

New Vaccines for Influenza Season 2013–2014

By Karen Lewis, MD, AIPO Medical Director

There will be six newly licensed influenza vaccines available this influenza season, in addition to the currently licensed vaccines. The Centers for Disease and Control and Prevention (CDC) has also changed the abbreviations that it uses for all of the influenza vaccines.

New Abbreviations for Influenza Vaccines

CDC will use IIV to refer to inactivated influenza vaccines, rather than the previous abbreviation of TIV. Trivalent inactivated influenza vaccines will be abbreviated as IIV3. IIV3 vaccines will contain two influenza A strains (H1N1 and H3N2) and one influenza B strain (this season the B will be from the Yamagata lineage). Some of the newly licensed vaccines have four influenza strains, so they are quadrivalent inactivated influenza vaccines and will be abbreviated as IIV4. IIV4 vaccines will have the same two strains of influenza A (H1N1 and H3N2), as well as two strains of influenza B (both Yamagata and Victoria lineages).

There is a new quadrivalent live-attenuated influenza vaccine. Therefore, the trivalent live-attenuated vaccine will be abbreviated as LAIV3, and the quadrivalent live-attenuated influenza vaccine will be abbreviated as LAIV4.

Until now, all influenza vaccines have been grown in chicken eggs. However, one of the newly licensed IIV3 vaccines is made by a cell culture technique using canine kidney cells to grow the influenza virus. It falls under the umbrella of IIV3 vaccines, but it can also be abbreviated as cclIIV3, when clarification is needed.

Finally, the sixth newly licensed influenza vaccine is manufactured by recombinant technology, no egg antigens are present. The part of the influenza virus genome that codes for hemagglutinins is spliced into the genome of a baculovirus that is grown in

cell culture using an insect cell line. As the baculoviruses grow, influenza hemagglutinins are also produced. The hemagglutinins are then harvested and made into influenza vaccine. This vaccine is trivalent, having the same two influenza A strains and one influenza B strains as the IIV3 vaccines. It is abbreviated as RIV3. RIV3 can be used in people with severe anaphylactic reactions to eggs.

New Influenza Vaccines

CDC makes no recommendations for any type or brand of licensed influenza vaccine over another, within approved indications. The recently-licensed vaccines are acceptable alternatives to other previously-licensed vaccines indicated for their respective age groups when otherwise appropriate.

GlaxoSmithKline has two new quadrivalent inactivated influenza vaccines (IIV4): Fluarix Quadrivalent® and FluLaval Quadrivalent® that will be available in addition to their IIV3 products. Fluarix Quadrivalent® and FluLaval Quadrivalent® are indicated for people ages three years and older. The previously licensed FluLaval® (IIV3) has a new age indication of three years old and older.

Sanofi Pasteur's new quadrivalent inactivated influenza vaccine (IIV4): Fluzone Quadrivalent® will be available in addition to their licensed IIV3 products. Fluzone Quadrivalent® is licensed for people ages six months and older.

MedImmune has a new quadrivalent live-attenuated influenza vaccine (LAIV4): FluMist Quadrivalent® which is expected to replace LAIV3 this season. LAIV4 is indicated for healthy, nonpregnant people ages two years through 49 years. LAIV4 is not approved for people with egg allergies of any type.

Novartis has received approval for a trivalent cell culture-based inactivated influenza vaccine (cclIIV3): Flucelvax®. It is approved for

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people ages 18 years and older. Although no chicken eggs are used in the production of Flucelvax[®], the influenza virus that is used in the vaccine previously was grown in eggs. Therefore, the recommendation is that cclIV3 be used in the same way with egg-allergic individuals as the other IIV vaccines. IIV vaccines can be given to people with mild to moderate reactions to eggs, but the patient needs to be watched for 30 minutes after the injection. See Morbidity and Mortality Weekly Report (*MMWR*), September 20, 2013.

Protein Sciences manufactures the new influenza vaccine that uses recombinant technology (RIV3): FluBlok[®]. It is approved for people ages 18 years through 49 years. Since no egg is used in the manufacture of Flublok[®], patients who have severe anaphylactic reactions to eggs can be safely immunized with Flublok[®].

Pregnant Women and Influenza Vaccination

LAIV is not recommended for use during pregnancy. Women who are or will be pregnant during influenza season should receive IIV vaccines. Nursing mothers can receive either LAIV or IIV vaccines. Pregnant and postpartum women do not need to avoid contact with people recently vaccinated with LAIV.

More Detailed 2013-2014 Influenza Vaccine Recommendations

For detailed recommendations about influenza vaccines for the 2013-2014 season, see *MMWR* September 20, 2013, <http://www.cdc.gov/mmwr/pdf/rr/rr6207.pdf>.

Highs and Lows of Immunization Coverage Are Revealed in NIS Results

By Jennifer Ralston-King, AIPO Immunization Assessment Coordinator

The most recent National Immunization Survey (NIS) results were released by the Centers for Disease Control and Prevention (CDC) in September, 2013. The surveys were conducted in 2012 when the toddlers included were 19 to 35 months of age, and the teens were 13 to 17 years old. Complete survey results are available online at www.cdc.gov/vaccines/stats-surv/nis/default.htm.

