

Rotavirus and Hepatitis A Vaccines

Pink Book Web-on-Demand Series

August 16, 2022

Elisha Hall, PhD, RD

Health Education Specialist

NCIRD, CDC

Learning Objectives

- Describe the Advisory Committee on Immunization Practices General Best Practice Guidelines on Immunization.
- 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.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: WD4564-081622
- CE credit expires: July 1, 2024
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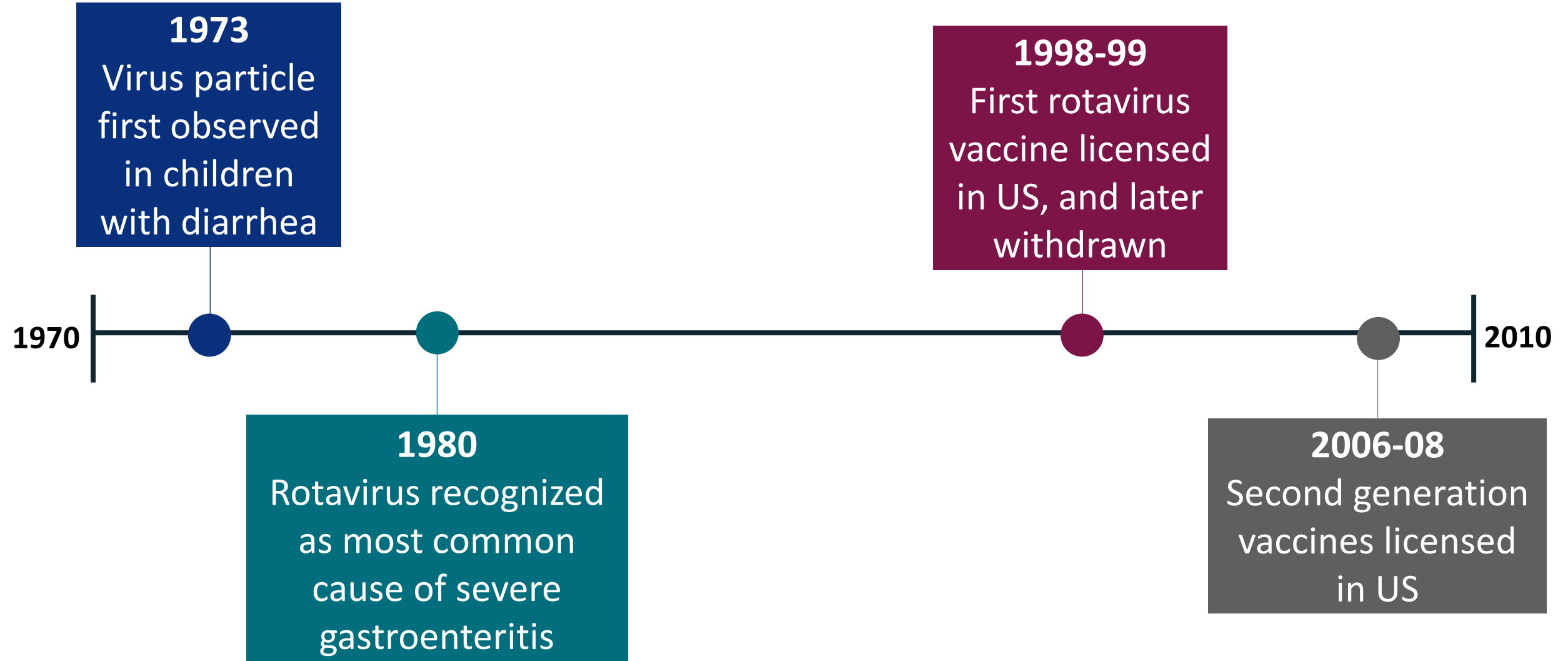
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Rotavirus Disease

