

# **Immunization Protocol**

Rabies Vaccine (Imovax®, RabAvert®)		
Last Reviewed	09 May 2024	
Last Revised	09 May 2024	
This order expires	31 May 2026	

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### 1. What's new

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. Verify needle length for intramuscular (IM) injection.
- F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks and use proper IM administration technique.
- G. Ensure epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction.
- H. Administer a 1.0-mL dose of rabies vaccine according to the appropriate schedule and indication.
- I. If administering post-exposure prophylaxis, assess patient's tetanus vaccination status and co-administer, if indicated.
- J. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature	Date
Health Officer Signature	Date

# 3. Vaccine schedule for rabies<sup>3,5</sup>

# **Pre**-exposure prophylaxis

Dose and Route - 1.0 mL, IM <sup>3</sup>		
Dose	Minimum acceptable age	Spacing
1	All age groups	Day 0
2		Day 7
Booster		See section 5, recommendations for use.

# Post-exposure prophylaxis - unvaccinated person<sup>3</sup>

Dose and Route – 1.0 mL, IM		
Dose	Minimum acceptable age	Spacing
1		Day 0
2	All age groups	Day 3
3		Day 7

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4	Day 14
5*	Day 28

<sup>\*</sup> Necessary only for patients who are immunocompromised.

# Post-exposure prophylaxis - previously vaccinated person<sup>3</sup>

Dose and Route – 1.0 mL, IM		
Dose	Minimum acceptable age	Spacing
1	All age groups	Day 0
2		Day 3

# 4. Licensed Rabies vaccines<sup>1,2</sup>

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Imovax		Single-dose vial of freeze-dried vaccine	Licensed for all	
RabAvert	Rabies	and diluent in a pre- filled syringe	ages	No

# 5. Recommendations for use<sup>3,4</sup>

A. Pre-exposure for high-risk persons.<sup>3</sup>

Risk Category	Who this typically affects	Recommendations
Category 1	Laboratory workers handling live or	2-dose pre-exposure
Highest risk	concentrated rabies virus	prophylaxis. Check titer every 6 months; booster if
		titer <0.5 IU/mL.
Category 2	People frequently handling bats, having	2-dose pre-exposure
	contact with bats or entering high-	prophylaxis. Check titer
	density bat environments.	every 2 years; booster if titer
	People performing animal necropsies.	<0.5 IU/mL.
Category 3	People who interact with mammals that could be rabid (other than bats). Risk conditions last longer than 3 years after	2-dose pre-exposure prophylaxis, <b>plus</b> :
	receiving pre-exposure prophylaxis.	Check titer once 1 to 3 years after pre-exposure
	This group includes most:  - Veterinarians  - Veterinary technicians	prophylaxis; booster if titer <0.5 IU/mL.

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	<ul> <li>Animal control officers</li> <li>Wildlife biologists</li> <li>Wildlife rehabilitators</li> </ul>	OR 1 dose booster between 3
	<ul><li>Trappers</li><li>Spelunkers (cave explorers)</li></ul>	weeks and 3 years following pre-exposure prophylaxis.
Category 4	Same risk factors as category 3 but at risk for less than 3 years after receiving pre-exposure prophylaxis.  This group includes: International travelers to endemic or high-risk countries.	2 dose pre-exposure prophylaxis
Category 5	General U.S. population	None

# B. Pre-exposure prophylaxis for persons with altered immunocompetence:

For persons with altered immunity, the same series is recommended, but a titer is needed after completion of the vaccine series; a rabies antibody titer no sooner than 1 week after completion of the series (but ideally 2–3 weeks after it) should be ≥0.5 IU/mL. If it is not, an additional dose should be administered followed by another titer check. If two such additional doses fail to achieve the minimum acceptable antibody titer, public health authorities should be consulted for case-specific guidance.

C. **Serologic testing** for rabies virus neutralizing antibody is not routinely necessary for high-risk persons working in areas where rabies is uncommon to rare (infrequent exposure group). If these persons are subsequently exposed, they will require post-exposure prophylaxis for a previously vaccinated person.

### D. Post-exposure treatment:4

- a. For unvaccinated persons, a combination of rabies immune globulin (RIG) and 4 vaccine doses is recommended for both bite and nonbite exposures. Unvaccinated persons who are immunocompromised should receive a 5<sup>th</sup> vaccine dose. Use of RIG is not covered in this protocol.
- For persons who have previously received either pre- or postexposure prophylaxis, 2 vaccine doses are recommended, and RIG is not needed.
- c. If the bite was from a dog, cat, or ferret, and the animal is healthy and available for observation, hold prophylaxis unless clinical signs of

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- rabies develop in the animal. If the animal remains healthy for 10 days after the bite, the risk of rabies transmission is negligible, and post-exposure prophylaxis would not be indicated. If the animal is unavailable, consult with public health officials.
- d. If post-exposure prophylaxis has been initiated and laboratory testing of the animal's brain indicates the animal that caused the exposure is not rabid, prophylaxis may be discontinued.

