

Exempting a dog or cat from a routine rabies vaccination schedule is a very serious decision and should always be made judiciously since forgoing vaccination has the potential to adversely affect both animal and human health. In order to increase the likelihood that dogs and cats for which a vaccine exemption is in keeping with legal requirements (see excerpt from the *Code of Virginia* below), the Virginia Department of Health asks veterinarians to review the following information prior to applying for a rabies vaccine exemption.

### Rabies vaccination exemption summary and best practices

- Veterinarians must apply for a rabies vaccine exemption via a standard application form available through their local health departments.
- Applications should only be submitted for a dog or cat with a documented medical history that strongly suggests that vaccinating would be life-threatening to that animal.
- If approved, an exemption is valid for 1 (one) year.
- Veterinarians should educate owners that an exemption can be used for obtaining a license for dogs (and, in some localities, a license for cats) in the Commonwealth, but CANNOT be used as a substitute for a current rabies certificate in response to an exposure.
- Veterinarians should educate owners that a dog or cat for which no current rabies certificate can be produced and is assessed as exposed to rabies may be subject to euthanasia or up to 6 months strict isolation as well as a booster vaccination in response to the exposure.
- Veterinarians should caution owners that private businesses such as grooming facilities and boarding kennels may not accept an exemption certificate in lieu of a rabies certificate and so an exempted animal's access to these and other facilities may be limited.
- Veterinarians should caution owners that the governing body of any locality may place restrictions on exempted animals if thought necessary to protect public health and safety.

### Per Code of Virginia § 3.2-6521, paragraph D:

"The Board of Health shall, by regulation, provide an exemption to the requirements of subsection A if an animal suffers from an underlying medical condition that is likely to result in a life-threatening condition in response to vaccination and such exemption would not risk public health and safety. For the purposes of § 3.2-6522, such exemption shall mean that the animal is considered not currently vaccinated for rabies. For the purposes of §§ 3.2-5902, 3.2-6526, and 3.2-6527, such exemption shall be considered in place of a current certificate of vaccination."

Full text available at: <a href="http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+3.2-6521">http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+3.2-6521</a>



Information, including a standardized application form, is available through your local health department. A directory of local health departments can be found at <a href="https://www.vdh.virginia.gov">www.vdh.virginia.gov</a>. When you apply to your local health department for a rabies vaccination exemption, you will be asked to provide information via a standardized application about the dog or cat's medical history with a particular emphasis on how this history informs the likelihood that a life-threatening condition will occur in response to vaccination.

An exclusive list of specific diseases or conditions has not been identified for this process. Veterinarians should review a dog or cat's medical history and apply for an exemption if, based on past documented medical history, they feel a case can be made for vaccination as a life threatening procedure associated with that particular dog or cat. Examples of serious medical conditions that may warrant exemption include, but are not limited to, immune-mediated diseases (e.g., IMHA), injection site sarcoma and vaccine site cutaneous ischemic vasculitis. When anaphylaxis has been a problem for a dog or cat, prior to applying for an exemption, veterinarians should consider strategies such as modifying the vaccination schedule to reduce the number of vaccines given simultaneously, using a nonadjuvanted vaccine, using a subcutaneous rather than an intramuscular route of administration and premedicating the patient with an antihistamine approximately 15 minutes before the vaccination. Chemotherapy may cause a suboptimal response to vaccine, however, some studies would suggest that the assumption that chemotherapy is immunosuppressive in dogs may not be true in all instances and that chemotherapy does not necessarily preclude administration of vaccines.<sup>2,3</sup> In general, in the absence other medical history that could be argued would make vaccination a life-threatening event, age, breed, number of previous rabies vaccinations and/or all indoor lifestyle would generally not be considered conditions that warrant exemption.

Particularly if a dog or cat has a history of a self limiting or mild adverse reaction to a vaccine or there is a baseline of general concern about adverse vaccine reactions in any patient, veterinarians are encouraged to consider such interventions as increasing the intervals between other vaccinations, prioritizing administration of core vaccines, serologic testing to monitor immunity to certain pathogens like feline panleukopenia and canine distemper virus, using a premedication and/or avoiding administering more than one vaccine to that patient per office visit.

Current national guidance in regard to rabies antibody measurements in animals would indicate that rabies antibody levels (i.e., titers) should not be used as a substitute for a current vaccination status in managing rabies exposures or determining the need for booster vaccinations. Interpreting titers as they relate to whether or not a dog or cat will remain well if exposed to rabies is challenging. Rabies antibody levels are a good indicator of a dog or cat's response to the rabies vaccine and antibodies are an important component of protection if a dog or cat is exposed to rabies. However, since other immunologic factors also play a role in preventing rabies and our abilities to measure and interpret those other factors are not well developed, there is concern about using rabies antibody levels as the sole determinant of a dog or cat's immune system to withstand an exposure or need for a routine booster vaccination in accordance with the manufacturer's labeling.



