Original article

Bacterial contamination of blood products for transfusion in the Democratic Republic of the Congo: temperature monitoring, qualitative and semi-quantitative culture

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Background - Bacterial contamination of blood for transfusion is rarely investigated in low-income countries. We determined the contamination rate of blood products in the Democratic Republic of the Congo.

Material and methods - In this prospective observational study, blood products in one rural and two urban hospitals (paediatric and general) contained a satellite sampling bag by which blood was sampled for culture in a blood culture bottle (4 mL) and on an agar-coated slide to estimate colony forming units (CFU/mL). Bacteria were identified with biochemical tests and MALDI-TOF (Bruker). Exposure time >10 °C was assessed on a subset of blood products.

Results - In total, 1.4% (41 of 2,959) of blood products were contaminated with 48 bacterial isolates. Skin (e.g., *Staphylococcus* spp.) and environmental (e.g., *Bacillus* spp.) bacteria predominated (97.8% of 45 isolates identified). Bacterial counts were ≤10^3 CFU/mL. Contamination rates for the urban paediatric, urban general and rural hospitals were 1.6%, 2.4% and 0.3%, respectively (p=0.004). None of the following variables was significantly associated with contamination: (i) donor type (voluntary 1.6%, family 1.2%, paid 3.9%); (ii) type of blood product (red cells 1.6%, whole blood 0.6%); (ii) season (dry season 2.4%, rainy season 1.8%); (iv) age of blood product (contaminated 8 days *vs* non-contaminated 6 days); and (v) exposure time >10 °C (median for contaminated and non-contaminated blood reached maximum test limit of 8 hours).

Discussion - A bacterial contamination rate of 1.4% of whole blood and red cells is similar to results from high-income countries. Implementation of feasible risk-mitigation measures is needed.

Keywords: *bacterial contamination, blood safety, blood transfusion, Africa South of the Sahara, Democratic Republic of the Congo.*

INTRODUCTION

In Africa, 5.6 million blood donations are collected every year. Progress has been made to assure blood safety regarding the four infection markers: human immunodeficiency virus, hepatitis B virus, hepatitis C virus, and syphilis[1]. Other transfusion-transmitted

Arrived: 21 April 2020
Revision accepted: 18 June 2020
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Blood Transfus 2020; 18: 348-58 DOI 10.2450/2020.0108-20

infections, such as bacterial infections, are rarely studied in low-income countries, despite the fact that, in high-income countries, bacteria are a leading risk of infection from blood transfusion[2]. Bacterial contamination rates have been seriously underestimated in sub-Saharan African, as evidenced by studies demonstrating rates between 0.3% to 17.5% (*Online Supplementary Content*, **Table SI**)[3-17]. To date, no studies have investigated bacterial contamination of blood in Central Africa. We aimed to determine the bacterial contamination rate in blood products in three hospitals in the Democratic Republic of the Congo (DRC), investigate associated factors, and assess bacterial counts.

MATERIALS AND METHODS

Study sites

The DRC is the second most populated country in sub-Saharan Africa (84 million inhabitants), with 70% living in rural areas[18,19]. Blood transfusion is managed by the National Blood Transfusion Centre (Centre National de Transfusion Sanguine, CNTS, Kinshasa) as part of the Ministry of Health, and works as a decentralised organisation with transfusion centres at provincial and reference hospitals and at health posts. For this multi-centric, prospective, observational study, the blood banks of three hospitals in the DRC were selected.

The Hôpital Pédiatrique Kalembe Lembe is a 150-bed children's hospital in Kinshasa, with a 96% bed occupancy and around 1,500 blood products distributed from the CNTS in 2018, hereon referred to as "urban paediatric hospital".

The Hôpital Provincial Général de Référence is a 2,000-bed urban referral hospital in Kinshasa with a 70% bed occupancy and 6,922 blood donations in 2018, hereon referred to as "urban general hospital". The hospital relied on a self-supporting blood bank supply.

The Hôpital Saint-Luc Kisantu is a 340-bed referral hospital in the rural area of Kisantu, with a 95% bed occupancy, hereon referred to as "rural hospital". This hospital was supported by multiple external partners and relied on an on-site blood bank, with 4,893 donations in 2018.

In all blood banks, donors were asked about their general health, fever, recent surgery, and possible wounds, but donor temperature was not taken.

Blood collection, blood product sampling and Timestrip monitoring

During the study, we did not interfere with the hospitals' antiseptic, venepuncture or blood processing procedures. Donor skin was disinfected with povidone-iodine (rural hospital) or denatured ethanol 70% (CNTS and urban general hospital) and no diversion pouches were used. At the CNTS and urban general hospital, red cells were prepared by manual removal of plasma to a waste container (open system) or to a secondary blood bag (closed system). The rural hospital only used the closed system.

Red cells and whole blood were sampled for culture between July 2018-February 2019 covering both the rainy (October through May) and dry (June through September) seasons. Serologically disqualified blood products were excluded.

