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Overall this is a good review article. While this is an interesting topic, I would recommend authors to rewrite the abstract to make it concise and right on the points. The authors have discussed the importance of register database, but also need to discuss about importance of prospective, randomized clinical trials for evaluation of the implants. The authors mentioned the new legislation but did not specifically describe it, do you mean guidelines? in some countris it is not possible to make it a legislative action. The guidelines for establishing a registry are indeed needed in order to obtain meaningful data.

Reply:
The abstract is revised, some refernce of RCT´s are included, although this is a bit out of scope oft he article. So i appologise for being not entirly comprehensive on that. Legislation was referring tot he Medical Device Directive (under revision right now) and FDA-guidance documents, not clinical guidelines. I have revised the working to make this more clear.

The authors present a very interesting paper on a very important field as medical devices regulation is. The paper also has some interesting comments on ethical issues. I think that in general the paper is good. However, it lacks of some references according to WJO editorial style: - Page 5 "ASR" should be written in full and then in brackets; further citations can be written in acronymic. The same for "3M": it should be followed by TM. - We guess that Lit 13 means "limitations number 13", but where are the other 12? This must be explained. - In page 7 after the sentence "LI Havekin…" there should be a reference. - Some other references should be in all the following pages.

Reply:
Revisions were done accordingly. Lit. 13 refers to a reference

This is a well written pleading on the current aspects of scientific review in orthopedics. The authors expect increasing importance of registar data for orthopedic implants. Although this idea may be true, I think it is important to mention the place of registar data in the development of new implants. In the end, register data will of course give the most information on implant survival. However, before this data is available, other (biomechanical and clinical) studies are still needed before prothesis are implanted in large groups of patients. The authors should stress this more in the article. It would be interesting if the authors could mention a paragraph on for who/when/how (etc) registerdata is available. Furthermore, there are some statements without adequate references. For instance: 'the number of incidents registered does not seem te decrease, rather the contrary is true.' and 'about half of the implants examined ... as a measure of average patient care' Reference style should be checked.

Reply:
Revision was done accordingly. Availability of register data is a continous process, starting in scandinavia decades ago, which will last for several decades. It is hard to do some useful and precise statements for an editorial. Sorry.

Your opinions are interesting and may in fact be valid. Lacking any scientific methodology I would liken this more to an editorial and opinion paper. As such it may be of interest to the readers.

Reply: Thanks for the statement