Because of the challenges associated with rabies immunology and because rabies is a fatal disease that can also infect people, it is recommended that evidence of circulating rabies virus antibodies not be used as a substitute for current vaccination in managing rabies exposures.<sup>4,5</sup>

### **Vaccine Safety and Reporting Vaccine Adverse Events**

#### Cats

Although the administration of biological products can never be entirely free of risk, in general, currently available feline vaccines have an excellent safety record. In the most substantial survey to date, adverse reactions were reported for all cats presented to Banfield Pet Hospitals in the United States from 2002 to 2005. In that time, 2,560 vaccine-associated adverse events (VAAEs) were documented within 30 days of administration of 1,258,712 doses of vaccine to 496,189 cats (51.6 VAAEs/10,000 cats vaccinated). Ninety two percent of these reactions were reported within the first 3 days and, where clinical signs associated with the adverse event were reported (66% of cases), lethargy with or without fever was the most common adverse event reported. Of the 496, 189 cats included in this study, death was reported in four cats. This study found that the risk of an adverse event significantly increased as the number of vaccines per office visit increased.<sup>6,7</sup>

In regard to injection site sarcoma (ISS) development, current estimates based on larger epidemiologic studies (published between 2002 and 2007) suggest that the risk of sarcoma development following vaccination is actually very low (probably well below 1/10,000 doses of vaccine). In one web based survey, participants reported administering 61,747 doses of vaccine to 31,671 cats. Postvaccinal inflammatory reactions developed in 73 cats (11.8 reactions/10,000 vaccine doses), and qualifying vaccine site-associated sarcomas developed in 2 cats. A large, multicenter case-control study of risk factors associated with vaccine-associated sarcomas in cats, did not find that any single manufacturer or vaccine brand that had a significantly higher or lower association with group (case vs control) as compared with any other manufacturer or brand. 8,9

#### Dogs

Today, it is generally agreed that canine vaccines have an excellent safety record. Although documentation associated with vaccine associated adverse events in veterinary medicine is limited, severe adverse reactions are considered uncommon.<sup>10</sup>

In a retrospective cohort study of more than a million dogs, risk factors were investigated for adverse events documented within 3 days of vaccination. In this study, 4,678 adverse events (38.2/10,000 dogs vaccinated) were associated with administration of 3,439,576 doses of vaccine to 1,226,159 dogs. Most events were



recorded the same day as the vaccination, with clinical signs consistent with type I hypersensitivity such as facial edema, urticaria, generalized pruritis, and vomiting. Death was reported in association with vaccination in 3 dogs equating to 2.4 deaths/1,000,000 dogs vaccinated. The greatest risk was associated with the total number of vaccines received at the office visit. In addition, risk for dogs that weighed equal to or less than 5 kg was more than 4 times the risk for dogs that weighed greater than 45kg.<sup>11</sup>

### Reporting vaccine associated adverse events

Although reporting of vaccine adverse events in the U.S. is voluntary, veterinarians are encouraged to report known and suspected adverse reactions. In the United States, veterinarians are encouraged to report vaccine adverse events to the Technical Services section of the manufacturer of the product(s) suspected to have caused the reaction prior to contacting the regulatory agency, the USDA Center for Veterinary Biologics (CVB).

Alternatively, veterinarians may contact the CVB directly; 3 options are available:

- Online: http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth and then choosing the "Veterinary Biologics" menu option
- Fax or mail: Download PDF form from CVB website and:
  - » Fax to 515-337-6120 or
  - » Mail to the CVB at 1920 Dayton Ave, PO Box 844, Ames IA 50010 or
  - » Call the CVB at 800-752-6255

The client must also be aware that a rabies vaccination exemption may be used only for the purposes of obtaining a license for the individual animal in the state of Virginia. The exempted animal will be subjected to the same dispositions as unvaccinated dogs and cats as outlined in the Code of Virginia and Virginia Guidelines for Rabies Prevention and Control. For example, currently vaccinated dogs and cats that meet the health department's definition of exposure to laboratory confirmed or suspect rabid animals (e.g., raccoons, skunks, bats, groundhogs and foxes) are confined for 45 days, while unvaccinated dogs and cats who are assessed as exposed would be subject to euthanasia or up to six (6) months strict isolation. In addition, in each exposure scenario, the animal is to be given a booster vaccination in response to the exposure. Moreover, businesses such as privately owned veterinary hospitals, grooming facilities, boarding facilities and dog parks may not accept an exemption certificate in lieu of a current rabies certificate and, therefore, an exempted animal's access to these facilities may be denied. Clients must also be aware that the governing body of any locality may require that an exempted animal be confined on the owner's property or kept on a leash, or both, or otherwise restrained if it is thought necessary to protect public health and safety. The governing body of any locality may also require that a form of unique identification is associated with an exempted animal.



The exemption certification may not be recognized outside the Commonwealth of <u>Virginia</u>. If owners intend to travel out of state with an exempted animal, they should contact public health officials where they intend to travel to determine the appropriate actions. Owners should also be educated on minimizing the risk of the animal becoming exposed to rabies by keeping it on their premises or on a leash at all times to decrease exposure to other animals, especially wild animals.

The exemption is good for a one (1) year. If the animal's condition persistently precludes rabies immunization, a new request must be submitted annually.

If an exemption is granted, the local health department shall issue a rabies vaccination exemption certificate that will be distributed to the requesting veterinarian and local animal control agency. The requesting veterinarian should then provide the exemption certificate to the animal owner. This will allow the veterinarian to maintain a copy in the patient's medical record, as well as facilitate a veterinarian-client discussion about issues concerning animals exempted from rabies vaccinations.

In order to obtain the rabies exemption application, contact your local health department (http://www.vdh.virginia.gov/lhd/). Your local health department will provide directions how to submit the application.

For more information about rabies, visit http://www.vdh.virginia.gov/Epidemiology/DEE/Rabies/

The Virginia Department of Health thanks you for serving our community by providing the best health care to our animals and protecting both people and pets from rabies.

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