Guidance document for incidents that involve COVID-19 vaccinations

Important considerations when recording a vaccination incident in Datix CIMS

This document should be read in conjunction with the Datix CIMS Notifier User Guide.

Introduction

A COVID-19 vaccination incident is any preventable event which could have or did lead to harm of a vaccine recipient. In the context of vaccination, incidents that may reduce vaccine effectiveness should also be regarded as having the potential to cause harm. COVID-19 vaccination incidents may be related to vaccine products, procedures and systems. They can include incidents involving communication, product labelling/packaging/nomenclature, preparation, distribution, storage, administration, education, monitoring, and use.

The COVID-19 vaccines currently listed in Datix CIMS are:

- COVID-19 vaccine Pfizer-BioNTech BNT162b2 (COMIRNATY)
- COVID-19 vaccine AstraZeneca ChAdOx1-S

As new COVID-19 vaccines become available for use in Western Australia they will be added to Datix CIMS. The naming convention uses 'COVID-19 vaccine' at the beginning of the name for consistency.

Some Health Service Providers (HSPs) have requested that specific locations relating to COVID-19 vaccination clinics be created in Datix CIMS. If you are unsure of the correct location to record for a clinical incident related to COVID-19 vaccination, please contact your local clinical governance/safety and quality team for advice.

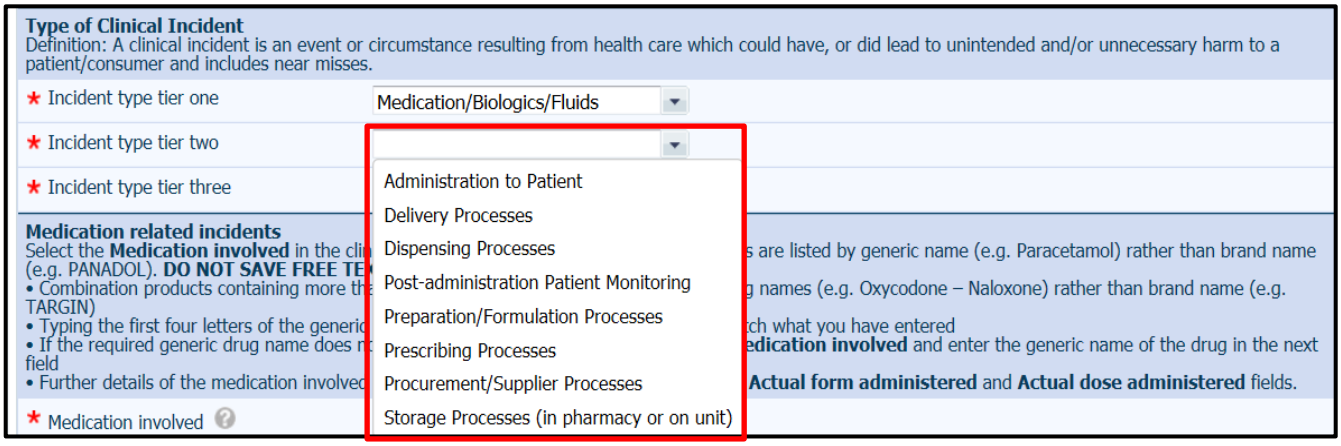
There is a separate process for recording adverse reactions following vaccine administration. The Western Australian Vaccine Safety Surveillance system (WAVSS) is the central reporting service in WA for any significant adverse events/side effects that the vaccine recipient may experience following immunisation (please refer to Section 6 for further information).

Choosing the correct type of incident

While many clinical incidents related to COVID-19 vaccination are likely to be categorised as 'medication incidents' in Datix CIMS, it is possible that other incident types may be appropriate depending on the circumstances (e.g. an incident related to the COVID-19 vaccination booking system may be better categorised as 'Administrative Processes'). Please contact the Patient Safety Surveillance Unit (PSSU) via PSSU@health.wa.gov.au if you require assistance with the categorisation of clinical incidents related to COVID-19 vaccination in Datix CIMS.

The remainder of this guidance document relates to COVID-19 vaccination clinical incidents that are categorised as medication incidents at incident type tier one. It is important to select the correct part of the medication process where the incident occurred from the incident type tier two drop-down list, as different tier three choices are available depending on the tier two option chosen (see Appendix 1 for a list of descriptions of tier two and tier three categories that may be more frequently used for vaccination-related clinical incidents).

1. **Incident type <u>tier one</u>:** select ‘Medication/Biologics/Fluids’ when recording a vaccination related clinical incident.



2. What incident type do I select for tier two?

There are several options that can be selected for the tier two incident type for COVID-19 vaccine-related incidents. These include:

- Administration to Patient
- Delivery Processes
- Post-administration Patient Monitoring
- Preparation/Formulation Processes
- Procurement/Supplier Processes
- Storage Processes

Please note that when reference is made to a ‘Patient’ in Datix CIMS incident type selections, this should be regarded as relating to the to ‘vaccine recipient’. A vaccine recipient who is also employed in the WA health system is to be considered a ‘patient’ in this context.

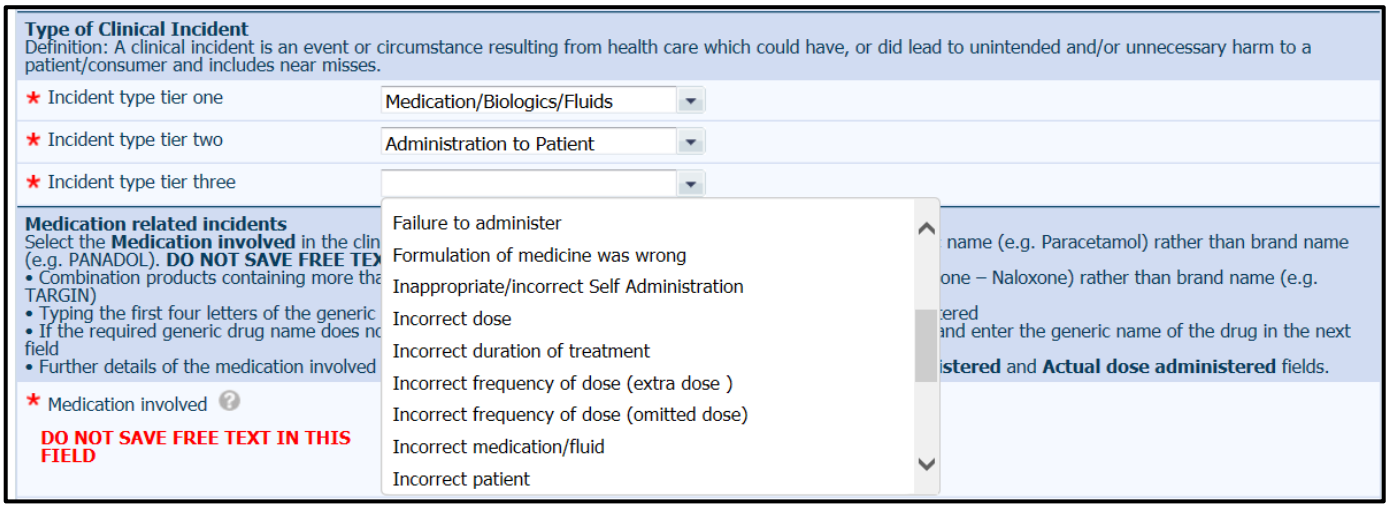
Note: Most COVID-19 vaccines will be administered under the Structured Administration and Supply Arrangements (SASA) and will not have an associated prescription for each dose. Therefore, the tier two categories of Prescribing Processes and Dispensing Processes will usually not be relevant for clinical incidents related to COVID-19 vaccines.

Two incident types that are often confused are ‘Administration to Patient’ and ‘Dispensing Process’.

Tier two incident type	Description
Administration to Patient	If a vaccine recipient has been administered a vaccine, then it is an ‘Administration to Patient’ incident type. It involves the 6 rights of medication/vaccine administration, encompassing assessment/screening of suitability for the vaccine, the selection of the correct vaccine and appropriate preparation and administration of the vaccine by a suitably skilled clinician to the correct person on each occasion. Documentation of administration in the vaccination clinic is to be captured in VaccinateWA.
Dispensing Processes	This step includes the process of dispensing the medication from a pharmacy undertaken by a pharmacist. Unless the vaccine has been dispensed for a specific COVID-19 vaccine recipient from the pharmacy department, the ‘Dispensing Processes’ tier two incident type will not be applicable for COVID-19 vaccines.

