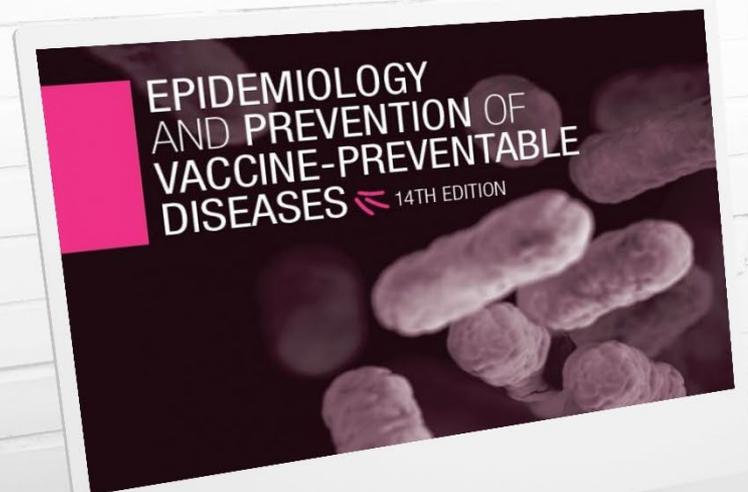


Hepatitis A Vaccines

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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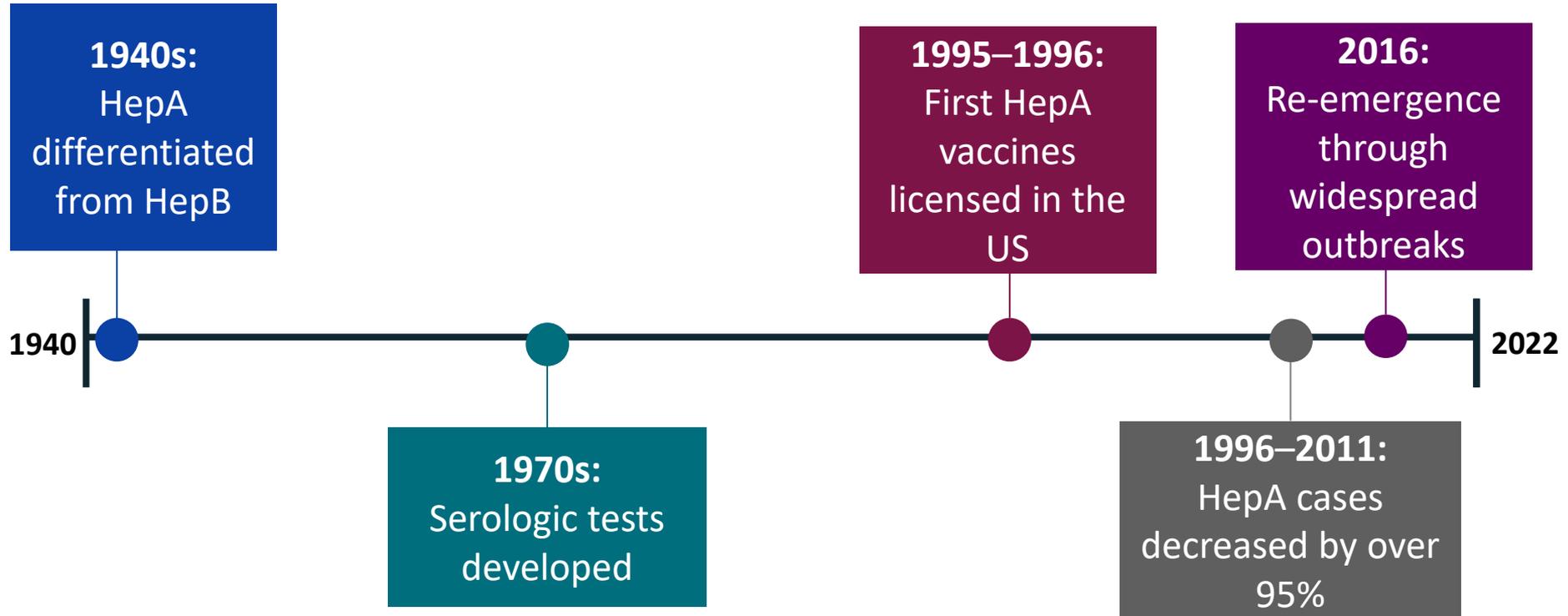
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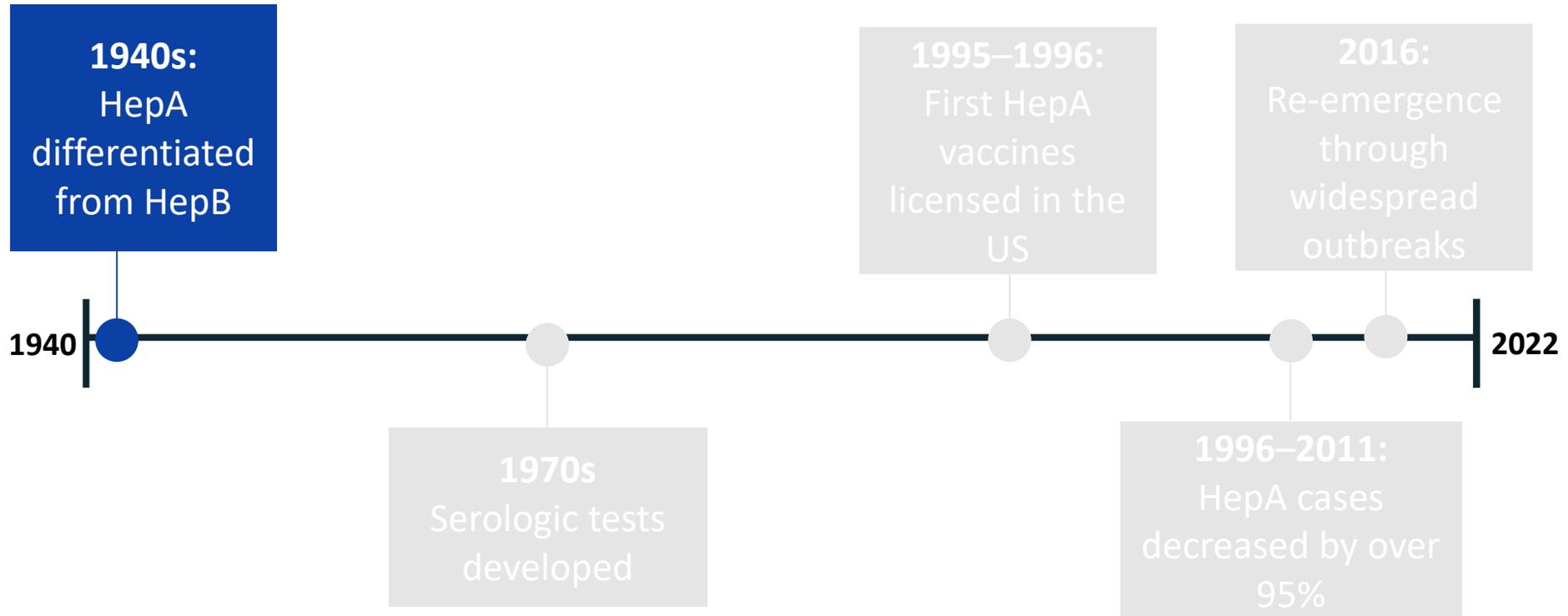
1

