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SERRATIA MARCESCENS BACTEREMIA TRACED TO AN INFUSED NARCOTIC

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ABSTRACT

Background From June 30, 1998, through March 21, 1999, several patients in the surgical intensive care unit of a hospital acquired *Serratia marcescens* bacteremia. We investigated this outbreak.

Methods A case was defined as the occurrence of *S. marcescens* bacteremia in any patient in the surgical intensive care unit during the period of the epidemic. To identify risk factors, we compared patients with *S. marcescens* bacteremia with randomly selected controls. Isolates from patients and from medications were evaluated by pulsed-field gel electrophoresis. The hair of one employee was tested for fentanyl.

Results Twenty-six patients with *S. marcescens* bacteremia were identified; eight (31 percent) had polymicrobial bacteremia, and seven of these had *Enterobacter cloacae* and *S. marcescens* in the same culture. According to univariate analysis, patients with *S. marcescens* bacteremia stayed in the surgical intensive care unit longer than controls (13.5 vs. 4.0 days, $P<0.001$), were more likely to have received fentanyl in the surgical intensive care unit (odds ratio, 31; $P<0.001$), and were more likely to have been exposed to two particular respiratory therapists (odds ratios, 13.1 and 5.1; $P<0.001$ for both comparisons). In a multivariate analysis, receipt of fentanyl and exposure to the two respiratory therapists (adjusted odds ratio for one therapist, 6.7; $P=0.002$; adjusted odds ratio for the other therapist, 9.5; $P=0.02$) remained significant. One respiratory therapist had been reported for tampering with fentanyl; his hair sample tested positive for fentanyl. Cultures of fentanyl infusions from two case patients yielded *S. marcescens* and *E. cloacae.* The isolates from the case patients and from the fentanyl infusions had similar patterns on pulsed-field gel electrophoresis. After removal of the implicated respiratory therapist, no further cases occurred.

Conclusions An outbreak of *S. marcescens* and *E. cloacae* bacteremia in a surgical intensive care unit was traced to extrinsic contamination of the parenteral narcotic fentanyl by a health care worker. Our findings underscore the risk of complications in patients that is associated with illicit narcotic use by health care workers. (N Engl J Med 2002;346:1529-37.)

SERRATIA MARCESCENS has been implicated as a pathogen in a large array of infections.[1] Nosocomial *S. marcescens* outbreaks have been associated with contaminated equipment, such as transducers[2,3] and bronchoscopic equipment[4]; contaminated fluids and cleaning solutions[5-7]; contaminated hands or fingernails of employees[8]; and a reduced nurse-to-patient ratio.[9]

From June 30 through September 30, 1998, nine cases of *S. marcescens* bacteremia were detected in the surgical intensive care unit of a 455-bed tertiary care facility. Because of the rarity of serratia species in clinical specimens and the similar antimicrobial-susceptibility patterns in these cases, eight of the nine isolates were sent to a secondary laboratory for genotyping. When the laboratory was unable to determine the genotype of the isolates, they were sent to the Centers for Disease Control and Prevention (CDC) for pulsed-field gel electrophoresis, which showed that seven of the eight isolates had indistinguishable patterns. From October 1, 1998, to March 11, 1999, 16 more patients acquired *S. marcescens* bacteremia, and the CDC was invited to assist in the investigation of this outbreak. After our investigation began, a 26th patient was found to have *S. marcescens* bacteremia. The objectives of our investigation were to define the extent of the problem, identify the source and risk factors, and implement control measures.

METHODS

Determination of Trends over Time

We reviewed the hospital's microbiology records for bloodstream infections caused by serratia species and other gram-negative bacteria from July 1996 through March 1999; we then compared the rates of bacteremia during the epidemic period (from June 30, 1998, through March 21, 1999) and before the epidemic period (from July 1, 1996, through June 29, 1998). Serratia species isolated from tissues other than blood during the epidemic period also were reviewed.

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Definition and Ascertainment of Cases

A case was defined as any instance of *S. marcescens* bacteremia in a patient in the hospital's surgical intensive care unit that was diagnosed during the epidemic period. Cases were identified by review of infection-control, microbiologic, and medical records.

