



*OFFLU avian influenza virus characterisation meeting
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Options for a Poultry Vaccine Selection Process

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Goal

Make scientific recommendations on global, regional and/or national avian influenza vaccine seed strains for poultry vaccines

Structure

- **Come under auspices of Avian Influenza Technical Activity (Chair: Ian Brown)**
- **Members to include:**
 1. **OFFLU - WHO VCM Group**
 2. **OFFLU Avian Influenza Contributors:**
 - **Diagnostic virology**
 - **Molecular virology**
 - **Epidemiology**
 - **Vaccinology**
 - **Serology**
 - **Cartography**
 - **Challenge models**

Components:

1. Annual or biannual evaluation
2. Define and optimize the data gathering process
3. Define AIV subtypes to be explored initially & those for expansion over time
4. Update the inventory & phylogeny of circulating poultry viruses with accessible hemagglutinin sequences
5. Review & analyze antigenic data for AIVs
6. Compile & review vaccination/challenge study results
7. Communicate very clearly & openly on this process with national authorities as well as with the private industry, & facilitate early and open sharing of data & knowledge with international & national vaccine manufacturers

Components:

8. Conduct a preliminary review of the vaccines used in the field including products, seed strains, manufacturers & challenge strains, and disseminate results
9. Make recommendations on challenge strains for efficacy determination & licensing
10. Make use and/or develop interlinked interoperable bioinformatics tools
11. Harmonize laboratory protocols & analysis
12. Develop better methods to assessment vaccine effectiveness in the field of resource poor countries compiled and identify gaps in vaccine effectiveness data

Outcomes:

- 1. Make recommendations for poultry avian influenza vaccine seeds and challenge strains on annual or biannual basis**
- 2. Post findings and recommendations of the annual/biannual consultation online at the OFFLU website with credit to the contributing labs**
- 3. Indicate to manufacturers where isolates for vaccine strains can be found**
- 4. Regularly update and post a vaccine and seed strain inventory and availability**

Funding:

1. **Funds or in-kind contributions to support this activity such as travel for experts from developing countries.**
2. **FAO and OIE could explore fund to pay for a meeting and consultancy to help for the coordination or data analysis**
3. **Explore external sources of funds excluding vaccine companies or vaccine industry groups; e.g., Gates Foundation.**

Conflict of Interests:

OFFLU will identify required paperwork for members for disclosure stating potential conflicts of interest (between FAO, OIE, WHO). All PAIVC consultants will sign the disclosure stating potential conflicts of interest, recapitulating the ethics standards of the WHO VCM

Proposed Steps

1. **Confirm memberships and agreed Terms of Reference of the task with timeline and specific expected outputs with OIE, FAO and OFFLU committees**
2. **Explore functional linkages with the OFFLU WHO VCM group**
3. **Appoint AIVC group members**
4. **Define and optimize the data gathering process (epidemiologic, genetic and antigenic data and their analyses)**
5. **Define avian influenza virus subtypes to be explored initially and those for expansion over time**
6. **Identify availability of harmonized poultry reagents for HI testing**

Proposed Steps

7. Establish a clear and open communication process with national authorities, especially HPAI endemic countries, as well as with the private industry, and the define communication mechanisms with OIE and FAO. This will improve the chance of direct impact, convince countries to share their data at an early stage and avoid tensions with international and national vaccine manufacturers
8. Agree on a dissemination plan for outputs: format of the information, location of posting, frequency for updating, clearance process, responsibilities, etc.
9. Raise regular funding for the group to be active
10. Make any specific arrangement required for access to antigenic cartography software and expertise

Terms of Reference: Regarding Circulating Viruses

1. **Update the inventory and phylogeny of circulating poultry viruses with accessible HA sequences, both published and unpublished**
2. **Select poultry viruses that require antigenic testing, if data is missing solicit additional viruses from OFFLU Reference Centres**
3. **Conduct serological tests and antigenic analysis on circulating viruses using poultry and ferret antisera to reference viruses**

Terms of Reference: Regarding Circulating Viruses

4. **Make use and support the development of interoperable bioinformatics tools to facilitate easy collection and analysis of data, including good standard operating procedures (SOPs), such as working space in IRD, linked with EMPRES-i for epidemiologic data, easy access to antigenic mapping functions and if available, prediction tool of the matching based on the genetic data**
5. **Harmonize the production of reference antisera for poultry, hemagglutination inhibition (HI) protocols, antigenic maps, etc, for use both with the public health and the animal health sectors**

Terms of Reference: Regarding Vaccines

1. **Compile and review vaccination/challenge study results – identify gaps in challenge study results**
2. **Conduct a preliminary review (and keep it updated through means to be defined) of the vaccines used in the field and challenge strains for official vaccine efficacy tests, collect feedback from various stakeholders on this task and potential implications of this approach on vaccine production and use**
3. **Update the previous inventories of FAO and CFSPH of available vaccine products and vaccine strains in various countries (and keep it updated through means to be defined) and disseminate results**
4. **Make recommendations as to appropriate challenge strains and required additional challenge studies**

Terms of Reference: Regarding Vaccination

1. **Better assessment of vaccine effectiveness in the field as most countries do not have the means to do a wide post-vaccination monitoring. With epidemiologists, guidelines can be developed on how to best assess vaccine effectiveness based on risk-maps of virus circulation, on value chains, on sectors of production vaccinated, vaccine products, etc.; and field results can be collected and compiled and identify gaps in vaccine effectiveness data**

Terms of Reference: Regarding Others

1. Produce dissemination outputs as defined in the dissemination plan
2. Support regional workshops for laboratory staff for improved data harmonization, sharing and streamlining