CONCLUSIONS OF THE SAGE WORKING GROUP ON INFLUENZA VACCINES

Professor Liz Miller
Public Health England (UK)
Chair of the Working Group

- Review of the 2007 SAGE recommendation on the constitution of a H5N1 Vaccine Stockpile

- Review of the 2009 SAGE recommendation on inter-pandemic use of H5N1 vaccines in the light of the current epidemiology of H5N1

H5N1 Stockpile: Rationale for Review

The SAGE recommendation as endorsed by the WHA re the establishment of a vaccine stockpile has been reiterated in the 2011 "Pandemic Influenza Preparedness" (PIP) Framework

In the absence of a revised SAGE recommendation, the PIP Framework will continue to contain 2 potentially contradictory provisions, i.e. the recommendations to DG/ WHO:

- to establish a *physical* vaccine stockpile

vs

- to engage into agreements with manufacturers to provide a percentage of their weekly *live* pandemic vaccine production ("SMTA-2") during a pandemic

H5N1 Stockpile: Options

Option 1

A physical stockpile of H5N1 vaccines produced and stored before a pandemic to be distributed in the event of a pandemic

Option 2

No stockpile, with reliance on established agreements regarding donated vaccine during a pandemic

H5N1 Stockpile: Options - Pros & Cons

Option 1 (physical stockpile)

Pros

- Timely availability
- Potential to prime high-risk individuals early in a pandemic (for boost with the actual pandemic vaccine once available)

Cons

- Potential antigenic mismatch
- Supply not assured, as H5N1 not in production
- High cost of maintaining a physical stockpile

Option 2 (donation agreements)

Pros

- Better antigenic match
- Supply assured
- Lower cost to WHO
- Simpler logistics
- Not reliant on manufacturers' inter-pandemic production schedules

Cons

- Delayed vaccine availability
- Potential communication challenges for WHO resulting from these delays

H5N1 Stockpile: Summary of arguments

- PIP Framework secures access through legally binding contracts with manufacturers for access to live vaccine production
- No significant change in H5N1 epidemiology, i.e. no geographical expansion in recent years
- Risk of poor antigenic/strain match (evolving H5N1 clades, H7N9 in China, H3N2 in USA) with stockpiled H5N1 vaccine
- Value of a stockpiled vaccine in containment or even delay of a nascent pandemic doubtful

H5N1 Stockpile: WG Recommendation

- WHO should not create a stockpile of H5N1 vaccines
- WHO should ensure real-time access to pandemic vaccines under the “Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits” or “PIP Framework.”

Inter-pandemic use of H5N1 Vaccines: Rationale for Review

- The existing SAGE recommendation re the inter-pandemic use of vaccine was made in 2009 therefore timely to review the current epidemiology of H5N1 and consider whether existing recommendations still stand
- Furthermore, given the additional experience with H1N1 pandemic strain vaccines, there is more knowledge about potential risk benefit of such vaccines

Interpandemic use of H5N1 Vaccines:

Table 3. Summary of SAGE recommendations on the use of currently licensed human H5N1 influenza vaccines in the interpandemic period

	Strongly recommended[a]	Recommended[b]	May be made available[c]	Not recommended
Laboratory workers: higher risk groups other laboratory workers	✓		✓	
First responders to avian outbreaks		✓		
Persons in potential contact with HPAI H5N1 virus			✓	
Essential workers (excluding HCWs)				✓
HCWs, enzootic areas: in designated referral facilities other HCWs		✓	✓	
General population				✓
Priming or immunizing essential personnel or the general public against a potential pandemic H5N1 virus				✓

Interpandemic use of H5N1 Vaccines: Summary of Arguments

- no clear change in the level of risk to exposed populations has been observed
- no changes in populations at risk for HPAI H5N1 virus infection have been observed
- while risk remains low, even in exposed populations, certain high risk groups may benefit from vaccination given the severity of the disease if infected

Interpandemic use of H5N1 Vaccines: WG Recommendation

The 2009 recommendations for use of licensed H5N1 vaccine during inter-pandemic periods should remain unchanged, i.e.

- Vaccination is strongly recommended for laboratory workers involved in certain high-risk activities
- Vaccination is recommended for (a) 1st responders to human or animal HPAI H5N1 cases or outbreaks and (b) HCW who evaluating/managing patients with suspected or confirmed HPAI H5N1 virus infection in designated referral facilities.
- Vaccine cannot be recommended for (a) persons potentially in contact with infected animals, (b) essential workers in areas where HPAI H5N1 virus is enzootic (c) general population.
- Insufficient evidence exists to recommend use of H5N1 vaccines to immunologically prime individuals.