Rotavirus and Hepatitis A Vaccines

Pink Book Web-on-Demand Series

August 16, 2022

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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**
- **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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Disclosure Statements

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.

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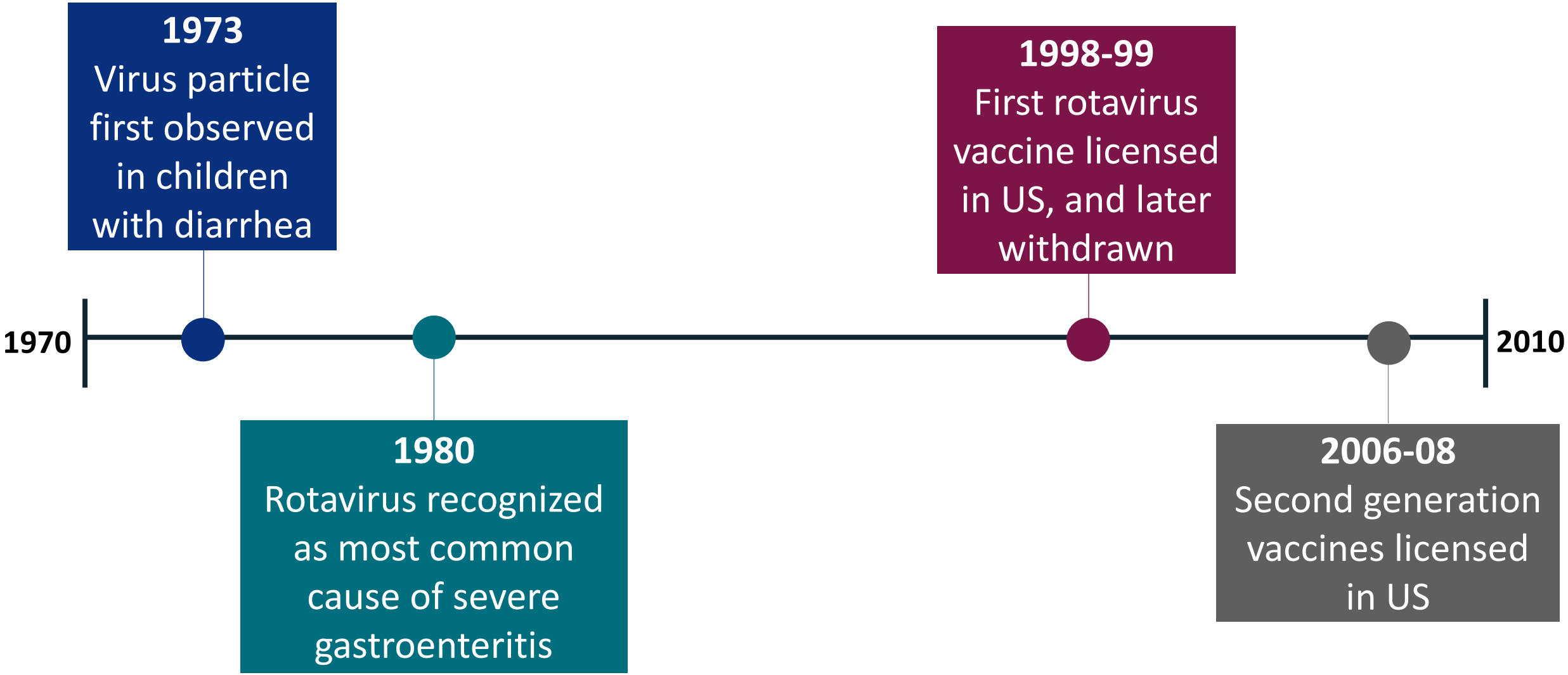
Rotavirus Disease

Rotavirus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Virus particle first observed in children with diarrhea
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Rotavirus recognized as most common cause of severe gastroenteritis
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First rotavirus vaccine licensed in US, and later withdrawn
2006-08
Second generation vaccines licensed in US
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Rotavirus

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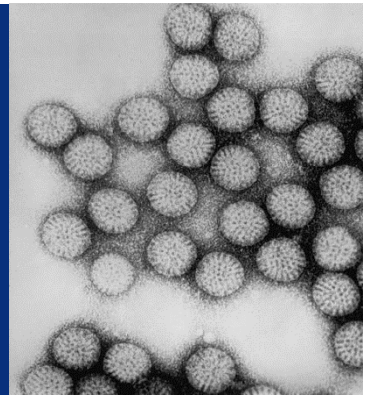

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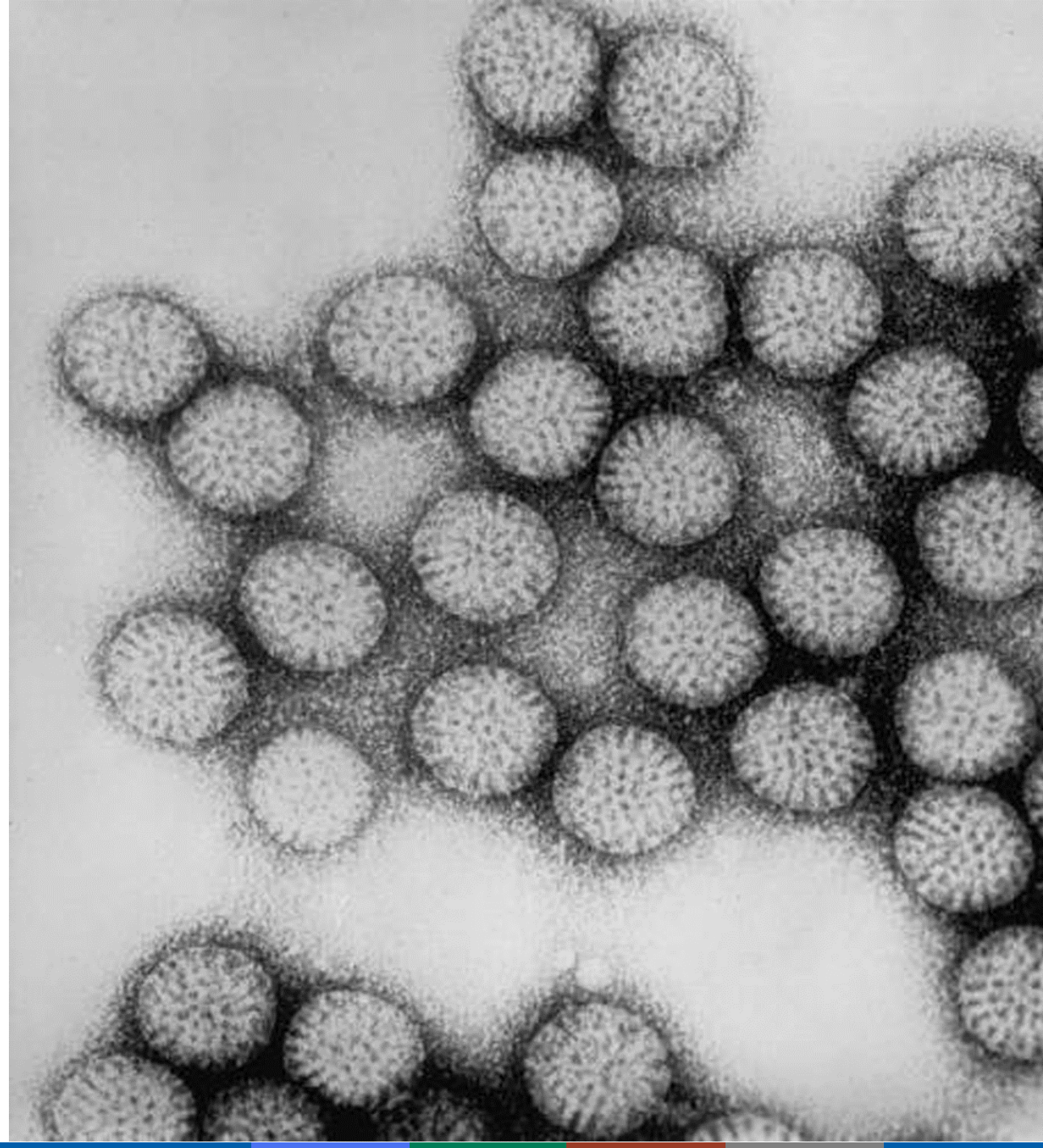
Rotavirus

