

Audit of procedures for monitoring the quality of water used in the preparation of dialysis fluid in adult haemodialysis units in Scotland – 2015

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Introduction

Quality assurance of the water used in the preparation of dialysis fluid is of great importance as haemodialysis (HD) exposes the blood of the patient to more than 300 litres of water per week through a non-selective dialyser membrane compared with an average of 12 litres per week through a highly selective membrane (intestinal tract) in healthy individuals. Intact dialyser membranes are known to be permeable to bacterial contaminants as well as permitting backdiffusion and backfiltration of chemical contaminants from the dialysate.

Table 1 summarises the quality standards for testing for chemical and microbiological contaminants in water used in the preparation of dialysis fluid, which have been endorsed by the Association of Renal Technologists and UK Renal Association:

<http://www.renal.org/Clinical/GuidelinesSection/Haemodialysis.aspx>

Achieving these standards of water purity usually requires a combination of softening, carbon filtration and reverse osmosis along with an effective disinfection programme for all pipework between the treatment plant and dialysis machines. Patient safety on HD is dependent on maintaining a supply of treated water which achieves the above standards at all times. In addition to quality assurance of treated water by regular monitoring for chemical and microbiological contaminants in the renal unit good clinical governance requires ongoing vigilance within the hospital to ensure that there is no inadvertent contamination of the water supply to the renal unit with aluminium, fluoride, chlorine (or chloramine) or hydrogen peroxide by hospital or external contractors.

This audit was performed in 2015 to assess if all HD units were following the above guidance on quality assurance of water used for HD after an earlier audit performed in 2010 had shown that a minority of units were not complying with some of the recommendations.

Methods

This audit of monitoring of product water quality in the 9 hub haemodialysis units in Scotland (and their satellite units) is based on a questionnaire using the standards on preparation of water for use for haemodialysis recommended by the Renal Association and Association of Renal Technologists (Appendix). The questionnaire was sent to the renal technicians covering each of the renal units in Scotland in 2010 and the units were informed of the analysis of the data returned from each unit. The audit cycle was repeated in February 2015 using the same questionnaire.

Results

Analysis of the 2010 audit showed that all of the procedures for monitoring the quality of water used in the preparation of dialysis fluid were followed by the 9 hub and 23 satellite HD sites except:

- 3 hub sites and their satellite units and 1 satellite unit in the Glasgow network did not meet the recommended minimum frequency for testing for endotoxin (monthly)
- 3 hub sites and their satellite sites did not meet the minimum frequency of testing for viable bacteria (monthly)
- 2 hub sites and their satellite units did not meet minimum frequency for testing for chemical contaminants (3 monthly)
- 1 hub site and its satellites and 3 satellites in the Glasgow network did not meet the minimum recommended frequency of testing for chlorine (weekly)

This data from 2010 was reported back to the renal units and the SRR and the same format of questionnaire and analysis was used when the audit cycle was repeated in 2015.

a) water treatment facilities for HD in Scotland in 2015

The number of hub renal units in 2015 was the same but the number of satellite units has increased and data was available from 24 satellite units (Table 2). The 2015 audit identified 789 serviced HD stations including stations in the workshops as well as treatment areas (Table 2). The HD stations within the paediatric renal unit based in the Royal Hospital for Sick Children, Glasgow are not included in this audit as the paediatric renal unit was about to transfer to a new HD water treatment plant at the South Glasgow University Hospital.

All sites apart from 3 small satellite units supported by the hub in Aberdeen units have centralised reverse osmosis. The water treatment plant facilities in all of the units fulfil the criteria required for producing water used for HD (Table 2). HDF is performed in most hub and satellite units but HDF is usually not performed in patients' homes. One unit (Crosshouse) performs HDF at home installations using individual reverse osmosis units capable of heat disinfection and machines fitted with in line filtration. Test results show that meeting the standards quoted in Table 1 for TVC and EU levels is easily achievable i.e. <100 colony forming units/ml and <0.25 EU/ml. With this quality of treated water and the use of in line filtration HDF can be used for home dialysis as well as hospital dialysis. Due to the environment and incorrect sampling points proving that ultrapure water is delivered consistently from the home based reverse osmosis units is difficult.