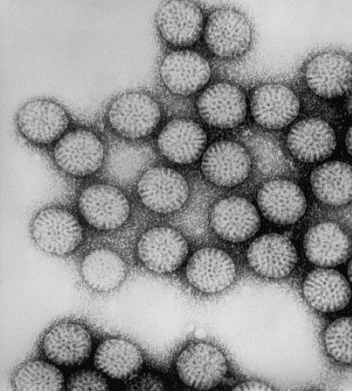
Rotavirus



Rotavirus

1973

Virus particle
first observed
in children
with diarrhea



1998-99

First rotavirus
vaccine licensed
in US, and later
withdrawn

1980

Rotavirus recognized
as most common
cause of severe
gastroenteritis

2006-08

Second generation
vaccines licensed
in US



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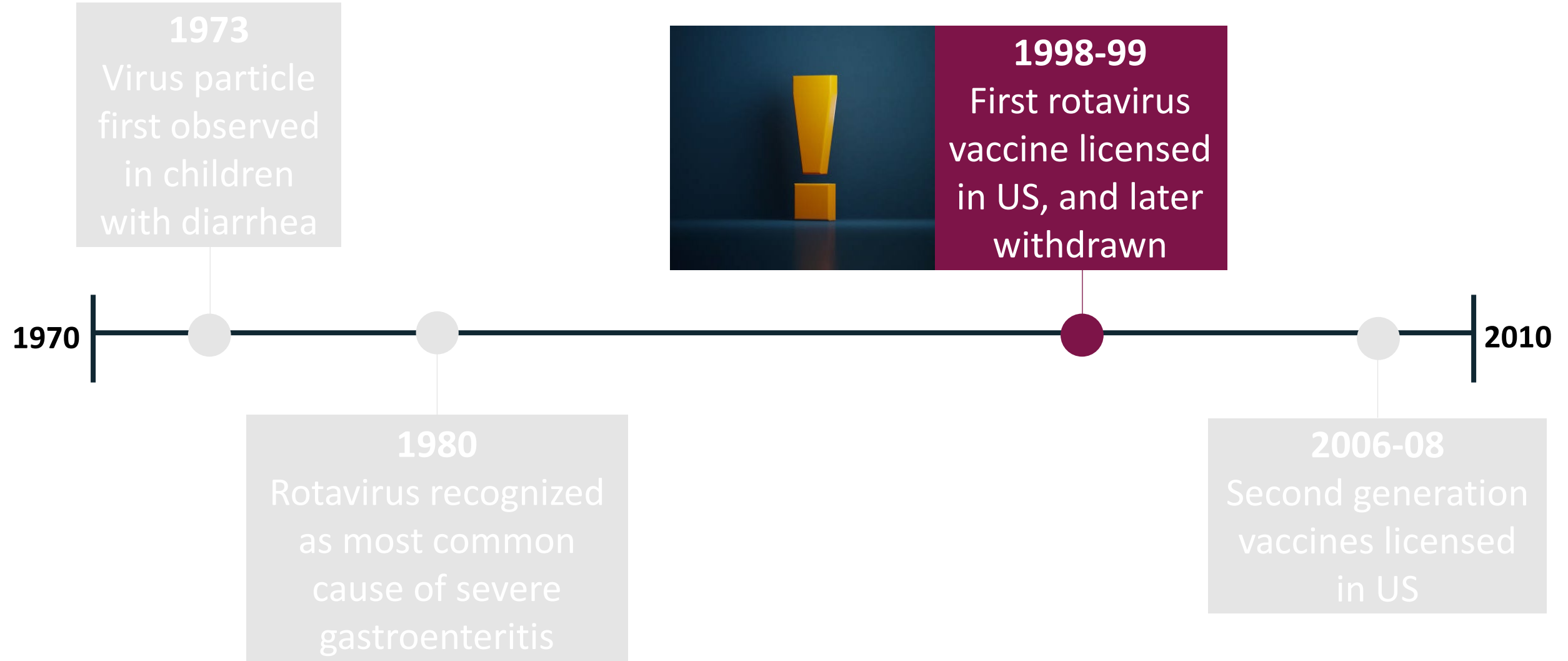
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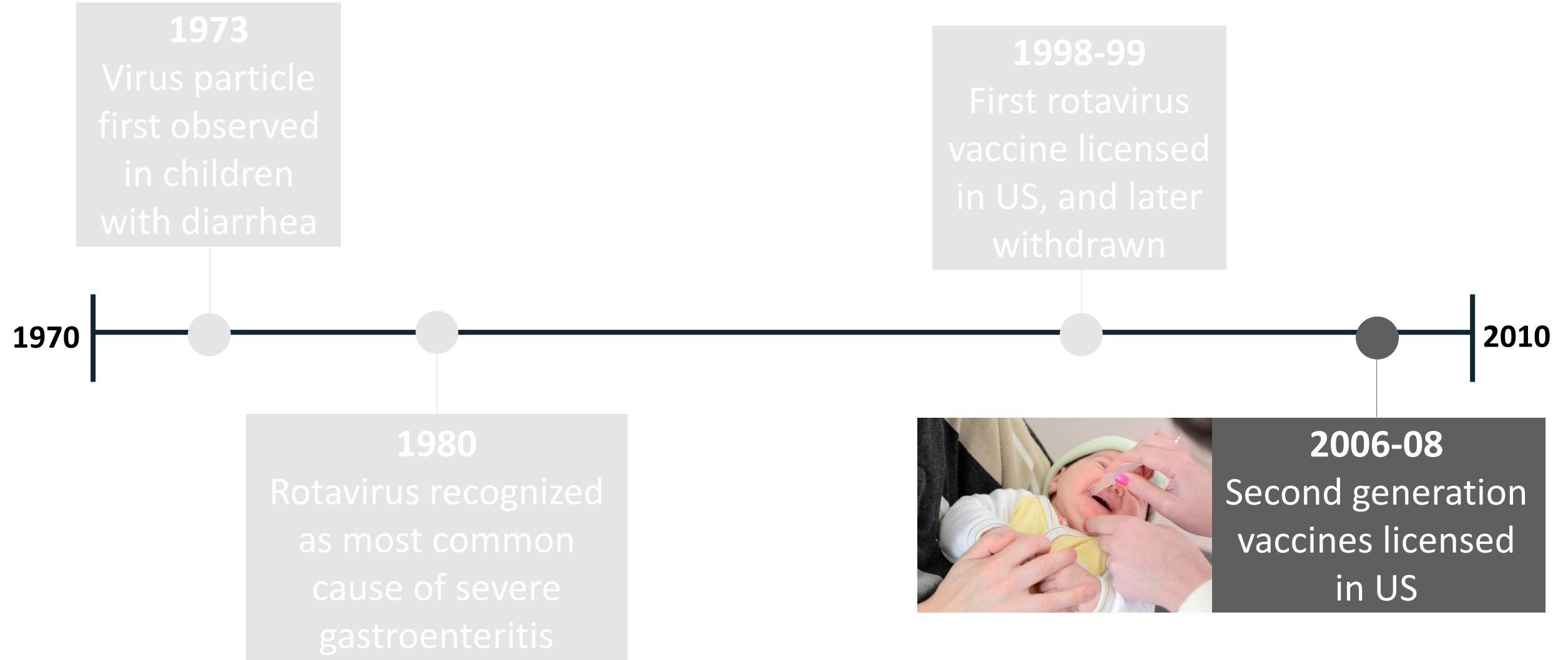
2010

1970

Rotavirus

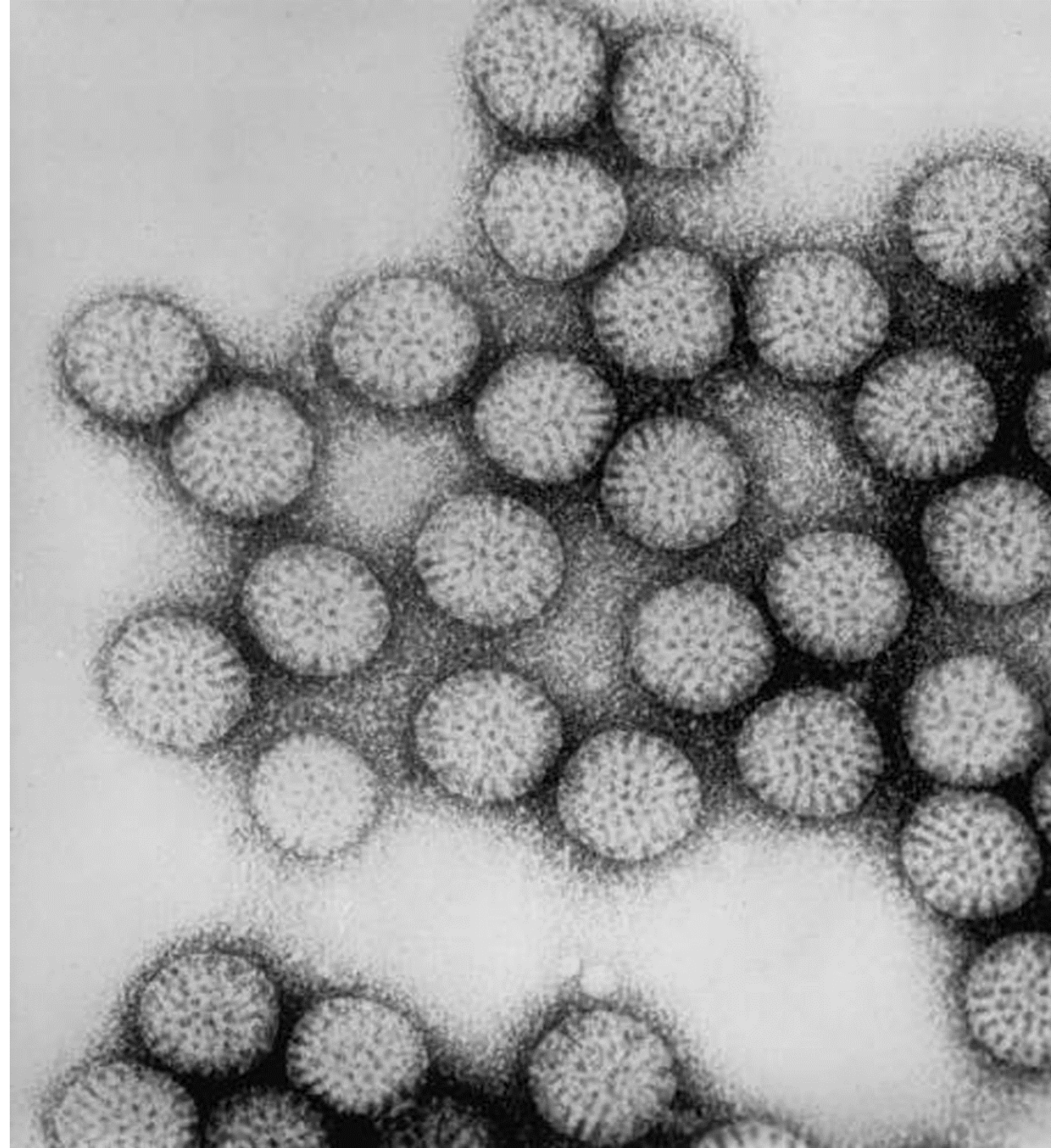


Rotavirus



Rotavirus

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



Rotavirus Transmission and Pathogenesis



**Transmitted by
fecal-oral route**



**Enters through
mouth;
replicates in
small intestine**



**Correlates of
protection
poorly
understood**



**Reinfection can
occur at any age**

Rotavirus Transmission and Pathogenesis



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Correlates of
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**Reinfection can
occur at any age**

Rotavirus Clinical Features

- Disease most common in children
- Short incubation period
- First infection after 3 months of age generally most severe



Rotavirus Clinical Features

- **Most common symptoms:**
 - Watery diarrhea
 - Vomiting
 - Fever
 - Abdominal pain
- **Gastrointestinal symptoms generally resolve in 3-7 days**



Rotavirus Complications

- Infection can lead to severe diarrhea, dehydration, electrolyte imbalance, and metabolic acidosis
- Children who are immunocompromised may experience severe prolonged gastroenteritis

Rotavirus Disease Burden in the United States:

Prevaccine Era



2.7 million
infections



>400,000
physician visits



55,000–70,000
hospitalizations

20–60 deaths

Rotavirus Disease in the United States: Burden Averted After Vaccine Introduction



280,000
clinic visits



62,000
emergency
department visits



45,000
hospitalizations

2

**Rotavirus
Vaccines**

Rotavirus Vaccines

- Live vaccines
- Administered orally



Rotavirus Vaccines

Vaccine product	Age indications (package insert)	Age indications (ACIP)
RotaTeq (RV5)	6–32 weeks of age	6 weeks–8 months, 0 days of age
Rotarix (RV1)	6–24 weeks of age	6 weeks–8 months, 0 days of age

Rotavirus Vaccines

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Rotavirus Vaccine Efficacy

74%-87%

**Any rotavirus
gastroenteritis**

85%-98%

**Severe
gastroenteritis**

Significant ↓

**Physician visits
Hospitalizations**

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3

Rotavirus Clinical Considerations

Rotavirus Vaccination Schedule

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1 st dose	2 nd dose	See Notes		

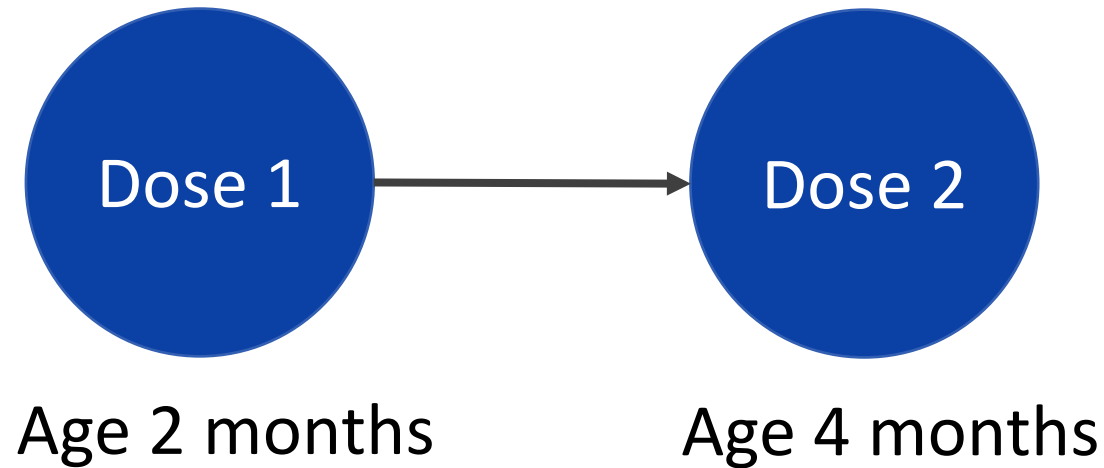
Notes: <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-rotavirus>

*ACIP off-label recommendation for both vaccines because the labeled maximum age for the first dose of RV5 is 12 weeks

Rotavirus Vaccination Schedule

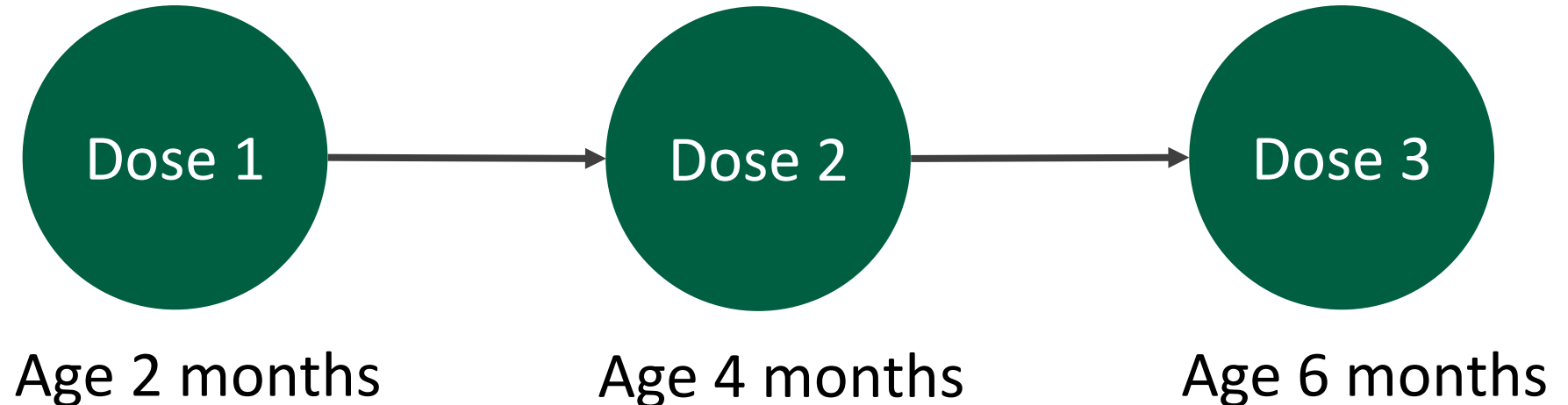
RV1 (Rotarix):

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
6 weeks

Maximum
age, dose 1
14 weeks, 6
days*

Maximum
age for any
dose
8 months, 0
days

Minimum
interval
4 weeks

Maximum
interval
None

*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

Rotavirus Vaccination Schedule

Minimum
age
6 weeks

Maximum
age, dose 1
14 weeks, 6
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Maximum
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Minimum
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Maximum
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Rotavirus Vaccine Recommendations

- **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 available product**
- **If any dose in the series was RV5 or the vaccine brand is not known, a 3-dose schedule should be followed.**

Rotavirus Vaccine Recommendations

- Few safety or efficacy data on doses close together
- ACIP recommends that providers do not repeat the dose if the infant spits out or regurgitates the vaccine
- Administer remaining doses on schedule

Rotavirus Vaccine and Preterm Infants

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

Rotavirus Vaccine Administration

■ Preparation:

- RV5 (RotaTeq): None
- RV1 (Rotarix): Must be reconstituted BEFORE administering

■ Route/Site: Administer ***ORALLY (PO)***

- The infant may eat or drink immediately following vaccine administration
- May administer via gastrostomy tube

■ May be administered during the same clinical visit as other vaccines

Vaccine Administration Errors



Route: Injected

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



**1st dose given
after 14 weeks,
6 days**

- Dose counts
- Continue series with recommended intervals



**Any dose given
after 8 months,
0 days**

- Dose counts
- No more doses should be given

Vaccine Administration Errors



Route: Injected

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



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4

Safety

Rotavirus Vaccine Contraindications

Rotavirus

Severe allergic reaction to a vaccine component (including latex) or following a prior dose of vaccine. RV1 (Rotarix) oral applicator contains latex rubber.

