Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection

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DOI: https://doi.org/10.46409/sr.GZZU9683

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Boquiren Quitevis, J. (2022). Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection. [Doctoral project, University of St Augustine for Health Sciences]. SOAR @ USA: Student Scholarly Projects Collection. https://doi.org/10.46409/sr.GZZU9683

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Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection

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The Manuscript Partially Fulfills the Requirements for the

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Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection

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Abstract

Practice Problem: Kidney failure affects 0.1% - 0.2% of the general population, yet the dialysis expenditure is 5%-7% of total healthcare budget spending. The increase incidence of chronic disease will result in more End Stage Renal Disease patients on dialysis along with more comorbidities. Thus, it is imperative for health organizations to have well established protocols and guidelines to manage the care of the dialysis patient.

PICOT: The PICOT question that guided this project was: in patients receiving dialysis at an acute care dialysis unit (P), does utilizing a Standardized Policy for Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection (I) compared to no policy (C) affect infection rates within eight weeks?

Evidence: The evidence supported the need to optimize microbiological surveillance procedures, test pure water to ensure infection prevention practices, and ensure water safety protocols with monitoring and testing.

Intervention: Collaboration with the organization’s dialysis peer group, regional lab, infection prevention, and dialysis educator helped to develop a regional standardized policy, as well as build the water testing standards into the regional lab’s information technology’s platform.

Outcome: A regional standardized policy based on the Centers for Medicare & Medicaid Services (CMS) and Association for the Advancement of Medical Instrumentation (AAMI) standards was developed and integrated into the regional lab’s information technology platform in efforts to ensure quality of care and safety. The project positively impacted clinical practice and improved infection rates, in which staff were compliant and competent after being trained.

Conclusion: It is important to have strategies to reduce the risk of infection associated with dialysis; therefore, the project emphasized the importance of having a standardized policy to mitigate infections and ensure both quality of care and patient safety.
Quality Reporting on Dialysis Water Testing and Dialysis

Machine Disinfection

Chronic diseases impact many individuals affecting both health and quality of life (Raghupathi & Raghupathi, 2018). In the United States (U.S.) chronic diseases account for nearly 75% of aggregate healthcare spending, or an estimated $5300 per individual yearly (Raghupathi & Raghupathi, 2018). “Chronic diseases are among the most prevalent and costly health conditions in the United States. Nearly half (approximately 45%, or 133 million) of all Americans suffer from at least one chronic disease, and the number is growing” (Raghupathi & Raghupathi, 2018, p.431). McCullough et al., (2019) indicated that chronic kidney disease (CKD) is an example of such a condition that is associated with adverse health outcomes, including the progression to end-stage renal disease (ESRD). Due to the multiple comorbidities of patients on dialysis, there is a high likelihood the patient will at one time or another need hospitalization; therefore, the patient will need dialysis performed during a stay in the hospital. According to Himmelfarb et al. (2020), the risk of infection is notably higher in patients on dialysis than in the general population due to access-related infections in patients on hemodialysis with central venous catheters and peritonitis-related infections in patients on peritoneal dialysis. It is important for the organization to have strategies to reduce the risk of infection associated with dialysis; therefore, this should be a clinical priority.

Policies, guidelines, and monitoring are imperative to mitigate infections and ensure quality of care in the dialysis patient; thus, this evidence-based project implemented a standard policy for dialysis water testing and machine disinfection. The setting, stakeholders, systems change, as well the implementation plan with timeline and budget, evaluation plan, and dissemination plan of the project are outlined. This evidence-based project includes the
significance of the problem, the population, intervention, comparison, outcome, time (PICOT) question, evidence-based practice framework, change theory, evidence search strategy, evidence search results, and themes with practice recommendations.

**Significance of the Practice Problem**

The burden of ESRD will increase in the U.S. population through 2030 due to demographic, clinical, and lifestyle shifts in the population and improvements in renal replacement therapy (RRT) (McCullough et al., 2019). According to McCullough et al. (2019), there are a multitude of population factors that may influence trends in ESRD incidence and prevalence, but age, race, hypertension, and diabetes are strong predictors for ESRD. Other factors that may influence ESRD include gender, ethnicity, and body mass index (McCullough et al., 2019). Kidney failure will continue to become more complex due to the aging of the population and with the increase of chronic conditions such as diabetes mellitus and hypertension, it is expected that not only ESRD incidence and prevalence will increase, but healthcare costs will continue to rise (Himmelfarb et al., 2020).

Although kidney failure only affects 0.1% - 0.2% of the general population, the total dialysis expenditure is 5-7% of total healthcare budget spending (Himmelfarb et al., 2020). Ultimately, the increase incidence of chronic disease will result in more ESRD patients on dialysis along with more comorbidities. It is imperative for health organizations to have well established protocols and guidelines to manage the care of the dialysis patient (Himmelfarb et al., 2020). According to Thomas-Hawkins et al. (2020), the dialysis inpatient unit is a dynamic area, which includes an interprofessional team, advanced machine technology, and patients with multiple comorbidities. It is noted that water quality, infection control, medication errors, and miscommunication are just some of the potential areas that can become a risk to patient safety.
and quality (Thomas-Hawkins et al., 2020). According to Bendar and Latham (2014), the industry of dialysis has strict water treatment guidelines and infection control practices, which are mandated by CMS to ensure water quality and safety for the patient.

The project intervention entailed the creating of a standardized policy for quality reporting on dialysis water testing and machine disinfection to ensure that safety measures are adhered to for the dialysis patients. Acute dialysis nurses care for dialysis patients for 4-6 hours daily if the patient remains in the medical center (Bonner, 2007). The organization did not have regional standardized policies or guidelines that included quality reporting for dialysis water testing and machine disinfection prior to this project. The organization did have infection concerns with Central Line Associated Blood Stream Infections (CLABSI). According to the Regional Infection Prevention Consultant, data is collected on CLABSI which uses the metric of the standardized infection ratio (SIR). This is a calculation of how many infections there are at the medical center in comparison to how many are expected. Any number over 1.0 is not acceptable; therefore, the goal is to have an SIR of less than 0.5. There is also data collected on the Count of Infections at the organization, which is compared with the Predicted Number of Infections. Data provided for first quarter 2021 showed an Infection Count totaling 71, a predicted value of 55.7 and SIR of 1.27. The prior fourth quarter of 2020 showed an Infection Count of 31, predicted number of 42.6, and SIR of 0.73. Hence, there is a concern for this outcome of infection due to the increases in each area. Testing the water’s bacterial count and machine disinfection is both a CMS and AAMI standard (see Appendix H). This evidence-based project intervention was important for patient safety, as well as quality to ensure that infection prevention standards are met and to decrease the likelihood of infections.

**PICOT Question**
In patients receiving dialysis at an acute care dialysis unit (P), does utilizing a Standardized Policy for Quality Reporting on Dialysis Water Testing and Dialysis Machine Disinfection (I) compared to no policy (C) affect infection rates within eight weeks? The population are the patients who receive dialysis at the acute dialysis unit in a medical center. The organization has 13 medical centers throughout the California region from the San Fernando Valley to San Diego; however, the project piloted a standardized policy in one medical center unit. The intervention consisted of having dialysis staff use a standardized policy for quality reporting for the dialysis machine disinfection and water testing. This intervention is in comparison to not having any policy or guideline. The project was implemented over an eight-week timeframe, which provided enough time to develop, implement, and evaluate the pilot project.

