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## Synopsis:

The American Academy of Pediatrics does not recommend that patients with a serious egg allergy receive the seasonal influenza vaccine, as the flu vaccine typically contains egg protein. We can offer your child an influenza vaccine (Fluarix) which contains only a trace amount of egg and has been well-tolerated by our egg-allergic patients for the past several years. We administer the Fluarix in a divided dose and observe and treat for any signs of allergy should they occur. The entire appointment takes approximately 1 ½ hours. Please contact our office if you are interested in being added to our flu shot schedule. Depending on demand and availability, we may not be able to accommodate everyone who is interested in receiving the Fluarix.

*Please note, this does not address issues related to the Novel H1N1 ("swine flu") influenza vaccine, and Fluarix does not protect against the Novel H1N1 flu virus.*

## ***PARENTS: PLEASE READ PRIOR TO YOUR CHILD'S INFLUENZA IMMUNIZATION APPOINTMENT***

### **Seasonal Influenza Vaccination in Children with Egg Allergy: What You Should Know\***

#### **WHY DO I NEED TO READ THIS?**

This document provides information about the yearly influenza vaccine with regard to children with egg allergy. Families considering having the influenza vaccine administered at the Jaffe Institute will need to make decisions about the vaccine prior to their appointment. The vaccine is not generally recommended for children with anaphylactic egg allergy so use in this context is "off label".

Please read the following carefully:

#### **WHAT DO THE INSTITUTE DOCTORS RECOMMEND?**

If you decide to pursue vaccination (see below) for your child with possible anaphylactic egg allergy we are **strongly recommending** vaccination with the **Fluarix® brand vaccine**. This vaccine is *currently approved in the US for persons ages 18 and older. However, it is approved for children 6 months of age and older in Europe. It is also approved for children older than 3 months of age in Australia.* We are recommending this vaccine because:

**-The vaccine has only trace amounts of egg protein (<1.0 mcg/0.5mL dose)**

**-Previous studies\*\* showed a vaccine with this amount of egg could be given safely to children with egg allergy (a two-injection approach was used)**

**-We have used the Fluarix vaccine for the past 3 years with no significant side effects**

**-Other available vaccines can have about 40 times the amount of egg as this vaccine**

**-The administration procedure is simpler and less stressful for children (fewer tests and fewer injections compared to vaccines that are approved for infants/children but have more egg in them) – see the section “What is Involved in Getting the Vaccine” for more details)**

Please read the remainder of the information on this form and when making an appointment notify us of your plans for selecting the Fluarix® or another vaccine.

If you would like to receive a different influenza vaccine, you may obtain the vial from your pediatrician and bring it with you to your appointment. We request that you discuss the pros and cons of receiving an influenza vaccine with your child’s pediatrician before coming to the appointment.

We may not be able to accommodate every family who wishes to pursue vaccination.

Your child should be off antihistamines prior to the appointment (if possible).

## **ADDITIONAL IMPORTANT INFORMATION:**

### **WHAT IS THE INFLUENZA VACCINE?**

This vaccine is formulated each year to protect against what is expected to be the type of “flu” that may occur in the flu season. It does not protect against infections with other agents causing flu-like symptoms (such as the common cold). It is NOT formulated to protect against “Bird Flu” or “Novel H1N1 Swine Flu.” The effectiveness of the vaccine can vary and it is not predictable prior to the flu season.

### **WHO SHOULD GET THE SEASONAL FLU VACCINE?**

Over the past several years, the recommendations have changed to include an increasing number of potential candidates for the vaccine. The influenza vaccine is now recommended for the following people:

- Children aged 6 months through 18 years.
- People with chronic medical conditions, such as asthma.
- Women who will be pregnant during the influenza season.
- People aged 50 years and older.
- People in nursing homes or long term care facilities.
- Household contacts of people who are at high risk of developing complications from the flu.
- Household contacts and caregivers of children aged <5 years, adults aged >50 years, and adults with chronic health conditions, with particular emphasis on contacts of children aged <6 months.
- Adults and children who have immune suppression.
- Adults and children who have any condition that may compromise respiratory function or who are at risk of aspiration.
- Healthcare workers.

You may wish to discuss your child’s eligibility for the vaccine with your pediatrician. Your pediatrician can also review the effectiveness of the vaccine and typical side effects.

## **WHAT ABOUT EGG ALLERGY AND THIS VACCINE?**

Influenza vaccines contain measurable and variable amounts of egg protein. Therefore, vaccination presents an allergic risk for people with egg allergy. The influenza nasal spray vaccine also contains egg. The MMR vaccine does not contain appreciable egg, and is considered of no special risk for persons with egg allergy. Therefore, tolerating MMR does not indicate the flu vaccine would be tolerated.

## **CAN OR SHOULD A PERSON WITH EGG ALLERGY GET THE VACCINE?**

The answer to this question is not straight-forward because the vaccine presents a risk that must be weighed against potential benefits. The risks may be higher depending upon the amount of egg in the vaccine and the severity of the egg allergy. The benefits may be more important for a child with worse asthma, an immune system weakness (e.g., a child on cancer chemotherapy) or other factors.

### *Children with “anaphylactic” egg allergy*

The American Academy of Pediatrics (AAP) Committee on Infectious Disease (in a document called the REDBOOK) says that children with “systemic anaphylactic” egg allergy should “generally not receive [the vaccine] because of a risk of adverse reactions, the likely need for yearly immunization, and the availability of [medications] against influenza infection.” They define anaphylactic egg allergy as generalized hives, drop in blood pressure, or upper or lower airway blockage after eating egg. Jaffe Institute doctors are reluctant to administer influenza vaccine to children with this history and current egg allergy.

