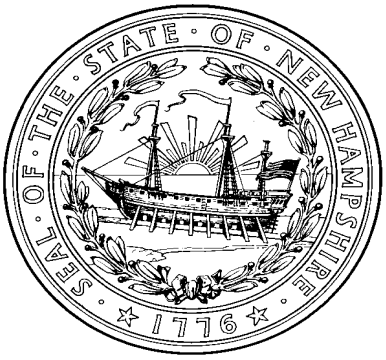
Health Care Provider's Guide to Rabies Prophylaxis



New Hampshire
Department of Health and Human Services
Division of Public Health Services

September 7, 2009

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Abbreviations Used in this Document

ACIP	Advisory Committee for Immunization Practices
CNS	Central Nervous System
FAQ	Frequently Asked Questions
HDCV	Human Diploid Cell Vaccine
HRIG	Human Rabies Immune Globulin
NH	New Hampshire
NH DHHS	New Hampshire Department of Health and Human Services
PCECV	Purified Chick Embryo Vaccine
PEP	Postexposure Prophylaxis
RFFIT	Rapid Fluorescent Focus Inhibition Test
RVA	Rabies Vaccine Adsorbed
VAERS	Vaccine Adverse Event Reporting System

I. Background

Rabies exists on every continent in the world except Australia and Antarctica. In developing countries, it is common to have stray dogs serve as a reservoir for this disease; however, in developed countries including the United States, wild animals serve as the predominant reservoir. In the United States each year, between 16,000 and 39,000 people are treated with rabies postexposure prophylaxis following exposure to rabid or suspect rabid animals. Wild animals, such as raccoons, skunks, bats and foxes account for the majority of animal rabies cases reported annually in the United States, while domestic animals are associated with fewer than 10% of all reported cases. This finding is consistent with New Hampshire (NH) statistics from 2001 through 2007: yearly, an average of 32 wild animals test positive for rabies, and an average of only two domestic animals test positive for rabies. There has been only one case of human rabies in NH since 1990. This case occurred in 1996 and originated from a dog bite in Nepal.

After an exposure to a rabid animal, the rabies virus is taken up by the peripheral nerves, travels to the central nervous system (CNS), and eventually causes acute encephalomyelitis. Although the incubation period for rabies in humans is usually 1 to 3 months, a range from 9 days to several years has been reported. Once clinical signs of rabies appear, the disease is nearly always fatal. Fortunately, the available rabies biologics (human rabies immune globulin and human rabies vaccine) are effective in preventing rabies if given in a timely manner following exposure to a rabid animal.

This guide will review rabies prophylaxis for humans. Additional details may be found in the most current Centers for Disease Control and Prevention guidelines (Human Rabies Prevention – United States, 2008: Recommendations of the Advisory Committee on Immunization Practices). There are many scenarios that can make the decision to administer postexposure prophylaxis complex. Though the decision to administer postexposure prophylaxis is ultimately between the clinician and their patient, Public Health Professionals are available 24-hours per day, every day of the year to assist in answering your questions and making prophylaxis decisions.

II. State and Local Assistance

New Hampshire Department of Health and Human Services (NH DHHS)

Public Health Professionals at the NH DHHS Communicable Disease Control Section are available to assist health care providers in making prophylaxis decisions by calling (603) 271-4496 between 8:00 a.m. and 4:30 p.m. on weekdays. Department on-call Public Health Professionals can be reached during nights, weekends, and holidays by calling (603) 271-5300. Please ask to speak to the on-call Public Health Professional. As indicated, Public Health Professionals will also perform contact investigations and assist in arranging animal testing.

New Hampshire Public Health Laboratories

To submit an animal sample to the NH Public Health Laboratories for rabies testing contact a Public Health Professional at NH DHHS using the contact information listed above.

New Hampshire Department of Agriculture, Markets, and Food

The State Veterinarian at the NH Department of Agriculture, Markets, and Food is available to assist with questions about rabies in animals. Please call (603) 271-2404.

New Hampshire Department of Fish and Game

New Hampshire Fish and Game officials are available to assist in the capture and euthanasia of wildlife. Please call (603) 271-3361.

Municipal Animal Control Officer

Municipal Animal Control Officers assist in the capture and quarantine of domestic animals. Contact information can be obtained from local officials or the NH Department of Agriculture, Markets, and Food.

III. Who Needs to Receive Rabies Postexposure Prophylaxis?

Administration of rabies postexposure prophylaxis (PEP) is a medical urgency, not a medical emergency. Prior to providing PEP, a risk assessment should be performed to ensure PEP is indicated. Because PEP can cause adverse reactions, when possible, alternative measures, such as animal quarantine or testing, should be utilized before initiating PEP.

The decision to administer PEP should be based on the following criteria:

1. Nature of the exposure
2. Species of animal involved in the exposure
3. Availability of the animal for quarantine or rabies testing

a. Type of Exposure

The risk of rabies transmission and appropriateness of PEP depends on the type and location of exposure. Please consult a Public Health Professional if you have questions about what is or is not an exposure.

i. Not an Exposure: Indirect contact and activities such as petting an animal or having contact with its blood, urine, or feces does not typically constitute an exposure. Additionally, the rabies virus does not persist in the environment. Desiccation, ultraviolet irradiation, heat and many common disinfectants and detergents readily inactivate the rabies virus. In general, if the suspect material is dry, the virus can be considered noninfectious. PEP is not indicated if an exposure has not occurred.

ii. **Bite Exposure:** The most dangerous route of rabies exposure is from the *bite* of a rabid mammal. Bite is defined as: any penetration of the skin by teeth. Bites located in the head, neck, and shoulder regions could potentially lead to more rapid exposure of the CNS to the rabies virus. Provoked bites (acquired when feeding or handling an apparently healthy animal) are associated with lower risk than unprovoked bites.

iii. **Non-bite Exposure:** Non-bite exposures from terrestrial animals rarely cause rabies. However, occasional reports of non-bite transmission suggest that such exposures require assessment. Examples of non-bite exposures include:

1. Contamination of open wounds, abrasions, mucous membranes, or theoretically, scratches with saliva or other potentially infectious material (i.e., neural tissue)
2. Aerosolized rabies virus – four cases of rabies in humans have been attributed to probable aerosol exposure in laboratories and bat-filled caves
3. Surgical recipients of organs transplanted from patients who died of rabies

iv. **Bat Exposure:** Exposures to *bats* deserve special assessment, because bats are associated with most cases of human rabies acquired in the United States. Additionally, bites and scratches from a bat can be minor or undetectable. Any interaction with a bat is considered an exposure unless the potentially exposed person can say with certainty that a bite, scratch, open wound, or mucous membrane exposure did not occur. If a bat is found indoors, persons shall be considered exposed if they were in the **same room** as the bat and unaware if direct contact may have occurred (Example: a sleeping person wakens to find a bat in the room or an adult witnesses a bat in the room with a previously unattended child, mentally disabled, or intoxicated person). PEP is not warranted for the entire household, just those in the **same room** with the bat. See also III, b, iii Bats.

b. Animals Involved in Human Exposure

If an exposure has occurred, the risk of rabies transmission and appropriateness of PEP depends on the species, availability, and sometimes health of the animal involved in the exposure.

i. **Domestic Dog, Cat, or Ferret**

A dog, cat, or ferret with a history of continuously current rabies vaccination is unlikely to become infected with rabies. PEP decisions will depend on the health and availability of the cat, dog, or ferret.
In all cases of domestic animal bites, statutory authority for quarantine decisions rests with local authorities who must be contacted in order to assist with quarantine issues.

1. Available and Healthy

   a. A healthy domestic dog, cat, or ferret that exposes a person should be confined and observed for 10 days, regardless of the animal's previous vaccination status. The municipal animal control authority must be contacted to assist with quarantine (see State and Local Assistance section).
   b. Those that remain alive and healthy 10 days after being involved in an exposure would not have been shedding rabies virus in their saliva, so they would not have been infectious at the time of the exposure; therefore, PEP is not necessary.
   c. Any illness in the animal during the confinement period must be evaluated by a veterinarian and reported immediately to the NH DHHS. If signs suggestive of rabies develop in the animal, PEP should be initiated. The animal should be euthanized immediately and tested for rabies by the NH Public Health Laboratories.
   d. If the animal involved in the exposure is a stray or unwanted animal, it should either be confined and observed for 10 days or euthanized immediately and submitted for rabies testing. PEP should not be initiated unless the animal becomes ill or the rabies test is positive.

2. Available and Not Healthy

   a. It is suggested that any ill animal be evaluated by a veterinarian and be euthanized for rabies testing if indicated. PEP should be initiated immediately and can be discontinued if the test is negative.
   b. There are laws governing when to euthanize dogs, cats, and ferrets that are displaying symptoms, which indicate a likelihood that the animal is afflicted with rabies. For guidance on this subject, please see RSA 436:105 or contact the New Hampshire State Veterinarian.

3. Not Available and Healthy

   a. The municipal Animal Control Officer must be contacted and can assist in capturing a suspect animal.
   b. If the animal can be captured within 3 days, it can be confined and observed for 10 days from the date of the exposure (follow the above rules for observation).
   c. If the animal cannot be captured within 3 days, PEP should be considered.

4. Not Available and Not Healthy

   a. PEP should be initiated as soon as possible following exposure.

ii. Wild Terrestrial Carnivores (including but not limited to raccoon, skunk, fox, coyote, and groundhog):

Raccoons, skunks, and foxes are the terrestrial carnivores most often infected with rabies in New Hampshire. Though groundhogs (woodchucks) are rodents, they are included here, because a significant number of them have been found to be rabid. There is no established quarantine period for wild animals. If an exposure has occurred, rabies testing of the animal is the only means to determine the need for PEP.

1. Available

    a. Suggestive clinical signs of rabies among wildlife cannot be interpreted reliably; therefore, all wild terrestrial carnivores involved in an exposure should be considered potentially rabid.
    b. Wild terrestrial carnivores that are available for diagnostic testing should be euthanized as soon as possible and submitted to the NH Public Health Laboratories for rabies testing. The Department of Fish and Game should be contacted and can assist in capturing and/or euthanizing a suspect animal.
    c. PEP should be initiated immediately if the animal tests positive for rabies, the animal was ill and exposed the person in the area of the head/neck/shoulder, or testing will be delayed for more than 3 days. PEP can be discontinued if the test is negative.

2. Not Available

    a. The animal should be considered rabid, and PEP should be initiated as soon as possible following the exposure.

iii. Bats

Rabid bats have been documented in all states except Hawaii, and bats are increasingly implicated as an important wildlife reservoir of rabies virus transmitted to humans.

Transmission of the rabies virus can occur from minor unrecognized bites from bats. If a bat is found indoors, persons shall be considered exposed if they were in the **same room** as the bat and unaware if direct contact may have occurred (e.g., a sleeping person wakens to find a bat in the room or an adult witnesses a bat in the room with a previously unattended child, mentally disabled, or intoxicated person). PEP is not warranted for the entire household, just those in the **same room** with the bat.

PEP is recommended for all persons with a bite, scratch, or mucous membrane exposure to a bat; unless, the specific bat is available and tests negative for rabies or the exposed person can say with certainty that these types of exposure did not occur.

1. Available

    a. Bats that are involved in a human exposure and are available for diagnostic testing should be euthanized as soon as possible and submitted to the NH Public Health Laboratories for rabies testing. The Department of Fish and Game should be contacted and can assist in capturing and/or euthanizing the suspect bat.
    b. PEP should be initiated immediately if the animal tests positive for rabies, the animal exposed the individual in the area of the head/neck/shoulder, or testing will be delayed for more than 3 days (PEP can be discontinued if the test is negative).

2. Not Available

    a. The animal should be considered rabid, and PEP should be initiated as soon as possible following exposure (see above for the definition of exposure as it pertains to bats).

iv. Rodents and Lagomorphs (including but not limited to squirrel, chipmunk, rat, mouse, hamster, guinea pig, gerbil, rabbit, and hare)

1. Rodents and lagomorphs are not reservoirs of the rabies virus. They are rarely infected with rabies and have not been known to cause human rabies in the United States. Exposure to small rodents and lagomorphs rarely ever necessitates PEP.
2. In rare situations of unprovoked attacks or obvious neurologic illness, testing the animal for rabies or PEP for the individual might be considered. Consult with a Public Health Professional.

v. Other (including but not limited to livestock, horse, exotic animals, and wild animal hybrids)

Consult Public Health Professionals for all other types of animals identified in a potential rabies exposure.

IV. Postexposure Prophylaxis

The most important initial procedure following a possible rabies exposure is thorough wound cleansing and management. When a documented or likely exposure has been confirmed, postexposure prophylaxis should be administered regardless of the length (days, weeks, months) of the delay since the exposure.

a. Treatment of the Wound

i. *Thorough wound cleansing* using water and soap. If available, a virucidal such as diluted providone-iodine solution should be used.
ii. Determine if the patient needs a booster dose of tetanus.
iii. Antibiotics and wound closure should be considered on a case-by-case basis.

b. Human Rabies Immune Globulin (HRIG) Administration

i. Administer to previously unvaccinated patients – provides immediate, passive rabies virus-neutralizing antibody.

ii. DO NOT give HRIG to previously vaccinated patients (i.e., those people who have completed a pre-exposure or postexposure vaccination regimen with HDCV (Human Diploid Cell Vaccine), PCECV (Purified Chick Embryo), or RVA (rabies vaccine adsorbed) OR previous vaccination with any other type of rabies vaccine and a documented history of antibody response to the prior vaccination).

iii. DO NOT modify protocol – administer only as recommended below:

1. Ideally administer at the same time as the first dose of vaccine (day 0). May be given through the 7th day following the first dose of vaccine (can interfere with vaccine driven immunity after day 7).
2. Dose = 20 IU/kg IM 1 time only.
3. As much as possible of the full dose should be infiltrated into and around the wound(s), and the remainder administered intramuscularly at an anatomical site distant from the vaccine site (sites recommended: deltoid or quadriceps muscles; site not recommended: gluteal area). Subsequent doses of rabies vaccine in the 5-dose series can be administered in the same anatomical location where the HRIG dose was administered, if this is the preferable site for vaccine administration (deltoid muscle in children and adults and midlateral aspect of the thigh in infants).

c. Rabies Vaccine (HDCV or PCECV) Administration

i. <u>Not Previously Vaccinated</u>

1. On June 24, 2009, the Advisory Committee for Immunization Practices (ACIP) changed its recommendations for rabies postexposure prophylaxis vaccine protocol for persons not previously vaccinated from 5 doses to 4 doses. The new 4-dose recommendation will not be reflected on the package insert, and rabies vaccine manufactures will continue to promote the five-dose series. Along with CDC and ACIP, NH DHHS now recommends the 4-dose protocol for all **immunocompetent patients**.
2. DO NOT modify protocol – administer only as recommended below:
   a. Administer human diploid cell vaccine (HDCV) or purified chick embryo cell culture vaccine (PCECV) at a dose of 1.0 ml IM on days 0, 3, 7, and 14.
   b. Deliver into deltoid muscle in children and adults and into the midlateral aspect of the thigh in infants. DO NOT deliver vaccine into gluteal area; failures have been observed.
   c. All doses must be given, unless the animal causing the exposure was available and was proven negative by rabies testing.

ii. Previously Vaccinated

1. Previously vaccinated individuals are those people who have completed a pre-exposure or postexposure vaccination regimen with HDCV, PCECV, or rabies vaccine adsorbed OR previous vaccination with any other type of rabies vaccine and a documented history of antibody response to the prior vaccination.
2. Human rabies cases have occurred among those who received rabies pre-exposure prophylaxis but did not receive rabies postexposure prophylaxis after an exposure, indicating that pre-exposure prophylaxis in humans is not universally effective without postexposure prophylaxis.
3. DO NOT modify protocol – administer only as recommended below.
    a. DO NOT give HRIG.
    b. Administer human diploid cell vaccine (HDCV) or purified chick embryo cell culture vaccine (PCECV) at a dose of 1.0 ml IM on days 0 and 3.
    c. Deliver into deltoid muscle in children and adults and into the midlateral aspect of the thigh in infants. DO NOT deliver vaccine into gluteal area, failures have been seen.
    d. All doses must be given, unless the animal causing the exposure was available and was proven negative for rabies.

iii. Additional Considerations

1. When an **immunocompromised patient** receives PEP, they should receive the 5-dose series, and serum samples should be tested for antibodies 1 to 2 weeks after the last vaccine to ensure adequate response (see VIII, d). Consult with a Public Health Professional.
   http://www.cdc.gov/mmwr/preview/mmwrhtml/00023141.htm
2. If postexposure prophylaxis was initiated outside of the United States using one of the regimens or vaccines of nerve tissue origin, additional prophylaxis might be necessary when the patient returns for care in the United States. Consult with a Public Health Professional.
3. Delays in postexposure vaccination schedule
    a. For minor deviations from the schedule (a few days), vaccination can be resumed as though the patient were on schedule by maintaining the same interval between doses. (Example: miss day 7, get vaccinated on day 10 – remaining dose should be administered on day 17.)
    b. If significant deviations from the schedule occur (weeks), immune status should be assessed using serologic testing 7 to 14 days after the final dose in the series (see VIII, d). Most interruptions in the vaccine schedule do not require re-initiation of the entire series. Please consult a Public Health Professional to discuss the situation.

V. Adverse Reactions

a. Human Rabies Immune Globulins (HRIG)

HRIG has a good safety profile – no immediate hypersensitivity reactions or immune-complex-like diseases are reported. Additionally, there is no evidence of other diseases being transmitted by commercially available HRIG in the United States.

i. Local reactions (50% - 100%): pain at injection site
ii. Systemic reactions (75%): low-grade fever and headache
iii. Although not reported specifically for HRIG, angioneurotic edema, nephritic syndrome, and anaphylaxis have been reported after receipt of immune globulin. These reactions occur so rarely, that a causal relationship between immune globulin and these reactions has not been established.

b. Rabies Vaccine (HDCV or PCECV)

Human diploid cell vaccine (HDCV) or purified chick embryo cell culture vaccine (PCECV) have similar profiles. Serious reactions following rabies vaccine administration are very rare.

