Update on Novel Influenza Vaccine Work Group

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June 25, 2015

ACIP Meeting

Work Group Charge

- Develop recommendations for use of influenza A (H5N1) vaccine during inter-pandemic period

H5N1 Vaccines in HHS Stockpile

- Four H5N1 vaccines in HHS stockpile

Virus	Clade	FDA licensure
A/Vietnam/1203/2004	1	Yes (Sanofi)
A/Indonesia/5/2005	2.1.3.2	Yes (GSK)
A/bar-headed goose/Qinghai/1A/2005	2.2	No
A/Anhui/1/2005	2.3.4	No

- Use of vaccine in HHS Stockpile is limited
  - Permit use during pandemic or for clinical studies
  - Permit strain change only during an emergency
- Use of vaccines in HHS Stockpile not possible during in inter-pandemic times

Vaccine Produced Post-Licensure

- One licensed vaccine (Q-Pan, GSK) is being produced post-licensure
  - HHS/BARDA supported additional vaccine production, post-licensure
  - Manufacturer producing one lot (~100,000 doses)
  - Vaccine will be ready late 2014/early 2015
  - A portion of this will be stored at NIH and made available to their investigators
- Work group will focus on
  - This vaccine (Q-Pan)
  - Identifying target audience

The Way Forward

- GRADE evidence for use of Q-Pan vaccine
  - Safety
  - Immunogenicity
  - (Clinical efficacy endpoint studies are not feasible)
- Identify high-risk groups during inter-pandemic period
- If warranted, craft policy for use of post-licensure vaccine in these risk groups during inter-pandemic period
- May propose language for vote at Oct 2014 ACIP meeting