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Bacterial contamination of single and multiple-dose parenteral injection vials after opening and antibiotic susceptibility of isolates at Jimma Medical Center, Jimma, Southwest Ethiopia

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SUMMARY

Background: Single- or multiple-dose vials are prone to bacterial contamination after improper handling and can be potential reservoirs of microorganisms that could be transmitted to the patient through the parenteral route. The present study aims to assess the magnitude of the problem and associated factors at Jimma Medical Center (JMC), Jimma, Southwest Ethiopia.

Methods: A cross-sectional study design was conducted at JMC from July 2021 to October 2021. A total of 384 parental medications and nurse interviews that were administered in 11 wards and 3 intensive care units were included. Samples were processed and identified by conventional bacterial culture methods.

Results: The overall prevalence of vial contamination due to aerobic bacteria was 21 (5.5%) among multiple-dose vials and none of the single-dose vials. The highest level of contamination (8, 38.1%) was found in the paediatric ward. *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* were the most common microorganisms identified vial contamination, 6 cases (28.5%) and 5 cases (23.8%) respectively Multidrug resistance was identified in 95.2% of the isolates, with all Gram-negative isolates showing a multidrug resistance against the tested antibiotics. In multivariate logistic regression analysis, vial contamination was strongly associated with reuse of syringe and/or needle, the environment where medication was handled, and the storage conditions.

Conclusion: In this study, the prevalence of vial contamination was high. The bacterial isolates from vials were also resistant to commonly prescribed antimicrobial drugs. Healthcare professionals must strictly adhere to basic infection control practices as per standard guidelines to reduce the risk of infection from contaminated vials.

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Introduction

Injectable drugs are widely used to prevent, diagnose, and treat various diseases in healthcare settings [1]. This includes chemotherapy, intravenous antibiotics, vaccines, and medications used for anaesthesia. Medical injections are also used in conjunction with surgery, endoscopy, pain control, and cosmetic or complementary and alternative medical procedures [2]. Injectable medication must be sterile and safe manufacturing and pharmacy practices to maintain sterility are important [3]. The required medication must be prepared safely and administered in a manner that maintains sterility and which minimises the risk of infection. Safe administration relies on compliance with the protocols detailed in guidelines from the Centers for Disease Control and Prevention (CDC) [4].

According to the CDC, injection safety has been recognised, predominantly in low- and middle-income countries, as a public health concern [5]. Approximately 20 million new hepatitis B virus (HBV) infections, 2 million new hepatitis C virus (HCV) infections, and 250,000 new human immunodeficiency virus (HIV) infections have been included in the estimated global burden of illness associated with unsafe injections since 2000 [6]. In recent years, the number of outbreaks due to unsafe injection procedures was reported to have increased in the United States [1].

In addition, a report from The Joint Commission in 2014 described that at least 49 outbreaks had occurred since 2001 because of the mishandling of injectable medical items [7]. HBV or HCV transmission was involved in 21 of these outbreaks. The other 28 were outbreaks of bacterial infections, mostly invasive bloodstream infections [7]. Although many of these outbreaks occurred in hospital settings, a high percentage occurred in pain management clinics, where injections are often given into the spine and other sterile areas using preservative-free medicines, and in cancer clinics that typically provide chemotherapy or other infusion services to patients who may be immunocompromised [1,7]. Moreover, during this period, more than 150,000 patients were required to undergo blood-borne pathogen testing after their potential exposure to unsafe injections [1,7].

The CDC is aware that the misuse of single dose vials *(*SDVs) has been associated with at least 19 outbreaks of blood-borne and bacterial infections since 2007 [7]. Seven were blood-borne pathogen infections, and twelve were bacterial infections. Most of these outbreaks occurred in the outpatient setting, while eight occurred in pain remediation clinics [1,7]. These examples probably underestimate the harm resulting from the misuse of SDVs. Due to the difficulties of tracing the misuse of vials, the adverse effect of misusing a vial is usually not observed immediately [8]. Adverse effects related to unsafe injection procedures and lapses in infection management practices are underreported, and it remains a challenge to quantify the true incidence of such occurrences [7].

According to a study conducted in the anesthesiology unit in South Africa, 6.4% multiple-dose vial *(*MDV) microbial contamination was identified [9]. In a major teaching hospital in Shiraz Iran, 5.6% bacterial contamination was identified with no difference in contamination rate among different wards or medication types [10]. Similarly, 5.36% microbial contamination was identified in SDVs and MDV in a respiratory diseases teaching hospital in Tehran, Iran [11].

To the best of our knowledge, there has been limited research conducted specifically on the bacterial contamination of single- and multiple-dose parenteral injection vials after opening and the antibiotic susceptibility of the isolates. The aim of this study was to assess bacterial contamination of single- and multiple-dose parenteral injection vials after opening, the antibiotic susceptibility of the isolates and the associated risk factors at Jimma Medical Center, Jimma, southwestern Ethiopia.

