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A Large Outbreak of Hepatitis C Virus Infections in a Hemodialysis Clinic

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Abstract

BACKGROUND—In November and December 2012, 6 patients at a hemodialysis clinic were given a diagnosis of new hepatitis C virus (HCV) infection.

OBJECTIVE—To investigate the outbreak to identify risk factors for transmission.

METHODS—A case patient was defined as a patient who was HCV-antibody negative on clinic admission but subsequently was found to be HCV-antibody positive from January 1, 2008, through April 30, 2013. Patient charts were reviewed to identify and describe case patients. The hypervariable region 1 of HCV from infected patients was tested to assess viral genetic relatedness. Infection control practices were evaluated via observations. A forensic chemiluminescent agent was used to identify blood contamination on environmental surfaces after cleaning.

RESULTS—Eighteen case patients were identified at the clinic from January 1, 2008, through April 30, 2013, resulting in an estimated 16.7% attack rate. Analysis of HCV quasispecies

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identified 4 separate clusters of transmission involving 11 case patients. The case patients and previously infected patients in each cluster were treated in neighboring dialysis stations during the same shift, or at the same dialysis station on 2 consecutive shifts. Lapses in infection control were identified. Visible and invisible blood was identified on multiple surfaces at the clinic.

CONCLUSIONS—Epidemiologic and laboratory data confirmed transmission of HCV among numerous patients at the dialysis clinic over 6 years. Infection control breaches were likely responsible. This outbreak highlights the importance of rigorous adherence to recommended infection control practices in dialysis settings.

Hepatitis C virus (HCV) infection is several times more prevalent among hemodialysis patients than the general US population.^{1–3} Outbreaks of new HCV infections have been reported in US dialysis centers, typically associated with lapses in infection control (IC), including improper parenteral medication handling and preparation, inadequate cleaning and disinfection of environmental surfaces between patient treatments, and poor hand hygiene and glove use.^{3–5}

In November 2012, the Philadelphia Department of Public Health (PDPH) was notified of 2 patients at an outpatient hemodialysis clinic (Clinic A) who had documented seroconversion to HCV antibody positive status. Four additional seroconversions were identified in December 2012. Despite interventions by the clinic after PDPH assessed IC practices and provided recommendations, a new HCV infection was identified in April 2013. PDPH and the Centers for Disease Control and Prevention (CDC) performed an epidemiologic investigation to evaluate the extent of the outbreak and assess potential modes of transmission and risk factors for HCV acquisition.

METHODS

The clinic performed HCV antibody tests upon admission for all patients and then annually in January for susceptible patients. Monthly serum alanine aminotransferase (ALT) tests were performed on all patients. When ALT levels were elevated, HCV antibody testing was performed.

Definitions

We defined an incident case patient as a Clinic A patient who was HCV-antibody (anti-HCV) negative upon admission screening but subsequently found to be anti-HCV positive (ie, “newly infected”). A previously infected patient was one who was anti-HCV positive upon admission to Clinic A. Susceptible (ie, at-risk) patients were those not infected with HCV (ie, anti-HCV negative) upon admission.

Because most cases were asymptomatic, case patients’ estimated date of onset of HCV infection was defined as the first date the serum ALT level was above the upper limit of the normal range (ie, >45 IU/mL). The exposure period was defined as 3 months to 2 weeks prior to the estimated date of onset. For incident case patients whose seroconversion was not preceded by a documented serum ALT elevation, we defined the exposure period as the 6 months to 2 weeks before the first positive anti-HCV result.

Case Finding

We reviewed HCV test results of all patients who were treated at the clinic from January 1, 2008, through April 30, 2013 (including active patients and patients who transferred out or died), to identify incident case patients and previously infected patients.

Case Description

For all infected patients identified through case finding, medical records were abstracted and data were entered into Epi Info, version 7 (CDC). We obtained treatment schedule and station data—that is, the dialysis stations and shifts of patients' treatment sessions—for all incident cases during their exposure periods. We compared station assignments and treatment schedules among infected patients identified as having closely related virus to evaluate potential links in space and time.

Case patients were interviewed by PDPH to identify hepatitis C risk factors during exposure periods, symptoms of acute hepatitis C, and whether patients were notified of their diagnosis and referred for HCV treatment evaluation.

Laboratory Testing

Serum samples collected from HCV-infected patients (ie, incident case patients and previously infected patients) at the clinic in April 2013 were sent to CDC's Division of Viral Hepatitis Laboratory. HCV RNA was amplified by real-time polymerase chain reaction from anti-HCV positive samples. HCV RNA-positive samples underwent sequencing of the 300-nucleotide NS5b coding region to determine genotype as described.⁶ In addition, the HCV hypervariable region 1 was sequenced to determine HCV quasispecies using the Roche/454 pyrosequencing technology.⁶ A phylogenetic tree was developed to illustrate and compare the hypervariable region 1 quasispecies distribution of incident cases and previously infected patients.

IC Observation

We observed patient flow and IC practices at the clinic. We focused on (1) staff hand hygiene and glove use, (2) vascular access care, (3) parenteral medication preparation and administration, and (4) environmental and machine surface cleaning and disinfection between shifts and at the end of day. A standard set of tools was used to record our observations (<http://www.cdc.gov/dialysis/prevention-tools/index.html>).

Environmental Assessment

An environmental assessment was performed with 3 objectives: (1) to identify blood contamination on surfaces, (2) to confirm the presence of human hemoglobin in potential blood contamination identified, and (3) to assess cleaning practices.

To identify potential invisible blood contamination on surfaces, we used Bluestar Forensic latent blood reagent (Bluestar), a forensic chemiluminescent agent that reacts with hemoglobin. Bluestar Forensic was used to identify the possible presence of blood on dialysis machines and patient chairs after terminal cleaning and on chairs in the clinic's waiting area and in the patients' bathroom. An immune assay (Hexagon OBTI; Bluestar) was

used to confirm the presence of human hemoglobin. We were able to perform only 1 assessment when no patients were being treated and all the machines and chairs had been cleaned and disinfected the evening before.

To evaluate the thoroughness of cleaning, we applied Glo Germ oil (Glo Germ) to a dialysis machine's high-touch surfaces before completion of the last dialysis shift on the day of the assessment. After cleaning was performed, we exposed surfaces to UV light; fluorescence upon exposure to UV light indicates persistence of Glo Germ because of lack of adequate cleaning. This exercise was used to demonstrate to staff the importance of thorough cleaning and disinfection.

RESULTS

Description of Clinic A

Clinic A was a stand-alone dialysis center with 66 patients being dialyzed at the time of the investigation. The clinic had a total of 24 stations in 3 pods. Each pod had a total of 8 stations in 2 rows (4 stations in each row). Dialysis machines were close to each other, with no barrier between them. The clinic operated 3 shifts on a Monday-Wednesday-Friday schedule. Shifts 1 and 2 were very busy, and the transition time between those shifts was short, approximately 15 to 20 minutes.

There were 6 technicians (usually 2 assigned to each pod), 2 registered nurses, and 1 licensed practical nurse working per shift. The clinic maintained a log of technician and nurse schedules, along with the stations where specific patients were dialyzed each day, which were not assigned and could change daily.

Case Patient Characteristics

Of Clinic A's 66 patients in April 2013, 26 (39%) were infected with HCV. Case finding identified a total of 18 patients who seroconverted since 2008 (Figure 1). Eight case patients seroconverted in 2012 ($n = 7$) or 2013 ($n = 1$) on the basis of their first anti-HCV positive tests. Forty-eight Clinic A patients were at risk during this time, thus the attack rate for 2012–2013 was 16.7% (8/48). Figure 1 describes the exposure periods and dates of the first positive HCV test for all 18 case patients. Only 3 case patients had documented symptoms consistent with acute hepatitis: 1 reported vomiting, 2 reported diarrhea. Two case patients had no ALT elevation (ie, all documented ALT values prior to seroconversion were normal); neither of them showed any symptoms suggestive of acute hepatitis. Table 1 describes the characteristics of case patients. Although 14 case patients (78%) had hospitalizations and 10 (56%) had invasive procedures during their exposure period, no common exposures (eg, overlap in hospitalizations or same surgeries) were identified. Three case patients had died and the cause of death was not reported in the charts.

