Reviewer's report

**Title:** Using clinical trial data and linked administrative health data to reduce adverse drug events associated with the uptake of newly released drugs by older Australians: a model process

**Version:** 1  **Date:** 29 October 2010

**Reviewer:** Graziano Onder

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This is an interesting study evaluating how results of RCT on newly released drugs are applied in the real world. Authors describe the case of rofecoxib, showing how this drug has been widely used in patients usually excluded by RCT (i.e. with CV disease). I believe the manuscript needs minor revisions:

1. I do suggest to shorten the text of the manuscript and to reduce the number of tables. For example 1999 and 2000 cohort can be combined.

2. Table 1 nicely summarizes exclusion criteria most commonly used by RCTs assessing the efficacy of rofecoxib. However, exclusion criteria used by these trials may be much more stringent than those listed in the table. For example RCT listed as ref 17 excluded patients with ‘... an unstable medical condition; a history of cancer or alcohol or drug abuse in the five years before the study,...’ Patients with morbid obesity and those who required or who had been receiving treatment with aspirin, ticlopidine, anticoagulants, cyclosporine, misoprostol, sucralfate, or proton-pump inhibitors or treatment with histamine H2–receptor antagonists in prescription-strength doses...’ and RCT listed as ref 18 included patients ‘...if they had at least moderate pain when walking (40 mm) and a minimum increase in pain when walking (15 mm)’ and excluded those with ‘... clinically significant abnormalities on physical or laboratory examinations at the screening visit’ (?). This means for example that results of these studies can not be applied to hospitalized patients or to those unable to walk. I suggest to report in a table or in the text the list of exclusion criteria included in the 14 trials mentioned at page 11 and to limit the analysis to those most commonly observed in the RCTs (as those listed in Table 1).

3. It would be interesting to see what is the real distribution of exclusion criteria listed in table 1 in the 1999 and 2000 (combined) cohorts. Rather than presenting the datum on CVD medications it may be interesting to show data on individual exclusion criteria (i.e. CHF, hypertension, anticoagulant, etc.)

4. In the tables please present also % and not only absolute numbers.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interests'