Paediatric Active Enhanced Disease Surveillance (PAEDS)

Hospitalised Influenza: Study Protocol

BACKGROUND

By July 12th 2009 Australia had confirmed over 8000 cases of influenza A H1N1 09 (swine flu) and 18 deaths in the pandemic declared by the WHO in June 2009.[1] An H1N1 09 vaccine is being developed by CSL for mass vaccination in Australia in late 2009t.[2] Children are particularly vulnerable to influenza, have the highest hospitalisation rates, and are the major community reservoir and source of infection.[3] In 2007, 122 children were admitted to the Children's Hospital at Westmead in Sydney (12 requiring intensive care) with seasonal influenza, representing 530 hospital admission days.[4] Few eligible children had been vaccinated or received antivirals and many were inappropriately investigated and treated.[4] Children, particularly those with underlying risk factors, may suffer severe complications of seasonal influenza, including encephalopathy, myocarditis, rhabdomyolysis (reported in one child with H1N1 09 in Victoria) and Guillain-Barre Syndrome (GBS).[3] Although most H1N1 09 infections in Australia have been mild, deaths have been reported. Future mutations may be associated with community spread of H1N1 09 and increased viral virulence, resulting in more severe disease and significant impacts on health resources. GBS, a demyelinating disease, may also follow influenza vaccination[5] and has been associated with swine flu vaccines.[6] The Global Advisory Committee on Vaccine Safety recently recommended that urgent GBS surveillance be established globally.

Surveillance of H1N1 influenza and adverse vaccine outcomes is urgent and essential in Australia for several reasons. We will likely be the first country to introduce the new vaccine (for which safety data are limited) and thus our data on its efficacy and safety will inform global (particularly Northern Hemisphere) policy. There are concerns regarding H1N1 vaccines because of the significantly increased risk of GBS noted in the 8 weeks after mass vaccination in New Jersey (1 case:100,000 vaccines).[5] Immediate identification and investigation of GBS cases will be vital to determine whether GBS is triggered by infection or vaccination so that public confidence in vaccination is not undermined. Detailed Australian data on the clinical presentation, management and outcomes of influenza (H1N1 09) in children are also essential to guide clinical practice and development of public health policy. Although existing laboratory surveillance schemes provide data on numbers of confirmed cases of influenza, these data are not sufficiently detailed or timely.

AIMS

Our ***primary aim*** is to use PAEDS to conduct hospital-based surveillance to identify and document clinical and laboratory findings in children hospitalised with severe influenza and its complications and children with GBS in major paediatric hospitals in Sydney, Melbourne, Adelaide and Perth.

Specific aims.

1. To identify children hospitalised with proven influenza and, where possible, to compare 2009 data with historical background rates of hospitalisation for influenza.

2. To collect, from children with H1N1 09 infection, information about vaccination, history, presentation, diagnosis, management, complications, outcomes ≤ 1 month after discharge.

3. To collect, from children with severe complications of influenza caused by any influenza strain, detailed information (as in 2) and correlate clinical and laboratory (virological) data.

4. To identify children hospitalised with Guillain Barre Syndrome and collect information about recent (in the last month) influenza vaccination and/or proven influenza illness.

5. To provide weekly updates to the DoHA to inform policy and clinical practice and undertake timely analysis and publication of data

CASE DEFINITION AND REPORTING INSTRUCTIONS

Data on all cases of ***children hospitalised with influenza*** should be recorded if they meet the following criteria:

(i) Child is age under 15 years at the time of diagnosis of influenza
(ii) Virological diagnosis of influenza is confirmed on testing of nasal/throat swab specimens
(iii) Child is admitted to hospital*

* N.B. the definition of 'hospital admission' varies according to the hospital (e.g. 8 hours for CHW, 4 hours for RCH, 'undergone formal admission' for WCH.

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Data on children with ***Guillain Barre Syndrome*** will be collected through PAEDS using the AFP questionnaire, with additional questions regarding whether the child has had recent influenza infection or influenza vaccination.

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