Quasispecies Analyses of Infected Patients

Twenty-three serum samples from 13 case patients and 10 previously infected patients at the clinic in April 2013 were available for additional laboratory testing. Of these 23 patients, 11 case patients and 2 previously infected patients belonged to 4 clusters (Figure 2).

Given the high homology (99.66% nucleotide identity) and close clustering of HCV quasispecies between case patient P and 1 previously infected patient, HCV transmission could have occurred from this patient to case patient P. For the other clusters, there was a link between patients in each cluster; however, the transmission direction is more difficult to speculate. Secondary transmission could have occurred in any of the clusters.

We reviewed the treatment time and dialysis station assignment data for case patients and previously infected patients in each cluster to assess commonalities. For each cluster, the treatment station data for the exposure period of patients who seroconverted later was compared with the data for the same period of patients who were infected earlier. In each cluster, there was evidence that the case patients and previously infected patients were treated in nearby stations during the same shift, or at the same station on 2 consecutive shifts (with the case patients following the patients who were infected earlier). Most of these stations where transmission occurred were located in 1 particular pod.

IC Observations

Before our investigation, when PDPH visited the clinic in December 2012 and when the clinic's manager performed audits of IC, lapses in IC practices were identified (eg, staff moved between machines without changing gloves or used ungloved hands without hand hygiene after touching machines, the clinic did not clearly label clean sinks and dirty sinks, a stationary medication cart in the nursing station within the treatment area was used as the location for medication preparation). The clinic then moved medication preparation to a separate room away from the patient care area and had only nurses draw the parenteral medications instead of technicians. During our investigation, generally good hand hygiene and aseptic technique during parenteral medication preparation and administration were observed. However, multiple lapses in IC were identified (Table 2). Most lapses were during vascular access (eg, lack of appropriate glove change and hand hygiene during vascular access procedures, inadequate application of antiseptic) and cleaning and disinfection of environmental surfaces (eg, insufficient application of disinfectant, wiping machine surfaces with patient still in station, not disinfecting all surfaces).

Environmental Assessment

Table 3 lists the objects selected for assessment and results. The dialysis chair with reaction to Bluestar Forensic solution and positive Hexagon OBTI result was in the implicated pod mentioned above. This prompted us to inspect all the chairs in the clinic and we identified visible bloodstains on the inside of the armrests of 4 of the chairs, indicating that the chairs were not thoroughly cleaned.

In summary, bloodstains were seen on 1 dialysis machine, on dialysis station televisions, and on patient chairs. Three samples produced a positive Hexagon OBTI result: 1 from the dialysis chair side table, 1 from the chair in the waiting area, and 1 from a dialysis station television. Multiple surfaces tested positive by Bluestar Forensic but negative by Hexagon OBTI. We attributed these results to either an extremely low concentration of blood in the samples or a false-positive reaction to dried bleach on the surfaces.

The use of Glo Germ on a machine identified numerous areas that were not cleaned thoroughly. We used this test as an educational tool to show technicians, facility managers, and the medical director where cleaning was suboptimal.

DISCUSSION

We identified multiple clusters of transmission of HCV at Clinic A with a total of 18 newly infected patients from January 1, 2008, through April 30, 2013. Genetic links between infected patients' viruses and analysis of epidemiologic data (treatment station assignment, healthcare exposures) supported our hypothesis that transmission occurred to case patients at Clinic A, most likely owing to lapses in IC.

