Issues to consider when developing vaccination programmes against high pathogenicity avian influenza (HPAI)

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Introduction

- Vaccines have already been used against HPAI in multiple countries
- Mainly in places where the virus was already endemic and there was little or no likelihood of elimination of virus but also in places at high risk of exposure (Hong Kong SAR)
- Already evident that vaccination will play a role in the prevention and control of H5Nx HPAI viruses in the Americas (already being used or considered)
- Will discuss some decisions that have to be made when considering inclusion of vaccination, and once it is adopted
- Will introduce two concepts – “AI Vaccine Stewardship” and the “AI Vaccination Cycle”

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Main ways that vaccination is used

- Vaccination can be used (in partnership with other measures):
  - as a **preventive measure**, in high risk places before infection occurs in poultry. It might be in response to an increase in the threat level (one form of WOAH Code emergency vaccination) or as an on-going programme (one form of WOAH Code systematic vaccination)
  - as an **aid to control new outbreaks** when they occur (another form of WOAH Code emergency vaccination)
  - to **reduce the likelihood of infection and prevent disease** in poultry and humans in "endemic" countries -"suppressive" vaccination **(a**nother form of WOAH Code systematic vaccination)
  - to **support virus elimination** from poultry where this is possible
- Most vaccines available require individual injection of birds

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Emergency preventive vaccination based on a change in the threat level

- When a signal is obtained that a country is at high risk of virus incursion via migratory birds (e.g. USA in December 2021, South America in 2022)

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alert

FAO ALERT FOR CENTRAL AMERICA AND SOUTH AMERICA: H5 HIGH PATHOGENICITY AVIAN INFLUENZA – RISK FOR INTRODUCTION AND SPREAD

13 September 2022

offlu OIE FAO

23 December 2021

OFFLU statement on outbreak of H5N1 high pathogenicity avian influenza in Newfoundland, Canada

"Pre-emptive vaccination may be considered for high risk species such as turkeys or layer chickens, provided a vaccination strategy is well established"

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Emergency preventive vaccination based on a change in the threat level

- Provides a short window in which to achieve high levels of immunity in high risk populations
- Resistance to application in exporting nations largely due to trade issues
- Need sufficient supplies of well-matched vaccine
- Unlikely to be used the first time the risk increases given the extent of the outbreak will be unknown (e.g. current situation in South America)

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Emergency vaccination for outbreaks

- Following new outbreaks in places where they have not occurred before
- Need vaccine available
- Can help limit outbreaks and best applied early
- Might result in virus elimination from poultry if applied early
- Potential for transmission of virus by vaccination teams if ring vaccination applied (but can be managed)

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Systematic preventive vaccination based on an on-going threat

- Used when it is evident that the threat of HPAI persists
- Either on-going outbreaks or regular high threat of incursion
- Hong Kong SAR has been using vaccine as a preventive measure but has a zero tolerance for infection
- Therefore the vaccination program is accompanied by a strong multilayered surveillance system to demonstrate “freedom” from infection

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Trade issues and vaccination

- If an exporting country, need to resolve the trade issues before commencing vaccination
- Some trading partners would implement bans on imports of meat from one sector (e.g. unvaccinated broilers) if vaccination is used in an unrelated sector (e.g. turkeys)
- No valid scientific or legal reason why use of vaccine should affect trade as long as there is an appropriate surveillance system in place for detecting infection in vaccinated (and unvaccinated) flocks

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Vaccination and emergence of antigenic variants

- Expected to occur over time if vaccinated birds are exposed to virus
- Occurs more rapidly if vaccinated birds are exposed repeatedly to virus
- Can develop if birds have low level immunity (allowing breakthrough infections)
- Also occurs when vaccination is not being used (e.g. H6 viruses in China)
- May not be due to local use of vaccines (imported variants)
- Need monitoring system in place and, when appropriate, update of vaccines

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Vaccination and endemic infection

- Vaccination commenced in countries such as China, Viet Nam, Indonesia and Egypt **because the virus was already endemic** and standard control measures could not eliminate the virus from poultry
- In these places **virus elimination from poultry was a distant goal** (and one that might never be achieved)
- Importance of "**AI vaccine stewardship**" and adherence to the "**AI vaccine cycle**" to ensure progress in disease prevention and control

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"AI Vaccine Stewardship"

Some similarities to "Antimicrobial Stewardship"

1. Vaccines should not be used as a replacement/substitute for other methods of disease prevention but to add an additional layer of biosecurity/protection *
2. The decision to use vaccine is just the beginning of the process, not the end
3. Need to choose appropriate vaccines that provide protection against circulating strains
4. Use vaccines in accordance with manufacturer's recommendation (dose and timing)
5. Monitor selected vaccinated flocks to ensure vaccine is producing the desired immune response, to plan timing of boosters (if required) and (if used) to monitor for infection **

*one exception is free-ranging ducks for which few biosecurity measures are feasible at the production level

**may be all flocks if elimination/demonstration of freedom in vaccinated flocks is the target

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"AI Vaccine Stewardship"

6. Need to monitor viruses regularly for evidence of antigenic changes and update vaccines when required
7. Beware of import of novel antigenic variants (trade or wild birds)
8. Replace (deregister) vaccines that no longer afford protection from disease and virus shedding
9. Ensure vaccination is done in a manner that does not transmit the virus

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"AI Vaccine Stewardship"

10. Regularly re-assess the need for and nature of vaccine programmes and modify programmes accordingly (see AI vaccination cycle)
11. Special attention should be paid to farms or markets where infection occurs or persists, despite appropriate usage of vaccines
12. Examine ways to modify production and selling practices that facilitate transmission and replication of the virus

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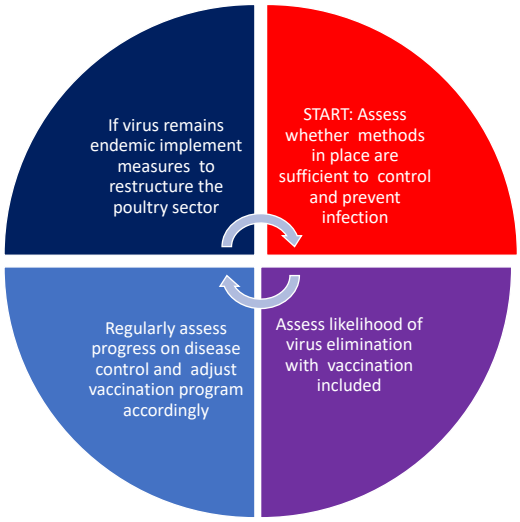
The "AI Vaccination Cycle" in places where HPAI is occurring in poultry



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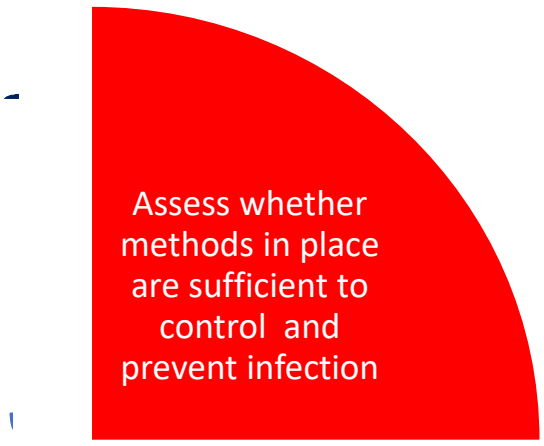
The "Vaccination Cycle" in places where HPAI is occurring in poultry



- When existing measures (e.g., stamping out and movement controls) are not sufficient to eliminate the virus, or are not sustainable, consider adding vaccination
- If used, determine which sectors would benefit most from vaccination, where to vaccinate, and with which vaccine
- Certain sectors/locations will not require vaccination
- Determine how to deliver vaccine to smaller flocks effectively, if included
- Ensure only suitable well-matched vaccines are registered and used