Case–Control Study

To identify which patients in the surgical intensive care unit were at risk for *S. marcescens* bacteremia, we compared patients with such bacteremia (case patients) with randomly selected controls (patients who stayed in the hospital's surgical intensive care unit for at least 48 hours during the epidemic period without acquiring gram-negative bacteremia). Factors assessed included demographic and clinical characteristics of the patients and exposure to devices, procedures, and medications. The severity of illness was assessed by means of the Acute Physiology and Chronic Health Evaluation (APACHE II) score,[10] determined within 24 hours after admission to the surgical intensive care unit. To assess exposure to health care workers, we determined which physicians, nurses, and respiratory therapists had contact with case patients and controls as documented by their signatures in the medical records. Data on exposure were collected for case patients from the time of admission to the surgical intensive care unit until the diagnosis of the *S. marcescens* bacteremia. Exposure data for controls were collected from the time of admission to the surgical intensive care unit up to the median length of stay at which *S. marcescens* bacteremia was diagnosed in the case patients (seven days), or until discharge from the surgical intensive care unit, if the control stayed in the unit for less than seven days.

Review of Procedures and Microbiologic Studies

We reviewed pharmacy procedures and infection-control policies and practices in the surgical intensive care unit and respiratory-therapy areas.

S. marcescens isolates from case patients were sent to the CDC for species confirmation, antimicrobial-susceptibility testing, and pulsed-field gel electrophoresis by standard methods.[11] On March 17, 1999, tracheal or urinary cultures were obtained from all patients in the surgical intensive care unit to identify those with colonization. Prior environmental cultures performed by hospital personnel were reviewed. Water samples from the rooms in which case patients had stayed, the offices of the surgical intensive care unit and the respiratory-therapy area, the nursing stations of the surgical intensive care unit, and the restrooms in the vicinity of the surgical intensive care unit were sent to the CDC for processing.[12] Cultures of medications infused at the time of onset of symptoms in the case patients were obtained and processed in the hospital's microbiology laboratory. Medication bags used for selected patients were forwarded to the CDC for additional testing. Cultures were obtained from unopened bottles or vials of selected medications and from the hands of a sample of health care workers by the hand-wipe method.[13]

Statistical Analysis

Data were collected on standardized forms and analyzed with use of Epi Info software (version 6.03, CDC) and SAS software (version 6.12, SAS Institute). The rates of bacteremia before and during the epidemic period were compared by the chi-square test. For the case–control study, categorical and continuous variables were compared with use of appropriate univariate tests. Odds ratios and 95 percent confidence intervals were calculated. Multivariate logistic-regression analyses were performed in which all variables that were significant ($P<0.05$) in univariate analysis were included.

RESULTS

Trends over Time in the Rate of *S. marcescens* Bacteremia

The hospital-wide rate of *S. marcescens* bacteremia was significantly higher during the epidemic than before the epidemic (0.43 vs. 0.028 infection per 1000 patient-days, $P<0.001$). *S. marcescens* was significantly more likely to be isolated from patients in the surgical intensive care unit than from other patients (6.2 vs. 0.06 isolates per 1000 patient-days, $P<0.001$). The rates of *S. marcescens* bacteremia in areas other than the surgical intensive care unit were similar during and before the epidemic (0.02 vs. 0.06 infection per 1000 patient-days, $P=0.2$). In contrast, the rate of *S. marcescens* bacteremia in the surgical intensive care unit was significantly higher during the epidemic than before it (8.1 vs. 0.1 isolates per 1000 catheterization-days, $P<0.001$). Only 10 serratia isolates from sources other than blood or catheters were identified during the epidemic period; 3 of these were obtained from case patients after bacteremia had been identified.

Identification and Characteristics of Patients with *S. marcescens* Bacteremia

Twenty-six patients with *S. marcescens* bacteremia were identified during the epidemic period (Fig. 1). The median length of stay in the surgical intensive care unit before a positive blood culture was obtained was 7 days (range, 2 to 26). Seventeen of these patients were male (65 percent); the mean age of the patients was 48.2 years (range, 17 to 87). Of the 26 cases of bacteremia, 8 (31 percent) were polymicrobial, in 7 of which (27 percent) *Enterobacter cloacae* was identified in the same culture as *S. marcescens*, and 13 (50 percent) were persistent (*S. marcescens* was identified in blood cultures on two or three different dates over a range of two to nine days). Eleven patients (42 percent) were receiving antimicrobial agents to which the *S. marcescens* isolate was susceptible at the time the positive blood culture was obtained. In contrast, 11 cases of polymicrobial bacteremia were detected during the epidemic period; only 3 did not include serratia species.