Participants in the NIS are contacted through random-digit telephone dialing that now includes mobile phones and landlines. After a parent is interviewed and asked about a child's immunization history, a follow up survey is sent to the child's immunization provider(s) to verify vaccine doses administered.

The chart below compares coverage levels released this year to the coverage levels released in 2012. Arizona's 19 to 35 month old children had immunization coverage levels within two to three percentage points of mean U.S. coverage levels for most antigens. Arizona is one of only nine states where the Hepatitis B birth dose is at or above 80%. At 83%, Arizona is well above the U.S. mean for this dose. Of concern is Arizona's MMR coverage level of 88%. Arizona is one of only thirteen states with MMR coverage below the 90% target.

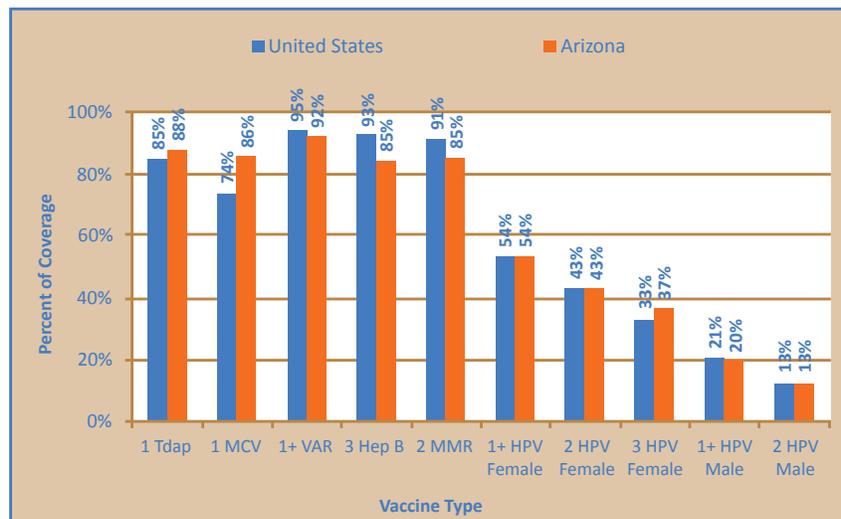
National Immunization Survey Comparison of 2012 to 2013 Results				
Percentages in this table are rounded to the nearest whole number	Arizona		United States	
	September 2012	September 2013	September 2012	September 2013
Birth Dose Hep B	71%	83%	69%	72%
4 DTaP	86%	83%	85%	83%
3 Polio	94%	92%	94%	93%
1 MMR	87%	88%	92%	91%
3+ Hib (complete series)	82%	80%	80%	81%
3 Hep B	87%	91%	91%	90%
2 Hep A	51%	55%	52%	53%
2+ Rotavirus	65%	72%	67%	69%
4 PCV	83%	84%	84%	82%
1 Varicella	88%	86%	91%	90%
4:3:1 (4DTaP, 3IPV, 1MMR)	80%	79%	83%	81%
4:3:1:3:3:1 (4DTaP, 3IPV, 1MMR, 3-4 Hib full series, 3 HepB, + 1VAR)	64%	69%	71%	72%

The Teen NIS results indicate that Arizona providers are doing an excellent job of immunizing adolescents with MCV and Tdap. Arizona's coverage levels for both vaccines have increased dramatically since the first teen NIS results were released in 2009, as shown in the next chart. The first estimates of male HPV coverage levels were released in 2012. Since then the percentage of Arizona adolescents who have received at least one HPV dose has increased from 8% to 20%. Among Arizona's female adolescents, the coverage level for one or more doses of HPV has increased only three percentage points, from 51% to 54% over the past four years.

Highs and Lows of Immunization Coverage Are Revealed in NIS Results *continued...*

NIS Teen Coverage Level Results 2009–2013					
	2009	2010	2011	2012	2013
Tdap 1	54%	67%	77%	85%	88%
MCV 1	52%	70%	79%	83%	86%
HPV 1+ (Female)	51%	53%	53%	55%	54%
HPV 1+ (Male)	N/A	N/A	N/A	8%	20%

Arizona’s teen coverage levels are compared to those of the U.S. in the graph below. Our coverage levels for Tdap, MCV and HPV 3 (females) are all above coverage levels for the United States. Arizona’s MMR #2 and Hep B #3 coverage estimates are several percentage points below those of the U.S., prompting a recommendation that providers double-check the immunization histories of teens for these important vaccine doses.



Arizona Partners Against Pertussis Join Forces in Mohave County

By Gail Hock, MS, RN, PHCNS-c, TAPI Program Manager—Community Partnerships



Dr. Lewis with Colorado City community members

In response to increasing rates of pertussis in Mohave County this year, an informal partnership was formed to protect vulnerable infants and build relationships to help keep the residents of Colorado City healthy. The health care providers and staff from Hildale Clinic in Colorado City have been attending the Arizona Department of Health Services (ADHS) Immunization Program’s annual immunization conference for a decade and value an evidenced-based approach to disease prevention. They wanted to do more to help keep the infants, children and families they serve healthy.

Concerned about the rising rates of pertussis in their county, the Hildale Clinic staff, nurses from the Mohave County Health Department and the ADHS Immunization Program Office (AIPO) began “strategizing” about how best to bring an immunization/infectious disease update to the remote area of Colorado City. A flurry of phone calls and emails in early May brought partners together to plan an all-day immunization update and infectious disease in-service. This in-service was held at Colorado City’s Fire Station #3 on May 29, 2013. The Arizona Chapter of the March of Dimes supported the travel, The Arizona Partnership for Immunization (TAPI) provided an immunization update and educational materials and AIPO’s own Dr. Karen Lewis spoke on infectious disease. Fire Station #3 served as our classroom and base of support for TAPI’s administrative staff. We spent the day with an engaged audience of 35 in the morning and over 100 in the afternoon. The Hildale Clinic staff and the Mohave County Health Department nurses were instrumental in encouraging other clinic staff, WIC employees and emergency responders to attend. Colorado City Fire Station #3 was a wonderful setting for this opportunity, complete with state of the art computers and projectors, and we were welcomed with a delicious lunch brought in by the community. Dr. Lewis and the TAPI staff ended the day with a tour of the Hildale Clinic.

This successful effort brought valuable education to the health and social service providers of Colorado City and built important relationships between ADHS, TAPI, the Mohave County Health Department and the residents of this rural community. We know we’re successful when we work together where our values intersect – healthy babies, healthy moms, healthy families and a healthy community!

Women Need Tdap Vaccine During Every Pregnancy

By Karen Lewis, MD, AIPO Medical Director

The American College of Obstetricians and Gynecologists (ACOG) and the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) now recommend that every pregnant woman receive a pertussis vaccine (Tdap) during every pregnancy. ACOG published its recommendations in June 2013.¹ Guidance on implementation of ACIP's recommendations is expected soon in Morbidity and Mortality Weekly Report ([MMWR](#)).

The uptake of Tdap among pregnant women has been low so far, with only about 2.6% of women receiving Tdap during a recent pregnancy. New data indicates maternal antibodies against pertussis are short-lived, so Tdap vaccination in one pregnancy will not provide high levels of antibodies to protect newborns during subsequent pregnancies.² Tdap can be given any time during pregnancy, but the highest level of transplacental antibodies can be achieved if the pregnant woman is vaccinated between 27-36 weeks gestation.¹

The United States has had increasing cases of pertussis reported over the past several years. Provisional case counts of pertussis in the US for 2012 showed 41,880 cases. In addition, 14 infants less than 12 months old died from pertussis in 2012.²

Infants are at the highest risk of dying from pertussis. The best way to protect infants from pertussis is to make sure that pregnant women get pertussis vaccine (Tdap) in every pregnancy. Grandparents, siblings, and anyone who cares for infants or comes in close contact with infants should be fully vaccinated against pertussis.²

References

1. American College of Obstetricians and Gynecologists. Committee Opinion. Update on Immunization and Pregnancy: Tetanus, Diphtheria, and Pertussis Immunizations. Committee on Obstetric Practice. Number 566. June 2013.
2. Centers for Disease Control and Prevention (CDC). Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women—Advisory Committee on Immunization Practices (ACIP), 2012. *Morbidity and Mortality Weekly Report*. February 22, 2013.



Guest Shots

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 introduce Mutiu Okanlawon, Pharm.D.



Dr. Okanlawon is the primary contact for the Arizona Vaccines for Children program at Tséhootsooí Medical Center (TMC) in Fort Defiance, Arizona. He is currently serving as a lieutenant with the United States Public Health Service. Dr. Okanlawon was born and raised in Osogbo, Southwest Nigeria and migrated to the United States in 2002. He graduated with a Doctor of Pharmacy degree from University of Illinois at Chicago in 2011. While in pharmacy school, he obtained a certification in Pharmacy-based Immunization Delivery. Dr. Okanlawon co-developed and manages the first ever Pharmacy-based Immunization Clinic at TMC.

Questions:

What impact have you seen immunizations make, both in your professional and personal life?

Professionally, I have witnessed a serious pertussis outbreak in the Fort Defiance community. Everyone knows how much havoc this can wreak if not controlled. Our first response is to make sure everyone is up to date on their DTaP or Tdap vaccines. Then, we offer prophylactic medication such as azithromycin to individuals who want it. Based on this proactive response, we have seen a significant decrease in pertussis incidence in our community. We are a very isolated community; therefore vaccines play a crucial role in preventing widespread preventable brutal diseases.

Personally, I grew up in a rural community in Nigeria. I remember several kids in my neighborhood contracting measles and polio. There are vaccines available for these diseases but the economic situation of people did not permit routine vaccination. Everyone relied on the public health officials who usually offered the vaccines for free. However, they only came occasionally and the vaccines were not always sufficient for everyone. These inconsistencies made it too late for some children to be vaccinated and some contracted the disease. I feel fortunate to have all the vaccines readily available for my family here in the United States.

