

Vaccinate for Life Summer 2015

Arizona Schools' Increasing Non-medical Exemption Rates Come to a Halt

By Alexandra Bhatti, MPH, Immunization Assessment Manager

Rising non-medical exemption rates have been a concern in Arizona for many years. **Over the last decade non-medical exemption rates have seen an increase leading to a decrease in coverage rates.** A non-medical exemption can be either a religious belief exemption or a personal belief exemption. In Arizona parents may exempt their children from state required immunizations for childcare and pre-school entry for religious reasons in the form of a religious belief exemption form. Likewise, Arizona parents may exempt their children from state required immunizations for K-12th grade for personal beliefs in the form of a personal belief exemptions form. These two exemptions are not interchangeable: religious exemptions are only for childcare and pre-school and personal beliefs exemptions are only for K-12th grade.

Why are efforts to decrease non-medical exemption rates such a critical task? As exemption rates increase, immunization coverage rates decrease which leads to eroding community immunity. Community immunity, also known as herd immunity, is defined by the Centers for Disease Control and Prevention (CDC) as: "A situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community." The threshold necessary to maintain community immunity varies depending on the vaccine-preventable disease. For example, 95% coverage is ideal for measles. Those unvaccinated are at a higher risk of contracting the vaccine preventable disease when coverage drops below 95% because there are less vaccinated individuals to provide a buffer.



The 2014-2015 was the first school year in a decade, where non-medical exemption rates did not increase. In fact, both kindergarten and childcare facilities saw a slight decrease in use of non-medical exemptions. It is important to note that this data was collected prior to the measles outbreak in Arizona. There are many potential reasons for this shift in non-medical exemption rates; one is the implementation of the Action Plan to Address Vaccine Exemptions. This plan included updating the vaccine exemption form to detail potential consequences of not vaccinating. The form also makes it clear that if there is an outbreak of a vaccine preventable disease in a school and a child isn't vaccinated against that disease, he or she may not be allowed to attend school for up to 3 weeks or until the risk period ends. (continued on next page)

In This Issue

SCHOOL BUS

- Arizona Schools' Increasing Non-medical Exemption Rates Come to a Halt
- Summary of Reportable
 Vaccine-Preventable Diseases
- CDC Drops Preference for
 Nasal Spray Influenza Vaccine
 in Children
- Two New Vaccines to Protect Against Meningococcal Serogroup B Disease
- New Nine-Valent Human
 Papillomavirus Vaccine
 Recommendations
- Guest Shots
- The CDC Childhood
 Immunization Champion
 Award, 2015
- Vaccine Center Update
- ASIIS Update

Inserts

- 2015 TAPI Cloud Award Winners/2016 Award Requirements
- VIS Updates: Hib HPV-Gardasil 9 Pneumococcal Polysaccharide (PPSV23) Rotavirus Tdap Td

Arizona Schools' Increasing Non-medical Exemption Rates Come to a Halt (continued)

Additionally, the Arizona Immunization Program Office now publishes school and pre-school immunization coverage and exemption rates on our website. Every school and pre-school hears from our office, whether they submitted an Immunization Data Report (IDR) or not. Schools and pre-schools with over 95% coverage receive a Certificate of Excellence in Immunization Coverage and schools with 100% compliance receive a Certificate of Recognition for Stellar Compliance.

There is a notable difference in non-medical exemption rates between public, private, and charter schools. While Arizona's total kindergarten personal belief exemption rate decreased in the 2014-2015 school year, the private school population's personal belief exemption rate increased. This could be



because this year the state assessed 100 additional private schools. Nevertheless, private (9.2%) and charter (8.3%) personal belief exemption rates are double that of public (3.5%).

While one year cannot provide sufficient data to determine a trend, it is a welcomed change. After all, as Louis L'Amour once said, "Victory is won not in miles but in inches. Win a little now, hold your ground, and later, win a little more." The Arizona Immunization Program Office is determined to continue working with stakeholders and the community to decrease non-medical exemption rates and strengthen community immunity for vaccine preventable disease and ultimately improve and ensure the health and wellness of the Arizona community.

ADHS Immunization Program Office Statistics page: http://azdhs.gov/phs/immunization/statistics-reports/index.php

Action Plan to Address Exemption: http://azdhs.gov/phs/immunization/documents/statistics-reports/ action-plan-address-vaccine-exemptions.pdf

Summary of Reportable Vaccine-Preventable Diseases January–June, 2015^{1,2}

By Susan Goodykoontz, Vaccine-Preventable Disease Epidemiologist

	JAN-JUNE 2015	JAN-JUNE 2014	JAN-JUNE 5-YEAR MEDIAN
Measles	7	0	1
Mumps	0	9	3
Rubella (Congenital Rubella Syndrome)	O (O)	O (O)	O (O)
Pertussis (confirmed)	356 (207)	305 (166)	962 (166)
Haemophilus influenzae, serotype b invasive disease (<5 years of age)	2 (1)	O (O)	1 (1)
Meningococcal infection, invasive	3	9	9
Streptococcus pneumoniae, invasive	432	525	537
Hepatitis A	26	15	42
Hepatitis B, acute	15	18	79
Hepatitis B, chronic	572	445	443

¹ Data are provisional and reflect case reports during this period.

