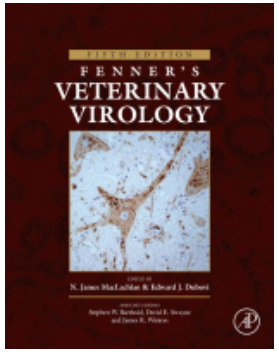
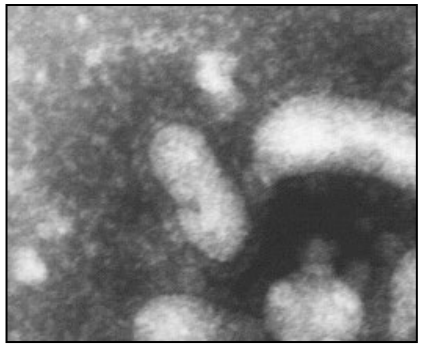
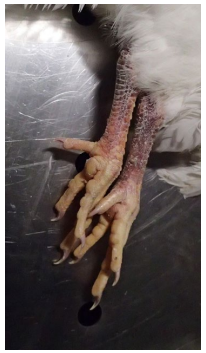
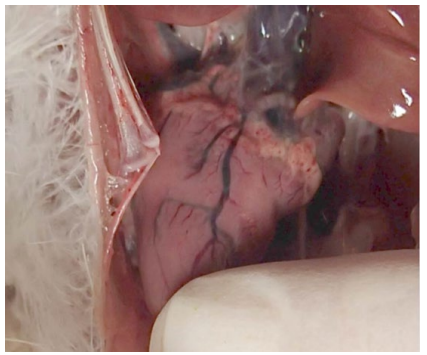
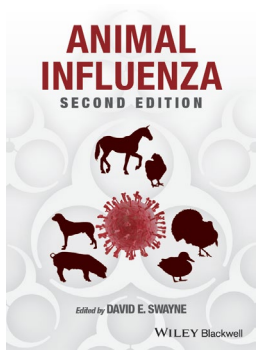
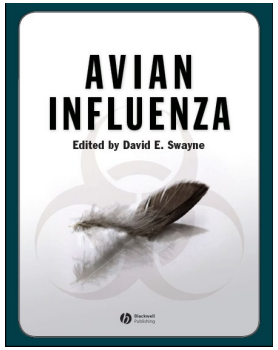




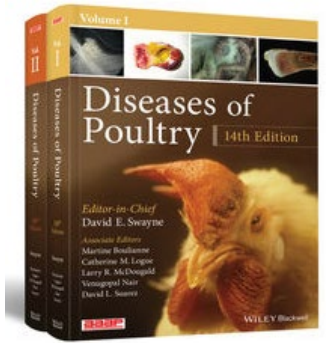








Global HPAI Vaccine Usage and Barriers to Increasing Application



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Disclaimer: This presentation is based on current scientific data and is not an endorsement of any specific product or company

