Reviewer's report

Title: Evolution of Patients' Complaints in a French University Hospital: Before and After Study of the Impact of a Law Regarding Patients’ Rights

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Reviewer: Roland Friele

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Review regarding the manuscript on the Evolution of Patients’ Complaints in a French University Hospital …

1. The issue at hand is relevant. An attempt is made to assess the impact of new legislation on the number and type or complaints using a pre-post design. This is interesting.

2. However, the manuscript is in need of several major compulsory revisions.

3. The first issue is the ‘theoretical framework’. This is developed poorly. The introduction gives us some information on the type of laws that were introduced in France. These laws seem to provide a broad array of measures to strengthen the position of patients. These laws do not specifically focus on complaints handling. Authors suppose that these measures may have contributed to increased expectations on behalf of patients, leading to an increase in complaints. One could, on the other hand, argue that an improvement in patients right might lead to a decrease in complaints.

I would like to invite the authors to elaborate a bit more on this. Several studies have been done on patient expectations of complaints handling, also recently published in this journal. Such studies may be used to build the hypotheses that strengthening the position of patients will lead to an increase in patient complaints. Studies have shown that the main reason for patients to file a complaint is not the desire for financial compensation but to expose that things went wrong and to get an answer from the hospital or doctors that the reoccurrence of the situation will be prevented.

4. A clear research question is lacking. What question is answered? I suppose that authors want to study the impact of new legislation on the number of type of complaints. But in the conclusions paragraph this issue is not addressed at all.

5. The third issue is the design of the study. This will be the hardest to repair.

Authors want to establish a relationship between the introduction of new laws and the number or type of complaints. Authors also notice a greater consciousness among patients of their rights...(in the discussion). Their statistics show a strong correlation between time and the number/type of complaints. But, is this relationship caused by the introduction of new legislation?
If authors want to study the impact of the legislation a simple correlation will not do. Authors should disentangle the impact of time as a continuous variable and the impact of new legislation as a dichotomous variable. Would a regression analysis including time as a continuous variable and as a dichotomous variable work? Authors say they did a sensitivity analysis between two periods. To me it is not clear what they did.

Authors describe that 2.116 complaint letters were received, of which 164 for medical issues. It is not clear how this selection was made. How reliable and valid was this procedure? What was the interrater agreement for judging a complaint? Furthermore it is not clear why this selection was made. When you are interested in the impact of new legislation on the number of complaints, why restrict the analysis to a small fraction of all complaints (less than 10%). Patient rights do not only relate to the area of medical errors.

6. Interesting data are provided in table 2. However, I don’t know why these data are presented. They do not relate to a research question. What do authors want to let us know: that patients and departments are in agreement on the fraction of complaints for medical issues that are related to a medical error? To test agreement, wouldn’t cross tabulation be a better test? And, to me it is not clear how authors decided whether or not a complaint is related to a medical error. Usually this is a very complex matter.

7. The discussion lacks focus. Improvements may be made once the manuscript contains an clear research question and a better ‘theoretical framework’.

The discussion ends with an opinion of the authors: the analysis of complaints may help to improve hospital functioning. This opinion is not supported by the article.

Either such supporting notions should be included in the results section of the article (and in the research question) of the opinions should be deleted.

**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:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests