

AMA Position on Vaccinations Outside of General Practice - 2021

1. Introduction

Vaccination is one of the most successful and cost-effective health interventions. Vaccination against vaccine-preventable disease (VPD) is a proven method of reducing the incidence of, and deaths from, diseases such as COVID-19¹, measles, tetanus, diphtheria, and *Haemophilus influenzae* type B. Australia's comprehensive vaccination program means that the occurrence of VPD is now very rare². This, together with improved vaccination rates³ means Australia has an excellent record of achievement in the prevention of disease through immunisation.

The Global Vaccine Action Plan 2011-2020⁴ encouraged countries to demonstrate a commitment to immunisation by setting ambitious but attainable national targets. Australia set the national aspirational coverage target at 95 per cent for the percentage of children who have received all the vaccines recommended for their age. While the target has been reached in some instances nationally the target remains slightly elusive⁵. Nevertheless, the COVID-19 pandemic has provided a strong reminder of the power of vaccination in preventing disease⁶ and resurgences of diseases such as measles have highlighted the importance on ongoing need for vaccination vigilance⁷. The subsequent Immunization Agenda 2030 aspiring to see everyone fully immunised, regardless of location, age, socioeconomic status or gender-related barriers and emphasizing immunisation as an essential part of primary health care.

In order to maintain Australia's vaccination record and strive towards the national aspirational target the community must be confident in the safety and quality of

¹ Department of Health COVID-19 Vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

<https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021>

² The Australian Immunisation Handbook, 10th Edition, Department of Health, 2015

<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home>

³ Annual Immunisation Coverage Report 2019. National Centre for Immunisation Research and Surveillance. Released November 2020.

[https://www.ncirs.org.au/sites/default/files/2020-](https://www.ncirs.org.au/sites/default/files/2020-11/NCIRS%20Annual%20Immunisation%20Coverage%20Report%202019%20Final.pdf)

[11/NCIRS%20Annual%20Immunisation%20Coverage%20Report%202019%20Final.pdf](https://www.ncirs.org.au/sites/default/files/2020-11/NCIRS%20Annual%20Immunisation%20Coverage%20Report%202019%20Final.pdf)

⁴ WHO Global Vaccine Action Plan 2011-2020

http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/

⁵ Annual Immunisation Coverage Report 2019. Op.cit

⁶ World Health Organization website page: <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

⁷ Immunization Agenda 2030. <http://www.immunizationagenda2030.org/>

vaccination services. This position statement outlines the principles for conducting vaccinations outside of general practice that the AMA believes will ensure safety and quality.

2. Delivery of vaccination services

About 90 percent of Australians have a GP they call their own. The vast majority of vaccination in Australia is provided by general practice. GPs provide vaccination to all ages as one of their many preventative health activities. This is provided in the context of patient centered, comprehensive, longitudinal and accessible care. GPs frequently undertake this both opportunistically when patients present for other concerns and as planned vaccinations

Every year GPs see 82% of children aged <15 years, with immunisation consistently the 2nd most prevalent problem managed at attendance⁸. Importantly, this enables GPs to provide other services in conjunction with immunisation services. These include addressing parental concerns, developmental assessment and management, nutrition and parenting assessment and education. GPs provide the vast majority of vaccination to adults. This is frequently undertaken opportunistically in the context of presentations for other conditions. In 2020, GPs delivered 67% of all influenza vaccines⁹ with number of influenza vaccinations in March and April of that year three times more than for the same period the previous year and almost nine times more than in 2018¹⁰. In the roll out of COVID-19 vaccines, the biggest single provider of vaccination was general practice¹¹, providing more than half of the nation's COVID-19 vaccinations.

