

Managing adverse drug reactions: time to get serious

Identifying these reactions is a good start, now we must focus on managing and preventing them

Australia's voluntary reporting system for adverse drug reactions has one of the highest per capita reporting rates in the world.¹ Reports to the Australian Adverse Drug Reactions Advisory Committee have played a significant international role in identifying previously unrecognised adverse drug reactions (ADRs), such as hepatitis with flucloxacillin and amoxicillin–clavulanic acid.¹

However, in this issue of the Journal (*page 267*), Burgess and colleagues remind us that, although identifying ADRs is important, managing and preventing them are equally critical.² Their study in Western Australia showed that the rate of ADRs associated with hospitalisations in people aged 60 years and over more than doubled between 1991 and 2002.² South Australian data for all age groups showed a similar rise and correlated strongly with changes in medication use in the community.³ National data also show increases,^{3,4} although the correlation with medication use is less clear. As the Australian coding standards allow ADR codes to be applied to any diagnosis, not just the principal diagnosis,⁵ the WA data may represent all ADRs, not just those linked to admission or

length of stay. Efforts to improve coding will have contributed to some of the observed rise as, for example, rates in SA increased in the year casemix funding was introduced. Increases in the number of hospital admissions over time will also have contributed, but the strong correlation with medication use in SA suggests an exposure effect.

The rise in ADRs is not inevitable. The Quality in Australian Health Care Study estimated that 43% of adverse drug events were potentially preventable.⁶ Similarly, an Australian study of ADRs in oncology patients demonstrated that 48% of predictable ADRs were potentially preventable.⁷

The questions raised by Burgess et al's study are: why are ADR rates rising and why have we been unable to prevent the rise, given the preventability estimates? Burgess et al suggest the rise represents a failure of the national strategies to improve the quality and safety of medicine use. There are many data available with which to dispute this claim. Over 100 performance indicators are used to routinely monitor the National Strategy for Quality Use of Medicines, with

more than 85% of them demonstrating improvements over time and significant development of services and resources.⁴ The National Prescribing Service (NPS) has driven cultural change about quality prescribing in general practice, with more than 50% of general practitioners now voluntarily participating in initiatives to improve prescribing.⁸ Improvements in antibiotic, antidiabetic, analgesic and antihypertensive use have been seen, in keeping with NPS messages.⁸ The Safety and Quality Council are also driving cultural change, supporting the National Medication Safety Breakthrough Collaborative, which has worked with 100 hospitals and over 480 staff. This initiative is now focusing on disseminating knowledge of and sustaining successful practices.

What the data on ADRs in hospitals indicate is our failure to focus on management strategies for ADRs as a specific topic within the national initiatives. Quality use of medicines and safety initiatives have generally focused on development of services, appropriate selection of medicines and error reduction. The focus for ADRs has remained predominantly on reporting and identification, with less emphasis on management.

To improve ADR management, we must improve our information sources. Product and consumer information list ADRs but usually fail to provide management strategies. Incidence estimates in product information are based on the initial clinical trials and not easily updated when postmarketing surveillance is based on voluntary reporting. Information on the duration of side effects and consumer experience with medicines is also limited. Providing lists of ADRs does little to change behaviour; management strategies are required.⁹ The data-linkage studies now under way will enable better incidence data to be developed, as well as identify population groups most at risk of ADRs. The newly established consumer reporting service will also facilitate better understanding of consumer perspectives. This must be incorporated into information sources and supported by clear instruction on management.

Detection of ADRs in routine clinical practice must also be improved, with more training needed in this area for health professionals. An Australian study of older people considered at high risk of medication misadventure found that 19% had had an ADR which had not been detected in routine clinical care, even though most were using multiple medicines, had comorbidities and were aged over 65 years.¹⁰

The other major requirement is to increase participation in services demonstrated to improve use of medicines and to help prevent ADRs. While consumer medicine information is now available for over 2000 products, it is not provided routinely and continues to be regarded negatively among some health professionals, despite consumer calls for information on side effects.¹¹

Home-medication reviews involving general practitioners, pharmacists and patients have been shown to resolve or ameliorate ADRs in 56% of cases.¹² However, the 26 000 home-medication reviews undertaken in 2003–2004¹³ represented about 10% of the population likely to benefit from the service.

