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IABS Meeting on High Pathogenicity Avian Influenza Vaccination Strategies to prevent and control HPAI: Removing unnecessary barriers for usage

October 25 - 26, 2022

WOAH World Organisation for Animal Health

PARIS - FRANCE





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Sponsors

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About the Conference

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Since October 2020, H5Nx 2.3.4.4b lineage of HPAI has spread across Europe, Middle East, Africa and Asia and is a threat to spread into North America. The uncontrolled spread of these viruses through wild aquatic bird migration is of utmost concern and ongoing climate changes contribute to a wider seasonal migration pattern. In addition, the keeping of poultry in free range systems has reduced physical separation of poultry and wild birds increasing risk of HPAI introduction into poultry. Thus, maintaining avian influenza freedom in poultry and preventing zoonotic infections are an increase challenge.

Vaccination can be a useful tool for prevention and control, but its use is prohibited or severely restricted in many countries worldwide. Wider use of avian influenza vaccination would increase sustainable poultry production, improve animal welfare, reduce economic damage, reduce human infections, and contribute to consumers and animal welfare acceptance of control programs.

A harmonised vaccination strategy with updated vaccine strains and innovative vaccine technologies, combined with appropriate diagnostics, surveillance, and disease management, can offer a better approach than stamping-out alone.

This workshop is intended to discuss how to reduce barriers for broader use of vaccination in avian influenza prevention and control strategy.

The workshop will be an open-discussion forum with participation by a wide variety of stakeholders (WOAH, WHO, OFFLU, FAO, WTO, governments, breeding companies, animal welfare, human health, consumers, retailers, scientists, etc).



Scientific and Organizing Committee

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lan Brown, APHA & OFFLU, UK

Sjaak de Wit

GD Deventer, European College of Poultry Veterinary Science
The Netherlands

Madhur Dhingra, FAO, Italy

Timm Harder, FLI, Germany

Rick Hill, IABS, USA

Carmen Jungbäck, IABS-EU, Germany

Gounalan Pavade, WOAH, France

Connie Schmellik-Sandage, USDA, USA

Les Sims, Consultant Veterinarian in Asia, Australia

David Swayne, USDA, USA

Richard Webby, WHO Collaborating Center for Influenza, USA

David Zeman, AAVLD, USA



Scientific Program Tuesday 25th of October, 2022

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Session 1: Introduction to the meeting including objectives and expected outputs/incomes

Moderators: Sjaak de Wit

09:00 – 09:05 Welcome from IABS - **Rick Hill, President IABS, USA**

9:05 – 09:10 Welcome from WOAH - Monique Eloit, General Director, WOAH, France

Welcome from FAO - Madhur Dhingra, Head of EMPRES-AH, FAO, Italy

Vaccine usage to control high pathogenicity avian influenza and barriers to more effective usage: Setting the scene - **David Swayne**, **Department of Agriculture**, **USA**

Session 2: Preventive vaccination in places where virus is not endemic in poultry and maintaining freedom from infection in poultry is the goal

Moderators: David Swayne

09:45 – 10:15

Factors that inhibit usage of preventive vaccination and ways to overcome them - Les Sims, Asia Pacific Veterinary Information Services, Australia

0:15 – 10:35 Trade in poultry and poultry products from places where vaccine is being used

The current avian influenza code chapter and use of vaccination as preventive or emergency measure - Etienne Bonbon, President of the OIE Terrestrial Animal Health Commission, Italy

Vaccination Rules in EU - **Moritz Klemm, Team Leader: Animal Diseases and International, European Commission, Belgium**

10:35 – 11:00 Morning Tea / Coffee



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11:00 – 11:40

Challenges of vaccine availability

11:00 - 11:30

Vaccines available and systems for usage in the field - Erica Spackman, Department of Agriculture, USA

11:30 – 11:40

Biological industry challenges to developing, registering (including updating strains), and making vaccines available for HPAI control - **Carel du Marchie**, **Health for Animals**, **France**

11.40 - 12.20

Surveillance for HPAIV in Vaccinated Populations

11:40 – 12:10

Developing appropriate surveillance systems that provide confidence that HPAI virus is not circulating in poultry - **Timm Harder**, **Fredrick Loeffler Institute**, **Germany**

12:10 - 12:20

What do we have in the commercially available toolbox now and what are the advantages and disadvantages of existing systems - Sjaak de Wit, President of the European College of Poultry Veterinary Science, The Netherlands

12:20 – 12:30

Public Health considerations of avian vaccination - **Richard Webby, St Jude's Children's Hospital, USA**

12:33 - 1:30

Lunch

1.30 - 2.30

Facilitated Panel Discussion/ Hypothetical Vaccination Scenarios for preventive vaccination in poultry (including free-range chickens) in a country with zero tolerance for HPAI virus infection

Panel-Facilitator: Vaugh Kubiak, IABS, France - Panelists (5-6):

- Wim Pelgrim Chief Veterinary Officer of the Netherlands,
 The Netherland
- 2. Giovanni Cattoli International Atomic Energy Agency, Austria
- Moritz Klemm Team Leader: Animal Diseases and International, EU Commission, Belgium
- **4.** Jeremy Ho Agriculture, Fisheries and Conservation Department, Hong Kong
- 5. Emmanuelle Soubeyran Chief Veterinary Officer, France
- **6.** Francesco Bonfante IZSVe, Padova, Italy



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2:30 - 3:30

Five Breakout groups to discuss and analyse the options presented and propose alternatives

3:30 - 3:50

Afternoon Tea

3:50 - 5:00

Break out group presentations ($5 \times 10 \text{ mins}$ and final deliberations/summation by the panel (20 minutes)

End of day 1



Scientific Program

Wednesday 26th of October, 2022

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Session 3: Vaccination for outbreak control in countries where virus is not endemic in poultry and the goal is maintaining/regaining freedom from infection

Moderators: Les Sims

Brief introduction by organizers

Why use vaccination as a control measure and not just use stamping out?

Avian Influenza vaccination field experience especially for emergency use Carol Cardona, University of Minnesota, USA

Emergency vaccination in control of other transboundary animal pathogens and relevance to avian influenza - Arjan Stegeman, Utrecht University, The **Netherlands**

Global Trade issues 9:40 - 9:50

9:10 - 9:40

9:10 – 9:2

9:40 - 9:50

WTO perspective of avian influenza and trade in poultry products - Christiane Wolff, Secretary of SPSS Committee of the World Trade Organization (WTO), **Switzerland**

Options for vaccines for emergency use including Mass Applied Vaccines and Pharmaceutical intervention options available and what might be developed - Ian Brown, DeltaFlu Research Consortium, United Kingdom

Morning Tea/Coffee

Case Study. A practical exercise - emergency vaccination in mega-layer farms in the face of an outbreak (pre- and post-outbreak) in a country that is/ was free from infection and wants to regain freedom from infection in poultry



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Case Study. A practical exercise - emergency vaccination in mega-layer farms in the face of an outbreak (pre- and post-outbreak) in a country that is/ was free from infection and wants to regain freedom from infection in poultry

Panel-Facilitator: Vaugh Kubiak, IABS, France

- 1. Julie L. Gauthier - Department of Agriculture, USA
- 2. Mathias Voss - EU Poultry Veterinarians Study Group, Germany
- 3. Geetha Srinivas - USDA, Center for Veterinary Biologics, USA
- 4. Carole Cardona - Poultry Veterinarian, USA
- Dr Peter Wijnen Private Poultry Veterinarian, The Netherland **5**.
- Guillermo Zavala Private Poultry Veterinarian, Latin America 6.

Break-out Groups

Lunch

1:45 - 3:00

Case Study Continues - Reports from Breakout Group

3:00 - 3:30

Afternoon Tea/Coffee

Session 4: Vaccination in places where virus is endemic

Moderators:

Series of four short presentations. Experiences from countries with endemic infection where vaccination has been used against HPAI

China - Hualan Chen, China

3:45 - 4:00

Latin America - Guillermo Zavala, Private Poultry Veterinarian, Latin America

Indonesia - Hendra Wibawa, Indonesia

Egypt - Arafa Abdelsatar, RLQP, Egypt



Scientific Program

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Questions from audience on how to improve the process

Session 5: summary sessions, conclusions and recommendations

Moderators: Les Sims

4:45 - 5:30

Conclusions and Recommendations

Summary session including next steps and conclusions and recommendations Moderators of the sessions 10' each:

- 1. Sjaak de Wit
- 2. **David Swayne**
- 3. Les Sims
- 4. Ian Brown

End of Conference



Upcoming IABS Conferences and Workshops

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2022



8th Annual IABS Statistics Workshop

Workshop – Advancing the Impact of CMC Statistics for a New Generation of Statisticians, Scientists, and Modelers

November 7-10, 2022

2023



3Rs implementation in veterinary vaccine batch-release testing:
Current state-of-the-art and future opportunities

Brussels, Belgium
November 16, 2022



Globally Harmonized
Specifications: Current State
and Future Opportunities
A Hybrid Meeting

Basel, Switzerland

January 10-12, 2023



Maintening the Quality of Vaccines through the Use of References Standards
Current Challenges and Future Opportunities

