

Seasonal Influenza Vaccination July 10, 2012

Immunization Branch Kenzi Guerrero, MPH, Epidemiologist Tony Aragon, MS, Epidemiologist



Seasonal Influenza Vaccination

- Overview
 - 2012–2013 Influenza Strain
 - Types of Influenza Vaccine
 - Who should get vaccinated
 - Vaccine Effectiveness
 - Coverage Rates
 - Influenza Vaccine Development
 - Influenza Vaccine Safety
 - Q & A

Influenza Strain Selection

- Each Year
 - Food and Drug Administration (FDA)
 - World Health Organization (WHO)
 - U.S. Centers for Disease Control and Prevention (CDC) and
 - Other institutions study virus samples collected from around the world.
- flu viruses that are the most likely to cause illness during the upcoming flu season

Annual Influenza Vaccine Production Timeline

Surveillance

Step

- Influenza vaccine protects against three prominent virus strains, which must first be identified before production can begin each year.
- Ongoing global surveillance is key to predict-ing which three strains will circulate each influenza season.



YEAR-ROUND

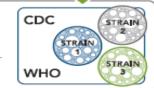
Step

Strain Selection

- World health officials¹ analyze and identify the dominant circulating strains.
- The strains are submitted to the Food and Drug Administration (FDA) to recommend which three to include. The FDA distributes

seed viruses to manufacturers to begin the production process.

· Manufacturers' scientists predict the circulating strains for the coming season and begin preparing vaccine at risk before final FDA selection.2



JANUARY-MARCH

Manufacturing and Production^{3,4}

Step 3

- Each virus strain is produced separately and later combined to make one vaccine.
- Millions of specially prepared chicken eggs are used to produce the vaccine. For seven months, fertilized eggs are delivered to the

manufacturer. Each egg is cleaned with a disinfectant spray and injected with one strain.

 The eggs are incubated for several days to allow the virus to multiply. After incubation the virus-loaded fluid is harvested.

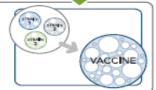


JANUARY-JULY

Purification and Testing^{3,4}

Step

- The virus fluid undergoes multiple purification steps and a special chemical treatment to ensure the virus is inactivated, or "killed."5
- The virus is split by chemically disrupting the whole virus.
- . Viral fragments from all three strains are collected from different batches, and combined upon completion of quality control tests.
- Manufacturers and the FDA test the vaccine concentrate to determine amount and yield of the virus to ensure concentrate is adequate for immunization.



JUNE-OCTOBER

Filling and Packaging

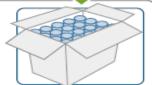
- Upon FDA approval and licensing, the vaccine is released for distribution in time for immunization.
- Manufacturers begin filling the doses into vials and syringes, which are then sealed and

carefully inspected before labels are applied to show the vaccine batch, lot numbers and expiration date.

· Each lot must be specifically "released" by the FDA before manufacturers can ship.

Depending on viral yields and virus activity,

late season immunization.



JULY-DECEMBER

Shippina

Step

- Vaccine shipments typically begin in August/ September and continue into November.
- With CDC's support, partial shipments are sent early in the season to all customers to ensure broad access for high-risk patients.



AUGUST-NOVEMBER; BEYOND AS NEEDED

Vaccination

OCTOBER AND BEYOND

Step

- The CDC recommends particular high-risk populations at risk for influenza and related complications to be immunized every year. Other persons who wish to reduce their risk for influenza may choose to be immunized.
- Immunization generally begins in October or as soon as vaccine becomes available and continues through the influenza season which typically ends in March.
- Immunity develops approximately two weeks following vaccination.4



2012-2013 Influenza Strain

- On February 23, 2012 the World Health Organization (WHO) recommended that the Northern Hemisphere's 2012-2013 seasonal influenza (flu) vaccine be made from the following three vaccine viruses:
 - an A/California/7/2009 (H1N1)pdm09-like virus;
 - an A/Victoria/361/2011 (H3N2)-like virus;
 - a B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

Types of Flu Vaccine

- Trivalent inactivated Vaccine (TIV)
 - The regular trivalent inactivated vaccine that's given intramuscularly is approved for people 6 months of age and older, including healthy people, those with chronic medical conditions, and pregnant women.
 - A "high dose" trivalent inactivated vaccine also given intramuscularly containing 4 times the amount of antigen as the regular TIV that is approved for use in people 65 and older. It was introduced in 2009-2010.
 - An intradermal trivalent inactivated vaccine that is given into the dermal layer of the skin via a single dose, prefilled microinjection syringe and that contains less antigen than the intramuscular TIV formulations. The intradermal vaccine was approved for use in people 18 through 64 years of age in 2011.
- Live, Attenuated Vaccine
 - The Live, Attenuated Intranasal Influenza Vaccine (LAIV) that is given as a nasal spray and can be used in healthy people 2-49 years of age who are not pregnant.

Who should get vaccinated?

- Advisory Committee on Immunization Practices (ACIP)
 - annual influenza vaccine for all people aged 6 months and older.
- Children 6 months through 8 years
 - require 2 doses of the influenza vaccine during their first season of vaccination.
 - 2 doses should be administered a minimum of 4 weeks apart.

Target Groups

- People who are at high risk of developing serious complications like pneumonia if they get sick with the flu. This includes:
 - People who have certain medical conditions including asthma, diabetes, and chronic lung disease.
 - Pregnant women.
 - People 65 years of age and older
- People who live with or care for others who are at high risk of developing serious complications.
 - Household contacts and caregivers of people with certain medical conditions including asthma, diabetes, and chronic lung disease.

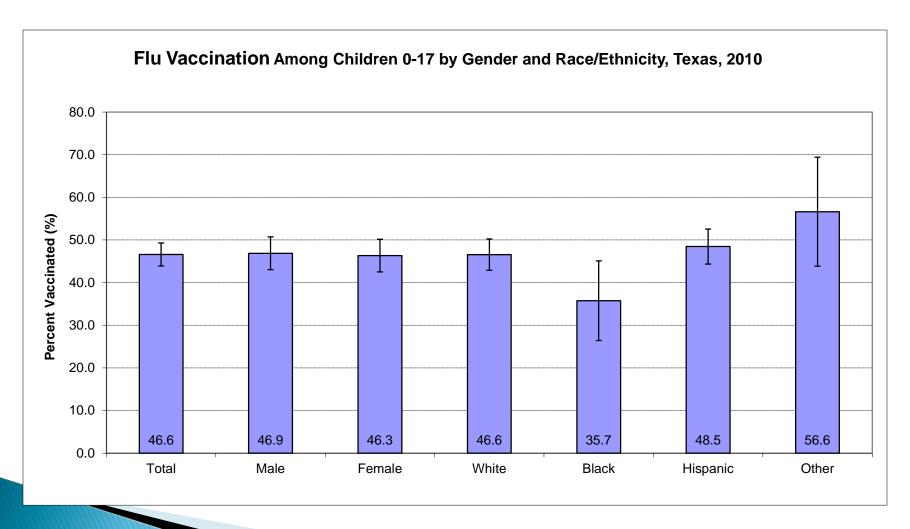
Who should not get the vaccine?

- Children younger than 6 months of age
- People who have a moderate-to-severe illness with a fever
- People with a history of Guillain-Barré Syndrome (GBS) that occurred after receiving flu vaccine
- People who have a severe allergy to chicken eggs.
- People who have had a severe reaction to a flu vaccination.

How effective is the flu vaccine?

- How well the flu vaccine works (or its ability to prevent influenza illness) can range widely from season to season and also can vary depending on who is being vaccinated
- At least two factors play an important role in determining the likelihood that flu vaccine will protect a person from influenza illness:
 - Characteristics of the person being vaccinated, such as their age and health
 - The similarity or "match" between the flu viruses in the vaccine and those spreading in the community
- Preliminary data for the 2010-2011 flu season indicate that flu vaccine effectiveness was about 60% for all age groups combined

