Reviewer’s report

Title: A national clinical decision support infrastructure to enable the widespread and consistent practice of genomic and personalized medicine

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Reviewer: David Gurwitz

Reviewer’s report:

The authors present compelling ideas and discussion and make a call to various healthcare stakeholders concerning the establishment of a US national clinical decision support (CDS) infrastructure for promoting the clinical uptake of personalized medicine. The idea presented is convincing and the manuscript should be published, so that healthcare policy makers can discuss it. The time seems right as well, with a new US administration expected to be more favorable to invest in improved healthcare for its citizens.

There is no doubt that pharmacogenetics and personalized medicine offer a great promise of safer and more effective medicines. However, there are many obstacles besides the lack of a dedicated CDS infrastructure which hinder the clinical uptake of pharmacogenetics. The authors should explain in the background section that lack of CDS infrastructure is only one item among many barriers needed to be removed for bringing personalized medicine to the clinic. These include, among others, lack of prospective trials validating genetic markers for taking pharmacotherapy decisions; lack of pharmacoeconomics studies showing that such diagnostics would be cost-effective; lack of relevant education for healthcare professionals; and an overall general reluctance of the pharma sector to promote personalized medicine, reflecting worries of segmenting their markets.

These barriers have been discussed in many reviews and commentaries on personalized medicine. For example, see: Need et al, Nat Genet. 2005 Jul;37(7):671-81; Lunshof et al., Pharmacogenomics. 2006 Mar;7(2):237-41; Giacomini et al, Nature. 2007 Apr 26;446(7139):975-7. The authors have to be careful to not create the false impression that having such national CDS in place would clear the way for bringing pharmacogenetics to the bedside.

Another topic that is not covered – and is pertinent with regard to the authors’ fifth recommendation – concerns the costs associated with and the best strategy for the creation of a national CDS infrastructure for personalized medicine. For example, establishing such unit within the framework of The Centers for Disease Control and Prevention (CDC), possibly with shared advisory board with the US Food and Drug Administration (FDA), could facilitate the proposed national CDS infrastructure and reduce its operating costs. The roles for the CDC and the FDA are not mentioned in the current version – and they probably should.
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