History of intussusception

Severe combined immunodeficiency (SCID)

Rotavirus Vaccine Precautions

Rotavirus

Moderate or severe illness

Altered immunocompetence (except SCID, which is a contraindication)

- Limited data do not indicate a different safety profile in HIV-infected versus HIV-uninfected infants

Chronic gastrointestinal disease

Conditions Incorrectly Perceived as Contraindications or Precautions

Rotavirus

Prematurity

Immunosuppressed household contacts

Pregnant household contacts

Rotavirus Vaccine Adverse Events

Adverse Reaction	
RV5	
Diarrhea	18.1%
Vomiting	11.6%
Otitis media, nasopharyngitis, and bronchospasm	Greater rates
RV1	
Irritability	11.4%
Flatulence	2.2%

Rotavirus Vaccine Adverse Events

■ Intussusception

- No increased risk observed during clinical trials of RV1 and RV5
- Post-licensure evaluation in some countries identified low-level risk post-vaccination
- Risk estimated as 1 excess case per 20,000-100,000 in the US

5

**Storage &
Handling**

Vaccine Storage and Handling

- Store rotavirus vaccines in a refrigerator between 2°C and 8°C (36°F and 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

RV1 (Rotarix)

Ages: 6 weeks through 8 months, 0 days
Maximum age for 1st dose is 14 weeks, 6 days
Maximum age for last dose is 8 months, 0 days

Route: Oral (PO)

Reconstitute RV1 powder ONLY with manufacturer-supplied sterile water/calcium chloride/xanthan diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) or at controlled room temperature up to 25°C (77°F) and discard if not used within 24 hours.

Do NOT inject

Tip cap of prefilled diluent oral applicator contains latex

RV5 (RotaTeq)

Ages: 6 weeks through 8 months, 0 days
Maximum age for 1st dose is 14 weeks, 6 days
Maximum age for last dose is 8 months, 0 days

Route: Oral (PO)

Do NOT inject

RV1 (Rotarix)



Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) or at controlled room temperature up to 25°C (77°F) and discard if not used within 24 hours.
Tip cap of prefilled diluent oral applicator contains latex

Knowledge Check

- True or false: 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



Knowledge Check

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

B) False



6

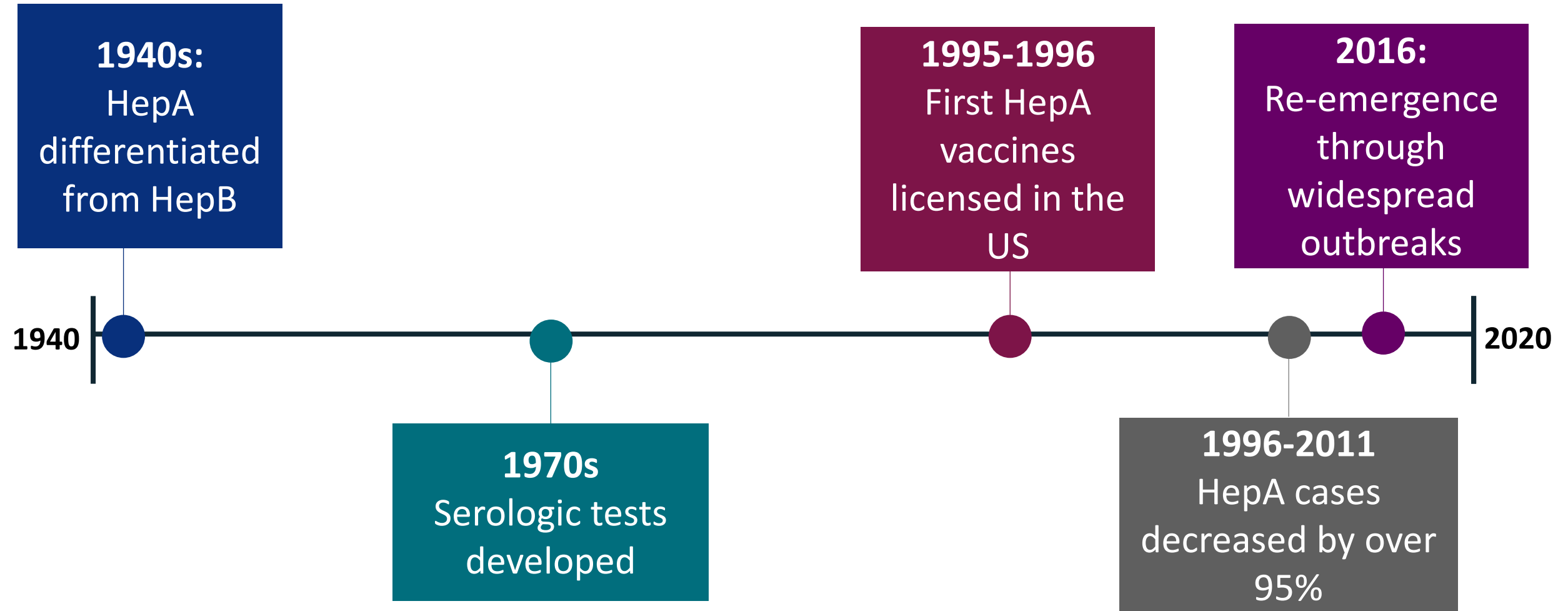
Rotavirus Resources

- Ask the Experts—Rotavirus FAQs:
 - https://www.immunize.org/askexperts/experts_rota.asp
- CDC Rotavirus Disease and Vaccination:
 - <https://www.cdc.gov/rotavirus/index.html>
- Questions and Answers—Rotavirus What You Should Know:
 - <https://media.chop.edu/data/files/pdfs/vaccine-education-center-rotavirus.pdf>
- Standing Orders for Administering Rotavirus Vaccine:
 - <https://www.immunize.org/catg.d/p3087.pdf>

7

Hepatitis A Disease

Hepatitis A



Hepatitis A

1940s:
HepA
differentiated
from HepB

1940

1970s
Serologic tests
developed

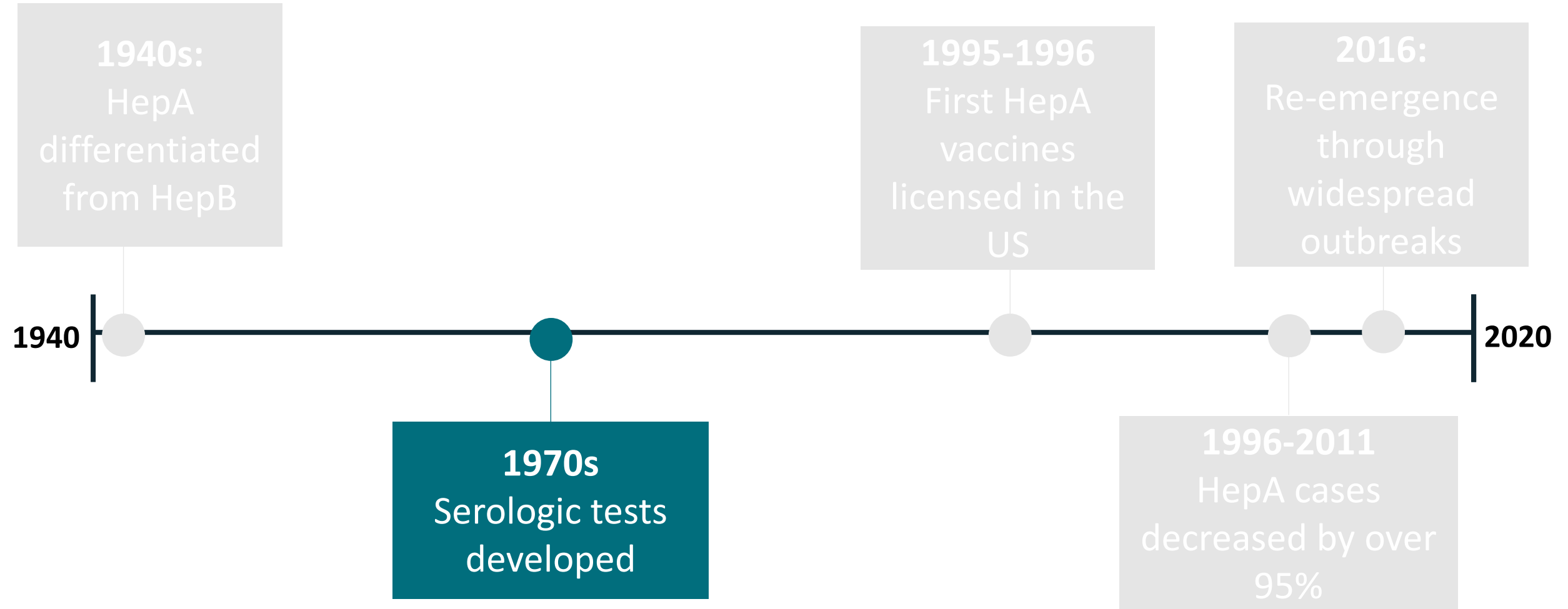
1995-1996
First HepA
vaccines
licensed in the
US

