監測及流行病學處

衞生防護中心
Centre for Health Protection
保障市民健康
Protecting Hong Kong's health

Surveillance
And
Epidemiology
Branch

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9 December 2009

Dear Doctor,

Human Swine Influenza (HSI) Vaccine and
Reporting of Guillain-Barre Syndrome (GBS) following HSI Vaccination

I am writing to update you of the new human swine influenza (HSI) vaccines and solicit your support in reporting Guillain-Barre Syndrome (GBS) following HSI vaccination to the Department of Health.

As you may be aware, the Government has secured a supply of three million doses of HSI vaccines (PANENZA® from Sanofi-Aventis), which is an inactivated non-adjuvanted monovalent vaccine. The first batch of vaccines will arrive in Hong Kong in mid-December and the HSI vaccination programme will follow shortly. The details of the vaccination programme will be provided to you separately.

To prepare for the programme, we have prepared an information sheet to provide you more details concerning the usage of this HSI vaccine (PANENZA®).

In Hong Kong, the Scientific Committees of the Centre for Health Protection recommended five target groups to receive the vaccines with priority. The complete recommendation and its rationale can be obtained from the website of the Centre for Health Protection:
http://www.chp.gov.hk/files/pdf/recommendations_on_human_swine_influenza_(hsi)_vaccination.pdf

I would like to draw your attention that persons with *pre-existing medical conditions including pregnancy* belong to one of the five target group. *Pre-existing medical conditions* refer to chronic cardiovascular disease (except hypertension without complication); chronic pulmonary disease; chronic metabolic disease; chronic renal disease; immunocompromised; children and adolescents (aged 6 months to 18 years) on long-term aspirin therapy; severe obesity (BMI ≥ 30); and chronic neurological condition

衞生防護中心乃衞生署轄下執行疾病預防及控制的專業架構
The Centre for Health Protection is a professional arm of the Department of Health for disease prevention and control

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that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration or those who lack the ability to care for themselves for their increased risk of complications and death associated with influenza infection.

Vaccination is the best way to protect against HSI infection and the complications. As the antigens contained in the HSI vaccine represent an excellent match to the currently circulating virus strain, the vaccine is expected to give at least the same level of protection as seasonal influenza vaccine, which is approximately 70-90% protection against clinical disease in healthy adults.

Regarding safety of HSI vaccine, the vaccine being used has a production method and safety profile comparable to the usual seasonal influenza vaccines which have been used for more than 60 years. So far, a total of 65 million people had received HSI vaccine worldwide. According to the World Health Organization (WHO) and countries that have already launched HSI vaccination programmes, the frequency of adverse reactions reported is well within the expected range for seasonal influenza vaccines. In fact, the HSI vaccine will be incorporated into the seasonal influenza vaccine according to the WHO's recommended vaccine formulation for the 2010 influenza season for the southern hemisphere.

As expected from background incidence, a few suspected cases of Gullain-Barre Syndrome (GBS) have been reported in people following temporally HSI vaccine administration in overseas countries. As you appreciate, GBS occurs in the general population and the occurrence of GBS following HSI vaccination may be a chance occurrence of random events and may not necessarily indicate a causal relationship. All GBS following HSI vaccination reported are being investigated by WHO and the respective health authorities. So far, the number of GBS reported among those received HSI vaccine in overseas countries does not exceed the normal background rates of this illness.

As a precautionary measure to ensure vaccine safety, DH has enhanced the surveillance programme for GBS following influenza vaccination in Hong Kong to monitor the incidence of this condition and detect any signs of excess over the background rate. All GBS cases with history of HSI vaccination will be investigated and reviewed by an expert panel to determine the strength of association. In Hong Kong, the background rate of GBS is about 7.7 per million population per year (HA hospital admission data, 2000-08). Based on this background rate, it can be derived statistically that for a population of 3 million who receive vaccination, up to 12 background GBS cases with history of HSI vaccination may be found during 120 days post-vaccination and still lie within statistical expectation.

