

Update on H1N1 Virus

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Global situation

Up to the 2nd of August, in Europe there have been confirmed 26,513 confirmed cases with 40 deaths. Globally there are 158,357 confirmed cases with 1,212 deaths. However the actual number of persons worldwide who have contracted H1N1 virus is likely to be ten times what has been confirmed.

Local situation

The first two cases confirmed to be positive to H1N1 virus in Malta occurred on 1st July. During that week the initial response was to contain the number of infected cases. The confirmed cases were isolated for 7 days from onset of illness and given antiviral treatment whilst their close contacts were identified and put in voluntary quarantine for 7 days and given prophylaxis with antivirals for 10 days. Within a week there were 48 confirmed cases positive to Influenza A, H1N1 and 14 confirmed cases positive to Influenza A. The majority of confirmed cases were imported cases due to travel to Spain, UK and Cyprus. The first locally transmitted cases occurred in Gharb, Gozo. From the first 62 cases, 81% reported fever while 68% had sore throat and 65% a dry cough.

On 8th July the National Pandemic Committee of Health decided to switch from containment phase to mitigation phase and it was decided that only those persons who were at high risk of developing complications from influenza would be swabbed if they develop influenza-like illness and those that come positive will be treated with antivirals. Tracing of close contacts stopped. The 3 groups considered at high risk were:

- 1) children under 5 years of age;
- 2) pregnant women;
- 3) those suffering from the following chronic diseases (chronic respiratory and heart disease, diabetes, immunosuppression and chronic renal failure).

Up to end of week 32 there were 497 negatives, 101 influenza A positives and 222 Influenza A H1N1 positives. Since mitigation started, we have had 9.7 % of our high risk groups positive to Influenza A and 20.4% positive to Influenza A H1N1.

Sentinel surveillance on influenza-like symptoms started to be collected from 15th July both epidemiologically and virologically (doctors are encouraged to participate - please visit <http://www.thesynapse.net/articles/viewarticle.asp?artid=11094>). Out of 58 sentinel patients swabbed, 25 (43%) were found to be positive to Influenza A H1N1, 8 (14%) positive to Influenza A and 25 (43%) were negative. During week 30 the rate of influenza-like illness was 110.67/1000 consultations.

Adverse effects of Antivirals

Like all medication, antivirals have side effects. Two studies were done by the Health Protection Agency in the UK at the beginning of the epidemic. A study done on 103 children at three London schools showed that 53% suffered side effects.

The most common were nausea (29%), stomach pain or cramps (20%) and problems related to sleeping (12%). Another study done on a secondary school found that 51% of pupils had symptoms of nausea (31%), headaches (24%) and stomach ache (21%).

All side effects caused by antivirals should be reported to the Medicines Authority.

H1N1v influenza in pregnant women

The CDC (Communicable disease Centre in the US) collected data from pregnant women infected with influenza A H1N1 virus and concluded that they are at an increased risk for complications from the virus, with a higher estimated rate of hospital admissions than in the general population. Information about the safety and effectiveness of antivirals during pregnancy is scarce.

The European Medicines Agency (EMA) CHMP assessment report (29/5/09) stated that based on experimental animal studies, Oseltamivir therapy during pregnancy is not expected to increase the risk of congenital anomalies. Overall from the data collected there does not appear to be evidence to suggest that maternal exposure to oseltamivir was associated with adverse pregnancy or foetal outcome.

The conclusion was that overall, the benefit of using Oseltamivir in pregnant or breast-feeding women outweighs the risk to the foetus in the context of a novel influenza H1N1 pandemic situation.

shown that Zanamivir crosses the placenta and is secreted in breast milk. However taking

the overall data, it is suggested that the benefit in pregnant and breast-feeding women outweighs the risk in a pandemic situation.

H1N1 influenza in children under 1 year of age

The CHMP report (29/5/09) states that it acknowledges that there is limited data available supporting the use of Oseltamivir in children below 1 year of age. However considering the urgent need for recommendations to treat this population since an H1N1 pandemic situation has been declared and these children are at high risk of developing complications of influenza, the appropriate dosage for treatment for children below 1 year of age is 2-3mg/kg twice daily for 5 days. Children below 3 months of age should be treated under medical supervision in hospital.

Pandemic vaccine

A press release by EMA (24/7/09) states that they are reviewing data on H1N1 vaccines. 4 mock up vaccines developed by Baxter, GlaxoSmithKline and Novartis have already been approved in the EU based on earlier data generated with the H5N1 virus strain. These vaccines were developed with the knowledge that the virus strain would be changed in the event of a declared pandemic to include the strain causing the pandemic. Clinical trials have initiated on efficacy, immunogenicity and safety of the vaccine and initial results are expected from September 2009. As with all medicines, rare adverse reactions can only be detected during the wider use of the vaccine. Besides the mock up vaccines, a number of pandemic vaccines are currently under development and preliminary data from GSK and Sanofi Pasteur are also being assessed by the Committee on an accelerated basis. ☐

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been confirmed*