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Science Editor  
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Subject: revisions submitted article (ESPS Manuscript number: 11891)

Utrecht, the Netherlands, July 2014

Dear H. Miura,

Thank you for the opportunity to resubmit our manuscript (ESPS Manuscript number: 11891) entitled "Quality of intensive care performance: How should we monitor performance in the future?" for possible publication in World Journal of Critical Care Medicine. We thank the reviewers for the valuable comments. The adjustments based on these comments clearly contributed to the quality and readability of the manuscript.

Below we reply to each comment of the reviewer. We have marked the adjustments in the revised manuscript.

We hope that the revised manuscript is suitable for publication in World Journal of Critical Care Medicine and look forward to your final decision.

On behalf of all authors,

Yours sincerely,

Tim K. Timmers

A handwritten signature in black ink, appearing to read 'Timmers', with a large, sweeping initial stroke.

## **Reviewer #1:**

**The paper could be strengthened in two areas:**

- 1. Final editing is needed.**

The entire manuscript has been reviewed by a native English speaker. Several sentences have been changed.

- 2. Although you have indicated the need for including sensitive and appropriate outcome indicators such as readmission and HRQOL, it is unclear how risk adjustments will be executed. At least, you could site some relevant references available from the Agency for Healthcare Research and Quality ([www.AHRQ.gov](http://www.AHRQ.gov)).**

The purpose of our article is to discuss the topic “How should we monitor intensive care performance in the future?” extensively, with the advantages and disadvantages of the current situation. Ideally, bringing this debate to the next level with the relative consequence that international research should be started to investigate a ‘new’ and ‘better’ evaluation system to measure performance of given care. Our hypothesis is that we, maybe, should not develop new indicators, but update our current evaluation system in which not a single indicator is used but rather a combination of these indicators (already in use) should be implemented to measure the performance of given care within the intensive care. Hypothetically, performance should be evaluated through the combination of survival (SMR) and the health status (QoL) at the time of discharge, together with the readmission rates. As yet, this combination of both outcome measurements has not been used in a single benchmark value. This is not going to be a simple implementation, because there are several factors to be considered first. These factors are well documented in the article within each section.

Concerning the references, the article contains 72 relevant references. This is more than usual, we agree. Adding even more references from [www.AHRQ.gov](http://www.AHRQ.gov) would bring more confusion about the given information from these different references, and, therefore, not improving the message of the article..

## **Reviewer #2:**

**This manuscript reviews aspects linked to the choice of quality of care indicators in intensive care units, which is an important but difficult concern.**

### **Major Points**

- 1. The title is not clear: what does “quality of intensive care performance” mean? Does this refer to quality of care improvement through the use of performance measurements? Or do the authors want to speak about assessing the performance of quality of care by itself?**

We would like to thank the reviewer for his/her careful reading. We understand the difficulty in apprehending our title “Quality of intensive care performance: How should we monitor performance in the future?”. And we agree with the reviewers’ comment that the title should be changed to eliminate incorrect interpretations. The title should refer to the difficulties of assessing the performance of different ICUs. Therefore, we have adjusted the title to ‘Intensive care performance: How should we monitor performance in the future?’.

2. **English language need to be checked here and in the whole manuscript. In the current version of the letter, sentences are sometimes complicated, unclear, inaccurate, and the substance and main messages appeared therefore highly vague?**

The entire manuscript has been reviewed by a native English speaker. Several sentences have been changed.

3. **Introduction: The authors stated that “the goal of IC is to provide the highest quality treatment”. What does “quality treatment” means? Is the quality of IC only related to treatment?**

We agree with the reviewer that this point was not clearly described in the text. The meaning of the sentence “The goal of intensive care is to provide the highest quality treatment in order to achieve the best outcome for critically ill patients” is that intensive care medicine should have as the main objective to deliver the best outcome for critically ill patients. This objective is most of the time only possible because of the high quality of different treatment options, because of the (difficult/ severe) condition patients are in. We agree with the reviewer that this sentence is vague, and therefore, we have changed this sentence to eliminate misunderstanding. The new sentence is: “The goal of intensive care is to achieve the best outcome for critically ill patients, and usually this is accompanied by the use of very complex care”.

