Are Australian Human Research Ethics Committees effectively promoting prospective trial registration?

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ANZCTR | Australian New Zealand Clinical Trials Registry

Background

The importance of clinical trial registration

There is growing recognition internationally of the need to record the existence of clinical trials so that a true picture of the evidence for a particular new treatment, drug, medical device or therapy is publicly available. Clinical trials registries, such as the Australian New Zealand Clinical Trials Registry (ANZCTR), may help to:

- Provide patients and health practitioners with access to up-to-date information about trials being conducted worldwide.
- Allow health professionals to investigate evidence behind new treatments, therapies or drugs arising from publicly listed trials.
- Assist in identifying gaps in research and prevent unnecessary duplication of clinical trials.

The Australian National Statement on Ethical Conduct in Human Research (2007)

The National Statement on Ethical Conduct in Human Research (The Statement) is a joint document of the National Health and Medical Research Council (NHMRC), Australian Research Council, and the Australian Vice-Chancellors’ Committee aiming to promote ethical human research and clarifying the responsibilities of organisations, individuals, and ethical review bodies on the ethical design, conduct, and dissemination of results of human research.

Clause 3.3.12 of The Statement maintains that:

"Before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible register" ²

Aims

There is a lack of published knowledge about what Human Research Ethics Committees (HRECs) are doing to encourage clinical trial registration in Australia. The aim of the HREC survey was to ascertain:

(1) Any changes in their mechanisms for promoting prospective trial registration; and
(2) The proportion of approved trials that were registered on a World Health Organization-recognised clinical trials registry.

Methods - [survey conduct]

Two forms were posted to the 227 approved Australian HRECs in 2008 gathering information about the HRECs themselves via a HREC survey form (HSF) and a clinical trials data collection form (DCF). Two survey periods were undertaken, pre- and post-roll-out of The Statement in August/September 2007.

The survey required institutions to report their compliance with the revised conditions of the Statement from January 1st 2008. Respondents were asked to supply up to 10 consecutive clinical trials they had approved from April 2007 (Survey #1) and from April 2008 (Survey #2). Comparisons of data pre- and post-rollout of The Statement were calculated using January 1st 2008 as the cut-off.

Results

63/227 (28%) HRECs replied to Survey #1 and 43 (19%) to Survey #2. Of those that responded, the majority approved <10 clinical trial applications annually (Survey #1: 41%; Survey #2: 56%).

The number of HRECs that included a question about trial registration on their application forms increased slightly post-publication of The Statement (Survey #1: 46%; Survey #2: 55%) (Figure 1).

88% of HRECs in Survey #1 and 82% in Survey #2 did not include trial registration as a condition of ethics approval in their standard approval letter (Figure 2).

Conclusions

At the time the survey was conducted, trial registration rates were low, and the lack of processes for encouraging trial registration before and after the publication of The Statement may have contributed to this. Only about half of HRECs had a question about clinical trial registration, and <80% did not have a standard approval letter with a trial registration condition.

From these findings, HRECs could play a more proactive role in improving compliance by requiring prospective trial registration as a condition of ethics approval.

We acknowledge the low response rate of our survey, and therefore our results should be interpreted with caution.

References