

PHARMACY NEWSCAPSULE

Wisconsin Department of Health and Family Services

Division of Quality Assurance

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Influenza Pandemic

By: Doug Englebert, R.Ph

Many of us may hear about pandemic influenza planning, or that the bird flu or another type of flu is coming, and simply shrug it off. History shows that the possibility of a pandemic influenza is a serious matter, and planning is important to minimize the impact of a pandemic influenza outbreak.

Let's look at some facts about the influenza pandemic of 1918-1919.

- Between 20 and 40 million people died world-wide during this pandemic.
- It has been called the most devastating epidemic in recorded world history.
- It was most deadly for people ages 20 to 40.
- 28% of all Americans were infected by this influenza virus.
- An estimated 675,000 Americans died of influenza during the pandemic.
- The average life span in the United States was depressed by 10 years due to the pandemic.

A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity, and for which there is no vaccine. The disease spreads easily person-to-person, causes serious illness and death, and can sweep across the country and around the world in very short time. A worldwide influenza pandemic could have a major effect on the global economy; including travel, trade, tourism, food consumption, and eventually, investment and financial markets.

Planning for pandemic influenza by individuals, business, government, and industry is essential to minimize a pandemic's impact. Lessons learned from the past indicate that another flu pandemic will occur at some point in the future. Some actions that can be taken now include:

- Getting flu shots on an annual basis;
- Adhering to good hand washing techniques at all times; and
- Addressing flu outbreaks in facilities immediately and involving public health.
www.pandemicflu.gov and <http://www.osha.gov/Publications/3328-05-2007-English.html>

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New Medications

Brand Name	Generic Name	Use
Doribax	Doripenem	Antibiotic for intra-abdominal and urinary tract infections.
Isentress	Raltegravir	Treatment for HIV.
Selzentry	Maraviroc	Antiretroviral for treatment of HIV.
Somatuline	Lanreotide	Depot injection for acromegaly.
Tekturna	Aliskiren	Treatment for hypertension.
Exelon	Rivastigmine	Transdermal patch for dementia.

Medication of the Month By Doug Englebert, R.Ph. Neupro®, Rotigotine

Neupro is used for treatment of the signs and symptoms of early-stage Parkinson's disease.

Neupro should be started at 2 mg/24 hours patch. Based upon individual patient clinical response and tolerability, Neupro dosage may be increased weekly by 2 mg/24 hours, if tolerated, and if additional therapeutic effect is needed. The lowest effective dose was 4 mg/24 hours. The highest recommended dose is 6 mg/24 hours. Doses above 6 mg/24 hours have not shown any additional therapeutic benefit. If it is necessary to discontinue use of Neupro, it should be discontinued gradually. The daily dose should be reduced by 2 mg/24 hours with a dose reduction preferably every other day, until complete withdrawal of Neupro.

Neupro is applied once a day. The adhesive side of the transdermal system should be applied to clean, dry, intact healthy skin on the front of the abdomen, thigh, hip, flank, shoulder, or upper arm. The transdermal system should be applied at approximately the same time every day, and at a convenient time for the patient.

The application site for Neupro should be moved on a daily basis. Neupro should not be applied to the same application site more than once every 14 days, and should not be placed on skin that is oily, irritated, or damaged, or where it will be rubbed by tight clothing. Because applying external heat, e.g., a heating pad, sauna, or hot bath, to the transdermal system may increase the amount of drug absorbed, patients should be instructed not to apply heating pads or other sources of heat to the area of the transdermal system. The transdermal system should not be exposed to direct sunlight.

Common or frequent side effects of the Neupro include contact dermatitis, leg pain, malaise, fever, fainting, urinary incontinence, and weight increase. Neupro is associated with nausea, vomiting, and general gastrointestinal distress. Nausea and vomiting may occur more frequently during initial therapy and may require dose adjustment. Hallucinations can occur during treatment with Neupro. Neupro may

cause the development of postural (orthostatic) hypotension with or without symptoms such as dizziness, nausea, syncope, and sweating. Due to these possible symptoms, caution should also be used when patients are taking alcohol, and/or sedating medications (like benzodiazepines and antipsychotics) due to the additive effects.

