may encounter in the near future.

Abobotulinumtoxin A for injection (Dysport[®]), for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain and for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age.

Antithrombin, recombinant for infusion (Atryn[®]), for the prevention of perioperative and peripartum thromboembolic events in patients with hereditary antithrombin deficiency.

Artemether-lumefantrine tablets (Coartem[®]), for the treatment of acute, uncomplicated malaria infections in adults and children.

Asenapine tablets (Saphris[®]), for the acute treatment of

schizophrenia and manic or mixed episodes associated with bipolar disorder in adults.

Interferon beta-1b for injection (Extavia[®]), for the treatment of relapsing forms of multiple sclerosis.

Benzyl alcohol lotion (Ulesfia[®]), for the treatment of head lice infestation.

Bepotastine ophthalmic solution (Bepreve[®]), for the treatment of ocular itching associated with allergic conjunctivitis.

Besifloxacin ophthalmic suspension (Besivance[®]), for the treatment of bacterial conjunctivitis.

C1 esterase inhibitor, human for infusion (Berinert[®]), for the treatment of acute abdominal or facial attacks of hereditary angioedema in adults and adolescents.

Canakinumab injection (Ilaris[®]), for the treatment of familial cold autoinflammatory syndrome and Muckle-Wells syndrome.

Colchicine tablets (Colcrys[®]), for the treatment of gout flares and familial Mediterranean fever.

Dronedarone tablets (Multaq[®]), for the maintenance of normal heartbeat in certain patients with a history of paroxysmal or persistent atrial fibrillation or atrial flutter.

Ecallantide injection (Kalbitor[®]), for the treatment of acute attacks of hereditary angioedema.

Everolimus tablets (Afinitor[®]), for the treatment of advanced renal cell carcinoma.



Febuxostat tablets (Uloric[®]), for the reduction of elevated serum uric acid levels in patients with gout.

Ferumoxytol injection (Feraheme[®]), for the treatment of iron deficiency anemia in adults with chronic kidney disease.

Fibrinogen concentrate, human for infusion (Riastap[®]), for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency.

Golimumab injection (Simponi[®]), for the once-monthly treatment of adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis.

Haemophilus b conjugate vaccine (Hiberix[®]), for the prevention of invasive disease caused by *Haemophilus influenzae* type b in children 15 months through 4 years of age.

Human papillomavirus bivalent vaccine, recombinant for injection (Cervarix[®]), to protect against cancers caused by infection with human papillomavirus types 16 and 18.

Iloperidone tablets (Fanapt[®]), for the acute treatment of schizophrenia in adults.

Influenza virus vaccine, inactivated (Agriflu[®]), for active immunization of adults against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.

Immune globulin, human for injection (Gammaplex[®]), for the treatment of patients with primary humoral immunodeficiency.

Japanese encephalitis vaccine, inactivated (Ixiaro[®]), for the prevention of disease caused by Japanese encephalitis virus in adults.

Milnacipran tablets (Savella[®]), for the treatment of fibromyalgia.

Ofatumumab for infusion (Arzerra[®]), for the treatment of chronic lymphocytic leukemia in patients whose cancer does not respond to other chemotherapy.

Pancrelipase capsules (Creon[®]), for the treatment of pancreatic insufficiency in adults and children with exocrine pancreatic insufficiency resulting from cystic fibrosis or other conditions.

Pazopanib tablets (Votrient[®]), for the treatment of advanced renal cell carcinoma.

Pitavastatin calcium tablets (Livalo[®]), for the improvement of cholesterol levels in patients who have not been able to control their dyslipidemia through diet and exercise.

Pralatrexate injection (Foloty[®]), for the treatment of peripheral T-cell lymphoma in patients whose disease has returned or not responded to previous therapy.

Prasugrel tablets (Effient[®]), to reduce the rate of myocardial infarction and stroke in patients with acute coronary syndrome who are undergoing a catheter-based procedure to reopen an occluded coronary artery.

Romidepsin for injection (Istodax[®]), for the treatment of cutaneous T-cell lymphoma in patients who have already received at least one systemic therapy for the disease.

