PATIENT INFORMATION: Flu Season Is Coming!

With the flu season in progress, getting vaccinated should be on top of your priority list. The Centers for Disease Control and Prevention (CDC) recommends that everyone aged 6 months and older be vaccinated yearly. But this year, when you head to your doctor’s office, pharmacy, health department, clinic, or even school or employer to get your flu vaccine, there are a few changes to be aware of.

The biggest and most important change for the 2013-2014 flu season is the move away from a one-size-fits-all vaccination mentality and the move towards an individualized approach. This means that there will be more options when it comes to selecting the right vaccine for you. With up to six different types of flu vaccines available this year, this article will give you the low-down on proper vaccine selection.

New additions to the flu vaccine lineup this year include a quadrivalent vaccine, which protects against four strains of influenza instead of the traditional three (trivalent), and an egg-free vaccine for those who are allergic to eggs. Recent years have also seen the addition of a high-dose vaccine for people 65 years or older and a vaccine that is injected just below the skin for those who fear big needles.

The CDC does not recommend any one vaccine over another. Everyone aged 6 months and older is eligible for the traditional, trivalent vaccine, but there are some cases when one of the newer vaccines is a better option.

If you want something besides the traditional intramuscular injection: For those who fear needles or prefer a different route of administration, there are two options.

- **Option 1: Live-attenuated, nasal vaccine.** This vaccine is a nasal spray, which completely eliminates the use of a needle. In order to be eligible for the nasal vaccine, you must currently be healthy, non-pregnant, and between the ages of 2 and 49 years.
- **Option 2: Intradermal, trivalent vaccine.** While this vaccine still uses a needle, it is a much smaller needle. The vaccine is injected just under the skin instead of into the muscle. This vaccine is for people aged 18-64 years old.

If you are allergic to eggs: Depending on the severity of your egg allergy, the new recombinant (egg-free) vaccine might be your best bet.

- **Mild allergy:** If you experienced only hives after egg exposure, then you can receive either an intramuscular vaccine (trivalent or quadrivalent) or the new recombinant (egg-free) vaccine. Talk to your health care provider for more information.
- **Severe allergy:** If you have a more serious reaction to eggs, then the recombinant (egg-free) vaccine is a better solution for you. This vaccine is for people aged 18-49 years old.

If you are 65 years or older: Aging puts you at greater risk for a more severe illness from influenza and decreases your body’s ability to form a good immune response to the vaccine.

- **High-dose vaccine:** The high-dose intramuscular vaccine is supposed to give you a better immune response and better protection against the flu.

**Quadrivalent vaccines:** This year, there are vaccines that protect against four influenza

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The standard therapy for lower urinary tract symptoms (LUTS) in men is alpha-blockers. The drug of choice for erectile dysfunction (ED) is a PDE-5 inhibitor. An association between LUTS and ED is suspected; however, a causal relationship has not been established. For patients with LUTS refractory to alpha-blocker treatment or not well controlled on monotherapy, the options are limited and often include surgery. The combination of PDE-5 inhibitors and alpha-blockers demonstrated a synergistic effect in several studies and may be an effective alternative to monotherapy.1,3

A randomized, double-blind, crossover study determined that the combination of tamsulosin and tadalaﬁn was more effective than monotherapy in 30 men.1 Eligible men were 50 years old and had a history of LUTS secondary to benign prostatic hyperplasia (BPH). Exclusion criteria were PSA >4 ng/mL, history or evidence of prostate cancer, prostatic surgery or other invasive procedure to treat BPH, or post-void residual volume (PVR) >250 mL. The patients were assigned either 0.4 mg tamsulosin or 0.4 mg tamsulosin + 20 mg tadalaﬁn. The patients received treatment daily for 6 weeks then switched to the other treatment for an additional 6 weeks. Monotherapy with tamsulosin improved urinary symptoms and quality of life compared to baseline, but combination treatment caused greater improvement from baseline (p < 0.001). Urinary flow rate (Qmax) and PVR were improved signiﬁcantly with both therapies compared to baseline, but no signiﬁcant difference was seen between the groups. ED symptoms improved with the combination but not with tamsulosin alone. All patients preferred the combination over monotherapy. Adverse drug reactions were minor. Limitations to the study included the lack of a washout period between treatments. In addition, the prostate size was not evaluated and may have an effect on treatment outcomes.1

