

Pandemic A(H1N1) influenza vaccination in China

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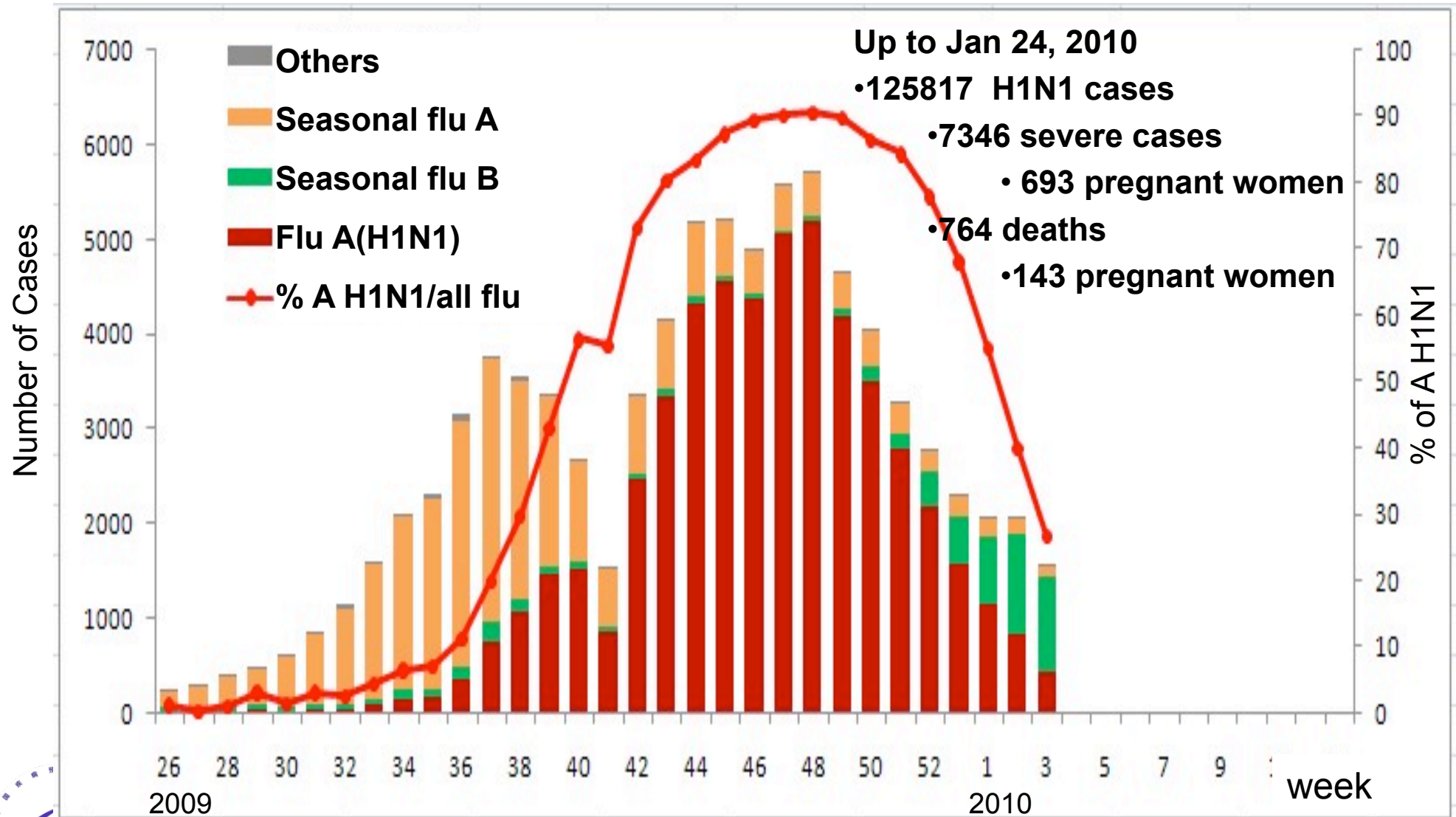


Outline

- Epidemic
- Clinical trials
- Quality control and vaccine supply
- Public vaccination
- Conclusions and recommendations