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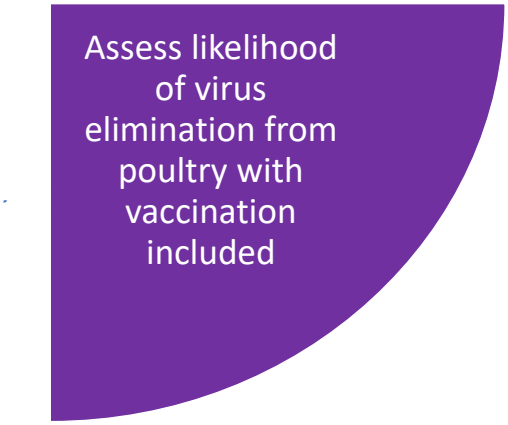
The "Vaccination Cycle" in places where HPAI is occurring in poultry



- Is there a reasonable probability that vaccination plus biosecurity and targeted culling can halt transmission of/eliminate the virus?
- Assessment is based on
  - the nature of the poultry sector,
  - capacity to vaccinate
  - availability of appropriate vaccines
  - capacity to design and implement an appropriate surveillance system
- Factors that get in the way include:
  - large number of free-ranging domestic ducks
  - live bird markets not managed to prevent infection
  - complex chains from producer to sale
  - persistence of virus in wild bird populations
  - inappropriate usage of vaccines

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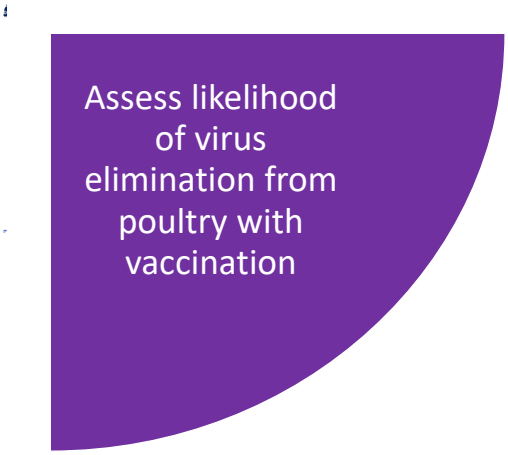
The "Vaccination Cycle" in places where HPAI is occurring in poultry



- If yes, shift to/retain a virus elimination policy
- Requires a surveillance system to detect all cases of infection in vaccinated flocks, with characterisation of viruses
- If no, adopt a suppression policy that acknowledges elimination is not possible in the short to medium term
- Adjust surveillance to monitor for disease outbreaks in vaccinated flocks and markets and to check for antigenic variants

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The "Vaccination Cycle" in places where HPAI is occurring in poultry

- 3 to 12 months later (and repeated)
- Assess the extent to which vaccination is helping to prevent infection and disease
- This requires an appropriate surveillance system for detecting infection
- This review might include decisions to:
  - cease vaccination if the virus is no longer circulating in poultry regionally and/or the risk from wild birds has disappeared
  - change vaccines/vaccine antigens
  - changes the scope of the programme
  - continue vaccination as before

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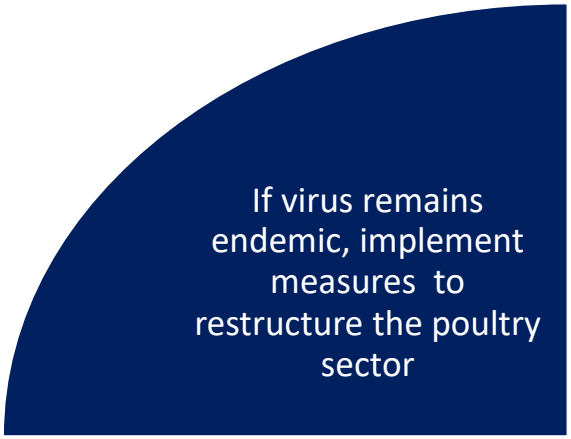
The "Vaccination Cycle" in places where HPAI is occurring in poultry



