Drug & Poison Information Center—Faculty of Pharmacy—Tanat University

Drug & Poison Information Bulletin

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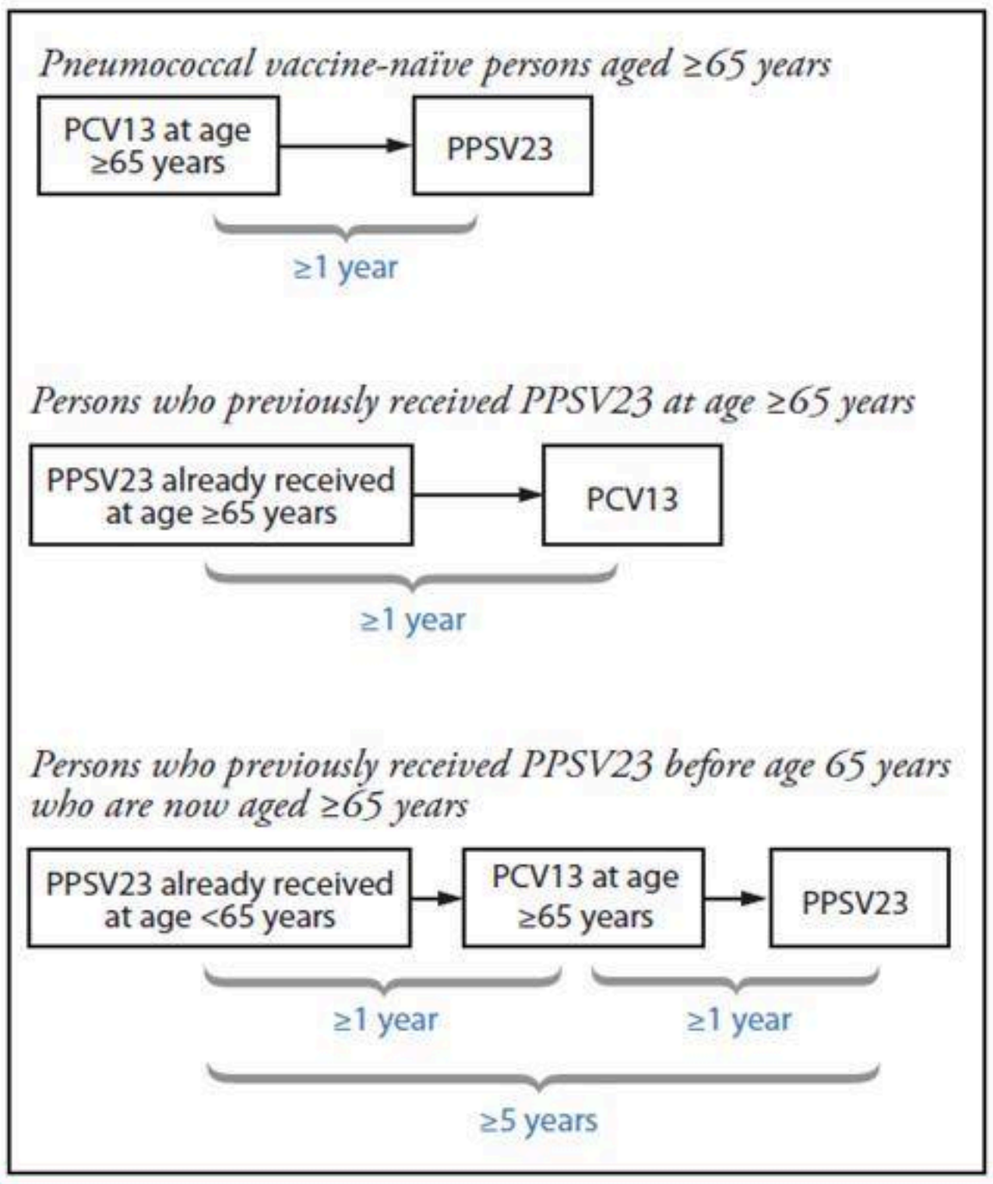
Intervals between Pneumococcal Vaccines in Elderly: New Recommendations of the Advisory Committee on Immunization Practices

Two pneumococcal vaccines are currently used: the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23).

