

Practical Considerations for an H5N1 Stockpile

Relevant experience with existing vaccine stockpiles

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Introduction

- **H5N1 threat continues**
- **Virus continues to mutate**
- **Vaccines most effective and powerful prevention tool**
 - Seasonal influenza vaccines used in some countries, but not in others
- **Current influenza vaccine production < 500 million trivalent/year**
- **Production capacity in developing countries**
 - Largely does not yet exist

H5N1 Vaccine Stockpile

- Can be created
- Endorsed by WHO's Expert Advisory Committee on Immunizations, Vaccines and Biologicals (SAGE).
- Vaccine types and limited production capacity key issues.
- Lead time to produce pandemic vaccines at least 6 months
- National regulatory and legal issues important
 - Licensing parameters for H5N1 have been developed.
- Multiple potential uses of H5N1 vaccine stockpile

Operational Framework: H5N1 Stockpile

- Two main (complementary) options
 - Physical stockpile
 - Purchase arrangement for future pandemic influenza vaccines.
- Have been created for other diseases
- Consistent with the IHR (*International Health Regulations*)

(1) Operational Framework: WHO H5N1 Vaccine Reserve Stockpile

- **Funded by international donors and donations of vaccine manufacturers**
- **Release and use based on pre-determined decision criteria**
- **Some WHO functions**
 - Procure vaccine
 - Help countries address legal requirement & pre-registration for countries
 - Develop operating procedures, including replenishment needs
 - Help procure other key ancillary supplies, e.g., single use needles and syringes

(2) Operational Framework: WHO National Pledged H5N1 Vaccine Stockpile

■ Various options

- Countries could commit and store proportion of their national stocks to WHO to be released if needed**
- Based on willingness of Member States to participate**

■ Financing options must be developed.

■ Many technical issues

- Vaccine type(s)**
- Stockpile location**
- Pre-determined release criteria**

(3) Approach for Pandemic Influenza Vaccines

- **No current pandemic and impossible to predict**
 - Which influenza strain
 - When will occur
 - Where will occur
- **WHO and funding partners to explore pre-contracting arrangements**
- **WHO and its advisory bodies to develop decision criteria for release**

Financing Issues

- **Member states could**
 - Contribute vaccine stocks
 - Pledging a percentage of national stockpiles to WHO
 - Provide funds
- **Funding contributions**
 - Immediate funds
 - Advance Market Commitments
 - GAVI Board to review influenza on May 12
- **Manufacturers can donate vaccine stocks**

Legal considerations

- **Ownership of pledged vaccine stocks**
- **Litigation arising from adverse events**
- **Considerations will include that vaccine provided to a country for emergency response would only be released on acceptance of a legal disclaimer absolving WHO and the original donor of all liability from adverse events**

WHO Experience with Vaccine Stockpiles

- WHO has stockpile experience with vaccines to prevent 3 diseases, & several drug facilities
- IHR(2005) has central role in decision making
- Public-private partnerships to nurture new vaccine development
- Management costs important
- Ability to deploy rapidly essential