

# Vaccination, consent and multidose vials

Mark R Diamond and Angela O'Brien-Malone

Multidose vials (MDVs) for injectable drugs and vaccines are known to be associated with an increased risk of infection in injected patients. Although safety has undoubtedly improved since the case of vaccination-associated fatal septicaemia in two workers at a factory in Geelong during the Hong Kong influenza pandemic of 1968,<sup>1</sup> infections due to vial contamination still occur.<sup>2-4</sup> (For a recent, comprehensive review of infection risk associated with MDVs, particularly in immunisation programs, see Gosbell and colleagues.<sup>5</sup>)

It was therefore not surprising that an outcry followed the announcement by the Minister for Health and Ageing that most of the Australian Government's order of 21 million doses of vaccine against the pandemic (H1N1) 2009 influenza virus (Panvax, CSL Limited, Melbourne, Vic) would be supplied in MDVs. The Australasian Society for Infectious Diseases considered the risks posed by the MDVs to be sufficiently serious for them to write to the Commonwealth Chief Medical Officer, urging him to delay distribution of the vaccine until it could be supplied in single-dose vials.<sup>6</sup> However, the Australian Government Department of Health and Ageing (DoHA) refused to delay and proceeded with the distribution of MDVs, arguing that their use had always formed part of the government's pandemic plan.<sup>7</sup>

Before distributing the MDVs, the DoHA developed and published guidelines for their safe use.<sup>8</sup> The MDVs were then distributed with accompanying patient information sheets<sup>9</sup> and consent forms.<sup>10</sup>

## What is the duty of a vaccinating practitioner?

Before 1992, the common law in Australia had used a single yardstick for measuring the competence with which a medical practitioner carries out diagnosis or treatment, and the degree to which a medical practitioner satisfies his or her obligation to provide information to patients. That yardstick, known as the Bolam principle, can be formulated as "a rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion".<sup>11</sup>

In 1992, the High Court of Australia adopted a new approach. In *Rogers v Whitaker*,<sup>12</sup> the court allowed that a responsible body of professional opinion could still provide a starting point for deciding whether a medical practitioner had acted with appropriate skill and care; but with regard to the provision of information, the court determined that the "law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment". It was not the probability, per se, of an adverse outcome that was to be determinative in whether or not a patient should be told of a particular risk. Rather, the judges went on to say that

a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.<sup>12</sup>

This strongly suggests that if you are a medical practitioner or a nurse about to vaccinate a patient, then it is incumbent on you to

## ABSTRACT

- Multidose vials (MDVs) for injectable therapeutic agents, including vaccines, pose a risk of infection to injected patients as a result of contamination of the vials.
- The Australian Government Department of Health and Ageing (DoHA) distributed the vaccine against pandemic (H1N1) 2009 influenza in MDVs. The distribution was accompanied by consent forms.
- The consent forms provided an inadequate basis for a discussion with patients about the risks associated with the use of MDVs.
- The High Court of Australia has previously held that medical practitioners who fail to explain the material risks of medical procedures to their patients might be held liable in negligence for any adverse sequelae of the procedures, even if the risks are very low.
- Medical practitioners, nurses, medical indemnity insurers and the DoHA should prepare now for the probable future use of MDVs by developing a consent form that would provide a solid foundation for a discussion of material risks with patients seeking vaccination.

MJA 2011; 194: 414-416

explain to the patient, in a way they understand, the material risks of having the vaccination. It is not up to the patient to know about all the possible risks; nor is it up to the patient to formulate questions about things they did not know that they needed to know. That is the responsibility of the health professional.

The reasonableness of meeting such a demand in a pandemic emergency might well be argued. Yet, as Justice Kirby noted in *Chappel v Hart*: "These standards have fairly been described as onerous. They are. But they are the law ... When not complied with ... it should occasion no surprise that legal consequences follow."<sup>13</sup>

## The DoHA guidelines and consent form

In light of *Rogers v Whitaker*,<sup>12</sup> how should the publications of the DoHA relating to the pandemic influenza vaccine<sup>9,10,14</sup> be regarded?

The status of the guidelines for the administration of the vaccine from the MDVs is clear. Having been formulated by an expert technical group, they serve as an authoritative indication of the views of a responsible body of medical opinion. Consequently, a nurse or medical practitioner who administers the vaccine in accordance with the guidelines is unlikely to be held to be negligent in their performance of the treatment.

But what of the obligation on the vaccinating practitioner to warn a patient of the material risks of vaccination, and what of the consent form?