If the potential benefits are overwhelming, vaccine testing and gradual administration, for example over 5 injections (see below), could be considered.

### *Children without “anaphylactic” egg allergy or severity not known.*

Most children with egg allergy have not experienced anaphylaxis. Some may have had mild reactions and some may not know what would happen if they ate egg because they avoid it based upon a positive test. Unfortunately, it is not possible to know “severity” from a positive blood or skin test to egg (or vaccine). You or your doctor may have a good guess about severity from your child’s experiences and underlying allergic problems (e.g., asthma, past severity of reactions). However, there is no certain way to know.

The AAP Redbook says that “Less severe or local manifestations of allergy to egg are not contraindications to administration of influenza vaccine and do not warrant skin testing.” This would mean that if your child definitely has mild reactions to eating egg, they could get the vaccine in the usual manner (a single injection). However, Institute doctors recognize that this situation still presents some degree of risk, and that the severity is often unknown. Depending upon the flu vaccine and your child’s history, your preferences, your pediatricians preferences and other factors, we may perform testing and possibly a step-wise injection.

## **WHAT ABOUT OTHER CONTENTS OF FLUARIX®?**

Fluarix is formulated without preservatives and does not contain thimerosal. Each 0.5mL dose contains octoxynol-10 ( $\leq 0.120$  mg),  $\alpha$ -tocopheryl hydrogen succinate ( $\leq 0.1$ mg), and polysorbate 80 ( $\leq 0.380$  mg). Each dose may also contain residual amounts of hydrocortisone ( $\leq 0.0016$  mcg), gentamicin sulfate ( $\leq 0.15$  mcg), formaldehyde ( $\leq 50$  mcg), and sodium deoxycholate ( $\leq 50$  mcg) from the manufacturing process

## **WHAT VACCINES ARE AVAILABLE?**

There are several different brands for injection. Unfortunately, the brands “approved” for young children contain more egg than one approved for age 18 and up (see above). We do not have data saying whether the brand with less egg has been tested in the US for younger children or if there is a difference in efficacy, but it is used in infants in other countries. Therefore, the brands approved for younger children carry more reaction risk with regard to egg (and require more tests and more injections). The nasal spray vaccine has egg.

## **WHAT IS INVOLVED IN TESTING?**

Depending upon the factors described above, allergy testing with the vaccine may be recommended. Skin testing will initially be done with the influenza vaccine by the standard prick testing method. **YOUR CHILD MUST BE OFF OF ANTIHISTAMINES FOR THIS TESTING** (the number of days off varies by type of antihistamine, ask our office staff). If the prick test is negative, "intradermal" skin testing may be done depending upon the egg content of the vaccine. In this test, a small needle is used to inject diluted vaccine into the skin. If tests are negative, the vaccine may be given in a single injection. If the tests are positive, which in our past experience they most often are for the vaccines approved for younger children, then decisions about giving the vaccine are made. Our testing procedures will vary depending upon the amount of egg in the vaccine used.

## **WHAT IS INVOLVED IN GIVING THE VACCINE?**

If the skin testing is positive, either the vaccine will not be given or the vaccine may need to be given in multiple doses, depending upon various factors (risks, potential benefits, amount of egg in the vaccine, etc). Depending upon these assessments, your doctor may provide the vaccination in 2 to 5 divided doses. The injections will start with a small amount of the vaccine and will increase with each dose given. The injections will be given approximately 10-20 minutes apart. Your child will be observed for approximately 30 minutes following the last injection. Even when the vaccine is given slowly in this manner, there is a risk of an allergic reaction, including anaphylaxis. You will be asked to sign a form indicating that you understand the risks. The total appointment time could be up to 3 hours, or longer if significant reactions occur.

## **WHAT ELSE SHOULD I KNOW?**

Children aged 6 months to 8 years who are getting the vaccine for the first time are advised to get 2 doses, separated by 4 weeks. Also, if your child only received one dose last year, and is under 8 years of age, 2 doses are recommended for the current influenza season.

Depending upon the availability of vaccine and number of people coming for evaluations, we may not be able to accommodate second vaccinations. If first vaccination was performed without a reaction, we may advise that the second vaccine be given by your pediatrician.

*It is likely that we will be suggesting uses of vaccines that would be considered "off-label" because the dosing, risk about egg allergy, and/or age group for which the vaccine is intended is not as directed on package labeling. You will be informed of this and asked to sign a form indicating that you are aware of this and agree. Vaccine visits are time consuming and directed; please do not plan to address additional allergic problems during a visit for flu vaccine. Your egg-allergic child must be currently healthy to receive the vaccine (no increasing rashes, hives, current wheezing, etc).*

Depending upon demand and vaccine availability, we may not be able to accommodate every patient requesting vaccination.

*\*This information is based upon recommendations from the 2009 Redbook from the American Academy of Pediatrics, expert opinion, and upon experiences over several past seasons. The availability of influenza vaccine and the amount of egg in the vaccines can vary seasonally and our recommendations may change accordingly. The above should not be construed to represent a single possible course of action. Your child's specific history and ongoing experiences with the available preparations may indicate a different course of action.*

\*\* James JM, Zeiger RS, Lester M, Sampson HA et al.. J Pediatr. 1998;133:624-628.  
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