Author's response to reviews

Title: Risk adjustment for inter-hospital comparison of primary cesarean section rates: need, validity and parsimony

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Version: 3 Date: 30 June 2006

Author's response to reviews: see over
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Version: 2 Date: 30/06/2006

Author's response to reviews: see over
Object:

MS: 1279588359634721
Risk adjustment for inter-hospital comparison of primary cesarean section rates: need, validity and parsimony . Dr Maria Pia Fantini et. al.

Thank you for consideration of our manuscript for publication in your journal. We have reviewed the above manuscript according to your reviewer’s comments.

Reviewer # 1 ( Kimberly D Gregory)

Version: 1 Date: 22 May 2006

Reviewer's report:
General
Overall, good study that complements what is already in the literature supporting the rationale for risk adjustment when comparing hospital performance. Offers another method for doing so, and demonstrating potential change in ranking once this is done

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
None

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
n/a

Discretionary Revisions (which the author can choose to ignore)

Authors might want to make a stronger case as to how this method improves on existing methods, for risk adjustment especially given that 5/8 conditions could be considered absolute indications for cesarean (e.g.previa, malpresentation, etc).

In order to obtain more precise estimates of probability of outcome without compromising validity, a specific goal of this study was to identify a "parsimonious" model that included only actual confounders of the comparison between centres. Including, in a risk adjustment model, factors that do not induce a relevant bias on the measure of association may reduce precision. To act as a confounder a variable must be associated with the outcome of interest and be heterogeneously distributed between categories of exposure (i.e. hospitals). The predictive ability of a factor, estimated in terms of adjusted strength of association with outcome, cannot be considered
a sufficient reason to be included in a risk adjustment model. The adjusted ORs obtained by using the "parsimonious" model were similar to those obtained by the "full" model, but the estimates were more precise. We underline that any risk-adjustment model used to compare hospitals must be time- and population-specific and results cannot be generalized. We think, however, that the methodology described in this study could be used in other settings and would yield valid results.

What next?: Accept after discretionary revisions

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: No
Declaration of competing interests:
I have no competing interests

Reviewer # 2 (Chao-Hsiun Tang)

Version: 1 Date: 24 May 2006

a) Major Compulsory Revisions

1. Methods:

1) Page 6, second paragraph of the methods section: In addition to the diagnosis of dystocia, the diagnosis of foetal distress is also very subjective and is not a risk factor in itself. Including it in the regression may mask important differences by adjusting away subjective practice differences between hospitals. Also, fetal distress may be related to various conditions (diabetes, hypertension, collagen vascular disease, etc.), again introducing possible redundancies into the regression.

1) We agree and fetal distress has been excluded from the analysis, but the results are quite similar to the previous ones. In our study there is not an important relation between this risk factor and other conditions (diabetes, hypertension, collagen vascular disease, etc): all correlation coefficients are lower than 0.1.

2) Statistical analyses, Methods section: process of conducting the analysis should be clearly stated. Unit of analysis - each single live birth, should be pointed out.

2) Done

3) Page 7, second paragraph of the methods section: The authors stated that the reference category included hospitals with the lowest adjusted c-section rates based on the full model. Does this mean that that the authors firstly rank the
adjusted c-section rates based on the full model presented in Table 2, and choose 4 hospitals (K, Q, R, and Z) with the lowest adjusted c-section as the reference groups; and secondly adding 25 hospital dummies representing the rest of the 25 hospitals into the full model and into the parsimonious model presented in Table 2 and obtain the results of the adjusted ORs in Table 4. I would like these processes to be clearly stated in the Methods section

3) Done

4) Page 8, second paragraph of the Methods section, the authors stated that they identified eight variables as confounders from the change-in-estimate procedure. Table 3 also provides the occurrence of their confounding effect on total comparisons. However, according to the results reported in Table 2, in addition to these 8 variables, there is another one— intrauterine growth retardation, which is also a statistically significant risk factor in the parsimonious model. Please explain the inconsistency in reporting these results.

