

REPORT OF THE COMMITTEE ON FOREIGN AND EMERGING DISEASES

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The Committee met on October 23, 2012 at the Greensboro Sheraton Hotel, Greensboro, North Carolina, from 8:00 a.m. to 6:30 p.m. There were more than 130 members and guests present. Dr. Paul Gibbs welcomed the Committee and guests and Dr. Tammy Beckham provided an update on 2011 Committee resolutions.

Time-Specific Paper

Dr. Wim H.M. Van der Poel, Senior Scientist at the Central Veterinary Institute of Wageningen University and Research Centre presented a time-specific paper on the 2011 Schmallenberg Virus Outbreak. The paper in its entirety is included at the end of this report.

Presentations and Reports

Update on the National Research Council Report: *Meeting Critical Laboratory Needs for animal Agriculture: Examination of Three Options*

Terry McElwain

Executive Director, Washington Animal Disease Diagnostic Laboratory, Associate Director, School for Global Animal Health

Dr. McElwain provided an update and overview of the NRC Study: *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of three Options*. McElwain described the charge to the NRC committee and the process utilized during the study. The three options that were studied were discussed in detail. Recommendations and conclusions from the study were discussed and reviewed during this update.

Mexico CSF and END-Progress on International Recognitions of Disease Free Status for CSF and Efforts to Meet APHIS END Requirements

Dan Sheesley

Chief Executive Officer, Sheesley Enterprises, LLC

The main objective of this project was to provide technical assistance and guidance to both Ministry of Agriculture, Livestock, Rural Development, Fishing and Food (SAGARPA), National Services of Food and Agriculture, Health, Safety and Quality. (SENASICA) and USDA Animal and Plant Health Inspection Service (APHIS) in establishing a framework for collaborative relationships to obtain the recognition of specific regions of Mexico as Classical Swine Fever (CSF) and Exotic Newcastle Disease (END) free.

High priority was given to upgrading laboratory diagnosis and reporting procedures, as well as standardizing processes nationwide for laboratory diagnosis methodology, epidemiological surveillance activities, follow up and closure of suspect cases and the establishment of emergency plans for the control and elimination of CSF and END outbreaks.

Methodology included analysis of training needs, design of "Quick Guide" and other standardized field investigation tools, standardization of diagnostic laboratory protocols, thorough documentation and presentation of the required information for USDA for consideration of recognition of CSF free regions and END low risk regions. Sheesley Enterprises conducted comprehensive series of mock reviews for APHIS inspection visits and facilitated the bilateral negotiation meetings held between Mexico and the United States.

Current results include USDA certification of Mexican official laboratories for CSF diagnosis. The recognition by APHIS of Baja California, Baja California Sur, Sonora, Chihuahua, Nayarit, Campeche, Yucatán and Quintana Roo as CSF free states and the probable CSF free recognition for the states of Jalisco, Colima, Michoacan, Zacatecas, San Luis Potosi, Guanajuato and Queretaro. The certification and standardization of Mexico official laboratories for the END diagnosis is well underway, however, further work on the END phase of project was interrupted by the recent outbreak of Avian Influenza.

Update: Department of Homeland Security (DHS), Science and Technology (S&T) Directorate.

Michelle Colby

Branch Chief for Agricultural Defense in the Chemical and Biological Defense Division of DHS Science and Technology Directorate

A brief update on the animal health related research and development (R&D) projects funded by the Department of Homeland Security's Science and Technology Directorate. Dr. Colby provided an overview of the methods by which entities can do business with the DHS S&T Ag Defense Branch. There are three methods of funding: 1) Grant; 2) **Cooperative Research and Development Agreement (CRADA)**; and 3) Contract. The grant process is a competitive process with the deliverables to include publication, report or completion of a project. The contract is also a competitive process in which the deliverable is a product or service. The CRADA is awarded by the Notice of CRADA intent and either party may approach the other to initiate. The deliverable is a product or services agreed to on both sides. Contact information for the program SandT@dhs.gov.

