

Ethics review and use of reminder letters in postal surveys: are current practices compromising an evidence-based approach?

Stuart C Howell,* Susan Quine,†
Nicholas J Talley‡

*PhD Candidate, c/- Department of Medicine, Nepean Hospital, PO Box 63, Penrith, NSW 2750; †Associate Professor, School of Public Health; ‡Professor of Medicine, Department of Medicine, Nepean Hospital and University of Sydney. howells@wahs.nsw.gov.au

TO THE EDITOR: Survey data are difficult to publish when response rates fall below 60%. Reminder letters are the most reliable method of improving response rates in postal surveys,^{1,2} and three to four reminders are needed to achieve the 60% benchmark. The additional benefit of sending five or more reminders appears negligible, suggesting that four is the optimum number to maximise response rates using this approach.¹

Our recent experiences suggest that human research ethics committees (HRECs) are seeking to limit the number of reminder letters on the grounds that they could be construed as harassment of research subjects. We recently submitted applications to two HRECs, seeking permission to conduct a multicentre postal survey in our local area. One committee approved the use of a single reminder letter, while the second approved the use of two. We appealed both decisions, citing evidence from earlier studies.^{1,2} The first committee reversed its decision and subsequently approved use of three reminders; the second committee upheld its decision to allow only two reminders. Thus, our study was effectively restricted to two reminder letters.

These experiences highlight two limitations of the ethics review process in Australia. First, the process is highly fragmented and lacks standardisation. HRECs exist as autonomous and independent entities, with varying interpretations of ethical practice. The decisions of one

committee frequently undermine those of another. This is frustrating for researchers, who often have to seek permission from two or more committees during the course of a study.

Second, the process confers higher status on the rights of study participants than on the methodological demands of science. Whenever there is any actual or perceived conflict between the two, HRECs consistently rule in favour of individual rights. Researchers are reluctant to challenge the decisions of their local committee, as there is no independent review process, and appeals are usually referred back to the original committee. The result is a directive and autocratic process which fails to consider the demands of scientifically valid research.

Under current guidelines of the National Health and Medical Research Council, HRECs may endorse procedures that are potentially invasive or intrusive, provided certain conditions are met:

- the procedures are scientifically justified;
- there is no acceptable alternative; and
- reasonable steps are taken to protect individual rights.

This certainly provides scope for sanctioning four reminder letters in postal surveys.

1. Koloski N, Talley NJ, Boyce PM, Morris-Yates AD. The effects of questionnaire length and lottery ticket inducement on the response rate in mail surveys. *Psychol Health* 2001; 16: 67-75.

2. Kalantar JS, Talley NJ. The effects of lottery incentive and length of questionnaire on health survey response rates: a randomised study. *J Clin Epidemiol* 1999; 52: 1117-1122. □

Jeanette E Ward

Director, Division of Population Health, South Western Sydney Area Health Service, 1 Campbell Street, Liverpool, NSW 2170.
jeanette.ward@swsahs.usw.gov.au

COMMENT: Howell and his coauthors invite human research ethics committees (HRECs) to standardise their judgements about key aspects of methods, such as response-aiding strategies.¹ Their balanced and thoughtful analysis of their experience in securing approval from two HRECs for

reminders to enhance response rates to a postal community survey adds to previous concerns about decision-making by HRECs in Australia.^{2,3}

In an era of evidence-based healthcare, there are two main reasons to insist that HRECs only approve protocols for surveys that propose scientifically based procedures to increase response rates. First, applicants are applying empirical insights from previous research in their own practice. Hence, methods are evidence based. Second, applicants are doing their best to ensure the validity of their future data. As eloquently quantified elsewhere, surveys with low response rates are plagued by response bias.⁴ Indeed, it was recently asserted that, for mailed surveys, “you need an 80–85% response rate to make it epidemiologically significant”.⁵