Methods

Study design & setting

The study was conducted at Jimma Medical Center (JMC). JMC is one of the oldest public hospitals found in the town of Jimma in the Oromia regional state, Ethiopia. The JMC is a referral hospital which serves 20,000 inpatients annually, with 205,000 outpatient visits, and 11,000 emergency cases. JMC is categorised into different departments (units) for service provision. The units have inpatient as well as separate outpatient departments. An institution-based cross-sectional study was conducted at JMC from July 2021 to October 2021.

Study samples

The samples in this study comprised single- and multiple-dose vials of parenterally administered solutions for therapeutic purposes from all wards and three intensive care units (ICUs) of JMC during the study period. Solutions which were excluded were those for immunisation and contraceptive purposes.

Sampling technique

A consecutive sampling technique was applied until the desired sample size was reached. To avoid sampling bias, samples that have some common similarities were coded to avoid repeating the same vial.

Data collection and instrument

A pretested self-administered questionnaire was used to collect factors that may cause vial contamination by attending nurses. Data were collected from a total of 384 nurses who were working in the department where the samples were collected. The questionnaires were collected from medical, surgical, paediatrics, ophthalmology, neonatology, maternity, gynaecology, orthopedics, oncology, psychiatry, ~~and~~ maxillofacial wards and three ICUs: medical, adult, and paediatric ICUs.

During data collection, each sample was labelled with a specific serial number; the detailed labelling of this information was recorded in a separate sheet for details of each sample including the date and time of sample collection, the name of the medication, ward, type of dose, preservative status, date and time of opening or preparation, storage condition, and expiration date of the vials.

All SDVs and MDV injectable drugs that had been opened and were currently in use were well mixed before sampling, and the rubber stoppers were swabbed with 70% alcohol. Using sterile techniques, the vials were inverted, and 100 μL of the medication was withdrawn with a sterile 1mL insulin syringe. Then,

the sample was immediately transported to the microbiology laboratory.

Bacterial isolation and identification

The sample was inoculated onto blood and MacConkey media (Oxoid, United Kingdom) by the streak plate technique and then incubated at 37 °C for 24 hr. All bacterial growth was examined for colonial morphology, Gram staining, type of haemolysis on blood agar, and standard confirmatory identification tests according to the guidelines of the Clinical and Laboratory Standards Institute (CLSI). Conventional biochemical tests, such as catalase and coagulase tests, were used for the identification of Gram-positive bacteria. Gram-negative bacteria were identified by using conventional biochemical media (Oxoid, UK), such as÷ triple sugar iron agar, urea agar, citrate agar, lysine iron agar, SIM (sulfur, indole, and motility) agar and oxidase tests [12].

Antimicrobial susceptibility testing on bacterial isolates

Antimicrobial susceptibility testing was carried out using Kirby-Bauer's disc diffusion technique on Muller-Hinton agar (MHA) according to CLSI [13]. The drugs tested for bacteria included gentamicin (CN-10 μg), ciprofloxacin (CIP-5 μg), trimethoprim/sulfamethoxazole (SXT-25 μg), ceftazidime (CAZ-30 μg), meropenem (MEM-10 μg), imipenem (IMI-10 μg), ampicillin (AMP-30 μg), chloramphenicol (CLR -30 μg), tetracycline (TET-30 μg), amikacin (AMI-30 μg), ceftriaxone (CTR-30 μg), cefoxitin (CFO-30 μg), clindamycin (CLI -2 μg), penicillin (P-10 U) and erythromycin (ERY-15 μg) [13]. The diameter of inhibition around the discs was measured to the nearest millimeter and interpreted as sensitive (S), intermediate (I), or resistant (R) according to the defined breakpoints of CLSI [13].

Data quality control

The reliability of the study findings was ensured by implementing recommended quality control measures throughout the whole process of the laboratory work. All materials, equipment, and procedures were adequately controlled. Aseptic techniques were used in all steps of specimen collection, transportation, and inoculation onto culture media to minimise contamination. All culture plates were prepared according to the directions of the manufacturers. From the prepared media, 5% were incubated at 37 degrees Celsius overnight if there was any contamination or not. Different American Type Culture Collection (ATCC) bacterial strains (such as *Escherichia coli* (ATCC 25922), *S. aureus* (ATCC 25923), *Pseudomonas aeruginosa* ATCC 27853, *Proteus mirabilis* ATCC 35659, *Klebsiella pneumoniae* ATCC 700603, and *Salmonella enteritidis* ATCC 13076) were used to ensure quality control of culture plates, biochemical test media and antimicrobial susceptibility testing discs [14].

Statistical methods and data analysis

Data entry was performed using EpiData version 3.1 and then double-checked and exported to SPSS version 23 for further analysis. Frequencies and percentages were calculated to summarise the results and are presented in tables and figures. The association of dependent and independent variables and the strength of associated factors were determined using bivariate logistic regression. A variable showing a statistically significant association (*P* value less than 0.25) was further analysed for multivariate logistic regression, and a *P* value of less than 0.05 was considered statistically significant.

