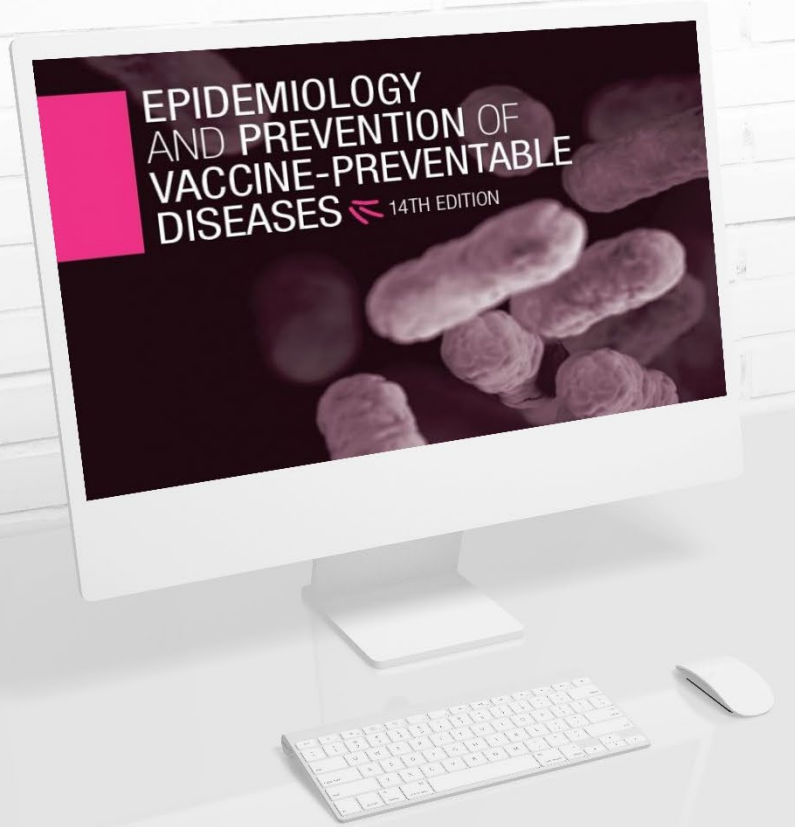
National Center for Immunization and Respiratory Diseases

Rotavirus Vaccines



Pink Book Web-on-Demand Series

Eva Meekins, DNP, MHA, MN, RN
Nurse Educator
Immunization Service Division

Learning Objectives

- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

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- To claim continuing education (CE) for this course, please follow the steps below by July 1, 2026.
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- Pass the post-assessment at 80%.
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https://www.train.org/cdctrain/welcome

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- **In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies during the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.**
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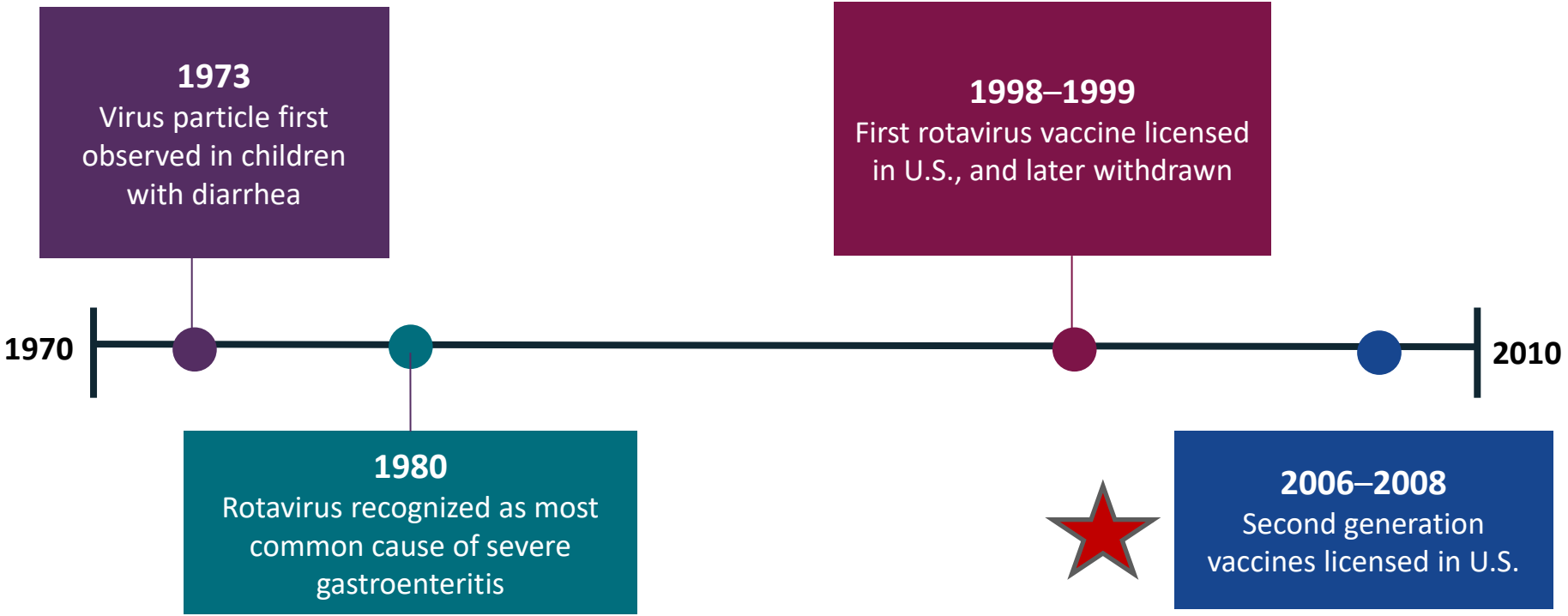
- **CDC did not accept financial or in-kind support from any ineligible company for this continuing education activity.**
- **The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.**

