

Rotavirus Vaccine

Current as of 12/04/2020



I will provide a discussion of the epidemiology of rotavirus disease as well as the vaccine recommendations for prevention of rotavirus disease.

About This Publication

This publication was designed to help prelicensure nursing faculty incorporate appropriate elements of the [IRUN Curriculum Framework](#) into their existing curricula. This content is also available in a PowerPoint file located on the [IRUN web page](#).

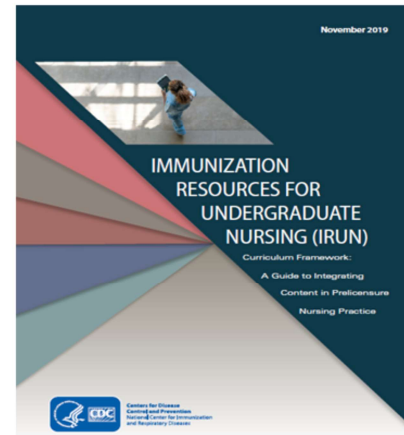
Please submit questions or comments about this publication via the [IRUN web page](#).

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(READ SLIDE)

Immunization Resources for Undergraduate Nursing (IRUN) Curriculum Framework Topics

- Public Health Perspective
- Immune System/Immunology
- Vaccine-Preventable Diseases
- Immunization Strategies
- Types of Vaccines
- Immunization Schedules
- Communications
- Legal/Ethical Issues
- Vaccine Storage and Handling
- Vaccine Administration
- Documentation
- Vaccine Safety



- The Immunization Resources for Undergraduate Nursing (IRUN) Curriculum Framework consists of 12 topic areas with corresponding learning objectives and suggested resources. In these vaccine-preventable disease PowerPoint slides, we will use these topical areas and framework to learn about rotavirus vaccines.
- For more information about the IRUN Curriculum Framework topics or resources, please visit the IRUN web page, which can be accessed by clicking on the graphic in this slide.

Learning Objectives

- Describe the etiologic agent, pathogenesis, clinical manifestations and epidemiology of rotavirus disease.
- Describe barriers to vaccination and strategies to increase vaccination coverage for rotavirus disease.
- Identify rotavirus vaccine (RV) indications, contraindications, and precautions.
- Discuss the importance of appropriate spacing and timing of RV doses.

Following today's lecture, you will be able to meet these nine learning objectives.
(READ SLIDE)

Learning Objectives Continued

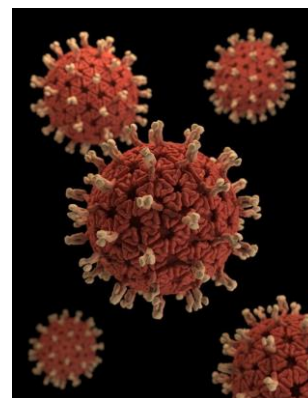
- Describe correct vaccine and diluent storage and handling.
- Define the steps for proper RV administration.
- Describe proper RV documentation and adverse event reporting practices.
- Explain the nurse's role in preventing rotavirus transmission.
- Locate resources relevant to current RV vaccine recommendations.

(READ SLIDE)

PUBLIC HEALTH PERSPECTIVE

Global Impact of Rotavirus Disease

- First identified as a cause of diarrhea in 1973
- By 1980, rotavirus was recognized as the most common cause of severe gastroenteritis in infants and young children globally.
- Worldwide distribution
 - Higher mortality in developing countries
 - Rotavirus infects nearly all children by 5 years of age in settings without vaccination.



Graphical representation of rotavirus virions

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/rotavirus/index.html>; image source: <https://phil.cdc.gov/details.aspx?pid=21351>.

In 1973, a virus particle was observed in the intestinal tissue of children with diarrhea. By 1980, rotavirus was recognized as the most common cause of severe gastroenteritis in infants and young children globally.

Rotavirus infections in infants and young children can lead to severe diarrhea, dehydration, electrolyte imbalance, and metabolic acidosis. Children who are immunocompromised because of congenital immunodeficiency or bone marrow or organ transplantation may experience severe, prolonged gastroenteritis.

Rotavirus is found worldwide, although it is more fatal in developing countries. Rotavirus infects nearly all children by 5 years of age in settings without vaccination.

Prevaccine Rotavirus Disease Burden in the United States

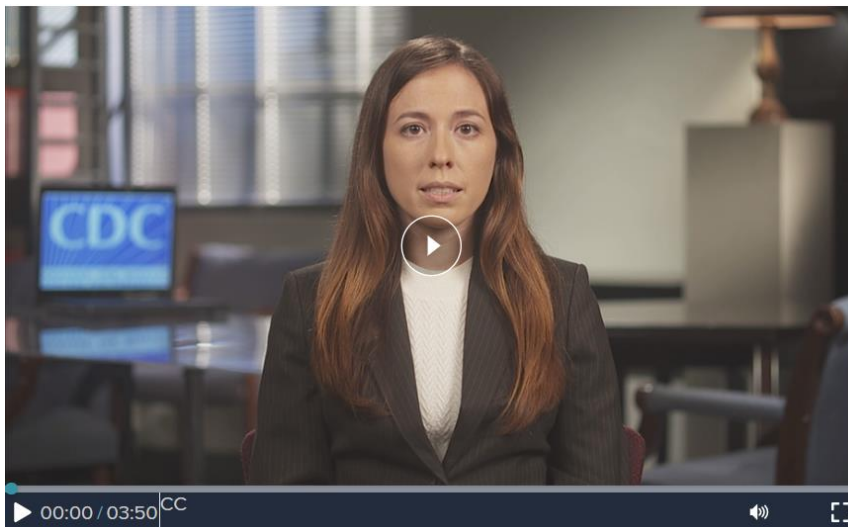
- Annually responsible for:
 - 2.7 million diarrheal infections
 - More than 400,000 physician visits
 - 200,000 emergency department visits
 - 55,000–70,000 hospitalizations
 - 20–60 deaths
- \$1 billion in direct and indirect costs

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/rotavirus/surveillance.html>.

This slide shows the enormous disease burden of rotavirus in the United States before vaccines were available and infants were routinely vaccinated.

In the prevaccine era, rotavirus was responsible for 2.7 million diarrhea infections, more than 400,000 physician visits, 200,000 emergency department visits, 55,000–70,000 hospitalizations (for dehydration), and 20–60 deaths annually. All of this adds up to \$1 billion in direct and indirect costs.

Postvaccine Rotavirus Disease Burden in the United States



[Rotavirus Is Still With Us—How to Prevent an Outbreak](#)

(click to launch video in new window)

Information from

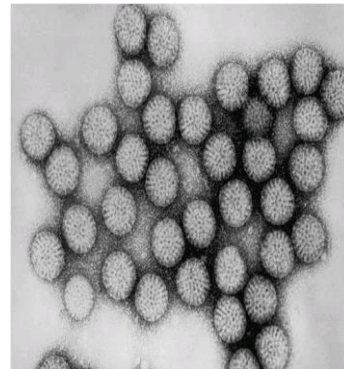
<https://www.medscape.com/viewarticle/903521#:~:text=Rotavirus%20vaccination%20is%20the%20best,susceptible%20to%20severe%20rotavirus%20disease.>

- Even with vaccine availability, rotavirus outbreaks still occur today. The video, linked on this page describes recent cases and outbreaks in the post-vaccine era.

IMMUNE SYSTEM/IMMUNOLOGY

Rotavirus

- Double-stranded RNA virus
- From 2009–2013, five strains of rotavirus (G1–G3, G9,G12) accounted for 90% of cases in the United States.
 - In 2012 and 2013 the G12 strain was the dominant genotype, each of those years accounting for >68% of infections.