Guest Shots continued...

As a pharmacist you have a unique role in immunizing, different from a provider in a doctor's office. Please describe your role.

The pharmacist's role in immunization is not that different from other health care providers. We do a little bit more advocacy and we are more accessible. For example, the TMC pharmacy closes late and opens on weekends providing more opportunity to get immunized for individuals with busy schedules. We are also readily available to answer any question that patients and other providers have. I currently serve as the unofficial primary contact for vaccine-related questions at TMC, therefore I answer questions that providers have about vaccine schedules, side effects and number of doses. We also go out to the community to educate people about immunizations and administer vaccines to qualified patients. It also does not hurt that Medicare Part B reimburses pharmacists for their immunization services. This brings additional revenue to facilities that have immunizing pharmacists.

What are immunization education needs and opportunities that you see in your area?

Some people still need to know why they or their children are getting several vaccine injections. According to our pediatric nurses, some parents feel their children are getting too many shots. They know it is necessary but cannot really understand the varieties. We should educate parents better on this. Also, you can never have too much community outreach. We need to continue going to neighborhoods to inform people of immunizations and offer vaccines to qualified patients.

Given the high HPV vaccination series completion rates in your area, do you have any suggestions you can give to others to achieve higher rates?

The high HPV vaccination rates in our area are mostly due to our relentless pediatric nurses. According to them, getting both

parents involved in vaccination is the key; most especially getting the fathers involved. The fathers are less resistant and more understanding of the need for their male and female children to get the HPV vaccine. Another contributor to the completion rate of HPV can be attributed to the high level of trust between the pediatricians and parents.

How do you think we can lower immunization exemption rates in Arizona?

There should be more public announcements dispelling any rumors of vaccine associations with autism, febrile seizures and other conditions. I think the groups of people who are against vaccination overshadow those in support of vaccination. I feel more organizations need to stand up for immunizations. They should provide education and impact success stories through the media to the public.

What is the main concern parents express when making the decision to vaccinate their families?

Safety: with all the misinformation going around about diseases being linked to vaccines, some parents are worried about the safety of their children. Once properly educated, a lot of concerned parents usually feel more comfortable with immunizations.

How do you answer parents who are reluctant to give their children vaccines?

First, I would ask what their concerns are and try to educate them on it. Then, I would continue to inform them of the good things vaccines have done for me and the people I know. My parents still believe that the polio vaccine I received as a child saved my life and based on the damage that the disease did to people around me, I feel the same way.

Please finish the sentence: I Immunize because... **it save lives**

Summary of Reportable Vaccine-Preventable Diseases January–July 2013^{1,2}

By Susan Goodykoontz, Vaccine-Preventable Disease Epidemiologist

Case counts refer to probable and confirmed cases.

	Jan.–July, 2013	Jan.–July, 2012	Jan.–July 5-Year Median
Measles	1	3	2
Mumps	1	3	4
Rubella (Congenital Rubella Syndrome)	0 (0)	0 (0)	0 (0)
Pertussis (confirmed)	812 (606)	730 (350)	233 (39)
<i>Haemophilus influenzae</i> , serotype b invasive disease (<5 years of age)	2 (2)	1 (0)	1 (1)
Meningococcal infection, invasive	10	1	8
<i>Streptococcus pneumoniae</i> , invasive	596	477	575
Hepatitis A	50	54	46
Hepatitis B, acute	88	94	94
Hepatitis B, chronic	646	504	587

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

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

Vaccine Center Update

By Tiffany McRae, Vaccine Center Manager



Ordering Influenza through ASIIS/VOMS for 2013-2014 Season

Providers are now required to place their influenza order through ASIIS/VOMS. Here are some important tips to keep in mind when placing your order in the system.

- Inventory reconciliation must occur before an order is placed by the provider. This is the requirement for all vaccine orders. If you have not reconciled in ASIIS within 14 days, the system will take you to the reconciliation screen before you can place your order.
- Temperature logs must be submitted up to the day before a provider places an order, no exceptions.
- Once the provider has placed an order, the VFC vaccine ordering team will make every attempt to approve that order; however, if there are vaccines that are not currently available, the VFC ordering team will approve the vaccines in your order that are available and backorder the ones that are not. When the backordered vaccines become available, the VFC program will contact you for current temperature logs to ensure that temperatures in your refrigerator are still appropriate to receive new vaccines and the order will be approved.
- Always check the comments section in your VFC order first before contacting the Vaccine Center with questions about your order. We provide a significant amount of communication with the provider through ASIIS/VOMS.

For additional information regarding influenza or influenza ordering please contact the Vaccine Center at (602) 364-3642.

Vaccine Shortages and Delays

During this past year, several vaccines have been on allocation, shortage or have been delayed. Questions come in from providers regularly about why these vaccine delays occur and how it impacts the provider practice. We have provided a short Q & A to answer these questions.

Q. Why are there vaccine shortages?

- A. Shortages of recommended childhood vaccines have occurred in the past and still occur on a limited basis. Some shortages are widespread while others are localized. There are many reasons for these shortages, such as companies leaving the vaccine market, manufacturing or production problems, and insufficient stockpiles. Some shortages are specific to only one manufacturer, and other vaccine options may still be available. When shortages of vaccines occur on a widespread basis, recommendations for temporary changes in the childhood immunization schedule are provided by the CDC and ACIP as needed. Summary information about the projected duration is also supplied.

Please visit www.cdc.gov/vaccines/vac-gen/shortages/ for more information.

Q. Who can I contact to find out if there is a shortage on a vaccine I currently use for VFC children?

- A. Questions concerning vaccine supply problems can be answered by the Arizona VFC Program Office.

Vaccine Center Update **continued...**

Q. Will the vaccine center choose vaccines for me (the provider) during a vaccine shortage?

A. In most instances no. Arizona is a choice state. This means providers will be responsible for choosing vaccines that appropriately meet their needs during a shortage.

Q. Where can I find additional resources regarding regulatory issues related to vaccine supply?

A. Providers can go to the FDA's web page on Biological Product Shortages at www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm. This page provides additional information regarding regulatory issues related to vaccine supply.

If you have additional questions about vaccine shortages, please contact the Arizona VFC Program Office at (602) 364-3644.

ASIIS Update

By S. Robert Bailey, ASIIS Program Manager

The ASIIS program at ADHS is seeing many staffing changes. Here is a brief summary:

1. New support staff for the ASIIS HelpDesk are Sandra Johnson, Sydney Holman and Desiree Long.
2. Current ASIIS Program Manager S. Robert Bailey will be leaving in late October. He is taking a position with the division of Licensure. His replacement has not yet been identified.
3. ASIIS has hired a new system maintenance coordinator, Rob Martinez, who will be handling ASIIS upgrades and developments.
4. ASIIS is still seeking a qualified candidate for one vacant position – a data analyst position. For the complete job description and to apply, go to azstatejobs.gov.
5. Dr. Roy Teramoto, recently retired from the Indian Health Service, has volunteered his services to assist with the establishment of electronic reporting interfaces with

Arizona tribal and Indian Health Services sites. Thanks to Dr. Teramoto for this generous and much needed assistance to ASIIS.

In addition to these staffing changes, ASIIS continues to make progress with a number of providers who are testing electronic reporting interfaces and expects to finalize connections with over 150 providers during the next several months. As medical providers consider their strategies for meeting Meaningful Use requirements, those interested in electronic reporting to the Arizona Immunization Registry should contact the ASIIS program for information and assistance.

ASIIS expects to have solutions available for electronic registration of VFC providers and for electronic cold-chain reporting within the coming weeks. Providers who are interested in using these features should expect written guidance from the VFC program soon. For ASIIS questions, please contact the ASIIS Hotline at (877) 491-5741 or locally at (602) 364-3899.

New Employees



Desiree Long, Client Support Coordinator
Sandra Johnson, Customer Service Hotline Specialist
Sydney Holman, Customer Service Hotline Specialist



Dana Goodloe, Office Chief

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

www.azdhs.gov/phs/immun/index.htm

MANAGING EDITOR:

Wendy O'Donnell

EDITORS:

Dana Goodloe, Laura Oxley, Brenda Jones

CONTRIBUTORS:

Dr. Karen Lewis, Jennifer Ralston-King, Gail Hock, Dr. Mutiu Okanlawon,
Susan Goodykoontz, Tiffany McRae, Steven "Rob" Bailey

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)

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Arizona law requires that schools, preschools and childcare facilities obtain this form, completed by a physician or registered nurse practitioner, in order for a child to be exempted from immunization requirements for medical reasons.

Medical Exemption Form

This is the official ADHS-provided form used by physicians and registered nurse practitioners to document that 1) due to the child's health or medical condition, the child may be adversely affected on a temporary or permanent basis by one or more of the required vaccine doses; 2) a child has laboratory evidence of immunity to one or more specific vaccine-preventable diseases and lab results are attached; or 3) the child has a history of Varicella (chicken pox) disease.

Child's Name _____ Date of Birth _____

To be completed by a physician or registered nurse practitioner to exempt a child from childcare or school immunization requirements.

Printed Name of Physician or Nurse _____

Signature of Physician or Nurse _____ Date _____

Please list each vaccine included in the exemption and the reason for the exemption:

Please indicate whether this is a **permanent** exemption or a **temporary** exemption

If the exemption is **temporary**, please list the date the exemption ends _____

Parent/Guardian Section:

1. I am aware that in the event the state or county health department declares an outbreak of a vaccine-preventable disease for which I cannot provide proof of immunity for my child, he or she may not be allowed to attend childcare and/or school until the risk period ends, which may be up to 3 weeks or longer.
2. I am aware that additional information about vaccine preventable diseases, vaccines, and reduced or no cost vaccination services is available from my local county health department and Arizona Department of Health Services. (www.azdhs.gov/phs/immun/index.htm).

Parent/Guardian Signature _____ Date _____

Arizona Revised Statutes 15-873, <http://www.azleg.state.az.us/ars/15/00873.htm>, and Arizona Administrative Code, R9-5-305, http://www.azsos.gov/public_services/Title_09/9-05.htm, and R9-6-706, http://www.azsos.gov/public_services/Title_09/9-06.htm describe the requirements for medical exemptions in childcare and school settings.



La ley de Arizona requiere que las escuelas, centros preescolares y guarderías utilicen este formulario oficial de ADHS, firmado y completado por un médico o enfermera registrada, para que un niño sea exento de los requisitos de inmunización por razones médicas.

Formulario de Exención por Razones Médicas

Este es el formulario oficial, suministrado por ADHS, utilizado por los médicos y enfermeras registradas para documentar que 1) debido a su salud o condición médica, el niño puede ser afectado de forma temporal o permanente por una o más de las vacunas requeridas; 2) el niño tiene evidencia del laboratorio de inmunidad a una o más enfermedades prevenibles por vacunación y los resultados del laboratorio se adjuntan a este documento; o 3) el niño tiene un historial médico que incluye la varicela.

Nombre del Niño _____ Fecha de Nacimiento _____

Para ser completado por un médico o enfermera registrada para eximir a un niño de los requisitos de vacunación escolares y de guarderías.

Nombre del médico o la enfermera _____

Firma del médico o la enfermera _____ Fecha _____

Por favor, indique cada vacuna incluida en la exención y el motivo de la exención.

Por favor, indique si e una exención **permanente** o una exención **temporal**

Si la exención es temporal, indique la fecha en que termina la exención. _____

Sección del Padre / Tutor:

1. Soy consciente de que en el caso que el departamento de salud estatal o del condado declare un brote de una enfermedad prevenible por vacunación y yo no pueda presentar prueba de inmunidad para mi hijo, él o ella no puede ser permitido asistir a la guardería y/o la escuela durante un máximo de 3 semanas o hasta que termine el período de riesgo.
2. Soy consciente de que la información adicional acerca de las enfermedades prevenibles por vacunación, vacunas y servicios de vacunación reducidos o sin costo está disponible en mi departamento de salud local y el Departamento de Servicios de Salud de Arizona (ADHS). (www.azdhs.gov/phs/immun/index.htm)

Firma del Padre/Tutor _____ Fecha _____

Estatutos Revisados de Arizona 15-873, <http://www.azleg.state.az.us/ars/15/00873.htm>, y el Código Administrativo de Arizona R9-5-305, http://www.azsos.gov/public_services/Title_09/9-05.htm, y R9-6-706, http://www.azsos.gov/public_services/Title_09/9-06.htm describen los requisitos para exenciones médicas en guarderías y las escuelas.



August 22, 2013

Dear Colleague:

In your daily practice as a health care provider, you know the value of prevention and the positive impact it can have on your patients' health. I am writing today to encourage you to discuss the benefits of annual flu vaccination with your patients. Flu vaccination can reduce flu illness, antibiotic use, doctors' visits and lost time from work, as well as prevent hospitalizations and deaths.

The 2012-2013 influenza season was a reminder of how unpredictable and severe influenza can be. Influenza activity began early in the United States and was high for 15 weeks. The season also was more severe than recent seasons. Hospitalization rates, especially in older adults, were the highest recorded since CDC began tracking that data, and deaths attributed to pneumonia and influenza (P & I) were the highest recorded in nearly a decade. Sadly, the number of pediatric deaths (158) also was the highest since that type of surveillance began, with the exception of the 2009 H1N1 pandemic.

CDC currently recommends annual influenza vaccination for people 6 months of age and older with few exceptions. Studies have shown repeatedly that a health care provider's recommendation plays a critical role in a patient's decision to get a seasonal flu vaccine. For example, pregnant women receiving a health care professional's recommendation and offer of vaccination were nearly 5 times more likely to get vaccinated (73.5%) than women not receiving a recommendation or offer (15.4%). While annual vaccination is recommended for nearly everyone 6 months and older, it is especially important for people who are at high risk of developing serious complications from flu, including children younger than 5 years, people 65 and older, pregnant women and anyone with a chronic medical condition.

We know that the effectiveness of flu vaccines can vary from season to season, but we also know there is significant evidence to support the benefits of vaccination each year. CDC influenza vaccine effectiveness studies show the 2012-2013 flu vaccine reduced the risk of flu-associated medical visits from influenza A (H3N2) viruses by one half and from influenza B by two-thirds for most of the population. This was true across age groups, with the exception of seniors. Our studies indicate that the vaccine did not work as well at protecting older adults against influenza A (H3N2) viruses. These findings highlight both the need for continued efforts to create better vaccines, but also the important benefits that can be captured by increasing influenza vaccination rates across all age groups with currently available vaccines. One CDC study concluded that flu vaccination prevented an estimated 13.6 million flu cases, 5.8 million medical visits and nearly 113,000 flu-related hospitalizations in the United States over a 6-year period (2005-2011). The more people we vaccinate, the more people we can help protect.

CDC encourages you and all other health care providers to begin influenza vaccination of your patients as soon as vaccine is available in the community. As last season demonstrated, the timing of flu season can vary from one year to the next, so it is critical that patients be protected before significant influenza activity begins.

This season, there are more flu vaccine options than ever. With that in mind, it is increasingly important for both providers and patients to have access to the most up-to-date resources. Vaccine information for the 2013-2014 flu season is available at <http://www.cdc.gov/flu/protect/vaccine/vaccines.htm>. All providers are encouraged to review this information and be ready to answer questions and recommend the appropriate vaccine for your patients.

Please recommend that your patients get their influenza vaccine every year to help protect them against this serious and potentially deadly illness. Thank you for all you do every year to help protect your patients and community against influenza.

Best regards,

A handwritten signature in black ink, appearing to read "Anne Schuchat". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anne Schuchat, MD
Assistant Surgeon General, US Public Health Service
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

INFLUENZA VACCINES LICENSED IN THE UNITED STATES Summary by Karen Lewis, MD UPDATED: 9/24/2013						
						
Company	Formulation and Number of Strains [§]	Trade name	Ages	How to Give	Grown in chicken eggs	OK to use if egg allergy
NEWLY LICENSED INFLUENZA VACCINES						
Medimmune	LAIV4	FluMist Quadrivalent [®]	2-49 yo	Intranasal	Yes	No
GSK	IIV4	Fluarix Quadrivalent [®]	≥ 3 yo	IM	Yes	Yes [¶]
GSK	IIV4	FluLaval Quadrivalent [®]	≥ 3 yo	IM	Yes	Yes [¶]
Sanofi Pasteur	IIV4	Fluzone Quadrivalent [®]	≥ 6 mo	IM	Yes	Yes [¶]
Novartis	ccIIV3	Flucelvax [®]	≥ 18 yo	IM	No*	Yes [¶]
Protein Sciences	RIV3	FluBlok [®]	18-49 yo	IM	No [°]	Yes
PREVIOUSLY LICENSED INFLUENZA VACCINES						
CSL	IIV3	Afluria [®]	≥ 9 yo ^Δ	IM	Yes	Yes [¶]
GSK	IIV3	Fluarix [®]	≥ 3 yo	IM	Yes	Yes [¶]
GSK	IIV3	FluLaval [®]	≥ 3 yo **	IM	Yes	Yes [¶]
Medimmune	LAIV3	FluMist [®]	2-49 yo	Intranasal	Yes	No
Novartis	IIV3	Fluvirin [®]	≥ 4 yo	IM	Yes	Yes [¶]
Novartis	IIV3	Agriflu [®]	≥ 18 yo	IM	Yes	Yes [¶]
Sanofi Pasteur	IIV3	Fluzone [®]	≥ 6 mo	IM	Yes	Yes [¶]
Sanofi Pasteur	IIV3	Fluzone High Dose [®]	≥ 65 yo	IM	Yes	Yes [¶]
Sanofi Pasteur	IIV3	Fluzone Intradermal [®]	18-64 yo	Intradermal	Yes	Yes [¶]
<p>[¶] Permitted if mild to moderate egg allergy, but not when there is anaphylactic reaction to eggs.</p> <p>*Influenza virus grown in cell culture (not eggs) but vaccine may not be completely free of egg protein due to influenza viruses having previously been grown in eggs.</p> <p>[°]Manufactured with recombinant DNA technology by inserting influenza hemagglutinin genes into baculoviruses; as the baculoviruses grow in cell culture, they also produce influenza hemagglutinins.</p> <p>[§]Abbreviations: IIV: Inactivated influenza vaccine. ccIIV: Cell culture inactivated influenza vaccine. RIV: Recombinant influenza vaccine. LAIV: Live attenuated influenza vaccine. The numbers at the end of the abbreviations show how many influenza strains (3=2A, 1B; 4=2A, 2B). IM: Intramuscular.</p> <p>^ΔMay be given at age ≥ 5 years old If there is no other age-appropriate, licensed inactivated seasonal influenza vaccine available for a child aged 5-through-8 years who has a medical condition that increases the child's risk for complications from influenza.</p> <p>**Newly approved age indication.</p>						
<p>➤ For more details, see Morbidity and Mortality Weekly Report, September 20, 2013.</p>						

Influenza Vaccine

What You Need to Know

(Flu Vaccine, Live, Intranasal)

2013-2014

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?

Influenza (“flu”) is a contagious disease that spreads around the United States every winter, usually between October and May.

Flu is caused by the influenza virus, and can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, or a weakened immune system. Flu vaccine is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine is the best protection we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Live, attenuated flu vaccine—LAIV, Nasal Spray

There are two types of influenza vaccine:

You are getting a **live, attenuated influenza vaccine** (called LAIV), which is sprayed into the nose.

“Attenuated” means weakened. The viruses in the vaccine have been weakened so they can’t make you sick.

A different vaccine, the “flu shot,” is an **inactivated** vaccine (not containing live virus). It is given by

injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year’s flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. LAIV protects against 4 different influenza viruses.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts several months to a year.

Some illnesses that are **not** caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

LAIV may be given to people **2 through 49 years of age**, who are not pregnant. It may safely be given at the same time as other vaccines.

LAIV does not contain thimerosal or other preservatives.

3 Some people should not get this vaccine

Tell the person who gives you the vaccine:

- **If you have any severe (life-threatening) allergies**, including an allergy to eggs. If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you should not get a dose.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you have gotten any other vaccines in the past 4 weeks, or if you are not feeling well.** They might suggest waiting. But you should come back.



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- **You should get the flu shot instead of the nasal spray if you:**
 - are pregnant
 - have a weakened immune system
 - have certain long-term health problems
 - are a young child with asthma or wheezing problems
 - are a child or adolescent on long-term aspirin therapy
 - have close contact with someone who needs special care for an extremely weakened immune system
 - are younger than 2 or older than 49 years. (Children 6 months and older can get the flu shot. Children younger than 6 months can't get either vaccine.)

The person giving you the vaccine can give you more information.

4 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 very rare. LAIV is made from weakened virus and **does not cause flu**.

Mild problems that have been reported following LAIV:

Children and adolescents 2-17 years of age:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Adults 18-49 years of age:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems that could follow LAIV:

- A severe allergic reaction could occur after any vaccine (estimated less than 1 in a million doses).

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 behavior changes.

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 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 is only for reporting reactions. They do 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.

7

How can I learn more?

- Ask your doctor.
- 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/flu

Vaccine Information Statement (Interim)
Live Attenuated Influenza Vaccine

07/26/2013

42 U.S.C. § 300aa-26

Office Use Only



Influenza Vaccine

What You Need to Know

(Flu Vaccine,
Inactivated)

2013-2014

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

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1 Why get vaccinated?

Influenza (“flu”) is a contagious disease that spreads around the United States every winter, usually between October and May.

Flu is caused by the influenza virus, and can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, or a weakened immune system. Flu vaccine is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine is the best protection we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Inactivated flu vaccine

There are two types of influenza vaccine:

You are getting an **inactivated** flu vaccine, which does not contain any live influenza virus. It is given by injection with a needle, and often called the “flu shot.”

A different, **live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year’s flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. Inactivated flu vaccine protects against 3 or 4 different influenza viruses.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts several months to a year.

Some illnesses that are not caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

A “high-dose” flu vaccine is available for people 65 years of age and older. The person giving you the vaccine can tell you more about it.

Some inactivated flu vaccine contains a very small amount of a mercury-based preservative called thimerosal. Studies have shown that thimerosal in vaccines is not harmful, but flu vaccines that do not contain a preservative are available.

3 Some people should not get this vaccine

Tell the person who gives you the vaccine:

- **If you have any severe (life-threatening) allergies.** If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get a dose. Most, but not all, types of flu vaccine contain a small amount of egg.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you are not feeling well.** They might suggest waiting until you feel better. But you should come back.



U.S. Department of
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Centers for Disease
Control and Prevention

4 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 very rare. Inactivated flu vaccine does not contain live flu virus, so **getting flu from this vaccine is not possible.**

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

Mild problems following inactivated flu vaccine:

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

Moderate problems following inactivated flu vaccine:

- Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems following inactivated flu vaccine:

- A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).
- There is a small possibility that inactivated flu vaccine could be associated with Guillain-Barré Syndrome (GBS), no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.

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 behavior changes.

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 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 is only for reporting reactions. They do not give medical advice.

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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.

7 How can I learn more?

- Ask your doctor.
- 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/flu

Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine

07/26/2013

42 U.S.C. § 300aa-26

Office Use Only



Rotavirus 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?

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 U.S. had at least one rotavirus infection before their 5th birthday.

Every year:

- 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.

Rotavirus vaccine has been used since 2006 in the United States. Because children are protected by the 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 of rotavirus vaccine 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)

Rotavirus vaccine is a liquid that is swallowed, not a shot.

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

Rotavirus vaccine is very good at preventing diarrhea and vomiting caused by rotavirus. 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.

3 Some babies should not get this vaccine

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose.

A baby who has a severe (life threatening) allergy to any component 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 probably get the vaccine today. Babies who are moderately or severely ill should probably 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 long-term steroids
 - cancer, or cancer treatment with x-rays or drugs



4 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 very 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

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

Serious problems

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 U.S. infants to 1 in 100,000 U.S. infants who get rotavirus vaccine. Your doctor can give you more information.

5 What if there is a serious reaction?

What should I look for?

- 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 behavior changes.

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 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 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.
- 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**.

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Vaccine Information Statement (Interim) Rotavirus Vaccine

08/26/2013

42 U.S.C. § 300aa-26

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