Reviewer's report

Title: Abstracts in high profile journals often fail to report harm.

Version: 2 Date: 4 November 2007

Reviewer: Sheena Derry

Reviewer's report:

General

This is a well conducted review dealing with an important aspect of adverse event reporting. Abstracts are usually the first, and often the only, part of a paper to be read, and should accurately report the study’s findings.

English is not the author’s first language, and I think the manuscript would benefit from some minor changes to words and sentences to make it read more fluently.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. Methods/Population and setting. State now the random selection was made: computer generated, random numbers table. We expect trials to report this, and should do so here.

2. Methods/Population and setting. “A purposive sample of leading journals was selected taking into account both their 2003 impact factor (figure 1)”. Is there something missing from this sentence, or should “both” be omitted?

3. Methods/Analysis.” Descriptive measures and exact confidence intervals …. I am unsure what the authors mean by “exact”, but note that they give results to three significant figures. Given that the numbers involved are a few tens to hundreds, I think this implies spurious precision. It is common to use two significant figures.

4. Results/Table 1. There is inconsistency between the text and the table resulting, I think, from the text reporting funding from industry compared to public institutions (cPR 1.29, CI not given) and the table comparing funding from public institutions compared to industry (cPR 0.77, 95% CI 0.60 to 0.97). It would be sensible to report the same thing in both places, for consistency and clarity.

5. Discussion. I calculate that 33% of articles did not report harm (120/363), and 47% of studies reporting harm in the text did not report it in the abstract (113/263).

6. Discussion. I do not think that mortality is a valid proxy for clinical significance in this context, so cannot infer from this study “that authors report harm in abstracts driven by statistics more than by clinical significance of harm”.
Thankfully few patients die in clinical trials.

7. Discussion. In Table 1 for the comparison of industry and public institution funding there is borderline statistical significance at the 5% level. There should be some comment on this. Given that there were only 226 articles in the comparison, and my guess (data not given) is that the majority were from industry, I would not put too much weight on this result. Similarly, the comparison of sample size is only just statistically significant at the 5% level. Perhaps it would be more accurate to say that this study did not demonstrate a robust difference in likelihood of reporting of adverse events in the abstract according to these two criteria.

8. Implications. Para 1. I hope, although I may be wrong, that clinicians and policymakers do not base their judgements on abstracts alone. An important implication of this study is that if adverse events are not flagged up in abstracts, those who are looking for information about them will not know to look further, to read the whole article, to find out about them – even if it is only to find reassurance that there were no differences between test treatment and comparator. Since most trials are not powered to detect differences in rates of adverse events, it is important that it is easy to locate studies with adverse event data so that they can be reviewed, and where appropriate combined with other similar studies, to determine rates with greater confidence. Studies that do not mention adverse events in the abstract may be overlooked in such reviews, except by the most diligent of reviewers, with consequent “loss” of data.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Abstract/Methods/Analysis. Use “corrected prevalence ratio”, and give abbreviation since it is used later in the abstract.
2. Abstract/Results. % is used inconsistently for confidence intervals
3. Keywords. Remove comma after “Abstracts”
4. Background. It is not only drug companies that have conflicts of interest. I suggest changing i.e. to e.g.
5. Methods and Results. “number of branches” and “42 articles had more than one branch”. The term “branch” is unusual. Perhaps “treatment arm” or “comparison” would be more familiar to readers.
6. Results. Para 3. “10% reported a statistically significant harm”. Give the numbers in addition to the percentage (e.g. 14/135). This is important when n is small.
8. Discussion. Para 3. “..longer sample size ..” should read ..”larger sample size ..”
Discretionary Revisions (which the author can choose to ignore)

1. I found the text in Methods quite dense, and would recommend breaking up the sections into paragraphs with the use of bullet points or lists where appropriate.

For example:

Two main endpoints were examined:
• the proportion of RCTs reporting or quantifying harm in the abstract
• the proportion of RCTs that mention or quantify harm in the abstract when harm was reported in the main body of the article.

Harm was defined as any possible adverse consequence of an intervention or therapy. Other studied predictors. We considered as explanatory factors:
• funding source (drug or device companies vs public institutions)
• use of placebo as control group
• the sample size (using the median value -200 patients - as a threshold)
• the main endpoint direction of effect (defined as favouring, being neutral or opposing the intervention)
• clinical significance of harm in the text (using mortality vs no mortality as a proxy)
• whether the harm reported in the main text was statistically significant (yes vs no).

2. In my version, the second line of the title for Figure 2 was cut off. Check that this is corrected for resubmission.

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests