G8 Aluminium and other trace metals in haemodialysis water in Scottish renal units 1999-2008

Introduction

Haemodialysis (HD) exposes a patient to over 300 L of water per week via a non-selective membrane. Appropriate purity of this water is achieved by a combination of softening, carbon filtration, reverse osmosis (RO), and ultrafiltration. Maximum acceptable levels of trace metal contaminants in treated water for haemodialysis have been established by the Association for the Advancement of Medical Instrumentation (AAMI)[1], International Organization for Standardization (ISO) 13959[2], and the European Pharmacopoeia (EP)[3], and it is essential that chemical and microbiological purity of the treated water is confirmed by regular monitoring. The current UK Renal Association (UKRA) Guidelines[4] advise application of the most stringent of these recommendations. Testing at regular intervals for many of these trace substances is mandatory.

G8.1 Standards for mandatory testing of trace metals in water for dialysis

Contaminant	Maximum concentration mg/L = ppm (mmol/L)	Standards	Monitoring frequency
Aluminium	0.01	EP,AAMI,ISO	3 monthly
Calcium	2 (0.05)	EP,AAMI,ISO	3 monthly
Copper	0.1	AAMI,ISO	3 monthly
Magnesium	2 (0.08)	EP	3 monthly
Potassium	2 (0.05)	EP	3 monthly
Sodium	50 (2.2)	EP	3 monthly

G8.2 Summary of discretionary testing of trace metals in water for dialysis			
Contaminant	**Criteria**	**Standards**	**Monitoring frequency**
Arsenic	Omit if evidence permits	AAMI,ISO	3 monthly
Cadmium	Omit if evidence permits	AAMI,ISO	3 monthly
Chromium	Omit if evidence permits	AAMI,ISO	3 monthly
Lead	Omit if evidence permits	AAMI, ISO	3 monthly
Mercury	Omit if evidence permits	AAMI, ISO	3 monthly
Barium	Indication only	AAMI,ISO	As indicated
Silver	Indication only	AAMI,ISO	As indicated
Thallium	Indication only	AAMI	As indicated
Tin	Indication only	ISO	As indicated
Zinc	Indication only	EP,AAMI,ISO	As indicated

In Scotland, aluminium is one of nine trace elements which are routinely measured. Historically, dialysate water contamination was the main cause of aluminium toxicity, and monitoring has largely eliminated this. Excretion of aluminium is critically dependent on renal function. It is inadequately excreted through kidneys when eGFR <30 mL/min and is only slowly removed by dialysis since 90% is bound to transferrin. It accumulates in bone, parathyroid glands and the brain where it can cause problems such as anaemia, osteomalacia, and encephalopathy.

Methods

Analysis of aluminium and other trace metal levels in supply and treated dialysis water samples in Scotland from 1999-2008 was performed at the Scottish Trace Element and Micronutrient Reference Laboratory based at Glasgow Royal Infirmary.

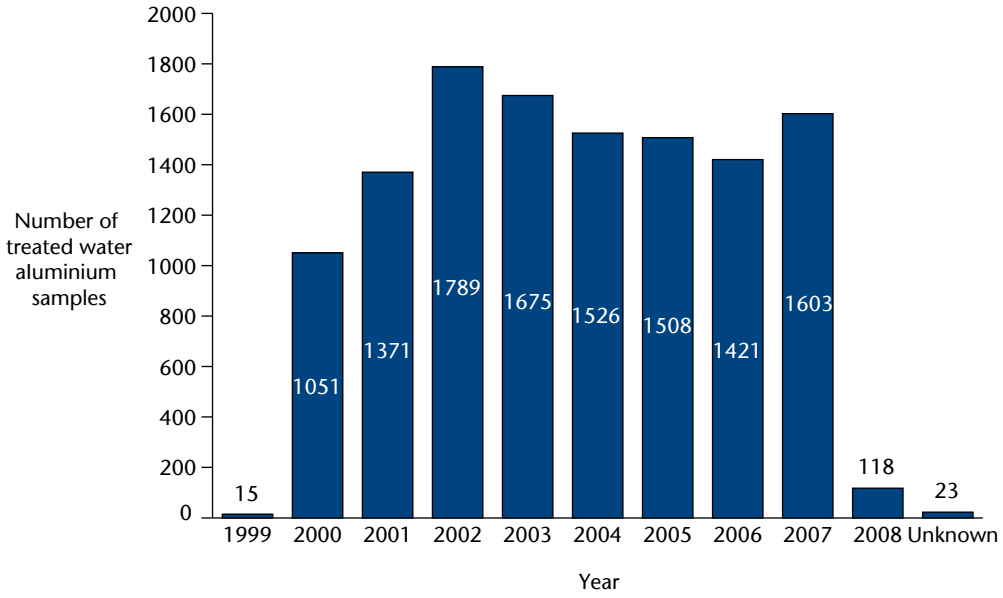
Results

In total, 2670 tap (untreated) water and 12100 treated water samples were received by the laboratory for measurement of sodium, potassium, calcium, magnesium, copper, zinc, silver, lead, and aluminium concentrations. Of the 12100 treated water samples, only 234 (1.9%) had an aluminium concentration higher than the current guidelines.