3. What incident type do I select for tier three?

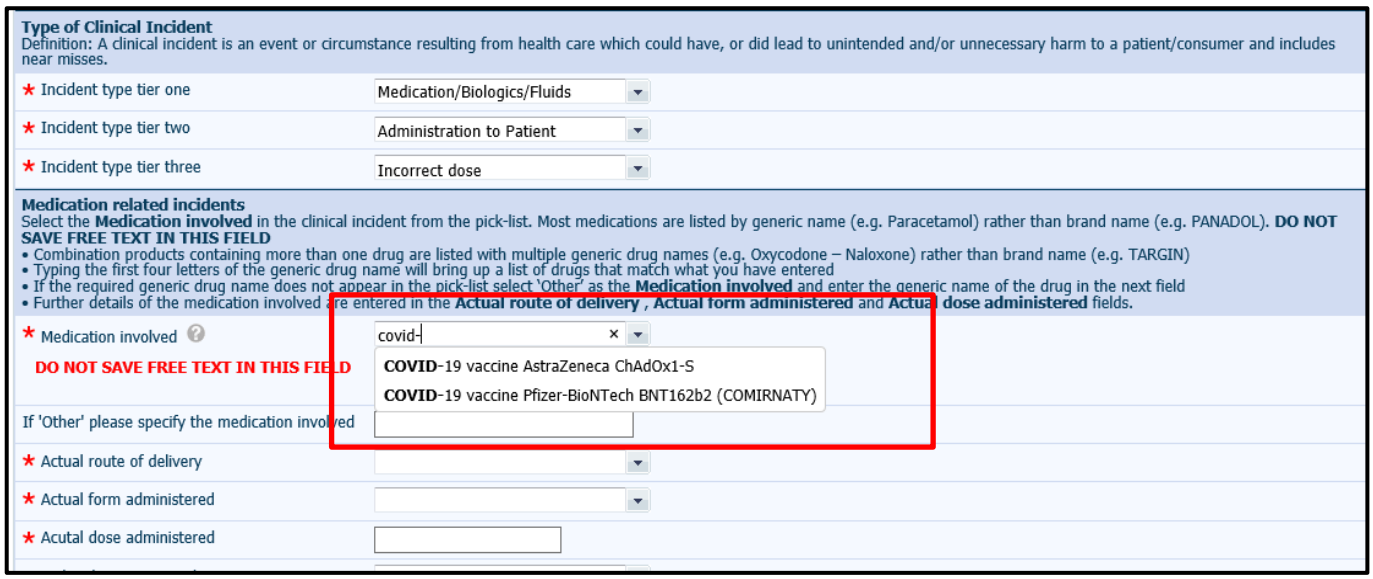
Please refer to Table 2 for some of the incident type tier three options that are most relevant to COVID-19 vaccines.



4. Choosing the COVID-19 vaccine involved

Tip

By typing 'COVID' in the Medication involved field, a list of COVID-19 vaccines will be shown in a drop-down list. Select the COVID-19 vaccine involved in the incident. **DO NOT enter free text in the Medication involved field.**



5. Clinical incident details

When submitting a clinical incident, it is important to include as much information as possible about:

- what happened
- why the incident may have occurred
- what factors may have contributed to the incident occurring.

These details will assist the review process to develop strategies to reduce the risk of similar incidents occurring again.

Incident Example 1: Incorrect dose administered.

Was the reason for the incorrect dose because:

- The incorrect dose was drawn up into the syringe
- There was leakage between the needle and the syringe due to not securing the needle properly
- There was leakage between the needle and the syringe due to equipment failure.

Incident Example 2: Several vials of vaccine were left outside of the fridge for an extended period of time.

Was the reason for the stock experiencing a temperature excursion because:

- There was insufficient storage space in the fridge when a new delivery arrived
- The patients for whom the doses were allocated for did not show up for their appointments as expected
- There was a refrigeration failure
- The nurse was interrupted whilst taking stock out of the fridge
- There was a failure of the inventory management system.

6. Recording Adverse Events Following Immunisation (AEFI)

Existing WA vaccine surveillance structures will enable vaccine monitoring, assess vaccine effectiveness, and understand and address adverse events. The Western Australian Vaccine Safety Surveillance system (WAVSS) is the central reporting service in WA for any significant adverse events following immunisation (AEFI). All adverse reactions requiring treatment should be reported as soon as possible after the event, as per statutory requirement to notify adverse events after immunisation which is specified in the Public Health Act 2016 and the Public Health Regulations 2017. The safety of COVID-19 vaccines will be monitored continuously throughout the rollout of the Vaccination Program. WAVSS will carefully monitor and respond to any safety issues identified, providing individual support to immunisation providers and clinical assistance for families affected by an AEFI.