An open label, randomized study evaluated 62 men (ages 50-76 years) and found signiﬁcant improvement with the combination of alfuzosin and sildenaﬁl over monotherapy with either agent.2 Included men had moderate to severe untreated LUTS and ED. The patients received alfuzosin 10 mg, sildenaﬁl 25 mg, or a combination of both drugs daily for 12 weeks. A signiﬁcant improvement in urinary symptoms and erectile function occurred with the combination therapy compared to both baseline and monotherapy with either drug. PVR and Qmax improved signiﬁcantly with alfuzosin alone and the combination but not with sildenaﬁl alone. Adverse drug reactions were minor, and the combination treatment was tolerated well. The study was limited by the experimental dose of sildenaﬁl 25 mg/day while higher doses, without the concomitant use of alpha blockers, have demonstrated a signiﬁcant effect on LUTS. Other limitations included the lack of blinding and the small number of patients.2

Another 12-week, open label, randomized study evaluated 66 men with a history of ED and LUTS and found signiﬁcant improvement with the combination of alfuzosin and tadalaﬁn.3 The patients received either alfuzosin 10 mg, tadalaﬁn 20 mg or a combination of both drugs daily. Erectile function improved in patients using monotherapy with either medication, but the most improvement was seen with the combination therapy. Urinary symptoms improved markedly with combination therapy over either monotherapy. Adverse events resulted in six patients dropping out of the study from headache, dizziness, constipation, and/or back pain. Limitations of the study included the lack of blinding and small number of patients.3

The combination of an alpha-blocker and a PDE-5 inhibitor was more effective at reducing the symptoms of LUTS and ED than either drug alone in multiple studies. The synergistic effect of the combination may be a good alternative to patients not controlled on monotherapy. Large, randomized, blinded trials are needed to fully examine the role of combination therapy using alpha-blockers and PDE-5 inhibitors in patients with LUTS.

By Bryan Wisherd, PharmD Candidate
PATIENT INFORMATION: The 411 on Germs

Germs are everywhere around us, and we cannot always detect their presence. Most germs live only a short time outside the body but some like the influenza (flu) virus can survive for 24 hours, which allows time for someone to come along and get infected. As winter approaches, here are simple steps to help protect you and your family from sickness.

**Hand washing saves lives**
Washing hands with plain soap and running water is the best way to prevent illness and the spread of infection. Run hands under water and scrub with soap for at least 20 seconds before rinsing. Air dry or use a clean towel to dry your hands; do not use your clothes as a hand towel. If soap and water are not available, use a hand sanitizer which contains at least 60% alcohol. Hand sanitizers do not kill all germ types and are not effective on visibly dirty hands because they cannot cut through dirt and oil. Rub the sanitizer over the entire surface of the hands and fingers until the product is dry.

The routine use of antibacterial soap is not recommended because bacteria can develop resistance to the antibiotic in the soap. Antibiotic resistance is a bacteria’s ability to reduce or resist the effects of an antibiotic. The bacteria changes, becomes hard to treat, and can quickly spread, infecting others. Every time you use an antibiotic cleanser, the sensitive bacteria die but the resistant ones multiply. To help prevent resistance, always follow the manufacturer’s directions on the product’s label. The FDA determined that antibacterial-containing products have no benefits over their non-antibacterial counterparts.

**At the Store**
Wipe down the handle and baskets of shopping carts before using. Little children frequently ride in carts and mouth the handles. They may also have gone to the bathroom during the ride. It is estimated that 50% of carts are infected with harmful bacteria because carts are not routinely cleaned. Also, remember to wash your hands or use hand sanitizer often.