Electron micrograph of rotavirus

Information from Bowen, M. D., Mijatovic-Rustempasic, S., Esona, M. D., Teel, E. N., Gautam, R., Sturgeon, M., Azimi, P. H., Baker, C. J., Bernstein, D. I., Boom, J. A., Chappell, J., Donauer, S., Edwards, K. M., Englund, J. A., Halasa, N. B., Harrison, C. J., Johnston, S. H., Klein, E. J., McNeal, M. M., Moffatt, M. E., ... Payne, D. C. (2016). Rotavirus Strain Trends During the Postlicensure Vaccine Era: United States, 2008–2013. *The Journal of infectious diseases*, 214(5), 732–738. <https://doi.org/10.1093/infdis/jiw233>; image source: <https://phil.cdc.gov/Details.aspx?pid=273>.

As you can see in this picture, rotavirus received its name because it looks like a wheel. “Rota” means wheel in Latin.

Rotavirus is a double-stranded RNA virus.

From 2009–2013, five strains of rotavirus (G1–G3, G9,G12) accounted for 90% of cases in the United States.

In 2012 and 2013 the G12 strain was the dominant genotype, each of those years accounting for >68% of infections.

Rotavirus Immunity

- Antibodies against virion glycoproteins VP7 and VP4 probably important for protection.
- Recovery from a first infection usually does not lead to permanent immunity.
 - However, rotavirus infections decrease the probability and severity of later infections.
- Clinical trials and effectiveness studies have shown good duration of protection up to 2 years and in some cases beyond.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/rotavirus/clinical.html>; Velázquez FR, Matson DO, Calva JJ, Guerrero L, Morrow AL, Carter-Campbell S, Glass RI, Estes MK, Pickering LK, Ruiz-Palacios GM. Rotavirus infection in infants as protection against subsequent infections. *N Engl J Med*. 1996 Oct 3;335(14):1022-8. doi: 10.1056/NEJM199610033351404. PMID: 8793926.

The immune correlates of protection from rotavirus are poorly understood. Serum and mucosal antibodies against virion glycoproteins VP7 and VP4 are probably important for protection from disease. Cell-mediated immunity probably plays a role in protection and in recovery from infection.

Recovery from a first rotavirus infection usually does not lead to permanent immunity. After a single natural infection, 38% of children are protected against any subsequent rotavirus infection, 77% are protected against rotavirus diarrhea, and 87% are protected against severe diarrhea. Subsequent infections confer progressively greater protection and are generally less severe than the first.

The duration of immunity from rotavirus vaccine is not precisely known. In the main clinical trials for the two currently licensed rotavirus vaccines, good efficacy was demonstrated for up to 2 years and in some cases beyond.

VACCINE-PREVENTABLE DISEASES

Rotavirus Pathogenesis

- Entry through mouth
- Replication in epithelium of small intestine
- Rotavirus antigen detectable in serum in severe infections.
- Infection leads to isotonic diarrhea.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>.

The virus enters the body through the mouth. Viral replication occurs in the villous epithelium of the small intestine.

Rotavirus antigen detectable in serum in severe infections. Recent evidence indicates that up to two-thirds of children with severe rotavirus gastroenteritis show the presence of rotavirus antigen in serum (antigenemia).

Infection may result in decreased intestinal absorption of sodium, glucose, and water, and decreased levels of intestinal lactase, alkaline phosphatase, and sucrase activity, and may lead to isotonic diarrhea.

Rotavirus Epidemiology

Reservoir	Human (GI tract and stool)
Transmission	Fecal-oral route
Temporal pattern	Winter and early spring
Communicability	2 days before to 10 days after onset of symptoms

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/rotavirus/clinical.html>; <https://www.cdc.gov/rotavirus/surveillance.html>.

The reservoir of rotavirus is the human gastrointestinal tract and stool of infected persons.

Transmission occurs by the fecal-oral route, both through close person-to-person contact and by fomites (surfaces contaminated by stool).

The disease is more common during winter and early spring seasons, especially given the shift in the post-vaccine era. The disease typically peaks in March.

Infected persons shed large quantities of the virus beginning 2 days before the onset of diarrhea and for up to 10 days after the onset of symptoms.

Rotavirus Clinical Features

- Short incubation period: onset of diarrheal symptoms occurring in less than 48 hours after infection
- First infection is generally most severe.
- May be asymptomatic or severe diarrhea, fever, and vomiting
- Gastrointestinal symptoms generally resolve in 3–7 days.
- Clinical features are similar to other pathogens.
 - Confirm with laboratory diagnostic testing of stool

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/rotavirus/clinical.html>; <https://www.cdc.gov/rotavirus/surveillance.html>.

The incubation period for rotavirus is short, with onset of diarrheal symptoms occurring in less than 48 hours after infection.

The clinical manifestations of infection vary and depend on whether it is the first infection or a reinfection. The first rotavirus infection is generally the most severe.

Symptoms vary from asymptomatic to severe diarrhea, fever, and vomiting resulting in dehydration.

The gastrointestinal symptoms generally resolve in 3 to 7 days.

The clinical features and stool characteristics of rotavirus diarrhea are similar to other pathogens. As a result, confirmation of a diarrheal illness as rotavirus requires laboratory diagnostic testing of stool.

IMMUNIZATION STRATEGIES

Barriers to Routine Vaccination in the United States: Health Care Access

- **Barriers to health care access:**
 - Language barriers
 - Lack of trust in providers
 - Transportation problems
 - Inconvenient office hours
 - Patient/parent misinformation
 - Vaccine stigma
 - Competing provider priorities
 - Low awareness of vaccination benefits
 - Receipt of care from multiple providers
 - Complex vaccination schedule
 - Vaccine cost
 - Breaks in insurance coverage

- Vaccination coverage among children enrolled in Medicaid or with no health insurance was lower than that among children who were privately insured.

Information Hill HA, Yankey D, Elam-Evans LD, Singleton JA, Pingali SC, Santibanez TA. Vaccination Coverage by Age 24 Months Among Children Born in 2016 and 2017 — National Immunization Survey-Child, United States, 2017–2019. *MMWR Morb Mortal Wkly Rep* 2020;69:1505–1511. DOI: <http://dx.doi.org/10.15585/mmwr.mm6942a1external icon.>; Walker TY, Elam-Evans LD, Yankey D, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2018. *MMWR Morb Mortal Wkly Rep.* 2019;68:718–723; Escoffery C, et al. Facilitators and Barriers to the Implementation of the HPV VACs (Vaccinate Adolescents Against Cancers) Program: A Consolidated Framework for Implementation Research Analysis. *Prev Chronic Dis.* 2019;16:E85.

To effectively develop and employ strategies to increase vaccination coverage in our communities, we must have a thorough understanding of what barriers exist, that prevent individuals from vaccination.

Barriers

Barriers to health care access and use among the publicly insured include language barriers, lack of trust in providers, transportation problems, inconvenient office hours, patient/parent misinformation, vaccine stigma, competing provider priorities, low awareness of vaccination benefits, receipt of care from multiple providers, complex vaccination schedules, vaccine cost, breaks in coverage and other individual and systems level barriers.

Health insurance and poverty status are interrelated factors associated with lower vaccination coverage in young children. Vaccination coverage among children enrolled in Medicaid or with no health insurance was lower than that among children who were privately insured. The prevalence of being completely unvaccinated was highest among uninsured children (4.1%), lower among those enrolled in Medicaid (1.3%), and lowest among those with private insurance (0.8%).

