The Immunisation Advisory Centre

COVID-19 EDUCATION

MINISTRY OF HEALTH
MANATŪ HAUORA

Clinical review of early COVID-19 AEFIs

This document outlines the review process for people reporting cases of Adverse Events Following Immunisation (AEFI) whilst the patient is at the COVID vaccination site (typically within the first 30 minutes) and to support people experiencing adverse events in their decision-making about a subsequent vaccine dose.

It is recommended that a designated clinical quality and safety officer reviews all pertinent AEFIs that occur within the post-vaccination observation period, on a regular basis. This would include all events that would raise concerns or questions about administering subsequent doses in their region. For each given event:

1. **Locate the individual in the CIR** and review the adverse event as detailed at the time.
2. **Gather further information as required** to ascertain what occurred, and relevant medical history. This may include:
   - Reviewing the clinical portal for admission notes, results of investigations, and previous admissions/clinic notes.
   - Contacting the patient for more details.
   - Contacting their GP.
3. **Make an assessment as to the safety of the next dose using the rubric below** and clinical judgement. It is recommended that clinician(s) with appropriate knowledge and experience be available for advice regarding serious AEFIs and decisions about subsequent doses.

VACCINE DOSE RUBRIC

Patient characteristics	Action
Prior history of allergic reaction to inhalant, food, venom Family history of allergies Co-morbidities Breast-feeding Pregnancy Immune suppression Minor non-allergic symptoms to first dose, such as site pain or redness, vasovagal or pre-vasovagal symptoms (including nausea/vomiting, dizziness, light-headedness).* History of anaphylaxis to another vaccine and/or multiple drugs (injectable and/or oral).**	**Proceed with vaccination** With an observation period of 20-30 minutes.
Events requiring extended observation, additional support or referral for care. For example: develops chest pain following first dose. Urticaria following first dose within the first 30 minutes. Wheeze/SOB immediately following first dose.	**Refer for advice** Proceed with vaccination after discussion with nominated specialist with an observation period of 20-30 minutes. Next vaccination may occur at a site with increased support and/or observation to at least 30 minutes.
Severe multisystem allergic reaction to the first dose of the Pfizer vaccine.	**Refer for advice** Referral to nominated specialist for assessment pathway and decision about next dose.

*Note: for those with vasovagal-type symptoms it may be appropriate to offer opportunity to lie down immediately after receiving vaccine.
**Note: may suggest vaccination at a site with increased support and/or increased observation period to at least 30 minutes.

IMAC06/2021

TYPES OF IMMEDIATE ADVERSE EVENTS AND REVACCINATION PLANS

Non-serious adverse event	These can all be safely revaccinated, though may need additional support, e.g. offer the next dose lying down or bring a support person.
Other non-allergic events	Those with non-allergic events and symptoms can be safely revaccinated after discussion with the nominated specialist. They may need additional support such as: - Having something to eat on hand or their usual medications– for example their GTN spray, asthma inhaler, migraine medication or glucose tablets. - Bringing a support person. - Having the next dose lying down. - Arranging for the next dose to be given at a site able to provide a different level of support appropriate to the patient's needs. It is recommended that DHBs have a site/s where such patients are directed to for closer observation or support.
Immediate allergic type symptoms or event	Such as urticaria or wheeze/SOB occurring at any time while the patient is still at the vaccination site after their immunisation (note: gastrointestinal symptoms are not a concern). This should be discussed with the DHB nominated clinician and a plan agreed.
Severe allergic reaction to Pfizer vaccine	These must be referred to the nominated specialist pathway for assessment, and a plan developed for the next dose.*

* Additional non-urgent specialist clinical advice for AEFI can be obtained by calling **0800 IMMUNE (466 863)** or emailing **0800immune@auckland.ac.nz**. Medical advisors at the Immunisation Advisory Centre are are available to support this non-urgent clinical advice as necessary.

4. Document the plan in the CIR, for example, by making a 'New Note' in the record of the dose associated with the adverse event. The template below is a suggestion of the elements to include in your documentation.

ADVERSE EVENT REVIEW

Note Title	Second dose plan
Adverse event reviewed:	In conjunction with XXX, and after discussion with the patient (as appropriate)
Background:	As appropriate
Assessment:	Non-allergic event and can be safely re-vaccinated (as appropriate)
Further actions or details:	As required eg offer next dose lying down (as appropriate)
Patient is aware of plan above:	(as appropriate)
Signed:	(Clinical quality and safety officer)

5. Ensure other actions and details have been actioned as appropriate, and that the patient is aware of and happy with the plan and has had an opportunity to ask questions.

6. The vaccination site lead and clinical lead should be aware of the plan if there are particular details that should be communicated to the site.

CALL 0800 IMMUNE (466 863) FOR NON-URGENT CLINICAL ADVICE

IMAC06/2021