June, 2023



Abdel-Satar Arafa

Virology Chief Researcher Organization / Company:, NLQP, Animal Health

Research Institute

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Abdel-Satar Arafa, Chief Researcher virologist and molecular biologist, graduated from Faculty of Veterinary Medicine, Cairo University 1994 and got Master and PhD in 2000 and 2006 respectively in the area of molecular virology. He worked for Animal Health Research Institute (AHRI)- Giza from 1995 in Poultry diseases Department -Tumor & Immunosuppressive disease unit and in the National Laboratory for Veterinary Quality Control on Poultry Production (NLQP) from 2001 till now as a Researcher, Quality Manager and Head of Gene Analysis Unit, then now the Head of NLQP. Since 2006, and after emerging of avian influenza in Egypt, he obtained extensive training in different Animal Health organization (OIE) Reference laboratories in Europe and USA. He got the first prize for innovation in agriculture research awarded from the Arab Organization for Agriculture Development, League of Arab States in 2010 for the research paper presented that described the first record of this disease in Egypt. He awarded the State's Incentive (Encouraging) Award in Agricultural Science (2011): Academy of Scientific Research and Technology, Egypt. He shared in more than 15 scientific research projects and 5 cooperative projects. The role was ranged from student research fellow, assistant researcher, Co-PI and PI. Through those projects, many Master and Ph.D Theses were done, as well as many scientific research papers have been published and the data were presented in scientific conferences. He is still working in the area of genetic characterization of many disease causing agents in poultry and in other animals like avian and animal influenza, Newcastle disease virus, Infectious bronchitis virus, avian tumor viruses, Rabbit Hemorrhagic disease virus, avian Metapneumoviruses and foot and mouth disease virus. He published more than 90 scientific research papers in international peer reviewed journals in the area of his specialty; besides more than 38 technical supervisions for Master and PhD Theses from different Egyptian Universities.

Abstract

Abdel-Satar Arafa

NLQP, Animal Health Research Institute - Giza, Egypt

"VACCINATION IN PLACES WHERE VIRUS IS ENDEMIC: Egypt Practice to control HPAI"

Abdel-Satar Arafa, Mohamed H El-Husseiny, Nahed Yehia, Neveen Rabie, Mohamed Samy, Abdullah Selim, Naglaa M Hagag, Ahmed M Erfan, Samah Eid, Momtaz A Shahein, Mahmoud Naguib Reference Laboratory for Veterinary Quality Control on Poultry Production, Animal Health Research Institute, Agriculture Research Center, Giza 12618, Egypt.

Highly pathogenic avian influenza HPAI (H5N1) was first reported in Egypt in 2006; the disease was widely spread in both commercial and household sectors with declared endemic status since 2008. H5N1 of clade 2.2.1 was the ancestral strain in 2006 and subjected for several mutations that led to emergence of variant clades 2.2.1.1 and 2.2.1.1a in 2008. In 2014, new clade was emerged (2.2.1.2) that led to exacerbated increase in the number of human cases. HPAI H5N8 virus of clade 2.3.4.4 was first detected in Egypt in late 2016. Since then, the virus has spread rapidly among different poultry sectors, becoming the dominant HPAI H5 subtype reported. The continuous circulation of multiple subtypes for several years led to the emergence of the first natural reassortment event in domestic poultry in Egypt, like the HPAI H5N2 virus that was isolated from a commercial duck farm in 2018 that carried the HA gene from H5N8 and the NA gene from H9N2.

On the other hand, H5N1 virus of clade 2.3.4.4b has spread widely in Europe, Asia and western and south Africa in late 2020 causing infection of birds as well as human cases have been reported. In the last few years, extensive epidemiological surveillance was conducted including more than half a million samples collected from different poultry sectors (farms/backyards/live bird markets) from all governorates in Egypt to detect the circulating influenza viruses. The HPAI H5N1 virus of clade 2.4.3.3b was recently identified in 2021 in multiple species of wild birds in Egypt underlines the risk of its spread to domestic poultry. Vaccination was used as a main control measure in Egypt to combat HPAI soon after its first introduction in 2006. Sence then mass and extensive vaccination was used all over the country. Inactivated vaccines as well as vector -based recombinant H5 vaccine are used in different vaccination programs to overcome the antigenic variation among different circulating viruses. However, serological monitoring was limited to moderate and large-scale production sectors.

In conclusion, Egypt is still endemic for H5 avian influenza over the past 15 years. Continuous epidemiological and molecular monitoring of influenza virus spread in different bird species is required. The recent HPAI H5Nx viruses in poultry in Egypt are genetically distinct from the majority of licensed vaccines used in the field. The efficiency of currently used vaccines should be revised routinely and updated to ensure acceptable protection against HPAI H5Nx viruses.



Dr Etienne Bonbon

Senior Veterinary Advisor

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Etienne Bonbon has been Senior Veterinary Advisor to the FAO Animal Health Service, Emergency Management Centre for Animal Health, since May 2017.

He received his diploma in Veterinary Medicine in 1987, DVM in 1989, and Master's degree in human and animal epidemiology in 1991. Primarily a private practitioner in rural areas, he has been a Veterinary Public Health Inspector in the French Ministry of Agriculture since 1991. From 1992 to 2017, he was successively: Deputy Director of Veterinary Services in continental France and Martinica; Head of the Export Unit at General Directorate for Food in Paris; Regional Veterinary Attaché for the Near and Middle East in Beirut, and then for Northern Asia in Beijing; Seconded to the European Commission in DG Santé in Brussels; Head of the Communication Unit of the OIE and Advisor to the Director General of the OIE in Paris; and Seconded to the European Union Delegation to the OECD, UNESCO and OIE in Paris. He has been President of the OIE Terrestrial Animal Health Standards Commission since 2015, after having been Vice-President since 2009, and was reelected in May 2021 for a three-year term.

Abstract

Dr Etienne Bonbon

Animal Health Service - Food and Agriculture Organization of the United Nations - Roma, Italia

"The WOAH Code chapter on HPAI: recommendations regarding vaccination as disease prevention or control and consequences on status, surveillance and trade."

INTRODUCTION: The purpose of WOAH Standards (Codes and Manuals) are a.o. to help prevention of the spread of pathogenic agents via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade. Their application should be in accordance with obligations under the SPS Agreement, i.e. a country's import health measures must be based on WOAH Standards, or on an import risk analysis in the absence of a relevant standard or if a Member chooses to adopt measures more stringent than the WOAH standard, which is very frequent.

ISSUES: Countries too often use the WOAH Codes as 'menus' where they take only what suits or can justify their policies, rather than as a basis to develop and update those policies. They notably do not recognise easily the notion of free vs. infected zones. They also over interpret some recommendations of the Codes. As a result, the impact of trade issues linked to a specific disease threat are often surpassing the direct impact of the disease. Moreover, methods to prevent and control the disease may also have consequences on trade, as is the case with vaccination.

RELEVANT GUIDANCE: Under the WOAH Code Chapter 10.4. on HPAI, vaccination may be recommended under specific conditions, including as an effective complementary control tool when a stamping-out policy alone is not sufficient. Vaccination will not affect the high pathogenicity avian influenza status of a free country or zone if surveillance supports the absence of infection. This surveillance will depend on a number of epidemiological and production factors. Member Countries seeking the demonstration of freedom from HPAI in vaccinated population should also refer to the chapter on avian influenza in the Terrestrial Manual. Evidence to show the effectiveness of the vaccination programme should also be provided.

CONCLUSIONS: Regarding sanitary conditions for trade, the first important issue is to establish HPAI free zones and compartments, as there are no current WOAH recommendations for trade in birds, eggs or fresh meat from infected zones. As there are no 'blocking' recommendations linked with vaccination, it can be implemented not only in infected zones, but also in free zones if needed (after impact assessment) and well supported by surveillance on both effectiveness of vaccines and vaccination campaigns, and on absence of virus circulation. Thus, accurate surveillance, biosecurity and good quality of vaccines are the key elements to avoid importing countries systematically consider vaccinated zones as infected ones.



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Since 2010, Francesco Bonfante has been working as a veterinary virologist, in the Division of Comparative Biomedical Sciences of the Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe), building a strong background in vaccine challenge studies with avian and murine animal models, evaluating the clinical and virological efficacy of licensed and prototype avian influenza vaccines against HPAI and LPAI viruses. Since 2016, Dr. Bonfante has been coordinating the Laboratory of Experimental Animal models and Alternative Methods. In 2019, IZSVe was designated as European Reference Laboratory for Avian Influenza and Newcastle diseases.

F. Bonfante supervises and conducts research in the area of preparedness and response to emerging viral threats, in particular with respect to avian influenza viruses. His main research activities aim to understand the evolutionary dynamics driving the emergence of avian influenza viruses with pandemic potential from wild birds and poultry. The evolving ecological and virological scenario of HPAI in Europe poses logistic as well as scientific challenges that require fast and accurate evidence to inform risk assessment activities and the implementation of cost-effective countermeasures.

To this end, Dr. Bonfante is currently working to develop in vivo/in vitro platforms for the prompt phenotypic characterization of emerging avian influenza viruses (LPAI, HPAI and non-notifiable AI strains) leading to the determination of viral features such as diffusivity, virulence and zoonotic potential.



