

Recommended clinical protocol for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials (MDV) for children aged ≥6 months to <3 years and for all people aged ≥3 years

prepared by
The Australian Technical Advisory Group on Immunisation (ATAGI)

Rationale

The pandemic (H1N1) 2009 influenza vaccine will be distributed in multi-dose vials (MDV). MDV are not in common use in Australia and so it has been necessary to develop guidelines to ensure safe and efficient delivery of the vaccine by the health care professional.

This guideline recognises that the vaccine may be administered in a wide variety of settings ranging from dedicated immunisation clinics for large-scale vaccination, to individual vaccination in a non-dedicated immunisation setting. Immunisation providers need to identify their own setting and which procedures will apply. Smaller scale immunisation providers are encouraged to institute measures that will minimise vaccine wastage, such as running special immunisation sessions.

Aims

This protocol aims to ensure MDV are used appropriately; to prevent the potential transmission of infectious diseases; to minimise the potential risk of MDV contamination; to minimise the potential risk of medical errors; to reduce potential wastage associated with the use of MDV; and to ensure the delivery of a potent vaccine to the patient.

Note: Standard precautions following the Australian Government Department of Health and Ageing "*Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*" must be adhered to at all times.

<http://www.health.gov.au/internet/main/publishing.nsf/content/icg-guidelines-index.htm>

Office-based practices (including general practices) must adhere to the RACGP Infection Control Standards for Office-Based Practices, 4th Edition.

www.racgp.org.au/infectioncontrol

In addition, procedures need to be applied in accordance with relevant steps outlined in Chapter 1.3, 1.4 and 1.5 of *The Australian Immunisation Handbook*, 9th Edition, 2008.

1. Equipment required

2. Procedure

A. When a single dose is required

B. Non-dedicated immunisation settings

C. Dedicated immunisation clinic settings

3. Precautions

1. EQUIPMENT REQUIRED:

- Dedicated refrigerator maintained between +2°C and +8°C according to the National Vaccine storage Guidelines *Strive for 5* www.immunise.health.gov.au.
- Suitable packaging of vaccines for transportation to outreach immunisation services according to the *Strive for Five National Guidelines* www.immunise.health.gov.au.
- Access to a clean preparation area for drawing up vaccine dose(s), away from direct patient contact and distraction.
- Dose preparation (VacPacs will be supplied):
 - supply of sufficient sterile, single use 1mL syringes and needles of suitable size and gauge. Allow 1 syringe and 2 needles for each patient.
 - One needle for draw up from the MDV: 23 gauge is used when a single dose is required or in a non-dedicated immunisation setting (Refer to section A & B);

- For dedicated clinics a single 19 gauge is used for multiple extractions from the MDV (Refer to Section C); and
 - One 23 gauge needle for administration of the vaccine.
 - supply of 70% isopropyl alcohol wipes.
 - approved sharps disposal container.
 - MDV(s) of H1N1 influenza vaccine, either:
 - 5mL presentation (from which a maximum of either 20 x 0.25 mL doses [for children aged ≥6 months to <3 years] or 10 x 0.5 mL doses [for persons aged ≥3 years can be drawn])
 - 10mL presentation (from which a maximum of 36 x 0.25 mL doses [for children aged ≥6 months to <3 years] or 18 x 0.5mL doses for [persons aged ≥3 years can be drawn]. Note: there will be some wastage due to dead space in needles, syringes etc)
 - If drawing up several doses for immediate use during an immunisation session have a suitably sized, clean container which is protected from light and labelled clearly with:
 - the date and time doses were drawn;
 - the name of the person who prepared the doses;
 - vaccine name;
 - MDV batch number; and
 - expiry time of drawn doses.
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2. PROCEDURE:

1. Perform hand hygiene prior to accessing supplies and handling MDV.
2. Gather the required vaccination equipment as detailed above.
3. Ensure that cold chain conditions between +2°C and +8°C have been maintained in the practice fridge. *If the cold chain has not been maintained, **DO NOT USE** the MDV but do not discard until you have contacted and received advice from your local Public Health Unit or State/Territory Health Department Immunisation Program.*
4. Remove a MDV from the fridge. Check the expiry date. **Always** check the MDV before removing the cap to make sure you have the correct vaccine type.
5. If the MDV has previously been accessed (ie. a dose withdrawn), check the time and date of first access recorded on the MDV. **DO NOT USE** if more than 24 hours has elapsed since first access.
6. Shake the vaccine MDV. The vaccine should appear clear or very slightly opalescent (like seasonal influenza vaccine). *Examine the MDV for any particulate matter, discoloration or turbidity. If unsure, **DO NOT USE** but do not discard until you have contacted and received advice from your local Public Health Unit or State/Territory Health Department Immunisation Program. (Have the batch number and date your practice received the MDV available.)*
7. If unopened, record on the side of the MDV, the date and time that the MDV is first being accessed. Remove the protective plastic cap from the top of the MDV. **DO NOT USE** if the box of MDV has just been opened for the first time and the protective cap is missing from any MDV.
8. Inspect the bung (also known as septum, stopper or diaphragm). *If there is any doubt about the integrity of the bung, eg. MDV leaks when turned upside down, **DO NOT USE** but do not discard the MDV until you have contacted your local Public Health Unit or State/Territory Health Department Immunisation Program.*
9. Rub the bung of the MDV with a 70% isopropyl alcohol swab. Allow the bung to dry for 30 seconds.

10. Vaccine preparation:

A. WHEN A SINGLE DOSE IS REQUIRED (eg. for opportunistic vaccination)

- i. Attach a clean, sterile drawing up needle (usually 23 gauge as supplied in VacPac) to a sterile syringe, and insert the needle through the bung into the MDV using an aseptic technique.
- ii. Draw up either a 0.25 mL single dose (for children ≥ 6 months to < 3 years) or a 0.5mL single dose (for persons aged ≥ 3 years), using an aseptic technique.
- iii. Remove the drawing up needle with the filled syringe attached. Avoid touching the top of the MDV. *Never leave a drawing up needle inserted into a MDV if you have finished drawing up because it leaves the MDV vulnerable to contamination. Discard the drawing up needle immediately into the sharps disposal container.*
- iv. Attach a **new** sterile 23 gauge injection needle to the filled syringe ready for administration to the patient.
- v. If any doses remain in the MDV, refrigerate the MDV between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$ immediately after completion of vaccine draw-up. *Ensure that the date and time of first opening is written on the MDV.*
- vi. If further vaccine doses are to be drawn up from the same MDV (for next patient(s) requiring vaccination within that same 24 hour period) steps 4–9 **MUST** be repeated before drawing additional single or multiple doses.

B. NON-DEDICATED IMMUNISATION SETTINGS

(When a small number of doses, eg. between 2 and 9 doses, are required)

Note: Refer to C. below for larger scale dedicated immunisation settings when the entire contents of a MDV are to be used in one session.

- i. Perform steps 4–9.
- ii. Attach a sterile drawing up needle (usually 23 gauge as supplied in VacPac) to a sterile syringe, and insert the needle through the bung into the MDV using an aseptic technique.
- iii. Draw up either a 0.25 mL single dose (for children ≥ 6 months to < 3 years) or a 0.5mL single dose (for persons aged ≥ 3 years), using an aseptic technique.
- iv. Withdraw the drawing up needle and attached filled syringe. Avoid touching the top of the MDV. Detach the filled syringe from the drawing up needle using an aseptic technique. *Never leave a drawing up needle inserted into MDV if you have finished drawing up because it leaves the MDV vulnerable to contamination. Discard the drawing up needle immediately into the sharps disposal container.*
- v. Attach a **new** sterile 23 gauge injection needle to the filled syringe ready for administration to the patient.
- vi. Inspect the bung and cleanse as in step 9 above. Further vaccine doses should be drawn up without delay using a **new** sterile 23 gauge drawing up needle with a **new** sterile syringe. Doses should be drawn up without interruption or distraction.
- vii. Once the required numbers of doses are drawn, if any doses remain in the MDV, refrigerate the MDV between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$. *Ensure that the date and time of first opening is written on the MDV.*

