



Family Medicine Clinical Pharmacy Forum Vol. 3, Issue 6 (November/December 2007)

Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see, please contact us.

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Drug Therapy:

New Drug Warning – Byetta[®] and pancreatitis

After reviewing 30 reports of acute pancreatitis in patients taking Byetta[®] (injectable antidiabetic agent), the FDA has asked Amylin Pharmaceuticals, the maker of Byetta[®], to add information about acute pancreatitis to the “Precautions” section of the product label. Healthcare providers need to be alert for signs and symptoms of acute pancreatitis in their patients who are on Byetta[®]. Symptoms to watch for include: persistent severe abdominal pain, nausea, vomiting, and laboratory data showing elevated serum amylase and/or lipase. Byetta[®] does have side effects of nausea, vomiting, diarrhea, and indigestion; but severe pain would be suspicious for pancreatitis. If pancreatitis is confirmed, Byetta[®] should not be resumed. Practitioners should use caution when prescribing Byetta[®] and should avoid prescribing to patients who have risk factors for pancreatitis; such as gallstones, severe hypertriglyceridemia, or alcohol use. <http://www.fda.gov/cder/drug/infopage/exenatide/default.htm>

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Zoledronic Acid (Reclast[®]) and improved survival

Zoledronic acid (Reclast[®]) is a once yearly bisphosphonate that is delivered intravenously. A recent study in the New England Journal of Medicine tested the efficacy and safety of zoledronic acid in patients who had undergone a surgical repair of a hip fracture in the last 90 days. The Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly (HORIZON) trial was a randomized, double-blind, placebo-controlled trial that enrolled 2127 patients and randomized these patients to either receive yearly zoledronic acid infusions or to receive placebo. All patients were given supplemental Vitamin D and calcium and were followed up for a mean of 1.9 years.

New fractures were recorded in patients randomized to zoledronic at a rate of 8.6% and the placebo group had a new fracture rate of 13.9% (P=0.001). 9.6% of the patients in the zoledronic acid group died while 13.3% in the placebo group died (P=0.01). It was found that the rates of renal and cardiovascular adverse events, including atrial fibrillation and stroke, were similar in both groups. The authors concluded that a yearly infusion of zoledronic acid within 90 days of a hip fracture could reduce the rate of new fractures and decrease mortality.

NEJM 2007;357:1799-809.

Drug Safety:

Safety of nonprescription cough and cold medicines

The FDA met recently to discuss the safety of OTC cough and cold medications in infants and children

- Effectiveness of nonprescription pediatric cough and cold remedies continues to be debated; evidence has shown they are not safe for young children.
- The FDA has received 123 reports of death associated with nonprescription cough and cold products in children under age six.
- FDA's advisers recommend against using OTC cough and cold medications in children less than two years old.
- The majority of the advisers recommend against using OTC cough and cold products in children under age six and several advisers suggested these products were not safe in children under 12.
- The FDA is currently considering the recommendations and contemplating actions which will likely include changes in product labeling.

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Advice for parents

- Do not use cough and cold products in children under two unless given specific directions by a healthcare provider
- Cough and cold medicines only treat symptoms, they do not cure the common cold, the child will get better with time.
- Liquid medications should be measured using a measuring device that is marked to deliver the recommended dose. A kitchen teaspoon or tablespoon should not be used for medicine.
- Use only pediatric medications for children; do not give medicine that is intended for adult use.

Regulatory Issues:

Pharmacist billing codes Become Permanent

- Two years after temporary codes were issued; pharmacists have a permanent set of current and procedural terminology (CPT) codes to bill for cognitive services.
- The codes were developed through the collaboration of Pharmacist Services Technical Advisory Council (PSTAC) which includes representatives from APhA, ACCP, ASHP, NACDS, NCPA, ASCP, and AMCP.
- This decision was made by the American Medical Association (AMA) after they reviewed evidence of the temporary codes being used to provide medication therapy management (MTM) to hundreds of thousands of patients.
 - Between 2004 and 2006 2.8 million face to face MTM encounters occurred, 86% of visits took place in non-government ambulatory settings
- The codes allow pharmacists to record and seek reimbursement for interventions including creating a medication profile, reviewing medication histories, and making recommendations to improve outcomes or compliance
- Permanent codes can be used to bill for services beginning January 1, 2008, temporary codes can be used through the end of 2007
 - 99605-Initial 15 minutes of MTM service for a new patient (replaces temporary code 0115T)
 - 99606-Initial 15 minutes of MTM service for an established patient (replaces temporary code 0116T)
 - 99607-Additional 15 minutes of MTM (replaces 0117T)

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Drug Withdrawal: Exubera® – inhaled insulin

On October 18, 2007, Pfizer announced that they will no longer be making Exubera®. The decision to remove Exubera® was due to the low number of patients using the medicine and not due to any safety concerns. Exubera® will continue to be available until January 16, 2008, but patients currently on Exubera® should find substitute diabetic medications. Pfizer will honor requests from patients for refunds for unused product or inhalers. The required information and deadlines can be found at:

<http://www.exubera.com/content/Questions.jsp> Any non-returnable products may be placed in the household trash.

Medicare Part D enrollment deadlines

Patients may sign up for Medicare Part D prescription drug coverage when they first become eligible, which is 3 months before and 3 months after their 65th birthday. If a person does not sign up during this eligibility period and decide they want to join later, they may have to pay a penalty fee. Patients who decide to enroll later may sign up during specified periods. The current enrollment period is from November 15, 2007 to December 31, 2007. If your practice has patients that want to sign up they must do it before December 31, 2007. For more information go to www.medicare.gov

Technology Advances:

New TB Test – QuantiFERON®-TB Gold

QuantiFERON®-TB Gold (QFT-G) is a new Mycobacterium tuberculosis (TB) test approved by the FDA on May 2, 2005. It requires whole blood and can test for TB and latent TB infection. The QFT-G contains two antigens for M. tuberculosis – ESAT-6 and CFP-10. The blood sample is incubated for 16-24 hours and the amount of interferon-gamma (IFN-gamma) is measured. If a person is infected their white blood cells will release IFN-gamma. Sensitivity is similar to the TB skin test and the CDC recommends that QFT-G may be used in all circumstances in which the TB skin test could be used. The QFT-G test may be more specific than the purified protein derivate (PPD) test as it uses fewer and more specific antigens. Advantages and disadvantages of the QFT-G testing method are listed below.

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Advantages:

- Single patient visit
- Results in 24 hours
- No reader bias
- Not affected by prior bacilli Calmette-Guérin (BCG) vaccination
- Does not boost responses for subsequent tests

Disadvantages:

- Blood draw needed
- Limited data in people less than 17 years old and people that are immunocompromised
- Test is subject to lab error
- Blood must be processed within 12 hours

<http://www.cdc.gov/tb/pubs/tbfactsheets/QFT.htm>

<http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>

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