Update: National Veterinary Services Laboratories

Elizabeth Lautner

Director National Veterinary Services Laboratories (NVSL), USDA-APHIS

Key diagnostic activities NVSL engaged in during 2012 included the identification of the fourth case of BSE in the US, implementing test protocols for detecting Schmallenberg virus, and supporting ongoing investigations of an Influenza A H3N2 virus infecting both swine and humans. From October 1, 2011 through August 1, 2012, NVSL received over 60,000 accessions and has processed over 162,000 samples, with approximately 432,000 tests being reported to clients. The Diagnostic Bacteriology Laboratory continues to support VS efforts in antimicrobial resistance and the tuberculosis and brucellosis programs. Other activities of the Diagnostic Virology Laboratory included test support for the vesicular stomatitis virus outbreak in NM and CO, and identification of a novel influenza virus (H3N8) from harbor seals on the East Coast. The Pathobiology Laboratory coordinated a validation study for three new immunohistochemistry platforms for scrapie and chronic wasting disease program testing, in collaboration with the National Animal Health Laboratory Network (NAHLN). NVSL also provided training and proficiency testing on various diagnostic test methods for US and international audiences. This last year NVSL laboratories distributed over 4700 kits for 22 different diseases. We continue providing diagnostic laboratory expertise to international countries, and responded to 15 requests for assistance including a collaborative project to develop and deploy a Teschovirus vaccine to Haiti. This year NVSL also received designation as an Office of International Epizootics (OIE) reference laboratory for FMD, and as a Food and Agriculture Organization (FAO) reference center for animal influenza and Newcastle disease, bovine tuberculosis and paratuberculosis.

Update: Foreign Animal Disease Diagnostic Laboratory

Fernando Torres-Velez

Director, USDA-APHIS-NVSL Foreign Animal Disease Diagnostic Laboratory (FADDL)

No summary available.

Update: Plum Island Animal Disease Center Foreign Animal Disease Research Unit (FADRU)

Luis Rodriguez

Research Leader, FADRU, USDA-ARS

The Foreign Animal Disease Research Unit (FADRU) at Plum Island Animal Disease Center is the primary laboratory in ARS responsible for research on foreign animal diseases (FAD) of livestock, such as foot-and-mouth disease (FMD), classical swine fever (CSF), African swine fever (ASF) and vesicular stomatitis (VS), diseases that could be accidentally or deliberately introduced into the United States in acts of agro-terrorism. The mission of the FADRU is to carry out the research needed to understand the pathogenesis of these microbes and the host response to them, and to translate this knowledge into useful interventions and diagnostic tools for an effective response. During the last year, there have been important developments and accomplishments, including the successful re-initiation of ASF research; licensing of the Ad5-FMD vaccine discovered by ARS scientists, continuation of development of marker CSF live-attenuated vaccine and characterization of the re-emerging VS virus in New Mexico. FADRU scientists made great progress toward understanding FMDV, ASF and CSFV functional genomics, pathogenesis and immunology identifying a number of critical interactions between host-cell and viral proteins. They also made great progress in understanding the immune responses against FMD including the T-cell responses that had been previously poorly characterized. These accomplishments are documented in 23 peer-reviewed scientific articles published in the most prestigious journals. Additionally two patents were filed on next generation FMD vaccines. The FADRU had a very strong and successful year due in great part to the continued support not only of USDA base funds, but also extramural support from stake holders and sponsoring agencies including Department of Homeland Security (DHS), State Department, Department of Defense (DoD), Wellcome Trust, National Science Foundation (NSF) and National Pork Board among others.

Update: Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD)

Juergen Richt

Director CEEZAD, Kansas State University

CEEZAD is the Co-Lead for the DHS Center of Excellence for Zoonotic and Animal Disease Defense (ZADD). Together with the Foreign Animal and Zoonotic Disease Defense Center (FAZD), CEEZAD addresses challenges posed by high priority foreign animal and zoonotic diseases. CEEZAD's research program is in its third year of implementation. Currently, CEEZAD's research portfolio is represented by projects in the areas of vaccine development, diagnostics, epidemiology/modeling and education with participation of universities, government agencies, and industry partners. The major focus in the vaccine area is on the development of subunit and vector-based vaccines for RVFV and continuing expansion and development of CEEZAD vaccine platforms. Diagnostic and detection efforts focus on the development of multiplex (RT) PCR tests for agents important for agricultural species and unbiased detection and molecular characterization of emerging novel pathogens. Several projects are devoted to the epidemiology, risk assessment, and decision to development for Rift Valley fever virus (RVFV). Through the Education and Outreach Overlay, CEEZAD supports continuing education courses on emerging diseases of animals and training for BSL-3 containment. Recently, CEEZAD in collaboration with Center for Food Security and Public Health (CFSPH), held a workshop on Vaccine and Diagnostics for Transboundary Animal Diseases in Ames, Iowa, and was awarded a grant through the Kansas Biosciences Authority for development of diagnostics and prophylactics against Schmallenberg virus, a recently emerged pathogen of ruminant species in Europe.