Ian Brown

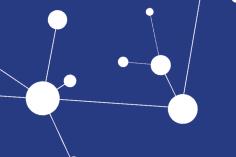
Director of WOAH/FAO International Reference Laboratory for Avian& Swine Influenza and Newcastle Disease

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lan provides a broad range of disease consultancy at both international and national level to a wide range of stakeholders on all the aforementioned diseases, specialising in science evidence and laboratory application as directly relevant to disease control. Ian is a founder member of the OFFLU Laboratory Network. He is currently chairperson of the OFFLU steering committee. Ian has undertaken country specific missions to advise on the control of HPAI.

His specific research interests include the epidemiology, pathogenicity, transmission and infection dynamics in relation to the control of influenza in animal hosts including zoonotic threat. Ian holds a visiting Professorship position in Avian Virology at the University of Nottingham and Honorary Professorship in Pathobiology and Population Sciences with Royal Veterinary College, University of London.



Abstract

Ian Brown

APHA Weybridge, Woodham Lane, New Haw, Addlestone. Surrey. KT15 3NB United Kingdom

Options for vaccines for emergency use including Mass Applied Vaccines and Pharmaceutical intervention options available and what might be developed

BACKGROUND: Emergency vaccination brings many challenges but essentially a product is required that can be sprayed or delivered through feed or by water (or possibly in-ovo for some categories). Ideally there should be no transmission from flock to flock so replication incompetent vaccine is desirable however limited transmission within a single flock can enhance flock level immunity. The problem can be mitigated if a non-influenza vector is used. For many poultry diseases live vaccine strains are used but for avian influenza the major concern over any live product would be that it could revert to virulence or genetically reassort and therefore present challenges for regulatory approval.

PROPOSED SOLUTIONS: Options for use in an emergency scenario are predominantly either through the use of live avian influenza viruses that are attenuated in some form or by using a vector vaccine which contains an inserted influenza gene, that provides protective immunity to the bird. The perceived risks of reversion have largely confined in field use of live influenza vaccines (LAIV) in pigs. Detection of LAIVs following reassortment with other wild type viruses has confounded use but some experimental studies have tested such vaccines based on low path viruses. Alternatively, H9N2 for example has been shown to induce cross serotype responses to H5 HPAI.

Viral vector vaccine currently have the greatest experience for utility in this setting but not all vectors lend to successful spray administration. Newcastle disease has been used as a bivalent live recombinant vaccine containing an H5 HA gene insert but problems can be encountered through MDA/vaccinal immunity to NDV. Therefore, consideration should be given to a delivery vector to which there is no pre-existing flock immunity. There are numerous examples of different vector types but selection of a vector that can undergo limited replication in the target host is important. There is increasing interest in delivery through water with oral vaccines and these systems have often used a bacterial vector or subunits attach to an immune-stimulant. Further some studies have demonstrated that plants can be used as a vehicle for vaccine expression and offer the possibility they can be introduced through feed.

Novel technologies now enable the possibility to modify a vaccine with immune stimulator for induction of both innate and adaptive responses and can be delivered through systems such as nano particles. Furthermore, there is increasing research into the use of agonists of the immune system as adjuvants to potentiate immune responses and these can be delivered to mucosal surfaces to block initial virus attachment and replication.

CONCLUSIONS: Experience with the emergency vaccination to protect against high pathogenicity on scale is very limited. Mode of vaccination for practicality and speed necessitates delivery through spray, feed or water. Due to possible concerns over safety of live viruses alternative systems are within reach and have been applied in different settings. Adapting and improving existing approaches or through development of novel systems by exploiting advances in vaccinology, through gene editing and use of molecular tools offers strong promise for the future.



Carol Cardona

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Dr. Carol Cardona is the Pomeroy Chair in Avian Health for the College of Veterinary Medicine at the University of Minnesota. Her research focuses on viral diseases of poultry, the management of risk in animal disease emergencies, and biosecurity approaches. Dr. Cardona has received numerous awards from the poultry industry and peers for her efforts in disease control. She received her doctor of veterinary medicine degree from Purdue University and her doctorate from Michigan State University. As the Pomeroy Chair, Dr. Cardona collaborates with practitioners in Minnesota's poultry industry, other scientists and veterinarians, and the Minnesota Board of Animal Health.

Through this outreach work and the partnerships that result from it, she is able to advance strategic approaches to animal health and well-being that would be beyond the reach of an individual researcher.

Abstract

Carol Cardona

University of Minnesota - St.Paul, USA

BACKGROUND: Vaccination for notifiable types of influenza A viruses (H5/7) subtypes have been undertaken in emergency situations, most notably in Mexico, Italy, China, and the United States. The goals of each program differed as did the settings and thus, the outcomes. Vaccination in the face of an HPAI emergency, in Hong Kong, Italy, and Pakistan has also been done with similarly variable outcomes. But there is also a lot to be learned from the use of influenza vaccines in field settings, something that has been done annually in the United States, although not at a notifiable level.

CHALLENGES: Its easy to say that vaccination and immunization are the same in controlled studies. But, in field settings, the gap between the two grows. In fact, the delivery of vaccines and the subsequent serosurveillance to measure immunity are, in fact, essential to the successful use of vaccination. Under the best of conditions on a single poultry farm, achieving immunity can be a challenge. If we consider the different conditions presented by the varied poultry settings in a country and the chaos of an emergency, immunization seems to be an insurmountable challenge.

PROPOSED APPROACH: The insurmountable challenge is not really so large when we break it down. I think at an operational level we face several concrete challenges.

- 1. Triggers for use and goals for the use of emergency vaccination. As we have seen in the past, these are key determinants of what will actually happen.
- 2. Implementation of programs. Engage experts in poultry field vaccination (field vets, vaccine manufacturers, emergency management, etc) to undertake the challenges of HPAI vaccination in an emergency situation under a global microscope.
- 3. Surveillance for immunity in an ongoing and realistic way.
- **4.** The will and thus the funding to do it all. Engage poultry decision makers in real conversations about the tipping points of when vaccination becomes necessary.

CONCLUSIONS: As we face a global HPAI challenge, we can learn from the past and from analogous settings to make the best choices for the present. It will take a village.



Giovanni Cattoli

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Mr Giovanni Cattoli, DVM, holds a PhD in Epidemiology and Control of Zoonotic Diseases. In his present position, he is the Head of the Animal Production and Health Laboratory of the Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture. Mr. Cattoli has been previously positioned in Italy as Director of the Division of Research & Innovation and the Division of Virology of Istituto Zooprofilattico Sperimentale delle Venezie. The divisions which include several national and international (OIE/FAO) reference laboratories for animal and zoonotic diseases, including the OIE and FAO avian influenza reference laboratory.

At the Joint FAO/IAEA Centre, Mr. Cattoli is leading an international team focused on research and technology transfer applied to transboundary animal and zoonotic diseases detection and control as well as on animal genetics to improve livestock productions and disease resistance. He and his team coordinate a global veterinary laboratory network (VETLAB Network) in Africa and Asia and conducts several activities to build capacity and transfer technologies in limited resourced countries. He is author or co-author of more than 350 publications, including peer-reviewed manuscripts, proceedings and book chapters.



Hualan Chen

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Dr. Hualan Chen is a professor in the Harbin Veterinary Research Institute of Chinese Academy of Agricultural Sciences. She is currently the director of the National Avian Influenza Reference Laboratory of China, the OIE Avian Influenza Reference Laboratory, and the FAO Animal Influenza Reference Center. Her research focus is the study of influenza virus and the development of vaccines against this virus. She performs extensive basic research to understand the evolution and the genetic basis of the virulence and host range of avian influenza viruses, and has published over 200 papers in international peer-reviewed journals, such as Science, Cell Research, Cell Host & Microbe, and PNAS. She established several platforms for avian influenza vaccine development, and nearly 300 billion doses of the vaccines developed by her have been used to control H5 and H7N9 influenza viruses in poultry in China and other countries.

She was selected as one of "the 10 people that mattered in 2013" by Nature, and was awarded the 2016 L'Oréal-UNESCO For Women in Science Awards. She was elected as a member of the Chinese Academy of Sciences in 2017 and a member of the World Academy of Sciences for developing countries in 2018.

Abstract

Hualan Chen

Animal Influenza Laboratory, Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences - Harbin, China

"Cull plus vaccination" — a strategy adopted in China for highly pathogenic avian influenza control

INTRODUCTION: Avian influenza viruses bearing the hemagglutinin (HA) gene of the H5 subtype and H7 subtype have caused 2,634 human cases around the world, including more than 1,000 deaths. These viruses have caused numerous disease outbreaks in wild birds and domestic poultry, and are responsible for the loss of at least 367 million domestic birds around the world since 2005. Many countries in Europe and North America control highly pathogenic influenza by culling infected and suspected birds, whereas some countries, including China, have adopted a "cull plus vaccination" strategy.

CHALLENGES: Influenza virus mutates easily, and mutation of the HA gene often causes antigenic variation. The biggest challenge for the vaccination strategy is ensuring that the vaccine matches the circulating virus.

APPROACH BEING TAKEN: To address this challenge, a platform for generating vaccine seed viruses by using reverse genetics was established, and an ideal vaccine seed virus containing the modified HA gene and native NA gene of a prevalent H5 or H7 virus and the internal genes of the high-growth A/Puerto Rico/8/1934 (H1N1) (PR8) virus can be generated within a week. Since 2004, ten different H5 seed viruses and four H7 seed viruses generated by reverse genetics have been used for inactivated vaccine production to control and eliminate avian influenza viruses in China.

CONCLUSIONS: Vaccines have been used in poultry to successfully prevent highly pathogenic influenza virus infection in China; even though the globally circulating H5 viruses have been detected in many species of wild birds and occasionally in ducks or geese in recent years, they have never caused problems on routinely vaccinated poultry farms in China, and the pervasive H7N9 viruses have been nearly eliminated in China.



Sjaak De Wit

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Sjaak de Wit is senior researcher at Royal GD and Professor Integrated Poultry Health at the Faculty of Veterinary Medicine of the Utrecht University, the Netherlands. He is involved in HPAI since the massive outbreak of HP H7N7 in 2003 in the Netherlands. Since then, Sjaak is involved in visiting farms with suspected cases of LP and HP AI. The involvement also includes the responsibility for the validation and accreditation of the serological tests that are used for the Dutch AI monitoring and surveillance programme performed at Royal GD. Sjaak is also involved in the reporting of the International Proficiency Testing Scheme for the detection of antibodies to avian influenza virus in which laboratories from about 40 countries are participating annually.

Finally, Sjaak is involved in scientific research concerning the pathogenesis, host-virus interaction, immunology, epidemiology, transmission, risk factors, and vaccination against avian influenza virus.

Abstract

Sjaak De Wit

Royal GD and University of Utrecht - Utrecht, the Netherlands

"What do we have in the commercially available toolbox now and what are the advantages and disadvantages of existing systems?"

Vaccination can be a useful tool for prevention and control of avian influenza virus (AIV), but only as part of a multifaceted approach that also includes appropriate diagnostics, surveillance, and disease management. Being able to Differentiate Infected from Vaccinated Animals (DIVA) or flocks is of major importance to be able to show freedom of infection and to detect (subclinical or silent) infections in vaccinated flocks. Many tests for the detection of AIV or its antibodies are commercially available. Antibody tests include ELISA's against AIV antibodies in general or specific subtypes, hemagglutination inhibition test, Agar Gel Precipitation test. Tests that detect the virus itself include on-site techniques that detect the antigen of AIV such as lateral flow tests and tests that detect the genome of AIV such as RT-PCR and LAMP.

Use of appropriate diagnostics is essential to be able to monitor and control the AIV situation. In this presentation, an overview will be presented of the commercially available tests and the advantages and disadvantages of existing systems for the use in unvaccinated and vaccinated flocks and kinds of vaccines that have been used.



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Dr Madhur S Dhingra, is the Head of the Emergency Prevention System for Animal Health (EMPRES-AH), and co-lead of One Health priority programme (OHPPA) in FAO.

She is responsible for policy and strategic guidance for the prevention and control of high impact transboundary livestock and zoonotic diseases, as well as emerging pathogens. She leads the work on early warning, and progressive biosecurity management for enhancing national resilience to threats to the food security and global health. This work is implemented in coordination with global and regional partners, through the FAO-WOAH Global Framework on the progressive control of transboundary animal diseases (GFTADs) and the Quadripartite. Earlier, Dr Dhingra has worked with FAO in various capacities in Asia and Africa, leading multistakeholder projects on evidence based risk management along livestock value chains, and animal health systems strengthening. Within her work, she has led risk assessments for several priority zoonoses and transboundary diseases, and development of tools and frameworks for early warning, integrated One Health Intelligence and progressive biosecurity management.

Before joining FAO, she served in the national and state veterinary services of India, implementing disease control programmes on Rinderpest, foot and mouth disease, HPAI etc. and the ensuring the delivery of animal health services and livestock development programmes. Dr Dhingra has a PhD in spatial epidemiology from the Université Libre de Bruxelles, a Master's in International Animal Health from University of Edinburgh, and a Master's in Veterinary Sciences (MVSc-Virology) from India. Madhur brings with her more than 20 years of experience across multiple geographies and an inherent understanding of multisectoral approaches to managing animal health, supporting livelihoods, and ensuring food security through sustainable and resilient livestock systems.



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Carel du Marchie Sarvaas is Executive Director of HealthforAnimals, the global animal health association. HealthforAnimals represents the top 10 global animal health companies developing and manufacturing veterinary pharmaceuticals, vaccines, parasiticides, diagnostics, digital products, etc. Its corporate members are Boehringer Ingelheim, Ceva, Elanco, IDEXX, Merck/MSD, Phibro, Vétoquinol, Virbac, Zenoaq and Zoetis. It also represents the interests of 29 national animal health associations – in total 85% of the global animal health sector.

The animal health industry provides value to society by protecting animals, and as a consequence, humans from diseases. These products keep pets and food-producing animals healthy. The public health benefits we bring include safer and more secure food supplies, more efficient production for increased food supply, improved sustainability, and prevention of the transmission of zoonotic

Carel joined HealthforAnimals in 2014 after holding the position of Director at EuropaBio, the Biotechnology Association. Prior to EuropaBio, Carel worked at international consultancies and think tanks in Brussels and Washington DC, advising clients active in the food, agriculture, chemicals, nanotech and biotech sectors. He is Dutch national, married, has four children and holds degrees from the University of Leiden and the Johns Hopkins University.



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Olivier Espeisse (DVM, Maisons-Alfort, and MBA, Bowling Green State University) practiced dairy veterinary medicine in Normandy before moving to the veterinary pharmaceutical industry, where he has been particularly involved in association work at global and European level. He is a member of the IABS VPC.



Julie Gauthier

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Dr. Julie Gauthier received a DVM degree from Michigan State University College of Veterinary Medicine in 1993. After working in mixed animal practice in Florida and Connecticut, she earned a Master of Public Health degree from Yale University School of Public Health in 2002. Julie joined USDA APHIS Veterinary Services in 2002 as a field Veterinary Medical Officer investigating animal disease outbreaks in southeastern Florida.

In 2008, she moved to Raleigh, NC where she has worked in several different roles for Veterinary Services: evaluating foreign countries' animal health status, preparing the nation for animal disease outbreaks such as avian influenza, and in her current role, coordinating national poultry health programs, including the response to the 2022 U.S. HPAI outbreak.



Timm Harder

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Timm Harder is a virologist with a veterinary background and broad interest in influenza viruses, particularly of avian and porcine hosts. His study fields range from diagnostic improvements, molecular epidemiology, and pathogenicity, to applied preventive measures and regulatory issues. He is head of the national avian influenza reference laboratory at Friedrich-Loeffler-Institute, Isle of Riems, Germany. The laboratory is an active member in international networks of the World Health Organization for Animal Health (WOAH, OFFLU) and the Food and Agriculture Organization (FAO) of the UN for research and diagnosis on animal influenza.

Abstract

Timm Harder

Friedrich Loeffler Institute - Riems, Germany

"Developing appropriate surveillance systems that provide confidence that HPAI virus is not circulating in poultry"

BACKGROUND: Increased and extended pressure of incursions of high pathogenicity avian influenza (HPAI) by secondary spread among poultry holdings and/or from infected migratory wild bird populations has been noticed globally. This places vaccination against HPAI into focus as a complementary prevention tool including Europe and North America.

CHALLENGES: Given the necessity of tackling both the genetic flexibility of HPAI viruses and the rapid turnover rates of large poultry populations, goal-oriented use of HPAI vaccines is highly demanding. Ill-matched vaccine antigens and inappropriate vaccination schemes may induce insufficient or patchy poultry population immunity, potentially fostering the selection and silent circulation of field virus variants escaping vaccination, thereby counteracting the purpose.

PROPOSED APPROACH: Controlled vaccination aiming at reducing clinical sequelae of HPAIV infection and economic losses and at decreasing risk of transfer of zoonotic HPAIV across the avian-human interface must be flanked by appropriate surveillance. Adamant prove is sought that products from HPAIV-vaccinated poultry do not impose any risk of virus spread or exposure. Otherwise, trust of trading partners and consumers might be lost. Therefore, surveillance requires tailoring at several levels: (i) It ensures appropriate vaccination coverage and presence of an adequate population immunity; (ii) It guarantees absence of HPAIV circulation in vaccinated herds; (iii) It continues to assess HPAI-infection trends in unvaccinated parts of the poultry population.

CONCLUSIONS: Careful planning ahead of any vaccination intention is pivotal. Endeavoring the above-defined goals of surveillance is complex and can become costly. Surveillance strategies fit for purpose must be tailored specific to different geographic, economic and epidemiological situations. Conjecturing HPAI vaccination campaigns should include exit scenarios as well.

<u>Biosketch</u>



Rick Hill
President of IABS
Board Member
Veterinary Biologicals Committee Member
Biologicals Section Editor
USA

Dr. Richard E. Hill, Jr., (Rick) received a D.V.M. degree from Michigan State University in 1983 and following graduation, worked in private veterinary practice. In 1985, he joined the USDA and worked as a field Veterinary Medical Officer before joining the Biologics Program in 1986. Rick worked as an Inspector, Epidemiologist, and Team Leader, for the Biologics Program where he was involved in regulatory compliance and coordination of the pharmacovigilance program.

In 1990, he received an M.S. degree in Veterinary Preventive Medicine at Iowa State University and is a Diplomate in the American College of Veterinary Preventive Medicine. In 1995, Dr. Hill transferred to the position of Quality Assurance Manager, responsible for overseeing the Quality Assurance Program at the National Veterinary Services Laboratories and Center for Veterinary Biologics Laboratory. In November 1998, he rejoined the Center for Veterinary Biologics as Director of Licensing and Policy Development and then served as the Center Director from 2005 through 2013. In 2013, Dr. Hill assumed the position of Executive Director for Veterinary Services, National Import and Export Services until his retirement in 2016 after 30+ years of Federal service.

Dr. Hill remains active in veterinary medicine through volunteer positions with the American Veterinary Medical Association as member and Chair of the Council on Biologic and Therapeutic Agents and as President of the American College of Veterinary Preventive Medicine. Dr. Hill is a long-term member of IABS, Biologicals Section Editor, and served as inaugural member and Chair of the Veterinary Scientific Conference Committee; (now the Veterinary Biologicals Committee).

He is currently serving as President on the Board and is Past President of the North American Affiliate (IABSNA).



Jeremy Ho

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After graduating in Doctor of Veterinary Medicine from National Taiwan University in 2013, Dr. Jeremy Hojoined the Agriculture, Fisheries and Conservation Department (AFCD) in the Hong Kong Special Administrative Region Government as a Veterinary Officer in January 2014. Dr. Ho has worked in the Tai Lung Veterinary Laboratory since 2014 focusing on works related to molecular diagnostics and veterinary pathology, primarily handling cases related to avian influenza (AI). In 2018, Dr. Ho was seconded to work in the World Organisation for Animal Health (WOAH) Regional Representation for Asia Pacific in Tokyo for around 5 months to assist in various regional events. After his return to Hong Kong, he was subsequently posted to the Animal Health Division in AFCD in 2019 to oversee the local chicken farms and pig farms in Hong Kong, and has been responsible to monitor AI vaccination and biosecurity standards in chicken farms since then. From 2020 – 2022, Dr.

Ho has also worked with the City University of Hong Kong as a consultancy team member and contributed in the development and the publication of a number of regional or international guidelines for WOAH and the Food and Agriculture Organization (FAO) in relation to African swine fever. In 2022, being the field veterinarian, Dr. Ho has been working to update the H5/H7 Al vaccine being used in local chicken farms in Hong Kong with a view to better protect vaccinated flocks against currently circulating strains of Al viruses in the region.

<u>Biosketch</u>



Finland

Miia Jakava-Viljanen DVM, PhD, Specialist in Animal Disease Chair, Veterinary Biologicals Committee

Following positions at the Helsinki University in Finland in teaching microbiology, immunology and epidemiology, and research, as a veterinarian, Dr Miia Jakava- Viljanen joined the Finnish Food Authority as Head of Section involved in virology, epidemiology and veterinary vaccines, and batch release and testing of vaccines. She subsequently moved into the policy area, assuming the post of Government Counsellor at the Ministry of Agriculture and Forestry of Finland worked with Animal Health and Welfare legislation, rabies, pet movement, bee health, animals used for scientific purposes (3Rs), EU co-financed programs, funding for research projects and collaboration with Russia. Seconded to the European Commission, she was involved in the implementation of the EU legislation on Animal Health and participated to the work on EU climate change. She joined the European Medicines Agency in 2014 - 2019 as National Expert where she was responsible to provide consultation and expertise specifically in the area of veterinary biologicals, immunological medicines and emerging therapies, EU legislation and policy as scientific/content lead. Currently she is working at the Finnish Food Authority.

She is an expert of EDQM European Pharmacopoeia Group 15V (vaccines and sera) since 2002. She joined IABS in 2019 and is a member of the executive board and the Chair of the Veterinary Biologicals Committee. She is organizing IABS meetings focusing on the veterinary field.



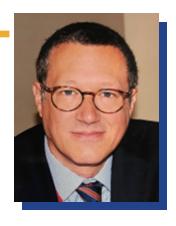
CarmenJungbäck Board Member

Board Member Secretary, IABS-EU Germany

Dr Carmen Jungbäck graduated from the Tierärztliche Hochschule, Hannover with a degree in Veterinary Medicine. In 1981, after a few years as an animal surgeon she joined the Paul-Ehrlich-Institut, (Federal Agency for Sera and Vaccines), Langen, Germany, where she was Head of the section Veterinary Virology 1 until retirement in 2016. The section's area of activities comprises vaccine licensing and testing, with special expertise in viral vaccines for poultry. In this context, the practical testing of vaccines during licensing and for official batch release is one of the major responsibilities.

She was also member of a number of advisory boards to the EDQM-OMCL Network, Ph.Eur Group 15V and CVMP-IWP and JEG3R at EMA dealing with IVMPs under various aspects.

At IABS she is member of the board and Chair of the Veterinary Biologicals Committee and Vice-President of IABS - EU. She is organizing IABS meetings; focusing on the veterinary field. As member of IABS-EU she is involved in the IMIprojects (ZAPI and Vac2Vac).



Moritz Klemm

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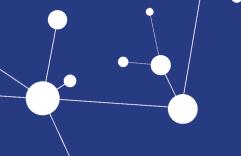
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Dr Moritz Klemm has been team leader for animal diseases and international within the animal health unit of the European Commission's Directorate General for Health and Food Safety (DG SANTE) since 2021, responsible for prevention and control mainly of EU "Category A" diseases, and for relations with WOAH/OIE, EuFMD and FAO/WOAH GF-TADs. He graduated from the veterinary faculty of Ludwig Maximilian University of Munich in 1997 (DVM) and obtained a doctoral degree (Dr. med. vet.) in molecular virology from the same university in 2001. After a traineeship with the European Commission in Brussels in 2000/2001 (animal health and welfare unit, DG SANCO), he was PostDoc at the Institute for Molecular Virology, Medical Faculty, Technical University of Munich from 2001-2003 (Modified Vaccinia Ankara group).

From 2003-2009, he was an official with the German Federal Ministry of Food, Agriculture and Consumer Protection in Bonn (food and feed safety, animal nutrition, meat hygiene), and was seconded to DG SANCO in Brussels in 2005/2006 (feed safety). He joined the European Commission in Brussels as permanent official in 2009, working in the animal health unit of DG SANCO / DG SANTE since then (animal health communication from 2009-2011, relations with OIE and related EU import and international animal health policies from 2010-2021).



Moritz Klemm

European Commission - Brussels, Belgium

"Vaccination rules in the EU"

INTRODUCTION: Since 2019, the EU has experienced increasingly severe epidemic seasons of HPAI, with the 2021-2022 season being the worst ever experienced by the Union. The number of wild birds found infected every year constantly increased, leading to high concentrations of virus in the environment.

ISSUES: Unlike in previous years, the HPAI virus continued to circulate in wild birds in the EU during the 2022 summer months, in particular in different species of seabirds, and continued to pose a risk for poultry populations.

Consequently, the EU has faced in recent years a constant increase both in the length of the risk period and in the level of risk for the HPAI virus to be passed from wild birds to poultry.

Biosecurity continues to be a cornerstone preventive measure to protect poultry from infection with HPAI virus from the environment, but vaccination could be a complementary preventive or control tool to be used, if effective vaccines would become available.

PROPOSED APPROACH: The new legal framework for animal health in the EU (Regulation (EU) 2016/429 "Animal Health Law") has changed the paradigm in respect of vaccination. Now, Member States have the possibility to use vaccination for ensuring the most effective prevention or control of HPAI.

The EU is preparing to adapt its actions in accordance with the new epidemiological situation and the increasing level of risk, embracing solutions that could strengthen prevention and control of HPAI in poultry. Therefore, the European Commission is adopting specific rules on vaccination against HPAI, to ensure harmonisation of the surveillance and risk mitigation measures to be implemented in vaccinated establishments, to ensure continuation of safe trade from those establishments. This approach is in line with WOAH standards.

In addition, as there is not much experience with vaccination against HPAI in the EU in recent years, the European Food Safety Authority (EFSA) has been mandated by the European Commission to issue a Scientific opinion on this topic.

CONCLUSIONS: The characteristics of the poultry sector in EU Member States are not uniform (e.g. as regards infrastructure, main type of production, contribution to national economy, export orientation). Therefore, a "fit for all" vaccination strategy is not feasible. The EU rules allow for appropriate flexibility and leave to each Member State the possibility to decide on the use of vaccination as a preventive or control measure for HPAI.



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Vaughn Kubiak has over 40 years of experience in global animal health, with a primary focus on development, licensure, and maintenance of global veterinary biologicals. He has helped develop and improve conventional and innovative immunological veterinary medicinal products for all major species during his career.

Vaughn has worked for a number of global animal health companies, with positions in R&D, QA/QC, regulatory affairs, product management, and commercial operations. Prior to his retirement from full-time activities in 2019, Vaughn spent the last 17 years with Zoetis Inc., where he held management positions in Regulatory Affairs, Biologicals Process Development, and Biological Analytical Development. During his last role in Zoetis (2009 – 2019), he was responsible for the European, Middle East, and African Biological Regulatory Affairs team in Sandwich, England and then Zaventem, Belgium. Vaughn remains connected to the Animal Health Industry, however, through limited consulting. He holds a Bachelor of Science and a Master of Science in Microbiology from the Ohio State University and Emory University, respectively.



Dr Gounalan Pavade

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Dr Gounalan Pavade is a Veterinarian with specialisation in Veterinary pathology. He attended the Veterinary Universities in India to obtain his Bachelor, Master and Doctorate degree in Veterinary Sciences. For his work on 'Pathology of Newcastle disease virus and its interaction with mycotoxins in layer chicken', he received the University Gold medal for best PhD student in avian studies and Jawaharlal Nehru award for outstanding doctoral thesis research in agricultural and allied sciences.