General Control of HPAI

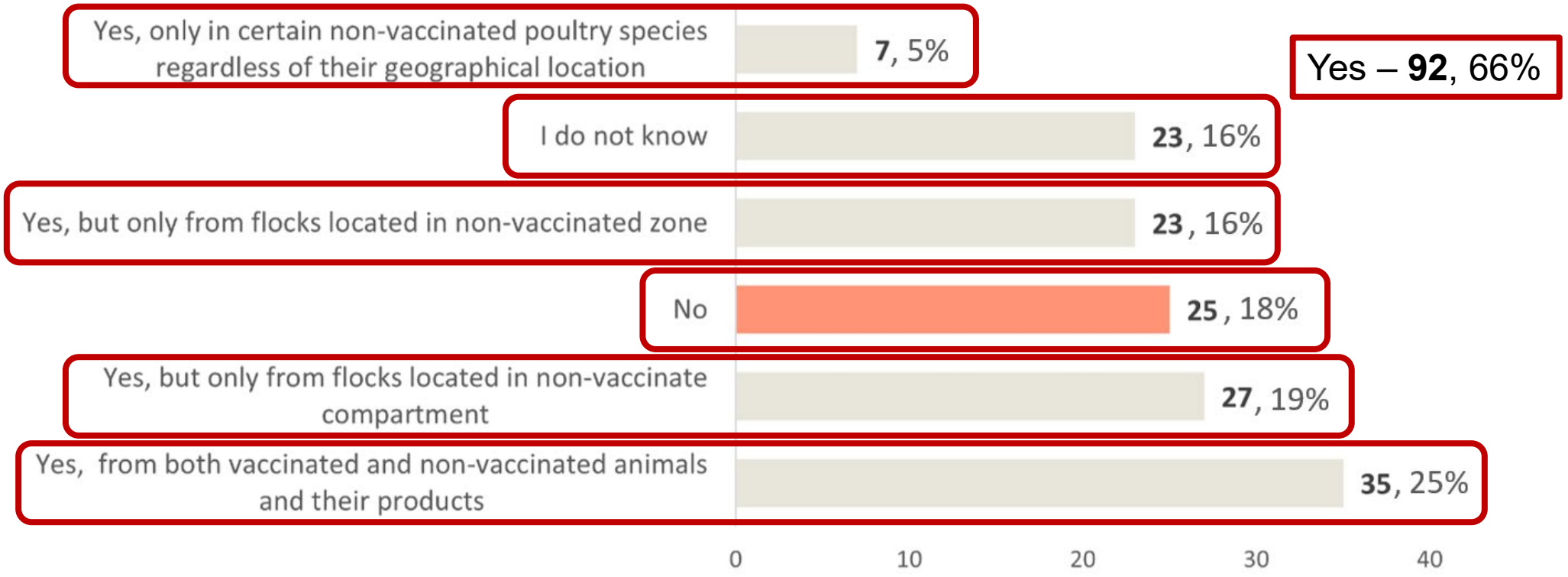
- **World Organization for Animal Health (WOAH/OIE) consensus for severe transboundary animal diseases (e.g. HPAI) is elimination and stamping-out has been the preferred strategy**
- **Changing ecology and epidemiology of the H5Nx Gs/GD Eurasian clade 2.3.4.4 HPAI has challenged a single view-point and strategy:**
  - **Many countries eliminated Gs/GD HPAI through stamping-out program, but some have had multiple re-introduction and elimination cycles (e.g. South Korea and Japan)**
  - **Other countries had delays in elimination through stamping-out programs associated with various reasons - limited veterinary services, restricted finances, delayed logistics, inadequate diagnostic systems, lack indemnities, etc., and the HPAI virus became entrenched in poultry**
  - **Some countries with entrenched HPAI have undertaken systematic (routine) vaccination for national food security needs without likelihood of elimination in immediate future (e.g. China, Egypt, Indonesia, Vietnam, Bangladesh)**
  - **Other countries have done targeted/ring emergency vaccination programs to limit the virus infection and spread, in order to allow stamping-out programs to catch-up and have led to elimination in the mid-2000's (e.g. Côte d'Ivoire, Sudan)**

World Organization for Animal Health (WOAH)

- **WOAH Guidelines:**
  - **Terrestrial Animal Health Code – chapter 10.4.**
  - **Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2022 - Chapter 3.3.4.**
- **Outcome- and risk-based provisions to control & prevent the spread of HPAI through international trade while avoiding unjustified restrictions**
- **Supports trade in vaccinated poultry in the presence of appropriate surveillance to demonstrate freedom from HPAI virus infection. Why and how?**
  - **Similar requirement as in non-vaccinated poultry**
- **Principal barriers:**
  - **Trade blockage by importing countries**
  - **Surveillance to demonstrate freedom from infection**
  - **Time for national registration and biologics company production cycles**

World Organisation for Animal Health
Founded as OIE

General Control of HPAI



WOAH - March 2023 Survey of CVOs: Would your country import poultry products in compliance with WOAH Standards if the exporting partner implement vaccination against HPAI (140 responses)

Survey Vaccinated Poultry to Find Infection

DIVA (Detecting Infected among Vaccinated Animals)

Virological Surveillance ('Biosensor'): active infection

- Identifiable, susceptible population looking for the virus
  - Non-vaccinated sentinel birds that die (logistically very difficult)
  - Daily mortality or sick birds in vaccinated population ("bucket surveillance")
  - Environmental samples – eg waterers, egg belts, etc. (need specific studies)
- Detection virus by RRT-PCR pooled swabs (pools of up to 11 swabs)

