

## Microbial contamination and labelling of self-prepared, multi-dose phenylephrine solutions used at a teaching hospital

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**Background:** Common practice at Chris Hani Baragwanath Academic Hospital (CHBAH) is to use boluses from a self-prepared, multi-dose phenylephrine solution to treat spinal anaesthesia-induced hypotension in patients undergoing a Caesarean section. The aims of this study were to determine if there was microbial contamination of the solutions and to evaluate whether healthcare workers adhered to appropriate labelling and aspiration practices.

**Methods:** A sample was collected and the labelling data were documented from the solutions found in the two obstetric theatres at CHBAH over a three-month period. The samples were sent to a laboratory for microbial investigation.

**Results:** Microbial contamination was identified in 6.4% of samples collected. The name of the solution was indicated on 100% of the containers and the concentration of the solution was on 96.4%. The date the solution was prepared was indicated on 74.6% of containers and the time the solution was prepared was on 57.3%. Only 8.2% of healthcare workers who prepared the solution confirmed it by placing a signature on the container. Labelling data were written directly on 100% of the containers and a spike-device was used in 64.5% of the containers.

**Conclusions:** This study demonstrated microbial contamination of the solution and may indicate an infection hazard. Healthcare workers also did not adhere to appropriate labelling and aspiration practices. This is important for all patients from a patient safety perspective and the need to improve quality of care.

**Keywords:** contamination, microbial, multi-dose, phenylephrine, self-prepared solutions

Anaesthetists are responsible for the safe use of anaesthetic-associated drugs.<sup>1</sup> Recent studies have implicated anaesthetists in the transmission of pathogens to patients during regional<sup>2,3</sup> and general<sup>4,5</sup> anaesthesia. Microbial contamination of multi-dose vials<sup>6-9</sup> and anaesthetic equipment<sup>10-13</sup> are two of the main mechanisms by which patient-to-patient transmission of pathogens can occur in anaesthesia.<sup>14</sup> Current infection control practices of anaesthetists working in developed countries falls short of accepted recommendations.<sup>14-17</sup> A matter of particular concern is the infection risk due to unsafe injection practices that are associated with the use of single-dose vials for multiple patients<sup>18-20</sup> and the use of multi-dose vials.<sup>6-9</sup>

International guidelines on preventing contamination of anaesthetic-associated medication<sup>21,22</sup> clearly state that preservative-free vials are single-patient, single-dose items. There is, however, evidence in the literature that single-dose vials can be used for multiple patients if safe injection practices and aseptic technique are adhered to.<sup>23</sup>

The SASA Guidelines for Infection Control in Anaesthesia in South Africa 2014,<sup>24</sup> which was published after completion of our study, states that bags or bottles containing intravenous solutions should never be used as a common source of supply for more than one patient. Spike-devices to remove fluid from infusion bottles or bags for several uses or patients should also never be used.

The correct labelling of medication in anaesthetic practice is a key element of safe medication administration.<sup>25</sup> Inappropriate labelling of medication has been identified as a cause for medication administration errors in general<sup>26,27</sup> and in anaesthetic practice.<sup>28-30</sup> Anaesthetists can be held legally accountable for medication administration errors and the administration of contaminated medication.<sup>31</sup>

Common practice at Chris Hani Baragwanath Academic Hospital (CHBAH) is to use boluses of a self-prepared phenylephrine solution (referred to as the solution) to treat hypotension, due to the vasodilatory effects of a spinal anaesthetic, in stable patients undergoing a Caesarean section. This solution is usually prepared by adding one ampoule of phenylephrine (10 mg/ml) to 200 ml of fluid (normal saline or Ringer's lactate) to produce a phenylephrine solution (50 ug/ml), which then acts as a multi-dose vial that is used for multiple patients. The 200 ml intravenous fluid vaculitres used to prepare this solution do not contain any bactericidal or bacteriostatic agents. There is no evidence in the literature or in the package information from the manufacturer that phenylephrine has any anti-bacterial activity.

It has been observed that this solution is often labelled incorrectly, used for more than 12 h on multiple patients and strict aseptic technique is not always adhered to when using this solution as a multi-dose vial. This solution thus has the potential for microbial contamination.

The aims of this study were to determine if there was microbial contamination of the solutions used at CHBAH and to evaluate whether healthcare workers adhered to appropriate labelling and aspiration practices with regard to the solutions.

**Methods**

Approval to conduct this study was obtained from the Human Research Ethics Committee (Medical), University of the Witwatersrand and other relevant authorities. A prospective, descriptive research design was used. Data were collected over a period of three months, from 1 October to 7 December 2012.

The solutions found in the two obstetric theatres at CHBAH were included in this study. Due to financial constraints the sample size of this study was limited to 110 samples and a convenience sampling method was used. Solutions with < 10 ml of solution left in the container were excluded from the study. If any breach in the aseptic technique used during the collection and transportation of the samples occurred, these samples were then also excluded.

Samples taken from the solutions were sent to the National Health Laboratory Service (NHLS) for microbiological investigation. The labelling data on the solution containers were also documented. The data collected are listed in Table 1.

All samples were collected by one author (AvdH). An aseptic technique was used to collect a 10 ml sample from each solution container. This technique included washing hands before taking the sample, wearing sterile gloves while collecting the sample, using a new needle and syringe to aspirate each sample if the rubber septum needed to be punctured, using a new syringe to aspirate each sample directly from the spike-device if such a device was in situ, disinfecting the rubber septum or spike of each container with 70% isopropyl alcohol and waiting two minutes after disinfection to allow for drying of the disinfectant before aspirating the sample.

An aerobic blood culture bottle (BacT/ALERT®, Biomereaux, SA) was then inoculated with the sample and used to culture the solutions. The labelling data on the solution containers were documented on a data collection form.

An attempt was made to deliver the blood culture bottles to the NHLS as soon as possible after sample collection. In consultation with a microbiologist it was decided that if there was a delay in transporting the sample to the laboratory it should be stored at room temperature (20–25°C) for not more than 12 h since there was a concern that extreme temperatures and prolonged delays could affect the bacterial growth.

Table 1: Data collected from solutions

Data collected
Microbial contamination
Microorganism isolated
Name and concentration of solution indicated
Date and time solution prepared indicated
Indication of whom prepared and checked the solution
Type of labelling method used
Method used to aspirate the solution

The processing of the samples and identification of the microorganisms were done by qualified laboratory personnel using standard microbiological laboratory equipment and procedures.

Data capturing was done using a Microsoft Excel 2007® spreadsheet (Microsoft Corp, Redmond, WA, USA). Descriptive and inferential statistics were used to analyse the data. Statistical analysis was performed using GraphPad InStat® (GraphPad Software, La Jolla, CA, USA), a statistics program. A *p*-value of < 0.05 was considered as statistically significant.

**Results**

A total of 111 samples were collected. One sample was excluded from the study due to a breach in the aseptic technique. Microbial contamination was identified in seven (6.4%) of the 110 samples (95% confidence interval of 1.8% to 10.9%). The contaminating microorganisms are shown in Table 2.

The labelling and aspiration practice with regard to the solutions is shown in Table 3.

Of the solutions that had microbial contamination, six (85.7%) had spike-devices in situ. Using Fisher’s exact test, the association between the aspiration method of the solution and microbial contamination of the solution was not statistically significant (*p* = 0.4178) (Table 4).

Table 2: Microbial contamination of the solutions

Microorganisms	Number	Percentage
Coagulase negative staphylococci	3	2.7
<i>Brevundimonas vesicularis</i>	1	0.9
<i>Bacillus</i> species	1	0.9
<i>Micrococcus</i> species	1	0.9
<i>Pseudomonas alcaligenes</i>	1	0.9
Total	7	6.4

Table 3: Labelling and aspiration practices

Presence of labelling and aspiration practice	Number	Percentage
Name of solution	110	100
Concentration of solution	106	96.4
Date solution was prepared	82	74.66
Time solution was prepared	63	57.3
Healthcare worker’s signature	9	8.2
Information written directly on container	110	100
Spike-device used	71	64.5

Table 4: Association between aspiration method and microbial contamination

Factor	Microbial contamination	No microbial contamination	Total
Spike-device	6	65	71
No spike-device	1	38	39
Total	7	103	110

Note: *p* = 0.4178.

## Discussion

The use of multi-dose vials in general and anaesthetic practice remains controversial due to the risk of microbial contamination. Presently there are conflicting results reported in the literature regarding the risk of microbial contamination of multi-dose vials.<sup>7,9,19,23,32-39</sup> Currently SASA does not endorse the practice of sharing single-dose vials between multiple patients.<sup>24,40,41</sup>

From a review of the literature the microbial contamination rates of multi-dose vials range from 0% to 27%.<sup>42</sup> Recent studies have shown that multi-dose vials, and even single-dose vials used for multiple patients, can be used safely if safe injection and medication vial utilisation practices are adhered to.<sup>23,36-39</sup> In our study seven (6.4%) of 110 samples were contaminated with microorganisms. This is similar to the results of Motamedifar *et al.*<sup>6</sup> who reported a microbial contamination rate of 5.6%. It is, however, substantially higher than the microbial contamination rate of 0.9% reported by Mattner *et al.*<sup>9</sup> This might not reflect the true microbial contamination rate since only contamination with aerobic bacteria was investigated in our study. Any microbial contamination of medication administered to patients poses a health risk. It is clear from our study that safe injection practices with regard to the solutions are not adhered to and that there is a relatively high risk for microbial contamination of the solution. This is of concern since patients are at risk of developing nosocomial infections when the solution is used.