- 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

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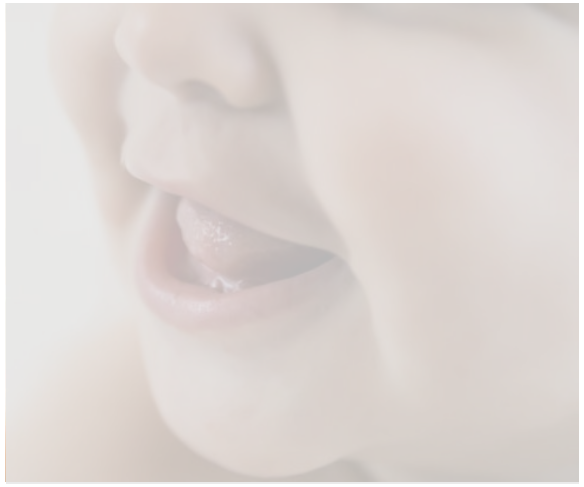

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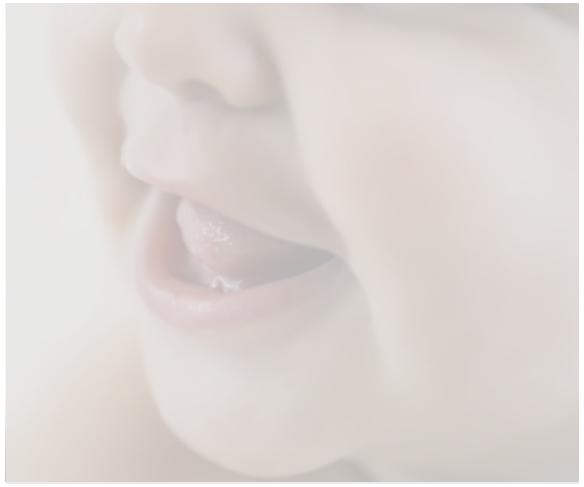

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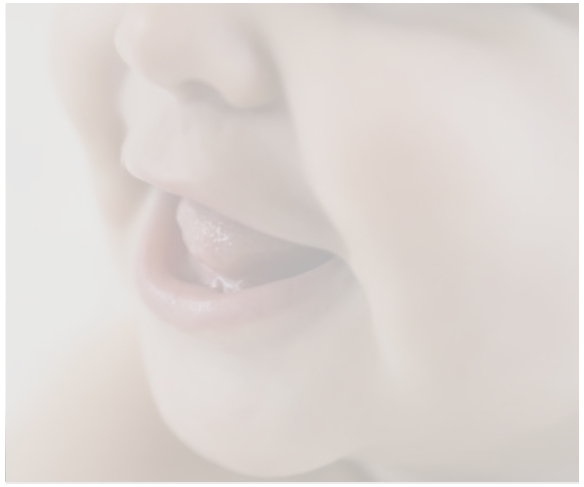

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Rotavirus Clinical Features

- 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

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Rotavirus Vaccine Efficacy

74%-87%	85%-98%	Significant ↓
Any rotavirus gastroenteritis	Severe gastroenteritis	Physician visits Hospitalizations

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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)			1st dose	2nd dose	See Notes		

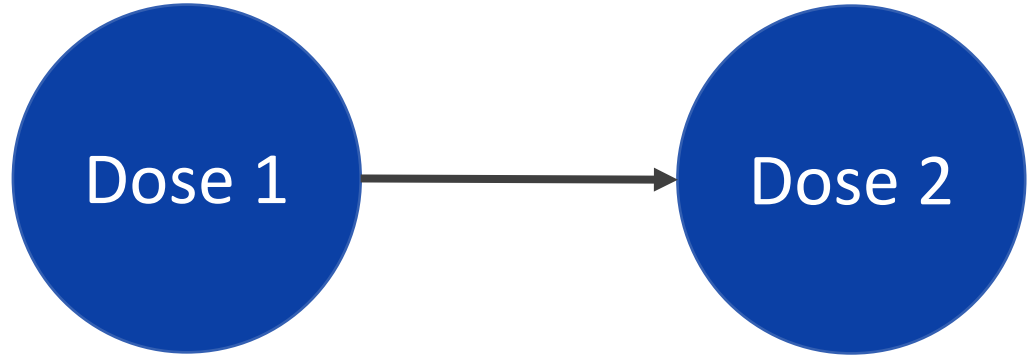
Notes: https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-rotavirus

