

Audit of monitoring of the quality of water used in preparation of dialysis fluid in Scotland in 2010

1. Background

An audit of the procedures used by the Scottish haemodialysis units in 2007 to monitor and safeguard the quality of dialysis water was reported in the Scottish Renal Registry Report 2008 available at <http://www.srr.scot.nhs.uk>. This report described significant variance in how the different units adhered to the recommendations of the UK Renal Association on monitoring of the quality of dialysis water. These UK Renal Association recommendations were a consensus of the expert opinions of the Association of Renal Technologists (ART) and were based on ISO standards <http://www.renal.org/Clinical/GuidelinesSection/Haemodialysis.aspx>.

The lack of a unified approach to monitoring of the quality of water used for haemodialysis and related therapies was discussed by the renal technology staff and Dr Mactier at the Scottish Renal Association meeting in Dundee on 19th March 2010. It was agreed a further questionnaire to audit current practice of monitoring water quality in 2010 was merited and would be prepared for circulation to all parent units by Dr Mactier with questions based on the recommendations of the RA haemodialysis guideline.

2. Audit of procedures for monitoring the quality of water used in preparation of dialysis fluid in Scotland

An audit of monitoring of water quality for haemodialysis in all main renal units and satellite haemodialysis units in Scotland was repeated in the summer 2010 using the questionnaire shown in Appendix 1.

All of the procedures for monitoring the quality of water used in the preparation of dialysis fluid - recommended by the Renal Association/Association of Renal Technologists <http://www.renal.org/Clinical/GuidelinesSection/Haemodialysis.aspx> - were followed by the 9 hub main renal units and 23 satellite haemodialysis sites except:

- 2 hub sites and their satellite units (Raigmore and Dumfries) did not meet minimum frequency for testing for chemical contaminants (3 monthly) (Guideline 3.3)
- 1 hub site and its satellites (Dumfries) and 3 satellites in the Glasgow network (GRI, Inverclyde and Vale of Leven) did not meet the minimum recommended frequency of testing for chlorine (Guideline 3.3)
- 3 hub sites and their satellite units (Raigmore, Dumfries and Aberdeen) and 1 satellite unit in the Glasgow network (GRI) did not meet the recommended minimum frequency (monthly) for testing for endotoxin (Guideline 3.4)
- 3 hub sites and their satellite sites (Raigmore, Dumfries and Aberdeen) did not meet the minimum frequency (monthly) of testing for viable bacteria (Guideline 3.4)

The methods and testing facility used also varied greatly and have been rationalised since 2007. Most renal units use local or national NHS testing facilities apart from

Vale of Leven, Raigmore, Stornoway, Fort William, Dumfries and Stranraer which use either the supplier of their water treatment plant or private laboratories. In addition all units will have centralised reverse osmosis after 2010 which should reduce the high cost of testing for endotoxin on a regular basis in centres which previously were using single point of use reverse osmosis units.

The audit in 2007 also identified reliance on point of care testing in some units:

- point of care testing remains standard practice for chlorine testing although the specific methodology used varied widely (5 testing methods were in use in 2010)

The audit in 2007 showed a lack of uniformity on whether action was taken if chemical or microbial contaminants exceeded 50% of the maximum recommendation i.e. there was no documented policy for such action in 2 of 11 parent units (Guideline 3.5). This recommendation is now followed in all units.

Reporting and clinical governance procedures differed among the renal units.

The responsible officer for water quality was:

- a senior renal consultant in 5 units,
- the local consultant of each satellite unit in 1 unit,
- a senior renal nurse in 2 units
- a senior NHS technical staff in 1 unit.

Standard Operating Procedure for monitoring of the quality of water used in preparation of dialysis fluid in Scotland

The renal technical teams in each haemodialysis unit should follow the procedures agreed by the Association of Renal Technologists which have been published as section 3 of the Renal Association Clinical Practice Guideline on haemodialysis in 2009. The guidelines below refer to water used in the preparation of dialysis water in main and satellite haemodialysis units. Separate guidance has been produced for home haemodialysis (1).

