Issues and Challenges in Influenza A(H1N1) Pandemic Vaccine

Current guidelines and recommendations

Lessons learnt and future directions

Dr E. David G. McIntosh

MBBS MPH PhD FAFPHM FRACP FRCP&CH FFPM DRCOG DCH Dip Pharm Med

Global Scientific Affairs Senior Expert, Novartis Vaccines

Honorary Clinical Senior Lecturer, Imperial College, London

Introduction

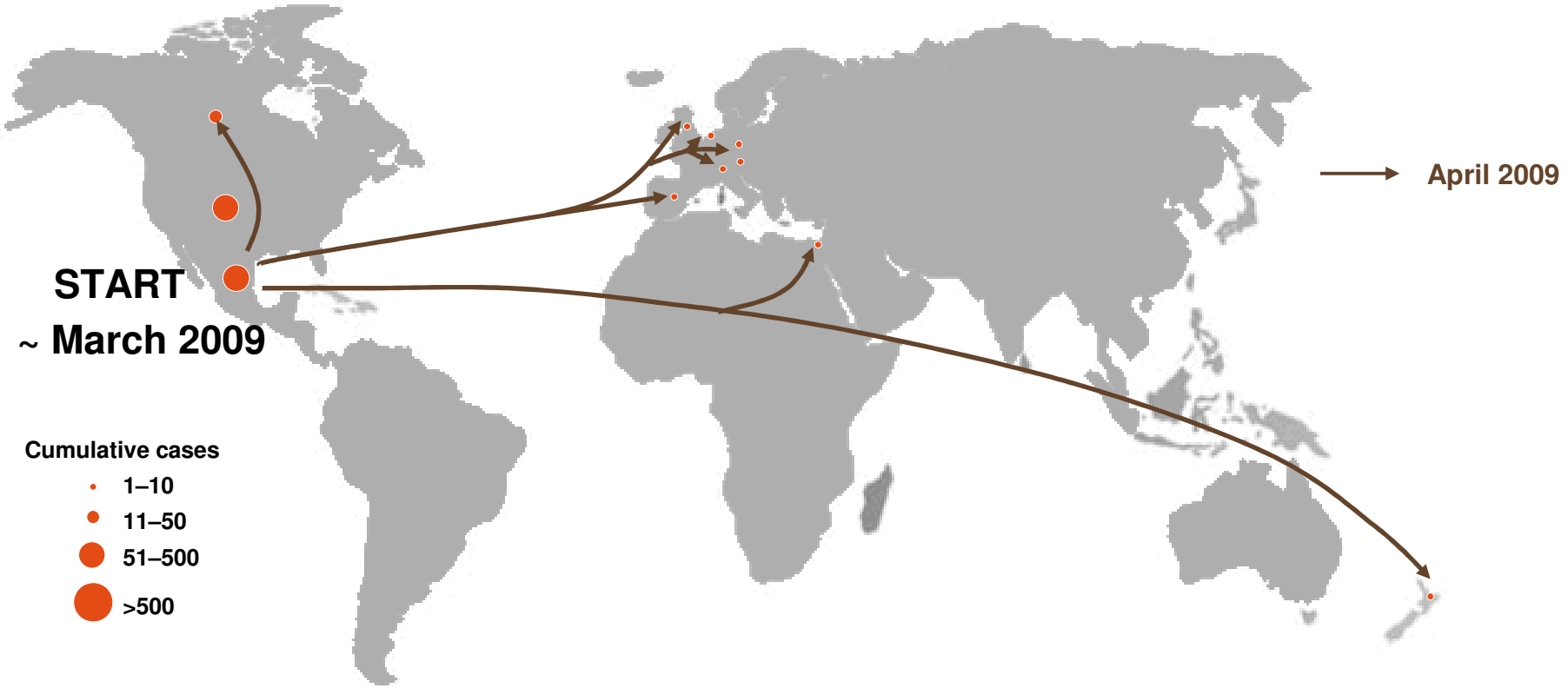
Background to the Influenza A(H1N1) pandemic

- The emergence of avian influenza A(H5N1) followed by the A(H1N1) influenza pandemic has focused the attention of the public and health authorities alike on the potential for prevention using the appropriate vaccines
- Note the importance of paediatric vaccination in interruption of influenza transmission (Esposito and Principi, 2009)
- High rates (78%) of hospitalisation for infants and children under the age of 4 years for non-pandemic influenza A in Finland (Peltola *et al*. 2003)

Esposito S, Principi N. The rational use of influenza vaccines in healthy children and children with underlying conditions. Current Opinion in Infectious Diseases 2009; 22: 244-9.
Peltola V, Ziegler T, Ruuskanen O. Influenza A and B virus infections in children. Clinical Infectious Diseases 2003; 36: 299-305.

Pandemic influenza A(H1N1) rapidly spread worldwide

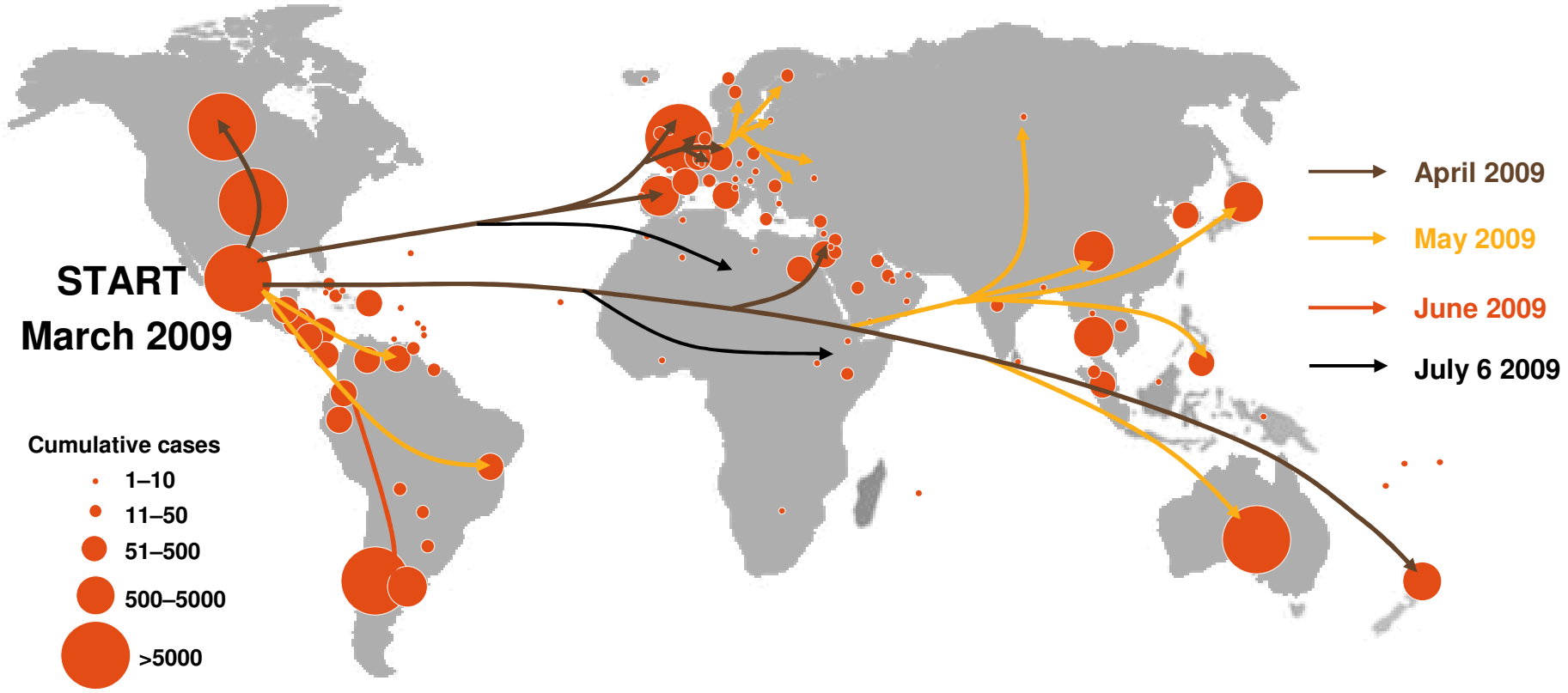
First confirmed cases in the US – mid-April



Pandemic influenza A(H1N1) 2009 first reported by the US and Mexico, April 26
Pandemic Phase 4 declared on April 27 and Phase 5 on April 29
On April 30, total cases 257 and 8 deaths reported by 11 countries

1. WHO, 2009. New influenza A (H1N1), number of laboratory confirmed cases, available at: http://www.who.int/csr/don/h1n120090622_0800.png (accessed 30 April 2009)

More than 180,000 cases & 1800 deaths in 177 (of 192) countries worldwide

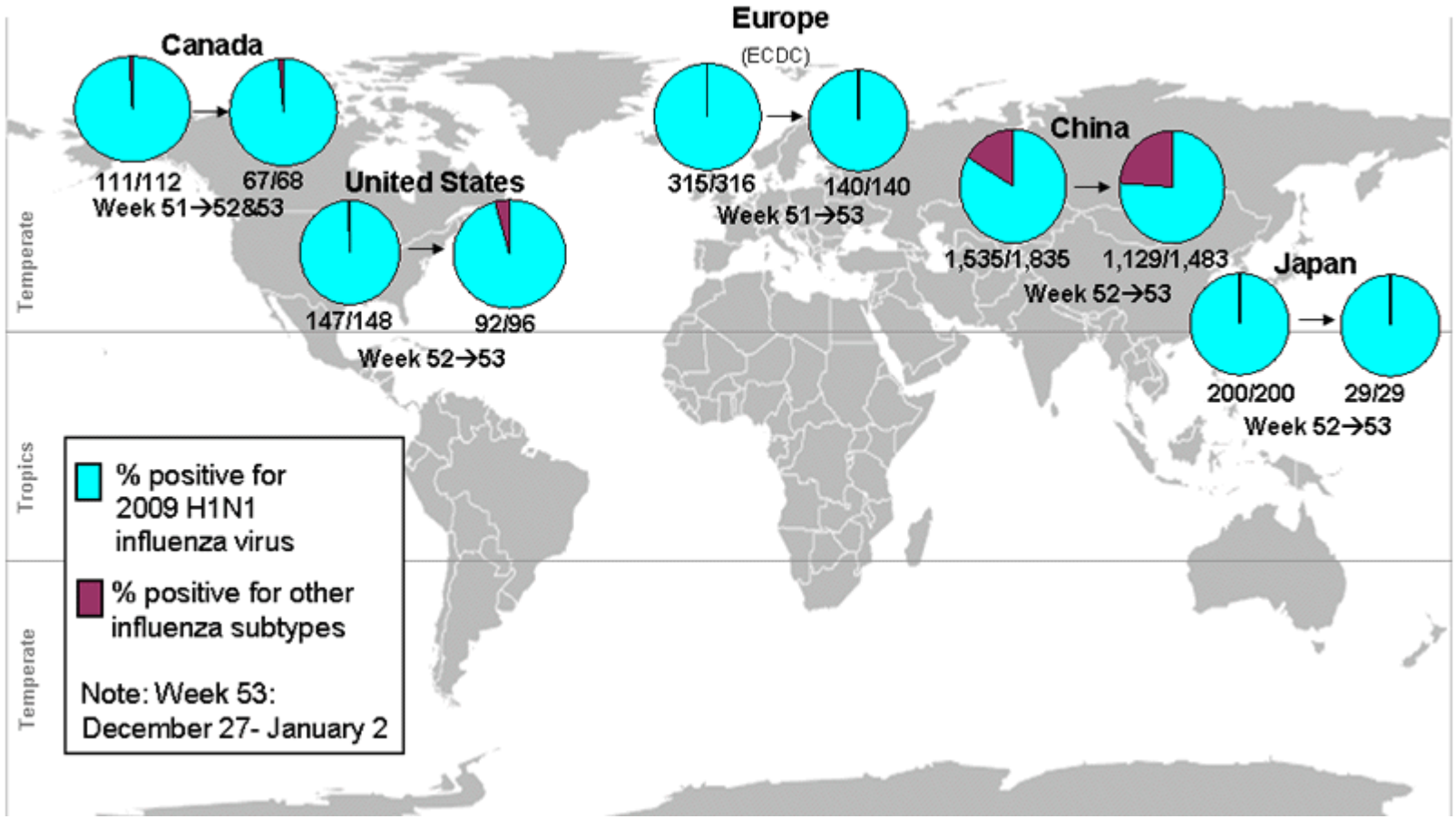


US, Mexico, Canada, UK, Chile and Australia account for ~76% of total cases

* Date of last report for July 2009.

