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சுகாதார அமைச்சு
Ministry of Health

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Date)

05th July 2010

Provincial/Regional Directors of Health Services,
Directors of Teaching Hospitals/Specialized Campaigns,
MSS/DMOO of Provincial/Base Hospitals,
Heads of Decentralized Units,
Regional Epidemiologists, Medical Officers (MCH),
Medical Officers of Health,
Port Health Officers.

Provision of Influenza A (H1N1) Vaccine in Sri Lanka

Sri Lanka has received a stock of Influenza A (H1N1) vaccine donated by the World Health Organization as a part of mitigation measures for the Influenza A (H1N1) pandemic.

Though there is no activity of Influenza A (H1N1) in the country at present, considering the possibility of another wave, the Ministry of Health has decided to make vaccines available to following categories on request.

- (1) health care workers
- (2) other front line workers who are at risk
 - a. staff at entry point to the country (Air Port / Sea Port)
 - b. members of the armed forces and police
 - c. individuals involved in tourism industry
- (3) patients with chronic morbidity
- (4) any person who travels to a foreign country
- (5) any other person who considers him/herself at risk

Please organize vaccination in your division/institute for the groups referred to above as per attached guidelines on request basis and intimate your vaccine requirements to the Epidemiology Unit as early as possible. Please inform all concern on the availability of this vaccine at your institution.

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Dr. U. A. Mendis
Director General of Health Services

Cc.

1. Chairman – Sri Lanka Airport and Aviation Authority
2. Chairman – Sri Lanka Ports Authority
3. Director of Medical Services, Sri Lanka Army, Navy, Air force
4. Director, Police Hospital, Colombo 05
5. Director General, Sri Lanka Tourist Board

Guidelines on administration of Influenza A (H1N1) 2009 vaccine

1. INTRODUCTION:

This vaccine is a monovalent, unadjuvanted inactivated, split-virus vaccine, produced by the CSL Biotherapies (Parkville, Australia). Using one of the candidate reassortant vaccine viruses recommended by the WHO. The vaccine was prepared in embryonated chicken eggs with the same standard techniques that are used for the production of seasonal trivalent inactivated vaccines.

2. GROUPS FOR VACCINATION IN SRI LANKA

The following groups will be considered for vaccination against influenza A/H1N1.

- (a) **Health workers** in both public and private health care institutions which include both curative and preventive health care institutions. All Medical Officers, Assistant and Registered Medical Officers, Nursing Officers, Paramedical staff, clerical staff, attendants, labourers, security staff and any other staff attached to curative health care institutions are eligible to receive the vaccine on their request. In preventive health care institutions, MOH, AMOH, other Medical Officers, PHNS, SPHM, PHM, SPHI, PHI, PPO, HMA, labourers or any other staff attached to preventive health institutions (RDHS, MOH offices, and special campaigns) should receive the vaccine on their request.
- (b) **Individuals with potential high risk of severe disease and complications** of pandemic influenza A/H1N1 at any age as indicated in the General Circular No: 01-37/2009 should also be considered for vaccination. These individuals will comprise of
 - People with at least one chronic morbidity potentially capable of leading to severe disease, rapid progression or complication of pandemic influenza A/H1N1
 - Chronic lung diseases including bronchial asthma
 - Chronic cardiovascular disorders excluding hypertension
 - Chronic renal, hepatic and haematological conditions including sickle cell disease,
 - Metabolic disorders including diabetes mellitus
 - People with immunosuppressive conditions
 - Immunosuppression caused by medications
 - HIV/AIDS
 - Those with disorders compromising respiratory function
 - e.g. spinal cord injuries, seizure disorders
 - Any other disease deemed high risk by a consultant physician /paediatrician or any other specialist medical officer
- (c) **Any front line worker who is at risk of influenza A/H1N1**
 - Staff at entry point to the country (Air port/sea port)
 - Members of the armed forces and police
 - Individuals involved in tourism industry
- (d) **Any person who travels to a foreign country**
- (e) **Any other person who considers him/herself at risk**

3. DOSE AND SCHEDULE

since data on the use of this vaccine in children is not yet available, it is generally recommended to adults adolescents and children 10 years of age and older.

Children aged 10 years to 18 years

A single dose of 0.5 ml

Adults over 18 years

A single dose of 0.5 ml.

Route and site of administration

intramuscularly to the deltoid muscle of the upper arm.

4. STORAGE

Vaccine should be stored at 2–8°C (36–46°F). Do not freeze. Protect from light. The vaccine in the vial must be used within 24 hours after piercing the stopper. Do not use Influenza A (H1N1) 2009 Monovalent Vaccine beyond the expiration date printed on the label.

