

Vaccine Administration: Clinico-Legal Advice



Reading time:
Jayson Nagpiing

Last Modified on 01/05/2024 1:59 pm AEST

Tags: [Medico-Legal](#) | [Medical Practitioner](#) | [Practice Risk Management](#) | [FAQs](#)

Over the last decade, Australia has successfully achieved control of several vaccine preventable diseases with high routine vaccination coverage. There has been significant investment in the provision of cold chain guidelines and patient safety and risk minimisation education for vaccine providers. Breaks in the cold chain, lack of compliance to storage guidelines, exposure of vaccines to unacceptable temperatures and the concomitant loss of potency are all real concerns of which healthcare practitioners should be aware and they must be prepared to manage these adequately. Additionally, it must be considered that failures in technique or inadequate informed consent of the risks can lead to complaints and claims.

Frequently asked questions

What possible clinico-legal risks do I face in providing vaccinations?

In MIPS' experience, such issues can be rare and may not relate to all members, however they may be associated more with the manufacturer of the vaccine. In the instances where conduct of MIPS members is called into question, it is usually regarding issues such as wrongful administration of a vaccine to an individual, incorrect dosage, inappropriate follow-up of storage, cold chain management guidelines, inadequate dissemination of information about expected and rare side effects, lack of informed consent and disclosure of material risks; as well as family or custody issues arising from one parent's refusal to vaccinate a child. In these circumstances, there is a risk of a claim, complaint or an investigation (including regulatory) into your provision of healthcare, therefore it is always our advice that you alert MIPS if there is any occurrence of an adverse or unexpected outcome following a vaccination.

How can I reduce my clinico-legal risk when administering vaccinations?

Closely follow government advice from health authorities, the TGA, Medicines Australia, the National Immunisation Program, your College and the vaccine manufacturers. Always provide appropriate and adequate informed consent and good medical practice as defined by AHPRA. You must clearly document your consult advice, discussion and outcome in the patient's health record.

What should I do about patients who refuse to be vaccinated?

Ultimately the patient or parent/guardian must provide consent for a vaccination. Many individuals may be concerned about the risks or they do not clearly understand the benefits to the individual or the overall public health interests. In some cases, Government benefits or access to childcare may be prevented if certain vaccinations do not proceed. Your time and good communication may be required in assisting hesitant patients and information together with the provision of further government and health sector evidence-based resources may be required. Your discussions and the patient's ultimate decision needs to be clearly documented in the patient's record.

What should I do if a patient experiences an adverse event following administration of a vaccine?

Ensure you understand the recommendations stipulated by the Australian Health Department regarding how to manage **Adverse Events Following Immunisation (AEFI) including anaphylaxis**, and that you have the right equipment available. Document information about the vaccine you administer and report any adverse effects. Advice can be found in the **Immunisation Handbook**

from the Department of Health

If a patient has an adverse result, notify MIPS.

Will MIPS cover me in case of an adverse event related to administering a vaccine?

The **MIPS Indemnity Insurance Policy** provides cover for civil liability and defence costs for matters arising from healthcare provided by you. Within the policy, healthcare is defined:

"Healthcare means: Any care, treatment, advice, service or goods provided for the physical or mental health of a person..." See **Member Handbook** for full definition.

The administration of vaccinations would normally fall under the definition of healthcare, therefore MIPS will provide assistance and indemnity to members, subject to the terms and conditions of the policy and Member handbook.

Key advice to mitigate clinico-legal risks

- Keep up to date with advice from the Government Health Department and other authorities
- Ensure correct storage of all vaccines
- Ensure staff are adequately trained in:
 - Vaccine storage and vaccine cold chain standards
 - Effective responses to patients' concerns
 - Effective disclosure of material risks and formal informed consent is gathered to vaccinate
 - Clinical features, management and epidemiology of vaccine allergic responses
 - The use of personal protective equipment
 - Effectual communication approaches with patients
- Implement a formal monitoring routine to ensure proper equipment operation
- Audit your vaccine storage facilities regularly
- Implement adequate contingency plans to manage cold chain breaches and power breaks in your practice
- Implement open disclosure protocols to manage unexpected adverse events. Always contact MIPS as soon as an adverse event occurs to seek tailored advice to the situation.

Any queries, [contact MIPS](#)

Insurance cover is subject to the terms, conditions and exclusions of the policy. The information provided is general advice only and does not take into account your personal circumstances or needs. You should review the **Member Handbook Combined PDS and FSG** and/or contact MIPS on 1800 061 113, before making a decision. Information is current as at the date published.

Useful resources

- [COVID-19 vaccine information for GPs](#)
- [COVID-19 vaccination training program](#)
- [ACRRM Vaccination Information](#)
- [Australian Immunisation Handbook](#)
- [Australian National Immunisation Program](#)
- [Australian Immunisation Register](#)
- [Australian Commission on Safety and Quality in healthcare – Australian Open Disclosure Framework](#)
- [National Adverse Events Following Immunisation \(AEFI\) reporting form](#)
- [National Vaccine Storage Guidelines 'Strive for 5'](#)
- [RACGP Cold Chain Management](#)
- [RACGP Immunisation errors](#)
- [RACGP Standards for general practices \(5th edition\)](#)
- [RACGP - Improving vaccination cold chain in the general practice setting](#)
- [RACGP - National guide to a preventive health assessment for Aboriginal and Torres Strait Islander people \(immunisation\)](#)
- [RACGP - Infection prevention and control standards \(Section 2.1: Staff immunisation\)](#)

Related articles



[CAREER LEADERSHIP PROGRAM >](#)