Very few drug-interaction studies have been done with Neupro. However, Warfarin, Sinemet, and Digoxin did not present drug interactions. In theory, antipsychotics could decrease the effectiveness of Neupro.

Neupro was studied in very few people over 75 years old. Therefore, much is still unknown about this medication and its effect on elderly individuals.

Nursing Home Guidance Update By Doug Englebert, R.Ph.

What are the requirements for sleep medications?

The requirements for sleep medications are the same as for all other medications. When a sleep medication is considered and/or used for a resident in a nursing home, the medication is required to have the following:

- 1) **Appropriate indication for use:** What is the cause of the sleeping problem? Is it due to too much caffeine? Is the lack of sleep due to adverse reactions from other medications? Is the sleep issue due to noise or room temperature? In these situations, other solutions may be more appropriate than medication to address the sleep issue; such as reducing caffeine intake, adjusting noise levels or room temperatures. It is very important to first determine the cause of the problem before taking corrective action.
- 2) **Adequate monitoring:** If the medication is started after other causes are ruled out, is there adequate monitoring? Is the medication working? Does the person sleep during the times desired? Is the medication causing any problems like daytime sleepiness? The medication must be monitored for effectiveness and/or for adverse reactions.
- 3) **Adequate duration:** Is the medication used for the appropriate time? Most sleeping medications used for insomnia are approved to be used for a short duration. When the medication is used beyond the manufacturer's recommended or approved time frame, you should consider reducing the medication in order to determine if the medication is still needed. The guidance for a nursing home is that this evaluation should be made quarterly or every three months while the resident is receiving the medication.
- 4) **Appropriate dosage:** Is the dosage appropriate? This mainly applies to those individuals over 65 years old. In most cases, sleeping medications should be used in lower doses for the elderly. When sleeping medications are used in the elderly at a higher dose than recommended, then justification should be provided.

- 5) Adverse events consideration: When adverse events seem to be resulting from the sleeping medication, then a decision for continuing or discontinuing the medication must be made. Is the medication providing great benefit, and can the adverse condition be controlled? If not, the medication may not be appropriate.

The CMS State Operations Manual provides guidance for specific medications in these areas. The guidance for monitoring, dose, etc. is different for each type of medication. The requirements however are the same for all medications.

Consultant Corner By Doug Englebort, R.Ph.

In a hospital do medications need to be locked?

On November 27, 2006, Centers for Medicare and Medicaid Services published changes to the federal regulations for medication storage in a hospital in the Federal Register. The regulations state the following:

“482.25 (b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. (2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate. (ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area. (iii) Only authorized personnel may have access to locked areas.”

There is no question that controlled substances must be kept locked. However, for non-controlled substances there is now an option to simply have medications “secure.” At this time, there is no guidance to surveyors as to what “secure” may mean. However, there are comments from CMS on the rule change in the Federal Register. Some of those comments include the following:

- 1) An area in which staff are actively providing patient care or preparing to receive patients, that is, setting up for procedures before the arrival of a patient, would generally be considered a “secure area.”
- 2) (In regard to an operating room suite) When the entire suite is not operational or otherwise not in use, for example, weekends, holidays, and after hours, the suite would not be considered secure. When the suite is closed or otherwise not in use, all drugs and biologicals should be locked. A hospital may choose to lock the entire suite....
- 3) Areas restricted to authorized personnel only would generally be considered “secure” areas.

These comments do not substitute for guidance to surveyors; however, the comments give you some idea of how CMS is defining “secure.” When evaluating medication storage as “secure,” it would be prudent to ask questions about the designated area. Can only staff get into that area? Is staff present when medications are unlocked? Are there mechanisms to monitor that area, e.g., camera? If medications are not secure then this regulation would need to be cited by health facility survey staff.