Table I
Sociodemographic characteristics of nursing staff at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021

Variables		Frequency	Percentage
Sex	Female	228	59.4
	Male	156	40.6
Age	≤32	228	59.4
	>32	156	40.6
Ward	Medical	56	14.6
	Paediatrics	47	12.2
	Surgical	45	11.7
	Ophthalmology	32	8.3
	Neonatology	31	8.1
	Maternity	26	6.8
	Gynaecology	24	6.3
	Oncology	22	5.7
	Orthopaedics	20	5.2
	Maxillofacial	15	3.9
	Psychiatry	12	3.1
	Adult ICU	24	6.3
	Paediatric ICU	18	4.7
	Medical ICU	12	3.1
Work Experience	≤6	231	60.2
	>6	153	39.8

Ethics

Ethical clearance was obtained from the Jimma University Ethical Review Board. After adequately explaining the objective and purpose of the study, permission was granted from the JMC administrative body and from the patient or patient family to withdraw samples from vials. The interviews were conducted after written consent was obtained from the nurses. Vials with a positive result were communicated to their respective health professionals.

Results

Socio-demographic characteristics of the participants

A total of 384 nurse participants were included during the study period to collect data associated with vial contamination. Of these participants, 228 (59.4%) were females, and 156 (40.6%) were males. Their ages ranged from 24 to 64, with a mean age of 32 years and a standard deviation of 6.05 years. The mean work experience of the participants was 6 years, and the majority of them had less than six years' work experience (231, 60.2%). Data were collected from eleven wards and three ICUs (Table I).

Table II
Name of medication, ward and the respective number of sampled vials at JMC, Jimma, Southwest, Ethiopia, from July 2021 to October 2021

Medication	Ward/unit	Respective number of sampled vials	Frequency	Percent (%)
Ceftriaxone	Paediatric, Medical, Surgical, Orthopaedic, Maternity, Gynaecology, Neonatology, Maxillofacial, Ophthalmology, Pedi ICU, Oncology and Adult ICU	16,4,13, 17,11,7, 8,13,3,6, 7,2	107	27.9
Ceftazidime	Paediatric, Neonatology, Ophthalmology, Oncology, Paediatric ICU	6, 1,7,1,2	17	4.4
Vancomycin	Paediatric, Medical, Surgical, Neonatology, Ophthalmology, Paediatric ICU, Oncology and Adult ICU	6,2,2,3,9,7,3,1	33	8.6
R insulin	Paediatric, Medical, Medical ICU	6,11,2	19	4.9
NPH insulin	Medical, Neonatology, Medical ICU	10, 2, 2	14	3.6
NaCl (normal saline)	Paediatric, Medical, Surgical, Maternity, Neonatology, Gynaecology, Paediatric ICU, Medical ICU, Oncology	12,1,9, 3,4,2, 4,3,8	46	12
Dextrose 5%	Paediatric, Surgical, Maternity, Neonatology, Paediatric ICU, Oncology	2,4,1,1,3,6	17	4.4
Sodium lactate	Paediatric	1	1	0.3
Frusamide	Medical	3	3	0.8
Metronidazole	Paediatric, Medical, Surgical, Orthopaedic, Maternity, Gynaecology, Neonatology, Maxillofacial, Pedi ICU, Oncology	2,8,8,9,5,9,3,4,2,1	51	13.3
Propofol	Surgical, Operation room and anaesthesiology	1,2	3	0.8
Ketamine	Surgical, Adult ICU, Operation room	1,2,3	6	1.6
Thiopentone	Operation room and anaesthesiology	1	1	0.3
Suxamethonium	Surgical, Operation room and anesthesiology	2,1	3	0.8
Vecuronium	Operation room and anesthesiology	1	1	0.3
Morphine	Paediatric ICU, Paedicatric oncology and Adult ICU	1,1,1	3	0.8
Pethidine	Operation room and anaesthesiology	1	1	0.3
Metoclopromide	Operation room and anaesthesiology	1	1	0.3
Atropine	Operation room and anaesthesiology	1	1	0.3
Ciprofloxacin	Surgical, Paediatric oncology	2, 1	3	0.8
Gentamicin	Paediatric oncology	1	1	0.3
Heparin	Medical, Surgical, Orthopaedic, Medical ICU	13,2,2,1	18	4.7
Potassium chloride	Surgical	1	1	0.3
Dexamethasone	Neonatology, Paediatric ICU	1,2	3	0.8
Hydrocortisone	Paediatric ICU	2	2	0.5
Calcium gluconate	Neonatology	1	1	0.3
Ampicillin	Pediatric, Paediatric ICU	1,3	4	1.0
Lidocaine	Surgical, Paediatric ICU	3,1	4	1.0
Magnesium sulfate	Maternity	6	6	1.6
Omeprazole	Paediatric, Adult ICU	1,3	4	1.0
Ondansetron	Paediatric oncology	2	2	0.5
Bupivacaine	Surgical	1	1	0.3
Sodium pentothal	Surgical	1	1	0.3
Tramadol	Medical	1	1	0.3
Modecate	Psychiatry	2	2	0.5
Distilled water	Paediatric	2	2	0.5
Total			384	100

