



Session I-18: Report on the ICCVAM International Workshop on Vaccines

Session I-18: Oral presentations

I-18-569

International workshop on alternative methods to reduce, refine, and replace the use of animals in human vaccine potency and safety testing

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Few medical interventions have had a greater impact on human health than vaccines. Immunization efforts have resulted in the global eradication of smallpox, and the elimination of polio, measles, and rubella in the Americas. Prior to the release of post-licensing production lots of vaccine, regulatory authorities require testing to ensure potency and safety, which can involve large numbers of animals that experience unrelieved pain and distress. NICEATM-ICCVAM organized an international workshop with ECVAM, JaCVAM and Health Canada to review the state of the science and identify priority activities to advance scientifically sound alternative methods that can reduce, refine and replace animal use in vaccine potency and safety testing. Nearly 200 scientists from 13 countries identified relevant knowledge and data gaps, and identified necessary priority research, development, and validation activities. Diphtheria and

tetanus toxoids, pertussis, rabies, anthrax, inactivated polio, and combination vaccines were identified as the highest priority vaccines because they use large numbers of animals and induce significant pain and distress during testing. Research into specific mechanisms of vaccine protection and identifying clinically relevant immunological markers was considered necessary to successfully implement *in vitro* alternatives. Participants agreed that broader acceptance and use of alternative methods would require broader access to information, increased global communication among regulatory authorities, research institutions, and vaccine manufacturers, and harmonization of testing requirements. Implementation of the workshop recommendations is expected to advance alternative methods for vaccine potency and safety testing that will benefit animal welfare while ensuring continued protection of human and animal health.



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International workshop on alternative methods to reduce, refine, and replace the use of animals in veterinary vaccine potency and safety testing

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Veterinary vaccines represent an important tool for improving animal and human health by preventing a wide range of infectious diseases in animals and reducing serious zoonotic diseases in people. However, regulatory testing to meet vaccine lot release requirements can require large numbers of animals that may experience unrelieved pain and distress. NICEATM-ICCVAM organized an international workshop in partnership with ECVAM, JaCVAM and Health Canada to review the state of the science of human and veterinary vaccine potency and safety testing, and to identify priority activities to advance scientifically sound alternative methods that can further reduce, refine and replace animal use. Nearly 200 scientists from 13 countries participated in the workshop during which they identified relevant knowledge and data gaps and priority research, development and validation activities to address these gaps. This included identifying opportu-

nities to apply new science and technology to develop improved methods. The highest priority vaccines were Rabies, *Clostridium sp.*, and *Leptospira sp.* vaccines because they require large numbers of animals and involve significant pain and distress. Vaccine challenge testing, which often requires live viruses and bacteria hazardous to laboratory workers, livestock, pets, and wildlife, were also considered high priorities. Collaborations between human and veterinary researchers working on vaccines for the same or similar organisms were recommended to leverage scientific resources and expedite progress. Implementation of the workshop recommendations will likely advance alternative methods for vaccine potency and safety testing to benefit animal welfare while ensuring continued protection of animal and human health.