



Influenza at the interface between animals and humans

**Coordination at EU level by the European
Commission**

Brussels 30 October 2009

Interface?



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■ 14 April

■ 15 April

■ 24 April

■ 27 April

■ 11 June

■ 11 June

First death reported in
Mexico

First cases USA

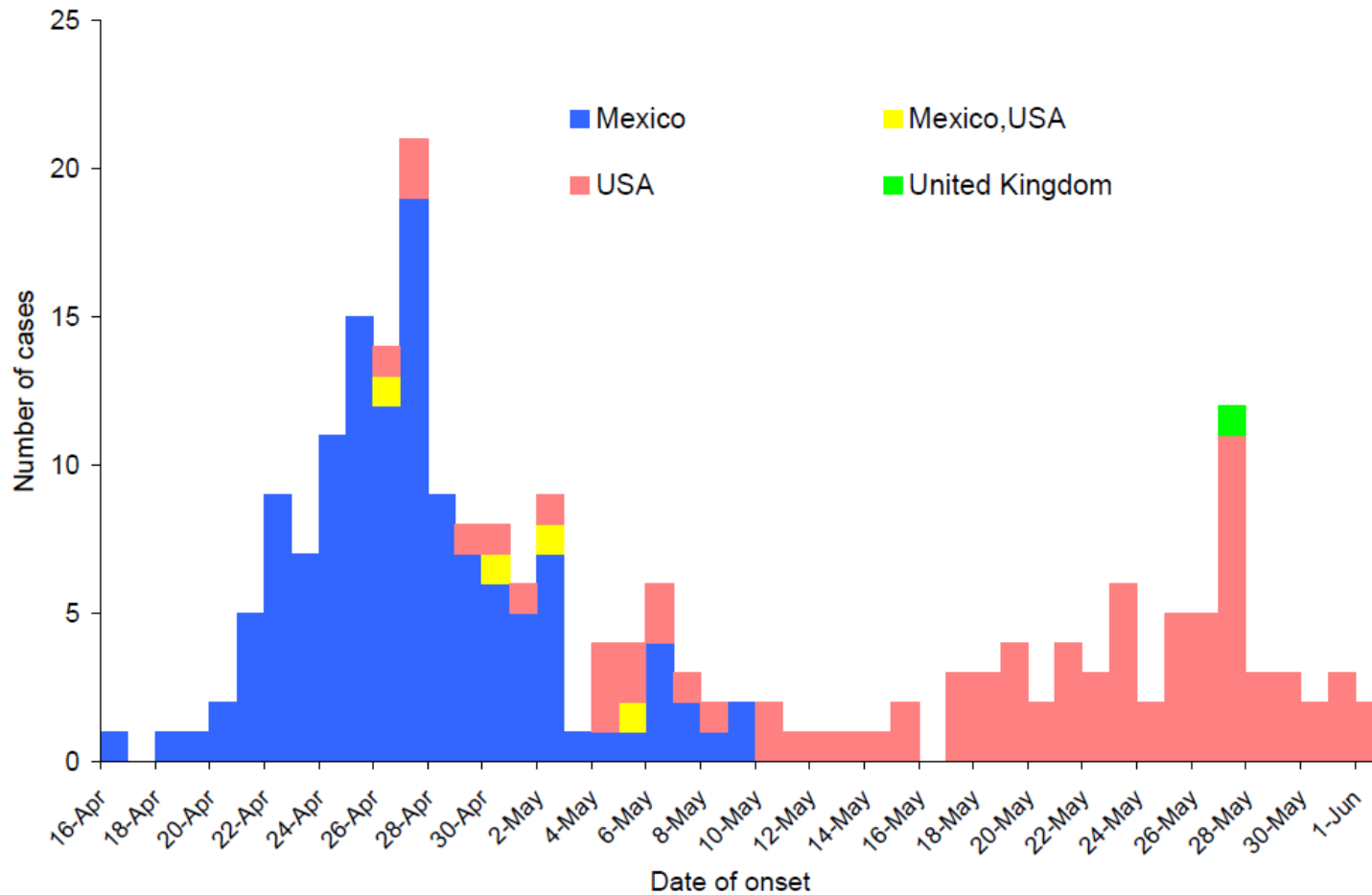
Outbreak in USA

First case EU (in ES)

>70 countries report
transmission

WHO declares level 6

H1N1 - Early Reports



- Treaty (Art. 152) obliges Member states to coordinate their policies in close liaison with the Commission
- EU legislation on communicable disease obliges Member states to inform each other of cross border outbreaks, and of measures they intend to take
- IHR obliges Member states to inform WHO of outbreaks which constitute a public health emergency



- Since end April 2009, need for coordination of measures because of fast moving public health threat in several member states and internationally
- Regular audio conferences of EU Health Security Committee and of the Early Warning and Response System
- Discussion of current problems of risk management
- Identification of issues for which scientific risk assessment was needed

- Case definition for reporting at EU level
- Travel advice
- Use of antivirals
- Development of a vaccine strategy
- Surveillance and reporting
- Communication to the public

- The main problems encountered were the number of issues to be discussed, and the short time of each meeting
- This imposed a short agenda and rapid rhythm of work for Commission, Member States and scientific risk assessment bodies

- Extraordinary Health Council 30 April
- Regular Health Council 9 June
- Informal Health Council 6-7 July
- Extraordinary Health Council 12 October
- Friends of the Presidency Group

- Commission asked to take further
 - procurement processes for vaccines including resale
 - risk-benefit assessment and marketing authorisation
 - Pharmaco-vigilance and surveillance
 - communication through communicators network of the HSC
 - national planning assumptions
 - guidance / principles / toolkits for business continuity planning at EU level
 - overview of provisions and capacities for managing of cross-border, inter-sectorial and trans-boundary disruptions
 - update Community pandemic influenza preparedness and response plan

- Commission Communication
- 5 Staff Working Documents:
 - Vaccination strategies
 - Joint procurement of vaccines
 - Approval process of vaccines and antivirals
 - Support for third countries
 - Communication strategy to the media and to the public

Sets out the main issues related to vaccination strategies with a pandemic vaccine against the Pandemic (H1N1) 2009 virus:

- ❖ **likelihood of limited amounts of vaccines initially**
- ❖ **challenges to healthcare systems if large scale vaccination campaign is needed**
- ❖ **need for a carefully planned vaccination strategy**
- ❖ **need for an effective communication to the public**

- Preparatory measures for an accelerated assessment of applications for marketing authorizations of Pandemic vaccines
- Various anti-viral medicines received approval for marketing in the past and are available for treatment of pandemic influenza
- Paper provides an overview on the key steps and issues related to the regulatory process for vaccines in the shortest time possible
- Need to ensure appropriate pharmaco-vigilance mechanisms at the EU level
- Ensure that the European market authorisations are closely coordinated with U.S regulatory approval

- Pursue joint procurement of vaccine against Pandemic (H1N1) 2009 virus for those Member States with no current orders in place
- Set up a mechanism to help joint procurement of vaccines for interested Member States.
- Proposes also options for helping the Member States in negotiation process
- Examines sale between Member States of excess supplies of vaccines

Today

- Vaccination campaigns have begun
- Logistic problems with supply and delivery (GP's, Vaccine Stations, Employers, Hospitals)
- Reinforced post marketing surveillance; some cases of incidents noted
- One dose or two? EMEA maintains 2 doses for now
- Widespread infections in EU and in North America, with declaration last week of health emergency in USA

■ Global Health Security Initiative (G7+Mexico)

- Ministerial meetings in Cancun on 10-11 June and in Brussels on 11 September; Next ministerial meeting in London December 2009
- Decided to merge the issues on vaccine policy being worked on in EU and by USA
- Sharing of information on vaccine development and strategy

- EU added value of existing networks such as Health Security Committee and EWRS proven in action
- Role of agencies in risk assessment (ECDC/EFSA/EMEA) also established
- Satisfactory sharing of information (with some exceptions)
- Generally short lead time for response
- Good coordination between animal health and human health sides

THANK YOU FOR YOUR ATTENTION !!!

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more confident citizens



Public Health



Food safety



Consumer Affairs

Public Health Web site:

http://ec.europa.eu/dgs/health_consumer/publichealth_en.htm

•EU Health portal

http://ec.europa.eu/health-eu/index_en.htm

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