Reviewer’s report

Title: Reporting of harm in randomized controlled trials evaluating stents for percutaneous coronary intervention

Version: 3 Date: 27 November 2008

Reviewer: Susan Ellenberg

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• Major Compulsory Revisions

1. The details of the search strategy and other aspects of study methods are indicated as appearing elsewhere, but the “elsewhere” is a manuscript whose status is “submitted.” Since the credibility of this type of review depends heavily on the methodology used this does not seem acceptable. It is not clear why the material here could not have been subsumed into the primary paper on quality of reporting.

2. On p. 5 the authors indicate that they reviewed whether members of DSMBs for trials that had such committees were blinded. It is not clear what they mean here, as there are many things to which one could be “blinded.” In any case, there is no further mention of blinding of DSMB members so it is not clear why this issue is raised here. (Note: the particular question of whether a DSMB should see data by coded treatment arm (A vs B) or should have access to the actual treatments is quite controversial; it should not be assumed that a "blinded" DSMB represents the ideal, as many (I believe most) experienced DSMB participants would strongly disagree with that position.)

3. The rationale for dichotomizing the impact factor at 3 (that is, why “3” was chosen) should be provided. It is not clear why the authors chose to dichotomize this factor, thereby reducing power to assess whether this factor has any effect on the outcome of interest.

4. The conclusion is confusing. The authors state that “several harm related data are adequately accounted…” This suggests that some harm related data are not adequately presented, which seems to be more the message of the results section. Perhaps the authors simply inadvertently omitted the word “not” from the sentence?

5. Table 1 is also unclear. For example, if 89% of the papers describe systematical collection of all adverse events, how can it be that only 35% of the papers describe collection of adverse events other than MAC(C)E?

• Discretionary Revisions

On p. 11 the authors note that functioning of DSMBs was not described in sufficient detail to permit an adequate appraisal of whether it operated properly. It is not typical to see a detailed discussion of DSMB/DMC operations in the report.
of a clinical study. I do not think there is any consensus regarding the extent of
information about a DSMB that should be included in a published report. Further,
there is substantial variability in how DSMBs/DMCs operate and lack of
consistency and/or consensus on many aspects of optimal committee operations.
For example, the authors indicate that DSMBs should be independent of the
sponsor—what information would authors have to provide to assure reviewers
such as the authors of the current manuscript that the DSMB was truly
independent? I believe this would require a lot of detail, more than virtually any
journal editor would permit. The authors might consider whether such details,
while undeniably of some interest, might not better be provided in an electronic
file that interested readers could access.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a
statistician.

**Declaration of competing interests:**

My only interest that I suppose could be considered as influencing my remarks is
that I am an author of a book on data monitoring committees and some of my
comments to the author reflect opinions offered in that book by myself and my
co-authors.