Production of veterinary vaccine from eggs
Questions to veterinary experts

- Could production of egg-derived poultry vaccines in a human vaccine facility assist in sustainability of the facility?
- Which vaccines?
- Is it feasible?
- Is it cost-effective?
Answers from veterinary vaccine experts

- It is possible to manufacture veterinary and human vaccines in the same location, but whether this can happen will depend on national legislation.
  - Previous meetings with WHO suggested that making human vaccines in veterinary facilities not readily feasible.
  - Converse may be more feasible.

- For veterinary influenza vaccines, currently the supply meets demand on the veterinary side.
High Pathogenicity Avian Influenza Vaccines (HPAI)

- H5N1, H5N2, H7N3, H7N9

- **2002-2010**: 113 Billion doses of H5 /H7 vaccine used
  - China: 15-25 Billion/yr
  - Egypt: 1.3 Billion/yr
  - Indonesia, Vietnam: 0.2-0.4 Billion/yr

- OIE Global AI H5 vaccine bank: 65 million H5N2
  - 56 million doses provided to Vietnam and Egypt

- 95% Inactivated virus.
  - 5% live: recombinant fowl pox virus / newcastle disease virus
Vaccine economics (inactivated virus)

- China, Vietnam:
  - Cost of vaccine $0.016
  - Other costs of vaccination $0.021

- Indonesia:
  - Profit from sale of a chicken $0.3
  - Cost of vaccine $0.018

- Nigeria
  - Cost of vaccine $0.04
Seed strains used

- H5 and H7 LPNAI viruses from previous outbreaks in poultry (H5N2, H5N7, H5N9, H7N2 and H7N3)

- H5N1 classic reassortant LPAI virus with the haemagglutinin gene from an H5 wild waterfowl virus

- Reverse-genetic-generated LPAI viruses (two H5N1 viruses and an H5N3 virus).

- Issues: access to seed strains?
What is in the vaccine?

- Inactivated virus + oil emulsion (water-in-mineral oil)

- Antigen
  - HA dose varies from manufacturer
  - Approval based on challenge studies. No defined HA content!
  - Ranges shown to be effective: 0.25 – 1 ug
    - In some studies 0.02 up to 20ug used.

- Main difference between veterinary and human production is in down-stream processing.
  - Minimal purification, emulsification with mineral oil.
Is this enough for a business?

- There is a big market (billions/yr) but apparently supply meets demand
- Profits on poultry influenza vaccines are very low
- COG should be below 1c per dose ~ 1c/ug.
- Is this possible if being done under regulatory conditions for human vaccine production?

Proposal: bulk virus production in shared facility, downstream processing in veterinary facility.
Other egg-derived vaccines

- Newcastle disease virus vaccine (live)
- Avian encephalomyelitis vaccine (live / inactivated)
- Egg drop syndrome 76 vaccine (live / inactivated)
- Duck Plague vaccine (live)
- Fowl pox vaccine (live)
- Infectious bronchitis vaccine (live / inactivated)
- Infectious bursal disease vaccine (live / inactivated)
- Marek's disease vaccine (live / inactivated)
Conclusion

- Technically, producing veterinary vaccines in a human vaccine facility could be a way to use the embryonated eggs from a dedicated flock for human influenza vaccine and innoculation and harvesting line.

- The regulatory challenges need to consider both the human and veterinary points of view of NRA. Maintaining GMP critical.

- Downstream processing is so different that should be in a separate facility.

- Business case is not evident – price of vaccines low, global market needs met. National needs may not be met.