Fortunately, there is the most rigorous evidence (Level 1) for specific response-aiding strategies for surveys of medical practitioners in Australia.⁶ Howell and colleagues cite two recent studies of response-aiding strategies in lay surveys. Yet such compelling evidence appears to have been inadequate to secure identical responses from at least two HRECs. That both required Howell and colleagues to apply “homoeopathic” measures to their reminders (sending two rather than the proven four reminder letters) suggests that these HRECs may have been poorly apprised of the relevant scientific literature, unconvinced of its generalisability, or concerned about the acceptability of proposed procedures to research participants. As current National Health and Medical Research Council (NHMRC) guidelines provide a framework for approving research procedures that are “scientifically justified”, it seems HRECs would benefit from regular and independent updates about key methodological advances, such as response-aiding strategies, their benefits, risks and harms.

I am mindful that such methodological guidance must not add unnecessarily to the copious reading that is already typically demanded of members of HRECs. Perhaps the NHMRC Australian Health Ethics Committee could consider this issue in its next triennium, to commence 2003.

1. Howell SC, Quine S, Talley NJ. Ethics review and use of reminder letters in postal surveys: are current practices compromising an evidence-based approach? [letter]. *Med J Aust* 2003; 178: 43.

2. Ockham's razor. The ethics of ethics committees. Broadcast Sunday 14 July 2002. Transcript available at <http://www.abc.net.au/rn/science/ockham/stories/s604355.htm> (accessed 30 Aug 2002).

3. Komesaroff P. Clinical research in the emergency setting: the role of ethics committees. *Med J Aust* 2001; 175: 630-631.

4. Evans SJ. Good surveys guide. *BMJ* 1991; 302: 302-303.

5. Leeder S, quoted by Purcell C. Dispute continues over GP numbers. *Med Observer* 2001 Mar 1: 3.

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).

6. Young JM, Ward JE. Improving survey response rates: a meta-analysis of the effectiveness of an advance telephone prompt from a medical peer [letter]. *Med J Aust* 1999; 170: 339. □

Withdrawal of methylphenobarbitone

Mervyn J Eadie

Neurologist, Ladhope Chambers, 131 Wickham Terrace, Brisbane, QLD 4000.

TO THE EDITOR: The recent information that methylphenobarbitone (60 mg tablets) will be unavailable after 1 January 2003 has caused anxiety in patients with epilepsy previously treated satisfactorily with this drug. The suggested substitution of phenobarbitone, primidone or a newer antiepileptic agent seems appropriate. However, patients and perhaps practitioners may assume, as my patients have, that phenobarbitone and primidone are equivalent to methylphenobarbitone on a milligram-for-milligram or a tablet-for-tablet basis. This may not be so. The equivalence is close to 30 mg of phenobarbitone for 60 mg methylphenobarbitone, and probably around 200 mg of primidone for 60 mg of methylphenobarbitone.¹ Plasma phenobarbitone concentrations should be checked before and after any changeover.

In recent years, several other old, but therapeutically satisfactory, neurological drugs have also been withdrawn from the Australian market (oral neostigmine, several anticholinergic antiparkinsonian agents, ethosuximide and some phenytoin preparations, and the only ergotamine preparation not also containing caffeine).

Subject to safety issues, ethics committees usually will not approve a clinical trial of a new drug unless patients who benefit from it are guaranteed supplies until the drug is marketed. Surely similar considerations should apply for patients who have had completely satisfactory long-term responses to marketed drugs. If such drugs must be withdrawn, except for safety reasons, there should be extensive prior consultation with prescribers and patient groups, prescribers should know the situation before their patients discover it from other sources, and there should be a sufficient lead time for everyone receiving the drug to return for another prescription (and for advice) before the drug becomes unavailable (a minimum lead time of six months in the case of drugs subsidised under the Pharmaceutical Benefits Scheme).