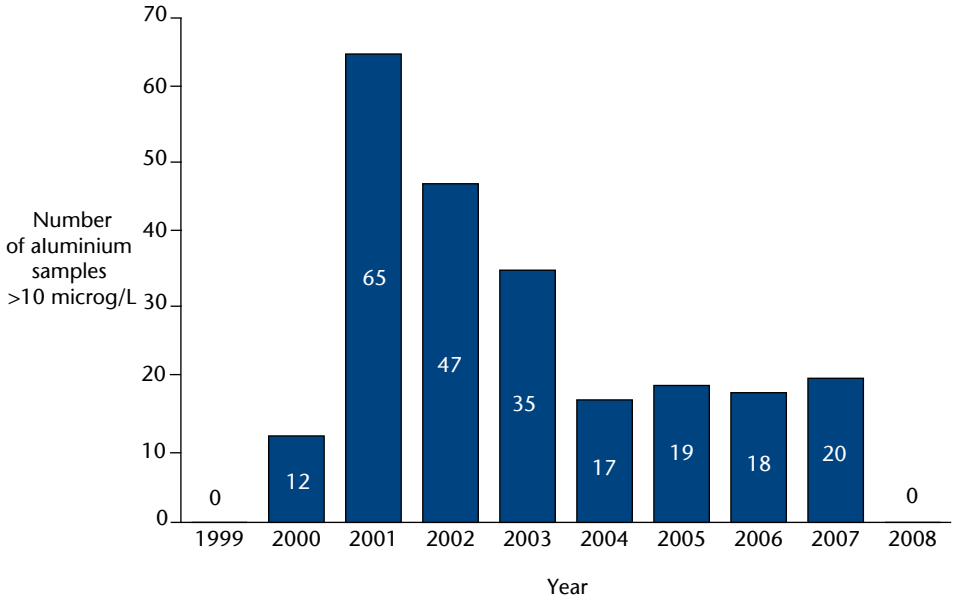
G8.3 High trace metal concentrations in treated dialysis water

Contaminant	No. high concentrations	% samples high	Monitoring guideline
Aluminium	234	1.9	Mandatory
Calcium	137	1.08	Mandatory
Copper	8	0.06	Mandatory
Lead	69	0.56	Omit if evidence permits
Magnesium	17	0.14	Mandatory
Potassium	14	0.11	Mandatory
Silver	2	0.02	Only if indicated
Sodium	9	0.07	Mandatory
Zinc	42	0.34	Only if indicated

G8.4a Total number of treated water aluminium samples per year



G8.4b Number of samples with aluminium concentration >10 microg/L by year



G8.5 Number of treated water samples tested for aluminium by renal unit

Renal unit	Total treated water samples	Number with aluminium concentration >10 microg/L	Median (IQR) aluminium concentration microg/L
ARI	271	2	2 (1,2)
XH	414	7	2 (1,3)
DGRI	71	1	1 (1,2)
GRI*▫	7690	81	2 (1,3)
MONK	843	49	4 (2,8)
NINE	140	2	2 (1,2)
QMHD	545	36	3 (2,6)
RAIG	28	1	1 (1,1)
RHSC	31	0	2 (1.75,2.25)
RIE	1016	29	2 (1,4)
WIG*	1048	26	2 (1,5)

* Renal units with large HD units without central RO.
▫ Renal unit with 25-30 home HD patients.