4. **Introduction: The next sentence is about intrinsic and extrinsic risks; but to which risk does this refer to?**

Intrinsic risk is referring to the disease-related risks and the extrinsic risk to care-related risk on survival outcome. An example of an intrinsic risk is the development of sepsis in a patient with infectious complications after abdominal surgery, and for extrinsic risk could be the association of the high nurses-workload with ICU mortality. The articles of Metnitz *et al.* (Metnitz PGH. From risk assessment to risk management. *Crit Care Med* 2010; 16: 475-6.) and Teres *et al.* (Teres D, Lemeshow S. Why severity models should be used with caution. *Crit Care Clin* 1994; 10: 93-115) explain these different risks. All patients carry both an intrinsic risk and an extrinsic risk at the same time. Both authors describe in their articles that these risk factors are the fundament of the general outcome prediction model (GOPM). We did not find it necessary to explain the intrinsic and extrinsic risk in our article, because both authors already did, reference 16 and 17 in our article.

5. **Then: “indicators to measure quality of care are increasingly being used and focus on patient outcome”. Yes, but this depends on what you want to assess, in terms of quality. Quality indicators may be related to outcomes, but also structure and processes. In an overall view of quality of care in ICU, considering all 3 dimensions may be important. If the goal here is to focus on outcomes, this needs to be stated. “quality of care performance research should give more information about the extrinsic risks rather than the intrinsic ones”?**

We agree with the reviewers' comment that “Quality indicators may be related to outcomes, but also structure and processes”. However, in the beginning quality indicators have been developed to evaluate patient outcome, and it is still used for this item up-to-today. At the moment, these indicators are being used to investigate the structure and processes as well,

solely to improve these factors. However, structure and processes are extrinsic factors (concerning the extrinsic risk as mentioned above), and therefore have an effect on patient survival outcome. Studying outcome (whether it is hospital or ICU outcome), the ‘complete’ treatment is measured and investigated, concerning intrinsic and extrinsic risk at the same time. As mentioned in our article: “the extrinsic risks that patients carry should be as low as possible”, because each new development in critical care treatment over the past 30 years has been implemented to improve the quality of care. Disease-related (intrinsic) risks are the same within each hospital for the patient with exactly the same disease and patient condition. And, ideally, when we want to evaluate the quality of hospital/ intensive care performance, this research gives us more information about the extrinsic risk (structure/ process of care/ nurse’s workload, etc) rather than the intrinsic ones. We believe that this item is correctly stated in our article.

6. **I do not understand this sentence. “evaluation is becoming increasingly difficult because of the presence of an increasing variety in case mix for all the different intensive care units”. Again, which case mix? Hospital case mix, patient case mix, units in hospital case mix? More accurate sentences are needed.**

Case mix is a melting-pot for all differences in patient population. Case mix is, therefore, heterogeneous, and consists of differences between hospitals/ patients/ and also ICU’s. The differences between several hospitals are not really an issue, because globally there are no ‘real’ specialized hospitals (except for child hospitals and veteran hospitals). And even if there are these specialized hospitals, the problem in case mix is not within the hospital system itself but in the difference between patients being admitted to these hospitals (compared to other hospitals). The same issue is concerning to specialized intensive care units; the admitted patients within each different unit determine the difference in case mix. Therefore, case mix is most of the time used for different patient-illness related demographics. Nevertheless, we understand the misleading use of the word ‘case mix’; therefore, we have added the word ‘patient’ to the ‘case mix’ to eliminate incorrect interpretation.

7. **“Normalize certain ICU population differences”: please check the English and the sentence. You may normalize a population, but what do you mean by normalize differences?**

We agree with the reviewer that this sentence is not correct. It should say “normalize certain different ICU populations”. We have changed this sentence.