Case–Control Study

In a univariate analysis, case and control patients were similar in terms of sex, age, the proportion undergoing surgery, the proportion requiring mechanical ventilation, the proportion requiring respiratory therapy, the proportion with exposure to fentanyl anywhere in the hospital, and mortality. Patients with *S. marcescens* bacteremia were significantly more likely than controls to have been admitted because of trauma; to have a longer stay in the surgical intensive care unit, a higher median temperature, or rigors; to have undergone bronchoscopy; and to have received a blood transfusion or fentanyl, particularly as a continuous infusion, in the surgical intensive care unit (Table 1). The median number of days of continuous fentanyl infusion and the median total dose were higher for case patients than for controls. Further-

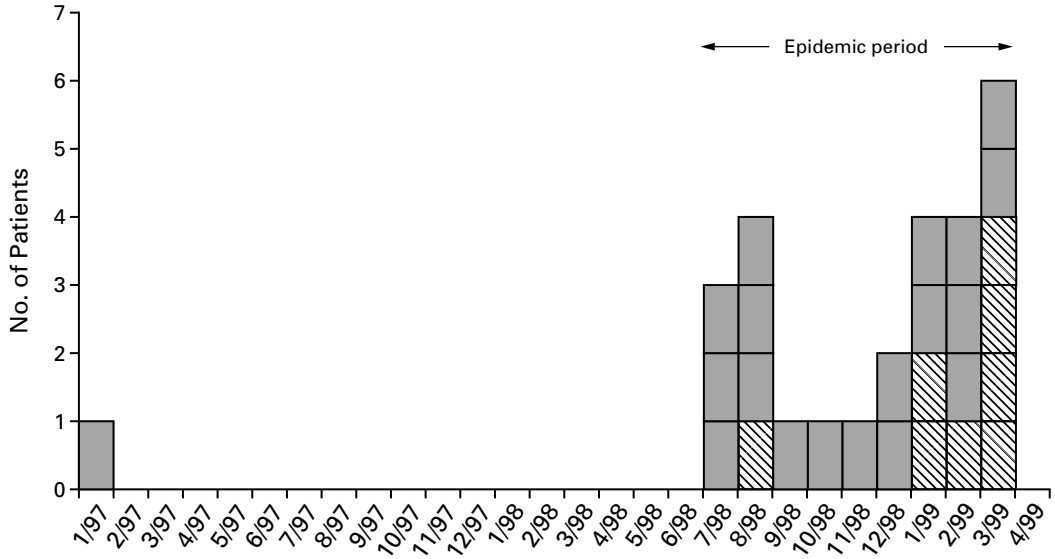


Figure 1. Distribution of Cases of *Serratia marcescens* Bacteremia from January 1, 1997, to April 30, 1999. Hatched blocks indicate patients with polymicrobial bacteremia.

more, in 17 case patients (65 percent), the blood culture that yielded *S. marcescens* was collected while they were receiving a fentanyl infusion or within 24 hours after they had received a fentanyl infusion.

Background of Personnel

Three types of health care workers had substantial contact with patients in the surgical intensive care unit: physicians, nurses, and respiratory therapists. A single surgical team provided care for most of the patients in the surgical intensive care unit, and several subspecialty services assisted. Designated surgical intensive care unit nurses were not permanently assigned to a particular station. Eight respiratory therapists were assigned to the surgical intensive care unit, and numerous other respiratory therapists (more than 30) cared for patients in the surgical intensive care unit as well as other patients.

Univariate analyses indicated that several health care workers were associated with a patient's having *S. marcescens* bacteremia (Table 1). One physician (Physician 5) was significantly associated with such bacteremia; however, he had recorded contact with only 15 of the 26 case patients. No nurse had recorded contact with more than 10 case patients. Among the respiratory therapists, five were significantly associated with bacteremia. One respiratory therapist (designated Respiratory Therapist 18) had documented contact with 23 of 26 case patients (88 percent). Furthermore, Respiratory Therapist 18 worked within 48 hours before a positive culture was obtained in two of three case patients with no contact documented by their individual medical records.

Analysis of data on the health care workers was complicated, because many different employees provided care to any given patient throughout the patient's hospital stay, and even within one hospital day. This was particularly true of the respiratory therapists (Fig. 2).