At the CNTS, a satellite sampling bag (PB-1TR050M6B, Terumo BCT Europe N.V., Zaventem, Belgium) was sealed (TSCD-II, Terumo BCT Europe N.V.) to all blood products before shipment to the urban paediatric hospital. In the urban general and rural hospital, double blood bags containing a satellite sampling bag (PB2CD456M0B and 8PB2CD356M0B, Terumo BCT Europe N.V.) were used for blood donation (**Figure 1**).

A Timestrip label (TP153, Timestrip UK Ltd., Cambridge, UK) was activated and attached to the bottom of the blood product to monitor product temperature (**Figure 1,** *Online Supplementary Content*, **Figure S1**).

At compatibility testing or expiration, Timestrip results were recorded on a scale from 0 to 8 hours (h). The satellite sampling bag was filled with approximately 16 mL of blood from the main bag and disconnected with a sterile sealer or, in case of power failure, by cutting between two tubing knots. Satellite bags were refrigerated and transported daily to the bacteriology laboratory for culture (Institut National de Recherche Biomédicale in Kinshasa or hospital bacteriology laboratory in Kisantu).

Blood culture inoculation

Blood product samples were processed in the biosafety cabinet (urban hospitals) or next to a Bunsen burner flame (rural hospital). Blood was cultured qualitatively and semi-quantitatively.

For qualitative culture of blood from the paediatric hospital, 4 mL of blood (0.8-1.6% of 250-450 mL total blood volume) were inoculated into a blood culture bottle (BacT/ALERT PF, bioMérieux, Marcy-L'Etoile, France),

