



This Guide is designed to support pharmacists and their teams to prepare for and deliver current & future injectable services, including immunisations, scheduled and unscheduled medicines. In following the steps below, pharmacists can identify, assess and prepare for delivering a vaccine or medicines by injection service in their pharmacy.

Please note: the Guide is general in nature, and there may be variations and additional considerations for certain medicines.

Considerations before providing the service

These key considerations are essential to review before implementing a new vaccine or medicines by injection service in your pharmacy. For further insight, please see the CPD-accredited AJP article from November 2023 “Look before you leap! A risk management guide to introducing a new pharmacy service”.

Compliance with state/territory legislative requirements and best practice guidelines

Familiarise yourself with legislation and regulations in your local jurisdiction.

Resources & Practice Setting

Location, facilities & equipment

- Ensure consultation area meets legislative, privacy and professional practice requirements.
- Facilities for handwashing and safe disposal of sharps, PPE, and waste.
- Restrict public access to sharps and medicines.
- Management of multiple components for injection, e.g. diluent, needles, co-administration of medicines.
- Dressings and first aid equipment ready.
- Anaphylaxis kit in-date and sufficient to manage all circumstances.

Cold Chain Management

- Review current version of National Vaccine Storage Guidelines Strive for 5 – Principles of safe vaccine storage management for full information.
- Domestic refrigerators are not suitable for storage of vaccines.

- All vaccine refrigerators require a data logger.
- Twice-daily recording of the current, minimum and maximum temperatures.
- Equipment and protocols for management of cold chain breaches.
- Report temperature excursions outside of temperature and time limits.
- Perform Vaccine Storage self-audits every 12 months.
- Annual servicing of vaccine refrigerator(s).
- Advise patients with future doses to leave stock in pharmacy refrigerator.

Staffing and workforce considerations

Workflow considerations

- Ensure staff capacity is sufficient to meet workload demands – managing other pharmacy duties, minimise distractions to vaccinating pharmacist, delegation of booking tool management, managing walk-ins.

Education & Training

- Ensure pharmacists and staff have attained and renewed certifications.
- Be aware of the approved product information.
- Comply with the limits to legislative authority for pharmacist administration by injection.
- Access to Australian Immunisation Handbook.
- Awareness of potential risks/injuries, e.g. SIRVA, vasovagal episode, anaphylaxis.
- Training on privacy obligations, e.g. professional services area, discussions, records.
- Inclusion of relevant CPD in annual CPD Plan and Record.
- Schedule annual self-audit of entire service.
- Educate all staff on safe handling and storage requirements for vaccines.
- Emergency action plans & staff training in the event of adverse events, needle stick injury and anaphylaxis.

Documentation and record-keeping

Standard Operating Procedures

- OH&S considerations: training and protocols for sharps disposal, infection control, adverse events.
- Process for administering products with >1 vial or >1 dose.
- Process for identification and quarantine or disposal of expired products.
- Booking tool activated and reviewed regularly for updates as they occur.
- General inventory management, including around stock provided to pharmacy at no charge, e.g. NIP, compassionate stock, clinical trials, patient support programs.
- Preparing patient for attendance, e.g. advice on suitable clothing, possible wait times, preparing children.
- Collaboration with prescriber to confirm administration by pharmacist when medicine prescribed on prescription.
- Obtaining and retaining patient consent.

Insurance

- Pharmacists required to have Professional Indemnity Insurance arrangements for all aspects of their practice, as part of the Pharmacy Board Registration Standards.
- Business Insurance to cover all personnel and stock.

Providing the service

Patient Consultation & Injection

Patient consultation

- Always check the Australian Immunisation Register (AIR) before vaccinating.
- Confirm patient identity and expected medication/vaccine prior to administration using open-ended questions to avoid Yes/No answers, e.g. “Please confirm your full name and date of birth” and “Please confirm what medicine/vaccine you expect today”.
- Informed Consent and informed financial consent gained and recorded.
- Establish eligibility is met, including clinical review.
- Patient counselling – confirm medication, indication, process, expectations, adverse reactions, provision of written information.

