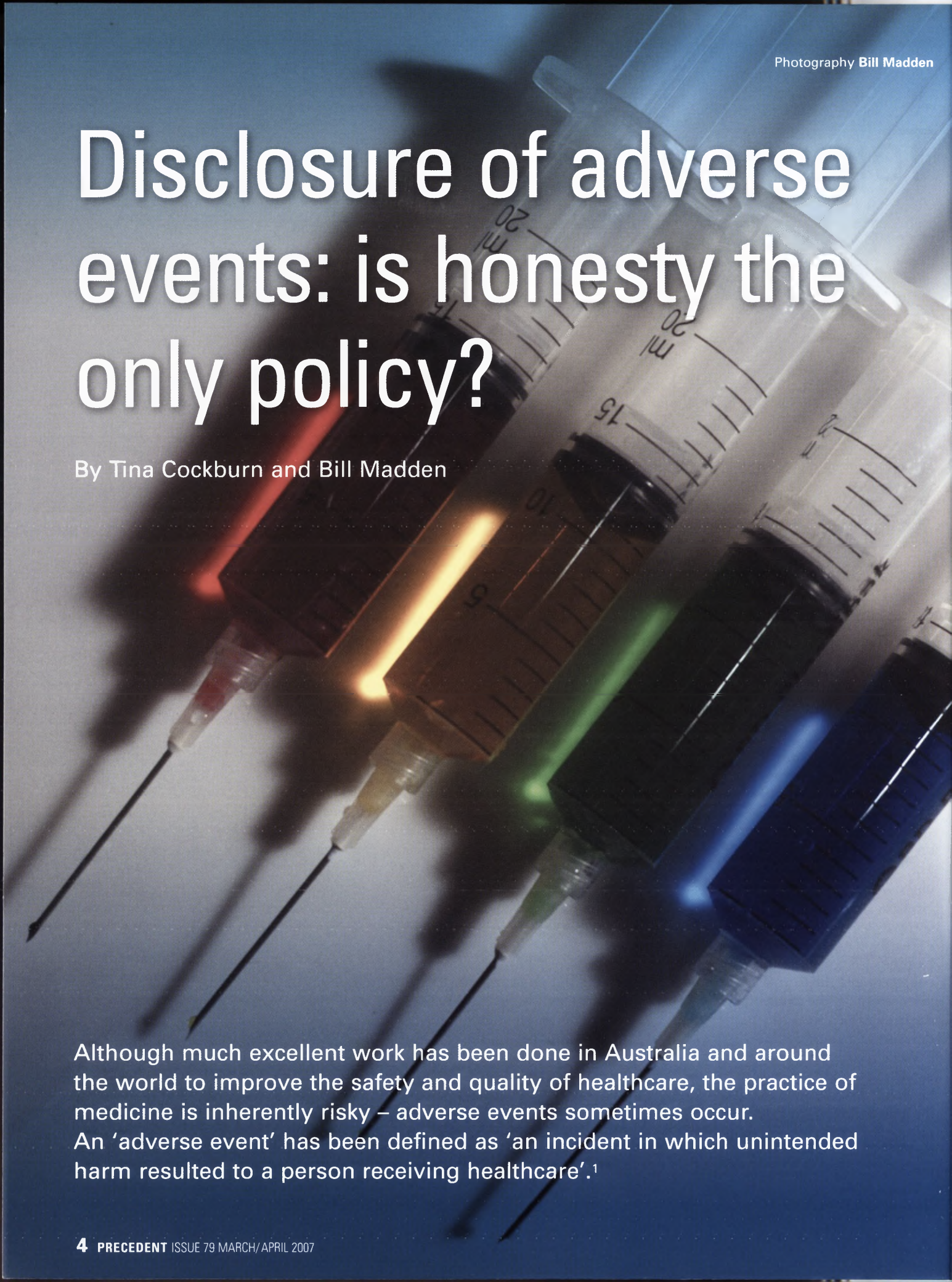

Photography **Bill Madden**

Disclosure of adverse events: is honesty the only policy?

