Reviewer’s report

Title: P.Re.Val.E.: Outcome Research Program for the Evaluation of Health Care Quality in Lazio, Italy

Version: 2 Date: 19 September 2011

Reviewer: ENRIQUE BERNAL-DELGADO

Reviewer’s report:

MAJOR COMPULSORY REVISIONS

Comment 1 (to response #1)

I do thank the authors for further detailed explanation, although they refer partially to what I was asking for.

From my point of view, backed on recent research [*], the estimation of the cluster effect by using multilevel analysis is worthwhile to determine what the magnitude of variation in hospital (area) outcomes attributed to a hospital is, as opposed to that amenable to the patient.

As compared to a “rho statistic” around 10% (just as a matter of example), a rho statistic including the null value (or close to it) would have quite a different relevance. In the latter, we cannot rule out that the differences among hospitals are just explained by differences in the case-mix of patients.

Therefore, it is not just about estimating the standard errors accounting for non-independent observations (as suggested by the authors) but on estimating the magnitude of the variation amenable to the cluster – hospitals or areas in this case-study. This is a particularly useful measure when it comes to providing decision-makers with relevant information.

On a different point, authors are correct when highlighting the possibility of point-estimates “bias”. Although possible, in our experience the smoothing effect is more on the small numbers, having a negligible effect in the majority of hospitals, particularly as for studies with large sample size.

My concern on the cluster effect has not been sufficiently addressed along the reply provided by the authors. It will be worth adding an additional statistic estimating the magnitude of this effect (e.g. rho statistic, intra-class correlation index, median odds ratio) to each one of the indicators under study.

[*] Maybe of use in this specific piece of work:


Comment 2 (to response #2)

I do thank the clarification, and I do agree on the importance of showing the size as a reference for discussion for decision-makers - a 2-fold difference has a different impact depending on the basal rate of events. But I do not see the argument provided to justify the use of p-values in providing a better insight for discussion, when guidelines are so clear in the other way around; and particularly, when your contribution is on the context of a scientific journal.

In any case, the adjusted risk-ratios are not expected to follow a normal distribution; conversely, they are expected to be skewed. If true: Would those areas/hospitals with p values below 10% change the statistical significance when estimating the appropriate (robust) confidence intervals? Confidence intervals provided by multilevel analysis are more conservative – i.e. reducing the possibility of flagging as bad performers hospitals affected (in fact) by small numbers. A table showing the two elements, p-values and confidence intervals, would be illustrative along this discussion.

MINOR ESSENTIAL REVISION

Comment #3 (to response #4)

The authors reply on risk adjustment methodology “all possible confounders have been identified” brings another issue up which is “over-adjustment”. Using all possible confounders may drive to over-adjustment, if no previous judgment upon the clinical rationale behind each indicator is made. I am not clear after reading the explanation, if authors have made or not this specific assessment.

Over-adjustment, described by Patrick Romano in several papers, may mislead conclusions by concealing real differences, particularly in those more complex providers – large hospitals treating complex patients.

The remaining reflections and questions have been properly addressed

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests