

Evidence-based healthcare 10 years on: is the National Institute of Clinical Studies the answer?

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TO THE EDITOR: The recent creation of the National Institute for Clinical Studies (NICS) is an exciting new opportunity for bridging the gap between evidence and practice.¹

In carrying out this task, NICS will be directed by the members of its Board. Balanced stakeholder representation on the Board is required for NICS to produce optimal results. At present the Board consists of nine members, of whom eight are medical practitioners. The importance of doctors in the process and implementation of quality improvement initiatives is indisputable. However, other healthcare professionals also play a central role in achieving quality health outcomes for patients.² Board membership more representative of its stakeholders would provide NICS with a broader range of perspectives, which could only be seen as beneficial.

Given the current debate surrounding ethics and evidence-based healthcare, the values and expectations of healthcare consumers also need to be taken into account.³ One of the definitions of quality in healthcare is “consistently meeting or exceeding informed customers’ opinion”.⁴ It is crucial that the consumer’s voice be heard in matters relating to healthcare research and in the implementation of quality initiatives. As the relevance and acceptability of quality initiatives undertaken by NICS will have an impact on health outcomes for consumers, it is important that such initiatives take into account the preferences of consumers. For this reason, we believe it is imperative that NICS include a consumer on its Board.

An example of successful integration of a wide range of stakeholders onto a board is the Federal Government-funded National Health Priority Action Council, with representation from State/Territory, Indigenous and consumer groups and a balanced gender mix. We hope that NICS has strategies in place to enhance stakeholder representation on its Board, as this may be a factor in determining whether or not NICS becomes another forgettable acronym.

1. Silagy C. Evidence-based healthcare 10 years on: is the National Institute of Clinical Studies the answer [editorial]? *Med J Aust* 2001; 175: 124-125.

2. Donabedian A. The quality of care: how can it be assessed? *JAMA* 1988; 260: 1743-1748.
3. Leeder S, Rychetnik L. Ethics and evidence-based medicine. *Med J Aust* 2001; 175: 161-164.
4. Headrick L, Neuhauser D. Quality health care. *JAMA* 1995; 273: 1718-1720. □

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IN REPLY: The Board of the National Institute of Clinical Studies (NICS) agrees strongly with Hall and Lauder that closing the gap between evidence and practice involves input from consumers. We also agree that the Board of Directors should seek to incorporate input from consumers in its strategic and operational activities.

Of equal concern to the Board is ensuring the input of other stakeholder groups also currently not reflected in the composition of Board membership. For example, nursing and allied health professions comprise about 80% of the healthcare workforce and have shown strong leadership in relation to evidence-based practice. We are keen to see such groups actively involved in all aspects of the Institute’s work.

As a Federal Government-owned company, the selection and appointment process for Board members is the responsibility of government and our constitution does not allow the Board to change its own membership. However, the Board is seeking input from both consumers and other key stakeholder groups, both through its initial consultation processes and through establishment of Board advisory groups specifically focused on consumer issues and nursing and allied health. These groups will provide direct and valued input into the strategic and operational activities of the NICS.

Our first round of consultation, with over 300 organisations, highlighted a number of areas where there are currently major gaps between evidence and practice, such as cardiac failure, various forms of cancer treatment, prevention of deep vein thrombosis in hospitalised patients, prevention of bedsores, and prescribing of psychotropic drugs for children. We are now examining ways in which the NICS might usefully help in some of these areas to identify barriers and possible solutions that can be rolled out across the healthcare system and sustained. The success of the NICS in achieving this will depend on the willingness of all stakeholders (including health professionals, consumers and managers) to work together in a constructive way. □

COX-2 inhibition and thrombotic tendency

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TO THE EDITOR: I am concerned that several statements in the article on cyclooxygenase-2 (COX-2) inhibition by Cleland and colleagues¹ do not accurately reflect the clinical data.

The authors postulate a prothrombotic tendency of celecoxib on the basis of the CLASS study (comparing celecoxib with ibuprofen or diclofenac)² and four case reports. The authors concede that celecoxib has no effect on the rate of myocardial infarction (MI) in the CLASS study (a conclusion also reached by the United States Food and Drug Administration [FDA] review of CLASS³), which would seem to contradict their hypothesis that celecoxib is prothrombotic.

Cleland and colleagues speculate that the differences between the CLASS study and the VIGOR study (which compared rofecoxib with naproxen)⁴ may be explained by low-dose aspirin use in CLASS and failure to use aspirin in 4% of patients in VIGOR with “CV [cardiovascular] risk factors”. This speculation is unfounded. In the CLASS study patients in all treatment groups who used aspirin had higher MI rates than non-aspirin users, and presumably this higher rate would have been observed in VIGOR if aspirin users had been enrolled. This higher rate is probably because aspirin use serves as a marker for increased CV risk. In patients in CLASS similar to the 4% with “CV risk factors” in VIGOR, MI rates were similar in the celecoxib and non-steroidal anti-inflammatory drug (NSAID) groups (data on file, Pharmacia) and numerically much lower than in the VIGOR study subgroup.

On the basis of these two flawed arguments, Cleland and colleagues apparently extrapolate the high rate of MI seen with the use of rofecoxib to celecoxib and suggest that high MI rates are a “class” effect. This proposal is scientifically unsound and is not supported by other clinical data, including over 12 000 patients in the celecoxib registration program (data on file, Pharmacia). No celecoxib study has shown an increased risk of MI compared with traditional NSAIDs.

The authors correctly assert there is “little clinical evidence from community use to suggest that selective COX-2 inhibition has serious unwanted effects other than those seen with standard NSAIDs”, but imply there are few community data. In fact, community use of celecoxib in Australia (at least 1.5 million