Hepatitis A Disease

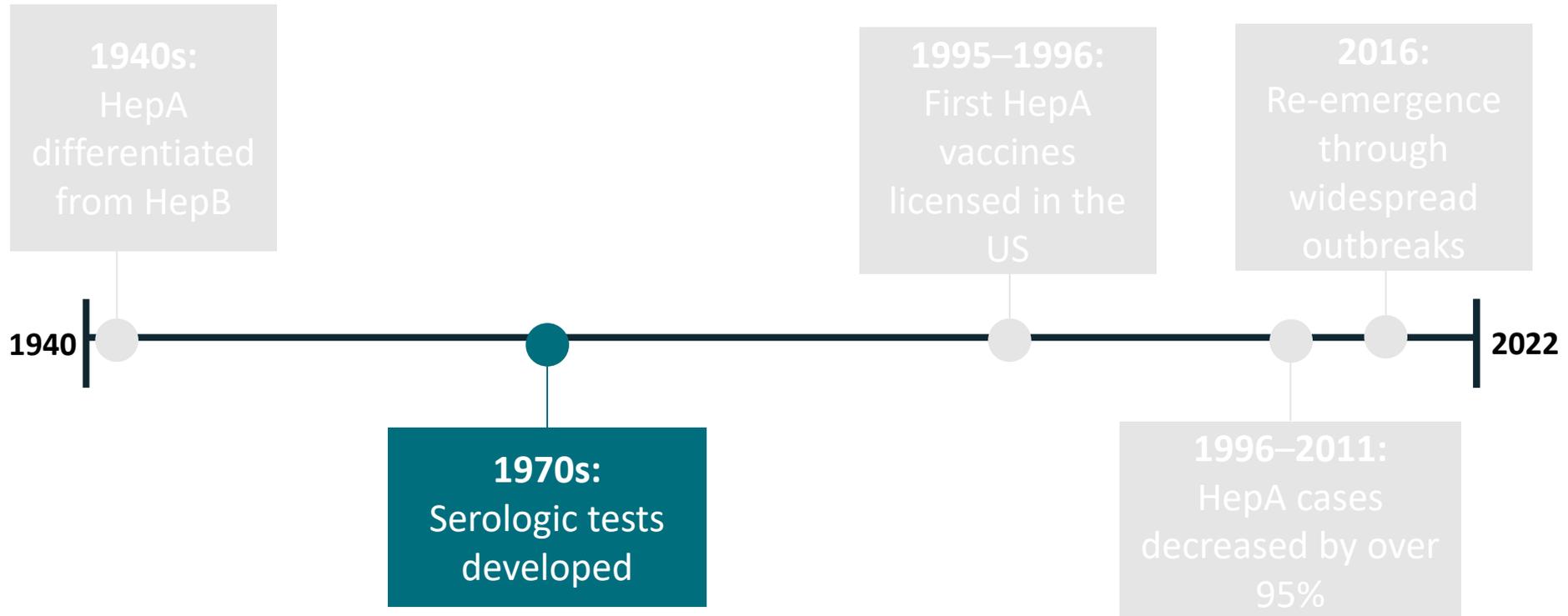
Hepatitis A



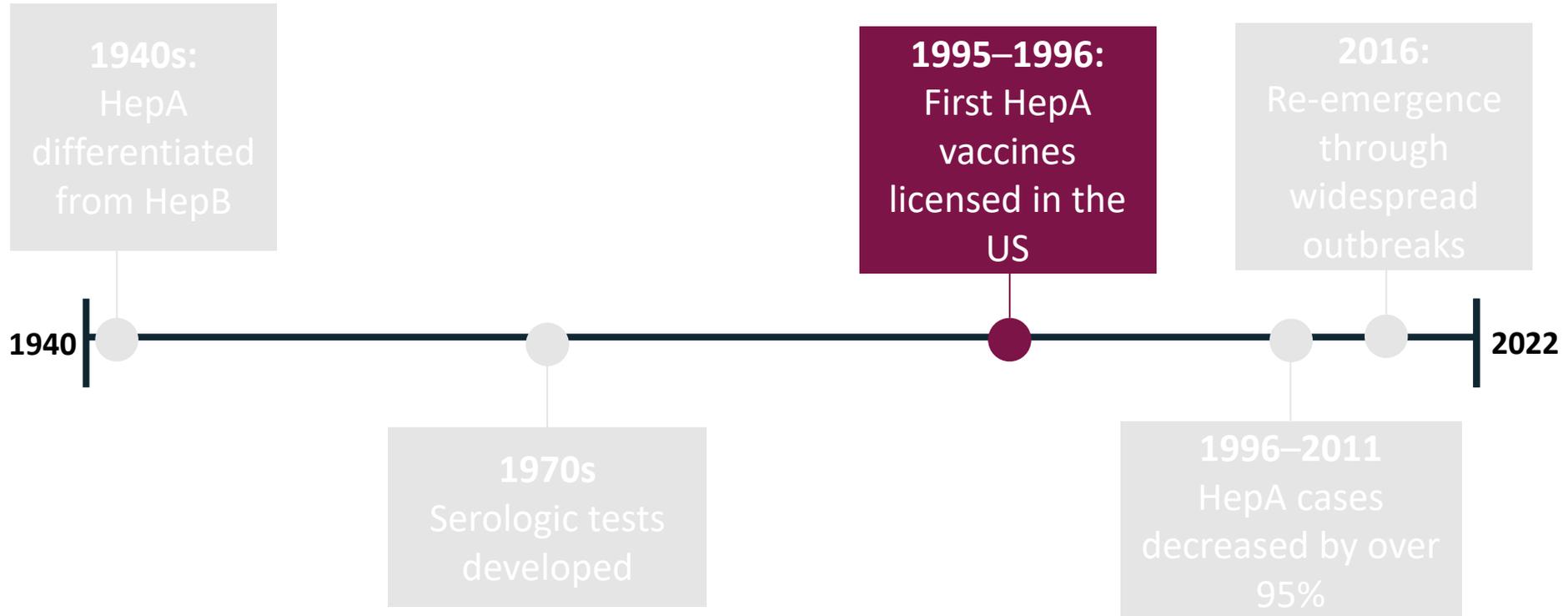
Hepatitis A



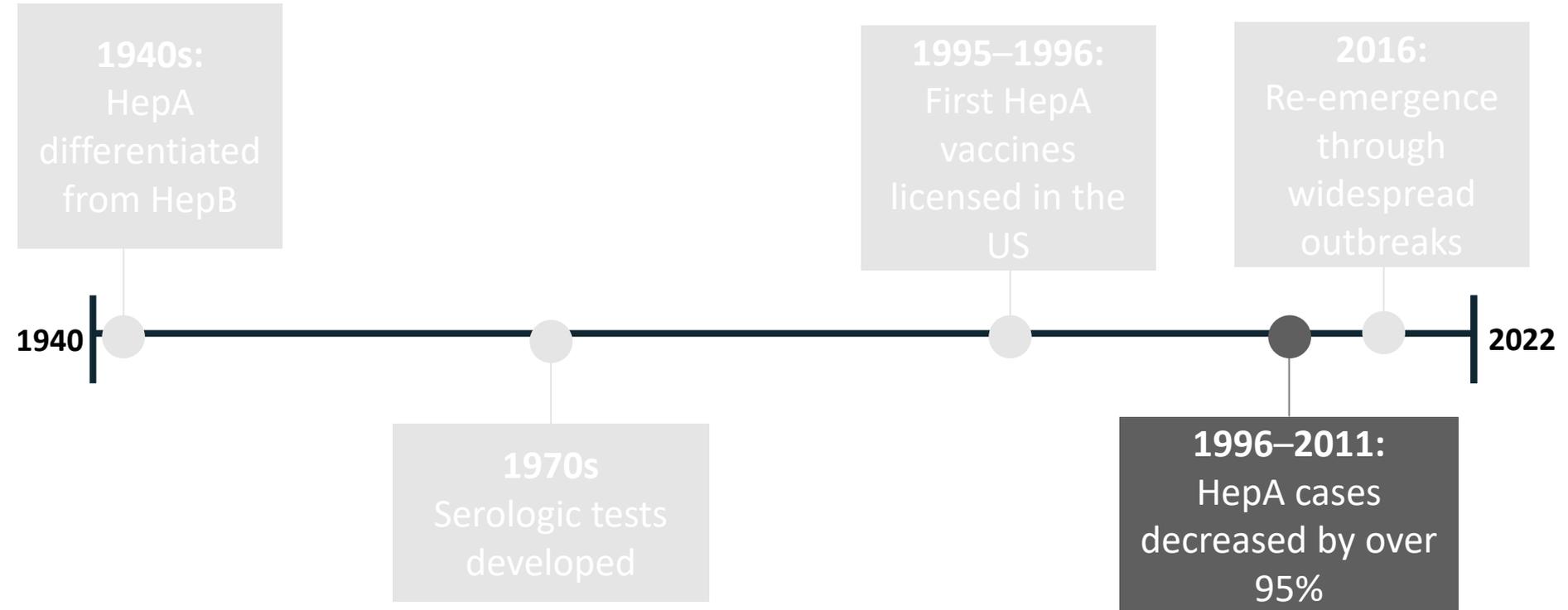
Hepatitis A



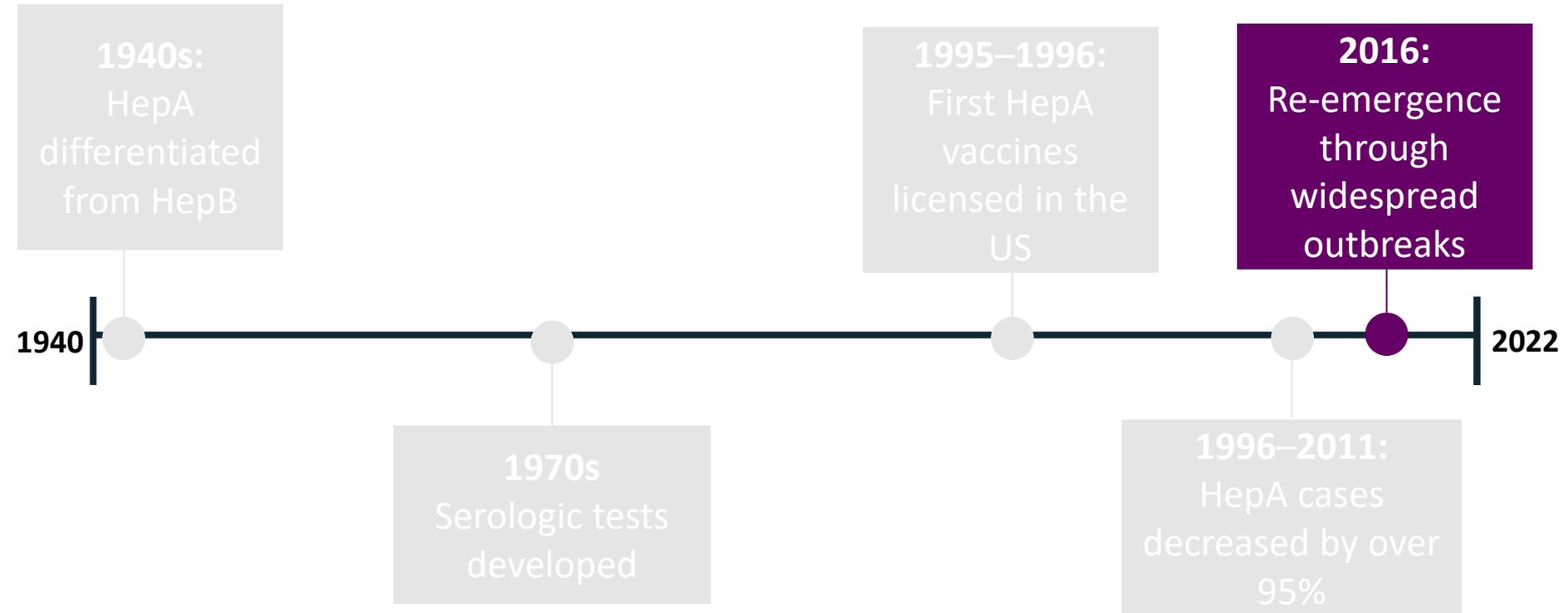
Hepatitis A



