TYPHOID VI POLYSACCHARIDE INACTIVATED VACCINE

I. ORDER FOR ADMINISTRATION

- 1. Screen for contraindications.
- 2. Provide a current Vaccine Information Statement (VIS), answering questions.
- 3. Obtain a signed Vaccine Administration Record (VAR).
- 4. Give a single 0.5 ml dose of Typhoid vaccine intramuscularly to eligible persons ≥18 years of age.
- 5. There are no known interactions of Typhim Vi® vaccine with drugs or foods. No studies have been conducted in the US to evaluate interactions or immunological interference between the concurrent use of Typhim Vi® vaccine and drugs (including antibiotics and antimalarial drugs), immune globulins or other vaccines (including common travelers vaccines).

Pharmacist signature Date

Electronic copy of this protocol available at http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml

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II. LICENSED TYPHOID VI POLYSACCHARIDE VACCINE

Product	Vaccine components	Acceptable	Preservatives
Name		Age Range	
Typhim Vi ®	25 μg of purified Vi polysaccharide	≥2 years	No Thimerosal
(sanofi-			
pasteur)			

III. INDICATIONS FOR USE

Typhim Vi® vaccine is indicated for active immunization against typhoid fever for persons two years of age or older.

Immunization with Typhim Vi® vaccine should occur at least two weeks prior to expected exposure to *Salmonella* Typhi.

Typhim Vi® vaccine is not indicated for routine immunization of individuals in the United States. Immunization against typhoid fever is indicated for the following groups:

- 1) Travelers to areas in which there is a recognized risk of exposure to S. Typhi, particularly those who will have prolonged exposure to potentially contaminated food and drink.
- 2) Persons with intimate exposure (i.e., continued household contact) to a documented S. Typhi carrier, and
- 3) Microbiology laboratorians who frequently work with S *typhi*.

Current CDC advisories should be consulted with regard to areas with a risk of exposure to S. Typhi. Travelers should use caution in selecting food and water, even if vaccinated.

An optimal re-immunization schedule has not been established. Re-immunization every two years under conditions of repeated or continued exposure to *Salmonella* Typhi is recommended.

The vaccine will not protect against serotypes of Salmonella other that *S.* Typhi.

IV. VACCINE SCHEDULE FOR TYPHOID VI POLYSACCHARIDE				
DOSE	RECOMMENDED AGE	DOSAGE SCHEDULE	BOOSTER	
1	≥18year of age ^{1,2}	Single injection of 0.5	After 2 years ³	
	,	ml Intramuscularly ²		

¹Although this vaccine is licensed for persons ≥2 years of age, Oregon pharmacist's, by law, currently may not administer this vaccine to persons <18 years of age.

V. CONTRAINDICATIONS & PRECAUTIONS

Contraindications	Precautions		
1. History or hypersensitivity to any component of this vaccine.	Acute infection or febrile illness may be reason for delaying use of this vaccine.		
	2. No animal reproduction studies that have been conducted with this vaccine. It should be given to pregnant women only if clearly needed. When possible, delaying vaccine until the second or third trimester is a reasonable precaution.		
	3. It is not known if typhoid Vi polysaccharide is excreted in human milk. There are no data to warrant the use of this product in nursing mothers for passive antibody transfer to an infant.		
	4. Safety and effectiveness of this vaccine have been established in children ≥ 2 years of age. For children below the age of 2, safety and effectiveness have not been established.		

²The dose is given intramuscularly, in the deltoid in adults and either the deltoid or the vastus lateralis for children.

³ Reimmunization of US travelers with a single 0.5 ml dose every two years under conditions of repeated or continued exposure to Salmonella Typhi is recommended.

VI. ADVERSE REACTIONS

Systemic events may include fever (100.4° F in 1% of vaccinees) and headache (1.5%–3% of vaccinees). Localized reactions include injection site pain, erythema, and induration; these usually resolve within 48 hours.

VII ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per Oregon Revised Statute 855-041-0510.

VIII. OTHER CONSIDERATIONS

- 1. This vaccine has not been evaluated for carcinogenic potential, mutagenic potential, or impairment of fertility.
- 2. If typhoid Vi polysaccharide vaccine is administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected immune response may not be obtained.
- 3. Even in a susceptible individual with normal immune function, vaccination with this vaccine is not expected to protect 100% of susceptible persons. In all instances, travelers are advised to take personal precautions to minimize their exposure to contaminated food and drink.

IX. STORAGE & HANDLING

Parenteral drug products should be inspected visually for particulate matter or discoloration prior to administration. If either of these are seen, the vaccine should not be administered.

The vaccine is a clear, colorless solution.

Vaccine should be stored between 2-8°C (35-46°F). Do not freeze.

X. REFERENCES

CDC. Typhoid vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR, 1994; 43 (No. RR-14); 1–7. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00035643.htm

Sanofi pasteur. Typhim Vi® package insert. Available at: http://www.vaccineshoppe.com/image.cfm?doc_id=9373&image_type=product_pdf.

CDC. Typhoid Fever. In: Health Information for International Travel 2008 Atlanta: U.S. Department of Health and Human Services, Public Health Service, 2008: 345–9. Available at: http://wwwn.cdc.gov/travel/yellowBookCh4-Typhoid.aspx