WHO, 2009. Pandemic (H1N1) 2009, situation update,
available at: http://www.who.int/csr/don/2009_07_06/en/index.html (accessed 6 July 2009)

International co-circulation of 2009 Influenza A(H1N1) and seasonal influenza
(As of January 04, 2010; posted January 11, 2010, 11:00 AM ET)



http://www.cdc.gov/h1n1flu/updates/international/map.htm

South-East Asia

Update

WHO

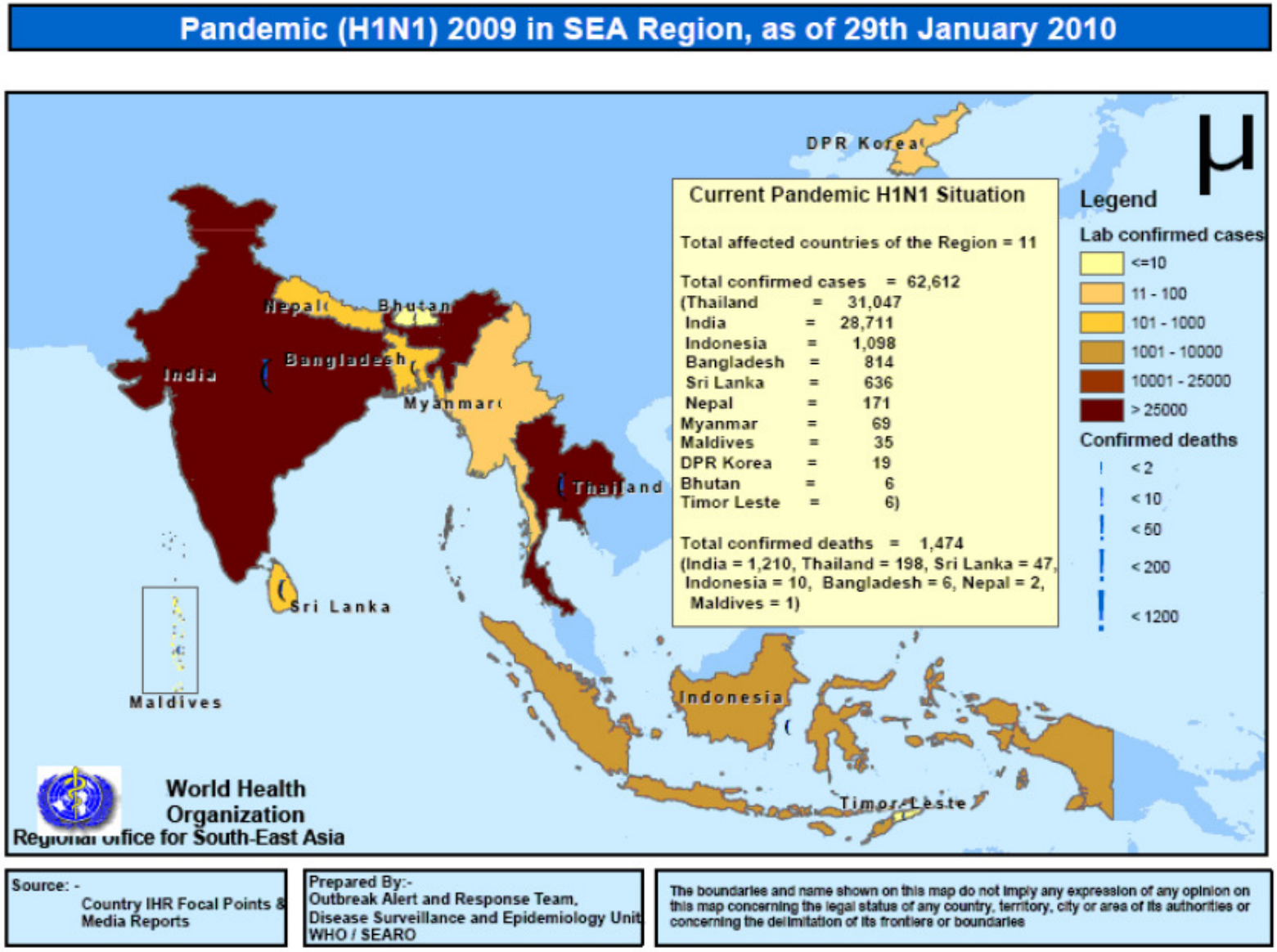
Situation update 29th January 2010

- In southeast Asia, transmission of pandemic influenza virus A(H1N1) persists, but current activity levels are low. In Vietnam, influenza activity has declined substantially since peaking during October and November 2009. In Thailand, focal outbreaks of influenza were reported from a few provinces in northern and central parts of the country, however, overall ILI activity remains low.
  - Latest available statistic for The Philippines from WHO: 3207 cases with 6 deaths as of 30 July 2009

http://www.who.int/csr/don/2010_01_29/en/index.html

Pandemic influenza A(H1N1) South-East Asia WHO

http://www.searo.who.int/en/section10/Section2562.htm



United States and Australia

Mortality, update, vaccination recommendations

Laboratory Confirmed Influenza-Associated Hospitalizations and Deaths from August 30 2009 to January 9, 2010 (USA)

Cases defined by	Hospitalisations	Deaths
Influenza laboratory tests	38,455	1,779

http://www.cdc.gov/h1n1flu/updates/us/#totalcases

U.S. Influenza-associated Paediatric Mortality

Date reported	Lab confirmed 2009 influenza A(H1N1) paediatric deaths	Lab confirmed influenza A subtype unknown paediatric deaths	Lab confirmed seasonal influenza	Total
Jan 3 2010 to Jan 9 2010	6	1	0	7
Since Aug 2009	195	40	1	236
Cumulative since Apr 26 2009	255	43	2	300

http://www.cdc.gov/h1n1flu/updates/us/#totalcases

Neurological complications in children with influenza A(H1N1) virus infection, Dallas, Texas, U.S.A.

	Patient A	Patient B	Patient C	Patient D
Age	17 y	10 y	7 y	11 y
Neurological diagnosis	encephalopathy	seizures, encephalopathy	seizures	encephalopathy
Onset after respiratory sxs	1 day	4 days	2 days	1 day
Max temperature	39.2C	40.0C	38.2C	38.9C
CT scan	No parenchymal abnormality	Single punctate calcification	No intracranial abnormality	No intracranial abnormality
MRI	ND	No parenchymal abnormality		No intracranial abnormality
EEG	ND	Encephalopathy	Localized cerebral dysfunction	Encephalopathy
Antiviral rx	oseltamivir	oseltamivir + rimantadine	oseltamivir + rimantadine	oseltamivir + rimantadine

Brock E, *et al*. MMWR 24 July 2009; vol 58(28): 773-778
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5828a2.htm

Pregnancy is associated with increased risks for hospitalization and death due to influenza A(H1N1) virus infection

US population	Pregnant women
Cases	
5469	34 (0.6% of total cases)
Proportion hospitalized - % [hospitalized/total]	
4.2% [229/5469]	32.4% [11/34]
Fatal cases % [fatal/total]	
0.8% [45/5469]	13% [6/34]

- **Illness similar to non-pregnant women except for greater dyspnoea**
  - **6 developed pneumonia**
- **65% were in 1st or 2nd trimesters:**
  - **2 nonfatal cases gave birth; one to live twins; one miscarried at 9 weeks**
  - **6 fatal cases: 5 live births by Cesarean section; one nonviable 11 wk fetus**

Jamieson DJ et al Lancet 2009; 29 July

Pregnant women had a 5X higher risk of hospitalization for influenza A(H1N1) virus than general population, Australia, 2009

- Early estimates of increased risk for hospitalization of pregnant women were too low (RR 3.2-4.2). This study found RR for hospitalization compared to general population or to women of reproductive age was 5.1-5.2.