Other multidisciplinary approaches such as clinical pharmacy, hospital discharge planning and case conferencing services have all been shown to reduce adverse drug events,³ but only 13 000 case conferences and 96 000 discharge-planning services were funded under Medicare's Enhanced Primary Care packages in 2003–2004.¹⁴ The latter services account for 3% of hospital admissions involving

overnight stays. These services are relatively new, which may contribute to the low uptake. However, their administrative requirements also need to be streamlined, as general practitioners have found them to be bureaucratic and onerous.¹⁵ In addition, trying to incorporate new services on top of existing practice may be adding to the burden and low uptake. It may be necessary to redesign general-practice systems to accommodate these new ways of working.

Finally, we require a cultural and attitudinal change to the preventability of ADRs and to multidisciplinary practice. ADRs are often considered part of the price to be paid for the therapeutic benefit of medicines. The rise in ADRs despite preventability estimates suggests that we are currently paying too high a price. Preventing ADRs requires active participation by everyone.

Elizabeth E Roughead

Senior Lecturer, Quality Use of Medicines and Pharmacy Research Centre,
School of Pharmacy and Medical Sciences
University of South Australia, Adelaide, SA libby.roughead@unisa.edu.au

- 1 Boyd IW. The role of the Australian Adverse Drug Reactions Advisory Committee (ADRAC) in monitoring drug safety. *Toxicology* 2002; 181-182: 99-102.
- 2 Burgess CL, Holman CDJ, Satti AG. Adverse drug reactions in older Australians, 1981–2002. *Med J Aust* 2005; 182: 267-270.
- 3 Safety and Quality Council. Second national report on patient safety, improving medication safety. Canberra: Australian Council for Safety and Quality in Health Care, 2002.
- 4 Quality Use of Medicines and Pharmacy Research Centre. Measurement of the quality use of medicines component of Australia's National Medicines Policy. Canberra: Department of Health and Ageing. Available at: www.health.gov.au/internet/wcms/publishing.nsf/Content/nmp-pdf-qum-nmp-cnt.htm (accessed Jan 2005).
- 5 National Centre for Classification in Health. International statistical classification of diseases and related health problems, 10th revision, Australian modification (ICD-10-AM). Vol 5. 3rd ed. Sydney: NCCH, 2002.
- 6 Day RO, Shenfield G, Smith AJ. The Quality in Australian Health Care Study (QAHCS): drug related adverse events. Presented at the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) Conference, 1995; Adelaide, SA.
- 7 Lau PM, Stewart K, Dooley M. The ten most common adverse drug reactions (ADRs) in oncology patients: do they matter to you? *Support Care Cancer* 2004; 12: 626-633.
- 8 National Prescribing Service. Evaluation report no. 7. Sydney: NPS, 2004.
- 9 Weatherby LB, Nordstrom BL, Fife D, Walker AM. The impact of wording in "Dear doctor" letters and in black box labels. *Clin Pharmacol Ther* 2002; 72: 735-742.
- 10 Roughead EE, Barratt JD, Gilbert AL. Medication-related problems commonly occurring in an Australian community setting. *Pharmacoepidemiol Drug Saf* 2004; 13: 83-87.
- 11 Benton M, Snow K, Parr V. Evaluation of the medicines information for consumers (MIC) program. A marketing research report prepared for the Pharmacy Guild of Australia. Sydney: Taylor Nelson Sofres plc, 2004. Available at: www.guild.org.au/public/researchdocs/MICfinal_rep_9Nov04.pdf (accessed Jan 2005).
- 12 Gilbert AL, Barratt JD, Roughead EE. Medication management services: alleviating adverse drug reactions. *Pharmacoepidemiol Drug Saf* 2002; 11 Suppl 1: S39.
- 13 Pharmacy Guild of Australia. Cumulative national HMR claims. Available at: www.guild.org.au/public/dmmfiles/statscumulnat.pdf (accessed Dec 2004).
- 14 Health Insurance Commission. Medicare Benefits Schedule (MBS) item statistics reports. Available at: www.hic.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml (accessed Dec 2004).
- 15 Mitchell GK, de Jong IC, Del Mar CB, et al. General practitioner attitudes to case conferences: how can we increase participation and effectiveness? *Med J Aust* 2002; 177: 95-97. □