The Egyptian Journal of Hospital Medicine (July 2025) Vol. 100, Page 3407-3414

Assessment of Standard Criteria Implementation in Haemodialysis Water Treatment Units in Qena Governorate

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ABSTRACT

Background: Adequate water quality is crucial in haemodialysis to prevent complications and ensure patient safety. Adhering to established guidelines can significantly enhance the efficacy of treatment and reduce risks associated with contaminated water. **Aim:** This study aimed to assess adherence to standard criteria in haemodialysis (HD) water treatment units in Qena Governorate, focusing on infrastructure, water treatment components, infection control and staff awareness.

Methods: This cross-sectional study involved 36 haemodialysis water treatment units. Data were collected using a structured questionnaire-based on international guidelines, including Caring for Australasian with Renal Impairment (CARI) and Association for the Advancement of Medical Instrumentation (AAMI). **Results:** The mean number of water treatment units per HD facility was 1.17 ± 0.45 with an average of 21.89 ± 11.61 dialysis machines available. Most units (69.4%) did not have water tanks located on the ground floor, which poses safety concerns. Additionally, deficiencies in essential components such as reverse osmosis systems and chlorine detection devices were noted. Notably, 27.8% of participants reported breakage or leakage in connections, and 11.1% did not maintain a clean environment within the unit. Staff participation in training and awareness of water quality monitoring were insufficient, with only 16.7% attending training sessions. **Conclusion:** Most units partially met Ministry of Health (MOH) and AAMI standards, with achievements like proper water pressure, but faced issues like location impact, inconsistent air conditioning, missed disinfection, and inadequate staff training. Enhancing staff education, upgrading infrastructure, and implementing stricter monitoring protocols to mitigate contamination risks associated with water treatment systems is essential.

Keywords: Haemodialysis, Water treatment, Patient safety, Infection control, Standards compliance.

INTRODUCTION

Haemodialysis (HD) is a widely utilized form of renal replacement therapy across the globe [(1)]. The process relies on the exchange of blood with dialysis fluid through a thin, semipermeable membrane, which is crucial to the dialysis procedure [(2)]. Proper water treatment is essential for ensuring a safe and effective supply of water for haemodialysis [(3)]. The quality of water used in preparing dialysis fluid is a critical requirement for haemodialysis and related therapies. International standards, including the Caring for Australasian with Renal Impairment (CARI) guidelines, have been established to encourage the implementation of appropriate water treatment facilities for haemodialysis [(4)]. During haemodialysis, patients may be exposed to over 300 liters of water each week through the semipermeable membrane of the dialyzer. This significant increase in water exposure necessitates careful monitoring and control of water quality to prevent the transmission of harmful substances to patients [(5)]. The water used for preparing haemodialysis fluids must undergo treatment to meet the quality standards outlined by the Greater Metropolitan Committee Taskforce (GMCT) and the Association for the Advancement of Medical Instrumentation (AAMI). The water pre-treatment system typically comprises various components, including sediment filters, water softeners, carbon tanks, micro-filters, ultraviolet disinfection units, reverse osmosis systems, ultra-filters, and storage tanks. The selection of these components depends on the quality of the feed water and the system's capacity to produce and maintain appropriate water quality [(6)]. Guidelines and recommendations are crucial for ensuring positive health outcomes, as inadequate water quality can have serious implications for patient safety and wellbeing. Notable symptoms of water contamination include anemia, bone disease, hypertension, hypotension, muscle weakness, neurological decline, and even fatalities due to hazardous substances like aluminum, chloramine, copper, zinc, fluoride, nitrates, bacteria, and endotoxins [(7 - 9)]. The water treatment process aimed to eliminate both chemical and microbial contaminants to levels below established safety limits. This process is characterized by two main phases: (i) pretreatment, which removes constituents from the feed water to protect downstream components, and (ii) water treatment, which physically and/or chemically eliminates any remaining contaminants [(10, 11)].

Different microorganisms present in water can lead to human diseases, including infections caused by pathogenic bacteria and pyrogenic reactions [(12)]. Every haemodialysis unit should maintain written policies and procedures for the safe operation of water pre-treatment systems. These policies should encompass education, sampling and testing of water, documentation and analysis of results, identification of trends, and actions to be taken in response to high test results, alongside adherence to Occupational Health and Safety principles. Medical, nursing, and technical staff working in dialysis

Received: 23/03/2025
Accepted: 21/05/2025

units share the responsibility for the safe operation of the water pre-treatment systems [13, 14]. Therefore, this work aimed to evaluate the application of standard criteria in haemodialysis water treatment units utilizing a pre-designed questionnaire over a three-month period.

MATERIALS AND METHODS

This cross-sectional study was conducted in the haemodialysis units of Qena Governorate, following the approval of the institutional ethical committee at the Faculty of Medicine, Menoufia University. aimed at assessing the application of standard criteria in haemodialysis water treatment units.

Sample size and technique :There were a total of 36 haemodialysis water treatment units in Qena Governorate. A sample size of 36 units was included in the study using a comprehensive sampling technique [14, 15]. The study was based on a structured questionnaire. The multiple-choice questionnaire was developed by the researcher in accordance with the Ministry of Health (MOH) protocol and international guidelines, including the CARI and AAMI guidelines. Its validity, relevance, and difficulty level were assessed after a pilot study involving 10% of the sample size, with input from nephrologists and a public health professor.

The questionnaire was organized into eight sections: Infrastructure, components of the HD water treatment unit, infection control policies, safety policies, sterilization and sanitation, monitoring efficiency, technical staff evaluation and awareness of the unit, and results from monthly water sampling. The questionnaire included the following considerations:

- The preferred location of the HD water treatment unit on the ground floor.
- Capacity and area requirements according to MOH guidelines, with a minimum room size of 12 m².
- Ventilation and temperature, with a preference for air conditioning.
- Public network water as the best and nearly sole valid source for supplying the unit.

The components of the HD water treatment unit included: Primary and treated water tanks, Sand filter, Carbon filter, Water softener, Micron cartridge, UV lamp, Bacterial filter, Four pumps, Reverse osmosis (RO) system, Pressure meters, Stainless steel faucet for sampling to prevent rust. Instructional labels for the unit's contents and specific records for the unit, containing all relevant information.

Ethical approval: Prior to the commencement of the study, each participant completed a written consent and it was authorized by Menoufia Faculty of Medicine's local Ethical Research Committee. Additionally, the Institutional Review Board approved the study that was conducted in accordance with ethical standards and the Declaration of Helsinki and its amendments under code no. [1/2021INTM-2].

Statistical Analysis

Data were entered into a computer and analyzed using IBM SPSS software version 20.0 (Armonk, NY: IBM Corp). Qualitative data were presented as frequencies and percentages. The Kolmogorov-Smirnov test was employed to assess the normality of distribution. Quantitative data were characterized by range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR). The significance of the results was determined at a 5% level.

RESULTS

The mean number of water treatment units serving the hemodialysis (HD) unit was 1.17 ± 0.45 with a range of 1 to 3 units. The average number of dialysis machines available in the unit at the time of visit, excluding spare machines, was 21.89 ± 11.61 with a range of 3 to 42 machines. The mean number of daily shifts in the hemodialysis unit was 3.08 ± 0.77 ranging from 2 to 4 shifts. The mean number of maintenance technical staff responsible for the unit, along with their shifts, was 1.36 ± 1.02 with a range of 0 to 4 staff members. Lastly, the average number of nursing technicians assigned to the unit and their shifts was 0.17 ± 0.38 with a range of 0 to 1 technician [Table 1].

