Immunization Pharmacy Protocol

Rabies Vaccine (Imovax®, RabAvert®)	
Last Reviewed	07 June 2022
Last Revised	07 June 2022
This order expires	30 June 2024

Table of contents

1. What's new

Formatting changes. Updated pre-exposure prophylaxis to the currently recommended 2-dose regimen for adults.

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. Administer a 1.0-mL dose of rabies vaccine according to the appropriate schedule and indication.

G. If administering post-exposure prophylaxis, assess patient's tetanus vaccination status and co-administer, if indicated.

H. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks and use proper IM administration technique.

I. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Pharmacist Signature Date

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3. Vaccine schedule for Rabies

Pre-exposure prophylaxis

Dose and Route - 1.0 mL, IM[3]		
Dose	**Minimum acceptable age**	**Spacing**
1	Adults ≥18 years	Day 0
2		Day 7
Booster		See section 5, recommendations for use.

Dose and Route - 1.0 mL, IM[5]		
Dose	**Minimum acceptable age**	**Spacing**
1	Children 7-18 years	Day 0
2		Day 7
3		Day 21-28
Booster		See section 5, recommendations for use.

Post-exposure prophylaxis – unvaccinated person[3]

Dose and Route – 1.0 mL, IM		
Dose	**Minimum acceptable age**	**Spacing**
1	7 years	Day 0
2		Day 3
3		Day 7
4		Day 14
5*		Day 28

* Necessary only for patients who are immunocompromised.

Post-exposure prophylaxis – previously vaccinated person[3]

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

4. Licensed Rabies vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Imovax[1]	Rabies	Single-dose vial of freeze-dried vaccine and diluent in a pre-filled syringe	Licensed for all ages	No
RabAvert[2]				

5. Recommendations for use

A. Pre-exposure for high-risk persons.[3]

Risk Category	Who this typically affects	Recommendations
Category 1 *Highest risk*	Laboratory workers handling live or concentrated rabies virus	2-dose pre-exposure prophylaxis. Check titer every 6 months; booster if titer <0.5 IU/mL.
Category 2	People frequently handling bats, having contact with bats or entering high-density bat environments.	2-dose pre-exposure prophylaxis. Check titer every 2 years; booster if titer <0.5 IU/mL.

	People performing animal necropsies.	
Category 3	People who interact with mammals that could be rabid (other than bats). Risk lasts longer than 3 years after receiving pre-exposure prophylaxis. This group includes most: – Veterinarians – Veterinary technicians – Animal control officers – Wildlife biologists – Wildlife rehabilitators – Trappers – Spelunkers (cave explorers)	2-dose pre-exposure prophylaxis, **plus:** Check titer once after 1 to 3 years after pre-exposure prophylaxis; booster if titer <0.5 IU/mL. **OR** 1 dose booster between 3 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:**[3]

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. Routine serologic testing for rabies virus neutralizing antibody is not 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]

Bite from a dog, cat, or ferret. If healthy and available for observation, hold prophylaxis unless clinical signs of rabies develop. If animal is unavailable, consult with public health officials.

6. Contraindications

A. **Post-exposure Prophylaxis**: Since rabies is almost always fatal, there are no contraindications to vaccination for post-exposure prophylaxis, including pregnancy.[4]

B. **Pre-exposure Prophylaxis:** History of anaphylaxis to the vaccine or any vaccine component.[3]

Vaccine	Vaccine Excipient Summary
Imovax[1]	Human albumin, neomycin sulfate, phenol red, beta-propiolactone.
RabAvert[2]	Chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B.

7. Warnings and precautions:[3-5]

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 Section ohd.acdp@dhsoha.state.or.us.

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.

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 is produced in chick embryo cell culture. Persons with a history of serious allergic reaction to egg ingestion should be vaccinated with Imovax or if unavailable, RabAvert should be used with caution.

b. Imovax is produced in human diploid cells.

8. Other considerations[5]

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; or

• the person's antibody status is being monitored routinely due to occupational exposure to rabies virus.

9. Side effects and adverse reactions

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.[1]

Adverse Event (Imovax[1] and RabAvert[2])	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 30%

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Imovax[1] and RabAvert[2]	2 - 8 °C	Do not freeze.	Administer immediately after reconstitution.

11. Adverse events reporting

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

VAERS Reporting Table:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. N/A

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290(2).

12. References

1. Imovax® package insert October 2019. Available at https://www.fda.gov/media/75709/download. Accessed 07 June 2022.
2. RabAvert® package insert 2018. Available at https://www.fda.gov/media/83874/download. Accessed 07 June 2022.
3. 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(18) 619-627. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7118a2-H.pdf. Accessed 07 June 2022.
4. Use of a Reduced (4-Dose) Vaccine Schedule for Postexposure Prophylaxis to Prevent Human Rabies. MMWR 2010; 59(02) 1-9. Available at: https://www.cdc.gov/mmwr/pdf/rr/rr5902.pdf. Accessed 07 June 2022.
5. Human Rabies Prevention—United States, 2008. MMWR 2008; 57(03). Available at: https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf. Accessed 07 June 2022.

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: model immunization protocols.

Electronic copy of this pharmacy protocol is available at: protocols.