Hepatitis A



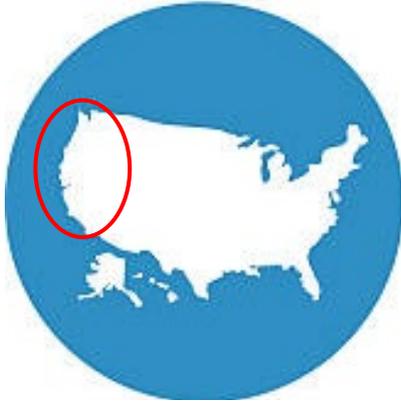
Hepatitis A



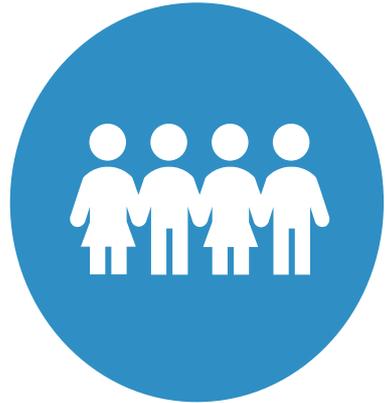
Hepatitis A Prevaccine Era



**Occurred in large,
nationwide epidemics**



**Higher in
western states**



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

Hepatitis A Postvaccination Introduction

**Vaccination
initiation in 1996**

**Fewer than 1
case per 100,000**

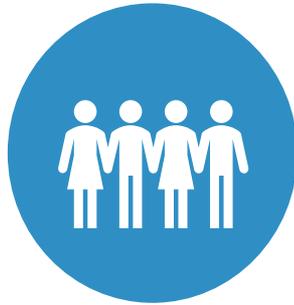
**1996 to 2011:
Cases decreased
95.5% overall**