- This might include:
  - changing to centralised slaughter of domestic ducks,
  - changes to live bird market management,
  - compulsory remedial actions/penalties for repeated infection on farms and markets, etc
- Must be based on capacity to implement changes and assessment of feasibility, in conjunction with stakeholders
- Maintain vaccination as part of the control strategy if virus remains endemic
- Public Health/One Health obligations need to be met – do not want another human pandemic or spillback to wild birds

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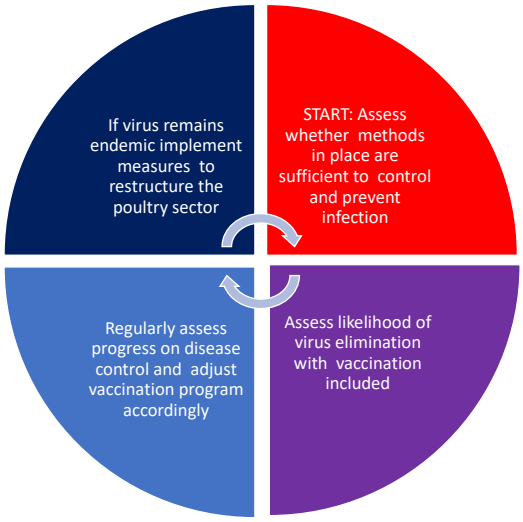
The "AI Vaccination Cycle" should be continuous



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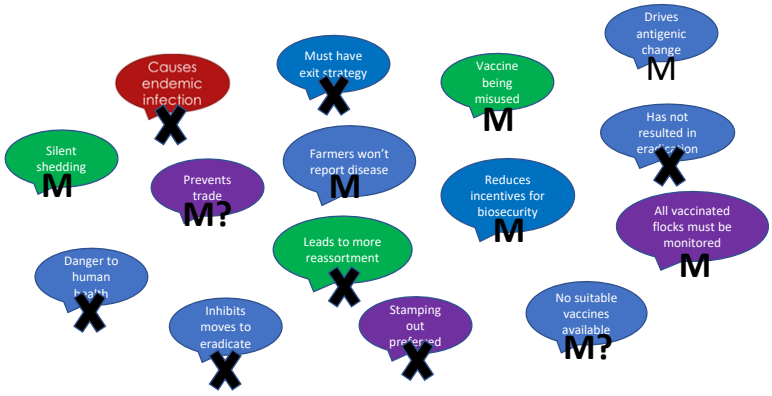
Barriers to Vaccination

Some of the "reasons" given for rejecting use of preventive vaccination – not all are valid (X) and all can be overcome (M or have the potential to be overcome(M?)



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Vaccination and surveillance

- Surveillance system must match the situation, capacity and objective of vaccination
- Well targeted surveillance is generally more effective and cheaper than random sampling, even for demonstrating “freedom from infection” in vaccinated flocks
- Serological DIVA only one method for detecting evidence of infection in vaccinated flocks and not generally applicable if other AI virus also circulating. Does not provide information on recent infection (c.2 weeks before testing)
- Preferred methods include dead bird monitoring, environmental samples (e.g. waste water from farms, slaughterplants, swabs of cutting boards)
- Do not need to (or have the capacity) to monitor every flock in places with endemic infection when suppression is the goal
- Multilayered system is preferred, starting with evidence of response to vaccine and testing at multiple points along the value chain

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Conclusions

- Vaccination is valuable for prevention and control of HPAI and can assist in eliminating the virus
- Introduction of vaccination is just the first step
- Need to implement the 12 steps of AI vaccine stewardship and follow the AI vaccination cycle
- Thank you for your attention

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