Reviewer's report

Title: A methodological approach to identify external factors for indicator-based risk adjustment illustrated by a cataract surgery register

Version: 3
Date: 12 February 2014
Reviewer: Stefan Sauerland

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This study aimed to develop a systematic approach for selecting external factors that need to be adjusted for in quality assurance. By using two different approaches quite similar sets of variables were identified, which shows that this methodology apparently leads to valid and reliable results. It is interesting to see that the authors’ approach is similarly successful in identifying highly prevalent but also more rare conditions as external risk factors.

Major Compulsory Revisions:

1. The extremely low model fit is discussed as one of the study’s problem. Nevertheless, it would be unrealistic to expect a model fit of $R^2 > 80\%$. Many previous studies that used multivariate methods to analyze postoperative complication rates unfortunately do not report on the proportion of variance explained or $R^2$, but it is not uncommon to find Nagelkerke’s $R^2$ in the range of 20\% to 40\%. To some extent, complications after surgery occur by chance, and this holds true especially for less difficult or less risky types of surgery.

2. The authors’ decision to consider the stratified analyses more robust than the multivariate regression model is not straightforward. The stratified analyses also cause problems, because external factors are not independent from each other. In table 4, for example, female gender was found to be a significant predictor for visual rehabilitation. As there are no medical reasons to expect females to recover faster than men after cataract surgery, this statistical finding is simply due to the fact that on average females are older than men.

3. On two occasions, the two methodological approaches come to different conclusions: First, severe farsightedness was identified by statistical significance, but this variable failed to reach clinical relevance (8.3\% difference). Secondly, presence of at least one ocular risk factor was clearly significant in the stratified and multivariate analysis, but this variable did not meet the criterion of clinical relevance (7.9\% difference). If the authors had defined a 5\% rather than a 10\% cut-off value for the criterion of clinical relevance, the results for the two criteria would have produced identical results. Therefore, it might be worthwhile to rethink the 10\% threshold in future studies, even if the outcome of interest is a frequent event.

4. On page 11, death and endophthalmitis are discussed as outcome variables, because both events have a very low incidence (<1\%). Admittedly, the 10\% cut-off value would need adjustment, because no subgroup of patients in cataract
surgery will ever have a mortality or an endophthalmitis rate of 10% or higher. Rather than proposing a flexible incidence-dependent threshold, however, the authors should deliberate about whether a relative rather than an absolute criterion would be more suitable.

5. The previous comment shows that the two criteria proposed by the authors are in fact closely related to each other. If the presence or absence of an external factor is associated with a large absolute difference in the outcome of interest, it can be expected that this absolute difference is also found to be significant in stratified or multivariate analysis focused on relative differences. Because of the advantages of multivariate modelling it appears much more valid to rely on the multivariate analysis. Thus, the clinical relevance criterion does not confer any additional information and most probably could be deleted.

6. The dichotomization of external factors appears unjustified. Categorization of continuous data, especially dichotomization, reduces the ability of statistical analysis to explain the outcome of interest. If continuous variables such as age or baseline visual acuity are dichotomized, their influence on outcomes may be underestimated or simply remain undetected. In the context of quality assurance not all data are collected as continuous variables, but age in years is certainly recorded very easily. Moreover, it should be described in the methods section, whether the cut-off value of 80 years was defined prospectively or retrospectively (after data inspection).

Minor Essential Revisions:
7. On page 11, the term “minute prevalence difference” is used. Apparently, the authors mean a “minor prevalence difference”.
8. There is a typo in table 5: Please correct “constrasts” into “contrasts”.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

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