² These counts reflect the year reported or tested and not the date infected.

CDC Drops Preference for Nasal Spray Influenza Vaccine in Children

By Karen Lewis, MD, AIPO Medical Director

For the 2014-2015 influenza season, the Centers for Disease Control and Prevention (CDC) had expressed a preference for the nasal spray influenza vaccine over the influenza shot for children 2-8 years old. However, subsequent analysis of recent data did not show that nasal spray vaccine was superior to an influenza shot in this age range. Therefore, in February 2015, the CDC's Advisory Committee on Immunization Practices (ACIP) did not renew the 2014-2015 preference for using the nasal spray flu vaccine instead of the flu shot in healthy children 2-8 years old. ACIP still recommends that everyone 6 months and older get an annual influenza vaccine, but with no preference¹ stated for either the nasal spray vaccine or the influenza shot in healthy children 2-8 years old.

The 2014-2015 influenza season² in the United States was moderately severe overall and especially severe in adults aged \geq 65 years, with predominant circulation of antigenically and genetically drifted influenza A (H3N2) viruses. The majority of influenza (H3N2) circulating viruses were distinct from the influenza A (H3N2) virus in the 2014-2015 influenza vaccine. Therefore, vaccine efficacy was estimated at about 19% in all ages in preventing medical visits associated with influenza.

The Food and Drug Administration (FDA) has recommended² that the 2015–16 influenza trivalent vaccines in the United States keep the same influenza A (H1N1) virus of past years, but change to a different influenza A (H3N2) virus and a different influenza B (Yamagata lineage). The quadrivalent influenza vaccines will keep the same influenza A (H1N1) virus and the same influenza B (Victoria lineage), but will also contain a new influenza A (H3N2) and a new influenza B (Yamagata lineage) comparable to the changes in the trivalent vaccines. The new influenza A (H3N2) component for the 2015-2016 influenza season vaccine is similar to most of the 2014-2015 influenza season's circulating influenza A (H3N2) viruses.

¹CDC Newsroom. ACIP Reaffirms Recommendations for Annual Influenza Vaccination. Feb. 26, 2015. ²CDC. Influenza Activity – United States, 2014–15 Season and Composition of the 2015–16 Influenza Vaccine. June 5, 2015 / 64(21);583-590.

Two New Vaccines to Protect Against Meningococcal Serogroup B Disease

By Karen Lewis, MD, AIPO Medical Director

The Food and Drug Administration (FDA) has approved the use of two vaccines, Trumenba[®] and Bexsero[®], for use against Neisseria meningitidis serogroup B. Trumenba[®] and Bexsero[®] are both FDA- licensed for people ages 10-25 years old.

Both vaccines are manufactured by recombinant technology using Escherichia coli to produce the various meningococcal proteins that are used in the vaccines. Trumenba® is recommended as a three dose series with the 2nd dose 2 months after the 1st dose, and the 3rd dose 6 months after the 1st dose. Bexsero® is approved as a two dose series with the 2nd dose given at least 1 month after the 1st dose. The two brands are not interchangeable. The same brand of meningococcal serogroup B (MenB) vaccine should be used to complete the entire series.

The Centers for Disease Control and Prevention (CDC) recommends the use of MenB vaccines for people 10 years of age and older who are at increased risk of meningococcal disease.¹ These include four groups: 1) People with persistent complement component deficiencies or those taking eculizumab;² 2) People with anatomic or functional asplenia, including sickle cell disease; 3) Microbiologists who routinely are exposed to isolates of N. meningitidis; and 4) People identified to be at increased risk because of a meningococcal B outbreak. The CDC recommendations for MenB vaccines for high risk individuals do not have an upper age limit.

MenB vaccine is available through the Vaccines for Children (VFC) program for children ages 10-18 years old who are in the high-risk groups mentioned above. The CDC does not express a preference for either MenB vaccine. MenB vaccine can be given at the same time as a quadrivalent meningococcal vaccine (containing serogroups A, C, W135, and Y) but at a different anatomic site, if feasible.

MenB vaccine is not currently recommended for children under 10 years old who are at risk for meningococcal serogroup B disease. It is not recommended for persons who travel to areas where meningococcal disease is hyperendemic or epidemic because it is usually not meningococcal serogroup B which cause the epidemics. MenB vaccine is not currently recommended for routine use in college students, military recruits, or all adolescents.¹

However, at the June 2015 meeting of CDC's Advisory Committee on Immunization Practices (ACIP), the committee voted for permissive use of MenB vaccine for 16-23 years olds, with a preferred age of 16-18 years old. A permissive recommendation allows for individual clinical decisionmaking and will be incorporated into the guidelines for MenB vaccines used within the VFC program. ACIP's recommendations are not official CDC policy until they are published in Morbidity and Mortality Weekly Report.

