

ORIGINAL ARTICLE

Outbreak of *Tsukamurella* Species Bloodstream Infection among Patients at an Oncology Clinic, West Virginia, 2011–2012

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OBJECTIVE. To determine the source and identify control measures of an outbreak of *Tsukamurella* species bloodstream infections at an outpatient oncology facility.

DESIGN. Epidemiologic investigation of the outbreak with a case-control study.

METHODS. A case was an infection in which *Tsukamurella* species was isolated from a blood or catheter tip culture during the period January 2011 through June 2012 from a patient of the oncology clinic. Laboratory records of area hospitals and patient charts were reviewed. A case-control study was conducted among clinic patients to identify risk factors for *Tsukamurella* species bloodstream infection. Clinic staff were interviewed, and infection control practices were assessed.

RESULTS. Fifteen cases of *Tsukamurella* (*Tsukamurella pulmonis* or *Tsukamurella tyrosinosolvans*) bloodstream infection were identified, all in patients with underlying malignancy and indwelling central lines. The median age of case patients was 68 years; 47% were male. The only significant risk factor for infection was receipt of saline flush from the clinic during the period September–October 2011 ($P = .03$), when the clinic had been preparing saline flush from a common-source bag of saline. Other infection control deficiencies that were identified at the clinic included suboptimal procedures for central line access and preparation of chemotherapy.

CONCLUSION. Although multiple infection control lapses were identified, the outbreak was likely caused by improper preparation of saline flush syringes by the clinic. The outbreak demonstrates that bloodstream infections among oncology patients can result from improper infection control practices and highlights the critical need for increased attention to and oversight of infection control in outpatient oncology settings.

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Over 600,000 oncology patients receive outpatient chemotherapy in the United States annually and are at increased risk for bloodstream infections because of the use of immunosuppressive chemotherapy and long-term invasive lines.^{1–3} *Tsukamurella* species are gram-positive bacilli that have been isolated in the environment from soil and sludge and are uncommonly reported to cause human disease.⁴ The organism is frequently misidentified as other bacteria, such as *Nocardia* species or *Rhodococcus* species.^{4–7} Bloodstream infections, the most common presentation of *Tsukamurella* species infections, primarily occur in patients with indwelling central lines and/or immunosuppression.^{4–6,8}

In October 2011, microbiology staff at an acute care hospital in West Virginia (hospital A) noticed that the proportion of blood cultures that grew potential contaminants (eg, gram-

positive bacilli) had recently increased. The most recent isolates, which had been identified as *Bacillus* species, all came from patients treated at the same oncology clinic (clinic A). This cluster was reported to the West Virginia Bureau of Public Health (WVBPH), which performed an on-site investigation at clinic A. Identified lapses in infection control practices were addressed.

Isolates from the cluster were subsequently determined by the Centers for Disease Control and Prevention (CDC) to be *Tsukamurella* species. Because additional cases continued to be reported, WVBPH and the oncology clinic requested that the CDC conduct an additional on-site investigation in June 2012. We describe findings from the investigation of the first reported outbreak of *Tsukamurella* species infections.

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METHODS

Case Definition and Case Finding

A case was defined as an infection in a patient treated at clinic A during the period January 2011–June 2012 in which *Tsukamurella* species was isolated from a blood or catheter tip culture. Because clinical cultures from clinic A patients were processed by hospital laboratories, case finding was performed by reviewing microbiology laboratory results from hospital A and other area hospitals during the period January 2011–June 2012. Because of the concern for potential misidentification, all gram-positive bacillus isolates from blood and catheter tip cultures were identified from hospital A's microbiology records. If not already identified as *Tsukamurella* species, morphologies from Gram stains were reviewed to determine whether they were consistent with *Tsukamurella* species. From other area hospitals, microbiology laboratory staff were asked to report *Tsukamurella* species isolates from blood or catheter tip cultures. If they lacked the capability to identify *Tsukamurella* species, they were asked to report clusters of *Bacillus* species from blood or catheter tip cultures.

