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Hemodialyzer Reuse and Gram-Negative Bloodstream Infections

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Abstract

Background—Clusters of bloodstream infections caused by Burkholderia cepacia and *Stenotrophomonas maltophilia* are uncommon, but have been previously identified in hemodialysis centers that reprocessed dialyzers for reuse on patients. We investigated an outbreak of bloodstream infections caused by *B cepacia* and *S maltophilia* among hemodialysis patients in clinics of a dialysis organization.

Study Design—Outbreak investigation, including matched case-control study.

Setting & Participants—Hemodialysis patients treated in multiple outpatient clinics owned by a dialysis organization.

Predictors—Main predictors were dialyzer reuse, dialyzer model, and dialyzer reprocessing practice.

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Contributions: Study concept and design: CE, JW, ML, KR, DN, EE, JR, PRP; data acquisition/analysis/interpretation: CE, JW, ML, KR, DN, MB, SH-S, JR, PRP; statistical analysis: CE, DN, PRP; laboratory support: HM-M; study supervision: EE, JR, PRP. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. CE takes responsibility that this study has been reported honestly, accurately, and transparently; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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SUPPLEMENTARY MATERIAL

Table S1: Characteristics of dialysis organization facilities by definite case status.
Table S2: Characteristics of visited clinics (A–F).
Table S3: Positive *B cepacia* or *S maltophilia* environmental samples or patient isolates.
Figure S1: Dialyzer header and associated parts of a typical dialyzer.
Item S1: Supplemental methods.
Note: The supplementary material accompanying this article (http://dx.doi.org/10.1053/j.ajkd.2016.09.022) is available at www.ajkd.org

Outcomes—Case patients had a bloodstream infection caused by *B cepacia* or *S maltophilia*; controls were patients without infection dialyzed at the same clinic on the same day as a case; results of environmental cultures and organism typing.

Results—17 cases (9 B *cepacia* and 8 *S maltophilia* bloodstream infections) occurred in 5 clinics owned by the same dialysis organization. Case patients were more likely to have received hemodialysis with a dialyzer that had been used more than 6 times (matched OR, 7.03; 95% CI, 1.38–69.76) and to have been dialyzed with a specific reusable dialyzer (Model R) with sealed ends (OR, 22.87; 95% CI, 4.49–∞). No major lapses during dialyzer reprocessing were identified that could explain the outbreak. *B cepacia* was isolated from samples collected from a dialyzer header-cleaning machine from a clinic with cases and was indistinguishable from a patient isolate collected from the same clinic, by pulsed-field gel electrophoresis. Gram-negative bacteria were isolated from 2 reused Model R dialyzers that had undergone the facility's reprocessing procedure.

Limitations—Limited statistical power and overmatching; few patient isolates and dialyzers available for testing.

Conclusions—This outbreak was likely caused by contamination during reprocessing of reused dialyzers. Results of this and previous investigations demonstrate that exposing patients to reused dialyzers increases the risk for bloodstream infections. To reduce infection risk, providers should consider implementing single dialyzer use whenever possible.

INDEX WORDS

Hemodialysis; dialyzer reuse; dialyzer reprocessing; bloodstream infection (BSI); *Burkholderia cepacia*; *Stenotrophomonas maltophilia*; Gram-negative bacteria; patient safety; outbreak; contamination; decontamination; human error; infection prevention; dialysis organization; end-stage renal disease (ESRD); case-control

More than 400,000 individuals receive maintenance hemodialysis for end-stage renal disease in the United States.[1] More than 6,000 outpatient clinics provide regular hemodialysis treatments for these patients. Each treatment requires the use of a dialyzer[2] (Fig S1, provided as online supplementary material). Some dialyzers are designated for single-use, whereas others may be reused for multiple treatments of the same patient. Reusable dialyzers must be reprocessed using a multistep procedure involving rinsing, testing, and disinfection of the dialyzer and associated parts, such as removable header caps and O-rings.[3] Dialyzer reuse has been associated with adverse outcomes,[4] including bloodstream infections (BSIs),[5] pyrogenic reactions,[6–8] hospitalizations,[9] and death.[9–11]

Burkholderia cepacia and *Stenotrophomonas maltophilia* are Gram-negative bacteria commonly found in water and soil. In health care settings, previous outbreaks of BSIs caused by these pathogens have been associated with contaminated medication, improper handling and disposal of used medical equipment, and inadequate hand hygiene.[12–14] Outbreaks of BSI caused by these and other similar pathogens among hemodialysis patients have been attributed to contamination during dialysis circuit priming practices, lapses in medication preparation and handling, the practice of dialyzer reuse and reprocessing, and improper storage and disinfection of reused dialyzers.[15–23]

In August 2014, the California Department of Public Health and the Centers for Disease Control and Prevention (CDC) became aware of clusters of BSIs caused by *B cepacia* and *S maltophilia* among hemodialysis patients at multiple outpatient dialysis clinics owned by a single dialysis organization. In September 2014, we initiated an investigation that included a matched case-control study, direct observations of infection control practices and dialyzer reprocessing at select dialysis organization clinics, and environmental sampling and testing of reprocessed dialyzers from dialysis organization clinics. The purpose of the epidemiologic analysis was to assess risk factors for infection. We conducted observations of key practices to identify lapses that could have led to the outbreak. Environmental sampling was performed to help identify possible sources of contamination that resulted in patient infections.

