

# **Model Immunization Protocol**

Typhoid Vaccines (Typhim Vi®, Vivotif®)			
Last Reviewed	12 December 2024		
Last Revised	12 December 2024		
This order expires	31 December 2026		

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### 1. What's new

Biennial review. No substantive changes.

# 2. Oregon immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications and precautions.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.

- E. For injectable typhoid vaccine, verify needle length for intramuscular (IM) injection.
- F. For injectable typhoid vaccine, ensure epinephrine hydrochloride solution (1:1,000), oxygen and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction. Refer to <u>Guidelines for Managing Adverse Events Following Immunization</u>.
- G. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- H. Ask client to remain seated in the clinic for 15 minutes after injectable vaccination to decrease the risk of injury should they faint.
- I. For oral typhoid vaccine, provide patient instructions for use.

Health Officer Signature	Date
Health Officer Signature	Date

# 3. Vaccine schedule for Typhoid

# Typhim Vi<sup>3</sup>

Dose and Route: 0.5 mL, IM			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	≥2 years	≥2 years	
Booster			2 years since last dose, if needed

# Vivotif<sup>2</sup>

Dose and Route: 1 capsule, oral			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	≥6 years	≥6 years	
2			48 hours
3			48 hours
4			48 hours
Booster	Entire series may be repeated every 5 years, if needed.		

# 4. Licensed Typhoid vaccine

Product Name	Vaccine Components	Acceptable Age Range
Typhim Vi <sup>3</sup>	Salmonella Typhi Ty2 strain: 25 µg	≥2 years
Vivotif <sup>2</sup>	Salmonella Typhi Ty21a: 2.0–10.0x10 <sup>9</sup> colony-forming units Nonviable S. Typhi Ty21a: 5–50x10 <sup>9</sup> bacterial cells	≥6 years

### 5. Recommendations for use

- A. Immunization against typhoid fever<sup>1</sup> is indicated for the following groups:
  - a. Travelers to areas in which there is a recognized risk of exposure to Salmonella Typhi, particularly those who will have prolonged exposure to potentially contaminated food and drink.
  - b. Persons with intimate exposure (e.g., continued household contact) to a documented *S*. Typhi carrier.
  - c. Microbiology laboratorians who frequently work with S. Typhi.
- B. Current CDC advisories should be consulted regarding areas with a risk of exposure to *S*. Typhi. Typhoid vaccines are 50–80% effective. Travelers should use caution in consuming food and water, even if vaccinated. Infections with drug-resistant strains can be fatal.<sup>5</sup>
- C. Typhoid vaccines will not protect against serotypes of *Salmonella* other than Typhi.<sup>2,3</sup>
- D. Use of Typhim Vi:3
  - a. May be used in patients ≥2 years of age.
  - b. Booster doses may be given every 2 years if there is expected to be repeated or continued risk of exposure to *Salmonella* Typhi.<sup>1,3</sup>
  - c. Immunization should occur at least two weeks prior to potential exposure to *S.* Typhi.<sup>1</sup>
- E. Use of Vivotif:<sup>2</sup>
  - a. May be used in patients ≥6 years of age.
  - b. Oral vaccines can be administered simultaneously or at any interval before or after other live vaccines (injectable or intranasal) if indicated. This includes live, attenuated yellow fever vaccine or immune globulin if indicated.<sup>1</sup>

- c. When indicated: Oral cholera vaccine should be administered <u>before</u> the oral typhoid vaccine, and at least 8 hours should separate the cholera vaccine and the first dose of typhoid vaccine.<sup>6</sup>
- d. Immunization (i.e., ingestion of all four doses) should be completed at least one week prior to potential exposure to *Salmonella* Typhi.<sup>1</sup>
- e. Instruct patient on proper use of Vivotif:<sup>2</sup>
  - i. Inspect blister pack to ensure that foil seal and capsule are intact.
  - ii. Each capsule should be taken on an empty stomach, ≥ 2 hours after eating and at least 1 hour before the next meal. Swallow one capsule one hour before a meal with cold or lukewarm water (≤37°C or 98.6°F), on alternate days (days 1, 3, 5, 7).
  - iii. Do not chew capsule.
  - iv. Swallow as soon as possible after placing in mouth.
  - v. Do not expose capsule to direct sunlight.
  - vi. It is essential to replace unused vaccine in the refrigerator between doses.
  - vii. Patient should call vaccine administrator if vaccine is taken incorrectly or mishandled.
- f. Dispense vaccine with prescription label and provide client with adequate insulation for safe transport (e.g., provide sufficient ice on warm days to protect vaccine until client can get the vaccine into cold storage).
- g. Re-immunization is recommended every five years for persons under conditions of repeated or continued exposure to *Salmonella* Typhi.<sup>1</sup>

### 6. Contraindications:

A. History or hypersensitivity to any component of the vaccine.

Vaccine	Excipients <sup>7</sup>
Typhim Vi	Formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride.
Vivotif	Sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin.