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I take this opportunity to appeal to you to watch out for and report **any patient who is suspected or diagnosed of GBS and had received HSI or seasonal influenza vaccine within 120 days before disease onset**.

For reporting, please fill in and fax the attached report form on "GBS following Influenza Vaccination" (Part I to VII) and Adverse Drug Reactions Report Form to the Central Notification Office at 2477 2770 and Adverse Drug Reaction Monitoring Unit at 2572 4570. For notification of GBS cases with history of HSI vaccination outside office hours, apart from faxing the forms to us, please also call our Chief Pharmacist at 9862 0614. For more information, please refer to the guidance notes for adverse drug reaction reporting on the website of Pharmaceutical Service: http://www.psdh.gov.hk/eps/eng/html/adrform-20.jsp

In Hong Kong, traditional winter peaks of seasonal influenza most commonly occur in February and March. Recent experience from overseas countries including USA, Canada, Japan and South Korea show that second waves of HSI in these countries have arrived earlier than the traditional seasonal winter peak and the ILI activities in these countries have already exceeded the peak activity of the spring wave as well as previous regular flu seasons, with increasing trend of influenza associated hospitalization and deaths. Although most patients with HSI infection suffer from mild illness, a subset of the population are still at risk of complication and death from the illness. Vaccination is the best way to protect them from complications and the benefits of receiving the vaccine far outweigh its risks. In this connection, I appeal to you to explain to your staff and clients, especially persons who fall into the five target groups, on the benefits of receiving HSI vaccines as soon as possible after the start of HSI vaccination programme.

Let us work together to prepare for the second wave of the pandemic.

Yours sincerely,

(Dr SK CHUANG)
Consultant Community Medicine (Communicable Disease)
Centre for Health Protection
Department of Health

Enclosures

1. Information sheet on HSI vaccine
2. Guillain-Barre Syndrome Following Influenza Vaccination Report Form (Part I to Part VII)
3. Adverse Drug Reactions Report Form

Information Sheet on Human Swine Influenza (HSI) Vaccine

HSI Vaccines

Immunisation is one of the most important strategies in the control of HSI pandemic. Currently, several types of HSI vaccines are available worldwide, which include unadjuvanted and adjuvanted inactivated vaccines and live attenuated vaccines. According to the World Health Organization (WHO), all different types of HSI vaccines should offer effective protection against HSI.

PANENZA®

The Hong Kong Government has procured a total of 3 million doses of PANENZA® from Sanofi-Aventis, which is an unadjuvanted inactivated vaccine. PANENZA® is also used in overseas HSI vaccination campaign such as France, Spain and Luxemburg. Application for marketing authorization is submitted in Italy and Germany as well. Sanofi-Aventis is also supplying unadjuvanted inactivated HSI vaccines to the United States under the brand name "Influenza A (H1N1) 2009 Monovalent Vaccine".

Each vial of vaccines contains 5ml (10 full doses) and each dose (0.5ml) consists of 15 micrograms of antigen and 45 micrograms of thiomersal. The vaccine should be given by intramuscular injection and preferably in the deltoid region.

PANENZA® is licensed for use in persons aged 6 months old and above. For children aged 6 months to 35 months, two half doses (0.25ml) should be given at least 3 weeks apart. For children aged 3 years up to 8 years two full doses (0.5ml) should be given at least 3 weeks apart. For persons aged 9 years and above, one full dose (0.5ml) should be given.[1]

PANENZA® can be given with other vaccines such as seasonal influenza vaccine and/or pneumococcal polysaccharide vaccine during the same clinic visit but at different injection sites.

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[1] While the product information leaflet specifies two full doses (0.5ml) be given at least 3 weeks apart for persons above 60 years of age, the Scientific Committees of the Centre for Health Protection recommend **one full dose for persons aged above 60**, taking into account the latest scientific information and overseas experience on the use of the vaccine. The Ministry of Health in France also decided to give one full dose of PANENZA® in persons aged above 60.