METHODS

Case Definition

A definite case was a positive blood culture for *B cepacia* or *S maltophilia* from September 1, 2013, through September 30, 2014, in a patient who had received hemodialysis at any dialysis organization clinic in the previous week. A possible case was a positive blood culture for *Pseudomonas aeruginosa, Proteus* species, *Morganella morganii, Serratia marcescens, Xanthomonas* species, *Ralstonia pickettii*, or *Candida parapsilosis* during the same timeframe in a patient who had received hemodialysis at any dialysis organization clinic in the previous week.

Case Finding and Review

The dialysis organization provided outpatient dialysis services in several states. The dialysis organization maintains a database of microbiology results for specimens submitted to their centralized laboratory from any of their clinics. We reviewed these data to identify all positive blood cultures for an organism of interest between April 1, 2012, and September 30, 2014. We examined this expanded timeframe in order to understand the baseline frequency of infections.

We performed additional case finding by contacting infection preventionists at 14 local hospitals that frequently cared for patients from clinics A and B (dialysis organization clinics with highest case counts). Infection preventionists were asked to query their hospital microbiology records for any admission or emergency department blood culture positive for *B cepacia* or *S maltophilia* for September 1, 2013, through September 30, 2014. For all positive infection preventionist responses, we determined whether the patient was a dialysis organization client and if case definition criteria were met.

We developed a standard form to abstract information from electronic medical records for patient demographics, medical history, dialysis session details, and relevant outcomes. We collected dialyzer use count, which was recorded in the electronic medical record as the number of times a specific dialyzer had been used prior to that treatment session.

Case-Control Study

Only definite cases were included in the case-control study and subsequent analysis. We performed a 1:3 matched case-control study, with cases and controls individually matched on clinic and treatment date, to assess risk factors associated with BSIs following dialysis treatment. Controls were randomly selected from patients who were treated at the same clinic on the same date as the matched case. For each case, we first determined the likely exposure date, and for that date, obtained a complete list of all patients treated at the case patient's clinic. This patient list was then numbered and a random number generator was used to facilitate random selection of 3 controls for each case. Thus, each case patient's exposure date was matched to a treatment date of controls. The case patient's exposure date was defined by the timing of symptom onset (ie, fever, chills, or low blood pressure) relative to dialysis treatment. For case patients whose symptom onset was during dialysis, the date of onset was the presumed exposure date. For case patients whose symptom onset occurred before or after a dialysis treatment session, the presumed exposure date was the most recent dialysis treatment that preceded symptom onset. Patients were excluded from control selection if any of the following criteria were met 7 days prior to or after the exposure date of interest: positive blood cultures for any organism, antibiotic exposure, or signs or symptoms of a BSI (ie, fever, chills, or unexplained decrease in blood pressure). If a patient was excluded, another control was randomly selected from the patient list.

All statistical analyses were performed using SAS Enterprise Guide, version 5.1 (SAS Institute Inc). Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using matched univariate logistic regression with exact conditional analysis. Dialyzer use count was examined as a categorical and continuous variable. For the categorical variable, we divided dialyzer use into 2 categories relative to the median number of dialyzer uses among all cases and controls.

Clinic Observations and Reprocessing Assessment

We conducted site visits at 6 dialysis organization clinics and separated observations into categories based on the types of procedures observed. This was done to better understand how practices differed between dialysis organization clinics. Category 1 observations included observations of injectable medication preparation and handling and handling, and reprocessing of used dialyzers. Category 2 observations targeted infection control practices of the hemodialysis treatment, including vascular access care, management of blood tubing during priming, and disinfection of prime buckets. At clinics A and B, we performed both category 1 and 2 observations in order to better understand what may have contributed to the large number of cases there. We performed only category 1 observations at clinics C to F, which were chosen based on geographic location (ie, closest to where the team was based), dialyzer reprocessing equipment in use, and occurrence of cases. These clinics were visited to provide more information on how reprocessing methods were performed across dialysis organization clinics, including clinics with and without cases. Some clinics that had definite cases were not visited due to geographic limitations.

Company-Wide Assessment

We conducted an organization-wide assessment of dialyzer reprocessing practices by examining data provided by the dialysis organization. Requested information included data for reprocessing equipment (whether automated or manual) and percentage of patients at each clinic undergoing treatment with reusable dialyzers.