1

Rotavirus Disease

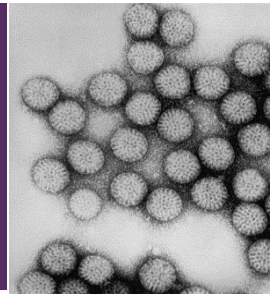
Rotavirus



Pinkbook: Rotavirus | CDC

Rotavirus

1973
Virus particle first observed in children with diarrhea



A specific infectious cause was detected in less than 30% of cases before 1970s.

1970 — 2010

1980
Rotavirus recognized as most common cause of severe gastroenteritis

2006–2008
Second generation vaccines licensed in the US

https://www.cdc.gov/vaccines/pubs/pinkbook/rota.html#rotavirus

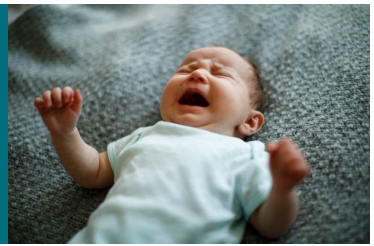
Rotavirus

1973
Virus particle first observed in children with diarrhea

Prevaccination Era:
- **95% of U.S. children infected before their 5th birthday**
- **Estimated 2.7 million cases per year worldwide**
- **500,000 pediatric deaths per year worldwide**

1970 — 2010

1980
Rotavirus recognized as most common cause of severe gastroenteritis



2006–2008
Second generation vaccines licensed in US

https://www.cdc.gov/vaccines/pubs/pinkbook/rota.html#rotavirus

Rotavirus

1973
Virus particle first observed in children with diarrhea

1998–1999
First rotavirus vaccine licensed in U.S., and later withdrawn

1970 — 2010

1980
Rotavirus recognized as most common cause of severe gastroenteritis

Why withdrawn?

- **Intussusception seen in 1 out of 10,000 cases**

https://www.cdc.gov/vaccines/pubs/pinkbook/rota.html#rotavirus

Rotavirus

1973
Virus particle first observed in children with diarrhea

1980
Rotavirus recognized as most common cause of severe gastroenteritis

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2006–2008
Second generation vaccines licensed in U.S.

1970

2010

https://www.cdc.gov/vaccines/pubs/pinkbook/rota.html#rotavirus

Annual Rotavirus Disease Burden in the United States: Prevaccination Era

Approximately 410,000 provider visits

205,000–272,000 emergency department visits

55,000–70,000 hospitalizations

Approximately 20–60 deaths per year among children less than 5 years of age

Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Rotavirus Disease in the United States: Burden Averted After Rotavirus Vaccine - 2006

280,000 clinic visits

62,000 emergency department visits

45,000 hospitalizations

Pinkbook: Rotavirus | CDC

Estimated Rotavirus Vaccination Coverage Among Children Born in 2019 and 2020 — National Immunization Survey, United States

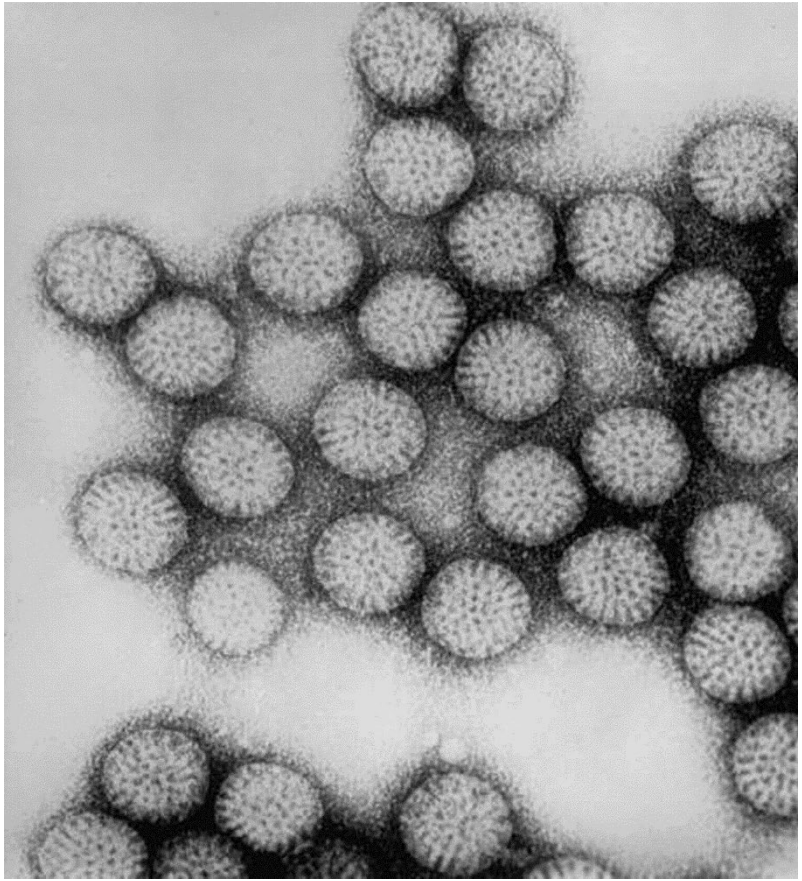
Vaccine/Dose	2019–2020
Rotavirus (by age 8 months)*	76.6%