The aerobic bacteria contaminating the solutions in this study include coagulase-negative staphylococci (2.7%), *Brevundimonas vesicularis* (0.9%), *Bacillus* species (0.9%), *Micrococcus* species (0.9%) and *Pseudomonas alcaligenes* (0.9%). This is similar to the results of Motamedifar *et al.*<sup>6</sup> and Mattner *et al.*<sup>9</sup> It is evident from the literature that the contaminating microorganisms identified in our study have been implicated as opportunistic pathogens that could lead to clinically significant infections in immunocompromised patients.<sup>43-47</sup> This is especially important at CHBAH since a large proportion of South African patients are immunocompromised and susceptible to opportunistic infections.<sup>48</sup>

The literature shows that the inappropriate labelling of medication is a cause of medication administration errors in general<sup>26,27</sup> and in anaesthetic practice.<sup>28-30</sup> Labelling recommendations for medication containers include colour-coded labels for different medication classes, patient name, patient hospital number, name of medication added to the container, amount of medication added, total volume of diluent in container, concentration of solution, date and time solution was prepared, signature of healthcare workers who prepared and checked the solution, and route of administration.<sup>25,49</sup>

In our study the name of the solution was indicated on all 110 (100%) containers from which samples were collected. This is similar to the results reported by Mattner *et al.*<sup>9</sup> where the medication type was indicated on 99.1% of multi-dose vials. The concentration of the solution was indicated on 106 (96.4%) of the 110 containers, which is similar to the 96.9% reported by Mattner *et al.*<sup>9</sup> The date the solution was prepared was indicated on 82 (74.6%) of the 110 containers, which is substantially higher than the 50% reported by Mattner *et al.*<sup>9</sup> The time the solution was prepared was indicated on 63 (57.3%) of the 110 containers. It is clear from the results of our study that the solutions are inappropriately labelled and that there is risk of an administration error when these solutions are used.

Recommendations for correct medication labelling and administration are that the healthcare worker who prepared the medication should sign the medication container.<sup>25,49</sup> In our study only nine (8.2%) healthcare workers who prepared the solution placed a signature on the container. The majority of the solutions in our study were administered to patients without knowing who prepared the solution. This has medico-legal implications.

Writing directly onto the container should be avoided as the ink can leach from the PVC container into the intravenous fluid and has been shown to be toxic to animals.<sup>50-52</sup> In our study the labelling data were written directly on all 110 (100%) containers from which samples were collected. This result shows that a potentially toxic solution may have been administered to patients.

The Association for Professionals in Infection Control and Epidemiology position paper on safe injection, infusion and medication vial practices in health care<sup>53</sup> strongly discourages the use of a spike-device inserted into a medication vial septum because it leaves the vial vulnerable to contamination. In our study a spike-device was used in 71 (64.5%) of the 110 containers. This is substantially higher than the results reported by Mattner *et al.*<sup>9</sup> where 41.4% of multi-dose vials had spike-devices. Although the association between the aspiration method of the solution and microbial contamination of the solution was not statistically significant ( $p = 0.4178$ ), it must be noted that six of the seven contaminated solutions contained a spike-device.

An extensive research doctorate by Jansen<sup>31</sup> that comprehensively addressed from a legal perspective various errors which can occur with regard to dispensing, preparation and administration of medication emphasised that healthcare workers experience a great deal of uncertainty with regard to their legal position and medication administration. Jansen<sup>31</sup> further concluded that healthcare workers do not view medication administration as the high-risk activity that it is.

An important medication error that anaesthetists are legally accountable for is the administration of contaminated medication.<sup>31</sup> In our study seven (6.4%) solutions were contaminated and these contaminated solutions were administered to patients. Jansen<sup>31</sup> further stated that a healthcare worker should only administer medication that was appropriately checked by the healthcare worker. Our study did not evaluate whether anaesthetists checked the solutions appropriately when it was prepared. However, 101 (91.8%) solutions had no signature indicating who had prepared the solution and anaesthetists were aspirating and administering solutions from these containers.

Anaesthetists can be held legally accountable for medication errors. The medication errors identified in our study include administration of contaminated medication, failing to appropriately check all medication prior to administration and failing to adequately label medication.

Our study was contextual and focused on the microbial contamination and labelling of a solution prepared and used by anaesthetists working in the two obstetric theatres at CHBAH. This limits the generalisation of the results.

Due to financial constraints the sample size was limited to 110 samples. Our study was a pilot observational study with no

sample size calculation for statistical power. This limits the conclusions that can be derived from our study.

Only microbial contamination with aerobic bacteria was investigated.

Only categorical data were collected and therefore the association between the length of time the solution was in use and microbial contamination of the solution could not be investigated.

### Conclusion

Our study demonstrated microbial contamination of the solution and this may indicate an infection hazard. Safe injection practices were also not adhered to when intravenous medications were prepared and administered, which includes correct labelling practices. This is especially important at CHBAH since a large proportion of South African patients are immunocompromised and thus susceptible to opportunistic infections. An important medication error that anaesthetists are legally accountable for is the administration of contaminated medication. Furthermore, inappropriate labelling of medications is a cause of medication administration errors and this may have serious legal implications for the anaesthetist. The use of multi-dose vials in both general and anaesthetic practice remains controversial, and more studies with a larger sample size are required to establish whether this practice increases the risk of clinically significant infection.

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*Conflict of interest* – The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this paper.

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