Given the standing of the DoHA, it would have been natural for medical practitioners and nurses to assume that the consent form provided an authoritative guide to the consent process and that by

using it, they would be protected from being sued for failing to inform patients of the risks associated with the pandemic influenza vaccine MDVs. Such was not the case. Neither the information sheet nor the consent form<sup>10</sup> made mention of the specific infection risks associated with the use of MDVs. The omission is surprising given that Guillain-Barré syndrome, for example, was specifically mentioned as a risk despite the fact that its incidence is extremely low and, as the consent form noted, “the association with this vaccine is not proven”. Further, there was no suggestion that the vaccinating health professional should discuss the risks associated with the use of MDVs with the patient. Instead, the form required the patient to attest to the vague statement that they had “had the opportunity to discuss medical concerns with the vaccinator or other health care provider”. But a concern is not a risk; a concern is a matter which has attracted the attention of the patient. A concern might be completely unfounded, but risks are independent of the patient’s cognisance, and it is “material risks” that the law requires health practitioners to discuss with their patients.

To illustrate the point, consider a patient who is concerned that the pandemic influenza vaccine contains irradiated peanut oil (which it does not). It might be good practice to address the patient’s concern but the law places no obligation on the vaccinating health practitioner to do so. In contrast, a patient might read the statement about MDVs on the consent form with the same lack of regard as they would read a description of new packaging for corn flakes. Nonetheless, the law requires the practitioner to see past the patient’s lack of concern and to consider whether vaccination poses a risk that is material to the patient in the sense described in *Rogers v Whitaker*.

By following the administration guidelines issued by the DoHA, medical practitioners and nurses could have confidence that they would be largely protected against a negligence suit alleging a failure to exercise due skill and care. But a similar reliance on the consent form to guide them through a legally adequate discussion to inform their patients would be misplaced for two reasons. First, the consent form drafted by the DoHA is inadequate as a basis for a discussion about vaccination-associated risks, particularly as it omits the known (albeit low) risks of infection from MDVs. Second, although it is useful to have written material to supplement a discussion about risks,<sup>15</sup> the discussion is an essential part of the process that is necessary to protect the health practitioner from an action in negligence. In *Stapley v Fisher*,<sup>16</sup> for example, a doctor was found to have failed to warn his patient adequately of some of the potential complications of surgery, despite having arranged for the patient to be given printed information about the risk of the very injury that he sustained.

To overcome these inadequacies, the consent form could suggest to patients in high-risk groups who want immediate protection from the pandemic influenza virus, that they might choose to accept the low risks associated with MDVs and be vaccinated early; and patients who are at lower risk of pandemic influenza, or who wish to avoid any infection risk associated with MDVs, might choose to delay their vaccination until single-dose prefilled syringes become available.

### Should the vaccinating health practitioner be concerned?

A health practitioner who is familiar with the recent good track record in Australia of the use of MDVs might believe that there is

little risk of being sued for events related to their use — and it is true that there have, as yet, been no reports of iatrogenic infection associated with the use of the pandemic influenza vaccine MDVs. However, there is reason for medical practitioners to be uneasy. In particular, insufficient time has passed for some possible iatrogenic infections to become apparent. In the past, there have been notable outbreaks and fatalities associated with bacterial contamination of MDVs.<sup>1,17-20</sup> However, diseases of modern concern, including HIV, hepatitis C and the prion diseases, can have long lags between infection and diagnosis,<sup>21</sup> and between diagnosis and discovery of the source of infection.<sup>22</sup> It was only in 1997, for example, that it came to light that southern Italy is an area of hyperendemicity for hepatitis C virus<sup>23</sup> and that the excess infections most probably resulted from iatrogenic transmission associated with Salk polio vaccinations between 1956 and 1965.<sup>22</sup> Further, while the thiomersal in MDVs is effective against bacteria, there is no evidence that it is effective against HIV, hepatitis C or prion diseases.<sup>5,24</sup>

### The future

It is not possible to mitigate the existing legal risks associated with the 2009 use of pandemic influenza vaccine MDVs. Nonetheless, given that the Australian Government has stated that MDVs form an integral part of the National Action Plan for Human Influenza Pandemic,<sup>7,25</sup> it would be helpful if the medical profession, medical indemnity insurers and the DoHA were to cooperate in the development of guidelines for informing patients of the risks associated with MDVs. One of the most useful courses of action would be to transform the existing DoHA consent form into a guide for medical practitioners to use in their discussions with patients about vaccination risks. This would also have the effect of assisting medical practitioners to comply with the consent guidance published in the *Australian immunisation handbook*.<sup>15</sup>

The use of MDVs in the National Action Plan was originally conceived as part of a response to the spread of highly pathogenic avian (H5N1) influenza virus. Indeed, if an epidemic of H5N1 influenza ever occurs in Australia, any risks associated with MDVs will pale in comparison with the risk posed by the typical 50% case-fatality rate among H5N1-infected people. Nonetheless, in the absence of a change in the law, it will still be for patients to weigh those risks and to exercise their right to accept, refuse or delay vaccination, having had the risks discussed with them by a knowledgeable health professional.

### Competing interests

None identified.

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### References

- 1 Plueckhahn VD, Banks J. Fatal haemolytic streptococcal septicaemia following mass inoculation with influenza vaccine. *Med J Aust* 1970; 1: 405-411.
- 2 Phadke MA, Joshi BN, Warekar UV, et al. Toxic shock syndrome: an unforeseen complication following measles vaccination. *Indian Pediatr* 1991; 28: 663-665.