We observed multiple lapses in IC practices, including vascular access care, hand hygiene, as well as cleaning and disinfection of dialysis stations. The presence of bloodstains on multiple surfaces at the clinic pointed to poor environmental cleaning and disinfection. Although not observed at the time of our investigation, poor medication handling practices, including the preparation of medications on a cart in the treatment area, might also have been a risk factor. In addition, Clinic A presumably restricted technicians from performing medication administration because they might not have adhered to recommended aseptic technique. We believe that these suboptimal IC practices likely contributed to the repeated transmission of HCV among patients in Clinic A. These factors are well-known causes of HCV transmission in this setting.^{3-5,7-10} The transmission of HCV among patients who were in proximity during the same shift or shared a station between consecutive shifts has also been reported.¹¹⁻¹³

In this investigation, 15 case patients lacked documented symptoms and 2 lacked ALT elevations. These 2 case patients were identified by reviewing serial anti-HCV results; the new acute HCV infection case definition used by the National Notifiable Diseases Surveillance System does not require clinical symptoms if a documented seroconversion occurs (<http://wwwn.cdc.gov/ndss/conditions/hepatitis-c-acute/case-definition/2012/>). This highlights the importance of routine hepatitis C serology testing, which is a recommended practice.^{14,15} The clinic identified the seroconversions in 2012 and 2013 as a result of screening and reviewing tests; however, previous case patients had not been promptly identified. Therefore, when routine ALT and HCV screening is performed, providers should review the results and take appropriate action in a timely manner¹⁵; early intervention at the clinic before 2012 could have prevented many subsequent HCV infections. Unfortunately, in this clinic, and as with another investigation,⁴ we found that not all case patients were informed of their HCV diagnosis.

Our environmental testing allowed us to confirm human blood contamination on surfaces at the clinic. The use of forensic chemiluminescent agents and hemoglobin detection kits to identify blood contamination in dialysis settings has been reported.^{7,16} In a previous outbreak, Bluestar Forensic was used with limited success.¹² The agent requires a completely dark environment that can be difficult to achieve in healthcare facilities. In addition, the agent also reacts with bleach, which is a widely used disinfectant in dialysis clinics. In this investigation, we were able to arrange a completely dark environment in a

laboratory room for the testing. To address the potential for false-positive results from bleach, we used Hexagon OBTI to confirm the presence of human hemoglobin. We believe this provided more convincing evidence of blood contamination of surfaces at the clinic.

This investigation raised several issues regarding clinic management and layout. First, we believe that the space available for each station at the clinic was not adequate—for example, we observed 2 dialysis machines in use within 1 foot of each other. The Facility Guidelines Institute's Guidelines for Design and Construction of Hospitals and Outpatient Facilities recommends a space of 80 square feet for each treatment station and a minimum of 4 feet (1.22 meters) between dialysis chairs, which was not followed at Clinic A.¹⁷ Clinics not meeting these criteria should consider expanding the space for each station and between stations, or install walls between stations to reduce crowding between patients and equipment that could facilitate cross-contamination. Second, the clinic operated only 3 days per week. We believe this condensed schedule contributed to the crowding in the facility; quick turnaround time between shifts may have also increased the workload burden on staff, all of which could lead to suboptimal IC practices. A 6-day-per-week schedule is more typical in facilities of similar size and patient volume. This was suggested to the clinic as one way to reduce the number of patients dialyzed per day and spread out treatments in space and time. Third, poor IC practices have been highlighted many times as contributors to HCV outbreaks in dialysis settings⁵; therefore, having strong IC support at the clinic is important. The support may include (1) providing regular infection prevention training to staff and performing staff competency assessments, (2) having a sufficient number of staff to ensure all IC procedures are performed adequately throughout the day, and (3) having a staff member on site with infection prevention expertise to serve as an IC manager, perform practice audits, and address breaches in a timely manner. The necessary support for IC should be made as a policy at both the clinic level and the corporate level. Following the investigation, PDPH worked with Clinic A to provide multiple training sessions to clinic staff. The clinic increased turnaround time between patient treatment shifts to allow adequate environmental cleaning and disinfection but maintained the 3-day-per-week operations schedule. The clinic also used audit tools to routinely audit IC practices. Follow-up visits by PDPH confirmed improved IC practices at the clinic.

