

**For information on
11 January 2010**

Legislative Council Panel on Health Services

Human Swine Influenza Vaccination Programme

Purpose

This paper informs Members of the latest position of the Human Swine Influenza (HSI) Vaccination Programme.

Background

2. At the meeting on 14 December 2009, Members were informed of the implementation of the HSI Vaccination Programme. Members noted that HSI vaccination will be provided to five target groups, namely patients with chronic illness and pregnant women, children aged between six months and under six years old, elderly aged 65 and above, healthcare workers, as well as pig farmers and pig-slaughtering industry personnel. The vaccination programme has started in the public sector on 21 December 2009 and private doctors started participating in the programme on 28 December 2009.

Up-take rate of HSI vaccines

3. As at 1 pm on 7 Jan 2010, a total of **93,854** doses of HSI vaccines were given by the Hospital Authority and the Department of Health to the target groups. A breakdown showing the number of vaccines administered to each target group is given below.

Category of target groups	No. of HSI vaccines administered
Community living elderly persons aged 65 years or above	48,705
Persons under 65 years with chronic illness	25,142
Pregnant women	889
Healthcare workers	7,635
Children between the age of 6 months and less than 6 years	11,022
Pig farmers and pig-slaughtering industry personnel	461
Total	93,854

4. Regarding the private sector, as at 1 pm on 7 January 2010 we have received a total of **19,710** reimbursement claims from private doctors who have enrolled in the HSI Subsidy Scheme to provide vaccination to the target groups.

Suspected case of Guillain-Barre Syndrome

5. On January 6, 2010, the Centre for Health Protection (CHP) of the Department of Health (DH) received report of a suspected case of Guillain-Barre Syndrome (GBS) affecting a 58-year-old man who complained of lower limb weakness and was admitted to the hospital. He had received HSI vaccination four days before onset of symptoms. This is the first serious adverse event reported since the implementation of the vaccination programme.

6. The Expert Group on Serious Adverse Events following HSI vaccination of CHP met on January 7 2010 to discuss this case. The Expert Group concluded that the clinical features of the patient were 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. The statement issued by the Expert Group after the meeting is at the **Annex** (English version only).

7. A few cases of GBS occur every month on average in Hong Kong. In October, November and December 2009, ten, ten and six cases of GBS were recorded by the Hospital Authority respectively. GBS and other adverse events reported following HSI vaccination may or may not involve a causal relationship.

8. To date, we note that about 50 cases of GBS have been reported following HSI vaccination worldwide, in which 32 were from the United States and eight were from Canada. While these cases are being investigated by overseas health authorities, the rates of GBS cases do not exceed the background rates in these countries. In fact, the rates of GBS among vaccinated persons were found to be lower than expected in Canada and Europe.

9. The World Health Organization (WHO) also reported that the number of GBS worldwide is in line with normal background rates of this illness. To date, the WHO has found no evidence suggesting a causal relationship between GBS and HSI vaccination. CHP will continue to closely monitor the local and global situation.

Advice Sought

10. Members are invited to note the content of this paper.

Food and Health Bureau
Department of Health
January 2010



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