Currently he is working as Scientific Coordinator (Avian influenza) at the World Organisation for Animal Health (WOAH) at its Headquarters, Paris since 2010. His main activities at WOAH involve administration of OFFLU network (WOAH-FAO network of expertise on animal influenza), Secretariat support to WOAH Biological and Aquatic Animal Health Standards Commission, establishment and coordination of scientific laboratory networks and providing technical support for animal and zoonotic diseases including animal influenza, African swine fever, PPR, rabies, MERS-CoV and camel diseases. In this role, he participates in international activities on animal influenza, organises technical meetings on avian, swine and equine influenza and interacts with WHO influenza network on issues related to the animal-human interface.

Gounalan has published over 20 articles in peer reviewed journals and represented WOAH in several international conferences and symposium.



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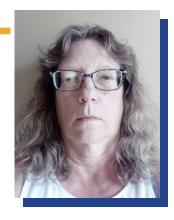
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Wim Pelgrim Graduated in 1986 as an agricultural engineer and in 1992 as a veterinarian. He started working at the predecessor of the Netherlands Food and Consumer Product Safety Authority (NVWA) and in international development cooperation in Ecuador. From 2000 he continued his career at the animal health department at the Ministry of Agriculture. He participated in in several animal disease crisis that the Netherlands had to deal with (classical swine fever as an official veterinarian at the NVWA and food and mouth disease, bluetongue, Q fever and low and high pathogenic avian influenza as a policy advisor at the Ministry).

From 2009 up to 2011 he was seconded at the Trade department of the OIE. In 2021 he became acting Chief Veterinary Officer and since 2022 Chief Veterinary Officer of The Netherlands.



Connie Schmellik-Sandage

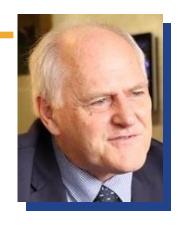
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I am a Senior Staff Microbiologist with the Center for Veterinary Biologics (CVB). I review data to support licensing of veterinary biologics in the United States. I have developed an interest in poultry during my time with CVB. I worked also within the program in poultry virology laboratory and doing inspections at firms preparing veterinary biologics. Prior to joining CVB, I did a post-doc with the lowa State Veterinary School. My bachelor's degree is from lowa State University in Microbiology and my PhD is from Purdue University in Microbial Genetics and Molecular Biology.



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Les Sims is a veterinarian (BVSc (Hons) Melb 1977, MANZCVSc (Diagnostic Pathology 1987), MRCVS) who has worked in both disease diagnosis and disease management in Asia and Oceania. He was involved in two outbreaks of highly pathogenic avian influenza in Australia in 1985 and 1992. He oversaw most government veterinary activities in Hong Kong SAR (1997-2002) and led the team developing control and preventive measures for avian influenza, including the initial H5N1 zoonotic outbreak in 1997, and subsequent decisions on prevention.

This included the decision to add vaccination to the suite of preventive measures. He continues to provide support to the Hong Kong government as a private consultant. For the past 18 years, Dr Sims has provided advice and services as a consultant to the United Nations Food and Agriculture Organization (FAO), and through FAO, to a range of countries in Asia on avian influenza control/prevention. This included assisting in designing appropriate vaccination programmes against avian influenza. He is also a member of the OFFLU steering committee and the technical committee for this meeting.



Les Sims 1/2

Asia Pacific Veterinary Information Services - Australia

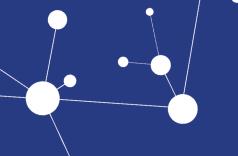
"Factors that inhibit usage of preventive vaccination and ways to overcome them"

Many factors have been proposed as barriers to and/or disadvantages of preventive vaccination against high pathogenicity avian influenza viruses. Many of these represent genuine concerns. All can be managed, although some may take longer than others to overcome. Some concerns are spurious or based on misconceptions about the extent of silent infection that occurs in well vaccinated flocks. The misconceptions are, in part, based on experiences from countries where vaccination was introduced to contain, but not eliminate viruses, and where production and selling systems facilitate transmission of HPAI viruses. Well vaccinated flocks of chickens with good immunity to the circulating field strain(s) represent a low risk for sustained infection. Although immunity in vaccinated birds may not prevent all virus shedding if exposed to virus, studies involving transmission from challenged vaccinated chickens to vaccinated contact chickens demonstrate that transmission can be prevented even when some shedding in challenged chickens occurs. Cessation of transmission has also been demonstrated in flocks of chickens that were vaccinated in the face of outbreaks. Development of antigenic variants resulting from vaccination is also seen as a disadvantage.

Antigenic variant viruses can be generated through serial passage when poorly vaccinated birds are exposed to virus and have arisen in some countries with endemic infection. However, it will occur rarely in places where exposure of vaccinated birds to virus occurs infrequently. If there is a zero tolerance for sustained infection in vaccinated flocks and action taken when infection is detected through regular surveillance, sustained infection in vaccinated flocks won't occur - the key driver of antigenic change. If systems are in place to detect infection, the main threat from antigenic variants arises from import of an antigenic variant strain from elsewhere. This has affected vaccination programmes in several countries and is managed by updates to vaccines when novel strains occur or are detected in neighbouring areas.

Early warning systems and disease intelligence, such as the programme being developed by OFFLU on antigenic characterisation of circulating viruses will help to overcome this concern as will approval of cassette systems that allow updating of vaccine antigens without full re-registration as a new product. Effects on trade should be overcome if appropriate surveillance systems are in place and importing countries are provided with information that virus is not circulating in vaccinated flocks. Surveillance systems that are both cost effective and comprehensive can be developed and may include different methods to those used for other vaccines, including testing of routine dead birds and suitable environmental samples for presence of virus.

At present, some countries are not prepared to vaccinate because of the fear that other countries will ban



Les Sims 2/2

imports even if they demonstrate virus is not circulating in poultry. This should become less of a problem once more countries recognise that they have to adopt vaccination because of the unacceptably high threat posed by endemic infection in wild birds, maintain a zero tolerance for infection, and take action to stamp out the virus when infection is detected in vaccinated and unvaccinated flocks.

Fears that use of vaccination will result in endemic infection in poultry are based on experiences from countries where viruses were already endemic when vaccination commenced. Hong Kong SAR, where preventive vaccination has been used for 20 years demonstrates that vaccination does not lead to endemic infection if managed appropriately. A multifaceted surveillance system there, including testing for response to vaccination serologically and testing for virus in farms and markets is used to detect higher risk flocks and evidence of infection.

Availability of suitable vaccines is an issue that has inhibited introduction of vaccination to some regions. Part of this is due to non-acceptance of serological DIVA-incompatible killed antigen vaccines. These vaccines can still be used successfully (as done in Hong Kong SAR). A lack of supply of suitable products that meet national or regional biosafety requirements is also an issue, with market forces also playing a role in some regions. Overcoming this issue will depend on vaccine manufacturers having confidence that they have an on-going market for their vaccines, or it may require novel, alternative funding mechanisms as occurring with antimicrobials.

Barriers to vaccination can and should be overcome. The benefits of using vaccination as an additional preventive measure, including the marked reduction in the need to cull infected flocks and markedly reduced circulation of virus in commercial poultry, provide strong incentives for finding ways to overcome the perceived and actual barriers to implementation.



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Emmanuelle Soubeyran (DVM) has been appointed deputy director general for food, CVO and OIE Delegate for France as of June 21.

Since 2016, she has been the dean of VetAgro Sup, an institution that brings together the National Veterinary School of Lyon, the School of Agronomy of Clermont-Ferrand and the National School of Veterinary Services (FVI-ENSV).

Emmanuelle Soubeyran is a veterinarian who graduated in 1990. She obtained a doctorate in veterinary medicine from the School of Medicine of Toulouse in 1993. She began her career in 1998 as a veterinary inspector from 2001 to 2003.

She then joined the General Directorate for Food, where she was successively deputy then office manager in food safety department (2002-2007). From 2007 to 2009 Emmanuelle Soubeyran worked in the cabinet of Michel Barnier, Minister of Agriculture, as a counselor on safety issues (animal health, planth health and food safety). From 2009 to 2016, she has held different positions in the General Directorate for Food: head of the department of quality and plant protection, head of the department of health measures in primary production, head of the food department.



Erica Spackman

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Dr. Spackman has been a Research Microbiologist with the US Department of Agriculture, Agricultural Research Service. US National Poultry Research Center in Athens, Georgia, USA for 20 years. She got her master's degree and PhD in Animal Science at the University of Delaware, where her graduate work focused on poultry diseases. She has been the recipient of 10 professional awards including the Presidential Early Career Award for Science and Engineering. She has edited a book, Animal influenza virus, and has authored or co-authored 26 book chapters and over 130 peer-reviewed scientific papers. She serves an avian influenza subject matter expert to numerous groups including the US National Poultry Improvement Plan and has been an instructor at numerous workshops on AIV diagnostics and outbreak response. Her research focuses on viral diseases of poultry, with a primary focus on avian influenza virus.

More recently Dr. Spackman has worked with SARS-CoV-2 environmental stability in agricultural settings. Specific research interests with AIV currently include: vaccines, diagnostics, pathobiology in avian species, and practical approaches to preventing and responding to outbreaks.