Injection

- Preparation of medicine – check and record batch and expiry details, dilution requirements, technique.
- Assess and manage patient readiness, e.g. patients uncomfortable with injections, patients with past reactions to vaccines or injections, children.

Post-Injection

Patient monitoring

- Counselling the patient, including explanation of recommended observation time, pain management, activity limitations, reporting of any possible adverse events, means to contact pharmacist for related enquiries, referral to other practitioner(s) as necessary.
- Pharmacist to be aware of how to manage adverse events (needle stick injury, SIRVA) and understand reporting systems available, e.g. PDL to notify incidents, TGA to report adverse reactions.

Documentation and record-keeping

- Australian Immunisation Register, dispensing history, GP letter where necessary. Note duration of time for retaining of records.
- Reporting and documentation of any incidents, near misses, adverse events and patient follow-up.

Reviewing the service

- Implement Continuous Quality Improvement protocols, e.g. reviewing near-miss and incident reports, adverse reactions reports, planning for future services (staffing levels, stock control, booking tool processes, other relevant aspects).

Need to report an incident?

Easily report it online now at pdl.org.au

Useful pharmacist resources

- Australian Immunisation Handbook
- Australian Technical Advisory Group on Immunisation (ATAGI)
- COVID-19 Vaccine Operations Centre on 1800 318 208
- Department of Health & Aged Care – Reporting and managing adverse vaccination events
- National Centre for Immunisation Research and Surveillance Australia (NCIRS)
- National Vaccine Storage Guidelines ‘Strive for 5’
- PDL Professional Officers
- PSA Injection Guidelines, PSA Practice Guidelines for pharmacists providing immunisation services
- Quality Care Pharmacy Program
- SHPA Australian Injectable Drugs Handbook
- State/territory health department Immunisation Unit or Public Health Units

Guide to Medicines by Injection:

Cold chain management for vaccine storage and supply

Prepared by PDL as a supportive document for annual self-auditing of a pharmacy's cold chain processes, for staff induction and team training, and when a review of processes is required e.g. after a cold-chain incident. This is not a definitive list. Information provided is current as of January 2024. For further details, refer to the current National Vaccine Storage Guidelines 'Strive for 5'.

Risk Management: Ensure Good Processes in Place

General

- Educate all people responsible for handling vaccines so that they understand the importance of effective vaccine management. Ensure orientation for new staff includes explanation of vaccine management.
- Nominate a staff member to be responsible for vaccine management, and a back-up staff member to take responsibility in their absence.
- Ensure that all people involved in vaccine transport, storage and administration are trained in vaccine management to ensure that the vaccines remain potent and effective.
- Contact names and numbers are available for reporting cold chain breaches, refrigerator and/or data logger maintenance issues, power failures.
- Back-up vaccine storage options are documented and tested.
- Perform a **self-audit** of vaccine refrigerators **every 12 months** (or more often if problems with equipment or cold chain breaches). Refer to National Vaccine Storage Guidelines 'Strive for 5' 3rd Edition Appendix 2: Vaccine Storage Self Audit for checklist.
- Vaccines for administration in a general practice setting should be taken from the pharmacy directly to the clinic immediately before the scheduled administration. If an immunisation provider has a concern the vaccine has been stored outside of the recommended range of +2C to +8C, then the **vaccine should not be administered**.
- **Foil bags from pharmacies are not effective** in keeping vaccines at the correct temperature e.g. when the vaccine is left in a car or stored in a domestic refrigerator.
- Ensure ice packs/gel packs and insulated storage are available for power outages and transporting vaccines.

