Reviewer's report

Title: Effect of a multi-faceted quality improvement intervention on inappropriate antibiotic use in children with non-bloody diarrhoea admitted to district hospitals in Kenya.

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Reviewer: Thilo T Bertsche

Reviewer's report:

General remarks:
Thank you very much for giving me the possibility to review this interesting paper. It deals with the practical implementation of an intervention focusing on optimized guideline adherence. Data in this field, especially in non-developed countries, are indeed frequently missing. I believe, therefore, this paper addresses an important area of practical clinical research. However, a strong limitation of this paper is, that the results shown here did not include the prespecified trial endpoints. Additionally, the paper should be more focused on the clinical implications of the results. For this reason, I would recommend to consider the following remarks to improve the paper especially for potential readers in patient-related settings:

1 Title:
No remarks

2 Abstract (please consider the following remarks also for the full text and vice versa remarks for the full text also for the abstract if appropriate):
2.1 Concerning main study end-points?: the authors should state in the abstract that the outcome inappropriate antibiotics use? was not a prespecified trial endpoint, because this fact is an important while assessing the results. (ii)
2.2 I wonder if endpoint? is really the appropriate term in this context. I consider it as confusing for the reader if aspects of the main study and the here shown results are mixed? the authors should focus in the results shown here (antibiotic use is rather an outcome than an endpoint), only on the aspects of antibiotic use and include some more aspects about the main study in the methods. (ii)
2.3 The authors should explain their study design in the abstract in more detail (including also partial interventions? used in the control). (i)
2.4 A few important patient and setting characteristics should be added in the abstract. (ii)
2.5 The authors should state that additional requirements for antibiotic use had been taken into account before deciding about inappropriate antibiotic use. Otherwise it will lead to misunderstanding that only diarrhea was considered. (ii)

2.6 Why did the authors not provide the absolute numbers of the primary outcome (prevalence of irrational antibiotic use in the intervention and in the control group)? This would be very helpful to assess the results in addition to the given odds ratio. (i)

3 Background:
3.1 The authors should add some clinical data from literature explaining why the simple (but practical particularly for non-developed countries) distinction into bloody and non-bloody diarrhea without considering further clinical aspects is an appropriate procedure. They should state what are the main pathogenic agents causing bloody diarrhea in the setting addressed by the study. (i)

3.2 The authors should give some more information about some details of the main study in this paragraph (e.g. how was ?quality of inpatient care? defined?). (i)

4 Methods:
4.1 I wonder if the ?partial intervention? in the control group was typical for the setting. If not, it seems to be rather a comparison of a ?small? to a ?big? intervention than a comparison to a control. A procedure of routine care cannot be declared unethical before an additional effect of an intervention was not proven to be clinically relevant. The authors should clarify this. (i)

4.2 The authors should provide some information about the economic impact of the interventions. The strategies in the intervention groups seem to be rather cost-intensive and I wonder if they can be practically used in routine patient care in non-developing countries limiting the generalizability of this study. (i)

4.3 The authors should provide detailed information on how far the intervention concept, which was designed for other study endpoints of a main study, addressed the aim of the study shown here. (i)

4.4 The sentence ?the primary endpoint was the 3rd follow-up survey? sounds confusing and should be modified (what was actually assessed as the primary endpoint?). (iii)

4.5 As I understand the study design a positive ethic vote is mandatory. The authors should state that an ethic committee was involved for ethical reasons or give detailed information why it should not be necessary. (i)

4.6 The interventions should not only address the use of...
antibiotics but also rehydration and hygiene aspects. Were those aspects addressed by the intervention? (ii)

4.7 The authors described that only complete case-records were included. However, in an "intention-to-treat? analysis all case-records should be included (e.g. with a worse-case scenario). If only completed records have been included, this can cause a substantial bias. Authors should consider this point in the discussion. (ii)

5 Results:

5.1 Figure 2 seems difficult to read. I would recommend putting the data rather in a table. Authors should avoid using different intensities of grey which can hardly be distinguished from each other. (ii)

5.2 Figure 4 shows large differences especially in the control hospitals group (grey). Sometimes the fluctuations in controls have an even larger extent than the effects on the intervention group or the baseline level in controls is lower than the effect in the intervention. This seems to limit the clinical relevance of the data, even if statistical methods might show significance. The authors should discuss those aspects or explain in the paper why those results can clearly prove an effect when comparing intervention to control group. (i)

6 Discussion:

6.1 The paper addresses a lot of statistical aspects. Beyond question, using appropriate statistical methods is an essential part of a study. However, particularly in the discussion the authors set a strong focus on statistical questions while on the other hand delivering only rare clinical aspects. In my opinion, the authors should include more clinical considerations and literature dealing with those aspects (such as strategies to improve clinical guideline adherence). This would make the data more interesting for readers with clinical background. Additionally one have to state, that although statistical analysis is broadly discussed, the strongest limitations of this study lay in this area: only small number of included hospitals, lack of a control group offering only ?usual? support (w/o any additional intervention), and missing data (as mentioned by the authors). (i)

6.2 It would be more interesting to get an impression whether the results shown in this study are comparable to other similar surveys and what clinical consequences may result, if they can be generalized to other settings (e.g. also in so called developedcountries, where missing guideline adherence is also a great drug-related problem). The authors should discuss the potential risk of false treated patients. E.g. is it relevant if patients were not treated with antibiotics in case they have no bloody diarrhea but antibiotics were necessary or in case antibiotics were given in patients with bloody diarrhea but (the chosen antibiotics) were contraindicated (e.g. what is about Clostridium difficile infections.)? (ii)
6.3 In conclusions and recommendations for further work I would expect some considerations about the generalizability of the intervention particularly when considering their costs. Here, the authors should only relay on facts proven by their results. (ii)

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

Quality of written English: Acceptable

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.