American Journal of Infection Control 45 (2017) 799-804

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Improving water quality in a dialysis unit using root cause analysis

Pallavi Yadav MBBS, MHA, CQPA [a,†], Dawn England MPH, CPHQ, CIC [a], Caprice Vanderkolk RN, MS, BC-NE [b], Pui-Ying Iroh Tam MD [a,c,*,‡]

[a] Department of Infection Prevention, University of Minnesota Medical Center, Minneapolis, MN
[b] Adult and Pediatric Dialysis Unit, University of Minnesota Medical Center, Minneapolis, MN
[c] Division of Pediatric Infectious Diseases and Immunology, Department of Pediatrics, University of Minnesota Medical School, Minneapolis, MN

Key Words:
Hemodialysis
Patient safety
Quality improvement
Sphingomonas paucimobilis
Reverse osmosis

Background: Water quality levels from hemodialysis (HD) and reverse osmosis (RO) machines in dialysis units must meet standards set by the American Association of Medical Instrumentation. Researchers used a root cause analysis (RCA) approach to identify and address factors affecting water quality in the HD and portable RO machines at our institution.
Methods: A multidisciplinary team reviewed processes, interviewed staff members, and identified opportunities to improve the current sampling and machine disinfection processes. The RCA team identified and implemented 5 interventions, of which 3 were process (changes in water sampling technique, machine disinfection processes, and allocation of machine maintenance duties) and 2 were structural (regular cleaning of water sampling tubes and spigots and addition of new water sampling sites in the system) measures.
Results: Postimplementation of new protocols, 100% of water cultures of HD and RO machines consistently met the required regulatory standards as recorded over a period of 8 months.
Conclusions: RCA approach helped improve patient safety, quality of care, streamlined processes, and improved efficiencies of work for staff within the HD program.

Dialysis patients are exposed to large amounts of water from the dialysis machines; if the water is insufficiently treated for bacterial and chemical contaminants their health may be in serious jeopardy. Dialysis units in hospitals receive their water from the municipal water supply that goes through the hospital water distribution systems. These water distribution systems are complex networks made up of various types of piping material, bends, loops, deadlegs, and storage tanks that cause low water flow or stagnation that can increase the chances of biofilm formation. A number of pathogens thrive in biofilm and, according to some estimates, these pathogens may be up to 3,000 times more resistant to public water supply bacteriostatic agents than their free-floating counterparts.[1] Hemodialysis (HD) patients are at a higher risk for clinical hazards such as pyrogenic reactions, septicemia with severe hypotension, and shock from the dialysis water.[2,3] Hence, measuring and tracking water quality and rates of infection are important for quality maintenance and infection prevention in dialysis programs and is also a Center for Medicare and Medicaid Services requirement under recommendations from the Association for the Advancement of Medical Instrumentation (AAMI).[4,5] There are few published studies discussing systematic quality improvement approaches addressing water quality issues. However, a couple of academic articles[6,7] and guidelines[5] have been published that discuss quality improvement approaches solving water quality issues. Notably, some of these studies exist in the environmental and engineering domains.[6] There is a dearth of good-quality, crossover academic articles that tie together the biomedical, microbiologic, and clinical aspects of dialysis water.

We performed a study in the dialysis unit after *Sphingomonas paucimobilis* was isolated from water specimens from the HD and portable reverse osmosis (RO) machines, and concerns were raised about the potential influence on dialysis patients. Root cause analysis (RCA) is a framework for structured investigations of safety incidents. RCA is a widely used quality improvement tool that helps analyze errors by identifying underlying problems while avoiding focus on mistakes committed by individuals.[8] To address and

* Address correspondence to Pui-Ying Iroh Tam, MD, Malawi-Liverpool Wellcome Trust, P.O. Box 30096, Chichiri, Blantyre 3, Malawi.
E-mail address: irohtam@mlw.mw (P.-Y. Iroh Tam).
Conflicts of interest: None to report.
†Current affiliation: Virginia Commonwealth University Health, Richmond, VA.
‡Current affiliation: Malawi-Liverpool Wellcome Trust, Blantyre, Malawi.

0196-6553/
http://dx.doi.org/10.1016/j.ajic.2017.02.007

optimize water quality in the dialysis unit, we used the RCA approach to identify the factors contributing to high levels of bacteria in the water cultures and to make recommendations for quality improvement. Our goals for this article are to describe how we used the RCA approach to systematically identify the causes of poor dialysis water quality and depict the influence of this approach on the dialysis water quality at our center.

MATERIALS AND METHODS

Setting

The setting was the adult dialysis unit at the University of Minnesota Medical Center, Minneapolis, MN. The dialysis unit has 6 patient rooms where dialysis machines are run on both day and evening shifts. For severely ill patients unable to be transferred to the unit, portable dialysis and RO machines are transported to their rooms. The dialysis unit has 12 HD machines and 7 RO machines in total. The University of Minnesota Institutional Review Board granted a waiver for this study because it did not involve human subjects.