Strategies for High Vaccination Coverage: Vaccines for Children (VFC) Program

- Vaccines for Children program created in 1993
- Children through age 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:
 - Medicaid eligible
 - Uninsured
 - American Indian or Alaska Native
 - Underinsured



Information from: Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Kang Y. Vaccination Coverage Among Children Aged 19–35 Months — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2017;66:1171–1177. DOI: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>; <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>; <https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html>. Image from: <https://www.cdc.gov/vaccines/programs/vfc/index.html>

Partially, in response to a U.S. based measles outbreak between 1989-1991, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the Vaccines for Children (VFC) Program. VFC became operational October 1, 1994. Known as section 1928 of the Social Security Act, the Vaccines for Children program is an entitlement program (a right granted by law) for eligible children, age 18 and younger.

Children living below and up to a certain percentage above the poverty level are eligible for Medicaid and are entitled to vaccines through the Vaccines for Children, or VFC.

Uninsured children, American Indians or Alaska natives are eligible for VFC benefits.

And finally, a child who is insured, but doesn't have insurance that covers VFC program vaccines are eligible to receive VFC vaccine through federally qualified health center or rural health clinic.

Although many children are eligible for VFC vaccine coverage, some families might not be aware of the VFC program, might be unable to afford fees for visits to a vaccine provider, or might need assistance locating a physician who participates in the VFC program. Thus, CDC has undertaken several activities designed to elucidate potential barriers to early childhood vaccination from the perspective of state immunization programs and health care providers enrolled in the VFC program. There are also plans to assess parental experience with and barriers to accessing vaccination services.

Strategies for High Vaccination Coverage

- Reduce barriers to immunization.
- Provide recommendation for vaccination and reinforcement.
- Reduce missed opportunities.
- Schedule next immunization visit before patient leaves the office.
- Utilize reminder and recall for patients.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; Vaccination Coverage by Age 24 Months Among Children Born in 2015 and 2016—National Immunization Survey-Child, United States, *MMWR*/ October 18, 2019 / 68(41);913–918. ; <https://www.cdc.gov/vaccines/programs/iqip/index.html>

As described in a previous slide, recognizing the barriers to immunization and implementing strategies minimize barriers is necessary to increase vaccination coverage.

Recommending the vaccine is one of the most effective strategies for increasing vaccination coverage for patients of all. As the most trusted profession in the U.S, nurses play a critical role in recommending vaccines to those in their communities. We will discuss more strategies for recommending vaccines in subsequent slides.

“Reducing missed opportunities” means establishing a policy to vaccinate at every visit if vaccinations are indicated. To decrease missed opportunities, providers need to use every patient encounter to screen for, strongly recommend, and offer needed vaccinations to patients, taking advantage of tools, such as the ones shown later in this presentation, to support effective communication with patients and parents.

Another strategy to increase vaccination coverage is scheduling the next immunization visit before the patient leaves the office.

Reminder/recall systems are cost-effective methods to identify and notify families when children are due for vaccinations or are already behind. Reminders (for vaccines due soon) and recalls (for overdue vaccines) can be delivered by telephone, text message, letter, postcard, or other methods. Most reminder and recall notices are tailored for individuals, and many include educational messages about the importance of vaccination.

Strategies for High Vaccination Coverage

- Employ Immunization Quality Improvement For Providers (IQIP) Process and Strategies:
 - <https://www.cdc.gov/vaccines/programs/iqip/at-a-glance.html>
- Maintain thorough documentation in patient records.
- Utilize Immunization Information Systems (IISs)

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/programs/iis/index.html>

The Immunization Quality Improvement for Providers process and strategies promotes and supports implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents. More information about the IQIP program can be found using the link on this slide.

Other important strategies consist of good record-keeping through documentation in patient records and the use of immunization information systems to assess vaccination status and record vaccines administered.

Immunization Information Systems (IISs)

- IISs are confidential, computerized databases that record all vaccine doses administered by providers to persons residing within a given geopolitical area.
- IISs provide consolidated immunization histories that help in determining appropriate vaccinations.
- All immunization providers are encouraged to document all administered vaccines in an IIS.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; About Immunization Information Systems <https://www.cdc.gov/vaccines/programs/iis/about.html>; <https://www.cdc.gov/vaccinesafety/concerns/history/gardasil-recall-faq.html>.

- By 2 years of age, over 20% of children in the U.S. typically have seen more than one health care provider, resulting in scattered paper medical records. Immunization information systems (IISs) help providers and families by consolidating immunization information into one reliable source. IISs are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health care providers within a geographic area.
- Immunization providers are strongly encouraged to participate in an IIS. Laws governing use of IISs vary by state or region. Some states mandate use of an IIS to document vaccinations for certain patients. Providers should be aware of state and/or regional requirements for IIS reporting in their jurisdiction.

TYPE OF VACCINE

Advisory Committee on Immunization Practices (ACIP)

- A group of medical and public health experts who develop recommendations for the use of vaccines in the civilian population of the United States
- Provides guidance on use of vaccines and other biologic products to U.S. Department of Health and Human Services, CDC, and the U.S. Public Health Service
- ACIP recommendations are standard of care in the United States.

Information from Advisory Committee on Immunization Practices <https://www.cdc.gov/vaccines/acip/committee/index.html>.

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations for the use of vaccines in the civilian population of the United States. ACIP recommendations are considered standard of care in the U.S.

Type of Vaccine

Rotavirus vaccine is a live vaccine (also known as an “attenuated vaccine”).

A live vaccine:

- Is weakened form of the pathogen
- Must replicate in the body to induce an immune response
- Causes immune response virtually identical to natural infection

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.vaccines.gov/basics/types/index.html>.

Currently, there are two rotavirus vaccine products licensed for use in the United States. Both are live, attenuated vaccines. The viruses in the vaccine are weakened so that they will not cause disease in a person with a competent immune system, but they will induce a protective immune response in most vaccinated persons.

Live vaccines must replicate in the body to induce an immune response that is virtually identical to natural infection. It is the initiation of this immune response that allows for antibody production and immunity.

Rotavirus Vaccine Products

Two rotavirus vaccine products are available in the United States.

Vaccine product	Age indications
RV1 (Rotarix®)	6 weeks to 24 weeks of age
RV5 (RotaTeq®)	6 weeks to 32 weeks of age

Neither vaccine contains thimerosal or other preservatives .

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/about-vaccine.html>; <https://www.fda.gov/vaccines-blood-biologics/vaccines>.

As previously mentioned, there are currently two rotavirus vaccine products licensed for use in the United States.

RV1 or Rotarix® is manufactured by GlaxoSmithKline and was licensed by the FDA in 2008. Rotarix® contains one live rotavirus strain and is indicated for use in infants ages 6 weeks to 24 weeks of age.

RV5 or RotaTeq® is manufactured by Merck and was licensed by the FDA in 2006. RotaTeq® contains five live rotavirus strains and is indicated for use in infants ages 6 weeks to 32 weeks of age.

Neither vaccine contains thimerosal or other preservatives.

Additional resources on rotavirus vaccine products are listed in the resources and references slides at the end of this presentation.

Vaccine Impact and Efficacy

- Both vaccines have significantly reduced physician visits for diarrhea and reduced rotavirus-related hospitalizations.
- Protective against:
 - Any rotavirus gastroenteritis: 74–87%
 - Severe gastroenteritis: 85–98%
- No ACIP preference for one product (Rotarix® vs. RotaTeq®) over the other

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
<https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/about-vaccine.html>.

In a large study evaluating children during the first 2 years of life, RV5 (RotaTeq®) vaccine reduced the incidence of office visits for rotavirus gastroenteritis by 86%, emergency department visits for that outcome by 94%, and hospitalizations for that outcome by 96%. One study found RV1 (Rotarix®) to be 96% effective in reducing hospitalizations through two rotavirus seasons.

Both RV1 (Rotarix®) and RV5 (RotaTeq®) were found to be protective against any rotavirus gastroenteritis, including severe gastroenteritis. Large clinical studies have found that the vaccine products demonstrated 74–87% protection against gastroenteritis of any severity and 85–98% protection specifically against severe gastroenteritis.

Because of similar estimates of efficacy and safety, the Advisory Committee on Immunization Practices does not state a preference for one vaccine product over the other.

IMMUNIZATION SCHEDULES

ACIP Rotavirus Vaccine Recommendations: Pediatric

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See Notes												

- ACIP recommends rotavirus vaccine beginning at 2 months of age.
- This vaccine is only recommended for infants.
- Routine pediatric recommendations are found in the [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#).

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>.

ACIP recommends RV vaccine beginning at 2 months of age. Routine pediatric vaccine recommendations are found in the [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#).

In the graphic on this slide, the yellow bars indicate recommended time frame for each RV dose. The notes referenced in the 6-month yellow bar can be found in the Immunization Schedule linked on this page.

Vaccination Schedule by Product

Vaccine Product	ACIP Abbreviation	2 months of age	4 months of age	6 months of age
Rotarix®	RV1	✓	✓	
RotaTeq®	RV5	✓	✓	✓

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/recommendations.html>.

The vaccine should be administered as a series of either 2 doses of RV1 (Rotarix®) at ages 2 and 4 months or 3 doses of RV5 (RotaTeq®) at ages 2, 4, and 6 months.

ACIP Vaccine Recommendations: Pediatric

First dose of series:

- Series may be started as early as 6 weeks of age.
- Maximum age for first dose is 14 weeks, 6 days.*

Last dose of series:

- Maximum age for any dose is 8 months, 0 days, even if the series is incomplete.*

Interval between doses:

- Minimum interval between doses is 4 weeks.
- There is no maximum interval between doses.

*Off label use

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>; https://www.immunize.org/askexperts/experts_rota.asp.

The ACIP developed age recommendations that vary from those of the manufacturers

The vaccination series for both vaccines may be started as early as 6 weeks of age.

ACIP recommendations state that the maximum age for the first dose of both vaccines is 14 weeks 6 days. Vaccination should not be initiated for infants age 15 weeks 0 days or older because there are insufficient data on the safety of dose #1 in older infants. This is an off-label recommendation for RV5 since the product information states a maximum age of 12 weeks.

The maximum age for any dose of either rotavirus vaccine is 8 months. No rotavirus vaccine should be administered to infants older than 8 months even if they have not completed the series. This is an ACIP off-label recommendation for both vaccines because the labeled maximum age for RV1 (Rotarix®) is 24 weeks, and the labeled maximum age for RotaTeq® is 32 weeks.

The minimum interval between doses of rotavirus vaccine is 4 weeks. ACIP did not define a maximum interval between doses. It is preferable to adhere to the recommended interval of 8 weeks between doses (the minimum interval is 4 weeks). If the interval is longer, the infant can still receive the vaccine as long as it can be given on or before 8 months of age. It is not necessary to restart the series or add doses because of a prolonged interval between doses.

ACIP Vaccine Recommendations: Pediatric

Complete the series with the same vaccine product whenever possible.

- If product used for a prior dose or doses is not available or not known, continue or complete the series with the product that is available.
- If any dose in the series was RV5 (RotaTeq®) or the vaccine brand used for any prior dose is not known, follow the 3-dose schedule.
- Remember—children should receive all doses of rotavirus vaccine before they turn 8 months old.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/recommendations.html>.

ACIP recommends that the same rotavirus vaccine product should be used for all doses in the series whenever possible.

Sometimes providers do not know the product that was previously administered or do not have that product in their inventory. If this occurs, vaccination should not be deferred, and the provider should continue or complete the series with the product that is available.

If any dose in the series was RV5 (RotaTeq®) or the vaccine brand is not known, a 3-dose schedule should be followed.

And remember—the maximum age for any dose in the series is 8 months.

ACIP RV Vaccine Recommendations: Pediatric

- Infants with documented rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still begin or complete the 2- or 3-dose schedule.

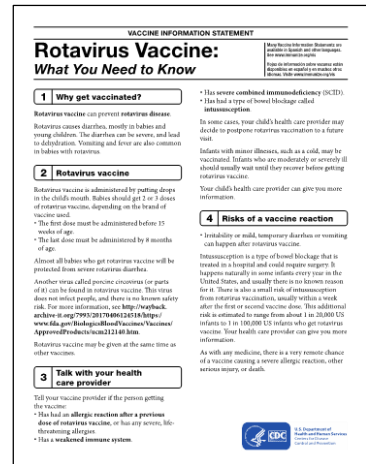
Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>.

Infants with documented rotavirus gastroenteritis before receiving the full rotavirus vaccine series should still begin or complete the 2- or 3-dose series following the age recommendations. As noted earlier, the initial rotavirus infection may provide only partial protection against subsequent rotavirus disease.

COMMUNICATIONS

CDC Rotavirus Vaccine Information Statement (VIS)

- Federal law requires that a VIS be provided to a patient, parent, or legal representative before each dose of certain vaccines.
- VISs explain both the benefits and risks of the vaccine the patient is receiving.



Information from vaccine information statements www.cdc.gov/vaccines/hcp/vis/; foreign language versions <https://www.immunize.org/vis/>.

All public and private vaccine providers are required by the National Childhood Vaccine Injury Act to give the appropriate VIS to the patient (or their parent or legal representative) prior to every dose of certain vaccines. VISs have been translated into about 40 languages. These can be found on the website of CDC's partner, the Immunization Action Coalition. You can access the website by clicking on the image on the right of the slide. Additional resources on the use of VISs are listed in the resources and references slides at the end of this presentation.

CDC Vaccine Information Statement (VIS)

How to provide a VIS prior to vaccination:

- Paper copies of the VIS can be printed and given to patients prior to vaccination.
- Permanent, laminated office copies may be given to patients to read prior to vaccination.
- Patients may view VISs on a computer monitor or other video display.
- Patients may read the VIS on their phone or other digital device by downloading the pdf file from CDC's website.
- Patients may be given a copy of a VIS during a prior visit, or told how to access it through the internet, so they can read it in advance. These patients must still be offered a copy to read during the immunization visit, as a reminder.

Always offer the parent or legal representative an opportunity to ask questions about the vaccine you are administering.

Patients must still be offered a copy of the VIS to take away following the vaccination. The patient may decline.

Information from <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>.

All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act to give the appropriate VIS to the parent or legal representative prior to every dose of rotavirus vaccine

Paper copies of the VIS can be printed and given to the parent or legal representative.

Permanent, laminated office copies may be given to the parent or legal representative to read.

Parents or legal representatives may view VISs on a computer monitor or other video display.

Providing the VIS as an attachment or weblink contained within an email sent to the parent/legal representative.

Parents or legal representatives may read the VIS on their phones or other digital devices by downloading the pdf file from CDC's website.

Parents or legal representatives may be given a copy of a VIS during a prior visit or told how to access it through the internet so they can read it in advance. These patients must still be offered a copy to read as a reminder during the immunization visit.

Always offer the parent or legal representative an opportunity to ask questions about the vaccine you are administering.

Providers can make VISs available to the parent or legal representative on paper or in electronic form. The parent or legal representative must be offered a copy of the VIS to take home, but they may decline.

If the parent/legal representative is not present, provision of the VIS prior to vaccination must be coupled with a method to verify parent/legal representative receipt of the VIS, in addition to parent/legal representative consent to vaccination in compliance with the applicable state medical consent law.

LEGAL/ETHICAL ISSUES

Legal and Ethical Considerations

State vaccination requirements

- 20 states in the U.S. had rotavirus vaccination mandates for child care facilities and school (as of January 2020).

