Other information

Item 23. Registration number and name of trial registry

Example—“The trial is registered at ClinicalTrials.gov, number NCT00244842.”

Explanation—The consequences of non-publication of entire trials, selective reporting of outcomes within trials, and of per protocol rather than intention-to-treat analysis have been well documented. Covert redundant publication of clinical trials can also cause problems, particularly for authors of systematic reviews when results from the same trial are inadvertently included more than once. To minimise or avoid these problems there have been repeated calls over the past 25 years to register clinical trials at their inception, to assign unique trial identification numbers, and to record other basic information about the trial so that essential details are made publicly avail‑ able. Provoked by recent serious problems of with‑ holding data, there has been a renewed effort to register randomised trials. Indeed, the World Health Organisation states that “the registration of all interventional trials is a scientific, ethical and moral responsibility” (www.who. int/ictrp/en). By registering a randomised trial, authors typically report a minimal set of information and obtain a unique trial registration number. In September 2004 the International Committee of Medical Journal Editors (ICMJE) changed their policy, saying that they would consider trials for publication only if they had been registered before the enrolment of the first participant. This resulted in a dramatic increase in the number of trials being registered. The ICMJE gives guidance on acceptable registries (www.icmje.org/faq.pdf). In a recent survey of 165 high impact factor medical journals’ instructions to authors, 44 journals specifically stated that all recent clinical trials must be registered as a requirement of submission to that journal. Authors should provide the name of the register and the trial’s unique registration number. If authors had not registered their trial they should explicitly state this and give the reason.