i. Local reactions (most common – 11% - 90%): pain, redness, swelling, itching, and/or induration at the injection site
ii. Systemic reactions (less common – 5% - 56%): fever, headache, dizziness, myalgia, weakness, and gastrointestinal symptoms
iii. Hypersensitivity reactions (rare – 6% of booster doses): urticaria, pruritic rash, and angioedema within 1 to 14 days post-injection
iv. Neurologic adverse events (very rare): resemble Guillain-Barré syndrome – have complete recovery

c. Additional Considerations

i. Once initiated, PEP should not be discontinued due to local or mild systemic adverse reactions to the vaccine. The health care provider can try switching to the other available vaccine or managing the reactions with anti-inflammatories, antihistamines, and antipyretics.
ii. Discontinuing PEP is not usually indicated, even in cases of severe reaction.
iii. Contact the manufacturer or a Public Health Professional if additional guidance is needed.
iv. All clinically significant adverse events occurring following administration of rabies vaccine should be reported to the manufacturer and VAERS (Vaccine Adverse Event Reporting System), even if causal relation to vaccination is not certain. VAERS reporting forms and information are available at http://www.vaers.hhs.gov or by telephone (800-822-7967). Web based reporting is available at https://secure.vaers.org/VaersDataEntryintro.htm.

v. Clinically significant adverse events following HRIG administration should be reported to the Food and Drug Administration's MedWatch at http://www.fda.gov/MedWatch

VI. Obtaining Rabies Biologics

In New Hampshire, sources of rabies biologics (vaccine and HRIG) may include emergency departments, urgent care facilities, and travel clinics.

Human Rabies Immune Globulin (HRIG)

- HyperRab™ S/D
  - Talecris Biotherapeutics Bayer Biological Products
  - 1-800-243-4153 or http://www.talecris-pi.info
- Imogam® Rabies-HT
  - Sanofi pasteur
  - 1-800-822-2463 or http://www.vaccineplace.com/products/

Vaccine

- Imovax® Rabies = Human diploid cell vaccine (HDCV)
  - Sanofi pasteur
  - 1-800-822-2463 or http://www.vaccineplace.com/products/
- RabAvert® = Purified chick embryo cell vaccine (PCECV)
  - Novartis Vaccines and Diagnostics
  - 1-800-244-7668 or http://www.novartisvaccines.com/us/portfolio/us_portfolio.shtml

VII. Indigent Patient Programs

Both rabies vaccine manufacturers have patient assistance programs that provide medications to uninsured or underinsured patients.

- Sanofi pasteur's Indigent Patient Program (providing Imogam® Rabies-HT and Imovax® Rabies) is administered through the National Organization for Rare Disorders. Information is available by telephone (877-798-8716) or e-mail (nnadiq@rarediseases.org).
- Information on Novartis Pharmaceuticals Patient Assistance Program for RabAvert® is available at http://www.corporatecitizenship.novartis.com/patients/drug-pricing/assistance-programs.shtml or e-mail (corporatecitizenship@novartis.com).

VIII. Pre-exposure Prophylaxis

Pre-exposure prophylaxis may be indicated for individuals at increased risk of exposure to the rabies virus. These individuals include, but are not limited to: veterinarians, veterinary technicians, animal control officers, shelter workers, laboratory personnel preparing rabies specimens, cavers, some international travelers, and persons working closely with high-risk wildlife species. Individuals who have received pre-exposure prophylaxis are not considered immune to rabies and should receive PEP if an exposure to rabies occurs (see section on modified PEP protocol: IV, c, ii Previously Vaccinated).

a. Administer human rabies diploid cell vaccine (HDCV) or purified chick embryo cell culture vaccine (PCECV) at a dose of 1.0 ml IM on days 0, 7, and 21 or 28.
b. Patients who have completed this series are considered 'previously vaccinated'.
c. It is recommended that antibody titers be checked every 6 months for the continuous-risk category (rabies research workers and rabies biologics production workers) and every 2 years for the frequent-risk category (rabies diagnostic laboratory workers, cavers, veterinarians, veterinary staff, animal control workers/wildlife workers in enzootic areas, and all people who frequently handle bats).
d. If the antibody titer is below 1:5 serum dilution by rapid fluorescent focus inhibition test (RFFIT), a single booster dose of vaccine is given. It is not recommended to use ELISA testing to evaluate rabies titers.

IX. Additional Resources

Centers for Disease Control and Prevention, Human Rabies Prevention – United States, 2008: Recommendations of the Advisory Committee on Immunization Practices, MMWR 2008; 57(No. RR-3): 1-39.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5703a1.htm

Centers for Disease Control and Prevention: Rabies website:
http://www.cdc.gov/rabies/

New Hampshire Department of Health and Human Services Website:
http://www.dhhs.nh.gov/DHHS/CDCS/rabies.htm

- Rabies Fact Sheet
- FAQs About Bats for Healthcare Workers
- Vaccine Information
- Rabies Specimen Guidelines
- Diseases in Wildlife
- Bat Proofing