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

Rotavirus Vaccination Schedule

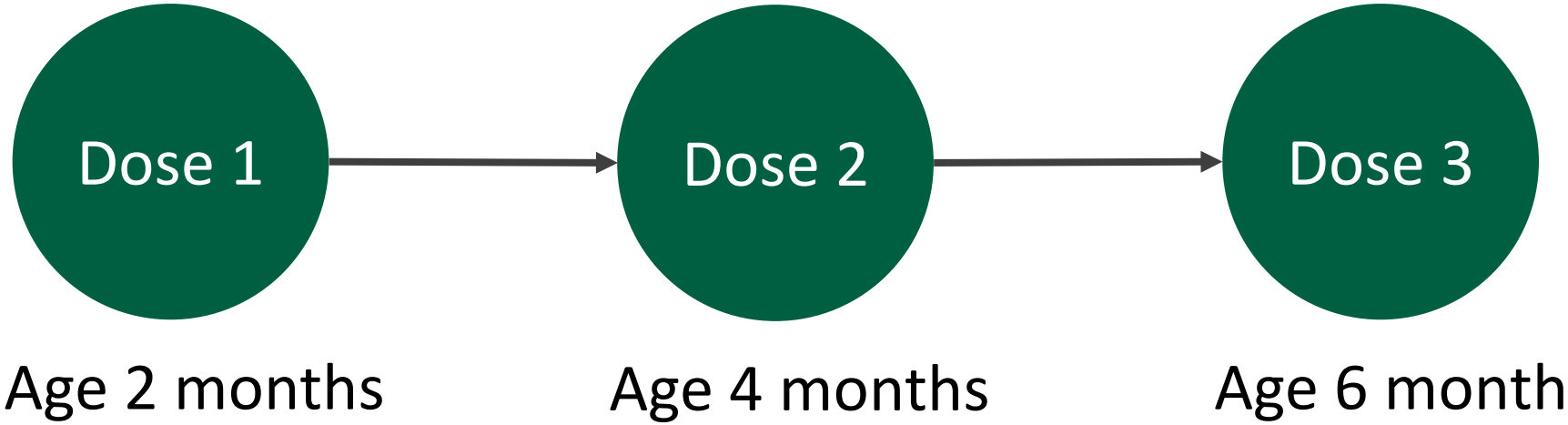
RV1 (Rotarix):

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

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14 weeks, 6 days*

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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

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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)

Lyophilized RV1 component + Manufacturer's sterile water-calcium carbonate-xanthan diluent = Rotarix vaccine

Do NOT inject

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

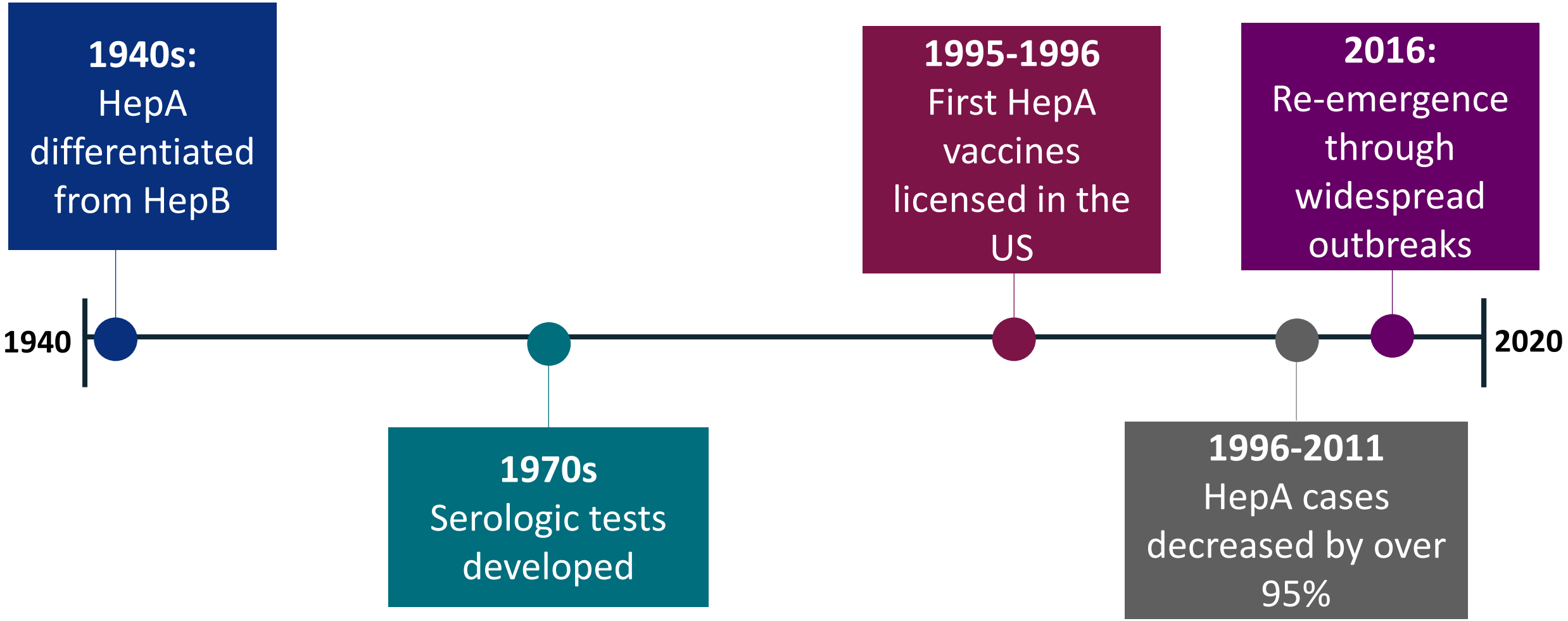
Rotavirus Resources

- 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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HepA differentiated from HepB
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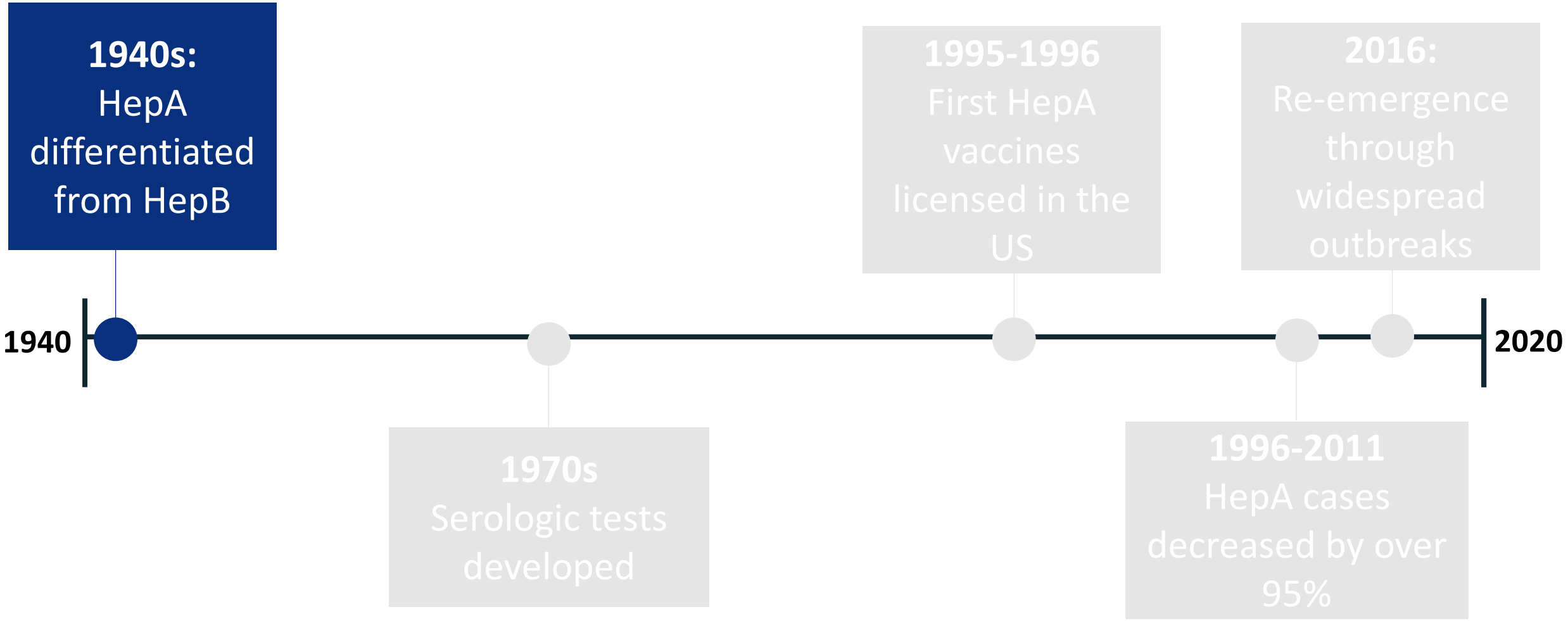
1970s
Serologic tests developed
1995-1996
First HepA vaccines licensed in the US
1996-2011
HepA cases decreased by over 95%
2016:
Re-emergence through widespread outbreaks
2020