In addition to delivering vaccinations in their general practices, vaccination clinics and services are also provided by GPs outside of their practice. GPs frequently provide vaccination to elderly and vulnerable patients and those with disabilities at home, at residential aged care and supported accommodation facilities GPs also are regularly contracted by State Governments to deliver the childhood vaccination programs provided through schools and community centers. GPs may be contracted to provide workplace seasonal influenza vaccinations or in cases of emergency, such as a pandemic or outbreak of a preventable disease, vaccinations at a place convenient to

⁸ Bayram C, Harrison, C, Charles J, Britt H. 2015. 'The kids are alright' – Changes in GP consultations with children 2000-15. Australian Family Physician. Volume 44. No 12. December 2015. pp 877-879

⁹ Department of Health. Influenza (flu) vaccines reported to the Australian Immunisation Register (AIR) as at close of business 26 August 2021.

<https://www.health.gov.au/sites/default/files/documents/2021/09/influenza-flu-immunisation-data-influenza-flu-immunisation-data-27-september-2021.pdf>

¹⁰ <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/record-165-million-flu-vaccines-to-protect-australians>

¹¹ Woodley M, Numbers confirm GPs are the 'backbone' of COVID vaccine rollout. News GP. RACGP 28 April 2021. <https://www1.racgp.org.au/newsgp/professional/numbers-confirm-gps-are-the-backbone-of-covid-vacc>

the community. Similarly, GPs may also be contracted by residential aged care facilities to provide vaccinations to residents.

Vaccination services are also delivered by a range of non-GP providers in a variety of settings. The most common of these are influenza vaccination through pharmacy settings and childhood immunization through maternal child health settings.

3. Safety and Quality

The vast majority of GPs (90.4%¹²) work in an accredited practice. These ensure high standards for the maintenance of cold chain, storage, administration and other quality control. Where vaccinations are provided within an accredited general practice, patients and the community can be confident that the practice has appropriate processes in place to maintain the efficacy of vaccines and ensure standards are met for the provision of vaccines. Such processes are a requirement under the RACGP Standards of General Practice against which practices are accredited. Approximately 84% of general practices are accredited.¹³

Whether vaccinations are provided by accredited or non-accredited practices, it is incumbent upon all medical practitioners that they adhere to the principles of good medical practice as provided for in the Medical Board of Australia's *Good Medical Practice: A Code of Conduct for Doctors in Australia*¹⁴.

From a safety and quality perspective, vaccinations provided outside of general practices, such as in pharmacies, nurse or Aboriginal immunisation health care worker clinics, maternal child health services, aged care facilities, and military posts, whether delivered by GPs or by other medical or health professionals, should be subject to the same safety and quality and accountability requirements as those provided within a general practice.

This is particularly important with regard to:

- ensuring patients are medically advised so they may give informed valid consent;
- pre-vaccination screening;
- vaccine efficacy;
- adherence to occupational health and safety standards;
- being prepared for, equipped and trained to manage anaphylaxis;
- monitoring for, recognising and treating adverse reactions;
- documentation and record keeping;

¹² BEACH Report (2015) *General Practice Activity in Australia 2014-15*

¹³ The Royal Australian College of General Practitioners. *General Practice: Health of the Nation 2020*. East Melbourne, Vic: RACGP, 2020.

¹⁴ Medical Board of Australia (2014) *Good medical practice: a code of conduct for doctors in Australia*. <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

- uploading vaccination information to the Australian Immunisation Register (AIR); and
- reporting adverse events to the appropriate authorities.

To ensure patient safety and the efficacy of vaccines, providers of vaccinations outside of general practices must meet a minimum set of standards that are compliant with governing regulations and existing guidelines and best practice.

4. Existing Guidelines for Vaccinations

*The National Vaccine Storage Guidelines: Strive for 5*¹⁵ provides practical advice to Australian vaccination service providers about maintaining the cold chain and preventing and managing cold chain breaches. They also discuss protocols for purchasing, transporting, storing, managing and monitoring the temperature consistency of vaccine stocks. Product information for each vaccine should be individually referred to along with clinical advice from the Australian Technical Advisory Group on Immunisation.

GP accreditation bodies such as Australian General Practice Accreditation Limited (AGPAL) and Quality Practice Accreditation (QPA) utilise the procedures and protocols outlined in the guidelines when assessing if general practices meet criterion regarding vaccine potency, under the standard for clinical support processes in the current edition of the *RACGP standards for general practice*.

