Reviewer's report

Title: Clearing up the hazy road from bench to bedside. A framework for integrating the fourth hurdle into translational medicine

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Reviewer: Mike Drummond

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This paper discusses the additional challenges posed by the ‘fourth hurdle’ to the manufacturers of health technologies, especially devices and procedures. It develops a ‘process-oriented framework’ that interested parties can use to monitor the changes in fourth hurdle policies.

The main audience for the paper appears to be those working within research and development departments within the companies, since there are implications for the studies (of product effectiveness) that they conduct. For this group there is a major need for a general overview paper such as this. Therefore, it should have high priority for publication.

I thought that the paper was fairly comprehensive and was fair and accurate in its discussion of the issues. The only major topic that the authors might consider saying more about is the growing field of ‘coverage with evidence development’, or conditional reimbursement. This seems to be being offered as the main way of getting round the evidence gap that the authors highlight. (See Tunis and Pearson Health Affairs 2006;25:1215-30)

Although the paper is probably worth publishing as is, I think that several improvements could be made.

1. Although I understand that it makes sense to concentrate on 3 jurisdictions, the authors say that they searched 44 websites of HTA entities. My guess is that in many jurisdictions the situation regarding the fourth hurdle is unclear. However, it would be good if some kind of summary from all 44 institutions could be produced.

2. On page 9, more details could be given on the criteria used to select technologies for evaluation. There is a review by Noorani et al in Int J Tech Assess Healthcare 2007;23:310-5

3. For this audience, more could be said about the criteria being used for evidence. I’m not sure that this audience appreciates the need for comparisons of the technology with relevant alternatives (not discussed), or the difference between a cost-effectiveness and cost-utility study. Perhaps something could be added in the ‘Background’ section, where the fourth hurdle is discussed. Also, for this audience, it is important to stress why the ‘standard’ evidence on efficacy is inadequate for reimbursement discussions, namely: lack of relevant comparisons, lack of meaningful endpoints and too short a follow-up.
4. Whereas the use of a case study is welcome, I didn’t think that it was discussed in enough detail to be really meaningful. For example, although there was efficacy data, exactly why was it deemed insufficient? What outcomes are relevant in this field? What is the current standard of care and what potential advantages does the new technology offer? Is it particularly useful for certain patient subgroups? etc.