The withdrawal of useful neurological drugs in Australia has reached the stage where therapeutic options are becoming limited. In the case of drugs required for

long-term use, to protect the interests of new patients it has become necessary to consider whether the drug will continue to be available for the expected duration of the patient's therapy. In this regard, the prescriber's only guide may be the track record of the firm which markets the drug otherwise chosen.

1. Eadie MJ, Hooper WD. Other barbiturates — methylphenobarbital. Chapter 55. In: Levy EH, Mattson R, Meldrum BS, Perucca E, editors. *Antiepileptic drugs*. Philadelphia: Lippincott-Williams and Wilkins, 2002. □

Prevalence of pain among nursing home residents in rural New South Wales

C Roger Goucke

President, Australian Pain Society; c/- Department of Pain Management, Sir Charles Gairdner Hospital, Nedlands, WA 6009.
roger.goucke@health.wa.gov.au

TO THE EDITOR: The recent article by McLean and Higginbotham¹ and the accompanying editorial by Melding² highlight the problems faced by elderly people in aged-care facilities. It is likely that many elderly people living alone in the community are suffering equal, if not worse, pain.

At a recent strategic planning meeting, the Australian Pain Society identified this group of people as a high priority for the development of pain management treatment strategies. These strategies are now well into the development process.

While it is appropriate for the Journal to focus on medical practitioners' care of these patients, it must be remembered that most direct care for people in aged-care facilities is delivered by nurses and nurse assistants/carers. The Australian Pain Society will be focusing its strategies on non-drug techniques that can be used by this group of healthcare workers. Assessment and documentation of pain-related behaviour, particularly in people with cognitive impairment, is critical if progress is to be made. It is also

important to appreciate the contribution in this area from other allied health professionals, such as physiotherapists, psychologists and occupational therapists. These practitioners have much to offer this patient group and have been important contributors to the Australian Pain Society's management strategies.

It is hoped that State and federal funding can be made available for nurse educators to deliver these low-tech, non-drug management strategies within aged-care facilities.

The two articles quite rightly focus on the regular use of simple oral analgesics, such as paracetamol, and low-dose opioids. Oral analgesics, together with more widespread use of non-drug treatments (eg, exercise, transcutaneous electrical nerve stimulation, hot and cold topical applications, relaxation, distraction, mental stimulation, lifestyle modification) and increased awareness among aged-care workers of the problems and solutions, should lead to an enhanced quality of life for this growing sector of our community.

1. McLean WJ, Higginbotham NH. Prevalence of pain among nursing home residents in rural New South Wales. *Med J Aust* 2002; 177: 17-20.
2. Melding PS. Can we improve pain management in nursing homes [editorial]? *Med J Aust* 2002; 177: 5-6. □

Pain management programs in residential aged care

Robert H Llewellyn-Jones,* Karen A Baikie,[†] Heather E Smithers,[‡] Philip D Funnell[§]

*Lecturer, †Senior Research Psychologist, ‡Research Officer, Department of Psychological Medicine, University of Sydney, Sydney, NSW; §Rehabilitation Physician, Rehabilitation and Aged Care Department, Hornsby Ku-ring-gai Hospital, Hornsby, NSW
rljones@mail.usyd.edu.au

TO THE EDITOR: The articles by Melding¹ and McClean and Higginbotham² highlight the important problem of chronic pain in residential care.

We have conducted two studies to investigate factors related to depression in

Self-reported pain frequency and severity among residents of aged-care facilities

	Study 1 (1994) (n = 513)	Study 2 (2000–2001) (n = 148)
<i>Pain frequency</i>		
Not at all	230 (44.8%)	54 (36.5%)
Rarely/occasionally	115 (22.4%)	52 (35.1%)
Frequently/constantly	168 (32.8%)	42 (28.4%)
<i>Pain severity*</i>		
Minimal/mild	58 (20.5%)	27 (28.7%)
Moderate	98 (34.6%)	36 (38.3%)
Severe/bad as could be	127 (44.9%)	31 (33.0%)

*Severity rated only for residents experiencing pain.