Vial solutions and associated processes

From a total of 384 samples, 236 (61.5%) vials were MDVs, and the remaining 148 (38.5%) were SDVs collected from eleven wards and three ICU units, with 36 medication types. The highest numbers of parenteral medications were collected from three major wards: Pediatrics 55 (14.3%), Medical 53 (13.8%), and Surgical 48 (12.5%). The most frequently sampled medications were ceftriaxone 107 (27.9%), metronidazole 51 (13.3%), and normal saline 46 (12%) (Table II). Of the total MDVs, 157 (66.5%) were preservative-free, whereas the remaining 79 (33.3%) contained preservatives. However, all SDVs (148, 38.5%) were preservative-free. Almost three quarters (77.1%) of the medications were stored at room temperature, while the remaining 88 (22.9%) were stored in the refrigerator. Of the collected parenteral medications, 73 (19%) were stored out of the manufacturer's

recommendation. None of the MDV medications were in date at on the day of opening. Almost all vials were being used within their expiration period. Four insulin vials' expiration date labels were not legible upon checking.

Prevalence of contamination in different departments

Contamination was detected among five wards and two intensive care units. The highest 8 (38.1%) and the lowest 1 (4.8%) prevalence of contamination were observed in paediatrics and surgical wards, respectively (Figure 1). Contamination was not detected in the following wards: ophthalmology, maternity, gynecology, orthopedics, psychiatry, maxillofacial wards, and medical ICUs.

Prevalence of contamination according to type of medication

From a total of 36 types of medication, contamination was identified among the 9 medications (Table III). The most frequently contaminated parenteral solutions were listed in the following descending order: normal saline 10 (47.6%), dextrose 3 (14.3%), and omeprazole 2 (9.5%). Contaminations were not detected in any of the antibiotic vials. No mixed contamination was detected in any of the MDVs. Of the contaminated parenteral medications, 4 (44.4%) had preservatives. However, the remaining medication 5 (55.6%) was preservative-free. All contaminated medications had been stored at room temperature.

Prevalence of isolated bacteria

From the 384 parenterally administered solutions enrolled in the study, 21 bacteria were isolated. The overall prevalence of contamination in this study was 5.5%. Out of the total bacterial isolates, five different pathogenic bacterial species were identified. Gram-negative bacteria were more dominant than Gram-positive bacteria. Gram-negative and Gram-positive bacteria were involved in 18 (85.7%) and 3 (14.3%) contaminations, respectively. P. aeruginosa was the most common Gram-negative bacterium, followed by K. pneumoniae, constituting 6 (28.5%) and 5 (23.8%) isolates, respectively. Coagulase-negative *staphylococci* (CoNS) were the only Gram-positive bacteria isolated. (Figure 2).

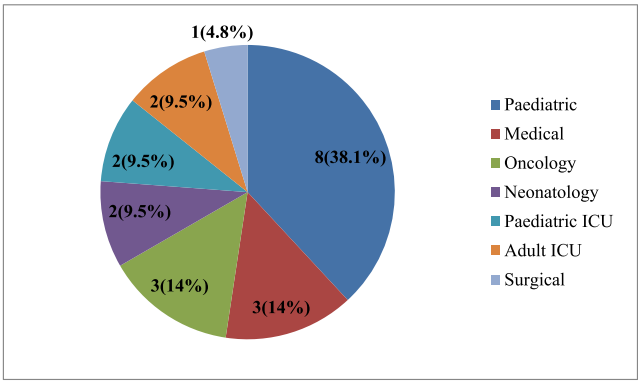

Figure 1. Distributions of contamination among ward and the intensive care unit at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021.

Antimicrobial susceptibility patterns

A total of 15 different types of antimicrobial agents were used to test the antimicrobial pattern of the pathogenic bacteria isolated from contaminated vials. Both Gram-negative and Gram-positive isolates revealed different levels of resistance to the antimicrobials tested. Of the total, 18 (85.7%) Gram-negative isolates were sensitive to imipenem (14, 77.8%), amikacin (11, 61%), chloramphenicol (10, 55.6%), and gentamicin (9, 50%). Antimicrobial drug resistance profiles of the Gram-negative bacterial isolate revealed a relatively high resistance rate against ceftriaxone (16, 88.9%) and ceftazidime (14, 77.8%). Among the 3 Gram-positive bacteria (all CoNS) isolated all 3 (100%) were resistant to penicillin, followed by 2 (66.7%) to ampicillin, tetracycline, ciprofloxacin, and erythromycin. One out of the 3 Gram-positive bacteria (1, 33.3%) was sensitive to gentamicin, sulfamethoxazole-trimethoprim, and clindamycin. Of the 3 CoNS isolates, meticillin resistance was found in 2 (66.7%) (Table IV).