By Tina Cockburn and Bill Madden

Although much excellent work has been done in Australia and around the world to improve the safety and quality of healthcare, the practice of medicine is inherently risky – adverse events sometimes occur. An 'adverse event' has been defined as 'an incident in which unintended harm resulted to a person receiving healthcare'.[1]

> 'Medical mistakes happen and when they do the only course open to the physician is to advise the patient of the medical error. … The decision to tell the truth is foundational, as is the basic principle that the patient, not the physician, has the right to make complex choices and decisions relating to her medical planning and care. The standard of practice requires physicians to promptly and fully disclose errors to their patients. Patients have a right to be fully informed of errors and to have their medical options fully disclosed and discussed. Physicians are to be honest in their interactions with patients, to respect the rights of their patients, and in particular, to respect the right of their patients to make informed choices about their healthcare. Physicians are required to recognise potential and actual conflicts of interest, and to place their patients' interest above their own. These are the longstanding and commonly understood principles guiding every physician confronted with a medical error.'[2]

Various studies have documented the nature and extent of medical error. For example, in 1977 the Californian medical insurance feasibility study[3] – a review of some 21,000 medical records – found that 4.6% of hospitalisations resulted in iatrogenic injury (adverse outcomes), with about 0.8% (1 in 126) of such injuries probably involving negligence.[4] In 1990, a Harvard University study of 30,000 hospital discharges reached very similar conclusions – 3.7% and 1.0%.[5]

The 1995 Quality in Australian Health Care Study (QAHCS)[6] indicated that 16.6% of people admitted to hospitals in the study sample experienced an adverse event associated with their care. In 13.7% of these cases, there was permanent disability, and 4.9% resulted in death. Of the adverse events reported in the QAHCS, 51% were considered preventable. Subsequent re-analysis of the QAHCS data to allow for international benchmarking indicated that the Australian adverse event rate may be closer to 10%, which is comparable with findings in the UK, USA, New Zealand, and Denmark.[7] The First National Report on Australian Patient Safety 2001[8] noted that re-analysis of the QAHCS study found that the Australian and US studies had a virtually identical rate of serious adverse events – about 2% of cases (1.7% leading to serious disability and 0.3% to death).[9]

In Australia, practical guidelines for the open disclosure of adverse events to patients have been in place for some time. More recently, state and territory medical boards have adopted codes of conduct that include provisions concerning the disclosure of medical error, although the published *Code of Ethics* of the Australian Medical Association (AMA)[10] has not yet been modified to incorporate express disclosure obligations.[11]

Although the medical profession may recognise the need for some form of compensation for negligently injured patients, in Australia there is currently no widely recognised legal obligation to disclose to the patient a medical practitioner's knowledge or suspicion of an adverse event. In particular, although many Australian jurisdictions now have some statutory protection for those who apologise or express regret to patients following an adverse event or outcome,[12] there is no corresponding express statutory duty to disclose medical error,[13] as in some parts of the US.[14]

In Australia, there is no widely recognised legal obligation to disclose an adverse event.

In addition to ethical considerations such as respect for patient autonomy, medical professionalism and institutional responsibility, non-disclosure of adverse events has practical implications for patients. As opposed to others injured as a result of negligence, an ordinary patient receiving negligent medical treatment may have little, if any, perception that an adverse event or negligence has affected his or her medical outcome. This is, perhaps, more evident where the patient was affected by anaesthesia, sedation, was a child or was under a disability at the time. In the medical negligence chapter of his final report to the Lord Chancellor on the civil justice system in England and Wales, Lord Woolf observed:

> 'It would be difficult to exaggerate the effect on potential claimants of the problems they encounter in obtaining information, coupled with the knowledge that defendants have easy access to medical information and opinion…'[15]

Non-disclosure may mean that the patient loses the opportunity to obtain remedial treatment. For example, in *Wighton v Arnot,*[16] investigation and disclosure of the suspected adverse event would have made a difference to the patient's long-term prognosis, but it was too late to successfully repair the severed nerve by the time the patient discovered what had happened.[17] Further, non-disclosure may mean that a patient is unaware of an entitlement to pursue a civil action for financial compensation,[18] or at least to negotiate with the relevant medical practitioner as to payment of fees for further treatment.

The importance of both open disclosure and an apology, where appropriate, as a way of improving communication and trust between patients and healthcare providers – and ultimately avoiding unnecessary litigation – has been identified by Dr Albert Wu:

> 'In over 25 years of representing both physicians and patients, it became apparent that a large percentage of patient dissatisfaction was generated by physician attitude and denial, rather than the negligence itself. In fact, my experience has been that close to half of malpractice cases could have been avoided through disclosure or apology but instead were relegated to litigation. What the majority of patients really wanted was simply an honest explanation of what happened, and if appropriate, an apology. Unfortunately, when they were not only offered neither but were rejected as well, they felt doubly wronged and then sought legal counsel.'[19]

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Most patients want an **honest** explanation of what happened and, if appropriate, an **apology**.