Estimated relative risk of the cumulative incidence of hospitalisation, admission to an intensive care unit or death from pandemic H1N1 influenza in pregnant and Indigenous Australians, May-October 2009

Outcome	Number	Population at risk	Rate/100,000	Relative risk	95% confidence interval	Comparator
Hospitalisation, all	4,833	21,373,998	22.6	n.a.	n.a.	Comparison of at-risk population derived from total population
ICU admission, all	650	21,373,998	3.0			
Death, all	186	21,373,998	0.9			
Hospitalisation, pregnant women	278	237,215	117.2	5.2	4.6 to 5.8	Pregnant women versus all non-pregnant
ICU admission, pregnant women	47	237,215	19.8	6.5	4.8 to 8.8	
Death, pregnant women	3	237,215	1.3	1.4	0.4 to 4.5	
Hospitalisation, Indigenous status	803	534,350	150.3	6.6	6.2 to 7.2	Indigenous versus non-Indigenous
ICU admission, Indigenous status	100	534,350	18.7	6.2	5.0 to 7.6	
Death, Indigenous status	24	534,350	4.5	5.2	3.4 to 7.9	

Kelly H, Mercer GN, Cheng AC. Quantifying the risk of pandemic influenza in pregnancy and indigenous people in Australia in 2009. Eurosurveillance 17 Dec. 2009; vol 14(50). http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19441 (accessed 18 Feb 2010)

www.eurosurveillance.org

United States CDC situation update

29th January 2010

- "Flu activity in the United States for the week of January 17 to 23, 2010 remained about the same as during the previous week as reported in FluView. Flu activity is relatively low at this time. Most flu continues to be caused by 2009 H1N1 viruses, with very little seasonal flu spreading so far. Flu activity, caused by either 2009 H1N1 or seasonal flu viruses, may rise and fall, but it is expected to continue for several more months"

http://www.cdc.gov/H1N1FLU/

United States CDC situation update – vaccination

29th January 2010

- "CDC recommends influenza vaccination as the first and most important step in protecting against flu.
- CDC is now encouraging everyone to get vaccinated against 2009 H1N1, including people 65 years and older.
- While less common than with seasonal flu, severe illnesses and deaths from 2009 H1N1 have occurred in every age group, including people 65 and older.
- Vaccination of people with certain health conditions is especially important because they are more likely to get serious flu-related complications. Health complications that increase the risk of being hospitalized from 2009 H1N1 include:
  - Lung disease like asthma or chronic obstructive pulmonary disease (COPD)
  - Diabetes
  - Heart disease
  - Neurological disease
  - Pregnancy"

http://www.cdc.gov/H1N1FLU/

Recommendations for influenza A(H1N1) vaccination in Australia

At-risk groups

- Pregnant women
- Parents and guardians of infants up to 6 months of age
- People with underlying chronic conditions, including:
  - Heart disease
  - Asthma and other lung diseases
  - Cancer
  - Diabetes
  - Kidney disease
  - Neurological disease
  - Other chronic conditions
- People who are severely obese
- Indigenous health workers
- Frontline health workers
- Community care workers

http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf

Panvax

CSL Biotherapies egg-based pandemic influenza vaccine

- Received licence in:
  - USA 15th Sept 2009
  - Australia 19th Sept 2009
  - Singapore 9th Oct 2009

http://www.csl.com.au/s1/cs/auhq/1236380109044/content/1236380109063/content.htm

http://www.h1n1vax.com.au/s1/cs/auvx/1247066989802/content/1247066992399/home.htm

Not licensed in The Philippines

Europe

England, ECDC, pandemic influenza A(H1N1) vaccines

Department of Health, England

Letter from the Chief Medical Officer dated 27th January 2010

Current situation

Though the rates of hospitalisation and admissions to critical care facilities have fallen, substantial numbers of patients are still receiving treatment in this way. Deaths from pandemic H1N1 (2009) influenza continue to occur. The fall in complications from influenza tends to lag behind falls in incidence.

It is now clear that mortality from H1N1 (2009) influenza overall has been lower than in previous pandemics and in some 'flu seasons. However, the disease has disproportionately affected young people, and this is where most complications have occurred, particularly in those with pre-existing chronic illness. For example:

- Deaths from pandemic H1N1 (2009) influenza amongst younger adults have been more than 30 times higher than deaths amongst the same age group in the 2008 'flu season
- Rates of hospitalisation have been particularly high amongst the under fives
- Some people have been so seriously ill that they have required ECMO (Extracorporeal Membrane Oxygenation).

