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 stopcock: luer lock cap vs. luer access split septum (Q-Syte)

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Author's response to reviews: see over
Dear Mrs. Harris,

I am submitting to *BMC Infectious Diseases* 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®)”

We are engaged in this work with the hygiene risk of patients in a hospital, a topic which is always important in the clinical routine. Many patients receive a central venous catheter or port system prior to therapy to assure correct drug administration and to avoid extravasation. The risk of contaminating the middle port (C-Port) of a three-way stopcock is estimated on 20% to 98%. Even appropriate hygienic intervention maintenance carries the
risk of contaminating the C-Port, a risk that increases with the number of interventions. Because a lower rate of interventions may also be equated with better hygiene, we compared luer lock caps with a new “closed access system” with regard to hygiene (patient safety), process optimization (work simplification, process time), and efficiency (costs).

May I ask you to kindly forward this paper for refereeing and possible publication in **BMC Infectious Diseases**.

Neither the paper as submitted, nor any similar paper, in whole or in part, has been or will be submitted to or published in any other primary scientific journal. All of the authors agree to the content of the paper and to being listed as an author on the paper. All authors disclose any commercial associations that might create a conflict of interest in connection with submitted manuscripts. No competing financial interests exist.

Sincerely,

Fabian Pohl, MD
Dear Mr. Nathaniel A. Nazareno,

I would like to refer to your Questions about my paper

“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®)”.

1) **Figures:**

I uploaded figure 1, 2 and 6 in higher resolution. If it is still too low please notify me.

2) **Requesting ethics statement:**

In the paper we did not use any personal patient data, the investigation was anonymous and was related to the probed product. There was no change in therapy, because we did not modify the change interval. Therefore we did not need an approval by an ethics committee. Nevertheless we asked every patient about his informed consent. The reported research was in compliance with the Helsinki Declaration, we stated this also in the method section but again, our paper reports no research carried out on humans or human material or specific physic human data.

3) **Requesting consent statement:**

All used three-way cocks were from adult patients treated in the Department of Radiooncology, University Hospital Regensburg, Germany. All patients were asked in
front to give their written informed consent. We also stated this now in the method section.

4) **Requesting trial registration:**

First, this was not a prospective, randomized trial. For this reason we did not report a clinical trial and did not mention this in our paper. The reported data are observational and uncontrolled. In addition, our report details experience at a single institution.

A clinical trial would evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on large groups of people. We examined an application observation with a small random sample. The BD Q-Syte® itself is already an approved medical device by the German Federal Institute for Drugs and Medical Devices (BfArM).

This paper wants to demonstrate the complexities of health care system supply lines. A multitude of persons and viewpoints are involved in decisions regarding supply purchases; potential infection control concerns are only one, albeit a very important, consideration. In heavily bureaucratized and outsourced hospital supply systems, decisions regarding device distribution are not easily communicated throughout.

Again, this was not a prospective, randomized or clinical trial.

5) **Competing interest:**

*Potential conflicts of interest.* WH is employed at the Risk Management, Becton Dickinson GmbH, Heidelberg, Germany. He was in an advisory capacity for the
discrete event simulation, Becton Dickinson GmbH, Heidelberg, Germany paid also for the smears and hygienic analyses. All other authors: no conflicts.

Changes in the paper as follows:

1) Page 2:

**Background:** Deletion of the word “new” ahead luer access split septum system because the BD Q-Syte® is already an approved medical device by the German Federal Institute for Drugs and Medical Devices (BfArM). Completion with the information that the BD Q-Syte® is already an approved medical device at the end of the passage.

2) Page 4:

Completion of a passage, that give more information about Figure 1, which three way cock and luer lock cap is used in our department.

Figure 1 shows an example of a TWC closed with a blue luer lock cap at the C-Port, here the Discofix 3SC® from B. Braun Melsungen, Germany. The shown luer lock cap is called Combi-Stopper, blue® and made by Dispomed Witt OHG, Gelnhausen, Germany. Many other companies are producing luer lock caps and TWC, e.g. CLS Medizintechnik und Vertrieb, Adelebsen, Germany or Becton Dickinson GmbH, Heidelberg, Germany.

3) Page 5:

Completion with the information that the BD Q-Syte® is already an approved medical device.
“The BD Q-Syte® is already an approved medical device by the German Federal Institute for Drugs and Medical Devices (BfArM).”

4) Page 7:

Completion with requested consent statement:

Phase 2 / Hygiene and patient safety

In the 2nd phase of the project, smears were carried out at the TWC C-ports to evaluate possible contamination and thus health risks for patients. All used TWC were from adult patients treated in the Department of Radiooncology, University Hospital Regensburg, Germany. All patients were asked in front to give their written informed consent. The research was in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html).

5) Page 12:

Completion with the information that we did not perform a clinical trial in the Discussion:

The contamination rates indicated in other trials correspond with the data obtained in our observation. It might be objected that our observation was not a prospective, randomized trial and reports only experience at a single institution.

6) Page 13:

Replacement of the name “study” to the name “observation”.

Completion of the passage Competing interests:
“Competing interests

Potential conflicts of interest. WH is employed at the Risk Management, Becton Dickinson GmbH, Heidelberg, Germany. He was in an advisory capacity for the discrete event simulation. Becton Dickinson GmbH, Heidelberg, Germany paid also for the smears and hygienic analyses. All other authors: no conflicts.

7) Page 16:

Completion of legend to Figure 1:

**Figure 1 -**

TWC-luer lock cap (ACTUAL-condition)

Blue luer lock cap at C-Port of TWC (example of TWC, here *Discofix 3SC®* from B. Braun Melsungen, Germany. Example of luer lock cap, here *Combi-Stopper, blue®* from Dispomed Witt OHG, Gelnhausen, Germany)

Sincerely,

Fabian Pohl, MD