Hepatitis A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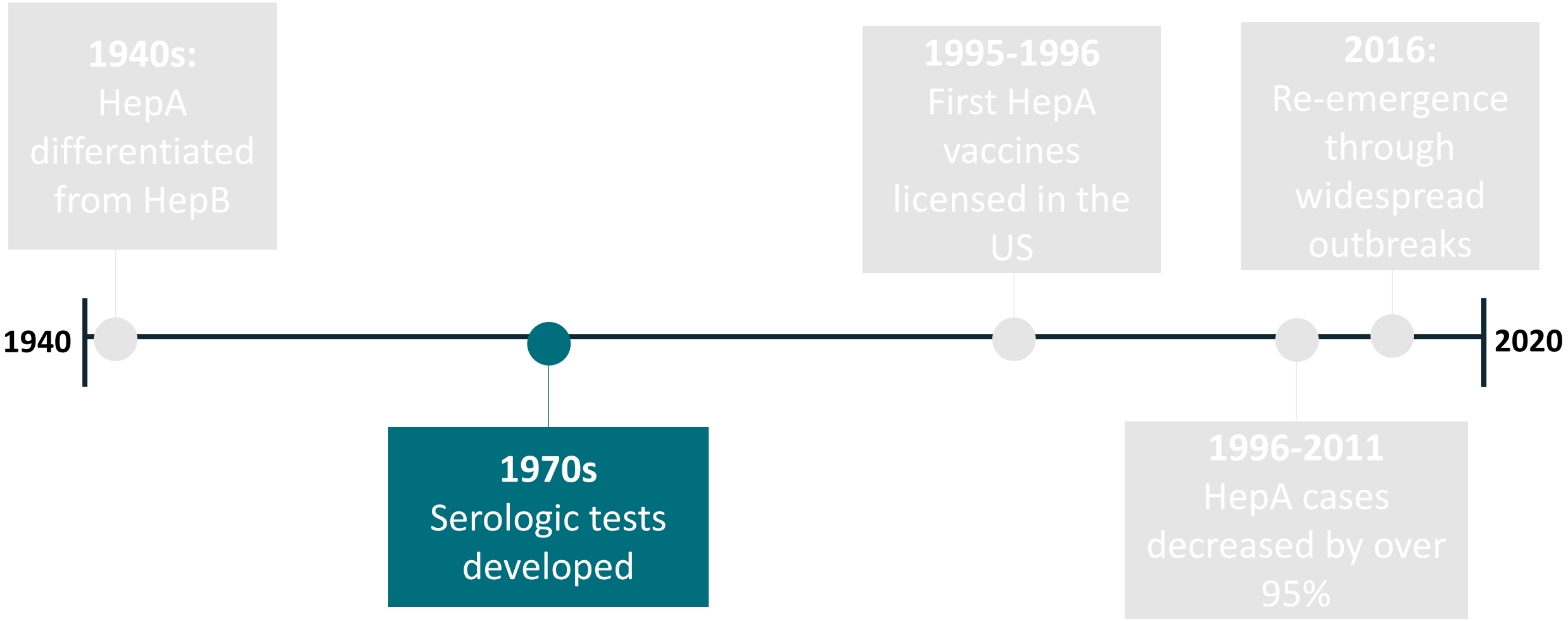
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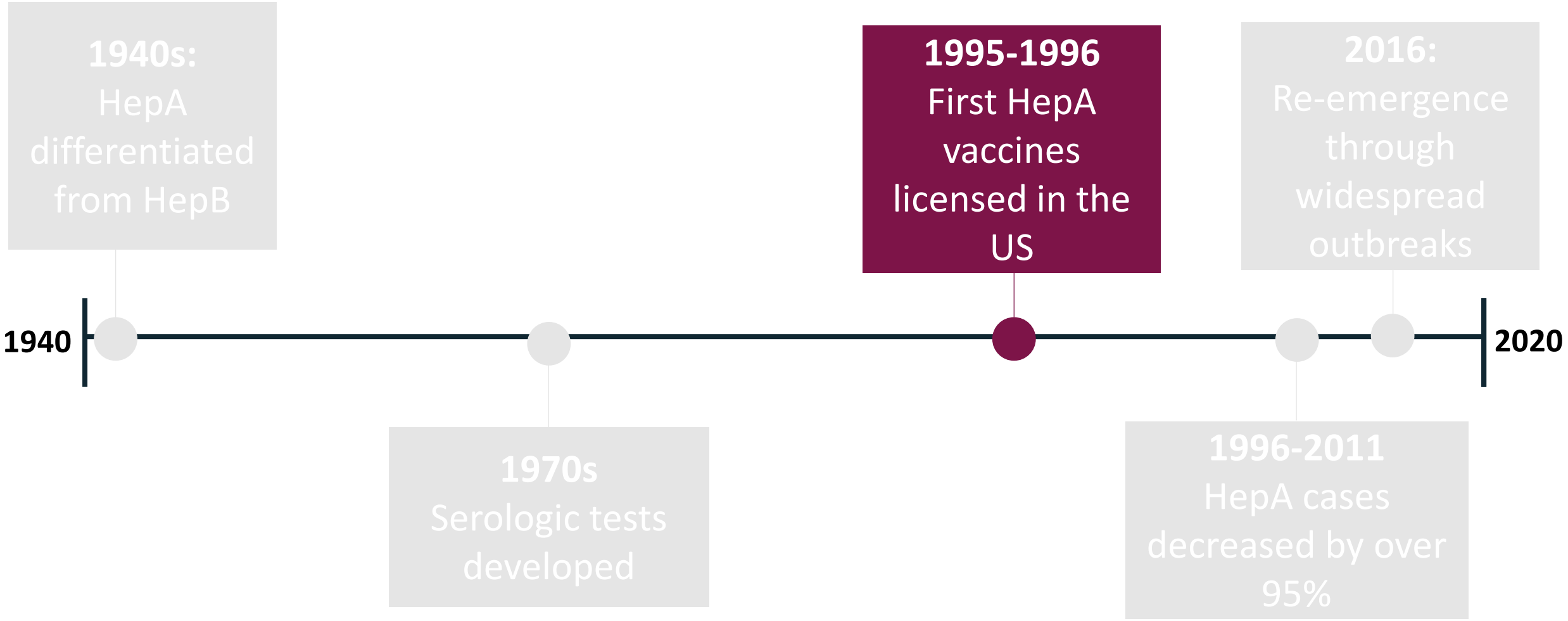