**Evidence-Based Practice Framework & Change Theory**

This project used the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model, which provided a problem-solving approach to clinical inquiries and clinical decision-making. It used a three-step process called PET: practice question, evidence, and translation (Dang & Dearholt, 2017). The goal of this model was to ensure the latest research and practices are utilized (Dang & Dearholt, 2017). The JHNEBP Model simplifies the EBP process and helped cultivate a culture of care based on evidence (Wyant, 2017). This model also depicted the three elements of nursing practice, education, and research, which are the underpinnings of the nursing profession, as well as took into consideration the internal and external factors that impacted outcomes associated with the identified EBP initiative (Parkosewich, 2013). The model has a process to level and grade the quality of evidence (Dang & Dearholt, 2017). For instance, to apply the JHNEBP Model, this project entailed a practice question that looked at how a
Standardized Policy for Quality Reporting on Dialysis Water Testing and Machine Disinfection affected infections, in which evidence is utilized and evaluated to translate and implement the evidence into clinical practice.

The change theory selected for this project is Kotter’s Change Theory. According to Baloh et al. (2018), Kotter’s framework can help nurse managers guide change. The process improves an organization’s chances for successful change. The steps included: 1) create a sense of urgency, 2) build a guiding coalition, 3) develop a strategic vision, 4) enlist a volunteer army, 5) enable action by removing barriers, 6) generate short term wins, 7) sustain acceleration, and 8) institute change (Najjar & Ascione, 2020). This framework provided a basis for understanding engagement and instituting change in efforts to be successful in leading change within an organization (Najjar & Ascione, 2020). This model helped to create the vision, facilitate communication, create engagement, and addressed barriers to get stakeholder and staff buy-in, and removed implementation obstacles.

**Evidence Search Strategy**

The evidence search strategy included using the databases of CINAHL, PubMed, and ProQuest. The keywords were dialysis machines, water testing or water cultures, infection prevention, and patient safety. The Boolean connectors and/or were used in the search. For the CINAHL database, the keywords dialysis machines, water testing, and infection prevention were used, in which the limiters were English and Academic Journals from the time frame of 2003 to 2021. For the PubMed database, the keywords dialysis machines, water cultures, and infection prevention was utilized in which the time frame was from 1996 to 2021. For the OVID database, the keywords dialysis machines, water testing, infection prevention, and patient safety were used, in which the limiters were the English language, journals, articles, with the time frame of 2010 to
2021, as well as having a star rating of three. The articles that included dialysis machine water testing, patient safety, and infection prevention were part of the inclusion. However, articles that were not in the U.S., not in English, and were not pertaining to dialysis or the dialysis patient were part of the exclusion. To create a full body of evidence there was not a limitation to full text only and the time frame was extended to 1997. The total number of articles found from the databases were 31 supporting the practicum topic. There were 24 articles removed due to being duplicates, being from other countries, or did not entail elements of this practicum project such as water testing to improve infection (see Figure 1).

Evidence Search Results

The search results from ProQuest include a total of 20 articles; however, only six were retained because of duplication, addressed only general infection prevention, or were not in English. The search results from PubMed include a total of nine articles, in which five articles were kept. The four articles that were removed were from the countries of Africa, Italy, and pertained to a specific dialysis water system rather than water culture best practices. There were two search articles from CINAHL, in which one was removed due to its focus on Home Hemodialysis rather than water culture practices to decrease infection. A total of 31 articles were yielded; however, 24 were removed. This resulted in six articles, four being quantitative and two being qualitative studies (see Appendix A).

It is important to rate the level and quality of the articles in efforts to rate the evidence (Wyant, 2017). The articles included in the evidence table have four articles that are Level IV and one article that is Level III, in which five of the articles are grade B and one article is grade C (see Table 2).

Themes with Practice Recommendations
The evidence from the articles had several themes to support the intervention based on the PICOT question: In patients receiving dialysis at an acute care dialysis unit (P), does utilizing a Standardized Policy for Quality Reporting on Dialysis Machine Disinfection and Water Testing (I) compared to no policy (C) affect infection rates within eight weeks. The evidence supported the need to optimize microbiological surveillance procedures, test pure water to ensure infection prevention practices, and ensure water safety protocols with monitoring and testing. A multidisciplinary team to identify effective processes to improve water sampling and machine disinfection with using standardized procedures and protocols for water testing that follow guidelines along with audits for monitoring the water testing and disinfection process to ensure correct infection prevention practices was established (Bolasco et al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999; Yadav et al., 2017; Yassin, et al., 2020).

Prior studies show that the outcome of infection prevention was positively impacted due to the improvement of procedures and equipment with the most current guidelines, as well as the need for staff to have guidelines to effectively monitor the dialysis water system with the utilization of AAMI as considered the consensus for standards to ensure infection prevention (Bolasco et al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999; Yadav et al., 2017; Yassin, et al., 2020). Monitoring and the surveillance of practices ensured there are no outbreaks of blood stream infections related to inadequate disinfection of water (Bolasco et al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999; Yadav et al., 2017; Yassin, et al., 2020). Therefore, creating effective process changes based on evidence from prior studies such as changes in water sampling techniques, machine disinfection processes, and allocation of machine maintenance duties and structural changes such as regular cleaning of water sampling tubes, and adequate policies and procedures were needed (Bolasco et
al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999; Yadav et al., 2017; Yassin, et al., 2020). Both dialysis water testing and machine cleaning must be performed effectively in a process and procedure that meets standards to ensure infection prevention and patient safety. Overall, the themes can be categorized into standard, process, and accountability.

**Standard**

The performing of a task that meets the appropriate standard is critical, especially as it relates to dialysis water testing (Laymen-Amato et al, 2013; Payne & Curtis, 2018; Yassin, et al., 2020). The 2004 AAMI RD52 standard and CMS regulations state that bacteria levels in hemodialysis water should not exceed 100 colony forming units per milliliters (Units/ML) (Laymen-Amato et al, 2013; Payne & Curtis, 2018; Yassin, et al., 2020). As part of this standard, levels that are violated would require the healthcare organization to take action to address this problem such as disinfection or re-testing (Laymen-Amato et al, 2013; Payne & Curtis, 2018; Yassin, et al., 2020). Endotoxin testing of product water is another aspect of water testing. The standard is that results should not exceed 0.25 endotoxin units per milliliter (EU/ML) and actions must be taken when the level exceeds 0.125 EU/ML (Laymen-Amato et al, 2013; Payne & Curtis, 2018; Yassin, et al., 2020). Although, the 2004 AAMI RD52 standard and CMS regulation allows 100 Units/ML higher levels of bacteria and endotoxins remain in compliance, recommendations for bacterial and endotoxin levels are more stringent than the minimum CMS requirements (Laymen-Amato et al, 2013).

**Process**

The dialysis water testing standards must be part of the policies and guidelines for the organization to follow for ensuring infection prevention and patient safety (Bolasco et al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999; Yadav et al., 2017;
According to Wang et al., (1999), outbreaks in hemodialysis units commonly happen when inadequate disinfection of water treatment occurs; therefore, processes for disinfection and testing are critical. According to Bolasco et al. (2012), effective quality controls and processes for dialysis water and equipment can lead to improved optimization of surveillance.

**Accountability**

The accountability of providing the dialysis treatment belongs to the health organization and the health team performing the care. It is imperative that the correct standards are utilized for any processes in the policies, as well as ensuring that the healthcare team is accountable for its performance (Bolasco et al., 2012; Layman-Amato et al., 2013; Payne & Curtis, 2018; Wang et al., 1999). Healthcare staff must be knowledgeable of the standardized practices in place because exposure to improperly treated water or substandard dialysate can be dangerous to patients (Layman-Amato et al., 2013; Payne & Curtis, 2018). The accountability lies with staff understanding the clinical ramifications of water treatment and dialysate preparation for hemodialysis as part of the entire dialysis process (Layman-Amato et al., 2013; Payne & Curtis, 2018). Furthermore, it was important to document and track that the water testing and disinfection is being performed per policy and procedure.

