



Analysis of hemodialysis water quality from 2008 to 2016 in Minas Gerais, Brazil

Análise da qualidade da água de hemodiálise durante o período de 2008 a 2016 em Minas Gerais, Brasil

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ABSTRACT

Water quality requirements for hemodialysis are crucial for preventing health risks for renal patients. The objective of this study was to assess the quality of the water used for hemodialysis treatments in the state of Minas Gerais. The analytical results for 25 parameters in 1056 hemodialysis water samples from 89 renal dialysis units were analyzed. Data were obtained through the Minas Gerais Hemodialysis Unit Quality Monitoring Programme between July 2008 and December 2016. The effects of the Programme on patient health protection were assessed by evaluating compliance with legal limits and the efficacy of implementing inspections from 2012. Considering the 1056 samples analyzed, 264 (25%) presented at least one parameter in disagreement with current legislation. Conductivity (9.8%), endotoxin (6.9%), fluoride (4.2%) and heterotrophic bacteria (2.2%) were the most critical parameters. Nevertheless, the concentrations of all these parameters (except fluoride) decreased after implementing inspections. The average levels of 15 parameters decreased throughout the study period. The annual percentage of non-compliance decreased from 44% in 2008 to 23% in 2016. It was verified the relevance of the implementation of the Program in the prevention of possible disorders to the patients' health, indicating the importance of its continuity.

Keywords. renal insufficiency chronic, renal dialysis, water quality, health surveillance, public health.

RESUMO

Os requisitos de qualidade da água para a hemodiálise são cruciais para prevenir riscos à saúde de pacientes renais. O objetivo foi avaliar a qualidade da água utilizada nos tratamentos de hemodiálise em Minas Gerais. Os dados foram obtidos por meio do Programa de Monitoramento da Qualidade dos Serviços de Hemodiálise do Estado entre julho de 2008 e dezembro de 2016. Os resultados analíticos para 25 parâmetros em 1056 amostras de água em hemodiálise de 89 unidades renais foram analisados. Os efeitos do Programa na saúde dos pacientes foram avaliados através da conformidade dos limites legais e da eficácia da implementação de inspeções a partir de 2012. Considerando-se as 1056 amostras analisadas, 264 (25%) apresentaram pelo menos um parâmetro em desacordo com a legislação vigente. Condutividade, endotoxina, fluoreto e bactérias heterotróficas foram os parâmetros mais críticos. No entanto, as concentrações de todos esses parâmetros (exceto flúor) diminuíram após a implementação das inspeções. Os níveis médios de 15 parâmetros diminuíram ao longo do período do estudo. O percentual anual de não conformidade diminuiu de 44% (2008) para 23% (2016). Verificou-se a relevância da implantação do Programa na prevenção de possíveis transtornos à saúde dos pacientes, indicando a importância de sua continuidade.

Palavras-chave. insuficiência renal crônica, hemodiálise, qualidade da água, vigilância sanitária, saúde pública.

INTRODUCTION

Chronic renal failure consists of the progressive and irreversible loss of kidney function, and can be caused by various disorders that affect a large number of people worldwide, such as high blood pressure, diabetes, chronic kidney inflammation, among others^{1,2}. Affecting between 8 and 16% of the world population, kidney disease can be considered one public health problem¹. Monitoring the quality of water for hemodialysis is of great relevance for public health and a fundamental tool for the prevention of risks to the health of renal patients².

When the kidneys are not able to maintain electrolyte balance and remove toxic substances from the body, hemodialysis treatment is available to perform these functions². In Brazil, the characteristics of the water to be used in procedures of hemodialysis must be compatible with the quality requirements established by Board of Directors Resolution (RDC) n° 11 (13/03/2014) of the National Sanitary Surveillance Agency (ANVISA)³.

Minas Gerais is located in the southeast region of Brazil and is the 2nd most populous state in the country⁴. According to the Brazilian Chronic Dialysis Survey, the estimated annual average number of new patients increased in 2017, being more than 40 thousand for the first time, and only two states (São Paulo and Minas Gerais) received almost 37% of new patients⁵. In addition, in the past 15 years, the number of Brazilian patients with chronic kidney disease has increased 4.2 times more than the number of active dialysis units⁵.

To ensure that water for hemodialysis poses no adverse risks to patients, the Minas Gerais State Health Surveillance (Vigilância Sanitária – VISA) agency, in a joint initiative with the Ezequiel Dias Foundation (FUNED), performs annual inspections as a key external quality control tool to assess compliance with legal limits through the Minas Gerais Hemodialysis Unit Quality Monitoring Programme⁶.

In Brazil, the most significant event to highlight the importance of hemodialysis water quality control occurred in 1996 at the Institute of Kidney Diseases in Caruaru, Pernambuco, where the water used for hemodialysis was contaminated with microcystin, causing the death of 65 hemodialysis patients⁷. Therefore, hemodialysis water quality monitoring plays a key role in controlling and reducing risk factors and protecting public health.

Previous studies have reported the results of quality monitoring programmes for hemodialysis water in another countries⁸⁻¹¹. In Brazil, only a small number of these studies have been published, involving only a few states¹²⁻¹⁵. No studies on similar monitoring programmes conducted in the state of Minas Gerais have been published thus far. So, considering the relevance of this subject, the objective was to assess the quality of the water used for hemodialysis treatments in Minas Gerais state and evaluate the effectiveness of the monitoring programme in reducing risks to dialysis patients.

MATERIAL AND METHODS

The Minas Gerais Hemodialysis Unit Quality Monitoring Programme was implemented to monitor all renal dialysis units located in the State. It started in 2002 and remained in operation until late 2011 to act as guidance; that is, upon evidence of non-compliance, the renal dialysis unit was guided by VISA to adopt necessary measures to correct the irregularities. From 2012, the programme began operating through inspections with the implementation of administrative proceedings and other legal actions, citing the occurrence of non-compliance as a sanitary infraction¹⁶⁻¹⁹. In cases of non-conformities, the interdiction of renal dialysis units helped to ensure the safety of hemodialysis patients, constituting a key implication of the programme.

Samples and parameters evaluated

The results of 1056 hemodialysis water samples from 89 renal dialysis units registered in the programme and located in the 12 mesoregions of Minas Gerais, collected between July 2008 and December 2016, were assessed. The samples were collected, at least once a year, by trained VISA technicians at the capillary processing room of each renal dialysis unit and were sent to FUNED to analyse 25 quality parameters established by ANVISA RDC n°11/2014³.

The samples were analysed according to the analytical methods described by the Standard Methods for the Examination of Water and Wastewater²⁰ and the United States Pharmacopeia²¹ and by recommended analytical conditions and general information. Importantly, ANVISA RDC n°154/2004²² was revoked by ANVISA RDC n° 11/2014³, which changed the maximum permitted levels (MPLs) for bacterial endotoxin and heterotrophic bacteria.

The results were compared with the MPLs established by the law in force in each study period^{3,22}. The limits of quantification (LQs) considered in the processes of intra-laboratory validation of the respective methods were specified according to the Document de Orientação sobre Validação de Métodos Analíticos (Guideline on Validation of Analytical Methods)²³ (Table 1).

Table 1. Hemodialysis water quality parameters, maximum permitted levels (MPLs), according to ANVISA RDC n° 154/2004^a and n° 11/2014, and limits of quantification (LQs) considered in this study