8. **“At that time a general outcome prediction model (GOPM) had been developed, the intrinsic risk had been adjusted in such a way that, after their application in the evaluation of the quality of care, performance mainly illuminates the extrinsic risk factors”. What does “illuminates the extrinsic risk factors” mean”? What was the general outcome? Death? SMR?**

As mentioned above, if one wants to evaluate the quality of hospital/ intensive care performance, then the researchers are really trying to investigate the extrinsic risks. Through the investigation of these extrinsic risks, comparison with other institutions (hospitals or ICU’s) is possible. Comparison with other institutions is hardly possible if the used general outcome prediction model (GOPM) does not adjust for the differences within the patient case mix. This would be the same as comparing ‘apples to oranges’. Up-to-today the outcome of these GOPMs is mortality. However, not mortality in reality but the predicted mortality for this investigated cohort. Using several GOPMs this methodology has become the ‘gold

standard' to compare ICUs across different geographical areas or within a specific individual nation, or other specific subgroups (Moreno RP, Hochrieser H, Metnitz B, Bauer P, Metnitz PGH. Characterizing the risk profiles of intensive care units. *Intensive Care Med* 2010; 36: 1207-1212). In order to use this GOPM result for comparison reasons the standard mortality ratio (SMR) has been developed, and until today, one of the SMR is the most used ICU performance measurement. The SMR has been developed in a period that the evaluation of quality of care was done exclusively through primary patient outcome (short-term mortality). The SMR value gives insight in the observed mortality compared with the associated predicted mortality. The answer to the question of the reviewer: 'What does "illuminates the extrinsic risk factors" mean?' is that evaluation of the quality of care and, therefore, performance of the institution is ultimately to reveal the 'good' or 'bad' extrinsic risk in order to improve these extrinsic factors.

**9. The authors mentioned then the gold standard as being "several GOPMs". Again, this is too confused, because few lines after, they speak of problems related to the fact that only single estimates are considered.**

We agree with the reviewer that this point is indeed difficult to apprehend. Until today, the general outcome prediction models (GOPM) result and the, thereby, calculated standard mortality ratio (SMR), are the only comparison indicators between different Hospitals/ Intensive care units/ and even Units, if the outcome is exclusively through primary patient outcome (short-term mortality). As mentioned above, the SMR is the most used ICU performance measurement. These GOPMs have been updated and adjusted several times and even different models have been developed just to eliminate the disease-related (intrinsic) risks and, therefore, clarify the care-related (extrinsic) risk. Because of the purpose and the constantly updated models, these GOPMs have become the 'gold standard' to compare ICUs across different geographical areas or within a specific individual nation, or other specific subgroups. However, in the use of general outcome prediction models, several limitations should be considered (as we have mentioned in our article): 1) The SMR produces a single value. A single estimate considers the performance of an ICU to be constant over the whole spectrum of the severity of illness. In other words, an ICU with a 'good' performance (low SMR) is assumed to be uniformly good for both low-risk and high-risk patients; likewise, an ICU with a 'bad' performance (high SMR) is assumed to be uniformly bad. However, this assumption is likely not true, since performance can vary not only between ICUs but also within the same unit across patients and doctors. Several studies have provided conclusive evidence that the clinical performance of ICUs may vary over the spectrum of severity of illness [Moreno RP, Hochrieser H, Metnitz B, Bauer P, Metnitz PGH. Characterizing the risk profiles of intensive care units. *Intensive Care Med* 2010; 36: 1207-1212 / Metnitz PGH. From risk assessment to risk management. *Crit Care Med* 2010; 16: 475-6 / Moreno RP, Bauer P, Metnitz PGH. Characterizing performance profiles of ICUs. *Crit Care Med* 2010; 16: 477-481 / Civetta JM. Scoring systems: Do we need a different approach? *Crit Care Med* 1991; 19: 1460-1461 / Metnitz PGH, Moreno RP, Almeida E, *et al.* SAPS 3 – From evaluation of the patient to evaluation of the intensive care unit. Part 1: Objectives, methods and cohort description. *Intensive Care Med* 2005, 31: 1336-1344 / Moreno RP, Metnitz PGH, Almeida E, *et al.* SAPS 3 – From evaluation of the patient to evaluation of the intensive care unit. Part 2: Development of a prognostic model for hospital mortality at ICU admission. *Intensive Care Med* 2005, 31: 1345-1355]. 2) It is unknown whether variations in SMR reflect quality of care or case mix differences. In the past, GOPMs have been revised or even updated to newer versions to predict expected death more accurately and improve corrections for case mix differences. However, before a new GOPM version is used, many years have

elapsed. Although, the newer third and fourth versions of the APACHE prognostic model were developed many years ago, the APACHE II score is still one of the prediction models most widely used. 3) There is no consensus which GOPM must be used for which type of ICU (general mixed unit, specialized unit, or even in different sub-populations). For critical care physicians there are three overall GOPMs for predicting overall mortality and used for performance evaluations: the APACHE model, the MPM system and the SAPS model. These scoring systems differ in the choice and the relative weight given to patient characteristics and physiological parameters. Quality of care performance evaluation should be done with the same - and ideally most reliable - outcome prediction model for each intensive care unit. Because there is no consensus which GOPM should be used, they seem to be used randomly. We agree with the reviewer that this point is indeed difficult to apprehend, nevertheless, we have documented these described limitations in our article according to the current literature. We have made slight improvements in the mentioned limitations. We understand that the contradiction exists between 'golden standard' and limitations. It is just because of this contradiction that we describe this topic so extensively, and that we dedicate an exclusive article to discuss the topic: "How should we monitor intensive care performance in the future?".

- 10. Indicators, either mortality rates or quality of life at discharge, or readmission rates are all important, depending on the purpose of their use. This is not discussed. It seems that the authors try to appeal for replacing some indicators by others, or to balance which is better than the other. Was their goal to state that they plan to start future research to develop new performance indicators? Or was it only to make the list of what is currently used with their advantages and disadvantages according to the mathematical model used? And to state explicitly that new indicators are urgently missing to have a more appropriate picture of quality of care in ICU?**

We like to thank the reviewer for bringing up this topic. Until today, the performance indicators for intensive care evaluation are done through the use of short-term mortality and readmission rates within 48 hours. The later one is a leading performance indicator of the quality of intensive care medicine, recommended by the Quality Indicators Committee of the Society of Critical Care Medicine [Angus DC. Grappling with intensive care unit quality: does the readmission rate tell us anything? *Crit Care Med* 1998; 26: 1779-1780]. Several questions arise in the continuous debate at congresses and in the literature: "How do we measure quality of care, and how accurate and representative is this measurement?". Medicine is constantly being improved and adjusted/ updating according to new insights and research developments. Our opinion is that these used performance indicators need to be updated as well. The mentioned difficulty is indeed "how" and "which future indicators should we use". As pointed out by the reviewer, all the three mentioned indicators are important. However, we think that these indicators should not be used as a 'single' indicator as it is the case for today. A possible solution for the 'future' should be the use of a combination of the most important evaluation indicators of today.

The primary purpose of our article is indeed to discuss the topic "How should we monitor intensive care performance in the future?" extensively, with indeed the advantages and disadvantages of the current situation. Starting the debate and maybe bringing the debate to the next level, and therefore, interesting researchers on the right functional places within our medical society. Ideally, future research to develop new performance indicators or methods

should be done internationally, because evaluation of given care is an ongoing debate and, therefore, struggle on every level of care performance (not only applicable for the intensive care evaluation, but also suitable for comparison of given care between different hospitals or even different general practitioners). Secondly, we describe the expected difficulties implementing a combination of indicators.

**11. Then how to proceed? What is the conclusion? what does this manuscript help in the perspective of a new ICU having to choose indicators in the future?**

As mentioned above, the primary goal of our article is to discuss the topic “How should we monitor intensive care performance in the future?” extensively, with the advantages and disadvantages of the current situation. Ideally, bringing this debate to the next level with the relative consequence that international research should be started to investigate a ‘new’ and ‘better’ evaluation system to measure performance of given care. Our hypothesis is that we, maybe, should not develop new indicators, but update our current evaluation system in which not a single indicator is used but rather a combination of these indicators (already in use) should be implemented to measure the performance of given care within the intensive care. We agree with the reviewer that the current conclusion is not sufficient, therefore, we have changed the last section of the article.