Power source reliability

- Set and check that refrigerator alarm will activate when outside +2°C to +8°C.
- Place a warning sticker on the electricity meter box: 'Do not turn off power before consulting the person responsible for vaccine management'.
- Mark the power source clearly, so the refrigerator is not unplugged or turned off accidentally. Ensure that all staff, including cleaners, are educated on vaccine refrigerator maintenance.
- Consider installing a power point locking device or have the refrigerator 'wired in' so it can't be accidentally unplugged.

Maintenance

- Have the refrigerator serviced every 12 months and ensure that it is in good working order.
- Maintain all documentation and records of refrigerator maintenance.
- Recalibrate a stand-alone data logger annually or according to the manufacturer's recommendations.
- Change the data logger battery at least every 6 to 12 months or as indicated by the manufacturer.
- Check the accuracy of a stand-alone thermometer at least every 12 months.
- Change the thermometer battery at least every 6 to 12 months or as indicated by the manufacturer.

Temperature Monitoring: Stay safe, stay in range

- Check and record the vaccine refrigerator temperature (current, minimum and maximum) **twice daily: before the refrigerator is used for the first time and at the end of each day. If the temperatures are outside the recommended +2°C to +8°C range, immediately implement cold chain breach protocols. Twice-daily minimum and maximum temperatures must still be manually recorded as a timely alert to any breach in the cold chain.**
- Several vaccine temperature-monitoring devices can be used to monitor the cold chain. At a minimum, all vaccine refrigerators must have a basic data logger and thermometer to continuously monitor temperatures. Information from the data logger should be downloaded at least weekly, reviewed and digitally stored.
- A battery-operated minimum/maximum thermometer can assist in monitoring refrigerator temperatures in an emergency and is essential for temperature monitoring during mobile or outreach immunisation sessions.

Checklist for data loggers

- Place the data logger where it is easily seen and in the middle of the vaccines.
- Data loggers should be set to record temperatures at 5-minute intervals.
- Measure the current, minimum and maximum temperatures twice daily, and record them.
- Set the alarm system to alarm outside the +2°C to +8°C range. Check that the alarm is working.
- Train all staff to recognise the alarm and download information from the data logger.
- Download and record information as soon as possible after an alarm is activated.
- If recordings are outside the +2°C to +8°C range, follow the cold chain breach protocol (see Appendix 3) and notify the relevant state or territory health department.
- Regularly check and record the accuracy of the data logger. Inbuilt data loggers should be checked for accuracy according to the manufacturer's recommendation.
- Change the battery according to the manufacturer's recommendation, or when the battery life displayed is low. Record the date the battery is changed.

Cold Chain Breaches: What to do if it happens

A 'cold chain breach' occurs when vaccine storage temperatures deviate outside the recommended range of +2°C to +8°C. The optimal storage temperature for vaccines is +5°C (Reference: National Vaccine Storage Guidelines 'Strive for 5' 3rd Edition Appendix 3: Cold Chain Breach Protocol.)

All vaccine temperatures recorded below +2°C or above +8°C must be reported to your state or territory health department. **This does not include temperature deviations or excursions in which the temperature reaches a maximum of up to +12°C for 15 minutes or less.**

Summary of Actions for Cold Chain Breaches

1. Immediately isolate the vaccines.
2. Keep vaccines refrigerated between +2°C and +8°C, and label 'Do not use'. Vaccines may need to be transferred to an alternative purpose-built vaccine refrigerator or cooler.
3. Contact your state or territory health department as soon as possible (during business hours). The health department will require vaccine details, data logging and twice-daily temperature readings to assess the breach.
4. Do not discard any vaccine until advised to do so by your state or territory health department.
5. Take steps to correct the problem and to prevent it from recurring.
6. For privately purchased vaccines, contact the manufacturer for advice.

Reference: National Vaccine Storage Guidelines 'Strive for 5' 3rd Edition Appendix 3: Cold Chain Breach Protocol.

Department of Health resources, e.g. Quick Reference Posters and Power Warning stickers <https://www.health.gov.au/resources/collections/national-vaccine-storage-guidelines-resource-collection>