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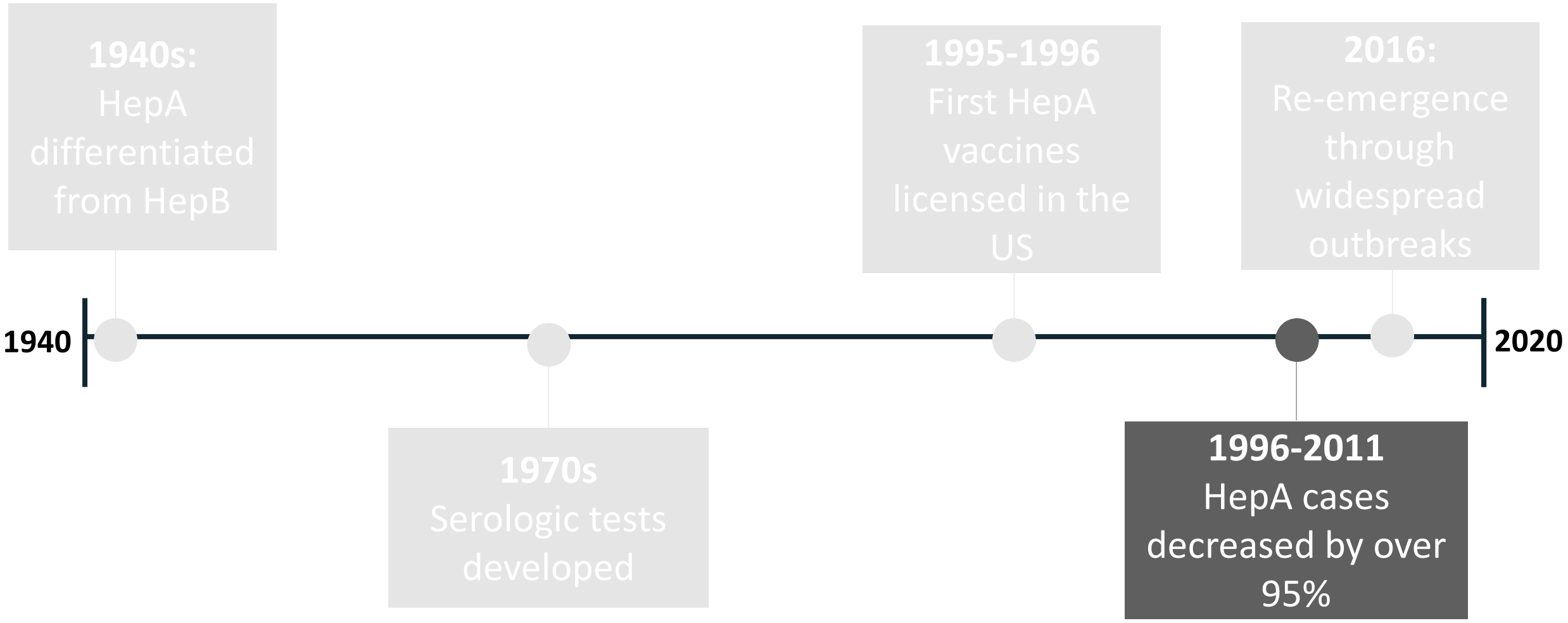
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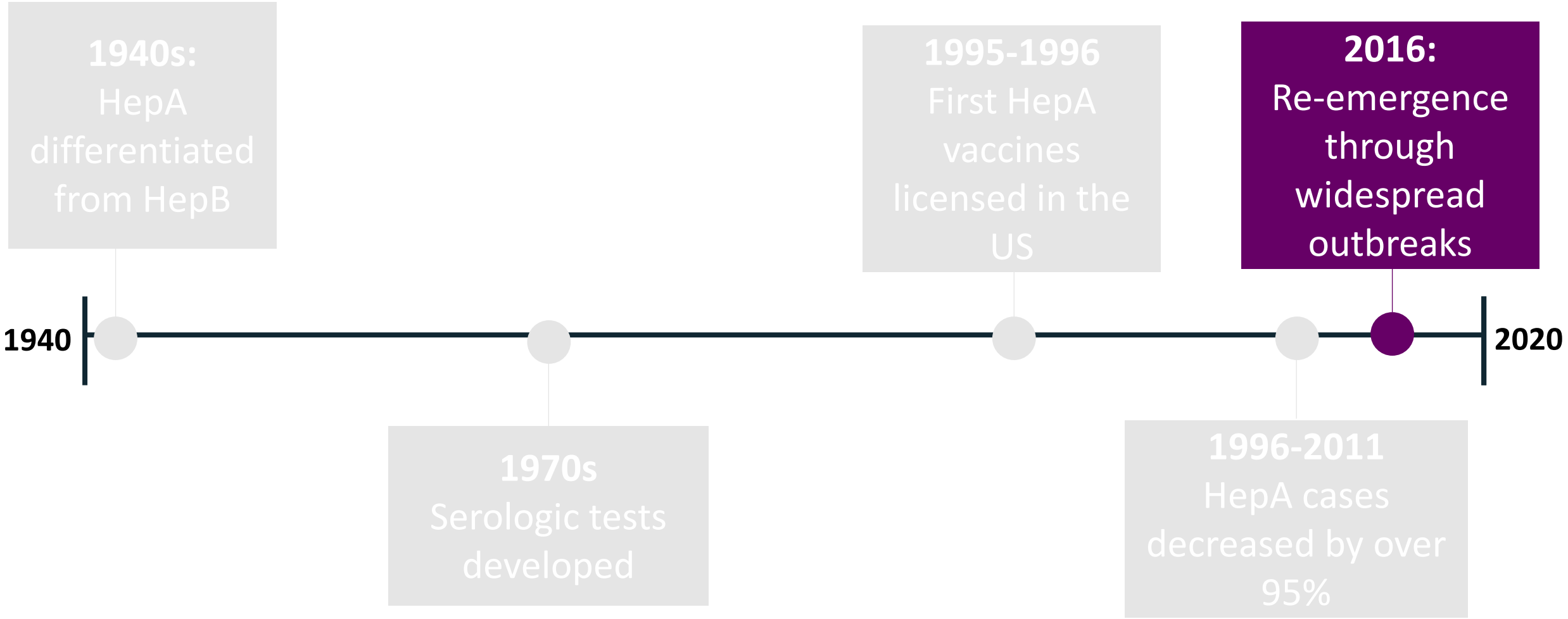