Contraindications of PANENZA® include known hypersensitivity to any of the constituents of the vaccine, including thiomersal, to ovalbumin and any other egg proteins, to chicken proteins, to neomycin, to octoxinol-9 and to formaldehyde.

As the antigens contained in HSI vaccine represent an excellent match to the currently circulating virus strain, the vaccine is expected to give at least the same level of protection as seasonal influenza vaccine, which is approximately 70-90% protection against clinical disease in healthy adults. Should there be any antigenic drift of the HSI virus, it is expected that the vaccine strain should be able to afford a degree of cross protection against HSI infection in general.

Please refer to the product information for detailed characteristics of PANENZA®.

Safety of HSI Vaccines

HSI vaccination programmes with various type of HSI vaccines have been launched in over 40 countries worldwide, including Mainland China, the United States, the United Kingdom, Canada and Australia. Sixteen of these countries have been providing programme details to WHO and it is estimated that around 80 million doses of pandemic vaccine have been distributed and around 65 million people have been vaccinated. All data compiled to date indicate that pandemic vaccines match the excellent safety profile of seasonal influenza vaccines, which have been used for more than 60 years. In fact, the HSI vaccine will be incorporated into the seasonal influenza vaccine according to the WHO's recommended vaccine formulation for the 2010 influenza season for the Southern Hemisphere.

According to WHO and countries that have launched HSI vaccination programmes, commonly reported adverse events of HSI vaccines include swelling, redness, or pain at the injection site. Other adverse events such as fever, headache, fatigue, and muscle aches, occurring shortly after vaccine administration were less commonly reported. These symptoms resolve spontaneously, usually within 48 hours. The frequency of allergic reactions is well within the expected range. In November 2009, a batch of vaccines manufactured by GSK (an adjuvanted vaccine) appeared to be associated with increased frequency of more severe forms of allergic reaction such as anaphylaxis. The use of this particular batch of vaccines was terminated pending further investigation. Please note that PANENZA® has not been associated with severe allergic reactions to date.

As expected from background incidence, a few suspected cases of Guillain-Barre syndrome (GBS) have been reported in people following temporally HSI vaccine administration in overseas countries. All such cases are being investigated by WHO and respective health authorities to determine whether these are randomly occurring events or if they might be associated with vaccination. So far, the number of GBS reported among those who received HSI vaccine in overseas countries does not exceed the normal background rates of this illness.

December 2009
Centre for Health Protection
Department of Health

Completed form should be faxed to CENO at 2477 2770 and ADR Monitoring Unit at 2572 4570

Guillain-Barre Syndrome Report following Influenza Vaccination

Note:

Part I – VII to be completed by attending/ reporting physician

(Staff of the Department of Health may contact the reporting physician and/or patient for more information)

Part VIII to be completed by the Department of Health

Part IX to be completed by Expert Group

I. Reporting Information

Date of report: _____ (am/pm)

Attending / reporting physician: _____

Contact phone number: _____

II. Personal Particular Information

(affix patient's gum label here)

III. Clinical History

Date of onset: _____ (dd/mm/yy)

Clinical presentation:

Recent history of influenza-like illnesses or other infections?

_____

Motor functions

☐ Symmetrical / *Asymmetrical* weakness* ☐ Ascending / *Descending* weakness*

☐ Upper limb involvement ☐ Lower limb involvement

☐ Facial muscle weakness ☐ Bulbar weakness

☐ *Eye muscle weakness*

*cross out the inappropriate option

Remarks: _____

_____

Sensory functions

☐ Loss of proprioception ☐ Areflexia
☐ Deep arching muscle pain ☐ Dysesthesias
☐ *Loss of pain sensation* ☐ *Loss of temperature sensation*

Remarks: _____

_____

Autonomic functions

☐ Wide fluctuation in BP ☐ Orthostatic hypotension
☐ Cardiac arrhythmia ☐ *Sphincter dysfunction*

Remarks: _____

_____

Others

☐ SIADH ☐ Encephalopathy
☐ *Fever (early stage)*

Remarks: _____

_____

IV. Past Medical History

Past history/family history of GBS and other neurological diseases?