Antibiograms showed that almost all 20 (95.2%) isolates were resistant to three or more classes of commonly used antimicrobial agents. The observed multidrug resistance (MDR) for three and four antimicrobial agents was 1 (4.8%) and 4 (19%), respectively. The frequency of MDR was found in all Gram-negative bacteria 18 (100%), whereas 2 (66.7%) out of the total three Gram-positive bacteria showed MDR. None of the isolates showed sensitivity to all antibiotics used (Table V).

Factors associated with vial contamination

In bivariate logistic regression analysis, reuse of syringe and/or needle with significance value (P=0.047), medication drawing environment (P=0.035), storage conditions (P=0.002), new glove used before injection (P=0.122), expiration date before use (P=0.131) and compliance with hand washing (P=0.065) were the candidate variables for multivariate logistic regression analysis. In multivariate analysis, reuse of needle and/or syringe, medication drawing environment and storage conditions showed statistically significant associations with vial contamination (P=0.032), [AOR (95% CI) =2.830 (1.095−7.319)], (P=0.036), [AOR (95% CI) =2.768 (1.071−7.153)] and (P=0.001), [AOR (95% CI) = 28.65 (3.765−218.068)], respectively.

The results of this study indicate that the chance of vial contamination by the reuse of a syringe and/or needle was increased by 2.83 times (AOR; 2.83 [95% CI, 1.095−7.319]) compared with the use of a sterile needle and/or syringe for single use. Similarly, the odds of vial contamination increased by 2.77 (AOR; 2.77 [95% CI, 1.071−7.153]) times when drawing medication in a contaminated environment. The chance of vial contamination was increased by 28.65-fold when the vial was stored out of the manufacturer's guidance compared to storing vials according to the manufacturer's guidance 28.65 (3.765−218.068) (Table VI).

Discussion

In this study, bacterial contamination was detected in vials containing preservatives as well as in preservative-free vials. This finding emphasises the importance of safe medication

Table III
Distribution and frequency of isolated bacteria, source of medication, storage condition, preservative status and wards/units for vials at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021

Ward/unit	Isolated bacteria	Source of medication	Storage condition	Preservative status	Frequency	Percentage
Medical	CoNS	NPH insulin	RT	Present	1	0.3
	Pseudomonas aeruginosa	R insulin	RT	Present	1	0.3
	Acinetobacter spp	Heparin	RT	Present	1	0.3
Paediatric	CoNS	NS	RT	Absent	1	0.3
	K. pneumoniae	Dextrose	RT	Absent	1	0.3
		NS			1	0.3
	K. aerogenes	Potassium chloride	RT	Absent	1	0.3
	Pseudomonas aeruginosa	NS	RT	Absent	2	0.5
	Acinetobacter spp	NS	RT	Absent	2	0.5
Surgical	*Klebsiella pneumoniae*	Propofol	RT	Present	1	0.3
Neonatology	CoNS	NS	RT	Absent	1	0.3
	Pseudomonas aeruginosa	NS	RT	Absent	1	0.3
Oncology	*K. pneumoniae*	NS	RT	Absent	1	0.3
	Pseudomonas aeruginosa	NS	RT	Absent	1	0.3
	Citrobacter koseri	Dextrose	RT	Absent	1	0.3
Paediatric ICU	*K. pneumoniae*	Dextrose	RT	Absent	1	0.3
	K. aerogenes	Sodium lactate	RT	Absent	1	0.3
Adult ICU	*Pseudomonas aeruginosa*	Omeprazole	RT	Absent	1	0.3
	K. oxytoca	Omeprazole	RT	Absent	1	0.3
Total					21	5.5%

CoNS = Coagulase negative *staphylococci*, RT= Room temperature, NS= Normal saline, R insulin = Regular insulin.

injection practices, regardless of the preservative content of vials. Therefore, the presence of preservatives itself cannot be guaranteed for contamination-free medication practices unless the aseptic technique used among the nurses working in different wards and exposure of the contents of the vials to environmental factors is also controlled.

The overall prevalence of vial contamination in this study was 5.5%, which is consistent with two previous studies from Iran that showed contamination rates of 5.6% and 5.36%, respectively [10,11]. The contamination rate in this study was higher than that of other similar studies conducted in Germany (0.9%) and Austria (4%) [15,16]., In the current study, the length of the study period was longer than that in a previous study in Germany, which collected a sample on a single day, and all 227 MDVs were collected [15]. Similarly, the study conducted in Austria incorporated only a total of 96 vials from different wards except for intensive care units [16].