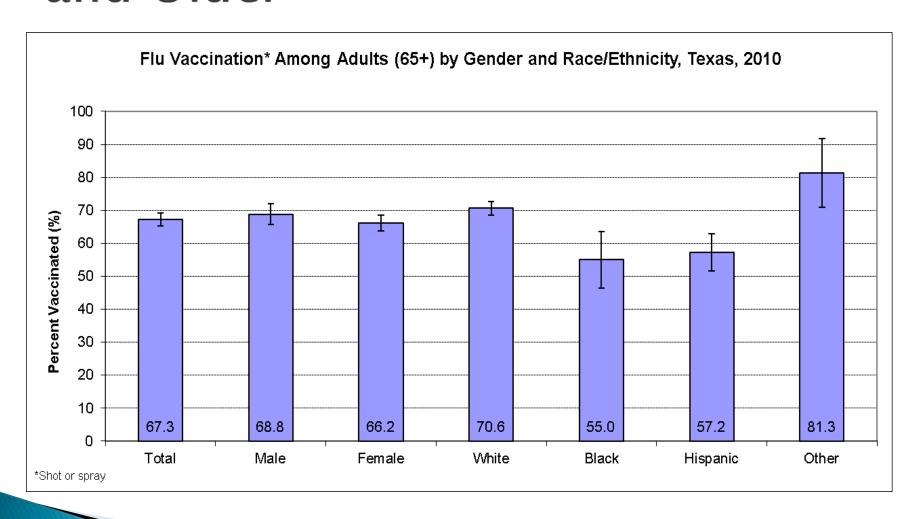
Flu Vaccine Coverage in Children



Source: Texas Bena Pal Risk Factor Surveillance

System

Flu Vaccine Coverage in Adults 65 and Older



New Vaccine Developments

- On February 29, 2012, quadrivalent flu vaccine manufactured by MedImmune was licensed by FDA for use in the United States.
 - administered as a nasal spray
 - approved for use in people ages 2 through 49 years
 - The vaccine is the first to contain four strains of the influenza virus, two influenza A and two influenza B lineage strains
- The vaccine will most likely not be available for the 2012-2013 flu season.

Flu Vaccine Safety

- The CDC and the FDA closely monitor for any signs that the vaccine is causing unexpected adverse events
- Work with state and local health officials and other public health partners to investigate any unusual events.
- Most common side effects from flu vaccines soreness, redness, tenderness or swelling where the flu shot was given and nasal congestion after the flu vaccine nasal spray.

Vaccine Adverse Event Reporting System (VAERS)

- National program managed by both CDC and FDA to monitor the safety of all vaccines licensed in the United States.
- Anyone can file a VAERS report.
- VAERS relies on information included in these reports to monitor for clinically serious adverse events or health problems that follow vaccination.

WEBSITE: www.vaers.hhs.gov

E-MAIL: info@vaers.org

FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-Free Information 1-800-822-7967 PATIENT IDENTITY KEPT CONFIDENTIAL		For CDC/FDA Use Only VAERS Number Date Received
Patient Name:	Vaccine administered by (Name):	Form completed by (Name):
Last First M.I.	Responsible	Relation
Address	Physician Facility Name/Address	to Patient
City State Zip	City State Zip	City State Zip
Telephone no. ()	Telephone no. ()	Telephone no. ()
State 2. County where administered	3. Date of birth 4. Patient age	
I 7 Describe adverse event(s) (symptoms signs	mm dd yy	M F mm dd yy 8. Check all appropriate:
7. Describe adverse event(s) (symptoms, signs, time course) and treatment, if any.		Patient died (date mm / og /y/)
		Life threatening illness Required emergency room/doctor visit
		Required hospitalization (days) Resulted in prolongation of hospitalization
		Resulted in permanent disability None of the above
9. Patient recovered YES NO UNKNOWN		10. Date of vaccination 11. Adverse event onset
12. Relevant diagnostic tests/laboratory data		
		AM AM Time PM
13. Enter all vaccines given on date listed in no. 10		
Vaccine (type) Manufacturer Lot number Route/Site No. Previous doses		
a		
c.		
d		
14. Any other vaccinations within 4 weeks prior to the date listed in no. 10		
Vaccine (type) Manufacturer	Lot number Route/Site	No. Previous Date doses given
b.		
15. Vaccinated at:	16. Vaccine purchased with:	17. Other medications
	clinic/hospital Private funds Military	Funds
Public health clinic/hospital Other/ur		
18. Illness at time of vaccination (specify) 19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)		
20. Have you reported		Only for children 5 and under
this adverse event To doctor To m	anufacturer 22. Birth weightlb	23. No. of brothers and sisters oz.
21. Adverse event following prior vaccination (check all applicable, specify) Only for reports submitted by manufacturer/immunization project Onset Type Dose no. 24. Mfr from proj. report no. 125. Date received by mfr from proj.		
In patient Event Age Vaccine in series 24. Intr./imm. proj. report no. 25. Date received by mir./imm.proj.		
In brother or sister	26. 15 day report? ☐ Yes ☐ No	27. Report type Initial Follow-Up
Form VAERS-1(rpa) Health care providers and manufacturers are required by law (42 USC 300a-25) to report reactions to vaccines listed in the Table of Reportable Events Following immunization. Reports for exactions to other vaccines are valuatory except when required as a condition of immunization grant awards.		



Questions

and

Answers



References

- CDC, What You Should Know for the 2012-2013 Influenza Season
 - http://www.cdc.gov/flu/about/season/fluseason-2012-2013.htm#recommendations
- TX DSHS Immunization Branch
 - http://www.dshs.state.tx.us/immunize/default.s htm
- > TX DSHS Infectious Disease Control Unit, Influenza
 - http://www.dshs.state.tx.us/idcu/disease/influen za/