THE OPEN DISCLOSURE STANDARD

In 2003, the Australian Council for Safety and Quality in Health Care (ACSQHC), succeeded by the Australian Commission on Safety and Quality in Health Care from 2006,[20] obtained the endorsement of the Australian health ministers for a national open disclosure standard. The standard is a resource, with no legal standing, designed to assist those seeking to implement open disclosure. 'Open disclosure' is defined as open communication when things go wrong in healthcare; its elements include an expression of regret, a factual explanation of what happened, consequences of the event, and the steps being taken to manage the event and to prevent a recurrence.[21] In relation to the practical implementation of the disclosure guidelines, it has been noted:

> '...as long as stakeholders recognise and accept that the open disclosure process should not and is not intended to constitute a detailed forensic analysis of the event but is rather confined to the prompt and emphatic notification of the fact that things went wrong, coupled with an undertaking (where that can be given) to conduct and report back on relevant follow-up, many of the difficulties will be avoided.'[22]

NSW Health will release comprehensive open disclosure guidelines in April 2007, which aim to improve the way adverse events are managed.[23]

CODES OF PROFESSIONAL CONDUCT

Section 99A(1) of the *Medical Practice Act* 1992 (NSW) provides that the NSW Medical Board (NSWMB) 'may establish a code of professional conduct setting out guidelines that should be observed by registered medical practitioners in the conduct of their professional practice'. Section 99A(4) provides that the 'provisions of a code of professional conduct are a relevant consideration in determining for the purposes of this Act what constitutes proper and ethical conduct by a registered medical practitioner'.

In July 2005, the NSWMB obtained approval for a code of professional conduct entitled *Good Medical Practice: The Duties of a Doctor Registered in New South Wales*.[24] Standard 2.5 contemplates disclosure of adverse events to patients in cases of serious harm:

> '2.5 ... act immediately to put matters right, if it is possible, if a patient under your care has suffered serious harm, through misadventure or for any other reason. You should explain fully to the patient what has happened and the likely short and long-term effects. When appropriate, you should offer an apology. If the patient lacks the maturity to understand what has happened, you should explain the situation honestly to those with parental responsibility for the child. If the patient is cognitively impaired you should provide explanation to the patient's parent, guardian, carer or person responsible.'

This provision is modelled on the comparative provision in the *Good Medical Practice* guidelines developed by the UK General Medical Council (GMC),[25] although the UK guidelines contemplate disclosure in *all* cases of harm, not just *serious* harm. It is open to debate as to whether the qualification in the NSW provision is justifiable and, as serious harm is not defined, there is some uncertainty as to the circumstances in which the ethical obligation to disclose medical error arises.[26]

Most other state and territory medical boards have adopted provisions in essentially the same terms as the NSWMB Code.[27] However, the Queensland provision[28] contemplates a broader disclosure obligation which, like the UK provision, is not limited to serious harm. The Queensland provision says:

> '**2.5 If things go wrong**
>
> 2.5.1 If a patient under your care has suffered or may suffer harm, through misadventure or for any other reason, you should act immediately to put matters right if that is possible. You should explain fully to the patient what has happened and the likely short and long-term effects. This explanation should be provided to those who have legal responsibilities for a patient when that situation arises. When appropriate, you should offer an apology.'

Failure to disclose an adverse event to a patient, especially where a patient has been deliberately misled as to events that occurred during treatment, may give rise to disciplinary action on the basis of professional misconduct or gross negligence.[29]

LEGAL STANDARD OF CARE

In *Naylor v Preston Area Health Authority*,[30] referring to *Lee v South West Thames Regional Health Authority*,[31] Sir Donaldson MR noted, by way of obiter, that a duty of candid disclosure 'is but one aspect of the general duty of care, arising out of the patient/medical practitioner or hospital authority relationship and gives rise to rights both in contract and in tort'.[32] Such an obligation is founded on notions such as the protection of bodily integrity, individual autonomy and the right to self-determination.

In the first instance judgment in *Breen v Williams*,[33] Justice Bryson held that there is an obligation to disclose adverse events that have occurred during treatment as an ordinary incident of aftercare, but only while treatment continues.[34] He said:

> '...communication with the patient, both before and after treatment, of the diagnosis, advice about what treatment is proposed, and of a report of what treatment has taken place are all integral and essential parts of treatment. ...
>
> Informing a patient of what treatment has been given and what has taken place while doing so, whether or not there has been a catastrophe, is integrally and necessarily >>

> part of giving medical treatment to a person. One cannot stick a needle into a person and walk away wordless, as one would with a horse. I would respectfully say that Donaldson MR's observations appear to me to be correct and plainly so, but that they relate to treatment and not access to medical records, or to the provision of information after everything which could be regarded as treatment has concluded.'

Consistent with this view, in *Wighton v Arnot*,[35] Justice Studdert held that 'the exercise of due care' extended to taking steps to investigate suspected adverse events and disclosing to the patient what occurred, even if the investigations were inconclusive.[36]

In *Wighton*, there was no finding that the defendant doctor had been negligent in the performance of the operation, or in severing the nerve.[37] However, his Honour held that the doctor's treatment following the severance of the nerve was negligent in that:

- he failed to inform the plaintiff of his suspicion that he had severed that nerve;[38]
- he failed by appropriate examination to confirm that he had severed the nerve; and
- he failed to refer the plaintiff to an appropriate specialist for timely remedial surgery.

It seems, therefore, that the doctor may not have been liable had he disclosed the adverse event to the patient.

Although it has been suggested that therapeutic privilege may be a defence to non-disclosure of adverse outcomes,[39] this was not accepted in *Wighton*.[40]

In *Wighton*, the negligence claim was made out because the expert evidence established that the usual practice would have been to disclose and investigate the suspected adverse event, and provide an opportunity for remedial surgery if necessary, and because the patient suffered damage as she lost the opportunity to have prompt remedial treatment due to the practitioner's breach of duty.[41] Without proof of damage recognised by the law of negligence, however, a claim for damages in negligence for breach of duty to disclose will fail.[42] If it were possible to frame the cause of action in trespass on the basis that consent was vitiated by fraud,[43] this issue would not arise, given that trespass is actionable per se.[44]

As to the standard of care, it would seem that the new ethical guidelines relating to disclosure of adverse events will now be evidence of widely accepted competent professional practice in Australia for the purposes of establishing the standard of care under s5O of the *Civil Liability Act* 2002 (NSW), and its comparative provisions elsewhere. Alternatively, in the event that peer professional opinion was led to the effect that the standard of care did not require open disclosure, there may be scope for the court to intervene under s5O(2), on the basis that such a view was 'irrational'.[45]

CONCLUSION

Honesty and trust are central to the healthcare professional:patient and healthcare institution:patient relationship, and healthcare professionals and institutions want to do 'the right thing' by their patients:

> 'Honest, effective and open communication is the foundation of the relationship between clinicians and patients. Telling the truth is always the right thing to do. Concealing the truth is wrong.'[46]

Although 'concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient',[47] as noted by the ACSQHC, there is no evidence that open disclosure will necessarily lead to increased litigation:

> 'Adhering to the principles of the Open Disclosure Standard may result in an increase in legal claims. We know, however, that many health care errors do not become the subject of litigation and, unless the harm suffered by the patient is serious, legal action is unlikely to be taken. It is possible that open disclosure may assist patients who have suffered an adverse event to make a claim by providing them with the necessary information and understanding on which to base a claim. However, evidence suggests that following the principles of open disclosure may actually reduce a patient's desire to pursue legal action.'[48] ■