¹CDC. Morbidity and Mortality Weekly Report. Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥10 Years at Increased Risk for Serogroup B Meningococcal Disease. June 12, 2015 / 64(22);608-612.

2 Alexion Pharmaceuticals. Package insert for Soliris®.

New Nine-Valent Human Papillomavirus Vaccine Recommendations

By Karen Lewis, MD, AIPO Medical Director

At the end of 2014, the Food and Drug Administration (FDA) licensed a nine-valent human papillomavirus vaccine (9vHPV) for use in females as young as 9 years old through 26 years old, and for use in males as young as 9 years old through 15 years old.¹

Human papillomavirus (HPV) is associated with cervical, vulvar, and vaginal cancer in females, penile cancer in males, and anal cancer and oropharyngeal cancer in both females and males.² The majority of all HPV-associated cancers are caused by HPV 16 or 18, types contained in the two-valent vaccine (2vHPV), the four-valent vaccine (4vHPV) and the 9vHPV. In the United States, approximately 64% of invasive HPV-associated cancers are attributable to HPV 16 or 18 and 10% are attributable to the five additional types in 9vHPV: HPV 31, 33, 45, 52, and 58. HPV 6 or 11 (types found in 4vHPV and 9vHPV) cause 90% of anogenital warts and most cases of recurrent respiratory papillomatosis.³

The Centers for Disease Control and Prevention (CDC) recommends that the new 9vHPV vaccine be used along with the other recommended HPV vaccines. The CDC recommendations include routinely giving HPV vaccine to all boys and girls at age 11 or 12 years, with HPV vaccine use recommended for females through age 26 and for males through age 21, as well as for men through age 26 who are immunocompromised or who have sex with men.²

The 2vHPV, 4vHPV, and 9vHPV are each administered in a 3-dose schedule. The 2nd dose is given at least 1-2 months after the 1st dose, and the 3rd dose at least 6 months after the 1st dose. If the vaccine schedule is interrupted, the vaccination series does not need to be restarted. Any recommended HPV vaccine, including 9vHPV, may be used to complete a previously begun HPV vaccine series.²

If health-care providers do not know the previously given HPV vaccine, or if they are in settings transitioning to 9vHPV, any available HPV vaccine product may be used to continue or complete the series for females for protection against HPV 16 and 18. For males, 9vHPV or 4vHPV may be used to continue or complete the series. There are no data on efficacy of fewer than 3 doses of 9vHPV. A clinical trial is ongoing to assess alternative dosing schedules of 9vHPV. However, HPV vaccination should not be delayed pending availability of 9vHPV or of future clinical trial data.²

HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. 4vHPV and 9vHPV are contraindicated for persons with a history of an anaphylactic reaction to yeast. 2vHPV should not be used in persons with anaphylactic latex allergy.²

HPV vaccines are not recommended for use in pregnant women, but pregnancy testing is not needed before vaccination. If an HPV vaccine dose has been given during pregnancy, no clinical intervention is needed. However, Merck has established a new pregnancy registry for health-care providers to report patients who are exposure to 9vHPV during pregnancy. Patients and health-care providers can also report an exposure to HPV vaccine during pregnancy to the Vaccine Adverse Event Reporting System (VAERS).

¹ Merck & Co., Inc. Gardasil®9 package insert.

² Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices. Morbidity and Mortality Weekly Report. March 27, 2015 / 64(11);300-304.

³National Institute of Health. Recurrent Respiratory Papillomatosis or Laryngeal Papillomatosis.

Guest Shots: Someone You Love: The HPV Epidemic

In order to represent different viewpoints from around the state we have established the "Guest Shots" section. Each quarter we will have contributing writers or interviews from immunization professionals across the state. This quarter we would like to highlight a collaborative event conducted to raise awareness of the devastating effect of human papillomavirus (HPV)-related cancer and the importance of the HPV vaccine.

Contributed by Gail Hock, MS, RN, PHCNS-bc, Program Manager, Community Partnerships, TAPI

The documentary *Someone You Love: The HPV Epidemic* chronicles the journey of five women as they battle HPV related cancers with a resounding message of the need for increased awareness of HPV related cancers and the vaccine that reduces the risk of this cancer. The women's stories bring perspective to this often misunderstood disease that kills close to 250,000 women around the globe each year.

Nontraditional prevention partnerships provide unique opportunities to improve health. In efforts to reduce the risk of HPV related cancers through HPV vaccination awareness, the Junior League of Phoenix, Genesis City (a program for disenfranchised youth), Arizona Oncology, The Arizona Partnership for Immunization (TAPI), Scottsdale First Church of the Nazarene and the Arizona Immunization Program Office (AIPO) collaborated on screening the powerful documentary. The screening was held on April 9, 2015 hosted by Scottsdale First Church of the Nazarene. (continued on next page)

Guest Shots: Someone You Love: The HPV Epidemic (continued)

Approximately sixty people attended the event and also had the opportunity to dialogue with a panel including an oncology nurse practitioner, a pastor, an HPV cancer survivor and a public health nurse following the screening. In addition to the documentary two HPV cancer survivors representing the Southwest Chapter of the National Cervical Cancer Coalition staffed an information table and answered attendees' questions. Exit surveys revealed that 100% of those who completed the surveys would choose to vaccinate their child against HPV and close to 90% will be sharing what they learned about HPV cancers and prevention with others.