We also want to highlight the importance of HCV surveillance, prompt reporting of new infections to health departments, and referral of infected patients to medical care. Current guidelines recommend routine HCV antibody testing every 6 months for all susceptible patients, and at more frequent intervals following the identification of 1 or more seroconversions.^{14,15} Because infected patients often lack symptoms, timely testing and careful review of results are critical to identifying new HCV infections. In the wake of this outbreak, Clinic A performed monthly HCV antibody and ALT testing of all uninfected patients under the guidance of PDPH. As of December 2013, no new cases had been identified and the clinic has resumed semiannual anti-HCV screening. The effort to frequently screen, communicate results to patients, and refer infected patients to care requires coordination between clinic staff, its medical director, and specialists outside the facility.

The investigation had several limitations. First, we were unable to obtain blood samples from all cases to perform viral sequencing because some patients had died. Therefore, the relatedness of some cases was unknown. Second, we were not able to perform the environmental assessment using Bluestar on all the machines and chairs as well as the medication preparation area because of the facility lighting. We were also unable to interrupt the patient care schedule to assess adequacy of cleaning in between patient treatments (vs at the end of the day). The former would be a more relevant representation of surface contamination experienced by most patients. However, evidence of blood contamination on the randomly chosen machine and chair may reflect the generally suboptimal cleaning and disinfection practice at Clinic A. Finally, there were important changes in IC practices (eg, injectable medication preparation) that occurred before our investigation. Therefore, our observations might not reflect the breaches that contributed to transmission.

In conclusion, this was one of the largest outbreaks of HCV infection among dialysis patients that we have encountered in the past decade. Although it remains critically important for dialysis clinic staff to continue adherence to current recommended IC practices to prevent spread of HCV and other infections, more aggressive strategies may be needed to stop HCV outbreaks from occurring in outpatient hemodia-lysis centers.

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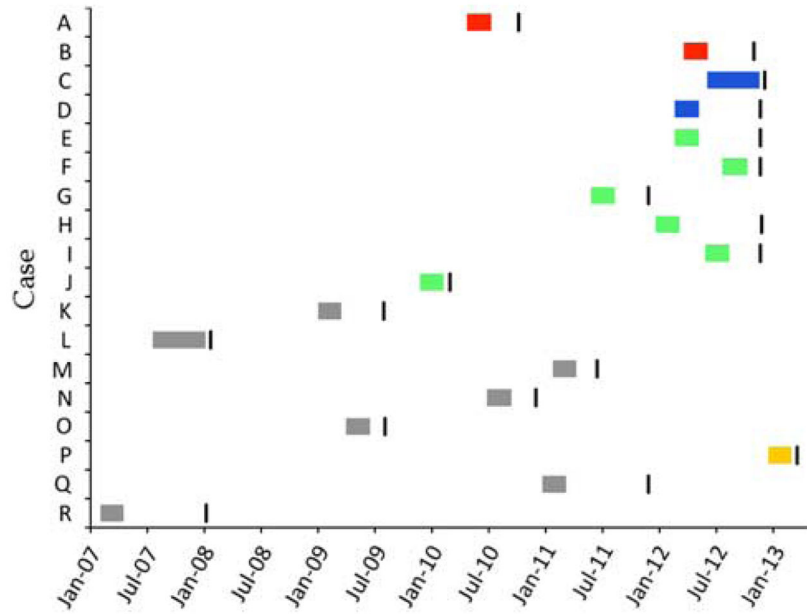


Figure 1. Exposure period and first hepatitis C virus (HCV)–positive test of 18 case patients, Clinic A, 2008–2013. Anti-HCV, antibody to HCV. ■, Positive HCV test (anti-HCV or HCV RNA); ■, Case patients’ exposure period (cluster 1); ■, Case patients’ exposure period (cluster 2); ■, Case patients’ exposure period (cluster 3); ■, Case patient P’s exposure period; ■, Other case patients’ exposure period.