Environmental and Dialyzer Sampling and Laboratory Testing

Collection and Processing of Surface and Water Samples—The dialysis organization performed sampling on the Renaclear (Medivators, Inc.) dialyzer header-cleaning machine at clinic A prior to arrival of the investigation team. We collected additional environmental samples from multiple clinics using 3M Sponge-Sticks and swabs. Renatron reprocessing machine (Medivators) connectors, dialyzer rinsing equipment, and faucet heads were sampled. Reverse osmosis water samples were collected at multiple clinics from a variety of points in the water distribution loop.

Each 3M Sponge-Stick was separated from its handle and homogenized in a blender (Stomacher 400C) in phosphate-buffered saline with Tween-80. This fluid was centrifuged and cultured on blood agar plates, MacConkey II agar, and trypticase soy broth. Swabs were rolled onto the first quadrant of a MacConkey II agar plate and then streaked across the plate to isolate colonies. The swab was then vortexed in trypticase soy broth to release any microorganisms. All trypticase soy broth cultures were incubated overnight, before being streaked for isolation on blood agar plates and MacConkey II agar. All plates were incubated for up to 2 days at 35°C, then screened for suspect colony growth.

Finally, we evaluated water sample quality using heterotrophic plate counts as previously described.

Collection and Processing of Dialyzers—A convenience sample of 15 reused dialyzers from 6 dialysis organization clinics was provided for testing at the CDC. The purpose of this testing was to determine the adequacy of the dialysis organization's typical reprocessing procedure by assessing microbiological organism burden in reprocessed dialyzers. Dialyzers were reprocessed by the individual clinics following their normal automated reprocessing procedures and filled with peracetic acid, then shipped to the CDC. All dialyzers were selected by the dialysis organization without input from the team and prior to the team's arrival on site. Two of these dialyzers were collected from clinic A; none were collected from clinic B.

At the CDC, dialyzers were flushed with sterile saline. Peracetic acid levels of both the undiluted dialyzer eluent and saline rinse from the venous port were measured using midrange peracetic acid strips (LaMotte). The saline flush was then filtered through a polycarbonate filter and placed on tryptic soy agar with 5% sheep's blood (blood agar plate; Becton Dickinson) and *B cepacia* selective agar (Remel) plates. All plates were incubated at 30°C and screened for growth at 48 hours. polycarbonate filter and placed on tryptic soy agar with 5% sheep's blood (blood agar plate; Becton Dickinson) and *B cepacia* selective agar (Remel) plates. All plates were incubated at 30°C and screened for growth at 48 hours.

Organism Identification and Strain Typing—Organism identification was confirmed using an automated biochemical identification system (Vitek 2; bioMérieux) or with a MALDI-TOF (matrix-assisted laser desorption/ionization time-of-flight) mass spectrometer (Bruker Daltonics). Pulsed-field gel electrophoresis (PFGE) was performed on all *B cepacia* and *S maltophilia* isolates, including those collected from the Renaclear devices. Tenover criteria were used to compare the isolate PFGE patterns. Isolates with >95% similarity in PFGE band patterns were considered closely related. Detailed laboratory methods are included in the online supplemental methods (Item S1).

Ethics and Informed Consent

This activity underwent human subjects review at the CDC and was determined to constitute a nonresearch urgent public health response. As such, institutional review board review was not required. Because only pre-existing data were used, informed consent was not obtained.

RESULTS

Case Finding

We identified 17 definite cases (9 *B cepacia* and 8 *S maltophilia)* and 12 possible cases (Fig 1) for September 1, 2013, through September 30, 2014. Of definite cases, 8 occurred at clinic A; 6, at clinic B; and 3, at 3 other clinics. Two of the definite cases were identified through case finding at local hospitals. Possible cases included 5 P aeruginosa, 4 S marcescens, and 3 Proteus species BSIs. Possible cases occurred across 10 dialysis organization clinics. For the 17 months preceding the investigation period (April 1, 2012, to September 1, 2013), dialysis organization records documented 3 instances of BSIs caused by *B cepacia* or *S maltophilia* and 10 BSIs caused by organisms included in the possible case definition (Fig 1).

Case Characteristics

The 17 definite cases occurred in 16 case patients. One case patient had 2 infections, each with a different organism, more than 21 days apart. Definite cases were characterized by chills (76%) and fever (59%). Hospitalization due to infection occurred in 6 (35%) definite case patients, with no deaths reported (Table 1). All definite cases occurred in clinics that practiced dialyzer reuse (Table S1).

Case-Control Study

Case patients and matched controls were similar in age, sex, dialysis treatment schedule, and catheter use (Table 2). All cases and controls were treated with polysulfone membrane dialyzers. A higher proportion of case patients than controls were treated with a reused dialyzer (94% vs 76%) and received nocturnal hemodialysis (24% vs 10%), but these differences were not statistically significant.