5. CONTRAINDICATIONS

- Individuals with known hypersensitivity to eggs, chicken protein, Thiomersal (for Thiomersal containing vaccines only), neomycin or polymyxin B sulphate (Though this vaccine contains a limited amount of egg protein, these proteins can induce immediate hypersensitivity reactions among persons who have severe egg allergy)
- Anyone who has had a life threatening reactions to a previous dose of any influenza vaccine

6. PRECAUTIONS:

Immunization must be postponed in people who have febrile (Fever $>38^{\circ}\text{C}$) and acute illness

Precautions should be taken to avoid undesirable reactions before administering the I A /H1N1/ 2009 MV vaccine. These precautions include review of the recipient's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine although it is not a contraindication.

If Guillain Barre Syndrome (GBS) has occurred within 6 months of previous influenza vaccination, decision to administer I A /H1N1/ 2009 MV vaccine should be based on careful consideration of potential benefits and risks.

I A /H1N1/ 2009 MV vaccine could be administered to immunocompromised individuals including those who are receiving systemic corticosteroids and immunosuppressive therapy. However, it has to be borne in mind that they may have diminished immune response.

All vaccine centers should have emergency trays and relevant health staff in ready to manage possible anaphylactic reactions if it occurs following administration of I A /H1N1/ 2009 MV.

7. ADVERSE EFFECTS FOLLOWING IMMUNIZATION

IA/H1N1/2009 CSL MV is relatively a new vaccine and therefore information on AEFI specific to IA/H1N1/2009 CSL MV detected in clinical trials and post marketing surveillance is limited at the moment. This limited information demonstrates that the IA/H1N1/2009 CSL MV is safe and well tolerated. Since the CSL's trivalent seasonal influenza vaccine is manufactured by the same process, AEFI due to influenza A/H1N1/2009 CSL MV should be very much similar to that due to trivalent seasonal influenza vaccines. Therefore based on clinical trials and post marketing surveillance data of seasonal influenza vaccines and influenza A/H1N1/2009 CSL MV, following AEFI are possible for IA/H1N1 MV.

AEFI in adults:

Most common local AEFI were tenderness, pain, redness and swelling at the injection site
Most common systemic AEFI were headache, malaise and muscle ache

AEFI in children

Most common local AEFI were pain redness and swelling at the injection site.
Most common systemic AEFI irritability, rhinitis, fever, cough, loss of appetite, vomiting, diarrhea, headache, muscle ache and sore throat

The majority of these events are mild to moderate in intensity and self limiting

Please note that serious allergic reactions including anaphylactic shocks are possible after administration of CSL influenza A/H1N1/2009 MV as these reactions have been reported in post marketing surveillance of trivalent seasonal influenza vaccine

8. USE IN SPECIFIC GROUPS

Pregnancy:

Safety and effectiveness of Influenza A /H1N1/ 2009 MV have not been established in clinical trials in pregnant women. However it is widely accepted by regulatory authorities worldwide (ACIP, TGA, WHO) that the benefits of vaccinating pregnant women outweigh the risks. As pregnant women are at increased risk for severe disease, potentially resulting in spontaneous abortion and/or death, especially during the second and third trimesters of pregnancy, inactivated non-adjuvanted Influenza A /H1N1/ 2009 vaccines similar to most inactivated seasonal influenza trivalent vaccines are considered the preferred option given the extensive safety data on their (inactivated, non-adjuvanted seasonal influenza vaccine) use in pregnant women. USA, Canada, Australia, UK and many other countries recommend vaccination of pregnant women irrespective of the trimester against pandemic influenza A/H1N1. AEFI with inactivated seasonal influenza vaccines have not differed among pregnant and non-pregnant vaccinees. The CDC USA Immunization Safety Office reported in 2006 that the VAERS database (a passive surveillance system in the USA that collects spontaneously reported AEFI) indicated that there were no unexpected adverse events following trivalent influenza vaccines in approximately 2 million pregnant women vaccinated between 2000 and 2003. Considering the current epidemiological situation of H1N1 pandemic , currently it is recommended to consider the benefits and risks of vaccination on individual case by case basis before administering the vaccine during pregrnancy in Sri Lanka.

9. RECORD KEEPING

- (1) Fill an Influenza A / H1N1 immunization card for all vaccine recipients (EPID/INFA/H1N1V/02).
- (2) Maintain an immunization register for vaccine recipients (EPID/INFA/H1N1/03).
- (3) Complete the return of immunization of Influenza A / H1N1 vaccine by health institution (EPID/INFA/H1N1/04) and send it to the RDHS/RE of the district at the end of the program.
- (4) All RE's should complete "the return of immunization of Influenza A / H1N1, Epidemiology Unit at the end of the program.
- (5) Recording of AEFI should be carried out according to the currently existing practice in the EPI.