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Assessment of Standard Criteria Implementation in Heamodialysis Water Treatment Units in Sharkia Governorate

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Abstract

Introduction: Haemodialysis is the most well-established form of treatment for ESRD. **Method:** To evaluate the implementation of standard criteria in heamodialysis water treatment units in Sharkia governorate and to determine the weak points in application of standard criteria, and reach the optimal standards to improve pt. outcomes, across the sectional study was conducted at 30 heamodialysis units of Sharkia governorate, using a modified questionnaire was developed based on MOH protocol and international guidelines such as CARI guidelines, AAMI guidelines and others by the researchers. All data were collected, tabulated and statistically analyzed using SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA). **Results:** Of the 30 units, the majority more than 80% of the units achieved the infrastructure and schematic structure, contain water purification devices, good infection control policies, proper chemical disinfection, good monitoring and quality control, accepted maintenance technician evaluation and collected processed water samples results matched decree of 63 for 1996. **Conclusion:** Most of the studied units nearly fulfilled the standard specifications of both MOH and AAMI. Ensuring that water quality meets AAMI standards and recommendations will minimize patient exposure to potential contaminants such as chemical hazards and endotoxemia associated with the use of the treated water for HD.

Keywords

Water Purification, Pyrogenic Reactions, Reverse Osmosis (RO)

1. Introduction

Water treatment represents a fundamental aspect of modern hemodialysis technology [1]. International standards based on Caring for Australasian with Renal Impairment (CARI) guidelines and others have been developed to promote the installation of fit for purpose water treatment facilities for heamodialysis and to safeguard the routine production of dialysis water suitable for use for heamodialysis and haemodiafiltration [2]. Haemodialysis process may expose the patient to more than 300 litres of water per week across the semi-permeable membrane of the haemodialyser. The near 30 times increase in water exposure to dialysis patients requires control and monitoring of water quality to avoid excesses of known or suspected harmful elements being carried in the water transmitted to the patient [3] [4]. The water used for the preparation of heamodialysis fluids needs treatment to achieve the appropriate quality based on Greater Metropolitan Committee Taskforce (GMCT) guidelines and Association for Advancement of Medical Instrumentation (AAMI) guidelines as the water pre-treatment system includes various components such as sediment filters, water softeners, carbon tanks, micro-filters, ultraviolet disinfection units, reverse osmosis units, ultrafilters and storage tanks. The components of the systems are determined by the quality of feed water and the ability of the overall system to produce and maintain appropriate water quality [5] [6]. Some of the important possible signs and symptoms due to water contamination include anemia, bone disease, hypertension, hypotension, muscle weakness, neurological deterioration & even death due to hazardous chemicals as aluminum, chloramine, copper, zinc, fluoride & nitrates pluse Bacteria, endotoxin [7] [8] [9]. Once water enters a heamodialysis center, the goal is to achieve high quality and safe heamodialysis water and dialysate. Water treatment, system design, and distribution material choices are contributing factors. Dialysis water treatment should remove chemical and microbial contaminants to below established allowable limits and is characterized by two phases: 1) Pretreatment, where constituents are removed from the feed water to protect the downstream treatment components and 2) water treatment, which is the process of physically removing and/or chemically inactivating remaining chemical and/or microbial contaminants [10] [11]. This study aimed to evaluate the implementation of standard criteria in heamodialysis water treatment units in Sharkia governorate and to determine the weak points in the application of standard criteria, and reach the optimal standards to improve pt. outcomes.

2. Methods

A cross-sectional study using a pre-designed questionnaire was carried out in heamodialysis units of Sharkia governorate, Egypt throughout the period of search in 2020. Sharkia Governorate is one of the governorates of Egypt. It is located in the eastern part of Egypt. The governorate is named after its location; Sharkia's capital is the city of Zagazig. All heamodialysis units were included in

the study. No exclusion criteria were listed as all units could be submitted for the study. A total number of heamodialysis water treatment units in Sharkia governorate is 63 units. A sample size of 30 heamodialysis water treatment units will be included in this study using simple random technique based on a poll technique [12]. A well-structured but simple questionnaire was developed based on Egyptian MOH protocol [13] and international guidelines such as CARI guidelines and AAMI guidelines and others by the researcher [2] [3] respectively.

The questionnaire was divided into 7 sections of infrastructure, component of HD water TTT unit, infection control policies, sterilization and sanitation, monitoring efficiency, technical staff evaluation and results of monthly water sampling.

Data Handling: All data were collected, tabulated and statistically analyzed using SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA). Qualitative data were represented as frequencies and relative percentages, Quantitative data were expressed as mean ± SD (Standard deviation), and median and range for non-parametric data.

3. Results

Among 30 water treatment units were visited and underwent the questionnaire, the following data were found, 100% of the units achieved the infrastructure and schematic structure of the HD water except for the location of the units that there were 63.3% of the studied units were not in on the ground floor and there was one unit did not have any methods of lowering temperature and 40% of the units were using fans. There were 20% of the units causes building affection. 100% of the units had water purification devices and components except that there were 33.3% of the studied units did not have Reversed osmotic pressure device (RO) 2 membrane, 20% of the studied units did not have Reversed osmotic pressure device (RO) 3 membrane, 6.7% of the studied units did not have an automatic nitrate filter and one unit with broken TDS device. 100% of the units had good monitoring and quality control except that there was one unit that had a wet floor and another unit had a treated tank on the ground directly which cause its outlet from the side and minimal stagnation of the water in the bottom. 30% of the units had controlled breakage waited to be fixed. 100% of the units didn't had biomedical engineer, Internal supervision by specific medical staff assigned by the unit manager or Internal organized daily checklist with accepted forum. The majority of the units had good maintenance technician evaluation except that there were 6.7% of the studied units where their staff was absent, 10% of units with maintenance technician had no training and one of the studied units had its door open. All studied units had chemical disinfection and washing of HD water treatment units.

4. Discussion

Regarding sources of HD water treatment fed water; the study results as listed in Table 1 when was compared with a result of nationwide survey was done in

Canada on 23 renal programs, The majority of programs (94.1%) have had experience with patients using well water, and a minority of programs (35.3%) having had patients using surface water such as ponds or lakes [14]. In the study, examination of the HD water purification devices as listed in **Table 2** results were compared with a national survey was done in Italy on 148 centers concerned tap water treatment systems. (71%) of centers used a single system, in particular, RO in the majority of cases. A double water treatment system (double RO or single RO combined with an ion exchange deionizer) was used in (28%) of centers. A water storage tank was used by (65%) of centers. (85%) of centers reported that their deionizer water pipe distribution loops were made from sanitary PVC, while only (15%) used more inert materials [15]. Regarding the infection control policies and measures the results of the studied units as listed in **Table 3** were compared to those obtained from another study for the assessment of safety measures in haemodialysis units in Ismailia Governorate, it was found that 66.7% of the units were of good cleanliness of the place while 33.3% of them were to some extent clean and none of the studied units was of bad cleanliness level Regarding chemical disinfection of HD water treatment units methods of the studied unit's results as listed in **Table 4** when were compared with another survey in Lagos, Nigeria showed that most centers did not routinely disinfect their water storage tanks and distribution system. Sixty-six percent of centers carried out disinfection at 3- to 6-month intervals; only 16.6% disinfected its system every month while 16.6% rarely disinfected its system as it did so once a year [16]. On the other hand about monitoring and quality control of the studied HD water treatment unit's results as listed in **Table 5**, were compared with those obtained from another survey of six centers in Lagos, Nigeria about maintenance of UV system it stated that most centers did not change UV filament regularly. While 33% of centers had not replaced their UV filament since installation many years ago, 16.6% changed their UV filament 7 years after installation and another 16.6% changed their UV filament 9 years after installation. Of the centers, 16.6% had UV systems replaced 6 months after installation while another 16.6% had UV filament replaced 2 years after installation. None of the centers used bacterial filters [16]. It is recommended that there should be at least one maintenance technical staff per shift (Gorden *et al.*, 2008), in the studied unit's results as listed in **Table 6** when compared these results with those obtained from another study for the assessment of safety measures in haemodialysis units in Ismailia Governorate it was found that the working maintenance technical staff with mean and SD (2.9 ± 1.6). As regard the efficiency of HD water samples of the study in Sharkia Governorate as listed in **Table 7**, it was found that all studied units match MOH and AAMI standard specifications in collecting samples by 100% but not all tested samples match the decree of 63 for 1996 in the 1st testing as in the last month only 90% of units were accepted by the first time but when we re-tested the samples, they passed. It was founded that the cause of failure of the samples mainly due to chemicals or bacterial contamination as increase amount of nitrates, chloramines or *E. coli*. When five samples

