Reviewer's report

Title: Post-Marketing Surveillance for Percutaneous Transluminal Coronary Angioplasty Catheters: A Systematic Review

Version: 4 Date: 23 August 2013

Reviewer: Mariska M. G. Leeflang

Reviewer's report:

The manuscript has much improved. It is much clearer and more consistent. Also, the authors have responded to almost all of my comments in a satisfactory way. Only a few revisions remain.

Major Compulsory / Discretionary:
SIGN50 is not a checklist to assess quality, SIGN50 is a guide about how to do guidelines. It refers to several other checklists for quality. It would have been better if the authors would have referred to the checklists they used directly, rather than to an overall guidance. Anyway, I think the statement that SIGN50 is a checklist, is incorrect.

Minor Essential:
A typo under 'Selection criteria', 6th line: "For the our systematic review...". Remove either the or our.

Discretionary:
The search strategy looks fine, I don't think they missed a lot. Still, although the authors claim that restricting their search to English and French papers only will not result in bias, their aim was not to test a hypothesis or to come with a certain (pooled) percentage. The question is whether the authors would have found sufficient other studies in other languages to change their conclusion about the gap there is between the number of reports found and the number of reports from the FDA (probably not, as this gap is huge, even finding 10 additional studies may not close this gap).

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