The prevalence of vial contamination in the current study was lower than that in studies conducted in India (25%) and South Africa (6.4%) [9,17]. This variation might be due to the sample size, kinds of wards included and aseptic techniques. A previous study in India was a pilot study, and only 40 MDVs were collected from different ICUs [17]. Likewise, the research

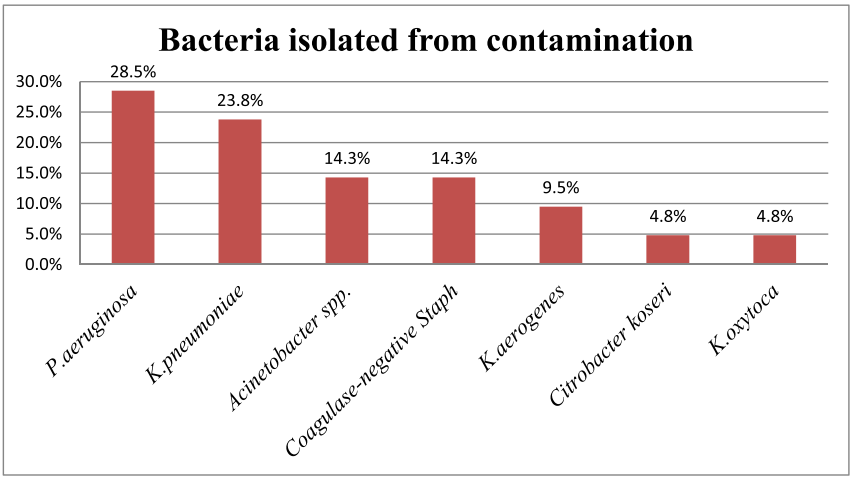

Figure 2. Prevalence and types of bacteria isolated from contaminated vials at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021.

Table IV
Antimicrobial resistance profiles of bacterial isolates (n = 21) at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021

Bacterial isolates	Total isolate	Resistance pattern of antimicrobial agents (%)													
		CLR	CN	AMI	TET	CTR	CIP	SXT	CAZ	MEM	IMI	AMP	CFO	P	CLI	ERY
K. pneumoniae	5	0	2 (40)	1 (20)	3 (60)	3 (60)	2 (40)	3 (60)	2 (40)	3 (60)	0	NA	NA	NA	NA	NA
P. aeruginosa	6	5 (83)	6 (100)	3 (50)	6 (100)	6 (100)	5 (83)	6 (100)	6 (100)	5 (83)	4 (66.7)	NA	NA	NA	NA	NA
Acinetobacter spp	3	1 (33.3)	1 (33.3)	2 (66.7)	2 (66.7)	3 (100)	2 (66.7)	2 (66.7)	3 (100)	1 (33.3)	0	NA	NA	NA	NA	NA
K. aerogenes	2	1 (50)	0	0	0	2 (100)	1 (50)	2 (100)	2 (100)	1 (50)	0	NA	NA	NA	NA	NA
Citrobacter koseri	1	0	0	0	0	1 (100)	1 (100)	1 (100)	1 (100)	0	0	NA	NA	NA	NA	NA
K. oxytoca	1	1 (100)	0	1 (100)	1 (100)	1 (100)	1 (100)	1 (100)	0	0	0	NA	NA	NA	NA	NA
Total	18	8 (44.4)	9 (50)	7 (39)	12 (66.7)	16 (88.9)	12 (66.7)	15 (83)	14 (77.8)	10 (55.5)	4 (22.2)	NA	NA	NA	NA	NA
CoNS	3	1 (33.3)	1 (33.3)	NA	2 (66.7)	NA	2 (66.7)	1 (33.3)	NA	NA	NA	2 (66.7)	2 (66.7)	3 (100)	1 (33.3)	2 (66.7)

CoNS Coagulase-negative *staphylococci*, NA not applicable, CLR chloramphenicol, CN gentamicin, AMI amikacin, TET tetracycline, CTR ceftriaxone, CIP ciprofloxacin, SXT sulfamethoxazole-trimethoprim, CAZ ceftazidime, MEM meropenem, IMI imipenem, AMP ampicillin, CFO cefoxitin, ERY erythromycin, P penicillin, CLI clindamycin.

conducted in South Africa was limited to only 110 self-prepare multiple-dose phenylephrine solutions, and the samples were included from two obstetric theatres [9].

The reasons for these differences may be due to many factors including the sample size; the study period; the type of collected sample; the reuse of needles and/or syringes; the medication drawing environment and storage conditions; direct or indirect contact with potentially contaminated surfaces; poor aseptic techniques employed during successive uses of vials.

In this study, the highest vial contamination was found in paediatric ward 8 (38.1%), and this finding is consistent with another study performed in Shiraz, southwestern Iran [10]. However, these results are different from another report from which reported the highest rate of vial contamination (14.28%) in interventional bronchoscopy units [11], . The reason for the highest contamination in the paediatric ward might be due to drugs administered for paediatric patients being based on the child's weight with different volumes being used may require additional manipulation and longer periods of storage of the vials at ambient temperature.

The most frequently contaminated solution in this study was normal saline 10 (47.6%), which is different from similar studies in India and Iran, where the most frequently contaminated solutions were insulin and heparin [11,17]. The possible reason for this inconsistency might be that the type of medication that was most frequently collected in the present study was normal saline, and since normal saline is preservative-free, it is more susceptible to contamination. In the previous study which was mainly conducted in India, only insulin and heparin were included [17].

In this present study, among the total bacterial isolates, Gram-negative bacteria (18, 85.7%) were more frequent than Gram-positive bacteria (3, 14.3%). The most frequently isolated bacterium was *P. aeruginosa* (6, 28.5%), followed by *K. pneumoniae* (5, 23.8%). Our finding is consistent with a similar investigation conducted in the USA [18]. However, this result is different from two other studies performed in Shiraz, southwestern Iran, and Tehran, northern Iran, which reported 88.9% and 81.82% prevalence of Gram-positive bacteria, respectively [11,18]. This observation may reflect the local pattern of hospital-acquired infections caused by Gram-negative bacteria.

Antimicrobial resistance represents a global health crisis and one of the most serious threats humans face today [19]. In this study, the importance of antimicrobial resistance in bacteria was also highlighted. This study found that among the Gram-positive bacteria, the CoNS strains isolated were resistant to commonly prescribed antibiotics. All 3 isolates (100%) were resistant to penicillin and 2 out of 3 (66.7%) were resistant to meticillin. The antimicrobial resistance patterns of Gram-negative bacteria also showed the highest rates of resistance to ceftriaxone 16 (88.9%) and ceftazidime 14 (77.8%). Overall, 20 (95.2%) of the bacterial isolates from this study were characterised as MDR bacteria. A possible reason is that hospital-acquired bacteria are typically more resistant to antimicrobials and can be spread from patient to patient in healthcare facilities, often via the contaminated hands of healthcare personnel, contaminated medical or surgical equipment, or the inanimate hospital environment. These organisms are generally highly efficient at upregulating or acquiring genes that code for mechanisms of antibiotic resistance.

Table V
Multiple antimicrobial resistance patterns (antibiogram) of isolated bacteria at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021

Resistance	Antimicrobial agent	Frequency-number (%)
Resistance to 2 drugs	P, CFO	1 (4.8%)
Resistance to 3 drugs	CTR, CAZ, TET	1 (4.8%)
Resistance to 4 drugs	TET, CRT, SXT, CIP	1 (4.8%)
	MEM, CN, CAZ, TET	1 (4.8%)
	CTR, CIP, SXT, CAZ	2 (9.5%)
	CFO, ERY, TET, CIP	1 (4.8%)
	CLR, SXT, CAZ, MEM	1 (4.8%)
Resistance to $\geq$ 5 drugs	AMP, P, CFO, ERY, TET, CIP	1 (4.8%)
	CTR, CAZ, AMP, AMI, TET, CIP	2 (9.5%)
	CN, AMI, TET, CIP, MEM, CAZ	1 (4.8%)
	CN, AMI, TET, CIP, MEM, CAZ	1 (4.8%)
	TET, CTR, SXT, MEM, CAZ	1 (4.8%)
	CLR, AMI, TET, CTR,CIP, SXT	1 (4.8%)
	CN, AMI, TET, CTR, SXT, CAZ	1 (4.8%)
	CLR, CN, TET, CTR, SXT, CIP, CAZ, MEM	1 (4.8%)
	CLR, CN, TET, CTR, SXT, CIP, CAZ, MEM, IMI	1 (4.8%)
	CLR, CN, AMI, TET, CTR, CIP, CAZ, MEM, SXT, IMI	1 (4.8%)
	CLR, CN, AMI, TET, CTR, SXT, CIP, CAZ, MEM, IMI	1 (4.8%)
	CLR, CN, TET, CTR, SXT, CIP, CAZ, MEM, SXT, IMI	1 (4.8%)

CLR chloramphenicol, CN gentamicin, AMI amikacin, TET tetracycline, CTR ceftriaxone, CIP ciprofloxacin, SXT sulfamethoxazole-trimethoprim, CAZ ceftazidime, MEM meropenem, IMI imipenem, AMP ampicillin, CFO cefoxitin, ERY erythromycin, P penicillin, CLI clindamycin.

