Author's response to reviews

Title: Incidence and costs of bleeding related Consequences in selected surgical procedures in the French hospital setting (a DRG analysis)

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Version: 3 Date: 20 March 2012

Author's response to reviews: see over
Cover letter

Dear Editor,

Please find attached a revised version of our manuscript.

We thank the reviewers that allow us to enhance our manuscript and especially the statistical analysis.

You will find below the answers to the questions of the reviewers as they were provided.

Feel free to contact us if you need further information.

Sincerely yours

Antoine Lafuma, MD
**Reviewer’s report**

**Title:** Incidence and costs of bleeding related Consequences in selected surgical procedures in the French hospital setting (a DRG analysis)

**Version:** 2  **Date:** 7 January 2012

**Reviewer:** Darryl T Gray

**Reviewer’s report:**

This is a study of hospital costs and prolonged length of stay associated with bleeding consequences seen in French surgical inpatient stays. It addresses an important issue and provides useful and interesting new data. However, the analysis and presentation raise some (generally addressable) issues. Specific comments follow:

**Major Compulsory Revisions (issues that need to be addressed in some fashion. Revisions to the analysis itself may not be required.)**

Understandably, the authors could not distinguish bleeding or transfusions occurring as a consequence of the original disease or injury or due to co-morbidities (e.g. coagulaopathy) from those attributable to surgery. Therefore, the bleeding episodes counted are not all consequences of surgery, as is stated or implied in various places in the text. This should be re-worded, e.g., as “transfusions or bleeding episodes” where applicable.

**ABSTRACT:**

Under “Design”, Please clarify the meaning of the sentence starting “The rates of hospitalizations over the expected average LOS” We replaced expected that was not adequate by average that correrspond to the method used. We replaced through.out the manuscript

**TEXT**

Page 5-- 3rd and 4th paragraphs: Is this study based on *ICD-9* or *ICD-9-CM* diagnosis codes? **This study is based on the ICD-10 codes** Did you use the French common classification of medical procedures (CCAM) to include interventional cardiac cath procedure and procedures such as endovascular aortic aneurysm repairs as “surgery”? **No, surgical procedures leading to a “surgery” hospitalisation are selected by the dedicated French Hospital Agency, coronary catheterisations are not considered as cardiac surgery.** An appendix listing of at least the categories of procedure codes used would help. **There are thousands of codes in the CCAM**

Page 5-- 4th paragraph and Page 7 – 2nd paragraph: Costing methods should be discussed in one place and better described, per various standard articles on cost analyses (Gold, Weinstein, Drummond, others). For example, did these (presumably) provider (rather than patient) perspective costs include hospital overhead? **(Yes)** Did public and private sector cost estimates for 2008 differ? **(Yes)** If so, how was this accounted for in the analysis of estimated costs for individual admissions? If costs of physician services were not addressed, this should be noted. **A paragraph was added to explain the method**
Page 6 – 1st paragraph: Do hospital stays of “not less than 2 days” here mean stays involving at least two calendar days (as opposed to stays of at least 48 hours which generally involves at least three calendar days)? Why was this criterion chosen? Note that it would exclude patients who were operated upon on the day of admission and died that day. What was the age range for included patients? It would appear that the different spectra of ages, procedures and co-variates seen in pediatric surgical cases would argue for separate analyses of such cases if they were included in the study at all.

It was a specific rule to split ambulatory stays (less than 48 hours) and complete hospitalisations (not less than 2 days). Patients who died are automatically considered in complete stays. There was no selection on age.

Page 6 – 2nd paragraph: The 11 CCAM codes for procedures carried out for secondary haemostasis should be indicated in an appendix. It should be clarified whether or not this included some procedures that could have been used to prevent bleeding rather than treat it. Are there no CCAM procedure codes for blood product transfusions? Would *ICD-9* or diagnosis code T81.0 include hematoma not requiring treatment? It is unclear if or how the investigators could distinguish pre-op from post-op transfusions. Were diagnoses that would argue for a pre-op risk of a need for transfusion (e.g. anemia or coagulopathy) captured and used in the analysis?

Secondary haemostatis procedures are only coded after a bleeding following a primary surgical procedure : example : secondary haemostatic procedure after cardiac procedure. These procedures are not used to prevent bleeding. Yes, there is a CCAM code for blood product transfusions but always used simultaneously with the ICD-10 code. A diagnostic is coded (and this is the case for T81.0) only if the disease is requiring treatement (a sentence was added)

Page 7 – 1st paragraph: Criteria used for the merger of DRGs should be better described. Why was this done? The DRGs merged into groups should be listed in a table under Results or in an appendix.