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>; <https://www.immunize.org/laws/rotavirus.asp>.

READ SLIDE

Legal and Ethical Considerations

Vaccine exemptions

- All states provide medical exemptions to vaccination requirements.
- Some states also offer religious and/or philosophical exemptions.
- Some states require these exemptions be sworn or affirmed through signed, notarized affidavits.
- Children with vaccine exemptions may be excluded from child care facilities or school during an outbreak of a vaccine-preventable disease.

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>.

READ SLIDE

Legal and Ethical Considerations

National Childhood Vaccine Injury Act (NCVIA)

- Passed by Congress in 1986
- Established Vaccine Adverse Reporting System (VAERS) to collect reports of vaccine adverse events
- Initiated the National Vaccine Injury Compensation Program (VICP) to compensate individuals who experience certain health events following receipt of a VICP-covered vaccine

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>.

Unsubstantiated vaccine injury claims caused a risk to the vaccine supply in the past because fear of lawsuits drove many manufacturers out of the vaccine business. In response, Congress passed the National Childhood Vaccine Injury Act in 1986. This law established the Vaccine Adverse Event Reporting System, which collects reports of vaccine adverse events and includes a reporting table for the National Vaccine Injury Compensation Program, which is administered by the Health Resources and Services Administration (HRSA). This program was also initiated by the law to compensate individuals who experience certain health events following vaccination. The VAERS reporting table complements the HRSA Injury Table, outlining distinct outcomes that are compensable, along with the time period when the outcome occurred following vaccination.

Legal and Ethical Considerations

Consent for vaccines

- There is no federal requirement for informed consent prior to immunization.
- Individual states may have laws outlining consent requirements.
- Health care systems/facilities also may have consent policies.

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>.

READ SLIDE

VACCINE STORAGE AND HANDLING

Vaccine Storage and Handling

- Store rotavirus vaccines in a refrigerator between 2°C-8°C (36°F-46°F).
- Store in the original packaging with the lids closed in a clearly labeled bin and/or area of the storage unit
 - Protect the vaccine from light.
- Store RV1 (Rotarix®) diluent in the refrigerator with the vaccine or at room temperature up to 25°C (77°F).
- Do not freeze vaccine or diluent.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/storage-handling.html>.

Rotavirus vaccine should be stored in the refrigerator between 2 and 8 degrees Celsius (or 36 through 46 degrees Fahrenheit).

It should be stored in the original packaging and protected from light.

The diluent for Rotarix® may be stored in the refrigerator with the vaccine or at a controlled room temperature up to 25 degrees Celsius (or 77 degrees Fahrenheit).

The vaccine or diluent should NEVER be frozen.

Vaccine Storage and Handling

Keys to vaccine storage

- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management
- Well-trained staff



"Keys to Storing and Handling Your Vaccine Supply" Video

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/storage-handling.html>; video link: <https://www2.cdc.gov/vaccines/ed/shvideo>.

Proper vaccine storage and handling are important factors in ensuring vaccine potency. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

The following are necessary to protect a vaccine inventory:

Reliable storage and temperature monitoring equipment

Accurate vaccine inventory management

Well-trained staff

Additional resources on storage and handling are listed in the resources and references slides at the end of this presentation.

VACCINE ADMINISTRATION

Before Vaccine Administration

- Assess for needed vaccines by reviewing the immunization history.
 - Accept only written (including electronic), dated medical records.
 - Compare to recommended vaccination schedule.
- Screen for contraindications and precautions.
- Discuss vaccine benefits, risks, and vaccine-preventable diseases using VISs and other reliable resources.
- Provide after-care instructions.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>.

The patient's immunization status should be reviewed at every health care visit. Using the patient's immunization history, health care personnel should assess for all routinely recommended vaccines, as well as any vaccines indicated based on health status, occupation, or other risk factors such as travel. Use the current immunization schedule based on the patient's age to determine all vaccines that are needed.

You can find a patient's immunization history by using information from immunization information systems, current and previous medical records, and personal vaccination record cards. For rotavirus vaccine, only written (including electronic) dated, medical records are acceptable.

Before administering any vaccine, patients should be screened for contraindications and precautions, even if the patient has previously received that vaccine. The patient's health status may change from one visit to the next or recommendations regarding contraindications and precautions may have changed. Using a standardized, comprehensive screening tool helps staff assess patients correctly and consistently. Staff should be knowledgeable about contraindications and precautions to vaccination and should only follow valid contraindications.

Health care personnel should assess the level and type of information each patient or parent needs—for example, not everyone wants the same level of medical or scientific information about vaccines. Health care personnel need to be ready to answer questions. Fortunately, there are many resources available to help providers stay up to date on vaccine-related information, including vaccine information statements. Parent/patient education should also include a discussion of comfort and care strategies after vaccination. After-care instructions should include information for dealing with common side effects such as injection site pain, fever, and fussiness (especially in infants). After-care instructions should also include information on when to seek medical attention and when to notify the health care provider about any concerns that arise following vaccination.

Contraindications

Screen for contraindications and precautions before administering vaccines.

Rotavirus vaccine should not be given to infants with:

- Severe allergic reaction to a vaccine component (including latex) or following a previous dose of vaccine
 - RV1 (Rotarix®) oral applicator contains latex rubber.
- History of intussusception
- Severe combined immunodeficiency (SCID)

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/recommendations.html>.

Patients and their family members count on health care personnel to administer vaccines safely. Screening helps prevent adverse reactions such as anaphylaxis.

As with other vaccines, rotavirus vaccine is contraindicated for infants who are known to have had a severe allergic reaction to a vaccine component or following a previous dose of vaccine. The oral applicator for RV1 (Rotarix®) contains latex rubber, so infants with a severe allergy to latex should not receive Rotarix®. These infants should receive RV5 (RotaTeq®) instead because the dosing tube does not contain latex.

Post-marketing studies of the currently licensed vaccines have detected an increased risk for intussusception following rotavirus vaccine administration. As a result, a history of intussusception is a contraindication to rotavirus vaccination.

Rotavirus vaccine should generally not be administered to infants with moderate or severe acute gastroenteritis. However, infants with mild acute gastroenteritis or other mild illnesses may be vaccinated.

Lastly, ACIP added severe combined immunodeficiency, or SCID, as a contraindication to rotavirus vaccination in response to reported cases of vaccine-acquired rotavirus infection in infants with SCID.

Additional resources for screening for vaccine contraindications and precautions are listed in the resources and references slides at the end of this presentation.

Precautions*

- Altered immunocompetence other than SCID Chronic gastrointestinal disease
- Spina bifida or bladder exstrophy
- Moderate or severe acute illness with or without fever

Delay vaccination for babies who are moderately or severely ill until they recover. This includes babies with moderate or severe diarrhea or vomiting.

*The decision to vaccinate if a precaution is present should be made on a case-by-case assessment of risks and benefits.

Information from <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/recommendations.html>;
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm>; <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.

While SCID is a contraindication to vaccination, other forms of altered immunocompetence or a weakened immune system are considered precautions as well . For children with known or suspected immune deficiency, consultation with an immunologist or infectious diseases specialist before administration of rotavirus vaccine should occur. Children who are immunocompromised because of congenital immunodeficiency, or hematopoietic stem cell or solid organ transplantation, sometimes experience severe, prolonged, and even fatal wild-type rotavirus gastroenteritis.

Spina bifida or bladder exstrophy are precautions for rotavirus vaccine due to high risk for acquiring latex allergy. Latex rubber is contained in the RV1 oral applicator whereas the RV5 dosing tube is latex-free. Therefore, some experts prefer that infants with spina bifida or bladder exstrophy receive RV5 instead of RV1 to minimize latex exposure in these children. However, if RV1 is the only rotavirus vaccine available, it should be administered, because the benefit of vaccination is considered to be greater than the risk for sensitization.

Rotavirus vaccine should generally be deferred in infants with acute, moderate or severe gastroenteritis, or other acute illness until the condition improves. However, infants with mild acute gastroenteritis or other mild acute illness can be vaccinated, particularly if a delay in vaccination will postpone the first dose of vaccine beyond 14 weeks 6 days of age.

Vaccine Preparation

- Perform hand hygiene.
- Use designated, clean preparation area.
- Prepare your own vaccines.
- Prepare vaccine only when ready to administer.
- Always follow the vaccine manufacturers' directions, located in the package insert.
- Check expiration date on the vaccine and diluent (if needed).

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html>.

Preparing vaccine properly is critical to maintaining the integrity of the vaccine during transfer from the manufacturer's vial to oral applicator for RV1 or when opening dosing tube for RV5. CDC recommends preparing vaccines just before administration. When preparing vaccines:

Follow strict aseptic medication preparation practices.

Perform hand hygiene BEFORE preparing vaccines.

Use a designated, clean medication area that is not adjacent to any area where potentially contaminated items are placed.

Always follow the vaccine manufacturer's directions, located in the package insert.

RV1 (Rotarix®) vaccine requires reconstitution. Only the diluent supplied by the manufacturer should be used to reconstitute the vaccine

Additional resources on vaccine preparation are listed in the resources and references slides at the end of this presentation.

RV Vaccine Administration

May be administered during the same clinical visit as other vaccines

Preparation

- RV1 (Rotarix®): Must be reconstituted before administering

Route

- Administer orally (PO).
- The infant may eat or drink immediately following vaccination administration.
- DO NOT repeat the dose if the infant spits out or regurgitates the vaccine or vomits after vaccination.



Nurse administering oral rotavirus vaccination to infant

Information from www.cdc.gov/vaccines/vpd/rotavirus/hcp/administering-vaccine.html#errors; image source: <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>.

Rotavirus vaccines can be given at the same visit as other vaccines.

As previously discussed, RV1 (Rotarix®) vaccine requires reconstitution. RV5 (RotaTeq®) comes in a manufacturer-filled oral dosing tube.

Both vaccines are administered orally. Infants may eat, drink, or breastfeed immediately after vaccination.

ACIP recommends that providers DO NOT repeat the dose if the infant spits out or regurgitates the vaccine or vomits after vaccination. Any remaining doses should be administered on schedule.

If either vaccine is injected, the dose is not valid, and an oral dose should be administered as soon as possible. Injection of RV should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov> even if an adverse reaction does not result from it.

We will discuss more about the Vaccine Adverse Event Reporting System in subsequent slides.

Vaccine Administration Techniques for RV1 (Rotarix®) and RV5 (RotaTeq®)



Information from <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>.

These videos describe vaccine administration techniques for RV1 (Rotarix®) and RV5 (Rotateq®). Both are good demonstrations of how to administer an oral vaccine.

Administration With Other Vaccines

- Rotavirus vaccine can be administered at the same doctor visit as DTaP vaccine, Hib vaccine, polio vaccine, hepatitis B vaccine, and pneumococcal conjugate vaccine.
- The infant's immune response to influenza vaccine administered at the same time as rotavirus vaccine has not been studied.

Information from <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/administering-vaccine.html>.

Rotavirus vaccine can be administered at the same doctor visit as DTaP vaccine, Hib vaccine, polio vaccine, hepatitis B vaccine, and pneumococcal conjugate vaccine. Available evidence suggests that rotavirus vaccine does not interfere with the immune response to these vaccines. The infant's immune response to influenza vaccine administered at the same time as rotavirus vaccine has not been studied. However, the Advisory Committee on Immunization Practices (ACIP) has recommended previously that an inactivated vaccine (e.g., inactivated influenza vaccine) may be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine (e.g., rotavirus vaccine).

DOCUMENTATION

Documenting Vaccinations

Document vaccinations in patient's permanent medical record. The following information should be included:

- Vaccine manufacturer
- Vaccine lot number
- Date of administration
- Name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside
- Edition date of the VIS and the date it was provided to the patient, parent, or legal guardian



Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.youtube.com/watch?v=xlyqUgKGFpk>.

Accurate and timely documentation can help prevent administration errors and curtail the number and cost of excess vaccine doses administered. In addition, preventing excess doses of vaccines may decrease the number of adverse reactions. All vaccines administered should be fully documented in the patient's permanent medical record. Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program are required to document the following information in the patient's permanent medical record:

Vaccine manufacturer

Vaccine lot number

Date of administration

Name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside

Edition date of the VIS distributed and the date provided

This federal law applies to all routinely recommended childhood vaccines, even for doses of these vaccines that are administered to adults. The law applies to the administering provider, who is not liable for previous lack of documentation.

Additional resources for documenting vaccinations after administration are listed in the resources and references slides at the end of this presentation.

Documentation: Best Practice Guidelines

- Best practice guidelines also include documenting:
 - Route
 - Dosage (amount)
 - Site
 - Expiration date
- Provide personal immunization record that includes the vaccinations and administration dates.
- Update medical records to include:
 - Adverse events after vaccination

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; ; <https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html>.

Medication administration best practices also include documenting the route, dosage (amount), site, and vaccine expiration date. The patient or parent/guardian should be given a personal immunization record that includes the vaccinations and date administered. Providers should update patients' permanent medical records to reflect any documented episodes of adverse events after vaccination.

Reporting Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS): A passive surveillance system to monitor adverse events following vaccination

Health care providers are required by law to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination

Health care providers are encouraged to report:

- Any adverse event after the administration of a vaccine
- Vaccine administration errors

Information from <https://vaers.hhs.gov/reportevent.html>.

Severe adverse events following vaccination are rare. Report significant adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event. VAERS accepts all reports, including reports of vaccine administration errors.

Health care professionals are required to report:

Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination within the specified time period

Reporting Adverse Events

VAERS Table of Reportable Events Following Vaccination

Vaccine/Toxoid	Event and Interval from Vaccination
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (21 days) B. Any acute complication or sequelae (including death) of above events (interval not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval-see package insert)

Information from https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf.

Providers should report all adverse events after vaccination to VAERS. This table reflects conditions reportable by law, but providers should report any adverse event that concerns them. Most infants who receive rotavirus vaccine have no problems. However, one adverse event that has generated a lot of attention is intussusception.

Rotavirus Vaccine Adverse Events

- Intussusception is a type of bowel blockage caused when the bowel folds into itself like a telescope.
 - There is a small risk of intussusception from rotavirus vaccination, usually within a week of administration of the first or second dose.
- In the United States, this additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 U.S. infants who get rotavirus vaccine.

Information from <https://www.cdc.gov/vaccines/vpd/rotavirus/>.

Intussusception is a type of bowel blockage caused when the bowel folds into itself like a telescope. There is a small risk of developing intussusception following rotavirus vaccination, usually within a week of administration of the first or second dose.

Large phase III clinical trials (more than 60,000 infants each) of RV5 and RV1 vaccine evaluated the occurrence of intussusception after vaccination. No increased risk for intussusception was observed for either vaccine. However, post-licensure monitoring was planned to evaluate for a possible risk of intussusception at a lower level than that able to be evaluated in the clinical trials. Post-licensure evaluations of RV5 vaccine and/or RV1 vaccine in some middle and high income countries have identified a low-level increased risk of intussusception following vaccination. In the United States, the risk is estimated as 1 excess case of intussusception per 20,000 to 100,000 vaccinated infants. The risk appears to be primarily during the first week following the first or second dose, but may extend up to 21 days following the first dose. Parents and health care providers should be aware of the low-level increased risk of intussusception following rotavirus vaccine so that infants with possible intussusception can be promptly evaluated.