Case definition and risk assessment

After water cultures revealed bacteria growth, patient risk assessment was done by members of the infection prevention team and patients who may have been affected by the dialysis water were screened. A case was defined as any patient (inpatient or outpatient) undergoing, or who within the last 8 weeks had undergone, HD in the dialysis unit with an intra- or postdialytic positive blood culture for *S paucimobilis*. Retrospective review of the electronic medical records of patients who received dialysis during the previous 2 months was performed to identify dialysis patients with *S paucimobilis* bacteremia or any another site infection. A real-time automatic alert was set up in a third-party electronic surveillance software program (Safety Surveillor; Premier, Charlotte, NC), and all dialysis patients were monitored automatically thereafter.

Water sampling

Water and dialysate samples were collected at various points in the water treatment system, including water ports in the dialysis unit, HD machines, and portable RO machines (supplementary Fig S1). Data from 3 types of water testing were collected and analyzed: dialysis water was sent for bacterial cultures performed at the University of Minnesota Infectious Diseases Diagnostic Laboratory, dialysis water was sent for testing of endotoxin levels (Limulas Amebocyte Lysate test; AmeriWater, Dayton, OH), and environmental water was sampled from water ports and dialysis machine wands and tested in the environmental infection prevention lab. Environmental water samples were obtained by opening the tap and allowing the water to run for at least 60 seconds before collection in a sterile, endotoxin-free container, in accordance with AAMI guidelines.[5] A trained staff member collected and hand delivered the samples to the environmental testing laboratory within 4 hours for culture once a month. Given cost constraints, bacterial growth was noted on multiple water specimens during the preintervention period, but only a sampling of representative plates were sent to the Infectious Diseases Diagnostic Laboratory for speciation. Thereafter, subsequent growth was identified presumptively based on morphology, color, and colony type.

Contamination levels in dialysis-quality water and the dialysate were reported in following 3 categories based on the AAMI standards: acceptable (<50 CFU/mL), actionable (50-199 CFU/mL), and unacceptable (≥200 CFU/mL).[5]

Bacterial assay technique

Trypticase soy agar or equivalent was used as culture media. Total viable counts were obtained using the membrane filter technique or the spread plate technique. Bacterial growth was reported as colony forming units at 24 and 48 hours. This is in accordance with AAMI guidelines.[5] The standard method for measuring endotoxin concentrations is the Limulas Amebocyte Lysate test,[9] of which our method used the kinetic assay methodology.

RCA approach

A multidisciplinary RCA team was formed, comprising infection preventionists (IPs), dialysis unit medical director and nurse manager, building facilities personnel, and biomedical technicians, and met at least twice a month. The IP conducted interviews with biomedical technicians, facility engineers, supply chain department, dialysis nurses, and physicians. In addition, nursing staff was directly observed during initiation and termination of dialysis treatment. Feedback and observations were used to develop a cause-and-effect chart and generate hypotheses, which were used to systematically guide process and structural improvement efforts.

To assess the success of process improvement interventions, water from HD and RO machines and the dialysis water loop was analyzed during the intervention period of 8 months (March-October 2016).

Cause-and-effect chart

Based on interviews and observations, an RCA cause-and-effect chart was created (Fig 1). This identified multiple potential underlying causes and contributing factors for the high bacteria levels in the dialysis water, of which 3 were process measures and 2 were structural measures. Cultures from first-drop specimen obtained after a standby period of 24 hours were significantly higher than after a 60-second rinse,[10] which suggested either biofilm presence in the system or a sampling error. Careful analysis of the pooled data from all water samples collected from January 2015-August 2016 found that the 2 common indicators for the presence of biofilm (erratic culture results where periods of spikes in bacterial counts are noted,[11] and the presence of high endotoxin levels with corresponding low bacterial assay result)[12] were not met. Therefore we disregarded the hypothesis of biofilm in the facility's main plumbing system as the causative source.

The possibility that the machines were old and not capable of being cleaned sufficiently was investigated. The total hours on each machine was checked and confirmed with 2 industry sources. Only some machines logged more than 10,000 hours of dialysis treatment, but even this was found to be common in dialysis centers and the possibility that machines themselves contributed to high water cultures was low. Another potential cause was improper machine maintenance. Multiple departments (dialysis nursing, biomed, and sterile processing department) were involved at various stages for machine cleaning and maintenance.

The RCA team identified discrepancies in the sampling process and equipment. The water spigots and tubes used to obtain water for culturing were not cleaned before collecting samples. Based on the causes and contributing factors identified, an intervention and action steps were developed to address these issues (Table 1),