

## Monitoring vaccine reactions in Australia

*Australia's effective monitoring system shows that serious reactions are rare*

Australia has achieved very high levels of vaccination coverage in the past 10 years, with 91% of children fully vaccinated at 12 months of age and 92.1% at 2 years.<sup>1</sup> Consequently, rates of vaccine-preventable diseases are very low. As the incidence of vaccine-preventable diseases declines, the safety and side effects of vaccines gain prominence, and an increasingly important role of health care professionals is to communicate the benefits and risks of vaccination to parents.<sup>2</sup>

Worries about vaccines date back more than 200 years, when Jenner's introduction of cowpox vaccine prompted cartoons in the satirical magazine *Punch* depicting vaccine recipients turning into cows. More recently, unproven and unjustified concerns about pertussis vaccine<sup>3</sup> and measles–mumps–rubella vaccine<sup>4</sup> have resulted in falls in vaccination uptake in the United Kingdom, and the needless deaths of children.<sup>3,4</sup>

Vaccine constituents, such as preservatives, stabilisers, adjuvants and biological growth media used in vaccine production, are necessary to ensure the efficacy, stability and safety of vaccines, but can also contribute to consumer concerns.<sup>5</sup> A recent review concluded that the amounts of aluminium, formaldehyde, antibiotics and yeast proteins in vaccines have not been found to be harmful to humans and animals in exposure studies.<sup>5</sup>

Currently, if providers have concerns about constituents of vaccines, they can consult the excellent booklet *Myths and realities*.<sup>6</sup> In addition, the National Centre for Immunisation Research and Surveillance (NCIRS) website (<<http://www.ncirs.usyd.edu.au>>) has a fact sheet relating to thiomersal: <<http://www.ncirs.usyd.edu.au/facts/f-thiomersal.html>>. The US Centers for Disease Control and Prevention have fact sheets on vaccine components at <<http://www.cdc.gov/node.do/id/0900f3ec8006587f>>.

The article by Eldred et al<sup>7</sup> in this issue of the *Journal* (page 170) is an important overview of vaccine components and constituents of vaccines in use in Australia, and is an important reference for vaccine providers to answer consumer concerns and questions.

Serious adverse events following vaccination are rare, and the risk of morbidity associated with these adverse events is generally far less than the risk from catching a vaccine-preventable disease. Nevertheless, it is extremely important to have in place adequate surveillance for adverse events associated with vaccines. Both the public and health care professionals need to feel confident of vaccine safety. Australia has had local reporting mechanisms for many years, but only since 2000 has there been a national reporting system.<sup>8</sup> Under the current system, which was driven by the dynamism of John McEwen, former Principal Medical Adviser of the Therapeutic Goods Administration (TGA), all adverse reports are coordinated by the Australian Adverse Drug Reactions Unit (ADRU) of the TGA. Adverse events associated with vaccines can be reported to ADRU by health care professionals or the public by telephone (02 6232 8386) or by prepaid reporting form ("blue card") or online at <<http://tga.gov.au/adr/bluecard.htm>>. The data are further analysed by NCIRS and regularly reported in *Communicable diseases intelligence*.<sup>9-11</sup>

The data are extremely reassuring: serious adverse events are rare. Between 2000 and 2004, only seven of 5128 adverse events reported following vaccination were reported as having persisted and resulted in sequelae.<sup>9-11</sup> Furthermore, the reporting of an

adverse event following vaccination implies an association in timing with vaccine administration, but does not necessarily mean the vaccine caused the reported adverse event.

Australia has an effective system for monitoring vaccine safety. In future, privacy laws permitting, it is hoped to link Australia's database of immunisations, the Australian Childhood Immunisation Register, with hospital admissions to be able to look actively at questions regarding the safety of specific vaccines.

It is vital that parents and providers are fully informed about the risk of vaccines and of the diseases they prevent. Australia's monitoring system will continue to gather the data for informed decision-making.

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