http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_111598.pdf

Department of Health, England

Letter from the Chief Medical Officer dated 27th January 2010

The continuing importance of vaccination

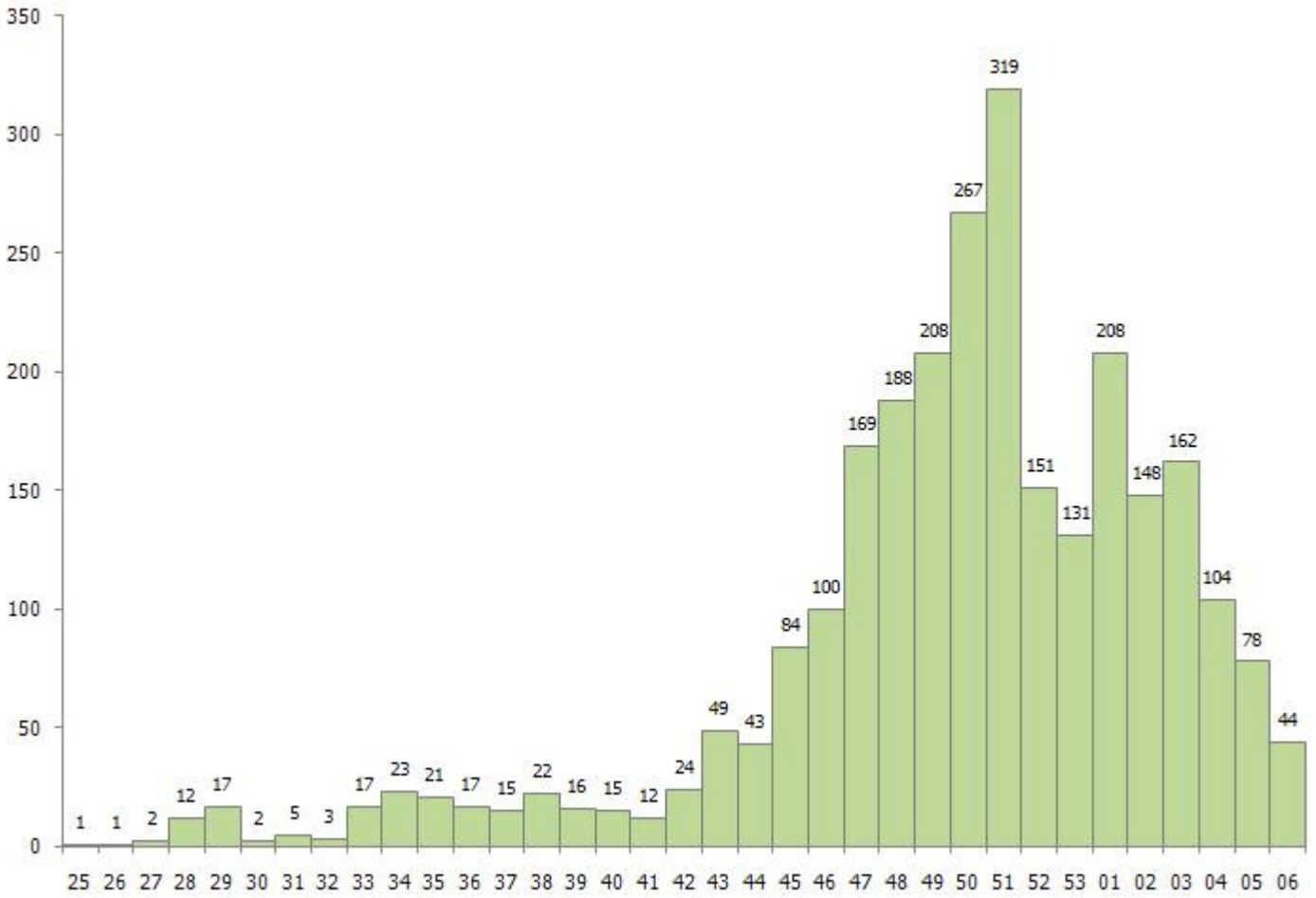
It is extremely important that we do not allow the current low levels of influenza like illness and the stand down of the NPFS to lead to a sense of complacency.

There is still considerable uncertainty about how the virus will behave over the coming months and years. Experts advise us that it is likely that pandemic H1N1 (2009) will be the predominant 'flu virus in the 2010 influenza season. The 2010 season may come earlier than usual and there may be outbreaks sparked by returning travellers from countries affected by the Southern Hemisphere 'flu season which starts quite soon.

There is also a risk that the genetic composition of the pandemic H1N1 (2009) virus will "drift" during its passage through the world and return to the United Kingdom to cause a more severe illness.

http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_111598.pdf

Influenza A(H1N1) pandemic situation Europe
2 678 deaths reported to week 6 2010 (15 Feb 2010)



http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/home.aspx (accessed 18 Feb 2010)

Weekly and cumulative influenza virus detections by type, subtype and surveillance system, weeks 40/2009–48/2009

	Current Week		Season	
Virus type/subtype	Sentinel	Non-sentinel	Sentinel	Non-sentinel
Influenza A	1261	6575	11615	54425
A (pandemic H1N1)	1151	5634	11026	46450
A (subtyping not performed)	80	907	504	7641
A (not subtypable)	0	0	50	278
A (H3)	0	0	4	21
A (H1)	30	34	31	35
Influenza B	2	11	43	52
Total Influenza	**1263**	**6586**	**11658**	**54477**

Note: A(pandemic H1N1), A(H3) and A(H1) includes both N-subtyped and not N-subtyped viruses

Source: European Influenza Surveillance Network (EISN)

http://ecdc.europa.eu/en/activities/surveillance/EISN/Newsletter/091204_EISN_Weekly_Influenza_Surveillance_Overview.pdf

European Influenza Surveillance Network

Executive Update 25th January 2010

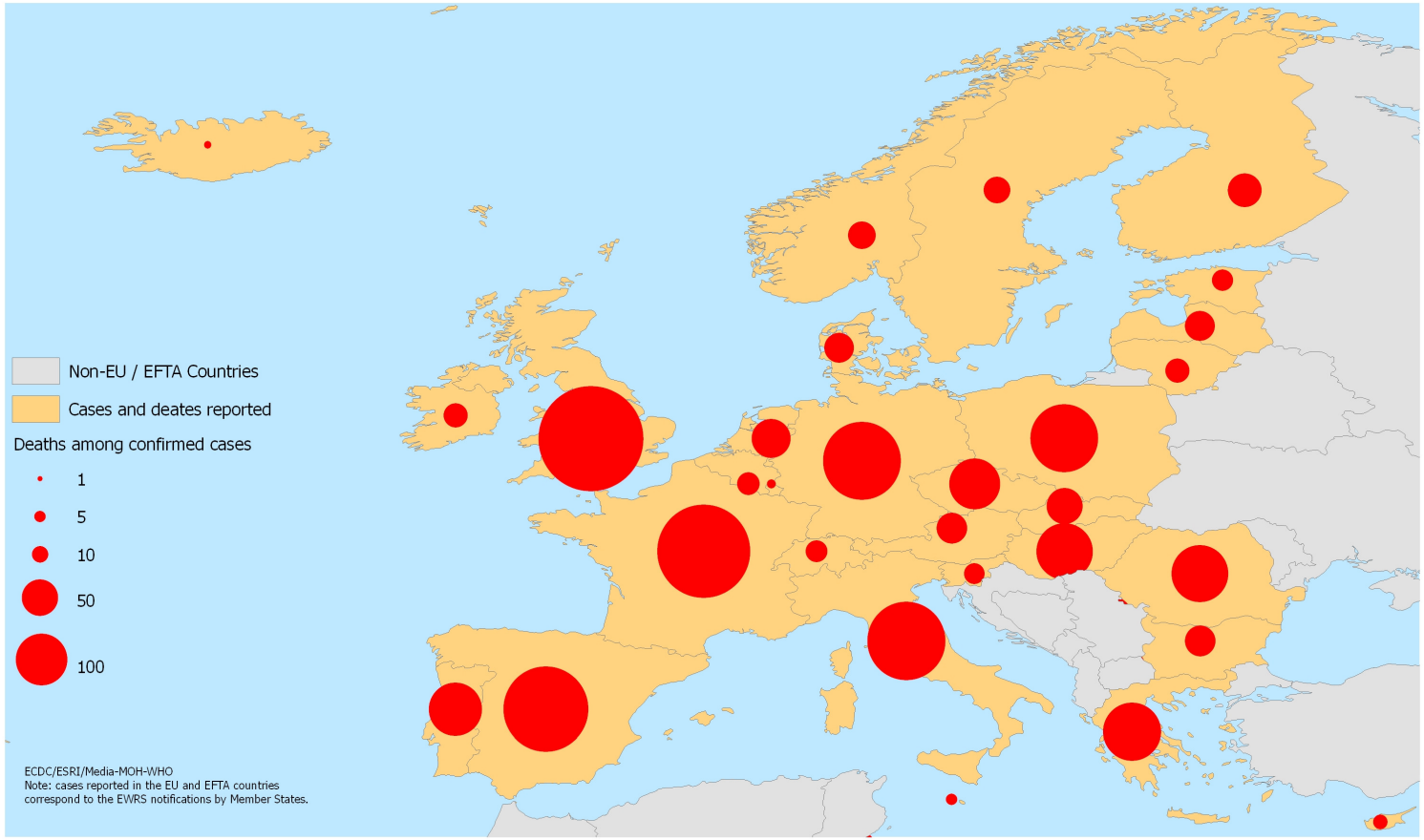
Weekly influenza surveillance overview (WISO) highlights