Notes: **1** Australian Council for Safety and Quality in Health Care (ACSQHC), *Open Disclosure Standard* (2003) http://www.safetyandquality.gov.au/OpenDisclosure_web.pdf, at 18 January 2007, at 3 (Key Terms) at p6. **2** In re accusation against Steven L Katz MD, Certificate no G-71332, no 03-2001-122617, Medical Board of California, http://publicdocs.medbd.ca.gov/pdl/Image.aspx. **3** DH Mills, *California Medical Association and California Hospital Association report on the medical insurance feasibility study*, San Francisco, Sutter, 1977. **4** For a discussion of the link between claims, errors and compensation payments in medical negligence litigation, see: DM Studdert, MM Mello, AA Gawande, TK Gandhi, A Kachalia, C Yoon, A Puopolo, TA Brennan, 'Claims, Errors, and Compensation Payments in Medical Malpractice Litigation' (2006) 354 (19), *New England Journal of Medicine* 2024; DM Studdert, MM Mello, TA Brennan, 'Medical Malpractice' (2004) 350 (3), *New England Journal of Medicine*, 283. **5** Harvard Medical Practice Study, *Patients, doctors, and lawyers: medical injury, malpractice litigation, and patient compensation in New York: report of the Harvard Medical Practice Study to the state of New York*, Cambridge, Mass, President and Fellows of Harvard College, 1990. **6** RM Wilson, WB Runciman, RW Gibberd, BT Harrison, L Newby, JD Hamilton, 'The Quality in Australian Health Care Study' (1995) 163 (9) *MJA*, 458. **7** ACSQHC, http://www.safetyandquality.org/articles/Action/advrsefact.pdf. **8** http://www.safetyandquality.org/articles/Publications/firstreport.pdf. **9** For a recent international comparison, see D Hindle, J Braithwaite, J Travaglia, R Iedema, 'Patient Safety: A Comparative Analysis of Eight Inquiries in Six Countries', 2006, Centre for Clinical Governance Research, Faculty of Medicine, University of NSW, Sydney. **10** AMA *Code of Ethics 2004*, editorially revised 2006. **11** By contrast, the American Medical Association's published set of principles of medical ethics contain express disclosure obligations: E-8.12 Patient Information, www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-8.12.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-7.05.HTM&nxt_pol=policyfiles/HnE/E-8.01.HTM&, at 18 January 2007. **12** The legislation is not uniform: see *Civil Liability Act* 2003 (Qld) ss68-72; *Civil Liability Act* 2002 (WA) ss5AF-5AH; *Civil Liability Act* 2002 (Tas) s7; *Civil Law (Wrongs Act)* 2002 (ACT) ss12-14; *Personal Injuries (Liabilities and Damages) Act* 2003 (NT) s13, ss11,12 cf *Wrongs Act* 1958 (Vic) s14I-14J (not admission but still admissible); *Civil Liability Act* 1936 (SA) s75 (not admission only). See P Vines, 'Apologising to avoid liability: cynical civility or

