

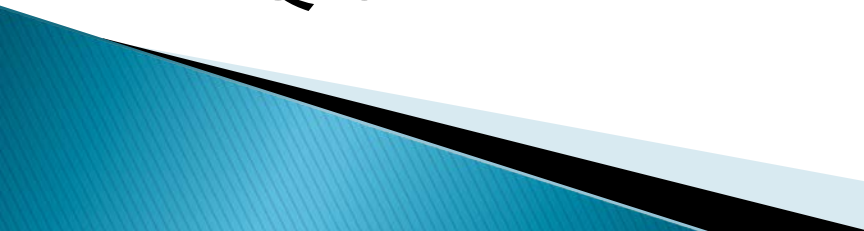
Seasonal Influenza Vaccination

July 10, 2012

Immunization Branch
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Seasonal Influenza Vaccination

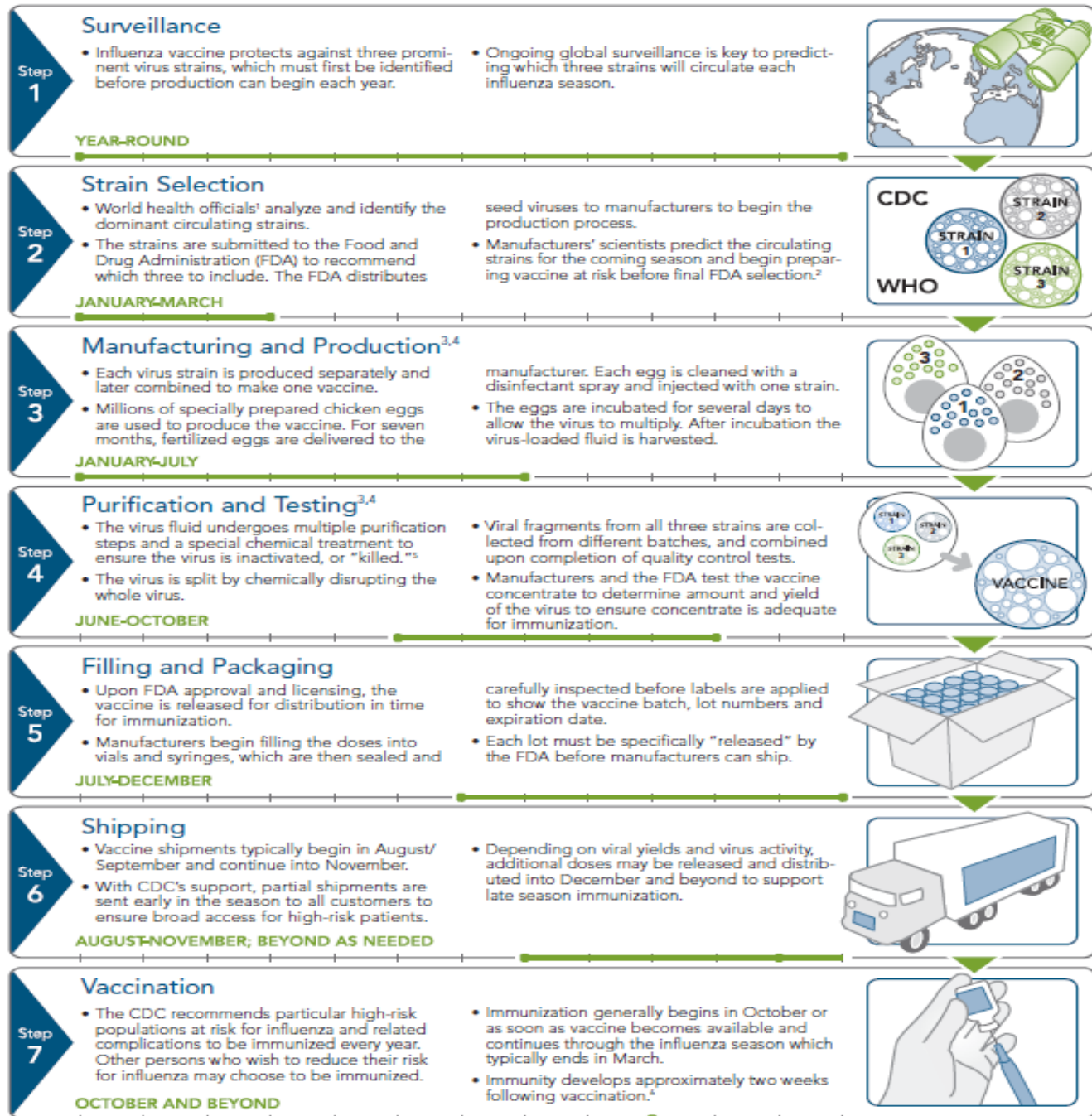
► Overview

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