In multivariate analyses, only receipt of a continuous fentanyl infusion and receipt of care from Respiratory Therapist 18 or Respiratory Therapist 3 were independent risk factors for *S. marcescens* bacteremia. Furthermore, when we performed multivariate analyses including only the 25 case patients and 24 controls who received continuous fentanyl infusions, receipt of care from Respiratory Therapist 18 or Respiratory Therapist 3 remained independent risk factors for *S. marcescens* bacteremia (Table 2).

Independently of our investigation, a report was filed at the hospital by a nurse in the surgical intensive care unit who witnessed Respiratory Therapist 18 manipulating intravenous infusions (including fentanyl) at the bedside of a patient on two occasions. She observed Respiratory Therapist 18 crouched down by the bedside (far from the ventilator) holding a needle. Both incidents involved a single patient (Patient 24), samples of whose fentanyl infusion grew clonal

TABLE 1. POTENTIAL RISK FACTORS IN PATIENTS WITH *SERRATIA MARCESCENS* BACTEREMIA AND CONTROLS FROM JUNE 30, 1998, THROUGH MARCH 21, 1999.*

POTENTIAL RISK FACTOR	PATIENTS WITH BACTEREMIA (N=26)	CONTROL PATIENTS (N=65)	ODDS RATIO (95% CI)	P VALUE
Categorical variables				
Patient characteristics or symptoms — no. (%)				
Trauma	16 (62)	14 (22)	5.8 (1.9–17.9)	<0.001
Fever	26 (100)	53 (82)	—†	0.02
Rigors	4 (15)	1 (2)	11.6 (1.1–294)	0.02
Death	3 (12)	2 (3)	4.1 (0.5–38.6)	0.13
Exposures — no. (%)				
Procedures or devices				
Bronchoscopy	11 (42)	4 (6)	11.2 (2.7–50)	<0.001
Transfusion	26 (100)	52 (80)	—†	0.02
Respiratory therapy	26 (100)	62 (95)	—†	0.55
Medications — no. (%)				
Fentanyl anywhere in hospital	26 (100)	59 (91)	—†	0.18
Fentanyl in SICU	25 (96)	29 (45)	31 (3.8–637)	<0.001
Continuous fentanyl infusion in SICU	25 (96)	24 (37)	42 (5.3–893)	<0.001
Lorazepam in SICU	18 (69)	22 (34)	4.4 (1.5–13.3)	0.002
Personnel — no. (%)				
Physician 5	15 (58)	12 (18)	6.0 (2.0–18.8)	<0.001
RT 18	23 (88)	24 (37)	13.1 (3.2–62)	<0.001
RT 3	18 (69)	20 (31)	5.1 (1.7–15.5)	<0.001
RT 16	19 (73)	21 (32)	5.7 (1.9–18.0)	<0.001
RT 11	19 (73)	25 (38)	4.3 (1.4–13.5)	0.003
RT 13	19 (73)	32 (49)	2.8 (0.9–8.6)	0.04
Continuous variables				
Length of SICU stay — days				
Median	13.5	4.0		<0.001
Range	3–40	2–45		
APACHE II score				
Median	18.0	14.0		0.09
Range	9–30	4–28		
Continuous fentanyl infusion				
Total dose — μg	27,979	6100		<0.001
No. of days				<0.001
Median	5	2		
Range	2–27	1–7		

*CI denotes confidence interval, SICU surgical intensive care unit, RT respiratory therapist, and APACHE II Acute Physiology and Chronic Health Evaluation.

†The odds ratio could not be determined.

strains of serratia and enterobacter species when cultured. Subsequently, Respiratory Therapist 18 agreed to testing of hair samples for fentanyl. Hair samples collected by personnel from the hospital on March 26, 1999, and sent to an independent laboratory were positive for fentanyl.[14,15] Respiratory Therapist 18 was placed on administrative leave and his hospital employment was subsequently terminated. The 26th case was diagnosed within three days after this employee's removal, and no additional cases have been identified in the more than two years since he left the hospital.

