

# Influenza A(H1N1)

19 May 2009 update

Meeting with Vaccine Manufacturers CEOs



World Health  
Organization

# Outline of presentation

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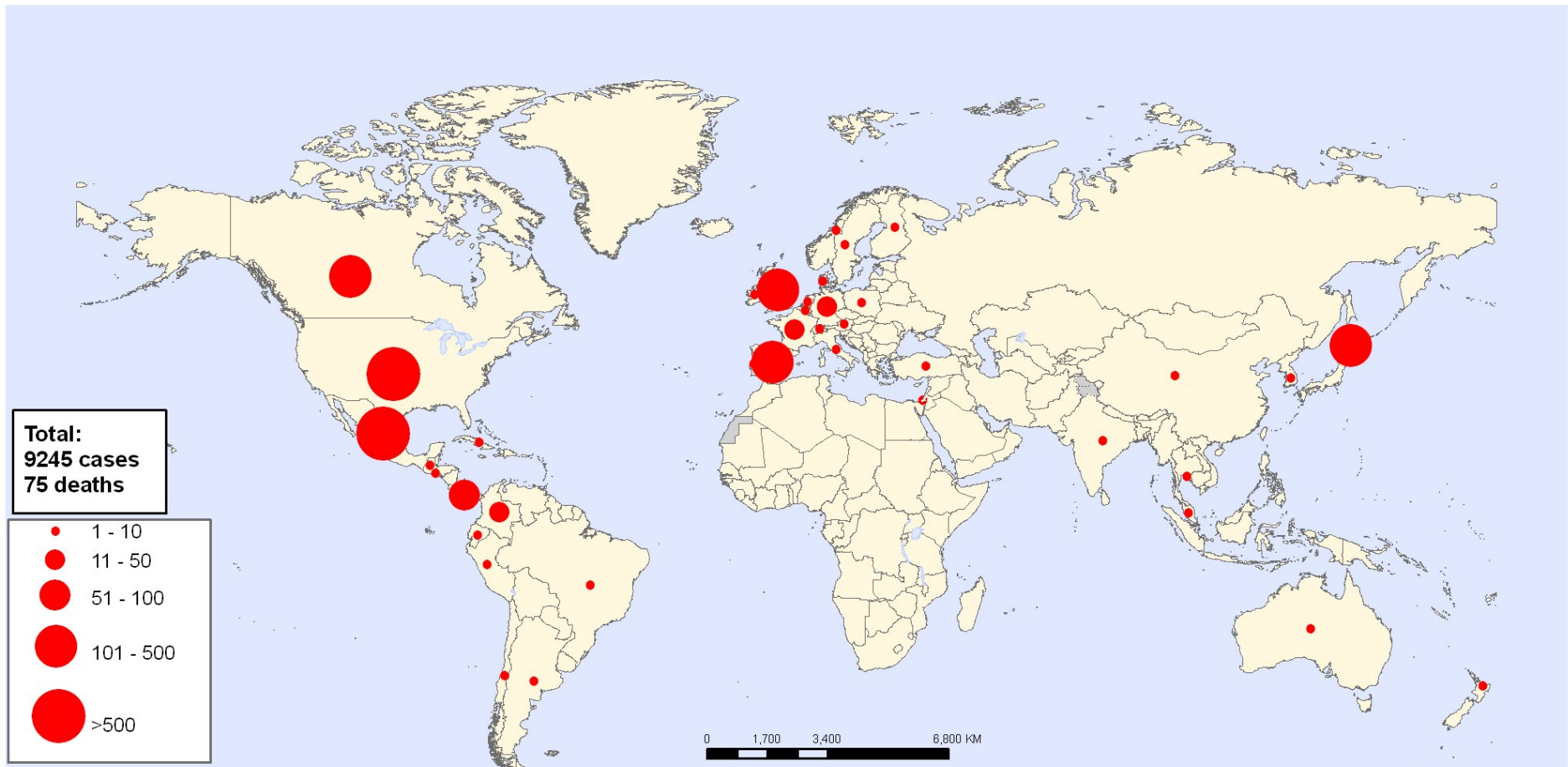
- Epidemiological situation
- Assessment of vaccine production capacity – results of the new WHO survey
- SAGE recommendations on vaccine production



# Epidemiological situation

New Influenza A (H1N1)  
Cumulative number of Laboratory confirmed cases as reported to WHO.

Status as of 18 May 2009  
16:00 GMT



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Map produced: 18 May 2009 05:45 GMT

Data Source: World Health Organization  
Map Production: Public Health Information  
and Geographic Information Systems (GIS)  
World Health Organization



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# Epidemiological situation -2

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19 May 2009: **Phase 5 of pandemic alert**

**Secondary attack rate** estimated between **22 and 33%**  
**More contagious** than seasonal influenza

Novel A(H1N1) is **susceptible to oseltamivir and zanamivir,**  
**resistant to amantadanes**

**Different assessment of severity** in Mexico and in the USA

**Case fatality ratio: in Mexico : 1.5 % ; in USA: less than 0.1%.**  
Similar to seasonal influenza?

**The main affected age groups** in Mexico and in the USA are  
**between 5 to 29 years old**



# Assessment of vaccine production capacity

## Methodology

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Questionnaire sent to **32 manufacturers** on 7 May 2009.