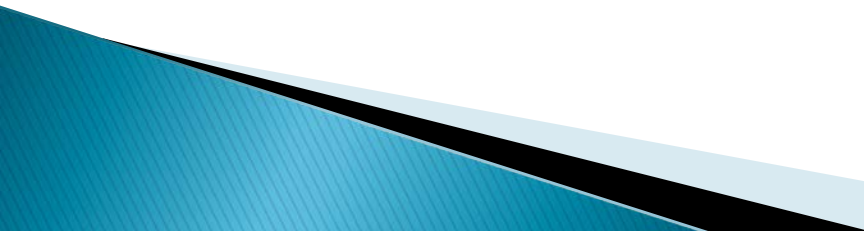
2012–2013 Influenza Strain

- ▶ 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.

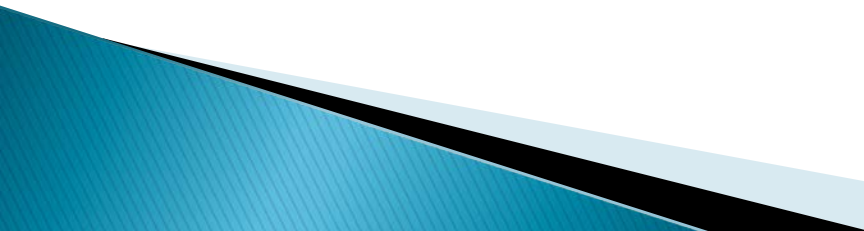
Who should get vaccinated?

- ▶ 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.

