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Role of Chemical Parameter on Quality of Water Treatment for Hemodialysis and Clinical Evaluation Results

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Abstract: *Water quality is one of the most important aspects of ensuring a safe delivery of hemodialysis. Contamination by metals and microbiological agents in hemodialysis water can cause clinical intercurrences in hemodialysis patients. Evaluating and assuring minimum levels of contamination from metals and microorganisms in hemodialysis water can improve patient safety. Water treatment plays a vital role in the delivery of safe and effective hemodialysis (HD). 3s & 1s*

The objective of the study was to determine the chemical quality of samples of water in a seven hemodialysis unit in IRAN. This study was to assess hemodialysis water quality in an output of reverse osmoses device on hemodialysis unit that the product of Novatis Teb company. Clinical evaluation has been done according to the MEDDEV. 2.7.1. For visualization and also analysis of data, Mini Tab software is used, 49 samples is chosen from 2016 September to 2018 December. The result of analysis in Mini Tab software shows that all chemical parameters in reverse osmosis device (NOVA RO 1000) are on allowable range according to ANSI/AAMI RD62:2001 standard.

Keywords: *water treatment, reverse osmoses, clinical experience, conductivity*

1. Introduction

Since the early 1960s, hemodialysis (HD) has been increasingly used for the treatment of acute renal failure and end-stage renal failure. Technologic advances in dialyzer membranes, dialysis machines and vascular access have made HD a routine procedure today. Nonetheless, it remains potentially hazardous, both as a result of mechanical malfunctions and human error. HD replaces kidney function by using a semi-permeable membrane inside a dialyzer to filter wastes and water from the blood into the dialysate fluid. Water is used in HD to prepare dialysate.

If dialysis water contains impurities such as bacteria, end toxins, metals, mud, sediment or chemicals, these impurities may enter the patient's bloodstream through the dialyzer membrane and cause disease or injury. Because dialysis uses large amount of water, even tiny amount of contaminants can be dangerous. Some substances can cause conditions such as anemia or pyrogenic reactions, while some substances can build up to toxic levels, causing long-term physical harm, and other substances are immediately toxic and can cause death. A normal person also encounters these contaminants through drinking water, but the healthy kidney is able to remove these substances. Renal failure patients do not have this capability. It is ironic that the same dialysis treatment that saves lives can also expose patients to substances that could injure them. In order to be safe for patients, dialysis water must be carefully treated with a water treatment system, consisting of a series of devices, each of which removes certain contaminants. 3s

In hemodialysis (HD), more than 90% of the dialysate delivered to the dialyzer is water. The more pure the water, the more accurate the dialysate prescription that is delivered, as long as the water is properly mixed with the correct concentrates and in the correct proportions. Water contamination can lead to anemia, alterations in blood pressure and acid-base balance, neurological issues, bone disease, and more, and patients may suffer acute or chronic problems from exposure to substandard dialysate.

The potential clinical symptoms of using inadequately purified water or contaminated dialysate are shown in Table 1 (3S). It is estimated that many reactions to inadequately purified water of go unreported because the chronic symptoms of kidney disease mineral bone disorder or chronic inflammation, can be insidious and attributed to problems secondary to end stage renal disease (ESRD) unless a patient exhibits an acute or sub-acute reaction. 2p

Chronic kidney disease (CKD) is associated with increased risk of adverse outcomes, including end-stage renal disease (ESRD) with a substantial reduction in life expectancy. One modality of treatment for ESRD is hemodialysis (HD), which requires the use of well treated, uncontaminated water. Patients on maintenance HD are exposed to as much as 350–500 L of water per week. The water is separated from patient's blood by a thin membrane of dialyzer through which transfer of contaminants is only limited by the size of contaminant. During HD, the usual net movement of water is from blood to dialysate, but movement of water from dialysate to blood can occur within the dialyzer through back-filtration.

This can lead to microbial contamination of patient's blood, causing pyrogenic reactions and sepsis and consequently severe hypotension and shock, which will further worsens patients' condition. 21sA dialysis patient who is treated 3 times a week with approximately 150 liters of dialysis fluid each time is exposed to 23,400 liters per year. In hemodialysis, huge amounts of water are used for diluting the concentrates to produce dialysis fluid. The water is produced on site by reverse osmosis units. The chemical and microbiological quality of the water is essential for dialysis patients. 1p

The chemical composition of water can cause acute and chronic complications during dialysis. For example, a high content of magnesium and calcium will lead to headache or hypertension. Heavy metals can accumulate in the body leading to various toxic side effects. A too high content of aluminum can cause anemia, encephalopathy or osteopathy. A water treatment system to provide sufficient cleaning should involve the use of reverse osmosis and ionization. Reverse osmosis units produce water of acceptable chemical quality that can be kept throughout the water system. The dialysis fluid consists of up to 99% of reverse osmosis water; in addition, chemicals are added, such as acids, salts and bicarbonate. 1p

Exposure to metals like aluminum (Al), cadmium (Cd), copper (Cu), lead (Pb), and zinc (Zn) over the maximum per- mitted values in hemodialysis water may cause anemia, nausea, vomiting, neurological disturbances, and bone pain. Additionally, microbiological water contamination can cause fever, cardiovascular alterations, nausea, vomiting, and hypo- tension. Even small concentrations of contaminants in water can lead hemodialysis patients into a chronic micro inflammation state 1sSpecifically, requirements for the chemical and microbiological quality of water are considered to apply in all settings, regardless of whether a single patient or many patients are being treated. (Table 2) RD 62.

Table1: *Effects of Chemical Contaminants in the HD Patient*

Signs and Symptoms	Possible Water Contaminant
Anemia	Aluminum, Chloramines, Copper, Zinc, Formaldehyde, Nitrates
Bone disease	Aluminum, Fluoride
Hypertension	Calcium, Sodium
Hypotension	Bacteria, Endotoxins, Nitrates
Metabolic acidosis	Low pH, Sulphates
Muscle weakness	Muscle weakness
Nausea and	Bacteria, Calcium, Copper, Endotoxins, Low pH, Magnesium, Nitrates, Sulphates, Zinc
Neurological deterioration and encephalopathy	Aluminum
Hemolysis	Chloramines, Copper, Nitrates, Formaldehyde

RO is based on a tangential flow filtration process in which water is pushed by high pressure through semipermeable membranes that can reject the majority of contaminants: up to 95–98% of dissolved salts, and up to 99% of bacteria, endotoxins and substances with a molecular weight of >200 Da are removed this way. RO membrane performance is measured by percent rejection, and final product water quality can be measured by either conductivity in micro Siemens/ cm or total dissolved solids (TDS) displayed as mg/L or parts per million (PPM). Conductivity is the ability of a solution to pass an electric current between two electrodes. The current is carried by ions; therefore, the conductivity increases with the number of ions present in solution and their mobility. The conductivity of water provides information on its chemical Composition. 1p &10sThe primary water purification process of choice in most applications is RO. It applies the rejection characteristics of ion exclusion semi-permeable membranes. In normal osmosis, water molecules will flow from areas of lesser solute concentration to that of greater concentration until the fluid concentration on both sides of the membrane is equal. Essentially, natural osmosis tries to dilute the side with the higher salt concentration to a point where both sides of the semi-permeable membrane have equal osmotic pressure. RO overcomes osmosis and concentrates salts on the reject side of the membrane, while collecting pure water on the product side. This is membranes. Also, membranes are susceptible to damage by chlorine and chloramines, extreme pH and bacterial degradation. Hence, appropriate pre-treatment of feed water is necessary to protect the RO membrane and can prolong its life by several years. Accomplished by applying high hydrostatic pressure to the feed water and driving water across the membrane. The end result is the production of purified water. This process can reject 90% to 99% of ionic as well as microbiologic contaminants, including bacteria, endotoxins, viruses, salts, particles and dissolved organic substrates. Depending on the quality of the source water, RO generally produces water that is safe for dialysis; otherwise, it may be necessary to polish the RO product water with a deionizer. Measuring the conductivity of the feed and product water and calculating the percentage of rejection from these measurements monitors the performance of RO devices. When the percentage of rejection falls below acceptable levels, the RO membrane has to be cleaned to restore its efficacy. Calcium, magnesium and iron can form scales on the RO. 3s

Reverse Osmosis (RO) is a separation technique that is suitable for a wide range of applications, especially when salt and/or dissolved solids need to be removed from a solution. Accordingly, RO can be used for seawater and brackish water desalination, to produce both water for industrial application, and drinking water. It can also be applied for the production of ultrapure water (e.g. semi-conductor, pharmaceutical industries) and boiler feed water. In addition, RO membrane systems are used for wastewater and water reuse treatments. Osmosis is a natural phenomenon which can be defined as the movement of pure water through a semi permeable membrane from a low to a high concentration solution. The membrane is permeable to water and some ions but rejects almost all ions and dissolved solids. This process (movement of water) occurs until the osmotic equilibrium is reached, or until the chemical potential is equal on both sides of the membrane. 6p

