

NHS Cambridgeshire

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR H1N1 INFLUENZA VACCINE(▼)

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Protocol Details	
Date comes into effect	July 2010
Date of expiry + review	September 2011 or in the light of significant changes in best practice
Staff characteristics	<p>Registered health care professional employed by the NHS organisation above or independent contractors within them, who has completed immunisation and vaccination training (theoretical and practical competency assessment), training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support (annual practice update session to be undertaken) and authorised to work under PGDs. Access to the current edition of the Green Book Immunisation against Infectious Disease (2006) and any relevant updates.</p> <p>www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254</p> <p style="text-align: center;">>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION << >> OF THIS PGD BEFORE WORKING UNDER IT <<</p>
Clinical Details	
Indication	This PGD is to be followed by all registered health care professionals, authorised to work under PGD, who carry out immunisations in hospitals, clinics, schools, surgeries, patients' homes or other locations. Facilities for treating anaphylaxis must be available.
Inclusion criteria	<p>Recommended for all aged 6 months and over (including breast feeding women) (Pandemrix®▼/Celvapan®▼) as identified within the Green Book Influenza chapter. Children should receive the GSK vaccine Pandemrix®▼.</p> <p>Pregnant women should receive the GSK vaccine Pandemrix®▼.</p> <p>Protection of travellers to southern hemisphere countries with the GSK vaccine Pandemrix®▼ see details at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_114372.pdf During their influenza season, information on the Southern Hemisphere flu season is available from the National Travel Health Network and Centre (website: www.nathnac.org).</p>
Exclusion criteria	<p>A confirmed anaphylactic reaction to a previous dose of the vaccine.</p> <p>A confirmed anaphylactic reaction to any component of the vaccine.</p> <p>A confirmed anaphylactic reaction to egg or chicken protein (Pandemrix®▼ only) as this vaccine is prepared in hens eggs.</p> <p>Children under the age of 6 months (Pandemrix®▼/Celvapan®▼)</p>
Precautions	<p>Immunisation should be postponed in patients with acute febrile illness/infection.</p> <p>Pandemrix® (▼) or Celvapan® (▼) can be given at the same time as other vaccines including the seasonal influenza vaccine and other childhood vaccines. Vaccines should be given at separate sites, preferably in different limbs.</p> <p>Pandemrix® (▼) and Celvapan® (▼) vaccine products are not interchangeable, so the same vaccine product must be used if a two dose schedule is being followed.</p> <p>Following a full course of vaccination antibody response in immunosuppressed patients may be insufficient, therefore their household contacts should also be offered vaccination.</p> <p>There are clear benefits to offering to pregnant women early protection against influenza H1N1 infection. A one-dose schedule of Pandemrix® (▼) should be given. There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated viral or bacterial vaccines or toxoids (Plotkin and Orenstein, 2004). There is no evidence of risk from thiomersal-containing vaccines to pregnant women or young children.</p>
Management of excluded patients	<p>Give further information about the vaccine or a future appointment to attend. In the case of a previous severe reaction refer to the appropriate medical officer e.g. Consultant or GP.</p> <p>Give information about H1N1 Influenza disease- signs and symptoms, contact number/website flu line and information on use of anti-viral medication.</p>
Action for patients not	Make patient aware of alternative, risks and potential consequences of not being

wishing to receive care under this PGD	vaccinated. Give advice about hand hygiene and avoiding Influenza Give information about H1N1 Influenza disease- signs and symptoms, contact number/website for concerns and information on use of anti-viral medication should H1N1 Influenza be contracted. Inform GP or refer to local policies. Document refusal in clinical records.
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CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR H1N1 INFLUENZA VACCINE(▼) VERSION: TEMPLATE-2010.4 (Page 2 of 4)

Description of Treatment	
Name of medicine	Influenza A (H1N1) Vaccine Trade Names: Pandemrix® (▼):manufactured by GlaxoSmithKline Celvapan® (▼):manufactured by Baxter Healthcare
Formulation and route	Intramuscular (Deltoid area of upper arm or anterolateral aspect of thigh) Subcutaneous route for those with bleeding disorders
Strength	Pandemrix® (▼) :1 mixed vial contains 10 doses Celvapan® (▼): 1 multi-dose vial contains 10 doses
Dosage	<p>Pandemrix® (▼):</p> <ul style="list-style-type: none"> • Children aged 6 months to 9 years: 0.25ml • Children aged 10 years and over and adults: 0.5ml • Immunocompromised children aged 6 months to 9 years: 0.25ml dose initially, with a repeated dose of 0.25ml at an interval of at least 3 weeks • Immunocompromised individuals 10 years and over, 0.5ml initially with a repeated dose of 0.5ml at an interval of at least 3 weeks <p>Celvapan® (▼):</p> <ul style="list-style-type: none"> • Adults and children aged 6 months and over, 0.5ml dose initially with a repeat dose of 0.5 ml dose at an interval of at least 3 weeks <p>Pandemrix® (▼): is the vaccine of choice for children and young people under 18 years of age because there is no data for Celvapan® in children.</p>
Repeated dose instructions	See above
Duration of treatment	See above
Quantity to supply	See above
Legal status	Prescription Only Medicine ▼ (POM)
Special Precautions	Explain indications, contraindications and cautions (Refer to Green Book)
Adverse effects	<p>Undesirable effects for Pandemrix® (▼) and Celvapan® (▼) vaccines may include: Headache, fever, insomnia, dizziness, somnolence, fatigue, malaise, arthralgia, myalgia, induration, lymphadenopathy, increased sweating, shivering and influenza like illness. Injection site reactions such as ecchymosis, swelling, pain and redness at the site, pruritus, rash.</p> <p>Gastrointestinal symptoms (such as diarrhoea, vomiting, abdominal pain, nausea)</p> <p>This list is not exhaustive. Refer to current BNF and SPC for complete list. If any side effects are reported, as these are both black triangle drugs, complete & submit a report to the MHRA using the swine flu ADR portal found at www.mhra.gov.uk/swineflu. This replaces the Yellow Card system for the H1N1 Influenza vaccine only</p>
Advice necessary	<ul style="list-style-type: none"> ▪ Give patient the patient information leaflet (PIL). Give patient record card and explain patient can also directly report any suspected adverse reactions directly to the MHRA ▪ Advice on the prevention and management of fever and other common/uncommon post-vaccination adverse effects. ▪ Date of next vaccination if a two dose schedule is being followed.

	<ul style="list-style-type: none"> Give advice about hand hygiene and avoiding Influenza.
Records and Follow Up	
Referral arrangements	Any health professional administering a vaccination must be able to identify and contact an appropriate medical officer, e.g. CMO, consultant paediatrician, GP, as necessary, e.g. in the case of an child with an egg allergy.
Records to be kept	As per local documentation requirements. Record the brand of vaccine given, batch number and expiry date/s. Give PIL, patient record card and explain the patient can also directly report any suspected adverse reactions directly to the MHRA. Document any reaction in patient's medical notes.
Follow up	Arrange subsequent vaccination, if a two dose schedule is being followed.
<p align="center">Protocol, organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.</p>	

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MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR H1N1 INFLUENZA VACCINE (▼)

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
Protocol Owner

Details of protocol owner	Name: Val Shaw Assistant Chief Pharmacist NHS Cambridgeshire, Huntingdon Area Office, California Road, Huntingdon PE29 1BN Contact Telephone: 01480 354379 Contact Email: val.shaw@cambridgeshire.nhs.uk
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Protocol Details

Date comes into effect	July 2010
Date of expiry + review	September 2011 or in the light of significant changes in best practice
Changes to previous version	Updated to reflect use as a travel vaccine to the southern hemisphere http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_11437.pdf
Staff characteristics	Registered health care professional employed by the NHS organisation(s) above or independent contractors within them, who has completed immunisation and vaccination training (theoretical and practical competency assessment), training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support (annual practice update session to be undertaken) and authorised to work under PGDs. Access to the current edition of the Green Book Immunisation against Infectious Disease (2006) and any relevant updates www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254 <p align="center">>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION << >> OF THIS PGD BEFORE WORKING UNDER IT <<</p>
Equality and Diversity	This PGD has been assessed as not raising any equality or diversity issues.

Protocol Authorisation

Lead Doctor	Name: Dr Lincoln Sargeant Position: Consultant in Public Health Signature: _____ Date: Signed by e-mail 19/7/10
Lead Pharmacist	Name: Val Shaw Position: Assistant Chief Pharmacist Signature:  H1N1 Date: 16/7/10
Lead Nurse	Name: Jan Gower Position: Lead Practice Nurse Clinical Governance Signature: _____ Date: Signed by e-mail 19/7/10

Appendix 1

The new advice (1st September 2010) from JCVI for the winter influenza season for all groups is summarised below :

Table 1: Influenza Vaccination for Different Groups for the 2010/11 Programme (from 1st September 2010) Group	Monovalent H1N1 Swine Influenza Vaccine	Trivalent Seasonal Influenza Vaccine
People in the usual seasonal influenza clinical risk groups aged 5 years – 64 years	X	√
All people aged 65 years and over	X	√
Children in the usual seasonal influenza clinical risk groups aged between six months and below five years	√ (if they have <u>not</u> previously received the Monovalent H1N1 Swine Influenza Vaccine)	√ (to be administered at the same time as Monovalent H1N1 Swine Influenza Vaccine if this is being given)
All immunosuppressed people who <u>have</u> previously received the monovalent H1N1 swine vaccine	X	√
All immunosuppressed children aged under 13 who have <u>not</u> received the monovalent H1N1 swine vaccine previously	√ (to be given at the same time as the first dose of Trivalent Seasonal Influenza Vaccine)	√ (dose one to be given at the same time as Monovalent H1N1 Swine Influenza Vaccine) √ (second dose to be given 4 weeks after the first)
All immunosuppressed people aged 13 years plus who have <u>not</u> received the monovalent H1N1 swine influenza vaccine previously	√ (to be given 4 weeks before the Trivalent Seasonal Influenza Vaccine)	√ (to be given 4 weeks after Monovalent H1N1 Swine Influenza Vaccine)
Pregnant women who are in a clinical risk group for seasonal influenza	X	√
Pregnant women who are not in a clinical risk group for seasonal influenza	X	√ (if they have <u>not</u> previously received the Monovalent H1N1 Swine Influenza Vaccine)
Frontline Health and Social Care Workers	X	√
Poultry Workers	X	√