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## Rabies Post-Exposure Prophylaxis: 2009 Changes to Schedules

### Background

Prior to July 2009, the standard rabies post-exposure prophylaxis (PEP) regimen for previously unvaccinated persons included human rabies immune globulin (HRIG) given on a per weight basis on day 0, and five doses of human rabies vaccine given on days 0, 3, 7, 14, and 28.<sup>1</sup> During 2008 when the national rabies vaccine supply was limited, a group of experts representing state and federal health agencies, academia, and professional organizations was convened to develop recommendations to address both present vaccine supply limitations and possible future true shortages. A Rabies Working Group was subsequently formed by the Advisory Committee for Immunization Practices (ACIP) to evaluate the possibility of reducing the number of vaccine doses in the human rabies PEP series from five to four.

During the June 24, 2009 ACIP meeting, the Rabies Working Group presented the results of an extensive review of historical rabies studies and current literature concerning the pathogenesis of rabies virus, clinical vaccine trials, animal studies, and epidemiologic surveillance data to determine the immunogenicity, effectiveness, and safety of a 4-dose PEP vaccination regimen. The Working Group asserted that existing data support the premise that four doses of vaccine elicit an immunologic response equivalent to five doses in immunocompetent persons. After much discussion, ACIP members voted in favor of accepting the recommendation to reduce the number of doses of rabies vaccine from five to four in previously unvaccinated immunocompetent persons undergoing PEP. A provisional recommendation was posted on the ACIP website on July 10, 2009.<sup>2</sup>

### Alaska's Revised PEP Regimens

For over 30 years, the Alaska Section of Epidemiology (SOE) has supplied rabies PEP free of charge to persons for whom it is indicated. Effective immediately, SOE will supply PEP according to the updated ACIP recommended regimens (Box).

#### Box. Alaska's Revised Rabies Post-Exposure Prophylaxis Regimens

##### *Previously vaccinated persons*

Rabies vaccine: Days 0 and 3  
HRIG: Not indicated

##### *Immunocompetent persons*

Rabies vaccine: Days 0, 3, 7, and 14  
HRIG: Day 0

##### *Immunosuppressed\* persons*

Rabies vaccine: Days 0, 3, 7, 14, and 28  
HRIG: Day 0

\*See below for details.

Immunosuppressed persons undergoing PEP should continue to receive five doses of rabies vaccine. After completing the series, 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. An immunocompromised 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.

Historically, ACIP recommendations have not always coincided with label claims and have, on occasion, made off-label recommendations based upon current scientific evidence presented to the committee. In the past, ACIP recommendations regarding intradermal administration of rabies vaccine in the United States preceded changes to vaccine labeling and licensing. The function of ACIP is to evaluate the available evidence and to make immunization recommendations based on the most recent data.

While the new ACIP recommendations are based on evidence that support a 4-dose regimen, vaccine manufacturers might continue to support the product insert that was developed at the time the product was licensed by the U.S. Food and Drug Administration (FDA). The U.S. Centers for Disease Control and Prevention (CDC) will publish the new ACIP PEP recommendations in an upcoming Morbidity and Mortality Weekly Report.

### Recommendations

- Contact SOE at 907-269-8000 Mon-Fri 8 AM to 5 PM or 800-478-0084 (after hours) to discuss possible exposures to rabies, to obtain testing of human specimens by referral to CDC or testing of animal specimens at the Alaska State Virology Laboratory (ASVL), and to obtain rabies PEP free of charge.
- PEP regimens should be based on the July 10, 2009 ACIP recommendations regardless of package insert. The Vaccine Information Statement is available at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rabies.pdf>
- PEP flow sheets, ASVL submission forms and other resources are available on SOE's rabies webpage: <http://www.epi.alaska.gov/id/rabies/default.htm>
- Despite past supply disruptions, rabies vaccine is currently commercially available, see CDC website <http://www.cdc.gov/rabies/news/RabVaxupdate.html>

### References

- Human Rabies Prevention – United States, 2008 Recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep* 2008;57(RR-3):1-28. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5703a1.htm?s\\_cid=rr5703a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5703a1.htm?s_cid=rr5703a1_e)
- Advisory Committee for Immunization Practices (ACIP) Provisional Recommendations for the Prevention of Human Rabies. Approved on June 24, 2009; posted July 10, 2009. Available at: <http://www.cdc.gov/vaccines/recs/provisional/downloads/rabies-July2009-508.pdf>