

Format for ANSWERING REVIEWERS

December 15th 2014

Dear Editor,



Please find enclosed the edited invited manuscript in word format (File name: CERTAIN R1_8)

Title: "Checklist for Early Recognition and Treatment of Acute Illness (CERTAIN): International Collaboration to Improve Critical Care Practice"

Authors: Marija Vukoja, Rahul Kashyap, Srdjan Gavrilovic, Yue Dong, Oguz Kilickaya, Ognjen Gajic for the CERTAIN investigators

Name of Journal: *World Journal of Critical Care Medicine*

ESPS Manuscript NO: 13444

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the reviewer:

Reviewer 1

This manuscript describes Checklist for Early Recognition and Treatment of Acute Illness (CERTAIN). The Primary Objectives of the CERTAIN Study are to iteratively refine electronic decision support tool (CERTAIN) and to implement CERTAIN into clinical practice in variable hospital settings and evaluate the impact of the tool on the care processes as well as patient outcomes. In the present manuscript, to ensure the effectiveness of the proposed intervention, access to the easy to use electronic checklist/decision support (CERTAIN) was coupled with structured training of bedside ICU providers.

Major comments:

C1) There was not confirmed explanation in the quality assurance, the participating site clinicians were trained in the use of CERTAIN by the local implementation teams, thus it was not clear whether the data collection process is completed by the same doctor.

R1. Thank you for the comment. The simulation training process is clarified in the revised manuscript. The site research coordinators will be trained in the study protocol, outcome measures, and data collection process via webinars conducted by the Outcomes group.

C2) The better care and better health at a lower cost were analyzed, but the results did not show the data to support.

R2. We hypothesized that implementation of CERTAIN will lead to better health at a lower cost in terms of lower resource utilization. We expect that appropriate delivery of care will lead to a reduction in use of expensive interventions in the ICU including: a) days of central line usage, b) bronchoscopies c) unplanned surgery, d) days of antibiotic use, e) number of radiology tests, f) tracheostomy use g) surgical feeding tubes i) days of mechanical ventilation, j) number of transfusions, k) duration of ICU stay, l) development of acute kidney injury.

CERTAIN study is ongoing and the data on effectiveness of CERTAIN will be

presented upon completion of the study. In this article we present development of CERTAIN tool as well as implementation strategy.

C3) In the text, the patient characteristics in this clinical research were unclear.

R3. The inclusion/exclusion criteria are clearly stated in study subjects section of the revised manuscript.

C4) Minor comments: 1) The explanation of figure.22 and 3 is too simple, it is necessary to increase the description of figure legends.

R4. We agree and have revised the figures accordingly. We removed figure 1 from the manuscript and provided more detailed technical description. We provided more detailed descriptions of Fig 2 and 3.

Reviewer 2

C1.) The concept is brilliant even with the lack of specifics. It would be nice if the authors elaborated the elements that are addressed by CERTAIN. Under characteristics, the authors mention " CERTAIN serves to organize appropriate data determined by a systematic review of end user data needs". It would be nice if the authors can elaborate on this. If they tweak it with different versions for different situations, will the results of study be generalizable?

R1. Certain content was refined by web-based survey of decision support needs. An international sample (Asia, Africa, Eastern Europe, and Latin America) of acute care providers completed a self-administered internet based survey to rank the itemized information according to point-of-care needs (from high to low priority). Experts from various international settings and backgrounds iteratively reviewed prioritized decision support content and validated it through a structured feedback. The detailed description on card template development has been previously presented and we provide the reference in the revised manuscript (*Bonneton BA et al. Development of bedside decision support cards based on the information needs of acute care providers. Critical Care Medicine; 2013 (41): A30-31*). A decision support card was made for each clinical problem, medication or intervention and was then validated through a modified Delphi process. Thus decision support cards are uniform for all users, although limited availability of some medications and equipment may preclude delivery of best care practices in resource limited settings. We acknowledge this as a limitation in the revised manuscript. Nevertheless, we expect to see improvement in proposed outcomes with the implementation of the CERTAIN tool.

C2. In the era of data breaches, how do the authors plan to maintain confidentiality and security of data?

R3. Thank you for the comment. We added a paragraph on securing patients' confidentiality and security of the data in the revised manuscript:

"All the cloud servers and database services used in CERTAIN project are secured by adopting Server Name Indication (SNI) based Secure Sockets Layer (SSL) protocol. Every request to the server required to be authenticated by our SSL certificate. The data stored in the Database are encrypted based on security requirements and every hospital has its own separated logical space. Data backup is also planned and implemented by setting up scheduled jobs in the server side.

Each study subject will be assigned a unique study identification number linked to his or her medical record number at the respective home site. We will use existing procedures to ensure that individual patient identifiers are kept separate from analysis files and are available only to project personnel on a need-to-know basis. All identified patient data necessary to complete this research will be created and stored in secure computers to which only project team members will have access. Only project personnel directly involved in the study will have access to identified patient data and medical charts at their respective site. All project personnel with access to patient data will be trained in the proper handling of such data."



; were corrected

ideration. If any questions please do not hesitate to contact me.



Marija Vukoja, MD, PhD

The Institute for Pulmonary Diseases of Vojvodina
Put doktora Goldmana 4, 21204 Sremska Kamenica
Serbia

E-mail: kojicic.marija@gmail.com

Phone: +381641446908