Each additional use of a dialyzer was significantly associated with increased BSI odds (OR, 1.07; 95% CI, 1.01–1.14). Cases were more likely than controls to have a dialyzer use count greater than the median number, which was 6 (OR, 7.03; 95% CI, 1.38–69.76). There was also a significant association between case status and the Model R dialyzer, a reusable

dialyzer with a sealed header (OR, 22.87; 95% CI, 4.49–∞) that was used by all case patients from clinic A but no case patients from clinic B.

Clinic Observations and Reprocessing Assessment

Visited clinics typically used a combination of manual and automated methods to reprocess dialyzers (Table S2). The dialyzer was first flushed with reverse osmosis water by hand or with the aid of a rinsing station. At 2 clinics (clinic A and one where no cases occurred), the header space (ie, area under sealed header caps, including ends of the dialyzer fiber bundle) was then additionally cleaned using an automated Renaclear machine to further remove blood clots, fibrin, and protein deposits. The dialyzer header cap was removed (if removable) along with the O-ring and disinfected using a 1% Peracidin (Angelini) solution. In clinics with automated equipment, the dialyzer was then wiped with a disinfectant-soaked cloth and attached to a Renatron machine, which flushed the dialyzer with disinfectant, performed a membrane leak test and dialyzer volume check, and then filled the dialyzer with a peracetic acid solution. In clinics without automated systems, the dialyzer was filled with manually prepared disinfectant solution and the volume and leak tests were performed by hand. The dialyzer was then manually flushed with 3.5% Peracidin and filled with the disinfectant. All Renaclear dialyzer header-cleaning machines were removed and discarded prior to the team's arrival, so related procedures could not be observed and detailed protocols were not available for review. The team was told by clinic staff that dialyzer reprocessing was rarely delayed following the completion of a treatment session. In circumstances in which delay was necessary (eg, following nocturnal dialysis), used dialyzers were refrigerated until the reprocessing technician arrived the next morning, when the normal reprocessing procedure was carried out.

The primary observed deviation from clinic protocol was in the handling of header caps and O-rings. Staff at multiple clinics failed to ensure that caps and O-rings were fully submerged in disinfectant solution. We also observed use of a high-pressure reverse osmosis water sprayer at clinic C to clean uncapped dialyzers and header caps. Hand hygiene procedures were not consistently followed in the reprocessing room. Staff at multiple clinics moved between the "clean" and "dirty" areas of the reprocessing room without changing gloves or performing hand hygiene. At clinics A and B, we observed no breaches during injectable medication preparation. Medication preparation areas were well separated from sinks. At clinic D, staff inappropriately rinsed prime buckets with tap water after disinfection of the bucket. Staff reported no recent changes in reprocessing procedures at any clinic, aside from discontinuation of the Renaclear machine use.

Environmental Sampling and Dialyzer Testing

In total, 40 environmental samples, 15 dialyzers, and 3 patient isolates (2 *B cepacia* and 1 *S maltophilia*) underwent testing. *B cepacia* was isolated from 2 swabs of Renaclear machine components (dialyzer header connector and water inlet) at clinic A and was indistinguishable from a clinic A case-patient isolate by PFGE. *B cepacia* was also isolated from reverse osmosis water and dialyzer rinsing equipment at clinic B; these differed from the clinic A case-patient isolate by either 2 or more than 7 bands upon PFGE analysis. *S maltophilia* was recovered from reverse osmosis water at clinic E, although it was unrelated

by PFGE to any case-patient isolate (Table S3). No other environmental sample tested positive for *B cepacia* or *S maltophilia*.

Fifteen Model R dialyzers were tested by CDC postreprocessing. The residual peracetic acid level for all dialyzers was >960 ppm (0.096% peracetic acid). S marcescens was cultured from one dialyzer (use count, 2), and *P fluorescens*, from another (use count, 3). Excess organic material was noted in the rinse solution of these 2 culture-positive dialyzers. Neither dialyzer collected from clinic A tested positive for organisms.

DISCUSSION

In this investigation, we identified an outbreak of BSIs caused by *B cepacia* and *S maltophilia* in multiple dialysis clinics consisting of 17 cases occurring over 13 months. Evidence from the investigation suggests that dialyzer reuse, reprocessing, and a specific dialyzer model contributed to increased risk for infection. Each additional use of the dialyzer significantly increased the risk for BSI by 7%, and higher dialyzer use count (>6) was associated with 7-fold increased risk for becoming a case. Among clinics that were visited, *B cepacia* was identified in reverse osmosis water and reprocessing equipment, and *S maltophilia* was also identified in reprocessing equipment, suggesting water introduced during reprocessing as the likely contamination source. Although lapses in infection control procedures were observed, we did not identify systematic problems in medication handling, vascular access care, management of blood tubing during priming, or dialyzer reprocessing that would have led to an outbreak of this magnitude. We determined that reuse and reprocessing under typical conditions can pose a risk for infection.