Several of the Glasgow satellites required further measures to be taken after installation to ensure the facilities met the criteria set down in ISO 13959 and ISO 23500 indicating that such testing should be performed before handover to renal services.

b) monitoring of chemical contaminants in water used for HD

All hub and satellite HD units met the criteria for testing of chemical contaminants other than chlorine and all apart from two units sent the samples for testing to the Scottish Trace Element unit in Glasgow (Table 3). Two of the units do not monitor chlorine levels at least weekly, one because of limitations to access to the PFI water treatment plant. In contrast one unit wished that monitoring of chlorine levels should be recommended daily instead of weekly and another unit monitors chlorine levels continuously electronically. Point of care testing remains standard practice for chlorine testing although the specific methodology used varies widely (5 testing methods were in use in 2010 and 7 methods in 2015).

c) monitoring of microbiological contaminants in water used for HD

All hub and satellite HD units met the criteria for testing for total viable bacteria and for endotoxin at least monthly (Table 4). Most units use national NHS testing facilities for endotoxin whilst 6 units use local facilities testing for total viable bacterial counts (3 use NHS laboratories and 3 use commercially operated laboratories). All units have an action plan if the monitoring tests exceed 50% of the maximum acceptable levels for endotoxin and/or total viable counts. Quality assurance of water used for HD in the smaller satellite units usually employed the same procedures for monitoring water quality as their hub units (Tables 3 & 4).

d) clinical governance

All of the units have standard operational policies in place (Table 5). Reporting clinical governance procedures differ among the renal units and the responsible officer for water quality is:

- a senior renal consultant in 8 units
- a senior renal nurse in 1 unit

Some units perform more than the minimum recommended testing: two units expressed the wish that testing for water hardness should be included in the standard recommendations and one unit (Dumfries) recommended that chlorine be tested daily to provide better patient safety and clinical governance (Tables 3 & 5).

Maintenance of the water treatment plant and monitoring of water quality was the responsibility of the NHS in the majority of sites but the PFI sponsor and/or supplier of the water treatment plant were responsible at 7 sites and a combination of NHS and supplier of the water treatment facility at 5 sites making communication and lines of responsibility for clinical governance less easy to achieve and maintain.

Conclusion

The recent audit in 2015 demonstrates a significant improvement in adherence to national guidelines on quality assurance of water quality used for HD in Scotland since the previous audit in 2010 using the same methodology. Only a few satellite units do not perform all forms of routine monitoring for chemical and microbiological contaminants as frequently as recommended. These two satellite units perform all forms of monitoring routinely but still monitor chlorine levels less frequently than recommended. Almost all hub and satellite units can now perform HDF as well as high-flux HD.

Table 1: Maximum allowable concentrations of chemical and microbiological contaminants in dialysis water (reproduced from ISO 13959: 2009)

Contaminant	Maximum recommended concentration	Recommended minimum frequency of testing
Aluminium	0.01 mg/l	Every 3 months
Calcium	2 mg/l (0.05mmol/l)	Every 3 months
Total chlorine	0.1 mg/l	Weekly
Copper	0.1 mg/l	Every 3 months
Fluoride	0.2 mg/l	Every 3 months
Magnesium	4 mg/l (0.15 mmol/l)	Every 3 months
Nitrate (as N)	2 (equates to 9 mg/l NO ₃)	Every 3 months
Potassium	8 mg/l (0.2 mmol/l)	Every 3 months
Sodium	70 mg/l (3.0 mmol/l)	Every 3 months
Total viable microbial count	less than 100 CFU/ml	Monthly
Endotoxin concentration	less than 0.25 EU/ml	Monthly

A programme of corrective measures should be commenced immediately if routine monitoring demonstrates chemical contaminant levels in excess of the maximum permitted levels or microbiological contaminants in excess of 50% maximum permitted levels.

Table 2: Water treatment plant facilities in Scottish renal networks in February 2015

Hub and satellite HD units in 9 Renal networks	Central RO	Number of "In Service" stations	Compliance with BS ISO 13959 and ISO 23500	Ultrapure Water	Can perform HDF?
Aberdeen	Y	39	Y	Y	Y
Inverurie	Y	8	Y	Y	Y
Elgin	Y	10	Y	Y	Y
Peterhead	Y	8	Y	Y	Y
Banff	N	6	N	Y	Y
Orkney	N	5	N	Y	Y
Shetland	N	4	N	Y	Y
NHS Grampian, Orkney & Shetland		80			
Crosshouse	Y	47	Y	Y	Y
Ayr	Y	15	Y	Y	Y
NHS Ayrshire & Arran		62			
Dumfries	Y	21	Y	Y	Y
Stranraer	Y	5	Y	Y	Y
Kirkcubright	Y	4	Y	Y	Y
NHS Dumfries & Galloway		30			
Glasgow Western	Y	50	Y	Y	N
Stobhill	Y	33	N	Y	Y
Victoria	Y	35	N	Y	Y
Glasgow Royal	Y	25	Y	Y	Y
Vale of Leven	Y	9	Y	Y	Y
Inverclyde	Y	22	N	Y	Y
Forth Valley	Y	38	Y	Y	Y
NHS Greater Glasgow & Forth Valley		212			
Monklands, NHS Lanarkshire	Y	75	Y	Y	Y
Ninewells	Y	62	Y	Y	Y
Arbroath	Y	9	Y	Y	Y
Perth	Y	14	Y	Y	Y
NHS Tayside		85			
Raigmore	Y	18	N	Y	Y
Belford	Y	7	N	Y	Y
Caithness	Y	4	N	N	N
NHS Highland		29			
Edinburgh Royal	Y	73	Y	Y	Y
Western General	Y	11	Y	Y	Y
St Johns	Y	13	Y	Y	Y
Borders General	Y	18	Y	Y	Y
NHS Lothian & Borders		115			
Victoria, Kirkcaldy	Y	57	Y	Y	Y
Queen Margaret Hospital	Y	33	Y	Y	Y
St Andrews	Y	11	N	N	N
NHS Fife		101			

“in service” stations includes all dialysis bays currently in use plus workshop and treatment stations

Table 3: Monitoring of chemical contaminants in water used for preparing dialysis fluid

Hub and satellite HD units	Trace elements at least every 3 months	Samples sent to	Chlorine at least weekly	Test method	Action if results reach 100% of maximum
Aberdeen , Inverurie, Elgin, Peterhead, Banff, Orkney , Shetland	Y	STE	Y	Chlorosense	Y
Crosshouse	Y	Alcontrol	Y	Chlorosense	Y
Ayr	Y	Alcontrol	Y	Chlorosense	Y
Dumfries	Y	Alcontrol	Y- wish daily testing of chlorine	Palintest, Chlorosense, Ultrasense	Y
Stranraer	Y	Alcontrol	Y	Alcontrol	Y
Kirkcudbright	Y	Alcontrol	Y	Alcontrol	Y
Glasgow Western Infirmary	Y	STE	Y	Serin Guardian Hisense	Y
Stobhill	Y	STE	Y	HACH colourimeter	Y
Victoria	Y	STE	N (monthly access)	Serin Guardian Hisense	Y
GRI	Y	STE	Y	HACH colourimeter	Y
Vale of Leven	Y	STE	Y	Test strips	Y
Inverclyde	Y	STE	Y	Palintest	Y
Forth Valley	Y	STE	N monthly		Y
Monklands	Y	STE	Y	Palintest	Y
Ninewells , Arbroath, Perth	Y	STE	Y	Palintest	Y
Raigmore	Y	STE	Y	Continuous electronic	Y
Belford	Y	STE	Y	Test strip	Y
Caithness	Y	STE	Y	Test strip	Y
Edinburgh Royal , Western General, St Johns, Borders General	Y	STE	Y	Hach colourimeter	Y
Kirkcaldy . Queen Margaret Hospital, St Andrews.	Y	STE	Y	Hach digital pocket colourimeter	Y

Table 4: Monitoring of microbiological contaminants in water used for preparing dialysis fluid

Hub and satellite HD units	Test for endotoxins at least monthly	Laboratory where samples are sent	Total viable counts at least monthly	Laboratory where samples are sent	Action if results reach 50% of maximum*
Aberdeen	Y	Aberdeen	Y	Aberdeen Lab	Y
Inverurie	Y		Y		Y
Elgin	Y		Y		Y
Peterhead	Y		Y		Y
Banff	Y	Endosafe	Y		Y
Orkney	Y	Endosafe	Y		Y
Shetland	Y		Y		Y
Crosshouse	Y	Westfield Caledonian Ltd	Y	Westfield Caledonian Ltd	Y
Ayr	Y	SNBTS	Y	SNBTS	Y
Dumfries	Y	Alcontrol Labs	Y	Alcontrol Labs	Y
Stranraer	Y	Alcontrol Labs	Y	Alcontrol Labs	Y
Kirkcudbright	Y	Alcontrol Labs	Y	Alcontrol Labs	Y
Glasgow Western	Y	SNBTS	Y	SNBTS	Y
Stobhill	Y	SNBTS	Y	SNBTS	Y
Victoria	Y	SNBTS	Y	SNBTS	Y
GRI	Y	SNBTS	Y	SNBTS	Y
Vale of Leven	Y	SNBTS	Y	GRI lab	Y
Inverclyde	Y	SNBTS	Y	GRI lab	Y
Forth Valley	Y	SNBTS	Y	SNBTS	Y
Monklands	Y	SNBTS	Y	GRI lab	Y
Ninewells, Arbroath, Perth	Y	SNBTS	Y	Alcontrol, Bellshill	Y
Raigmore	Y	SNBTS	Y	Scottish Water, Inverness	Y
Belford	Y	SNBTS	Y	Scottish Water	Y
Caithness	Y	SNBTS	Y	Scottish Water	Y
Edinburgh Royal, Western General, St Johns, Borders General	Y	SNBTS	Y	SNBTS	Y
Kirkcaldy, Queen Margaret Hospital, St Andrews	Y	SNBTS	Y	Fife Lab	Y

* perform additional disinfection of membranes and/or distribution pipework

Table 5: Clinical Governance in HD water plants in Scotland

Hub and satellite HD units	Standard Operating Procedures in place	Action if results reach 50% of maximum	Water plant maintenance	Lead for Clinical Governance
Aberdeen	Y	Y	NHS	Consultant
Inverurie	Y	Y	NHS	
Elgin	Y	Y	NHS	
Peterhead	Y	Y	NHS	
Banff	Y	Y	NHS	
Orkney	Y	Y	NHS	
Shetland	Y	Y	NHS	
Crosshouse	Y	Y	NHS	Consultant
Ayr	Y	Y	NHS	
Dumfries	Y	Y – wish daily testing of chlorine	NHS	Lead Nurse
Stranraer	Y	Y	NHS	
Kirkcudbright	Y	Y	NHS	
Glasgow				
Glasgow Western	Y	Y	NHS	Consultant
Stobhill	Y	Y	NHS	
Victoria	Y	Y	NHS	
Glasgow Royal	Y	Y	NHS	
Vale of Leven	Y	Y	NHS	
Inverclyde	Y	Y	NHS	
Forth Valley	Y	Y	PFI	
Monklands	Y	Y	Supplier	Consultant
Ninewells	Y	Y	NHS	Consultant
Arbroath	Y	Y	NHS	
Perth	Y	Y	NHS	
Raigmore	Y	Y	Supplier	Consultant
Belford	Y	Y	Supplier	
Caithness	Y	Y	Supplier	
Edinburgh Royal	Y	Y, wishes weekly water hardness + total chlorine < 0.1 mg/L	PFI + Supplier	Consultant
Western General	Y		NHS + Supplier	
St Johns	Y		NHS + Supplier	
Borders General	Y		NHS + Supplier	
Victoria, Kirkcaldy	Y	Y, wishes weekly water hardness + total chlorine < 0.1 mg/L	PFI + Supplier	Consultant
Queen Margaret Hospital	Y		NHS + Supplier	
St Andrews	Y		NHS + Supplier	

Appendix: Quality assurance of dialysis water questionnaire used in 2010 and 2015

Name and address of your parent renal unit and its satellites:

(please include a separate report for any satellite unit supported by your parent unit if different procedures for monitoring water quality are followed in the satellite unit)

Who is responsible for water sampling in your unit?

Name: _____ Title: _____
Employer: _____
Line manager: _____

Question 1 (based on RA Guideline 3.2, 3.6 & 3.7): Water treatment plant

1a. Do you have a centralised RO unit?

1b. How many stations does your RO supply?

1c. Was the current water treatment plant capable of meeting the requirements of BS ISO 13959 and ISO 23500 from the time of installation?

1d. Has the current water treatment plant been shown to produce ultrapure water reliably?

1e. Does your unit perform haemodiafiltration?

Question 2 (based on RA guideline 3.3: Chemical contaminants in water used for preparation of dialysis fluid)

2a. Do you monitor mandatory trace metals at least 3 monthly?

If not, how frequently do you perform this?

Please state where samples are sent and method if performed at point of care

2b. Do you monitor chlorine levels at least weekly?

If not, how frequently do you perform this?

Please state where samples are sent and method if performed at point of care

Question 3 (based on RA guideline 3.4: Microbiological contaminants in water used for preparation of dialysis fluid)

3a. Do you monitor endotoxin levels at least monthly?

If not, how frequently do you perform this?

Please state where samples are sent and method if performed at point of care

3b. Do you monitor total viable bacterial counts at least monthly?

If not, how frequently do you perform this?

Please state where samples are sent and method if performed at point of care

Question 4 (based on guideline 3.5 which recommends action of corrective measures if chemical or microbiological contaminants exceed 50% of maximum permitted level)

4a. Do you set in motion corrective measures and repeat testing if chemical contaminants exceed 50% of permitted maximum level?

4b. Do you set in motion corrective measures and repeat testing if total bacterial counts or endotoxin levels exceed 50% of permitted maximum level?

Question 5

5a. Do you have a written standard operating procedure for sampling, frequency and methods of monitoring, recording and reporting of continuing audit of dialysis water quality?

5b. Do you wish any changes to the circulated template for a standard operating procedure for monitoring of water quality in haemodialysis units?

5c. Who is responsible for planned preventive maintenance in your haemodialysis unit

5d. Who is responsible for clinical governance of your haemodialysis unit?

Thank you for completing this questionnaire.

We will collate the responses and circulate to all members of the group.