# Checklist 1:
# Vaccination training requirements

| Checklist 1: Staff vaccination training requirements | Completed | Signature |
|---|---|---|
| The vaccinator(s) is/are a healthcare practitioner who:[1]<br>• Has completed a recognised immunisation course and maintained recency of practice<br>• Is familiar with appropriate vaccine storage, pre- and post-vaccination assessment<br>• Has completed a recognised anaphylaxis course<br>• Is permitted and authorised by the relevant State/Territory legislation and Department of Health. | ☐ | |
| All clinic staff have been trained to recognise the signs of anaphylaxis. | ☐ | |
| All clinic staff are aware of the policies, procedures, and requirements for providing the vaccination services. | ☐ | |

*This table may be used to document training completed in clinic*

## TRAINING FOR VACCINATORS

The healthcare practitioner who will be administering the vaccinations must be an authorised immuniser. Nurses must have completed a recognised course in immunisation, be proficient at cardiopulmonary resuscitation (CPR) and first aid, and be permitted and authorised by the relevant State or Territory legislation and Department of Health to provide immunisation services.[1,2]

## TRAINING FOR VACCINATION CLINIC STAFF

Patient safety is the first priority and all clinic staff should be trained to recognise potential anaphylaxis and vasovagal episodes (sudden fall in blood pressure). They should also be aware of the policies, procedures, and requirements of providing a vaccination service.[1]



**References**

1. Australian Government Department of Health. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Canberra, 2018.
2. Australian Government. Training.gov.au. 10754NAT - Course in immunisation practice in primary healthcare. Available from training.gov.au/Training/Details/10754NAT [Accessed July 2020].

# Checklist 2:

# Day-to-day vaccine management requirements

| Checklist 2: Day-to-day vaccine management requirements<br>The checklist below is adapted from *The National Vaccine Storage Guidelines: Strive for 5* and covers key points.[1] For a more extensive checklist it is recommended the full guidelines are consulted. | Completed |
|---|---|
| All clinic staff have received recent training on vaccine management. | ☐ |
| All vaccine management policies and procedures are up to date. | ☐ |
| The right amount of vaccines are ordered for the right time. | ☐ |
| The person receiving vaccine deliveries checks there are no temperature breaches in transport and that the vaccines were packed appropriately. | ☐ |
| Vaccines are immediately transferred into the vaccination refrigerator and the date, type of vaccine, number of vaccines, and batch numbers recorded. | ☐ |
| A vaccination refrigerator temperature recording log is available and the temperature is taken twice daily. | ☐ |
| Contact numbers to report a cold-chain breach are clearly displayed. | ☐ |
| All temperature deviations outside +2°C and +8°C are reported to the relevant State or Territory Health Department and the responses documented. | ☐ |
| The vaccination refrigerator is in good working order and of sufficient size to store all required vaccines. | ☐ |
| In the event of power failure or refrigerator malfunction immediate alternative vaccination storage is available. | ☐ |

*The National Vaccine Storage Guidelines: Strive for 5* provides detailed guidance on the management of vaccines. A copy of the most current edition should be permanently available in the vaccination service area.



**References**

1. Australian Government Department of Health. National vaccine storage guidelines: strive for 5. Canberra: 2013. At: www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf

# Checklist 3:
# Setting up a vaccines refrigerator

| Checklist 3: Setting up a vaccines refrigerator[1] | Completed |
|---|---|
| The vaccines refrigerator is housed in the vaccination service area according to manufacturer's instructions. | |
| The refrigerator is clearly labelled as a vaccines fridge. | |
| The temperature of the refrigerator interior can be easily measured, is set to between +2°C and +8°C and has been checked for 48 hours before first use. | |
| A back-up minimum/maximum temperature probe has been placed inside the refrigerator. It should be housed in an empty vaccines package labelled 'thermometer', located on a middle shelf, towards the back. | |
| A temperature log book is located near the refrigerator and protocols for the regular monitoring and recording of temperature in place (at least daily). | |
| The refrigerator's power cable and plug are clearly labelled to avoid accidental removal from the power supply, or being switched off. | |
| There is ample space to store the vaccines, without overcrowding the shelves. | |
| If only a few vaccines are being stored, the addition of water bottles can help stabilise the refrigerator temperature. Refer to the manufacturer's instructions for more information on temperature stability. | |
| Back-up storage is available in the event of power failure or refrigerator malfunction. | |
| The refrigerator seal is checked regularly and the coils at the back of the fridge are kept dust free. | |
| The temperature probe and battery are checked annually. | |