The *Australian Immunisation Handbook*¹⁶ provides clinical guidelines for health professionals on the safest and most effective use of vaccines. The Handbook is an online resource which is updated as required.

State/Territory legislations determine who has access to and can administer vaccines and the reporting requirements of an adverse event following immunisation. State/Territory legislations are not always consistent with each other in this regard. The principles listed below account for the legislative differences. All vaccines must be administered in accordance with relevant legislation, best practice and the guidelines and recommendations as outlined in the Australian Immunisation Handbook.

5. Principles for Conducting Vaccinations Outside of General Practice

The AMA believes best practice is for vaccination to be provided by a medical practitioner or by a nurse under the supervision of a medical practitioner. This enables vaccination to be provided as a service alongside comprehensive patient care and preventative activities.

Where States/Territories have legislated to allow “Authorised Immunisers” (including

¹⁵ Dept. of Health and Ageing (2013) *The National Vaccine Storage Guidelines: Strive for 5*.
<https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>

¹⁶ Australian Immunisation Handbook. Department of Health.
<https://immunisationhandbook.health.gov.au/>

nurses, midwives, pharmacists and Aboriginal and Torres Strait Islander Health Care Workers) to administer vaccines independent of a medical order, each jurisdiction should have guidelines for immunisation providers who employ an “Authorised Immuniser”. This should also apply in circumstances (such as a pandemic response) where a State or Territory Policy Directive extends “Authorised Immuniser” status to other health practitioners or health practitioner students. These guidelines should be used in conjunction with the professional standards and guidelines that apply to each health discipline.

The following principles have been developed to provide a consistent framework for immunisations conducted outside of general practices:

Providers of vaccination outside general practice must:

- Be authorised under State/Territory legislation to obtain and administer vaccines. (In some jurisdictions a nurse administering a medication without the express consent of a (governing) doctor is a breach of the Medical Act, as it is deemed to be 'prescribing'. Mass immunisations should not proceed unless legislative requirements are met.)
- Be a medical practitioner; or
 - Be an Authorised Immuniser; under any relevant National legislation and practising in line with relevant State/Territory legislation; and
 - Hold a statement of proficiency in cardio-pulmonary resuscitation; and
 - Have completed an immunisation accreditation program and maintain authority to immunise; and
 - Be employed in connection with a vaccination program in a health service or a place of work.
- Act in accordance with the standards and procedures specified in the Australian Immunisation Handbook – particularly with regard to:
 - appropriate pre-vaccination screening;
 - obtaining valid informed consent; and
 - having an appropriately prepared anaphylaxis response kit on site.
- Have an Ahpra registered medical professional onsite that is trained for and able to administer first aid and respond to anaphylaxis.
- Have appropriate policy, procedures and monitoring in place to maintain cold chain as specified in the *National Vaccine Storage Guidelines: Strive for 5*¹⁷; at all stages of receiving, holding and transporting the vaccines, together with supporting documentation.
- Act in accordance with relevant State/Territory legislation.
- Report any suspected adverse reaction following immunisation to the Therapeutic Goods Administration (TGA) or relevant authority.

¹⁷ Dept. of Health and Ageing (2013) The National Vaccine Storage Guidelines: Strive for 5. <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>

- Keep complete records of administration including patient name, address, contact details, vaccination name and brand, batch no, site of immunisation and length of stay at place of administration after giving the vaccination.
- Provide the vaccine recipient with a record/certificate of vaccination.
- Upload the vaccination to the AIR.
- Advise the vaccine recipient's nominated GP of the vaccination.
- Adhere to all Privacy and confidentiality requirements including relevant guidelines for documentation maintenance and duration of storage.

The AMA is of the view that the Australian Commission on Safety and Quality in Healthcare (or similar body) should use these principles as the basis for developing standards to ensure safe and quality practice where immunisations are provided outside of accredited general practices.

At a minimum, in the interests of patient health, the AMA encourages any provider delivering vaccine services outside of general practice to adhere to the above principles.