1996-2011
HepA cases
decreased by over
95%

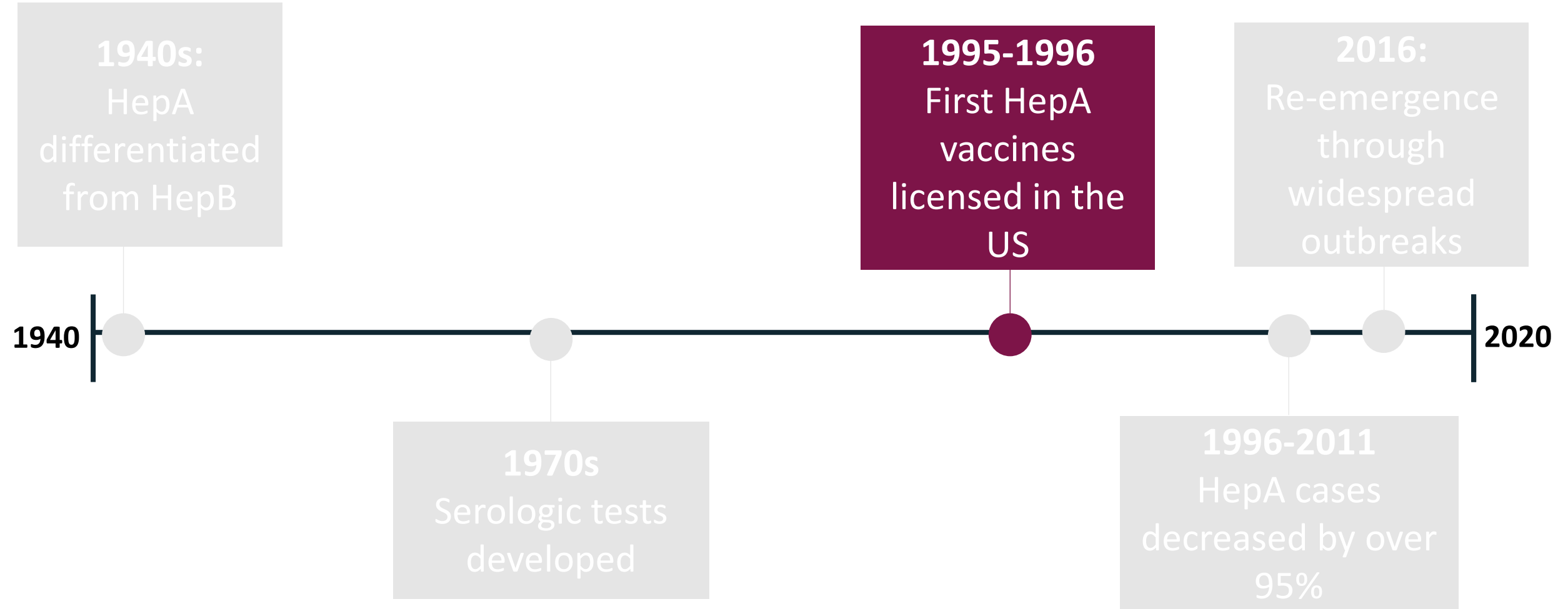
2016:
Re-emergence
through
widespread
outbreaks

