

## SETTING THE STANDARD? CLINICAL PRACTICE GUIDELINES AND MEDICAL NEGLIGENCE LITIGATION

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### I. INTRODUCTION

In recent years 'quality' issues have affected many areas in the community. The health care sector has not been immune to these developments, and quality has become an important issue in health care debates. Of particular concern has been the numbers of adverse events for patients in health care, and particularly the number of preventable adverse events. In the United States, the Harvard Medical Practice Study found that 3.7 per cent of hospitalised patients suffered an adverse event, and that 27.6 per cent of these (or 1 per cent of all hospitalised patients) experienced a negligent medical injury.<sup>1</sup> In Australia, the Quality in Australian Health Care Study (QAHCS) found that 16.6 per cent of admissions were associated with an adverse event, and that 51.2 per cent of adverse events were potentially preventable.<sup>2</sup> The QAHCS defined an adverse event as "(1) an unintended injury or complication which (2) results in disability, death or prolongation of hospital stay, and is (3) caused by health care management rather than the patient's disease".<sup>3</sup> A number of possible reasons were identified for the differences between the Harvard results and the QAHCS results. These included possible improvements in the quality of medical records in the period between the Harvard study and the QAHCS, and the fact that the Harvard study

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1 PC Weiler, HH Hiatt, JP Newhouse, WG Johnson, TA Brennan, LL Leape, *A Measure of Malpractice Medical Injury, Malpractice Litigation, and Patient Compensation*, Harvard University Press, 1993, p 43.

2 RM Wilson, WB Runciman, RW Gibberd, BT Harrison, L Newby and JD Hamilton, "The Quality in Australian Health Care Study" (1995) 163 *Medical Journal of Australia* 458.

3 *Ibid* at 461

focused on negligence while the Australian study focused on preventability.<sup>4</sup> In its Final Report, the Review of Professional Indemnity Arrangements for Health Care Professionals (PIR) recommended “that further study be undertaken to examine the relationship between the medical concept of preventability and the legal concept of negligence”.<sup>5</sup> Despite the differences between the two studies, the results of both studies highlight the number of adverse events in health care and have added to the increasing focus on improving quality. In this context, clinical practice guidelines have come to be seen as one means to improve quality by ensuring that health professionals have up-to-date information on those practices and treatments that can be regarded as ‘best practice’. Other quality tools include accreditation, credentialling, incident monitoring and peer review.<sup>6</sup> As increasing numbers of guidelines are developed and implemented, the implications of these guidelines both for medical practice and medical negligence litigation have become matters for discussion and debate.

## II. THE GROWING INTEREST IN GUIDELINES

Clinical practice guidelines (CPGs) have been described as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”.<sup>7</sup> While CPGs are often developed with a view to fostering better health care outcomes through the dissemination of knowledge of ‘best practice’, CPGs can also be developed with a view to reducing variations in clinical practice, as a response to medical malpractice litigation, and as a means of reducing the spiralling costs of health care.

The growing interest in CPGs has been a significant development in modern medicine. The potential impact of CPGs on medical policy and practice is enormous. Yet CPGs or ‘practice policies’ are not new to medicine. They have been in existence for hundreds of years with practice policies traditionally evolving over time through common practice tracked “through textbooks, journal articles, speeches, letters to the editor, pronouncements by department chairpersons, and conversations in hospital cafeterias”.<sup>8</sup> Eddy argues that there

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4 *Ibid* at 470 For further discussion of the results of the two studies see JJ McNeil and SR Leeder, “How Safe Are Australian Hospitals?” (1995) 163 *Medical Journal of Australia* 472; TA Brennan, “Medical Injuries. International Perspectives” (1995) 163 *Medical Journal of Australia* 475

5 Review of Professional Indemnity Arrangements for Health Care Professionals, *Compensation and Professional Indemnity in Health Care: Final Report*, Australian Government Publishing Service, Canberra, 1995 (hereafter “PIR”) para 2 53

6 For discussion of these see *The Final Report of the Taskforce on Quality in Australian Health Care*, Australian Government Publishing Service, Canberra, 1996, chapters 2 and 3

7 Institute of Medicine, *Clinical Practice Guidelines: Directions for a New Program* (eds MJ Field and KN Lohr) (Washington DC: Institute of Medicine, National Academy Press, 1990) quoted in National Health and Medical Research Council, *Guidelines for the Development and Implementation of Clinical Practice Guidelines*, Australian Government Publishing Service, Canberra, 1995 (hereafter NHMRC, *Guidelines*) p 1

8 DM Eddy, “Practice Policies: Where Do They Come From?” (1990) 263 *Journal of the American Medical Association* 1265.

are two shortcomings with this traditional approach. First, by linking policies to common practice, a tautologous situation is created whereby “policies for appropriate practices are determined by the collective actions of practitioners, but the actions of practitioners are themselves guided by the policies”.<sup>9</sup> The second problem with the traditional approach is that it assumes “that the outcomes of a medical practice can be sensed intuitively, without explicit analysis or description”.<sup>10</sup> However, as Eddy points out, this assumption is no longer true in the context of modern medical practice:

It is simply unrealistic to think that individuals can synthesize in their heads scores of pieces of evidence, accurately estimate the outcomes of different options, and accurately judge the desirability of those outcomes for patients. Wide ranges of uncertainty among practitioners, wide variations in beliefs among experts, and wide variations in actual practices all confirm what would be expected from common sense: the complexity of modern medicine exceeds the inherent limitations of the unaided human mind.<sup>11</sup>

It is in this climate that there has been an increased focus on the formulation of CPGs or practice policies. Increasingly, practice policies do not evolve, but are designed.<sup>12</sup> Furthermore, practice policies are being introduced as “active management tools” to be used for “quality assurance, recertification, utilization review, accreditation, coverage, and cost containment”.<sup>13</sup>

Information on clinical issues may come from a number of sources. Professional groups or organisations may issue position statements on particular clinical issues.<sup>14</sup> Government agencies or departments may also issue guidelines or standards on a variety of clinical matters.<sup>15</sup> In the United States, the Federal Government established the Agency for Health Care Policy and Research (AHCPR) in 1989. The AHCPR has sponsored CPGs in a range of clinical areas. In Australia, the National Health and Medical Research Council (NHMRC), is empowered under the *National Health and Medical Research Council Act 1992* (Cth) to issue guidelines on matters dealing with: health improvement; “prevention, diagnosis and treatment of disease”; “the provision of health care”; “public health research and medical research”; and “ethical issues relating to health”.<sup>16</sup> The Council is required under the Act to issue guidelines for medical research using human subjects, but must issue the guidelines exactly as they have been developed by the Australian Health Ethics Committee

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9 *Ibid* at 1269

10 *Ibid*

11 *Ibid* at 1272

12 DM Eddy, “Practice Policies - What Are They?” (1990) 263 *Journal of the American Medical Association* 877 at 880.

13 *Ibid*

14 For examples of position statements issued by professional groups see RE Gilbert, M Jasik, M DeLuise, CJ O’Callaghan, ME Cooper, “Diabetes and Hypertension: Australian Diabetes Society Position Statement” (1995) 163 *Medical Journal of Australia* 372; ER Somerville and JH Antony, “Position Statement on the Use of Rectal Diazepam in Epilepsy” (1995) 163 *Medical Journal of Australia* 268

15 See for example, NSW Health Department Working Party on Ear Disease in Aboriginal Children, *Guidelines on the Prevention and Control of Otitis Media and its Sequelae in Aboriginal Children* (1996) 164 *Medical Journal of Australia* (Supplement)

16 *National Health and Medical Research Council Act 1992* (Cth), s 7(1)(a).

(AHEC), one of the Council's Principal Committees.<sup>17</sup> The NHMRC has issued guidelines in a wide range of areas, including reproductive technology, cervical cancer screening, and the provision of information to patients.<sup>18</sup>

In 1995, the NHMRC published *Guidelines for the Development and Implementation of Clinical Practice Guidelines*.<sup>19</sup> These *Guidelines* set out ten "guiding principles" for the guideline development process:

- A The guideline development and evaluation processes should be outcome focused;
- B Clinical practice guidelines should be based on the best available evidence;
- C The method used to synthesise the available evidence should be the strongest applicable;
- D Guidelines should contain a statement concerning the strength of recommendations;
- E The process of guideline development should be multi-disciplinary and include consumers;
- F Guidelines should be flexible and adaptable to varying local conditions;
- G Guidelines should include a consideration of resources;
- H Guidelines should be implemented;
- I The implementation and validity of the guidelines should be evaluated; and
- J Guidelines should be updated regularly.<sup>20</sup>

A subsequent study found that the development of the "guidelines for guidelines" was "both timely and necessary" in terms of improving the quality of Australian CPGs.<sup>21</sup>

Following the development of its *Guidelines* the NHMRC has since published CPGs in a number of areas,<sup>22</sup> including the clinical management of early breast cancer, management of coronary heart disease, depression in young people, management of lower urinary tract symptoms in men, and the control of meningococcal disease, with guidelines on unstable angina and prevention of stroke also being developed.<sup>23</sup>

Developments in evidence based medicine have also been relevant to the development of CPGs. Evidence based medicine has been described as "the conscientious, explicit, and judicious use of current best evidence in making

17 *Ibid* s 8.

18 NHMRC, *Ethical Guidelines on Assisted Reproductive Technology*, Australian Government Publishing Service, 1996; NHMRC, *Screening to Prevent Cervical Cancer Guidelines for the Management of Women With Screen Detected Abnormalities*, Australian Government Publishing Service, 1994, NHMRC, *General Guidelines for Medical Practitioners on Providing Information to Patients*, 1993. (Hereafter, *Guidelines on Information*.)

19 NHMRC, *Guidelines*, note 7 *supra*.

20 *Ibid* p 7

21 JE Ward and V Grieco, "Why We Need Guidelines for Guidelines: A Study of the Quality of Clinical Practice Guidelines in Australia" (1996) 165 *Medical Journal of Australia* 574

22 See RA Smallwood and HM Lapsley, "Clinical Practice Guidelines: To What End?" (1997) 166 *Medical Journal of Australia* 592 on guideline development in Australia

23 *Ibid*. For discussion of the meningococcal guidelines see MS Patel et al, "New Guidelines for Management and Prevention of Meningococcal Disease in Australia" (1997) 166 *Medical Journal of Australia* 598 On the CPGs for unstable angina see AM Tonkin and CN Aroney, "Guidelines for Managing Patients With Unstable Angina Rating the Evidence and Rationale for Treatment" (1997) 166 *Medical Journal of Australia* 644.

decisions about the care of individual patients".<sup>24</sup> Randomised controlled trials provide information on health care outcomes for a larger population than an individual doctor in clinical practice can generally experience. However, busy clinicians may not have the time to read and evaluate all of the clinical trials that have been published in their area of practice. The Cochrane Collaboration, based in the United Kingdom but now with centres in other countries including Australia, aims to "prepare, maintain and disseminate systematic, up to date reviews of randomised controlled trials of health care, and when randomised controlled trials are not available, reviews of the most reliable evidence from other sources".<sup>25</sup>

