



**衛生防護中心**  
Centre for Health Protection

**Statement from the Expert Group on Serious Adverse Events  
following Human Swine Influenza Vaccination on a Case with  
Clinical Features Compatible with Guillain-Barre Syndrome (GBS)**

**CLINICAL HISTORY**

On 6 January 2010, the Centre for Health Protection (CHP) received report of a 58-year-old man who complained of lower limb weakness and was admitted to Queen Mary Hospital (QMH).

The patient developed sudden onset of bilateral calf pain and increasing lower limb weakness since 28 December 2009. He was admitted to QMH on 2 January 2010. He received human swine influenza (HSI) vaccine on 24 December 2009 in a government outpatient clinic.

Clinical examination revealed bilateral ascending lower limb weakness. Currently his condition is listed as serious and his vital signs are stable.

The first nerve conduction test showed prolonged distal motor latency, which was compatible with early phase of GBS and other demyelinating diseases. Magnetic resonance imaging (MRI) and cerebrospinal fluid (CSF) examination did not identify other cause for the symptoms. Other investigations are ongoing to confirm the diagnosis.

**VACCINE SAFETY FROM WHO AND OVERSEAS EXPERIENCE**

Over 80 million doses of HSI vaccines have been administered worldwide. To date, overseas reports on adverse events following HSI vaccination do not suggest human swine flu vaccine is associated with an increased risk of GBS. The World Health Organization (WHO) asserts that the number of GBS worldwide is in line with normal background rates of this illness.

## **LOCAL BASELINE OF GBS**

Between 42 and 65 cases of GBS are recorded each year based on Hospital Authority data from 2000 to 2009, irrespective of vaccination history, with more cases occurring during winter period. The number of GBS cases recorded in October, November and December 2009 was 10, 10 and 6 respectively.

## **EXPERT GROUP'S COMMENT**

The clinical features of this patient are compatible with GBS. Further tests are being conducted to ascertain the final diagnosis.

It is not possible to differentiate with reasonable certainty whether the relationship between HSI vaccination and the patient's symptoms is causal or coincidental (i.e., by chance).

A baseline number of GBS occurs in Hong Kong, it is expected that a certain number of cases will occur following vaccination coincidentally. The incidence of GBS in the month of December 2009 is within normal baseline level in the Hong Kong population. Current overseas experience with HSI vaccine found it has not led to increased rate of GBS above background level. The WHO asserts that HSI vaccine has similar safety profile as seasonal flu vaccine. From a population perspective, no association between HSI vaccination and GBS can be established at this point, but rare idiosyncratic response of an individual to any vaccines or drugs cannot be excluded.

## **CONCLUSION**

The clinical features of this patient are compatible with GBS. Further tests are being conducted to ascertain the final diagnosis. It is not possible to differentiate with reasonable certainty whether the relationship between HSI vaccination and the patient's symptoms is causal or coincidental (i.e., by chance).

To date, the World Health Organization has found no evidence suggesting a causal relationship between GBS and HSI vaccination and the number of GBS worldwide is in line with normal background rates of this illness. CHP is recommended to closely monitor the local and global situation.

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This statement represents a consensus view of members of the Expert Group reached in the light of scientific information accessible and examined at the time of its release.

7 January 2010