- 3 Katzenstein TL, Jorgensen LB, Permin H, et al. Nosocomial HIV-transmission in an outpatient clinic detected by epidemiological and phylogenetic analyses. *AIDS* 1999; 13: 1737-1744.
- 4 Feinmann J. Doctors call for ban on multidose vials after hepatitis C outbreak in US. *BMJ* 2010; 341: c4057.
- 5 Gosbell IB, Gottlieb T, Kesson AM, et al. Immunisation and multi-dose vials. *Vaccine* 2010; 28: 6556-6561.
- 6 Rosendorff D. Doctors warn: swine flu vaccine poses too many risks [radio transcript]. PM. Radio National. Australian Broadcasting Commission. 20 Aug 2009. <http://www.abc.net.au/pm/content/2008/s2662248.htm> (accessed Mar 2011).
- 7 Australian Government Department of Health and Ageing. Interim infection control guidelines for pandemic influenza in healthcare and community settings. June 2006. Annex to Australian Health Management Plan for Pandemic Influenza. Canberra: Commonwealth of Australia, 2006.
- 8 Australian Technical Advisory Group on Immunisation. Guideline for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials (MDV). Canberra: Australian Government Department of Health and Ageing and Royal Australian College of General Practitioners, 2009. [http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/\\$File/6013%20H1N1%20MDV%20Protocol%20v3%20CMYK%20SCREEN.pdf](http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/$File/6013%20H1N1%20MDV%20Protocol%20v3%20CMYK%20SCREEN.pdf) (accessed Mar 2011).
- 9 Australian Government Department of Health and Ageing. Getting the Panvax vaccine for pandemic (H1N1) 2009 influenza. Canberra: DoHA, 2009. [http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/\\$File/information%20sheet%20children.pdf](http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/$File/information%20sheet%20children.pdf) (accessed Mar 2011).
- 10 Australian Government Department of Health and Ageing. Pandemic (H1N1) 2009 influenza vaccine consent form. Canberra: DoHA, 2009. [http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/\\$File/6013%20H1N1%20Priority%20-%20Consent%20Form%20Web.pdf](http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/$File/6013%20H1N1%20Priority%20-%20Consent%20Form%20Web.pdf) (accessed Mar 2011).
- 11 *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] UKHL 1.
- 12 *Rogers v Whitaker* (1992) 175 CLR 479.
- 13 *Chappel v Hart* (1998) 195 CLR 232.
- 14 Australian Technical Advisory Group on Immunisation. ATAGI statement: Use of multi-dose vials in vaccination programs. Canberra: DoHA, 2009. <http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/national-vaccination-program#atagi> (accessed Mar 2011).
- 15 Australian Government Department of Health and Ageing; National Health and Medical Research Council. The Australian immunisation handbook. 9th ed. Canberra: Commonwealth of Australia, 2008.
- 16 *Stapley v Fisher* [2003] WADC 278.
- 17 Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. *Pediatrics* 1985; 75: 299-303.
- 18 Borghans JG, Stanford JL. *Mycobacterium chelonae* in abscesses after injection of diphtheria-pertussis-tetanus-polio vaccine. *Am Rev Respir Dis* 1973; 107: 1-8.
- 19 Simon PA, Chen RT, Elliott JA, Schwartz B. Outbreak of pyogenic abscesses after diphtheria and tetanus toxoids and pertussis vaccination. *Pediatr Infect Dis J* 1993; 12: 368-371.
- 20 Kellaway CH, MacCallum P, Tebbutt AH. The fatalities at Bundaberg. Report of the Royal Commission. *Med J Aust* 1928; 2: 2-19.
- 21 Becker NG. Infectious disease models. In: Gail MH, Benichou J, editors. Encyclopedia of epidemiologic methods. Chichester, UK: John Wiley and Sons, 2000: 447-450.
- 22 Montella M, Crispo A, Grimaldi M, et al. Assessment of iatrogenic transmission of HCV in southern Italy: was the cause the Salk polio vaccination? *J Med Virol* 2003; 70: 49-50.
- 23 Guadagnino V, Stroffolini T, Rapicetta M, et al. Prevalence, risk factors, and genotype distribution of hepatitis C virus infection in the general population: a community-based survey in southern Italy. *Hepatology* 1997; 26: 1006-1011.
- 24 Bujia J, Wilmes E, Kastenbauer E, Gurtler L. Influence of chemical allograft preservation procedures on the human immunodeficiency virus. *Laryngoscope* 1996; 106: 645-647.
- 25 Council of Australian Governments; Working Group on Australian Influenza Pandemic Prevention and Preparedness. National Action Plan for Human Influenza Pandemic. Canberra: Department of Prime Minister and Cabinet, 2010.

**Provenance:** Not commissioned; externally peer reviewed.

(Received 11 Aug 2010, accepted 6 Jan 2011)

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