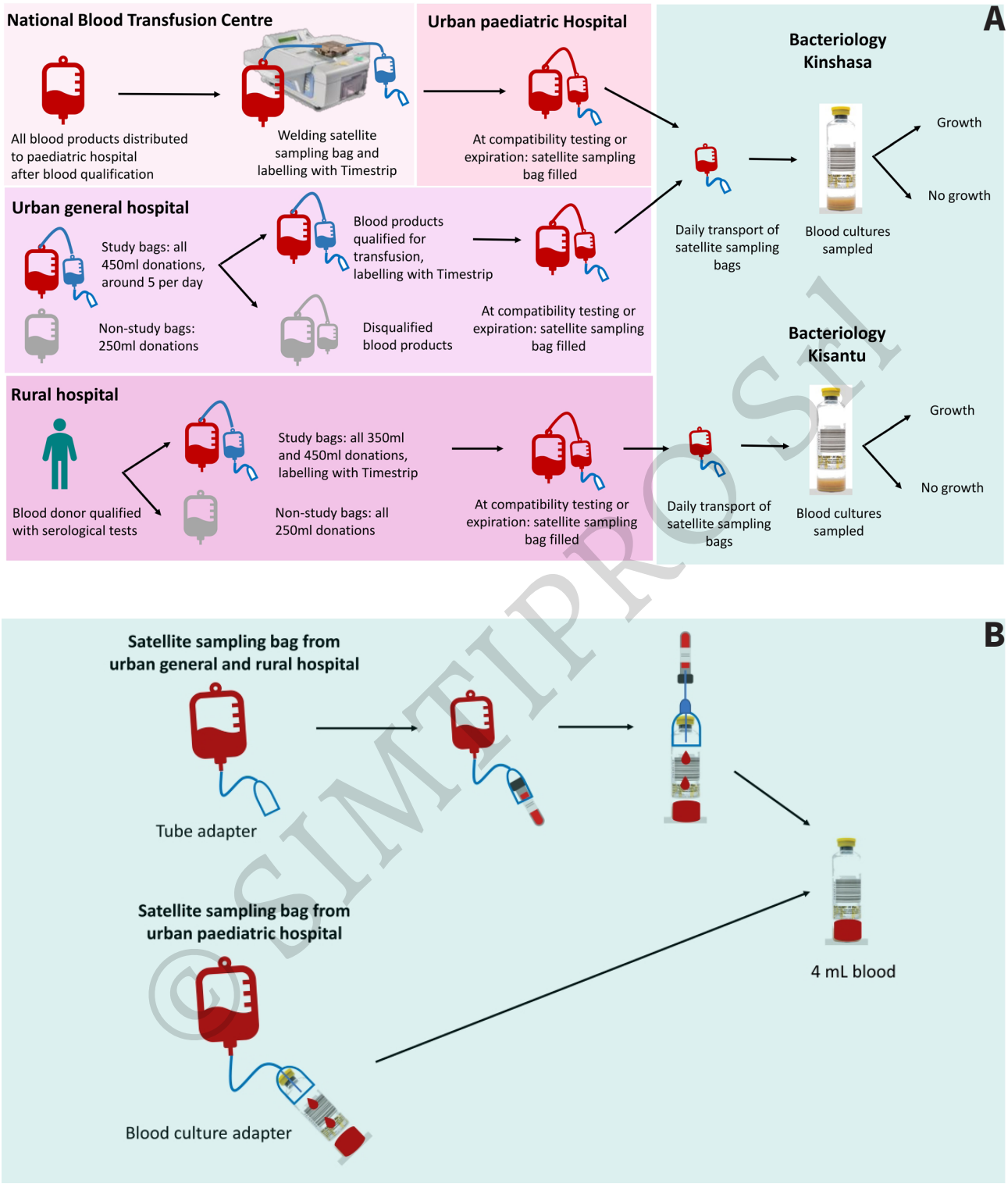

Figure 1 - Study flow of blood product sampling and culture
(A) Flow of blood product sampling in the three study hospitals, the National Blood Transfusion Centre, and the bacteriology laboratories. (B) Method of blood culture sampling from the satellite sampling bag in the bacteriology laboratory.

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allowing growth of aerobic and facultative anaerobic bacteria, *via* the adapter attached to the satellite sampling bag (**Figure 1**). For semi-quantitative culture, 2 mL of blood was sampled in a sterile plain tube and equally distributed on an agar-coated slide (C319100, Meus, Piove Di Sacco, Italy). Next, satellite sampling bags were stored at 2-6 °C until the end of analysis.

In the urban and rural hospitals, procedures were identical, except for qualitative blood culture for which 4 mL of blood were sampled in two sterile plain tubes (BD Vacutainer®, BD Benelux, Erembodegem, Belgium) before inoculation of the blood culture bottle *via* a Luer adapter (BD Vacutainer® Luer adapter, BD Benelux).

Qualitative culture

Blood culture bottles were incubated in a regular incubator at 35 °C for 7 days, and mixed and monitored for signs of growth daily[20]. As a control for no-growth, 20% of blood cultures underwent terminal sub-culture on Columbia 5% sheep blood agar (BD Benelux; Oxoid, Hampshire, UK) at day 7. Every blood culture with signs of growth was sub-cultured on Columbia 5% sheep blood agar (BD Benelux; Oxoid) and MacConkey agar (BD Benelux; Oxoid), followed by species identification using standard biochemical tests. For every grown blood culture, a repeat blood culture bottle was sampled (1-4 mL) from the stored satellite sampling bag and processed as described above.

Semi-quantitative culture

Before the study, 2-sided urine culture slides coated with cysteine-, lactose, and electrolyte-deficient agar and MacConkey agar were validated for use on blood. After inoculation with blood (see above), slides were incubated at 35 °C for 24-48 h. Bacterial counts were estimated according to the product insert, with no visible growth for counts $<10^3$ colony forming units (CFU)/mL.

Identification and storage of isolates

Bacterial isolates were stored in Tryptic Soy Agar (Oxoid) and shipped to the Institute of Tropical Medicine in Antwerp (Belgium) for confirmation of identification by MALDI-TOF (Bruker MALDI Biotyper, Bruker, Billerica, MA, USA) at the University Hospital of Leuven (Belgium) or by Analytical Profile Index (API 20NE, bioMérieux).

Data management and statistical analysis

Sample size was calculated with a 95% confidence level and 80% power, assuming a 5% contamination rate. Initially, a future intervention study was being considered to prove a decrease in contamination to 3%. In the present study, therefore, we aimed to collect 1,500 blood products from each study site. Recorded data were donor gender, age, type of donor (voluntary, paid or family donor), date of donation, type of product (red cells or whole blood), date of transfusion or disposal, Timestrip result, cultured blood volume, and day of culture growth. Rainfall data were taken from the Climate Change Knowledge Portal of the World Bank[19].

Data were entered into an Excel database (Microsoft, Redmond, WA, USA) and verified by a second person. Statistics were analysed with Vassarstats[21] and R (R Foundation for Statistical Computing, Vienna, Austria). Medians (Excel exclusive method) and proportions are depicted with interquartile ranges (IQR) and 95% confidence intervals (CI), respectively. As a denominator for proportions, the total number of cultured blood products with available data of the analysed variable was recorded. Differences between medians and proportions were tested by the Wilcoxon Mann-Whitney non-parametric test, Z-score, χ^2 or Fisher Exact test. The Spearman coefficient was calculated for correlation of quantitative values. A logistic regression model verified the association between bacterial contamination and a combination of variables. The Benjamini-Hochberg procedure corrected for multiple comparison; $p<0.03$ was considered statistically significant[22].

Ethical issues

Ethical approval was granted by the Institutional Review Board of the Institute of Tropical Medicine (Antwerp, Belgium), the Ethics Committee of Antwerp University, and the University Hospital of Kinshasa. Results of contaminated blood products were communicated to the blood bank biologist, who contacted the treating clinician in case of clinically relevant bacteria. For bacteria possibly originating from donor blood, the donor was asked permission for blood and skin culture.

