National ethics committee urgently needed

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TO THE EDITOR: We are writing to add our wholehearted support to the plea made by Carapetis et al[1] for a simplified ethical approval process for multicentre studies.

We are conducting two national case-controlled studies of cancer in Australia, funded by grants from the National Institutes of Health and the Department of Defense in the United States, as well as the National Health and Medical Research Council (NHMRC). Our ability to achieve full population coverage was a major competitive advantage in terms of securing international funding. However, to realise this objective, we have spent more than a year obtaining ethics approval from the myriad institutions controlling access to patients and the public.

We have been required to make more than 60 separate ethics applications, lodging about 550 copies of the proposal (a total of 40 000 sheets) at a cost of more than $7000 for paper and printing alone. When labour is included the cost of the initial submissions escalates to $16 000 (excluding substantial investigator time). Other costs include the extraordinary requirement of one ethics committee in Victoria that an investigator from Queensland personally attend a 10-minute interview at which no substantive issues were raised.

The ethical benefit of this investment must be questioned when the majority of changes required by committees have dealt with minor issues such as grammatical style that have little to do with patient protection. Inevitably, such directives are inconsistent across institutions. It is thus impossible to comply with all requests while maintaining a standard set of study documents.

These problems are accentuated for the increasing number of Australian researchers relying on overseas funding. For example, regulatory authorities in the United States insist that all ethics committees reviewing US-funded projects involving humans must have US federal approval to do so. In our experience, few Australian hospital ethics committees have this approval. Therefore, in addition to fulfilling standard institutional ethics requirements, we have also had to help several committees go through the lengthy process of securing US accreditation simply to approve our study!

For all the above reasons, we strongly believe that Australian researchers and patients would be best served by a single national ethics committee for large multicentre studies. This would also reduce the enormous burden currently placed on the individual committees. In the meantime, we thank Breen and Hacker[2] for their reminder to institutional ethics committees that the NHMRC national statement "empowers ethics committees to minimise unnecessary duplication".

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2. Breen KJ, Hacker SM. Privacy legislation and research [letter]. *Med J Aust* 2002; 177: 523-524. ❑

Correspondents

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There should be no more than 5 references. The reference list should not include anything that has not been published or accepted for publication. Reference details must be complete, including: names and initials for up to 4 authors, or 3 authors et al if there are more than 4 (see mja.com.au/public/information/uniform.html#refs for how to cite references other than journal articles).

Inappropriate use of hospital emergency departments

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TO THE EDITOR: Both adult and paediatric hospital emergency departments (EDs) are subject to inappropriate use.[1,2,3] Some families use the ED as a primary care provider,[4,5] often claiming that they have no regular general practitioner.[6] Such families may experience poorer overall health.[7,8] We hypothesised that providing such families with information about GPs in their area and emphasising the benefits of having a GP responsible for their long term healthcare might:

- facilitate the establishment of ongoing relationships between patients and GPs; and
- encourage families to use GPs more as their primary source of care.

We conducted a controlled trial (week-on, week-off randomisation) of families identified as having no regular GP who presented to the Royal Children's Hospital ED over four months. Information about the GPs interested in seeing children was located on a computer database. Medical staff were able to search for a GP whose surgery was close to the patient's street address. Families were provided with detailed information about the GP's practice (eg, opening times, languages spoken, etc). Parents were given a list of GPs and a map showing the locations of their surgeries, together with a letter of introduction; the families decided which GP they would attend. Families in the control group were just treated as usual. Families were then contacted after two months to see if they had visited a GP and whether regular contact had been established.

Over the four months, 216 families were enrolled; 96 were allocated to the intervention group. Despite our active encouragement, the ED medical staff provided the intervention material to families in the intervention group on just 49% of occasions.

We found that, two months after the initial ED visit, intervention-group fam-

ilies were no more likely to have established an ongoing relationship with a GP than control families (46 [38.3%] and 41 [42.7%], respectively; $P = 0.5$), irrespective of whether or not they received the intervention material.

In summary, this single intervention was not sufficient to alter healthcare-seeking behaviour of families with no regular GP. It seems the motivation to obtain a GP lies with the family. Thus, it would seem necessary to design and deliver an intervention that addresses the beliefs of families about the roles of various facets of the healthcare system. With time and work pressures, ED medical staff may not be in the best position to provide such intervention.

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4. Kini NM, Strait RT. Nonurgent use of the pediatric emergency department during the day. *Pediatr Emerg Care* 1998; 14: 19-21.
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Epidemiological modelling (including economic modelling) and its role in preventive drug therapy

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TO THE EDITOR: In their recent article on the use of modelling in pharmacoeconomics to estimate the potential benefits, risks and costs of preventive drugs, Liew and colleagues highlighted important strengths and limitations of this technique.[1] One limitation is that modelling is discretionary: different analysts elect different models and get different answers. We argue that modelling is the first step. The next step is testing the predictive validity of the model by systematically collecting cost and effectiveness data over a period of time. Then the predictions of the original analysis could be compared to what actually transpired.

The goal of pharmacoeconomics is the most accurate estimation of costs and benefits. The more these variables are truly study outcomes (that is, experimental and not constrained by assumptions of the economic model), the more valid the process. This will help reduce model discretion, improve data quality and increase the likelihood that the experiment could be replicated independently, the acid test of validity. In reducing the discretion inherent in pharmacoeconomics, we can allay the concerns of those who have questioned its underlying theory[2] and validity.[3]

If one does not know the benefit of a drug, one conducts a study. Equally, if one does not know the cost of a drug, one needs a study. This has been the impetus for randomisation in design of pharmacoeconomic studies, thereby decreasing reliance on economic modelling.[4] Furthermore, there are well-tested methods for quantifying the uncertainty of estimates obtained with randomised studies. In contrast, economic modelling assesses the robustness of the model assumptions, as reflected in the estimate, using sensitivity analysis. However, this analysis cannot separate uncertainties attributable to the model assumptions, uncertainty inherent in the data put into the model, and uncertainty of outcome estimates. One is left with nostalgia for the simplicity of the null hypothesis.

How can we move forward?

To reduce reliance on modelling and to collect better data, we propose that Australia, with its "culture of evaluation",[5] again take the lead by creating a new "conditional listing" category on the Pharmaceutical Benefits Scheme for all drugs, not just preventive therapy. This would be available for selected products with strong biological rationale but inadequate current evidence on cost-effectiveness. By necessity, these would include only high-volume/low-cost and low-volume/high-cost products, as high-volume/high-cost products are rarely developed, and low-volume/low-cost products are not problematic. The sellers would then collect prospective data to substantiate cost-effectiveness of the products or would have them delisted. This would be truly innovative and, like the Pharmaceutical Benefits Advisory Committee itself, a first for the Commonwealth. Certainly, no other jurisdiction is even considering this, let alone proposing systematic study.

With better data, we would learn which models and model assumptions yield accurate predictions. Of course, many challenges and difficulties will need to be addressed regarding this proposal, but in our opinion none are insurmountable, and the benefits of a program of this type clearly exceed the risks.

Competing interests: K R J was a medical regulator for the United States Food and Drug Administration from 1985 to 2001, and now works for M-TAG, a private company that performs clinical, epidemiological and health economic evaluations of drugs, devices and technology.

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IN REPLY: We agree with Johnson and Lassere about the value of longitudinal studies, especially clinical trials, in assessing healthcare benefits and costs. They are critical to informing clinical practice and health policy.

If it were possible to conduct these studies across a wide variety of settings, representing the range of "real life" practice, then there would be little need for epidemiological modelling. However, this is not possible. Clinical trials (with or without cost components) will only ever be conducted over relatively