



Position Statement on Vaccinations outside of General Practice

Introduction

Vaccination against preventable disease is a proven method of reducing the incidence of and deaths from diseases such as measles, tetanus, diphtheria, and *Haemophilus influenzae* type B. Australia's comprehensive vaccination program means that the occurrence of vaccine-preventable diseases (VPD) is now very rareⁱ. This, coupled with substantially improved vaccination rates in the last 20 yearsⁱⁱ means Australia has an excellent record of achievement in the prevention of disease through immunisation.

To help maintain Australia's record in this regard the community must be confident in the safety and quality of immunisation services.

Delivery

Vaccination services are delivered by a range of providers in a variety of settings. GPs, however are the predominant provider of vaccination services in Australia. GPs see 93%ⁱⁱⁱ of children in 0-6 year age group an average of seven times a year and currently deliver 64%^{iv} of all vaccinations. In addition to delivering vaccinations in their general practices, GPs are regularly contracted by State Governments to deliver the childhood vaccination programs provided through schools and community centers.

Vaccination clinics may also be provided by GPs outside of their practice. 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 where herd immunity levels are low, may provide vaccinations at a place convenient to the community.

Safety and Quality

The vast majority of GPs (85%^v) work in an accredited practice. Where vaccinations are provided within an accredited general practice patients can be confident that the practice has appropriate process in place to maintain the potency of vaccines. Such processes are a requirement under the RACGP Standards of General Practice (4th edition) against which practices are accredited. Approximately 67% of general practices are accredited^{vi}.

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*.

From a safety and quality perspective vaccinations provided outside of general practices, eg in pharmacies, nurse clinics, aged care facilities, military posts etc, whether delivered by GPs or by other medical or health professionals should be subject to the same safety and quality requirements for vaccinations provided within a general practice and the providers subject to the same level of accountability.

This is particularly important with regard to:

- ensuring patients are medically advised so they may provide informed valid consent,
- pre-vaccination screening,
- vaccine potency,
- adherence to occupational health and safety standards,
- being prepared for, equipped and trained to handle any anaphylaxis reaction,
- monitoring for, recognising and treating any adverse reaction,
- record keeping, and
- reporting adverse events to the appropriate authorities.

To ensure patient safety and the potency of vaccines providers of vaccinations outside of general practices should therefore be required to meet a minimum set of standards that are compliant with governing regulations and existing guidelines and best practice.

Existing Guidelines for Vaccinations

The National Vaccine Storage Guidelines: Strive for 5 provides practical advice to Australian vaccination service providers about maintaining the cold chain and preventing and managing cold chain breaches. The guidelines highlight the importance of storing vaccines at between +2°C to +8°C to maintain potency. They also discuss protocols for purchasing, transporting, storing, managing and monitoring temperature consistency of vaccine stocks.

Australian General Practice Accreditation Limited (AGPAL) and General Practice Accreditation (GPA) utilise the procedures and protocols outlined in the guidelines when assessing if general practices meet Criterion 5:3.2 Vaccine potency, under Standard 5.3, in the 4th edition of the *RACGP standards for general practice*.

The National Immunisation Handbook (9th edition) 2008 provides clinical guidelines for health professionals on the safest and most effective use of vaccines. The Handbook has three parts.

Part 1 addresses chronologically the steps involved around a vaccination encounter including:

- pre-vaccination procedures (cold chain, anaphylaxis response kit, consent, pre-vaccination screening and catch-up)
- administration of vaccines (route, needle size and injection site)
- post-vaccination procedures (adverse event reporting and recording of vaccinations)

Part 2 covers recommendations for the vaccination of special risk groups

Part 3 covers vaccines listed by disease

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.

Principles for Conducting Vaccinations Outside of General Practice

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

Providers must:

- Be authorised under State/Territory legislation to obtain and administer vaccines. (In some states, a nurse administering a medication without the expressed 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 if other:
 - Be a registered nurse; under the 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 procedures specified in the National Health and Medical Research Council's The Australian Immunisation Handbook – particularly with regard to:
 - appropriate pre-vaccination screening,
 - obtaining informed consent, and
 - having an appropriately prepared anaphylaxis response kit on site,
- Have appropriate procedures in place to maintain cold chain as specified in the National Vaccine Storage Guidelines: Strive for 5; at all stages of receiving, holding and transporting the vaccines plus supporting documentation.
- Act in accordance with relevant State/Territory legislation;
- Report any suspected adverse reaction following immunisation to the Therapeutic Goods Administration (TGA),
- 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; and: -
- Provide vaccine recipient with a record/certificate of vaccination, and

- Advise 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.

Conclusion

The community can be confident that systems for ensuring the quality control of and safe delivery of vaccines already exist for vaccines provided within general practice. It is important that where vaccines are provided outside of general practice that the community can have a similar level of confidence in the safety and quality of the vaccination service being provided.

It is important therefore that these principles should be used by the Australian Commission on Safety and Quality in Healthcare (or similar body) as a 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, that any provider delivering vaccine services outside of general practice adhere to the above principles.

ⁱ *The Australian Immunisation Handbook*, 9th edition, Department of Health and Ageing, 2008

ⁱⁱ *Australia's Health*, Australian Institute of Health and Welfare, 2010

ⁱⁱⁱ *Immunise Australia: The Seven Point Plan*, Department of Health and Ageing, 1997

^{iv} Australian Childhood Immunisation Register (ACIR) Provider statistics as at 30 September 2010

^v *General practice activity in Australia 2008-09*. C. Bayram, H. Britt et al. AIHW, 2009

^{vi} *Practice Incentive Program Performance Audit Report No 5. 2010-11*. National Audit Office. 2010