RO membranes. The RO membrane is the heart of the system. These membranes produce the purified water through RO). RO is just that, the opposite of osmosis. Osmosis is a naturally occur ring phenomenon involving the flow of water from a less-concentrated compartment (e.g., non-salty side) to the more concentrated compartment (e.g., salty side) through a semi-permeable membrane until solute equilibrium is obtained. In reverse osmosis, water (feed or supply water) is forced to flow in the opposite or unnatural direction across a semi-permeable membrane to the compartment with less concentration of solutes by means of high hydraulic pressure. 2p

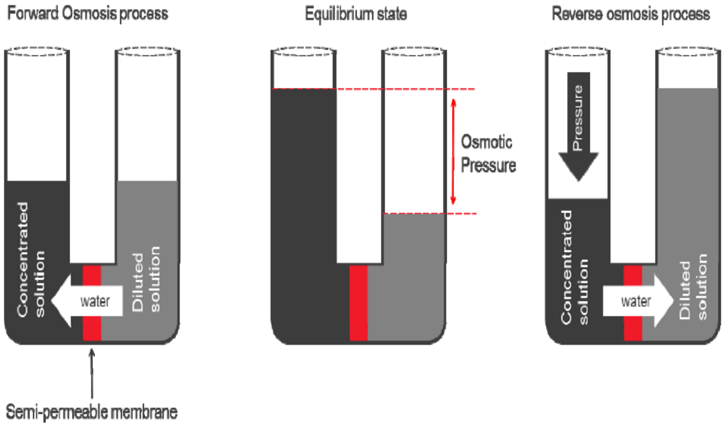

Figure1: *Reverse Osmosis Phenomena 6p*

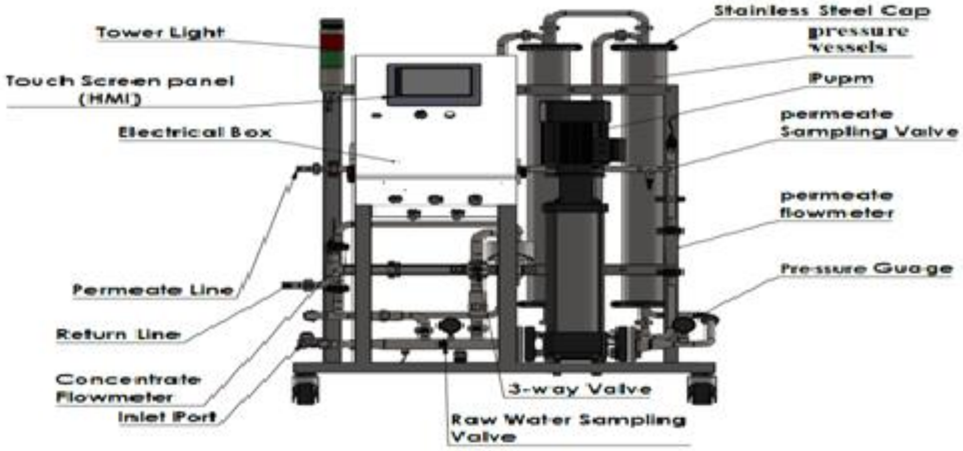

Figure2: *Nova RO 1000 (Novatis Teb Company)*

Table2: *Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple use) 4s &15s & 16s*

Contaminant	Maximum Concentration (mg/L)b
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate	(as N) 2.00
Sulfate	100.00
Thallium	0.002
Zinc	0.10

2. Material and Methods

Patients with end-stage kidney disease (ESRD) on maintenance hemodialysis (HD) are usually exposed to large volumes of dialysate, which is separated from patients' blood only by thin membrane of dialyzer. It is therefore essential to frequently monitor the quality of HD water to ensure that it meets the recommended standards. 21s

2.1. Chemical Sampling and Analysis

Data analysis by Mini Tab software related to reverse osmosis devices of Novatis Teb Company (chemical data)

For visualization and also analysis of data, Mini Tab software is used, about 49 samples is chosen from 2016 September to 2018 December. According to the Association for the Advancement of Medical Instrumentation (AAMI RD 62 standard), water and dialysate should be monitored monthly for bacterial endotoxins. Chemical contaminants At least every 3 months (Frequency of monitoring of product and dialysis water for hemodialysis). 5p & 1s & 25s

The following parameters were measured: Turbidity, Electrical Conductivity, PH, Total Dissolved Solids, and Total Hardness, Total alkalinity, Nitrate, Calcium, Magnesium, Sodium, Sulfate, Potassium (table 2). The evaluation of chemical contamination was carried out in seven hemodialysis units of reverse osmoses devices, in IRAN. The reference used in this research is ANSI/AAMI RD62:2001 Water treatment equipment for hemodialysis applications. The samples were collected from the reverse osmosis (RO; point 4).