Signatories to NH Health Care Provider's Guide to Rabies Prophylaxis

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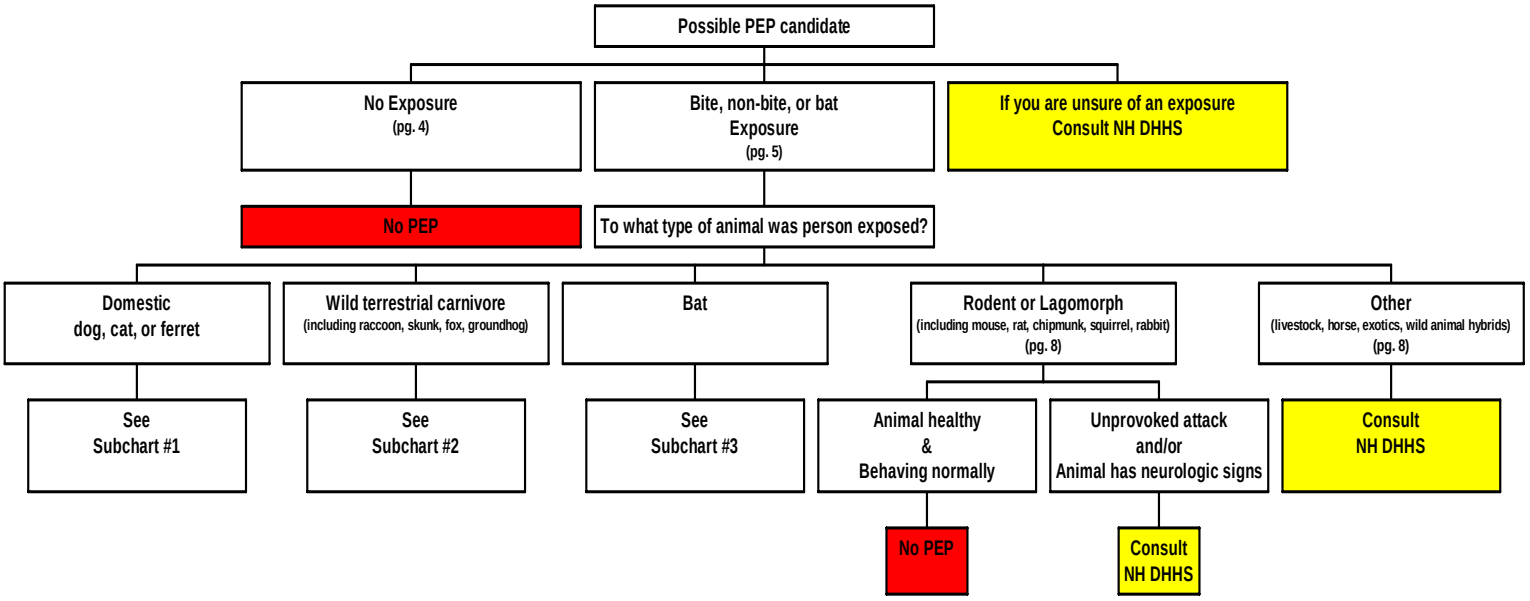
Document Review

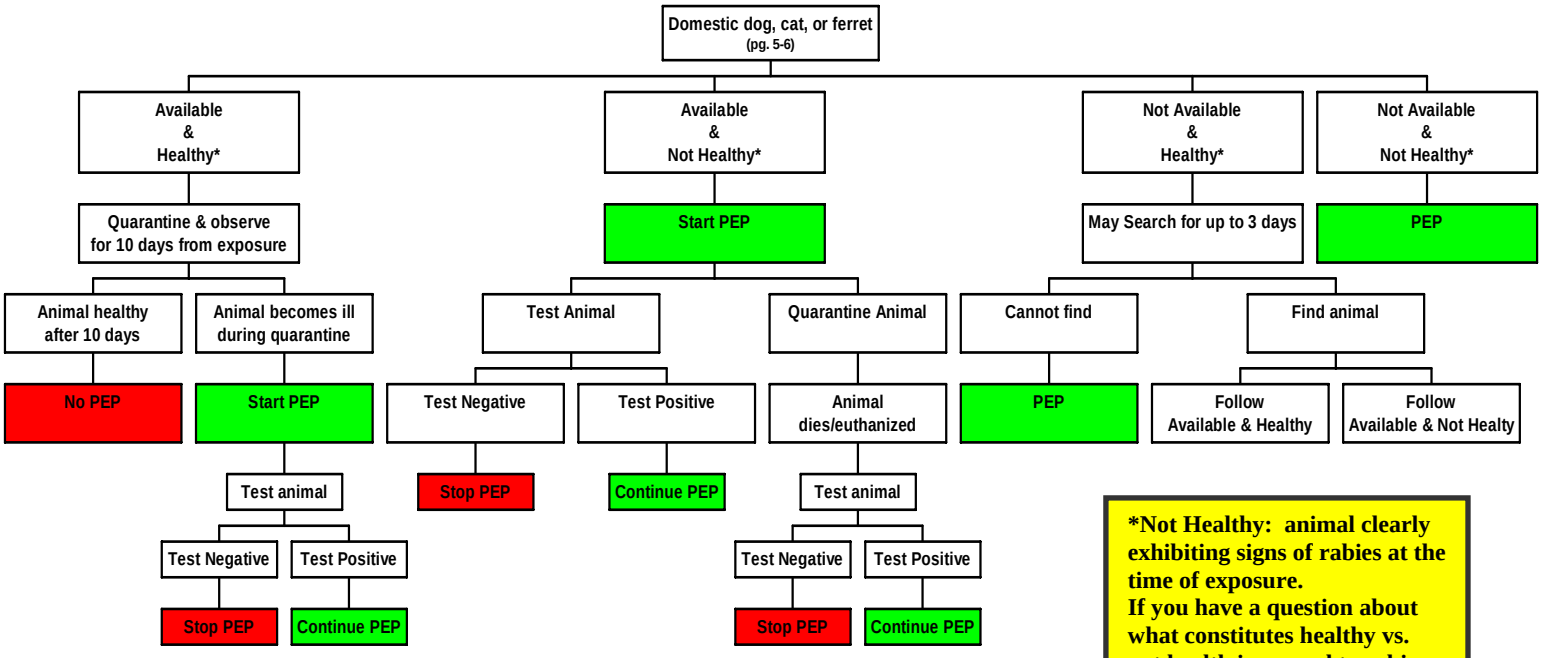
Version and Nature of Change	Revision Date