Microbiologic and Molecular Studies

Our March 17, 1999, surveillance cultures identified *S. marcescens* in only 1 of 22 patients who were then in the surgical intensive care unit. In addition, more than 50 environmental cultures performed by hospital staff during the epidemic period were negative for serratia species, as were all 19 water samples. Samples of intravenous infusions administered to two patients were recovered at the time of the onset of symptoms of bacteremia. *S. marcescens* and *E. cloacae* were isolated from cultures of the fentanyl infusions of one patient (Patient 21). Cultures of the dopamine infusion given during the same period to this patient were sterile. Fentanyl-infusion cultures from the second patient (Patient 24), who had documented bacteremia with both *S. marcescens* and *E. cloacae,* yielded *E. cloacae* at the hospital microbiology laboratory and *E. cloacae* and *S. marcescens* at the CDC. A review of the Food and Drug Admin-

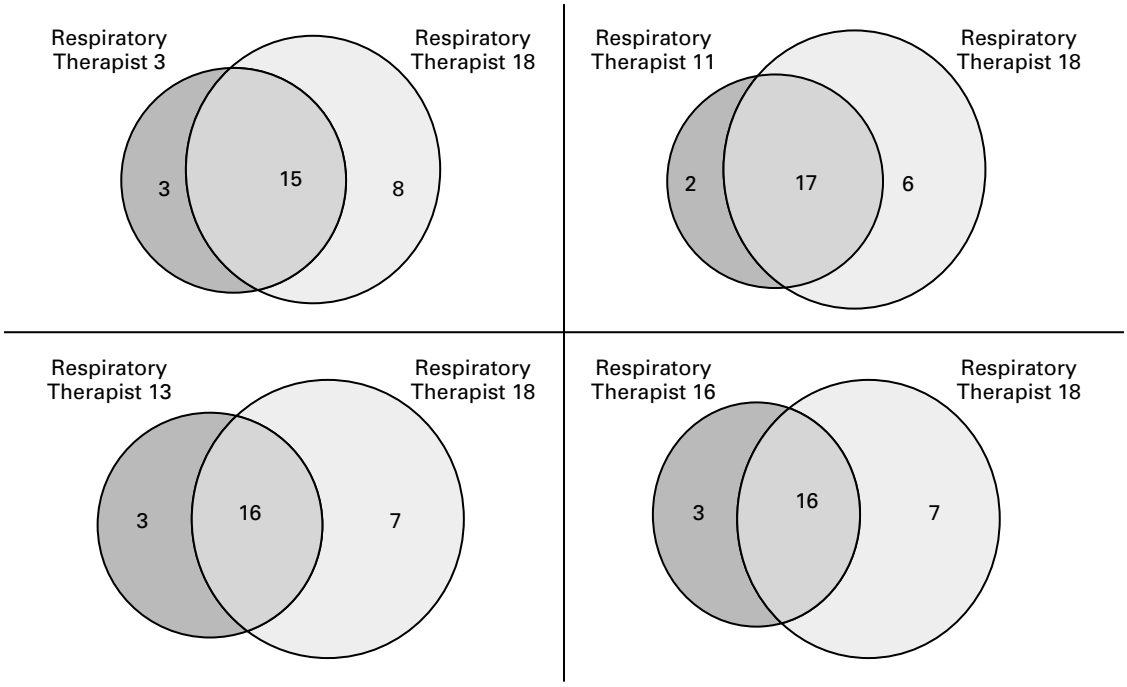


Figure 2. Exposure of 26 Case Patients to Respiratory Therapists.

Each circle indicates the number of patients with *S. marcescens* bacteremia in whose charts a respiratory therapist's signature was identified. The comparisons are for five respiratory therapists (designated 3, 11, 13, 16, and 18) associated with bacteremia in the univariate analyses.

istration Adverse Event Reporting System data base failed to identify reports of intrinsic contamination of this product from July 1998 through March 1999. Cultures of unopened fentanyl ampules were sterile. Of the 25 *S. marcescens* isolates from case patients that were sent to the CDC, 24 had similar patterns on pulsed-field gel electrophoresis. One case patient had an isolate with a unique pattern; this patient was the only one who did not receive continuous fentanyl in the surgical intensive care unit. The *S. marcescens* isolates cultured from fentanyl infusions administered to Patients 21 and 24 were indistinguishable from their blood isolates (Fig. 3A). All seven *E. cloacae* isolates from case patients and fentanyl-infusion isolates from Patients 21 and 24 were indistinguishable (Fig. 3B). Cultures from the hands of three hospital employees, including Respiratory Therapist 18, were negative for *S. marcescens* and *E. cloacae*.

DISCUSSION

Fentanyl, an opiate narcotic approximately 80 times as potent as morphine, has been used as an illicit drug.[16-18] Our investigation implicated fentanyl infused continuously in the surgical intensive care unit as the source of bacteremia. Numerous data identified Respiratory Therapist 18 as the most likely source of the extrinsic contamination. He was the respiratory therapist with the strongest association with patients who had bacteremia. Independently of our investigation, there were reports of probable tampering with fentanyl by Respiratory Therapist 18. In addition, a hair sample from Respiratory Therapist 18 contained fentanyl, documenting recent ingestion, injection, or infusion of fentanyl. After the removal of Respiratory Therapist 18, there were no further cases of *S. marcescens* bacteremia.

Another respiratory therapist routinely assigned to the surgical intensive care unit, Respiratory Therapist 3, was identified as associated with *S. marcescens* bacteremia in patients. However, eight case patients' medical records had been signed by Respiratory Therapist 18 but not by Respiratory Therapist 3. After our analysis, we recommended to the hospital personnel that hair from this respiratory therapist and from other respiratory therapists significantly associated ($P<0.05$ by univariate analysis) with the cases of *S. marcescens* bacteremia be tested for fentanyl. The hospital chose not to pursue further test-

TABLE 2. RESULTS OF MULTIVARIATE ANALYSIS OF RISK FACTORS FOR *SERRATIA MARCESCENS* BACTEREMIA, FROM JUNE 30, 1998, THROUGH MARCH 21, 1999.*

EXPOSURE	CASE PATIENTS	CONTROL PATIENTS	ODDS RATIO (95% CI)	P VALUE
	no. (%)			
All patients†				
Continuous fentanyl infusion in SICU	25 (96)	24 (37)	44.3 (4.7–421.8)	0.001
RT 18	23 (88)	24 (37)	6.7 (1.4–31.6)	0.002
RT 3	18 (69)	20 (31)	9.5 (2.3–39.0)	0.02
Patients receiving continuous fentanyl infusion in SICU‡				
RT 18	23 (92)	11 (46)	11.1 (1.9–68.7)	0.009
RT 3	17 (68)	4 (17)	8.9 (1.9–40.7)	0.005

*CI denotes confidence interval, SICU surgical intensive care unit, and RT respiratory therapist.

†Percentages are based on 26 case patients and 65 control patients.

‡Percentages are based on 25 case patients and 24 control patients.

ing, mainly because new cases had ceased to appear by that time. Thus, we cannot exclude the possibility that Respiratory Therapist 3 may have been an accomplice of Respiratory Therapist 18 or may have committed similar acts. However, we are unaware of any evidence implicating any respiratory therapist except Respiratory Therapist 18 in fentanyl tampering, and no further cases occurred, despite the presence of Respiratory Therapist 3 after the removal of Respiratory Therapist 18.

Respiratory Therapist 18 was implicated in the contamination of fentanyl, but it is uncertain how the fentanyl became contaminated. Despite repeated interviews by hospital personnel, Respiratory Therapist 18 never admitted illicit-drug use or theft. We hypothesize that reuse of needles to remove fentanyl may have led to inadvertent contamination. Another possibility is that a liquid was used as replacement for fentanyl after the theft of the drug to replace the missing volume of narcotic in the patients' infusion bags. Despite a search of the surgical intensive care unit and the related environment for devices or water sources that could have been used in the theft of fentanyl, no reservoir could be identified. A third possibility is that fentanyl became contaminated during manipulation by the implicated employee's hands. Cultures collected from the hands of Respiratory Therapist 18 were negative for serratia species and enterobacter species; however, Respiratory Therapist 18 was warned that he would be tested.

It remains unclear how Respiratory Therapist 18 used fentanyl. His arms had no needle tracks, but he could have injected fentanyl into another area of his body. Fentanyl is used preoperatively as an oral agent to supplement anesthesia[19]; an operating room supervisor's dependence on fentanyl has been reported to be associated with oral ingestion.[20]

Bacteremia associated with extrinsic contamination of a narcotic by a health care worker has been described previously. In 1991, Maki et al. described several *Ralstonia pickettii* (formerly known as *Pseudomonas pickettii*) infections related to contamination of fentanyl.[21] A pharmacist resigned in conjunction with this incident.