**Practice Recommendation**

The practice recommendation is to have a policy that encompasses the AAMI standards for dialysis water testing that healthcare staff can follow for accountability and guidance to ensure infection prevention. The strength of the recommendation is based on the evidence supporting the project’s PICOT. The evidence supported having a standardized policy to prevent infection and is needed for healthcare organizational staff to provide safe dialysis treatments.
The organization where the evidence-based change project was implemented is a non-profit organization, which is both a hospital and medical group with ambulatory clinics, as well as a health plan. Their mission is, “to provide high quality, affordable health care services and to improve the health of our members and the communities served” (Sim et al., 2014, p. 101). The vision is, “We are trusted partners in total health, collaborating with people to help them thrive, and creating communities that are among the healthiest in the nation” (Sim et al., 2014, p. 101). The organization was established in 1953 and has approximately 4.5 million members (Sim et al., 2014). The organization provides care by effectively using a model that is integrated by utilizing implementation, dissemination, and performance benchmarking feedback as an approach to chronic disease care delivery (Sim et al., 2014).

The stakeholders for this evidence-based change project were the Directors, Department Administrators, Dialysis Registered Nurses (RNs), Quality Department, Infection Prevention, and the patients receiving dialysis treatments, as well as the Regional Lab Operations Managers and their Lab Project Managers. This interprofessional collaboration was necessary in efforts to have this successful implementation due to the different scopes and disciplines the work involved. Also, it was helpful to include bio-medical services, information technology personnel, nurse educators, and ambulatory dialysis managers in efforts to get more support for the change. It was crucial to fully identify the scope of the project, what needed to be done, and how to accomplish the task for stakeholder support, and time to address any underpinnings for that change (Harris et. al, 2020). The main stakeholder is always the person who is actively involved in the project regardless of whether they are positively or negatively impacted by the project (Kogan et. al, 2015). Organization support was obtained because the project was identified as a need at a Regional Peer Meeting, in which the variation in policy or lack of policy pertaining to
dialysis water testing and machine disinfection was a concern. Also, it was found that there were different tools used for monitoring dialysis water testing and dialysis machine disinfection. A strengths (SWOT) analysis was done in a form of a survey, which revealed to be conclusive that there was variation in practice (see Appendix B). It was noted that within the region, some hospitals had a policy and others did not, some had a tool for monitoring, some reported the metric to the quality or infection prevention department, and others did no reporting or tracking. This variation can negatively impact infection leading to patient harm, as well as put the organization at risk because dialysis is highly regulated by both the state and federal government. The sustainability plan included monitoring this practice by creating a monitoring tool, in which results will be reported out to the infection prevention or quality department. Additionally, the dialysis educator will have this process as an annual skills competency to ensure this practice is sustained.

This project had several levels of system change for the organization. For instance, on a macro level, this policy will be used for Southern California Regional office to adopt in effort to have a standardized policy that is in alignment with infection prevention and quality standards. On a meso level, the change will affect 13 hospitals within the region. On the Micro level, the hospital where the evidence-based practice project was conducted has implemented the process.

**Implementation Plan with Timeline and Budget**

Prior to implementation, the evidence-based practice project needed support from the stakeholders and approval from the University of Saint Augustine for Health Sciences (USAHS) Evidence-Based Practice Review Council (EPRC) and the facility Institutional Review Board (IRB). Upon obtained approval, the implementation began with the utilization of the JHNEBP
Model and Kotter’s Change Model that served as a guide to lead the project. To reach the desired project outcome, the following objectives were established:

1) The standardized policy for dialysis water testing and disinfection were developed and approved prior to implementation.
2) Approval by the EPRC and IRB were obtained by November 2021.
3) Infection rate data was obtained prior and after implementation to measure outcomes.
4) Training of 95% of the nursing staff commenced after project approval.
5) There were audits of tool utilization for 95% compliance of the policy by December 2021.

**JHNEBP Model and Kotter’s Change Model**

The JHNEBP Model guided the evidence-based practice project by using the problem, evidence, and translation process (PET) and helped to create an evidence-based practice culture in the organization (Wyant, 2017). In this project, the problem is infection due to a lack of policy and procedure to ensure adequate water testing and machine disinfection. The evidence supported having policies and guidelines that adhere to AAMI standards. There is a practice problem of infection; thus, evidence was used to change this problem and translate evidence into practice.

Kotter’s change model furthermore served as a guide for the implementation objectives, for which the specific timelines were provided (see Appendix C). The steps of this project proposal included stakeholder support, team formation, vision creation, vision communication, obstacle removal, creation of wins, continued building on change, and anchored change in culture (see Appendix D). A standardized policy for dialysis machine water testing and machine disinfection was imperative to the organization because dialysis is highly surveyable by CMS,
Department of Health, and the Joint Commission; therefore, expressing the importance of this assisted in the creation of a vision for all the stakeholders to adopt this change of a standardized policy (see Appendix G). The monitoring tool enabled the evaluation of the policy process. The monitoring tool provided notes not only compliance of the change, but also the water’s bacteria level results which trigger the need for intervention. For instance, the bacteria water result will tell the dialysis staff whether the dialysis machine needs to be disinfected, if the water needs to be re-tested, or if a different machine should be utilized. Data collection on the rates of dialysis machine water testing and dialysis machine disinfection were performed, and a comparison with overall infection rates were examined to evaluate if the policy resulted in a decrease.

**Resources and Budget**

The resources for the project included the need for a project manager to gather information, solicit feedback for policy draft, and provide a final policy. The DNP student served in the role as the project manager. The project manager was the individual to educate on the policy, implement the policy processes, then monitor and track its usage, as well as collect data to evaluate infection results. The project manager needed specific qualities and skills to be successful. These skills included change management, transformational leadership, emotional intelligence, and self-confidence (MindTools, n.d.). It was helpful that the project manager is familiar with tools to assess if the organization is ready for change and able to effectively utilize evidence-based practice. For instance, the Implementation Leadership Scale (ILS) was utilized to measure the support for the evidence-based practice project (LOCI, n.d.). This scale looked at proactive leadership, knowledgeable leadership, supportive leadership, and perseverant leadership as it relates to evidence-based practice. The project budget expenses totaled $800 which consisted of supplies only (see Table 1). These project expenses were reasonable and
benefit to patient outcomes, especially as it compares to the cost of a patient’s hospital admission or survey deficiency. The annual average cost of a dialysis patient is $84,550; therefore, the cost will double or triple if they are admitted for an infection (Kindy et. al., 2018).

Results

The implementation of the evidence-based practice project first needed the approval from the USAHS EPRC. Once this was obtained, then approval from the facility IRB was attained. Approvals were needed to begin implementation of the evidence-based practice project.