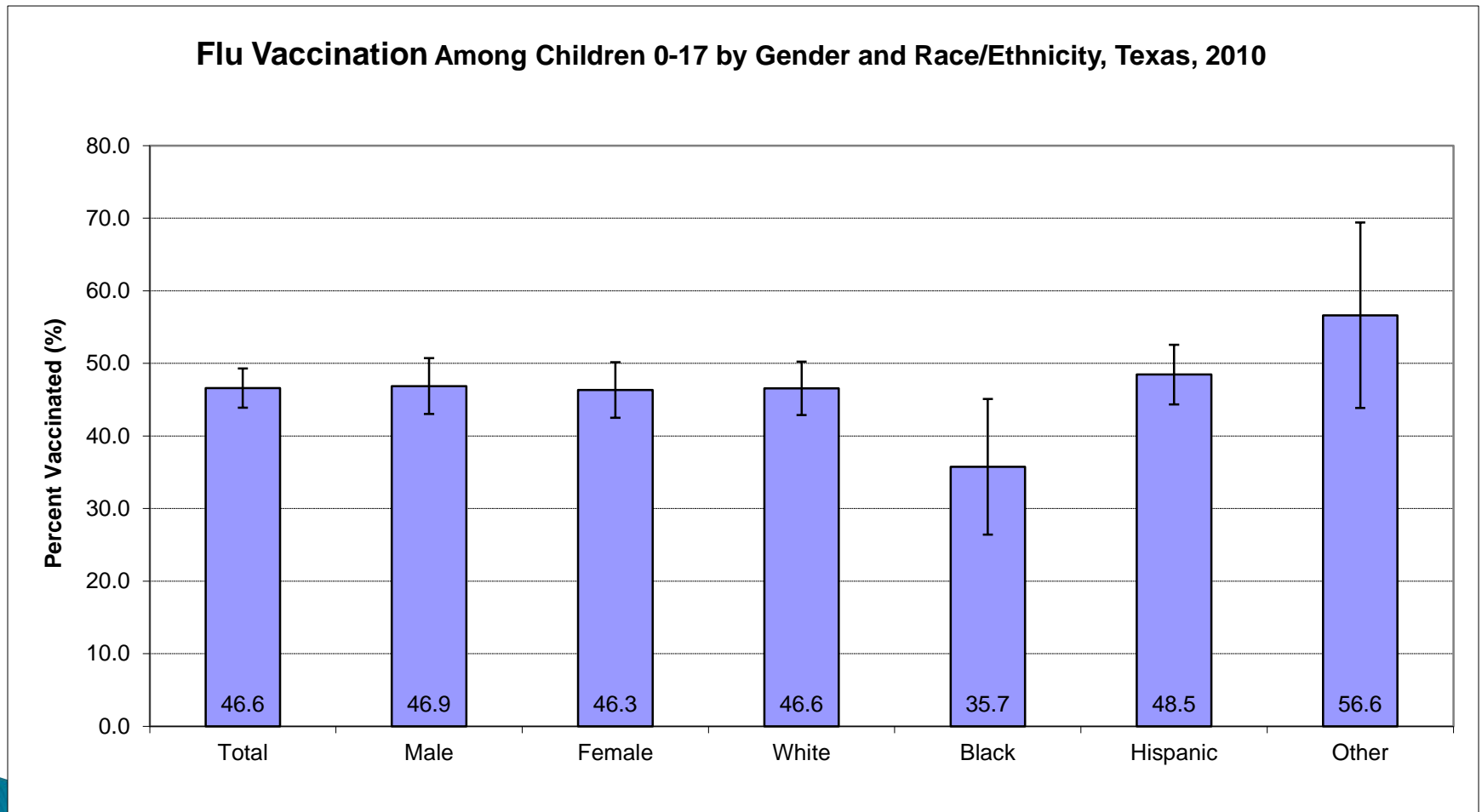
Who should not get the vaccine?

- ▶ 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.
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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

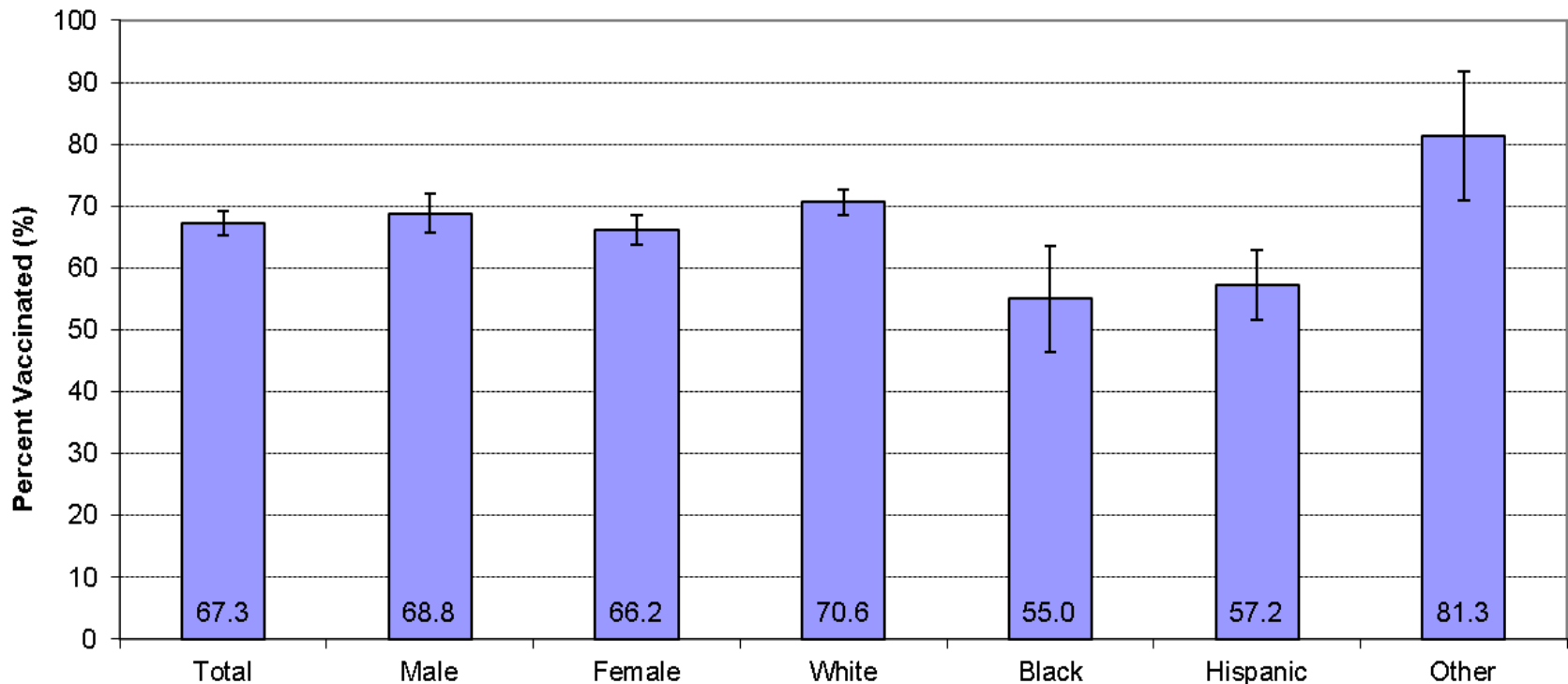
Flu Vaccine Coverage in Children



Source: Texas Behavioral Risk Factor Surveillance System

Flu Vaccine Coverage in Adults 65 and Older

Flu Vaccination* Among Adults (65+) by Gender and Race/Ethnicity, Texas, 2010

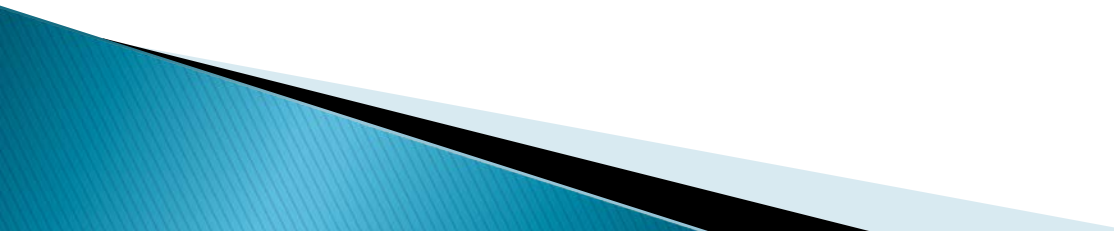


*Shot or spray

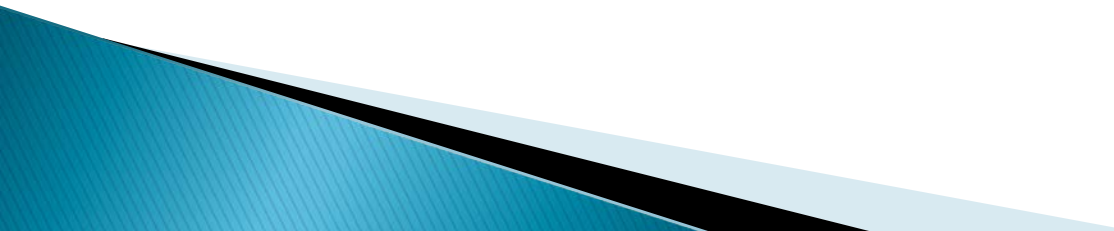
New Vaccine Developments

- ▶ 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.
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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.
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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: Last _____ First _____ M.I. _____ Address _____ _____ City _____ State _____ Zip _____ Telephone no. (____) _____			Vaccine administered by (Name): Responsible Physician _____ Facility Name/Address _____ _____ City _____ State _____ Zip _____ Telephone no. (____) _____			Form completed by (Name): Relation to Patient <input type="checkbox"/> Vaccine Provider <input type="checkbox"/> Patient/Parent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Other Address (if different from patient or provider) _____ City _____ State _____ Zip _____ Telephone no. (____) _____																									
1. State _____	2. County where administered _____	<input type="checkbox"/> 3. Date of birth mm / dd / yy	<input type="checkbox"/> 4. Patient age _____	5. Sex <input type="checkbox"/> M <input type="checkbox"/> F	6. Date form completed mm / dd / yy																										
<input type="checkbox"/> 7. Describe adverse event(s) (symptoms, signs, time course) and treatment, if any.				<input type="checkbox"/> 8. Check all appropriate: <input type="checkbox"/> Patient died (date mm / dd / yy) <input type="checkbox"/> Life threatening illness <input type="checkbox"/> Required emergency room/doctor visit <input type="checkbox"/> Required hospitalization (____ days) <input type="checkbox"/> Resulted in prolongation of hospitalization <input type="checkbox"/> Resulted in permanent disability <input type="checkbox"/> None of the above																											
9. Patient recovered <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN				<input type="checkbox"/> 10. Date of vaccination mm / dd / yy Time _____ AM _____ PM		<input type="checkbox"/> 11. Adverse event onset mm / dd / yy Time _____ AM _____ PM																									
12. Relevant diagnostic tests/laboratory data																															
<input type="checkbox"/> 13. Enter all vaccines given on date listed in no. 10 <table border="1" style="width:100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th>Vaccine (type)</th> <th>Manufacturer</th> <th>Lot number</th> <th>Route/Site</th> <th>No. Previous doses</th> </tr> </thead> <tbody> <tr><td>a. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>b. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>c. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>d. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> </tbody> </table>							Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	a. _____	_____	_____	_____	_____	b. _____	_____	_____	_____	_____	c. _____	_____	_____	_____	_____	d. _____	_____	_____	_____	_____