Person-to-Person Outbreaks of Hepatitis A Across the United States

- Through December 31, 2023



37 states



44,926 cases



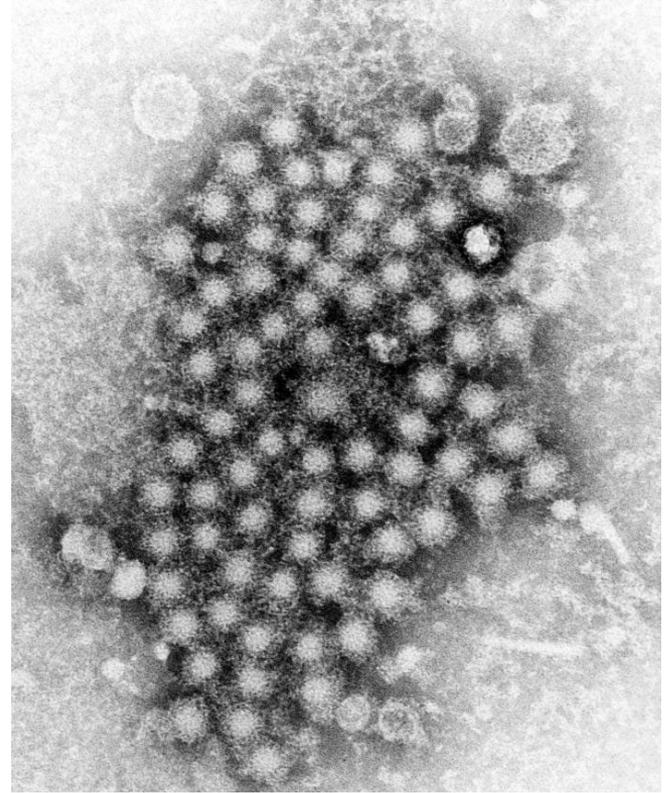
**27,457 (61%)
hospitalizations**



424 deaths

Hepatitis A Virus

- **Picornavirus (RNA)**
- **Humans are only natural host**
- **Stable at low pH**
- **Inactivated by temperature of 185°F or higher, formalin, chlorine**



Hepatitis A Virus (HAV) Transmission and Disease Pathogenesis



**Transmitted by
fecal-oral route**



**Replicates in the
liver**

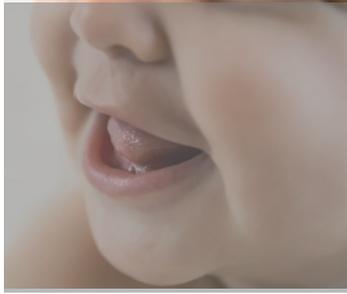


**Viral shedding
1 to 3 weeks**



**Incubation period
28 days
(15 to 50 days)**

HAV Transmission and Disease Pathogenesis



Transmitted by
fecal-oral route



**Replicates in the
liver**



Viral shedding
1 to 3 weeks



Incubation period
28 days
(15 to 50 days)

HAV Transmission and Disease Pathogenesis



Transmitted by
fecal-oral route



Replicates in the
liver



Viral shedding
1 to 3 weeks



Incubation period
28 days
(15 to 50 days)

HAV Transmission and Disease Pathogenesis



Transmitted by
fecal-oral route



Replicates in the
liver



Viral shedding
1 to 3 weeks



**Incubation period
28 days
(15 to 50 days)**

Hepatitis A Clinical Features

- **Inapparent (asymptomatic; no elevation of serum aminotransferase levels)**
 - 50% to 90% of infections acquired before the age of 5 years are asymptomatic.
- **Subclinical (asymptomatic; elevated serum aminotransferase levels)**
- **Clinically evident (with symptoms)**
 - 70% to 95% of infected adults will have symptoms.
 - Prodromal phase: fatigue, malaise, anorexia, fever, myalgias, dull abdominal pain, nausea, vomiting
 - Hepatitis: darkening of the urine, jaundice and pale-colored stools, appear after several days to a week
 - Extrahepatic complications: rare
- **Usually resolves within 2–3 months; complete recovery within 6 months**

Groups at Highest Risk for HAV Infection or Serious Complications

- **People at increased risk for HAV infection**
 - International travelers
 - Men who have sex with men
 - People who use illegal drugs (injection or non-injection drugs)
 - People with occupational risk for exposure (e.g., work with HAV in a lab)
 - 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 (HIV) infection

2

Hepatitis A Vaccines

Hepatitis A-Containing Vaccines

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



Hepatitis A-containing Vaccines in the United States

Vaccine Product	Age Indications
HAVRIX (GSK)	
Pediatric formulation	1–18 years
Adult formulation	19 years and older
VAQTA (Merck)	
Pediatric formulation	1–18 years
Adult formulation	19 years and older
TWINRIX (HepA/HepB; GSK)	
Adult formulation	18 years and older

[HAVRIX | FDA](#)

[VAQTA | FDA](#)

[TWINRIX | FDA](#)

Hepatitis A Vaccines

	Pediatric	Adult
HAVRIX	720 ELU (0.5 ml)	1440 ELU (1 ml)
VAQTA	25 U	50 U

ELU enzyme-linked immunosorbent assay units of inactivated HepA virus

U units of HepA antigen

Hepatitis A Vaccine

- **TWINRIX (HepA-HepB) combination vaccine contains:**
 - Hepatitis A 720 ELU (pediatric dose)
 - Hepatitis B 20 mcg (adult dose)

Hepatitis A Vaccine Efficacy*

Vaccine*	Site and Age Group	Number in Trial	Vaccine Efficacy (95% CI)
VAQTA, Merck, Sharpe, and Dohme (MSD) ¹	New York 2–16 years	1,037	100% (85–100%) [§]
HAVRIX, SmithKline Beecham (SKB) ²	Thailand 1–16 years	38,157	94% (74–98%)

*Pediatric formulation

[§] Determined 6–18 months after dose 1

Immunogenicity of Hepatitis A Vaccines

- **All licensed vaccines are highly immunogenic when administered to children and adolescents according to multiple schedules.**
 - 97%–100% of persons aged 2–18 years had protective levels of antibody 1 month after receiving the first dose.
 - 100% had protective levels 1 month after the second dose
- **Persistence of Anti-HAV antibodies**
 - Persist in vaccine recipients for at least 20 years after infant vaccination and at least 25 years after vaccination in childhood
 - Persist for at least 20 years in adults vaccinated with a 2-dose schedule as adults

