

balancing absolute risk and potential benefit at both the individual and population levels. Although debate continues about the best decision-assistance tool to be used, any system will need to be simple and practical to use within the time and resource constraints of an already overburdened primary healthcare sector.

Christopher R Levi

Neurologist, and Conjoint Senior Lecturer, Clinical Neuroscience Program
Hunter Medical Research Institute
Department of Neurology, John Hunter Hospital, Newcastle, NSW

Parker J Magin

Senior Lecturer, Discipline of General Practice
Faculty of Health, University of Newcastle, Newcastle, NSW

Balakrishnan R Nair

Professor of Geriatric Medicine
Faculty of Health, University of Newcastle, Newcastle, NSW

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Clinical practice guidelines: time to move the debate from the *how* to the *who*

Openness about all potential conflicts of interest, as well as the degree of agreement among members about the final guidelines, is the least we should expect

THE ASCENDANCY OF EVIDENCE-BASED medicine over the past decade has fostered an unprecedented growth in practice guidelines.¹⁻³ Departments of health and associated agencies, specialty societies and other medical organisations have all embraced the development of guidelines in the belief that adherence to their recommendations translates into benefits for patients (improved outcomes), practitioners (improved quality of care), and providers (improved cost-effectiveness).⁴

As the practice guideline movement has matured, the interest and debate surrounding guideline developments has shifted from the *what* to the *how*.⁵

In fact, the National Health and Medical Research Council's *Guidelines for the development and implementation of clinical practice guidelines*, published in 1995,⁶ was a pacesetter in the *how* of guidelines, and at its core are the three criteria that underpin the quality of guidelines:

- a balance of healthcare disciplines in the guideline development group, together with consumer representation;
- a systematic review of relevant literature and stratification of the data according to a hierarchy of levels of evidence; and
- the generation of evidence-graded recommendations that also take into account the generalisability of the evidence, its practice relevance and resource implications.

Despite the availability of guidelines for developing guidelines,^{6,7} recent reviews of practice guidelines have

Recommendations for managing conflict of interests in practice guidelines development³

- A formal process should exist to disclose potential conflict of interest before the guideline development begins.
- All members of the guideline group should be involved in a discussion of conflicts of interest and how significant relationships will be managed.
- Participants who have relationships with industry, government agencies, healthcare organisations or specialty societies need not necessarily be excluded, but the group has to decide among itself a threshold for exclusion.
- There must be complete disclosure to readers of the practice guidelines of financial and/or other relationships with industry, government agencies, healthcare organisations and specialty societies.

shown that most fail to meet quality standards.¹⁻³ This is hardly surprising, as guideline development is an intensive, laborious and at times uncertain task.⁸ In essence, it is a human affair with all its attendant nuances, complexities and biases.

These human elements are illustrated in this issue of the Journal by Edmonds and colleagues (*page 332*)⁹ in their account of the workings of the Australian COX-2-Specific Inhibitor Prescribing Group. The outcome of its deliberations is also published in this issue of the Journal (*page 328*).¹⁰

The process pursued by the Prescribing Group followed the essentials outlined in the Guidelines for Guidelines.^{6,7} The working party was multidisciplinary, but with a difference! It had a high proportion of academics and clinicians with connections with the pharmaceutical industry, together with an undeniable first — representatives from the pharmaceutical companies involved in marketing COX-2 inhibitors. Initially, the group was embroiled in a debate on conflict of interest and its impact on the credibility of the outcomes, but this was only the beginning. A clash of minds in the interpretation of evidence led to resignations from the group, as did irreconcilable differences about its ultimate recommendations. This story suggests that the debate in guideline development should now shift even further from the *how* to the *who*.

The major issues arising from the Australian COX-2-Specific Inhibitor Prescribing Group's deliberations involve aspects of conflicts of interest and the management of differing interpretations of evidence. The definition of conflict of interest is complex, but a pragmatic description is "conflicts of interests comprise those which may not be fully apparent and which may influence judgment of authors reviewers or editors. They have been described as those which, revealed later, would make a reasonable reader feel misled or deceived".¹¹ In contrast to the recent emphasis in disclosure of conflict of interest in scientific and medical publishing, it appears that this disclosure has a low profile in practice guidelines. In two extensive surveys on quality in more than 700 practice guidelines, a statement of conflict of interest was not among the standards surveyed.^{1,2} Further, a recent survey exploring the relationships between authors of clinical practice guidelines and the pharmaceutical industry³ showed that 81% of authors per guideline had links to the industry. Financial support for authors by pharmaceutical companies was declared in only two of the 44 guidelines surveyed, and industry financial support for the creation of the guideline in only 20. Relationships with the pharmaceutical industry are widely accepted as being a potent catalyst for the potentiality of conflict of interest.¹² But the time has come to explore conflicts in relationships with health departments, other government agencies, various healthcare providers and specialty organisations. Full and candid disclosure of conflict, as pursued by Edmonds and colleagues and as advocated by others (Box), is the only solution.

One inherent assumption of evidence-based medicine is that differences and controversies stemming from interpretation of data are inversely related to the quality of evidence. However, if the experience of the Australian COX-2-Specific Inhibitor Prescribing Group is anything to go by, this assumption would appear to be optimistic, as at the end of the exercise eight members of the group had resigned, essentially because of differing mindsets. The Journal has long encouraged authors of practice guidelines to cite the level of evidence underpinning recommendations. What remains intriguingly unknown is the range of levels of agreement on the evidence.

The account by Edmonds and colleagues is a refreshing and welcome exposition of the "real world" of guidelines development. Its central message is that practice guideline development is not a black-and-white affair, and that the time has come for open disclosure of conflicts of interest and the degrees of consensus or dissent. As guidelines have a powerful influence on clinical practice, doctors and their patients deserve nothing less than complete openness and transparency.

Martin B Van Der Weyden

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