The dialogue with the panel following the screening was lively and informative. The questions and answers dispelled myths, brought facts to the forefront and brought up new opportunities for prevention messaging through HPV vaccination. Bringing diverse



Michele Peetz, Arizona Oncology, Pastor Matt Rundio, Scottsdale First Church of the Nazarene, Shaundra L. Hall, National Cervical Cancer Coalition, Gail Hock, TAPI

partners together in a house of worship created a safe and respectful environment for spreading knowledge about the sensitive subject of cancer and opened minds and hearts about protecting our children's futures from HPV related cancers through vaccination.

If you would like to know more about hosting a screening of Someone You Love: The HPV Epidemic in your own community please contact Gail Hock at gailh@tapi.org

The CDC Childhood Immunization Champion Award, 2015





The Centers for Disease Control and Prevention (CDC) Childhood Immunization Champion Award was started in 2012 to recognize and honor individuals who are doing an exemplary job or going above and beyond to promote childhood immunizations in their communities. Each year, CDC honors one Immunization Champion from each of the 50 states and the District of Columbia. The CDC officially

announced the awardees during National Infant Immunization Week, April 18-25, 2015.

The 2015 Childhood Immunization Champion Award was awarded to Avein Saaty-Tafoya, Chief Executive Officer for Adelante Healthcare, Phoenix, for being an advocate for childhood immunizations in Arizona.

Avein Saaty-Tafoya knows how vaccine-preventable diseases can devastate communities. Before immigrating to the United States from the Middle East in 1977, she saw some of her childhood classmates suffer from diseases like measles and polio, and she witnessed people being quarantined for weeks to limit the spread of these diseases. This experience sparked her commitment to offering children an opportunity for a lifetime of better health through immunization.

Since 1996, Ms. Saaty-Tafoya has worked across the country to advocate for improvements in immunization. Through her work with Arizona Alliance for Community Health Centers and The Arizona Partnership for Immunization (TAPI), she has been instrumental in policy and practice changes that have increased access to vaccines and state immunization rates. Ms. Saaty-Tafoya is currently the Chief Executive Officer of Adelante Healthcare—a network of seven community clinics in Arizona. In this role, she has established vaccine champions at each clinic to oversee the immunization system. The vaccine champions make sure the clinics stay current on immunization changes and education, and implement best practices with all clinic clinicians. She has also partnered with TAPI and other organizations to test innovations to improve vaccine coverage.

When Ms. Saaty-Tafoya began her work with Adelante Healthcare, many of the clinics had rates as low as 37% coverage levels for their 2-yearold patients. Her implementation of an organization-wide immunization program was successful in increasing coverage in each clinic to over 90% and maintaining these coverage levels for more than 5 years.

Ms. Saaty-Tafoya's leadership, passion, and commitment to improve childhood immunization make her Arizona's CDC Childhood Immunization Champion.

Vaccine Center Update

By Lisa Underhill, MPA, Vaccine Center Manager

VFC Gardasil 9

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has approved Gardasil 9, the 9-valent human papillomavirus vaccine (9vHPV), for the Vaccines for Children Program (VFC). The current ACIP guidance recommends 9vHPV according to the same ages and dosing intervals as the previous recommendation for 4-valent HPV (4vHPV) for both females and males. A series started with 2vHPV (females) or 4vHPV (females and males) may be finished with 9vHPV. There is no recommendation for added doses of 9vHPV for those who have already completed the 2vHPV or 4vHPV series. The ACIP 9vHPV recommendation can be found in the March 27, 2015 MMWR article, "Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices."

The Arizona Vaccine Center began providing VFC 9vHPV vaccine for males and females on May 1, 2015.

We understand you have inventory of 4vHPV VFC vaccine still on hand and we ask that you use as much of this inventory as possible. Providers can use 2vHPV, 4vHPV, or 9vHPV to start and complete the series for females, and 4vHPV or 9vHPV for males.

If you have any questions about ordering VFC 9vHPV vaccine, please contact the Arizona Vaccine Center at 602-364-3642.

If you have any other HPV vaccine related questions, please contact the Arizona Immunization Program at 602-364-3630.

VFC Meningococcal B Vaccines

Both Meningococcal B vaccines (Trumenba and Bexsero) have been added to the CDC Vaccines for Children (VFC) contract. The pediatric recommendations for Meningococcal B vaccine target children ages 10-18 years who are at increased risk for meningococcal disease attributable to serogroup B, including children with immune deficiencies and children at increased risk of a disease outbreak attributable to serogroup B.

At the June 2015 meeting of CDC's Advisory Committee on Immunization Practices (ACIP), the committee voted for permissive use of MenB vaccine for 16-23 years olds (16-18 for VFC) with a preferred age of 16-18 years old. ACIP's recommendations are not official CDC policy until they are published in Morbidity and Mortality Weekly Report. Please refer to the VFC-ACIP Vaccine Resolution 6/15-1 Meningococcal (www.cdc.gov/vaccines/programs/vfc/providers/resolutions) for additional eligible group information.

Age Group	Vaccine	Routine Recommendations	Dosing Schedule	
10-18 years	MenB (Bexsero®,	High-risk (permissive use for	Two doses, at least one month apart	
	Novartis-GSK)	16-18 yo approved by ACIP)		
10–18 years Mer	MenB (Trumenba®, Pfizer)	High-risk (permissive use for	Three doses (0, 2, and 6 month schedule)	
		16-18 yo approved by ACIP)		

Recommended Vaccination Schedule and Intervals

The Arizona Vaccine Center began providing VFC Trumenba and Bexsero vaccine on May 1, 2015.

Temperature Log Submissions Using ASIIS-New Requirement

Starting January 1, 2016, recording temperatures in ASIIS will be required of all providers. The ASIIS Cold Storage module allows you to manage cold storage units and track temperatures in ASIIS. The temperatures recorded in ASIIS replace faxing or emailing temperature logs, allowing the Vaccine Center Team to review your temperature logs within ASIIS. This enhances the Vaccine Center Team's ability to efficiently receive, review, and process your vaccine orders. Please visit the ASIIS training page to access the Cold Storage Module step-by-step guide. If you have questions after reviewing the training or you notice any problems, please contact the ASIIS Help Desk via email at <u>ASIISHelpDesk@azdhs.gov</u> or via phone at 602-364-3899 or 1-877-491-5741.

Note: You must still retain a paper copy of the temperature logs on your cold storage unit.

Return Labels Now Available via Email

Beginning April 13, 2015 providers needing to return vaccine to the manufacturer have had the option of receiving shipping labels via email. The option of "Standard Email" vs. "Standard Mail" is recommended by the CDC as the more efficient method for receipt of shipping labels. (continued on next page)

Vaccine Center Update (continued)

In order to take advantage of emailed shipping return labels please make sure that the Vaccine Center has your most up-to-date primary email address on file. The "VFC Provider Contact Information Update Form" can be found here: http://azdhs.gov/phs/immunization/vaccines-for-children/index.php?pg=forms.

Once the Vaccine Center has received and processed your return request an email will be sent to the primary email address on file from McKesson Specialty Care Dist [mailto:pkginfo@ups.com]. The subject of the email will be titled "UPS Label Delivery, <Label tracking Number>." Please follow the shipping instructions included in the email.

Please call the Vaccine Center at 602-364-3642 if you have any questions about the vaccine returns process.

Smaller and More Frequent Orders

In an effort to decrease vaccine wastage due to too much vaccine on hand the CDC now recommends placing smaller, more frequent orders rather than large orders. This will minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit.

The CDC also recommends that providers place orders when they have a four-week supply of vaccine available. This will ensure that there is enough vaccine in stock to allow for any potential delays.

VFC Re-Enrollment for 2015-2016 is Coming Soon

We are working hard to have our online process ready for the upcoming 2015-2016 VFC re-enrollment. We will provide more information as it becomes available.

ASIIS Update

By Kelsey Pistotnik, MPH, CDC Public Health Advisor

Inventory Maintenance Tips

Each VFC vaccine dose must be accounted for within ASIIS. The following actions will help make this possible:

- All VFC vaccine orders must be "received" in ASIIS once the vaccine shipment arrives. Do not manually enter VFC vaccine doses in your ASIIS Inventory.
- All VFC vaccine transfers must be completed using the Vaccine Transfer functionality in ASIIS. Do not reconcile VFC vaccine using the Transfer reason.
 - Vaccine transferred in ASIIS will automatically decrement from your ASIIS inventory.
- All administered VFC vaccine doses must be recorded in ASIIS using the "Add Administered" function and selecting a vaccine on the Vaccination Detail Add screen. This will ensure accurate linkage between the patient and the VFC vaccine that was administered.
 - Usage of "Administered but not linked to a vaccine," "Matches Physical Inventory" "Correction of Invalid Dose" are NOT allowable reasons to use to subtract administered VFC vaccine from the ASIIS Inventory and will be counted as wasted vaccine in the future.
- Reconciling your ASIIS Inventory should only occur when you need to report Expired, Wasted or Spoiled vaccines.
 - Administered VFC vaccine doses should NOT be subtracted from the ASIIS inventory via reconciliation.
 - Correctly adding Administered Doses will allow for auto-decrementing and will reduce the time and effort needed to reconcile your inventory.
- After you administer the last dose of a lot number, check the ASIIS inventory to make sure that there are zero doses left in the inventory for that lot number.
 - If there are remaining doses, run the Inventory Transaction Report, the Lot Recall Report and Patient Detail Report for that lot number to determine why there are doses still reflected in the inventory.

For any questions regarding ASIIS please contact the Help Desk via email at <u>ASIISHelpDesk@azdhs.gov</u> or via phone at 602-364-3899 or 1-877-491-5741.