**At home**
Some germs are beneficial. The good germs help keep the bad germs in check by not letting them grow unobstructed. So use targeted hygiene practices when cleaning your home. Use disinfectants to target areas where harmful germs are most common, like kitchens and bathrooms. Germs can develop resistance to disinfectants in a similar manner as antibiotic resistance. Therefore, it is important to follow the manufacturer’s directions for use and use the product only for its intended purpose to prevent the development of resistance. Also, disinfectants do not kill germs instantly. One of the most common cleaning mistakes is not letting the disinfectant sit the recommended time before wiping it up. Use paper towels or clean rags when cleaning to decrease spreading germs around.

**The most common bugs**

Norovirus is a virus that can cause gastroenteritis, or inflammation of the stomach and intestines. Symptoms include stomach cramping, diarrhea, nausea, and vomiting. Norovirus infections are commonly referred to as stomach flu or food poisoning. This virus can also masquerade as the flu, causing low-grade fevers, muscle aches, chills, and fatigue. Infection occurs from contaminated food or water or person-to-person contact. Contaminated food and water is caused from contact with human waste or when handled by infected persons during preparation or service. The best way to prevent infection from Norovirus is through proper hand washing. Wash before and after eating and using the bathroom.

Escherichia coli or E. coli bacteria are found everywhere. Most forms are harmless, but some can cause illnesses. E. coli infection is commonly contracted from raw food like undercooked hamburger, but you should not judge the doneness of your meat by its color. The Centers for Disease and Control and Prevention (CDC) states 1 in 4 burgers turn brown before reaching what is considered the safe internal temperature of 160 degrees. Use a meat thermometer to determine doneness. Washing fruits and vegetables before eating can also decrease your risk of E. coli infection.

Salmonella bacteria cause food poisoning and is considered the deadliest foodborne germ. Most people associate Salmonella with uncooked eggs and poultry, but it can be found on fruits and vegetables. It has even been found in processed frozen potpies. Salmonella infection is more common in summer because the higher temperatures give the bacteria time to grow. To stave off this bug, keep hot foods hot (>145°F) and cold foods cold (<40°F). Also, do not let food set out more than 1 hour and wash fruits and vegetables before eating.

By Melissa Gilleard, PharmD Candidate

**REFERENCES:**


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strains (quadrivalent) instead of the traditional three (trivalent). Both the trivalent and quadrivalent vaccines include protection against two common Type A influenza strains called H1N1 and H3N2.

Type A influenza causes the majority of seasonal infections and usually causes more serious disease. There is also Type B influenza that circulates as one of two distinct families every season. Type B influenza is more common in children and young adults and causes a seasonal epidemic every 2-4 years.

In the past, vaccines have only included one Type B strain that is chosen based on CDC predictions. The new quadrivalent vaccines include two Type B strains, one from each major family, to take out the guesswork. The addition of the second Type B strain should prevent more cases of influenza and deaths than the trivalent vaccine with only one Type B strain.

It is important to remember that these numbers are only estimates and only time will tell how much of an impact these new vaccines will have.

The CDC estimates that roughly 30 million of the 135-139 million vaccine doses produced this year will be quadrivalent flu vaccine. A portion of intramuscular vaccines and all intranasal vaccines will be quadrivalent. The CDC does not recommend one vaccine variety over another, which means that any form will give you good protection. The quadrivalent vaccine may have more benefit for those who are at greater risk of Type B infection (children, young adults, and possibly seniors), but it is not currently recommended for any specific population.

With so many options, it may be a little confusing when getting your flu vaccine this year. The important thing to remember is that getting vaccinated is the best way to prevent the flu. Your vaccination provider will gladly help you decide on the right vaccine, so get out there and protect your health this flu season!