The percentage of facilities reusing dialyzers has declined since 1997, when ~82% of providers engaged in this practice.[3,26] In a 2012 survey of US dialysis centers conducted through the CDC's National Healthcare Safety Network, 24% of facilities reported reusing dialyzers (P.R.P., unpublished data). This trend has been attributed to a number of factors, including decreased cost for single-use dialyzers and more biologically compatible dialyzer membranes.[3,27,28]

A "safe" number of dialyzer reuses has not been established, and guidelines from the Association for the Advancement of Medical Instrumentation (AAMI) do not define such a threshold. Although AAMI guidelines recommend that reused dialyzers maintain at least 80% of their original blood volume, blood clots might begin to impede proper disinfection during reprocessing without causing a marked reduction in dialyzer volume. Clots in the dialyzer header or within fibers can reduce the surface area in contact with disinfecting solution and result in incomplete decontamination.

We found that a particular dialyzer type (Model R) was used by all clinic A case-patients and was associated with increased risk for infection. This high-flux dialyzer differed from others used by the dialysis organization in that its header caps were nonremovable. We observed that cleaning and disinfection of this dialyzer type was more difficult than for those with removable header caps, often requiring multiple rinsing cycles to remove visible blood and clots. Among the dialyzers tested, 2 reprocessed Model R dialyzers had visibly retained

biological material and were culture positive for Gram-negative organisms, despite having adequate levels of disinfectant present. This finding was extremely concerning because the dialyzers had only been used 2 or 3 times and no other disinfection steps are performed before a dialyzer is used on patients.

The presence of *B cepacia* on Renaclear machines that was indistinguishable from a patient isolate by PFGE supports the hypothesis that outbreak pathogens were introduced into dialyzers during reprocessing. This machine was specifically designed to aid in the precleaning of dialyzers featuring nonremovable headers. The sampled header-cleaner piece injects a disinfectant-water mixture into the dialyzer header and should be wiped with disinfectant between uses. Because we were unable to observe Renaclear use, it is possible that the contamination of this machine component was a result of nonadherence to manufacturer's instructions for Renaclear use and maintenance at the clinic. Of note, among clinics with cases, the Renaclear devices were only used at clinic A, and the Model R dialyzers were not in use at clinic B. Thus, these 2 exposures cannot explain all outbreak cases.

Outbreaks of Gram-negative bacteremia have previously been identified in the context of dialyzer reuse.[15–19] Errors in different steps in the reprocessing procedure have been implicated, including improper handling of used dialyzers,[16] cleaning of the header caps and O-rings,[15,17] inadequate disinfectant concentration,[30] and prolonged dialyzer storage and refrigeration prior to reprocessing.[18] These various error types illustrate the complexity of dialyzer reprocessing and numerous opportunities for lapses that can undermine disinfection.

Dialyzer reprocessing is a multistep process that may be challenging to perform successfully and implement consistently across multiple dialysis clinics. There is also a lack of standardization of practices within the dialysis industry. Current AAMI guidelines allow for multiple types of reprocessing procedures to satisfy the basic requirements that clinics must follow. Despite the heterogeneity observed among clinics in this investigation, all of the clinic reprocessing protocols would satisfy current AAMI guidelines. Clinics run by the dialysis organization used both manual and automated methods to reprocess dialyzers, and both methods are acceptable under AAMI. Fully manual dialyzer reprocessing methods are not prohibited in the United States despite the additional challenge posed to standardization of disinfection procedures and possible increased risk to patients.[31] Even among dialysis organization clinics with automated reprocessing procedures, practices for reprocessing O-rings and header caps were inconsistent. Other important quality control aspects of dialyzer reprocessing concerning duration of dialyzer storage and refrigeration were unable to be assessed due to poor or nonexistent record keeping. In a prior study, dialyzer reprocessing and refrigeration were associated with BSI, particularly those caused by *S maltophilia*.[18] More rigorous quality controls related to the disinfection process and demonstration that dialyzer reprocessing practices can be safely carried out in a typical dialysis clinic setting are needed.

Our investigation has a number of limitations. The small number of cases at each dialysis clinic limited our statistical power and ability to analyze the data using multiple regression to detect confounding. Additionally, our selection of facility-matched controls likely resulted

in overmatching on dialyzer use and reuse practices and further decreased our statistical efficiency. These issues may have prevented us from identifying significant associations with dialyzer reuse (vs single-use). Our assessment of reprocessing-related risk factors was limited to data that were consistently documented. We were unable to evaluate potentially important factors such as the interval from dialyzer use to reprocessing, dialyzer refrigeration, or other parameters of disinfectant preparation and reprocessing adequacy. We had only 3 patient isolates available for PFGE testing. No dialyzers were made available from clinic B (where a large number of cases occurred). Finally, only Model R dialyzers were submitted for testing; we were unable to test dialyzers with removable headers, which might be less susceptible to incomplete disinfection.