Case-Control Study

An unmatched case-control study was conducted to determine risk factors for *Tsukamurella* species bloodstream infection. All identified cases were included. Control subjects were selected from among patients seen at clinic A during the period September 2011–May 2012 who had a central line for at least 7 days during this time period and in whom *Tsukamurella* species had not been isolated from any clinical specimen. Two control subjects were selected per case patient. For both case patients and control subjects, a standardized data abstraction form was completed after reviewing clinic A and hospital A records to collect information regarding demographic characteristics, underlying medical conditions, hospital course (if applicable), and previous healthcare exposures.

Statistical analyses were performed using SAS, version 9.2 (SAS Institute). Categorical variables were analyzed using χ^2 statistics or Fisher exact test as appropriate. Continuous variables were compared using a Wilcoxon rank-sum test. *P* values less than .05 were considered statistically significant.

Assessments of Infection Control and Medication Preparation Practices

WVBPB and CDC teams interviewed clinic A staff and observed infection control procedures related to parenteral medication storage and handling, including chemotherapy preparation, and use of central lines, including drawing blood, flushing lines, and changing dressings.

Microbiologic Investigation

Environmental samples were obtained from clinic A for bacterial culture during site visits. In October 2011, these samples

included items used to prepare central lines for access. In June 2012, additional environmental samples were obtained, including swab samples from sink faucets and aerators, samples of water from sinks, and surface samples from patient examination rooms and where medications were prepared. Surface specimens were obtained using Sponge Sticks (3M). Hand cultures (Handi wipes; Clorox) from healthcare workers in clinic A were also obtained during June 2012.⁹

Environmental samples and hand cultures were blended in saline buffer containing polysorbate. The resulting homogenates were concentrated by centrifugation and then inoculated onto blood agar plates. Cultures were incubated at 37°C on blood agar plates for up to a week and screened for colony characteristics consistent with *Tsukamurella* species. Isolates were identified as *Tsukamurella* species by 16S RNA gene sequencing. To further characterize isolates, random amplification of polymorphic DNA polymerase chain reaction (RAPD-PCR) was performed using an adaptation of methods described elsewhere.¹⁰

RESULTS

Setting

Clinic A, an independently owned and operated oncology clinic located inside a hospital complex, provides outpatient oncology services including medical evaluations and infusions (eg, chemotherapy). Each day at clinic A, 20–30 patients receive infusions; most (more than 50%) do not have indwelling central lines. Clinic A does not use a pharmacy or employ a licensed pharmacist to assist with the preparation of infusions. Rather, nursing staff prepare medications in a dedicated clinic room containing a combination biological safety cabinet/chemical fume hood for preparing and handling chemotherapy agents. Other medications are prepared in an adjacent area within the same room. Clinic A's patients visit hospital A for services such as hospital admissions, collection of blood samples for culture, and selected other laboratory tests.

Description of Cases

Fifteen cases of *Tsukamurella* species infection were identified. Fourteen cases were reported from hospital A's laboratory. One case was reported from another hospital in the region. The majority of cases (9 [60%] of 15) occurred during the period September–October 2011, although some cases presented as late as February–May 2012 (Figure 1). The median age of all case patients was 68 years, 47% were male, and 93% were of white race. Case patients had received care at clinic A for a median of 9.5 months (range, 1–102 months). All case patients had received a diagnosis of malignancy, and all also had an indwelling central line, although central line types varied.

Case patients most commonly presented with fevers or chills (12 [86%] of 14 case patients with information available); 14 (93%) of 15 required hospitalization (Table 1). Most (67%) had more than 2 sets of cultures that grew *Tsukamurella*