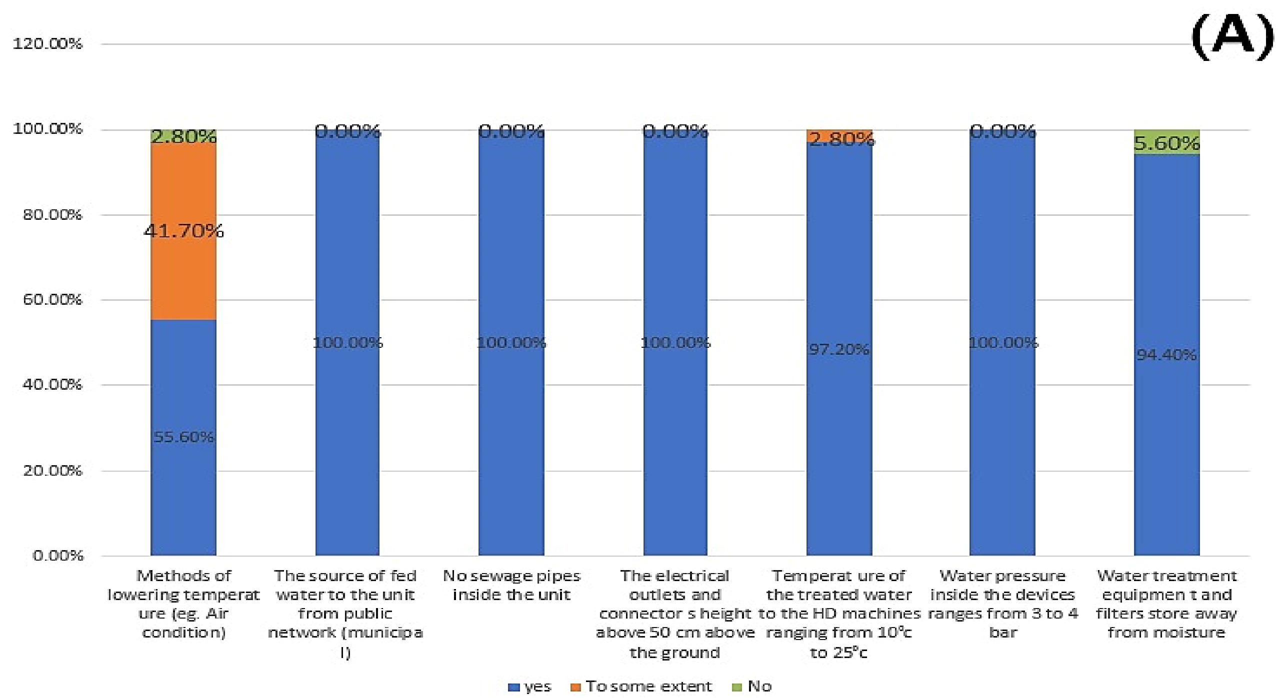
Table (1): Characteristics of the studied units