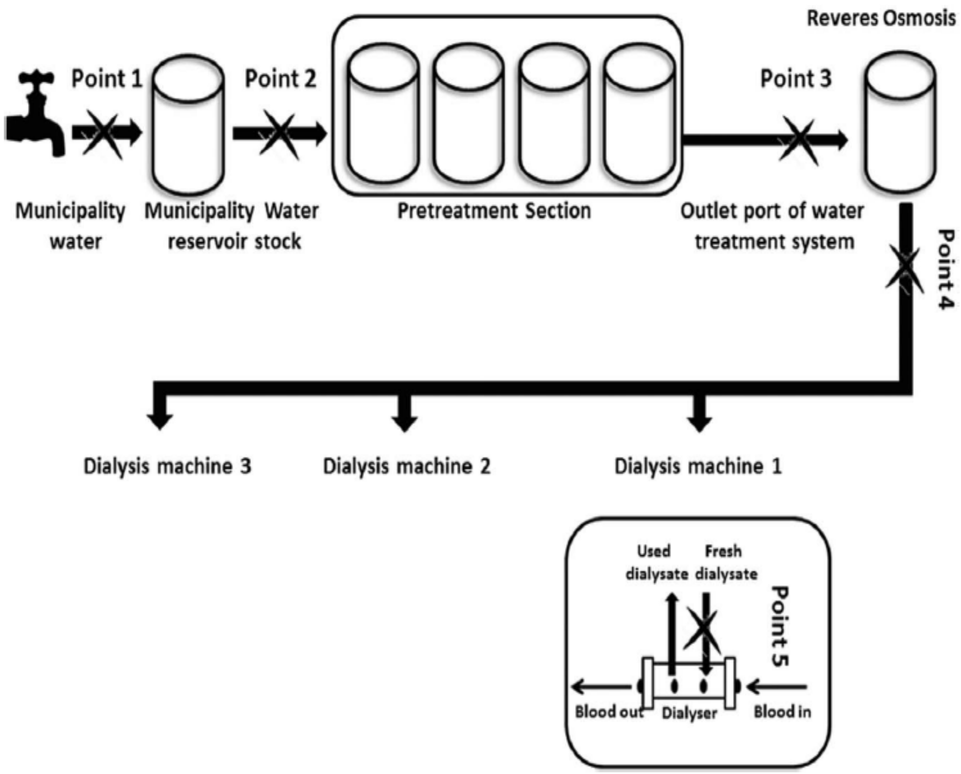

Figure3: *Diagram of treatment and distribution system of hemodialysis center and sampling points. 14 s*

3. Results

Statistical analysis: In figure 4 data on Minitab software is shown. In figure 5 Histogram of Ions (Nitrate, Calcium, Magnesium, Sodium, Sulfate, and Potassium) are shown. In figure 6 Histogram of Ions (overlaid on the same graph) are shown. In figure 7 Histogram of parameters (Temperature, Turbidity, Electrical Conductivity, Ph., Total Dissolved Solids, Total Hardness, Total alkalinity are shown. In figure 8 Normality Test of Electrical Conductivity is shown. Electrical Conductivity is one of the most important parameter in reverse osmosis device and Acceptable range for electrical conductivity must be less than 100 µmho/cm). (These results are obtained by the reference laboratory).

In figure 9 Normality Test of Nitrate is shown. In figure 9 Normality Test of Total Dissolved Solids is shown