Update: National Center for Foreign Animal and Zoonotic Disease Defense

Tammy Beckham

Director, DHS National Center for Foreign Animal and Zoonotic Disease Defense, Texas A&M University

The Foreign Animal and Zoonotic Disease (FAZD) Defense Center is a DHS National Center of Excellence. FAZD is the Co-Lead of the Zoonotic and Animal Disease Defense Center (ZADD) with the Center of Excellence for Emerging and Zoonotic Animal Diseases at Kansas State University. This presentation reviewed the FAZD portfolio to include the Biologic, Information Analysis and Education and Outreach components of FAZD and their activities throughout 2012. Most notably, FAZD Center is working with partners in federal, state, agricultural and private industries to develop biological countermeasures (agricultural screening tools) to support early detection and business continuity efforts within the US. The information analysis systems theme projects support continued development of the Ag Connect suite of tools. These tools include the Emergency Response Support System, the Laboratory Capacity Estimation Model, the Biosurveillance Field Entry System and the Enhanced Passive Surveillance System. The ERSS can be utilized for all phases of an emergency response (preparedness, response and recovery). The Education and Outreach Theme has developed K-12 programs as well as supporting the training of doctor of veterinary medicine (DVM) and graduate students through career development grant opportunities.

Update: National Animal Health Laboratory Network (NAHLN)

Sarah Tomlison

Associate Coordinator, NAHLN, USDA-APHIS

The National Animal Health Laboratory Network (NAHLN), established in 2002 as a partnership between 12 State and University diagnostic laboratories and USDA, has evolved to include over 60 State, University and Federal laboratories.

To create a consistent and credible framework for the NAHLN laboratories, the following Founding Principles were developed:

- Quality management standards
- Competency of laboratory personnel
- Standardized diagnostic techniques
- Reference materials and equipment
- Secure communications and reporting system
- Adequate facilities to ensure biosafety/biosecurity levels
- Assessment of preparedness through scenario testing

To support these principles, the NAHLN Program office has developed and delivered training courses that include Procedures for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents. Additionally, the NAHLN Program office has collaborated with the American Association of Veterinary Laboratory Diagnosticians (AAVLD) Accreditation Committee to develop the Quality Management System (QMS) Training Program. The NAHLN has been an active partner in collaborating with various stakeholder groups to enhance preparedness. Network function is being enhanced through collaboration with the Foreign Animal and Zoonotic Disease Defense (FAZD) and NAHLN laboratories on the development of the Laboratory Capacity Estimation Model (LCEM) which will evaluate and monitor the testing capacity during a disease outbreak as well as through web-based exercises that are currently being piloted. In addition, Ag Screening Tools workshops have been conducted by FAZD in collaboration with federal, state and industry partners to identify diagnostic and policy gaps. Based on input from these collaborations and with the assistance of NAHLN laboratories, multiple assays have been developed through funding provided by the Department of Homeland Security. Information from each activity has been used to prioritize actions needed to improve the Nation's ability to address transboundary diseases.

USDA Response to Schmallenberg Virus: Testing and Diagnosis

Diane Rodman

Veterinary Medical Officer, Diagnostic Virology Laboratory, National Veterinary Service Laboratory (NVSL), USDA-APHIS

An update on the USDA response to the EU outbreak of Schmallenberg virus was provided. Through collaborations and cooperation from EU laboratories, the USDA-NVSL Ames and NVSL-FADDL have obtained the capability to perform virus neutralization, PCR and virus isolation for detection of the Schmallenberg virus.

2012 California BSE Incident: Behind the Scenes

Annette Whiteford, State Veterinarian, California

Dr. Whiteford gave an update on the timelines of the bovine spongiform encephalopathy (BSE) outbreak in California in 2012. She also gave an overview of the communications and coordination process in handling and dealing with this recent outbreak and identification of a BSE positive dairy cow in California.

Avian Influenza in Jalisco, Mexico

Hugo Fragoso

Director, National Centre for Animal Health Verification (CENAPA), Mexico

The 2012 outbreak of H7N3 in Jalisco, Mexico was reviewed during this presentation. A timeline for detection, typing and response was outlined along with the numbers of premises and birds affected. Response strategies were discussed as well as effects on the egg industry in Mexico.

Assessment of National Strategies for Control of HPAI and H5/H7

Low Pathogenicity Notifiable Avian Influenza (LPNAI) with an emphasis on Vaccination Programs