**24** manufacturers who responded to the questionnaire are planning to produce novel H1N1 Influenza vaccine. All responses were collected and analyzed on 12 May 2009

1) Assessment of the **status of seasonal trivalent influenza vaccine production** as of: 31<sup>st</sup> of May 2009, 30<sup>th</sup> of June 2009, and 31<sup>st</sup> of July 2009

2) **Projections of production for the novel A(H1N1) influenza vaccine** considering that (i) yield of production will be similar to that for seasonal vaccine, (ii) most dose-sparing formulation will be selected, and (iii) production at full capacity



# Seasonal trivalent vaccine production capacity

Manufacturers	Total annual capacity (10 <sup>6</sup> doses)	2008 Northern hemisphere production (10 <sup>6</sup> doses)	2009 Southern hemisphere production (10 <sup>6</sup> doses)	2009 planned Northern hemisphere production (10 <sup>6</sup> doses)
<b>Companies A</b>	656.7	368.6	107.5	387.7
<b>Companies B</b>	195.3	92.5	5.0	96.0
<b>All</b>	852.0	461.1	112.5	483.7

**Companies A:** capacity to produce at least 2.10<sup>6</sup> doses of novel H1N1 vaccine per week

**Companies B:** capacity to produce less than 2.10<sup>6</sup> doses of novel H1N1 vaccine per week



# 2009 Northern hemisphere vaccine production status

	31 <sup>st</sup> May 2009			30 <sup>th</sup> June 2009			31 <sup>st</sup> July 2009		
	H1N1	H3N2	B	H1N1	H3N2	B	H1N1	H3N2	B
<b>Companies A</b>	67.4%	81.0%	38.1%	78.9%	84.1%	76.0%	92.4%	94.1%	92.3%
<b>Companies B</b>	55.5%	36.9%	35.0%	57.0%	60.8%	59.6%	75.8%	76.8%	83.2%
<b>All manufacturers</b>	65.1%	72.3%	37.5%	74.5%	79.5%	72.7%	89.1%	90.6%	90.5%
<i>Number of doses out of 483.7 10<sup>6</sup> initially planned (10<sup>6</sup>)</i>	<i>314.8</i>	<i>349.5</i>	<i>181.26</i>	<i>360.6</i>	<i>384.4</i>	<i>351.8</i>	<i>431.1</i>	<i>438.4</i>	<i>437.8</i>



# Novel H1N1 vaccine production: projections

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	Total	Whole	Split	Subunit	LAIV	Other
Vaccine	24	10	12	4	2	1
Adjuvanted	11	6	2	3	-	-



# Novel H1N1 vaccine production: projections

	All manufacturers	Companies A	Companies B
Weekly output ( $10^6$ doses)	94.3	81.0	13.3
6 months output ( $10^6$ doses)	2,452.2	2,106.0	346.2
Yearly output ( $10^6$ doses)	4,904.4	4,212.0	692.4
Manufacturers with advanced purchase agreements *	≥ 15 / 24	7 / 7	≥ 8/17
<i>Number of doses (<math>10^6</math>) reserved *</i>	≥ 610.5	≥ 500.5	≥ 110.0
Manufacturers willing to reserve 10% of doses for UN procurement	6 / 24	0 / 7	6 / 17
<i>Guaranteed doses (<math>10^6</math>) / year</i>	27.6	0	27.6
Manufacturers still undecided about potential contribution to UN	8 / 24	6 / 7	2 / 17
<i>Potential addit. doses (<math>10^6</math>) / year</i>	411.8	407.7	4.1

\* = Estimation by WHO secretariat



# May 19 SAGE recommendations on influenza A(H1N1) vaccines

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The following considerations underpinned the recommendations:

- . need for any recommendation to **balance both risks and benefits**
- . current **uncertainty about the severity** of A(H1N1) influenza illness
- . **readiness of candidate vaccine viruses** and reagents for large-scale vaccine production
- . **current status of production of seasonal vaccine for the Northern Hemisphere** and risks associated with premature cessation of seasonal vaccine production



# May 19 SAGE recommendations on influenza A(H1N1) vaccines

1. WHO should recommend at the earliest possible time **which vaccine viruses** should be used for vaccine development.
2. **Essential reagents** for calibration of antigenic content should be prepared as a priority.
3. WHO should help to assess the **growth property of vaccine viruses** and identify those with the best growth potential (to maximize the vaccine output).
4. Manufacturers are urged to **start preparing for a future recommendation on commercial-scale production**, through production of clinical trial batches and accelerated initiation of clinical trials of A(H1N1) vaccines.
5. These activities should **not interfere** with the current production of Northern hemisphere seasonal vaccine.



# May 19 SAGE recommendations on influenza A(H1N1) vaccines

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## Additional important comments:

- . An increase to pandemic alert phase 6 does **not** imply automatically triggering a switch from seasonal to A(H1N1) vaccines production.
- . A potential recommendation to start large-scale production of A(H1N1) vaccines is not considered to be a recommendation to start immunizing large population groups.