The relationship between evidence based medicine and CPGs is an important one. CPGs provide an important mechanism for providing medical practitioners with readily accessible information and evidence on 'best practice'. One of the guiding principles in the NHMRC's *Guidelines for the Development and Implementation of Clinical Practice Guidelines* is that "guidelines should be based on the best available evidence".<sup>26</sup> Furthermore, discussion of this principle indicates that guidelines are to indicate the strength of evidence upon which they are based.<sup>27</sup> For example, in the NHMRC's first set of evidence based CPGs, *The Management of Early Breast Cancer*, the scientific evidence for the various aspects of treatment covered by the guidelines is rated between four levels. Level I is described as the "gold standard" and at this level, "evidence is obtained from a systematic review of all relevant randomised controlled trials" while Level IV "represents the opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees".<sup>28</sup>

### III. THE DEBATE OVER CLINICAL PRACTICE GUIDELINES

#### A. Promoting Quality Health Care

The results of the Harvard Medical Practice Study in the United States and the Quality in Australian Health Care Study here in Australia have highlighted the number of preventable adverse outcomes in health care. The question of how best to reduce the number of adverse outcomes is a pressing issue for health professionals and health consumers. In this context, CPGs are seen as a possible solution. By providing a means of disseminating current knowledge of 'best practice' in medicine, and particularly the results of evidence based evaluations,

24 DL Sackett et al, "Evidence Based Medicine: What it is and What it isn't" (1996) 312 *British Medical Journal* 71

25 PIR, note 5 *supra*, para 3.13-3.18; quoting The Cochrane Collaboration, *Preparing, Maintaining and Disseminating Systematic Reviews of the Effects of Health Care Booklet*, p 5.

26 NHMRC, *Guidelines*, note 7 *supra*, p 7.

27 *Ibid*, p 8

28 National Health and Medical Research Council, *Clinical Practice Guidelines: The Management of Early Breast Cancer*, Australian Government Publishing Service, Canberra, 1995, p x

CPGs can be used to update the knowledge of medical practitioners in the clinical areas covered by the guidelines. It is hoped that with this educative role, CPGs will lead to positive changes in medical practice. There is also hope that guidelines will help to eliminate practice variations in the treatment of particular conditions that occur because of differing professional opinions about the best treatment options, patient preferences or other factors.<sup>29</sup> In its final report, the Taskforce on Quality in Australian Health Care acknowledged the role of CPGs and protocols in reducing practice variations and adverse outcomes:

Reducing inappropriate variation in the system by adopting clinical guidelines, protocols and pathways which reflect evidence based practice will improve safety and quality. [...] However, even when no good evidence exists of which form of care is 'right', there is good evidence to show that groups of clinicians who adopt intelligent standard clinical protocols have been able to improve the overall quality of care provided to their patients. In this situation standardised clinical protocols prevent adverse events by assisting consistent decision making and ensuring departures from standard care are quickly identified and questioned.<sup>30</sup>

Clinicians can however find guidelines difficult to interpret and to apply to their patients.<sup>31</sup> Furthermore, it cannot be assumed that the publication and dissemination of a guideline will by itself be sufficient to effect a change in clinical practices. In a study of obstetric practices in Ontario, both before and after the distribution of consensus guidelines which recommended lower rates of caesarean section delivery, Lomas et al reported little change in the practices of obstetricians after the guidelines had been released.<sup>32</sup> The study showed that most obstetricians knew of the guidelines although there was poor knowledge of the content of the guidelines as "[o]nly 3 per cent of the respondents correctly identified all four of the recommended actions and all four of the actions not recommended in the eight yes-or-no questions".<sup>33</sup> Two years after the guidelines had been released, 33 per cent of obstetricians surveyed reported that the guidelines had led to a change in their practices, with 67 per cent of these obstetricians reporting a reduction in the use of elective caesareans for women who had previously had a caesarean delivery.<sup>34</sup> However, when the actual numbers of caesareans performed before and after the guidelines were evaluated, there appeared to be little change in actual practices. The authors concluded:

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29 EM Wall, "Practice Guidelines Promise or Panacea?" (1993) 37(1) *Journal of Family Practice* 17. On practice variations in Australia see GV Wain, J Ward, BP Towler, "Gynaecological Care of Women With Abnormal Pap Smears. How Varied is Current Practice?" (1995) 162 *Medical Journal of Australia* 348 (finding "considerable variation in the management of minor lesions, provision of patient information and follow-up after treatment", p 348). See also PS Craft, JG Primrose, JA Lindner and PR McManus, "Surgical Management of Breast Cancer in Australian Women in 1993: Analysis of Medicare Statistics" (1997) 166 *Medical Journal of Australia* 626 (finding "substantial geographic variation in patterns of surgical management for breast cancer", p 626).

30 Note 6 *supra*, paras 3.39-3.40

31 M Ward, "Preventing Colon Cancer: The Problem With Guidelines or The Perils of Prevention" (1997) 166 *Medical Journal of Australia* 201

32 J Lomas, GM Anderson, K Domnick-Pierre, E Vayda, MW Enkin, WJ Hannah, "Do Practice Guidelines Guide Practice?: The Effect of a Consensus Statement on the Practice of Physicians" (1989) 321 *New England Journal of Medicine* 1306.

33 *Ibid* at 1308.