David Swayne

Director, USDA-ARS Southeast Poultry Research Laboratory

There have been 31 epizootics of H5 or H7 high pathogenicity avian influenza (HPAI) from 1959 to early 2012. The largest has been the H5N1 HPAI which began in Guangdong China in 1996, and has affected over 250 million poultry and/or wild birds in 63 countries. For most countries, stamping-out programs have been used in poultry to eradicate HPAI. However, 15 affected countries have utilized vaccination as a part of the control strategy. Greater than 113 billion doses were used from 2002-2010; 95.5% inactivated and 4.5% recombinant live vaccines. Mongolia, Kazakhstan, France, The Netherlands, Cote d'Ivoire, Sudan, North Korea, Israel, Russia, and Pakistan used <1% of the AI vaccine, and vaccination was targeted to preventive or emergency use. Five countries have utilized nationwide routine vaccination programs, accounting for 99% of vaccine use: 1) China (90.9%); 2) Egypt (4.6%); 3) Indonesia (2.3%); 4) Vietnam (1.4%); and 5) Hong Kong SAR (<0.01%). Six countries have enzootic H5N1 HPAI: 1) China, Indonesia, Egypt and Indonesia implemented vaccination after H5N1 HPAI became enzootic in poultry, and 2) Bangladesh and eastern India have enzootic H5N1 HPAI without vaccination. Vaccine use has prevented clinical disease and mortality, reduced human cases, and maintained rural livelihoods and food security. However, field outbreaks have occurred in vaccinating enzootic countries primarily because of inadequate coverage in the target species, but also some instances of vaccine failures

following antigenic drift of field viruses. The primary strategy for HPAI and H5/H7 LPNAI control will continue to be immediate eradication by a four component strategy: 1) education, 2) biosecurity, 3) rapid diagnostics and surveillance, and 4) elimination of infected poultry. Vaccination can be a second tier component or 'tool' when immediate eradication is not feasible.

Development of an Influenza Risk Assessment Tool

Susan C. Trock¹, Nancy J. Cox¹, & Stephen A. Burke^{1&2}

¹NCIRD, Influenza Division, CDC, Atlanta, GA; ²Battelle Atlanta Analytical Services, Atlanta, GA

Influenza pandemics pose a continuous risk to human and animal health and may engender food security issues. As new reassortant influenza A viruses are identified, pandemic preparedness strategies necessarily involve decisions regarding which viruses to target for further studies and mitigation efforts.

Scientific advances have yielded an explosion of information regarding influenza. Laboratory advances allowing for deep genome sequencing, three-dimensional crystallography, increased sophistication of experimental designs and studies have provided insight into differences among what heretofore might have been considered the same influenza virus. Additionally, there has been an increase in epidemiologic studies and surveillance, often gathering information from wildlife or domestic animals sources.

Resource limitations dictate that viruses posing the greatest risk to public or animal health be selected for further research and potentially as vaccine candidates. Recently there is interest in applying objective, science-based risk assessments to evaluating influenza viruses. Such assessments often seek to answer different questions. The CDC has proposed an Influenza Risk Assessment Tool (IRAT) to address two specific questions: 1) What is the risk that a virus not currently circulating in the human population has the potential for sustained human-to-human transmission; and 2) If the viruses were to achieve sustained human-to-human transmission, what is the risk that a virus not currently circulating in the human population has the potential for significant public health impact? These questions define the parameters of the Tool.

The IRAT is being developed with input from animal health partners and could also be applied to development of animal influenza vaccines.

Quad Foot-and-Mouth Disease (FMD) Code Project

Tom Smylie

Senior Staff Veterinarian, Canadian Food Inspection Agency

Can the three month vaccinate-to-die and six month vaccinate-to-live policies be aligned for trade in animal products?

In 2011 to 2012, Canada along with other QUAD country members undertook a literature review to explore if current science could support eligibility to regain World Animal Health Organization (OIE) status of FMD free country where vaccination is not practiced in three months following an outbreak where stamping-out and higher potency emergency vaccination is applied irrespective of whether vaccinate-to-live (currently six months) or vaccinate-to-die policies (currently three months) were used.

Alignment of the three month waiting period for products derived from animal vaccinated with homologous higher potency emergency vaccines is feasible. Additional risk mitigation measures to meet individual country's Appropriate Level of Protection (ALOP) as in any application of the Code may be necessary.

The Code provides recommendations for safe trade for germplasm and other animal products from vaccinates in a FMD free country where vaccination is practiced. Geographically and temporally limited use of higher potency FMD vaccines for emergency vaccination in a country with OIE status, FMD free country where vaccination is not practiced results in an insignificant increment to negligible in terms of products derived from such vaccinates. The increase in risk is significantly less than the risk level in countries eradicating FMD with routine conventional vaccination. This risk differential is recognized by the OIE in currently setting relative waiting periods and is evidenced by experimental and modelling studies.

Rather than stipulating a three or six month waiting period, the review proposes that the OIE set an acceptable level of statistical certainty for surveillance to (i) substantiate the absence of FMDV infection for an FMD free country where vaccination is not practiced; or (ii) demonstrate the absence of FMDV circulation for FMD free country where vaccination is practiced.