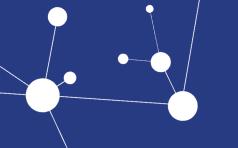
Erica Spackman

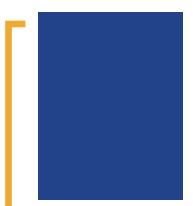
INTRODUCTION: Vaccine platforms currently available and in use for avian influenza in poultry include: inactivated whole virus, replicating vectored, and RNA particle vaccines.

ISSUES: Each vaccine platform has advantages and disadvantages. All of the platforms can induce immunity that will protect against death and disease. Some vaccines will reduce the quantities of virus excreted. All vaccines have better efficacy if they are closely related to the challenge virus. However, vectored vaccines seem to induce more broadly reactive immunity which can overcome divergence between the vaccine and challenge strain. Importantly, vaccine perform better in laboratory studies than in the field. Data on optimal application programs for many situations is missing and is based on other vaccines and industry logistics.

PROPOSED APPROACH: Vaccination should be approached with a plan that outlines goals and the process for vaccination as well as a relevant surveillance programs. Developing data on the best way to apply different vaccines in different situations, for example: production sectors, species, challenge strains, age of the host, etc.

CONCLUSIONS: Numerous vaccines with different formats are available, although licensed products vary among countries. The best vaccine is situation dependent and should be selected based on fit for purpose. Novel vaccine platforms are in development and may offer improved performance





Geetha Srinivas

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degree in Virology and Immunology with research focused on Newcastle disease virus. She earned her Ph.D. in 1995 in Veterinary Microbiology and Immunology. Dr. Srinivas started her career with a licensed biologics firm, Fort Dodge Animal Health in 1996. She managed the Virology Section in the Department of Product Development. She later joined the Center for Veterinary Biologics in 2003 as the biologics product reviewer, and currently Heads the Virology and Molecular Biology Section in the Policy, Evaluation, and Licensing Unit of the Center for Veterinary Biologics, USDA in Ames, Iowa, USA.



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Arjan Stegeman is full professor of Farm Animal Health and Epidemiology of Infectious Diseases at Utrecht University, The Netherlands. He is a veterinarian by training and a diplomate of the European College of Veterinary Public Health. His research is focused on the epidemiology of infectious diseases in farmed animals aiming to unravel the mechanisms that determine the population dynamics of infections and establish the effectiveness of intervention measures.

For that goal his group applies animal experiments, field studies and mathematical modelling. Regarding avian influenza, Arjan has been active at the science policy interface for many years.

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Arjan Stegeman

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"Vaccination to control transboundary animal pathogens and relevance to avian influenza"

BACKGROUND: Since the second half of the 20th century vaccination has been an indispensable tool to improve animal health. Although vaccination was initially developed to prevent disease and mortality, for several transboundary pathogens vaccination has demonstrated to be a useful tool to eliminate pathogens from animal populations.

CHALLENGES: To control transboundary pathogens vaccination induced immunity should sufficiently reduce transmission upon exposure and the aim can be 1) to stop transmission in an infected region, 2) prevent (re)infection in a free region at risk for infection or, 3) stop transmission in a region upon an unexpected reintroduction (emergency vaccination).

RELEVANT APPROACH: Vaccination has been used to eradicate several transboundary pathogens from animal populations in various regions of the world with the worldwide elimination of rinderpest as the most prominent example. Vaccination campaigns have also been successful in the elimination of Foot and Mouth disease (FMD) and Classical Swine Fever (CSF) virus. Of particular relevance to avian influenza is the eradication of Aujeszky's disease (AD) virus, a herpesvirus infection of pigs, which has demonstrated that an imperfect vaccine can be sufficient to eliminate a pathogen, as long as there is good vaccination coverage and accompanying DIVA surveillance. When an animal population itself is free from infection, but at risk for reintroduction of the pathogen vaccination can be used to prevent outbreaks should the virus reenter. Vaccination against Newcastle Disease (ND) in Europe and other parts of the world is an obvious example in poultry, although ND vaccination does not allow DIVA surveillance. FMD and AD serve as examples in other species. In case of an unexpected introduction in a susceptible population emergency vaccination is an option. Challenges here, besides the effectiveness of the vaccine are the size of the area to be vaccinated and the speed at which vaccination is carried out relative to the transmission rate of the pathogen. Again ND, CSF and FMD serve as examples.

CONCLUSIONS: Vaccination has shown its potential to control various transboundary animal pathogens. To be successful vaccination needs to be applied strictly, with sufficient coverage and accompanied by adequate surveillance. In that case even imperfect vaccines have potential to stop pathogen transmission.



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Dr. David E. Swayne for the past 28 years has been the Laboratory Director (1994-present) of Southeast Poultry Research Laboratory of the U.S. National Poultry Research Center, Agricultural Research Service, U.S. Department of Agriculture (USDA) in Athens, Georgia. SEPRL is USDA's in-house high biocontainment research laboratory that conducts research on poultry viral diseases, including those that impact trade. Dr Swayne is a research poultry veterinarian and veterinary pathologist. For past 35 years, his personal research has focused on understanding and controlling avian influenza in poultry and wild birds. Dr. Swayne has led or served on international animal and public health committees with World Health Organization, World Organization for Animal Health (OIE) and Food and Agriculture Organization and included a 16 month sabbatical at OIE to study global highly pathogenic avian influenza control programs and their impact on trade. He has served in various leadership roles in the OIE/FAO Animal Influenza Expert Network (OFFLU).

He has published over 350 peer-reviewed scientific articles on poultry health research, 115 book chapters, given 322 invited lectures and served as Editor or Associate Editor for 16 text and proceedings books including the editor of Diseases of Poultry, Avian Influenza and Animal Influenza textbooks, and Associate Editor for Avian Diseases, Influenza and Other Respiratory Viruses and Emerging Infectious Diseases peer-reviewed journals. Formerly, he served as a tenured faculty member in the College of Veterinary Medicine, The Ohio State University.

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"Vaccine Usage to Control High Pathogenicity Avian Influenza and Barriers to More Effective Usage: Setting the Scene"

Since October 2020, H5Nx 2.3.4.4b lineage of high pathogenicity avian influenza (HPAI) virus has spread across Europe, Middle East, Africa and Asia causing infections in wild aquatic birds and outbreaks in poultry.

In the fall 2021, the virus spread into North America. Europe and North America has met this challenge with stamping-out programs to eradicate the virus from poultry production systems. However, the virus is present in large numbers of migratory and resident aquatic birds with recurring exposure to domestic poultry populations resulting in outbreaks. When potent vaccines are available and properly applied, vaccination can be a crucial tool for prevention and control, but its use is prohibited or severely restricted in many countries worldwide. Wider use of avian influenza vaccination would increase resistance to HPAI infection of poultry, decrease HPAI spread, increase sustainable poultry production, improve animal welfare, reduce economic damage, reduce human infections, and contribute to consumers and animal welfare acceptance of control programs.

Various barriers to greater use of vaccine exist and scientific solutions will be proposed to mitigate the barriers including improved vaccines and vaccination programs, design, and implementation of appropriate surveillance programs, communicating the strengths of vaccination and providing scientific information to address incorrect information on vaccine use.



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Study of veterinary medicine at the Free University of Berlin, 1985 Examination as veterinarian. Dissertation: "Detection of type-specific antibodies against Infectious Bronchitis Virus"; 1987 Graduation and degree of Dr. med vet; 1997 Qualification as "Veterinary Specialist for Avian Diseases".

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Richard Webby is a Member of the Department of Infectious Diseases at St Jude Children's Research Hospital, Memphis, USA. He leads a research program that focuses on the risk to human health caused by influenza viruses circulating in animal populations. This program collaborates with partners worldwide to combine field and laboratory studies to understand the scope and nature of influenza viruses circulating at the human-animal interfaces. Dr Webby is also the Director of the World Health Organization Collaborating Center for Studies on the Ecology of Influenza.

In this role he contributes to influenza pandemic preparedness activities including assessing virus risks and developing candidate vaccine viruses to those of most concern.

Richard Webby

St Jude Children's Research Hospital - Memphis, USA

"Public Health considerations of avian vaccination"

The diversity of zoonotic influenza virus infections over recent years has been increasing. In response, the World Health Organization's Global Influenza Surveillance and Response System (GISRS) has intensifies its pandemic preparedness efforts. These efforts are multipronged, involve expertise from multiple sectors, and include development of candidate vaccine viruses (CVVs) suitable for vaccine development and also viral risk assessments utilizing the Tool for Influenza Pandemic Risk Assessment (TIPRA). TIPRA works by scoring a given virus on a number of risk elements that include "infection in animals" and "geographic distribution in animals".

As a successful influenza vaccination program in avian hosts has the potential to reduce both "infection in animals" and "geographic distribution in animals", it would, by default, reduce the perceived pandemic risk of a virus. A robust influenza vaccination program would also have a strong surveillance component which could provide valuable information to strengthen the existing GISRS and partner efforts to maintain a library of relevant CVVs. Together, a strong and well designed avian influenza vaccine program in birds has the potential to reduce risks to human health.