#### B. Vivotif:

 a. Do not give during an acute febrile illness. Postpone vaccination if persistent diarrhea or vomiting is occurring.

- b. Do not use during pregnancy.1
- c. Do not use in immunocompromised patients.1
- d. Oral typhoid vaccine should not be given to people taking antibacterial agents, as these may inactivate the vaccine. Vivotif should not be given until at least 3 days after the last dose of antimicrobial agent and, if possible, antimicrobial agents should not be started within 3 days of the last dose of Vivotif vaccine. A longer interval should be considered for long-acting antimicrobials (e.g., azithromycin).<sup>1</sup>
- e. Do not administer to children less than six years of age.2

# 7. Warnings and precautions:

#### A. Vivotif:

- a. Chloroquine and atovaquone-proguanil at doses used for malaria chemoprophylaxis can be given concurrently with oral typhoid vaccine. For guidance on concurrent administration of oral typhoid vaccine with other malarial medications, contact the CDC malaria hotline/clinical consult service at malaria@cdc.gov.5
- b. Vivotif should not be used for treatment of typhoid fever.<sup>2</sup>

### B. Typhim Vi:

- a. Acute or febrile illness may be reason for delaying use of this vaccine except when, in the opinion of the physician, withholding the vaccine entails a greater risk.<sup>3</sup>
- b. Vaccination of pregnant women should occur only if clearly needed.<sup>1</sup> The manufacturer of Typhim Vi recommends not vaccinating during the first trimester.<sup>3</sup>
- c. Typhim Vi should not be used to treat a patient with typhoid fever or a documented carrier.<sup>3</sup>

### 8. Other considerations

- a. Pregnancy: See sections 6 and 7.
- b. Breastfeeding: Breastfeeding mothers should be vaccinated according to the recommended schedule. Administration of most live or inactivated vaccines does not affect breastfeeding, breast milk, or the process of lactation.<sup>5</sup>

### 9. Side effects and adverse reactions

Adverse Event (Typhim Vi) <sup>3</sup>	Frequency
Injection site reactions (pain at the injection site,	Up to 97%
redness, swelling)	
Systemic reactions (malaise, nausea, diarrhea)	Up to 8%
Headache	Up to 16%
Fever	Up to 3%
Adverse Event (Vivotif) <sup>2</sup>	Frequency
Abdominal pain	Up to 6.5%
Nausea, diarrhea, vomiting	Up to 6%
Fever	Up to 3.3%

# 10. Storage and handling

All clinics enrolled with the Vaccines for Children (VFC) Program must <u>immediately</u> report any storage and handling deviations to the Oregon Immunization Program at 800-980-9431.

Vaccine	Temp	Storage Issues	Notes
Typhim Vi <sup>3</sup>	2–8°C (36– 46°F)	Do not freeze	
Vivotif <sup>2</sup>	2–8°C (36– 46°F)		Not stable when exposed to ambient temperatures. Expiration date is valid only if the cold chain has been maintained.

# 11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>.

# VAERS Reporting Table:

https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf

Event and interval from vaccination	
N/A	

### 12. References

1. Jackson B, Iqbal S, Mahon B. Updated recommendations for the use of typhoid vaccine – Advisory Committee on Immunization Practices, United States, 2015. MMWR 2015; 64:305–8. Available at:

- <u>www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a4.htm</u>. Accessed 12 Dec 2024.
- 2. Typhoid Vaccine Live Oral Ty21a (Vivotif®) package insert 2013. Available at: www.fda.gov/media/75988/download. Accessed 12 Dec 2024.
- 3. Typhoid Vi Polysaccharide Vaccine (Typhim Vi®) package insert 2020. Available at: <a href="https://www.fda.gov/media/75993/download">www.fda.gov/media/75993/download</a>. Accessed 12 Dec 2024.
- 4. Kroger A, Bahta L, Long S, Sanchez P. General Best Practices for Immunizations. . Available at: <a href="https://www.cdc.gov/vaccines/hcp/imz-best-practices">www.cdc.gov/vaccines/hcp/imz-best-practices</a>. Accessed 12 Dec 2024.
- 5. CDC. Yellow Book: Health Information for International Travel. 2024. Available at <a href="https://wwwnc.cdc.gov/travel/page/yellowbook-home">https://wwwnc.cdc.gov/travel/page/yellowbook-home</a>. Accessed 12 Dec 2024.
- Collins J, Ryan E, Wong K, et al. Cholera vaccine: Recommendations of the Advisory Committee on Immunization Practices, 2022. Available at: <a href="https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7102a1-H.pdf">www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7102a1-H.pdf</a>. Accessed 12 Dec 2024.
- 7. CDC. Vaccine Excipient Summary 2021. Available at: <a href="https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf">www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf</a>. Accessed 12 Dec 2024.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 0800-980-9431 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: <a href="https://www.oregon.gov/standing-protocols">www.oregon.gov/standing-protocols</a>