

1. Introduction

Haemodialysis requires large quantities of water. Contamination of the water may put patients at risk from both short (e.g. pyrogenic reactions) and long term complications (e.g. dialysis amyloidosis. Persistent inflammation has also been associated with malnutrition and accelerated atherosclerosis)(1). Chemical contamination can also lead to problems. Regular monitoring of water quality is an essential part of quality control in dialysis units. Samples should be tested for the presence of endotoxin, bacterial and chemical contamination. These serve as indicators of a breakdown in the quality of the water system within the units.

British Standards institute (BS EN 23500) states that, as a minimum standard, water for dialysis should have a bacterial count of <100CFU/ml and endotoxin concentration of <0.25EU/ml. Where haemodialfiltration with on line production of replacement fluid is performed, a much higher level of purity is required with a bacterial count of <0.1CFU/ml and endotoxin concentration of <0.03IU/ml.

A chemical analysis of the water is also carried out routinely to ensure that dialysis water meets the safe limits for the elements listed in table 1 below.

These are the standards currently in use over the Leicester Haemodialysis Network. It is likely that the higher standards will only be achieved by considerable upgrading and replacement of the water plant at a number of sites as recommended in the standards document for new installations.(2)

The results of bacterial counts and endotoxin concentrations only give a snap shot of the level of water contamination. The dialysis membrane provides a reasonably effective filter to the entry of bacteria or bacterial products into the patient's bloodstream. However, this protection is not infinite and could be overwhelmed by heavy contamination. However, detection of contamination should alert the clinical and technical/estates teams to the need for retesting, evaluation of the water plant and disinfection. Rarely, should it be necessary to disrupt haemodialysis schedules on the basis of the results of these tests.

2. Scope

This guideline covers all haemodialysis units and home dialysis installations within the Leicester Haemodialysis Network. The monitoring of water quality in NHS directly managed HD units (Leicester, Loughborough, Lincoln) monitoring is performed by ALS Laboratories on samples collected by the Renal Sciences team on a monthly basis. Home haemodialysis patients have the same checks of water performed at 6 monthly intervals.

Haemodialysis units run by independent providers under contract to the NHS are responsible for ensuring the continued supply and quality of water for haemodialysis and, as part of the service contract, monitoring of the water should be performed according to the same criteria.

Peterborough HD facility water facility is maintained and monitored by the local estates department.

3. Recommendations, Standards and Procedural Statements

3.1 FREQUENCY OF SAMPLING

- Samples for endotoxin testing should be taken at monthly intervals (6 monthly for home patients).
- Samples for microbiology for TVC counts should be taken at monthly intervals (6 monthly for home patients).
- Chemical analysis of most contaminants should be undertaken on a quarterly basis but chlorine should be checked weekly. See table 1 below
- Chlorine should be tested on a weekly basis as a minimum (monthly if possible for home patients). This is because of the daily and seasonal variation on chlorine and chloramines in the feed water. Chlorine can cause oxidative damage to the reverse osmosis membranes hence the need for more frequent monitoring. This is done on the water unit side.
- Other sampling for other chemical contaminants may be required at times (see reference 1)

Table 1: Maximum recommended concentrations and frequency of monitoring for chemical and microbial contaminants in water for dialysis

Contaminant	Criteria for inclusion in routine tests	Maximum recommended concentration (mg/l = ppm)	Test Frequency
Aluminium	Mandatory	0.01	3 monthly
Calcium	Mandatory	2(0.05mmol/L)	3 monthly
Total Chlorine	Mandatory	0.1	Weekly
Copper	Mandatory	0.1	3 monthly
Fluoride	Mandatory	0.2	3 monthly
Magnesium	Mandatory	2(0.08mmol/L)	3 monthly
Nitrate (as N)	Mandatory	2 (equates to 9mg/L NO ₃)	Weekly
Potassium	Mandatory	2 (0.05mmol/L)	3 monthly
Sodium	Mandatory	50 (2.2mmol/L)	3 monthly
Bacteria (TVC)	Mandatory	100cfu/ml for standard HD < 0.1cfu/ml for HDF	Monthly
Endotoxin	Mandatory	0.25IU/ml for standard HD <0.03IU/ml for HDF	Monthly

Microbiological samples must be tested within six hours of the sample being taken. It is necessary therefore to arrange prompt transport of the specimen to the testing centre.

3.2 SAMPLING

3.2.1 Leicester and Loughborough and Lincoln

- Microbiological samples are taken by the technical team on a monthly basis. These are sent to ALS laboratories.
- Chemical samples are collected by the UHL renal technical team and also tested by ALS laboratories.
- Results are reviewed on a monthly basis by the UHL renal technician team and unit Matron.

3.2.2 Peterborough

- Endotoxin testing: Samples are collected by Brookfield Multiplex (PFI maintenance contractor) at the beginning of each month. The samples are being sent to PCH microbiology lab, and then forwarded to: Food, Water and Environmental Microbiology Laboratory, Porton, PHE Porton Down, Salisbury, Wiltshire, SP4 0JG for analysis.
- Microbiology testing: Samples are collected by Brookfield Multiplex (PFI maintenance contractor) at the beginning of each month. The samples are being sent to PCH microbiology lab, and then forwarded to: Food, Water and Environmental Microbiology Laboratory, London, 61 Colingdale Avenue, London, NW9 5EQ for analysis.
- Chemical contaminant testing: Samples are collected by Brookfield Multiplex (PFI maintenance contractor) at the beginning of every 3rd month. The samples are being sent to PCH microbiology lab, and then forwarded to: ALS Environmental Ltd, Torrington Avenue, Coventry, CV4 9GU for analysis.
- Results come back to PCH microbiology laboratory and are then forwarded to the Peterborough Dialysis Unit matron/sister for action and record keeping.