VACCINE SAFETY

RV Vaccine Adverse Reactions

RV5 (RotaTeq®)

- Diarrhea 18.1%
- Vomiting 11.6%

RV1 (Rotarix®)

- Irritability 11.4%
- Cough or runny nose 3.6%
- Flatulence 2.2%

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; ; <https://www.fda.gov/vaccines-blood-biologics/vaccines/Rotarix>; <https://www.fda.gov/vaccines-blood-biologics/vaccines/rotate>.

Shown here are common adverse reactions following vaccination.

RotaTeq® recipients had a small but statistically significant increased rate of diarrhea (18.1%) and vomiting (11.6%) in the first week following vaccination compared with the placebo group.

Rotarix® recipients had Irritability (11.4%), cough or runny nose (3.6%), and flatulence (2.2%) more frequently during the 31 days after vaccination compared with the placebo group.

NURSING CONSIDERATIONS

Nursing Considerations

	Reaction Following Vaccine Administration	Supportive Treatment Recommendation
Mild to Moderate	RV5 <ul style="list-style-type: none"> • Diarrhea • Vomiting RV1 <ul style="list-style-type: none"> • Irritability • Cough or runny nose • Flatulence 	Usually self-limiting <ul style="list-style-type: none"> • Encourage rest and hydration and refer to provider if reactions persist or worsen
Severe	Intussusception <ul style="list-style-type: none"> • Vomiting • Blood in stool • Weakness • Irritability 	Immediate referral to hospital for radiologic assessment and treatment

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C.: Public Health Foundation; 2015; <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www.cdc.gov/vaccines/parents/by-age/months-1-2.html>.

Supportive Treatment

- Mild to moderate reactions to RV5 can include diarrhea and vomiting. Mild to moderate reactions to RV1 can include irritability, cough or runny nose, and flatulence.
- Treatment: Symptoms are usually self-limiting. Encourage rest and hydration and tell parents to contact the provider if reactions persist or worsen.
- Intussusception is a rare but severe reaction to rotavirus vaccine products. Signs include vomiting, blood in stool, weakness, and irritability.
- Treatment: Refer to a hospital immediately for radiologic assessment and treatment.

Nursing Considerations

Vaccinate with Confidence

- CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States
- Key priorities:
 - Protect communities.
 - Empower families.
 - Stop myths.



Child vaccination coverage remains high nationally, and most parents are confident in the safety and effectiveness of vaccines. However, the spread of myths and misinformation has put some communities at risk. When misleading information circulates, vaccination coverage can fall and increase the risk for outbreaks of vaccine-preventable diseases.

A New Approach

Vaccinate with Confidence is CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States.

Vaccinate with Confidence will strengthen public trust in vaccines by advancing three key priorities:

Protect Communities

Vaccination rates remain strong nationally, but pockets of under-vaccination persist in some locations, putting communities at risk for outbreaks. CDC will support states, cities, and counties to find these communities and take steps to protect them.

Empower Families

Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. CDC will expand resources for health care professionals to support effective vaccine conversations.

Stop Myths

To stop misinformation from eroding public trust in vaccines, CDC will work with local partners and trusted messengers to improve confidence in vaccines among at-risk groups, establish partnerships to contain the spread of misinformation, and reach critical stakeholders to provide clear information about vaccination and the critical role it plays in protecting the public.



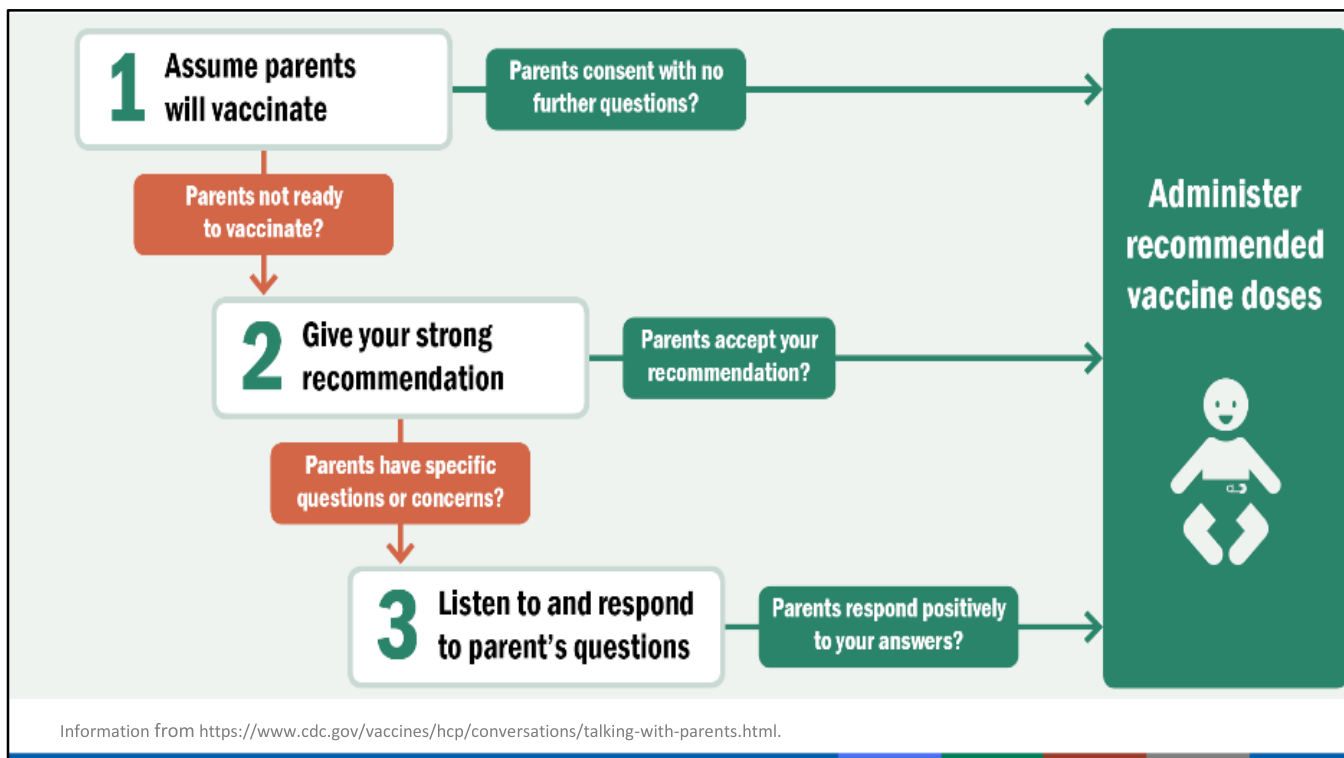
Photo courtesy of the American Academy of Pediatrics and AAP Academy.



Information from <https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html>.

Vaccinate with Confidence

- *Vaccinate with Confidence* is CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. This slide contains links to the *Vaccinate with Confidence* web page and fact sheet.
- *Vaccinate with Confidence* will strengthen public trust in vaccines by advancing three key priorities:
 - Protect communities.
 - Empower families.
 - Stop myths.
- *Protect communities*: Vaccination coverage remains strong nationally, but pockets of undervaccination persist in some locations, putting communities at risk for outbreaks. CDC will support states, cities, and counties to find these communities and take steps to protect them.
- *Empower families*: Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. CDC will expand resources for health care professionals to support effective vaccine conversations.
- *Stop myths*: To stop misinformation from eroding public trust in vaccines, CDC will work with local partners and trusted messengers to improve confidence in vaccines among at-risk groups, establish partnerships to contain the spread of misinformation, and reach critical stakeholders to provide clear information about vaccination and the essential role it plays in protecting the public



Nurses play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination coverage. You can all answer parents' questions, provide educational materials, and ensure that families make and keep immunization appointments.