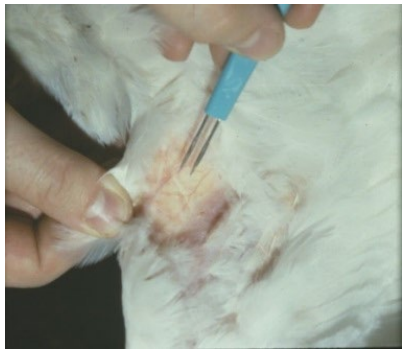
Serological Surveillance (Limited use – before stopping vaccination): historical perspective

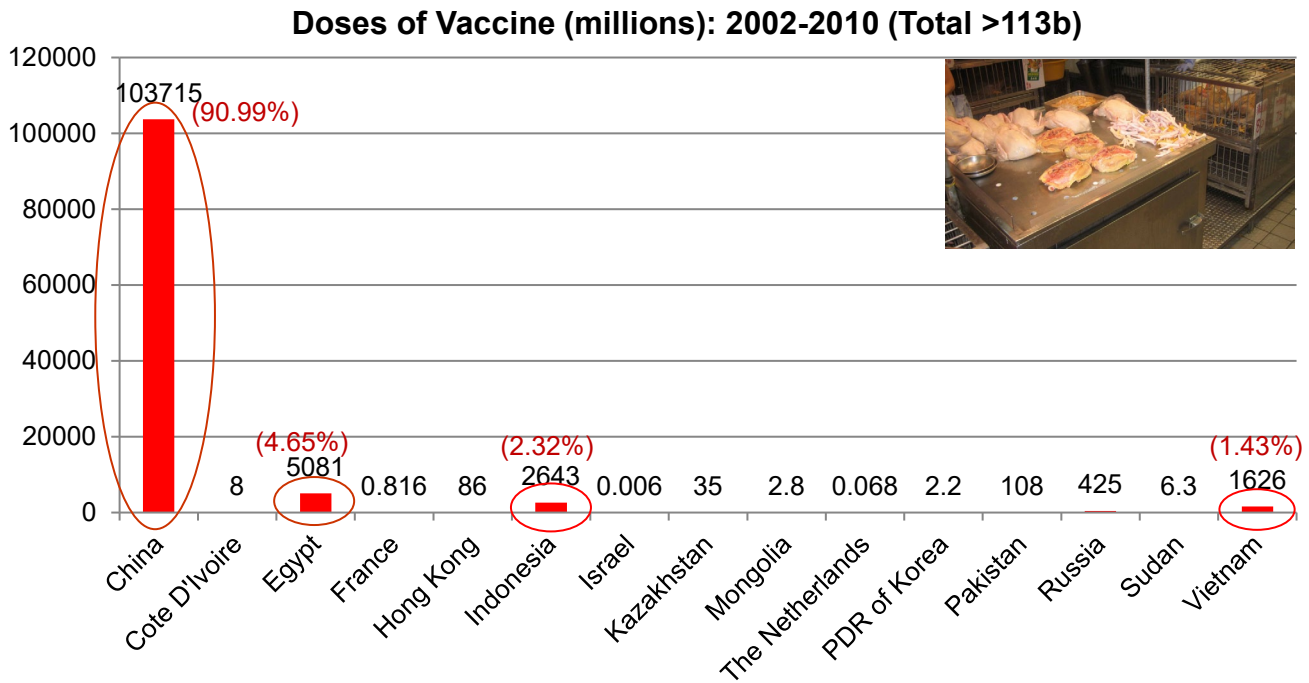
- Inactivated vaccine - vaccine/field virus different neuraminidase
- Hemagglutinin only vaccines (vectored, protein or nucleic acid): use AGID or ELISA NP/M antibodies
- Sample number and frequency determined by production country, prevalence and confidence interval (e.g. 5% and 95%, respectively)

Vaccination: Historical View

Historical view (national focused):

- **After HPAI become entrenched in poultry → vaccine used for food security and/or to reduce exposure of humans (>99% HPAI vaccine used, 2002-2010)**
  - **H5Nx Gs/GD Eurasian lineage – China (including Hong Kong), Indonesia, Vietnam, Egypt, Bangladesh**
  - **H7N3 N. American lineage – Mexico, Guatemala**
  - **H7N9 Eurasian lineage – China**

