Author's response to reviews

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

Authors:

Maria Pia Fantini (mariapia.fantini@unibo.it)
Elisa Stivanello (elisa.stivanello2@unibo.it)
Brunella Frammartino (brunella.frammartino@unibo.it)
Anna Patrizia Barone (barone@asplazio.it)
Danilo Fusco (fusco@asplazio.it)
Laura Dallolio (laura.dallolio@alma.unibo.it)
Paolo Cacciari (paocac@tin.it)
Carlo Alberto Perucci (dirdip@asplazio.it)

Version: 2 Date: 28 June 2006

Author's response to reviews: see over
Dear sir, Dear madam,
in light of the reviewers’ comments we have revised our manuscript and made all the 
required changes to the format of our paper.
The revised version following reviewers’ comment point by point is described below, for 
each comment (cursive type) follows the required change:

a) **Major Compulsory Revisions referred to Chao-Hsiun Tang’s (referee 2) report**

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 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 predictive 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. These 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 psychological 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 a civil status. Should they be referred as marital status?

      2) Changed

   3) Page 6, fifth paragraph: a special character is missing in the sentence an $\alpha$ 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 \textit{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.