Although parents frequently consult family members, friends, and web pages for information on vaccines, parents consistently rank their child's health care professionals as their most trusted source of vaccine information. This is true even for parents who are vaccine-hesitant or who have considered delaying one or more vaccines. Invoking nursing ethical principles of veracity and beneficence, nurses have a critical role in helping parents choose vaccines for their child. When discussing vaccines for children, it is best to stay informed about age appropriate vaccines for the child and about state mandates for vaccination.

Clearly state your strong recommendation for vaccination. If a parent has concerns, resists following the recommended vaccination schedule, or questions your strong recommendation, this doesn't necessarily mean they won't accept vaccines. Sometimes parents simply want *your* answers to their questions. Your willingness to listen to their concerns will play a major role in building trust in you and your recommendation.

VACCINE RESOURCES AND REFERENCES

Vaccine Resources and References

ACIP recommendations

- Current ACIP rotavirus vaccine recommendations
<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rotavirus.html>
- ACIP General Best Practice Guidelines for Immunization
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

Disease information

- CDC Rotavirus Disease and Vaccination www.cdc.gov/rotavirus/index.html
- Ask the Experts–Rotavirus FAQs www.immunize.org/askexperts/experts_rota.asp
- Questions and Answers–Rotavirus What You Should Know
<https://media.chop.edu/data/files/pdfs/vaccine-education-center-rotavirus.pdf>

Here is a list of vaccine resources and references.

Vaccine Resources and References

Immunization strategies

- Immunization information systems
<https://www.cdc.gov/vaccines/programs/iis/index.html>
- Immunization quality improvement for providers
<https://www.cdc.gov/vaccines/programs/iqip/at-a-glance.html>
- Comprehensive clinic assessment software application
<https://www.cdc.gov/vaccines/programs/cocasa/index.html>

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Vaccine Resources and References

Manufacturers' vaccine package inserts (PIs)

- Rotarix[®], GlaxoSmithKline <https://www.fda.gov/vaccines-blood-biologics/vaccines/rotarix>
- RotaTeq[®], Merck & Co., Inc <https://www.fda.gov/vaccines-blood-biologics/vaccines/rotateq>

Immunization schedules

- [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#)
- [Catch-Up Immunization Schedule](#)

Here is a list of vaccine resources and references.

Vaccine Resources and References

Communications

- Talking to parents about vaccines
<https://www.cdc.gov/vaccines/hcp/conversations/conv-materials.html>
- Recommending Vaccines for Children Under Two Years Old: Dr. Tolu Adebajo
<https://www.youtube.com/watch?v=s7xKvqoxIMA&list=PLvvp9iOILTQYCC6DnrG4FuRT8SpdUnMbZ&index=26&t=0s>
- Current vaccine information statements (VISs)
<https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>
- Instructions for Using VISs <https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html>
- Translated VISs <https://www.immunize.org/vis/?f=9>

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Vaccine Resources and References

Vaccine storage and handling

- *Vaccine Storage and Handling Toolkit*
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- “Keys to Storing and Handling Your Vaccine Supply”
<https://www.youtube.com/watch?v=VCzO8Zod8DI>

Vaccine Administration

- Vaccine Administration for Healthcare Professionals
<https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>

Here is a list of vaccine resources and references.

Vaccine Resources and References

Vaccine administration

- *Immunization Action Coalition* clinic tools screening for vaccine contraindications and precautions <https://www.immunize.org/clinic/screening-contraindications.asp>
- Standing orders for administering rotavirus vaccine www.immunize.org/catg.d/p3087.pdf
- CDC vaccine administration resource library <https://www.cdc.gov/vaccines/hcp/admin/resource-library.html>

Documentation

- Documentation of vaccinations after administration <https://www.youtube.com/watch?v=xlyqUgKGFPk>

Here is a list of vaccine resources and references.

GLOSSARY

Glossary

- **Aseptic Technique:** A technique that prevents or reduces the spread of microorganisms from one site to another
- **Communicability:** Ability to spread disease; also known as infectious.
- **Contraindication:** A condition that increases the likelihood of a serious adverse reaction to a vaccine for a patient with that condition. If the vaccine is given in the presence of that condition, the resulting adverse reaction could seriously harm the recipient.
- **Diluent:** A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration (manufacturers of freeze-dried vaccine also supply the corresponding diluents).

Glossary (continued)

- **Fomites:** Nonliving objects contaminated with microorganisms that can spread the microorganisms to other persons.
- **Gastroenteritis:** inflammation of the stomach and the intestines, with vomiting and diarrhea, usually as a result of bacterial or viral infection.
- **Live vaccine:** A vaccine in which live antigen is weakened (attenuated) through chemical or physical processes to produce an immune response without causing the severe effects of the disease. Also known as an “attenuated vaccine.”
- **Immunocompromised:** A condition in which the immune system is unable to protect the body from disease. This condition can be caused by disease (like HIV infection or cancer) or by certain drugs (like those used in chemotherapy). Individuals whose immune systems are compromised should not receive live, attenuated vaccines.

Glossary (continued)

- **Incubation period:** The length of time between entry of an infectious agent into the body and the beginning of disease symptoms.
- **Informed consent:** Process by which a patient or parent makes a voluntary decision about a procedure or intervention after being fully informed by a health care provider about the risks and benefits of the procedure or intervention; some states have informed consent laws for vaccination.
- **Intussusception:** A type of bowel blockage that happens when one portion of the bowel slides into the next, much like the pieces of a telescope; it is treated in a hospital and may require surgery.
- **Isotonic diarrhea:** passage of three or more loose or liquid stools per day in which net loss of sodium and water are in the same proportion as is normally found in extracellular fluid.

Glossary (continued)

- **Precaution:** A condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity.
- **Reservoir:** Habitat in which an infectious agent normally lives, grows, and multiplies; reservoirs include humans, animals, and the environment.
- **Severe combined immune deficiency (SCID):** Included in a group of rare, life-threatening disorders caused by at least 15 different single gene defects that result in profound deficiencies in T- and B-lymphocyte function.

Glossary (continued)

- **Standing orders:** Orders that authorize nurses, pharmacists, and other appropriately trained healthcare personnel, where allowed by state law, to assess a patient's immunization status and administer vaccinations according to a protocol approved by a medical director in a healthcare setting, a physician, or another authorized practitioner.
- **Supportive treatment:** Treatment provided to keep a person comfortable.
- **Temporal pattern:** Occurrence of health-related events by time.

Glossary (continued)

- **Thimerosal:** A mercury-containing preservative that has been used in some vaccines and other products since the 1930s. There is no evidence that the low concentrations of thimerosal in vaccines have caused any harm other than minor reactions such as redness or swelling at the injection site. However, in July 1999, the US Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated from vaccines as a precautionary measure. Today all routinely recommended childhood vaccines manufactured for the US market (except some influenza vaccines) contain either no thimerosal or only trace amounts.

Glossary (continued)

- **Vaccine Adverse Event Reporting System (VAERS):** A national vaccine safety surveillance program run by the Centers for Disease Control and Prevention and the Food and Drug Administration. VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collection information about adverse events that occur after vaccination.
- **Vaccine information statement (VIS):** A document produced by CDC that informs vaccine recipients or their parents or legal representatives about the benefits and risks of a vaccine being administered. All public and private vaccine providers are required by the National Vaccine Childhood Injury Act to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines.