

evidence or the process for inclusion or exclusion of studies? What was the level of evidence on which final recommendations were based?

Importantly, high quality guideline development processes require a “balance of healthcare disciplines in the guideline development group”.⁴ Getting the right “who” is a prerequisite for getting the “how” right. Edmonds et al state that membership was arbitrary, with predominant representation from rheumatologists and relevant pharmaceutical companies. Given the problems associated with physician–industry interactions,⁵ it has been suggested that authors with significant conflicts of interest should be excluded from participating in guideline development.⁶ The rationale for arbitrary selection of members and inclusion of members from the pharmaceutical industry is not explicitly stated.

These issues may have contributed to the difficulties the group experienced, and may detract from the validity of their recommendations. Future trips down the “road to consensus” should run more smoothly after careful consideration of the “what”, “how” and “who” at the outset — no “ifs and buts” about it.

1. Van der Weyden M. Clinical practice guidelines: time to move the debate from the how to the who [editorial]. *Med J Aust* 2002; 176: 304-305.
2. Edmonds JP, Day RO, Bertouch JW. The road to consensus: considerations for the safe use and prescribing of COX-2-specific inhibitors. *Med J Aust* 2002; 176: 332-334.
3. Current Opinion: Cox-2 inhibitors — the evidence. Darlinghurst: NSW Therapeutic Assessment Group, January 2001. Available at <<http://www.clin-info.health.nsw.gov.au/nswtag/publications/posstats/COX%202.pdf>>.
4. National Health and Medical Research Council. Guidelines for the development and implementation of clinical practice guidelines. Canberra: AGPS, 1995.
5. Wazana A. Physicians and the pharmaceutical industry. Is a gift ever just a gift? *JAMA* 2000; 283: 373-380.
6. Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA* 2002; 287: 612-617. □

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IN REPLY: Both Vitry and Hurley and Gazarian and Kaye would have had our consensus group address different or broader issues than safe prescribing and use of COX-2-specific inhibitors (CSIs). Indications for use, leakage and cost effectiveness are important issues, but our goal, clearly stated in our article,¹ was different and, we believe, important: if a clinician has

decided to use a CSI, what considerations are needed to prescribe the drug safely? Disagreements in reaching consensus were not, as suggested by Gazarian and Kaye, due to confusion about the aim of the exercise, but to differences in interpreting evidence and expressing conclusions in simple and direct terms. It would have been easy to avoid these problems by limiting participants to a small group of like-minded colleagues, but we chose to involve a broad range of people who may represent a more realistic spectrum of attitudes and approaches.

We find Vitry and Hurley gratuitously pejorative in their description of the participants in this exercise. With the exception of two rheumatologists with epidemiological expertise (who did not sign off on the position statement²), all the rheumatologists involved were members of one or both advisory boards. They were a relevant group precisely because this role should involve a responsibility to provide sound advice to the industry paying for it, and equally to the profession, both in the interests of good patient care. “Current financial links” is not the way such a consultancy is usually described. They call the exercise “at best a tight collaboration between some healthcare professionals and drug companies” and “at worst ... as the ‘happy end’ of a successful marketing campaign”. Given that one of the two pharmaceutical companies involved declined to sign off on the statement, as did two rheumatologists who were advisory board members for the other company, this is a curious outcome of “tight collaboration”.

With respect to the relative safety of selective versus non-selective COX inhibitors, our considerations were based on data available from peer-reviewed studies published to the end of May 2001 and available on the United States Food and Drug Administration website, as indicated in the position statement² and the accompanying article.¹ A number of the references quoted by Vitry and Hurley became available after May 2001. Renewed scrutiny and analysis of existing datasets is interesting, but the results are best used to decide whether unresolved issues are of sufficient importance to justify further studies, and how these could be designed to deliver evidence that will convince us all, one way or the other. We made the point at the conclusion of the position statement that this is an evolving field and that conclusions may well change with emerging data.³

We consider the statements made in the considerations article¹ represent a fair expression of our assessment of the data available to us. Not everyone in the group agreed. In publishing the position statement

with the list of participants who endorsed it and those who did not, and by adding an article on the process we adopted, we hoped to highlight the fact that there are controversies and uncertainties about aspects of CSIs which require careful consideration in clinical use and further high quality data to resolve currently unresolvable issues.

1. Edmonds JP, Day RO, Bertouch JW. The road to consensus: considerations for the safe use and prescribing of COX-2-specific inhibitors. *Med J Aust* 2002; 176: 332-334. http://www.mja.com.au/public/issues/176_07_010402/edm10003_fm.html
2. The Australian COX-2 specific Inhibitor (CSI) Prescribing Group. Considerations for the safe prescribing and use of COX-2-specific inhibitors. *Med J Aust* 2002; 176: 328-331.
3. Day RO. Another selective COX-2 inhibitor: more questions than answers [editorial]. *J Rheum* 2002; 29: 1581-1582. □

Guideline-discordant care in acute myocardial infarction: predictors and outcomes

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TO THE EDITOR: Advocating implementation of evidence-based clinical practice guidelines is one aspect of the current drive to provide quality healthcare across different centres.

Quality theory demands that outcomes are continuously sought and that practices are modified accordingly — the “quality loop”.

Therefore, Scott and Harper are to be applauded for their pursuit of improved outcomes, not just improved processes, in studying guideline-discordant care in acute myocardial infarction.¹ I believe that this type of study, which objectively demonstrates the role of practice guidelines in “real world” practice, is very important.

However, as a geriatrician, my patient population is unlikely to intersect with populations enrolled in large cardiology trials (eg, those for thrombolysis in myocardial infarction).^{2,3} Comorbidities, such as renal impairment, cognitive impairment and poor functional status at baseline, were not explicit exclusion criteria, but, when present, would have reduced an individual's chance of being enrolled.

These types of comorbidities are likely to be associated with a reluctance on the part of patients and physicians to pursue life-prolonging interventions. They are also likely to be associated with poorer outcomes, whatever the intervention. Therefore, I believe that these non-cardiac comorbidities are potential confounders for study designs, such as that of Scott and Harper.¹