Abstract

Rabies is a horror in which lethal viruses, with the help of millions of infected animals, can spread without control. The disease is fatal and is known to spread in nature, with the death rate of over 70,000 people worldwide each year. Government regulatory agencies and industry participants recognized that the current rabies vaccine potency testing method is outdated. The World Health Organization estimates that 15 million people receive post-exposure vaccine, but the methods used are outdated and need to be replaced.

Introduction

• Paper reviews the need to replace the traditional animal-based rabies vaccine potency testing methods.
• Recent developments in the field indicate that alternative methods are needed to replace the traditional methods.
• In the United States and other developed countries, rabies vaccines have been effectively administered to humans and animals, highlighting the importance of continuing research in this field.

Workshop Sessions

• Overview of current tests and regulatory requirements for rabies vaccine potency testing.
• International perspective on the incorporation of 3Rs alternatives in vaccine testing.
• Presented the currently available serological methods for the batch potency testing of human and veterinary rabies vaccines.
• Summarized public health needs for rabies vaccines in the United States, and the significant planned initiatives to address these needs.

Rabies Vaccine Potency Test Methods

Mouse Challenge Test (Protection-Based Method)
- Variations in the tests can be performed to assess the relative potency of different vaccine preparations.
- Immunogenicity is the key factor in determining the effectiveness of a vaccine.
- ELISA test for rabies vaccine potency determination is being used.

In Vitro Human Rabies Vaccine Immunoprophylaxis Test
- ELISA test for rabies vaccine potency determination is being used.
- A significant number of LABs have been using the SNT, with improved results.
- ELISA test for rabies vaccine potency determination is being used.

Workshop Summary Recommendations

• The development of alternative methods for rabies vaccine potency testing is a high priority. In the interim, humane endpoints, the use of anesthesia, and the use of analgesics should be implemented to minimize pain and distress, and (4) should be replaced as soon as possible.

Workshop Organizing Committee: ICCVAM Interagency Biologics Working Group and Ad Hoc Liaisons

References


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