Is the United States Really at Risk for Introduction of Rift Valley Fever Virus

Mo Salman

Professor of Veterinary Epidemiology; College of Veterinary Medicine and Biomedical Sciences, Colorado State University

Rift Valley Fever (RVF) continues to garner significant attention as a potential agricultural and zoonotic disease threat to the United States (USA). Major outbreaks have been recorded in many parts of sub-Saharan Africa since that time. The first report of RVF outside of Africa was attributed to the importation of cattle and small ruminants from the Horn of Africa. The aim of this presentation is to qualitatively assess the threat of introduction of RVF in non-endemic regions, particularly into the USA. Various routes of introduction will be discussed.

The United States Department of Agriculture (USDA) recently convened a group of infectious disease scientists within the federal government to assess and prioritize a list of damaging animal disease threats. RVFV was ranked fourth on this list. The likelihood of importation of infected animals into the USA is negligible as all livestock from locations in the world where Rift Valley Fever occurs are prohibited from entering the USA.

RVF virus most certainly does not warrant a ranking of fourth on a list of animal disease threats to the USA. If research work in the USA continues on this virus and disease it should be with the overt objectives of assisting areas of the world where the disease occurs and not for the highly unlikely introduction of virus into the USA.

Following Salman's presentation, several questions arose from the audience regarding the conclusions made in the presentation that RVF did not warrant a high ranking on the US disease threat list. Several committee members questioned and disagreed with the conclusions and stated that indeed, controlling and studying the disease in the endemic areas is important, generally felt that introduction into the US was a possibility that that the US should maintain this high on its threat list.

One Health

Valerie Ragan

Director, Center for Public and Corporate Veterinary Medicine, Virginia-Maryland Regional College of Veterinary Medicine

The concept of One Health, while not a new concept, is one that is gaining increased visibility and interest in the veterinary profession. The concept is often schematically demonstrated as three interlocking circles representing the linkages between animal health, human health, and environmental health.

The mission statement for the One Health Initiative states: Recognizing that human health (including mental health via the human-animal bond phenomenon), animal health, and ecosystem health are inextricably linked, One Health seeks to promote, improve, and defend the health and well-being of all species by enhancing cooperation and collaboration between physicians, veterinarians, other scientific health and environmental professionals and by promoting strengths in leadership and management to achieve these goals.

There are numerous examples of new interdisciplinary partnerships between agencies that are being developed to address zoonotic diseases worldwide. However, challenges remain for implementation, especially in underdeveloped countries where funding and education are limited, yet the threats of zoonotic diseases are exceedingly high. In this presentation, a perspective on enhancing implementation at the local level will be discussed, resulting in a proposal for a new One Health paradigm.

New World Screwworm Exercise in Florida with Historical and Current Threat Information

Gregory Christy

Division of Animal Industry, Florida Department of Agriculture and Consumer Services

Since 2000, 12 imported animals with a *Cochliomyia hominivorax* (New World Screwworm) larvae infestation have been identified in the United States. Although in those cases, the larvae were eliminated before the life cycle of the fly could be completed, awareness and constant surveillance is necessary to prevent further reintroduction of the pest into the US. It is estimated that if screwworm were reintroduced into the US and became established, losses in the southern US alone could exceed \$1 billion a year.

Because of this threat, on January 24-25, 2012, the Florida Department of Agriculture and Consumer Services (FDACS), Division of Animal Industry, hosted a *Cochliomyia hominivorax* (New World Screwworm) tabletop training exercise at the State Emergency Operations Center (SEOC) in Tallahassee, Florida. The simulated outbreak spread across multiple Florida counties and impacted livestock industries, pets, and public health. For two days, participants planned response actions to a series of realistic scenarios and were divided into a Multiagency Coordination (MAC) group, a simulated Incident Management Team (IMT), and a state-level Joint Information Center (JIC). Dr. John Welch, USDA-APHIS, International Services (IS) and Dr. Steve Skoda, USDA, Agricultural Research Services (ARS) attended the exercise and acted as subject matter experts on current USDA screwworm eradication programs.

Dr. Clarence Campbell, Florida's State Veterinarian from 1952 through 1991, presented information at the exercise about the joint state-federal screwworm eradication program in the southeastern US, which began in 1957 during his tenure. He was instrumental in the successful implementation of Florida's program. Using sterile flies produced in a converted WWII airplane hangar in Sebring, Florida, the 2-year campaign cost approximately \$11 million and eliminated the annual \$20 million in screwworm-related producer losses in the southeastern US.

The presentation will include information and historical pictures and video about the past joint state-federal *Cochliomyia hominivorax* (New World Screwworm) eradication program in the southeastern United States and the current sterile insect technique (SIT) eradication status in Mexico and Central America. The Florida training exercise, with its lessons learned, will be discussed, as well as recent developments regarding the USDA plan to end funding of a sterile fly plant in Mexico.

