

## Adverse drug events: counting is not enough, action is needed

Elizabeth E Roughead and Joel Lexchin

*To tackle this problem we need a systems approach involving multiple strategies*

An article in this issue of the Journal by Miller and colleagues (*page 321*)<sup>1</sup> provides further evidence of the magnitude and seriousness of the problem of adverse drug events (ADEs) in general practice. Their study highlights our ongoing failure to address the problem of ADEs — medication-related incidents that cause patient harm.

Each year in Australia, about 17.5 million people make 95 million visits to their general practitioner.<sup>2</sup> Based on Miller et al's estimate — that 10.4% of patients attending general practice experience an ADE — almost 2 million people have an ADE annually. Moreover, their findings show that these ADEs are not trivial, with about 1 million being moderate or severe and 138 000 requiring hospitalisation, a finding consistent with previous estimates.<sup>3</sup> Many of these ADEs are preventable, although the exact proportion of preventable events can be debated.

There have now been more than 30 Australian studies estimating the number of ADEs in different settings.<sup>3</sup> It is clear that counting is not enough — it is time for action, but what can be done?

Every developed country is trying to cope with the problem of ADEs. Australia has many structures and initiatives in place to reduce the occurrence of ADEs, and preventing ADEs necessarily involves them all.<sup>3</sup> Regulatory agencies, the medicines industry, quality use of medicines organisations and information providers, safety and quality organisations, professional bodies, health professionals and consumers can all assist.

Prevention of ADEs cannot occur without better knowledge. It is noteworthy that the Therapeutic Goods Administration has adopted the European Medicines Agency guideline on pharmacovigilance planning. Increased pharmacovigilance, including observational studies, will require a substantial increase in resources. In Canada, less than 10% of the budget for drug regulation is allocated to issues concerning marketed products, including safety. Yet, in 50% of new drugs, serious adverse drug reactions are detected after market approval.<sup>4</sup>

We need systems that can deal with the reality that only limited numbers of highly selected patients are studied before a drug is marketed. Regulators may have to consider restricting prescribing of new medications if they have limited safety information, particularly when equally efficacious therapy is available. New systems for detecting early signals of potential adverse drug reactions in expanded populations could complement the current reporting system for adverse drug reactions. An example is the Drug Safety Research Unit in the United Kingdom, which captures information on the first 10 000 patients using a newly marketed drug.<sup>5</sup> We need to capitalise on and expand the importance and significance of consumer reporting.

Instead of relying on pharmaceutical representatives (as a considerable proportion do), health professionals require easily accessible, balanced information sources that can be used in a

timely manner for their clinical decisions.<sup>6</sup> Pharmaceutical representatives frequently fail to supply safety information,<sup>7</sup> and their promotional techniques may lead to more widespread use of new medications. In Canada, there were almost 50 000 visits by pharmaceutical representatives to doctors for rofecoxib, and over 1 million samples were handed out in its first year on the market. This helped increase rofecoxib prescriptions by 125% in the following year and, in Ontario, led to increased hospital admissions for gastrointestinal bleeds.<sup>8</sup> By the time rofecoxib was withdrawn for safety reasons, it accounted for 40% of Australian expenditure on non-steroidal anti-inflammatory agents,<sup>9</sup> possibly exposing excessive numbers of people to unnecessary risk.

The activities of pharmaceutical representatives are regulated by Medicines Australia's code of conduct governing pharmaceutical promotion.<sup>7</sup> Medicines Australia must find ways to improve the provision of information to health professionals by the medicines industry through active monitoring of the code. If this is not possible, other methods of regulating promotion may need to be considered.

Leadership from professional bodies and quality use of medicines agencies is required. Promoting balanced information sources, as a key element of professional standards, may assist in preventing ADEs. Activities sponsored by the National Prescribing Service also should have just as much of a role in preventing ADEs as they do in promoting appropriate management options.

Developing a culture of safety in community practice will require leadership from the newly established Australian Commission on Safety and Quality in Health Care. We need a no-blame culture, supporting safer systems in practice, as well as incident monitoring, with timely feedback to practitioners and consumers. Medication safety improvement toolkits, similar to those developed for hospital practice,<sup>10</sup> may be suitable for community practice, but their effectiveness in this setting must first be assessed.

A study monitoring all incidents of potential or actual harm to general practice patients, including ADEs, found that the most common contributing factor was poor communication between practitioners and patients.<sup>11</sup> Professional bodies and medical schools might help by providing educational programs to improve GPs' communication skills about ADEs. Failure to recognise the signs and symptoms was another contributing factor to incidents.<sup>11</sup> Consumer Medicine Information needs to be routinely used in medical encounters, so that patients can recognise ADEs and know what to report to their GP, even if he or she fails to ask. Case-conferencing and reviewing patients' medication at home have the potential to reduce ADEs.<sup>3</sup> These services are funded, but still underutilised.

Poor communication between health professionals was another common cause of incidents,<sup>11</sup> highlighting the need for better information systems in community practice. It is health professionals, in consultation with patients, who must identify ADEs in

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practice. Therefore, computerised systems should alert GPs when patients receive new prescriptions and identify all medications they are receiving from any provider.<sup>12</sup> This knowledge can trigger GPs to ask about ADEs when patients first return after a new medication has been prescribed, as this is the interval in which most ADEs occur. Knowledge of what their patients are taking can help GPs flag which of their patients are at high risk; ADEs in this group are more likely to be fatal.<sup>13</sup>

If we do not develop a culture of safety, we will continue to have an extra 140 000 hospitalisations per year caused by ADEs. Although ADEs commonly occur in general practice, preventing them is not solely the responsibility of GPs. We need a systems approach involving multiple strategies to tackle this problem. Otherwise, patients will continue to suffer needlessly from ADEs.

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