RESULTS

Specifications of collected blood

From July 2018 to February 2019, a total of 2,959 samples were collected (**Figure 2**): 2,196 red cells and 487 whole blood samples (*Online Supplementary Content*, **Table SII**). Median (IQR) volume sampled for blood culture was 4.1 mL

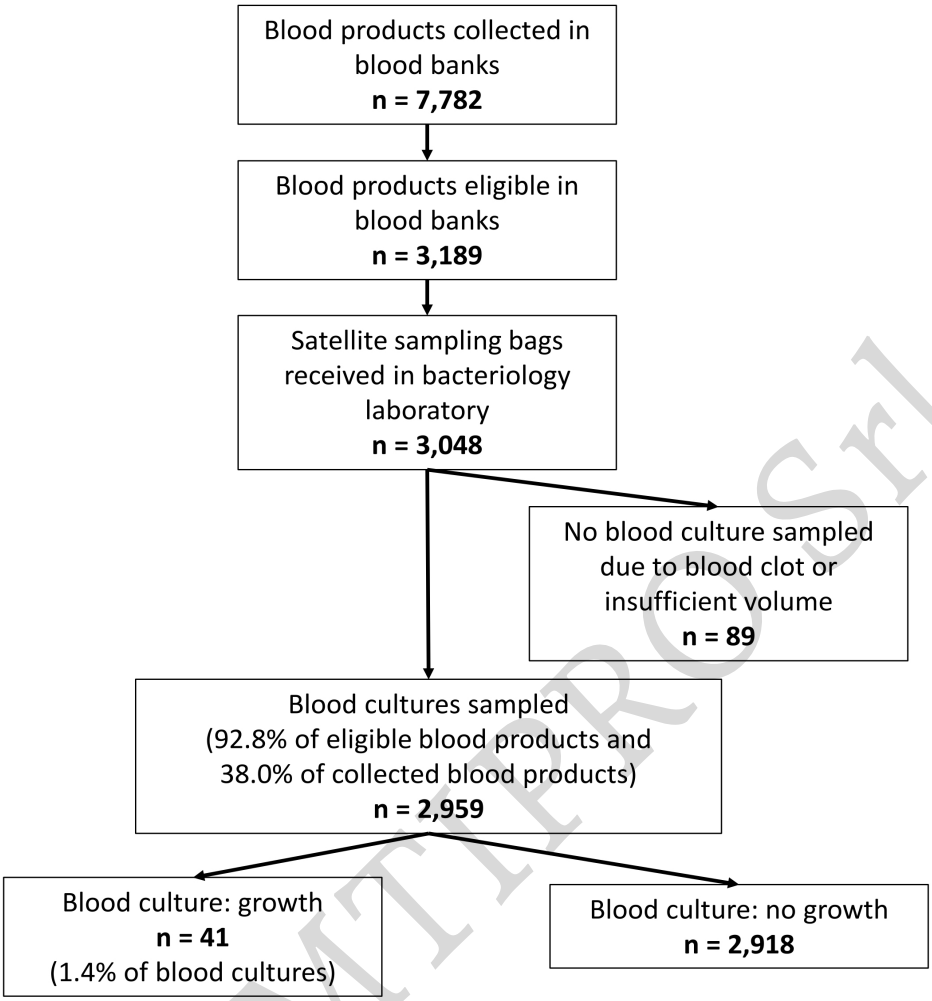

Figure 2 - Sample breakdown scheme
Eligible: blood products qualified according to sampling strategy.

(3.8-4.6) mL. Median (IQR) age of blood donors was 31.5 (25-41) years, the majority were male (87.2%, 2,347 of 2,690) and nearly two-thirds were family donors (65.6%, 1,916 of 2,921) (*Online Supplementary Content*, **Table SIII**). Median (IQR) age of cultured blood products at the time of blood transfusion was 6 days (**Table I**). *Online Supplementary* **Figure S2** shows the age of all cultured blood products. Timestrip reading results were retrieved from 2,095 blood products and correlated with the age of the blood product (r=0.43; p<0.000001) (*Online Supplementary Content*, **Figure S3**). Over half the cultured blood products for which data were available (54.4% of 2,102) were exposed to temperatures >10 °C for at least 8 h.

Differences among hospitals

Red cells accounted for 63.0% (n=655) of cultured blood products in the rural hospital compared to 99.8% (n=619) and 90.0% (n=922) in the urban paediatric and general hospital, respectively (*Online Supplementary Content*, **Table SII**). The paediatric hospital relied 100% on voluntary donors, whereas family replacement donors predominated in the urban general (79.6%, n=853) and rural (95.6%, n=1,063) hospitals. Paid donors were seen only in the urban general hospital (7.2%, n=77).