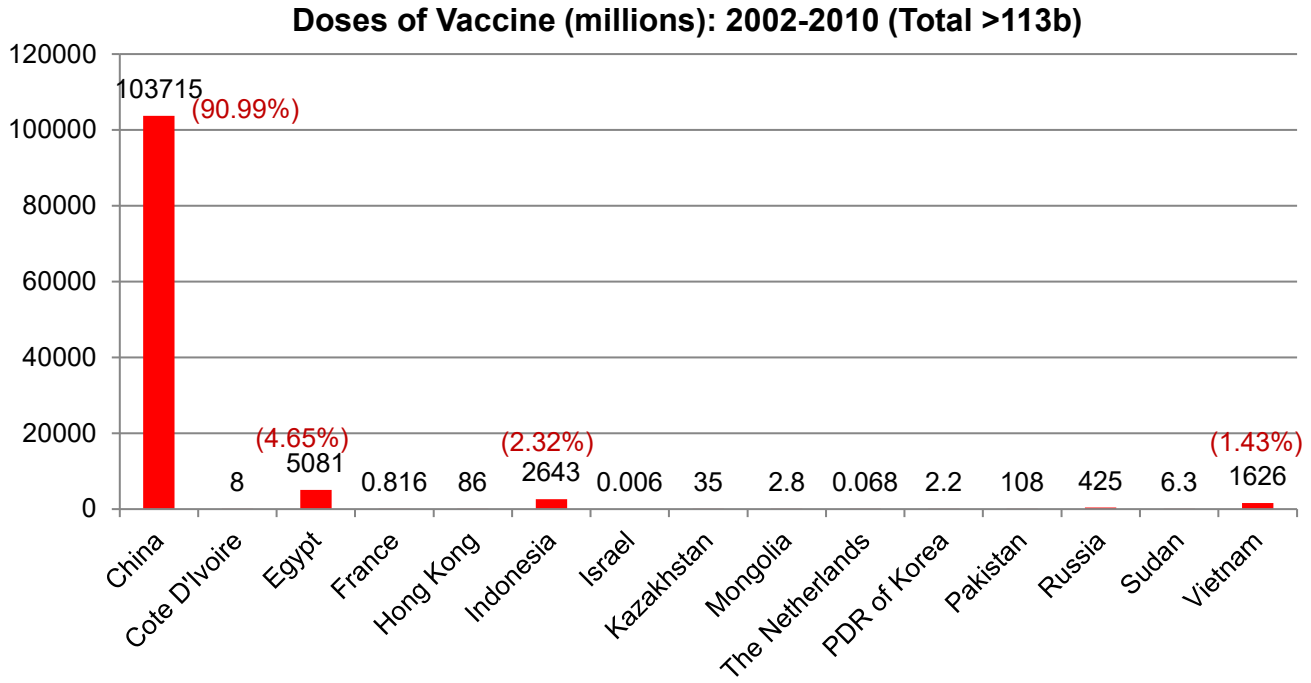




Swayne et al., OIE Sci Tech Rev 30(3):839-870, 2011

History: H5/H7 HPAI Vaccination Programs

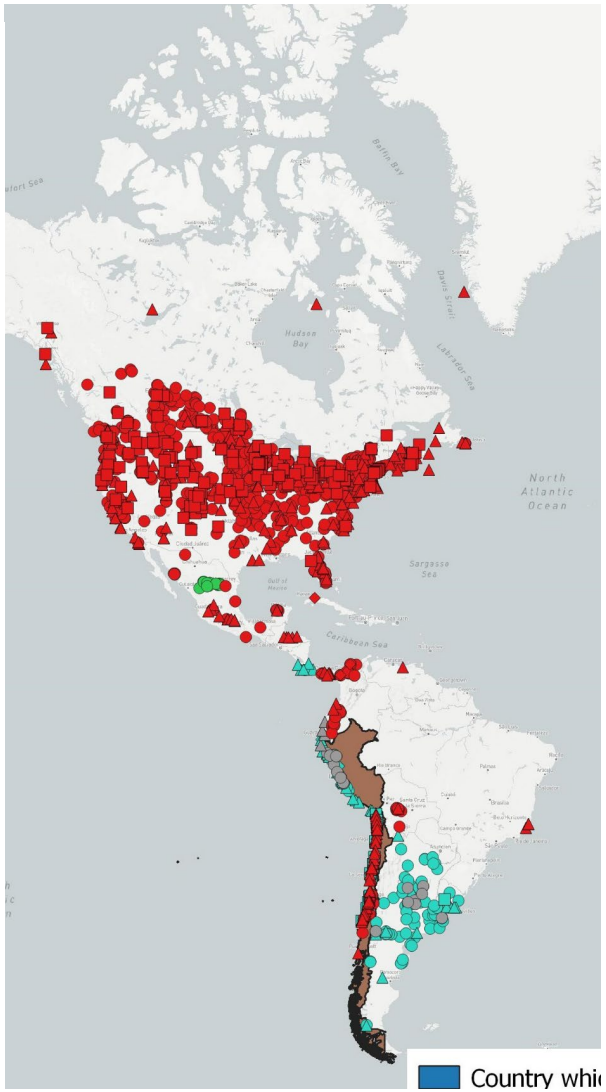
- **HPAI in high-risk situations (outbreaks in neighboring countries, wild bird cases, initial cases in poultry)**
  - **Preventive (<0.2%): Mongolia, Kazakhstan, France, The Netherlands**
  - **Emergency (<0.8%): Cote d'Ivoire, Sudan, N. Korea, Israel, Russia, Pakistan**



- **Additional countries that notified WOAH since 2005 - Armenia, Belarus, El Salvador, Germany, Jordan, North Korea, Kuwait, Laos, Niger, and Turkmenistan**
- **2023: Approval vaccination in EU (with 6 countries considering implementation)**
  - **France – domestic ducks, October start time for vaccination**
  - **Others considering – Netherlands (layers), Hungary (geese), Italy (turkeys), Czech Republic (geese), Belgium**

H5N1 Gs/GD Eurasian-lineage HPAIV: Vaccine in Americas

- **Control in the Americas – vaccination for H5N1 Eurasian lineage HPAI**
  - **Mexico and Guatemala: added emergency H5 Eurasian vaccines - ongoing vaccination with H5N2 LPAI and H7N3 HPAI N. American strains**
  - **Ecuador (14 million doses) and Bolivia (10 million doses): vaccination of long-lived poultry**