A sentence was added

Page 7 – 2nd paragraph: It is unclear what “and the characteristic of DRG that is not related to DRG allocation, the number of procedures” means. It is unclear how or why LOS and costs were adjusted for age and gender alone (vs other factors). Do public and private sector hospital cost estimates differ and if so, how was this accounted for in the analysis of estimated costs for individual admissions that were in fact in either public or private sector hospitals?

For costs, calculations were performed for both sectors simultaneously. Costs estimates were those of the private sectors for hospitalisations taking place in the private sector and those of the pulic sector for the hospitalisations performed in the public sector.

Page 7 – 3rd paragraph: What were numerators and denominators for “he rates of hospitalizations exceeding the expected average LOS”? How was the “expectedLOS” derived from PMSI data? (it was the average LOS of the given DRG that was calculated) It is unclear what the sentence: “Confounding variables were primarily
selected comparing DRGs with and without bleeding on the characteristics of the patients (age and gender) and of the DRGs (LOS, number of diagnoses and number of procedures) when model was considered to converge and covariates were statistically significant." means. Was this step-up, step-down or some other regression approach? What was the statistical significance criterion? How did the analysis account for possible clustering by hospital (which may reflect case-mix, propensity to transfuse, etc)? What statistical programs were used for the analysis? Did the authors consider propensity scoring as an approach to adjust for possible confounders of the comparison between cases with vs without bleeding complications/interventions in terms of resource use outcomes? (No it was not considered necessary) Was hierarchical modeling using generalized estimating equations or other approaches considered as a way to adjust for clustering of cases within hospitals? (No see below) If a given hospital had generally higher costs, and, as an independent issue, had more bleeding complications, then some of the cost difference attributed to bleeding would actually be due to hospital characteristics. Given the potential for non-Gaussian distributions of hospital costs and/or LOS, were log-transformations of costs or other approaches considered? (No we preferably used non transformed data according to Thompson and Barber (1)). Since post-op transfers TO other acute care hospitals were not included, then listed LOS and cost estimates would underestimate costs of the total inpatient episode of care. Could this potentially have been tracked using patient identifiers that track transfers? Please comment. NO this was considered marginal.

We intended to select variables that were statistically related to the different outcomes (number of procedures, number of secondary diagnoses, LOS and costs) and as they were all significant, so they were all selected

Page 8 – 3rd paragraph: #s of DRGs merged (into how many total groups?) should be noted.

24 DRGs

Page 9 – 2nd paragraph: How were categories for age and number of procedures determined? (This should go under “Methods”)

Categories were determined according to the distribution to have sufficient number of stays in each category for age, number of procedures and number of secondary diagnoses.

Page 11 onwards. The discussion should reflect consideration of issues such as those raised above as they pertain to Methods and Results.

Discussion section was modified according to reviewer’s recommendations

Page 13 – 1st paragraph: This study was entirely industry-funded and the authors are all Ethicon or Cemka-Eval employees. The existence of company products potentially relevant to the study should be briefly noted. For example, it would be useful for readers to know if any of these companies make or support companies that make products that prevent or reduce bleeding or its consequences. Such companies

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could benefit directly or indirectly from results showing larger costs attributable to such consequences and this should be noted.

A sentence was added in the acknowledgment section

Minor Essential Revisions:

Writing in what may be the authors’ second language may be difficult. However, the numerous typographical and English word usage errors in this manuscript make following it difficult at times. These could be corrected through manuscript review performed by a native English speaker.

An English native speaker reviewed the manuscript

Page 3-- 1st paragraph (and elsewhere): For surgical patients who *present* with bleeding, transfusion, death or other outcomes from hemorrhage may represent a consequence of the underlying condition (e.g., vascular trauma, ruptured aortic aneurysm) or a complication caused by the surgical intervention itself. The abstract and paper should make clear the degree to which the authors are distinguishing between or combining these two phenomena. Referring to “bleeding consequences” implies but could more clearly state that the authors are combining these two phenomena.

A sentence was added

Page 5-- 3rd and 4th paragraphs: How many diagnosis and how many procedure code fields were available in the data? It is unclear what point is being made by noting haemostasis procedures here. It would help to list under “Methods” those haemostasis procedures used to capture admissions with bleeding consequences”.

A sentence was added page 5 3d paragraph

Page 6 – 1st paragraph: Does “2008” refers to the year of the first (or only) relevant surgical procedure, the date of admission, or the date of discharge?

Discharge

Page 6 – 4th paragraph: The ease of computation with current software would argue that even DRGs with “bleeding consequence” below 10% could have been analyzed. Yes but we have 88 surgical DRGs and this could have been difficult to describe and statistical models with low rates would have been more difficult to be completed.

Page 8 – 4th paragraph: What does “surgical cohort” mean here?

corrected

Page 9 – 1st paragraph: Again, the need to restrict this to DRGs with bleeding rates exceeding 10% is unclear. What “levels of severity” were used and how were they determined?

We performed the calculations for the other DRGs but with low bleeding rates, statistical models were not convincing.

Page 9 – 2nd paragraph: For “number of procedures in class” exactly 12 procedures appears in two categories and this should be corrected.

A sentence was added
Page 11 – 1st paragraph: What does “and multiple surgeries” mean?

Multiple orthopaedic surgeries

Page 11 – 2nd paragraph: Which DRGs “had more procedures”, and how was this determined? What does the sentence “When assessing the LOS associated with bleeding related consequences, we were obliged to perform indirect analysis using the rate of exceeding the expected DRG LOS due to the algorithm of assigning DRG codes in France.” mean?

Sentence was modified

Page 12 – 1st full paragraph: Please clarify the passage “If we compare the number of surgical patients transfused during the “one day” national survey [8] on transfusions, we can observe that 742 surgical patients were transfused with erythrocyte units during the survey. If we adjust on the total number of erythrocytes unit consumed per year in the French hospitals (n=2,013,863 in 2006) [7], the number of erythrocytes unit recorded during the survey (n=5,765) then the pooling rate can be estimated at 1/350. During our PMSI analysis, the 77,921 surgical patients that were considered with bleeding and the vast majority because of transfusions, therefore our estimate represents approximately one third of the number expected with transfusions alone (77,921/742/1/350). “ References with URLs should better describe the actual citation. Dates that URLs were last accessed should be included.

This was done and added in the URL references

Figure 1: The X axis should start at 0 to avoid visual distortions in showing WB rates. WB rates for all DRGs should appear at least in an appendix.

This was done

Figure 3: Costs should be described as adjusted or unadjusted

We included unadjusted costs in the figure

Figure 4: LOS should be described as adjusted or unadjusted

We included unadjusted LOS in the figure

Figures 3 and 4 should show DRG groups in the same order, or in rank order.

They were modified

Figure 5: What is “(17 mots alors maximum 15 mots)” ?

OK sentence deleted

Discretionary Revisions:
The sentence: "Then the rate of hospitalisations over the mean of the WB-DRG stays was compared between hospitalisations WB and WoB.“ could be better phrased.

The sentence was modified

Figure 6: The title could be more descriptive. The text below it need not be repeated from the text.
The title was modified and the text deleted

Level of interest: An article of importance in its field
Quality of written English: Needs some language corrections before being published
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:
I declare that I have no competing interests.
Reviewer’s report
Title: Incidence and costs of bleeding related Consequences in selected surgical procedures in the French hospital setting (a DRG analysis)
Version: 2 Date: 20 December 2011
Reviewer: Veerasathpurush Allareddy
Reviewer’s report:
Dear Editor,
I have reviewed the manuscript titled “Incidence and costs of bleeding related Consequences in selected surgical procedures in the French hospital setting (a DRG analysis) Bleeding during surgery in France”. This study addresses an interesting topic and this manuscript is worth considering for publication. However, I recommend that the authors address the following issues –

1. In the introduction section, please clearly state the hypothesis to be tested.
   A sentence was added in the background section

2. It would be helpful if the authors briefly mentioned the different variables available in the dataset in their description of the database.
   A sentence was added in the methods section

3. What surgical procedures were included? I would recommend that the authors at least provide a summary list of the 10 or 20 most frequently reported/performed surgical procedures.
   There are thousands of procedures as this nomenclature is very detailed for example there are 8 codes for coronary artery

4. It is clear that the authors adjusted for the effects of age and gender. However, it is likely that presence of co-morbid conditions, severity/complexity of surgical procedure, concomitant procedures performed, occurrence of other complications, etc could possibly influence length of stay and hospital costs. I would suggest a more comprehensive adjustment for all possible confounding factors. Also, hospital costs could be influenced by the location or type of hospital. This needs to be adjusted in the analysis alluding to hospital costs.
   To be consistent with the different analyses we performed and adjustment including the number of procedures and the number of secondary diagnoses

5. Hospital charge/cost data typically tends to be skewed. How was the skewed nature of this variable taken into consideration? -
   We used non parametric tests for costs comparisons (see foot note)

I would recommend that the authors address the above mentioned issues before the manuscript is further considered for publication

Level of interest: An article whose findings are important to those with closely related research interests
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'