Appendix 1

Flowchart for Rabies Postexposure Prophylaxis



Subchart #1

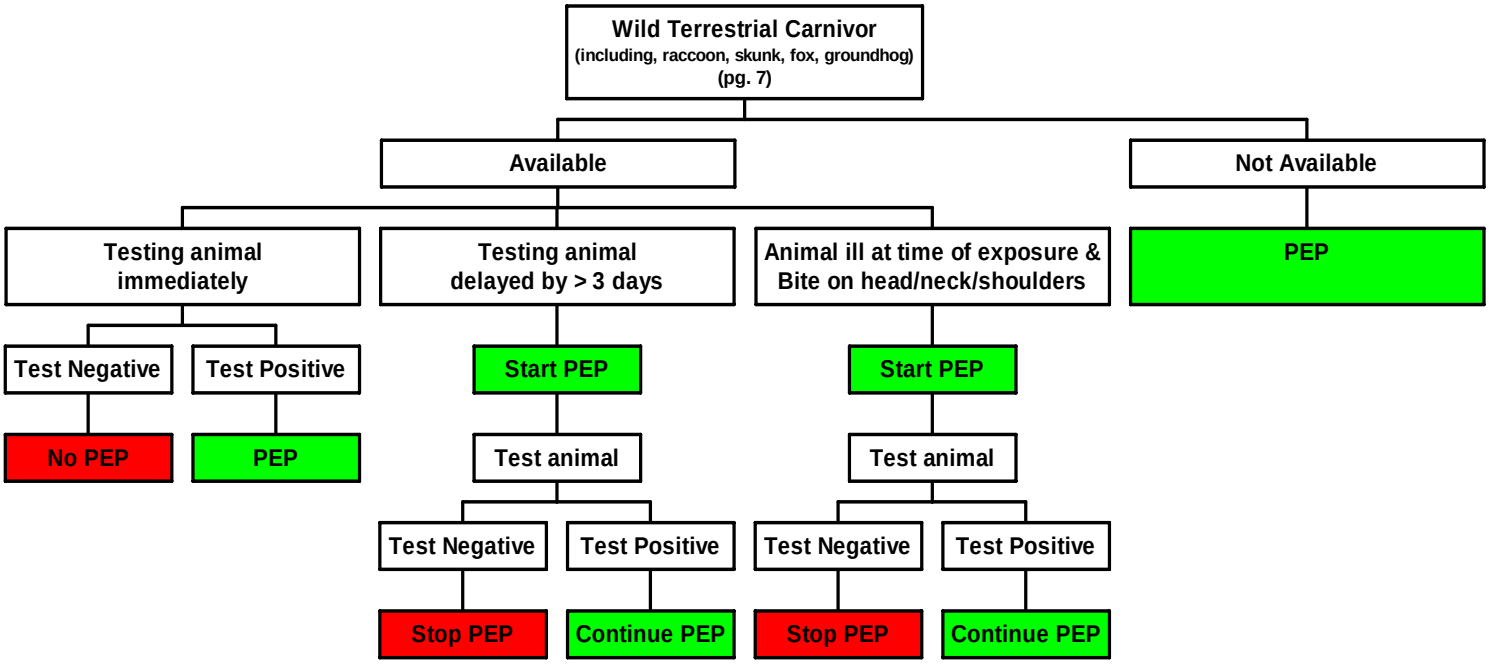


***Not Healthy: animal clearly exhibiting signs of rabies at the time of exposure.**
If you have a question about what constitutes healthy vs. not health in regard to rabies, please contact NH DHHS