  - **Peru: vaccinated egg layers and pullets (28M), light breeders (1.5M), heavy breeders (7.2M) and turkey breeders and meat turkeys**
  - **Uruguay – 10 million doses in chickens**
  - **El Salvador -**
  - **USA: approved vaccination of California Condors (testing in vultures in Rehab Center)**
  - **Columbia: examining vaccination of egg-layers in high-risk areas (maximum of 60 million doses)**



https://en.wikipedia.org/wiki/California_condor

“AI Vaccine Stewardship”

@FAO/Mohamed Moussa

Best practices, transparency, rigor, responsibility…

Some similarities to “Antimicrobial Stewardship”

1. Vaccines should not be used as a replacement or substitute for other methods of disease prevention but to add an additional layer of 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

Concepts of Les Sims

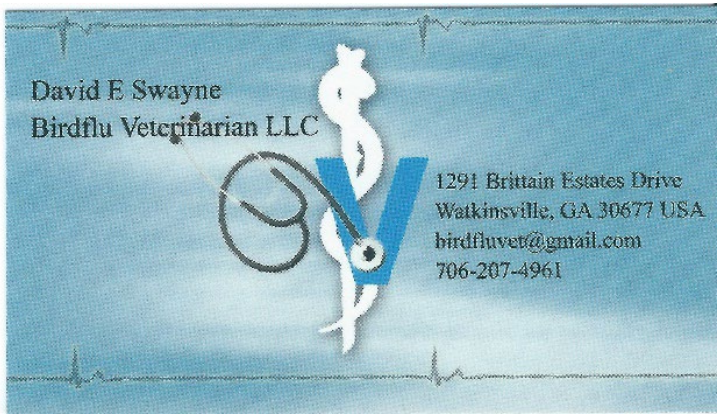
“AI Vaccine Stewardship”

@FAO/Mohamed Moussa

6. Need to monitor viruses regularly for evidence of antigenic changes and update vaccines when required
7. Be aware of possibility for import of novel antigenic variants (live bird 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
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

Concepts of Les Sims

Thank you for your attention!



2023 - present

USDA

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