34 *Ibid*

“this high level of awareness, the apparently positive attitudes, and the reported changes in practice coexisted with a demonstrated poor knowledge of the actual recommendations and very little actual change in practices”.<sup>35</sup>

A more recent Australian study of the attitudes of general practitioners to clinical practice guidelines also reported positive attitudes to CPGs,<sup>36</sup> with 92 per cent of respondents regarding CPGs as “Good educational tools”.<sup>37</sup> However, only 26 per cent of respondents found CPGs “Extremely/very influential” in their management of patients, although 63 per cent found them “Somewhat/a little influential” in patient management.<sup>38</sup> In terms of which factors were regarded as “Extremely/very important” in influencing a general practitioner’s decision whether to follow a guideline, 88 per cent of respondents reported it was “Whether guideline based on evidence such as systematic reviews”; with other factors including “Endorsement by State health department” (77 per cent) and “If guideline provides details of financial costs of its recommendations” (69 per cent).<sup>39</sup> It is interesting to note that 85 per cent of respondents believed that CPGs were generally “Developed by experts who don’t understand general practice” and 70 per cent reported that CPGs were generally “Good in theory but useless in practice”.<sup>40</sup>

The view reported by general practitioners in the study by Gupta, Ward and Hayward that CPGs are developed by experts without an understanding of general practice, highlights the importance of doctors from the relevant area of practice to which the CPGs are directed being involved in the guideline development process. The Australian Medical Association (AMA) has also made it clear that doctors should be involved in guideline development. In its position statement on CPGs the AMA stated that “CPGs are relevant only if they are developed and regularly updated by practising doctors” and that “Practising clinicians must therefore have majority representation on any committee formed to develop CPGs”.<sup>41</sup>

It is also clear that appropriate implementation of CPGs is needed if they are to be effective, both in terms of general education and in terms of their ability to change doctors’ practices. The NHMRC’s *Guidelines* provide that CPGs “should be implemented” by being “promoted and introduced in such a way that practitioners and consumers: (i) become aware of them; and (ii) use them”.<sup>42</sup> The Taskforce on Quality in Australian Health Care has recommended that a variety of ways be used to implement CPGs and that the effectiveness of the various implementation strategies used be evaluated.<sup>43</sup> Yet even the benefits of greater implementation strategies for CPGs have been questioned. One

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35 *Ibid* at 1310.

36 L Gupta, JE Ward, RS Hayward, “Clinical Practice Guidelines in General Practice A National Survey of Recall, Attitudes and Impact” (1997) 166 *Medical Journal of Australia* 69

37 *Ibid* at 71

38 *Ibid*

39 *Ibid*

40 *Ibid*

41 MS Rice, “Clinical Practice Guidelines” (1995) 163 *Medical Journal of Australia* 144 at 145

42 NHMRC, *Guidelines*, note 7 *supra* p 10

43 Note 6 *supra* para 3.44

commentator has argued that as more effort is put into implementing guidelines, the costs associated with implementation will increase, and “It is highly doubtful that even the full implementation of extensive, enforceable guidelines would produce substantial cost savings”.<sup>44</sup>

## B. ‘Cookbook Medicine’?

There is concern amongst some health professionals that CPGs will be applied in a rigid manner that will lead to ‘cookbook medicine’ and will impinge on the clinical freedom of doctors. It has been argued that: “guidelines should be used to inform medical decision making, not to enforce medical decisions”.<sup>45</sup> The AMA’s position statement on CPGs states that “CPGs can never replace a doctor’s clinical judgement relating to individual patients”.<sup>46</sup>

The criticism that CPGs can lead to ‘cookbook medicine’ is one deserving of recognition. If rigidly applied, CPGs could lead to an erosion of the freedom of individual doctors to exercise their clinical judgment in their patient’s best interests. Furthermore, patients do not necessarily present to doctors as an average or typical case meeting a statistical norm.<sup>47</sup> A patient’s medical condition may be complicated by other factors, including other medical conditions. The patient may have more than one condition for which more than one CPG may be relevant. The relationship between these various conditions and between these conditions and the CPGs is a matter requiring the exercise of clinical judgment. As it would be impossible to produce CPGs to cover the medical condition of every patient who may present to a doctor, CPGs can only be drafted in terms of generalities and must be drafted in such a way as to allow for the exercise of clinical judgment in cases which are non-average, complex, or do not come within the CPG for some other reason.

Yet CPGs can also assist doctors in the exercise of their clinical judgment. The Professional Indemnity Review noted in its *Final Report*, “Many culinary and clinical disasters have no doubt occurred where tried and proven recipes have not been followed, or some ingredient has been accidentally omitted”.<sup>48</sup> What is important is that CPGs are formulated in such a way that health professionals benefit from the knowledge provided in the guidelines, while still retaining the freedom to exercise their clinical judgment in the application of those guidelines to a specific patient. This can be done. For example, two of the “guiding principles” in the NHMRC’s *Guidelines for the Development and Implementation of Clinical Practice Guidelines*, are “Guidelines should be flexible and adaptable to varying local conditions” and “Guidelines should include a consideration of resources”.<sup>49</sup> The NHMRC’s *Clinical Practice*

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44 JP Kassirer, “The Quality of Care and the Quality of Measuring It” (1993) 329(17) *New England Journal of Medicine* 1263 at 1264.

45 *Ibid.*

46 Note 41 *supra* at 145

47 EH Kluge, “Clinical Practice Guidelines and the Law” (1996) 155 *Canadian Medical Association Journal* 574 at 575.

48 PIR, note 5 *supra* para 3.74.

49 NHMRC, note 7 *supra* p 7.



*Guidelines: The Management of Early Breast Cancer* state in their introduction: “These guidelines are not rigid procedural paths. They are inclusive, not prescriptive. They aim to provide information on which decisions can be made, rather than dictate a specific form of treatment.”<sup>50</sup> In addition, the breast cancer guidelines provide information on the needs of “women from rural and remote areas” and on “ethnic and cultural issues” in the treatment of early breast cancer.<sup>51</sup>

With careful drafting, problems of ‘cookbook medicine’ in the structure of the guidelines can be overcome. Clinicians and patients should be able to have the benefits of the CPGs without clinicians being unduly restricted in the exercise of their clinical judgment.

### C. CPGs as a Funding Tool

While CPGs can be used as a tool for improving the quality of health care, there are also concerns about their potential use as a funding tool by insurers and government. For insurers, CPGs offer a way of ensuring that unnecessary treatments are not performed, quality will be improved and costs will be reduced. There is potential for CPGs to be used by insurers as a means of authorising treatment in a way that could lead to the US-style ‘managed care’.<sup>52</sup>

For government, the link between CPGs and funding is potentially very strong. As governments grapple with ballooning costs of health care, there is a real incentive to find a mechanism that discourages the use of ineffective or unnecessary practices, and that improves the safety of health care through the minimisation of adverse outcomes. It is in this context that governments will seek out the most effective means of implementing CPGs so as to change medical practices in line with the guidelines. Rejecting the tort system as a slow and time-consuming way of responding to failures to follow guidelines,<sup>53</sup> the Professional Indemnity Review recommended that Commonwealth funding under Medicare could be an appropriate tool in some cases:

The PIR recommends that the Commonwealth Government establish a mechanism that links findings from evidence based medicine and outcome studies (including adverse event studies) to reviews of funding for various medical services under the Medicare Benefits Schedule, so that financial incentives can be used to influence clinicians to adopt treatment choices that are the most beneficial for patients, either because they have better outcomes or fewer adverse events, or because the preferred treatment is less costly.<sup>54</sup>

The Taskforce on Quality in Australian Health Care has also recommended a link to funding as a means of ensuring compliance with CPGs, arguing that “Funding of health care is currently tied to throughput; a balancing link to quality is essential”.<sup>55</sup> The Taskforce recommended that governments at the

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50 Note 28 *supra* pp ix-x.

51 *Ibid* pp 102-4.

52 G Fairfield and R Williams, “Clinical Guidelines in the Independent Health Care Sector” (1996) 312 *British Medical Journal* 1554.

53 PIR, note 5 *supra* para 3.82

54 *Ibid* para 3 83, Recommendation 19.

55 Note 6 *supra* para 3.45

### Commonwealth, State and Territory level:

investigate systems of differential reimbursement for both institutional and individual health care providers according to the degree to which their care provision conforms to best practice once national guidelines have been produced.<sup>56</sup>

Linking compliance with CPGs to government health care funding is unlikely to be popular with health professionals who may see it as an infringement of their clinical freedom. In addition, a link between compliance and funding makes it clear that any CPGs upon which funding is based must make allowance for factors such as variations in the resources available to particular institutions. For example, it would be unrealistic for small country hospitals to be judged against guidelines which did not take account of the differing resources available between city and country. Furthermore, it has been argued that it may be a "double-edged sword" to use guidelines to target "inappropriate care", since this term could cover both overutilisation and underutilisation of resources.<sup>57</sup> To the extent that CPGs recommend services which are currently underutilised, CPGs may in fact increase, rather than decrease health care costs.<sup>58</sup> It has been argued that:

protocols are designed for the 'average patient' and therefore with complicated patients the need for additional resources will be easily justified, but it is unlikely that an uncomplicated patient will consume fewer resources than those laid down by the protocol.<sup>59</sup>

CPGs potentially offer an appealing and relatively 'quick-fix' solution to governments concerned over spiralling health care costs. Yet it is clear that it cannot simply be assumed that CPGs will lead to lower costs.

### D. CPGs and Litigation

There is also considerable potential for CPGs to be used in medical negligence litigation. The relevance of these guidelines to litigation, both in Australia and overseas, is the subject of the remainder of this article.

## IV. LEGISLATING THE STATUS OF GUIDELINES

The widespread development of CPGs in a wide variety of clinical specialties coupled with the introduction of legislation using CPGs as a defence in medical negligence actions in some US states,<sup>60</sup> has sparked interest about the use of CPGs in medical negligence actions.<sup>61</sup> Some states in the United States have

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56 *Ibid* recommendation 15

57 Wall, note 29 *supra* at 18

58 *Ibid.*

59 R Gama and S Featherstone, "Letter: Investigations Getting From Guidelines to Protocols" (1991) 303 *British Medical Journal* 522 at 522.

60 See note 62 *infra*

61 See for example RE Leahy, "Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines" (1989) 77 *California Law Review* 1483, MA Hall, "The Defensive Effect of Medical Practice Policies in Malpractice Litigation" (1991) 54 *Law and Contemporary Problems* 119; TA Brennan, "Practice Guidelines and Malpractice Litigation: Collision

introduced CPGs in legislation so that they can be used as a defence in medical malpractice litigation by physicians who have followed the guideline. The best known of these state schemes is the one introduced in Maine, although other states have also introduced legislation addressing guidelines.<sup>62</sup>

The Maine State legislature created the Medical Liability Demonstration Project in 1990. Under this project, CPGs in four specialties were introduced into state law with the hope that this would remove the need to litigate over the standard of care in medical negligence cases.<sup>63</sup> The specialties for which practice guidelines were developed were: anesthesiology (covering: documentation; intraoperative monitoring; postanesthesia care; and "preoperative laboratory testing"); emergency medicine (covering: "cervical spine x-rays for acute trauma patients"; and "transfer of patient to other hospitals"); obstetrics and gynaecology (covering: "caesarean delivery for failure to progress"; "assessment of fetal maturity prior to repeat caesarean delivery or elective induction of labor"; hysterectomy; tocolysis; "presumed ectopic pregnancy in a clinically stable patient"; "singleton breech presentation"; "perinatal herpes simplex virus infections"; "intrapartum fetal distress"; and "antepartum management of prolonged pregnancy"); and radiology (covering: screening mammography, antepartum ultrasound; outpatient angiography; and barium enema examinations on adults).<sup>64</sup>