3.2.3 Commercially Operated Renal Units

- Commercially operated renal units have their own arrangements in place for water quality monitoring. However, where the service has been contracted to UHL, the arrangements will mirror those in place at the Leicester Renal Unit.
- Monthly reports of bacterial counts and endotoxin levels should be provided to chief renal technician at UHL for assurance of water quality
- Monthly collated reports of chlorine and quarterly reports of chemical analysis should be provided to haemodialysis unit matron

3.3 TAKING THE SAMPLES

- Materials Required

Sterile gloves

Sterile wipes

Bucket and waste bag

Alcontrol biological and chemical analysis sample suite kit

- Sampling points

Water inlet

After reverse osmosis unit

Dialysis circuit

- Method

Identify the sampling site

Put on sterile gloves

Wipe the sampling site with sterile wipes

Allow approximately two litres of water to run into a bucket

Fill all containers as required

Complete the appropriate request forms

Dispose of gloves and other waste material in waste bag

3.4 TEST METHODS

3.4.1 Microbiology

Water samples will be tested for:

Coliforms/100ml

E. coli/100ml

Total colony count/ml R2A Pour Plate

Yeastral agar will be used for the total colony counts

3.4.2 Endotoxin assay

Assayed by Limulus Amoebocyte Lysate assay by ALS Laboratories

3.5 ACTION LIMITS

ISO 23500 states that if routine monitoring shows a microbiological and endotoxin count exceeding 50% of the recommended maximum levels, remedial methods should be put in place immediately. These would be at the following counts:-

3.5.1 Microbiology

- Presence of TVC >50CFU/ml

- Testing laboratories will telephone the sender when colony counts are above the action limits and when presumptive coliform/E.coli are isolated.

3.5.2 Endotoxin Assay

- >0.125EU/ml

Testing laboratories will telephone the sender when endotoxin assay results are above the action limit.

3.5.3 Chemical Analysis

- Contaminant maximum recommended concentrations identified within Tables 1 above.

3.6 ACTION WITHIN THE UNITS

3.6.1 If bacterial count of post RO water exceeds 50 CFU/ml or endotoxin concentration exceeds 0.125EU/ml, urgent disinfection of the ring main will be ordered. This should be done as soon as possible without disrupting the standard haemodialysis schedule. This will continue as normal unless there is any evidence of a clinical problem.

3.6.2 In the event of a clinical problem (e.g. pyrogenic reactions) occurring in association with microbiological evidence of a failure in water quality, an urgent risk assessment of continuing haemodialysis treatment at the affected facility should be made by the haemodialysis unit matron, nephrology consultant, chief renal technician, infection control team and clinical director/head of service. During the normal working week, this should be possible within 24hours. At the weekend, this should be discussed between HD matron (or senior nurse), on call consultant nephrologist and on call microbiologist. Given the risk of disruption of dialysis schedules to patients with end stage renal failure it is envisaged that it would be rarely necessary to suspend standard haemodialysis.

3.6.3 Haemodialfiltration with on line replacement fluid production however should be suspended if repeated bacterial counts >100CFU/ml or endotoxin values >0.25EU/ml are identified. It should only be re-started once 2 values below these levels at least a week apart are available.

3.6.4 Exceptions to 3.6.3 may be made on an individual case where the patient tolerates standard HD poorly. This should be discussed carefully with the patient and be approved by the HD matron and lead consultant for that patient.

3.7 RESPONSIBILITIES

- Renal Technicians at Leicester – collection of samples for endotoxin/microbiology & chemical analysis at UHL and NHS directly managed satellite units
- Chief Renal Technician – Review of all TVC, Endotoxin & Chemical Analysis results, reporting of results to Medical staff, HD Unit Matrons and associated relevant persons. Control & organisation of all necessary routine and non-routine chemical disinfections.
- Medical staff – review of abnormal results with Chief Renal Technician, HD Unit Matrons, estates and microbiology staff; identification of patient-related events which may be related to water quality.
- Results of TVC and endotoxin measurements in water for dialysis for all HD sites will be reviewed quarterly at the Nephrology Infection Prevention meeting

4. Education and Training

All HD matrons, HD nephrology consultants, HHD nurses and renal technical team need to be familiar with the content of this guideline.

5. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
Performance against standards	Results of water tests	See table	Renal technical team/ Renal IP committee

6. Legal Liability Guideline Statement

See section 6.4 of the UHL Policy for Policies for details of the Trust Legal Liability statement for Guidance documents

7. Supporting Documents and Key References

7.1 Stenvinkel P. Heimbürger O. Paulter F. Diczfalussy U. Wang T. Berglund L. Jogestrand T. Strong association between malnutrition, inflammation, and atherosclerosis in chronic renal failure. *Kidney Int* 1999;55:1899-911

7.2 Hoenich N, Mactier R, Morgan I, et al. Guideline on water treatment systems, dialysis water and dialysis fluid quality for haemodialysis and related therapies. Clinical Practice Guideline. Prepared on behalf of The Renal Association and The Association of Renal Technologists. January 2016.

7.3 BS EN ISO 23500: *Water for haemodialysis and related therapies*

8. Key Words

Haemodialysis, water, endotoxin, microbiology

9. Abbreviations

CFU - colony forming units

TVC - total viable counts

HDF - Haemodiafiltration

HD - Haemodialysis

RO - reverse osmosis

RA - Renal Association

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DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

Author / Lead Officer:	Graham Warwick Mike Jones Thelma Mushambi	Job Title: Consultant Nephrologist Technical and Supplies Manager Renal SpR	
Reviewed by:	Nephrology HD consultants HD Matrons Lorraine Bertram Dickens, Service Manager		
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