National Pandemic (H1N1) 2009 Influenza Vaccination Program - Information for General Practice

Prepared by DOH H1N1 vaccination team
September 2009
Emergence of Pandemic (H1N1) 2009 Influenza

- International recognition of novel virus in April 2009 (a.k.a. H1N1 Influenza 09, Pandemic (H1N1) 2009, swine flu)

- Illness in most is generally mild with symptoms similar to seasonal influenza

- Unusual features:
  - younger age of cases
  - relative sparing of the 60+ group compared to seasonal influenza
  - lower respiratory tract disease in hospitalised patients
PANVAX® H1N1 Vaccine

- Manufactured in Australia by CSL Limited
- Made using the same method used each year to produce the seasonal influenza vaccine
- Vaccine is distributed in 5mL (10 dose) and 10mL (18 dose) multi-dose vials (MDV) with thiomersal used as a preservative
- Registered by the TGA on Friday 18 September for use in people over the age of 10 years
- The campaign is expected to start on Wednesday 30 September
- Clinical trial data demonstrates sufficient immune response & an acceptable safety profile after one 15mcg (0.5mL) dose in immunocompetent adults
10 mL MDV – blue packaging – 18 doses
Panvax® H1N1 Vaccine
H1N1 Pandemic influenza vaccine
(split virion, inactivated)

For intramuscular or deep subcutaneous injection, 0.5 mL dose
10 x 5 mL Multi-dose Vials

CSL Limited 45 Poplar Road Parkville VIC

5 mL MDV – pink packaging – 10 doses
Why vaccinate?

- Protect those most at risk of severe illness from influenza
- Build a widespread level of immunity to the pandemic virus across NSW
- Reduce the likelihood of influenza outbreaks in institutional settings (e.g., prisons, Aged Care Facilities and boarding schools)

The vaccine is FREE and OPTIONAL.
Who can be vaccinated?

- The vaccine is available to anyone who wants to protect themselves against pandemic influenza

- It is important to encourage some groups to be vaccinated – these groups have been called “priority groups”
Priority groups

- Pregnant women
- Obese people
- Aboriginal people
- Healthcare workers
- Community carers/family carers involved with direct patient care
- People in remote or isolated communities
- Parents of very young children

- People with certain chronic medical conditions:
  - Chronic kidney/liver/lung disease (including asthma)
  - Chronic heart conditions
  - Blood disorders (including sickle cell disease)
  - Neurological disorders
  - Metabolic disorders (ie diabetes)
  - Weakened or suppressed immune systems (ie from cancers, medication, HIV/AIDS)

Other people may receive the vaccine if they wish.
Ordering vaccine and vacpacs

- GPs to order vaccine and vacpacs through State Vaccine Centre
- Allow three working days for delivery
- Deliveries will commence from Tuesday 22 September

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<tr>
<th>PROVIDER DETAILS</th>
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<tr>
<td><strong>Date:</strong></td>
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<tr>
<td>Practice Name:</td>
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<td>Delivery Address:</td>
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<td><strong>Phone:</strong></td>
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<td><strong>Fax:</strong></td>
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**DECLARATION:**

For practices with only a single practitioner, this declaration must be made by the practitioner. For practices with multiple practitioners this declaration must be made by a duly authorised practitioner or practice manager on behalf of the practice.

- I/we agree to store the vaccine between 2°C to 8°C and to comply with cold chain recommendations in the National Vaccine Storage Guidelines: Store for 5.
- I/we agree to adhere to strict infection control practices whilst using multi-dose vaccine vials.
- I/we will read and adhere to the endorsed Multi-dose Vial Guidelines when available. They will be placed on the NSW Health website.

Name of authorised practitioner:

Signature:

Date: / / 

<table>
<thead>
<tr>
<th>ORDER:</th>
<th>Number of doses to be supplied</th>
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<tbody>
<tr>
<td>PANVAX (H1N1 pandemic influenza vaccine)</td>
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<tr>
<td>Australian Government Vaccination Packs (Disposable equipment for 200 vaccinations)</td>
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</table>
Vaccine transport, storage and handling

- State Vaccine Centre will distribute vaccine, vacpacs & consent forms to general practices based on received orders.


- Vaccine stored between +2°C and +8°C
Authority to administer PANVAX®

- **Authorised Nurse Immunisers**
  - Registered Nurses who have undertaken the required training and meet other specified conditions (PD2008_033 *Immunisation Services – Authority for Registered Nurses*)

- **Registered Nurses**
  - Registered Nurses working under medical direction

- **Endorsed Enrolled Nurses**
  - Enrolled Nurses who have completed an approved medication course **AND** work under the direction and supervision of a Registered Nurse **AND** have a written order from the medical practitioner for the individual client
Multi-dose vial (MDV) guidelines

- MDV Guidelines will be available on the NSW Health H1N1 Influenza 09 website. Adherence with these Guidelines is mandatory.

- Use of MDVs is consistent with PD2007_77 (*Medication Handling in NSW Public Hospitals*) and PD2007_036 (*NSW Infection Control Policy*) where ‘there is no other alternative available on the Australian pharmaceutical market.”

- A new needle and syringe must be used for each patient.

- Used drawing up and injection needles must be discarded immediately and **NEVER** reinserted into a MDV.

- The top of the 10mL vial must NOT be punctured more than 18 times.

- ATAGI have stated that a blunt 19G drawing up needle should not be used more than once on a vial. Use a long 23G needle (supplied with the VacPacs) instead if drawing up from a vial intermittently.
Vaccine Dosage & Administration

- 10mL MDV contains 18 doses (some volume for wastage).
- 5mL MDV contains 10 doses.
- The dose is 15mcg (0.5mls) per person.
- The vaccine is only to be administered to people aged 10+ (data on appropriate dosage for children under 10 to follow).
- An intramuscular or deep subcutaneous injection should be delivered to the upper arm (see Australian Immunisation Handbook, 9th edn.).
Will need to check with TGA guidance at registration

NSW Department of Health, 14/09/2009
Vaccine Preparation I

- Dilution/reconstitution is NOT necessary.

- A blunt tip drawing up needle may be used to draw up all the doses from a vial at once.
  - Appropriate if a clinic is being conducted, or number of people are being vaccinated in a short time period AND all the doses are likely to be used within 4 hours

- A 23G needle should be used to access the MDV if it is likely to be punctured more than once

- Syringes with drawn-up vaccine must be discarded at the end of the vaccination session or at 4 hours, whichever is the shorter. This situation should only occur in mass clinic settings, otherwise each dose should be drawn up for a particular patient and used immediately.
Vaccine Preparation II

- the vaccine must be stored at 2 - 8°C prior to and immediately after each use
- the vaccine must be protected from light during storage
- the vaccine in the vial must be used within 24 hours once the stopper has been pierced
- the stopper is to be pierced no more than 18 times to ensure stopper integrity
- aseptic technique must be used to withdraw each dose, using a separate sterile needle and syringe
- at the end of the 24 hour period, any remaining contents within the vials should be discarded
Vaccination during pregnancy

- Pregnant women are at greater risk of severe illness from Pandemic (H1N1) 2009 Influenza.

- Pregnant women, in any trimester, are encouraged to be vaccinated against Pandemic (H1N1) 2009 Influenza.

- The vaccine is not ‘live’ and is not known to be a risk to unborn babies.

- Vaccines with thiomersal have been shown to be safe for administration to pregnant women.

- Women with concerns about the vaccination should be directed to speak with their usual healthcare provider.

- MotherSafe – free hotline for women and healthcare providers
  (02) 9382-6539 – Sydney metro    1800 647 848 – NSW country
Vaccination for children

- Vaccination for children under 10 years will not be available at the start of the program.
- Immunogenicity data from a clinical trial for children under 10 is expected in mid-October 2009.
- Vaccination for small children will be provided in single dose pre-filled syringes (thiomersal free).
- Thiomersal has been removed from many vaccines used for young children as a precaution to lower babies’ and young children’s total exposure to mercury as other sources are more difficult to eliminate.
- There is no evidence that thiomersal has caused any developmental or neurological abnormalities.
### Contraindications and precautions

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<thead>
<tr>
<th>Contraindications</th>
<th>Precautions</th>
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<tr>
<td>Previous anaphylaxis from any influenza vaccine</td>
<td>As with all injectable vaccines, appropriate medical treatment and supervision should always be available to manage the rare event of an anaphylactic reaction following administration of the vaccine.</td>
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<tr>
<td>Previous anaphylaxis from any vaccine component, including antibiotics neomycin or polymyxin</td>
<td>In immunocompromised patients, the antibody response may be lower.</td>
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<td>Under 6 months of age (under 10 years old initially)</td>
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<td>Severe allergy to eggs</td>
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Side effects

- Low grade fever/headache
  - Take paracetamol but consult doctor if fever persists

- Pain or redness at the injection site
  - Apply a cold compress

- Muscle aches
  - Take paracetamol to relieve discomfort

- Drowsiness

- Seek medical advice for anything considered serious or unexpected

NDoH3
yes
NSW Department of Health, 14/09/2009
Adverse event reporting

- For **this vaccination program only**, providers are to report directly to ADRAC as soon as possible after the event either by:
  - Electronic reporting:
  - Blue Form:
- If assistance is required contact your local Public Health Unit.
Records Management

- Consent forms are available from the NSW Health website
- The use of consent forms is not mandatory
- Consent forms should be retained with the patient record
- Patient information sheets are also available from the NSW Health website
- It is strongly recommended that patients are provided with a patient information sheet.
For more information

- **General inquiries about Pandemic (H1N1) 2009 Influenza:**
  Australian Government H1N1 influenza 09 information hotline 180 2007

- **NSW-specific issues:**