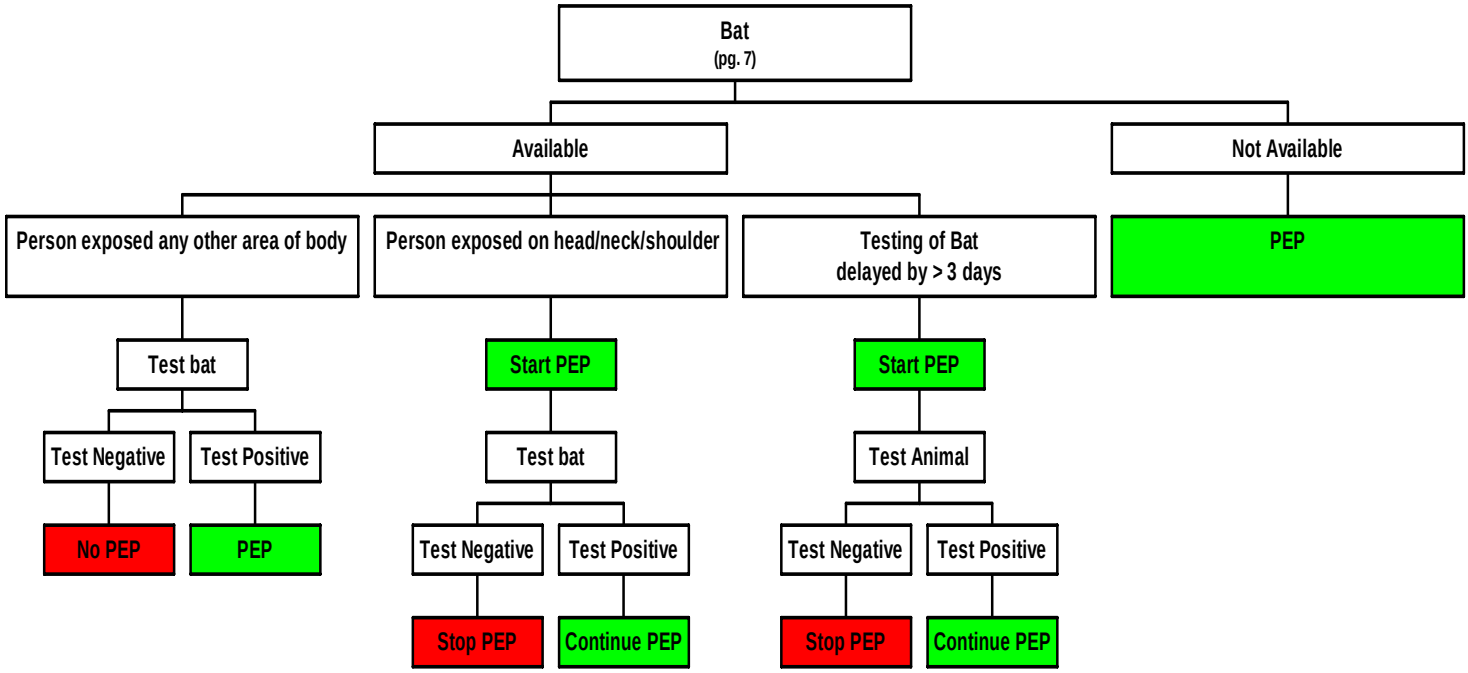
These algorithms are intended for guidance only. Please make sure that you have the most current version and contact NH DHHS if you have any questions.

Consultation with NH DHHS recommended for exposures in area of head/neck/shoulders

Subchart #2



Subchart #3



These algorithms are intended for guidance only. Please make sure that you have the most current version and contact NH DHHS if you have any questions.

Appendix 2

Process

The NH State Public Health Veterinarian, Dr. Jason Stull, and the EIS Officer, Dr. Sherry Burrer developed the first draft of this document. They used the Centers for Disease Control and Prevention, Human Rabies Prevention – United States, 2008: Recommendations of the Advisory Committee on Immunization Practices as the main reference document to achieve an approach that is consistent with national recommendations. NH DHHS Public Health Professionals and Dr. Elizabeth Talbot then reviewed the document and recommended revisions were made. The original document was presented to the New Hampshire Communicable Disease Epidemic Control Committee (CDECC). After approval by CDECC, the document was presented to the Director of NH DHHS, State Veterinarian of NH Department of Agriculture, Markets, and Food, the Director of NH Public Health Laboratories, and the Chief of Law Enforcement of NH Department of Fish and Game. All parties approved the document on September 7, 2009, with the understanding that this is a dynamic document that will be modified based on science and policies developed at the state and national level and currently available best practices.