Saxagliptin tablets (Onglyza[®]), to help control blood glucose concentrations in patients with type 2 diabetes.

Telavancin for injection (Vibativ[®]), for the treatment of complicated skin and skin-structure infections in adults.

Tolvaptan tablets (Samsca[®]), for the treatment of patients with hypervolemic or euvolemic hyponatremia.

Ustekinumab for injection (Stelara[®]), for the treatment of severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy.

Vigabatrin tablets and solution (Sabril[®]), for the treatment of infantile spasms and as add-on therapy for the treatment of complex partial seizures in adults.

Nursing in-service

Date _____





High Fiber Diet May Influence COPD Risk

Published on Health News
By Madeline Ellis
March 15, 2010

Dietary fiber, also known as roughage, is probably best known for its ability to prevent or relieve constipation, but fiber can provide many other health benefits as well. Because it is not easily digested, fiber passes relatively intact through the digestive tract, including the stomach, creating a feeling of fullness. This can be helpful for people trying to lose or manage their weight. Fiber delays the absorption of cholesterol, which can lower the risk for heart disease. And because of its ability to slow the absorption of sugars, fiber helps regulate blood sugar levels, which is important in avoiding diabetes. But researchers may have only recently uncovered fiber's greatest benefit—people who eat enough of it may have a lower risk of developing chronic obstructive pulmonary disease (COPD).

A new study published in the *American Journal of Epidemiology*, which followed more than 100,000 adults from 1984 to 2000, found that out of 111,580 participants who followed a high-fiber diet, only 832 were diagnosed with COPD during the study period—which equates to a rate of less than 1%. Of those, 234 were diagnosed

among the one-fifth of study participants with the lowest fiber consumption; while 107 cases were seen among the one-fifth with the highest intake of fiber.

Even when other factors were taken into account, including smoking, age, weight, and exercise habits, the group with the highest fiber intake still had a one-third lower risk of COPD than the group that consumed the least fiber. However, when researchers analyzed the association between COPD and specific fiber sources—fruits, vegetables, and grains—only fiber from grains was independently linked to a lower risk of lung disease once smoking and other factors were taken into account.

Researchers say that, unfortunately, even though it makes perfect sense that because fiber has both antioxidant and anti-inflammatory properties that could affect the development of chronic lung disease, the study findings do not prove that high-fiber diets can prevent COPD. They note that it is always difficult for studies to tease out the possible health effects of any single nutrient in the diet and the fact that grain fiber was independently linked to COPD raises the possibility that components of whole grains other than fiber are at work.

Cigarette smoking is the leading cause of COPD. Most people who have COPD smoke or used to smoke. Long-term exposure to other lung irritants, such as air pollution, chemical fumes, or dust may also contribute. “For COPD prevention, the most important public health message remains smoking cessation,” the researchers, led by Dr. Raphaelle Varraso of the French national

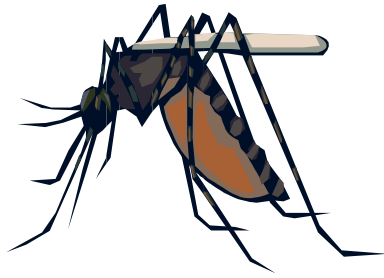
health institute INSERM, wrote, “but our data suggest that diet, another modifiable risk factor, might also influence COPD risk.”

Health experts recommend a minimum of 20-30 grams of fiber a day for most people. The problem is that most people in the U.S. don't get enough fiber to realize its potential benefits. According to the American Dietetic Association, the typical American eats only about 11 grams of fiber a day.



Including foods that provide fiber in your diet isn't difficult. Grains like wheat, rye, oats, buckwheat, millet, rice and sorghum all have high levels of fiber, especially when eaten whole. Legumes such as beans, lentils, split peas, and others are also great sources of fiber and can be eaten in a wide variety of ways. Whole fruits with edible skins along with dried fruits contain lots of fiber, as do green leafy vegetables like broccoli, kale, and chard, along with squashes like acorn, pumpkin, and spaghetti. Finally, many nuts also have useful dietary fiber and can be eaten on the go.