By Joe Symbal, PharmD Candidate

REFERENCES:


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Approximately 1 in 5 people are infected with the flu annually. The highest rate of infection is in school-age children. The Centers for Disease Control and Prevention (CDC) recommends vaccination against the flu for everyone ≥ 6 months old who do not have contraindications to vaccination. While the peak influenza activity is in January or later, outbreaks can occur as early as October. Hence, the influenza vaccine can be given as soon as it is available (usually in September) and anytime during the flu season.1

Antigenic drift (mutations in the RNA genome of the flu virus) changes the way the immune system recognizes the flu virus; hence the need for annual vaccination for protection against new virus strains. The World Health Organization (WHO) and US Food and Drug Administration (FDA) recommend that trivalent vaccines contain the following virus strains for the 2013-2014 flu season:

- A/California/7/2009 (H1N1)-like virus
- A/Victoria/361/2011 (H3N2)-like virus
- B/Massachusetts/2/2012-like virus

The new quadrivalent vaccines will also contain a B/Brisbane/60/2008-like virus. Experts recommended adding a fourth strain since it is difficult to predict which influenza B strain will be more prevalent during a flu season. The quadrivalent vaccines are as effective as the trivalent vaccines with similar adverse effects. Five new products have been approved by the FDA. To avoid confusion due to the increased number of formulations, the abbreviations TIV (trivalent inactivated influenza vaccine) and LAIV (live attenuated influenza vaccine) will no longer be used. The new abbreviations are:

- IIV3 = inactivated influenza vaccine, trivalent, standard dose or high-dose
- IIV4 = inactivated influenza vaccine, quadrivalent, standard dose
- RIV3 = recombinant influenza vaccine, trivalent
- LAIV4 = live-attenuated influenza vaccine, quadrivalent
- ccIIV3 = cell culture-based inactivated influenza vaccine, trivalent

The new formulations for 2013-2014 are:

- Quadrivalent live attenuated influenza vaccine (LAIV4, FluMist® Quadrivalent) which replaces the trivalent live attenuated influenza vaccine
- Quadrivalent inactivated influenza vaccines (IIV4, Fluarix® Quadrivalent, Fluzone Quadrivalent, Fluzone Quadrivalent), available in addition to the trivalent formulations
- Trivalent cell culture-based inactivated influenza vaccine (ccIIV3, Flucelvax®)
- Recombinant hemagglutinin vaccine (RIV3, Flublok®)

Flublok® and Flucelvax® are new trivalent formulations. Flublok® is a recombinant vaccine made from hemagglutinin from the influenza virus. It is associated with more injection site reactions like pain and redness. Flublok® also has a shorter expiration date (16 weeks from the date of production). One advantage of Flublok® is that people between 18 and 49 years with an egg allergy and no contraindications can use it because it is egg-free. Other patients outside of the recommended age with mild reactions to eggs should be given the inactivated vaccine and observed for 30 minutes. Patients with severe allergies should be referred to a physician.

Flucelvax® is prepared from influenza virus grown in cultured cells instead of chicken embryos. While it is not made in chicken eggs, the seed virus is made in chicken eggs. Hence, it is not recommended for individuals with severe allergic reactions to eggs. Flucelvax® comes in pre-filled syringes.

The CDC’s Advisory Committee on Immunization Practices (ACIP) does not prefer one vaccine over another, within approved indications and recommendations. The chart on page 6 contains all the vaccines available for the 2013-2014 flu season.

By Isaac Akinola, PharmD Candidate

REFERENCE:

### 2013-2014 Influenza Vaccines

<table>
<thead>
<tr>
<th>Abbreviation(s)</th>
<th>Inactivated Vaccines</th>
<th>Live Attenuated Vaccines</th>
<th>Recombinant Vaccine (Flublok®)</th>
<th>Cell Culture Vaccine (Flucelvax®)</th>
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* Two doses separated by at least 4 weeks are needed for children 6 months to 8 yrs in the first season the vaccine is administered.
† Not all TIV preparations are licensed for young children.
‡ Administer without regard to interval if other vaccine is inactivated; observe four-week interval if other vaccine is live.
§ Fluzone® HD is indicated for individuals 65 years of age and older.


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**College of Health Professions**  
**and Biomedical Sciences**  
**Drug Information Service**  
The University of Montana  
Skaggs School of Pharmacy  
32 Campus Drive  

Phone: 406-243-5254  
Fax: 406-243-5256  
Email: druginfo@umontana.edu

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