Clemens R, et al. <https://pubmed.ncbi.nlm.nih.gov/7876648/>; McMahon BJ, et al. <https://pubmed.ncbi.nlm.nih.gov/7876615/>;

Nalin, DR. VAQTA hepatitis A vaccine, purified inactivated. *Drugs Future* 1995;20:24-29; Van Herck K, et al. <https://pubmed.ncbi.nlm.nih.gov/16117704/>;

Sharapov UM, et al. <https://pubmed.ncbi.nlm.nih.gov/22371069/> Mosites E, et al. <https://pubmed.ncbi.nlm.nih.gov/32535018/>; Ramaswamy M, et al. <https://pubmed.ncbi.nlm.nih.gov/33448443/>

3

Hepatitis A Vaccination and Clinical Considerations

Hepatitis A 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).

Vaccine and other immunizing agents	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)	No recommendation/ not applicable				See Notes		2-dose series, See Notes			Range of recommended ages for catch-up vaccination							



No recommendation/
not applicable



Range of recommended ages
for certain high-risk groups



Range of recommended
ages for all children



Range of recommended ages
for catch-up vaccination

Hepatitis A Recommended Adult Immunization Schedule by Age Group, United States, 2024

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024

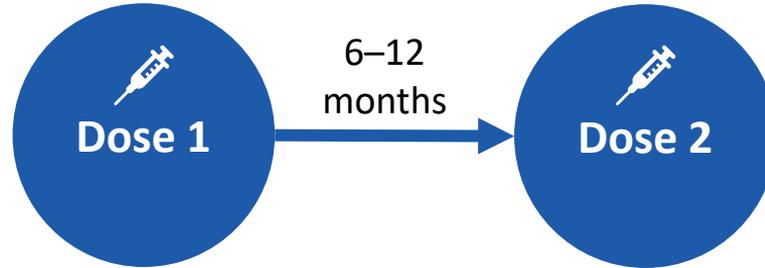
Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			

Recommended vaccination for adults with an additional risk factor or another indication

Hepatitis A Vaccination Schedule

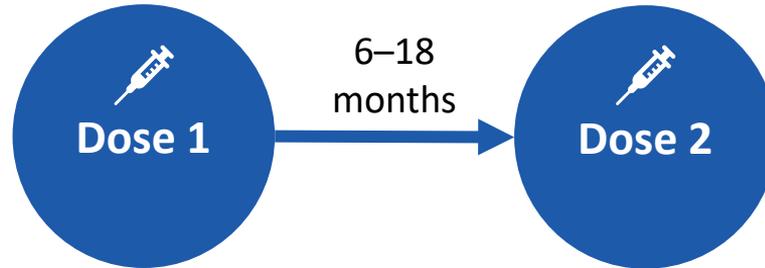
HAVRIX

- 2-dose: 0, 6–12 months
 - Children, adolescents, and adults



VAQTA

- 2-dose: 0, 6–18 months
 - Children, adolescents, and adults

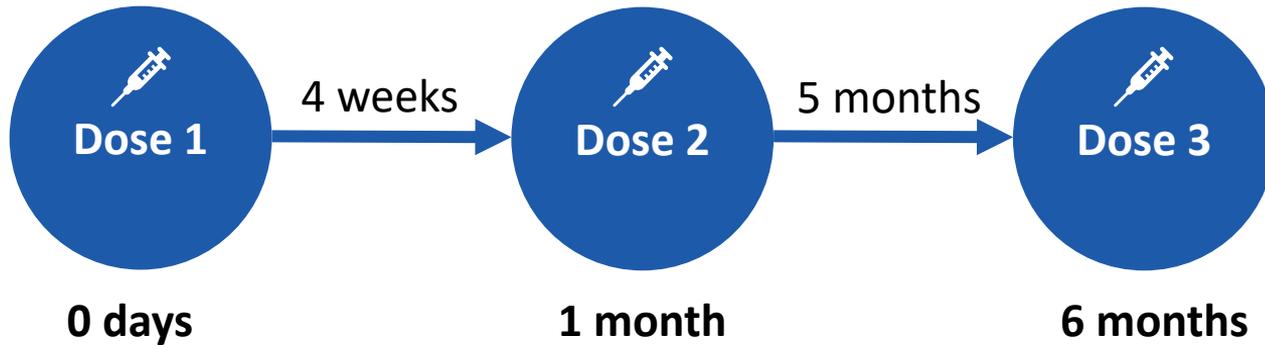


The same product is preferred, but vaccines are interchangeable.