- During week 02/2010, only Bulgaria, Malta, Poland and Romania reported medium influenza like-illness/severe acute respiratory infection activity (ILI/ARI) in the EU and EEA.
- Of the 684 sentinel samples tested, 18.1% were positive for influenza of which more than 99% were 2009 pandemic influenza A(H1N1) virus.
- The number of cases of severe acute respiratory infection (SARI), measured by week of onset, continued to decline in week 02/2010.
- Of the 123 cases of severe acute respiratory infection, 44 (36%) were known to have required intensive care unit admission and 28 (23%) needed respiratory support.
- Detection of 2009 pandemic influenza A(H1N1) viruses resistant to oseltamivir remains sporadic; of 1260 viruses reported, 34 (2.7%) were resistant.

http://ecdc.europa.eu/en/activities/surveillance/EISN/Pages/home.aspx

Announced cumulative number of confirmed fatal cases of 2009 pandemic influenza A(H1N1) in EU and EFTA countries, as of 15 Feb 2010

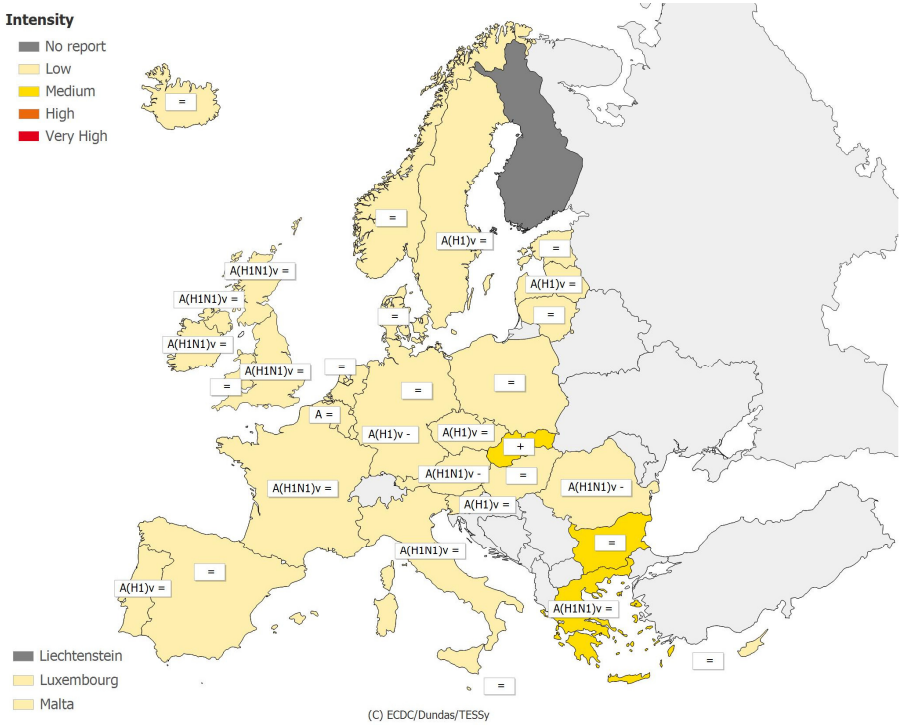
Announced cumulative number of confirmed fatal cases of 2009 pandemic influenza A(H1N1) in EU and EFTA countries, as of 15 February 2010, 09.00 CEST



[2] http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/home.aspx **(accessed 18 Feb 2010)**

2009 influenza A(H1N1) Intensity map

European Influenza Surveillance Network – week 5 2010



* A type/subtype is reported as dominant when > 40 % of all samples are positive for the type/subtype.

Legend:

Low	No influenza activity or influenza at baseline levels	**-**	Decreasing clinical activity
Medium	Usual levels of influenza activity	**+**	Increasing clinical activity
High	Higher than usual levels of influenza activity	**=**	Stable clinical activity
Very high	Particularly severe levels of influenza activity	**A**	Type A
		A(H1)v	Type A, Subtype H1v
		A(H1N1)v	Type A, Subtype H1N1v

http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/home.aspx (accessed 18 Feb 2010)

ECDC Health Education

On the use of specific pandemic influenza vaccines

According to current (August 2009) evidence on the pandemic (H1N1) 2009, the following can be identified as risk groups:

- people aged less than 65 years with chronic underlying conditions, namely:
  - chronic respiratory diseases;
  - chronic cardiovascular diseases;
  - chronic metabolic disorders (notably diabetes);
  - chronic renal and hepatic diseases;
  - persons with deficient immunity (congenital or acquired);
  - chronic neurological or neuromuscular conditions; and
  - any other condition that impairs a person's immunity or prejudices their respiratory function.
- young children (especially those younger than two years old); and
- pregnant women.

http://ecdc.europa.eu/en/healthtopics/Documents/0908_Influenza_AH1N1_On_the_use_of_specific_pandemic_influenza_vaccines.pdf

