Author's response to reviews

Title: Risk of infection due to medical interventions via central venous catheters or implantable venous access port systems at the middle port of a three-way cock: luer lock cap vs. luer access split septum system (Q-Syte(R))

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Author's response to reviews: see over
Dear Mr. Nazareno,

I would like to refer to both reviewers about our manuscript entitled:

“Risk of infection due to medical interventions via central venous catheters or implantable venous access port systems at the middle port of a three-way stopcock: luer lock cap vs. luer access split septum (Q-Syte®)”

All comments of the last comments were processed, the manuscript was changed in the way the reviewers suggested.

Sincerely,

Fabian Pohl, MD
1) I am satisfied that ethical commitee approval is not required but i wonder then who approved study specific consent forms?
Answer:
For the study specific consent forms we used the template on the web page of our local ethical committee, which you can find on the indicated link:
http://ethikkommission.uni-regensburg.de/index.php/PatInfo.html
Even if we needed no ethical committee approval for our paper, we used the approach for the execution of the study as described by our local ethical committee including the template for the consent form. The paper and the additional material (e.g. consent forms) was shown to the local ethics committee and they did not insert a complaint about the approach.

2) More information is required regarding the mean number of samples collected from each patient for each group. For example, results may be biased if 20 samples were obtained from 1 patient in one of the study groups.
Answer:
We got the 100 samples from 25 patients. 12 patients were in the group with the luer lock cap (4 samples each patient), 12 patients in the group with the luer access split septum system (4 samples each patient). Only one patient (two times for admission) was in both groups (2 samples each study group). So the mean number of samples collected in each group was 3.84.
We stated this now also in the paper (page 9).

12 patients belonged to group A (4 samples each patient), 12 patients to group B (4 samples each patient). Only one patient (two times for admission) belonged to both groups (2 samples for each study group).

3) A ‘positive sample’ would be best explained as the presence of 1 or more CFU.
Answer:
To specify the definition of “positive sample” we modified the method section on page 9 in the following way:

A sample was stated as positive with the presence of one or more colony forming units (CFU).
4) The authors state that it was felt that there was no need to translate diagrams 3 and 4 into English but they simply show the complexity of handling. I disagree and whilst a translation has been provided in the key, the diagram should just be in English so that it is not further complicated.

Answer:
Figure 3 and 4 are now translated into English.

5) It isn't necessary to give examples of companies who make three-way stopcocks (page 4).

Answer:
The paragraph was removed.

6) I still maintain that any discussion of results should be accompanied by statistical analysis.

Answer:
I assume that you are talking about the mean working time. The main difference regarding the handling per intervention between the luer access split septum system and the luer lock cap is the smaller number of work procedures with the luer access split septum system in comparison to the luer lock cap as demonstrated in figure 3 and 4.

So I still hold the opinion that the mean working time for both procedures would give no additional information. To address your comment I attached two statistical diagrams, to summarize the costs for both processes.
Minor Essential Revisions
1) There is a typo on page 5 line 6.
   Answer:
   The typo was corrected.

2) The title in figure 5 is still partly in German.
   Answer:
   The title was changed to English.

3) The word 'smear' still appears once in the abstract
   Answer:
   The proposal was converted.

Thank you very much for your constructive review.

Sincerely,

Fabian Pohl, MD
The authors addressed my concerns and appropriately considered my suggestions for revision. This paper has been markedly improved from the original submission.

**Major Compulsory revisions:**
Please make sure to use “TWC” or “three-way cock” consistently and correct the format of quotation marks throughout the paper.

**Answer:**
The proposal was converted.

**Abstract:**
1) Background: “The BD…Devices (BfArM)”. Please delete this part.

**Answer:**
The proposal was converted.

**Background:**
1) The background section seems too long and could be shortened considerably.

**Answer:**
The background section was shortened considerably.

2) This article still reads too much like an advertisement for the Q-Syte. The brand name and manufacturer should be listed only in methods section because three-way stopcock, luer lock caps, and split septum system are generic. Are there any specific characteristics in the Q-Syte® compared with other split-septum needleless connectors?

**Answer:**
Whenever possible we changed the brand name to “luer access split septum system”.

3) Page 5, Please change from “infusion hose set” to “infusion set”.

**Answer:**
The proposal was converted.

4) Page 5, line 6, line 11: “y BD”, “split septum. Of the Q-Syte®”: Please correct the grammatical errors.

**Answer:**
The typos were corrected.
Results:
1) The figure 5 legend should explain what the boxes and lines denote.
Answer: To specify figure 5, we modified the legend in the following way:

2-sample-t/ process costs: The box (-plot) represents the mean 50% of the values, the upper and lower orthogonal line (called whisker) the 25% of the superior and lower values. The line drawn through the box demonstrates the median values. The outliers are displayed with asterisks. The line between the ACTUALcost and NOMINALcost links the mean values, the symbols in the charts stand for the mean value of all samples, which serves as an estimate for m.

2) Last paragraph, “possible hygienic risk, 65.38%...”: How did you calculate this value?
Answer: We counted the risk points as seen in figure 3 and 4. Red points are risks of contamination due to working conditions, material properties and precincts, blue points are risks of contamination due to carelessness, forgetfulness and errors/work load and calculated the risk as seen in the diagram.

3) Page 10 last sentence, “Klebsiella oytoca”: Please change to “Klebsiella oxytoca”.
Answer: The typo was corrected.

Discussion:
1) Page 14 Lines 1-5 “Another way to reduce...patient safety”: This part should be deleted because you did not evaluate the silver coating catheter.
Answer: Part was deleted.

2) Page 14 Lines 6-9 “Using only one single infection...achieving this goal”: Your data does not support these description because you did not evaluate the rate of catheter-related infection.
Answer: Part was deleted.
Thank you very much for your constructive review.

Sincerely,

Fabian Pohl, MD