* Includes ≥2 doses of Rotarix monovalent rotavirus vaccine or ≥3 doses of RotaTeq pentavalent rotavirus vaccine; if any dose in the series is either RotaTeq or unknown, the default is to a 3-dose series. The maximum age for the final rotavirus dose is 8 months, 0 days.

Vaccination Coverage by Age 24 Months Among Children Born in 2019 and 2020 — National Immunization Survey-Child, United States, 2020–2022 | MMWR (cdc.gov)

Rotavirus

- Named for its wheel appearance
- Double-stranded RNA virus
- Highly communicable
- Very stable and can remain viable for weeks or months if not disinfected



Pinkbook: Rotavirus | CDC

Most common in infants and young children

Fecal-Oral Transmission

- Person-to-person contact
- Fomites (via toys, etc.)
- Stable on surfaces
- Viable for weeks or months
- Replicates in epithelium of small intestine

Pinkbook: Rotavirus | CDC

Rotavirus Clinical Features

- **Most common symptoms**:
  - Watery diarrhea
  - Vomiting
  - Abdominal pain
  - Fever (33%)
- **Incubation period less than 48 hours**
- **GI symptoms resolve in 3–7 days**

First infection after 3 months of age is generally the most severe – ***Why?***

Pinkbook: Rotavirus | CDC

Rotavirus Complications

- **Severe diarrhea**
- **Dehydration**
- **Electrolyte imbalance**
- **Metabolic acidosis**
- **Prolonged gastroenteritis in immunocompromised children**
  - Possible multiple organ involvement, including kidneys and liver

Pinkbook: Rotavirus | CDC

2

Rotavirus Vaccines

Rotavirus Vaccines

- Live, attenuated vaccines
- For oral use only, not for injection
- Administer orally by putting drops in the infant's mouth

Package Insert- RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

Rotavirus Vaccines

Vaccine Products	Age Indications (Package Insert)	Age Indications (ACIP Differs)
Rotarix (RV1)	6–24 weeks of age	6 weeks–8 months, 0 days of age
RotaTeq (RV5)	6–32 weeks of age	6 weeks–8 months, 0 days of age

Do *not* administer to infants older than 8 months, 0 days.

Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)
Package Insert - RotaTeq (fda.gov)
Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

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Package Insert - RotaTeq (fda.gov)

Rotavirus Vaccines

RV1 and RV5

- No adjuvants
- No antibiotics
- No preservatives
- No thimerosal

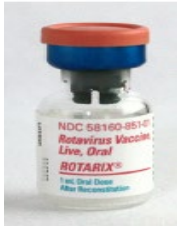
RV1

- Latex rubber in oral applicator

Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)
Package Insert - RotaTeq (fda.gov)
Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Vaccine Preparation

- **RV1 (Rotarix): Must be reconstituted before administering**
  - Discard within 24 hours of reconstituting



Lyophilized RV1 component

+

Manufacturer's sterile water-calcium carbonate-xanthan diluent

=

Rotarix vaccine

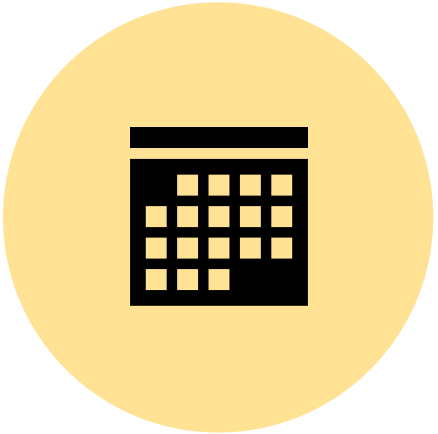
- **RV1 – liquid formulation**
- **RV5 (RotaTeq): Manufacturer-filled oral dosing tube**
  - No additional preparation required

Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)
Package Insert - RotaTeq (fda.gov)
Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Rotavirus Vaccine Administration

Administered orally

G-tube administration acceptable



Can be simultaneously administered

Rotavirus Vaccine Administration

Administered orally

G-tube administration acceptable

Can be simultaneously administered

Administering the Rotavirus Vaccine | CDC
New Liquid Formulation ROTARIX Licensure FAQ | CDC
Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

Rotavirus Vaccine Administration

Administered orally

G-tube administration acceptable

May flush G-tube after vaccine

[Administering the Rotavirus Vaccine | CDC]
[New Liquid Formulation ROTARIX Licensure FAQ | CDC]
[Package Insert - RotaTeq (fda.gov)]
[Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)]