https://wwwnc.cdc.gov/eid/article/26/5/19-1224_article

Hepatitis A Transmission and Pathogenesis

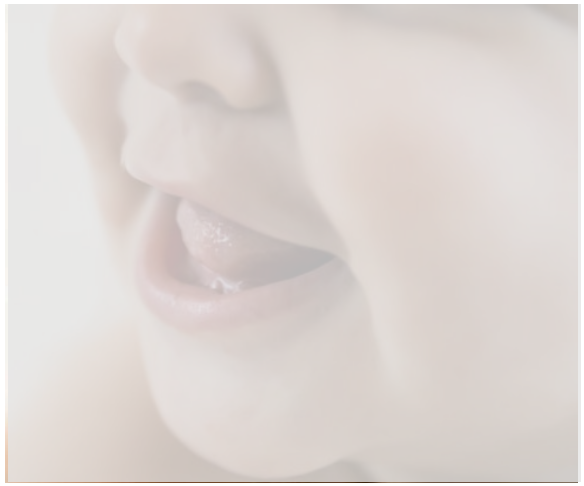
Transmitted by fecal-oral route

Replicates in the liver

Viral shedding 1 to 3 weeks

Incubation period ~28 days

Hepatitis A Transmission and Pathogenesis



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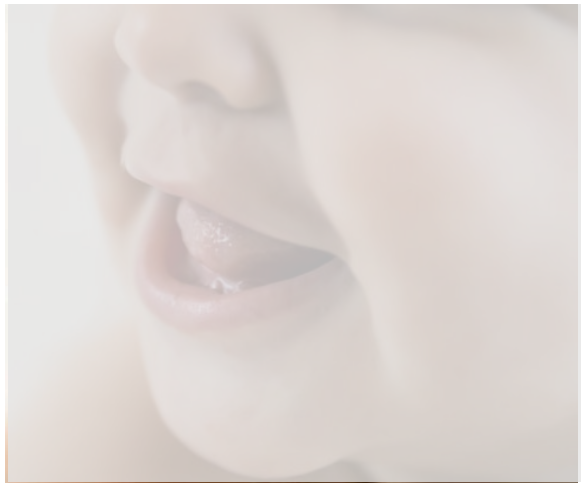

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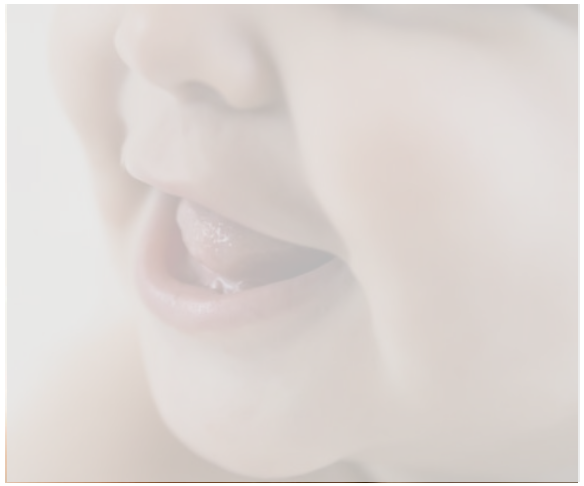

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Hepatitis A Clinical Features

