Reviewer's report

Title: Qualitative Assessment of Innovations in Healthcare Provision

Version: 2 Date: 29 October 2008

Reviewer: regina herzlinger

Reviewer's report:

The debate deals with an important issue: how a publically funded system, like that in the UK, can best address whether or not to pay for an innovation. The authors outline the benefits of innovation and correctly observe that the uncertainty around the effect of an innovation in improving patient wellbeing can, in most circumstances, be best judged over a long period of time. They suggest that a public/private fund be used to track these long term data and present a framework for evaluating the innovations which are worthy of such funding.

The authors do not address, however, how present day mechanisms to gather the long term data they seek would or should mesh with their proposed public fund. The mechanisms include U.S. FDA requirements that pharmaceutical firms maintain so-called Phase IV studies that oversee long term effects and that medical device firms file so-called MDRS, which track long term problems. Further, there exist clinical trials for diagnostics, like that conducted by California-based Genomic Health, which evaluated not only the sensitivity and specificity of the diagnostic but also whether it would be adopted by clinical physicians and if the adoption was cost-effective. In other words, this trial and the FDA collect the kind of information they want, without a public fund to support them. Although the data are collected in the U.S., they are certainly of value to public systems elsewhere.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

The authors should answer the question of why their proposed public/private fund would be more useful than the present FDA requirements and the incentives that CAUSE diagnostic firms like Genomic Health to conduct their novel clinical trials. All of these efforts are primarily funded by the firms involved, without any public sector support. What THEN IS the value added of public funding?

I am interested in their response

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:

no conflicts