# Setting up a vaccines refrigerator

All immunisation service providers must be familiar with and adhere to the *National Vaccine Storage Guidelines, Strive for 5 (3rd edition).* The publication can be downloaded free of charge from:[1] www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf

The vaccination service area must have suitable refrigerated storage for vaccines. Domestic refrigerators are not recommended and require additional policies and procedures to be in place – please consult *The National Vaccine Storage Guidelines: Strive for 5* for further information.[1,2]

The vaccines refrigerator should be housed in the vaccination service area or pharmacy dispensary, with access to the vaccines being determined by the relevant State or Territory legislation. Vaccines must be stored between +2°C and +8°C.[1,2]

## CONSIDERATIONS IF USING A DOMESTIC FRIDGE

Ensuring consistent temperature regulation can be more challenging if using a domestic refrigerator.

- Water bottles should be placed in the refrigerator drawers, door, and freezer compartment (alternatively, ice packs can be used in the freezer compartment). This will help maintain an even temperature.
- Before first use, rigorous temperature gauging is required, across all areas of the refrigerator, i.e. each shelf, front-to-back and side-to-side. The probe should be left in each position for at least 24 hours.
- Adjustments may need to be made to the refrigerator settings and the temperature re-assessed.
- Freeze-sensitive vaccines should never be stored in cold spots.



**References**

1. Australian Government Department of Health. National vaccine storage guidelines: strive for 5. Canberra: 2013. At: www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf
2. Australian Government Department of Health. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Canberra, 2018.

# Checklist 4:
# Cold-chain breaches

| **Checklist 4: Cold-chain breaches**<br>*A cold-chain breach has occurred if vaccine storage has occurred outside of the recommended 2 -8°C. It excludes fluctuations of up to 12°C for less than 15 minutes.*[1] | **Completed** |
|---|---|
| The vaccines were immediately isolated and labelled 'Do not use', and kept refrigerated between +2°C and +8°C. | ☐ |
| The relevant State or Territory Health Department was notified as soon as possible (for vaccines provided under the National Immunisation Program or State Government program). | ☐ |
| For privately purchased vaccines the manufacturer was contacted for advice. | ☐ |
| The following information was collected and reported:<br>• Date and time of the breach<br>• The type of refrigerator in which the vaccines are stored, i.e. whether a purpose-built vaccine refrigerator or domestic<br>• If using a purpose-built refrigerator, download the data logger to indicate the temperature range during the breach period<br>• If using a domestic refrigerator:<br>– are the vaccines in enclosed plastic containers?<br>– are there water bottles in the doors, unused shelves and drawers of the refrigerator?<br>• Minimum and maximum temperature reading<br>• Are cold chain monitors (CCMs) stored with the vaccines? If 'yes', be ready to report the reading when the breach was noticed<br>• Are the vaccines cold to touch?<br>• Has the vaccine refrigerator had any maintenance issues recently?<br>• Date and time of the last thermometer reset, battery change and accuracy check (domestic refrigerator) | ☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐ |

| Checklist 4: Cold-chain breaches<br>*A cold-chain breach has occurred if vaccine storage has occurred outside of the recommended 2 -8°C. It excludes fluctuations of up to 12°C for less than 15 minutes.*[1] | Completed |
|---|---|
| The following information was collected and reported *continued:* | |
| • Length of time the refrigerator temperature was outside +2°C to +8°C | ☐ |
| • Length of time that these problems have been occurring | ☐ |
| • Position of the temperature probe and vaccines in the refrigerator | ☐ |
| • Type and number of vaccines in the current stock | ☐ |
| • Expiry date of the vaccines | ☐ |
| • Have any vaccines been pushed up against the cooling plate or a cold air outlet? | ☐ |
| • Are all vaccines in their original packaging? | ☐ |
| • What was the cause of the cold chain breach and has it been rectified? | ☐ |
| • Has anybody been vaccinated with potentially affected vaccines? | ☐ |
| • Have the vaccines previously been exposed to temperatures outside of the +2°C to +8°C range? | ☐ |



**Reference**

1. Australian Government Department of Health. National vaccine storage guidelines: strive for 5. Canberra: 2013. At: www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf

# Checklist 5:
# Anaphylaxis management checklist

Clinics that provide vaccinations must be prepared to respond to a suspected anaphylactic episode. This requires having an accessible anaphylaxis response kit and clinic staff being suitably trained to deal with the situation.[1]

| Checklist 5: Anaphylaxis management | Completed |
|---|---|
| **An anaphylaxis response kit is available containing:**[1] | ☐ |
| • Adrenaline 1:1000 (minimum 3 in-date ampoules) | ☐ |
| • Drawing-up needles (minimum 3) | ☐ |
| • 1 mL syringes and 25 mm needles (minimum 3) | ☐ |
| • Cotton wool swabs | ☐ |
| • Pen and paper to record time of administration of adrenaline | ☐ |
| • Laminated copy of adrenaline doses | ☐ |
| • Laminated information to assist with identification and treatment of anaphylaxis. | ☐ |

## GUIDELINES FOR THE MANAGEMENT OF ANAPHYLAXIS

Intramuscular (IM) administration of adrenaline is the foundation of anaphylaxis treatment. Adrenaline is life saving and must be used without delay.[1]

- If patient is unconscious: Lie them on the left side and position to keep the airway clear
- If patient is conscious: Lie them supine in 'head-down and feet-up' position (unless this leads to breathing difficulties)
- If there are any respiratory and/or cardiovascular symptoms or signs of anaphylaxis, give IM adrenaline injection into the anterolateral thigh. Adrenaline is not required for generalised non-anaphylactic reactions. If in doubt, adrenaline should be given as no serious or permanent harm is likely to occur from mistakenly administering adrenaline to an individual who is not experiencing anaphylaxis
- Call for assistance
- Never leave the patient alone
- If available, administer oxygen by facemask at a high flow rate
- If no improvement in the patient's condition is seen within 5 minutes, repeat doses of adrenaline every 5 minutes until improvement occurs
- Check breathing; if absent, commence basic life support or cardiopulmonary resuscitation (CPR), as per the Australian Resuscitation Council guideline (available from www.resus.org.au/policy/guidelines)
- In all cases, transfer the patient to hospital for further observation and treatment
- Document the event in full, including the time and dose(s) of adrenaline given

*Antihistamines and/or hydrocortisone are not recommended for the emergency management of anaphylaxis.*

# Anaphylaxis management checklist

| Checklist 5: Anaphylaxis management | Completed |
|---|---|
| **Roles and responsibilities as outlined below have been assigned:**[1] | ☐ |
| The person who will administer adrenaline is the immuniser. If it is not possible | ☐ |
| _____ will administer adrenaline. | ☐ |
| The person who will call the ambulance is _____. | ☐ |
| The person who will meet and direct the paramedics to the patient is | ☐ |
| _____. | ☐ |
| They should meet the paramedics at | ☐ |
| _____. | ☐ |
| The person who will provide clinical handover to the paramedics is the immuniser. | ☐ |
| If this is not possible, _____ will provide the clinical handover. | ☐ |
| The person who will record the details of treatment provided, including time and dose | ☐ |
| of adrenaline administered, is _____. | ☐ |
| The person who will manage other patients/customers in the surgery/pharmacy is | ☐ |
| _____. | ☐ |
| The person who will report the adverse event following immunisation to | ☐ |
| the relevant State or Territory health authorities is the immuniser and/ or | ☐ |
| _____. | ☐ |



**Reference**

1. Australian Government Department of Health. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Canberra, 2018.

# Checklist 6:
# The vaccination service area

| Checklist 6: The vaccination service area | Completed |
|---|---|
| A temperature-monitored vaccine refrigerator. | ☐ |
| A suitable area for administering vaccinations must be created that:<br>• Does not allow the vaccination to be heard or observed by other people<br>• Is adequately lit<br>• Is maintained at a comfortable temperature<br>• Has a hand sanitisation and washing facility<br>• Is not cramped and has sufficient bench space, a chair, and first aid couch | ☐ |
| An in-date anaphylaxis response kit. | ☐ |
| An emergency response laminated poster. | ☐ |
| Access to the current editions of:<br>• *Australian Immunisation Handbook*<br>• *National Vaccine Storage Guidelines – Strive for 5* | ☐ |
| Policies and procedures for the vaccination service (for instance, a tailored version of the Travel Vaccine Toolkit). | ☐ |
| Equipment as detailed below.<br>**General equipment**<br>The Department of Health recommends the vaccination service area is stocked with the following equipment:[1]<br>• Cotton wool balls<br>• Gloves and protective eyewear (if the healthcare practitioner administering the vaccine is at risk of coming into contact with body fluids or if they have open lesions on their hands)<br>• Approved Australian standard sharps container<br>• Medical waste bin<br>• Hypoallergenic tape or latex-free bandaid<br>• Appropriate drawing-up and/or injecting needles<br>• Anti-bacterial wipes to clean work area<br>• Liquid hand soap or hand sanitiser<br>• Rattle or noisy toy to distract young children after the injection | ☐ |

A dedicated service area for the administration of vaccinations should be suitably equipped. The checklist above has been adapted from existing guidelines.[1]



**Reference**

1. Australian Government Department of Health. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Canberra, 2018.

# Checklist 7:
# Record keeping and patient privacy

| Checklist 7: Record keeping and patient privacy | Completed |
|---|---|
| Patient consent has been obtained, following:<br>• Information about the vaccination procedure and associated risks and benefits being provided<br>• Agreement by the patient to pay any fees | ☐ |
| The following information has been documented in the patient's vaccination record<br>• Details of the vaccine given including the dose number, brand name, batch number<br>• Date of vaccination<br>• Signature of the immuniser administering the vaccine<br>• Date that the next vaccination is due (if appropriate) | ☐ |
| Any adverse events have been reported to the relevant State or Territory Public Health Unit.<br>• Online at http://www.tga.gov.au/reporting-problems or by downloading an Adverse Events Following Immunisation (AEFI) form, available here: http://www.tga.gov.au/form/national-adverse-events-following-immunisation-aefi-reporting-form | ☐ |
| The adverse event has been recorded in the patient's vaccination record | ☐ |
| The vaccination has been added to the Australian Immunisation register.<br>https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/australian-immunisation-register-health-professionals | ☐ |
| The adverse event is reported to the Therapeutic Goods Administration (TGA)<br>• AEFI forms can be submitted to the TGA via email: adr.reports@tga.gov.au<br>fax: +61 2 6232 8392 or mail:<br>Therapeutic Goods Administration<br>PO Box 100<br>Woden ACT 2606 | ☐ |

Patient consent must be obtained and documented before administering any vaccinations, and then appropriate documentation of the vaccine given added to the patient's vaccination record. Any adverse events must also be documented. All clinic staff should understand patients' rights to confidentiality and the privacy legislation in relation to the recording of personal information.

**Disclaimer:** This checklist is intended for use as a guide only. The information is based on published literature, in addition to clinical experience gained from primary healthcare nurses, and may not reflect the procedures followed in your practice. There may be other procedures and/or considerations relevant to this checklist that may not have been taken into account. Use of this checklist is at the user's own risk and Sanofi Pasteur will not be responsible for any actions taken based on the use of this checklist. To the extent permitted by law, Sanofi Pasteur excludes all liability arising from the use of this checklist.

**References**

1. Australian Government Department of Health. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Canberra, 2018.
2. https://www.tga.gov.au/reporting-adverse-events

# Checklist 8:
# Reporting adverse events

| Checklist 8: Reporting adverse events | Completed |
|---|---|
| The relevant State or Territory Department of Health has been notified. These authorities will report all adverse events to the Therapeutic Goods Administration (TGA). | ☐ |
| The adverse event can also be reported directly to the TGA:<br>• Online https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase<br>• Via MIMS Online<br>• By phone<br>• By fax, email, or mail using a Report of suspected adverse reaction to vaccines form (a 'blue card'), available from: https://www.tga.gov.au/form/national-adverse-events-following-immunisation-aefi-reporting-form<br>**Contact details:**<br>Email: adr.reports@tga.gov.au<br>Phone: +61 2 6232 8392<br>Mail: Therapeutic Goods Administration<br>PO Box 100<br>Woden ACT 2606 | ☐ |
| Reporters are encouraged to provide as much detail as possible, but at bare minimum are asked to provide:<br>• contact details for the reporter (name, address, phone number)<br>• patient identifier (such as initials, date of birth or age, but not their full name)<br>• details of the vaccine involved<br>• details of the suspected adverse event. | ☐ |
| Reporters are also encouraged to provide information regarding the adverse event to the manufacturer of the vaccine administered. | ☐ |

Most adverse events associated with receiving a vaccination are minor and generally require no treatment – such as injection site tenderness or mild fever.[1] However, healthcare workers are encouraged to report any untoward medical event that occurs following vaccination, especially if they are unanticipated and/or serious.[2]

Clinic staff should carefully study the Product Information for every vaccine they administer and be familiar with potential adverse events.

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2. https://www.tga.gov.au/reporting-adverse-events