West Nile Virus Infection May Persist in Kidneys Years After Initial Infection

The Journal of Infectious Diseases
Contact: John Heys
December 7, 2009

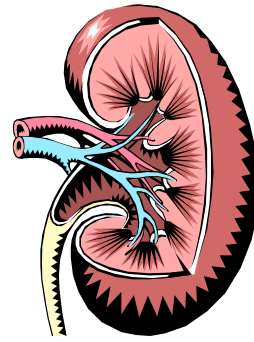
A new study shows that people who have been infected with West Nile virus may have persistent virus in their kidneys for years after initial infection, potentially leading to kidney problems.

Spread by infected mosquitoes, West Nile virus was first detected in the United States in 1999. Since then, approximately 25,000 human cases have been reported, causing more than 1,000 deaths. Many more have become infected without showing symptoms. Previous animal studies raised the possibility that patients may still be infected with the virus several years after recovering from their initial illness. Prior to this latest research, humans were thought to remain infected with West Nile virus only for the first few days of illness. The study, led by Kristy Murray, DVM, PhD at the University of Texas School of Public Health in Houston, demonstrates that not all individuals clear the virus from their system within the first few days—and that it can remain in the

kidneys for years, potentially leading to kidney failure.

Dr. Murray and her colleagues followed more than 100 patients in Houston with severe initial West Nile virus infections for seven years. Individuals were evaluated and blood samples collected every six months. More than half continued to have infection-related symptoms years after their initial illness, although symptoms began to plateau around two years after infection. The deaths of five participants due to kidney failure led researchers to consider whether the kidney could be a preferred replication site for the virus.

To test this hypothesis, Dr. Murray and her team collected urine samples from 25 patients from their original cohort and tested them for presence of West Nile virus. In this group, five patients (20 percent) tested positive for the virus. Viral RNA could be detected in the urine for at least six years following infection. Four of the five patients who tested positive for the virus also experienced chronic symptoms. Of these five, one patient developed kidney failure. These results show that West Nile virus is capable of long-term persistence in patients, particularly when chronic symptoms are present.



In an accompanying editorial, Ernest Gould, PhD, of the Centre for Ecology and Hydrology in Oxford, England, points out that this study raises the additional concern that West Nile virus and other flaviviruses may be transmitted to mosquitoes by apparently healthy humans or animals. This possibility has the potential to start epidemics in new regions of the world.

According to Dr. Murray, patients who have been infected with West Nile virus should “have their kidneys monitored by their physician for any evidence of disease and be aware that persistent infection of the kidneys can happen.” Dr. Murray also reminds the public to take proper precautions to protect themselves from mosquito bites during transmission seasons, typically the summer and fall, to avoid infection.

More research is needed to “understand the underlying mechanisms related to the shedding of virus particles in urine, whether shedding of the virus is constant or intermittent, and whether or not this represents true infection resulting in kidney

disease," the investigators say. They continue to evaluate all study participants, particularly in regard to kidney function. In addition, they are focusing on developing treatment options for those who remain infected with the virus.

Fast Facts

- Individuals who have had severe infections with West Nile virus may harbor the virus in their kidneys for many years.
- This study suggests that individuals infected with West Nile virus should have their kidneys monitored for disease and be aware that disease persistence can occur.

Vegetable Chili

Serves: 6, **Prep:** 30min | **Cook:** 40min
Total: 1hr 10min
<http://recipes.prevention.com>

- 3 tbsp olive oil
- 1/2 lb ground beef, pork, turkey, or chicken, (optional)
- 1 onion, finely chopped
- 3 cloves garlic, minced
- 2 sm eggplant, cubed
- 1 med zucchini, chopped (or use more eggplant)
- 2 carrots, chopped
- 1 C quartered mushrooms
- 1/4 tsp crushed red-pepper flakes
- 4 C canned kidney or pinto beans, rinsed and drained
- 1 box (26 oz) chopped tomatoes (about 3 c)
- 1 3/4 tsp salt
- 1 tsp ground cumin
- 1 tsp dried oregano
- 4 C water or stock
- 1/2 tsp freshly ground black pepper
- 2 tbsp chopped fresh cilantro or parsley, (optional)

Directions

1. Heat oil in large Dutch oven over medium heat. when hot, add meat, if using. season with salt and cook, stirring frequently, until well browned all over, about 5 minutes. remove meat from pan and drain off all but 3 tablespoons of the fat. (if you're skipping meat, put oil in pan and start recipe here.)