The guidelines in the specialties in the project would constitute an affirmative defence in a medical malpractice action from 1 January 1992, provided a minimum of 50 per cent of the state's specialists in each of the areas of the guidelines agreed to participate in the project by November 1991.<sup>65</sup> There were in fact high levels of participation in the project by eligible physicians, with participation rates varying from 87 per cent in radiology to 92 per cent in emergency medicine by 1 January 1992.<sup>66</sup>

The guidelines in the specialties included in the demonstration project have the effect of state law. As a result, the guidelines can be introduced in medical malpractice litigation in order to establish the standard of care. It is not necessary to use expert testimony to introduce the guidelines into evidence.<sup>67</sup> It is important to realise that the Maine law does not give physicians participating in the project an immunity from claims if they follow the guidelines. Rather the

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or Cohesion?" (1991) 16 *Journal of Health Politics, Policy and Law* 67, L Rinella, "The Use of Medical Practice Guidelines in Medical Malpractice Litigation - Should Practice Guidelines Define the Standard of Care?" (1995) 64 *University of Missouri Kansas City Law Review* 337; DW Garnick, AM Hendricks, TA Brennan, "Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?" (1991) 266 *Journal of the American Medical Association* 2856.

62 See A Wolff, "Practice Parameters in Health Reform. New State Approaches Precede Clinton Plan" (1993) 21 *Journal of Law, Medicine & Ethics* 394, discussing reforms in Maine, Florida, Vermont, Minnesota and Maryland.

63 United States General Accounting Office, *Medical Malpractice. Maine's Use of Practice Guidelines to Reduce Costs* (October 1993) (GAO/HRD-94-8), pp 2-3.

64 *Ibid* pp 31-95. Radiology was added to the project in mid 1991 at the request of radiologists in the State, pp 38-9.

65 *Ibid* p 19.

66 *Ibid* p 27

67 *Ibid* p 20

law allows participating physicians to raise compliance with the guidelines as an affirmative defence in an action for medical negligence.<sup>68</sup> Furthermore, a plaintiff is only entitled to raise the guidelines if the physician has introduced evidence of compliance with the guidelines at trial.<sup>69</sup>

Despite their exculpatory design, it has been argued that it is possible that the guidelines could still be used for inculpatory purposes against physicians because of the operation of Maine's pre-trial screening panel. It is argued that if the panel unanimously finds in the plaintiff's favour, despite the fact that the physician has raised compliance with the guidelines, the panel's finding would be admissible in a later trial.<sup>70</sup> Alternatively, the panel could find that the physician had complied with the guideline but that the physician was negligent, for example, if the patient's condition meant that the guideline should not have been followed in this instance. Therefore, even a finding of compliance does not necessarily mean that the panel will find that the physician was not negligent.<sup>71</sup> It has also been suggested that the guidelines will not necessarily eliminate the need for experts to be used as it may be necessary to use expert testimony if the plaintiff claims that the guidelines should not have been followed in the plaintiff's case.<sup>72</sup> As use of the guidelines by plaintiffs in evidence is not permitted unless the physician or hospital raised evidence of compliance with the guideline at the trial, it has been suggested that the legislation could be subject to challenge under both state and federal constitutions, on the grounds that it violates equal protection and due process clauses.<sup>73</sup>

It is too early to say whether the Maine project will have a positive result in terms of medical malpractice litigation. The Maine legislation originally envisaged that the Medical Liability Demonstration Project would last for five years, covering claims between 1 January 1992 and 31 December 1996.<sup>74</sup>

To date, legislation similar to that in Maine has not been enacted in Australia. However, in their report on *Informed Decisions About Medical Procedures*, the Law Reform Commissions of New South Wales and Victoria, and the Australian Law Reform Commission recommended that the NHMRC develop guidelines on the provision of information to patients<sup>75</sup> and raised the possibility of legislation specifying the evidentiary status of those guidelines.<sup>76</sup> The Report outlined two possible approaches to such legislation. The guidelines could either be "made *conclusive evidence* of the standard of reasonable care in relation to the

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68 J Begel, "Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation" (1995) 47 *Maine Law Review* 70 at 77 For discussion of the Maine project see also GW Kuc, "Practice Parameters as a Shield Against Physician Liability" (1994) 10 *Journal of Contemporary Health Law and Policy* 439.

69 Begel, *ibid* at 86

70 *Ibid*.

71 *Ibid* at 87

72 *Ibid* at 88.

73 *Ibid* at 93.

74 Note 62 *supra* at 395.

75 Law Reform Commission of Victoria, New South Wales Law Reform Commission, and Australian Law Reform Commission, *Informed Decisions About Medical Procedures* (June 1989), recommendation 2, p 28

76 *Ibid* p 29.

provision of information about proposed treatment, or of what constitutes ‘approved professional practice’” or the guidelines “could be made *admissible evidence* of the standard of reasonable care or approved professional conduct”.<sup>77</sup> The Report rejected the first option as it would be difficult to prepare guidelines that would be “sufficiently precise to define a standard for legal purposes yet operate fairly in all cases”.<sup>78</sup> In addition, the task of deciding the standard of disclosure required would in effect be given to “a non-judicial and largely professional body” rather than remaining with the courts.<sup>79</sup> In adopting the second option, the Report recommended:

Legislation should be enacted requiring that, in an action for damages for professional negligence, the courts will consider the guidelines in deciding whether a doctor has acted reasonably in relation to the provision of information.<sup>80</sup>

The guidelines recommended in the Report have been developed by the NHMRC.<sup>81</sup> The recommended legislation has not been enacted to date.