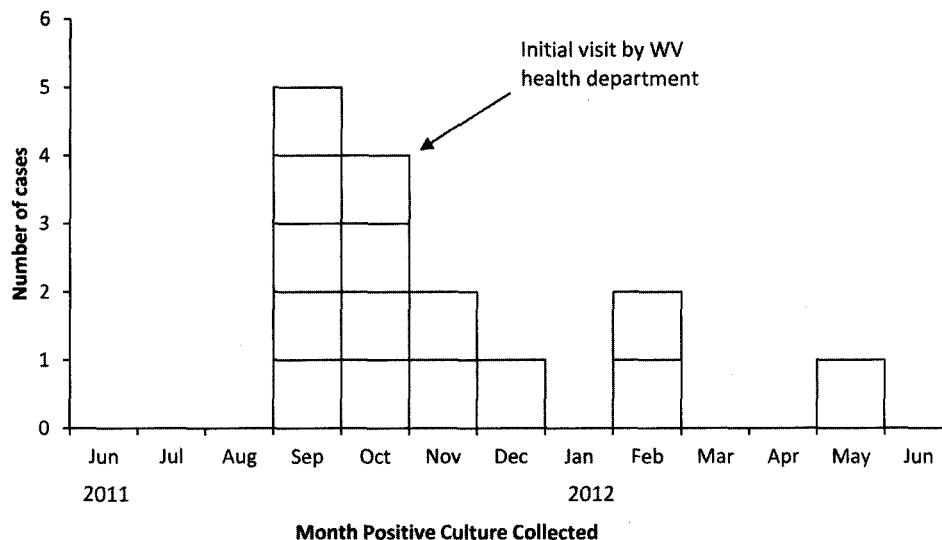


FIGURE 1. Epidemic curve of cases of *Tsukamurella* species infection by month in which positive culture was collected, clinic A patients, West Virginia (WV), 2011–2012.

species. Because most isolates were first reported to be *Bacillus* species, some treating clinicians initially regarded isolates as contaminants; initiation of therapy was delayed for 3 case patients. One case patient died within 30 days after first positive culture, although whether this death was attributable to *Tsukamurella* species infection was unclear.

Review of potential risk factors for infection did not reveal a shared healthcare worker, common location within clinic A where cases were treated, common chemotherapy regimen or other treatment given, or single date on which cases visited the clinic. However, all case patients had received saline for central line flushes at clinic A, the only specific healthcare exposure common to all cases. Notably, one case patient's central line was accessed only once by clinic A staff before the infection, when the line was flushed with saline. Six days later, the patient presented to the emergency department with neutropenia, fever, and hypotension; blood cultures obtained at this visit grew *Tsukamurella* species. In addition, all 3 case patients with late-onset infection (ie, infection with onset during February–May 2012) had implanted ports. Two of these patients did not receive any chemotherapy during the outbreak. Their ports were only accessed during monthly flushes with saline by clinic A staff.

Case-Control Study

Thirty control patients were included in the case-control study. The only significant risk factor for developing *Tsukamurella* species infection was receipt of saline flush from clinic A during September–October 2011 (14 [93%] of 15 case patients vs 9 [60%] of 15 control subjects; $P = .03$; Table 2). The single case patient who did not receive saline flush from clinic A during September 2011 had received saline flush in late August 2011 and developed illness a few weeks later.

Clinical characteristics, such as duration and type of central line, did not differ between case patients and control subjects. Other healthcare exposures, such as receipt of chemotherapy and previous hospitalization, were also not significant risk factors for *Tsukamurella* species infection.

Assessments of Infection Control and Medication Preparation Practices

During the October 2011 site visit, WVBPH staff noted that, rather than using prepackaged, commercially manufactured saline flush syringes, clinic staff predrew 10-mL saline flush syringes at the beginning of each day from a new 250-mL bag of normal saline within the chemotherapy hood. In the patient care area, clinic staff moistened nonsterile cotton balls with alcohol obtained from a common dispensing bottle to perform antisepsis of catheter connection caps and medication vials, which is a technique that could lead to inadequate antisepsis.

During the June 2012 site visit, several lapses in infection control practices were found pertaining to the preparation and handling of both chemotherapy and nonchemotherapy medications in the medication preparation room. For example, single-dose medication vials opened outside of the hood were stored and reused over multiple days. Furthermore, most nonchemotherapy medications were prepared next to a sink, which could contaminate medications with tap water. Although syringes and needles were discarded after use for patients, occasionally staff drew and combined multiple medications using a single syringe and needle, which could cross-contaminate medication vials being used for other patients if aseptic technique was not strictly followed. In addition, the chemotherapy hood was adjacent to a window that was opened intermittently, contrary to the stringent

TABLE 1. Clinical Characteristics of 15 Clinic A Oncology Patients with *Tsukamurella* Species Isolated from Blood or Catheter Specimens in West Virginia, 2011–2012

Characteristic	No. (%) of patients
Presenting symptom ($n = 14$) ^a	
Fever/chills	12 (86)
Hypotension	2 (14)
Malignancy	
All	15 (100)
Solid organ	13 (87)
Hematologic	2 (13)
Presence of central line	
All	15 (100)
Implanted port	8 (53)
Tunneled catheter	6 (40)
PICC line	1 (7)
Sets of cultures with <i>Tsukamurella</i> species, median no. (range)	3 ^b (1–8)
Outcomes	
Hospitalized for infection	14 (93)
Received antibiotic therapy for infection ^a ($n = 14$)	13 (93)
Required central line removal ^a ($n = 14$)	10 (71)
Death within 30 days	1 (7)

NOTE. Data are no. (%) of patients, unless otherwise indicated. PICC, peripherally inserted central catheter.

^a Clinical information not available for 1 patient.

^b All positive cultures were either blood cultures or catheter tip cultures.

air flow requirements specified in guidelines for safely preparing sterile medications (including chemotherapy).¹¹ When medications were prepared inside the hood, gloves were not regularly disinfected during use (eg, routine application of isopropyl alcohol to gloved hands), and insects had been seen on these gloves, which were stored on the windowsill.¹¹ Chemotherapy hood disinfection protocols were also not followed appropriately (eg, paper towels, with the potential to shed fibers and lead to contamination, and isopropyl alcohol of insufficient strength [47.5%] were routinely used to clean the hood).^{11,12}

Microbiologic Investigation

Of the *Tsukamurella* species isolates available from 13 case patients, all were either *Tsukamurella pulmonis* or *Tsukamurella tyrosinosolvans*, although some isolates could not be definitively assigned a species. On the basis of similar banding patterns, RAPD-PCR testing suggested that 12 of the 13 isolates might be related (Figure 2). No *Tsukamurella* species isolates were recovered from environmental samples.

Control Measures

On recommendation from WVBPH, after the October 2011 site visit, clinic A stopped preparing its own saline flush syringes and began using prepackaged manufactured saline flush. Clinic A staff also stopped using cotton balls for antiseptics, instead using prepackaged manufactured sterile 70% isopropyl alcohol pads to disinfect catheter connection caps and medication vials. After the June 2012 site visit, the win-

dow in the medication preparation room was permanently closed and sealed shut. General injection safety guidance was provided, with recommendations to consult a licensed pharmacist for additional evaluation and remediation of chemotherapy preparation practices. Clinic A was also asked to develop an infection control manual, document training of nurses in central line care, document observations of nursing technique, and develop a plan for tracking bloodstream infections from clinic patients. Clinic A complied with these requests.

DISCUSSION

This is the first reported outbreak and largest described cluster of *Tsukamurella* species infections. Affected patients all had underlying malignancies. Most also experienced persistent bacteremia that required hospitalization and central line removal. Although the source of the outbreak was not identified through environmental sampling, the epidemiologic investigation suggested that infusion of saline flush prepared by clinic A (before the health department's visit in October 2011) was the likely source of the infections. The only shared exposure among case patients was receipt of saline flush prepared by the clinic; for some case patients, this was the only medication infused through central lines. In addition, the saline flush prepared by clinic A staff was the only significant risk factor found in the case-control study. Finally, after clinic A stopped preparing its own saline flush, the frequency of cases decreased, further supporting the saline flush as the source of infection.

In this outbreak, some infections occurred several months after receipt of saline flush prepared by clinic A. This delay between exposure of a parenteral medication and development of bloodstream infection is not unprecedented. In a 2004 outbreak of *Pseudomonas fluorescens* bloodstream infections involving contaminated heparin, a number of cases occurred several months after their last exposure to the implicated heparin flush.¹⁴ In both the previous outbreak and ours, all late-onset cases involved implanted ports. Although implanted ports confer a lower risk of bloodstream infection than other types of indwelling central lines, ports might uniquely allow for a delayed presentation of bloodstream infection. The reservoir of a port, which lies beneath the septum, can develop biofilms as well as contaminated debris.¹⁵ In the *Pseudomonas* outbreak, it was postulated that, for late-onset cases, too few organisms were initially present to cause symptoms. Over time, the reservoir might become colonized via biofilms or contaminated debris, leading to bacteremia in later months.¹⁴ A similar phenomenon might explain the long delay between receipt of saline flush and development of symptomatic infection in some of our cases.