2. Return Dutch oven to stove over medium-high heat. add onion and garlic. cook and stir until just softened, about 1 minute. add eggplant, zucchini, carrots, mushrooms, and red-pepper flakes. cook, stirring occasionally, until vegetables begin to soften, 15 to 20 minutes, adjusting heat so that nothing scorches.

3. Add beans, tomatoes (with juice), salt, cumin, and oregano. return meat (if using) to Dutch oven. add enough water to submerge everything. bring mixture to a boil, reduce heat to medium, and cook, stirring occasionally and adding more liquid if necessary, 15 minutes. add black pepper, season with salt to taste, and sprinkle with cilantro, if desired.



Coming Soon: A Low-Heartburn Coffee?

U.S. News and World Report
 HealthDay
 By Elin Holohan, HealthDay Reporter
 March 22, 2010

For millions of coffee-lovers with delicate stomachs, scientists may have found a way to enjoy an eye-opening cup of java without gastrointestinal discomfort.

European researchers studying stomach-irritating chemicals in coffee have unexpectedly found one that actually inhibits acid production in the stomach. "The major import of our work is that it provides scientific

evidence that you can produce a more stomach-friendly coffee by varying the processing technology," said study author Veronika Somoza, professor and chair of the Research Platform of Molecular Food Science at the University of Vienna, Austria.

The finding offers the promise that coffee makers can produce a blend that will be easier on the tummy, Somoza said.

The scientists looked at coffee's effect on human stomach cells using a variety of preparations, including dark-roast, regular roast, decaffeinated and stomach-friendly. Instead of one single element, they identified a mixture of compounds—caffeine, catechols and N-alkanol-5-hydroxytryptamides—as the chemicals in coffee that promote the production of stomach acid.

But a fourth chemical, N-methylpyridinium, which is more common in dark roasts, such as espresso and French roast blends, was found to inhibit acid.

N-methylpyridinium is a product of the roasting process itself, resulting in dark roasts that are less likely than lighter ones to cause stomach irritation, according to the research.

Whether the findings will translate to human coffee drinkers remains unclear. The authors hope to conduct tests with human coffee drinkers this year.

Dr. Joseph Vinson, a professor of chemistry at the University of Scranton in Pennsylvania who has studied the antioxidant properties of coffee, said the study suggests the possibility of a less troublesome brew.

"Cell studies can be legitimate. They can lead to human studies that will say the same thing," said Vinson. "She [Somoza] has figured out a research approach that is one way to do it, and it's a question of whether it is relevant to the human realm."



Vinson predicted it will be.

"There's more than enough data [in the study] to make it interesting," said Vinson. "There can be this special coffee that doesn't bother you."

The potential market for a kinder, gentler coffee is huge. About 40 million people in the United States alone avoid java, often because of acid reflux disease, a common stomach problem for coffee drinkers, according to background information from the American Chemical Society. Stomach-friendly coffees are already on the market, but some doctors don't recommend them for

people with acid reflux, which pushes stomach contents back up the esophagus, causing heartburn.

Among them is Dr. Anthony A. Starpoli, director of gastroesophageal research at St. Vincent's Catholic Medical Centers in New York City, who doesn't advise drinking decaffeinated coffee either. "When you say you can have a little, it becomes a license to do whatever you want," said Starpoli about the advice he gives his patients. "I'm very strict about coffee," he added, because it causes serious stomach trouble for some.

The study suggests some balance of "good guys" and "bad guys" in coffee, and the process used to make it more stomach-friendly eliminates both, he noted. The study's identification of components causing problems for coffee drinkers is a valuable finding and supports his medical advice that some people should avoid drinking coffee entirely, he said.