The evaluation plan of the evidence-based practice project entailed an analysis of infection rates three months prior to the implementation of the standardized policy with comparisons of infections rates after the implementation of policy. The rates were evaluated by analyzing the percentage rates of the data to determine an increase or a decrease in the data trend. A percent decrease showed there is a clinically significant improvement in outcome. The Infection Prevention team collected data on CLABSI for the dialysis units, which uses the metric of the standardized infection ratio (SIR). This is a calculation of how many infections there are at the medical center in comparison to how many are expected. Any number over 1.0 is not good; thus, the goal was to have an SIR of less than 0.5. There is also data collected on the Count of Infections at the organization, which is compared with the Predicted Number of Infections. According to September 2021 data prior to the project implementation, the organization had an Infection Count of 18, with a Predicted Number of 12.356, and an SIR of 1.46. However, after the project implementation, there was an improvement in December 2021 data which showed the organization had a decrease Infection Count of 13, with a lower Predicted Number of 11.037, and a decreased SIR of 1.18. This overall percent decrease in infection prevention rate is not statistically significant, but it is clinically significant because this is an improvement based on
the data collected by the Infection Prevention Team. Prior to this project implementation, there was no standardized regional policy; thus, having this policy is another clinically significant outcome because there is now a policy based on EBP for the organization to utilize which ensures quality and safety for dialysis machine water testing and disinfection. This project was done in collaboration with the Dialysis Peer Group, Regional Lab, and Infection Prevention. The Regional Lab updated these dialysis water testing standards in their Lab IT platform. Therefore, there is alignment with results from Regional Lab and what is indicated in the implemented policy to ensure standardization of practice and workflow, thus ensuring safety and wellness for dialysis patients. The type of data collected and expected outcomes were part of the evaluation design plan (see Appendix E). The EBP project translated evidence into practice in which any decrease in infection demonstrated clinical significance. It was difficult to attain statistical significance due to the short time frame of the project.

Another aspect of the evaluation plan was to analyze other process outcomes, such as the percent of staff educated. It was expected that 95% of staff would be educated and trained on the new standardized policy and how to perform the policy workflows. This outcome resulted in 100%, in which staff were both educated and trained on the new standardized policy, the workflows, and the results expectations. The project manager did the initial trainings and those not captured were educated by the charge nurse. This was performed by using the train the trainer method. Additionally, the monitoring tool is another process outcome that was evaluated for 95% compliance to determine if the dialysis water testing and machine disinfection is completed, as well as identifying if the dialysis water testing results from lab are within appropriate levels. This outcome was also met at 100%, in which if the dialysis water testing results were not within appropriate levels, then it was noted that the dialysis department was
following the appropriate follow-up steps which were carried out by the dialysis RN. For instance, when the bacteria water testing result was not at standard, the machine was disinfected and re-tested to ensure it was within the standard of bacteria results prior to patient use.

The data collected included the water testing results, which showed that the policy process is being performed. This process was evaluated for compliance with infection prevention data. The data was collected and analyzed to determine if outcome measures were met. The Health Insurance Portability and Accountability Act (HIPAA) concerns were not relevant to the project because patient sensitive information was not collected or stored, nor was there a problem with missing data because the focus was based on the policy, which consisted of the staff performing dialysis water testing and dialysis machine disinfection based on the policy’s standards. A tool to perform the tracking of policy compliance and the tracking of dialysis water testing results was created (see Appendix F). This tool will continue to be used to report to the quality department or infection prevention department of the organization. To establish face validity, two RNs, the Dialysis Educator and the Department Administrator were able to understand the tool, provide feedback, and then use the tool correctly.

The overall financial impact of this project has the potential to be significant since the annual average cost of care for a dialysis patient is $84,550. Therefore, cost of care for a dialysis patient will double or triple with a hospital acquired infection (Kindy et al., 2018). Thus, mitigating risk for infection is key to ensure quality of care and to decrease unnecessary costs.

**Impact**

The outcome of the project supported the literature and effectively addressed the practice problem. The problem being there was no standardized policy for the dialysis nursing staff to follow for dialysis water testing and disinfection. The literature supported having a standardized
policy based on the CMS and AMMI standards in efforts to ensure quality of care and safety of dialysis treatments. Collaboration with the organization’s dialysis peer group, regional lab, infection prevention, and dialysis educator was effectively done, and as a result of the developed policy the water testing standards were built into the lab’s IT platform. Thus, allowed a positive impact and altered practice which will help to sustains the process and workflow of the policy for the future. This policy was implemented in one out of 13 medical center hospitals; however, will be expanded to all of the medical center hospitals for adoption. There will not be a need for additional funding because this policy was shared with the dialysis peer group in which there is representation from each medical center hospital to allow for quick future adoption.

Sustainability will be supported by Infection Prevention and Staff Education, in which it will be part of future annual competency training and quality reporting. The dialysis nurses will be performing scheduled dialysis water testing and disinfection based on the policy, in which if a result is not within standard, an action will then be done and documented in the dialysis log accordingly. Quality tracking will be done using the report out tool for reporting to quality or infection prevention.

Barriers to the project included the time it took to gain approval from EPRC and the organization’s IRB. The project also took place during the COVID-19 surge of the Omicron variant. The organization had to prioritize efforts on providing increased testing, access to COVID-19 vaccinations and boosters, and anti-viral intravenous therapy treatment despite limited resources and staff. Therefore, the time on implementation and evaluation was delayed and time for gathering data was shortened. Further barriers that affected time for implementation included the risk of a work stoppage for the organization in which time for planning and
strategizing was a focus for many weeks. While this did not occur, the planning was another reason why implementation time was limited.

**Dissemination Plan**

The EBP project was disseminated during the Peer Committee Meeting in which the final project update and results were shared with all stakeholders. These stakeholders included the dialysis directors, managers, educator, and infection prevention consultant. This communication was done verbally, in which the policy was reviewed, and the standards were discussed. There was a question-and-answer secession by the team in that all questions and concerns were addressed, and feedback was provided. Furthermore, potential opportunities for publishing the project implementation and its results in journals such as the American Nephrology Nurses Association (ANNA) or the American Organization for Nursing Leadership (AONL) will be explored. These mentioned professional organizations are both appropriate to the project because one is specific to Dialysis Nursing and the other is specific to Nursing Leadership. Any manuscripts will need peer review prior to ensure that the article is appropriately written with all the necessary elements included. Lastly, presenting the EBP project as an abstract, poster presentation, or podium presentation for the USA SOAR will be done, as well as exploring the same for American Nephrology Nurses Association (ANNA), the American Academy of Ambulatory Care Nursing (AAACN), or the American Organization for Nursing Leadership (AONL) in efforts to disseminate the project’s implementation and results to an even larger audience. The presenting at the AAA Chapter Sigma at the USAHS DNP Scholarly Project Symposium will be done to further disseminate and share the EBP project.
Conclusion

Dialysis patients, due to multiple comorbidities have a high likelihood for hospitalization. Hospitalization will require the patient to need dialysis performed. The risks of infection are notably higher in patients on dialysis than in the general population due to access-related infections in patients on hemodialysis (Himmelfarb et al., 2020). It is important for the organization to have strategies to reduce the risk of infection associated with dialysis; therefore, policies and guidelines to mitigate infections and ensure quality of care become crucial. It is with the mentioned EBP implementation of creating a standardized regional policy for dialysis water testing and dialysis machine cleaning that this project was able to significantly assist the organization to attain improved safety and quality. This evidence-based project paper effectively provided details on the significance of the problem, the PICOT question, evidence-based practice framework using JHNEBP module, Kotter’s change theory, evidence search strategy, evidence search results, and themes with practice recommendations. The setting, stakeholders, systems change, as well the implementation plan was also discussed. Furthermore, the timeline and budget, evaluation plan, and dissemination plan of the project were outlined.

Although kidney failure only affects 0.1% - 0.2% of the general population, the total dialysis expenditure is 5-7% of total healthcare budget spending (Himmelfarb et al., 2020). Kidney failure will continue to become more complex due to the population aging, as well as with the increase of chronic conditions such as diabetes mellitus and hypertension. It is expected that not only ESRD incidence and prevalence will increase, but healthcare costs will continue to rise (Himmelfarb et al., 2020). Thus, is critical for the organization to maintain quality and safety for patients on dialysis with the use of standardized policies such as the project that was implemented for dialysis water testing and dialysis machine disinfection.
References


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https://doi.org/10.1681/ASN.2018050531

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infection among patients undergoing hemodialysis. *Infection Control and Hospital Epidemiology, 30*(9), 840–847. https://doi.org/10.1086/605324


Table 1

Budget

<table>
<thead>
<tr>
<th>EXPENSES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies</td>
<td>800</td>
</tr>
<tr>
<td>Statistician NA- Intellectus Statistics</td>
<td>0</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>800</td>
</tr>
</tbody>
</table>
Table 2

*Evidence Table Level and Quality Grade*

<table>
<thead>
<tr>
<th>Citation</th>
<th>Level</th>
<th>Quality Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolasco, P. et al. (2012)</td>
<td>Level- IV</td>
<td>Grade- C</td>
</tr>
<tr>
<td>Yadav, P. et al. (2017)</td>
<td>Level- III</td>
<td>Grade- B</td>
</tr>
<tr>
<td>Yassin, et al. (2020)</td>
<td>Level-III</td>
<td>Grade- B</td>
</tr>
</tbody>
</table>
Figure 1

PRISMA 2009 Flow Diagram

Records identified through database searching ProQuest (n = 20)

Additional records identified through other sources (PubMed & Cinahl) (n = 11)

Records after duplicates removed (n = 31)

Records screened (n = 31)

Records excluded (n = 19)

Full-text articles assessed for eligibility (n = 12)

Full-text articles excluded, with reasons (staffing, COVID) (n = 6)

Studies included in qualitative synthesis (n = 2)

Studies included in quantitative synthesis (meta-analysis) (n = 4)


For more information, visit www.prisma-statement.org.

Reference page entry:

## Appendix A

### Summary of Primary Research Evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Design, Level</th>
<th>Sample</th>
<th>Intervention</th>
<th>Outcome Definition</th>
<th>Usefulness Results</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolasco, P., et al. (2012).</td>
<td>Design-Nonexperimental Level- IV Quality Grade- C</td>
<td>Sample- dialysis water samples Sample Size- 945 dialysis water samples</td>
<td>Intervention- Optimized microbiological surveillance procedures in 5 dialysis units</td>
<td>Outcome Improvement of procedures and equipment with the most current guidelines</td>
<td>Results- Over 16-year period dynamic procedures have shown RO should be considered a necessary investment. Daily overnight thermal disinfection procedures have proven to be more effective than frequent chemical disinfection</td>
<td></td>
</tr>
<tr>
<td>Layman-Amato, R.L., Curtis, J., &amp; Payne, G.M. (2013).</td>
<td>Design- CPG Level- IV Quality Grade- B</td>
<td>Sample- NA Sample Size- NA</td>
<td>Intervention- Pure water that ensures infection prevention practices is important for quality dialysis treatments. Water treatment and cultures are important to understand and monitor for quality and patient safety.</td>
<td>Outcome- Staff need guidelines and must be able to effectively monitor the dialysis water system.</td>
<td>Usefulness- Nurses need to be able to understand the clinical ramifications of water treatment and dialysate preparation for hemodialysis as part of the entire dialysis process.</td>
<td></td>
</tr>
<tr>
<td>Author(s)</td>
<td>Design</td>
<td>Sample</td>
<td>Intervention</td>
<td>Outcome</td>
<td>Usefulness</td>
<td>Key findings</td>
</tr>
<tr>
<td>-----------</td>
<td>--------</td>
<td>--------</td>
<td>--------------</td>
<td>---------</td>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Payne, G. &amp; Curtis, J. (2018).</td>
<td>CPG</td>
<td>NA</td>
<td>Water safety protocols are needed and must be understood</td>
<td>AAMI are considered the consensus standards. The latest is 2014, but they were set to be updated.</td>
<td>Staff must be knowledge and standardized practices must be in place. Exposure to improperly treated water or substandard dialysate can be dangerous to patients.</td>
<td></td>
</tr>
<tr>
<td>Wang, S. et al., (1999).</td>
<td>Cohort Retrospective Level- III Quality Grade- B</td>
<td>94 patients</td>
<td>Water samples were obtained from several locations in the water treatment system</td>
<td>Outbreaks of BSI is due to inadequate disinfection of water or distribution systems</td>
<td>Surveillance and infection control are important standards of practice. For any medical device it is necessary for user to understand proper handling, maintenance, and quality control.</td>
<td></td>
</tr>
<tr>
<td>Yadav, P. et al. (2017).</td>
<td>Retrospective Review Level- III Quality Grade- B</td>
<td>12 HD Machines and 7 RO Machines</td>
<td>Multi-disciplinary team reviewed processes, interviewed staff, and identified process to improve water sampling and machine disinfection.</td>
<td>Five interventions-3 were process changes (changes in water sampling techniques, machine disinfection processes, and allocation of machine maintenance duties) and 2 were structural (regular cleaning of water sampling standards.</td>
<td>Post implementation of new protocols, 100% of cultures of HD and RO machines consistently met the required standards.</td>
<td></td>
</tr>
</tbody>
</table>
were collected and analyzed tubes and spigots and addition of new water sampling sites in the systems).

Yassin, et al. (2020). Design-Nonexperimental Level-III Quality Grade- B Sample- 10 portable dialysis machines Sample Size- RO cultures were taken over 6 months Intervention- Procedures and protocols should follow AAMI guidelines, Audit of disinfection process to ensure correct Infection prevention practices.

Outcome- Adequate policies and procedures are needed, in which a 7 step investigation and correction can be done understand gaps.

Key findings- A major advance in HD is the use of Reverse Osmosis (RO) to improve the safety of the water use, as well as the use of the AAMI (Association for the Advancement of Medical Instrumentation) for cleaning guidelines. Guide: Less than 100 colony forming units (CUF) per ML of water and 0.1 Endotoxin units.

Legend:

RO- Reverse Osmosis

AAMI- Association for the Advancement of Medical Instrumentation

HD- Hemodialysis
## SWOT Analysis

<table>
<thead>
<tr>
<th><strong>Strengths</strong></th>
<th><strong>Weakness</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stakeholder agreement and support</td>
<td>• Variation in practice</td>
</tr>
<tr>
<td>• Need for standardization expressed and understood</td>
<td>• Variation in policy and standards</td>
</tr>
<tr>
<td>• Structures in place for communication</td>
<td>• Some areas lack a policy</td>
</tr>
<tr>
<td>• Leadership supportive of change</td>
<td>• Dialysis RNs unclear on practice</td>
</tr>
<tr>
<td>• Dialysis RNs competency on practice must be ensured and validated</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opportunities</strong></th>
<th><strong>Threats</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Organization is large but structure for communicating and implementing works well</td>
<td>• Dialysis is highly regulated by CMS, DHS, Joint Commission</td>
</tr>
<tr>
<td>• Organization is known for focus on quality, safety, focus on chronic disease management</td>
<td>• Subject to survey at any time due to regulations</td>
</tr>
<tr>
<td>• Organization is known for providing integrated and collaborative care</td>
<td>• Dialysis has strict infection prevention standards noted in the Conditions for Coverage (CFC) and by Network 18</td>
</tr>
<tr>
<td>• Organization has effective Electronic Health Record (EMR) and Health Information Exchange (HIE) for tracking and documenting care delivery</td>
<td>• Reimbursement is tied to meeting quality incentives as per CMS ESRD QIP (Quality Improvement Plan)</td>
</tr>
</tbody>
</table>
## Appendix C

### Project Schedule

<table>
<thead>
<tr>
<th>Activity</th>
<th>NUR7801</th>
<th>NUR7802</th>
<th>NUR7803</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meet with preceptor</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Prepare project proposal</td>
<td>X X X X X X X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explore and seek USA EPRC</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explore and seek IRB appropriate for project</td>
<td>X X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>if appropriate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop standard policy draft, obtain</td>
<td>X X X X X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>approvals and vetting.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implement policy</td>
<td>X X X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotter Step 1: Create Urgency-Express to</td>
<td>X X X X X X X X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>NUR7801</td>
<td>NUR7802</td>
<td>NUR7803</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>stakeholders’ policy is needed for regulatory and patient safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotter Step 2: Form a Powerful Coalition- Meet with Peer Committee Group to understand current process, and future policy needs, as well as gather feedback</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Kotter Step 3: Create a Vision for Change- Continue to express need for policy due to dialysis being highly surveyable by CMS, DHS, etc.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Kotter Step 4:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>NUR7801</td>
<td>NUR7802</td>
<td>NUR7803</td>
</tr>
<tr>
<td>----------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td>Week 1</td>
<td>Week 3</td>
<td>Week 5</td>
</tr>
<tr>
<td></td>
<td>Week 7</td>
<td>Week 9</td>
<td>Week 11</td>
</tr>
<tr>
<td></td>
<td>Week 13</td>
<td>Week 15</td>
<td>Week 1</td>
</tr>
<tr>
<td>Communicate the Vision- Show policy draft to Committee Peer Group, Dialysis RN Staff at huddles in efforts to get feedback, buy-in, and show its importance to patient safety and infection prevention.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotter Step 5: Remove Obstacles- Educate Dialysis RN Staff on the policy processes, as well as communicate updates to the stakeholders. Perform slow roll-out process, in which staff</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Activity</td>
<td>NUR7801</td>
<td>NUR7802</td>
<td>NUR7803</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>is to start once educated.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotter Step 6: Create Short-Term Wins-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Celebrate when the policy implementation is fully adopted, when</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>procedure for water testing is fully performed by staff that results in appropriate water testing</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Kotter Step 7: Build on the Change-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor tool with dialysis water testing results will be presented at medical center’s</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

The table indicates that the steps are being tracked weekly, with 'X' indicating that the activity is complete by that week.
### DIALYSIS WATER TESTING AND MACHINE DISINFECTION

<table>
<thead>
<tr>
<th>Activity</th>
<th>NUR7801</th>
<th>NUR7802</th>
<th>NUR7803</th>
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</thead>
<tbody>
<tr>
<td>quality/infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>prevention meetings.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collect data on rates of dialysis machine water testing and</td>
<td></td>
<td></td>
<td>X X X X</td>
</tr>
<tr>
<td>dialysis machine disinfection, and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>compare with overall infection rates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotter Step 8: Anchor the Changes in Culture- Report Out of the</td>
<td></td>
<td></td>
<td>X X X</td>
</tr>
<tr>
<td>dialysis water testing and dialysis machine disinfection will be done</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>at Quality/Infection Prevention Meetings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan with Staff</td>
<td></td>
<td></td>
<td>X X X X</td>
</tr>
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</table>
### DIALYSIS WATER TESTING AND MACHINE DISINFECTION

<table>
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<tr>
<th>Activity</th>
<th>NUR7801</th>
<th>NUR7802</th>
<th>NUR7803</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education that</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysis water testing and dialysis machine disinfection will be done at Educational RN Annual Competencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final report out of policy project, evaluation of infection rates since policy implementation, and exploration of project being publish for article will be done in efforts to support the change.</td>
<td></td>
<td></td>
<td>X X</td>
</tr>
</tbody>
</table>
Appendix D

Procedure Step

**Kotter Step 1: Create Urgency**

1. Identify the problem and gain stakeholder buy-in. There is already noted buy-in from stakeholders because this standardized policy was a request by the directors, managers, and staff at a Peer Committee Meeting. Urgency is created since the policy will support organizational survey and regulatory efforts.

2. The standardized policy for dialysis water testing and machine disinfection will be drafted by September 1, 2021. Policy development and vetting Approved by stakeholders and organization.

3. The approval by EPRC and institution will be obtained by mid-September 1, 2021

**Kotter Step 2: Form a Powerful Coalition**

1). Establish the project’s interprofessional team. Huddling with the lab team, RN staff, managers, project manager, and infection prevention group will ensure communication of the new policy implementation and monitoring processes.

**Kotter Step 3: Create a Vision for Change**

1) Creation of a standardized policy for dialysis machine water testing and machine disinfection is imperative to the organization because dialysis is highly surveymable by CMS, Department of Health, and the Joint Commission. Expressing the importance of this will assist in the creation of a vision for all the stakeholders to adopt this change.

**Kotter Step 4: Communicate the Vision**

1. Communicate the new policy with the Peer Committee Group, as well as huddling on the dialysis units directly with the Dialysis RN Staff.

2). Huddling with the lab team, RN staff, managers, and infection prevention group will ensure communication of the new policy and its processes.

**Kotter Step 5: Remove Obstacles**

1). Staff will be trained and educated on policy and tool.

2). There will be training of policy and tool by nursing staff measured by 95% completion by week 5.

3). Establish Face validity of tool.

4). Implementation of project begins immediately after approval and training.

The celebration of achievements will be done during staff meetings and huddles where staff will be recognized for this accomplishment.

5). Conduct audits of tool utilization measured by 95% compliance of the policy by week 8.

**Kotter Step 6: Create Short-Term Wins**

1) The celebration of achievements will be done during staff meetings and huddles where staff will be recognized for this accomplishment.

2). There will be audits of tool utilization measured by 95% compliance of the policy by week 7.

**Kotter Step 7: Build on the Change**
<table>
<thead>
<tr>
<th>Kotter Step 7: Build on the Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1). Present the results from the monitoring tool to the peer group and at staff meetings to show the positive performance. The monitoring tool will enable the evaluation of the policy process.</td>
</tr>
<tr>
<td>2). Collect data on the rates of dialysis machine water testing and dialysis machine disinfection performed, and compare with overall infection rates to evaluate if the policy resulted in a decrease.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kotter Step 8: Anchor the Changes in Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1). The monitor tool results will be in a Report Out to the Quality and/or Infection Prevention department.</td>
</tr>
<tr>
<td>2). Results of the pilot implementation will be shared with other medical centers to facilitate adoption.</td>
</tr>
<tr>
<td>3). This policy will be part of the educational annual competency for dialysis nurses to ensure that they are able to appropriately perform dialysis water testing and machine disinfection.</td>
</tr>
</tbody>
</table>
Appendix E

Evaluation Design and Data Analysis

<table>
<thead>
<tr>
<th>Outcomes/Variable Name</th>
<th>Variable Description</th>
<th>Data Source</th>
<th>Time Frame for Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection Rates</td>
<td>Increase or Decrease</td>
<td>Infection Prevention Data</td>
<td>Calculated Monthly by Team</td>
</tr>
<tr>
<td>Staff Education of Policy</td>
<td>% Complete</td>
<td>Attended Sign-in</td>
<td>Calculated at Training</td>
</tr>
<tr>
<td>Monitor of Tool Usage</td>
<td>% Complete</td>
<td>Logbook</td>
<td>Calculated Monthly by Result from Regional Lab</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Month &amp; Year</th>
<th>Infection Count</th>
<th>Predicted Number</th>
<th>SIR</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2021</td>
<td>18</td>
<td>12.356</td>
<td>1.46</td>
</tr>
<tr>
<td>December 2021</td>
<td>13</td>
<td>11.037</td>
<td>1.18</td>
</tr>
</tbody>
</table>
Appendix F

Quality Tracking and Reporting Tool

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Dialysate Culture (0.125 EU/mL)</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data points reflected in the chart are the monthly result.

Analysis:

CONCLUSION:

Action:
Appendix G

Regional Policy Draft

1.0 Policy Statement
This policy is to protect patients from exposure to bacteria, endotoxins, and endotoxin fragments in water used for hemodialysis that cause acute pyrogenic reaction as well as chronic inflammatory responses that lead to increased mortality and morbidity.

2.0 Purpose
To outline a procedure for collecting specimens for bacteria cultures and endotoxin testing requirements of water and dialysate used in hemodialysis.

3.0 Scope/Coverage
3.1 This policy will assist to define the proper procedures for collecting and handling specimens, as well as include storing and transporting in accordance with the National Patient Safety Goals, Infection Prevention Standards, and Laboratory Policy and Procedures.

3.2 This policy applies to all employees who are employed by any of the following entities (collectively referred to as "Kaiser Permanente":

3.2.1 Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals (together, KFHP/H);

3.2.2 KFHP/H's subsidiaries;

3.2.3 Southern California Permanente Medical Group (SCPMG)

4.0 Definitions
1. Culture – synonymous with bacteriologic testing or total viable microbial count
2. Limulus amoebocyte lysate (LAL) – synonymous with endotoxin testing

5.0 Provisions/Procedures
The dialysis water and dialysate shall have both cultures and LAL performed as recommended by the manufacturing company, in which the equipment will be operated and maintained as recommended. It is expected that the patient will receive optimal, efficient, and safe hemodialysis treatments free of complications related to contaminated dialysis water and/or dialysate. The equipment, dialysate, and dialysis water will be free of bacterial growth and endotoxins.

5.1 Documentation will be collected on the dialysis machine log sheet that cultures were performed, in which results will be available for the Chief, Medical Director, or Designee in that any abnormal results shall be shared.

5.2 Both cultures and LAL for dialysis water and dialysate will be reported to Quality and/or Infection Prevention per medical center as appropriate.
6.0 Procedure

6.1 Culture (Dialysis water and Dialysate) and LAL levels of product water and dialysate used for hemodialysis shall be tested monthly.

6.2 Product water samples shall be obtained from the first and last outlets of the water distribution loop, bicarbonate system pre-loop and post return, and 3 random dialysis stations. Dialysate samples shall be obtained from the dialysate sample port of the dialysis machine.

6.2.1 Sample ports shall not be disinfected with bleach or povidone-iodine.

6.2.2 Sample ports shall be flushed for 60 seconds before obtaining the sample.

6.2.3 Disinfection shall be done after samples are collected.

6.2.4 Specimens shall be collected, identified, handled, transported, and stored in accordance with National Patient Safety Goals without regard to whether such specimens are collected by laboratory personnel or the personnel of other departments or whether they are to be evaluated in-house or in a reference laboratory.

6.3 The identifying label shall be securely attached to the specimen container(s) such that it is not removable.

6.3.1 The identifying label shall be attached to the specimen container(s) at the time of collection and not before or deferred at a later time.

6.4 Medical Director/Designee, Department Administrator/Assistant Department Administrator, Clinical Department Supervisor (CDS) shall be notified when total viable microbial and LAL results are at **Actionable or Maximum Limits**.

6.4.1 When Culture and/or LAL level are within **Actionable Limit**, repeat testing shall be done within 48 hours of result notification.
6.4.2 When Culture and/or LAL level are at the **Maximum Limit on the RO water distribution loop**, per Medical Director's/Designee's discretion, may:

A. Terminate all treatments, return blood immediately (unless the patient(s) is showing signs and symptoms of pyrogen reaction), evaluate and/or arrange treatments for patients.
B. Disinfect the RO loop within 48 hours of result notification.
C. Draw sample post disinfection.
D. Run dialysis treatment after disinfection.

6.4.3 When Culture and/or LAL level are at the **Maximum Limit on the RO machine**, per Medical Director's/Designee's discretion, may:

A. Remove the offending equipment from service.
B. Disinfect the offending equipment within 48 hours of result notification.
C. Draw sample from the offending equipment post disinfection.
D. Use the offending equipment after disinfection.

6.4.4 When Culture and/or LAL level are at the **Maximum Limit on any of the dialysis machine** per Medical Director's/Designee's discretion, may:

A. Stop the treatment, return blood immediately (unless the patient(s) is showing signs and symptoms of pyrogen reaction, refer to unit policy # 200 – 006 pyrogen reaction protocol) and evaluate the patient.
B. Remove the dialysis machine from service.
C. Use another dialysis machine with a new, sterile set-up and continue with dialysis treatment.
D. Disinfect the offending equipment within 48 hours of result notification.
E. Draw sample from the offending equipment post disinfection.

### 6.5 Supplies:

- **6.5.1** Personal protective equipment (PPE) required: gown, gloves, mask, and face shield
- **6.5.2** 70 % Isopropyl alcohol swab/wipes and sterile gauze
- **6.5.3** Basin or graduated cylinder
- **6.5.4** Sterile LAL free or pyrogen free specimen cup
- **6.5.5** Specimen tubes
- **6.5.6** Specimen bags
- **6.5.7** 30 ML syringe
6.5.8 Ice or ice pack

6.6 Testing of RO water from water distribution loop:
6.6.1 Gather all equipment, wash hands, and wear clean gloves, mask and gown.
6.6.2 The RO unit must be running for at least 15 minutes before taking the sample.
6.6.3 Open the sample valve and allow water to flush in a basin for at least 60 seconds.
6.6.4 Unscrew the cap of the sterile specimen cup. Place cap facing upward to avoid contamination.
6.6.5 Catch water sample midstream into the sterile specimen cup and fill to 3/4 full. Turn off sample port.
6.6.6 Recap the specimen cup being careful not to contaminate. Turn off sample port.
6.6.7 Use alcohol wipes/swab to clean the top of *culture* specimen tube. Allow to the top of the collection tubes to dry completely.
6.6.8 Carefully peel back sticky label on the top of the specimen cup to expose the integral sampling device.
6.6.9 Collect correct volume of fluid in *culture* specimen tube by allowing the vacuum in the tube to be exhausted.
6.6.10 Unscrew cap on *LAL* specimen tube and place cap facing upward to avoid contamination.
6.6.11 Pour sample into LAL specimen tube up to 3/4 full.
6.6.12 Recap the *LAL* specimen tube being careful not to contaminate.
6.6.13 Immediately after collection, affix label on the specimen tubes and refrigerate at least 2 hours before shipping/transport.
6.6.14 Fill out requisition form and transport the specimen with ice pack.

6.7 Testing of dialysate from the dialysis machine:
6.7.1 Gather all equipment, wash hands, and wear clean gloves, mask, and gown.
6.7.2 The dialysis machine must be in proper conductivity and temperature before obtaining dialysate sample.
6.7.3 Turn dialysate flow rate (DFR) to 800 mL/min.
6.7.4 Squeeze the sides of the dialysate line sample port and allow dialysate to run into the prime bucket for at least 60 seconds.
6.7.5 Unscrew cap of the sterile specimen cup. Place cap facing upward to avoid contamination.
6.7.6 Catch the dialysate solution midstream into the sterile specimen cup and fill to 3/4 full.

6.7.7 Recap the specimen cup being careful not to contaminate. Turn off sample port.

6.7.8 Use alcohol wipes/swab to clean the top of the **culture** specimen tube. Allow to the top of the collection tubes to dry completely.

6.7.9 Carefully peel back sticky label on the top of the specimen cup to expose the integral sampling device.

6.7.10 Collect correct volume of fluid in **culture** specimen tube by allowing the vacuum in the tube to be exhausted.

6.7.11 Unscrew cap on **LAL** specimen tube and place cap facing upward to avoid contamination.

6.7.12 Pour sample into **LAL** specimen tube up to 3/4 full.

6.7.13 Recap the **LAL** specimen tube being careful not to contaminate.

6.7.14 Immediately after collection, affix label on the specimen tubes and refrigerate at least 2 hours before shipping/transport.

6.7.15 Fill out requisition form and transport the specimen with ice pack.

7.0 **References/Appendices**


8.0 Signature Lines

Include the signature(s) of the senior regional leader(s) that approved the document being submitted in accordance with the SCAL Regional Policy and Procedure Toolkit.

Signature: ___________________________ Date: ___________________________
[Regional Business Owner name and title]
Appendix H

CMS / AAMI Standard

AAMI – Association for the Advancement of Medical Instrumentation

The Association for the Advancement of Medical Instrumentation (AAMI) is a professional organization in which committees are composed of representatives that include health care professionals, patients, medical device manufacturers, and representatives of federal agencies. These committees have developed voluntary guidelines for medical products and procedures. The Renal Disease and Detoxification Committee (RDD) has developed standards for dialysis equipment manufacturers and recommended practices for end users.

As stated in the AAMI objectives, the voluntary standards for a medical device recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products.

A recommended practice provides guidelines to the end user for the use, care, and/or processing of a medical device or system. This does not address device performance per se, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained. The documents are adopted and published in harmony with the American National Standards Institute (ANSI).

All documents developed by ANSI/AAMI are reviewed at least once every 5 years. Substantial changes may result from the review and may pose challenges to the end user in adopting the changes. For example, RD52:2004 (intended for dialysis providers) and RD62:2001 (intended for equipment manufacturers) have undergone several reviews and changes. In
the years that followed, the Committee sought to harmonize with the international community to comply with the International Organization for Standardization (ISO). The harmonization resulted in significant changes to the quality, validation and methods to water and dialysate for hemodialysis as well as expanding from two documents to four (as noted). The latest documents that harmonize with ISO are:

- **ANSI/AAMI/ISO 26722:2009** Water treatment equipment for hemodialysis applications and related therapies (revision of RD62)
- **ANSI/AAMI/ISO 23500:2011** Guidance for the preparation and quality management of fluids for hemodialysis and related therapies (revision of RD52)
- **ANSI/AAMI/ISO 11663:2009** Quality of dialysis fluid for hemodialysis and related therapies (revision of RD52)
- **ANSI/AAMI/ISO 13958:2009** Concentrates for hemodialysis and related therapies (revision of RD61)

As a result of some of the challenges these standards caused to the US hemodialysis community, the AAMI RDD Committee approved and released a US deviation to the International ANSI/AAMI/ISO documents as stated above and has since published the following:

- **ANSI/AAMI 26722:2014** Water treatment equipment for hemodialysis applications and related therapies
- **ANSI/AAMI 13959:2014** Water for hemodialysis and related therapies
- **ANSI/AAMI 23500:2014** Guidance for the preparation and quality management of fluids for hemodialysis and related therapies
- **ANSI/AAMI 11663:2014** Quality of dialysis fluid for hemodialysis and related therapies
- **ANSI/AAMI 13958:2014** Concentrates for hemodialysis and related therapies
"Approved culture methods shall include one of the following:

- tryptone glucose extract agar (TGEA) or Reasoner's 2A supplemented with 4% sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17°C to 23°C, and an incubation time of 168 h (7 d); or
- Tryptase soy agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE), incubated at 35°C for 48 hours.

Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods. See USP <1231> for guidance on adoption of alternative methods."

This deviation of test methods surrounding agar medium, incubation temperature and incubation time was not adopted by ISO, but is now found within the latest ANSI/AAMI 2014 documents as a deviation. The microbiological requirements for water as stated in 13959 remain unchanged between the two standards groups:

<table>
<thead>
<tr>
<th>Microbiological Level</th>
<th>Water Standard</th>
<th>Water Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colony Forming Units</td>
<td>&lt; 100 CFU/mL</td>
<td>≥ 50 CFU/mL</td>
</tr>
<tr>
<td>Endotoxin Units</td>
<td>&lt; 0.25 EU/mL</td>
<td>≥ 0.125 EU/mL</td>
</tr>
</tbody>
</table>

Furthermore, there are no changes to the maximum level of chemical contaminants that can be found in product water used for hemodialysis and related processes. Keep in mind that the changes in the AAMI documents remain as voluntary requirements and are not enforceable unless the governing body Centers for Medicare and Medicaid Services (CMS) adopts the updated document as reference. As of October 2008, the CMS ESRD Interpretive
ANSI/AAMI 13959 – WATER FOR HEMODIALYSIS AND RELATED THERAPIES

This latest AAMI Standard (a revision of RD62) provides guidance for water requirements used in hemodialysis and related therapies. It includes any water used to prepare concentrates, the make-up of dialysate, hemodiafiltration and hemofiltration, and the practice of reprocessing dialyzers. This Standard only details water quality and does not provide specific guidance on water treatment equipment.

ANSI/AAMI 26722 – WATER FOR HEMODIALYSIS AND RELATED THERAPIES

This latest AAMI Standard (a revision of RD62) provides guidance for water treatment equipment for hemodialysis and related therapies. It is specifically directed to any manufacturer and/or supplier of water treatment systems and/or devices that are expressly used for hemodialysis or related therapies. This Standard not only includes all areas of use for dialysis water, but it also includes all devices, components, piping systems and fittings that connect potable water lines to product water lines along with water quality monitoring instrumentation. Water quality itself is not covered within this Standard, merely the method to achieve the desired outcome with reference to Standard 13959.

Guidance references the RD52:2004 and RD62:2001 documents for ANSI/AAMI and surveyors inspect provider's clinics and facilities based on those writings. Please note that surveyors and inspectors will measure provider's compliance to the Quality Assurance Program or Policies that they are adhering to within their practice.

The AAMI RDD recommendations are a result of expert consensus on how to safely handle water and concentrates and for the production and monitoring of dialysate for hemodialysis. It is also intended as a guide for physicians, and particularly the directors of dialysis facilities. The standards are an invaluable source of information and policy guidance that seeks to ensure patient safety while promoting technological advancements.
ANSI/AAMI 23500 – GUIDANCE FOR THE PREPARATION AND QUALITY MANAGEMENT OF FLUIDS FOR HEMODIALYSIS AND RELATED THERAPIES

This AAMI Standard (a revision of RD52) provides guidance for dialysis practitioners or providers on the preparation of dialysis fluids for hemodialysis and related therapies. It includes total management of water treatment equipment, concentrate powders to liquid, and the preparation of final dialysis fluids. But it excludes sorbent-based dialysis fluid regeneration systems, prepackaged solutions for continuous renal replacement therapy, and solutions for peritoneal dialysis.

ANSI/AAMI 11663 – QUALITY OF DIALYSIS FLUID FOR HEMODIALYSIS AND RELATED THERAPIES

This AAMI Standard (a revision of RD52) provides guidance for dialysis practitioners or providers on the minimum quality requirements for dialysis fluids used in hemodialysis and related therapies. It doesn't include water and concentrate requirements. It also excludes sorbent-based dialysis fluid regeneration systems, prepackaged solutions for continuous renal replacement therapy, and solutions for peritoneal dialysis.

ANSI/AAMI RD62 – WATER TREATMENT EQUIPMENT FOR HEMODIALYSIS APPLICATIONS

This Standard was developed as a replacement for the overall standard for dialysis RD5. In 2001, AAMI released the first version of RD62 water for dialysis and then again in 2006. Since then this has become a standard followed by many dialysis providers and is recognized throughout the world. This standard, although addressed to industry, has been adopted by most dialysis facilities.

This AAMI document gives recommendations for the entire fluid system from the pretreatment of water to the final dialysate production. All aspects of the system are discussed in detail. In 2008, CMS adopted this document as a standard of practice for the United States ESRD program.