

Drug-induced anaphylaxis in Australia: we need a national drug allergy registry

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A comprehensive adverse drug reaction registry with validated information would improve patient safety and care



Just over two years ago, the Victorian Department of Health introduced mandatory reporting of cases of anaphylaxis in people presenting to public and private emergency departments,¹ facilitating data collection unique in Australia. In this issue of the *MJA*, Drewett and colleagues report their analysis of the first two years of data collected, focusing on medication-related anaphylaxis.² While food allergy was the leading cause of anaphylaxis, especially in younger people, drug-related anaphylaxis accounted for 12% of all cases, and for a relatively high proportion in adults aged 40 years or more. Antimicrobial agents and non-steroidal anti-inflammatory drugs were most frequently involved.²

Immediate (IgE-mediated) drug allergy can lead to life-threatening anaphylaxis. While drug allergies are the most frequent causes of fatal anaphylaxis in Australia,^{3,4} no drug-related anaphylaxis deaths were recorded in the Victorian data.² Not all life-threatening adverse drug reactions (ADRs) are immediate. Non-immediate (T cell-mediated) severe cutaneous adverse reactions (SCARs) are also potentially lethal,⁵ but are not notifiable under the Victorian Anaphylaxis Notification Scheme. Neither Australian epidemiology data regarding SCARs, nor information on prevalence and mortality rates for ADRs for specific drugs, are available.

Overseas, several national anaphylaxis registries collect food and drug allergy data similar to those collected in Victoria. They differ markedly in design (live registries, fatal anaphylaxis registries) and purpose (research, clinical feedback, surveillance),⁶ but do not collect data on all ADRs, a critical deficit. The New Zealand ADR registry is more comprehensive: the Centre for Adverse Reactions Monitoring has one of the highest pharmacovigilance reporting rates in the world,⁷ and health professionals and the public can report ADRs to the centre for verification.

An alternative mechanism for collecting ADR information in Australia is the Therapeutic Goods Administration (TGA) adverse event notifications database.⁸ However, this provides only an incomplete record, as ADR reporting to the TGA is not mandatory; further, the TGA database does not differentiate between side effects, intolerance, and allergies. ADRs can also be recorded in individuals' My Health Records (MHR), but the information is not curated for data extraction. The MHR includes both patient- and doctor-reported information, and relies on general practitioners uploading and updating patient ADR



information included in shared health or hospital discharge summaries, as many specialists cannot add information to the MHR. Consequently, the TGA database and MHR are not substitutes for a national ADR registry.

Accurate case evaluation, documentation, and verification are essential when collecting ADR data. In the Victorian system, data can only be entered with case verification. For a national system, mandatory health professional reporting would be needed, as would streamlined online entry processes, possibly incorporated into electronic health records. Patients should be encouraged to discuss ADRs with their health care practitioners. Data quality is generally a challenge with patient records; overseas registries have mitigated the problem with verification processes.⁶

To ensure the quality of data, we need a standardised definition of anaphylaxis and standardised ADR terminology; a national ADR data collection system, or state-based systems that provide data that can be pooled; validation of the collected data; standardised ADR health professional education; and appropriate anaphylaxis and ADR coding in electronic health records.

The greatest benefit of a national ADR registry with validated information would be improved patient safety and care. In addition to drug-related anaphylaxis, a national ADR registry should also capture SCARs associated with serious long term effects, including high fatality risk. The registry should obtain data on ADR frequency and types, generating evidence for informing clinical practice. In addition, the registry would provide information about the drugs implicated, risk factors for allergy, and the ADR burden on the health system, which could inform resource allocation. The registry should capture data from hospital events, emergency department presentations, outpatient events, and events in primary care.

To establish an effective ADR registry, we need to overcome several obstacles, including legislative and terminology problems. It is critical that consistent ADR terminology is used. For example, the recently published *Acute anaphylaxis clinical care standard*⁹ provides a nationally standardised anaphylaxis

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definition, consistent with the Australasian Society of Clinical Immunology and Allergy guidelines,¹⁰ that could guide drug allergy reporting.

As the education of clinicians about ADRs is often limited,³ a national education program (with professional development points) is required to ensure that quality ADR information is entered into the registry. Electronic health records should enable accurate ADR documentation according to the level of clinician knowledge.

The Victorian Anaphylaxis Notification Scheme and similar overseas registries, even with their limitations, illustrate the benefits of collecting and reporting drug and food allergy data. Australia needs a national registry not only for cases of anaphylaxis, but for all severe ADRs. What are we waiting for?

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1 Victorian Department of Health. Anaphylaxis notifications. Updated 21 Oct 2021. <https://www.health.vic.gov.au/public-health/anaphylaxis-notifications> (viewed Mar 2022).

- 2 Drewett GP, Encena J, Gregory J, et al. Anaphylaxis in Victoria: presentations to emergency departments, with a focus on drug- and antimicrobial-related cases. *Med J Aust* 2022; 216: 520-524.
- 3 Lucas M, Loh RKS, Smith WB. Improving drug allergy management in Australia: education, communication and accurate information. *Med J Aust* 2019; 210: 62-64. <https://www.mja.com.au/journal/2019/210/2/improving-drug-allergy-management-australia-education-communication-and-accurate>
- 4 Mullins RJ, Wainstein BK, Barnes EH, et al. Increases in anaphylaxis fatalities in Australia from 1997 to 2013. *Clin Exp Allergy* 2016; 46: 1099-1110.
- 5 Demoly P, Adkinson NF, Brockow K, et al. International consensus on drug allergy. *Allergy* 2014; 69: 420-437.
- 6 Stiles S, Roche I, Said M, et al. Overview of registries for anaphylaxis: a scoping review. *JBI Evid Synth* 2022; 19: 1193-1201.
- 7 New Zealand Pharmacovigilance Centre. CARM (Centre for Adverse Reactions Monitoring). 2022. <https://nzphvc.otago.ac.nz/carm> (viewed Mar 2022).
- 8 Therapeutic Goods Administration (Australian Department of Health). Database of adverse event notifications. <https://www.tga.gov.au/database-adverse-event-notifications-daen> (viewed Mar 2022).
- 9 Australian Commission on Safety and Quality in Health Care. Acute anaphylaxis clinical care standard. Nov 2021. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/acute-anaphylaxis-clinical-care-standard> (viewed Mar 2022).
- 10 Australasian Society of Clinical Immunology and Allergy. ASCIA guidelines: acute management of anaphylaxis. 2021. <https://allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines> (viewed Mar 2022). ■