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Hendra Wibawa completed his PhD from the University of Queensland, Australia in the field of virology, molecular, and epidemiology for avian influenza. His PhD study was conducted in the Australian Center for Disease Preparedness (previously Australian Animal Health Laboratory) in Geelong, Australia from 2008-2012. He continued his post-doctoral research on infectious disease and epidemiology of avian influenza in Utrecht University, the Netherlands, from 2015-2017. Dr Wibawa served as Head of Molecular Diagnostics Laboratory at Disease Investigation Center (DIC) Wates, Indonesia from 2017-2021, and since April 2021 he has been designated as Director of DIC Wates up until now. Dr Wibawa coordinates Influenza Virus Monitoring (IVM) Network, an integrated molecular surveillance for detecting variation of avian influenza viruses circulating in Indonesia. He is now developing this network to not only monitor avian influenza virus, but also to monitor other important animal diseases, such as foot-and-mouth disease.

He also plays a role in developing molecular diagnostics and bioinformatics capacity for veterinary laboratories in Indonesia. Hence, DIC Wates has been appointed as ASEAN Regional Center for Bioinformatics since 2021. Dr Wibawa authored and co-authored about forty-five scientific papers for avian influenza. Recently, he also contributed in molecular epidemiology studies for COVID-19 (SARS-CoV-2) and Foot-and-Mouth Disease in Indonesia

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"Highly Pathogenic Avian Influenza Vaccination Strategy: Lesson Learned from the Implementation of Influenza Virus Monitoring Network in Indonesia"

Hendra Wibawa, Nuryani Zainuddin, Sri Handayani Irianingsih, Syafrison Idris, Nining Hartaningsih, Farida C Zenal, Luuk Schoonman

BACKGROUND: Highly Pathogenic Avian Influenza (HPAI) subtype H5N1 is endemic and considered as one of the major problems for the poultry industry in Indonesia since 2004. As vaccination program has been conducted for HPAI control, the Government of Indonesia began the implementation of a coordinated surveillance system (the Influenza Virus Monitoring (IVM) network) to monitor antigenic and genetic evolution of Avian Influenza (AI) viruses in poultry population.

MATERIAL AND METHOD: This molecular surveillance is based on the regional network of veterinary diagnostic laboratories, and is supported by a web-based data management system ("IVM Online"). This system included the use of virology and molecular detection and identification using virus isolation and PCR, followed by DNA sequencing, antigenic cartography, and bioinformatic analysis for vaccine seed and challenge strain selection to ensure a close antigenic match.

RESULTS: The effectiveness of the IVM network was demonstrated through the rapid identification and characterization of a novel HPAI H5N1 virus of clade 2.3.2.1c in 2012 which had a high pathogenicity not only to chickens but also for ducks. This network also immediately identified and reported to the government for the causative agent of low pathogenic AI outbreaks in layer farm in 2016 which due to subtype H9N2 virus infection. From these two events, Indonesian vaccine producers could produce inactivated vaccines for HPAI H5N1 and LPAI H9N2 based on the local strains. Recently in 2019, IVM network recommended to the government to update the HPAI H5N1 seed vaccines for better protection to major circulating HPAI H5N1 virus in poultry.

CONCLUSIONS: The example of the Indonesian IVM network has relevance for other countries seeking to establish laboratory networks for the surveillance of avian influenza and other pathogens.



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Christiane Wolff joined the Secretariat of the World Trade Organization in 1999. The main focus of her work is the Agreement on the Application of Sanitary and Phytosanitary Measures. Christiane is the Secretary of the SPS Committee and Head of the Secretariat's SPS Section; she also has extensive experience in dispute settlement work and technical assistance.

Years ago, Christiane worked at the German Development Bank KfW, where she managed projects in the areas of agricultural development and protection of natural resources in West Africa. Christiane has a background in agricultural economics and development studies.

Christiane Wolff

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"WTO perspective of avian influenza and trade in poultry products"

BACKGROUND: WTO perspective of avian influenza and trade in poultry products

ISSUES: Since the entry into force of the SPS Agreement in 1995, over 1500 notifications related to regulations on avian influenza have been circulated by WTO Members. While the numbers fluctuated at relatively low levels for many years, the number of notifications has seen a steep increase since 2020. Most of these have been circulated as emergency notifications, adopted quickly in the face of urgent health risks, and most of them indicate that the notified regulation is in conformity with the relevant international (WOAH) standard. Only 12 of the notifications contain a reference to vaccination. About 20 specific trade concerns relating to avian influenza-related trade measures have been raised since 1995, many of them repeated at several meetings over years. Of these, seven have been reported as resolved. Vaccination has only come up in one of these cases. Compliance with the WOAH terrestrial code chapter on HPAI has repeatedly been raised under the SPS Committee's procedure to monitor the use of international standards. There has been one dispute related to avian influenza under the WTO's Dispute Settlement Mechanism.

PROPOSED APPROACH: The SPS Agreement contains a reference to the international standards developed by WOAH. Any guidance developed by WOAH with respect to trade measures in relation to HPAI vaccination automatically becomes a reference point for WTO Members.

CONCLUSIONS: Trade restrictions related to avian influenza have a major impact on international trade and regularly show up in discussions at the WTO. Non-compliance with WOAH standards is a common complaint. Specific references to vaccination have so far been rare.



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Dr. Guillermo Zavala obtained a DVM and Specialty in Poultry Production and Pathology from the National Autonomous University of Mexico. He also holds a Master of Avian Medicine, Master of Science, and Doctoral Degrees (MAM, MSc, and PhD, respectively) from the University of Georgia (UGA). Dr. Zavala performed postdoctoral research at UGA and the University of Melbourne.

Dr. Zavala has worked for a broiler production company; two vaccine companies; one primary breeder company; two diagnostic laboratories; and worked for 11 years as faculty at UGA doing research on viral pathogenesis, clinical veterinary extension, and teaching at the veterinary and post-veterinary levels. Dr. Zavala has approximately 40 publications in refereed journals and has also collaborated in 4 reference books on avian diseases.

Dr. Zavala has presented no less than 800 conferences and lectures in various venues. He is currently the owner and founder at Avian Health International, LLC, a poultry consulting business doing veterinary work in over 50 countries. He remains as an adjunct professor at UGA, where he continues to be involved in teaching avian virology, poultry diseases and poultry husbandry.

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LPAI H5N2 is enzootic in Mexico and Northern Central America since approximately 1994. Occasional incursions of H5N2 have been documented in the Caribbean as well. HPAI H7N3 is enzootic in Mexico since approximately 2013, with occasional incursions in neighbouring countries. HPAI and LPAI have also caused occasional infections in broiler breeders and turkeys of Chile in South America, beginning in 2002. Overall, avian influenza is enzootic in Mexico and nearby countries, whereas LPAI and HPAI have been controlled in Chile by stamping out. Vaccines and vaccination are commonly used in enzootic countries for both H5 and H7. The biologicals utilized include recombinant vaccines using HVT or FPV vectors expressing H5 or H7 and whole virus inactivated vaccines propagated and inactivated using traditional technologies. Inactivated recombinant vaccines developed by reverse genetics technology are now some of the most used killed vaccines for grandparents, breeders, layers and broilers.

The most significant challenges industry faces for avian influenza control include: a) unharmonious collaborations between industry and Government; b) various obstacles for timely updates of vaccine master seeds to reflect the most prevalent lineages of viruses circulating in the field (heavy vaccination imposes significant immune pressure resulting in frequent emergence of HPAIV and most commonly LPAIV sublineages; c) significant lapses in biosecurity involving manure and bird movement as well as other deficiencies; d) commercialization systems that rely heavily on live bird marketing; e) vaccine and vaccination cost (a vaccination program for commercial layers in a high prevalence area may cost as much as \$250.00 USD or more per 1000 chickens, just for protection against avian influenza without considering the cost of vaccination against many other significant pathogens that also require vaccines and/or medication, the cost of cleaning and disinfection, extended down time, various biosecurity restrictions, loss of access to Al-free markets, etc.

Constant oscillations in product availability due to high mortality in broilers, breeders and layers impose a significant strain on the consumer via high poultry meat and egg prices during times of high challenge with AI, in countries with high meat and egg consumption and where the local purchasing power is generally low. Viable solutions or improvements are available for most of the five primary challenges presented herein, two of the most important ones being a strong collaboration with Government to allow for regular updates for vaccine master seeds, and a gradual reduction of commercialization of live birds from large integrators to large intermediary sellers.

<u>Biosketch</u>



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David Zeman is a native of ND and received a DVM from Oklahoma State University. After 2.5 years in private practice, he worked as a Resident and also acquired his PhD in Veterinary Pathology from LSU, and became a board certified diagnostic and research pathologist with special interests in infectious diseases of food animals, bone and joint diseases and surgical biopsies. After 31 years in academia, he retired as Professor, Head and Director Emeritus from South Dakota State University, Department of Veterinary and Biomedical Sciences. He was Associate Director or Director of the SD Animal Disease Research and Diagnostic Laboratory for nearly 20 years. Since retirement 8 years ago, he has enjoyed private practice as a diagnostic and R & D pathologist. He is also involved with professional association management, currently employed as Executive Director of the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and as Executive Director of the SD Poultry Industries Association.

He was an AAVLD accreditation auditor on 50 diagnostic laboratory site visits, and lead auditor on many. In 2006 he received the highest award offered in his discipline as a lab diagnostician, the AAVLD Pope Award. In 2003 he was named SD Veterinarian of the Year. David is married, father of 2, and has 4 grandchildren.



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