FADD Field Manual for Use in FAD Field Investigations

Liz Clark

Laboratory Training Specialist, Professional Development Staff, Plum Island Animal Disease Center

In 2010, a USDA Foreign Animal Disease working group was formed to review the Foreign Animal Disease Diagnostician (FADD) course. The group consisted of Animal and Plant Health Inspection Service (APHIS), Eastern and Western Region epidemiologists, state and federal FADDs, National Center for Animal Health representatives, Emergency Management (NCAHEM) and the Professional Development Staff (PDS). The group identified the need for additional Foreign Animal Disease (FAD) training support. Among the specific recommendations was a FAD Field Guide to include "Job Aids" designed to facilitate the state and federal FADDs during their FAD investigations.

The goal for the FAD Field Guide was to develop an easy-to-use, easily updateable guide in order to stay current on policies and procedures and for the field manual to serve as a reference guide for federal and state foreign animal disease diagnosticians who are called upon to perform FAD field investigations.

The FAD Field guide will be rolled out during the presentation and a review of the instructional DVD will be also be viewed. The presentation will also provide a brief overview of the current curriculum of the FADD course at the Plum Island Animal Disease Center. Included in the presentation will be current changes to the curriculum, additional training opportunities available to FADDs through area offices, new FADD CE requirements and an overview of the training conducted in 2012.

Committee Business

The USAHA Foreign and Emerging Disease Committee discussed a resolution to support development of a written response plan for a New world screwworm outbreak. The committee reviewed, discussed and passed this resolution. In addition, the committee reviewed and endorsed three resolutions from the joint AAVLD/USAHA Committee on Animal Emergency Management. These included a resolution to support the construction of National Bio and Agro-Defense Facility (NBAF), one to support the procurement of foot-and-mouth disease (FMD) vaccine for the national veterinary stockpile and one for the support of 840 radio-frequency identification (RFID) tags for tagging vaccinated animals during an FMD outbreak.

THE SCHMALLEMBERG VIRUS OUTBREAK IN EUROPE 2011-2012

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Abstract

In November 2011, a novel orthobunyavirus of the Simbu serogroup, the Schmallenberg-virus (SBV), was discovered using a metagenomic approach. The virus was associated with severe diarrhea and milk drop in dairy cattle and malformations of new-born lambs. As with related viruses such as Akabane virus, SBV seems to be transmitted by biting midges. Trans placental infection can result in malformations in fetuses of ruminants. During the epidemic, in thousands of farms in Germany, The Netherlands, Belgium, France, Italy, Spain, United Kingdom, Luxembourg, Denmark and Switzerland, acute infections of adult ruminants or malformed SBV-positive offspring were observed. Very high SBV seroprevalences were detected in adult ruminants in the core regions in the Netherlands, Germany and Belgium. As the family of Bunyaviridae contains several important zoonoses, studies were performed to elucidate its zoonotic potential. In a rapid risk assessment in December 2011 it was concluded that human infections were unlikely but could not be excluded. Therefore both in the Netherlands and Germany serosurveys in the human population were performed. Persons exposed to SBV, farmers and veterinarians, were tested. None of the tested individuals showed antibody to SBV and it was concluded that there is no evidence for zoonotic infection. Very soon after the SBV outbreak started, veterinary institutes in the affected countries worked together on the development of diagnostic tools, materials and protocols were rapidly exchanged. After RT-PCR virus detection methods were put in place, institutes focused on the development of antibody tests, which are indispensable for the needed epidemiological surveys. In February 2012, the world organisation for animal health (OIE) scientific committee endorsed recommendations for trade, and in March 2012 scientific support studies on Schmallenberg virus were started commissioned by the European commission and the involved EU member states.

Schmallenberg Virus First Detection and Spread

In November 2011, a novel orthobunyavirus was detected in plasma samples from cattle with fever and reduced milk yield in a farm near the German town of Schmallenberg (1). The Schmallenberg virus (SBV) was traced using a metagenomic approach with next generation sequencing. Schmallenberg virus belongs to the Simbu serogroup of the genus Orthobunyavirus and is most closely related to viruses of the Sathuperi species (2). The Schmallenberg virus infection represents the first known outbreak caused by a member of the Simbu serogroup in Europe.

First acute infections were detected in cattle in late summer 2011 in Germany and the Netherlands. These infections presented with a short fever period and a marked reduction in milk yield in dairy cattle. In a number of farms, especially in the Netherlands, severe diarrhea was a first striking clinical observation. Acute infections in sheep and goats in association with clinical signs were not seen. In the acute phase of the infection in adult animals a short viraemia of only 5-6 days occurred (1).

Malformations due to SBV infection have been observed from December 2011 onwards in stillborn or new-born lambs, calves and goat kids, which were usually born at term. The first SBV-induced malformed lambs were detected in the Netherlands in December 2011. The main pathological findings induced by SBV were identical to changes described for severe Akabane virus infections: arthrogryposis, torticollis, scoliosis and kyphosis, brachygnathia inferior and various malformations of the brain, cerebellum and spinal cord, including hydranencephaly and porencephaly (3; 4).

Examination of archived samples did not indicate the presence of SBV in Europe before 2011, and it could be concluded that the virus most likely was introduced in Europe in summer 2011. All notified cases of malformed lambs, calves and goat kids that emerged from December 2011 onwards were the delayed consequence of the infection of pregnant sheep, cattle and goats which took place in summer or autumn 2011. Within a few months, the infection had spread over a large area in Western Europe including Belgium, France, Germany, Luxembourg, the Netherlands, the United Kingdom and in 2012 also Switzerland. In 2012 an increasing number of infections were also reported from Poland, Italy, Spain and Denmark.

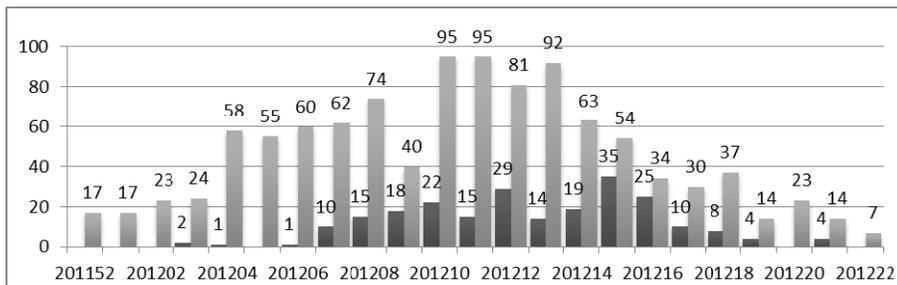


Figure 1. Numbers of brain tissue samples of calves in the Netherlands tested positive (dark grey bars) and negative (light grey bars) by RT-PCR, per week, from week 52 of 2011 until week 22 of 2012.

The first available information on SBV seroprevalence suggested that a large proportion of susceptible species (primarily ruminants) were exposed to the infection in the centre of the epidemic (> 95% in North Rhine-Westphalia). In the Netherlands, the estimated seroprevalence of antibodies to SBV in dairy cows was 72.5% for cattle sera collected between November 2011 and February 2012. High (70-100%) within-herd seroprevalences were observed in two SBV-infected sheep and dairy farms in which a considerable number of animals was tested (5). If SBV-specific antibodies convey protection against reinfection, the level of immunity in ruminant populations will be high in the Netherlands and in North-Western parts of Germany, while a further spread of SBV in or from regions with a lower seroprevalence can be expected in 2012/2013.

Arthropod Vectors

Although vector transmission has not yet been formally proven for SBV, findings indicate that biting midges (*Culicoides* spp.) play a central role in the transmission of the disease. SBV has been detected in *Culicoides* spp. in Belgium (6), Denmark (7), Italy, the Netherlands and Germany. In some cases, the infected insects could be typed as members of the *Obsoletus* complex or as *C. dewulfi*. It is not known if other arthropod vectors can also transmit the virus. First experimental infections in cattle at the Friedrich-Loeffler-Institut and in sheep at the Central Veterinary Institute in Lelystad do not suggest that direct horizontal transmission plays any role for SBV transmission (unpublished data).

Impact of the Schmallenberg Virus Outbreak

Economic losses due to Schmallenberg virus infections in livestock production can be considerable on a farm level. Within herds, the highest economic losses are observed in those sheep farms experiencing a high number of malformed lambs. Such malformations have been detected in about 4% of the sheep farms and about 1.3% of cattle farms in the outbreak region. In cattle farms, mostly single or few cases of malformed SBV-infected calves were reported and only a relatively small number of goat farms have been affected. Economic loss in cattle due to delivery of malformed calves is limited and may be lower than the losses due to milk yield reduction and return to service. However, to assess the impact of the SBV outbreak on animal production and animal welfare, it will be necessary to estimate the impact on return to service, milk yields, rates of dystocia, congenital malformations and nervous symptoms in offspring.

Nevertheless, SBV-infections caused substantial concern among farmers and in the general public, already before any calculations of economic losses have been made. The emergence of the infection had major impact on international trade of susceptible animals and animal products such as semen and embryos. Countries imposed restrictions on imports of live cattle from the EU. However, based on the updated OIE factsheet on SBV (8), the European Union (EU) is of the opinion that SBV does not deserve a treatment different from the one applied to Akabane virus, which causes a disease that is neither OIE listed nor notifiable in the EU nor subject to specific OIE standards or restrictions although it is endemic in many areas of the world.