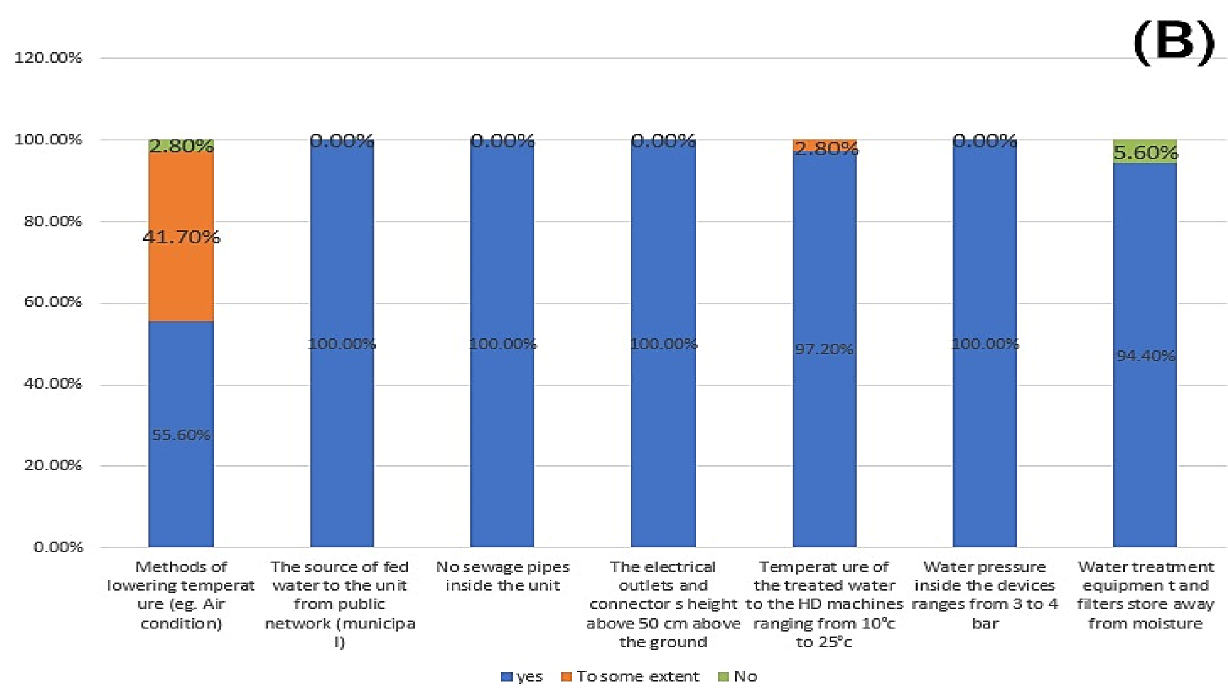
	Dialysis Units (no=36)
No. of water treatment units responsible for the HD unit	Range (1-3)
1	31 (86.11%)
2	4 (11.11%)
3	1 (2.77%)
Actual no. of machines provided by the unit at time of visit not include spare machines	Range (3-42)
<20	15 (41.66%)
>=20	21 (58.33%)
No. of the daily shifts of hemodialysis unit	Range (2-4)
2	9 (25%)
3	15 (41.66%)
4	12 (33.33%)
No. of maintenance technical staff responsible for the unit and their Shifts	Range (0-4)
0	6 (16.6%)
1	18 (50.0%)
2	6 (16.6%)
3	5 (13.8%)
4	1 (2.7%)
No. nursing technician responsible for the unit and their shifts	Range (0-1)
0	30 (83.33%)
1	6 (16.66%)

There were 25 (69.4%) didn't have the location of the water tank on the ground, 3 (8.3%) didn't have building affection in case of the unit presence upstairs, 1 (2.8%) had to some extent insulating wire on the windows, 1 (2.8%) didn't have methods of lowering temperature and 15 (41.7%) had to some extent some methods and 2 (5.6%) didn't have water treatment equipment and filters store away from moisture (Figure 1A & B).

In the study, 2 participants (5.6%) reported not having an automatic nitrate filter. Additionally, 7 participants (19.4%) lacked a reverse osmosis (RO) device with a 3-membrane configuration, while 10 participants (27.8%) did not have a RO device with a 2-membrane configuration. Furthermore, 3 participants (8.3%) did not possess total dissolved solids (TDS) and chlorine detection devices.

Regarding documentation, 3 participants (8.3%) indicated that there were some instructional labels for the unit's components, and 7 participants (19.4%) reported having some documentation for daily and monthly recordings (Figure 1 C).