Guideline 3.1 - HD: Concentrates for haemodialysis

Commercially produced concentrates are classified as medical devices and should be **CE marked** to demonstrate compliance with BS ISO 13958_2009 *Concentrates for haemodialysis and related therapies*. The water used for diluting the concentrates should comply with BS ISO 13959_2009 *Water for haemodialysis and related therapies* or meet the requirements stated in the European Pharmacopoeia (6th edition, 2007).

Guideline 3.2 - HD: Specification of water treatment system for haemodialysis

The complete water treatment, storage and distribution system should meet the requirements of BS ISO 26722_2009 *Water treatment equipment for haemodialysis applications and related therapies* and be shown to be capable of meeting the requirements of BS ISO 13959_2009 *Water for haemodialysis and related therapies* **at the time of installation**.

Guideline 3.3 - HD: Chemical contaminants in water used for the preparation of dialysis fluid

The concentrations of chemical contaminants in water used to prepare dialysis fluid should be monitored **at least 3 monthly, apart from chlorine which should be monitored at least weekly**. Chemical contaminants should not exceed the limits stated either in BS ISO 13959_2009 *Water for haemodialysis and related therapies* or in the European Pharmacopoeia (6th edition, 2007). A programme of improvement should begin immediately if routine monitoring demonstrates that concentrations of chemical contaminants exceed the maximum allowable limits.

Guideline 3.4 - HD: Microbiological contaminants in water used for the preparation of dialysis fluid

The concentration of microbiological contaminants (**total viable counts and endotoxin**) in water used for the preparation of the dialysis fluid should be monitored **at least monthly** and not exceed the limits stated in BS ISO 11663_2009 *Quality of dialysis fluid for haemodialysis and related therapies* (100 CFU/ml for bacteria and 0.25 EU/ml for endotoxin). **If routine monitoring demonstrates microbiological contaminant levels in excess of 50 CFU/ml and 0.125 EU/ml for bacteria and endotoxin (50% of the maximum permitted levels) a programme of corrective measures should be commenced immediately**.

Guideline 3.5 - HD: Microbiological contaminants in dialysis fluid

Dialysis fluid is produced by the mixing of treated water, acid and bicarbonate concentrates. The microbiological contaminant levels for acid and bicarbonate concentrates are defined in BS ISO 13958_2009 *Concentrates for haemodialysis and related therapies*. The microbiological quality of the dialysis fluid should not exceed the limits specified in BS ISO 11663_2009 *Quality of dialysis fluid for haemodialysis and related therapies*.

Guideline 3.6 - HD: Ultrapure dialysis fluid

All new water treatment plants should be capable of producing water suitable for the production of “ultrapure dialysis fluid”. The microbiological contaminant levels of ultrapure dialysis fluid should be < **0.1 CFU/mL** and < **0.03EU/mL**.

Guideline 3.7 - HD: Monitoring of feed and dialysis water for haemodialysis

Routine testing procedures for water for dialysis should form part of the renal unit policy and each unit should have standard operating procedures in place for sampling, monitoring and recording of feed and product water quality. The operating procedures should include details of the procedures to be followed if the prescribed limits are exceeded.

Contaminant	Frequency of testing
Chlorine	At least weekly
Total viable counts	At least monthly
Endotoxin	At least monthly
Chemical contaminants other than chlorine	At least every 3 months

A record of all routine monitoring data should be kept by senior renal technical staff with immediate reporting of any breaches to the renal consultant and service manager.

Reference

Dialysate for haemodialysis, Amendment 1 - Annex
C: Special considerations for home haemodialysis. AAMI (in press)

Appendix 1: Dialysis water analysis questionnaire 2010 (on behalf of Scottish Haemodialysis Units)

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? YES NO

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? YES NO

1d. Has the current water treatment plant been shown to produce ultrapure water reliably? YES NO

1e. Does your unit perform haemodiafiltration? YES NO

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? YES NO

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? YES NO

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? YES NO

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? YES NO
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? YES NO

4b. Do you set in motion corrective measures and repeat testing if total bacterial counts or endotoxin levels exceed 50% of permitted maximum level? YES NO

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? YES NO

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 - NHS technical staff, private contractor to PFI unit or water treatment plant supplier?

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.

Dr Robert Mactier and John Wright 29th March 2010