Rotavirus Vaccine Administration

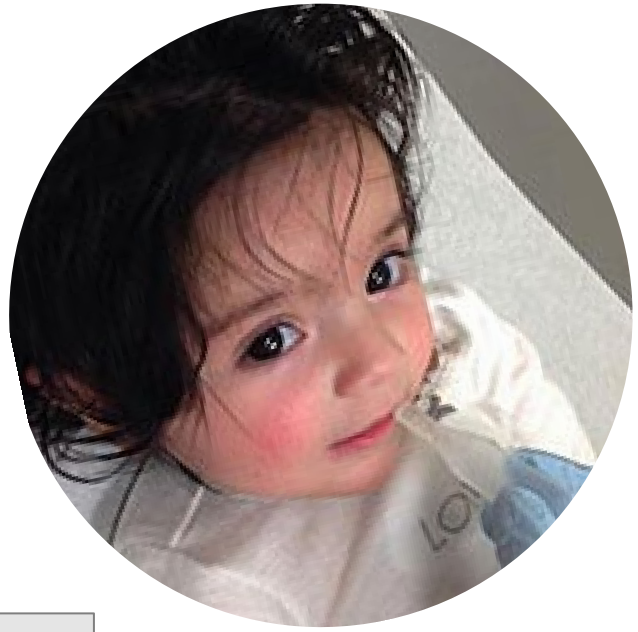
With or at any interval before or after non-live or live injectable vaccines.

Can be given on the same visit as other vaccine

ACIP General Best Practice Guidelines for Immunization | CDC
Administering the Rotavirus Vaccine | CDC
New Liquid Formulation ROTARIX Licensure FAQ | CDC
Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

According to the Package Insert

- **Do not repeat the dose if the infant spits out or regurgitates the vaccine**
- **So, what should you do?**
  - Administer remaining doses as scheduled
  - Maintain a minimum interval of 4 weeks



Clinical trials did not explore the safety or efficacy of administering more than one dose or of administering partial doses close together.

Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

Rotavirus Vaccine Efficacy

74%–87%	85%–98%	93%–95%
Any rotavirus gastroenteritis	Severe gastroenteritis	ED visits, hospitalizations

Pinkbook: Rotavirus | CDC

Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Rotavirus Vaccine Efficacy

74%–87%	85%–98%	93%–95%
Any rotavirus gastroenteritis	Severe gastroenteritis	Physician visits, hospitalizations

Pinkbook: Rotavirus | CDC

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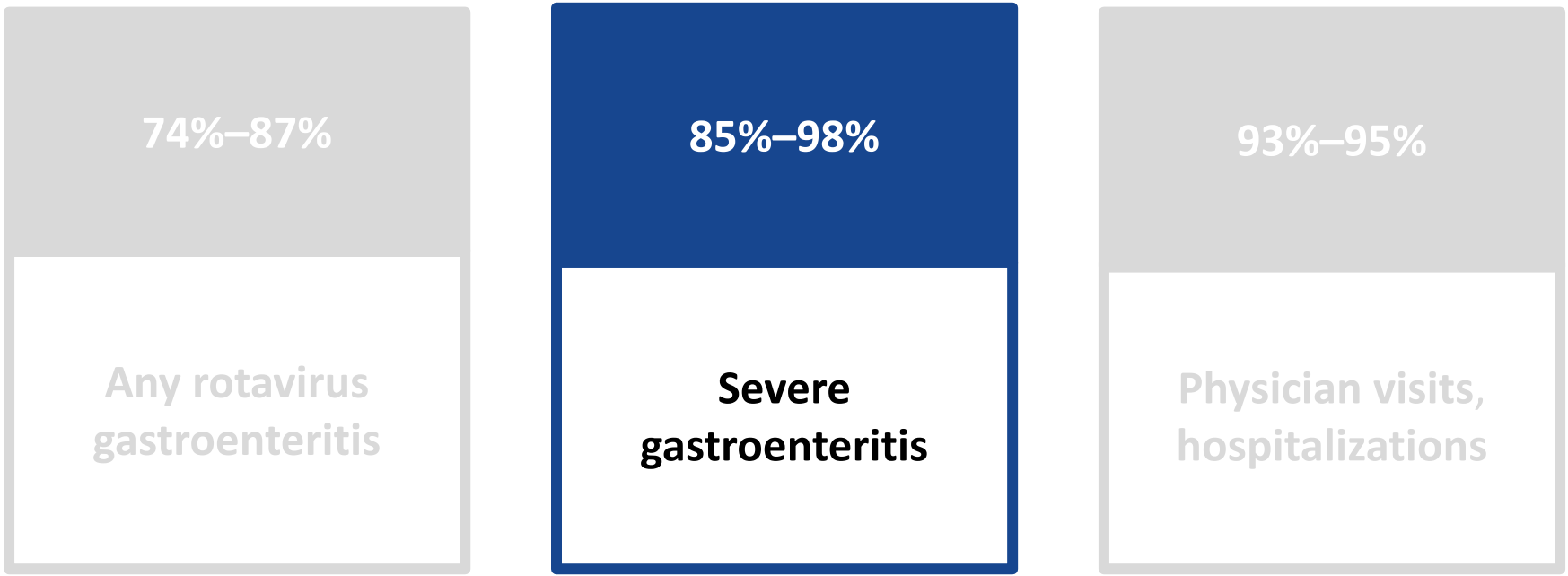
Rotavirus Vaccine Efficacy



Pinkbook: Rotavirus | CDC

Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Rotavirus Vaccine Efficacy

Pinkbook: Rotavirus | CDC

Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

3

Rotavirus Vaccination and Clinical Considerations

Rotavirus Routine Vaccination Recommendations Child and Adolescent Immunization Schedule

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024

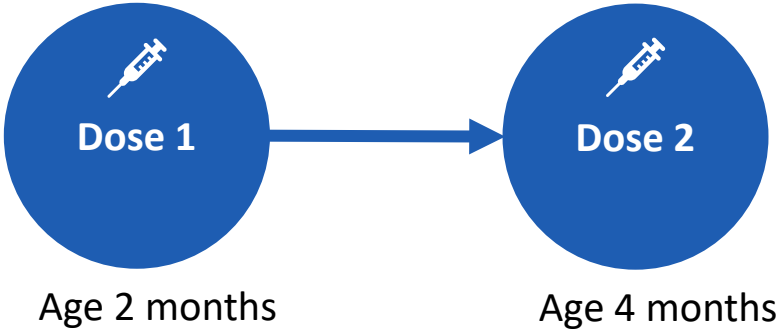
These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Recommended Immunization Schedule 0-18yrs-child-combined-schedule.pdf (cdc.gov)

Rotavirus Vaccination Schedule

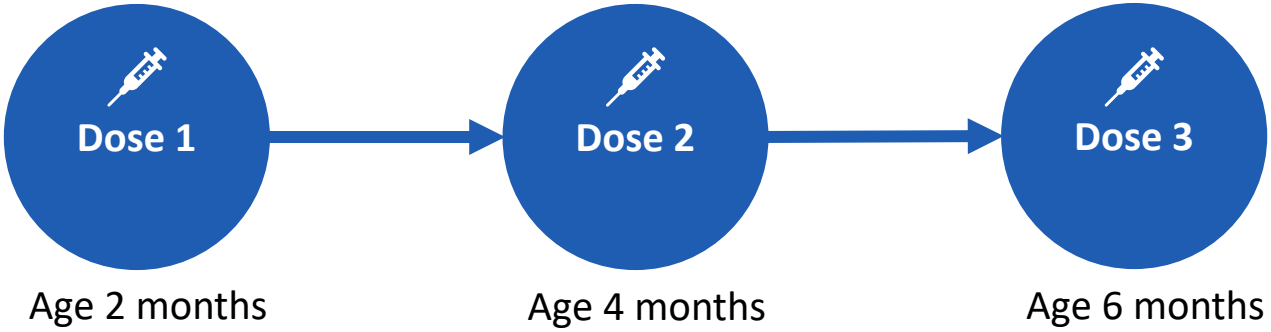
RV1 (Rotarix)

2-dose series at ages
2 and 4 months



RV5 (RotaTeq)

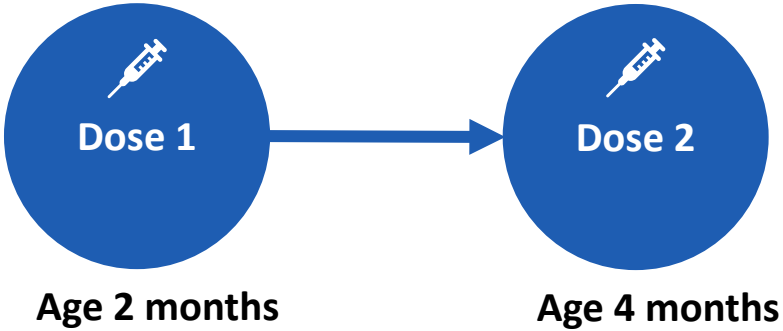
3-dose series at ages
2, 4, and 6 months



Rotavirus Vaccination Schedule

RV1 (Rotarix)

2-dose series at ages
2 and 4 months



RV5 (RotaTeq)

3-dose series at ages
2, 4, and 6 months

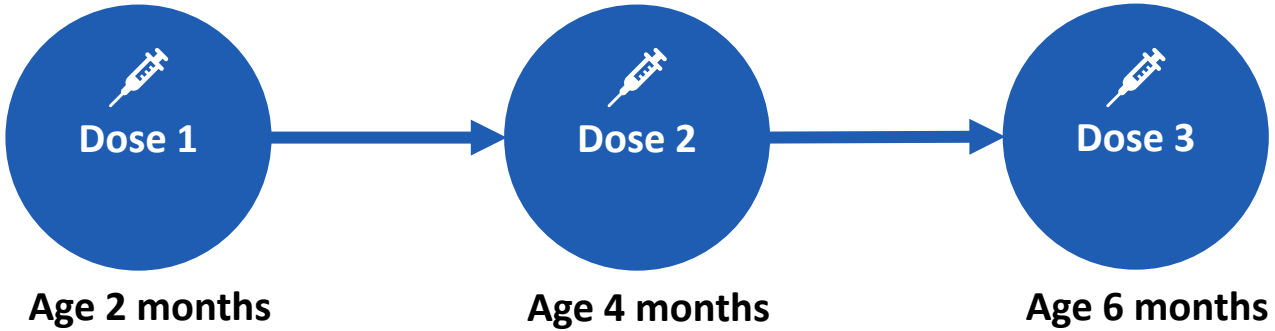
Rotavirus Vaccination Schedule

RV1 (Rotarix)