European Medicines Agency

Pandemic influenza A(H1N1) vaccines

- "In the European Union, procedures have been put in place to speed up the assessment and authorisation of vaccine that may prove vital in a pandemic situation"
- The following vaccines have benefited from these procedures:
  - Arepanrix®
  - Pandemrix ®
  - Celvapan ®
  - Focetria ®

http://www.ema.europa.eu/influenza/vaccines/home.htm

Not licensed in The Philippines

Arepanrix®

GSK egg-based adjuvanted pandemic influenza vaccine

- "Arepanrix® is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). Arepanrix® contains a flu strain called A/California/7/2009 (H1N1) v-like strain (X-179A)"
- "The company presented information from studies carried out with an earlier version of Arepanrix®, containing the 'bird flu' strain H5N1. This included one study in 4,561 adults, which looked at the ability of Arepanrix® H5N1 to trigger the production of antibodies ('immunogenicity') against this H5N1 strain, and one study comparing it with Pandemrix® H5N1. A further study compared Arepanrix® containing the pandemic flu strain H1N1 with Pandemrix® H1N1 in 334 adults. This study looked at the immunogenicity against influenza A(H1N1)v"
- "Because Arepanrix® is similar to Pandemrix®, the company used the data on the use of Pandemrix® in children to support the use of Arepanrix® in children"
- "The CHMP gave a positive opinion for the granting of a marketing authorisation valid throughout the European Union for Arepanrix® to GlaxoSmithKline Biologicals s.a. on 20 January 2010. The European Commission will issue a decision on this opinion in due course"

http://www.ema.europa.eu/influenza/vaccines/arepanrix/arepanrix.html

Not licensed in the Philippines

Pandemrix®

GSK egg-based adjuvanted pandemic influenza vaccine

- "Pandemrix® is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). Pandemrix® contains a flu strain called A/California/7/2009 (H1N1) v-like strain (X-179A)"
- "The European Commission granted a marketing authorisation valid throughout the EU for the H5N1 mock-up vaccine for Pandemrix® to GlaxoSmithKline Biologicals s.a. on 20 May 2008. The marketing authorisation for the H1N1 vaccine was granted on 29 September 2009"
- Note that Pandemrix® is also licensed in Singapore and Saudi Arabia

http://www.ema.europa.eu/influenza/vaccines/pandemrix/pandemrix.html

Not licensed in the Philippines

Celvapan®

Baxter cell culture-based non-adjuvanted pandemic influenza vaccine

- "Celvapan® is a vaccine that is given by injection. It contains influenza (flu) viruses that have been inactivated (killed). Celvapan ® contains a flu strain called A/California/07/2009 (H1N1)v"

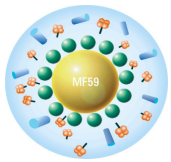
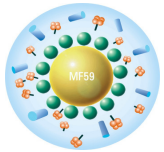
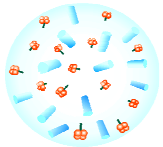
- "The European Commission granted a marketing authorisation valid throughout the EU for the H5N1 mock-up vaccine for Celvapan ® to Baxter AG on 4 March 2009. The change to the marketing authorisation for the H1N1 virus was authorised by the European Commission on 6 October 2009. The full assessment report will be published shortly"

http://www.ema.europa.eu/influenza/vaccines/celvapan/celvapan.html

Not licensed in The Philippines

Novartis' pandemic influenza A(H1N1) vaccines

All platforms have been used to produce H5N1 candidate vaccines

Pandemic Vaccine	Seasonal Platform	Licensure	Drug Substance	Antigen content	Adjuvant
Focetria ® 	Fluad Egg-derived	Europe, others	Subunit	7.5 µg HA per 0.5 ml dose	MF59C.1
Celtura® 	Optaflu MDCK cell	CH, Germany	Subunit	3.75 µg HA per 0.5 ml dose	50% MF59C.1
Influenza A(H1N1) 2009 	Fluvirin Egg-derived	US, others	Subunit	15 µg HA per 0.5 ml dose	None

Not licensed in The Philippines

Focetria® and Celtura® pandemic influenza A(H1N1) vaccines

Design of pivotal trials – two doses three weeks apart

- **Adults and elderly (N=600 for each product)**

Vaccines/Age	Adult (18 to 60 yrs)	Elderly (≥61 yrs)	Total
3.75 µg A/H1N1 + 1/2 dose MF59	120	120	240
7.5 µg A/H1N1 + full dose MF59	120	120	240
15 µg A/H1N1 plain	120		120
Total	360	240	600

- **Children, 6 months – 17 years (N=720 for each product)**

Vaccines/Age	(6m - <12m)	12m - >3y	3y - <9y	9y - <18y	Total
3.75 µg A/H1N1 + 1/2 dose MF59	80	80	80	80	320
7.5 µg A/H1N1 + full dose MF59	80	80	80	80	320
15 µg A/H1N1 plain	–	40	40	–	80
Total	160	200	200	160	720

- **Clinical trials in:** Germany, Switzerland, Belgium, Netherlands, Chile, Dominican Republic

Not licensed in The Philippines

FOCETRIA®

Summary of clinical results and resulting CHMP/EMEA indications

Age group	CHMP criteria met – 1 or 2 doses			Current label 7.5 µg + 100% MF59 **
	3.75 µg + 50% MF59	7.5 µg + 100% MF59	15 µg no adjuvant	
6-11 months	1	1	ND	2 doses
12-35 months	1	1	2	2 doses
3–8 years‡	1	1	2	1 dose
9–17 years‡	1	1	ND	1 dose
18–60 years	1	1	1	1 dose
>60 years	2	1	ND	2 doses

* Preliminary data after second dose: CHMP criteria achieved in ALL groups

** Additional variations from initial approval: vaccine strain change (to X181), 6 months persistence data in elderly, larger safety database (from 542 to 3,400 subjects)

‡ preliminary clinical data

Not licensed in The Philippines

Celtura®

Summary of clinical results and resulting PEI and Swiss Medic indications

Age group	CHMP criteria met – 1 or 2 doses			Current label
	3.75 µg + 50% MF59	7.5 µg + 100% MF59	15 µg no adjuvant	7.5 µg + 100% MF59 **
6-11 months	2	2	ND	2 doses
12-35 months	2	1	2	2 doses
3–8 years‡	1	1	2	1 dose
9–17 years‡	1	1	ND	1 dose
18–50 years	1	1	1	1 dose
>50 years	2	2	ND	2 doses