The Advisory Committee on Immunization Practices (ACIP) recommends that both PCV13 and PPSV23 be given in series to adults aged ≥65 years. A dose of PCV13 should be given first followed by a dose of PPSV23 at least 1 year later to immunocompetent adults aged ≥65 years.



Recommended intervals for sequential use of PCV13 and PPSV23 for immunocompetent adults aged ≥65 years — ACIP

The two vaccines should not be co-administered. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated.

** Source: www.medscape.com*

** Further information may be found at:*
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm#Tab

Inside this issue:

Management of acne: Canadian clinical practice guideline

For comedonal acne

- The guidelines recommend topical retinoids or benzoyl peroxide; fixed-dose combinations adapalene–benzoyl peroxide and clindamycin–benzoyl peroxide ; or the combination of clindamycin 1.2% and tretinoin 0.025% (as a gel) and, **for women**, combined oral contracep-tives may be considered.

For localized mild-to-moderate papulopustular acne

- The guidelines recommend benzoyl peroxide as monotherapy; topical retinoids as monotherapy; fixed-dose combination of clindamycin 1% and benzoyl peroxide 5% and the fixed-dose combination of adapalene 0.1% and benzoyl peroxide 2.5% (as gels); or the combination of clindamycin 1.2% and tretinoin 0.025% gel.

For more extensive moderate papulopustular acne

- The guidelines recommend addition of systemic antibiotics to the topical medications above, as recommended for mild-to-moderate papulopustular acne.
- **For women,** the guidelines recommend addition of combined oral contraceptives to the topical medications above, as recommended for mild-to-moderate papulopustular acne.

For severe acne

- The guidelines strongly recommend the use of oral isotretinoin or systemic antibiotics in combination with benzoyl peroxide, with or without topical retinoids.

N.B. Oral isotretinoin should only be prescribed by physicians with experience in prescribing and monitoring the drug. Strict pregnancy precautions must be followed.

* *Source: www.medscape.com*

**Further information may be found at:*
http://www.cmaj.ca/content/early/2015/11/16/cmaj.140665.

Safety Alerts

(1) DPP-4 Inhibitors for Diabetes Can Cause Severe Joint Pain

Dipeptidyl peptidase-4 (DPP-4) inhibitors for type 2 diabetes may cause joint pain so intense it is disabling, the US Food and Drug Administration (FDA) warned on August 28, 2015.

Clinicians prescribe DPP-4 inhibitors in conjunction with diet and exercise to reduce blood sugar levels in patients with type 2 diabetes. They are either combined with other diabetes drugs such as metformin or dispensed as stand-alone products.

In a search of the FDA Adverse Event Reporting System (FAERS) database, they identified 33 cases of severe arthralgia associated with DPP-4 inhibitors from October 16, 2006, through December 31, 2013, in its FDA Adverse Event Reporting System database. Twenty-eight of the cases involved sitagliptin. Saxagliptin, linagliptin, alogliptin, and Vildagliptin accounted for the rest of the 33 cases.

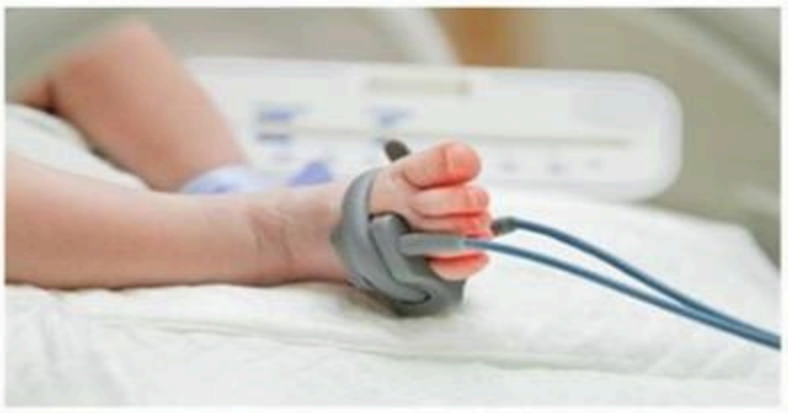
Patients began experiencing joint pain anywhere from one day to years after they started taking the drugs. Fortunately, the pain goes away, usually in less than a month, once patients stop taking the medicine.For ten patients, disabling pain required hospitalization.

Recommendation: Patients should not stop taking their DPP-4 inhibitor, but should contact their health care professional immediately if they experience severe and persistent joint pain. Health care professionals should consider DPP-4 inhibitors as a possible cause of severe joint pain and discontinue if appropriate.

Source: www.medscape.com, www.fda.gov

(2) Iodine-containing Contrast Agents for Medical Imaging: Drug Safety Communication-Rare Cases of Underactive Thyroid in Infants

BACKGROUND: Iodinated contrast media (ICM) are drugs containing iodine that are given to patients to enhance the ability to see blood vessels and organs on medical images such as X-rays or computed tomography (CT) scans. These images provide greater detail when necessary to help health care professionals diagnose potential problems.



ISSUE: FDA is advising that rare cases of underactive thyroid have been reported in infants following the use of contrast media containing iodine, also called "contrast dye," for X-rays and other medical imaging procedures. In all of the reported cases, the infants were either premature or had other serious underlying medical conditions. Available evidence leads FDA to believe that this rare occurrence is usually temporary and resolves without treatment or any lasting effects.

FDA approved changes to the labels of all ICM products to include information about these cases. No changes to current prescribing, administration, or monitoring practices are recommended. FDA will continue to evaluate this issue and will update the public when there is additional information. Manufacturers of ICM products have been required to conduct a study to investigate this safety issue further.

RECOMMENDATION: Parents and caregivers should contact their baby's health care professional for additional information or if they have questions or concerns about their baby receiving an ICM product. Infants typically do not show any visible signs of underactive thyroid. Health care professionals should continue to follow the label recommendations for ICM products. They should continue to use their clinical judgment to determine if testing for underactive thyroid is necessary.

Source:www.fda.gov [Posted November 17, 2015].

(3) Repaglinide - New Contraindication for Concomitant Use with Clopidogrel

Background: Repaglinide is an oral antidiabetic agent used for the treatment of type 2 diabetes mellitus. Clopidogrel is an oral antiplatelet agent used to prevent atherothrombotic events.

Issue: Novo Nordisk Canada and Health Canada have reviewed new safety information determining that coadministration of repaglinide and clopidogrel may lead to a significant decrease in blood glucose levels. Clopidogrel, a CYP2C8 inhibitor, may inhibit the metabolism of repaglinide, potentially increasing its systemic exposure and the risk of hypoglycemia. Health Canada has announced that a contraindication for concomitant use of these drugs has been added to the repaglinide Canadian product monograph and is being added to the clopidogrel product monograph.

Source: online.lexi.com, healthycanadians.gc.ca

New FDA Approved Drugs

Coagadex(Factor X,Human)

FDA approved ***Coagadex***, which is derived from human plasma, on October 20, 2015 for ***hereditary Factor X deficiency*** for on-demand treatment and control of bleeding episodes, and for perioperative (period extending from the time of hospitalization for surgery to the time of discharge) management of bleeding in patients with mild hereditary Factor X deficiency for individuals aged ≥12. Patients with the disorder are usually treated with fresh-frozen plasma or plasma-derived prothrombin complex concentrates (plasma products containing a combination of vitamin K-dependent proteins) to stop or prevent bleeding. The availability of a purified Factor X concentrate increases treatment options for patients with this rare bleeding disorder.