- **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**

https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm

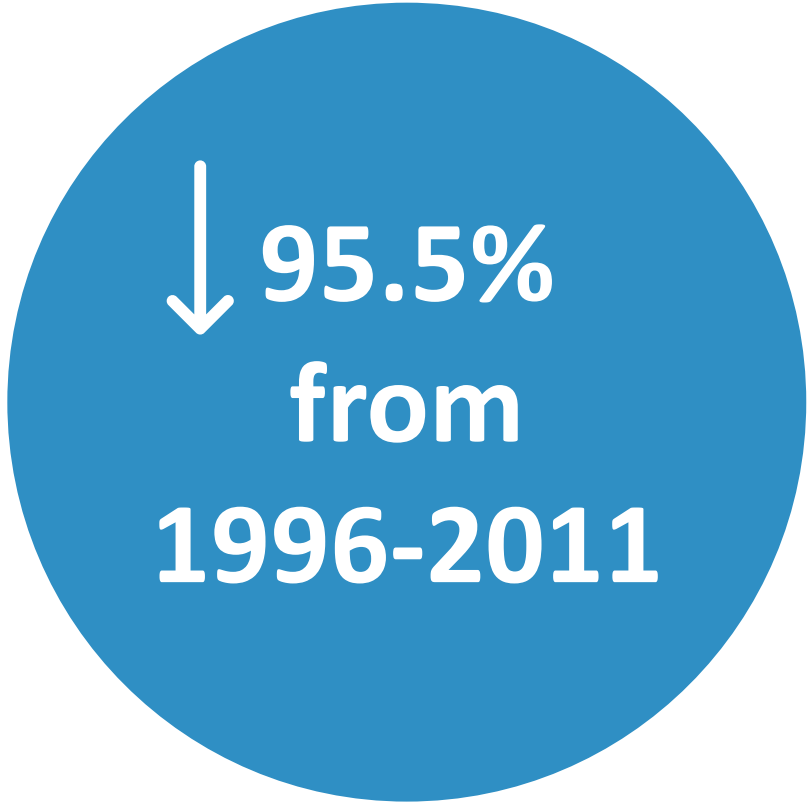
Hepatitis A Prevaccine Era

Occurred in large, nationwide epidemics

Higher in western states

Highest rates in children ages 2 through 18 years

Hepatitis A Post Vaccine Introduction



Hepatitis A Outbreaks

- As of July 22, 2022

37 states

44,000 cases

27,000 hospitalizations

424 deaths

https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm

8

Hepatitis A Vaccine

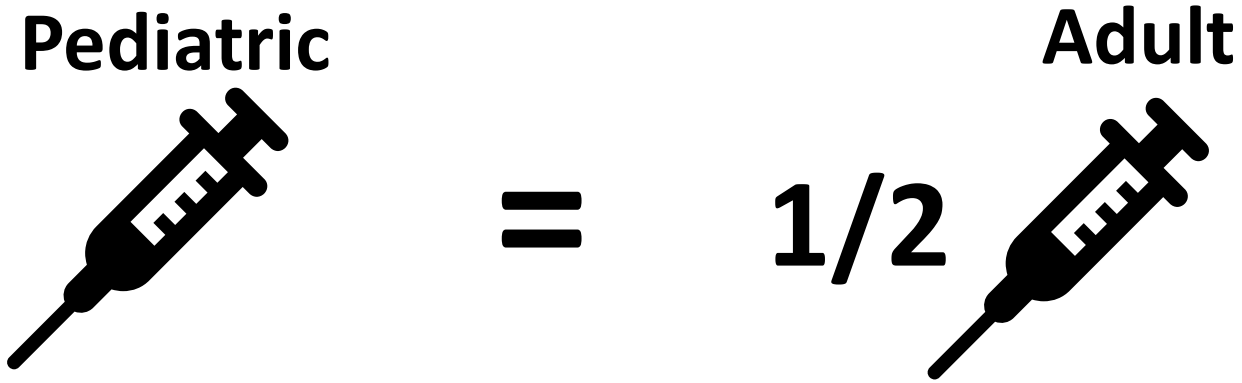
Hepatitis A-Containing Vaccines

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

Hepatitis A-Containing Vaccines

Vaccine product	Age indications
Havrix	
Pediatric formulation	12 months – 18 years
Adult formulation	19 years and older
Vaqta	
Pediatric formulation	12 months – 18 years
Adult formulation	19 years and older
Twinrix (HepA/HepB)	
Adult formulation	18 years and older

Hepatitis A Vaccines



- **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%

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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

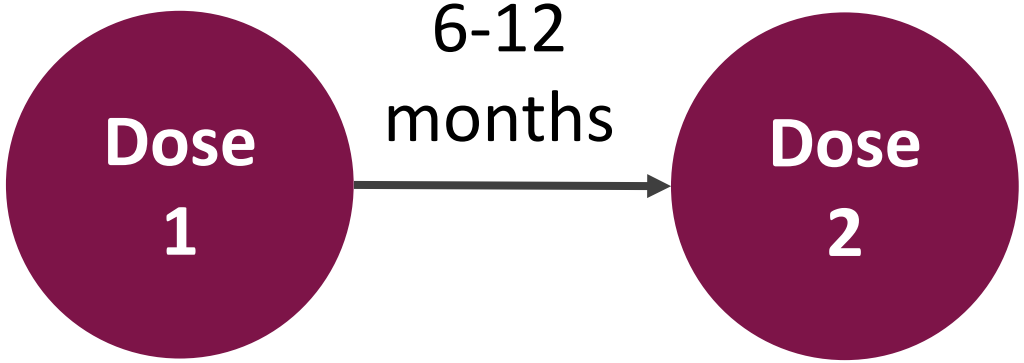
People at Increased Risk of HAV Infection or Severe Disease

- **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

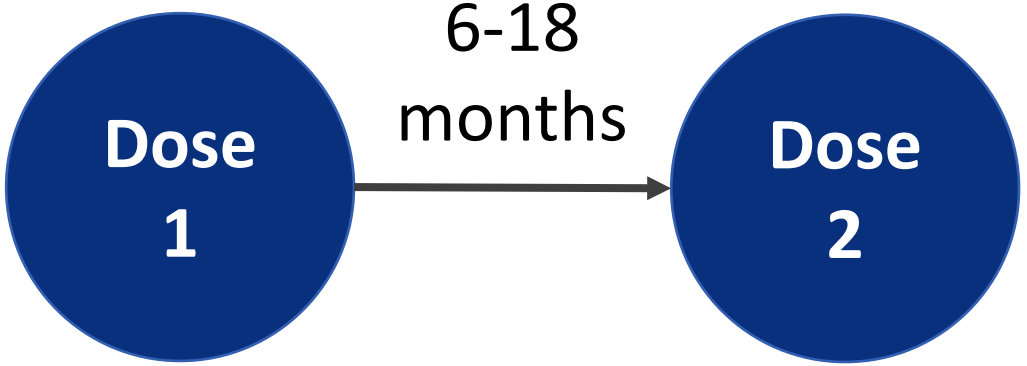
Havrix

- 2-dose: 0, 6-12 months



Vaqta

- 2-dose: 0, 6-18 months

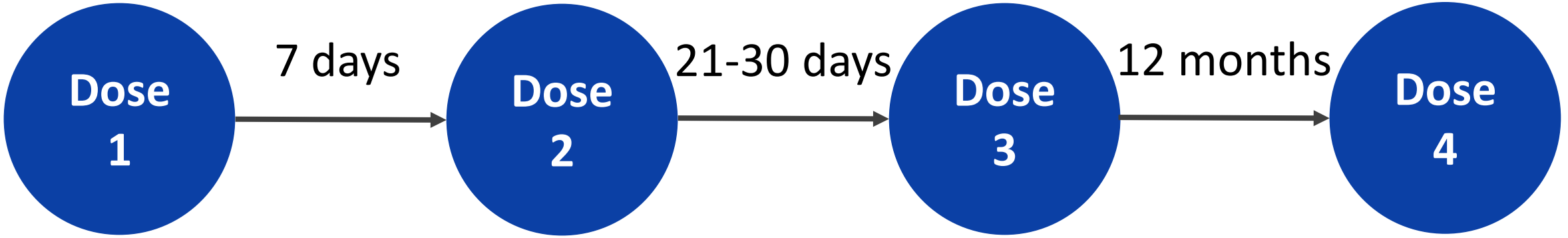


The same produce is preferred, but vaccines are interchangeable.