Blood products were significantly older in the urban general hospital (8.5 days) compared to the paediatric (6 days) and rural (3 days) hospitals; this difference was

Table I - *Age of contaminated* vs *non-contaminated blood products at the time of transfusion*

Blood products	Hospital			Total
	Urban paediatric	Urban general	Rural	
Total blood products (IQR)	6 days[1,2] (4-10)	8.5 days[1,3] (5-12)	3 days[2,3] (1-6)	6 days (3-10)
Contaminated blood products (IQR)	6.5 days (2.75-7.5)	9 days (6-11.75)	0 days (0-9)	8 days (4-11)
Non-contaminated blood products (IQR)	6 days (4-10)	8 days (5-12)	3 days (1-6)	6 days (3-10)
N. of contaminated blood products with available data (% of total)	12 (100% of 12)	26 (100% of 26)	3 (100% of 3)	41 (100% of 41)
N. of non-contaminated blood products with available data (% of total)	666 (91.4% of 729)	1,048 (97.3% of 1,077)	1,044 (93.9% of 1,112)	2,758 (94.5% of 2,918)

There was a significant difference in age of total blood products between all three sites. Overall, there was no significant difference in median age of contaminated and non-contaminated blood products (p=0.075), nor within the urban paediatric (p=0.78) or general (p=0.43) hospitals. Sample sizes of contaminated products in the rural hospital were too small for statistical analysis. [1,2,3]p<0.0001. IQR: interquartile range; N: number.

also significant between the paediatric and rural hospitals (**Table I**). Interestingly, in the urban hospitals, transfused blood products were older in the dry season (9 days; range, 6-13) days) compared to the rainy season (7 days; range, 4-10) days) (p<0.0001). Median (IQR) exposure times >10 °C were significantly different for all three hospitals (p≤0.0001): 8 h (range, 4-8 h) at the paediatric hospital, 8 h (range, 8-8 h) at the urban general hospital, and 5 h (range, 3-7 h) at the rural hospital (*Online Supplementary Content*, **Figure S3**).

As a general observation, there were differences in organisation of staff between the different study sites. In the rural hospital, 9 laboratory technicians rotated in the blood bank in day and night shifts, compared to 18 technicians in the urban general hospital. The CNTS had no night shifts and had a pool of "outsourced" blood sampling staff to assist mobile blood collections, as well as 4 CNTS technicians.

Blood products with bacterial growth

A total of 1.4% (41 of 2,959) of cultured blood products were contaminated with bacteria (**Table II**): all ≤10^3 CFU/mL. Repeat blood cultures showed growth for 27.8% (10 of 36) of cultures. Contamination rates were significantly higher in the urban general (2.4%) and urban paediatric (1.6%) hospitals compared to the rural (0.3%) hospital, even after correction for the variables set out below in a logistic regression (p=0.004). Apart from the hospital, none of the following variables was significantly associated with contamination: (i) donor type (voluntary 1.6%, family 1.2%, paid 3.9%, p=0.11); (ii) type of blood product (red cells 1.6%, whole blood 0.6%, p=0.13); (ii) season (dry season 2.4%, rainy season 1.8%, p=0.35); (iv) age of the blood product (contaminated 8 days *vs* non-contaminated 6 days, p=0.075); and (v) exposure time >10 °C: contaminated 8 h (range, 5.5-8 h) *vs* non-contaminated 8 h (range, 4-8 h), p=0.48 (**Table I**, **Figure 3**, *Online Supplementary Content*, **Tables SII** and **SIII**, **Figures S2** and **S3**).

Bacterial species isolated

The 41 contaminated samples yielded a total of 48 isolates, of which 45 could be identified (**Table III**). Six of 41 contaminated blood products contained more than one bacterial species. Skin bacteria (57.8%, n=26) such as coagulase-negative *Staphylococcus* spp. predominated, followed by environmental bacteria (40.0%, n=18) such as *Bacillus* non-cereus spp. Only one isolate, *Staphylococcus aureus*, potentially originated from donor blood; however, the donor had no clinical symptoms, nor growth of *Staphylococcus aureus* in blood and skin culture. Gram-negative species were rarely isolated (11.1%, n=5). Four of the five Gram-negative species originated from blood stored 10-12 days, whereas 63.5% of Gram-positive bacteria were isolated from blood products younger than 10 days.

DISCUSSION

In this study carried out in the DRC, we demonstrated among 2,959 blood products a bacterial contamination rate of 1.4%, with bacterial counts ≤10^3 CFU/mL. The majority of species were skin flora and environmental bacteria. None of the factors assessed for association with contamination reached statistical significance (type and age of blood product, type of donor, season, exposure time

Table II - *Growth of first and repeat blood cultures*

Culture		Hospital			Total
		Urban paediatric	Urban general	Rural	
First culture	Growth (n)	12	26	3	41
	Growth (%) (on total first cultures, 95% CI)	1.6%[2] (0.9-2.9)	2.4%[1] (1.6-3.5)	0.3%[1,2] (0.07-0.9)	1.4% (1.0-1.9)
	Total first cultures	741	1,103	1,115	2,959
Repeat culture	Growth (n)	0	10	0	10
	Growth (%) (on total repeat cultures)	0.0%	41.7%	0.0%	27.8%
	Total repeat cultures (% of growth in first cultures)	9 (75.0%)	24 (92.3%)	3 (100.0%)	36 (89.5%)

[1]p<0.0001, [2]p=0.004. n: number; CI: confidence interval.

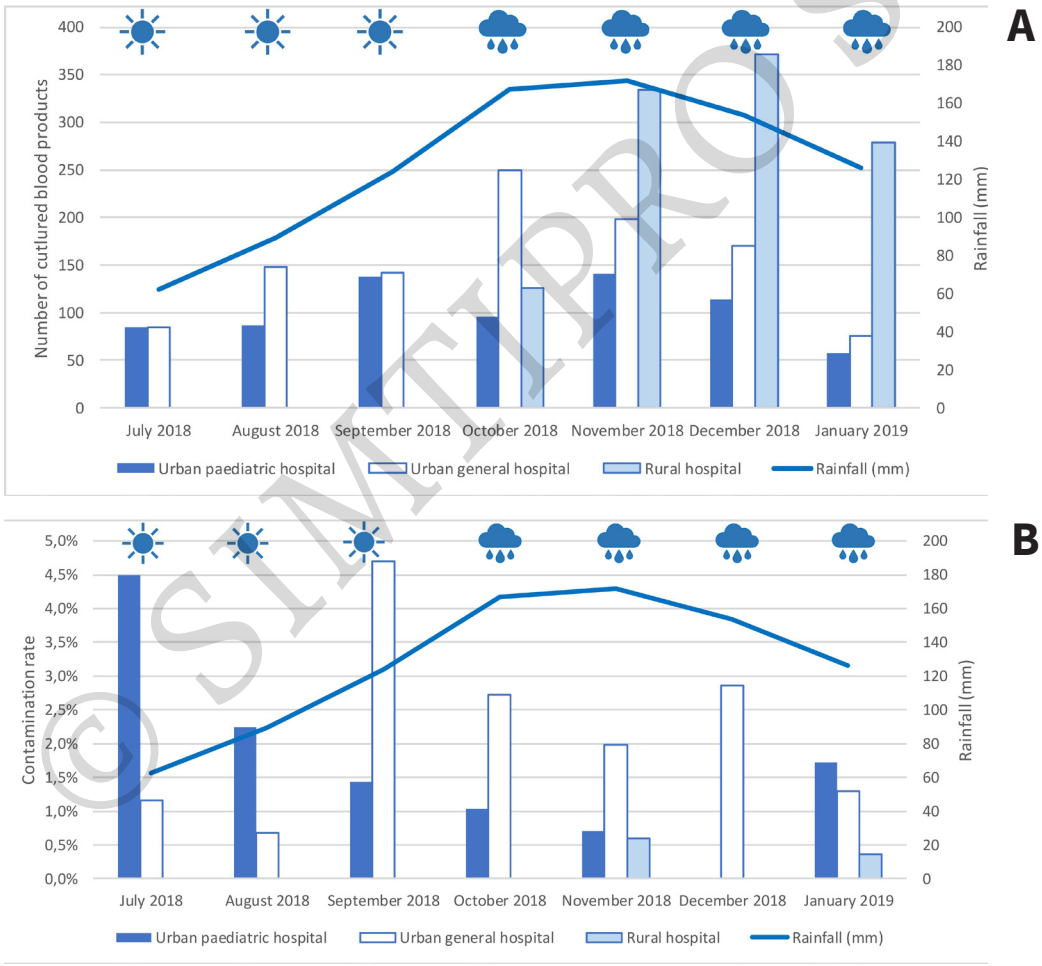

Figure 3 - Average rainfall *vs* number of cultured blood products and contamination rate per month of donation, per hospital

(A) Data were available for a total of 2,897 cultured blood products (97.9% of 2,959 samples). (B) Contamination rate of 41 blood products. There was no significant difference in contamination rates between dry *vs* rainy season (p=0.35).

Urban paediatric (dark blue), urban general (white), rural (light blue), average monthly rainfall in mm (line), rainy (cloud) and dry (sun) seasons.

Blood Transfus 2020; 18: 348-58 DOI 10.2450/2020.0108-20

Table III - *Bacterial species isolated from blood products, grouped according to possible origin*

