

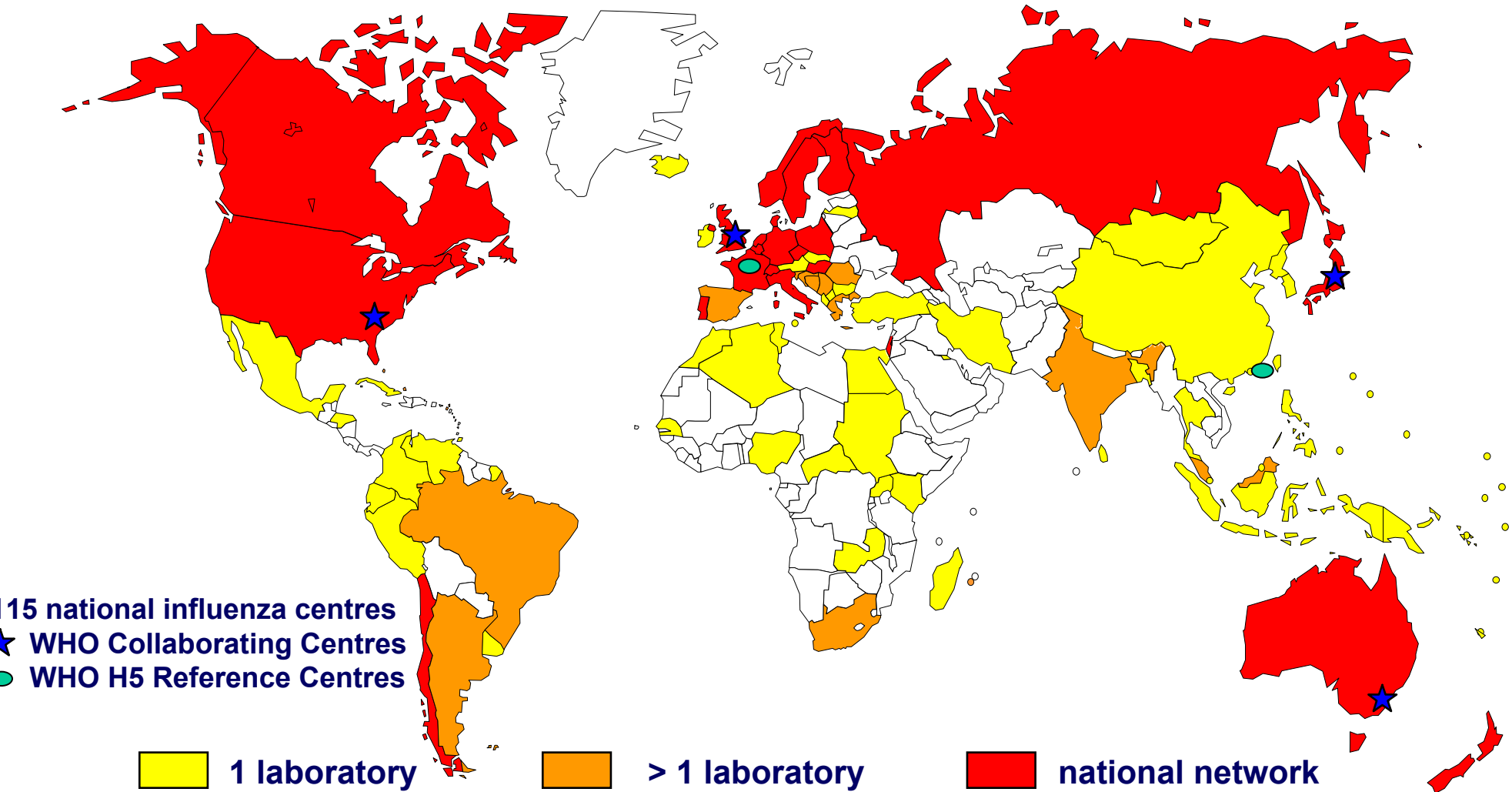
**Meeting on Options for Increasing
the Access of Developing Countries
to H5N1 and other Potential
Pandemic Vaccines**

**Geneva, 25 April 2007
Executive Board Room**

H5N1 threat has changed the status quo

- **Seasonal vaccine**
 - Use mainly in industrialized countries
 - Vaccine production reflect market demands
 - Free sharing of influenza viruses for over 50 years
- **H5N1**
 - Human zoonotic infections mainly in developing countries
- **Other potential pandemic vaccines**
 - Threat of pandemic greater than anytime since 1968
 - Need in both industrialized and developing countries
 - Current production capacity will not meet global need

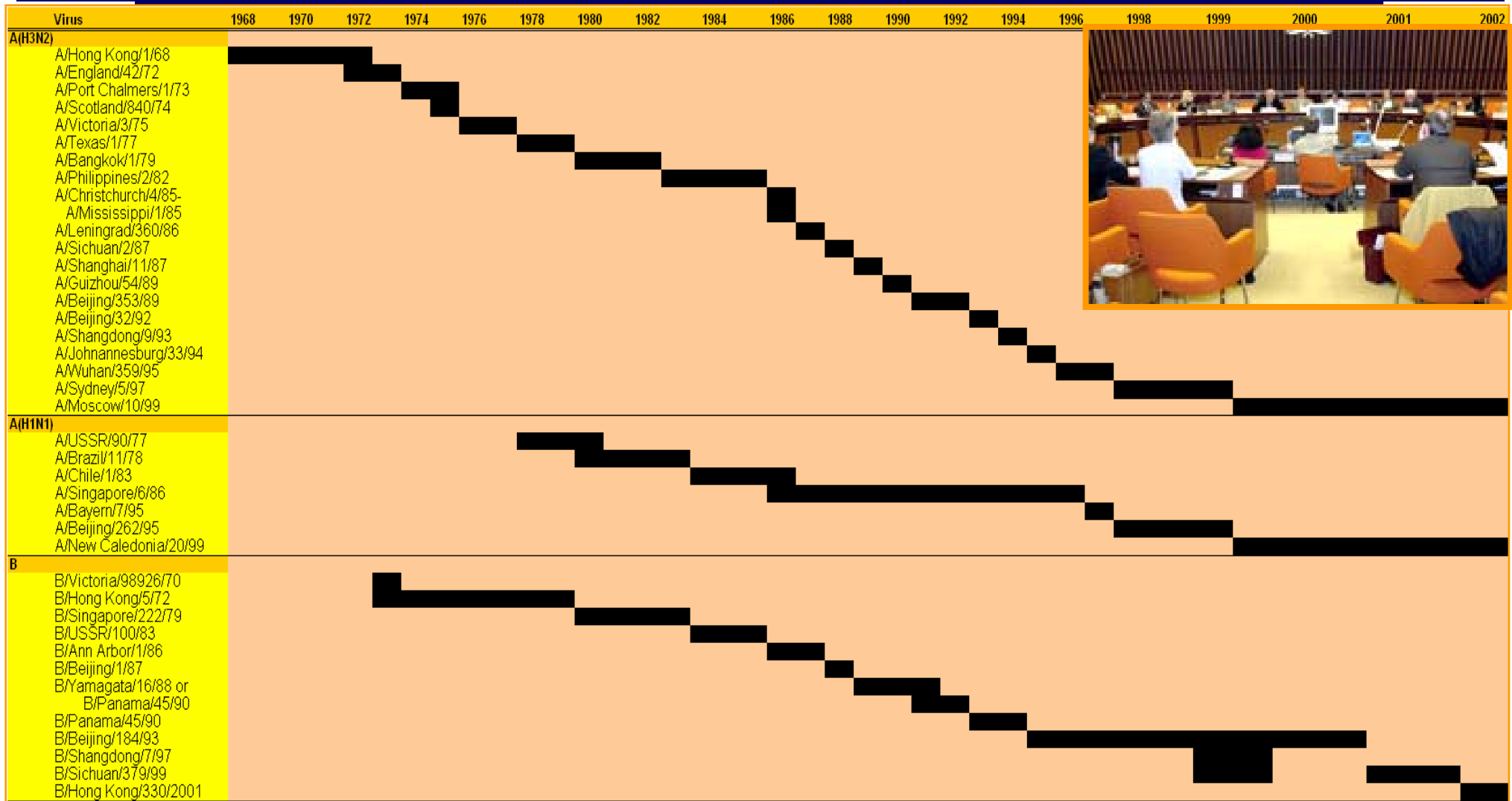
WHO influenza surveillance network: collective action to reduce vulnerability to influenza



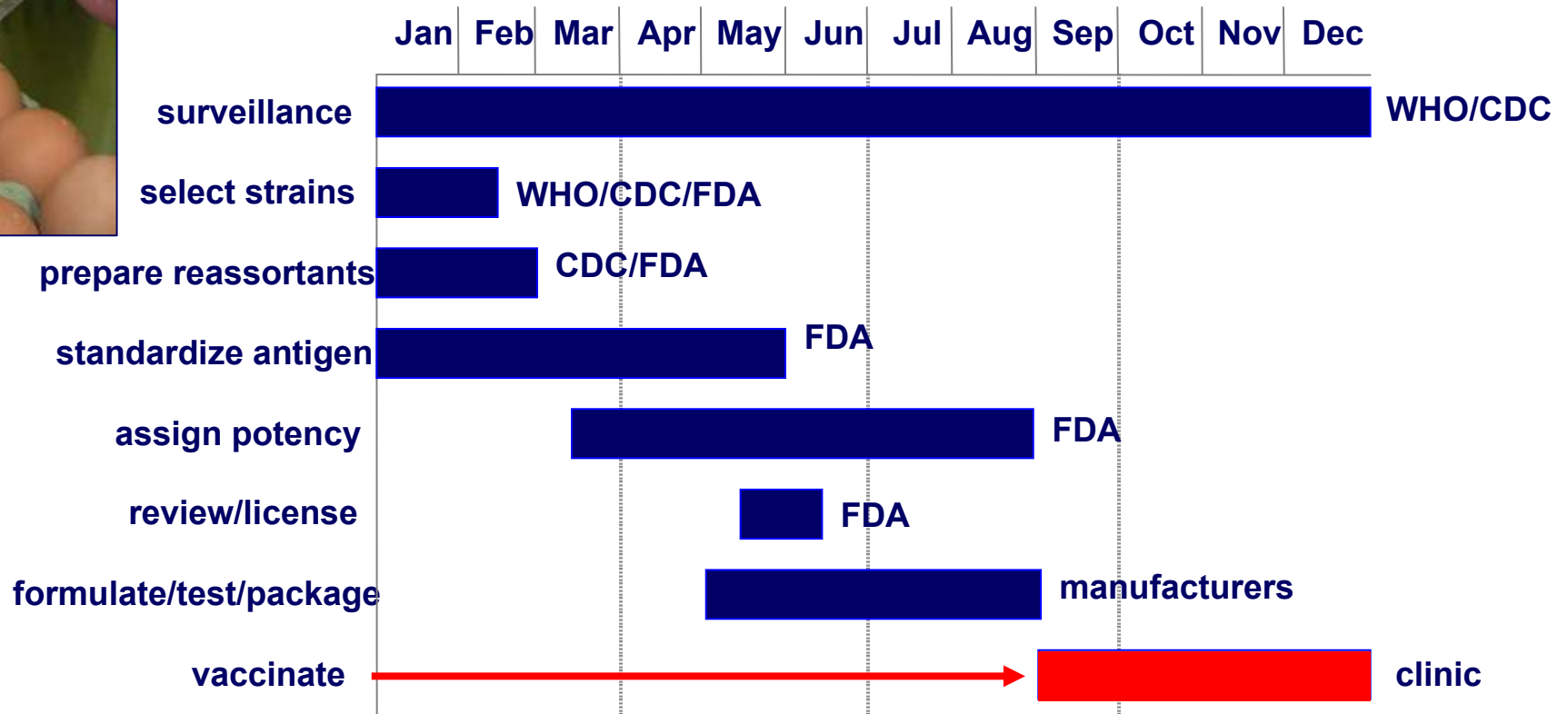
Global surveillance of influenza: influenza virus sharing for over fifty years

- **Over 10 000 influenza viruses isolated each year**
- **Results in essential public health information & actions**
 - Viruses tested for genetic & antigenic properties
 - Warning of new pandemic virus
 - Predominant & new strains identified
 - Updating of critical diagnostic tests needed worldwide
 - Vaccine strains identified & developed for vaccine
- **Vaccine viruses provided free to any qualified vaccine producer to foster maximum number of worldwide producers & supply**