_____

Reactions to previous vaccinations?

_____

Pre-existing disorders?

_____

Remarks:

V. Laboratory and Diagnostic Tests

CSF _____
EMG _____
Nerve conduction study _____
Other test(s) _____

Remarks:

VI. Management

Date of admission _____

ICU admission Y / N _____

Intubation Y / N _____

IVIG Y / N _____

Plasmapheresis Y / N _____

Other treatment _____

Complications and Outcome

Complication(s) Y / N _____

Completely recovered? Y / N _____

Permanent disability? Y / N _____

Outcome _____

Date of discharge _____

Cause of death _____

Remarks

VII. Differential Diagnosis (can choose more than one)

☐ GBS

☐ Non-GBS – acute myelopathies

☐ Non-GBS – vasculitis polyneuropathy

☐ Non-GBS – motor neurone disease

☐ Non-GBS – myasthenia gravis

☐ Non-GBS – infective cause (botulism, Lyme disease polyradiculitis, CMV polyradiculitis, West Nile Virus complications, poliomyelitis)

☐ Non-GBS – poisoning

☐ Others _____

Signed by attending / reporting physician : _____

Report can be returned by fax to 2572 4570
For follow-up report (see Guidance Notes), please provide ADRMU Ref. No.: _____

Department of Health
Adverse Drug Reactions (ADR) Report Form

Please read the following instructions:

1. Please read the Guidance Notes for ADR Reporting before completing the ADR report form.
2. This report form is used for voluntary report of all suspected ADR. There is no need to put down the full name of the patient.
3. ADR can be briefly described as a noxious and unintended response to a drug or vaccine when the normal dose is used.
4. Please provide information to every section. Information of individual reporter will be treated in strict confidence.
5. For further enquires, please contact the ADR Monitoring Unit of Pharmaceutical Service of the DH at 2319 8482.

Section (A): Patient Information

Patient initials or ref. no.: _____ Weight (if known): _____ kg

Sex: M/F* Date of birth: (dd/mm/yyyy) / / or age (at last birthday): _____

For female: Is she pregnant? Yes/No*

Section (B): About the Adverse Drug Reaction

Date of onset of ADR: (dd/mm/yyyy) / /

Description:_____

_____

ADR category (for vaccine related ADR only):

❑ Allergic reaction ❑ Local reaction ❑ Systemic reaction ❑ Neurological disorders

Severity:

❑ Life threatening ❑ Hospitalised on: (dd/mm/yyyy) / / ❑ Hospitalisation NOT required

All Drug Therapies/Vaccines Prior to ADR (Please use trade names and, for vaccine, indicate batch number. Please circle the suspected drug.)	**Daily Dosage** (dose number for vaccines e.g. 1st DTP)	**Route**	**Date Begun**	**Date Stopped**	**Reason for Use**

Section (C): Treatment & Outcome

Treatment of ADR : ❑ No ❑ Yes. Details: _____

Outcome:❑ Recovered ❑ Not yet recovered ❑Unknown ❑ Died on: (dd/mm/yyyy) / /

Sequelae: ❑ No ❑ Yes: ❑ Persistent disability ❑ Birth defect ❑ Medically significant events

Details: _____

Remarks (allergies or other relevant history):_____

_____

Section (D): Reporter Details

Name of Doctor/Chinese medicine practitioner/Dentist/Pharmacist*: _____

in private/public* service.

Correspondence Address_____

Date: _____ Tel. no.: _____Fax. no.: _____ Email: _____

* delete whichever inappropriate

Please seal the edge

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Please
Affix
Stamp

To: ADR Monitoring Unit
Pharmaceutical Service
Department of Health
3/F, Public Health Laboratory Centre
382 Nam Cheong Street, Kowloon

Please fold inside along the dotted line and seal the edge