* Preliminary data after second dose: CHMP criteria achieved in ALL groups

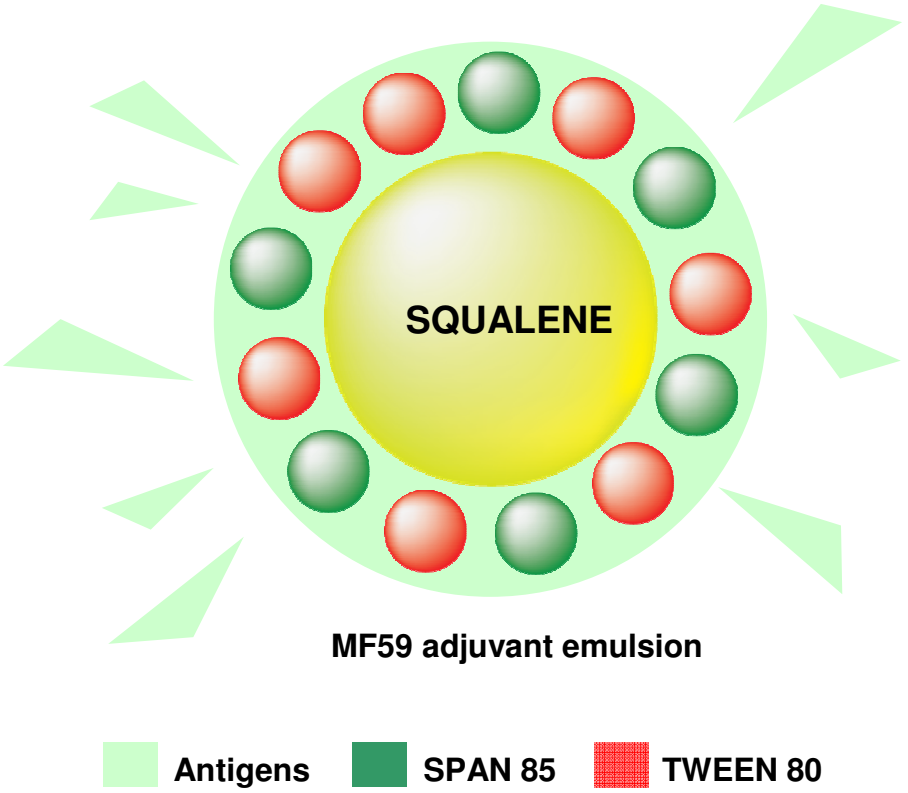
** Additional variations from initial approval: vaccine strain change (to X181), 6 months persistence data in elderly, larger safety database (from 542 to 3,400 subjects)

‡ preliminary clinical data

Not licensed in The Philippines

Safety of adjuvants:
MF59 - an established oil in water adjuvant

- **Oil-in-water emulsion adjuvant used in FLUAD®*, seasonal influenza vaccine licensed in Europe for ≥65 year olds since 1997 – 45 M doses distributed**
- **Clinical trials with various antigens on >33,000 subjects:**
  - **16,000 young adults**
  - **3000 children**
- **No safety signals in either clinical trial or pharmacovigilance databases**



Not licensed in The Philippines

* Novartis data on file

Exposures during pregnancy to MF59-adjuvanted and unadjuvanted influenza vaccines

	MF59- adjuvanted influenza vaccines	Unadjuvanted influenza vaccines
All pregnancies	**43**	**60**
Mean age (yr)	**26 (18-39)**	**26 (16-42)**
Median age (yr)	**24**	**25**
Outcome		
Normal	**30 (70%)**	**45 (75%)**
Abnormal	**9 (21%)**	**14 (23%)**
Induced abortions	**4 (9%)**	**1 (2%)**

- Available data do not indicate a difference in pregnancy outcomes in women exposed to MF59-adjuvanted and unadjuvanted influenza vaccines.

Tsai TF, Kyaw MH, Novicki D, Nacci P, Rai S, Clemens R. Exposure to MF59-adjuvanted influenza vaccines during pregnancy – A retrospective analysis. Vaccine 2010; 28: 1877-1880

Not licensed in The Philippines

A number of other companies have also manufactured pandemic influenza vaccines

Vaccine; manufacturer	Countries of manufacture	Manufacturing technology	Adjuvant	Countries of approval
Panenza®; Sanofi Pasteur/Aventis	France	Egg-based	No	France
Humenza®; Sanofi Pasteur/Aventis	France	Egg-based	Yes	
Panflu.1; Sinovac	China	Egg-based	No	China, Mexico
Inactivated H1N1 influenza vaccine; Hualan Biological	China	Egg-based	No	China
Green Flu-s; Green Cross	Korea	Egg-based	Available with and without	Korea
Fluval P; Omninvest	Hungary	Egg-based	No	Hungary
Inactivated A/H1N1 Influenza vaccine; Denka Seiken Co.	Japan	Egg-based	No	Japan
Inactivated A/H1N1 Influenza vaccine; Kaketsuken	Japan	Egg-based	No	Japan
Inactivated A/H1N1 Influenza vaccine; The Kitasato Institute	Japan	Egg-based	No	Japan
Inactivated A/H1N1 Influenza vaccine; Research Foundation for Microbial Diseases of Osaka University	Japan	Egg-based	No	Japan

WHO SAGE recommendations for influenza A(H1N1) vaccination

General Objectives for Pandemic Vaccination Strategies
Protect integrity of country's health-care system and critical infrastructure
Reduce morbidity and mortality
Reduce transmission of the pandemic virus within communities

Suggested Order of Priority, as Vaccine Initially Will be Insufficient
Healthcare workers
Pregnant women
Individuals >6 months with chronic medical conditions
Healthy adults >15 years to <49 years
Healthy children *(to reduce societal transmission)*
Healthy adults >49 years to <65 years
Healthy adults >65 years

Weekly Epidemiological Report 2009; 84: 301-8 at http://www.who.int/wer/2009/wer8430.pdf

US ACIP recommendations for influenza A(H1N1) vaccination

Selected Underlying assumptions
Enough vaccine for entire population will not be available immediately
2 doses will be needed for protection
Initial uptake will be similar to seasonal influenza vaccine but could change with severity of outbreak

General Principles
Vaccine should not be kept in reserve for later administration of the second dose
Seasonal vaccination should begin as soon as it is available for all recommended groups

US ACIP recommendations for influenza A(H1N1) vaccination

Initial Target Groups, as vaccine availability is uncertain
Pregnant women
Household and caregiver contacts of infants <6 m *(to reduce transmission to infants)*
Healthcare and emergency medical services workers
Persons 6 months - 24 years (In event of vaccine shortage, prioritize children 6 months – 4 years)
Persons 25 through 64 y with high risk medical conditions (In event of vaccine shortage, prioritize children < 19 years)
When vaccine availability is sufficient, also recommended
Healthy adults 18 years – 64 years
Persons ≥ 65 years

World Health Organization prequalification

For supply to United Nations agencies

- On 21 December 2009 the WHO granted prequalification for all three of the Novartis influenza A (H1N1) monovalent vaccines for supply to UN agencies
  - Cell culture with MF59 adjuvant subunit vaccine (6+ months of age)
  - Egg based with MF59 adjuvant subunit vaccine (6+ months of age)
  - Egg based non-adjuvanted subunit vaccine (4+ years of age)
- WHO prequalification also granted for trivalent seasonal subunit influenza vaccine
- Prequalification facilitates purchasing through UN agencies and enhances access for developing countries

Not licensed in The Philippines

Summary

- Pandemic influenza A(H1N1) still poses a threat and is still in circulation
- The global response has been responsible and appropriate
- Certain groups are at particularly high risk and these groups include pregnant women, infants and children
- A number of companies have manufactured vaccines against pandemic influenza A(H1N1)
- Recommendations on the use of these vaccines have been made by local, regional and global authorities