…erature	Date	Turbidity	pH	Electrical Conductivity	Total Dissolved Solids	Total Hardness	Total alkalinity	Carbonate	Bicarbonate	Calcium	Magnesium	sodium	Potassium	Sulfate	Chloride	Ammonia	Nitrite	Nitrate	Phosphate	code
23.7	96/07	0.56	6.35	28	15	3	5.0	0	5.0	2	1.0	5.00	0.01	5	5.1	0.01	0.056	2.000	0.01	A64471
23.8	96/07	1.32	6.58	4	2	0	1.0	0	1.0	0	0.0	0.82	0.01	5	0.7	0.01	0.005	1.100	0.01	A64173
24.0	96/07	0.57	7.10	8	5	0	2.0	0	2.0	0	0.0	2.00	0.01	5	1.5	0.01	0.005	1.500	0.01	A64176
23.9	96/07	0.58	6.68	6	4	0	1.5	0	1.5	0	0.0	1.30	0.01	5	1.0	0.01	0.005	1.800	0.01	A64179
23.2	96/07	0.41	6.93	17	11	0	4.0	0	4.0	0	0.0	3.90	0.04	5	3.3	0.01	0.005	2.500	0.01	A64364
23.3	96/07	0.27	5.91	5	3	0	1.0	0	1.0	0	0.0	1.10	0.01	5	1.0	0.01	0.005	1.000	0.01	A64367
22.4	96/07	0.20	6.23	11	6	0	2.0	0	2.0	0	0.0	2.50	0.20	5	2.6	0.01	0.005	1.800	0.01	A64355
18.2	96/08	0.81	5.17	7	4	0	1.0	0	1.0	0	0.0	1.50	0.18	5	1.8	0.01	0.005	1.700	0.01	A65634
20.3	96/10	20.30	5.49	9	5	0	2.0	0	2.0	0	0.0	2.00	0.08	5	1.7	0.01	0.005	1.100	0.01	A67184
20.7	96/10	1.73	6.12	13	8	0	1.0	0	1.0	0	0.0	3.00	0.12	5	3.7	0.01	0.005	1.600	0.01	A67023
20.9	96/10	0.54	7.94	46	32	10	14.0	0	14.0	7	3.0	6.00	0.11	5	6.3	0.01	0.005	1.800	0.01	A67026
21.0	96/10	0.73	6.42	8	5	0	1.0	0	1.0	0	0.0	1.70	0.11	5	2.0	0.01	0.005	1.900	0.01	A67029
20.0	96/10	0.73	6.22	11	6	0	2.0	0	2.0	0	0.0	2.50	0.01	5	2.1	0.01	0.005	1.500	0.01	A66654
22.3	96/10	0.93	7.40	22	13	0	6.0	0	6.0	0	0.0	5.00	0.01	5	3.4	0.01	0.005	1.500	0.01	A66620
20.0	96/10	1.09	7.06	29	20	2	8.0	0	8.0	1	1.0	6.00	0.07	5	4.7	0.01	0.005	0.038	0.01	A66636
18.9	97/01	0.36	5.32	9	5	0	2.0	0	2.0	0	0.0	2.00	0.01	5	1.7	0.01	0.005	1.500	0.01	A70271
20.0	97/01	0.62	5.65	14	9	0	4.0	0	4.0	0	0.0	3.00	0.20	5	2.0	0.01	0.005	1.100	0.01	A70067
20.8	97/01	0.89	5.93	28	19	0	7.5	0	7.5	0	0.0	6.60	0.15	5	4.7	0.01	0.005	2.000	0.01	A70070
21.1	97/01	2.67	6.19	13	8	0	3.0	0	3.0	0	0.0	2.30	1.10	5	2.6	0.01	0.005	1.100	0.01	A70432
21.4	97/01	0.32	6.16	20	14	0	6.0	0	6.0	0	0.0	4.40	0.20	5	2.7	0.01	0.005	1.000	0.01	A70015
21.0	97.01	0.17	6.31	27	17	0	5.0	0	5.0	0	0.0	6.50	0.02	5	6.2	0.01	0.005	1.000	0.01	A70018
21.3	97/01	0.39	6.00	8	4	0	2.5	0	2.5	0	0.0	1.90	0.01	5	1.0	0.01	0.005	1.000	0.01	A70021
19.2	97/01	0.46	6.47	46	35	5	15.0	0	15.0	4	1.0	6.00	3.75	5	6.0	0.01	0.005	2.000	0.01	A70098
21.2	97/07	1.00	5.76	11	6	0	3.0	0	3.0	0	0.0	2.50	0.05	5	2.0	0.01	0.005	1.100	0.01	A75276
22.4	97/07	0.40	5.70	10	5	0	2.0	0	2.0	0	0.0	2.20	0.01	5	2.0	0.01	0.005	1.000	0.01	A74942
22.4	97/07	0.49	6.20	35	24	5	10.0	0	10.0	1	3.9	5.80	0.14	5	4.8	0.01	0.005	1.900	0.01	A74943
21.9	97/07	0.93	6.24	9	6	0	3.0	0	3.0	0	0.0	2.10	0.01	5	1.5	0.01	0.005	1.900	0.01	A75376
24.3	97/07	0.66	5.64	13	8	0	3.5	0	3.5	0	0.0	2.80	0.01	5	2.0	0.01	0.005	1.100	0.01	A74622
21.6	97/07	0.64	5.96	15	9	0	4.0	0	4.0	0	0.0	3.20	0.38	5	2.2	0.01	0.005	1.100	0.01	A75504
21.0	97/07	0.61	6.29	20	12	0	5.0	0	5.0	0	0.0	4.80	0.07	5	3.6	0.01	0.005	1.600	0.01	A75510
21.6	97/07	0.61	6.15	24	17	0	8.0	0	8.0	0	0.0	5.80	0.01	5	3.0	0.01	0.005	1.900	0.01	A74517
21.2	97/07	0.46	5.88	34	21	0	5.0	0	5.0	0	0.0	7.30	0.60	5	8.8	0.01	0.005	1.000	0.01	A75221
27.7	97/04	0.39	5.05	14	8	0	4.0	0	4.0	0	0.0	3.30	0.05	5	2.3	0.01	0.005	1.000	0.01	A72644
25.2	97/04	0.33	7.45	29	20	10	10.0	0	10.0	2	0.0	2.30	0.06	5	2.7	0.01	0.005	1.300	0.01	A72160
26.6	97/04	0.62	6.11	23	16	0	7.0	0	7.0	0	0.0	5.10	0.35	5	3.4	0.01	0.005	1.100	0.01	A72083
26.8	97/04	0.57	6.93	14	9	0	3.5	0	3.5	0	0.0	3.00	0.22	5	2.5	0.01	0.005	2.000	0.01	A72893
25.8	97/04	0.09	6.14	11	7	0	3.0	0	3.0	0	0.0	2.30	0.02	5	1.8	0.01	0.005	1.100	0.01	A72247
26.7	97/04	0.70	5.91	13	7	0	4.0	0	4.0	0	0.0	2.70	0.01	5	1.7	0.01	0.005	1.800	0.01	A72760
26.3	97/04	0.87	6.18	21	13	0	5.0	0	5.0	0	0.0	4.50	0.01	5	4.1	0.01	0.005	1.800	0.01	A72754
20.6	97/10	0.76	5.19	8	4	0	2.5	0	2.5	0	0.0	1.80	0.01	5	1.0	0.01	0.005	1.100	0.01	A78318
21.8	97/10	0.75	7.45	14	9	5	5.0	0	5.0	2	2.0	1.00	0.01	5	1.6	0.01	0.005	0.800	0.01	A66617
19.7	97/10	0.86	5.23	14	8	1	3.0	0	3.0	0	1.0	2.80	0.01	5	3.0	0.01	0.005	1.000	0.01	A78396
20.5	97/10	1.45	6.08	18	11	1	4.0	0	4.0	0	1.0	3.60	0.01	5	3.3	0.01	0.005	0.005	0.01	A78402
21.5	97/10	1.03	5.91	7	4	0	2.8	0	2.8	0	0.0	1.70	0.01	5	1.0	0.01	0.005	1.100	0.01	A77922
21.3	97/10	1.13	6.94	53	35	0	17.6	0	17.6	0	0.0	10.90	2.16	5	5.9	0.01	0.005	1.900	0.01	A77923
19.8	97/10	1.18	5.98	23	15	0	5.0	0	5.0	0	0.0	5.10	0.01	5	5.0	0.01	0.005	1.900	0.01	A78236
19.7	97/10	0.87	3.95	4	2	0	0.0	0	0.0	0	0.0	1.00	0.01	5	1.2	0.01	0.005	1.500	0.01	A78239
19.9	97/10	0.72	5.41	17	10	0	3.0	0	3.0	0	0.0	4.00	0.01	5	4.3	0.01	0.005	1.900	0.01	A78242
20.3	97/10	0.62	5.77	8	4	0	2.0	0	2.0	0	0.0	1.80	0.01	5	1.5	0.01	0.005	1.000	0.01	A78373

Figure4: *Data in Minitab software*

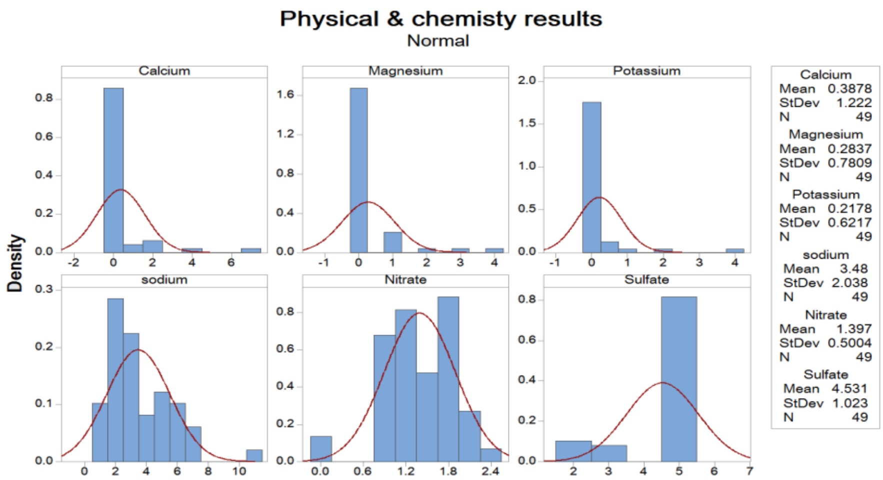

Figure5: *Histogram of Ions (Nitrate, Calcium, Magnesium, Sodium, Sulfate, Potassium)*

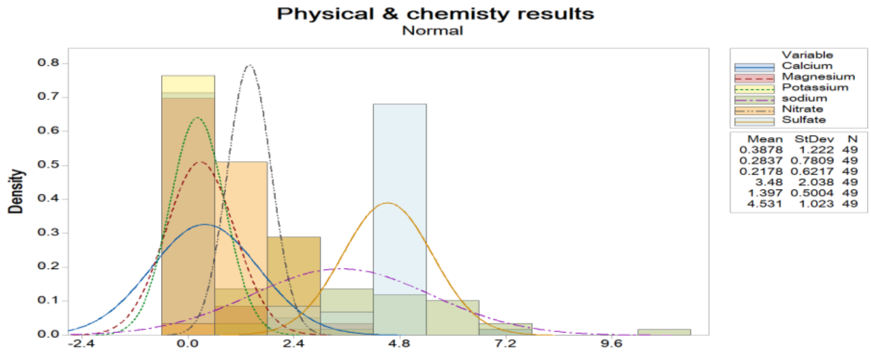

Figure6: *Histogram of Ions (overlaid on the same graph)*

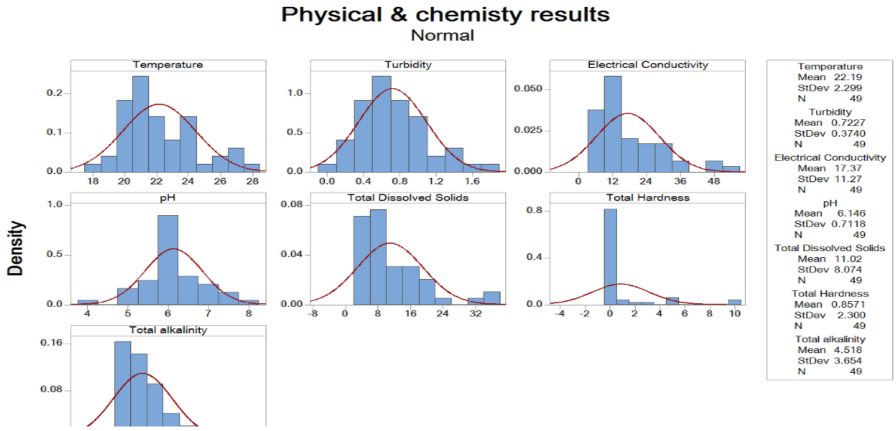

Figure7: *Histogram of parameters (Temperature, Turbidity, Electrical Conductivity, PH, Total Dissolved Solids, Total Hardness, Total alkalinity)*

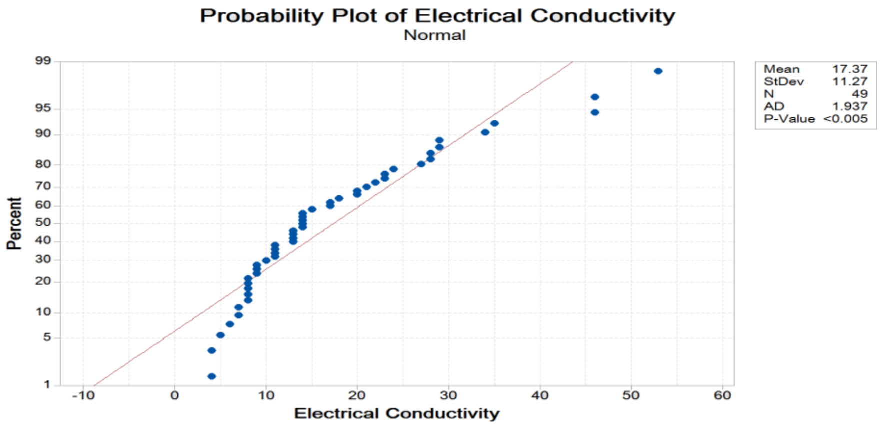

Figure8: *Normality Test of Electrical Conductivity*

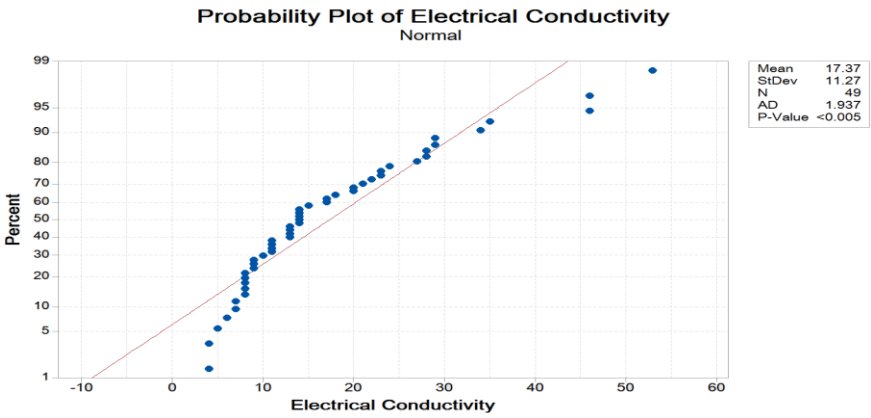

Figure9: *Normality Test of Nitrate*

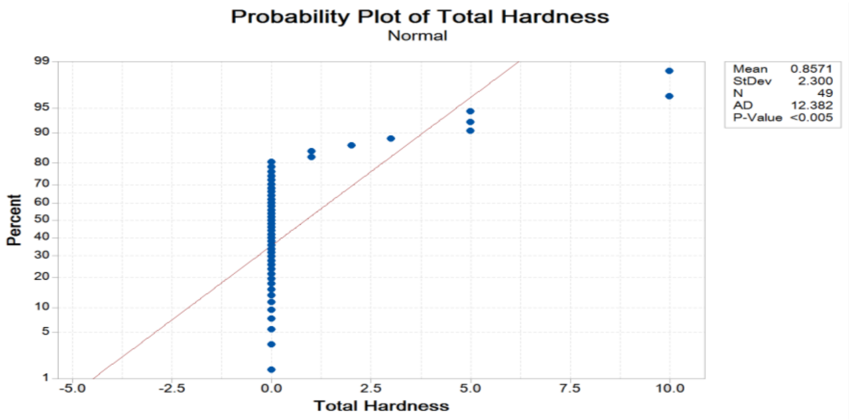

Figure10: *Normality Test of Total Dissolve Solid*

Chemical analysis results: The result of analysis in Mini Tab software shows that all chemical parameters in reverse osmosis device are on allowable range according to ANSI/AAMI RD62:2001 standard. (Chemical parameters in reverse osmosis device (NOVA RO 1000, Product of Novatis Teb Company) are on allowable range).

4. Conclusion

The water used in dialysis centers has a critical role in quality of care. The reverse osmosis for water treatment is used in hemodialysis to reduce the concentration of ions that can have negative effects on the patient. Reverse osmosis operating conditions influence the efficiency of the entire treatment system. 1s 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. 13s

Our study has shown that chemical quality samples of reverse osmoses devices (Novatis Teb Copmany devices) from 2016 September to 2018 December, no clinical intercurrences reported from hospitals.

In conclusion, because of the choose the compatible material according to the recommend of AAMI RD 62 Standard, (Materials compatibility), there is no residual risk and clinical intercurrences on 49 samples. Materials that contact dialysis water (including materials used in piping, storage, and distribution systems) shall not interact chemically or physically with that water so as to adversely affect its purity or quality. Water-contacting surfaces shall be fabricated from non-reactive materials (e.g. plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is specifically prohibited at any point beyond the water treatment device used to remove contaminating metal ions, most commonly a reverse osmosis system or a deionizer. The materials of any water treatment devices (including piping, storage, and distribution systems) shall be compatible with the means used to disinfect those devices. Chemicals infused into the water in the pre-treatment section, such as chlorine, acid, flocculants, and complexing agents, shall be adequately removed from dialysis water before they reach any point of use. Monitors or specific test procedures to verify removal of additives shall be provided 16s

Recommendations

As every chemical water contaminant has the potential to pose clinical problems for the dialysis patient, such water should undergo proper treatment. Routine monitoring, quality assurance, and continuous quality improvement should be enforced to ensure patient safety and quality outcomes. A follow-up survey, including microbiological and chemical analysis will be required to ascertain the effect on quality of life of the patients. 17s For design and development of reverse osmoses devise is recommend AAMI RD 62 standard, Water treatment equipment for hemodialysis applications & ISO 13959: Water for hemodialysis and related therapies ISO 26722: Water treatment equipment for hemodialysis and related therapies.

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