Hepatitis A Vaccination Schedule

TWINRIX

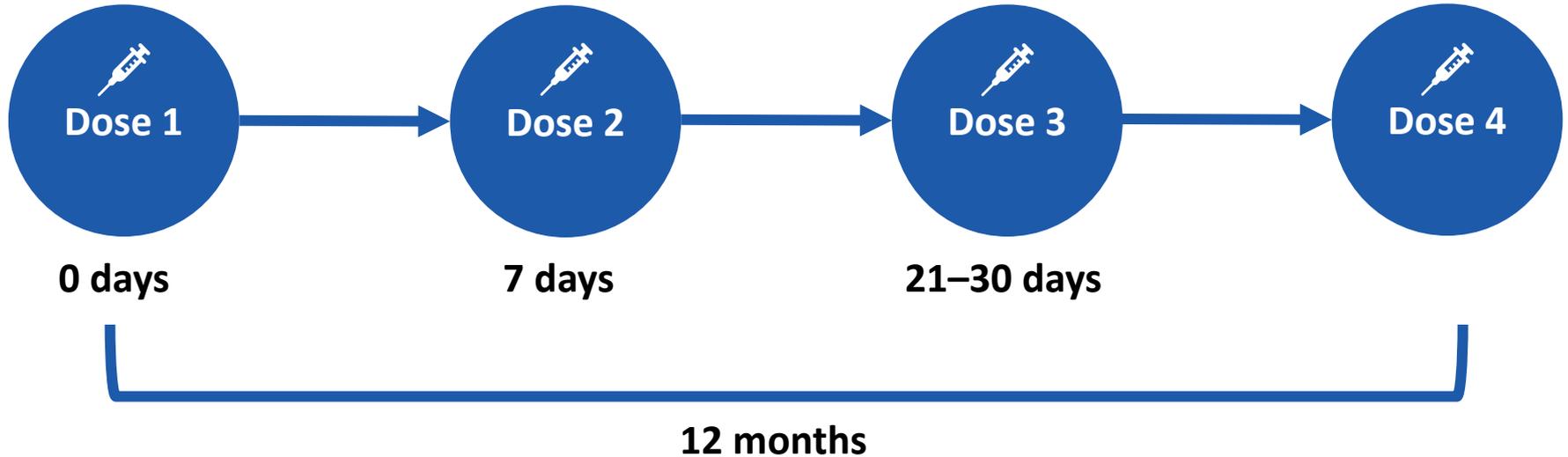
- 3-dose: 0, 1, 6 months
Adults



Hepatitis A Adult Vaccination Schedule: TWINRIX

TWINRIX

- 4-dose: days 0, 7, 21–30, followed by booster dose 12 months after 1st dose



TWINRIX and Single-component Hepatitis A Vaccine

- **Single-component HepA vaccine may be used to complete a schedule begun with TWINRIX, and vice versa.**
 - Formulation of single-component vaccine used depends on age:
 - Use pediatric formulation if 18 years of age or younger
 - Use adult formulation if 19 years of age or older
- **Acceptable schedules:**
 - 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



Knowledge Check

Twinrix, a combination vaccine containing hepatitis A and hepatitis B vaccines, is FDA approved for use only in people 18 years old or older.

- A. True
- B. False



Answer

Twinrix, a combination vaccine containing hepatitis A and hepatitis B vaccines, is FDA approved for use only in people 18 years old or older.

A. True



B. False

Hepatitis A Vaccination Schedule

Correct dosage
Based on age at
time of dose

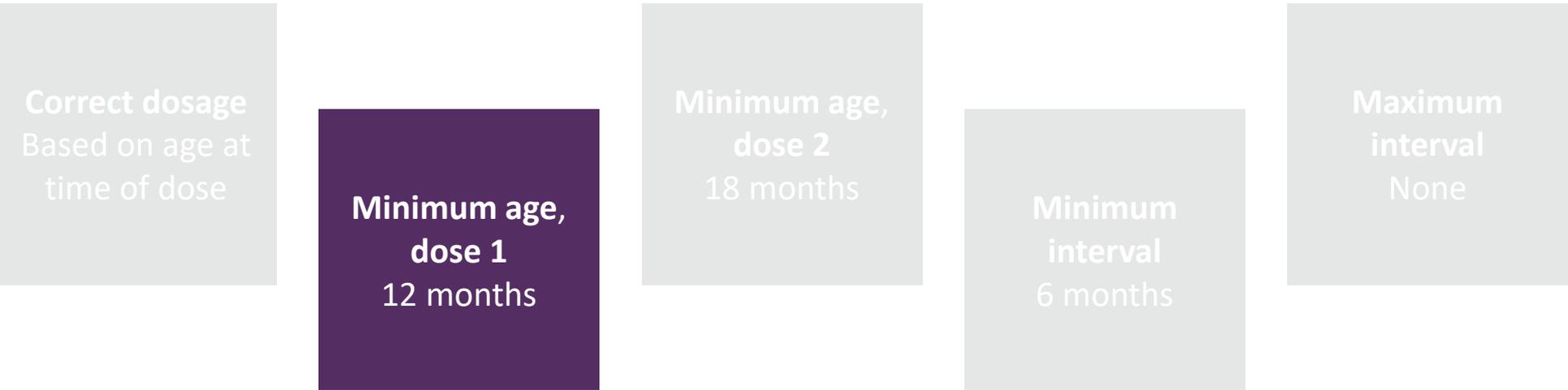
Minimum age,
dose 1
12 months

Minimum age,
dose 2
18 months

Minimum
interval
6 months

Maximum
interval
None

Hepatitis A Vaccination Schedule



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



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 ^{§§}

HAV Hepatitis A virus

HepA hepatitis A

IG immune globulin

Hepatitis A Vaccine for International Travelers: Infants

- When indicated, administer 1 dose HepA to infants ages 6–11 months traveling outside the United States.