4) It was a mistake: intrauterine growth retardation is not among the factors included in the parsimonious model. As the referee clearly intrauterine growth retardation is an important risk factor for c-section, but to act as a confounder it must be heterogeneously distributed between categories of exposure (i.e. hospitals) and This is not the case of intrauterine growth retardation. The predictable ability of this factor, estimated in terms of adjusted strength of association with outcome, cannot be considered a sufficient reason to be included in a parsimonious risk adjustment model.

2. Results:

Please provide descriptive statistics of the characteristics of women and newborns.

In table 2 we added the total number of births and the c-section rate for each factor.

3. Discussion:

1) Statement of principal findings should be reported at the first place. I suggest part of the third paragraph in page 10 move to the second paragraph in page 9.

1) Done

2) I would consider re-paragraphing the third paragraph in page 10 and the second paragraph in page 11. There two paragraphs are long and awkward.
2) Done

3) Page 9, last two paragraphs: The authors mentioned that the impact of risk-adjustment on hospital comparisons and rankings is different among studies. Please provide references and explain how different their results are. Similarly, please provide references as to what important methodological differences between the relevant literatures.

3) References provided but not explained methodological differences between the relevant literatures.

4) Page 10, second paragraph: The authors stated that "controlling for risk factors is a relatively new issue in obstetrics. I disagree! Risk-adjustment has been undertaken almost a decade ago (e.g. reference #26) as far as I know. The authors also pointed out that "various authors have studied the best way to compare c-section rates between hospitals." Please elaborate more about what are these various ways and what is the best way to compare c-section rates between hospitals. Again, please also further cite these references.

4) We agree: controlling for risk factors is not a relatively new issue in obstetrics. Moreover, the best way to compare c-section rates between hospitals does not exist. We have deleted our previous statements.

5) Page 10, last paragraph: The authors stated that they were not able to discuss the possible reasons that age (and civil status) is a risk factor of c-section and that age is possible to be related to selection factors at work in the health care system. I disagree! There are many studies that have examined the influence of maternal age on c-section. Aside for a psycho-social interpretation to the increased risk of age on c-section, there are also studies pertaining to biologic pathways that links advanced age and c-section. However, these issues do not need to be described in detail because it is not the main purpose of the present study.

5) We agree: maternal age is a risk factor of c-section and also a confounder. We were not able to explain the possible reasons of the heterogeneous distribution of this factor across hospitals. However, we have modified text.

6) Page 11, third paragraph: References 28-29 are not papers on risk adjustment of acute myocardial infarction.

6) Text was wrong but references were right.

7) Page 12, first paragraph: The authors stated that one of the limits of this study is the impossible of including several clinical factors in the model, such as gestational age. I disagree! The present study has included infant's birth weight in the predicted model. Consider most low birth weight babies are preterm, using LBW and preterm delivery is redundant in most cases.
7) We agree: gestational age and birth weight could be equivalent. Corrected.

b) Minor Essential Revisions

1. **Title:** Because the study subjects are women with no previous c-section, I suggest adding the word “primary” before cesarean section rates in the title.

   1. Title: we agree

2. **Methods:**

   1) Page 5, first sentence in last paragraph: If the data are appropriate, age grouping should be decade to decade, mid-decade to mid-decade or in five-year age groups (e.g. 30-39, 35-44 or 30-34, 35-39).

      1) we disagree

   2) Page 6, first sentence in first paragraph: Married, divorced-separated, single, widow, not declared are referred as civil status. Should they be referred as marital status?

      2) Changed

   3) Page 6, fifth paragraph: a special character is missing in the sentence α of 0.05 was chosen..

      3) corrected

3. **Tables:**

   1) **Table 2:** It is not correct to report P value smaller than 0.0001 as 0.0000. Please use p<0.0001 instead.

      1) we agree

   2) **Table 2:** There is no indication of the units used in some variables (e.g. infant birth weight).

      2) we added the units for infant birth weight

   3) **Table 4:** A type error occurs when the authors mistype 95% CI as IC 95%

      3) corrected
We are looking forward to receiving your reply.
Best regards, on behalf of all the authors.