After the June 2012 on-site investigation, one additional patient at clinic A acquired a *Tsukamurella* species bloodstream infection. WVBPH investigated and did not identify additional lapses in infection control practices at clinic A. However, this patient's history is similar to that of the other patients with late-onset cases: the patient had an implanted port and, before the start of the outbreak of *Tsukamurella* species infection, had only received monthly flushes of the port from clinic A.

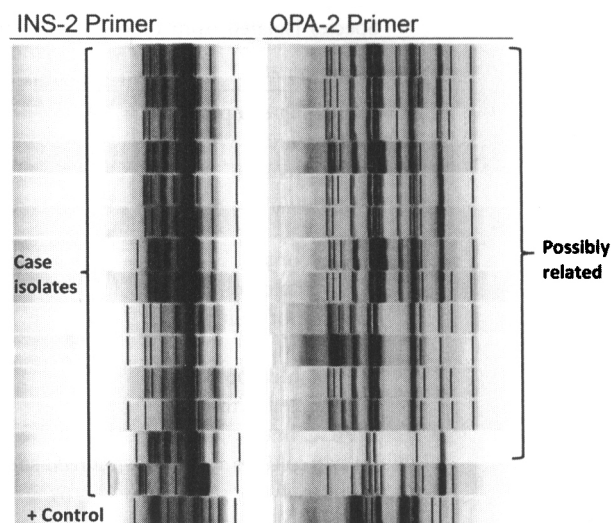


FIGURE 2. Results of random amplification of polymorphic DNA polymerase chain reaction (RAPD-PCR) of available *Tsukamurella* species outbreak isolates, West Virginia, 2011–2012. Positive control represents *Tsukamurella tyrosinosolvens* isolate unrelated to the outbreak. The primers used for RAPD-PCR were OPA-2 (Operon Technologies) and INS-2.¹³

Saline bags are not labeled as US Food and Drug Administration–approved multiple dose containers. Using a preservative-free bag of saline to prepare multiple predrawn saline flush syringes increases the likelihood of contaminating the flush when the practice is not performed under optimal con-

TABLE 2. Comparison of Demographic Characteristics, Clinical Characteristics, and Healthcare Exposures of Case Patients with Infection due to *Tsukamurella* Species and Control Subjects, Clinic A, West Virginia, 2011–2012

Variable	Case patients (n = 15)	Control subjects (n = 30)	P
Demographic characteristic			
Age, years, median (range)	67 (56–78)	68 (50–85)	.99
Male sex	7 (47)	10 (33)	.38
White race	14 (93)	30 (100)	.33
Clinical characteristic			
Diabetes	3 (20)	3 (10)	.38
Neutropenic at diagnosis ^a	4 (27)	9 (30)	1.00
Central line duration, days, median (range)	138 (31–1092)	192 (7–2253)	.93
Solid organ malignancy	13 (87)	25 (83)	1.00
Implanted port	8 (53)	16 (53)	1.00
Healthcare exposure			
Chemotherapy given in clinic within 30 days	11 (73)	22 (73)	1.00
Saline flush within 30 days before	13 (87)	23 (77)	.70
Saline flush Sep–Oct 2011, before culture	14 (93)	18 (60)	.03
Hospitalization within 30 days	7 (47)	7 (23)	.17

NOTE. Data are no. (%) of patients, unless otherwise indicated. CI, confidence interval; OR, odds ratio.

^a Neutropenia was defined as absolute neutrophil count less than 500 cells/mm³ on the date of collection of the first positive *Tsukamurella* species culture sample.

ditions. This practice has been implicated in previous outbreaks of bacterial bloodstream infections involving outpatient oncology facilities.^{16,17} When performed outside of an appropriate environment (eg, chemotherapy hood), this practice violates the injection safety component of standard precautions, which states that bags of intravenous solution should not be a common source of supply for multiple patients.¹⁸ In this clinic, although the saline flush syringes were prepared in a chemotherapy hood, accepted pharmacy standards for working in such a hood were not followed. The lapses in appropriate technique while working in the hood likely allowed repeated contamination of the saline from the environment (eg, via the open window) during the outbreak. Several other lapses in injection safety were also identified (eg, storage and reuse of opened single-dose vials).

These lapses are consistent with those reported in a number of other outpatient-associated outbreaks and highlight the challenge of ensuring proper infection control practices in these settings.^{16,17,19-21} As was evident with clinic A, not all outpatient facilities have dedicated infection control policies for patient protection, nor do all outpatient facilities consult regularly with individuals with training and expertise in infection prevention. Federal and state agencies establish infection control requirements for acute care hospitals. In contrast, in many states, no corresponding oversight exists for independent oncology clinics.

Oncology practices are unique among outpatient settings because of a highly immunosuppressed patient population and because of challenges with preparing and administering chemotherapy. The West Virginia state pharmacy code allows physicians to compound medications for their patients without the involvement of a licensed pharmacist;²² such laws vary by state. Problems can arise when, as occurred in clinic A, no staff members are knowledgeable in proper medication preparation practices. Strict adherence to published standards, such as chapter 797 of the United States Pharmacopeia and American Society of Health-System Pharmacists guidelines for handling hazardous drugs,^{11,12} is essential to ensure the safety of chemotherapy given to patients. However, outpatient oncology facilities might vary greatly in their awareness and adoption of these standards.

To help outpatient oncology facilities establish appropriate infection control strategies, the CDC developed a basic infection control plan tailored to these settings that outlines key policies and procedures needed to meet minimal requirements for patient safety.²³ These include the proper use and handling of injectable medications and correct procedures for accessing central lines. Outpatient oncology facilities without an existing plan are encouraged to use this document as a starting point. Facilities with an existing plan should ensure that it includes the essential elements outlined in the document. As recommended in the basic infection control plan, oncology outpatient facilities should consult with an infection preventionist for on-site evaluations and observations of practices. They should also consult with a pharmacist for

guidance on appropriate preparation and handling of chemotherapy medications. Additional work is in progress to characterize the scope of deviations from recommended chemotherapy preparation practices among outpatient oncology facilities. Understanding the magnitude of the problem will facilitate efforts to increase facility awareness of and adherence to applicable standards.

This outbreak also illustrates the need for standardized methodology to perform bloodstream infection surveillance in these settings. Although we were unable to determine the clinic's overall rate of bloodstream infection, there currently are no established methods to calculate bloodstream infection rates from outpatient settings, nor any standards by which to determine whether a given rate is elevated.

We acknowledge that the investigation has limitations. First, clinical information about patients was obtained solely by retrospective chart review, and we were unable to obtain information about exposures for the entire cohort of patients in the clinic. Second, in hospitals other than hospital A, the case-finding strategy focused on potential misidentification of the organism as *Bacillus* species. Because *Tsukamurella* species can be misidentified as other bacteria, some cases might have been missed.⁷ Third, infection control and medication preparation practices in clinic A changed over the course of the investigation; therefore, some practices that contributed to risk of infection might not have been observed. Fourth, environmental testing took place several weeks after the last case was identified, limiting our ability to identify potential environmental sources.

A combination of careful descriptive epidemiology with particular attention to outlier cases, direct observations, and analytic studies were needed to support this investigation, which pointed to deficiencies in medication preparation practices as the cause of these unusual infections. The following lessons can be learned from this investigation. First, gram-positive bacilli bloodstream isolates from patients with indwelling central lines might represent unusual organisms, such as *Tsukamurella* species. Second, breaches in medication preparation and handling in outpatient oncology settings are a potential source of infection, and more uniform standards and oversight are needed. Third, vigilance and cooperation between laboratory professionals, clinicians, and public health officials are essential for investigations of healthcare-associated outbreaks.

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Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

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