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b. _____	_____	_____	_____	_____																											
c. _____	_____	_____	_____	_____																											
d. _____	_____	_____	_____	_____																											
<input type="checkbox"/> 14. Any other vaccinations within 4 weeks prior to the date listed in no. 10 <table border="1" style="width:100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th>Vaccine (type)</th> <th>Manufacturer</th> <th>Lot number</th> <th>Route/Site</th> <th>No. Previous doses</th> <th>Date given</th> </tr> </thead> <tbody> <tr><td>a. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>b. _____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> </tbody> </table>							Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given	a. _____	_____	_____	_____	_____	_____	b. _____	_____	_____	_____	_____	_____							
Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given																										
a. _____	_____	_____	_____	_____	_____																										
b. _____	_____	_____	_____	_____	_____																										
15. Vaccinated at: <input type="checkbox"/> Private doctor's office/hospital <input type="checkbox"/> Military clinic/hospital <input type="checkbox"/> Public health clinic/hospital <input type="checkbox"/> Other/unknown			16. Vaccine purchased with: <input type="checkbox"/> Private funds <input type="checkbox"/> Military Funds <input type="checkbox"/> Public funds <input type="checkbox"/> Other/unknown		17. Other medications																										
18. Illness at time of vaccination (specify)			19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)																												
20. Have you reported this adverse event previously? <input type="checkbox"/> No <input type="checkbox"/> To health department <input type="checkbox"/> To doctor <input type="checkbox"/> To manufacturer			Only for children 5 and under																												
21. Adverse event following prior vaccination (check all applicable, specify) <input type="checkbox"/> In patient <input type="checkbox"/> In brother or sister <table border="1" style="width:100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th>Adverse Event</th> <th>Onset Age</th> <th>Type Vaccine</th> <th>Dose no. in series</th> </tr> </thead> <tbody> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> </tbody> </table>			Adverse Event	Onset Age	Type Vaccine	Dose no. in series	_____	_____	_____	_____	_____	_____	_____	_____	22. Birth weight _____ lb. _____ oz.		23. No. of brothers and sisters														
			Adverse Event	Onset Age	Type Vaccine	Dose no. in series																									
_____	_____	_____	_____																												
_____	_____	_____	_____																												
			24. Mfr./imm. proj. report no.		25. Date received by mfr./imm.proj.																										
			26. 15 day report? <input type="checkbox"/> Yes <input type="checkbox"/> No		27. Report type <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up																										

Questions and Answers

References

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