2020

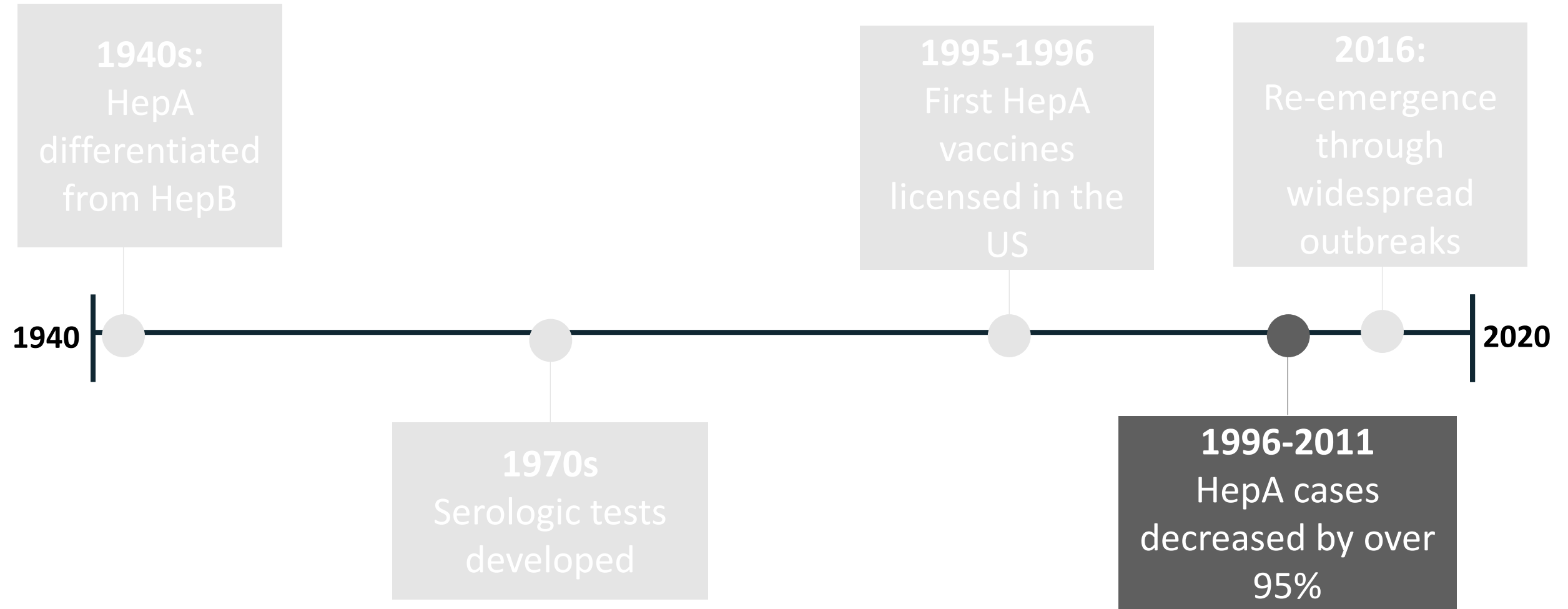
Hepatitis A



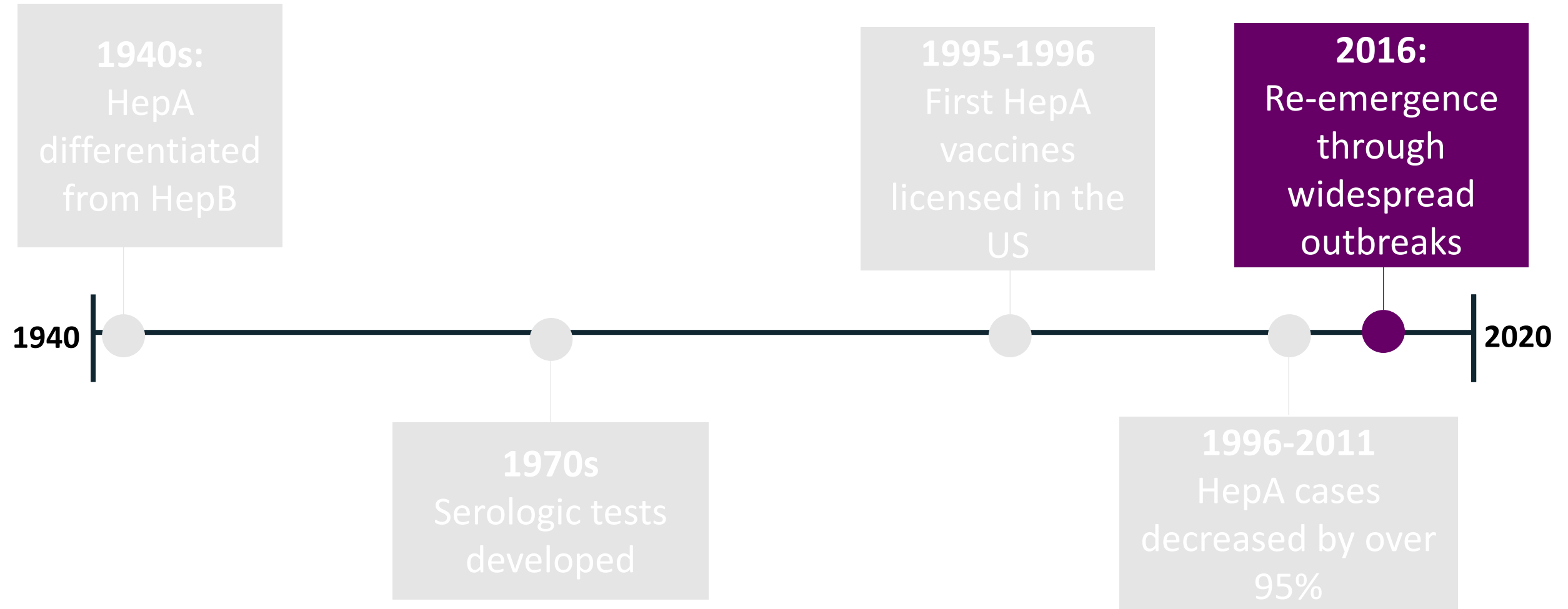
Hepatitis A



Hepatitis A



Hepatitis A



Hepatitis A Transmission and Pathogenesis



**Transmitted by
fecal-oral route**



Replicates in
the liver

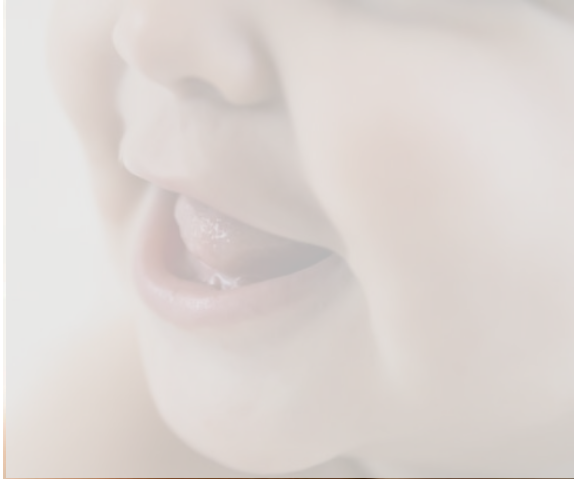


Viral shedding 1
to 3 weeks



Incubation period
~28 days

Hepatitis A Transmission and Pathogenesis



Transmitted by
fecal-oral route



**Replicates in
the liver**

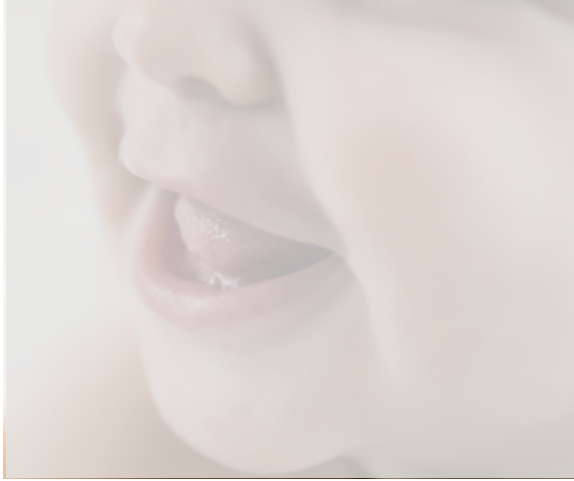


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Hepatitis A Transmission and Pathogenesis



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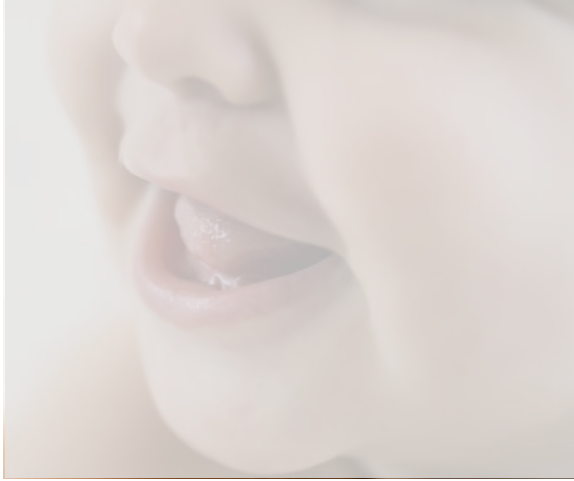


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Incubation period
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Hepatitis A Transmission and Pathogenesis



Transmitted by
fecal-oral route



Replicates in
the liver



Viral shedding 1
to 3 weeks



**Incubation period
~28 days**

Hepatitis A Clinical Features

- **The illness typically includes:**
 - Abrupt onset of fever
 - Malaise
 - Anorexia
 - Nausea
 - Abdominal discomfort
 - Dark urine
 - Jaundice
- **Usually resolves within 2-3 months**
- **Children generally asymptomatic, adults symptomatic**

Hepatitis A Prevaccine Era



**Occurred in large,
nationwide
epidemics**



**Higher in
western states**



**Highest rates in
children ages 2
through 18 years**

Hepatitis A Post Vaccine Introduction



The infographic consists of two large blue circles. The left circle contains the text '<1 case per 100,000'. The right circle contains a downward arrow followed by '95.5% from 1996-2011'. A decorative bar with segments of blue, purple, green, red, grey, and blue is located at the bottom of the slide.

**<1 case
per
100,000**

**↓ 95.5%
from
1996-2011**

Hepatitis A Outbreaks

■ As of July 22, 2022



37 states



44,000 cases



**27,000
hospitalizations**



424 deaths

8

Hepatitis A Vaccine

Hepatitis A-Containing Vaccines

- Non-live vaccine
- Administered by IM (intramuscular) injection



Hepatitis A-Containing Vaccines

Vaccine product	Age indications
Havrix	
Pediatric formulation	Birth – 18 years
Adult formulation	19 years and older
Vaqta	
Pediatric formulation	Birth – 18 years
Adult formulation	19 years and older
Twinrix (HepA/HepB)	
Adult formulation	18 years and older

Hepatitis A Vaccines

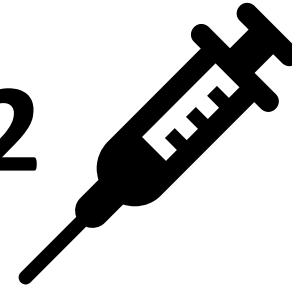
Pediatric



=

1/2

Adult



■ Havrix

- 720 El.U. (pediatric dose)
- 1440 El.U. (adult dose)

■ Vaqta

- 25 U (pediatric dose)
- 50 U (adult dose)

Hepatitis A Vaccines

- **Twinrix (HepA-HepB) combination vaccine contains:**
 - Hepatitis A 720 EL.U.(pediatric dose)
 - Hepatitis B 20 mcg (adult dose)

Example: Adult and Pediatric Doses



Scenario 1: An adult patient was given a pediatric dose of HepA vaccine by mistake.