"It shows a reason, and you always need to have a reason. At the end of the day, if you have significant acid reflux disease, you should not drink coffee," said Starpoli.

Production of a less-irritating coffee would be welcome news, because so many patients resist giving up their daily java, he said.

"It's almost a completely non-negotiable item for some of them," he said.

New Model Suggests Role of Low Vitamin D in Cancer Development

May 22, 2009

By Steve Benowitz

In studying the preventive effects of vitamin D, researchers at the Moores Cancer Center at the University of California, San Diego, have proposed a new model of cancer development that hinges on a loss of cancer cells' ability to stick together. The model, dubbed DINOMIT, differs substantially from the current model of cancer development, which suggests genetic mutations as the earliest driving forces behind cancer.

"The first event in cancer is loss of communication among cells due to, among other things, low vitamin D and calcium levels," said epidemiologist Cedric Garland, DrPH, professor of family and preventive medicine at the UC San Diego School of Medicine, who led the work. "In this new model, we propose that this loss may play a key role in cancer by disrupting the communication between cells that is essential to healthy cell turnover, allowing more aggressive cancer cells to take over."

Reporting online May 22, 2009 in the *Annals of Epidemiology*, Garland suggests that such cellular

disruption could account for the earliest stages of many cancers. He said that previous theories linking vitamin D to certain cancers have been tested and confirmed in more than 200 epidemiological studies, and understanding of its physiological basis stems from more than 2,500 laboratory studies.

“Competition and natural selection among disjoined cells within a tissue compartment, such as might occur in the breast’s terminal ductal lobular unit, for example, are the engine of cancer,” Garland said. “The DINOMIT model provides new avenues for preventing and improving the success of cancer treatment.”

Garland went on to explain that each letter in DINOMIT stands for a different phase of cancer development. “D” stands for disjunction, or loss of intercellular communication; “I,” for initiation, where genetic mutations begin to play a role; “N” for natural selection of the fastest-reproducing cancer cells; “O” for overgrowth of cells; “M” for metastasis, when cancer cells migrate to other tissues, where cancer can kill; “I” refers to involution, and “T” for transition, both dormant states that may occur in cancer and potentially be driven by replacing vitamin D.

While there is not yet definitive scientific proof, Garland suggests that much of the evolutionary process in cancer could be arrested at the outset by maintaining vitamin D adequacy. “Vitamin D may halt the first stage of the cancer process by re-establishing intercellular junctions in malignancies having an intact vitamin D receptor,” he said.

According to Garland, other scientists have found that the cells adhere to one another in tissue with adequate vitamin D, acting as mature epithelial cells. Without enough vitamin D, they may lose this stickiness along with their identity as differentiated cells, and revert to a stem cell-like state.

Garland said that diet and supplements can restore appropriate vitamin D levels, and perhaps help in preventing cancer development. “Vitamin D levels can be increased by modest supplementation with vitamin D3 in the range of 2000 IU/day,” he noted.

The researchers noted that many studies show an apparent beneficial effect of vitamin D and calcium on cancer risk and survival of patients with breast, colorectal and prostate cancer. However, there are some studies that have not found such benefit, especially when taking

smoking, alcohol and viruses into account. While more research needs to be done, Garland recommends that individuals should have their vitamin D level tested during an annual check up.

Garland and his colleagues have published epidemiological studies about the potential preventive effects of vitamin D for some two decades. Last year, his team showed an association between deficiency in sunlight exposure, low vitamin D and breast cancer. In previous work, they showed associations between increased levels of vitamin D3 or markers of vitamin D and a lower risk for breast, colon, ovarian and kidney cancers.

Other authors on the study include Edward D. Gorham, Sharif B. Mohr and Frank C. Garland, UC San Diego.

The Moores UCSD Cancer Center is one of the nation’s 41 National Cancer Institute-designated Comprehensive Cancer Centers, combining research, clinical care and community outreach to advance the prevention, treatment and cure of cancer. For more information, visit <http://health.ucsd.edu/cancer>