Pandemic A(H1N1) influenza in ILI Surveillance



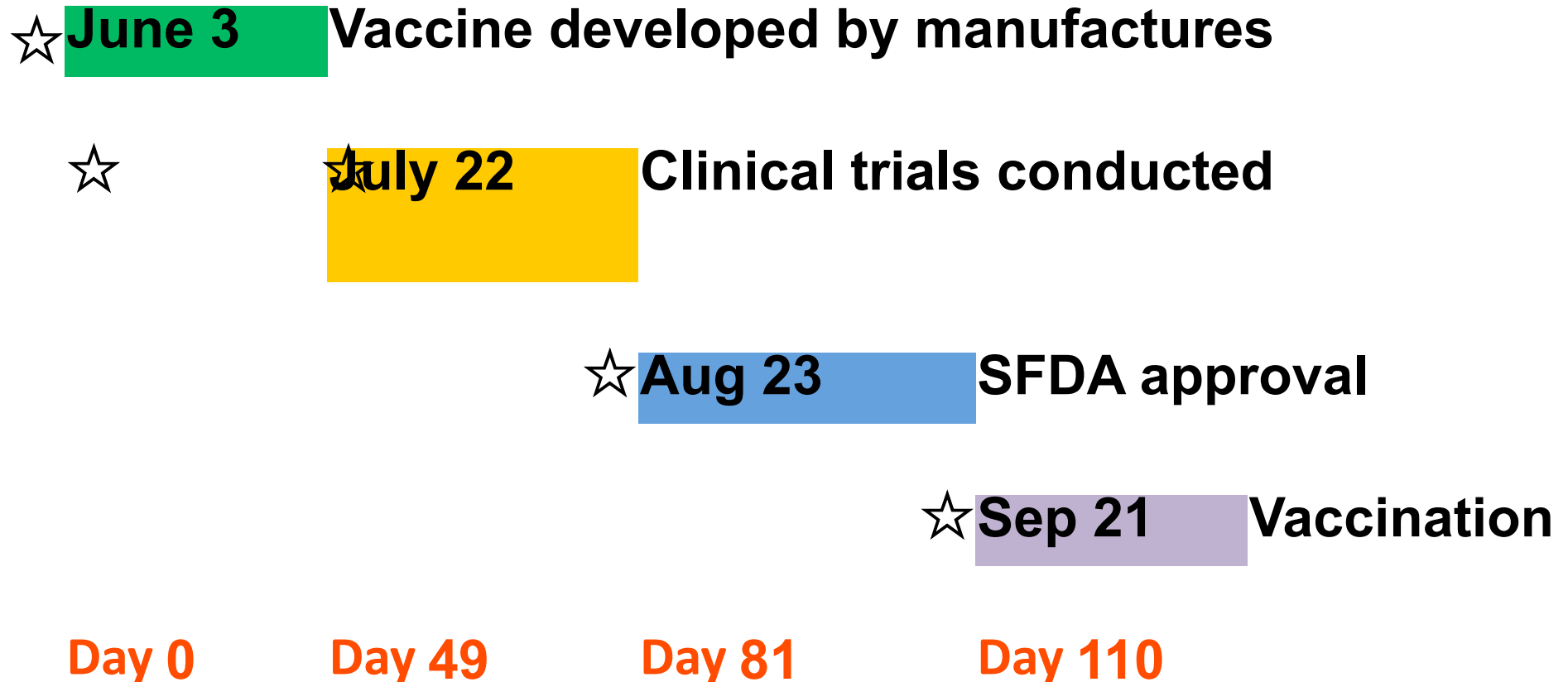
*Data source :National Notifiable Diseases Reporting System (NNDRS)
& Influenza surveillance system

Vaccine clinical trials

China CDC oversight in the consortium of clinical trials



Timeline of vaccine development



Results of clinical trials

- **Multicentre, double-blinded, randomized, placebo-controlled**
 - Targeting those aged > 3 years.
 - 12 691 volunteers
- **Safety in all vaccine formulations**
 - Well tolerated without immediate serious adverse events.
- **Effective among both 15µg and 30µg groups using split vaccine without adjuvant.**
 - Seroconversion and protective rates were > 85%
- **One dose of 15µg recommended.**

1. Xiaofeng Liang et. Safety and immunogenicity of 2009 pandemic influenza A(H1N1) vaccines in China: a multicentre, double-blind, randomized, placebo-controlled trial. *The Lancet*, 2009
2. Fengcai Zhu et. A Novel Influenza A (H1N1) Vaccine in Various Age Groups. *The New England Journal of Medicine*, 2009;361



Quality control and vaccine supply



Quality indicators of flu A H1N1 vaccine in China compared to WHO standards

Indicator	WHO	China	Chinese Company
HA ($\mu\text{g/ml}$)	24~36	24~36	24~36
Total Protein ($\mu\text{g/ml}$)	≤ 600	≤ 400	≤ 200
Endotoxin (ng/ml)		≤ 20	≤ 20
Egg Albumin (ng/ml)	≤ 1000	≤ 500	≤ 360



Source: China SDFA

Current status of flu A H1N1 vaccine regulation in China

- Lot release management
- Supervision of production process
- Quality control of raw materials, intermediate product
- Post-marketing surveillance
- Up to 29 Jan 2010
 - 10 Chinese manufactures produce H1N1 vaccine.
 - Manufacturers have submitted applications for release of 738 lots (138.7 million doses)
 - 575 lots (108.1 million doses) released by SFDA



Vaccination



Immunization strategy

Principles of immunization

- Informed consent; voluntary; free of charge
- Government provided vaccine and operational costs

- ★ **15 Sept 2009** High priority populations aged ≥ 3 years:
 1. Public servants in key positions (e.g., health staff)
 2. Students and teachers
 3. Chronic disease patients

- ★ **11 Dec 2009** Pregnant women

- ★ **7 Jan 2010** 6~35 months children
(2 dose schedule, 7.5ug/dose)



Flu A H1N1 vaccination

- High level official received the vaccine.
 - **To dispel public concerns regarding safety**
- High level supervision during mass vaccination
 - **To ensure vaccination is well carried out at local level**
- Risk communication
 - **to share information with media**
 - **Information released through MOH website**
- The first time influenza vaccine included in China's public program
 - **Free of charge and carefully monitored**
- Cooperation with international community
 - **Share information with WHO through regular meeting**



Minister Chen received the vaccine during clinical trials

Three information surveillance systems for flu A H1N1 established

- Vaccine Supply Information Management System
 - 93.7 million doses received by provinces
 - 83.1 million doses distributed to local CDC
- Case-based Vaccine Immunization Information Management System
 - 73.7 million vaccinated, 5% of total population.
 - 41.9 million (60%) individual information computerized
 - 56% students, 11% teachers, 10% doctors, 8% public servants
 - 28, 523 pregnant women, 363 children aged < 3 years
- Case-based AEFI Surveillance System
 - Reports by clinics or manufacturers
 - Surveillance system managed by CDCs
 - Investigations and diagnoses by AEFI expert teams



Data as of 29 Jan 2010

AEFI surveillance

7026 suspected AEFI reported (10/100 000)

- **Common reactions: 4973 (71%)**
- **Rare reactions: 843 (12%) , 1.2/100,000**
 - 614 (73%) hypersensitivity rashes
 - 74 serious reactions:
 - 39 anaphylactic shock, 25 laryngeal edema, 2 ADEM ,1 polyneuritis, 1 encephalopathy
 - 6 Guillain-Barre Syndrome (similar to baseline incidence)
- **Coincidental events: 639 (9%)**
 - 2 polyneuritis, 3 meningitis, 3 viral encephalitis
 - 7 deaths due to underlying disease, discarded as AEFI by autopsy.
- **Psychological reactions : 370 (5%)**
- **Under investigation :201, (2.9%)**
 - Including 3 polyneuritis, 1 meningitis



The data as of 29 Jan 2010

Challenges

- Flu A H1N1 cases are decreasing
 - Decreased willingness to be vaccinated
- 70 million doses not yet delivered
 - However, population immunity remains limited
 - Mass migration during Chinese spring festival may result in further virus transmission.
- Some priority groups are difficult to identify and vaccinate
 - Chronic disease patients



Conclusions and Recommendations

- Safe and effective flu A H1N1 vaccines have been produced and vaccination activities well-conducted
- All aspects of vaccine use, including AEFI, were documented
- Risk communication and public education need to be conducted more widely.
- H1N1 vaccine should be considered for global use in 2010.
 - Flu A H1N1 antigen as one of the components in seasonal vaccine.
- Cooperation between countries through WHO should continue to be strengthened



Thanks

