

STANDING DRUG ORDER

Administration of Panvax® H1N1 - Pandemic (H1N1) 2009 vaccine

<u>Effective:</u>	04 December 2009
<u>Validity:</u>	This order is valid for twelve months from the above date.
<u>Application:</u>	This standing drug order covers the administration of the Pandemic (H1N1) 2009 vaccines – Panvax® H1N1 and Panvax® H1N1 Junior – based on the recommendations from the Australian Department of Health and Ageing.
<u>Objective:</u>	To enable Registered Nurses and medication endorsed enrolled nurses (under the delegated supervision of a registered nurse) to administer the Pandemic (H1N1) 2009 vaccines – Panvax® H1N1 and Panvax® Junior – as part of the Queensland Health Pandemic response.

STANDING DRUG ORDER

I hereby authorize the implementation of this Standing Drug Order. Under this Order and in accordance with the provisions of the *Health (Drugs and Poisons) Regulation 1996* a registered nurse (Section 175(1)) or a medication endorsed enrolled nurse practicing under the delegated supervision of a registered nurse (Section 162(1)), may administer to a consenting adult or to a child with consent from a parent/guardian, as defined in this order, unless contraindicated, Pandemic (H1N1) 2009 vaccine as follows:

- to an adult or to a child aged 10 years or older – one dose (15µg) of Panvax® H1N1;
- to a child aged 36 months to 9 years – two doses (15µg per dose) of Panvax® H1N1, with the second dose given after an interval of at least 4 weeks;
- to a child aged 6 months to 35 months:
 - two doses (7.5µg per dose) of Panvax® H1N1, with the second dose given after an interval of at least 4 weeks, OR
 - two doses of Panvax® H1N1 Junior, with the second dose given after an interval of at least 4 weeks.

Signed: Original signed and authorised by

Dr Jeannette Young
Chief Health Officer

4 / 12 / 09

1. Panvax® H1N1 vaccination recommendations

Queensland Health will facilitate the vaccination of the Queensland population in accordance with the recommendations of the Australian Government.

One dose (15µg) of Panvax® H1N1 vaccine is recommended for adults and children from 10 years of age.

Vaccination of children from 6 months of age to 9 years of age is recommended in accordance with the table below.

Age	Dose	Formulation	Number of doses
6 months – 35 months	0.25ml (7.5µg)	Panvax H1N1 Junior pre-filled syringe or Panvax H1N1 multidose vial	2 doses at least 4 weeks apart
36 months – 9 years	0.5ml (15µg)	Panvax H1N1 multidose vial	2 doses at least 4 weeks apart

2. Purpose of this Standing Drug Order

Under the provisions of the *Health (Drugs and Poisons) Regulation 1996* registered nurses (Section 175(1)) and medication endorsed enrolled nurses (EEN) (Section 162(1)) are authorised to administer a restricted drug to a person on the oral or written instruction of a doctor or nurse practitioner, as well as a dentist or physician's assistant.

The purpose of this Standing Drug Order is to enable Registered Nurses and EENs working under the delegated supervision of a registered nurse, to administer the Panvax® H1N1 vaccine or Panvax® H1N1 Junior vaccine to eligible people, as defined by the Australian Government Department of Health and Ageing, in Queensland.

Delegation to EENs for the administration of this Order should be in accordance with the principles of the *Scope of practice framework for nurses and midwives*¹

3. Panvax® H1N1 vaccine

All influenza vaccines currently available in Australia, including the Panvax® H1N1 vaccine and Panvax® H1N1 Junior vaccine, are prepared from purified and inactivated (i.e. killed) influenza virus which has been cultivated in hen eggs. This means that (i) the vaccines are not live virus vaccines, and (ii) may contain traces of egg derived proteins.

Panvax® H1N1 vaccine has been formulated in multi-dose vials containing the preservative thiomersal. Panvax® H1N1 Junior vaccine is formulated in a single pre-filled syringe and does not contain any thiomersal.

Both Panvax® H1N1 vaccine and Panvax H1N1 Junior® vaccine contain antigen of the following type: A/California/7/2009 (H1N1) (NYMC X-179A) (A/California/7/2009 (H1N1)v-like) with:

- Panvax® H1N1 – 15 µg haemagglutinin (HA) per dose of 0.5ml; and
- Panvax H1N1 Junior® – 7.5µg haemagglutinin (HA) per dose of 0.25ml.

¹ *Scope of practice framework for nurses and midwives* (2005), Queensland Nursing Council, Brisbane.

4. Vaccine presentation

Panvax® H1N1

Panvax® H1N1 vaccine is presented in a multi-dose vial.

Each multi-dose vial contains a nominal 5 ml (10 doses packed in red boxes of 10 vials) or 10ml (18 doses packed in blue boxes of 50 or 10 vials) of vaccine and is closed with a latex-free stopper and sealed with an aluminium crimp seal. The aluminium seal has a plastic tear-away cap attached that is removed to gain access to the vial closure. The cap is present to protect the vial closure and to indicate if the vial has been tampered with. Once removed, the cap cannot be re-affixed to the vial.

An education package has been developed by Queensland Health detailing the safe use and administration of vaccine from multidose vials, using either a retractable or a conventional syringe. Additionally, guidelines have been developed by the Australian Technical Advisory Group on Immunisation (ATAGI) and the Royal Australian College of General Practitioners (RACGP) on the use of vaccine presented in multi-dose vials. Anyone administering Panvax® H1N1 vaccine from a multidose vial must ensure they have received appropriate training through study of at least one of these resources.

Panvax® H1N1 Junior

Panvax® H1N1 Junior vaccine is presented in a single pre-filled syringe. The 0.25ml pre-filled syringes are for single use and any remaining contents should be discarded in accordance with local requirements.

Errors in administration

Errors in administration of these vaccines should be reported to the nursing supervisor in accordance with local policies and in addition to the local Population Health Unit.

5. Vaccine transport and storage

Panvax® H1N1 vaccine and Panvax® H1N1 Junior vaccine should be transported and stored at +2°C to +8°C, and must not be frozen. If these vaccines been exposed to temperatures outside the +2°C to +8°C range, they should not be used and must be reported to the Queensland Health Immunisation Program on 3328 9888 during normal business hours.

6. Adverse events

NB. Because Panvax® H1N1 vaccines and Panvax® H1N1 Junior vaccine contain small portions of a killed virus, they are non-infectious and cannot cause influenza.

Local reactions, including redness and soreness at the injection site are common following any influenza vaccination, including vaccination Panvax® H1N1 vaccine and Panvax H1N1 Junior® vaccine. They are typically mild, and do not usually interfere with usual daily activities. They can be managed with a cold compress at the injection site, simple analgesics, etc.

Headache, fever, fatigue and muscle aches are less common following vaccination and may last for 1 to 2 days.

Immediate adverse events, anaphylaxis in particular, are very rare following influenza vaccination. They probably represent an allergic response to residual egg protein in the vaccine.

There have been reports of a possible association with swine influenza vaccination and the development of Guillain-Barré syndrome (GBS). Whether this is causal or only a temporal association is unclear. Viral and bacterial infections, especially *Campylobacter jejuni* and acute respiratory tract infections are the commonest antecedents of GBS. The estimated frequency of influenza-related GBS is four to seven times higher than the estimated frequency of influenza vaccine-associated GBS. If there is a causal association with influenza vaccine it is of the order of 1-2 per million people vaccinated. During the 1976 swine influenza vaccination campaign in the USA, about 10 persons per million vaccinated persons developed GBS. The reason why GBS developed in association with that specific vaccine has never been firmly established. Manufacturing processes for influenza vaccines have been significantly improved since then.

All adverse events must be reported by using the Queensland Health *Adverse Event Following Immunisation* form at:

http://www.health.qld.gov.au/ph/documents/cdb/adverse_event_immun.pdf

The completed form is to be faxed to the number as stated on the form.

7. Contraindications

Panvax® H1N1 vaccine and Panvax® H1N1 Junior vaccine are contraindicated in anyone who has experienced anaphylaxis following a previous dose of any influenza vaccine, or who has experienced anaphylaxis following any vaccine component (see description section of Package Insert), including the antibiotics neomycin or polymyxin.

These vaccines should not be used in anyone who has experienced anaphylaxis to eggs or chicken protein.

Vaccination of clients with acute febrile illness (fever >38.5°C) should be postponed until the symptoms have settled.

8. Special precautions

Persons who developed GBS within 6-8 weeks of having a seasonal flu vaccine may possibly be at increased risk of again developing GBS if given the Panvax® H1N1 vaccine or Panvax® H1N1 Junior vaccine. Medical advice should be sought prior to vaccinating someone with a history of GBS.

Pregnancy or lactation are not a contraindication for vaccination with Panvax® H1N1 vaccine. Vaccination with Panvax® H1N1 vaccine is strongly recommended for pregnant women and for parents of infants aged 0 – 6 months.

The immunological response may be diminished if the patient is undergoing long term, high dose corticosteroid or immunosuppressant treatment. Patients should be advised of this at time of vaccination.

9. THE STANDING DRUG ORDER

A Registered Nurse or an EEN working under the delegated supervision of a registered nurse, may administer the Panvax® H1N1 vaccine or Panvax® H1N1 Junior vaccine to any person aged 6 months or older provided that:

- the nurse is providing the vaccination for or on behalf of Queensland Health as part of the Queensland Health pandemic response;
- the nurse has ready access to the protocols, drugs (particularly 1:1,000 adrenaline) and equipment (including 1ml syringe for intramuscular injection of adrenaline) for the management of anaphylaxis;
- the vaccine cold chain is maintained according to Queensland Health Policy;
- valid consent, either verbal or written, is obtained from each client prior to vaccination, noting that valid consent requires that the client has received adequate information about the vaccine including possible adverse events following immunisation;
- each client or their legal guardian is asked if they have serious (i.e. anaphylactic) allergies to any component in the vaccine, particularly eggs;
- where a multi-dose vial is used, the expiry date is checked, the date and time of opening the vial is clearly marked, and less than 24 hours have passed since the vial was first opened;
- where a previously drawn up dose of vaccine is to be used, the syringe must be appropriately labelled (including content details, time and date of drawing up), less than 4 hours must have passed since the vaccine was drawn up, and the cold chain must have been maintained;
- the correct dose (15µg in 0.5ml for children 3 years and older and 7.5µg in 0.25ml for children 6 months to 35 months) is administered to the client;
- each dose is administered by intramuscular or subcutaneous injection, and the used syringe and needle disposed of according to standard infection control procedures;
- each client should remain in the clinic/hospital/surgery for 15 minutes following the vaccination;
- the details of each vaccination, including the date, batch number, and the name (and signature) of the person administering the vaccine are to be documented;
- any significant adverse event following influenza vaccination must be documented on a Queensland Health *Adverse Event Following Immunisation (AEFI) – Initial Report* form, located at:
http://www.health.qld.gov.au/ph/documents/cdb/adverse_event_immun.pdf