Parameter	MPL	LQ
Electrolytic conductivity (µS/cm)	10.0	1.0
Fluoride (mg/L)	0.20	0.20
Nitrate (mg/L)	2.0	0.5
Sulphate (mg/L)	100	50
Endotoxin ^b (EU/mL)	2.0	0.50
Endotoxin ^c (EU/mL)	0.250	0.125
Total coliforms ^d (Absence in 100 mL)	Absence	-
Heterotrophic bacteria ^b (UFC/mL)	200	1
Heterotrophic bacteria ^c (UFC/mL)	100	1
<i>Pseudomonas aeruginosa</i> ^c (NMP/100 mL)	-	1.1
Barium (mg/L)	0.10	0.05
Calcium (mg/L)	2.0	0.5
Copper (mg/L)	0.10	0.05
Magnesium (mg/L)	4.0	0.5
Potassium (mg/L)	8.0	0.5
Sodium (mg/L)	70.0	0.5
Zinc (mg/L)	0.10	0.05
Antimony (mg/L)	0.0060	0.0008
Arsenic (mg/L)	0.0050	0.0008
Mercury (mg/L)	0.0002	0.0002
Selenium (mg/L)	0.0900	0.0008
Beryllium (mg/L)	0.0004	0.0001
Cadmium (mg/L)	0.001	0.0005
Lead (mg/L)	0.005	0.001
Chromium (mg/L)	0.014	0.001
Silver (mg/L)	0.005	0.001
Thallium (mg/L)	0.002	0.001

Legend: ^aRegarding the parameters bacterial endotoxin and heterotrophic bacteria. ^bRegarding the 2008-2013 period, in accordance with ANVISA RDC n° 154/2004. ^cRegarding the 2014-2016 period, in accordance with ANVISA RDC n° 11/2014. ^dQualitative parameter; therefore, LQ is not applied. ^eParameter not mentioned in the law but whose monitoring is recommended by the United States Pharmacopoeia

The MPLs established in the Brazilian standard are in line with those determined by the United States Pharmacopoeia, except for the *Pseudomonas aeruginosa* parameter. This quality index is not included in ANVISA RDC n° 11/2014, but its routine monitoring is recommended by the United States Pharmacopoeia because this is the pathogen genus most frequently found in hemodialysis water^{3,21,24}.

The percentages of samples with results lower than the LQ, between the LQ and the MPL, and higher than the MPL were determined for each parameter, and the levels of bacterial endotoxin and heterotrophic bacteria were analysed in two historical data series according to the legislation in force in the different periods (2008-2013 and 2014-2016).

Statistical analysis

Data normality was assessed using the Shapiro-Wilk test, and homogeneity of variance was assessed using the F-test. The efficacy of implementing inspections was determined by comparing the medians (Mann-Whitney U test) between samples that were analysed for guidance (group 1; 2008-2011) and those analysed for inspection (group 2; 2012-2016). Importantly, comparisons between the guidance and inspection samples were not performed for tests with a median lower than the LQ (and, therefore, unquantifiable), tests with zero variability or for categorical variables.

The level of correlation between all water quality parameters throughout the monitoring period was also analysed using the Spearman's rank correlation test. The renal dialysis units were numerically ordered (from 1 to 89) to assess the occurrence of non-compliant samples among units and respective mesoregions, identifying the most critical cases, i.e., those with percentages of non-compliance higher than 25%. The significance level of all statistical tests was set to 5% ($\alpha = 0.05$), and the statistical software packages used were R software (version 3.4.2) and Excel (version 2013).

RESULTS

Table 2 outlines the number of hemodialysis water samples whose results were lower than the LQ, between the LQ and the MPL, and higher than the MPL, for each respective parameter.

Table 2. Number of findings lower than the limit of quantification (LQ), between the LQ and the maximum permitted level (MPL), and higher than the MPL defined in ANVISA RDC n° 154/2004^a and n° 11/2014 for each parameter

Parameter	< LQ	≥ LQ and ≤ MPL	> MPL	Total number of samples
Conductivity (µS/cm)	5 (0.5%)	923	101 (9.8%)	1029
Fluoride (mg/L)	711 (95.2%)	5 ^b	31 (4.2%)	747
Nitrate (mg/L)	633 (91.1%)	58	4 (0.6%)	695
Sulphate (mg/L)	816 (99.4%)	5	0	821
Bacterial endotoxin ^c (EU/mL)	646 (91.5%)	14	46 (6.5%)	706
Bacterial endotoxin ^d (EU/mL)	268 (81.5%)	36	25 (7.6%)	329
Bacterial endotoxin (total)	914 (88.3%)	50	71 (6.9%)	1035
Heterotrophic bacteria ^c (UFC/mL)	345 (49.2%)	347	10 (1.4%)	702
Heterotrophic bacteria ^d (UFC/mL)	188 (58.0%)	123	13 (4.0%)	324
Heterotrophic bacteria (total)	533 (52.0%)	470	23 (2.2%)	1026
Total coliforms (Absence in 100 mL)	-	-	20 (2.0%)	1026
<i>Pseudomonas aeruginosa</i> (NMP/100 mL)	385 (47.5%)	-	-	811
Calcium(mg/L)	999 (98.2%)	12	6 (0.6%)	1017
Sodium (mg/L)	420 (41.3%)	594	4 (0.4%)	1018
Zinc (mg/L)	1000 (99.8%)	0	2 (0.2%)	1002
Chromium (mg/L)	697 (99%)	6	1 (0.1%)	704
Silver (mg/L)	787 (99.8%)	1	1 (0.1%)	789
Antimony (mg/L)	674 (99.6%)	3	0	677
Arsenic (mg/L)	780 (99.6%)	3	0	783
Barium (mg/L)	997 (100.0%)	0	0	997
Beryllium (mg/L)	728 (99.2%)	6	0	734
Cadmium (mg/L)	811 (100%)	0	0	811
Lead (mg/L)	807 (99.4%)	5	0	812
Copper (mg/L)	1011 (99.3%)	7	0	1018
Magnesium (mg/L)	978 (99.2%)	8	0	986
Mercury (mg/L)	264 (100%)	0	0	264
Potassium (mg/L)	943 (97.7%)	22	0	965
Selenium (mg/L)	622 (99%)	6	0	628
Thallium (mg/L)	767 (100%)	0	0	767

Legend: ^aRegarding the parameters bacterial endotoxin and heterotrophic bacteria. ^bSamples whose value of fluoride was exactly the LQ (LQ = MPL). ^cResults regarding the period from 2008 to 2013 according to the MPL established by ANVISA RDC n° 154/2004, then in force. ^dResults regarding the period from 2014 to 2016 according to the MPL established by ANVISA RDC n° 11/2014

Table 3 outlines the results from the comparison of medians between the guidance (2008-2011) and inspection (2012-2016) periods of operation of the programme (Mann-Whitney U Test).

The renal dialysis units and the results from the analysed samples were grouped into 12 mesoregions of Minas Gerais according to the

divisions established by the Brazilian Institute of Geography and Statistics (IBGE)²⁵ and also outlines the renal dialysis units registered in the programme (ordered from 1 to 89), their respective mesoregions and the total numbers of analysed and unsatisfactory (higher than the MPL) samples from each mesoregion (**Table 4**).

Table 3. Comparisons of parameter medians between the guidance and inspection monitoring periods (from 2008 to 2011 and from 2012 to 2016, respectively) (Mann-Whitney U Test)

Parameter	Median value		p-value
	2008 - 2011	2012 - 2016	
Conductivity	8.3	4.9	0.011*
Silver	0.001	< LQ	0.111
Sodium	1.617	0.952	0.251
Bacterial Endotoxin	0.45	0.21	0.000*
Heterotrophic bacteria	14.2	11.5	0.004*
<i>Pseudomonas eruginosa</i>	1.14	< LQ	0.000*

Legend: *Significant difference between medians ($p < 0.05$; Mann-Whitney U Test)

Table 4. Mesoregions of Minas Gerais (n = 12), number of renal dialysis units registered in the Minas Gerais Haemodialysis Unit Quality Monitoring Programme (n = 89), renal dialysis units (and theirs codes), number of samples analysed from 2008 to 2016 (n = 1056), and number and percentage of unsatisfactory samples in each mesoregion

Mesoregion of Minas Gerais	Renal dialysis units	Unit code ^a	Analysed samples	Unsatisfactory samples
Campo das Vertentes	3	1 to 3	38	12 (32%)
Central Mineira	2	4 and 5	17	8 (47%)
Jequitinhonha	2	6 and 7	21	8 (38%)
Metropolitan Area of Belo Horizonte	24	8 to 31	314	64 (20%)
Northwestern Minas Gerais	2	32 and 33	26	22 (85%)
Northern Minas Gerais	6	34 to 39	73	31 (43%)
Western Minas Gerais	4	40 to 43	43	3 (7%)
Southern and Southwestern Minas Gerais	14	44 to 57	155	39 (25%)
Triângulo Mineiro and Alto Paranaíba	15	58 to 72	160	37 (23%)
Mucuri Valley	2	73 and 74	24	10 (42%)
Doce River Valley	4	75 to 78	52	10 (19%)
Zona da Mata	11	79 to 89	133	20 (15%)
Total	89	89	1056	264 (25%)

Legend: ^aUnits identified as the most critical: 1, 5, 6, 32, 39, 57, 70 and 73

DISCUSSION

Internationally, hemodialysis procedures are defined according to International Standard ISO n° 13.959 dated April 15, 2009²⁶. The parameters established in this international standard are also equivalent to those defined by the Brazilian standard and list the same maximum permitted levels, except for the conductivity and total coliform parameters, for which no reference values are defined internationally^{26,27}. Importantly, the 2008 revision of ISO n° 13.959/2009 lowered the endotoxin limit in hemodialysis water (0.25 EU/mL), thereby setting a more restrictive value, which was already adopted

by the European Pharmacopoeia²⁷. However, this MPL was adopted into Brazilian law only in 2014³.

Of the total number of samples analysed (1056), 264 (25%) had at least one quality parameter that did not meet the standard of the law in force (**Table 2**). Indeed, the percentage of contaminated samples may be considered worrying because they accounted for one quarter of all hemodialysis water samples. Furthermore, the patients subjected to hemodialysis were immunocompromised, and the contaminated dialysate would directly reach the bloodstream, which could easily and quickly affect the gastrointestinal areas, causing diarrhoea, pain, other various disorders and even death²⁴.

The results also showed that conductivity, endotoxin, fluoride and heterotrophic bacteria had the highest percentage of non-compliance, ranging from 2.2 to 9.8%. Conductivity had the highest percentage of values above the legal limit (9.8%), followed by endotoxin (6.9%) and fluoride (4.2%) (Table 2).

Depending on the concentration of oxygen dissolved in the aquatic environment, algae and cyanobacteria can be present in several water courses, in addition to water reservoirs. Cyanobacteria are easily adaptable in different environments lacking nutrients and oxygen or even with high concentrations of heavy metals. In addition, some species excrete organic compounds that can attribute taste to the water and, in excessive concentrations, even toxicity^{28,29}. The toxins produced by cyanobacteria differ according to their level of action in the human body, and among the toxins produced, endotoxins stand out.

As exposed by Ramirez³⁰, in the dialysate, bacterial growth can be intensified due to the presence of components such as glucose and bicarbonate, resulting in high levels of endotoxins. Due to the pore diameter of the semi permeable membranes used in the treatment of hemodialysis, it is unlikely that microorganisms will be able to overcome it, unlike its toxins.

The contact of water for hemodialysis contaminated by endotoxin with the blood of renal patients can lead to several pyrogenic reactions such as fever, chills, hypotension, malaise, tremors and nausea, or even long-term complications such as cachexia (extreme degree of weakness) and amyloidosis (abnormal protein accumulation in cell organs and tissues)³¹. In addition, contamination by high levels of endotoxins directly into the bloodstream is generally fatal²⁴.

In most samples (95.2%), the fluoride levels were not quantified and consequently were lower than the MPL (LQ = MPL). For conductivity, only 0.5% of samples were lower than the LQ of the method. The percent non-compliance of the other parameters was lower and mostly ranged from to 1%. For most parameters, greater than 97% of the results were lower than the LQs (Table 2).

Two high and discrepant values were found for the conductivity parameter in 2010

(104 and 730 $\mu\text{S}/\text{cm}$). These divergent results in 2010 came from the same dialysis service in the southern and south western regions of Minas Gerais regarding samples collected in the months of March and October.

This indicates that the results may be related to problems with Hemodialysis Water Treatment and Distribution System (STDAH), since the observed values are similar to the conductivity of natural waters (100 to 1000 $\mu\text{S}/\text{cm}$) and, not working properly, STDAH may not have been efficient in the treatment of water and, consequently, in the reduction of the original conductivity²⁹.

No sulphate results were higher than the MPL. In the nitrate test, only four samples (0.6%) showed unsatisfactory results. Most sulphate (99.4%) and nitrate (91.1%) results were lower than the LQs. Additionally, there were no non-compliant results for the following parameters: antimony, arsenic, barium beryllium, cadmium, lead, copper, magnesium, mercury, potassium, selenium and thallium.

The microbiological parameters also had a high percentage of results that were lower than the LQs, including 914 samples (88.3%) for endotoxins, 533 (52%) for heterotrophic bacteria and 385 (47.5%) for *Pseudomonas aeruginosa*. There were 20 unsatisfactory samples (2%) for total coliforms found throughout the study period (Table 2).

The present study has indicated that some parameters were critical when analysing the results from the monitoring performed by the Minas Gerais Hemodialysis Unit Quality Monitoring Programme. Among them, conductivity, fluoride and microbiological parameters are notable. This suggests that these parameters could be used in preliminary tests and could be assessed before the remaining parameters. In general, most of the other results were lower than LQs, thus highlighting the high percentage of compliance among the study samples.

The annual average levels of 15 quality parameters were negatively correlated with the total monitoring time, and ten of these correlations were significant ($p < 0.05$; Spearman's rank correlation test). The parameters with the most significant negative correlations were endotoxin (-0.594) and *Pseudomonas aeruginosa* (-0.825). Overall, the hemodialysis water quality has improved in the state of Minas Gerais throughout the years of programme monitoring.

For four parameters, significant decreases in the median concentration between the guidance (from 2008 to 2011) and inspection (from 2012 to 2016) periods of operation were also observed ($p < 0.05$; Mann-Whitney U Test) (**Table 3**). These differences were observed in some of the critical parameters (conductivity, bacterial endotoxin and heterotrophic bacteria). This demonstrates the efficacy of changing the type of programme (from guidance to inspection) and its contribution to improving the quality of the water used for hemodialysis.

Total non-compliance decreased from 44% (2008) to 23% (2016). This indicated a general trend of improvement in meeting the limits established by ANVISA RDC nº 11/2014 and a consequent reduction in the percentage of un satisfaction for all the parameters analysed in the study period. This find highlights the role of the monitoring in preventing health problems in the patients, and the importance of continuing the Program in Minas Gerais state.

Although there was an absence of data regarding the monitoring of water quality for hemodialysis in the state of Minas Gerais, there are some studies regarding monitoring carried out in other regions of Brazil. As exposed by a study was carried out in São Paulo about the Monitoring Program for Treated Water for Hemodialysis¹³, similar to the existing Program in Minas Gerais. Despite the fact that it did not include all the hemodialysis services in the State, it showed a significant improvement in the quality standard between the study period (2007 and 2008), in relation to compliance with legal provisions.

In Natal, Rio Grande do Norte, a study was also carried out in several dialysis services in the State, between October 2012 and March 2013. The authors concluded that the evaluation contributed to the knowledge of the reality of the water quality situation for hemodialysis in the State and that there is a need for constant monitoring to ensure the adequacy of the systems, in order to eliminate probable risk factors¹⁴.

In another study carried out in São Luís, Maranhão, the presence of contaminants in the water used in the treatment of hemodialysis was found in 70% of the evaluated hospital units, among which bacterial endotoxin, heterotrophic bacteria and *Pseudomonas aeruginosa* stand out. The results

therefore indicated the need to review the water quality control procedures for hemodialysis in the referred hospital units¹⁵.

In a study carried out in Recife, Pernambuco, 359 laboratory reports from a hemodialysis clinic in the city, referring to the period between January and December 2011, were evaluated. In general, satisfactory results were found. However, it was stated that the referred satisfaction, by itself, does not guarantee adequate quality, being essential the continuity of the monitoring actions in all stages of treatment until the arrival at the patient³¹. Thus, it is necessary to establish assessment tools and systematic maintenance of STDAH, in order to ensure safety and quality of services.

The analysis by state mesoregion showed that although north-western Minas Gerais had one of the lowest numbers of renal dialysis units registered in the programme (two), this mesoregion had the highest percentage of non-compliance (84.6%). Among the 22 unsatisfactory samples from this mesoregion, 15 (68.2%) were from the same renal dialysis unit (unit 32; **Table 4**).

The results also showed that eight unsatisfactory samples from the Central Mineira mesoregion (47.1%) were from the same renal dialysis unit (unit 5). Of the 31 unsatisfactory samples from the northern Minas mesoregion, 12 of were from unit 39 (38.7%). In addition, ten unsatisfactory samples from the Mucuri Valley mesoregion were from renal dialysis unit 73 (**Table 4**).

Unit 6 of the Jequitinhonha mesoregion had six (75.0%) of the eight unsatisfactory samples of this mesoregion. The results also showed that nine (75.0%) of the 12 unsatisfactory samples of the Campo das Vertentes mesoregion were from renal dialysis unit 1, and ten (25.6%) of the 39 non-compliant samples of southern and southeaster Minas Gerais mesoregion were from unit 57. Of the 37 unsatisfactory samples of the Triângulo Mineiro and Alto Paranaíba mesoregion, 13 (35.1%) were from unit 70 (**Table 4**).

Among the Campo das Vertentes, Central Mineira, Jequitinhonha, north-western Minas, northern Minas, southern and southwestern Minas, Triângulo Mineiro and Alto Paranaíba, and Mucuri Valley mesoregions, one renal dialysis unit from each mesoregion showed a high percentage of

unsatisfactory samples (higher than 25%, which was the overall mean of unsatisfactory samples), totalling eight (67%) units that were considered to be critical. This indicates the possible existence of sporadic problems in these units and in the final quality of the water for hemodialysis, requiring a more systematic monitoring of future samples to be collected in these areas.

Finally, as the technologies associated with hemodialysis treatment develop, renal therapy is increasingly perfected, being, therefore, a health treatment in increasing evolution. Thus, it is emphasized the importance of dialysis services reporting their results of water quality surveillance aiming at the safety of the renal patient's health. It is necessary to establish, more than analytical monitoring practices, tools for the assessment of said monitoring and systematic maintenance of STDAH, in order to ensure safety and quality of services⁶.

CONCLUSION

The present study indicated the relevance of particular parameters of the monitoring conducted within the Minas Gerais Hemodialysis Unit Quality Monitoring Programme, among which conductivity, fluoride and microbiological parameters are notable. The low variability and absence of non-compliant samples observed for most chemical components indicates that the other parameters are not critical for monitoring hemodialysis water. Therefore, the analytical tests that are routinely performed by the programme must be evaluated because testing only the most critical parameters as a preliminary screening could cut costs for the state without having negative health implications for renal patients.

The negative correlations assessed between parameters and monitoring years, as well as the decrease in the medians between the guidance and inspection periods indicate the role of the sanitary surveillance activities in protecting the health of renal patients at Minas Gerais state. In addition, the identification of renal dialysis units that recurrently failed to meet the legal limits suggests the need for a more consistent operation of the inspection bodies to ensure the safety of renal patients and to avoid their exposure to risks during treatment.

In general, the results showed that the quality of the water treated for hemodialysis in the state of Minas Gerais in the study period (from 2008 to 2016) improved in meeting the standards established by ANVISA. However, considering the gravity associated with the use of inadequate water, the finding of 25% non-compliant samples cannot be disregarded and indicates the importance of continuingly monitoring these parameters to ensure the safety of renal patients. Finally, the results of the present study indicate the importance of continuing the programme, especially inspections, which are key tools for controlling the quality of the water that is used for hemodialysis in the state of Minas Gerais.

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