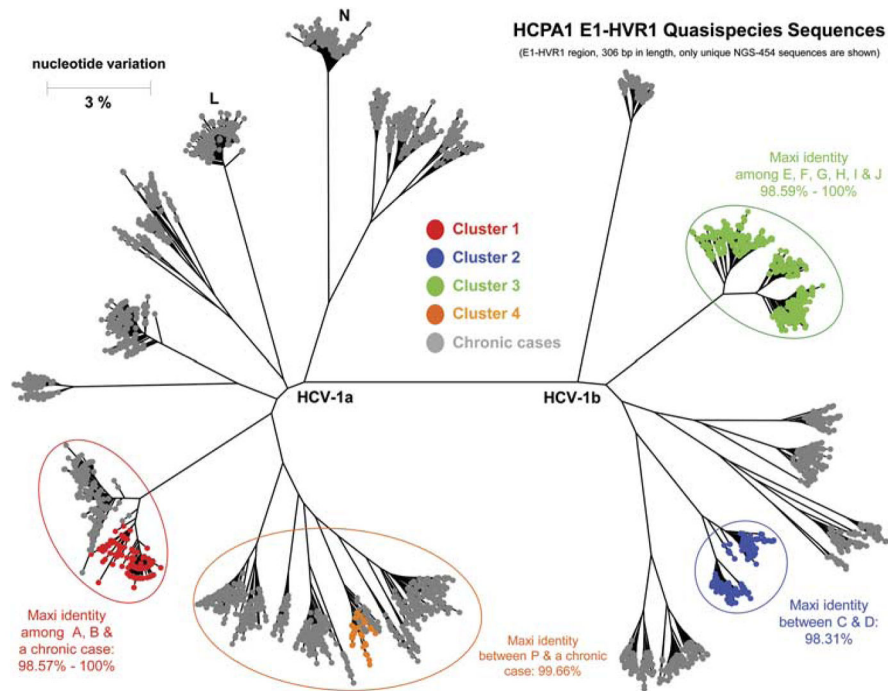


Figure 2. Results of hepatitis C virus (HCV) quasispecies analysis of 13 case patients and 10 previously infected patients at Clinic A. HVR, hypervariable region.

Table 1

Characteristics of 18 Case Patients, Clinic A

Characteristic	Cases
Male sex, n (%)	9 (50)
Age, median (range), y	63.5 (37–86)
Black race, n (%)	18 (100)
History of diabetes, n (%) ^a	9 (50)
History of hypertension, n (%)	14 (78)
Time from first hemodialysis to seroconversion, median (range), months	37.8 (5.6–220.1)
Symptoms of acute HCV infection, n (%)	3 (17)
Highest documented ALT, median (range), IU/mL ^b	183 (51–535)
During exposure period	
Most common treatment pod	
Pod 1, n (%)	18 (100)
Most common treatment shift	
Shift 3, n (%)	10 (56)
Heparin injection, n (%)	11 (61)
Iron sucrose injection, n (%)	8 (44)
Paricalcitol injection, n (%)	14 (78)
Erythropoietin injection, n (%)	14 (78)
CVC used for hemodialysis vascular access, n (%)	3 (17)
History of intravenous use, n (%)	0 (0)
Hospitalized or had hospital visit, n (%)	14 (78)
Had invasive procedure, n (%)	10 (56)
Other risk factors identified through interview (n =12)	
Close contact of confirmed or presumptive case, n (%)	1 (8)
Received blood products, organs, or tissues, n (%)	3 (25)
Exposure to another person's blood, n (%)	0 (0)
Sexual contact, n (%)	5 (42)
Sexual contact without condoms, n (%)	3 (25)
Injecting drugs, n (%)	0 (0)
Tattoo, piercing, n (%)	0 (0)

NOTE. ALT, alanine aminotransferase; CVC, central venous catheter; HCV, hepatitis C virus.

^aGlucose meter use was observed and found to be adequate.

^b2 case patients did not have documented elevation of ALT.