### 6. Contraindications 1-4

- A. **Post-exposure Prophylaxis**: Since rabies is almost always fatal, there are no contraindications to vaccination for post-exposure prophylaxis, including pregnancy.
- B. **Pre-exposure Prophylaxis:** History of anaphylaxis to the vaccine or any vaccine component.

Vaccine	Vaccine Excipient Summary
Imovax (HDCV)	Human albumin, neomycin sulfate, phenol red, beta- propiolactone.
RabAvert (PCECV)	Chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B.

# 7. Warnings and precautions:<sup>3-5</sup>

- A. Immunosuppression: Persons with immunosuppression may be administered pre-exposure prophylaxis with the understanding that the immune response may be inadequate. Patients who are immunosuppressed by disease or medication should postpone pre-exposure prophylaxis and consider avoiding activities for which pre-exposure prophylaxis is indicated. When this is not possible, post-vaccination virus neutralizing antibodies should be checked. A patient who fails to seroconvert after the third dose should be managed in consultation with their physician and the Oregon Acute and Communicable Disease Prevention Section: 971-673-1111; ohd.acdp@oha.oregon.gov
- B. Pregnancy: Pregnancy or breastfeeding is not a contraindication for post-exposure prophylaxis. If the exposure risk is substantial, pre-exposure prophylaxis may be indicated during pregnancy. Certain studies have indicated no increased incidence of abortion, premature births, or fetal abnormalities associated with rabies vaccination. Rabies exposure or the diagnosis of rabies in the mother should not be regarded as reasons to terminate the pregnancy.

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- C. **Allergies:** Persons who have a history of serious hypersensitivity to components of rabies vaccine or to other vaccines with components that are also present in rabies vaccine should be revaccinated with caution.
  - a. RabAvert (purified chick embryo cell vaccine [PCECV]) is produced in chick embryo cell culture. Persons with a history of serious allergic reaction to egg ingestion should be vaccinated with Imovax; if it is unavailable, RabAvert should be used with caution.
  - b. Imovax (human diploid cell vaccine [HDCV]) is produced in human diploid cells.

### 8. Other considerations<sup>5</sup>

For most persons, routine serological testing after pre-exposure or post-exposure prophylaxis to document seroconversion is not necessary unless:

- the person is immunosuppressed;
- significant deviations of the prophylaxis schedule have occurred;
- the patient initiated vaccination internationally with a product of questionable quality;
- the person's antibody status is being monitored routinely due to occupational exposure to rabies virus.

# 9. Side effects and adverse reactions<sup>1,2</sup>

Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually, such reactions can be successfully managed with anti-inflammatory, antihistaminic, and antipyretic agents.

Adverse Event (Imovax and RabAvert)	Frequency
Injection site events (pain)	Up to 84%
Injection site events (itching, redness, swelling)	Up to 45%
Systemic events (malaise, headache, dizziness, myalgia)	Up to 53%

# 10. Storage and handling<sup>1,2</sup>

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 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Imovax and	2°–8 °C	Do not freeze.	Administer immediately
RabAvert		Protect from light.	after reconstitution.

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## 11. Adverse events reporting

Report all 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

### 12. References

- Imovax® package insert October 2019. Available at <u>www.fda.gov/media/75709/download</u>. Accessed 09 May 2024.
- RabAvert® package insert October 2023. Available at <u>www.fda.gov/media/83874/download</u>. Accessed 09 May 2024.
- Use of a modified preexposure prophylaxis vaccination schedule to prevent human rabies: recommendations of the Advisory Committee on Immunization Practices—United States, 2022. MMWR 2022; 71:619–27. Available at: <a href="https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7118a2-H.pdf">www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7118a2-H.pdf</a>. Accessed 09 May 2024.
- 4. Use of a reduced (4-dose) vaccine schedule for postexposure prophylaxis to prevent human rabies. MMWR 2010; 59:1–9. Available at: www.cdc.gov/mmwr/pdf/rr/rr5902.pdf. Accessed 09 May 2024.
- 5. Human rabies prevention—United States, 2008. MMWR 2008; 57(03). Available at: <a href="https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf">www.cdc.gov/mmwr/PDF/rr/rr5703.pdf</a>. Accessed 09 May 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 1-800-980-9431 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/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx">www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx</a>

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