- viii. Store any prepared syringes between +2°C and +8°C in a suitably sized, clean container which is protected from light and labelled clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, MDV batch number and expiry time of drawn doses, until ready to be administered. *Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred.* Refrigerated syringes containing vaccine should be discarded at the end of the immunisation session or up to a **maximum interval of 4 hours** after the vaccines have been drawn up, whichever is earlier.
11. Clean and wipe down the preparation area and perform hand hygiene.
12. Ensure that the person administering the vaccine (if they did not draw up the dose) can readily identify that the syringe contains H1N1 influenza vaccine. Administer the vaccine to patient(s) according to the current *Australian Immunisation Handbook* recommendations: www.immunise.health.gov.au *Dispose of the used syringe and injection needle into an approved sharps container immediately after vaccine administration.*
13. Ensure that the MDV batch number is recorded in each patient's record.
14. If further vaccine doses are to be drawn up from the same MDV (for patients requiring vaccination within that same 24 hour period) steps 4–9 **MUST** be repeated before drawing additional single or multiple doses.
15. Dispose of the MDV within **24 hours** of opening. This is regardless of the number of doses remaining in that opened MDV.

C. DEDICATED IMMUNISATION CLINIC SETTINGS

In settings, such as schools or dedicated immunisation clinics, where many doses of vaccine are being administered during a session, the following modifications and/or additions to the above protocol apply:

- i. Vaccines must not be drawn up into syringes and then transported to the vaccination venue. Vaccine should only be drawn up into syringes at the site where it is to be administered, immediately before administration.
- ii. Once the vaccination clinic has been set up for the session, the health care professional should draw up a small quantity of vaccine sufficient to meet the initial needs of the clinic. Monitor ongoing patient throughput to avoid drawing up unnecessary doses.
- iii. In some States and Territories, best practice requires that the person drawing up the vaccine(s) should also administer the vaccine(s). State and Territory protocols should be adhered to where in place in this regard.
- iv. No more than 1 MDV or 18 x 0.5 mL (or 36 x 0.25 mL doses), whichever is greater, should be drawn up by one health care professional at a time. This will also limit the amount of time the vaccine is held in the syringe before administration, and reduce vaccine wastage.
- v. In a large clinic setting where all doses are to be drawn up from a MDV for administration within a single vaccination session it is permissible to use a single 19 gauge drawing up needle in the MDV bung to draw up all doses in succession. This must be done without delay or distraction, using an aseptic technique and a new syringe for each dose. A new sterile injection needle must be attached to each filled syringe ready for administration to the patient. *Never leave a drawing up needle inserted into the MDV if you have finished drawing up because it leaves the MDV*

vulnerable to contamination. Discard the drawing up needle immediately into the sharps disposal container when finished.

- vi. All MDV and drawn up doses should be kept between +2°C and +8°C and protected in a suitably sized, clean container which is protected from light and labelled clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, MDV batch number and expiry time of drawn doses.
- vii. At the end of the vaccination session (or up to a **maximum interval of 4 hours** after the vaccines have been drawn up, whichever is the earlier), any remaining pre-drawn syringes should be discarded. *Vaccine that has been drawn up into syringes and not administered may not be used on subsequent days. MDV must not be re-accessed beyond 24 hours after first opening.*

3. PRECAUTIONS

- No stability data are available for vaccine stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby reduce vaccine potency.
 - Therefore, do not keep vaccine in syringes beyond the time taken for a single vaccination session (or up to a **maximum interval of 4 hours** after the vaccines have been drawn up, whichever is earlier).
 - The practice of drawing up large quantities of vaccine hours or even days before a clinic is not acceptable.
- Do not allow MDV to become submerged in water or ice in a cool-box (“esky”). Always follow the National Vaccine storage Guidelines *Strive for 5* (www.immunise.health.gov.au) for storing and transporting vaccines. Do not use MDV if the bung has been in contact with water/ice in this manner as they may be contaminated.
- It is important that appropriately sized syringes and needles, as supplied in the VacPac, are used.
 - This is so the correct number of doses can be obtained from each MDV. This is important because although MDV are overfilled to allow for the amount of vaccine lost in the dead space of syringe and needles, this loss is exacerbated when larger syringes such as 2mL or 5mL syringes are used to deliver small volumes (either 0.25 mL or 0.5mL)
- Never pool or combine leftover contents of MDV for later use.
- Do not use a MDV if sterile procedures have not been followed or there is suspicion that the vaccine has been contaminated. **DO NOT** discard the MDV until you have contacted your local Public Health Unit or State/Territory Health Department Immunisation Program.