Arizona Department of Health Services

Bureau of Epidemiology and Disease Control Services Arizona Immunization Program Office 150 N. 18th Avenue, Suite 120 Phoenix, Arizona 85007-3233 (602) 364-3630 azdhs.gov/phs/immunization/

> MANAGING EDITOR: Wendy O'Donnell

EDITORS: Dana Goodloe, Brenda Jones, Holly Ward, Chris Minnick

CONTRIBUTORS: Alexandra Bhatti, Susan Goodykoontz, Dr. Karen Lewis, Gail Hock, Lisa Underhill, Kelsey Pistotnik

If you need this publication in an alternative format, contact the Arizona Immunization Program Office at (602) 364-3630 or 1-800-376-8939 (State TDD/TYY Relay)

Immunications was supported by Grant Number H23/CCH922545 from CDC. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

New Employee

Lisa Underhill, MPA Vaccine Center Manager









DR. DANIEL T. CLOUD OUTSTANDING PRACTICE AWARDS

2015 TODDLER REQUIREMENTS: 90% coverage level for 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 Hep B and 1 Varicella for two year olds. **2015 TEEN REQUIREMENTS:** 90% coverage level for 1 Tdap, 1 MCV and 2 HPV vaccinations for 15 year olds.

2015 TODDLER WINNERS:

El Rio - Pasqua Gila River Health Care -Pediatrics Adelante Health Care - Mesa Verde Valley Medical Clinic -La Paz CHD Cottonwood Adelante Health Care - Surprise Dr. Longoria Peds Adelante Health Care -Greenlee CHD - Clifton Wickenburg Greenlee CHD - Duncan Adelante Healthcare - Buckeye Sant Singh Khalsa, MD Adelante Healthcare - Gila Bend **Mesquite Pediatrics** Adelante Health Care - Phoenix Pinal CHD - Coolidge Navajo County Public Health -Yuma CHD Winslow Pinal CHD - Apache Junction Navajo County Public Health -Pinal CHD - Casa Grande Holbrook Pinal CHD - Mammoth Cigna - Chandler Mariposa CHC - Rio Rico Mountain Park - Baseline Canvonlands Healthcare - Lake Mountain Park - Gateway Powell Mountain Park - Goodyear Cigna - South Mountain Mountain Park - Maryvale Cigna - Stapley Mountain Park - Tempe **Tucson Pediatrics** Sun Life Center for Children U of A Health Network - Elks Sunset CHC - Somerton Clinic U of A Health Network -Sunset CHC - Yuma Wilmot Southwest Pediatrics Apache County PH Services Cigna - Phoenix Central District

Sunrise Pediatrics

North Country Healthcare - LHC

Paloma Medical Group -Pediatrics

Gateway Pediatrics

Pima CHD - South

Cigna - Deer Valley

2015 TEEN WINNERS:

Casa Grande Pediatrics

Cigna - Tempe

Ak-chin Clinic GRHC

Sulphur Springs Medical Center

U of A Health Network -Wilmot

Apache County PH Services District

All About Kids Pediatrics

Sun Life Family HC- San Manuel

El Rio - Pasqua

Adelante Health Care - Gila Bend

Desert Mission Community Health Services

2016 TODDLER REQUIREMENTS: 90% coverage level for 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 Hep B and 1 Varicella for two year olds.****NEW 2016 TEEN REQUIREMENTS:** 90% coverage level for 1 Tdap, 1 MCV and 3 HPV vaccinations for 15 year olds. Additional Teen Award for 90% Coverage for 2MCV for 17years only for who first meet 2016 teen requirements.

Hib Vaccine

What You Need to Know

1

Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually affects children under 5 years old. It can also affect adults with certain medical conditions.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems. This is called invasive Hib disease.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the lining of the brain and spinal cord. It can lead to brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death

Before Hib vaccine, about 20,000 children in the United States under 5 years old got Hib disease each year, and about 3% - 6% of them died.

Hib vaccine can prevent Hib disease. Since use of Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating. (Haemophilus Influenzae Type b)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

2 Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose:
 - 2 months of age
- Second Dose:
- 4 months of age
- Third Dose:
- 6 months of age (if needed,

depending on brand of vaccine)

• Final/Booster Dose: 12-15 months of age

Hib vaccine may be given at the same time as other vaccines.

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease.

Children over 5 years old and adults usually do not need Hib vaccine. But it may be recommended for older children or adults with asplenia or sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. It may also be recommended for people 5 to 18 years old with HIV. Ask your doctor for details.

Your doctor or the person giving you the vaccine can give you more information.



3

Some people should not get this vaccine

Hib vaccine should not be given to infants younger than 6 weeks of age.

A person who has ever had a life-threatening allergic reaction after a previous dose of Hib vaccine, OR has a severe allergy to any part of this vaccine, should not get Hib vaccine. Tell the person giving the vaccine about any severe allergies.

People who are mildly ill can get Hib vaccine. People who are moderately or severely ill should probably wait until they recover. Talk to your healthcare provider if the person getting the vaccine isn't feeling well on the day the shot is scheduled.

Δ

Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems following Hib vaccine:

• redness, warmth, or swelling where the shot was given • fever

These problems are uncommon. If they occur, they usually begin soon after the shot and last 2 or 3 days.

Problems that could happen after any vaccine:

Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

Older children, adolescents, and adults might also experience these problems after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5

What if there is a serious reaction?

What should I look for?

• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- · Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement **Hib Vaccine**



42 U.S.C. § 300aa-26

4/02/2015

3

HPV Vaccine Gardasil®-9

What You Need to Know

1

2

Why get vaccinated?

Gardasil-9 prevents many cancers caused by human papillomavirus (HPV) infections, including:

- cervical cancer in females,
- vaginal and vulvar cancers in females, and
- anal cancer in females and males.

In addition to these cancers, Gardasil-9 also prevents **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cancers.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans get infected every year. Many infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

HPV vaccine

Gardasil-9 is one of three FDA-approved HPV vaccines. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second and third dose 1-2 months and 6 months after the first dose.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests. (Human Papillomavirus)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

Some people should not get this vaccine

• Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.

Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



4 **Risks of a vaccine reaction**

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any problems with it.

Mild or moderate problems following Gardasil-9

- Reactions in the arm where the shot was given:
 - Pain (about 9 people in 10)
 - Redness or swelling (about 1 person in 3)
- Fever:
 - Mild (100°F) (about 1 person in 10)
 - Moderate (102°F) (about 1 person in 65)
- Other problems: - Headache (about 1 person in 3)

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

What if there is a serious 5 reaction?

What should I look for?

• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

7

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- · Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/hpv

Vaccine Information Statement (Interim) HPV Vaccine (Gardasil-9)



42 U.S.C. § 300aa-26

4/15/2015

Pneumococcal Polysaccharide Vaccine What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1

Why get vaccinated?

Vaccination can protect older adults (and some children and younger adults) from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis). Meningitis can cause deafness and brain damage, and it can be fatal.

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults over 65 years of age, and cigarette smokers are at the highest risk.

About 18,000 older adults die each year from pneumococcal disease in the United States.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:

- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten one or more doses of the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

3 Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.



4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1 out of 100 people develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/



What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 | Hov

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement PPSV Vaccine





Rotavirus Vaccine

What You Need to Know

1

Why get vaccinated?

Rotavirus is a virus that causes diarrhea, mostly in babies and young children. The diarrhea can be severe, and lead to dehydration. Vomiting and fever are also common in babies with rotavirus.

Before rotavirus vaccine, rotavirus disease was a common and serious health problem for children in the United States. Almost all children in the United States had at least one rotavirus infection before their 5th birthday.

Every year before the vaccine was available:

- more than 400,000 young children had to see a doctor for illness caused by rotavirus,
- more than 200,000 had to go to the emergency room,
- 55,000 to 70,000 had to be hospitalized, and
- 20 to 60 died.

Since the introduction of the rotavirus vaccine, hospitalizations and emergency visits for rotavirus have dropped dramatically.

2

Rotavirus vaccine

Two brands of rotavirus vaccine are available. Your baby will get either 2 or 3 doses, depending on which vaccine is used.

Doses are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed)

Your child must get the first dose of rotavirus vaccine before 15 weeks of age, and the last by age 8 months. Rotavirus vaccine may safely be given at the same time as other vaccines.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea. And most of these babies will not get rotavirus diarrhea at all.

The vaccine will not prevent diarrhea or vomiting caused by other germs.

Another virus called porcine circovirus (or parts of it) can be found in both rotavirus vaccines. This is not a virus that infects people, and there is no known safety risk. For more information, see www.fda.gov/ BiologicsBloodVaccines/Vaccines/ApprovedProducts/ ucm205547.htm. Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

3 Some babies should not get this vaccine

A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe allergy to any part of rotavirus vaccine should not get the vaccine. *Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.*

Babies with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

Babies who have had a type of bowel blockage called "intussusception" should not get rotavirus vaccine.

Babies who are mildly ill can get the vaccine. Babies who are moderately or severely ill should wait until they recover. This includes babies with moderate or severe diarrhea or vomiting.

Check with your doctor if your baby's immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system
- treatment with drugs such as steroids

4

• cancer, or cancer treatment with x-rays or drugs

Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. Serious side effects are also possible but are rare.

Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine:

Mild problems following rotavirus vaccine:

• Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.



Serious problems following rotavirus vaccine:

• Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery. It happens "naturally" in some babies every year in the United States, and usually there is no known reason for it.

There is also a small risk of intussusception from rotavirus vaccination, usually within a week after the 1st or 2nd vaccine dose. This additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 US infants who get rotavirus vaccine. Your doctor can give you more information.

Problems that could happen after any vaccine:

• Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/

What if there is a serious problem?

What should I look for?

5

For **intussusception**, look for signs of stomach pain along with severe crying. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest.

Your baby might also vomit several times or have blood in the stool, or could appear weak or very irritable. These signs would usually happen during the first week after the 1st or 2nd dose of rotavirus vaccine, but look for them any time after vaccination.