After the SBV outbreak was established in December 2011, a first assessment of the potential human health hazard was made using a risk profiling algorithm at the Dutch Institute for Public Health and the Environment (RIVM), by the German Robert Koch-Institut (RKI) and by the European Centre of Disease Control (ECDC) (9). Since the risk for zoonotic transmission of SBV could not be excluded in the beginning, health complaints of potentially exposed persons were monitored. Serological studies were performed in the human population and in particular among people living and/or working on SBV-affected farms. SBV-neutralizing antibodies were not detected in humans and it was concluded that there was no evidence for zoonotic transmission from either syndromic illness monitoring or serological testing (10:11). Therefore, the public health risk of SBV should be regarded as extremely low to negligible.

Diagnostics and Primary Measures

Diagnostic procedures for the detection of SBV infections became available very soon after the discovery of the virus and were rapidly distributed. They included (i) real-time RT-PCR (implemented and preliminary validated within days; validated commercial kits available after about three months; 12), (ii) neutralisations tests and indirect immunofluorescence (validated with the first virus isolate within a few weeks) and (iii) SBV antibody ELISAs allowing mass screening (available within about five months). These techniques allow the unambiguous diagnosis of SBV infections in malformed neonates by PCR or demonstration of pre-colostral antibodies with high sensitivity and specificity. The short viremia limits the use of RT-PCR for the detection of SBV infections in adult animals to the acute phase of the infection. The sensitivity is highest in animals presenting with fever.

Immediately after the emergence of SBV was recognized, the Netherlands was the first country to impose the obligatory notification of malformed calves, lambs and goat kids on test farms for SBV. It was thus possible to record accurately all infected farms. This measure was prompted by the fact that in the beginning a zoonotic potential could not be excluded and by the need to assess the impact of the epidemic rapidly. At a later stage, the disease was made notifiable in several other European countries including Germany and France. As a consequence, the number of notified cases (i.e. affected holdings in most countries) mainly reflects the distribution of SBV-induced malformations in neonates. The development of the epidemiological situation was swiftly communicated to trade partners and the general public. However, in the area of the epidemic the spread of SBV infections could only be recorded as no measures were feasible to control the outbreak.

For a vector transmitted infectious disease, prompt detection and instigation of control measures such as vaccination are crucial to prevent spread. However, a vaccine is not yet available for SBV. Therefore, further spread of SBV can currently not be influenced by control measures directly aimed at the virus. However several institutes and companies are in the process of developing SBV vaccines, but the availability of licensed products before 2013 is unlikely. As a consequence, as in the early phase of other new epidemics we currently will have to rely on biocontainment and biosecurity measures.

Conclusions

In the case of Schmallenberg virus the novel technology of metagenomics was proven to be very useful for early detection. Schmallenberg virus was detected in the acute phase of the epidemic before the first malformed lambs and calves were born. As a result, diagnostic tools were available very early and could be used to follow the cases of SBV-induced malformation and to study, for example, seroprevalences. Veterinary diagnostics in Europe have proven to be prepared for this kind of outbreak situations and it was shown that there is a very effective network of institutions working on epizootic diseases within the European Union. This network should be supported and improved, as currently is done by the EPIZONE European research Group (www.epizone-eu.net).

A re-emergence and further spread of SBV in Europe can be expected and the spread of SBV by *Culicoides* spp. may be more efficient than the spread of BTV in Europe. Taking the Australian experience with Akabane virus into account, a spread even to countries outside Europe may be possible.

The SBV affected region has some unique features which may favour the introduction of new pathogens: (i) numerous international airports, such as in Amsterdam, Brussels, Cologne, and harbours such as in Rotterdam; (ii) a high human population density with the need of importing large amounts of fresh goods like fruits, vegetables and flowers from all over the world every day; (iii) a high density of cattle and sheep which represent a perfect target for exotic infectious diseases of ruminants; and finally (iv) domestic populations of *Culicoides* spp. which are competent for diseases transmitted by biting midges. This means that new introductions of vector borne diseases must be expected in this region. Infectious diseases surveillance, screening and sentinel programs therefore are indicated. In addition novel technologies such as metagenomics with next generation sequencing and microarray analysis have to be further developed and used for the analysis of cases suspected of exotic infectious diseases. The awareness of farmers and veterinarians about the possible introduction of diseases has to be raised and maintained at a high level. National and international cooperation between institutes and also cooperation between authorities should be improved as much as possible. In addition the 'One Health' approach, involving inclusive collaboration between physicians, veterinarians and other health and environmental professionals, will be more and more important to combat emerging viral diseases.

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