In its *Final Report*, the Professional Indemnity Review concluded that legislation making CPGs “legally binding” in negligence actions was unlikely “at this time, though they may form part of future developments in this area”.<sup>82</sup> However, the PIR did recommend that the NHMRC (“as part of its guideline development work”), the Taskforce on Quality in Australian Health Care and others working on formulating “performance measures for health professionals”:

consider whether there are certain outcomes that should *prima facie* be considered likely to result from substandard care (Recommendation 110). Where such circumstances can be identified, the PIR recommends that the Department of Human Services and Health investigate the possibility of such outcomes attracting strict liability in any tort action seeking damages, either through Commonwealth or State legislation (Recommendation 111).<sup>83</sup>

## V. GUIDELINES AND MEDICAL NEGLIGENCE ACTIONS

Even without legislation which specifically adopts CPGs for use as a defence in medical negligence actions, CPGs can play an important role in litigation. There have been calls for judicial notice to be taken of CPGs, which have been formulated by an appropriate body, in cases involving the standard of care so that this issue is removed from the jury’s consideration.<sup>84</sup> The use of CPGs does have the potential to affect both the number of claims and the costs of settling medical malpractice actions.<sup>85</sup> CPGs may reduce the number of claims through an improvement in the quality of health care. They may also help lawyers to

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77 *Ibid.*

78 *Ibid.*

79 *Ibid.* p 30.

80 *Ibid.* p 30, recommendation 3

81 NHMRC, *Guidelines on Information*, note 18 *supra*

82 PIR, note 5 *supra* para 7.144.

83 *Ibid.* para 7 128

84 Leahy, note 61 *supra*.

85 Garnick et al, note 61 *supra*

assess whether a claim should be pursued and so may help to reduce the number of spurious claims. CPGs may also simplify medical negligence litigation if CPGs are accepted as evidence of the standard of care.<sup>86</sup>

However, CPGs could also have the potential to increase the number of medical negligence claims, by enabling better identification of negligent injuries. Given the number of negligently injured patients who do not claim compensation at present, the use of CPGs could facilitate an increase in the number of claims.<sup>87</sup> It has been argued that CPGs are unlikely to lead to significant reductions in the number and costs of medical negligence claims because guideline development is still at a relatively early stage and “a one-to-one match does not yet exist between the medical conditions now addressed by practice guidelines and the causes of claims”.<sup>88</sup> It is also unlikely that CPGs will have a substantial impact on the costs of settling claims as their use is unlikely to remove the need for expert testimony on the application of the CPG to the particular claim.<sup>89</sup>

Research from the United States suggests that the use of CPGs in medical negligence actions is a “two-way street” with CPGs being used for both inculpatory and exculpatory purposes.<sup>90</sup> In one study, more than 27 per cent of surveyed attorneys said that a CPG had been influential in their decision of whether to settle a case. A number of plaintiff attorneys surveyed (26.2 per cent) reported that CPGs had been influential in a decision not to take a case in the previous year and 30.9 per cent reported CPGs had been influential in a decision to initiate a case in the previous year.<sup>91</sup> For defence lawyers, CPGs often needed to be dealt with reactively after they had been raised by plaintiffs’ lawyers.<sup>92</sup> The study results also indicated that the use of CPGs did not affect the need for expert testimony as expert testimony was needed to introduce the CPGs into evidence, with the other side’s lawyers using experts to challenge the guidelines.<sup>93</sup> This “two-way street” use of CPGs in medical negligence claims contrasts quite markedly with the exculpatory focus, or “one-way street” of state legislation in the US, such as that introduced in Maine.<sup>94</sup> However, in support of the “two-way street” approach, Hyams et al argue: “before reducing or eliminating guidelines’ inculpatory function, the case must still be made that the inculpatory function produces undesirable results or that this function cannot coexist well with the exculpatory function”.<sup>95</sup>

There are concerns that the use of CPGs in medical negligence litigation could

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86 Garnick et al, note 61 *supra* at 2858 See also Brennan, note 61 *supra*

87 Garnick et al, note 61 *supra* at 2858.

88 *Ibid* at 2859.

89 *Ibid*

90 AL Hyams, JA Brandenburg, SR Lipsitz, DW Shapiro, TA Brennan, “Practice Guidelines and Malpractice Litigation. A Two-Way Street” (1995) 122 *Annals of Internal Medicine* 450. For further discussion of the use of CPGs in litigation in the United States see AL Hyams, DW Shapiro, TA Brennan, “Medical Practice Guidelines in Malpractice Litigation An Early Retrospective” (1996) 21 *Journal of Health Politics, Policy and Law* 289

91 Hyams et al (1995), note 90 *supra* at 453

92 *Ibid*

93 *Ibid*

94 Hyams et al (1996), note 90 *supra*, at 305-8.

95 *Ibid* at 311.

lead to doctors being held liable for a failure to follow a CPG. However, it is more likely that CPGs “will simply become another source of evidence available to litigants”.<sup>96</sup> CPGs could, therefore, be used by either the plaintiff or the defendant in a medical negligence action. As Hyams et al show, for plaintiffs’ lawyers CPGs can assist in deciding whether to initiate a claim or whether to settle a claim. For the defendant doctor, CPGs may or may not be of assistance in defending a claim. If the patient who is suing the doctor presented to the doctor with a condition that was clearly covered by relevant guidelines and the treating doctor failed to follow those guidelines in treating the patient, the plaintiff patient may seek to raise this as evidence of negligence. However, it is important to remember that guidelines are simply a guide and in the circumstances of a particular case there may be good reason for choosing not to follow the guidelines. An example of a situation in which this may occur is if the patient has a condition which is the subject of a guideline, but also has another medical condition. The second medical condition may in fact complicate the treatment of the first in such a way that the guideline cannot be followed strictly. In other words, there may be circumstances in which the patient falls outside the guideline in question. One commentator has noted:

As with a plumbline, a guideline can be heeded or not at the discretion of the clinician. However, a plumbline may only safely be ignored by a builder so long as the safety of a structure does not depend upon adherence to its guidance.<sup>97</sup>

Similarly, if a patient’s condition falls outside the guideline it may be inappropriate for a doctor to follow the guideline strictly. In short, the question of whether a failure to follow guidelines will result in a finding of negligence is highly dependent on the facts of the particular case and whether adherence to the guideline’s recommendations was clinically appropriate for the particular patient’s condition. These possibilities lend weight to Hyams et al’s<sup>98</sup> “two-way street” proposition that CPGs can be used for inculpatory and exculpatory purposes.

The currency of guidelines is also relevant to the use of CPGs in litigation. Unless guidelines are regularly updated they may be overtaken by more recent medical research. In these circumstances, it may be possible for expert evidence to cast doubt on the relevance of the particular guidelines in question to the individual case in question. The NHMRC has recognised the importance of maintaining the currency of CPGs stating in its *Guidelines*:

Since they need to be based upon the best available evidence, guidelines should be reviewed regularly and modified to take into account new research literature, new technologies and the results of the evaluations of guidelines outcomes data.<sup>99</sup>

There is no legislation in Australia giving CPGs the effect of state law

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96 EB Hirschfeld, “Practice Parameters and the Malpractice Liability of Physicians” (1990) 263 *Journal of the American Medical Association* 1556, discussing the evidentiary weight of CPGs in the United States

97 B Hurwitz, “The Authority and Legal Standing of Clinical Standards and Practice Guidelines” in A Miles and M Lugon (eds), *Effective Clinical Practice*, Blackwell Science Ltd, 1996, pp 205-25 at 208

98 Hyams et al (1995), note 90 *supra*

99 NHMRC, *Guidelines*, note 7 *supra* p 11

specifically so that they can be used as a defence in medical negligence actions such as was done in the Maine reforms in the United States. However, in a medical negligence case, an expert witness could raise specific guidelines in his or her evidence as an indication of what is regarded as accepted medical practice in the specialty in question.

It should be noted however, that under Australian law, evidence of professional opinion does not bind the court. Under the traditional British approach, a doctor would not be found liable for negligence if he or she had acted in accordance with a responsible body of professional opinion.<sup>100</sup> However this test - known as the *Bolam* test - was rejected by the High Court of Australia in *Rogers v Whitaker*<sup>101</sup> with the High Court deciding that the question of whether the required standard of care had been met was a matter for the courts to determine, although “responsible professional opinion will have an influential, often a decisive, role to play”.<sup>102</sup> In *Lowns & Anor v Woods & Ors*,<sup>103</sup> Kirby P stated:

if the medical practitioner who is sued establishes that he or she has conformed to ordinary medical practice within the specialty in question, the forensic burden shifts to the patient to satisfy the Court that, this notwithstanding, the ordinary practice did not conform to the reasonable care demanded by the law in the circumstances.<sup>104</sup>

On the same issue, Mahoney JA said:

to persuade a court to a factual conclusion that those skilled in the field are wrong in concluding that, [for example,] a particular treatment should/not be followed will require cogent reasons. It can be done; but the burden of factual persuasion will ordinarily be a heavy one.<sup>105</sup>

To the extent that CPGs have been issued by a reputable body and are accepted in the medical community as a statement of accepted professional practice, expert evidence on the guidelines may well be ‘influential’ or ‘decisive’ for a court. The Court would still be the final decider of whether the defendant doctor’s actions were reasonable in law.

## VI. CONCLUSION

The rates of adverse outcomes in health care that have been identified in studies in Australia and overseas highlight the importance of finding ways to minimise adverse outcomes and to improve health care quality. Clinical practice guidelines offer one possible response to this issue. As a means of disseminating information to doctors about current knowledge of ‘best practice’, information which is increasingly evidence based, CPGs can play an important educative role in health care. While guidelines are not a new development in medicine, the

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100 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

101 (1992) 175 CLR 479

102 *Ibid*, per Mason CJ, Brennan, Dawson, Toohey, McHugh JJ

103 (1996) Aust Torts Reports 81-376

104 *Ibid* at 63,157.

105 *Ibid* at 63,160-161.



increasing number that are now being developed and the increased focus on quality issues in health care have raised the profile of CPGs to an unprecedented degree. Concerns over 'cookbook medicine' must be addressed if the support of the medical profession for guidelines is to be sustained. However, careful drafting of guidelines in such a way as to make allowance for the exercise of clinical judgment in individual cases should overcome concerns over the potential for CPGs to infringe professional autonomy.

Australia has not yet taken the approach to guidelines that has been taken in some states in the US whereby adherence to specific CPGs can provide an affirmative defence in a medical negligence action. One should be cautious about adopting a statutory approach to guidelines which adopts CPGs for use in medical negligence actions. To date there is insufficient data on the US experience to be able to fully evaluate the statutory approach and more research would be needed to evaluate the likely impact in Australia of such legislation on health consumers, the medical profession and the community at large. Yet the absence of legislation similar to that in Maine does not mean that CPGs will not be used in Australian litigation. As has been shown above, US research indicates that CPGs can be used in disputes in both inculpatory and exculpatory ways. There is no reason to think that this would be significantly different in Australia. It is likely therefore, that CPGs will remain a "two-way street", being used by lawyers for both plaintiffs and defendants.