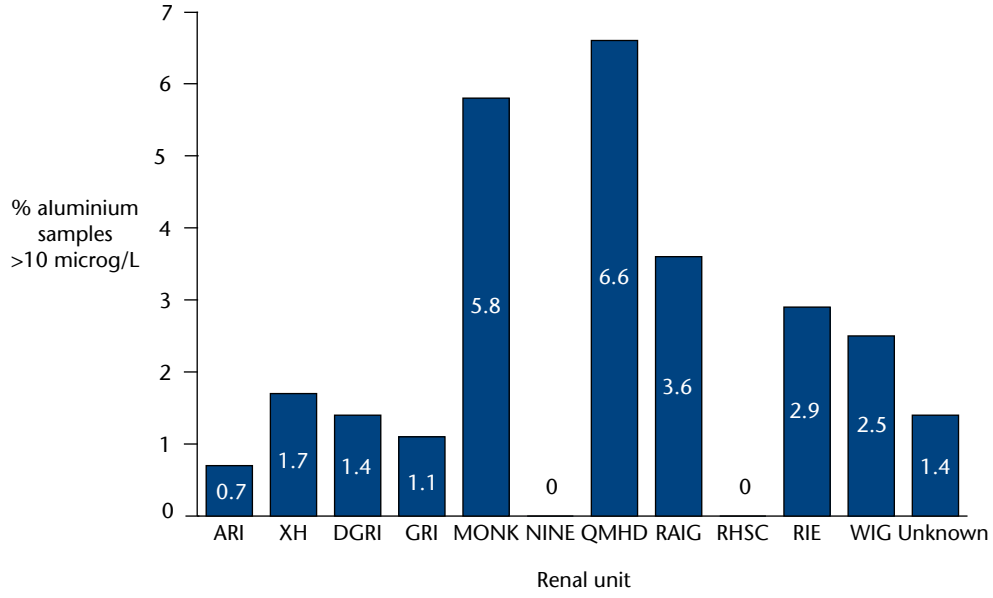
The proportion of treated water samples with high aluminium concentrations varied between the different renal units in Scotland.

G8.6 Number of samples and ROs by renal unit

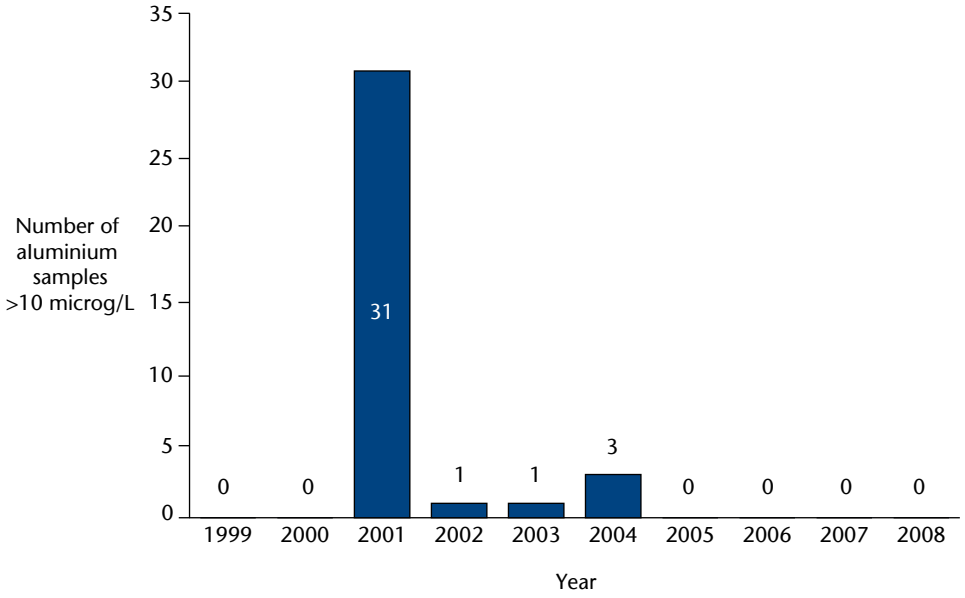
Renal unit	Total treated water samples	Number with high aluminium concentration >10 microg/L	Number Of ROs	Sampling frequency
ARI	271	2	7	1-2 monthly
XH	414	7	11	3 monthly
DGRI	71	1	8	1 monthly
GRI*▫	7690	81	114	1 monthly
MONK	843	49	13	1 monthly
NINE	140	2	6	1 monthly
QMHD	545	36	8	1 monthly
RAIG	28	1	8	6 monthly
RHSC	31	0	6	
RIE	1016	29	20	1 monthly
WIG*	1048	26	65	6 monthly

* Renal units with large HD units without central RO.
▫ Renal unit with 25-30 home HD patients.

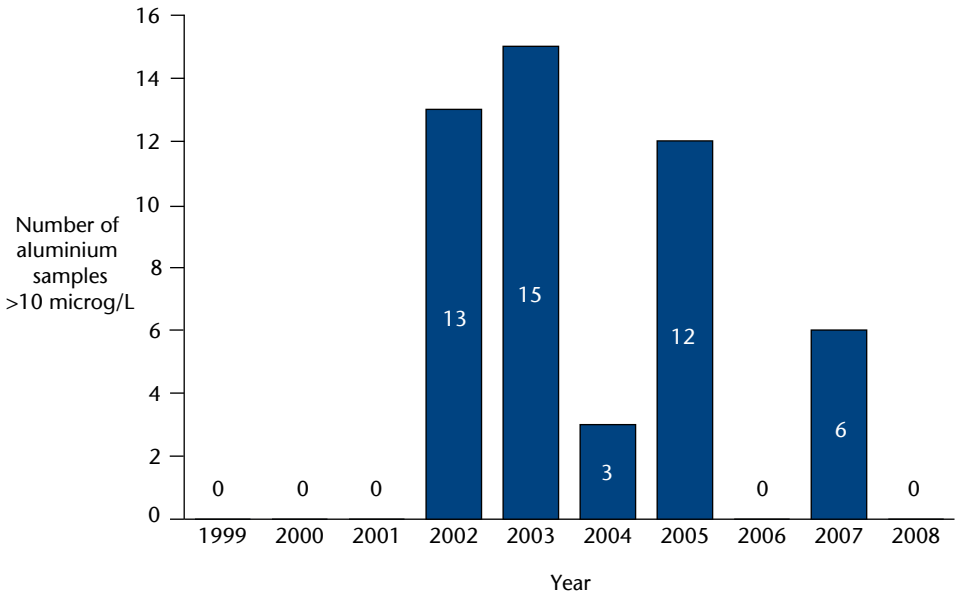
G8.7 Proportion of treated water samples with aluminium concentration >10 microg/L by renal unit



G8.8 Aluminium concentrations >10 microg/L in treated dialysis water from QMH Dunfermline by year



G8.9 Aluminium concentrations >10 microg/L in treated dialysis water from Monklands Hospital Airdrie by year



G8.10 Repeat testing of initially high treated water aluminium concentration			
Renal unit	**Number of samples with aluminium concentration >10 microg/L**	**% samples repeated**	**Median time to repeat aluminium sampling (days)**
ARI	2	50	52
XH	7	100	61
DGRI	1	0	
GRI	39	69	15
MONK	49	91	21
NINE	2	100	38
QMHD	36	97	35
RAIG	1	0	
RHSC	0		
RIE	29	62	31
WIG	26	73	50

Repeat testing of samples with high aluminium concentration was not reliably performed.

G8.11 Delay before repeat testing of samples of treated water with aluminium concentration >10 microg/L				
Renal unit	**% samples repeated**	**% repeated within 7 days**	**% repeated within 28 days**	**% of repeated samples with high aluminium concentration**
ARI	50	0	0	0
XH	100	14	43	0
DGRI	0	0	0	
GRI	69	15	49	0
MONK	91	20	60	36
NINE	100	0	50	0
QMHD	97	22	44	17
RAIG	0	0	0	
RHSC				
RIE	62	3	31	28
WIG	73	23	35	0

Discussion

During 1999-2008, each renal unit in Scotland labelled treated water samples for analysis differently. This made analysis of sample concentrations, particularly in respect to individual ROs, difficult and time-consuming. Since 2009, labelling of treated water samples has been standardised, allowing easier monitoring of results and follow-up of high concentrations.

A higher number of samples were sent for analysis of trace metal concentrations from renal units with a large number of single ROs, particularly the Glasgow units. Such large numbers from a few units makes comparisons difficult. Even taking the number of ROs into account for each unit, it appears that most units are measuring trace metal concentrations more frequently than the current UKRA guidelines of once every 3 months[1]. Seven of 11 units measured these trace metal concentrations every month. Despite the ubiquitous nature of aluminium in the environment, the overall proportion of treated water samples with high concentrations of aluminium, and other trace metals, was low. There were, however, differences in the proportion of high aluminium concentrations received from each unit, in particular, QMHD and MONK had proportionally more high aluminium concentrations. The reason for this is not known, although it is noted that the majority of high concentrations from QMHD were in 2001. Review of the method by which samples are taken, the policy of servicing ROs, and the guidelines for responding to high concentrations of aluminium in each unit may account for some of these differences.

Perhaps the most important finding was the variability of response to high aluminium concentrations. Such high concentrations were not consistently rechecked in any of the renal units, and when they were, it tended to take longer than 28 days. Standardised labelling of samples and review of the methods for reporting abnormally high concentrations to the renal units should improve both the number of samples which are rechecked, and also reduce delays.

References

1. Association for the Advancement of Medical Instrumentation. Standard RD52:2004-Dialysate for hemodialysis. AAMI, Arlington,VA.
2. International standard reference number ISO 13959: 2002 (E). Water for hemodialysis and related therapies.
3. European Pharmacopoeia, 3rd Edn (Supplement). Haemodialysis solutions, concentrated, water for diluting. Monograph 1167:1997 (corrected 2000, republished 2001). Strasbourg: Council of Europe 2001.
4. Mactier R. Module 3a-Haemodialysis. Renal Association Clinical Practice Guidelines 2007.