Look for anything else that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, or unusual sleepiness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is **intussusception**, call a doctor right away. If you can't reach your doctor, take your baby to a hospital. Tell them when your baby got the rotavirus vaccine.

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get your baby to the nearest hospital. Otherwise, call your doctor.

6

7

Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your doctor. Your healthcare provider can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Rotavirus Vaccine

04/15/2015 42 U.S.C. § 300aa-26



Tdap Vaccine

What You Need to Know

1

Why get vaccinated?

Tetanus, diphtheria and **pertussis** are very serious diseases. Tdap vaccine can protect us from these diseases. And, Tdap vaccine given to pregnant women can protect newborn babies against pertussis.

TETANUS (Lockjaw) is rare in the United States today. It causes painful muscle tightening and stiffness, usually all over the body.

• It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 10 people who are infected even after receiving the best medical care.

DIPHTHERIA is also rare in the United States today. It can cause a thick coating to form in the back of the throat.

• It can lead to breathing problems, heart failure, paralysis, and death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

• It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through secretions from coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, as many as 200,000 cases of diphtheria, 200,000 cases of pertussis, and hundreds of cases of tetanus, were reported in the United States each year. Since vaccination began, reports of cases for tetanus and diphtheria have dropped by about 99% and for pertussis by about 80%.

(Tetanus, Diphtheria and Pertussis)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

2 | Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for healthcare professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during every **pregnancy**, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Another vaccine, called Td, protects against tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have never gotten Tdap before. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor or the person giving you the vaccine can give you more information.

Tdap may safely be given at the same time as other vaccines.

Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.
- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTaP, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.
- Talk to your doctor if you:

3

- have seizures or another nervous system problem,
- had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
- ever had a condition called Guillain-Barré Syndrome (GBS),
- aren't feeling well on the day the shot is scheduled.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Tdap vaccine do not have any problems with it.

Mild problems following Tdap

(Did not interfere with activities)

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, sore joints (about 1 person in 10)
- Body aches (about 1 person in 3 or 4)
- Rash, swollen glands (uncommon)

Moderate problems following Tdap

(Interfered with activities, but did not require medical attention)

- Pain where the shot was given (up to 1 in 5 or 6)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 12 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 1 in 7 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 1 in 500).

Severe problems following Tdap

(Unable to perform usual activities; required medical attention)

• Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/

What if there is a serious problem?

What should I look for?

5

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.
- Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

7

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Tdap Vaccine



42 U.S.C. § 300aa-26

2/24/2015

4

Td Vaccine

What You Need to Know

1

Why get vaccinated?

Tetanus and **diphtheria** are very serious diseases. They are rare in the United States today, but people who do become infected often have severe complications. Td vaccine is used to protect adolescents and adults from both of these diseases.

Both tetanus and diphtheria are infections caused by bacteria. Diphtheria spreads from person to person through coughing or sneezing. Tetanus-causing bacteria enter the body through cuts, scratches, or wounds.

TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.

• It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of every 10 people who are infected even after receiving the best medical care.

DIPHTHERIA can cause a thick coating to form in the back of the throat.

• It can lead to breathing problems, paralysis, heart failure, and death.

Before vaccines, as many as 200,000 cases of diphtheria and hundreds of cases of tetanus were reported in the United States each year. Since vaccination began, reports of cases for both diseases have dropped by about 99%.

2

Td vaccine

Td vaccine can protect adolescents and adults from tetanus and diphtheria. Td is usually given as a booster dose every 10 years but it can also be given earlier after a severe and dirty wound or burn.

Another vaccine, called Tdap, which protects against pertussis in addition to tetanus and diphtheria, is sometimes recommended instead of Td vaccine.

Your doctor or the person giving you the vaccine can give you more information.

Td may safely be given at the same time as other vaccines.

(Tetanus and Diphtheria)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

3 Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any tetanus or diphtheria containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Td vaccine. *Tell the person giving the vaccine about any severe allergies*.
- Talk to your doctor if you:
 - have seizures or another nervous system problem,
 - had *severe* pain or swelling after any vaccine containing diphtheria or tetanus,
 - ever had a condition called Guillain Barré Syndrome (GBS),
 - aren't feeling well on the day the shot is scheduled.

4 Ris

Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Td vaccine do not have any problems with it.

Mild Problems following Td vaccine:

(Did not interfere with activities)

- Pain where the shot was given (about 8 people in 10)
- Redness or swelling where the shot was given (about 1 person in 4)
- Mild fever (rare)
- Headache (about 1 person in 4)
- Tiredness (about 1 person in 4)

Moderate Problems following Td vaccine:

(Interfered with activities, but did not require medical attention)

• Fever over 102°F (rare)

Severe Problems following Td vaccine:

(Unable to perform usual activities; required medical attention)

• Swelling, severe pain, bleeding and/or redness in the arm where the shot was given (rare).



Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/

What if there is a serious reaction?

What should I look for?

5

• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers. hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.



7

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement





42 U.S.C. § 300aa-26