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	Minimum age, dose 1	Minimum age, dose 2	Minimum interval	Maximum interval
Based on age at time of dose	12 months	18 months	6 months	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

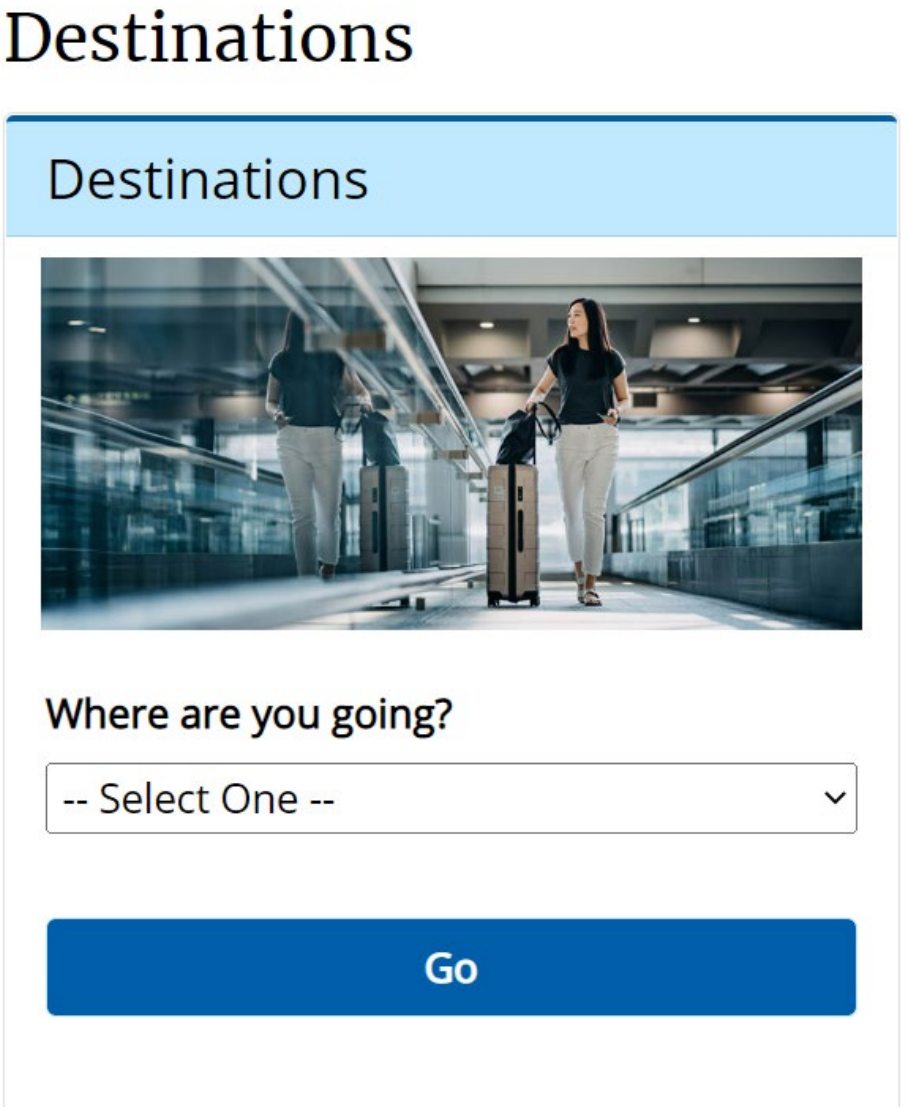
Minimum age, dose 2
18 months

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



https://wwwnc.cdc.gov/travel/destinations/list

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

Return

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§§

Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2020 | MMWR (cdc.gov)

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

MMWR 2007;56(No.41):1080-4

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**

https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1_appendix.htm

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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

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

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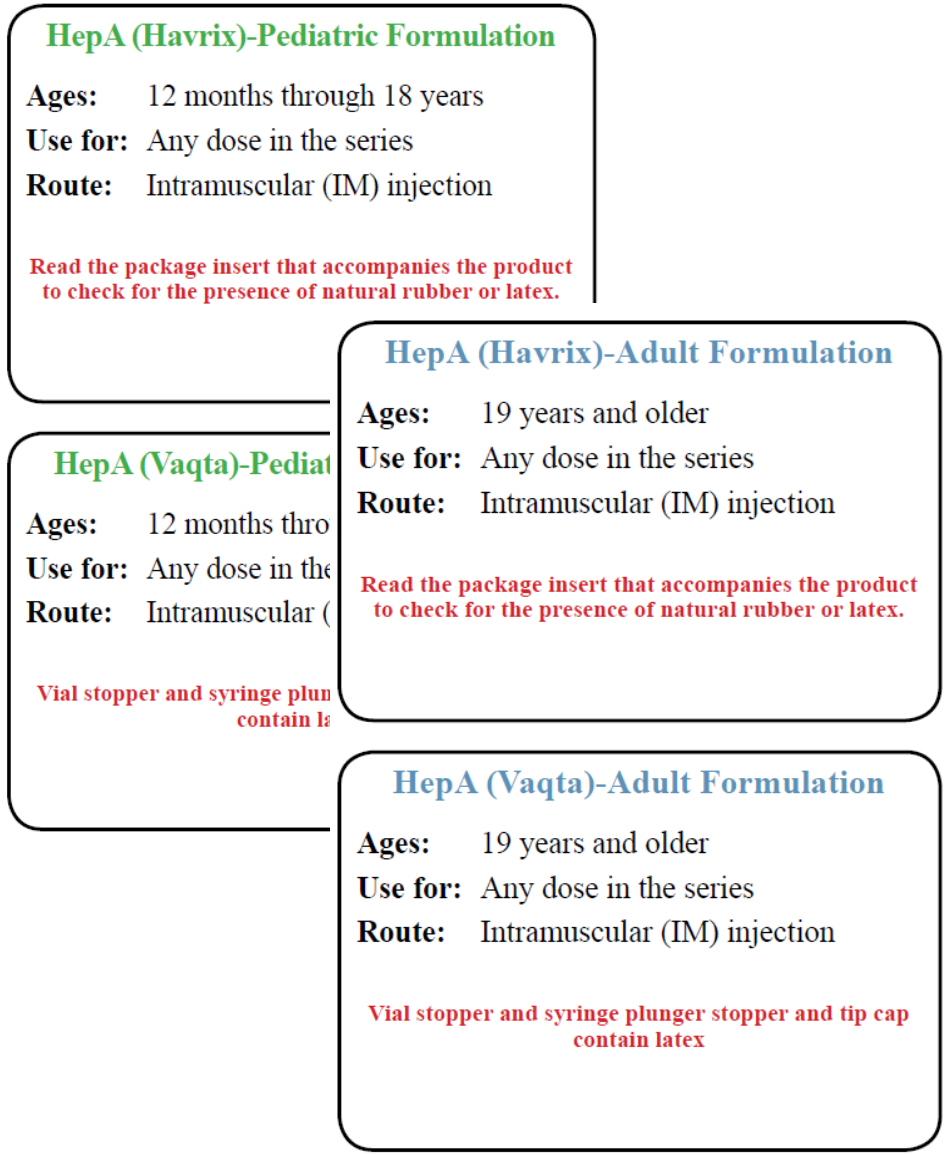
Storage & Handling

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



Vaccine storage label example
Available at https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

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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

E-mail Your Immunization Questions to Us

- NIPINFO@cdc.gov

Thank You From Atlanta!