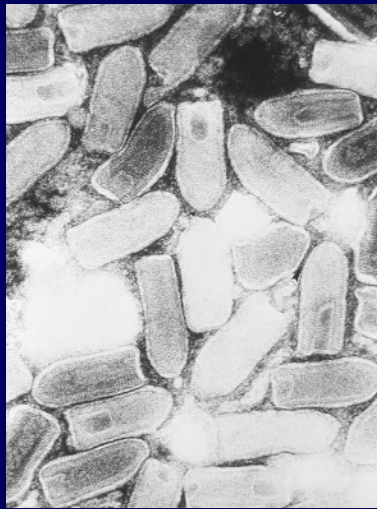


HUMAN RABIES BIOLOGICALS: SUPPLY UPDATE & FORMATION OF AN ACIP WORKING GROUP



Charles E. Rupprecht VMD, MS, PhD
Chief, Rabies Program
PRB/DVRD/NCZVED/CCID/CDC

The views expressed in this presentation are those of the author and not necessarily the institution

INTRODUCTION

- Rabies is enzootic among wildlife in the USA.
- The disease is preventable by avoiding exposure or administration of appropriate postexposure prophylaxis.
- Viral activity in animals varies geographically, and tends to peak during the summer months, especially among bats.
- Current availability of human rabies vaccines remains much less than ideal, for a variety of complex, inter-related reasons.
- Increased demand and limitations in vaccine supply create a very volatile public health environment.

EVENTS SINCE JUNE 08' ACIP

- 6/17: Novartis halts shipment of vaccine; Sanofi vaccine remains available
- 7/15 Novartis resumes shipping, for PEP only
- 8/8 Sanofi halts shipping of vaccine
- 8/29 Sanofi resumes shipping, for PEP only
- 9/4 Novartis halts shipping of vaccine
- 9/17 NVAC discussions on vaccine stockpile
- 10/7 Novartis resumes vaccine distribution, for PEP only

UNMET PRE-EXPOSURE NEEDS

- 'First responder' subjects at risk, before occupational exposure to rabies.
- Subjects include animal control workers, diagnosticians, veterinary staff, etc.
- Staff activities directly determine potential PEP management of exposed patients.

MASS HUMAN CONTACT WITH A RABID BAT, October 2008

- Approximately 100 families were evaluated for potential application of rabies postexposure prophylaxis in MT after 'contact' with a dead rabid bat that was brought to a school, demonstrating the effect that even single point sources and multiple public concerns may have on vaccine supply.

AD HOC WORKING GROUP MEMBERS

- D. Briggs, Kansas State University, *Alliance for Rabies Control*
- B. Cherry, New York State Department of Health, *CDC Zoonoses Working Group Liaison*
- R. Chipman, USDA/APHIS/Wildlife Services, *Wildlife Society Infectious Diseases Work Group*
- P. Cieslak, Oregon Public Health Division, *ACIP*
- L. Conti, Florida Department of Health, *Am. College of Veterinary Preventive Medicine*
- V. Dato, Pennsylvania Department of Health, *Am. Association of Public Health Physicians*
- J. Duchin, Public Health, Seattle & King County, & University of Washington, *National Association of County and City Health Officials*
- S. Fryhofer, Emory University School of Medicine, *American College of Physicians*
- P. Garman, Office of the Army Surgeon General, *Department of Defense*
- B. Grogg, Oklahoma International Travel Medicine Clinic, *International Society of Travel Medicine*
- G. Hansen, KS Department of Health & Environment, *AVMA Congressional Fellow*
- S. Jenkins, Virginia Department of Health, *American Veterinary Epidemiology Society*
- S. Katz, Duke Children's Health Center, *Infectious Diseases Society of America*
- J. Kazmierczak, WI Division of Public Health, *National Assoc. of State Public Health Veterinarians, Inc.*
- D. Kerr, Columbia Hospital Emergency Department, *American College of Emergency Physicians*
- K. Nusbaum, Auburn University, *Association of American Veterinary Medical Colleges*
- R. Ratad, Louisiana Department of Health, *Council of State & Territorial Epidemiologists*
- L. Robinson, Texas Department of State Health Services, *Binational Rabies Committee*
- W. Schaffner, Vanderbilt University School of Medicine, *National Foundation for Infectious Diseases*
- D. Shlim, Jackson Hole Wyoming Travel and Tropical Medicine Clinic, *International Society of Travel Medicine*
- B. Sun, CA Department of Public Health, *Compendium of Animal Rabies Prevention & Control Committee*
- C. Trimarchi, NY State Department of Health, *American Public Health Laboratory Association*
- J. Turner, University of Virginia, *American College Health Association*

HHS WORKING GROUP MEMBERS

CDC

National Center for Immunization and Respiratory Diseases:

W. Atkinson, G. Wallace, J. Santoli

National Center for Preparedness, Detection and Control of Infectious Diseases:

G. Galland, N. Marano, M. Meltzer

National Center for Zoonotic, Vector-borne & Enteric Diseases:

P. Arguin, J. Blanton, K. Christian, R. Franka, H. Henderson, I. Kuzmin, S. Recuenco, K. Robertson, C. Rupprecht, A. Tumpey

FDA

Center for Biologics Evaluation & Research

R. Levis, D. Scott

TIPPING POINTS FOR USE OF RECOMMENDATIONS

- Based upon a combination of historical animal rabies surveillance data, prior mass human rabies exposure situations, and conventional aggregate commercial seasonal distributions of product over time, a national shortage in biologicals would be forecast when expected PEP needs are projected to out strip estimated rate of use of available supplies of human rabies vaccines or immune globulins.

SUGGESTIONS OF THE AD HOC WORKING GROUP

- A draft of interim recommendations for human rabies prevention in the event of a forecast shortage of biologicals used in prophylaxis was previously distributed to ACIP, and favorable comments were received.

RABIES VACCINATION OPTIONS

- Use alternative schedules, such as the elimination of the 5th (final dose) of vaccine in a naïve patient during PEP, was one of the recommendations by the ad hoc work group.
- Based upon review of the draft document by ACIP members, the suggestion was made to evaluate this option for routine PEP use, regardless of a vaccine shortage.

FOCUS OF A NEW ACIP WORKING GROUP

- Review evidence for eliminating last PEP dose
- Draft recommendation for altered schedule
- Discuss at February 2009 ACIP meeting
- Present statement for consideration of a vote
- P. Cieslak (chair), S. Lett (ACIP member), others TBD

Source of Evidence for the ACIP Working Group

- Modern rabies virus pathogenesis concepts
- Basic immunization principles and kinetics
- Published literature on clinical trials
- Epidemiological surveillance on PEP failures
- Consultation with commercial partners

SUMMARY

- Supplies of biologicals used in human rabies prophylaxis are expected to remain less than ideal over the next year.
- CDC, FDA, HHS, industry, state health departments, and other national stake holders continue to work together towards productive solutions to mitigate current human rabies vaccine supply issues.
- Deliberations of an ad hoc national rabies working group resulted in the development of draft interim recommendations related to contingency actions that would be utilized in the event of any forecast actual shortages in the future.
- Formation of an ACIP working group to consider a reduced vaccine schedule for PEP is one outgrowth of this process.

REFERENCES

- Advisory Committee on Immunization Practices, Human Rabies Prevention, 2008, MMWR 57: RR-3.
- World Health Organization, Expert Consultation on Rabies, Geneva, Switzerland, 2005, Tech Rep Ser 931:1-88.
- Vaccines (ed. S. Plotkin, W. Orenstein, P. Offit), 5th Ed, 2008, Saunders/Elsevier.