Ages 6–11 months*

*Off-label recommendation

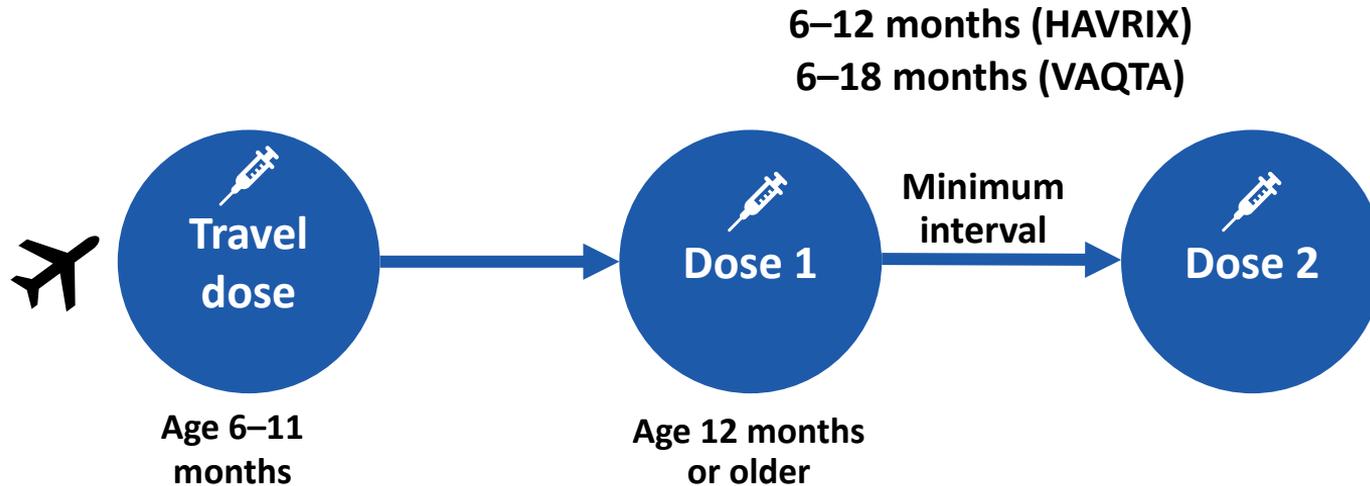
Hepatitis A Vaccine for International Travelers: Infants

- This travel-related dose does not count toward the routine 2-dose series.
 - It is not considered a valid dose.



Hepatitis A Vaccine for International Travelers: Infants

- Initiate routine 2-dose series at age 12 months or older.



This travel-related dose is not valid toward the routine 2-dose series.

Hepatitis A Vaccination for International Travelers: Children and Adults

- **Administer Hepatitis 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 United States where protection against hepatitis A is recommended.
 - One dose monovalent HepA vaccine protects most people.
 - 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 vaccine 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?

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

HepA Vaccination Additional Recommendations

- **Not routinely recommended for:**



Healthcare personnel



**Childcare
staff**



**Sewer workers
or plumbers**



**Persons receiving
blood products for
clotting disorders**

- **Food handlers may consider hepatitis A vaccination based on local circumstances.**
- **Any adult who wants to reduce their risk of hepatitis A can get vaccinated.**

Postexposure Prophylaxis (PEP)

- **HepA vaccine within 2 weeks of exposure to unvaccinated, recently exposed persons ages 12 months or older**
- **Coadministration of immune globulin (IG) (0.1 mL/kg) for certain 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 liver disease should receive both
- **Immune Globulin as PEP**
 - Younger than age 12 months
 - Persons for whom vaccine is contraindicated

4

Safety

HepA Vaccine: Contraindications

- **Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or following a prior vaccine dose**

HepA Vaccine: Precautions

- **Moderate or severe acute illness**



HepA Vaccine Adverse Events

Single-antigen Hepatitis A Vaccines

- Fever
- Injection site erythema
- Injection site swelling
- Rash

HepA - HepB

- Fever
- Headache
- Injection site pain
- Dizziness

Error: Giving a Pediatric Dose to an Adult



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

What should you do next?

Error: Giving a Pediatric Dose to an Adult



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

What should you do next?

- If error discovered the same clinic day, administer another “half” dose.
- If error discovered later, the dose is invalid.
- Administer a full adult repeat dose (no minimum interval).

Error: Giving an Adult Dose to a Child



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

What should you do next?

Error: Giving an Adult Dose to a Child



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

What should 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.

5

Storage and Handling

Hepatitis A Vaccine Storage and Handling

- **Store hepatitis A vaccine in a refrigerator between 2°C and 8°C (36°F and 46°F).**
 - Do not freeze
 - Discard if the vaccine has been frozen
- **Store pediatric and adult formulations:**
 - In the original packaging with the lids closed
 - In a labeled bin or area of the storage unit, not next to other vaccines
- **No diluent**

Storage and Handling Practices: Using Storage Labels

Havrix (HepA)

Store between 2°C and 8°C (36°F and 46°F)

Ages: 12 months and older
Presentation: Manufacturer-filled syringe
Do Not Freeze



Updated 3/6/2024

Vaqta (HepA)

Store between 2°C and 8°C (36°F and 46°F)

Ages: 12 months and older
Presentation: Single-dose vial OR manufacturer-filled syringe
Do Not Freeze



Updated 3/6/2024

Twinrix (HepA/B)

Store between 2°C and 8°C (36°F and 46°F)

Ages: 18 years and older
Presentation: Manufacturer-filled syringe
Do Not Freeze



Updated 3/6/2024

6

Hepatitis A Resources

Hepatitis A Resources

ACIP Hepatitis A Vaccine Recommendations | CDC

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepa.html>

Ask The Experts: Hepatitis A | Immunize.org

https://www.immunize.org/askexperts/experts_hepa.asp

Hepatitis A | Hepatitis A | CDC

<https://www.cdc.gov/hepatitis/hav/index.htm>

Hepatitis A Vaccination: For Healthcare Providers | CDC

<https://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html>

Hepatitis A Resources

Outbreaks of Hepatitis A Across the U.S. | CDC

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

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

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

Standing Orders For Administering Hepatitis A Vaccine to Children and Teens (Immunize.org)

<https://www.immunize.org/catg.d/p3077a.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



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