AEFI can be reported online via www.safevac.org.au or by contacting WAVSS staff by phone on **(08) 6456 0208** or email wavss@health.wa.gov.au . For detailed instructions, refer to the WAVSS reporting guide. When the Western Australian Vaccine Safety Surveillance (WAVSS) system receives a report from a patient on an adverse event following immunisation, WAVSS staff will:

1. Review the adverse event report and if necessary, contact the patient or reporter to gather more information to determine if the patient requires further assessment.
2. If further assessment is required, WAVSS staff will refer them to the COVID-19 vaccine adverse events following immunisation (AEFI) Adult Immunology Clinic at Sir Charles Gairdner Hospital (SCGH).
3. The COVID-19 vaccine AEFI Adult Immunologist will review and determine if they are able to be vaccinated without additional precautions (advised to re-book their vaccination as done previously) or be vaccinated under observation at SCGH if deemed clinically appropriate.
4. For patients who are advised to re-book their vaccination as done previously, they will be provided with a letter from WAVSS and/or the Adult Immunology Clinic to bring with them to their vaccination appointment.

COVID-19 vaccine common side effects indicate the start of an immune response, not an allergic reaction. Mild, short-term side effects from vaccination, including injection site reactions, fever, joint pain, muscle aches, fatigue, headaches, or worsened eczema a day after vaccination do not need to be reported to WAVSS.

Appendix 1 – Guidance for tier two and tier three incident types

Table 1 – Descriptions for tier two incident types

Tier two incident type	Description
Administration to Patient	When a nurse, midwife or doctor administers a vaccine to a vaccine recipient. It involves the 6 rights of medication administration, encompassing re-assessment of the need for the vaccine, the selection of the correct vaccine and appropriate preparation and administration of the vaccine by a suitable skilled clinician to the correct vaccine recipient on each occasion.
Delivery Processes	This step involves the vaccine being transferred from one setting to another (e.g. from the pharmacy department to the vaccination clinic)
Dispensing Process	When a pharmacist dispenses a vaccine for a specific person. This step includes the process of dispensing the vaccine from a pharmacy undertaken by a pharmacist. Unless the vaccine has been dispensed for a specific COVID-19 vaccine recipient from the pharmacy department, the 'Dispensing Processes' tier two incident type will not be applicable for COVID-19 vaccines.
Post-administration Patient Monitoring	This process step encompasses a suitable skilled clinician to assess the vaccine recipient and the effect that the vaccine is having post administration.
Preparation/Formulation Processes	This process step involves choosing the correct vaccine for administration. Preparation process is when the vaccine cannot be administered in its original form. It usually involves dilution of the product so that it can be administered parenterally. Sometimes different dilutions are required for a specific vaccine, and it is important that the correct dilution is followed for the preparation of the vaccine.
Prescribing Processes	When a doctor or nurse practitioner prescribes a vaccine for a patient. Most COVID-19 vaccines will be administered under the Structured Administration and Supply Arrangements (SASA) and will not have an associated prescription for each dose. Therefore, the tier two category of Prescribing Processes will usually not be relevant for clinical incidents related to COVID-19 vaccines.
Procurement/Supplier Processes	This step involves the distribution of vaccine to the ward or unit. In the case of COVID vaccination incidents this would relate more to supply of the vaccines from the manufacturer and/or Commonwealth to the State and then to each hospital; with Delivery Processes relating to the (daily) movement of vaccine stocks from hospital pharmacy departments to clinics.
Storage Process (in pharmacy or on unit)	This process relates to the storage of the vaccine and encompasses any special storage conditions (e.g. cold chain management) related to stability of the vaccine.

Table 2 – Descriptions for tier three incident types

Tier two incident type	Tier three incident type	Description
Administration to Patient	**Contraindication due to history of allergy**	A vaccine is administered to a vaccine recipient who has a known allergy to the vaccine or excipient of the vaccine (i.e. polyethylene glycol [PEG] or Polysorbate)
	Contraindication due to interactions with other medications	A vaccine is administered that is contraindicated due to an interaction with another medication/vaccine (e.g. not spacing vaccines apart sufficiently as per recommendations)
	Contraindication due to medical condition	A vaccine is administered that is contraindicated due to a medical complication/factor which may increase the chance of toxicity and/or side-effects. This can include cases where a COVID-19 vaccine is administered to a patient outside of the approved age range for the vaccine according to the Product Information or Standard Operating Procedures

Tier two incident type	Tier three incident type	Description
	Expired medication/fluid	The vaccine administered had passed its expiry date. This can be the original expiry date provided by the drug company or for sterile preparations that have shortened expiries due to dilution or at different temperature exposures. It is important to include the reason the vaccine has expired if it is related to delivery/storage of the vaccine
	Incorrect dose	The vaccine recipient was administered the incorrect dose of the vaccine
	Incorrect timing of dose (premature)	The vaccine recipient received a second dose that was too soon after the first dose was administered (according to the Standard Operating Procedures or Product Information)
	Incorrect medication/fluid	The vaccine recipient was administered an incorrect vaccine, medication or incorrect fluid replacement
	Incorrect patient	The vaccine recipient was administered medications that were prescribed for another patient
	Incorrect route of administration	The vaccination was administered via the incorrect route. For example, a vaccine might incorrectly be administered subcutaneously rather than intramuscularly
Delivery Processes	**Damaged/contaminated during delivery**	A vaccine was damaged/contaminated during the delivery process
	Delayed delivery to unit/ward	Vaccine delivery was delayed to appropriate unit/clinic
	Delivered to wrong destination	Vaccine was delivered to the wrong unit/clinic
Post-administration Patient Monitoring	**Failure to activate rapid response/resuscitation team**	Failure to escalate care in response to vaccination management
	Failure/insufficient response to significant change in patient status	Failure or insufficient response to a change in vaccine recipient status which would affect management of the vaccine recipient
	Failure/insufficient/incomplete monitoring	Monitoring for vaccine therapy was either insufficient or not undertaken
	Incorrect/insufficient triage in emergency situations	Involves incorrect/insufficient assessment and triaging of the vaccine recipient. Incident types involve inadequate assessment, escalation and management of vaccine recipient's requirements
	Unplanned elevation of care to intensive care setting	When patient deterioration results in transfer to intensive care setting (e.g. ICU) due to insufficient/inadequate monitoring of the vaccine recipient post-administration of the vaccine
	Unplanned transfer of care to other institution or clinical service	When vaccine recipient deterioration results in referral/transfer to specialised care due to insufficient/inadequate monitoring of the vaccine recipient post-administration of vaccine
Preparation/ Formulation Processes	**Expired constituents**	Date of administration has surpassed the expiry date provided on the label of the container of the vaccine and has been administered to the patient
	Incorrect preparation/formulation (dose/concentration)	When preparing a vaccine for administration, the incorrect vaccine, dose, or diluent is chosen prior to administration of the vaccine
	Medication delayed	The administration of the vaccine was delayed due to difficulties during the preparation process
	Omitted Ingredient	The diluent was omitted in the preparation unintentionally when preparing the vaccine for administration
	Use of damaged/contaminated ingredients	Vaccine integrity has been damaged or contaminated such that it is not suitable for administration, but has been administered to the vaccine recipient (i.e. coring of the bung has resulted in bung particles in the vaccine)

Tier two incident type	Tier three incident type	Description
Procurement/ Supplier Processes	**Damaged/contaminated product**	Vaccine integrity has been damaged or contaminated such that it is not suitable for administration
	Expired product	Date of administration has surpassed the expiry date provided on the label of the container of the vaccine but has not been administered to the vaccine recipient
Storage Processes (in pharmacy or on unit)	**Damaged/contaminated product**	Vaccine integrity has been damaged or contaminated such that it is not suitable for administration
	Expired product	Date of administration has surpassed the expiry date provided on the label of the container of the vaccine but has not been administered to the vaccine recipient
	Incorrect storage environment	Vaccine has not been stored appropriately as per requirements. For example, a medication requiring protection from light is stored outside of packaging resulting in the product degrading and being ineffective
	Non-secure storage of controlled substances	Schedule 4 vaccine has not been stored in correct safe location according to Medicines and Poisons Regulations 2016 and hospital policy
	Refrigeration failure	Medication requiring refrigeration has not been stored in the refrigerator or cold chain has been breached (refrigerator temperature has not been maintained within required range)