Antigenic shift and drift of the influenza virus: vaccine composition, 1968–2007



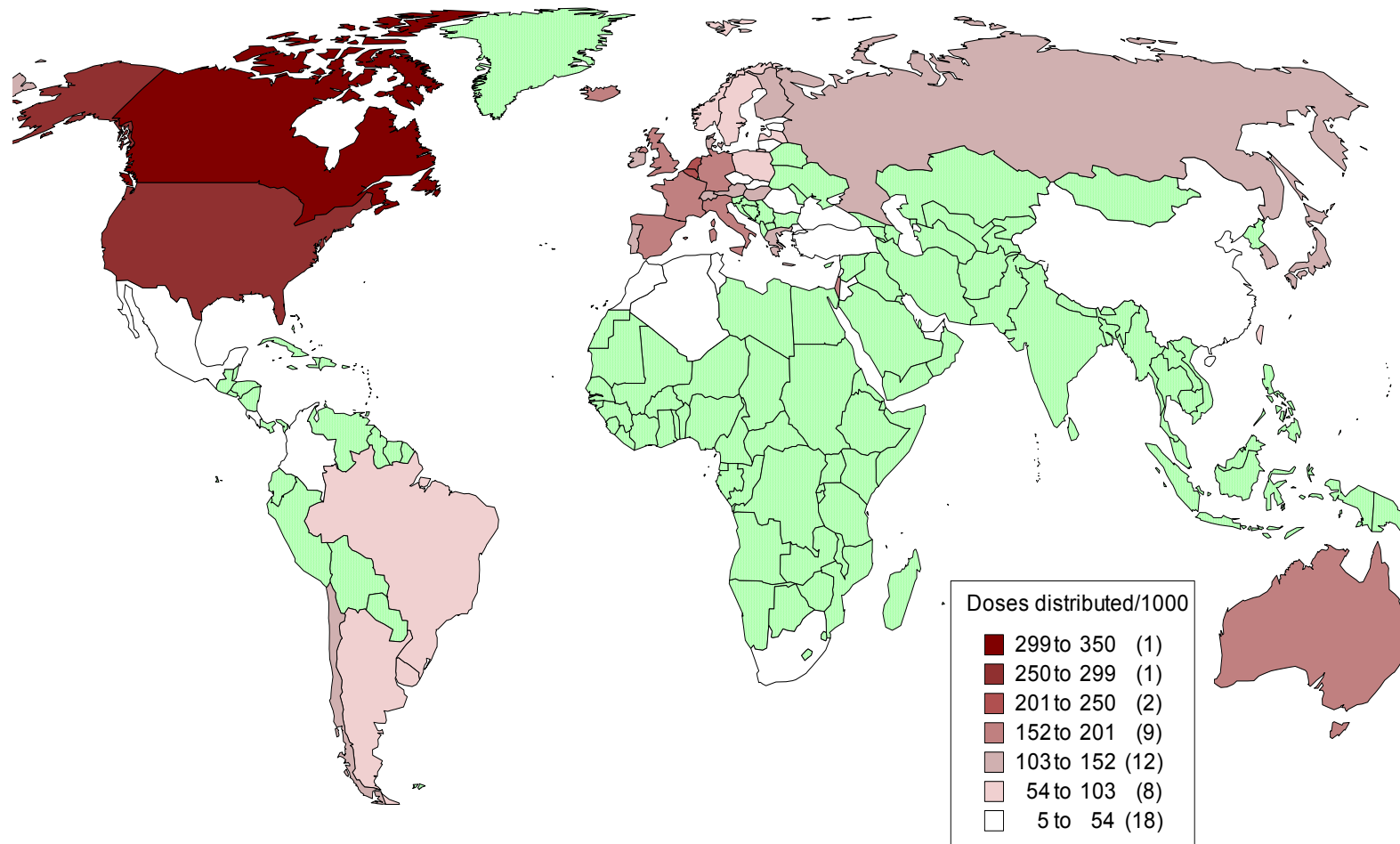
Six months required for seasonal influenza vaccine production



Soucre: CDC

Seasonal influenza vaccine production capacity severely limited

95% of annual global production (~ 350 million doses) marketed by 12 companies



Human influenza vaccine production capacity, 2006 estimate

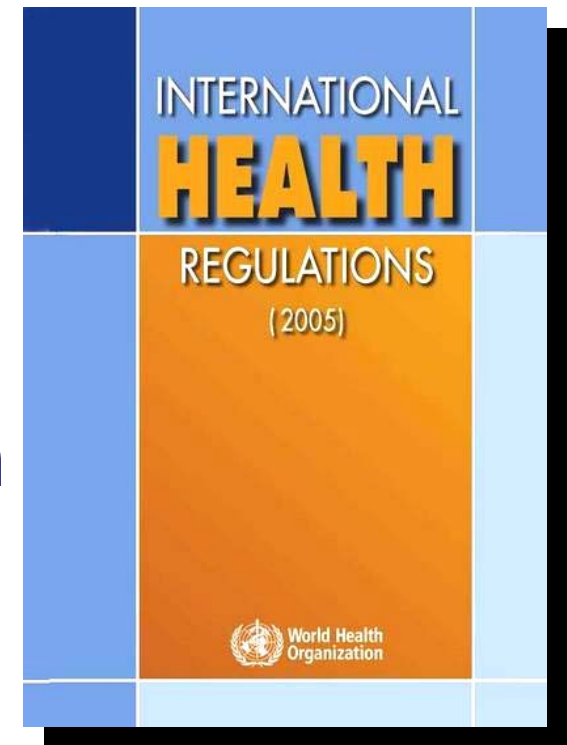
Region	Influenza Human Vaccine production in million doses
Latin America	19
North America	73
Europe	223
Asia	32
Africa	0
Total	347

Influenza vaccine production: Situation and Challenges

Short-term potential availability of influenza vaccine (per year)	
Current estimated production capacity estimate	350 million trivalent doses
Potential capacity if manufacturers maximize output (3 shifts / 24 hours)	500 million doses trivalent dose
Planned expansion in the next 2-3 years	Another 280 million trivalent doses (TOTAL of 780 million trivalent doses)
Expected maximum capacity in monovalent doses by 2009	2340 million monovalent doses

Voluntary application of the International Health Regulations (2005)

- World Health Assembly Resolution, May 2006
- Applied only to avian influenza
- Framework to manage risk assessment and reduction
- Strengthens collective global public health
- Decreases collective vulnerability



Priority issues in early implementation of IHR (2005)

- **Increase vaccine production capacity**
- **Implement influenza virus best sharing practices**
 - **Based on seasonal influenza virus sharing**
 - **Adapted to H5N1 & other new influenza viruses**
- **Review, develop & update policies on H5N1 vaccine use**

Global Action Plan: Main Strategies to increase influenza vaccine production

- **Increase use of seasonal influenza vaccine**
 - Protect population from seasonal flu
 - Develop robust economic foundation
- **Increase overall production capacity for pandemic vaccines & create capacity in new countries**
- **Research and development of new technologies**
 - Better, cheaper, more cross-protective

Activities completed: Global Action Plan

- 11 proposals received & reviewed from developing countries
- Initial grants (up to US \$2.5 million each) approved to 6 manufacturers:
 - Brazil
 - India
 - Indonesia
 - Mexico
 - Thailand
 - Viet Nam
- 87 low / middle income countries want financial support for pandemic vaccine

Best Practices for sharing of influenza viruses: extending to novel viruses

- For both seasonal and novel influenza viruses
- Outlines basic & equitable, principles, responsibilities and benefits of global influenza surveillance
 - 7 best practices
 - 10 operational recommendations
- Covers:
 - National virus and sequence sharing with WHO
 - Provision of candidate vaccine strains to qualified producers
 - Protection of research interests of participating Member States
 - Emphasizes surveillance for public health and not profit making

Differing perspectives & priorities for novel influenza virus sharing

- **Some scientific research groups**
 - Full availability of viruses & sequence data to all for research
- **Some virus originating countries**
 - Clearer operational procedures
 - More control over analyses / research
 - Linkage to receipt of some types of benefits
- **International community and WHO**
 - Continued effective global public health risk assessment and risk response activities under IHR (2005)

Clear Messages from Jakarta Meetings on sharing in the benefits of virus sharing

- **Developing country expectations**
 - Strengthening core laboratory capacities so that they can qualify for WHO designation and ensure
 - Greater access to critical resources such as H5N1 and other potential pandemic influenza vaccines
 - More transparent virus handling procedures
- **International community priorities (both industrialized and developing countries)**
 - No compromise in effective and functional global alert and response capabilities

Follow up to Jakarta meeting

- **Maintain best practices**
- **Strengthen operational procedures**
- **Strengthen WHO Collaborating Centres terms of reference**
- **Identify short term mechanisms to make H5N1 and pandemic vaccines available to complement longer term plans (GAP)**

SAGE Review of use of H5N1 vaccines

- **18 April 2007**
- **Potential H5N1 vaccine uses**
 - Pre-pandemic H5 priming
 - Rapid containment activity in early phase 4 event
 - Essential workers in event of H5N1 pandemic
- **Obtain guidance on the value of H5N1 stockpiling as means of supplementing GAP in short term**

SAGE Recommendations: review of current knowledge

- **Sufficient evidence for WHO to create a stockpile H5N1 influenza vaccine for countries without influenza vaccine production capacity or ability to purchase stockpiles of H5N1 vaccines**
- **Establish mechanisms for ensuring access to pandemic vaccine, should a pandemic be declared by the Director General, for distribution to developing countries without influenza vaccine production capacity or resources to purchase such vaccines.**

25 April Meeting

- **Objective:**
 - Investigate feasibility of establishing WHO stockpile of H5N1 vaccine
 - Investigate the feasibility of a mechanism to ensure better access to pandemic vaccines in developing countries in the event of an influenza pandemic