Theft of narcotics and the potential for resulting complications in patients remain a problem in health care settings. The episode described here might initially appear to be an isolated event related to poor judgment on the part of an employee. However, this outbreak persisted for more than nine months, with a large group of hospitalized patients potentially at risk. We are aware of another report of the theft of narcotics used in intravenous infusions[22,23] (and unpublished data). Although these cases were not associated with bacteremia, one episode received wide attention in the media because of concern about the possible spread of hepatitis B or hepatitis C virus.[22,23]

Estimates based on the 1991–1993 National Household Survey on Drug Abuse indicate that 4.2 percent of hospital workers acknowledge current illicit-drug use, and 8.9 percent of workers report previous illicit-drug use.[24] In a survey of anesthesia training programs in the United States, 214 (74 percent) had at least one report of illicit-drug use by a trainee or an instructor.[25]

In our investigation, hair testing documented fen-

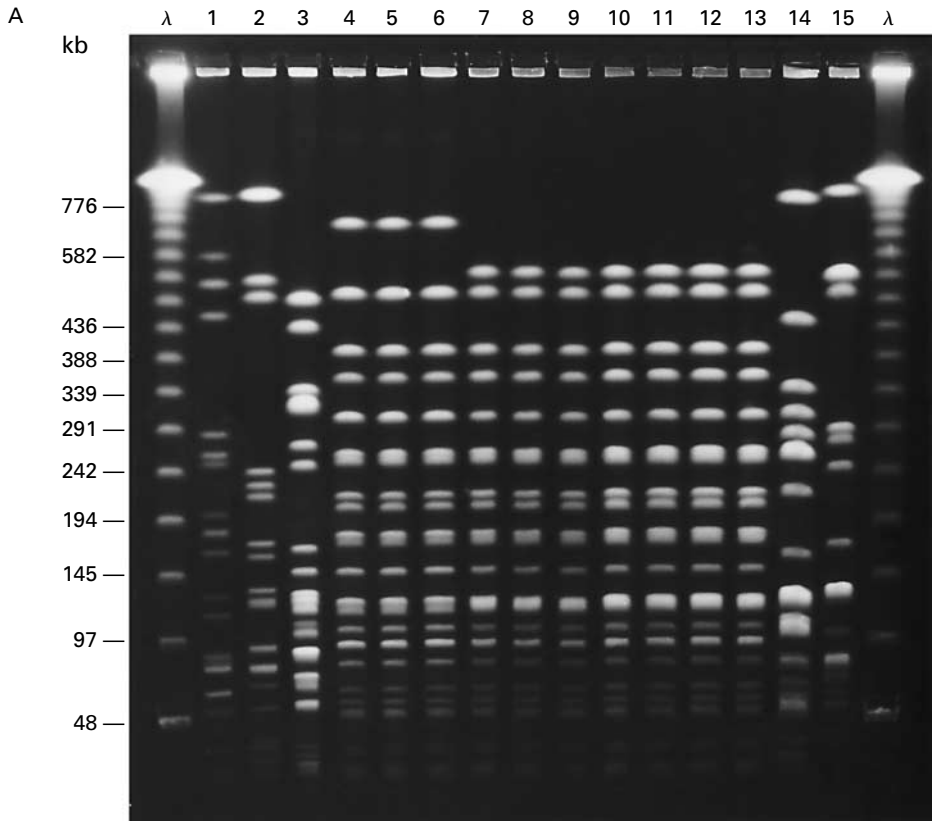


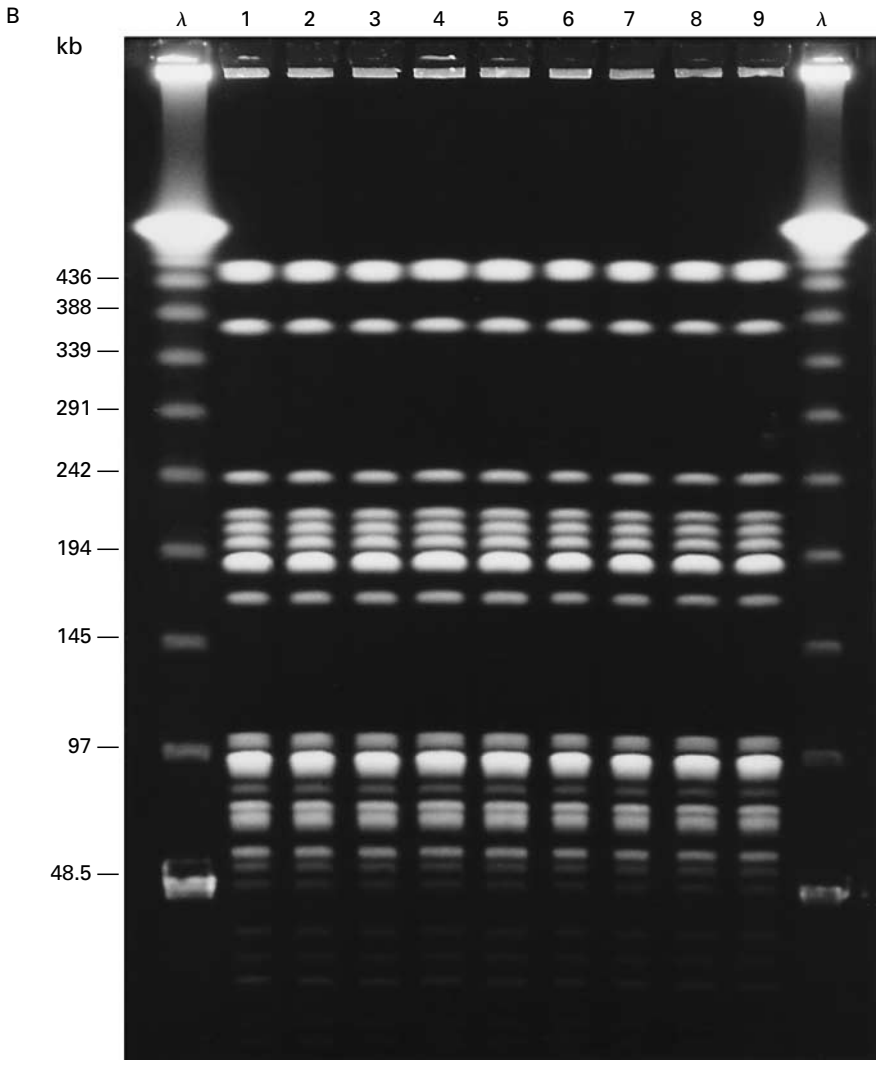
Figure 3. Pulsed-Field Gel Electrophoresis of Bacterial Isolates.

Panel A shows *Serratia marcescens* isolates. The lanes are as follows: λ, ladder DNA size marker; 1 to 3, *S. marcescens* isolates from a cluster of three infections that occurred more than one year before the outbreak; 4 to 6, Patients 2, 3, and 4 (identified early in the outbreak); 7 to 9, Patients 18, 19, and 20 (identified later in the outbreak); 10 and 11, isolates from blood and from fentanyl infusion in Patient 21; 12 and 13, isolates from blood and from fentanyl infusion in Patient 24; 14 and 15, catheter-tip and peritoneal isolates recovered from other unrelated patients after termination of the outbreak.

In Panel B (next page), *Enterobacter cloacae* isolates from seven patients with polymicrobial bacteremia are compared. The lanes are as follows: λ, ladder DNA size marker; 1 to 7, seven blood isolates from case patients (the isolate in lane 7 is from Patient 24); and 8 and 9, isolates recovered from fentanyl infusions in Patients 24 and 21.

tanyl abuse by the implicated health care worker, who denied such abuse. Hair testing can detect drug exposure over a longer period than testing of blood or urine.[14,15] Head hair grows about 1 cm (0.4 in.) per month, so a hair sample 10 to 13 cm (4 to 5 in.) long can supply evidence of a subject's drug use in approximately the previous 10 months. Hair-testing results are accepted by courts for prosecution purposes.[14,15,26] Thorough washing of the hair sample helps eliminate false positive results that might be produced by environmental contamination. Moreover, thorough review of respiratory-therapy procedures and procedures in the surgical intensive care unit confirmed that respiratory therapists did not have responsibility for narcotics and should not have had contact with needles or narcotic infusions.

Our investigation identified a number of controversies surrounding drug use by health care workers. Although the hospital had a policy that theft of narcotics should be investigated, there were no adequate mechanisms in place to deal with theft of patients' medications or possible resulting adverse events. The report of the CDC (a nonregulatory agency), including a recommendation to notify any respiratory-therapy regulatory agency, was sent to the hospital administration and the state health department. Additional



legal and ethical responsibilities of the hospital were addressed by its administration and legal counsel. The case was presented by a hospital official to the area district attorney, but legal action was not pursued because of insufficient evidence.

We are indebted to the infection-control, microbiology, administrative, and clinical staff of the hospital for their extensive assistance in our investigation of this outbreak.

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