Species	N. of bacterial isolates per hospital				Median (min-max) age of blood (days)
	Total	Urban paediatric	Urban general	Rural	
Donor blood	1 (2.2%)				
Staphylococcus aureus	1	/	1	/	3
Donor skin	26 (57.8%)				
Coagulase-negative Staphylococcus spp.	22	4	17[1]	1	8 (2-18)
Dermabacter hominis	1	1	/	/	15
Corynebacterium aurimucosum	1	1	/	/	15
Microbacterium spp.	2	1	/	1	2.5 (0-5)
Environment	18 (40.0%)				
Gram-positive	12 (26.7%)				
Bacillus cereus	2	/	2[1]	/	2 (1-3)
Bacillus spp. (non-cereus)	8	4	4[1]	/	8 (2-12)
Paenibacillus massiliensis	1	/	/	1	0
Rhodococcus rhodochrous	1	/	1	/	8
Gram-negative	5 (11.1%)				
Pseudomonas fluorescens	1	/	1	/	11
Klebsiella pneumoniae	1	/	1[1]	/	11
Cupriavidus spp.	1	/	1	/	12
Acidovorax temperans	1	/	1	/	10
Moraxella osloensis	1	/	1	/	4
Fungus	1 (2.2%)				
Aspergillus niger	1	/	1	/	13
Other	3				
Gram-positive rods	1	1	/	/	7
Gram-positive coccobacilli	1	1	/	/	13
No identification possible (no growth on subculture)	1	/	1	/	4
Total	48	13	32	3	

Age of blood at the time of transfusion is expressed in days with their range (min-max), if applicable. Percentages are calculated on the total number of identified isolates (excluding "other"). [1]Repeat blood cultures confirmed growth of first blood culture for eight coagulase-negative *Staphylococcus* spp. in seven cultures, one *Bacillus cereus,* one *Bacillus subtilis*, one *Klebsiella pneumoniae.*

>10 °C) except for the hospital: contamination rates in the rural hospital (0.3%) were significantly lower compared to the urban general and paediatric hospitals (2.4% and 1.6%, respectively).

The strengths of the study were the use of a closed sampling bag preventing contamination during sampling and its high sample size (close to 3,000 blood products), i.e., almost 6-fold more than in previous studies in sub-Saharan Africa (*Online Supplementary Content*, **Tables SI**)[12]. Furthermore, temperature of individual blood bags was tracked and bacterial counts were assessed, procedures which were not adopted in previous studies. A major limitation was the inherent low sensitivity of the culture-based method, with a volume of 4 mL sampled *vs* 2×8 mL processed in high-resource settings[23]. Semi-quantitative culture slides had a limit of detection of 10^3 CFU/mL; however, this is sufficient to detect concentrations above and below the clinically significant threshold of 10^5 CFU/mL[24,25]. Negative blood cultures at repeat sampling can be explained by reduced survival of bacteria during the extended cold storage of the satellite sampling bag (self-sterilisation), and by sampling error due to low bacterial counts[26]. Although the risk of first blood culture contamination during sampling was minimised, it was not completely excluded[27]. Conversely, the ten repeat cultures with growth consistently yielded

the same species as in the first sample, confirming the actual contamination of the product. Furthermore, the Timestrip precluded monitoring beyond its maximum scale of 8 h and the study period spanned only part of a single calendar year, precluding reliable assessment of seasonal effects.

The bacterial contamination rate in our study was lower than those previously reported in sub-Saharan Africa (0.3-17.5%) (*Online Supplementary Content*, **Tables SI**)[3-17]. Four studies also described low contamination rates (0.3-3.5%), with three of them giving special attention to aseptic sampling and/or the use of commercial culture bottles[9,12,13,16]. Most other studies relied on needle perforation of tubing for sampling and used homemade blood cultures with blind subculture, which imply a risk of introducing bacteria during laboratory procedures[28].

Most species we isolated were common skin (*Staphylococcus* spp.) and environmental (*Bacillus* spp.) contaminants. *Bacillus* spp. are dust-related; these are more frequent in tropical environments, and can form highly resistant spores which can survive initial skin antisepsis procedures[29,30]. Some species can be highly pathogenic, e.g., toxin-producing *Bacillus cereus*[31,32]. Similarly, *Klebsiella pneumoniae* isolated from one blood product is typically found in tropical environments and reported to be a leading cause of nosocomial bloodstream infections, also in the DRC[33,34]. Furthermore, one *Staphylococcus aureus* was isolated, which can cause severe transfusion-related sepsis. *Staphylococcus aureus* may be part of donor skin flora and occasionally causes transient bacteraemia[35].

In addition, species rarely observed in clinical samples or blood products were identified: *Acidovorax temperans,* environmental Gram-negative bacteria formerly belonging to the *Pseudomonas* genus; *Cupriavidus* spp., copper-resistant environmental Gram-negative rods; *Moraxella osloensis*, a Gram-negative coccobacillus which is part of the respiratory tract microbiome; *Rhodococcus rhodochrous,* an environmental Gram-positive coccobacillus that can survive in adverse conditions*; Dermabacter hominis,* a coryneform rod of human skin flora; and one environmental fungus, *Aspergillus niger*[36].

In previous studies, cold-tolerating Gram-negative organisms, e.g., *Pseudomonas fluorescens*, were more frequently detectable after proliferation during storage[37,38]. Interestingly, all four Gram-negative rods isolated in our study originated from blood stored for 10-12 days, whereas the majority of Gram-positive bacteria were isolated from younger blood products. However, despite the challenge of maintaining the cold chain during storage and transport, all bacterial counts in the present study fell ≤10^3 CFU/mL, i.e., below the clinically significant threshold for higher risk and severity of clinical transfusion reactions (10^5 CFU/mL)[24,39]. These counts were in line with previous studies on spiked red cells, as it can take weeks for bacteria to reach concentrations above 10^3 CFU/mL and most cultured blood products in the present study were younger than 10 days[26,40].