During the investigation, the dialysis organization temporarily suspended Model R dialyzer use company-wide and discontinued reuse at clinic B. In January 2015, a BSI caused by *S maltophilia* occurred in a dialysis organization patient treated with a reprocessed dialyzer; no further cases have been reported to California Department of Public Health. In late 2015, the dialysis organization completed plans to phase out dialyzer reuse at all clinics.

Contaminated reprocessed dialyzers resulting from incomplete disinfection were associated with an outbreak of BSIs affecting patients in multiple hemodialysis clinics. The results of this and previous investigations demonstrate that in practice, reuse and reprocessing of dialyzers poses an increased risk for infection to patients. Improved standardization of processes within the industry and guidance to ensure proper implementation of best reprocessing practices is needed. Providers should carefully consider the risks for infection related to dialyzer reuse and consider discontinuing reuse in the interest of patient safety. Whenever reuse is practiced, rigorous quality assurance programs should be in place to routinely document and evaluate all aspects of reprocessing and potentially related patient infections.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC or the authors' affiliated institutions. Use of trade names, commercial sources, or private organizations is for identification only and does not imply endorsement by the US Department of Health and Human Services and/or CDC.

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References

1. Saran R, Li Y, Robinson B, et al. US Renal Data System 2015 Annual Data Report: epidemiology of kidney disease in the United States. Am J Kidney Dis. 2016; 67(3 suppl 1):S1–S434.
2. Daugirdas, JT., Blake, PG., Ing, TS. Handbook of Dialysis. Philadelphia, PA: Lippincott Williams & Wilkins; 2012.
3. Lacson E Jr, Lazarus JM. Dialyzer best practice: single use or reuse? Semin Dial. 2006; 19(2):120–128. [PubMed: 16551289]
4. Pegues DA, Beck-Sague CM, Woollen SW, et al. Anaphylactoid reactions associated with reuse of hollow-fiber hemodialyzers and ACE inhibitors. Kidney Int. 1992; 42(5):1232–1237. [PubMed: 1453608]
5. Roth VR, Jarvis WR. Outbreaks of Infection and/or pyro-genic reactions in dialysis patients. Semin Dial. 2001; 13(2):92–96.
6. Rudnick JR, Arduino MJ, Bland LA, et al. An outbreak of pyrogenic reactions in chronic hemodialysis patients associated with hemodialyzer reuse. Artif Organs. 1995; 19(4):289–294. [PubMed: 7598647]
7. Gordon SM, Oettinger CW, Bland LA, et al. Pyrogenic reactions in patients receiving conventional, high-efficiency, or high-flux hemodialysis treatments with bicarbonate dialysate containing high concentrations of bacteria and endotoxin. J Am Soc Nephrol. 1992; 2(9):1436–1444. [PubMed: 1627766]
8. Alter MJ, Favero MS, Miller JK, Coleman PJ, Bland LA. Reuse of hemodialyzers. Results of nationwide surveillance for adverse effects. JAMA. 1988; 260(14):2073–2076. [PubMed: 3418871]
9. Feldman HI, Bilker WB, Hackett MH, et al. Association of dialyzer reuse with hospitalization and survival rates among U.S. hemodialysis patients: do comorbidities matter? J Clin Microbiol. 1999; 52(3):209–217.
10. Lowrie EG, Li Z, Ofsthun N, Lazarus JM. Reprocessing dialysers for multiple uses: recent analysis of death risks for patients. Nephrol Dial Transplant. 2004; 19(11):2823–2830. [PubMed: 15316099]
11. Lacson E Jr, Wang W, Mooney A, Ofsthun N, Lazarus JM, Hakim RM. Abandoning peracetic acid-based dialyzer reuse is associated with improved survival. Clin J Am Soc Nephrol. 2011; 6(2):297–302. [PubMed: 20947788]
12. Doit C, Loukil C, Simon AM, et al. Outbreak of Burkholderia cepacia bacteremia in a pediatric hospital due to contamination of lipid emulsion stoppers. J Clin Microbiol. 2004; 42(5):2227–2230. [PubMed: 15131197]
13. Moreira BM, Leobons MB, Pellegrino FL, et al. Ralstonia pickettii and Burkholderia cepacia complex bloodstream infections related to infusion of contaminated water for injection. J Hosp Infect. 2005; 60(1):51–55. [PubMed: 15823657]
14. Abe K, D'Angelo MT, Sunenshine R, et al. Outbreak of Burkholderia cepacia bloodstream infection at an outpatient hematology and oncology practice. Infect Control Hosp Epidemiol. 2007; 28(11):1311–1313. [PubMed: 17926285]
15. Oyong K, Marquez P, Terashita D, et al. Outbreak of bloodstream infections associated with multiuse dialyzers containing O-rings. Infect Control Hosp Epidemiol. 2014; 35(1):89–91. [PubMed: 24334805]
16. Welbel SF, Schoendorf K, Bland LA, et al. An outbreak of gram-negative bloodstream infections in chronic hemodialysis patients. Am J Nephrol. 1995; 15(1):1–4. [PubMed: 7872357]
17. Flaherty JP, Garcia-Houchins S, Chudy R, Arnow PM. An outbreak of gram-negative bacteremia traced to contaminated O-rings in reprocessed dialyzers. Ann Intern Med. 1993; 119(11):1072–1078. [PubMed: 8239225]
18. Rosenberg, J. Primary bloodstream infections associated with dialyzer reuse in California dialysis centers. Poster presented at: ISDA 2005; October 6–9, 2005; San Francisco, CA.
19. Kim, CY., Schillie, SF., Carmean, J., et al. Outbreak of bloodstream infections at an outpatient dialysis center. Poster presented at: SHEA 2009; March 19–22, 2009. San Diego, CA; Ohio: 2008.

