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To Whom It May Concern:

Please be advised that formal recommendations regarding changes in the vaccine dosing schedule for rabies postexposure prophylaxis will soon be released by the Centers for Disease Control and Prevention. This letter is to provide you with information about the change and to encourage you to begin to plan for the implementation of these changes.

On June 24, 2009, the American College of Immunization Practices (ACIP) approved the recommendation to reduce the number of rabies vaccines used for postexposure prophylaxis (PEP) from 5 doses to 4 doses in persons who are not immunosuppressed and who have not been immunized in the past. There will be no changes in recommendations for the use of human rabies immune globulin (HRIG), rabies preexposure immunization or abbreviated (2 dose) PEP in persons who were previously immunized using a cell culture vaccine or who have had a documented rabies virus neutralizing antibody titer.

Persons who are immunosuppressed with primary or secondary immune deficiencies (whether due to illness, medication or other therapy) should continue to receive rabies PEP according to the 5 dose schedule. In addition, for immunosuppressed persons, one or more serum samples should be tested for rabies virus neutralizing antibody by the rapid fluorescent focus inhibition test to ensure that an acceptable antibody response has developed after completing the 5 dose series.

On July 10, 2009, ACIP published provisional recommendations (see below), but they will not become official until accepted and published by the Centers for Disease Control and Prevention (CDC) Director, which is expected in several weeks. At that time, the Health Department will send a health advisory and post information on our website providing clinical guidance and a fact sheet addressing the change in recommendations. Until that time, the Health Department encourages you to review and prepare current protocols and documents to reflect the new recommendations.

Please be aware that based on discussion at the ACIP meeting, the rabies vaccine product inserts may not change when the new 4 dose schedule implemented. Product inserts are based upon data supplied to the Food and Drug Administration (FDA) and are not typically revised until the license holder requests a change by FDA. For further information please call the Bureau of Communicable Disease at 212-788-9830.

Sincerely,

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ACIP Provisional Recommendations for the Prevention of Human Rabies

Date of ACIP meeting and vote: June 24, 2009
Date of posting of provisional recommendations: July 10, 2009
On June 24, 2009, the ACIP approved new recommendations on the use of rabies vaccine for post-exposure prophylaxis for the prevention of human rabies.
A summary of the new provisional recommendations for the use of rabies vaccine follows:

Post-exposure Prophylaxis for Unvaccinated Persons:

Vaccine Use. A regimen of 4 one-mL vaccine doses of rabies vaccine (HDCV or PCECV) should be administered intramuscularly to previously unvaccinated persons with no immunosuppression. The first dose of the 4-dose course should be administered as soon as possible after exposure. This date is considered day 0 of the post-exposure prophylaxis series. Additional doses should then be administered on days 3, 7, and 14 after the first vaccination. Considerations for the site of the intramuscular vaccination remain unchanged.
Rabies Immune Globulin Use. The recommendations for use of immune globulin remain unchanged.

Post-exposure Prophylaxis for Previously Vaccinated Persons:

The recommendations for the post-exposure management of previously vaccinated individuals remain unchanged.

Post-Vaccination Serologic Testing:

No testing of healthy patients completing prophylaxis is necessary to document seroconversion, unless the person is immunosuppressed. When titers are obtained, specimens collected from 1 to 2 weeks after prophylaxis should completely neutralize challenge virus at a 1:5 serum dilution by the rapid fluorescent focus inhibition test (RFFIT).

Precautions - Immunosuppression:

Immunosuppression results from a wide variety of conditions. Primary or secondary immunodeficiencies may significantly reduce immune responses to vaccines. Given the large variety of immunocompromising conditions, as well as subsequent alterations in degrees of clinically significant immunodeficiencies, the evaluation of a potentially immunocompromised patient, as well as the decision about proper immunization of the immunocompromised patient, ultimately lies with the attending physician.
All rabies vaccines licensed in the U.S. are inactivated cell culture vaccines and as such can be administered safely to persons with altered immunocompetence. The effectiveness of such vaccinations and quality of elicited immune responses in immunocompromised patients could be suboptimal. Extensive monitoring of the immune response after rabies vaccination, specifically the determination of rabies virus-neutralizing antibodies, should be performed.
For persons with broadly defined immunosuppression, post-exposure prophylaxis should be administered using all 5 doses of vaccine, with the awareness that the immune response may still be inadequate. When administered to an immunosuppressed person, one or more serum samples should be tested for rabies virus neutralizing antibody by the RFFIT to ensure that an acceptable antibody response has developed after completing the series. A patient who fails to seroconvert with an acceptable antibody response after the fifth and last dose should be managed in consultation with their physician and appropriate public health officials.

The 2008 ACIP recommendations for the prevention of human rabies are otherwise unchanged, and are available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e507a1.htm

This document can be found at:
http://www.cdc.gov/vaccines/recs/provisional/downloads/rabies-July2009-508.pdf