Mechanism: Increase plasma levels of factor X and can temporarily correct the coagulation defect in these patients, as reflected by decrease in the activated partial thromboplastin time (aPTT) and prothrombin time (PT).

Dosage: Dose and duration depend on the severity of the factor X deficiency, location and extent of the bleeding, and the patient's clinical condition. Don't administer >60IU/kg daily.

Source: www.medscape.com, www.fda.gov

Refresh Your Knowledge

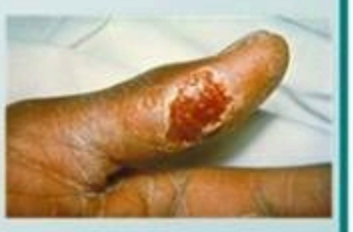
Tularemia

Tularemia is a disease of animals and humans caused by the bacterium *Francisellatularensis*. Rabbits, hares, and rodents are especially susceptible and often die in large numbers during outbreaks. Humans can become infected through several routes, including:

- Tick and deer fly bites.
- Skin contact with infected animals.
- Laboratory exposure.
- Inhalation of contaminated aerosols or agricultural dusts.

The signs and symptoms of tularemia vary depending on how the bacteria enter the body. Illness ranges from mild to life-threatening. All forms are accompanied by fever, which can be as high as 104 °F. Main forms of this disease are listed below:

-Ulceroglandular Tularemia(most common). A skin ulcer appears at the site where the bacteria entered the body. The ulcer is accompanied by swelling of regional lymph glands, usually in the armpit or groin.



-Glandular Tularemia.Similar to ulceroglandular tularemia but without an ulcer.

-Oculoglandular Tularemia .This form occurs when the bacteria enter through the eye. Symptoms include irritation and inflammation of the eye and swelling of lymph glands in front of the ear.

-Oropharyngeal Tularemia. This form results from eating or drinking contaminated food or water. Patients with orophyangeal tularemia may have sore throat, mouth ulcers, tonsillitis, and swelling of lymph glands in the neck.

-PneumonicTularemia(most serious form). This form results from breathing dusts or aerosols containing the organism or when other forms of tularemia are left untreated and the bacteria spread through the bloodstream to the lungs.

-Typhoidal Tularemia (rare and serious form).

Diagnostic testing: Tularemia can be difficult to diagnose. It is a rare disease, and the symptoms can be mistaken for other, more common, illnesses. For this reason, it is important to share with your health care provider any likely exposures, such as tick and deer fly bites, or contact with sick or dead animals. Blood tests and cultures can help confirm the diagnosis.

-***Growth of F. tularensis in culture*** is the definitive means of confirming the diagnosis of tularemia. Appropriate specimens include swabs or scrapings of skin lesions, lymph node aspirates or biopsies, pharyngeal swabs, sputum specimens, or gastric aspirates, depending on the form of illness. Paradoxically, blood cultures are often negative.

-***A presumptive diagnosis*** of tularemia may be made through testing of specimens using direct fluorescent antibody, immunohistochemical staining, or PCR.

-***Serologically***: by demonstrating a 4-fold change in specific antibody titers between acute and convalescent sera. Convalescent sera are best drawn at least 4 weeks after illness onset; hence this method may be useful for confirming the diagnosis but not for clinical management.

Treatment

-***Streptomycin*** is the drug of choice based on experience, efficacy and FDA approval. ***Gentamicin*** is considered an acceptable alternative, but some series have reported a lower primary success rate. Treatment with aminoglycosides should be continued for 10 days.

-***Tetracyclines*** may be a suitable alternative to aminoglycosides for patients who are less severely ill. Tetracyclines are static agents and should be given for at least 14 days to avoid relapse.

** Source: www.cdc.gov*

** Further information may be found at:*
http://www.mayoclinic.org/diseases-conditions/tularemia/basics/treatment/con-20028009

New Textbook Editions

**AHFSI DI®* contains the most trustworthy drug information available all in one place. It is the most comprehensive evidence-based source of drug information complete with therapeutic guidelines and off-label uses.

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