20. CDC. Outbreaks of gram-negative bacterial bloodstream infections traced to probable contamination of hemodialysis machines–Canada, 1995; United States, 1997; and Israel, 1997. MMWR. 1998; 47(3):55–59. [PubMed: 9461047]
21. Arnow PM, Garcia-Houchins S, Neagle MB, Bova JL, Dillon JJ, Chou T. An outbreak of bloodstream infections arising from hemodialysis equipment. J Infect Dis. 1998; 178(3):783–791. [PubMed: 9728548]
22. Wang SA, Levine RB, Carson LA, et al. An outbreak of gram-negative bacteremia in hemodialysis patients traced to hemodialysis machine waste drain ports. Infect Control Hosp Epidemiol. 1999; 20(11):746–751. [PubMed: 10580625]
23. Grohskopf LA, Roth VR, Feikin DR, et al. Serratia liquefaciens bloodstream infections from contamination of epoetin alfa at a hemodialysis center. N Engl J Med. 2001; 344(20):1491–1497. [PubMed: 11357151]
24. Rice, EW., Bridgewater, L., American Public Health Association, American Water Works Association, Water Environment Federation. Standard Methods for the Examination of Water and Wastewater. Washington, DC: American Public Health Association; 2012.
25. Tenover FC, Arbeit RD, Goering RV, et al. Interpreting chromosomal DNA restriction patterns produced by pulsed-field gel electrophoresis: criteria for bacterial strain typing. J Clin Microbiol. 1995; 33(9):2233–2239. [PubMed: 7494007]
26. Finelli L, Miller JT, Tokars JI, Alter MJ, Arduino MJ. National surveillance of dialysis-associated diseases in the United States, 2002. Semin Dial. 2005; 18(1):52–61. [PubMed: 15663766]
27. Robinson BM, Feldman HI. Dialyzer reuse and patient outcomes: what do we know now? Semin Dial. 2005; 18(3):175–179. [PubMed: 15934957]
28. Denny GB, Golper TA. Does hemodialyzer reuse have a place in current ESRD care: “to be or not to be?”. Semin Dial. 2014; 27(3):256–258. [PubMed: 24649806]
29. AAMI. Reprocessing of Hemodialyzers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013. Vol RD47:2008/2013
30. Bolan G, Reingold AL, Carson LA, et al. Infections with Mycobacterium chelonei in patients receiving dialysis and using processed hemodialyzers. J Infect Dis. 1985; 152(5):1013–1019. [PubMed: 4045242]
31. Toniolo AD, Ribeiro MM, Ishii M, da Silva CB, Jenne Mimica LM, Graziano KU. Evaluation of the effectiveness of manual and automated dialyzers reprocessing after multiple reuses. Am J Infect Control. 2016; 44(6):719–720. [PubMed: 26897699]

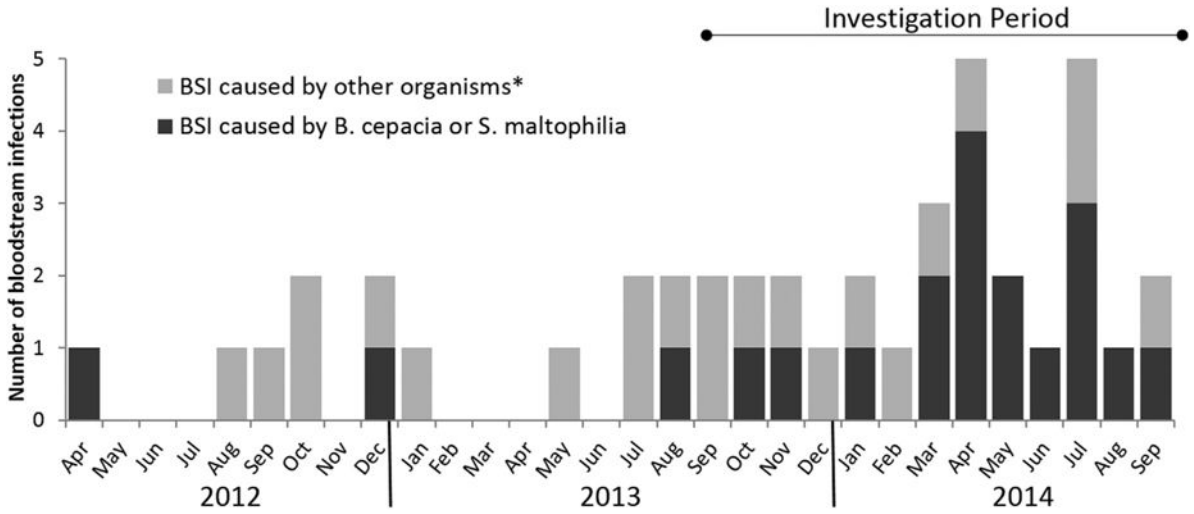

Figure 1.

Epidemic curve of bloodstream infections caused by select organisms at dialysis organization clinics, April 2012 to September 2014. **Pseudomonas aeruginosa, Proteus species, Morganella morganii, Serratia maracescens, Xanthomonas, Ralstonia pickettii*, or *Candida parapsilosis*.

Table 1

Characteristics of Definite and Possible Cases

	Definite	Possible	*P*[a]
Demographics	n = 16[a]	n = 12	
Age, y	59 (49–69)	62 (50–87)	0.8
Female sex	5 (31)	6 (50)	0.3
Race			0.04
White	5 (31)	7 (58)	
Black	4 (25)	3 (25)	
Asian	4 (25)	0 (0)	
Other	3 (19)	2 (17)	
Treatment characteristics	n = 17	n = 12	
Clinic			0.4
A	8 (47)	1 (8)	
B	6 (35)	0 (0)	
C	0 (0)	1 (8)	
E	0 (0)	2 (17)	
F	0 (0)	1 (8)	
G	1 (6)	0 (0)	
Other	2 (12)	7 (58)	
Dialysis treatment			
Reusable dialyzer	16 (94)	10 (83)	0.4
Dialyzer use count[b]	15 (7–21)	4 (0–7)	0.03
Catheter use	4 (24)	5 (42)	0.3
Symptoms during session	11 (65)	4 (33)	0.1
Model R dialyzer use	10 (59)	1 (8)	0.01
Treatment schedule			
MWF shift	10 (59)	7 (58)	0.9
Nocturnal shift	4 (24)	0 (0)	0.08
Outcomes			
Antibiotics given[c]	11 (65)	8 (67)	0.9
Hospitalized for infection	6 (35)	4 (33)	0.9
Died	0 (0)	1 (8)	0.2

Note: Values for categorical variables are given as count (proportion); for continuous variables, as median (range). All P values were calculated using the Mantel-Haenszel Chi-Squares method.

Abbreviation: MWF, Monday, Wednesday, and Friday.

[a] n = 16 due to 1 case-patient representing 2 cases.

[b] Dialyzer use count 5 number of times dialyzer was used prior to the treatment session of interest.

[c] Refers to antibiotics administered in the clinic.

Table 2

Exposures Among Definite Cases and Matched Controls

	Definite Cases (n = 17)	Controls (n = 51)	Matched OR (95% CI)
Demographics			
Age, y	59 [49–67]	64 [54–71]	0.99 (0.95–1.02)
Female sex	6 (35%)	19 (37%)	0.92 (0.24–3.27)
Dialysis treatment			
Reusable dialyzer	16 (94%)	39 (76%)	4.42 (0.60–197.2)
Dialyzer use count[a]	15 [7–21]	4 [0–15]	1.07 (1.01–1.14)
Dialyzer use count > 6[a]	13 (76%)	21 (41%)	7.03 (1.38–69.76)
Catheter use	4 (24%)	10 (20%)	1.26 (0.25–5.37)
Dialyzer model			
Model R (reuse/sealed)	10 (59%)	8 (16%)	22.87 (4.49–N)[b]
Model O1 (reuse)[c]	1 (6%)	16 (31%)	0.14 (<0.01–1.06)
Model O2 (single-use)[c]	1 (6%)	5 (10%)	0.58 (0.01–5.77)
Model O3 (single-use)[c]	0 (0%)	2 (4%)	__[d]
Model O4 (reuse)[c]	5 (29%)	15 (29%)	1.00 (0.23–3.76)
Model O5 (single-use)[c]	0 (0%)	5 (10%)	__[d]
Treatment schedule			
MWF shift	10 (59%)	33 (65%)	0.33[b] (0–6.33)
Nocturnal shift	4 (24%)	5 (10%)	3.65 (0.48–42.85)

Note: Values for categorical variables are given as count (proportion); for continuous variables, as median [interquartile range].

Abbreviations: CI, confidence interval; MWF, Monday, Wednesday, and Friday; OR, odds ratio.

[a]Dialyzer use count 5 number of times dialyzer was used prior to the treatment session of interest.

[b]A median unbiased estimate.

[c]Dialyzer Models O1 to 5 were made by the same manufacturer.

[d]OR was not calculated.