Table 2

Summary of Key Infection Control Observations

Infection control area	Tools used	Positive practices	Selected suboptimal practices
Hand hygiene (HH) ^{14,18}	http://www.cdc.gov/dialysis/prevention-tools/	<ul style="list-style-type: none"> Staff successfully used 72 (82%) of 88 observed HH opportunities Good HH before and after medication administration Good HH when leaving patient stations 	<ul style="list-style-type: none"> HH duration and thoroughness were not always adequate HH not performed in between touching the patient during a vascular access procedure and touching the machine's screen/ keyboard HH inconsistently performed before gloving One doctor was seen not performing HH before or after direct contact with patients
Medication preparation and administration ^{14,19,20}	http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html http://www.cdc.gov/injectionsafety/providers/provider_faqs.html	<ul style="list-style-type: none"> Separate room used for medication preparation (although a cart was used in patient care area before December 2012) Generally good HH and glove use when administering medication 	<ul style="list-style-type: none"> Catheter hubs and vial tops were not scrubbed vigorously with antiseptic swab Medication preparation was performed next to a sink, which could cause exposure to water splash
Vascular access care ^{14,21–23}	http://www.cdc.gov/dialysis/prevention-tools/	<ul style="list-style-type: none"> Consistent use of face shields and gloves 	<ul style="list-style-type: none"> Staff usually touched multiple objects (eg, screen, keyboard) with the same gloves between steps of the access procedure Staff were seen not performing HH before donning gloves for cannulation and needle removal procedures Cleanliness and rigorousness of antiseptic application varied
Cleaning and disinfection ^{14,24,25}	http://www.cdc.gov/dialysis/prevention-tools/	<ul style="list-style-type: none"> Some staff performed 	<ul style="list-style-type: none"> Most dialysis machines were

Infection control area	Tools used	Positive practices	Selected suboptimal practices
		cleaning thoroughly • Most times dialysis chairs were observed to be visibly wet with disinfectant	wiped with disinfectant while patient who just completed treatment was still in the chair • Staff did not consistently check the machine for visible soil/blood before cleaning • Staff cleaned and disinfected the machines when potentially contaminated items were still on the side table, very close to the machines being cleaned • The machines were visibly wet with disinfectant in only 2 of 9 observed cleaning sessions • Vigorousness of wiping varied • Cleaning and disinfection procedures were not performed in a standard manner • There were usually missed or undercleaned areas, eg, priming bucket and chair's side tables; the priming bucket was rarely disinfected during observation

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Table 3

Results of Environmental Assessments

Tested object	Tested area	Bluestar Forensic test	Hexagon OBTI test	Interpretation
Dialysis machine 1				
	Screen	No reaction
	Keyboard	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
	Acid and base administration port	No reaction
	Machine's right side	Not tested	...	Visible bloodstains near blood pressure holder
	Artery blood pressure cuff	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
	Prime bucket	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
Dialysis machine 2				
	Screen	No reaction
	Keyboard	No reaction
	Acid and base administration port	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
	Machine's right side	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
	Blood pressure cuff	No reaction
	Prime bucket	No reaction
Dialysis chair				
	Headrest	No reaction
	Armrest	No reaction
	Footrest	No reaction
	Chair side	No reaction
	Side table	Reaction	Positive	Invisible bloodstain
Two chairs in waiting area				
	Seat surface	Reaction (1 chair)	Positive	Invisible bloodstain
Bathroom				
	Sink	Reaction	Negative	Cross-reaction with remnant bleach or extremely low concentration of blood
	Door handle	No reaction
	Light switch	No reaction
	Toilet handle	No reaction
4 television sets within dialysis stations				
	4 sets with visible stains (of 24 sets)	Not tested	Positive (1 stain tested)	Visible bloodstain
Biohazard trash can with visible blood stain				
	Opening area of can	Strong reaction	Positive	Served as positive control

NOTE. Bluestar Forensic is a forensic chemiluminescent agent that reacts with hemoglobin; Hexagon OBTI is an immune assay used to confirm the presence of human hemoglobin.