2-dose series at ages
2 and 4 months

RV5 (RotaTeq)

3-dose series at ages
2, 4, and 6 months



Rotavirus Vaccination Schedule

Minimum age	Maximum age, dose 1	Maximum age for any dose	Minimum interval	Maximum interval
6 weeks	14 weeks, 6 days†	8 months, 0 days*	4 weeks	None

†ACIP off-label recommendation for both vaccine products because the labeled first dose maximum is 14 weeks 6 days, but the FDA package insert is silent on a first dose maximum.

*ACIP off-label recommendation for both vaccine products because the labeled maximum age for RV1 is 24 weeks, and the labeled maximum age for RV5 is 32 weeks

Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

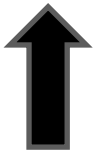
Rotavirus Vaccination Schedule

Minimum age		Minimum interval	Maximum interval
6 weeks	• **Do not start before**	4 weeks	None

Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

Rotavirus Vaccination Schedule

Minimum age	Maximum age, dose 1
6 weeks	14 weeks, 6 days [†]



- **Dose 1 should *not* be initiated *after* this age.**

[†]ACIP off-label recommendation for both vaccine products because the labeled first dose maximum is 14 weeks 6 days, but the FDA package insert does not include a first dose maximum

Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

Rotavirus Vaccination Schedule

Minimum age	Maximum age, dose 1	Maximum age for any dose
6 weeks	14 weeks, 6 days†	**8 months, 0 days***

Do not administer rotavirus vaccine to infants older than 8 months, 0 days of age.

*ACIP off-label recommendation for both vaccine products because the labeled maximum age for RV1 is 24 weeks, and the labeled maximum age for RV5 is 32 weeks

Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

Rotavirus Vaccination Schedule

What If…
Administered 5 or more days earlier than the minimum interval?

- **Do not count dose**
- **Repeat the dose**

Minimum interval	Maximum interval
4 weeks	None

[Birth-18 Years Immunization Schedule – Healthcare Providers | CDC]

Rotavirus Vaccination Schedule

What If…
Interval is prolonged?

- **Infant can still receive the vaccine, but vaccine must be given *before* infant is 8 months, 0 days of age.**
- ***Do not* restart series or add doses**

Maximum interval

None

Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

Rotavirus Vaccine Interchangeability

ACIP Recommendation:

- **Complete series with same vaccine product whenever possible**
  - If product used for prior dose(s) is not available or not known, continue or complete the series with available product
  - If any dose in the series was RV5 or an unknown product, follow a 3-dose schedule.

Ask the Experts (immunize.org)

Rotavirus Vaccination and Preterm Infants

- **ACIP supports vaccination of a preterm infant if:**
  - Chronological age is at least 6 weeks
  - Clinically stable
  - Vaccine is administered at or after discharge from nursery or neonatal intensive care unit

ACIP Vaccine Information Sources Guidelines for Immunization | CDC

Rotavirus Vaccination and History of Rotavirus Gastroenteritis

ACIP Recommendation:

- **Infants with previous infection *should* start or complete the schedule according to the age and interval recommendations.**
  - Previous infection might provide only partial protection against subsequent rotavirus disease.

Pinkbook: Rotavirus | CDC

Knowledge Check

What type of vaccine is rotavirus vaccine?

A. Inactivated whole-virus vaccine

B. Live, attenuated vaccine

C. Inactivated subunit vaccine

D. Live, bacterial vaccine

Answer

What type of vaccine is rotavirus vaccine?

A. Inactivated whole-virus vaccine

B. Live, attenuated vaccine

C. Inactivated subunit vaccine

D. Live, bacterial vaccine

4

Safety

Rotavirus Vaccine Contraindications

- **Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or following a prior dose of vaccine**
  - Latex ***is*** present in the RV1 oral applicator
    - Infants with spina bifida or bladder exstrophy at high risk for acquiring latex allergy
    - RV5 is latex-free and preferred for infants with a severe allergy to latex
- **History of intussusception**
- **Severe combined immunodeficiency (SCID)**

ACIP Contraindications Guidelines for Immunization | CDC
Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)
Pinkbook: Rotavirus | CDC

Rotavirus Vaccine Precautions

- **Moderate or severe illness**
  - May vaccinate if 1st dose delayed beyond 14 weeks and 6 days of age
- **Altered immunocompetence**
  - Except SCID, a contraindication
  - Limited data on HIV infection
- **Acute, moderate, or severe gastroenteritis**
- **Chronic gastrointestinal disease – data lacking**

ACIP Contraindications Guidelines for Immunization | CDC
Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)
Pinkbook: Rotavirus | CDC

Conditions Incorrectly Perceived as Rotavirus Vaccination Contraindications or Precautions

- **Prematurity**
- **Immunosuppressed household contacts**
- **Pregnant household contacts**

ACIP Contraindications Guidelines for Immunization | CDC

Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)</FONT> (cdc.gov)

Rotavirus Vaccine Adverse Events

RV5

• Diarrhea	18.1%
• Vomiting	11.6%
• Otitis media, nasopharyngitis, and bronchospasm	Greater rates

RV1

• Irritability	11.4%
• Flatulence	2.2%

Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

Rotavirus Vaccine Adverse Reactions

- **Intussusception**
  - Risk during first week following 1st or 2nd dose
  - May extend to 21 days
  - Estimated 1 case per 20,000 to 100,000 vaccinated infants

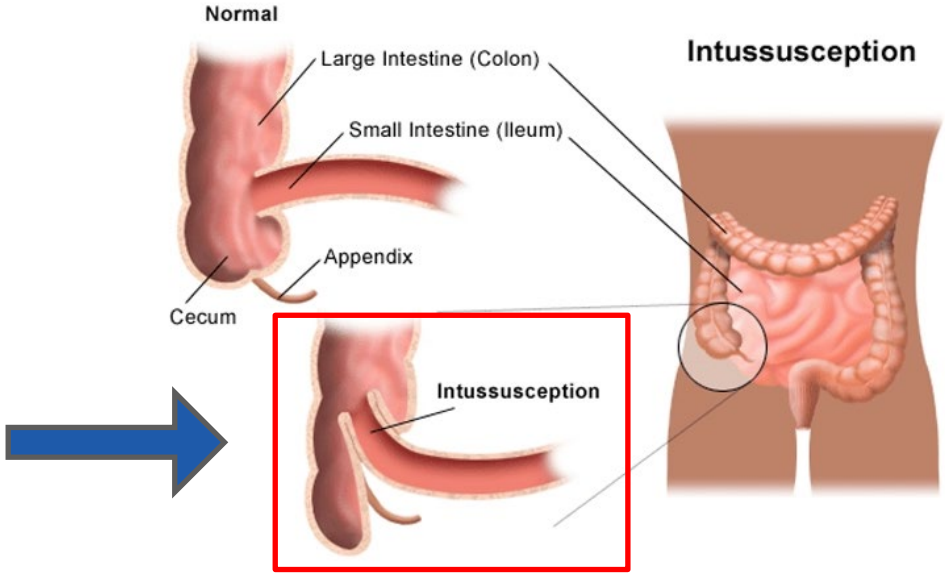


Image Source: Intussusception | Children's Hospital of Philadelphia (chop.edu)

Pinkbook: Rotavirus | CDC

Safety Information for Rotavirus Vaccines | CDC

Vaccine Administration Errors

Error
Dose injected

- Dose ***does not count***
- Repeat
  - After min interval
  - Before max age

Error
1st dose given after 14 weeks, 6 days

- Dose **counts**
- Continue series with recommended intervals

Error
Any dose given after 8 months, 0 days

- Dose **counts**
- Give no more doses

Ask The Experts: Rotavirus | Immunize.org
Administering the Rotavirus Vaccine | CDC

Vaccine Administration Errors

Error
Dose injected

- Dose ***does not count***
- Repeat
  - After min interval
  - Before max age

What If…

- **Vaccine inadvertently administered as an injection**
  - An oral dose should be administered after the invalid dose.

- Continue series with recommended intervals

- No more doses should be given

Ask The Experts: Rotavirus | Immunize.org
Administering the Rotavirus Vaccine | CDC
mm6304.pdf (cdc.gov)

Vaccine Administration Errors

Error:
Dose Injected

- Dose ***does not count***
- Repeat
  - After min interval
  - Before max age

Error
1st dose given after 14 weeks, 6 days

- Dose ***counts***
- Continue series with recommended intervals

What If…

- **Beyond age of 1st dose recommendation?**

- Dose counts
- No more doses should be given

Ask The Experts: Rotavirus | Immunize.org
Administering the Rotavirus Vaccine | CDC

Vaccine Administration Errors

What If…

- **Beyond maximum age for any dose?**

- Dose does NOT count
- Repeat after min interval or before max age

- Dose counts
- Continue series with recommended intervals

Error

Any dose given after 8 months, 0 days

- Dose **counts**
- Give no more doses

Ask The Experts: Rotavirus | Immunize.org

Administering the Rotavirus Vaccine | CDC

Knowledge Check

A child who is 16 weeks of age and has never received a dose of rotavirus vaccine should begin catch-up vaccination.

A. True

B. False

Answer

A child who is 16 weeks of age and has never received a dose of rotavirus vaccine should begin catch-up vaccination.

A. True

B. False

5

Storage and Handling

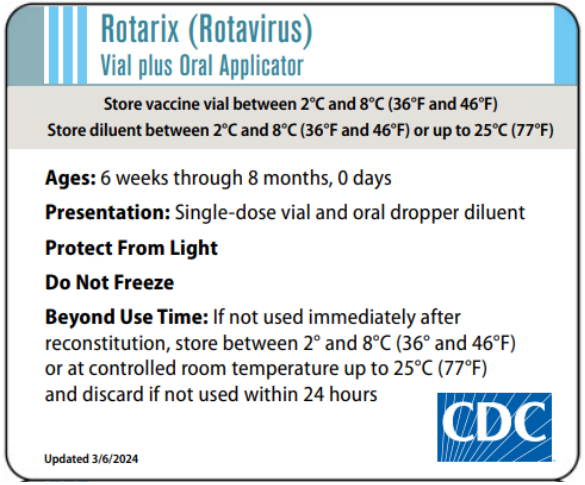
Rotavirus Vaccine Storage and Handling

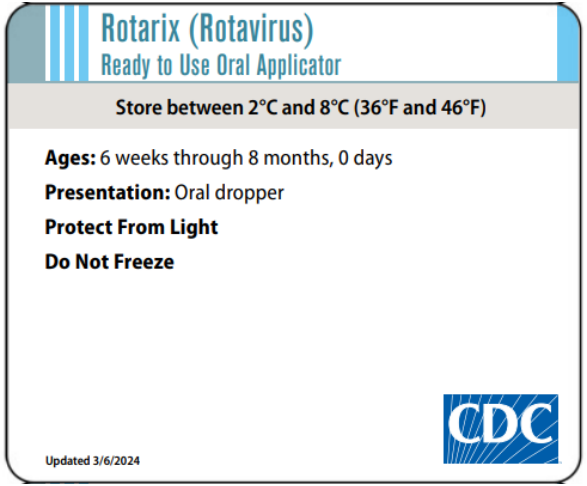
Vaccines	Vaccine Storage Temperature	Diluent Storage Temperature
RV1 vaccine (Rotarix)	2°C to 8°C (36°F to 46°F) • Do not freeze • Protect from light	2°C to 8°C (36°F to 46°F) or at a controlled room temperature up to 25°C (77°F). • Do not freeze. • Discard if the diluent has been frozen.
RV5 vaccine (RotaTeq)	2°C to 8°C (36°F to 46°F) • Do not freeze • Protect from light	No diluent

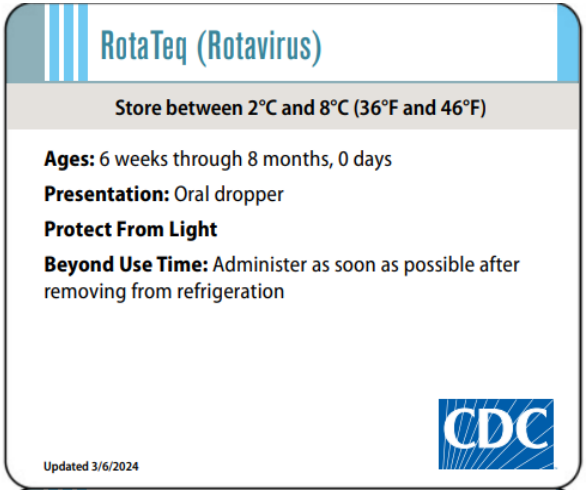
- **Store in the original packaging with the lids closed in a clearly labeled bin or area of the storage unit.**

ACIP Storage and Handling Guidelines for Immunization | CDC
Package Insert - RotaTeq (fda.gov)
Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) - ROTARIX (fda.gov)

Storage and Handling Practices: Using Storage Labels







Vaccine Labels: Storage and Beyond-Use Date Tracking (cdc.gov)

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Rotavirus Resources

Rotavirus Resources

About Rotavirus | Rotavirus | CDC

https://www.cdc.gov/rotavirus/about/index.html

ACIP Rotavirus Vaccine Recommendations | CDC

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rotavirus.html

Ask The Experts: Rotavirus | Immunize.org

https://www.immunize.org/ask-experts/topic/rotavirus/

Clinical Overview of Rotavirus | Rotavirus | CDC

https://www.cdc.gov/rotavirus/hcp/clinical-overview/index.html

Rotavirus Resources

Safety Information for Rotavirus Vaccines | CDC

https://www.cdc.gov/vaccinesafety/vaccines/rotavirus-vaccine.html

Standing Orders for Administering Rotavirus Vaccine to Infants (Immunize.org)

https://www.immunize.org/wp-content/uploads/catg.d/p3087.pdf

Rotavirus: What You Should Know | Vaccine Education Center (chop.edu)

https://media.chop.edu/data/files/pdfs/vaccine-education-center-rotavirus.pdf

CDC Clinical Resources

- www.cdc.gov/vaccines/
  - Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations and Guidelines
  - Recommended Immunization Schedules
  - Vaccine Storage and Handling Toolkit
  - Vaccine Information Statements

Pink Book Training Materials

Continuing Education Information

- To claim continuing education (CE) for this course, please follow the steps below by July 1, 2026.
- Search and register for course **WD4810-073024** in **CDC TRAIN**.
- Pass the post-assessment at 80%.
- Complete the evaluation.
- Visit “Your Learning” to access your certificates and transcript.
- If you have any questions, contact **CDC TRAIN** at train@cdc.gov or CE Coordinator, Melissa Barnett, at MBarnett2@cdc.gov

https://www.train.org/cdctrain/welcome

Email Us Your Immunization Questions:

nipinfo@cdc.gov

Thank You From Atlanta!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.