What do you do next?

Example: Adult and Pediatric Doses



Scenario 1: An adult patient was given a pediatric dose of HepA vaccine by mistake.

What do you do next?

- If error discovered the same clinic day: Administer another “half” dose
- If error discovered later: The dose is invalid; the patient should receive a full adult repeat dose

Example: Adult and Pediatric Doses



Scenario 2: A pediatric patient was given the adult dose of HepA vaccine by mistake.

What do you do next?

Example: Adult and Pediatric Doses



Scenario 2: A pediatric patient was given the adult dose of HepA vaccine by mistake.

What do you do next?

- The dose is valid
- Inform patient/parent about the error and the chance of increased risk of local reactions
- Continue with the next dose as scheduled, if applicable

Hepatitis A Vaccine Efficacy

■ HAVRIX (GSK)

- 40,000 children 1–16 years of age (Thailand)
- Vaccine efficacy 94%

■ VAQTA (Merck)

- 1,000 children 2–16 years of age (New York)
- Vaccine efficacy 100%

■ Twinrix (GSK)

- 1,551 healthy adults 17–70 years of age
- Vaccine efficacy HepA 99.9% and HepB 98.5%

9

**Hepatitis A
Clinical
Considerations**

Hepatitis A Children and Adult Vaccination Schedule

Children and adolescents

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
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										

Adults

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			

ACIP Hepatitis A Vaccine Recommendations: Pediatric

Children and adolescents

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
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										

- All children should receive vaccine at 12–23 months of age
- Catch-up vaccination for all unvaccinated children between 2 and 18 years

ACIP Hepatitis A Vaccine Recommendations: Adult

Adults

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			

- Recommended for adults at increased risk

People at Increased Risk of HAV Infection or Severe Disease

■ People at increased risk for HAV infection

- International travelers
- Men who have sex with men
- People who use injection or noninjection drugs (all those who use illegal drugs)
- People with occupational risk for exposure
- People who anticipate close personal contact with an international adoptee
- People experiencing homelessness

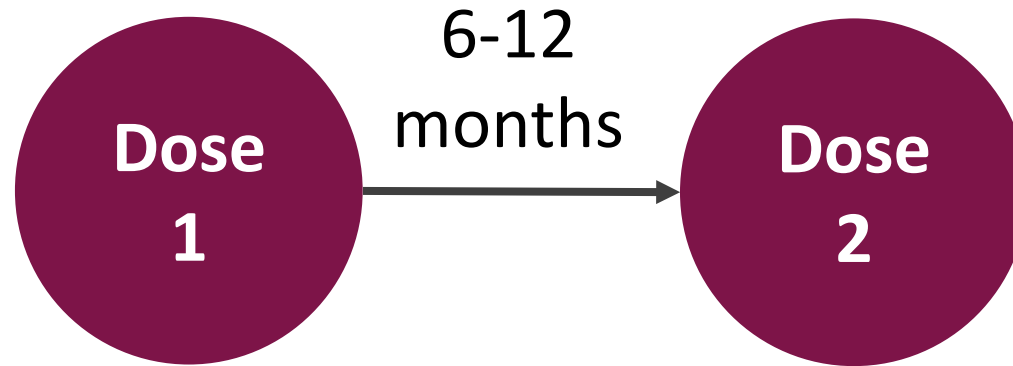
■ People at increased risk for severe disease from HAV infection

- People with chronic liver disease
- People with human immunodeficiency virus infection

Hepatitis A Vaccination Schedule

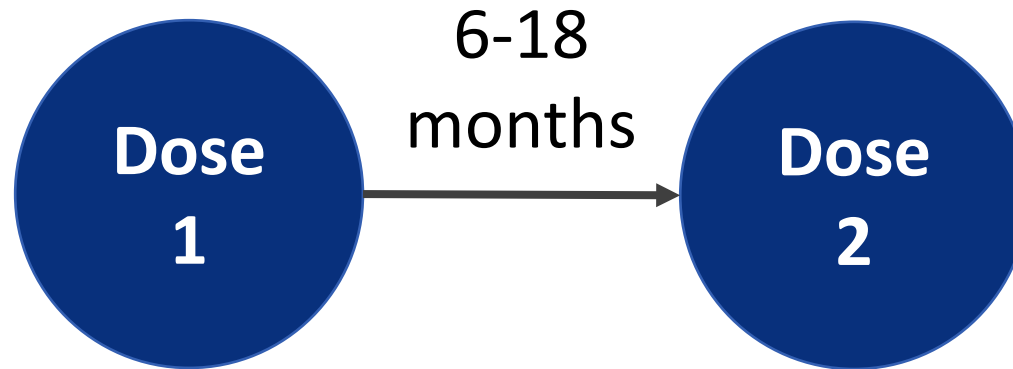
Havrix

- 2-dose: 0, 6-12 months



Vaqta

- 2-dose: 0, 6-18 months

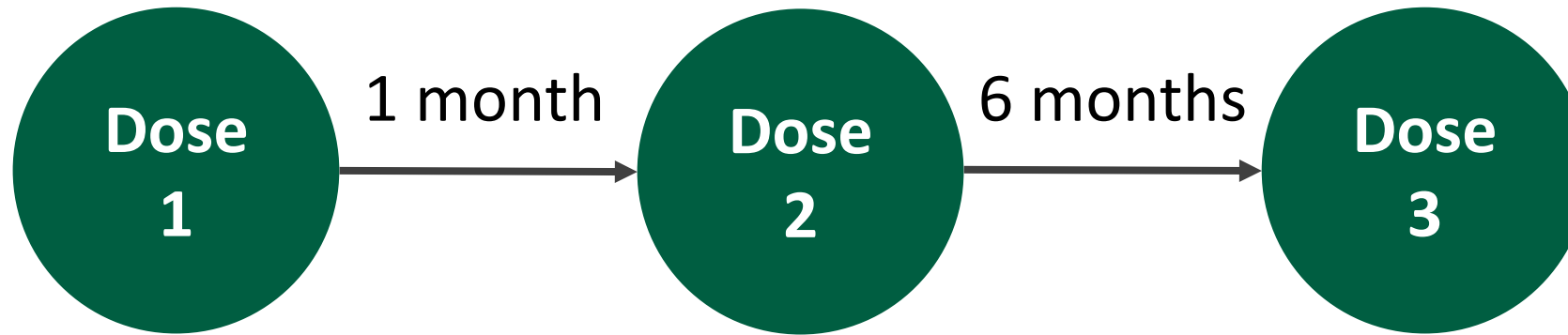


The same produce is preferred, but vaccines are interchangeable.

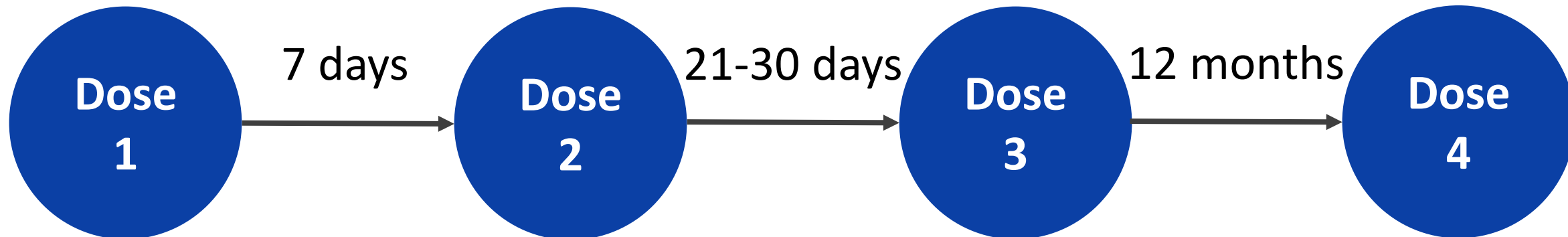
Hepatitis A Vaccination Schedule

■ Twinrix (adults)

- 3-dose: 0, 1, 6 months



- 4-dose: 0, 7, 21–30 days and booster dose at 12 months after first dose



Twinrix and Single-Component Hepatitis A Vaccine

- **Adult formulation hepatitis A vaccine may be used to complete a schedule begun with Twinrix and vice versa***
- **Acceptable schedules (ages 19 years and older)**
 - 2 Twinrix and 1 single-antigen hepatitis A
 - 1 Twinrix and 2 single-antigen hepatitis A
 - 1 single-antigen hepatitis A and 2 Twinrix or 1 single-antigen hepatitis A

*Use the pediatric formulation of single-component vaccine for persons 18 years of age and younger.
Use the adult formulation of single-component vaccine for persons 19 years of age or older.

Hepatitis A Vaccination Schedule

Correct Dosage

Based on age
at time of
dose

Minimum
age, dose 1
12 months

Minimum
age, dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A Vaccination Schedule

Correct Dosage

Based on age
at time of
dose

Minimum
age, dose 1
12 months

Minimum
age, dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A Vaccination Schedule

Correct Dosage

Based on age
at time of
dose

Minimum
age, dose 1
12 months

Minimum
age, dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A Vaccination Schedule

Correct Dosage

Based on age
at time of
dose

Minimum
age, dose 1
12 months

Minimum
age, dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A Vaccination Schedule

Correct Dosage

Based on age
at time of
dose

Minimum
age, dose 1
12 months

Minimum
age, dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A and International Travel

- Recommended for persons ages 6 months or older traveling to or working in countries with high or intermediate endemicity

Destinations

Destinations



Where are you going?

-- Select One --



Go

Summary: Hepatitis A Vaccine Recommendations and International Travel

TABLE 4. Recommendations for postexposure prophylaxis and preexposure protection, by age group and risk category — Advisory Committee on Immunization Practices, 2020



Indication and age group	Risk category and health status	HepA vaccine	IG*
Postexposure prophylaxis			
<12 months	Healthy	No	0.1 mL/kg
12 months–40 yrs	Healthy	1 dose [†]	None
>40 yrs	Healthy	1 dose [†]	0.1 mL/kg [§]
≥12 months	Immunocompromised or chronic liver disease	1 dose [†]	0.1 mL/kg [¶]
≥12 months	Vaccine contraindicated**	No	0.1 mL/kg
Preexposure protection (e.g., travel)^{††}			
<6 months	Healthy	No	0.1–0.2 mL/kg ^{§§}
6–11 months	Healthy	1 dose ^{¶¶}	None
12 months–40 yrs	Healthy	1 dose ^{***}	None
>40 yrs	Healthy	1 dose ^{***}	0.1–0.2 mL/kg ^{§§,†††}
>6 months	Immunocompromised or chronic liver disease	1 dose ^{***}	0.1–0.2 mL/kg ^{§§,†††}
>6 months	Persons who elect not to receive vaccine or for whom vaccine is contraindicated**	No	0.1–0.2 mL/kg ^{§§}

Hepatitis A Vaccine for International Travelers: Infants

- **Administer a single dose of HepA vaccine to infants 6–11 months of age^{*}**
- **Infants should restart the 2-dose series of HepA vaccine at 12 months of age or older as recommended**

^{*}Off-label recommendation

<https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a5.htm>

Hepatitis A Vaccination for International Travelers: Children and Adults

- **One dose of a monovalent hepatitis A vaccine protects most healthy people 1–40 years of age**
- **Administer Hep A vaccine to persons 1 year of age and older**
 - Start the series as soon as travel is being considered to an area outside the U.S. where protection against hepatitis A is recommended
 - The series should be completed for lifelong protection – even if the trip is over
 - Postvaccination testing is not recommended

Knowledge Check

- **A 20-year-old patient received a pediatric dose of HepA at 15 years old but did not finish the series. What action should you take to complete the series?**
- A. Administer 1 pediatric dose to complete the series
- B. Administer 1 adult dose to complete the series
- C. Restart the series; the patient will need 2 adult doses



Answer

- A 20-year-old patient received a pediatric dose of HepA at 15 years old but did not finish the series. What action should you take to complete the series?
- B. Administer 1 adult dose to complete the series



Hepatitis A Vaccination Additional Recommendations

- **Not routinely recommended for:**
 - Health care personnel
 - Childcare center staff
 - Sewer workers or plumbers
- **Vaccination of persons who receive blood products for clotting disorders (e.g., hemophilia)**
- **Food handlers may be considered based on local circumstances**

Postexposure Prophylaxis (PEP)

- **Administer HepA within 2 weeks of exposure to unvaccinated, recently exposed persons ages 12 months or older**
- **Coadministration of IG (0.1mL/kg) for certain circumstances for persons ages 40 years or older based on risk assessment**
 - Ability of person to develop protective level of antibodies after HepA vaccine
 - Magnitude of risk for HAV transmission post-exposure
 - Availability of IG and vaccine
- **Unvaccinated persons who are immunocompromised or have chronic live disease should receive both**

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Safety

Hepatitis A Vaccine: Contraindications

Hepatitis A Vaccine

Severe allergic reaction to a vaccine component or following a prior dose

Hepatitis A Vaccine: Precautions

Hepatitis A Vaccine

Moderate or severe acute illness

HepA Vaccine Adverse Events

Single-antigen hepatitis A vaccines	HepA-HepB
Fever	Fever
Injection site erythema	Headache
Injection site swelling	Injection site pain
Rash	Dizziness

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**Storage &
Handling**

Vaccine Storage and Handling

- Store hepatitis A vaccine in a refrigerator between 2°C and 8°C (36°F and 46°F)
- Store pediatric and adult formulations:
 - In the original packaging with the lids closed
 - In a clearly labeled bin and/or area of the storage unit-not next to each other

HepA (Havrix)-Pediatric Formulation

Ages: 12 months through 18 years

Use for: Any dose in the series

Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepA (Havrix)-Adult Formulation

Ages: 19 years and older

Use for: Any dose in the series

Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepA (Vaqta)-Pediatric Formulation

Ages: 12 months through 18 years

Use for: Any dose in the series

Route: Intramuscular (IM) injection

Vial stopper and syringe plunger contain latex

HepA (Vaqta)-Adult Formulation

Ages: 19 years and older

Use for: Any dose in the series

Route: Intramuscular (IM) injection

Vial stopper and syringe plunger stopper and tip cap contain latex

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Hepatitis A Resources

Child Resources

- Ask the Experts—Hepatitis A FAQs:
 - https://www.immunize.org/askexperts/experts_hepa.asp
- CDC Hepatitis A Disease:
 - <https://www.cdc.gov/hepatitis/hav/index.htm>
- CDC Hepatitis A Vaccination:
 - <https://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html>
- Standing Orders for Administering Hepatitis A Vaccine: Children and Teens:
 - <https://www.immunize.org/catg.d/p3077a.pdf>

Adult Resources

- Patient Education Materials about Hepatitis A
 - <https://www.cdc.gov/hepatitis/hav/patienteduhav.htm#cdc>
- Widespread outbreaks of hepatitis A across the U.S. | CDC
 - <https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm>

Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: WD4564-081622
- CE credit expires: July 1, 2024
- CE instructions are available on the Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

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Thank You From Atlanta!