Indeed, low-resource settings face challenges in the management of all four factors influencing bacterial contamination: (i) extent of exposure; (ii) ability to reduce this exposure; (iii) prevention of introduction of bacteria in the blood bag; and (iv) limitation of survival of introduced bacteria[35,41].

Hospital environments in low-resource settings may have high bacterial loads due to less efficacious cleaning procedures[42]. In addition, the rainy season, with its upsurge in malaria, may be associated with higher contamination rates probably linked to a higher blood demand and heavier workload[10]. In the present study, paid donors tended to have a higher proportion of contaminated blood products, but a study from Ghana did not confirm an association with type of donor[4].

Leading guidelines recommend an alcohol-based product for skin antisepsis[43,44], but the rural hospital, which used water-based povidone-iodine, had the lowest contamination rate. Moreover, none of the hospitals used diversion pouches, which have been proven to significantly reduce contamination rates[17,45]. Bacteria may also be introduced by inappropriate procedures such as re-pricking of the donor, cutting tubing to prepare blood components, and making knots in the tubing instead of sterile sealing[10,35]. Once bacteria have entered the blood bag, limited storage time and a proper cold chain reduce bacterial survival[35]. Although not reaching statistical significance, contaminated blood products in our study were older than non-contaminated blood. This association was noted in a study from Ghana, with a significantly higher contamination rate in blood products older than 10 days (27.3%) compared to younger products (10.2%)[4]. High temperatures and power failure are common and

challenge the cold chain, as shown in the present study: over half the samples had been exposed to >10 °C for at least 8 h, whereas in high-resource settings, the tolerance limit is 60 minutes[23].

The significantly higher contamination rate in two urban hospitals *vs* the rural hospital is probably multifactorial as none of the individual factors alone was significantly associated with contamination. Compared to the rural hospital, blood products transfused in the urban hospitals were older and exposed to >10 °C for longer, but also their pool of laboratory technicians was larger and more variable. Furthermore, all Gram-negative environmental bacteria and the majority of coagulase-negative *Staphylococcus* spp. originated from the urban general hospital, which suggests a higher bacterial exposure in this hospital.

The present 1.4% contamination rate is seemingly low when compared to previous publications in sub-Saharan Africa, but is similar to cross-sectional studies on contamination of red cells or whole blood in high-income countries (0.18-2.2%)[46-49]. However, in a rural hospital such as Kisantu Hospital (see above, nearly 5,000 transfusions yearly) this would correspond to one contaminated transfusion per week. Albeit mostly skin and environmental contaminants, and present in low concentrations, the bacterial species recovered are still dangerous for children under 5 years of age and childbearing women, who together represent the main transfused population in sub-Saharan Africa[1]. Furthermore, our results may underestimate contamination rates in the rest of the DRC, as they were obtained from better-served hospitals and practices are site-dependent. Therefore, haemovigilance in the DRC should be a focus for further research, in addition to a site-adapted risk analysis and evaluation of skin antisepsis and diversion pouches to reduce contamination rates.

CONCLUSION

Although the bacterial contamination rate of blood products in the DRC was lower than previously reported in sub-Saharan Africa, it is similar to cross-sectional contamination rates of whole blood and red cells in high-income countries. As contamination rates were hospital-dependent, site-adapted and feasible risk-mitigation measures need to be implemented to reduce them.

ACKNOWLEDGEMENTS

The authors are grateful to all blood donors and staff of the CNTS and study hospitals. In addition, we thank the Institut National de Recherche Biomédicale in Kinshasa, and specifically the bacteriology team, for their support in the organisation of the study. We also thank the Belgian Red Cross-Flanders for material support, input and feedback during the study set-up and manuscript writing. Finally we acknowledge Sien Ombelet for her assistance in statistical analyses.

FUNDING AND RESOURCES

A-SH was supported by Research Foundation - Flanders with travels and a PhD grant strategic basic research (number 37174).

Database access

To access the research database, a Data Access Request Form needs to be sent to ITMresearchdataaccess@itg.be, contact point at the Institute of Tropical Medicine, Antwerp, Belgium. All requests will be reviewed for approval by the Data Access Committee. Further information: https://www.itg.be/E/data-sharing- open-access.

AUTHORSHIP CONTRIBUTIONS

This study was designed by A-SH, JJ, OL and JeK. Data were collected and laboratory work was performed by A-SH, NN, JoK, AL, DK, CA and KL. Data were analysed by A-SH, JoK, NN and interpreted by A-SH, JJ, OL and PV. Finally, A-SH drafted the work. All authors critically revised the work and approved the final version.

The Authors declare no conflicts of interest.

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