practical morality?' (2005) 27 (3) *Sydney Law Review*, 483. **13** Liability may arise for non-disclosure on the basis that silence may amount to a misrepresentation under the *Trade Practices Act* 1974 (Cth) or *Fair Trading Acts*. **14** For example, *New Jersey Patient Safety Act* 26:2H-12.25(3)(d)NJSA 26:2H-12.23 et seq; *Pennsylvania Medical Care Availability and Reduction of Error (Mcare) Act* (2002) Act 13 of 2002 s308. **15** Chapter 15, para 68. **16** [2005] NSWSC 637. **17** *Ibid,* Studdert J at [33]. **18** In relation to limitations issues, see B Madden and T Cockburn, 'Duty to Disclose Medical Error in Australia' (2005) 14 (2) *Australian Health Law Bulletin* 13. **19** A Wu, 'Handling hospital errors: is disclosure the best defence?' (1999) 131(12) *Annals of Internal Medicine* 970 (21 December 1999). **20** Running in parallel in NSW is the work of the Clinical Excellence Commission. The inaugural report, *Patient Safety Clinical Incident Management in New South Wales: Analysis of First Year of IIMS Data, Annual Report 2005-2006* is available online at www.cec.health.nsw.gov.au, accessed 1 February 2007. **21** See ACSQHC, *National Open Disclosure Standard: Fact sheet* http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/3D5F114646CEF93DCA2571D5000BFEB7/$File/opendisclfact.pdf> at 18 January 2007. **22** Corrs Chambers Westgarth, *Open Disclosure Project: Legal Review* (2002) '2.1.3. The Health Professionals' p7; www.nsh.nsw.gov.au/teachresearch/cpiu/CPIUwebdocs/FinalLR858178v1.pdf at 18 January 2007. **23** Clara Pirani 'The hardest word', *The Australian*, 27 January 2007, http://www.theaustralian.news.com.au/story/0,20867,21123009-23289,00.html. **24** New South Wales Medical Board, *Code of Professional Conduct: Duties of a doctor registered with the New South Wales Medical Board* (2005). **25** General Medical Council, *Good Medical Practice* (3rd ed) London May (2001) at para 30; http://www.gmc-uk.org/guidance/good_medical_practice/index.asp at 18 January 2007. **26** See B Madden and T Cockburn, 'Bundaberg and beyond: Duty to disclose adverse events to patients – a duty of candour, even where harm is caused by others?' (2007) *JLM*, forthcoming. **27** NT: *Good Medical Practice Guidelines* 2.5; WA: *The duties of a medical practitioner registered with the Medical Board of Western Australia* s4.5, http://www.wa.medicalboard.com.au/pdfs/DutiesOfADoctor.pdf; Tasmania *'Guide to Good Medical Practice'* s2.5; ACT: *ACT Medical Board Standards Statement*; SA: *Code of Professional Conduct – Good Medical Practice – Duties of a doctor registered with the medical board of SA* s2.5; Victoria: *'Good Medical Practice'* s2.e. **28** Medical Board of Queensland, *'Good Medical Practice'* s25. **29** *Skidmore v Dartford & Gravesham* [2003] UKHL 27; In re accusation against Steven L Katz MD, Certificate no G-71332, no 03- 2001- 122617, Medical Board of California, 27 April 2005. For a discussion of the regulatory framework, see I Freckelton, 'Regulation of health practitioners' in I Freckelton and K Petersen, *Disputes and Dilemmas in Health Law*, The Federation Press, 2006. **30** (1987) 2 All ER 353. **31** [1985] 1 WLR 845 at 850 at 851 per Donaldson MR and Mustill J (obiter). **32** *Ibid,* 360. Such a duty has also been recognised in Canada: see *Stamos v Davies* (1985) 21 DLR (4th) 507 (Ont HC); *Gerula v Flores* (1995) 126 DLR 507. For a discussion of the US case law, see J Vogel and R Delgado, "To tell the truth": physicians' duty to disclose medical mistakes' (1980) 29 *UCLA Law Review* 52, and TR Le Blang and JL King, 'Tort liability for nondisclosure: the physician's legal obligations to disclose patient illness and injury' (1984–1985) 89 *Dickinson Law Review* at 26–30; 35–45. **33** Unreported, NSWSC 10 October 1994; BC9403138 per Bryson J. The case was finally determined on appeal to the High Court: *Breen v Williams* (1996) 186 CLR 71. **34** In the US, the duty to disclose has been held to extend beyond the duration of the treating relationship: *Mink v University of Chicago* 460 F Supp 713 (ND Ill 1978): 'When the University hospital became aware, or should have become aware, of facts which would induce a reasonable physician under the same circumstances to warn patients of the risks involved in treatment, a duty to notify arose. The fact the knowledge of the risk was obtained after the patient was treated does not alter the obligation. If the defendant fails to notify the patient when the risk becomes known, he has breached this duty.' **35** [2005] NSWSC 637. **36** *Ibid,* [38]–[39]; [64]. **37** *Ibid,* [36]; [37]–[38]; [65]–[67]. **38** Disclosure to the patient's general practitioner may have been sufficient: *Ibid,* [71] – [72]. **39** See TR Le Blang and JL King, 'Tort liability for nondisclosure: the physician's legal obligations to disclose patient illness and injury' (1984–1985) 89 *Dickinson Law Review* at 45–51. **40** *Wighton,* [69]. **41** See expert evidence of Dr McKenzie at [65]–[67]. **42** For a discussion, see *Harriton v Stephens* [2006] HCA 15 per Crennan J at [161]-[182]. **43** Discussed in T Cockburn and B Madden, 'Intentional Torts in Medical Cases' (2006) 13 *JLM* 311 at 314-15, fn 23-4. **44** Cockburn and Madden, n43 above at 316. **45** Considered in *Halverson v Dobler* [2006] NSWSC 1307 at [189]-[190]. It may be that given the inclusion of the adjective 'competent' in s5O(1) there is little scope for the irrational exception in any event: see B Madden, 'Locating the Law: Competence and Irrationality' (2006), 3 (5&6) *Australian Civil Liability* 54. **46** WM Barron and MG Kuczewski, 'Unanticipated Harm to Patients: Deciding When to Disclose Outcomes' (2003), 29 (10) *Joint Commission Journal on Quality and Safety* 551 at 552. **47** AMA Ethical Principle E-8.12 Patient Information. **48** www.safetyandquality.org/articles/Action/opendisclfact.pdf.

Tina Cockburn *is a senior lecturer in the Faculty of Law, Queensland University of Technology, in Brisbane.*
PHONE *(07) 3864 2003* **EMAIL** *t.cockburn@qut.edu.au*
Bill Madden *is national practice group leader in medical negligence, Slater & Gordon.* **PHONE** *(02) 9762 1722*
EMAIL *wmadden@slatergordon.com.au*

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