Table VI
Bivariate and multivariate logistic analysis of risk factors for vial contamination at JMC, Jimma, Southwest Ethiopia, from July 2021 to October 2021

Variables		Frequency	Percentage	COR		AOR	
				(95%CI)	*P* value	(95%CI)	*P* value
Sex	Male	156	40.6	1.654 [0.685—3.994]	0.263		
	Female	228	59.4	1*			
Age	$\leq$32	228	59.4	1.393 [0.549—3.533]	0.486		
	>32	156	40.6	1*			
Department	Ward	330	85.9	1.588 [0.359—7.022]	0.542		
	ICU	54	14.1	1*			
Experience	$\leq$6	231	60.2	1.081 [0.437—2.673]	0.866		
	>6	153	39.8	1*			
Single vial for a single patient	YES	359	95.8	1.160 [0.146—9.228]	0.888		
	NO	16	4.2	1*			
Reuse needle or syringe	YES	156	40.6	2.5 [1.011—6.183]	0.047	2.83 [1.095—7.319]	0.032
	NO	228	59.4	1*			
Compliance with hand washing	YES	205	53.4	2.400 [0.946—6.08]	0.065		
	NO	179	46.6	1*			
Disinfected top of the vial	YES	45	11.7	0.541 [0.174—1.686]	0.290		
	NO	339	88.3	1*			
Drawn medication in clean area	YES	233	60.7	1*			
	NO	151	39.3	0.377 [0.153—0.934]	0.035	2.77 [1.071—7.153]	0.036
Checked expiration date before use	YES	371	96.6	0.294 [0.061—1.435]	0.131		
	NO	13	3.4	1*			
Use new glove before injection	YES	331	81	4.948 [0.653—37.485]	0.122		
	NO	73	19	1*			
Check opening date	YES	148	38.5	0.623 [0.236—1.642]	0.338		
	NO	236	61.5	1*			
Store the vials accordingly	YES	199	51.8	1*			
	NO	185	48.2	0.042 [0.006—0.314]	0.002	28.65 [3.765—218.068]	0.001
Vials can be contaminated	YES	246	64.1	1.129 [0.445—2.869]	0.798		
	NO	138	35.9	1*			

Key: OR= odds ratio, CI = confidence interval, COR= crude odds ratio, AOR= adjusted odds ratio, 1* reference category.

In this study, 40.6% of participants responded that they reused syringes and/or needles. This finding is in agreement with a study in Cameroon (44%) [20]. However, this result is higher than previous survey reports in the USA, where 22% of anaesthetist nurses reused a syringe or needle to withdraw medication from a multidose vial [21]. In the current study, unsafe practices around not washing hands (46.6%) and not wearing or changing gloves (19%) were observed. This result was lower than that of a study conducted in India, which showed that 95.4% and 61.6% of participants did not wash their hands and wore/changed gloves, respectively [22]. The differences may reflect differences in the adherence of healthcare professionals to hand hygiene procedures.

The reuse of syringes and/or needles, the medication drawing environment and the storage conditions showed statistically significant associations with vial contamination (P=0.032), [AOR (95% CI) =2.830 (1.095−7.319)], (P=0.036), [AOR (95% CI) = 2.768 (1.071−7.153)] and (P=0.001), [AOR (95% CI) = 28.65 (3.765−218.068)], respectively. However, other factors, such as compliance with hand hygiene, disinfection on top of the vial, expiration date, use of new gloves before injection, and other variables investigated as possible risk factors for vial contamination, were not observed as significant predictors in this study.

The limitations of the study include that it was conducted in a single centre with relatively small numbers and that it did not include anaerobic bacteria, which can also cause vial contamination.

Conclusions

In conclusion, the present study confirmed microbial contamination of parenterally administered solutions, which indicates a potential risk of infection transmission. The overall prevalence of bacteria was high, and most of the isolates were Gram-negative bacteria. The majority of the bacterial isolates were multidrug resistant MDR). The use of MDVs is a convenient and economical option in developing countries such as Ethiopia. Conversely, they are also associated with the risk of contamination and nosocomial outbreaks of potentially life-threatening bloodstream infections. In the current study, the reuse of needles and/or syringes, medication drawing environment, and storage conditions of vials were more likely to be associated with vial contamination. The present study also revealed that there is a gap among healthcare professionals with regard to adherence to standard infection prevention and control guidelines to minimise the incidence of hospital-acquired infections.

We recommend that a regular training program should be introduced for healthcare workers regarding aseptic techniques. A clean environment should be provided for the preparation and administration of drugs. Reuse of the needle and/or syringe must be avoided. Healthcare workers must strictly adhere to basic infection control practices as per standard guidelines.

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Credit author statement

Abay Tabor generated the research idea, wrote the proposal, and participated in data collection, analysis, interpretation, and drafting of the manuscript. Abay Tabor, Zewudineh Shalemariam, Yared Alemu and Kasahun Gorems participated in data collection analysis and interpretation and critical review of the manuscript. In addition, Kasahun Gorems was part of the initiation of the research idea. Finally, all the authors critically reviewed the manuscript and overall write-up. All of them read and approved the final manuscript.

Author contributions

AT generated the research idea, wrote the proposal, and participated in data collection, analysis, interpretation, and drafting of the manuscript. All other authors participated in data collection, analysis and interpretation and critical review of the manuscript. In addition, KG was part of the initiation of the research idea. Finally, all the authors critically reviewed the manuscript and overall write-up. All of them read and approved the final manuscript.

Conflict of interest statement

The authors declare that they have no competing interests.

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