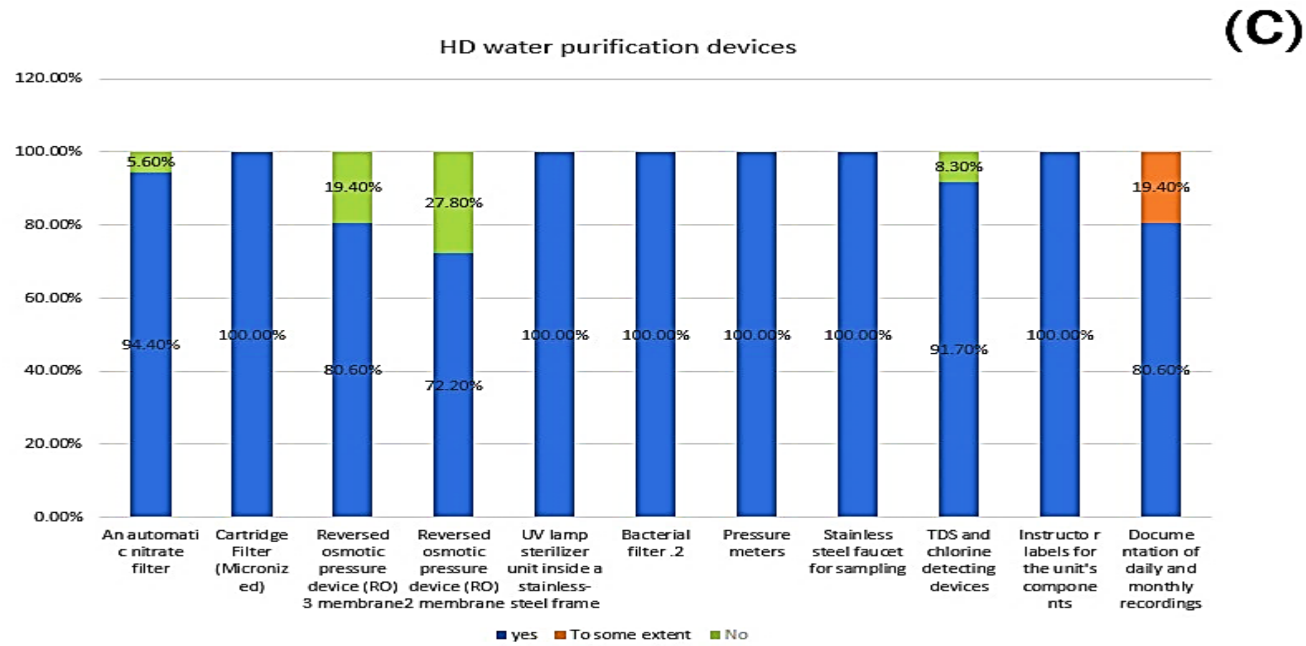


Figure (1 A, B & C): The conditions of hemodialysis units and centers.

The results showed that 4 participants (11.1%) did not consistently maintain a clean unit with a dry floor. Additionally, 10 participants (27.8%) indicated that the walls were, to some extent, smooth and easy to clean. Moreover, 4 participants (11.1%) reported not performing weekly disinfection regularly, while 1 participant (2.8%) did not have a base elevated above the ground to allow for proper drainage below the tank. Furthermore, 4 participants (11.1%) noted that the interior surfaces were, to some extent, smooth to facilitate continuous flow and prevent water stagnation. It was noted that 10 participants (27.8%) did not have a chlorine-free sample in a chemical reagent after performing the first chemical wash test. The findings revealed that 4 participants (11.1%) did not record readings related to pressure counters or ensure their efficient operation. Additionally, 10 participants (27.8%) reported experiencing breakage or leakage in some of the unit's connections and pipes. Furthermore, 5 participants (13.9%) indicated that they only partially recorded the readings related to pressure counters and ensured their proper functioning. Lastly, 4 participants (11.1%) reported that the salt level inside the brine tank was, to some extent, appropriate [Table 2].

Table (2): Monitoring and quality control of HD water treatment units

	Dialysis Units (no=36)					
	No		To some extent		yes	
	No.	%	No.	%	No.	%
Record the readings related to pressure counters and ensure that they work efficiently	4	11.1	5	13.9	27	75.0
Ensure the temperature of the pumps during operation is appropriate and there isn't strange sound	-	-	-	-	36	100.0
Monthly change of cartridge (micro) filters	-	-	-	-	36	100.0
Change the bacterial filter every two months	-	-	-	-	36	100.0
Salt level inside the Brian Tank is Appropriate	-	-	4	11.1	32	88.9
Salt stores away from moisture	-	-	-	-	36	100.0
Follow-up to RO readings	-	-	-	-	36	100.0
Follow-up hours of UV bulb operation and Readings	-	-	-	-	36	100.0
No breakage or leakage with any of the unit's connections and pipes	10	27.8	-	-	26	72.2
Labels show expiration date for each filter and the date of exchange	-	-	-	-	36	100.0
Record any drifts and the necessary correction action	-	-	-	-	36	100.0
Keep periodic maintenance reports of maintenance company according to their contract	-	-	-	-	36	100.0

The results indicated that among the unit staff, 5 participants (13.9%) did not attend work before the start of their shifts and were not present throughout their working hours. Additionally, 6 participants (16.7%) had not attended training sessions related to water treatment units. Furthermore, 9 participants (25%) reported that they only partially attended before the start of their shifts and maintained presence throughout their working hours. Lastly, 3 participants (8.3%) indicated that they had, to some extent, conducted daily measurements of treated water, including tests for chlorine and dissolved salts, before the start of each shift [Table 3].

Table (3): HD water treatment units staff (maintenance technician)

	Dialysis Units (no=36)					
	No		To some xtent		yes	
	No.	%	No.	%	No.	%
Attendance before the start of the shift and presence throughout the working hours	5	13.9	9	25.0	22	61.1
Daily measurements of treated water before the start of each shift for both (chlorine and dissolved salts)	-	-	3	8.3	33	91.7
Familiar with the handling of a high level of chlorine or any component drift in the treated water	-	-	-	-	36	100.0
Cleaning, disinfection and sterilization of tanks	-	-	-	-	36	100.0
Record daily chemical measurements, monthly result of water samples and periodic maintenance reports along with maintenance company	-	-	-	-	36	100.0
Attending training sessions concern with water treatment units	6	16.7	-	-	30	83.3
Closure of the unit door	-	-	-	-	36	100.0

Among the unit staff, 7 participants (19.4%) did not have results for the processed samples corresponding to the month of the check [Table 4].

Table (4): Efficiency of water samples in water treatment plants in dialysisunits

	Dialysis Units (no=36)					
	No		To someextent		yes	
	No.	%	No.	%	No.	%
Monthly sampling	-	-	-	-	36	100.0
The presence of the health observer	-	-	-	-	36	100.0
Sterilization and disinfection of stainless steel in Sparto and flame	-	-	-	-	36	100.0
Not to open the sample bottle except in front of the tap and sterilize its nozzle with flame	-	-	-	-	36	100.0
Wrap the cap with a gauze	-	-	-	-	36	100.0
Putting the bottle in a special coalman surrounded by snow	-	-	-	-	36	100.0
The result of the processed sample corresponds to decree of 63 for 1996 in the month of check	7	19.4	-	-	29	80.6

The analysis of the six samples showed that all chemical parameters were within the established normal range, indicating compliance with safety and quality standards essential for medical use. Bacteriological assessments also confirmed that all parameters fell within normal limits, suggesting no significant bacterial contamination and ensuring patient safety in the hemodialysis unit. Additionally, all mineral parameters were within the normal range, highlighting the presence of essential minerals at appropriate concentrations. Overall, these results demonstrate the effectiveness of the water treatment processes and adherence to safety standards, crucial for the health of patients undergoing treatment [Table 5,6,7].

Table (5): Chemical parameters of the collected water samples

	Random samples (no=6)						Normal reference
	1	2	3	4	5	6	
Cl^-	Nil	Nil	Nil	Nil	Nil	Nil	≤ 0.2 mg/L
Chloramine	Nil	Nil	Nil	Nil	Nil	Nil	≤ 0.1 mg/L
NH_3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
No_2	Nil	Nil	Nil	Nil	Nil	Nil	Nil
NO_3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
F	Nil	Nil	Nil	Nil	Nil	Nil	≤ 0.2 mg/L
SO_4	8.1	4.6	12.7	6	10.6	4.1	≤100 mg/L
Na+	5.3	5.8	1.4	2.9	4.4	5.3	≤70 mg/L
K+	Nil	Nil	0.9	Nil	Nil	Nil	≤5 mg/L
Ca++	Nil	Nil	Nil	Nil	Nil	Nil	≤5 mg/L
Mg++	Nil	Nil	Nil	Nil	Nil	Nil	≤4 mg/L
Conductivity (Us/cm)	41	35	20	22	14	50	≤300 us/cm
TDS	20	28	14	18	29	17	≤200 mg/L

Table (6): Bacteriology parameters of the collected water samples

	Random samples (no=6)						Normal reference
	1	2	3	4	5	6	
Coloniescounted x100ml	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Coliformcolonies counted x100ml	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria counted x1ml at 35°	6	4	4	7	5	5	≤50 cell/ml
Bacteria counted x1mlat 22°	10	8	7	11	10	9	≤50 cell/ml
Pseudomonas	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Strepto.	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Anaerobe	-ve	-ve	-ve	-ve	-ve	-ve	-ve

Table (7) : Minerals parameters of the collected water samples

	Random samples (no=6)						Normal reference
	1	2	3	4	5	6	
Ag	Nil	Nil	Nil	Nil	Nil	Nil	≤0.005mg/l
Al	Nil	Nil	Nil	Nil	Nil	Nil	≤0.01mg/l
Ba	0.0325	0.0328	0.015	0.0063	0.0376	0.0044	≤0.1mg/l
Cd	Nil	Nil	Nil	Nil	Nil	Nil	≤0.001mg/l
Cr	Nil	Nil	Nil	Nil	Nil	Nil	≤0.014mg/l
Cu	0.0138	0.0173	0.0188	0.0155	0.0053	0.0324	≤0.1mg/l
Fe	0.0304	Nil	0.0121	0.0116	0.0137	0.0258	≤0.1mg/l
Mn	0.0058	Nil	Nil	0.0104	0.0017	0.0136	≤0.1mg/l
Pb	0.0002	Nil	Nil	0.0002	0.0002	Nil	≤0.005mg/l
Se	Nil	Nil	Nil	Nil	Nil	Nil	≤0.09mg/l
Zn	0.024	0.011	0.007	0.023	0.007	0.024	≤0.1mg/l
As	Nil	Nil	Nil	Nil	Nil	Nil	≤0.005mg/l

DISCUSSION

The current study evaluated the implementation of standard criteria in hemodialysis water treatment units in Qena governorate. Each hemodialysis unit averaged 1.17 ± 0.45 water treatment units, ranging from 1 to 3. The mean number of operational machines during the visit, excluding spares, was 21.89 ± 11.61 with a range of 3 to 42. The average number of daily shifts was 3.08 ± 0.77 ranging from 2 to 4. Additionally, the average number of maintenance technical staff was 1.36 ± 1.02 ranging from 0 to 4, while nursing technicians averaged 0.17 ± 0.38 with a range of 0 to 1.

In a related study conducted by **Khamis *et al.*** [17] in Sharkia governorate, Egypt, a structured questionnaire was developed based on Egyptian Ministry of Health protocols and international guidelines, including CARI and AAMI. Their results mirrored the current findings, showing an average of 1.17 ± 0.461 water treatment units per hemodialysis unit, with a range of 1 to 3. The mean number of machines was slightly lower at 21.87 ± 12.59 ranging from 3 to 51. They reported an average of 3.03 ± 0.669 daily shifts, with a range of 2 to 4, and an average of 1.37 ± 1.03 maintenance technical staff, with a range of 0 to 4. This consistency across both studies underscores the adequacy of resources and staffing in hemodialysis units in different governorates of Egypt.

In the current study, 25 (69.4%) of the hemodialysis (HD) water treatment units lacked proper ground-level placement for the water tank, while 3 (8.3%) did not consider building effects if located on upper floors. Additionally, 1 (2.8%) had partial insulation on windows, and 15 (41.7%) reported some temperature control methods, whereas 2 (5.6%) did not store treatment equipment and filters away from moisture. In **Khamis *et al*.** [17] study, 63.3% of units were also not on the ground floor, and one lacked temperature control methods.

In the current study on hemodialysis (HD) water purification devices, 2 (5.6%) units lacked an automatic nitrate filter, 7 (19.4%) did not have a three-membrane reverse osmosis (RO) device, and 10 (27.8%) were missing a two-membrane RO device. Additionally, 3 (8.3%) lacked TDS and chlorine detection devices, while 3 (8.3%) had partial instructional labels for unit components and 7 (19.4%) had incomplete documentation of daily and monthly recordings. In **Khamis *et al.*** [17] study, 100% of units had purification devices, but 33.3% lacked a two-membrane RO device, and 20% did not have a three-membrane device. Regarding infection control, 4 (11.1%) units did not maintain a clean, dry floor, while 10 (27.8%) had somewhat smooth walls.

In the current study on health standards for water tanks, 4 (11.1%) units did not consistently perform weekly disinfections, and 1 (2.8%) lacked a proper base to allow drainage below the tank.

Khamis *et al.* [17] found that all units adhered to chemical disinfection protocols, with 70% having no breakage or leakage in connections. In comparison, a Nigerian study revealed that most centers did not routinely disinfect their water storage tanks, with only 16.6% disinfecting monthly [16].

In the current study on chemical disinfection of HD water treatment units, 10 (27.8%) did not have chlorine-free samples after the initial chemical wash. **Khamis *et al*.** [17] found that 76.7% of units had chlorine-free samples. Regarding monitoring and quality control, 4 (11.1%) did not record pressure counter readings, and 10 (27.8%) experienced breakage in connections. In contrast, **Khamis *et al.* [17]** reported 100% compliance in monitoring, with some minor issues. A Nigerian survey revealed that many centers did not replace UV filaments regularly, with some going years without maintenance [16].

In the current study regarding the staff of HD water treatment units, 5 (13.9%) did not attend before shifts and remain present throughout working hours, while 6 (16.7%) did not participate in training sessions related to water treatment. Additionally, 9 (25%) partially attended shifts, and 3 (8.3%) performed daily measurements of treated water for chlorine and dissolved salts. Conversely, **Khamis *et al.*** [17] reported that 100% of units lacked a biomedical engineer, internal supervision, or organized daily checklists. While most units had competent maintenance staff, 6.7% experienced staff absenteeism, and 10% of units had untrained technicians. It is recommended that at least one maintenance technician be present per shift. Comparatively, a study in Ismailia Governorate found an average of 2.9 ±1.6 maintenance staff per shift.

In the current study on the efficiency of water samples from dialysis unit treatment plants, 7 (19.4%) of the staff did not have processed sample results corresponding to the month of testing. In contrast, **Khamis *et al.*** [17] examined the efficiency of HD water samples in Sharkia Governorate and found that all units (100%) complied with the Ministry of Health (MOH) and AAMI standard specifications for sample collection. However, not all tested samples met the 1996 decree, with only 90% of units passing the initial test. Upon retesting, all samples met the standards, with the primary reasons for initial failures attributed to chemical or bacterial contamination, such as elevated levels of nitrates, chloramines, or E. coli were found to be within the normal range. Conversely, **Khamis *et al.*** [17] tested five random samples from various HD water treatment units and reported that all samples complied with the 1996 decree 63 concerning chemical, mineral, and bacteriological parameters. The AAMI guidelines recommend testing the final water for chemical contaminants during commissioning and then annually, with chloramine levels monitored at each treatment shift. Daily monitoring of individual water treatment components is also suggested to complement periodic chemical analyses. More frequent testing may be necessary in specific situations, such as significant seasonal fluctuations in water quality or when reverse osmosis (RO) rejection rates fall below 90%.

A study by **Pizzarelli *et al.*** [18] indicated that 29% of centers tested HD water monthly, while 14% tested every two months, and 37% conducted tests every three months. A separate study in Iraq monitored bacterial concentrations in water samples from six dialysis centers over five months, revealing high bacterial counts; 60% of samples exceeded the 50 CFU/mL threshold set by AAMI, with five centers showing counts above 100 CFU/mL. Regular and effective disinfection procedures are essential to maintain bacterial counts below the action level [19].

CONCLUSION

Most studied units partially meet the MOH and AAMI standards. Infrastructure achievements included sun-protected tanks, no sewage pipes within units, electrical outlets above 50 cm, treated water temperatures between 10 °C and 25 °C, water pressure between 3 to 4 bar, and good ventilation. However, shortcomings persist, such as units located upstairs affecting building integrity, inconsistent air conditioning use, inadequate moisture control for equipment, missed disinfection schedules, delayed TDS and chlorine documentation, insufficient maintenance staff training, and failure to meet the 1996 decree in initial water sample analyses.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of interests: The authors declare that they have no competing interests.

Funding: No funding for this research.

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