from five random HD water treatment units were tested in our regional laboratories regarding chemical, minerals and bacteriology parameters the results of all collected samples found to be corresponded to decree of 63 for 1996 as listed in Tables 8-10. AAMI recommends testing the final water for chemical contaminants at commissioning and then annually, except for chloramine, which should be monitored at each treatment shift. AAMI also recommends daily monitoring of the performance of individual water treatment components as a supplement to these periodic chemical analyses. More frequent chemical analyses can be necessary in some circumstances, such as when there are marked seasonal variations in supply, water quality, or when RO rejection falls below 90%. Italian study by Pizzarelli *et al.* showed that 29% of centers studied tested HD water every month, 14% every 2 months, 37% of centers every 3 months, 4% every 4 months, 12% every 6 months, and only 4% tested yearly [15]. Also a study in Iraq regarding bacterial concentration in water samples over 5 months of monitoring for six dialysis centers showed that most of the centers were with high bacterial count. Sixty percent of the analyzed samples were above the 50 CFU/mL in comparison to AAMI action level. Five out of the six dialysis centers showed even higher values (>100 CFU/mL in comparison to the AAMI maximum level).A regular and effective disinfection procedure, as an integral part of the hygienic maintenance of the water treatment units, must be performed in order to keep the bacterial counts' values below the action level [17].

Table 1. The infrastructure and schematic structure of the HD water treatment unit.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Location of the unit on the ground floor	19 (63.3%)	-	11 (36.7%)
• The area of the unit ≥ 12 m^2	-	-	30 (100%)
• Building affection in case of the unit presence upstairs	6 (20%)	-	24 (80%)
• Methods of lowering temperature (eg. air conditions)	1 (3.3%)	12 (40%)	17 (56.7%)
• The source of fed water to the unit from public network (municipal)	-	-	30 (100%)
• The electrical outlets and connectors more than 50 cm of the ground	-	-	30 (100%)
• Water treatment equipment and filters store away from moisture	2 (6.7%)	-	28 (93.3%)

Table 2. HD water purification devices and components.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Water pipes in the unit of PVC material	-	-	30 (100%)
• Primary water tank of PVC material	-	-	30 (100%)

Continued

• Processed water tank of PVC material	-	-	30 (100%)
• 4 water pumps of (processed tank and RO)	-	-	30 (100%)
• Automatic sand filter	-	-	30 (100%)
• Automatic carbon filter	-	-	30 (100%)
• A water softener filter	-	-	30 (100%)
• An automatic nitrate filter	2 (6.7%)	-	28 (93.3%)
• Cartridge Filter (Micronized)	-	-	30 (100%)
• Reversed osmotic pressure device (RO) 3 membrane	6 (20%)	-	24 (80%)
• Reversed osmotic pressure device (RO) 2 membrane	10 (33.3%)	-	20 (66.7%)
• UV lamp sterilizer unit inside a stainless-steel frame	-	-	30 (100%)
• Bacterial filter 2 mic.	-	-	30 (100%)
• Pressure meters	-	-	30 (100%)
• Stainless steel faucet for sampling	-	-	30 (100%)
• TDS and chlorine detecting devices	1 (3.3%)	-	29 (96.7%)
• Instructor labels for the unit's components	-	1 (3.3%)	29 (96.7%)
• Documentation of daily and monthly recordings	-	3 (10%)	27 (90%)

Table 3. Infection control polices of HD water treatment units.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Cleanness of the unit in general with dry floor	1 (3.3%)	-	29 (96.7%)
• The walls are smooth and easy to clean	-	11 (36.7%)	19 (63.3%)
• Pipes with fewest curves and angles as possible	-	-	30 (100%)
Health standers for water tanks			
• Dark & Tightly closed	-	-	30 (100%)
• Smooth from inside to accommodate continuous flow without stagnation of water	-	2 (6.7%)	28 (93.3%)
• Present on a base with height from the ground allow drainage to be below the tank	1 (3.3%)	-	29 (96.7%)
• Weekly cleaning	1 (3.3%)	-	29 (96.7%)

Table 4. Chemical disinfection of HD water treatment units.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
The concentration of the chemical washing solution 30% (60 g chlorine per cubic meter of treated water) and free of impurities.	-	-	30 (100%)
The chemical washing time per month is not less than four hours	-	-	30 (100%)
The sample is free of chlorine in a chemical reagent after chemical washing for the 1st test	-	7 (23.3%)	23 (76.7%)

Table 5. Monitoring and quality control of HD water treatment units.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Monthly change of cartridge (micro) filters	-	-	30 (100%)
• Change every two months for the bacterial filter	-	-	30 (100%)
• Store salt away from moisture	-	-	30 (100%)
• Follow-up to RO readings	-	-	30 (100%)
• Follow-up hours of UV bulb operation and readings	-	-	30 (100%)
• There is no breakage or leakage with any of the unit's connections and pipes	9 (30%)	-	21 (70%)
• Expiration date labels for each filter and the date of exchange	-	-	30 (100%)
• Record any drifts and the necessary correction action	-	1 (3.3%)	29 (96.7%)
• Keep periodic maintenance reports of maintenance company according to their contract	-	-	30 (100%)
• Biomedical engineer assigned for 24 hrs for the unit	30 (100 %)	-	-
• Internal supervision by specific medical staff assigned by the unit manager	30 (100%)	-	-
• Internal organized daily check list with accepted forum	30 (100%)	-	-

Table 6. HD water treatment plants staff (maintenance technician) evaluation.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Attendance before the start of the shift and presence throughout the working hours	2 (6.7%)	6 (20%)	22 (73.3%)
• Daily measurements of treated water before the start of each shift for both (chlorine and dissolved salts) and records	-	1 (3.3%)	29 (96.7%)
• Familiar with the handling of a high level of chlorine or any component drift in the treated water	-	-	30 (100%)
• Record daily chemical measurements, monthly result of water samples and periodic maintenance reports along with maintenance company	-	-	30 (100%)
• Attending training sessions concern with water treatment units	3 (10%)	-	27 (90%)
• Closure of the unit door	1 (3.3%)	-	29 (96.7%)

Table 7. Efficiency of water samples in water treatment plants in dialysis units.

	Dialysis Units (n = 30)		
	No	To some extent	Yes
• Monthly sampling	-	-	30 (100%)
• The presence of the health observer	-	-	30 (100%)
• Sterilization and disinfection of stainless steel in Sparto and flame	-	-	30 (100%)

Continued

• Not to open the sample bottle except in front of the tap and sterilize its nozzle with flame	-	-	30 (100%)
• Wrap the cap with a gauze	-	-	30 (100%)
• Putting the bottle in a special coalman surrounded by snow	-	-	30 (100%)
• The result of the processed sample corresponds to decree of 63 for 1996 during the last month	4 (13.3%)	-	26 (86.7%)

Table 8. Chemical parameters of the collected water samples.

Variable	Dialysis Units (n = 30)					Normal reference
	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	
Cl^-	Nil	Nil	Nil	Nil	Nil	≤0.2 mg/L
Chloramine	Nil	Nil	Nil	Nil	Nil	≤0.1 mg/L
NH_3	Nil	Nil	Nil	Nil	Nil	Nil
No_2	Nil	Nil	Nil	Nil	Nil	Nil
NO_3	Nil	Nil	Nil	Nil	Nil	Nil
F	Nil	Nil	Nil	Nil	Nil	≤0.2 mg/L
SO_4	12	3	4.8	4	14	≤100 mg/L
Na^+	4.6	0.8	1.6	1.8	5.8	≤70 mg/L
K^+	.05	Nil	Nil	Nil	.20	≤5 mg/L
Ca^{2+}	Nil	Nil	Nil	Nil	Nil	≤5 mg/L
Mg^{2+}	Nil	Nil	Nil	Nil	Nil	≤4 mg/L
Conductivity (Us/cm)	49	14	18	16	54	≤300 Us/cm
TDS	31	9	11	10	34	≤200 mg/L

Table 9. Minerals parameters of the collected water samples.

Variable	Dialysis Units (n = 30)					Normal reference
	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	
Ag (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.005 mg/l
Al (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.01 mg/l
Ba (mg/l)	0.041	0.0005	0.0003	0.003	0.036	≤0.1 mg/l
Cd (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.001 mg/l
Cr (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.014 mg/l
Cu (mg/l)	0.003	0.041	.005	.002	0.0041	≤0.1 mg/l
Fe (mg/l)	0.003	0.003	Nil	.002	0.03	≤0.1 mg/l
Mn (mg/l)	0.001	0.02	Nil	Nil	0.004	≤0.1 mg/l
Pb (mg/l)	0.0003	Nil	0.0002	Nil	Nil	≤0.005 mg/l
Se (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.09 mg/l
Zn (mg/l)	0.04	0.003	0.004	0.03	0.006	≤0.1 mg/l
As (mg/l)	Nil	Nil	Nil	Nil	Nil	≤0.005 mg/l

Table 10. Bacteriology of the collected water samples.

Variable	Dialysis Units (n = 30)					Normal reference
	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	
Colonies counted × 100 ml	Absent	Absent	Absent	Absent	Absent	Absent
Coliform colonies counted × 100 ml	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria counted × 1 ml at 35˚	7	4	4	4	5	≤50 cell/ml
Bacteria counted × 1 ml at 22˚	9	7	10	10	10	≤50 cell/ml
Pseudomonas	Absent	Absent	Absent	Absent	Absent	Absent
Strepto	Absent	Absent	Absent	Absent	Absent	Absent
Anaerobe	Negative	Negative	Negative	Negative	Negative	Negative

5. Conclusion

Most of the studied units fulfill the standard specifications of both MOH and AAMI in some points only. Regarding the infrastructure of the studied units, they achieved the standers only in some points as the area of units, away from direct sun exposure, source of fed water is municipal, under supervision of the unit manager also regarding the process of sample water collection under supervision of both inspector of the community and public health department and the regional laboratories specialist under certain specification, and the forum of the results, but other points are still show some shortage as presence of most of units upstairs cause building affection, not all units use air conditioning as a method of lowering temperature, no biomedical engineer assigned for any of the studied units, no internal organized supervision by specific medical staff or specific checklist, delay and missed daily documentation of TDS and chlorine, no enough training of maintenance staff, and not all collected water samples matches the decree of 63 for 1996 from the first analysis which need to be revised and updated by Egyptian MOH for better outcome.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Appendix

Table A1. Characteristics of the studied units.

	Dialysis Units (n = 30)
HD No. water treatment units responsible for the HD unit	
• Mean ± SD	1.17 ± 0.461
• Median (Range)	1 (1 - 3)
Actual no. of machines provided by the unit at time of visit no include spare machines	
• Mean ± SD	21.87 ± 12.59
• Median (Range)	20 (3 - 51)
No. of the daily shifts of hemodialysis unit	
• Mean ± SD	3.03 ± 0.669
• Median (Range)	3 (2 - 4)
No. of maintenance technical staff responsible for the unit and their shifts	
• Mean ± SD	1.37 ± 1.03
• Median (Range)	1 (0 - 4)