Reviewer’s report

Title: Intravenous to oral antibiotic switch therapy: a cross-sectional study in critical care units

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Reviewer: Giorgia Montrucchio

Reviewer's report:

Dear Authors,

I review with interest your manuscript "Antimicrobial stewardship programme in critical care units based on oral switch" - INFD-D-18-02192.

Certainly the scope of antibiotic therapy appropriateness and the development of targeted stewardship programs is of great importance and for that reason often addressed in the literature. The possibility of shift to oral therapy is a strategy widely used outside the context of ICU, but in fact hardly applied to critically ill patients, due to the characteristics of the patients themselves and the frequent impossibility of using the oral route. The proposed theme would therefore be interesting in itself.

However, in my opinion, your manuscript presents some fundamental structural problems.

The general structure of the study is not clearly defined, neither in the abstract nor in the article.

It is not clarified if the antibiotic-switch (intravenous to oral) intervention is the only intervention of the Antimicrobial Stewardship (AS) program mentioned, or if it is a part of a more inclusive strategy. However, in this case it is not clearly described what the AS includes- if other interventions, how they are performed, and how they can be measured, as well as whether they can impact on the evaluated switch.
Moreover, the groups of patients compared in the study are not well defined. In fact, septic patients are included (according to the criteria of the JAMA 2016 definitions, as it is specified later in the text, cf. "clinical conditions") but among them then you define those eligible for oral therapy according to clinical criteria, as: "patients feeding normally or with enteral feeding", "receiving other oral medications", "with sign and symptoms of infection but improving or partially resolved".

These criteria, however, define without doubt a less critical population of septic patients, certainly in good clinical evolution. Therefore, it seems difficult and conceptually wrong to compare it to patients who do not present such characteristics, and which certainly have worse clinical performance. Finally, to evaluate between the two groups the difference in mortality, length of stay and relative costs (although the latter calculated using methods that are not sufficiently clarified and standardized) does not appear adequate.

No mention is made of the extent to which the shift takes place - that is, after how many days of treatment, with which microbiological correlation. Nor is standardize the type of shift between molecules (to which IV antibiotic corresponds each oral antibiotic). The difference between direct oral and nasogastric tube (shredded tablets or oral solutions, if available) is not clarified, nor is it investigated in literature the possible impact of this route of administration.

The paragraph on methods is difficult to read, with numerous and essential references that have not been clarified. The discussion appears rather poor, tackles the AS theme in a generic way and does not provide a complete explanation of the results obtained. In my opinion, then, some concepts expressed in the discussion are incorrect: for instance, the presence of critical resistance to therapy has led to the impossibility to switch to oral therapy. It can not be said that oral therapy has had an impact on resistance.

In all its parts, the manuscript does not present sufficient bibliographic references to written statements, which however are rather generic and not specifically adapted to the ICU context.

Concerning the approval of the ethics committee, you stated that "Local Ethics Committee (Pontifícia Universidade Católica do Paraná) approved this study (CAAE number 74844017800000020) and consent was waived by the institutional review board": I would request you further explanations in this regard.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I recommend additional statistical review

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